

FAO SPECIFICATIONS AND EVALUATIONS
FOR AGRICULTURAL PESTICIDES

CLOTHIANIDIN

(*E*)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine

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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.

*NOTE: PUBLICATIONS ARE AVAILABLE ON THE INTERNET AT
<http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmps/en/>

PART ONE

SPECIFICATIONS

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CLOTHIANIDIN

INFORMATION

ISO common name

Clothianidin (ISO 1750 published)

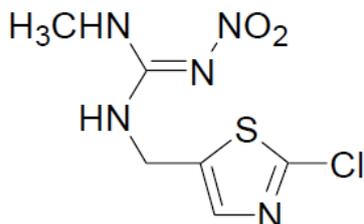
Chemical name

IUPAC (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine

CA [C(E)]-N-[(2-chloro-5-thiazolyl)methyl]-N'-methyl
-N''-nitroguanidine

Synonyms TI-435

Structural formula



Molecular formula

C₆H₈ClN₅O₂S

Relative molecular mass

249.7 g/mol

CAS Registry number

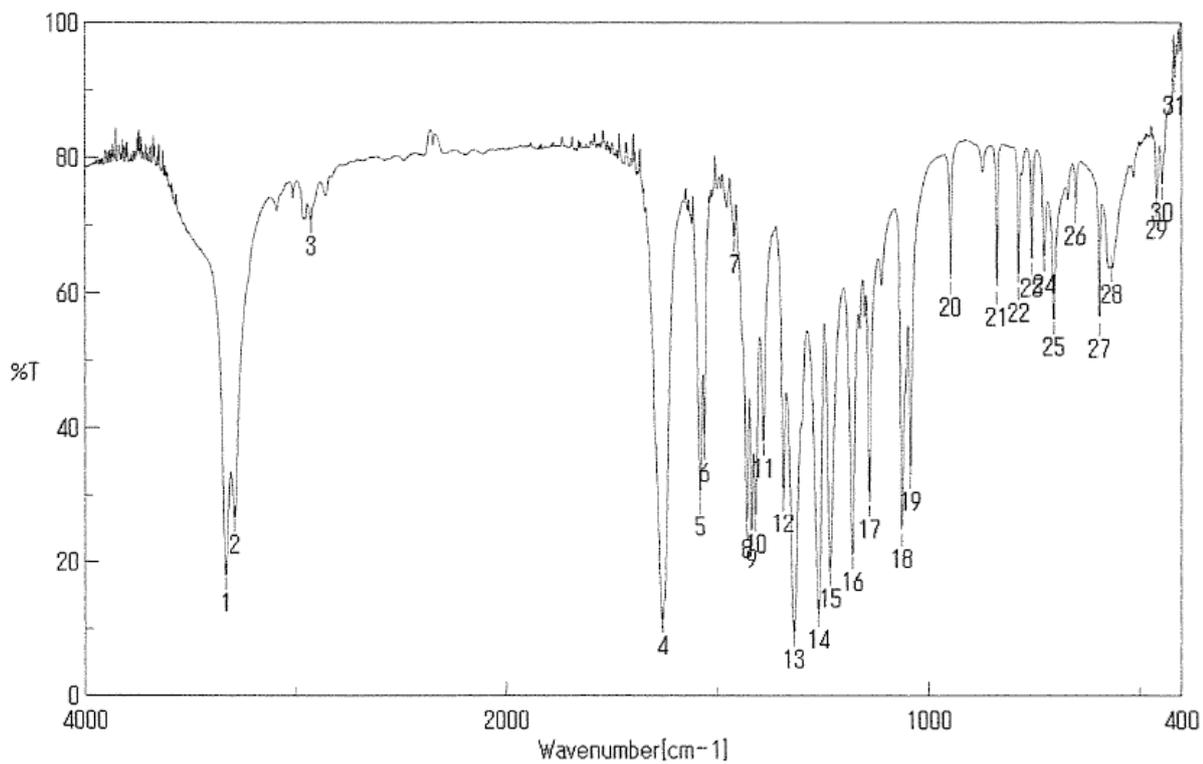
210880-92-5

CIPAC number

738

Identity tests

Retention time in reversed phase HPLC, IR spectrum



CLOTHIANIDIN TECHNICAL MATERIAL

738/TC (February 2010^{*})

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 reports (738/2009). It should be applicable to relevant products of this manufacturer, and those of any other formulators who use only TC from the evaluated sources. The specification is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for the products of other manufacturers who use TC from other sources. The evaluation report (738/2009) as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of clothianidin together with related manufacturing impurities, and shall be white to pale yellow crystalline powder free from visible extraneous matter and added modifying agents.

2 Active ingredient

2.1 Identity tests (738/TC/ 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 Clothianidin content (738/TC/ Note 1)

The Clothianidin content shall be declared (not less than 960 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 clothianidin content in TC, SC, SG and GR formulations were presented at the CIPAC Meeting in 2009 and provisionally adopted as CIPAC method. Prior to their publication in Handbook N, copies of the methods may be obtained through the CIPAC website, <http://www.cipac.org/prepubme.htm>

^{*} Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: <http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmps/ps/en/>

CLOTHIANIDIN AQUEOUS SUSPENSION CONCENTRATE

738/SC (February 2010^{*})

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 reports (738/2009). It should be applicable to relevant products of this manufacturer, and those of any other formulators who use only TC from the evaluated sources. The specification is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for the products of other manufacturers who use TC from other sources. The evaluation report (738/2009) as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of a suspension of fine particles of technical clothianidin, complying with the requirements of FAO specification 738/TC (February 2010), in the form of a white or brown viscous liquid with faint characteristic odor, in an aqueous phase together with suitable formulants. After gentle agitation the material shall be homogeneous (Note1) and suitable for further dilution in water.

2 Active ingredient

2.1 Identity tests (738/SC/ Note 2)

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 Clothianidin content (738/SC/ Note 1 and 2)

The clothianidin content shall be declared (g/kg or g/l at $20 \pm 2^\circ\text{C}$, Note 3) and, when determined, the average content measured shall not differ from that declared by more than the following tolerances:

Declared content in g/kg or g/l at $20 \pm 2^\circ\text{C}$	Tolerance
above 100 up to 250	$\pm 6\%$ or of the declared content

^{*} Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: <http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmps/ps/en/>

3 Physical properties

3.1 Pourability (MT 148.1, CIPAC Handbook F, p.348, 1995)

Maximum "residue": 4 %.

3.2 Spontaneity of dispersion (MT 160, CIPAC Handbook F, p.391, 1995) (Note 4)

A minimum of 90 % of the clothianidin content found under 2.2 shall be in suspension after 5 min in CIPAC Standard Water D at $30 \pm 2^\circ\text{C}$.

3.3 Suspensibility (MT 184, CIPAC Handbook K, p.142, 2003) (Note 4)

A minimum of 95 % of the clothianidin content found under 2.2 shall be in suspension after 30 min in CIPAC Standard Water D at $30 \pm 2^\circ\text{C}$.

3.4 Wet sieve test (MT 185, CIPAC Handbook K, p.149, 2003) (Note 5)

Maximum: 0.5 % of the formulation shall be retained on a 75 μm test sieve.

3.5 Persistent foam (MT 47.2, CIPAC Handbook F, p.152, 1995) (Note 6)

Maximum: 50 ml after 1 min.

4 Storage stability

4.1 Stability at 0°C (MT 39.3, CIPAC Handbook J, p.126, 2000)

After storage at $0 \pm 2^\circ\text{C}$ for 7 days, the formulation shall continue to comply with clauses for:

- suspensibility (3.3),
- wet sieve test (3.4),

4.2 Stability at elevated temperature (MT 46.3, CIPAC Handbook J, p.128, 2000)

After storage at $54 \pm 2^\circ\text{C}$ for 14 days, the determined average active ingredient content must not be lower than 95 % relative to the determined average content found before storage (Note 7) and the formulation shall continue to comply with the clauses for:

- pourability (3.1),
- spontaneity of dispersion (3.2),
- suspensibility (3.3),
- wet sieve test (3.4),

Note 1

Before sampling to verify the formulation quality, inspect the commercial container carefully. On standing, suspension concentrates usually develop a concentration gradient from the top to the bottom of the container. This may even result in the appearance of a clear liquid on the top and/or of sediment on the bottom. Therefore, before sampling, homogenize the formulation according to the instructions given by the manufacturer or, in the absence of such instructions, by gentle shaking of the commercial container (for example by inverting the closed container several times). Large containers must be opened and stirred adequately. After this procedure, the container should not contain a sticky layer of non-dispersed matter at the bottom. A suitable and simple method of checking for a non-dispersed sticky layer "cake" is by probing with a glass rod or similar device adapted to the size and shape of the container.

All the physical and chemical tests must be carried out on a laboratory sample taken after the recommended homogenization procedure.

