

FAO SPECIFICATIONS AND EVALUATIONS FOR AGRICULTURAL PESTICIDES

THIACLOPRID

N-{(2Z)-3-[(6-Chloro-3-pyridinyl)methyl]-1,3-thiazolan-2-yliden}cyanamide



FOOD AND AGRICULTURE ORGANIZATION *of* THE UNITED NATIONS

TABLE OF CONTENTS

	Page
DISCLAIMER	
INTRODUCTION	1
PART ONE	
SPECIFICATIONS FOR THIACTOPRID	2
THIACTOPRID INFORMATION	3
THIACTOPRID TECHNICAL MATERIAL (MAY 2010)	4
THIACTOPRID AQUEOUS SUSPENSION CONCENTRATE (MAY 2010)	5
THIACTOPRID SUSPO-EMULSION (MAY 2010)	8
THIACTOPRID OIL-BASED SUSPENSION CONCENTRATE (MAY 2010)	11
THIACTOPRID WATER DISPERSIBLE GRANULES (MAY 2010)	14
PART TWO	
EVALUATIONS OF THIACTOPRID	16
2010 FAO/WHO EVALUATION REPORT ON THIACTOPRID	17
SUPPORTING INFORMATION	19
ANNEX 1: HAZARD SUMMARY PROVIDED BY PROPOSER	22
ANNEX 2: REFERENCES	28

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.

From 2002, the development of WHO specifications follows the **New Procedure**, described in the 1st edition of “Manual for Development and Use of FAO and WHO Specifications for Pesticides” (2002) and amended with the supplement of this manual (2006), which is available only