Note 2 Methods for the identification and determination of clothianidin content in TC, SC, SG and GR formulations were presented at the CIPAC Meeting in 2009 and provisionally adopted as CIPAC method. Prior to their publication in Handbook N, copies of the methods may be obtained through the CIPAC website, <http://www.cipac.org/prepubme.htm>

Note 3 Unless homogenization is carried out carefully, it is possible for the sample to become aerated. This can lead to errors in the determination of the mass per millilitre and in calculation of the active ingredient content (in g/l) if methods other than MT 3.3 are used. 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 4 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, simpler methods such as gravimetric and solvent extraction determination may be used on a routine basis provided that these methods have been shown to give equal results to those of the chemical assay method. In case of dispute, the chemical method shall be the referee method.

Note 5 This test detects coarse particles (e.g. caused by crystal growth) or agglomerates (crust formation) or extraneous materials which could cause blockage of spray nozzles or filters in the spray tank.

Note 6 The mass of sample to be used in the test should correspond to the highest rate of use recommended by the supplier. The test is to be conducted in CIPAC standard water D.

Note 7 Samples of the formulation taken before and after the storage stability test should be analyzed concurrently after the test in order to reduce the analytical error.

CLOTHIANIDIN WATER SOLUBLE GRANULES

738/SG (February 2010^{*})

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 reports (738/2009). It should be applicable to relevant products of this manufacturer, and those of any other formulators who use only TC from the evaluated sources. The specification is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for the products of other manufacturers who use TC from other sources. The evaluation report (738/2009) as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of granules containing technical clothianidin, complying with the requirements of the FAO specification 738/TC (February 2010), in the form of blue-green fine particle with faint characteristic odor, and suitable carriers and/or necessary formulants. It shall be homogeneous, free from visible extraneous matter and/or hard lumps, free flowing, and essentially non-dusty. The active ingredient shall be soluble in water. Insoluble carriers and formulants shall not interfere with compliance with 3.2.

2 Active ingredient

2.1 Identity tests (738/SG/ 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 Clothianidin content (738/SG/ Note 1)

The clothianidin content shall be declared (g/kg) and, when determined, the average content measured shall not differ from that declared by more than the following tolerances:

Declared content in g/kg	Tolerance
above 100 up to 250	± 6 % or of the declared content

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: <http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmps/ps/en/>

3 Physical properties

3.1 Degree of dissolution and solution stability (MT 179, CIPAC Handbook H, p.307, 1998)

Residue of formulation retained on a 75 µm test sieve after dissolution in CIPAC Standard Water D at 30 ± 2°C.

Maximum: 2 % after 5 min.

Maximum: 2 % after 18 hours.

3.2 Persistent foam (MT 47.2, CIPAC Handbook F, p.152, 1995) (Note 2)

Maximum: 40 ml after 1 minute.

3.3 Dustiness (MT 171, CIPAC Handbook F, p.425, 1995) (Note 3)

Essentially non-dusty.

3.4 Attrition resistance (MT 178.2, CIPAC Handbook H, p.304, 1998)

Minimum: 98 % attrition resistance.

3.5 Flowability (MT 172, CIPAC Handbook F, p.430, 1995)

At least 98 % of the formulation shall pass through a 5 mm test sieve after 20 drops of the sieve.

4 Storage stability

4.1 Stability at elevated temperature (MT 46.3)

After storage at 54 ± 2°C for 14 days, 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 clauses for:

- Degree of dissolution and solution stability (3.1),
- dustiness (3.3),
- attrition resistance (3.4),

Note 1 Methods for the identification and determination of clothianidin content in TC, SC, SG and GR formulations were presented at the CIPAC Meeting in 2009 and provisionally adopted as CIPAC method. Prior to their publication in Handbook N, copies of the methods may be obtained through the CIPAC website, <http://www.cipac.org/prepubme.htm>

Note 2 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 3 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 cases of dispute the gravimetric method shall be used.

Note 4 Samples of the formulation taken before and after the storage stability test should be analyzed together after the test in order to reduce the analytical error.

CLOTHIANIDIN GRANULES

738/GR (February 2010*)

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 reports (738/2009). It should be applicable to relevant products of this manufacturer, and those of any other formulators who use only TC from the evaluated sources. The specification is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for the products of other manufacturers who use TC from other sources. The evaluation report (738/2009) as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of granules containing technical clothianidin, complying with the requirements of FAO specification 738/TC (February 2010), in the form of gray or red spheroidal granule with faint characteristic odor, together with suitable carriers and any other necessary formulants. It shall be dry, free from visible extraneous matter and hard lumps, free-flowing, essentially non-dusty and intended for application by machine.

2 Active ingredient

2.1 Identity tests (738/GR/ 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 Clothianidin content (738/GR/ Note 1)

Declared content in g/kg	Tolerance
up to 25	± 25 % of the declared content

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: <http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmps/ps/en/>

3 Physical properties

3.1 Nominal size range (MT 58, CIPAC Handbook F, p.173, 1995) (Note 2)

Not less than 950 g/kg of the formulation shall be within the size range 200 to 2000 µm.

3.2 Dustiness (MT 171, CIPAC Handbook F, p.425, 1995)

Nearly dust-free (Note 3).

3.3 Attrition resistance (MT178, CIPAC Handbook H, p.304, 1998)

Minimum 99 % attrition resistance.

4 Storage stability

4.1 Stability at elevated temperature (MT 46.3, CIPAC Handbook J, p.128, 2000)

After storage at $54 \pm 2^{\circ}\text{C}$ for 14 days, 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 clauses for:

- nominal size range (3.1),
 - dustiness (3.2),
 - attrition resistance (3.3),
-

Note 1 Methods for the identification and determination of clothianidin content in TC, SC, SG and GR formulations were presented at the CIPAC Meeting in 2009 and provisionally adopted as CIPAC method. Prior to their publication in Handbook N, copies of the methods may be obtained through the CIPAC website, <http://www.cipac.org/prepubme.htm>

Note 2 Higher ratios increase the risk of segregation and adverse effects on the flow rate. This should be checked with the machine to be used. The purchaser should check that the nominal size range is suitable for his requirements, since different size ranges may affect biological activity.

Note 3 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 4 Samples of the formulation taken before and after the storage stability test should be analyzed together after the test in order to reduce the analytical error.

CLOTHIANIDIN SUSPENSION CONCENTRATE FOR SEED TREATMENT

(Note 1)

738/FS (February 2011^{*})

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 reports (738/2009 & 738/2010). It should be applicable to relevant products of this manufacturer, and those of any other formulators who use only TC from the evaluated sources. The specification is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for the products of other manufacturers who use TC from other sources. The evaluation reports (738/2009 & 738/2010) as PART TWO, form an integral part of this publication.

1 Description

The material shall consist of a suspension of fine particles of technical clothianidin, complying with the requirements of FAO specification 738/TC (February 2010), in the form of white to off-white opaque slightly viscous liquid or dark pink to reddish opaque slightly viscous liquid with faint characteristic odour, in an aqueous phase together with suitable formulators, including colouring matter (Note 1). After gentle stirring or shaking, the material shall be a homogeneous uncoloured or coloured slightly viscous liquid, depending on the colour stated on the label (Note 2) and suitable for further dilution with water if necessary.

2 Active ingredient

2.1 Identity tests (738/FS, Note 3)

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 Clothianidin content (738/FS, Note 3)

The clothianidin content shall be declared (g/kg or g/l at $20 \pm 2^\circ\text{C}$, Note 4) and, when determined, the average content measured shall not differ from that declared by more than the appropriate tolerance.

^{*} Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: <http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmps/ps/en/>

Declared content in g/kg or g/L at 20 ± 2°C	Tolerance
above 250 up to 500	± 5% or of the declared content
above 500 Note: the upper limit is included in the range	± 25 g/kg or g/L of the declared content

4 Physical properties

3.1 **Pourability** (MT 148.1, CIPAC Handbook F, p.348, 1995)

Maximum "residue": 4 %.

3.2 **Wet sieve test** (MT 185, CIPAC Handbook K, p.149, 2003) (Note 5)

Maximum: 0.5 % retained on a 75 µm test sieve.

3.3 **Persistent foam** (MT 47.2, CIPAC Handbook F, p.152, 1995) (Note 6)

If the product is intended to be used after dilution, persistent foam is to be measured at a 50 % dilution. In those conditions, the maximum is 60 mL after 1 min. This clause is not applicable where the product is used without dilution.

3.4 **Suspensibility** (MT 184, CIPAC Handbook K, p.142, 2003) (Note 7)

If the product is intended to be used after dilution, suspensibility is to be measured at a 50 % dilution. In those conditions, a minimum of 90 % of the clothianidin content found under 2.2 shall be in suspension after 30 min in CIPAC Standard Water D at 30 ± 2°C. This clause is not applicable where the product is used without dilution.

5 Storage stability

5.1 **Stability at 0°C** (MT 39.3, CIPAC Handbook J, p.126, 2000)

After storage at 0 ± 2°C for 7 days, the formulation shall continue to comply with the clause for:

- wet sieve test (3.2).

5.2 **Stability at elevated temperature** (MT 46.3, CIPAC Handbook J, p.128, 2000)

After storage at 54 ± 2°C for 14 days (Note 8), the determined average active ingredient content must not be lower than 95 % relative to the determined average content found before storage (Note 9) and the formulation shall continue to comply with the clauses for:

- pourability (3.1),
 - wet sieve test (3.2),
 - suspensibility (3.4),
-

- Note 1 The influence of treatment on germination is of major importance but it is not the subject of a specification clause because no test method is applicable to all types of seeds. To avoid adverse effects, users should apply the formulation strictly according to the recommendations of the manufacturer and should not treat seeds for which effect on germination is not known. Treated seeds should be stored in a suitable container and should be protected from excessive temperature and moisture.
- The formulation shall contain a dye or pigment that permanently colours the seed after treatment (red is recommended). In some countries, there may be a legal requirement that a specific colour shall be used. The same colour must not be used for denaturing seeds intended for use as livestock feeding stuffs.
- Note 2 Before sampling to verify the formulation quality, inspect the commercial container carefully. On standing, suspension concentrates usually develop a concentration gradient from the top to the bottom of the container. This may even result in the appearance of a clear liquid on the top and/or sediment on the bottom. Therefore, before sampling, homogenize the formulation according to the instructions given by the manufacturer or, in the absence of such instructions, gently shake the commercial container (for example by inverting the closed container several times, large containers must be opened and stirred adequately). After this procedure, the container should not contain a sticky layer of non-dispersed matter at the bottom. A suitable and simple method of checking for a non-dispersed sticky layer ("cake") is by probing with a glass rod or similar device adapted to the size and shape of the container. All the physical and chemical tests must be carried out on a laboratory sample taken after the recommended homogenization procedure.
- Note 3 The extension of the scope of the HPLC method (CIPAC/4658) for the determination of clothianidin in FS and WS formulations (CIPAC/4692) was accepted as a provisional CIPAC method in 2010. Prior to its publication in Handbook N, copies of the method can be obtained through www.cipac.org/prepub.htm
- Note 4 Unless homogenization is carried out carefully, it is possible for the sample to become aerated. This can lead to errors in the determination of the mass per millilitre, and in calculation of the active ingredient content (in g/l) if methods other than MT 3.3 are used. 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 5 This test should detect coarse particles (e.g. caused by crystal growth) or extraneous materials which could cause blockage of spray nozzles or filters of the application equipment.
- Note 6 The mass of sample to be used in the test should correspond to the highest rate of use recommended by the supplier. The test is to be conducted in CIPAC standard water D.
- Note 7 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, simpler methods such as gravimetric and solvent extraction determination may be used on a routine basis provided that these methods have been shown to give equal results to those of the chemical assay method. In case of dispute, the chemical method shall be the referee method.
- Note 8 Unless other temperatures and/or times are specified. Refer to Section 4.6.2 of this Manual for alternative storage conditions.
- Note 9 Samples of the formulation taken before and after the storage stability test should be analyzed concurrently after the test in order to reduce the analytical error.

PART TWO

EVALUATION REPORTS

CLOTHIANIDIN

2010 FAO/WHO evaluation report based on submission of information from Sumitomo (FS)	17
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CLOTHIANIDIN

FAO/WHO EVALUATION REPORT 738/2010

Recommendation

The Meeting recommended that the specification for clothianidin FS proposed by Sumitomo Chemical Company, as amended, should be adopted by FAO.

Appraisal

The meeting considered data on clothianidin submitted by Sumitomo Chemical Co., Ltd., in support of a new FAO specification for FS.

The meeting was provided with a proposed specification for a clothianidin suspension concentrate for seed treatment (FS). The Meeting identified several issues with the draft specification.

Clauses for physical properties: persistent foam and suspensibility: the Meeting noted that these clauses were conditional "when diluted with water". The company explained that four different FS with clothianidin are manufactured and some are used undiluted, some after dilution with water. The specification is intended to cover both types. This explication was accepted by the Meeting.

Clause for storage stability: the draft specification included a clause on particle size distribution to be determined after the accelerated storage test. This is one of the clauses where the inclusion is "where required". The company explained that they had no objection to remove the subclause.

Clause for seed adhesion: the clause was not included in the draft specification. The company explained, that reasonable limits for FS in general could not yet be set. Adhesion is not only a quality criterion of the FS under evaluation, but also depending on type of seeds and conditioning prior to treatment. This explanation was accepted by the Meeting.

Analytical Method: A CIPAC method based on reversed phase HPLC has been developed for determination of clothianidin in TC, SC, GR and SG formulations and was presented at the 2009 CIPAC Meeting in El Salvador. An extension of the CIPAC Method for clothianidin FS was presented at the CIPAC Meeting 2010 in Slovenia and provisionally adopted.

CLOTHIANIDIN

FAO/WHO EVALUATION REPORT 738/2009

Recommendation

The Meeting recommended that the specifications for clothianidin TC, SC, GR and SG proposed by Sumitomo Chemical Company, as amended, should be adopted by FAO.

Appraisal

The meeting considered data on clothianidin submitted by Sumitomo Chemical Co., Ltd., in support of new FAO specifications for TC, SC, GR and SG.

Clothianidin is a white to pale yellow coloured crystalline powder. It has a low volatility and has a melting point of 176.8 °C. It is slightly soluble in water at 0.33 g/L at 20°C. It is not fat soluble and is not likely to bioaccumulate with a log P_{ow} of circa 0.9. It is considered to be stable to hydrolysis at all environmentally relevant pH's. It undergoes rapid photolysis with a half life of 3.3 hours at pH 7 at 25°C. Clothianidin is a strong base with a pK_a of 11.

The meeting was provided with confidential information on the manufacturing process and limits for minimum purity and for impurities, which were supported by 5 batch analysis data. Mass balances were 99.1 – 99.5 %. The minimum purity at 960 g/kg was questioned but it was confirmed by Sumitomo that this is necessary as production has not yet stabilised. A statement was provided by the Belgian regulatory authority confirming that the confidential data on the manufacturing process and declaration of composition submitted to the FAO were the same as those submitted to the national regulatory authority. The meeting considered that none of the impurities are relevant. A CIPAC method based on reversed phase HPLC has been developed for determination of clothianidin in TC, SC, GR and SG formulations and was presented at the 2009 CIPAC Meeting in El Salvador. The method was adopted as provisional CIPAC method.

The proposed specification for TC, SC, GR and SG were essentially in accordance with the requirements of the manual (FAO/WHO 2006). For the TC the melting point provided was for purified material and not the TC. Sumitomo were asked if they have data for the TC and they have now stated that this is not available. Finally it was considered as a minor issue and the melting point for the pure material was accepted.

In the specifications for the SC, GR and S G the meeting requested that the descriptions of the formulations should be more specific. The company have addressed this and revised specifications were provided. For these specifications the company were also asked why the after storage minimum active content was higher at 97 % than the standard 95 %. The company explained that clothianidin is very stable and their products will meet the higher percentage value. In the end the company were

happy to accept the 95 % as standard. For these specifications it was agreed that the method footnotes could be deleted as the CIPAC methods are presented in 2009, this has been done in the revised specification.

The draft specifications for SG and GR formulations, respectively, contained a clause for control of pH range. As clothianidin is not sensitive to hydrolysis in the pH range 5 to 9, the necessity of the clause was questioned by the meeting. It was confirmed that this is not needed and it has been removed from the specifications.

SUPPORTING INFORMATION
FOR
EVALUATION REPORT 738/2009

HISTORY

Clothianidin was developed by Takeda Chemical Industries in Japan in the 1990. This is also reflected in the development code number allocated to that compound - TI-435, with TI standing for Takeda Industries. Takeda was later incorporated into Sumitomo, and clothianidin was further developed jointly by Sumitomo Chemical Company (SCC) and Bayer CropScience (BCS). Therefore, some of the nonpublished studies referenced in the hazard summary are owned by SCC, some by BCS, and some by both companies.

USES

Clothianidin is a systemic insecticide which acts as acute contact and stomach poison. Clothianidin belongs to the chemical class of insecticides known as neonicotinoids and is classified by the Insecticide Resistance Action Committee (IRAC) as "nicotinic Acetylcholine receptor agonist / antagonist".

Clothianidin has a broad spectrum of activity, particularly against sucking insects such as aphids, leaf hoppers, thrips and white flies. Furthermore, various species of beetles (e.g. *Atomaria* spp., *Agriotes lineatus*, *Diabrotica* spp.) and some species of flies (e.g. *Oscinella* frit and *Pegomyia* spp.) and cut worm (e.g. *Agrotis* spp.) are effectively controlled. Clothianidin shows no efficacy against spider mites and nematodes. Products containing clothianidin are used as foliar and soil applications as well as seed treatments.

Table 1. Physico-chemical properties of pure clothianidin

Parameter	Value(s) and conditions	Purity %	Method reference (and technique if the reference gives more than one) and company report number/date
Vapour pressure	1.3 x 10 ⁻¹⁰ Pa at 25°C 3.8 x 10 ⁻¹¹ Pa at 20°C (extrapolated)	99.7 %	OECD 104 EC A.4 [101]
Melting point, boiling point and/or temperature of decomposition	Melting point: 176.8°C Boiling point: decompose before boiling Decomposition temperature: 242 °C	99.7 %	OECD 102 EC A.1 (DSC) [102]
Solubility in water	pH 7: 0.327 g/L at 20 °C determined in deionized water (resistivity > 17 MW)	99.7 %	OECD 105 (equivalent to EEC A.6, flask method) [103]
Octanol/water partition coefficient	pH 4 log P _{OW} = 0.893 at 25 °C pH 7 log P _{OW} = 0.905 at 25 °C pH 10 log P _{OW} = 0.873 at 25 °C	99.7 %	EEC A8 [104]
Hydrolysis characteristics	Half-life = 14.4 days at 50 °C at pH 9 Half-life = 3.7 days at 62 °C at pH 9 Half-life = 0.7 days at 74 °C at pH 9 Stable at 50 °C at pH 4 and 7 (<10% degradation after 5 days) Stable at 25°C at pH 5, 7 and 9 (<5% degradation after 33 days)	>98 %	EPA Series 161-1 EEC method C.7 [105]
Photolysis characteristics	Half-life 3.3 hours in sterile buffer pH 7 at 25°C Equivalent to 0.6 days of summer solar exposure at Phoenix, Arizona, US (40° latitude) using a Xenon lamp with UV cut-off filter at 290 nm. Intensity (300-800 nm) = 1027 W/m ² by radiometry. Photon flow density = 125.86 X 10 ¹⁴ s ⁻¹ cm ⁻² . Quantum yield (F) = 0.014	>99%	EPA Series 161-2 SETAC [106] [107]
Dissociation characteristics	pK _a = 11.09 (at 20°C)	99.7%	OECD 112 (spectrophotometric method) [103]

Table 2. Chemical composition and properties of clothianidin technical materials

Manufacturing process, maximum limits for impurities ³ 1 g/kg, 5 batch analysis data	Confidential information supplied and held on file by FAO. Mass balances were 99.1 – 99.5 %.
Declared minimum clothianidin content	960 g/kg
Relevant impurities ³ 1 g/kg and maximum limits for them	None
Relevant impurities < 1 g/kg and maximum limits for them:	None
Stabilisers or other additives and maximum limits for them:	None
Melting or boiling temperature range of the TC and/or TK	176.8 °C The value given is for pure material, a measurement for the TC is not available.

HAZARD SUMMARY

Clothianidin has not been evaluated by the WHO IPCS or by the FAO/WHO JMPR.

In EU the classification process is not yet finalized (but Annex I listing is already done). The classification has been discussed between the notifiers and the rapporteur member state and the proposal is reported as such in the draft assessment report:

FORMULATIONS AND CO-FORMULATED ACTIVE INGREDIENTS

The main formulation types available are SG, SC and GR.

Clothianidin is used alone or co-formulated with probenazole, cartap, validamycin, diclocymet, ferimzone, phthalide.

These formulations are registered and sold in many countries in Europe, Northern and Southern America, Africa, Asia and Australia.

METHODS OF ANALYSIS AND TESTING

The analytical method for determination of the active ingredient content is determined by reversed-phase HPLC with UV detection at 269 nm and external standardization.

The collaborative study for TC, SG, SC, and GR formulations were presented at the 2009 CIPAC meeting in El Salvador and were provisionally adopted as CIPAC Methods.

The methods for determination of impurities are based on HPLC- method using UV detection and internal standardization

Test methods for determination of physical and chemical properties of the technical active ingredient were OECD, EPA, and/or EC as indicated, while those for the formulations were CIPAC, as indicated in the specifications.

PHYSICAL PROPERTIES

The physical properties, the methods for testing them and the limits proposed for the SG, SC and GR formulations, comply with the requirements of the FAO/WHO Manual (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 clothianidin and is to be quantified as such.

Annex 1

HAZARD SUMMARY PROVIDED BY THE PROPOSER

Notes.

- (i) The proposer confirmed that the toxicological and ecotoxicological data included in the summary below were derived from clothianidin having impurity profiles similar to those referred to in the table above.
- (ii) The conclusions expressed in the summary below are those of the proposer, unless otherwise specified.

Table 3. Toxicology profile of clothianidin technical material, based on acute toxicity, irritation and sensitization

Species	Test	Duration and conditions or guideline adopted	Result	Reference
Rat male/female	Oral	JMAFF 59 NohSan No 4200; JMAFF 63-44; OECD 401; Directive 92/69/EC Method B.1.; Directive 92/18/EEC, L97; US-EPA Section 81-1; OPPTS 870. 1100 Purity: 96.0%	LD ₅₀ = > 5000 mg/kg bw	[201]
Rat male/female	Acute neurotoxicity gavage	US-EPA-FIFRA, Guideline 81-8(SS); US-EPA OPPTS 870.6200 0-100-200-400 mg/kg bw/d Purity: 95.2-96.0%	NOELs (male / female) Overall = > 60 / 100 mg/kg bw Neurotoxicity = > 400 mg/kg bw/d not neurotoxic	[202]
Mouse male/female	Oral	OECD 401; Directive 92/69/EC, Method B. 1.; Directive 92/18/EEC, L97; US-EPA Section 81-1; US-EPA OPPTS 870.1100 Purity: 96.0%	LD ₅₀ = 389 mg/kg bw (m) 465 mg/kg bw (f)	[203]
Rat male/female	Dermal	JMAFF 59 NohSan No 4200; JMAFF 63-44; OECD 402; Directive 92/69/EC, Method B.3.; Directive 92/18/EEC, L97; US-EPA Section 81-2; US-EPA OPPTS 870.1200 24 h semi-occlusive conditions Purity: 96.0%	LD ₅₀ = > 2000 mg/kg bw	[204]
Rat male/female	Inhalation	JMAFF 59 NohSan No 4200; JMAFF 63-44; OECD 403; Directive 92/69/EC, Method B.2.; Directive 92/18/EEC, OJEC, L97; USA-EPA Section 81-3; US-EPA OPPTS 870.1330 4.5 h exposure Purity: 96.0%	LC ₅₀ = > 6.141 mg/L	[205]
Rabbit male/female	Skin irritation	JMAFF 59 NohSan No 4200; JMAFF 63-44; OECD 404; Directive 92/69/EC, Method B.4.; Directive 92/18/EEC L97; US-EPA Section 81-5;	Non-irritating	[206]

		US-EPA OPPTS 870.2500 4 h exposure Purity: 96.0%		
Rabbit male	Eye irritation	OECD 405; Directive 92/69/EC, Method B.5.; Directive 92/18/EEC L97; US-EPA Section 81-4; US-EPA OPPTS 870.2400 24 h exposure Purity: 96.0%	Non-irritating	[207]
Guinea pig	Skin sensitization	OECD 406; Directive 92/69/EC, Method B.6.; Directive 92/18/EEC L97; US-EPA Section 81-6; US-EPA OPPTS 870.2600 Purity: 96.0%	Non-sensitizing	[208]

Table 4. Toxicology profile of technical clothianidin based on repeated administration (sub-acute to chronic)

Species	Test	Duration and conditions or guideline adopted	Result	Reference
Rat male/female	Sub-acute feeding	OECD 407; Directive 92/69/EEC (OJ No. L383A, 29.12.92), Part B, Method B.7.; EPA Guideline in Subdivision F. Hazard Evaluation: Human and Domestic Animals, November 1984; JMAFF 59 Nohsan No. 4200 4 weeks 0-1250-2500-5000-7500 ppm (equivalent to: 0-120-249-475-602 mg/kg bw/d (male), 0-137-228-454-689 mg/kg bw/d (female)) Purity: 97.5%	NOAEL = 120 / 137 mg/kg bw/d LOEL = 249 / 228 mg/kg bw/d	[209]
Mouse male/female	Sub-acute feeding	OECD 407; Directive 92/69/EEC (OJ No. L383A, 29.12.92), Part B, Method B.7.: EPA Guideline in Subdivision F. Hazard Evaluation: Human and Domestic Animals; JMAFF Nohsan No. 4200 deviation: duration 4 weeks 0-500-1000-2000-4000 ppm (equivalent to: 0-90-190-383-683 mg/kg bw/d (male) 0-122-248-491-619 mg/kg bw/d (female)) Purity: 97.5%	NOAEL = 190 / 248 mg/kg bw/d LOEL = 383 / 491 mg/kg bw/d	[210]
Dog female	Dose-range finding (palatability) feeding	Exposure to increasing dose levels 0 (for 11 days) - 3000 / 4000 / 5000 ppm (days 1-3 / 4-8 / 9-11) (equivalent to: 0- 51.1/50.8/51.8 mg/kg bw/d) Purity: 95.2%	NOEL = 51.8 mg/kg bw/d	[211]
Dog male/female	Dose-range finding feeding	Directive 88/302/EEC, Method B.27; US-EPA FIFRA Subdivision F, Section 82-1; US-EPA 870.3150; JMAFF 59 Nohsan No. 4200; mainly in accordance to OECD 409 4 weeks, 3 animals/sex/group 0-1250-2500-5000 ppm (equivalent to: 0-36.3-35.8-62.4 mg/kg bw/d (male) 0-35.6-52.3-57.4 mg/kg bw/d (female))	NOAEL = 36.3 / 35.6 mg/kg bw/d LOEL = 35.8 / 52.3 mg/kg bw/d	[212]

Species	Test	Duration and conditions or guideline adopted	Result	Reference
		Purity: 95.2%		
Rat male/female	Sub-acute dermal	US-EPA OPPTS 870.3200; JMAFF 59 Nohsan No. 4200; Directive 88/302/EEC (OJEC No. L 133/27) Part B; OECD 410 6 hrs/day, 28 days 0-100-300-1000 mg/kg bw/d Purity: 95.2%	NOEL = > 1000 mg/kg bw/d	[213]
Rat male/female	Sub-chronic feeding	FIFRA 82-1; TSCA 798.2650; US-EPA OPPTS 870.3100, OECD 408; JMAFF 59 NohSan No. 4200; Directive 87/302/EEC, part B 97 days 0-150-500-3000 ppm (equivalent to: 0-9.0-27.9-202 mg/kg bw/d (male) 0-10.9-34.0-254 mg/kg bw/d (female)) Purity: 95.3%	NOAEL = 27.9 / 34.0 mg/kg bw/d LOEL = 202 / 254 mg/kg bw/d	[214]
Dog male/female	Sub-chronic feeding	US-EPA-FTFRA Section. 82-1; US-EPA-OPPTS OPPTS 870.3150; OECD 409; JMAFF 59 Nohsan No. 4200; Directive 88/302/EEC (OJEC No. L 133/12), Part B 13 weeks 0-325-650-1500-2250 ppm (equivalent to: 0-9.2-19.3-40.9-58.2 mg/kg bw/d (male) 0-9.6-21.2- 42.1-61.8 mg/kg bw/d (female)) Purity: 95.2%	NOAEL = 19.3 / 21.2 mg/kg bw/d LOEL = 40.9 / 42.1 mg/kg bw/d	[215]
Dog male/female	Sub-chronic feeding	EPA-FIFRA Guideline 83-1; EPA-OPPTS Guideline Section 870.4100; OECD 452; JMAFF 59 Nohsan No. 4200, Directive 88/302/EEC, Part B 52 weeks 0-325-650-1500-2000ppm (equivalent to: 0-7.8-16.6-36.3-46.4 mg/kg bw/d (male) 0-8.5-15.0-40.1-52.9 mg/kg bw/d (female)) Purity: 95.2%	NOAEL = 36.3 / 40.1 mg/kg bw/d LOEL = 46.4 / 52.9 mg/kg bw/d	[216]

Species	Test	Duration and conditions or guideline adopted	Result	Reference
Rat male/female	Chronic oncogenicity feeding	JMAFF 59 NohSan No. 4200; OECD 453; EEC 88/302/EEC; FIFRA F, 83-5; OPPTS 870.4300 104 weeks 0-150-500-1500-3000 ppm (equivalent to: 0-8.1-27.4-82-157 mg/kg bw/d (male) 0-9.7-32.5-97.8-193 mg/kg bw/d (female)) Purity: 95.2-95.5%	NOAEL = 27.4 / 9.7 mg/kg bw/d LOEL = 82 / 32.5 mg/kg bw/d not carcinogenic	[217]
Mouse male/female	Oncogenicity feeding	JMAFF 59 NohSan No. 4200; OECD 451; EEC 88/302/EEC; FIFRA F, 83-2; OPPTS 870.4200 78 weeks 0-100-350-700/2000/2500/2000/1800 (week 1-4/ 5-10/ 11-34/ 35-termination 2000 ppm (m)/ 1800 ppm (f)) -1250 ppm (equivalent to: 0-13.5-47.2-171.4-251.9 mg/kg bw/d (male) 0-17.0-65.1-215.9-281.1 mg/kg bw/d (female)) Purity: 95.2%	NOAEL = 47.2 / 65.1 mg/kg bw/d LOEL = 171.4 / 215.9 mg/kg bw/d not carcinogenic	[218]
Rat male/female	Pilot reproduction one generation	US-EPA-FIFRA, Section 158.340, No. 83-4: US-EPA-TSCA, 40 CFR Section 798.4700: Guideline 87/302/EEC; OECD 416; J MAFF, 59 NohSan No. 4200 pre-mating 8 weeks 0-50-100-500-1000 ppm (equivalent during pre-mating to: 3.2-3.5 / 5.9-6.8 / 31.7-36.4 / 66.6 - 70.8 mg/kg bw/d) Purity: 95.2-96.0%	NOEL repro. = > 66.6 mg/kg bw/d	[219]
Rat male/female	Reproduction 2-generation	US-EPA, OPPTS 870.3800; Directive 91/414/EEC; OECD 416; JMAFF, 59 NohSan No. 4200 0-150-500-2500 ppm (equivalent to both generations combined: 0-10.2-32.7-179.6 mg/kg bw/d (male) 0-11.8-37.9-212.9 mg/kg bw/d (female) Purity: 95.3-96.0%	Parental NOEL = 32.7/11.8 mg/kg bw/d LOEL = 179.6/37.9 mg/kg bw/d Reproductive NOEL = >179.6/ >212.9 mg/kg bw/d Offspring NOEL = 10.2/11.8 mg/kg bw/d LOEL = 32.7/37.9 mg/kg bw/d	[220]

Species	Test	Duration and conditions or guideline adopted	Result	Reference
Rat female	Dose-range finding developmental toxicity	US-EPA OPPTS 870.3700 gestation days 6-19 0-125-250-500-1000 mg/kg bw/d Purity: 96.0%	Maternal NOAEL = not established LOEL = 125 mg/kg bw/d Developmental NOAEL = 125 mg/kg bw/d LOEL = 250 mg/kg bw/d	[221]
Rat female	Developmental toxicity	Guideline 88/302/EEC; OECD 414; US-EPA OPPTS 870.3700; JMAFF 59 NohSan no. 4200 gestation days 6-19 0-10-40-125 mg/kg bw/d Purity: 95.2%	Maternal NOEL = 10 mg/kg bw/d LOEL = 40 mg/kg bw/d Developmental NOAEL = 125 mg/kg bw/d LOEL = > 125 mg/kg bw/d not teratogenic	[222]
Rabbit female	Dose-range finding developmental toxicity	US-EPA OPPTS 870.3700 gestation days 6-28 0-62.5-125-250-500 mg/kg bw/d Purity: 96.0%	Maternal NOAEL = 62.5 mg/kg bw/d MTD < 125 mg/kg bw/d Developmental NOAEL > 62.5 mg/kg bw/d	[223]
Rabbit female	Developmental toxicity	Guideline 88/302/EEC, OECD 414; US-EPA OPPTS 870.3700; JMAFF 59 NohSan no. 4200 gestation days 6-28 0-10-25-75-100 mg/kg bw/d Purity: 95.2-95.5%	Maternal NOEL = 10 mg/kg bw/d LOEL = 25 mg/kg bw/d Developmental NOAEL = 75 mg/kg bw/d LOEL = 100 mg/kg bw/d not teratogenic	[224]
Rat male/female	Sub-chronic neurotoxicity feeding	US-EPA-FIFRA, Guideline 82-5(b); US-EPA OPPTS 870.6200 0-150-1000-3000 ppm equivalent to: 0-9.2-60-177 mg/kg bw/d (male) 0-10.6-71-200 mg/kg bw/d (female)	NOELs (male / female) Overall = 60 / 71 mg/kg bw d Neurotoxicity = >177 / >200 mg/kg bw/d not neurotoxic	[225]

Species	Test	Duration and conditions or guideline adopted	Result	Reference
		Purity: 95.3-96.0%		
Rat male/female	Developmental neurotoxicity feeding	US-EPA OPPTS 870.6300; US-EPA Guideline 83-3; US- EPA Pesticide Assessment Guidelines, Subdivision F, addendum 10, neurotoxicity day 0 of gestation until 22 days post partum 0-150-500-1750 ppm (equivalent to: 0-12.9-42.9-142 mg/kg bw/d (gestation) 0-27.3-90.0-299 mg/kg bw/d (lactation) Purity: 95.5-95.9%	NOELs (gestation / lactation) Maternal = 42.9 / 90.0 mg/kg bw/d Developmental = 12.9 / 27.3 mg/kg bw/d Developmental neurobehavioral effects > 142 / > 299 mg/kg bw/d	[226]

Table 5. Mutagenicity profile of technical clothianidin based on in vitro and in vivo tests

Species	Test	Duration and Conditions	Result	Reference
Salmonella typhimurium / escherichia coli	Reverse mutation assay 'Ames test' in vitro	Guideline 92/69/EEC, Method B.14.; OECD 471, US-EPA FIFRA section 84-2; JMAFF 59 NohSan no. 4200; Japan Ministry of Labour No. 77 S. typhimurium: TA 98, TA 100, TA 1535, TA 1537; E. coli: WP2uvrA ⁻ 0-50-150-500-1500-5000 µg/plate (+/- S9 mix) Purity: 95.2-96.0%	Positive (+S9 mix in TA 1535 only)	[227]
Salmonella typhimurium / escherichia coli	Reverse mutation assay 'Ames test' in vitro	Guideline 92/69/EEC, Method B.14.; JMAFF 59 NohSan no. 4200 S. typhimurium: TA 98, TA 100, TA 1535, TA 1537; E. coli: WP2uvrA ⁻ 0-313-625-1250-2500-5000 µg/plate (+/-S9 mix) Purity: ≥ 99%	Negative	[228]
Salmonella typhimurium	Reverse mutation assay 'Ames test' in vitro	Directive 92/69/EEC, Method B.14.; OECD 471; US-EPA 712-C-96-219, OPPTS 870.5265 S. typhimurium: TA 98, TA 100, TA 102, TA 1535, TA 1537 0-16-50-158-500-1581-5000 µg/plate/tube (+/-S9 mix) TA 102: 0-16-32-48-64-80-96-112 µg/plate (+/-S9 mix) Purity: 95.2%	Negative	[229]
Salmonella typhimurium	Reverse mutation assay 'Ames test' in vitro	Directive 92/69/EEC, Method B.14.; OECD 471; US- EPA 712-C-96-219, OPPTS 870.5265 S. typhimurium: TA 1535 Batch NLL 6100-3: 0-1000-2000-3000-4000-5000 µg/plate, Batch 30034708: 3000-5000-7000 µg/plate, 0-1000-2000-4000-6000-8000 µg/tube each batch +/- S9 mix, pre-incubation technique Purity: 98.6% (batch NLL 6100-3), 96.2% (batch 30034708)	Negative	[230]
Bacillus	DNA repair assay	JMAFF 59 Nohsan No. 4200 0-375-750-1500-3000-6000 µg/disc (+/- S9 mix)	Negative	[231]

Species	Test	Duration and Conditions	Result	Reference
subtilis	in vitro	Purity: ≥ 99%		
Chinese hamster lung (CHL) cells	Chromosome aberration assay in vitro	OECD 473; Directive 92/69/EEC, Annex V, Part B, Method B.10.; US-EPA FIFRA section 84-2 ; JMAFF 59 Nohsan No 4200 1st assay: 0-156.25-312.5-625-937.5-1250-1875 µg/mL 2nd assay: 0- 39 to 1875 µg/mL exposure 4 – 48 hrs, recovery 0 – 18 hrs, +/- S9 mix Purity: 96.0%	Positive (+/- S9 mix)	[232]
Mouse lymphoma cells	Gene mutation in mammalian cells in vitro	OECD 476; Directive 87/303/EEC no. LI 33, Method B. 14.; EPA FIFRA section 84-2; JMAFF 59 Nohsan No 4200 0-312.5-625-1250-1667-2500 µg/mL (+/-S9 mix) 0-300-600-1200-1600-2000 µg/mL (-S9 mix) 0-600-1200-1600-2000-2400 µg/mL (+S9 mix) Purity: 96.0%	Positive	[233]
Chinese hamster lung V79 cells	Gene mutation in mammalian cells in vitro	Directive 88/302/EEC; OECD 476; US-EPA712-C-96-221, OPPTS 870.5300 0-156-313-625-1250-2500-5000 µg/mL (+/- S9 mix) Purity: 95.2%	Negative	[234]
Mouse bone marrow cells	Chromosome aberration assay Micronucleus test in vivo	OECD 474; Directive 92/69/EEC, no. L383A, Method B.12.; EPA section 84-2; JMAFF 59 NohSan No. 4200 0-25-50-100 mg/kg bw (oral) Purity: 96.0%	Negative	[235]
Rat hepatocytes	Unscheduled DNA synthesis in vivo	In accordance with OECD draft guideline 'OECD Guidelines for Testing of Chemicals, Proposal for a New Guideline, "Genetic Toxicology: DNA Damage and Repair/ Unscheduled DNA Synthesis (UDS) Test with Mammalian Liver Cells In Vivo' and in addition Directive 88/302/EEC; OECD 482; US-EPA PB 84-233295	Negative	[236]

Species	Test	Duration and Conditions	Result	Reference
		0-2500-5000 mg/kg bw (oral) Purity: 95.2-96.2%		

Table 6. Ecotoxicology profile of technical clothianidin

Species	Test	Duration and conditions	Result	
Bobwhite quail <i>(Colinus virginianus)</i>	Acute oral	14d, US EPA Subdivision E, Guideline 71-1 (1982)	LD50 > 2000 mg /kg bw	[301]
Japanese quail <i>(Coturnix coturnix japonica)</i>	Acute oral	14d, US EPA Subdivision E, Guideline 71-1 (1982)	LD50 = 430 mg /kg bw	[302]
Bobwhite quail <i>(Colinus virginianus)</i>	dietary	8d, OECD 205 (1984)	LC50 > 5200 mg/kg diet	[303]
Mallard duck <i>(Anas platyrhynchos)</i>	dietary	8d, OECD 205 (1984)	LC50 > 5200 mg/kg diet	[304]
Bobwhite quail <i>(Colinus virginianus)</i>	Reproduction	20 weeks, OECD 206	NOEC = 500 mg/kg diet	[305]
Mallard duck <i>(Anas platyrhynchos)</i>	Reproduction	20 weeks, OECD 206	NOEC = 500 mg/kg diet	[306]
Rainbow trout <i>(Oncorhynchus mykiss)</i>	acute	96h, static, limit test, OECD 203	LC50 > 100 mg/l	[307]
Bluegill <i>(Lepomis macrochirus)</i>	acute	96h, static, limit test, OECD 203	LC50 > 120 mg/l	[308]

Fathead minnow <i>(Pimephales promelas)</i>	Chronic, ELS	33d, flow-through, US EPA Subdivision E, Guideline 72-4 (1982), US EPA OPPTS draft guideline 850.1400 (1996)	NOEC = 20 mg/l	[309]
Sheepshead minnow <i>(Cyprinodon variegatus)</i>	acute	96h, static, OECD 203	LC50 > 102.5mg/l	[310]
water flea <i>(Daphnia magna)</i>	acute toxicity	48h, static, OECD 202	EC ₅₀ > 120 mg/l	[311]
water flea <i>(Daphnia magna)</i>	Chronic toxicity	21d, semi-static, OECD 211	NOEC = 0.120 mg/l	[312]
Mysid shrimp <i>(Mysidopsis bahia)</i>	acute	96h, flow-through	LC50 = 0.053 mg/l	[313]
Mysid shrimp <i>(Mysidopsis bahia)</i>	Chronic, life cycle	39d, flow-through, OPPTS 850.1350	NOEC = 0.0097 mg/l	[314]
Oyster <i>(Crassostrea virginica)</i>	acute	96h, flow-through; OPPTS 850.1025	EC50 > 129.1 mg/l	[315]
Green alga <i>(Scenedesmus subspicatus)</i>	Chronic toxicity	72h, static, OECD 201	ErC50 > 270 mg/l	[316]
Green alga	Chronic toxicity	72h, static, OECD 201	ErC50 > 120 mg/l	[317]

<i>(Selenastrum capricornutum)</i>				
Sediment dwelling invertebrates <i>(Chironomus riparius)</i>	acute	48h, static	EC50 = 0.029 mg/l	[318]
Sediment dwelling invertebrates <i>(Chironomus riparius)</i>	chronic	28d, static, BBA	EC15 = 0.00072 mg/l	[319]
Duckweed <i>(Lemna gibba)</i>	chronic	14d, static renewal, US EPA OPPTS guideline 850.4400 (1996)	EC50 > 121 mg/l	[320]
Honeybee <i>(Apis mellifera)</i>	Acute oral Acute contact	48h, EPPO guideline n° 170 (1992)	Oral LD50 = 0.004 µg/bee Contact LD50 = 0.044 µg/bee	[321]
Parasitoid <i>(Aphidius rhopalosiphi)</i>	Laboratory	48h, tested as formulated product WG 500 g/kg SETAC (1994)	100 % mortality at 60 g a.s./ha	[322]
Predatory mite <i>(Typhlodromus pyri)</i>	Laboratory	14d, tested as formulated product WG 500 g/kg SETAC (1994)	69 % mortality at 60 g a.s./ha 97 % effect on reproduction at 60 g a.s./ha	[323]
Ground dwelling predatory species <i>(Aleochara bilineata)</i>	Laboratory	28d, tested as formulated product WG 500 g/kg SETAC (1994)	89 % corrected mortality at 75 g a.s./ha	[324]

Foliage dwelling predatory species <i>(Chrysoperla carnea)</i>	Laboratory	28d, tested as formulated product WG 500 g/kg SETAC (1994)	97 % corrected mortality at 60 g a.s./ha	[325]
Earthworm <i>(Eisenia fetida)</i>	acute	14d, OECD 207	LC50 = 13.2 mg/kg soil	[326]
Nitrogen transformation Soil respiration		28d, OECD 216 and 217	No significant effects (<25%) at 750 g a.s./ha (equivalent to 1 mg a.s./kg soil)	[327]
Terrestrial plants (10 species)	Seedling emergence	14d, OPPTS 850.4100 and 850.4225	NOEC = 225 g a.s./ha	[328]
Terrestrial plants (10 species)	Vegetative vigour	14d, OPPTS 850.4150	NOEC = 225 g a.s./ha	[329]

ANNEX 2. REFERENCES

Reference Number	Year Title Published / Unpublished SCC report No BCS doc. ID	Owner
[101]	Year: 2000 Title: Vapor Pressure of TI-435, Pure Active Ingredient Unpublished SCC report No: THP-0026 BCS doc ID: M-026219-03-2	SCC
[102]	Year: 2000 Title: Determination of melting point/melting range of TI-435 pure active ingredient (PAI) Unpublished SCC report No: THP-0018 BCS doc ID: M-025309-02-1	SCC
[103]	Year: 2000 Title: Determination of Dissociation Constant and Physical-chemical Properties of TI-435 Pure Active Ingrdient (PAI) (Density, Solubility, Octanol/Water Partition Coefficient, and Dissociation Constant) Unpublished SCC report No: THP-0013 BCS doc ID: M-026209-04-1	SCC
[104]	Year: 2001 Title: TI-435 (Pure Active Ingredient, PAI): Determination of the Effect of pH on Water Solubility and Partition Coefficient Unpublished SCC report No: not registered yet BCS doc ID: M-041740-01-1	
[105]	Year: 2000 Title: (14C)-TI-435: Hydrolytic stability Unpublished SCC report No: THP-0024 BCS doc ID: M-048047-01-1	SCC
[106]	Year: 2000 Title: Photolysis of [nitroimino-14C]TI-435 and [thiazolyl-2-14C]TI-435 in sterile aqueous buffer solution Unpublished SCC report No: THM-0013 BCS doc ID: M-023549-02-1	SCC
[107]	Year: 1999 Title: Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation of TI-435 in water Unpublished SCC report No: THP-0023 BCS doc ID: M-010153-02-1	SCC
[108]	Year: 2001 Title: Analytical method for analysis of TI-435 technical grade active ingredient (TGAI) Unpublished SCC report No: THA-0012 BCS doc ID: not registered	SCC
[201]	Year: 1997 Title: TI-435 - Acute oral toxicity study in the rat Unpublished SCC report No: THT-0047 BCS doc. ID: M-027393-01-1	SCC

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[202]	Year: 2000 Title: An acute oral neurotoxicity screening study with technical grade TI-435 in Fischer 344 rats Unpublished SCC report No: THT-0011 BCS doc. ID: M-027750-03-1	SCC
[203]	Year: 1997 Title: TI-435 - Acute oral toxicity study in the mouse Unpublished SCC report No: THT-0048 BCS doc. ID: M-027394-01-1	SCC
[204]	Year: 1997 Title: TI-435 - Acute dermal toxicity study in the rat Unpublished SCC report No: THT-0049 BCS doc. ID: M-027396-01-1	SCC
[205]	Year: 1998 Title: TI-435 - Single dose inhalation (head-only) toxicity study in the rat Unpublished SCC report No: THT-0070 BCS doc. M-027390-01-1	SCC
[206]	Year: 1997 Title: TI-435 - Skin irritation study in the rabbit Unpublished SCC report No: THT-0051 BCS doc. M-027402-01-1	SCC
[207]	Year: 1997 Title: TI-435 - Eye irritation study in the rabbit Unpublished SCC report No: THT-0050 BCS doc. M-027400-01-1	SCC
[208]	Year: 1997 Title: TI-435 - Skin sensitisation study in the guinea pig Unpublished SCC report No: THT-0065 BCS doc. M-027406-01-1	SCC
[209]	Year: 1997 Title: TI-435 - Toxicity to rats by dietary administration for 4 weeks Unpublished SCC report No: THT-0040 BCS doc. M-027408-01-1	SCC
[210]	Year: 1997 Title: TI-435 - Toxicity to mice by dietary administration for 4 weeks Unpublished SCC report No: THT-0041 BCS doc. M-027413-01-1	SCC
[211]	Year: 1998 Title: Palatability pilot study for dietary concentrations of TI-435 in dogs Unpublished SCC report No: THT-0078 BCS doc. M-027385-01-1	SCC

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[212]	Year: 2000 Title: 4-week dietary toxicity study with TI-435 in dogs Unpublished SCC report No: THT-0069 BCS doc. M-027342-01-1	SCC
[213]	Year: 2000 Title: 28-day dermal toxicity study with TI-435 in rats Unpublished SCC report No: THT-0071 BCS doc. M-027480-01-1	SCC
[214]	Year: 2000 Title: Technical grade TI 435 - A subchronic toxicity testing study in the rat Unpublished SCC report No: THT-0045 BCS doc. M-027268-01-1	SCC
[215]	Year: 2000 Title: 13-Week dietary toxicity study with TI-435 in dogs Unpublished SCC report No: THT-0003 BCS doc. M-036499-02-1	SCC
[216]	Year: 2000 Title: 52-week dietary chronic toxicity study with TI-435 in dogs Unpublished SCC report No: THT-0004 BCS doc. M-036542-01-1	SCC
[217]	Year: 2000 Title: 104-week dietary combined chronic toxicity and carcinogenicity study with TI-435 in rats Unpublished SCC report No: THT-0038 BCS doc. M-031986-02-1	SCC
[218]	Year: 2000 Title: 78-week dietary carcinogenicity study with TI-435 in mice Unpublished SCC report No: THT-0005 BCS doc. M-032363-02-1	SCC
[219]	Year: 2000 Title: A pilot reproductive toxicity study with TI-435 in the Sprague-Dawley rat Unpublished SCC report No: THT-0001 BCS doc. M-027255-01-1	SCC
[220]	Year: 2000 Title: A two generation reproductive toxicity study with TI-435 in the Sprague-Dawley rat Unpublished SCC report No: THT-0046 BCS doc. M-031280-02-1	SCC
[221]	Year: 1998 Title: Oral (gavage) dosage-range developmental toxicity study of TI-435 in rats Unpublished SCC report No: THT-0062 BCS doc. M-027430-02-1	SCC

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[222]	Year: 1998 Title: Oral (gavage) developmental toxicity study of TI-435 in rats Unpublished SCC report No: THT-0061 BCS doc. M-027416-01-1	SCC
[223]	Year: 1998 Title: Oral (stomach tube) dosage-range developmental toxicity study of TI-435 in rabbits Unpublished SCC report No: THT-0060 BCS doc. M-027436-02-1	SCC
[224]	Year: 1998 Title: Oral (stomach tube) developmental toxicity study of TI-435 in rabbits Unpublished SCC report No: THT-0059 BCS doc. M-027442-01-1	SCC
[225]	Year: 2000 Title: A subchronic neurotoxicity screening study with technical grade TI-435 in Fischer 344 rats Unpublished SCC report No: THT-0067 BCS doc. M-027986-01-1	SCC
[226]	Year: 2000 Title: Developmental neurotoxicity study of TI-435 administered orally via diet to CRL:CD BR VAF/PLUS presumed pregnant rats Unpublished SCC report No: THT-0068 BCS doc. M-027178-02-1	SCC
[227]	Year: 2000 Title: TI-435 - Reverse mutation assay 'Ames test' using salmonella typhimurium and escherichia coli Unpublished SCC report No: THT-0086 BCS doc. M-036520-01-1	SCC
[228]	Year: 1990 Title: Bacterial reverse mutation test of TIR-435 Unpublished SCC report No: THT-0087 BCS doc. M-036420-02-1	SCC
[229]	Year: 1997 Title: TI 435 - Salmonella/microsome test plate incorporation and preincubation method - revised version of Bayer report 26584, first revision - Unpublished SCC report No: THT-0079 BCS doc. M-009777-02-1	SCC
[230]	Year: 1996 Title: Special study - TI 435 - Salmonella/microsome test using salmonella typhimurium TA 1535 plate incorporation and preincubation method - revised version of Bayer report 25739 - first revision Unpublished SCC report No: THT-0080 BCS doc. M-009769-02-1	SCC

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[231]	Year: 1990 Title: DNA repair test of TIR-435 in Bacillus subtilis Unpublished SCC report No: THT-0097 BCS doc. M-036407-02-1	SCC
[232]	Year: 2000 Title: TI-435 - Chromosome aberration test in CHL cells in vitro Unpublished SCC report No: THT-0096 BCS doc. M-036479-02-1	SCC
[233]	Year: 2000 Title: TI-435 - L5178Y TK +/- mouse lymphoma assay Unpublished SCC report No: THT-0099 BCS doc. M-036462-02-1	SCC
[234]	Year: 1997 Title: TI 435 - Mutagenicity study for the detection of induced forward mutations in the V79-HPRT assay in vitro - revised version of Bayer report 26437, first revision - Unpublished SCC report No: THT-0095 BCS doc. M-009761-02-1	SCC
[235]	Year: 2000 Title: TI-435 - Micronucleus test in the mouse Unpublished SCC report No: THT-0098 BCS doc. M-036435-02-1	SCC
[236]	Year: 1997 Title: TI 435 - Test on unscheduled DNA synthesis with rat liver cells in vivo - revised version of Bayer report 26915, first revision - Unpublished SCC report No: THT-0100 BCS doc. M-009751-03-1	SCC
[301]	Year: 1998 Title: TI-435 technical - Acute oral toxicity (LD50) to bobwhite quail Unpublished SCC report No: THW-0119 BCS doc. M-027064-01-1	SCC
[302]	Year: 2000 Title: TI-435 technical: An acute oral toxicity study with the japanese quail Unpublished SCC report No: THW-0118 BCS doc. M-027285-01-1	SCC
[303]	Year: 1998 Title: TI-435 technical - Dietary LC50 to the bobwhite quail Unpublished SCC report No: THW-0120 BCS doc. M-027059-01-1	SCC
[304]	Year: 1998 Title: TI-435 technical - Dietary LC50 to the mallard duck Unpublished SCC report No: THW-0121 BCS doc. M-027068-01-1	SCC

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[305]	Year: 2000 Title: TI-435 technical: A reproduction study with the northern bobwhite (<i>Colinus virginianus</i>) Unpublished SCC report No: THW-0116 BCS doc. M-027293-01-1	SCC
[306]	Year: 2000 Title: TI-435 technical: A reproduction study with the mallard (<i>Anas platyrhynchos</i>) Unpublished SCC report No: THW-0117 BCS doc. M-027289-01-1	SCC
[307]	Year: 1998 Title: TI-435 technical - Fish (rainbow trout), acute toxicity test, 96 h, limit test Unpublished SCC report No: THW-0029 BCS doc. M-027029-02-1	SCC
[308]	2000 Year: Title: TI-435 technical - A 96-hour static acute toxicity test with the bluegill (<i>Lepomis macrochirus</i>) Unpublished SCC report No: THW-0027 BCS doc. M-031285-01-1	BCS, SCC
[309]	Year: 2000 Title: TI-435 technical: An early life-stage toxicity test with the fathead minnow (<i>Pimephales promelas</i>) Unpublished SCC report No: THW-0026 BCS doc. M-031516-01-1	BCS, SCC
[310]	Year: 1999 Title: TI-435 technical - Fish (Sheepshead minnow), acute toxicity test, limit test, 96 h, semi-static Unpublished SCC report No: THW-0028 BCS doc. M-027244-01-1	SCC
[311]	Year: 2000 Title: TI-435 technical - A 48-hour static acute toxicity test with the cladoceran (<i>Daphnia magna</i>) Unpublished SCC report No: THW-0043 BCS doc. M-031283-01-1	BCS, SCC
[312]	Year: 1998 Title: TI-435 technical - <i>Daphnia magna</i> reproduction test (21 d) Unpublished SCC report No: THW-0049 BCS doc. M-027071-02-1	SCC
[313]	Year: 2000 Title: TI-435 technical: A 96-hour flow-through acute toxicity test with the saltwater mysid (<i>Mysidopsis bahia</i>) - final report Unpublished SCC report No: THW-0057 BCS doc. M-019551-01-1	SCC

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[314]	Year: 2000 Title: TI-435 technical: A flow-through life-cycle toxicity test with the salwater mysid (<i>Mysidopsis bahia</i>) Unpublished SCC report No: THW-0058 BCS doc. M-026384-01-1	SCC
[315]	Year: 1999 Title: TI-435 technical - Oyster, acute toxicity test (shell deposition), limit test, flow-through, 96 h Unpublished SCC report No: THW-0059 BCS doc. M-028515-01-1	SCC
[316]	Year: 1998 Title: TI-435 technical - Alga, growth inhibition test (120 (h)) (<i>Scenedesmus subspicatus</i>) Unpublished SCC report No: THW-0040 BCS doc. M-027041-02-1	SCC
[317]	Year: 2000 Title: TI-435 technical - A 5-day toxicity test with the freshwater alga (<i>Selenastrum capricornutum</i>) Unpublished SCC report No: THW-0041 BCS doc. M-026366-01-1	SCC
[318]	Year: 2001 Title: TI-435: Comparative acute toxicity of <i>Chironomus riparius</i> with TZMU, MU, TZNG and MNG Unpublished SCC report No: THW-0051 BCS doc. M-032142-01-1	SCC
[319]	Year: 1999 Title: Influence of TI 435 technical on development and emergence of larvae of <i>Chironomus riparius</i> in a water-sediment system Unpublished SCC report No: THW-0052 BCS doc. M-011874-01-1	SCC
[320]	Year: 2000 Title: TI-435 technical - A 14-day static-renewal toxicity test with duckweed (<i>Lemna gibba</i> G3) Unpublished SCC report No: THW-0042 BCS doc. M-031279-01-1	BCS, SCC
[321]	Year: 1998 Title: Final report - TI-435 technical: Acute contact and oral toxicity to honeybees Unpublished SCC report No: THW-0104 BCS doc. M-027051-01-1	SCC
[322]	Year: 1999 Title: Final report - TI-435: Tier I standard laboratory bioassay of the effects of fresh residues on <i>Aphidius rhopalosiphi</i> (Hymenoptera, Braconidae) Unpublished SCC report No: THW-0125 BCS doc. M-027182-01-1	SCC

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[323]	Year: 1999 Title: Final report - TI-435: Tier I standard laboratory bioassay of the effects of fresh residues on <i>Typhlodromus pyri</i> (Acari, Phytoseiidae) Unpublished SCC report No: THW-0132 BCS doc. M-027179-01-1	SCC
[324]	Year: 1999 Title: A laboratory evaluation of the effects of TI-435 50% WDG on adults of the staphylinid beetle, <i>Aleochara bilineata</i> Unpublished SCC report No: THW-0131 BCS doc. M-027200-01-1	SCC
[325]	Year: 1999 Title: Final report - TI-435: Tier I standard laboratory bioassay of the effects of fresh residues on <i>Chrysoperla carnea</i> (Neuroptera, Chrysopidae) Unpublished SCC report No: THW-0129 BCS doc. M-027198-01-1	SCC
[326]	Year: 1998 Title: Final report - TI-435 technical: Acute toxicity to the earthworm <i>Eisenia foetida</i> Unpublished SCC report No: THW-0065 BCS doc. M-027046-01-1	SCC
[327]	Year: 1999 Title: The effect of TI-435 50 % WDG on soil microflora (OECD guidelines 216 and 217 for the testing of chemicals. Revised draft documents, January 1999) Unpublished SCC report No: THW-0020 BCS doc. M-027297-01-1	SCC
[328]	Year: 2000 Title: TI-435 50 % WDG: A toxicity test to determine the effects of the test substance on seedling emergence of ten species of plants Unpublished SCC report No: THW-0002 BCS doc. M-026377-01-1	SCC
[329]	Year: 2000 Title: TI-435 50 % WDG: A toxicity test to determine the effects of the test substance on vegetative vigor of ten species of plants Unpublished SCC report No: THW-0015 BCS doc. M-026381-01-1	SCC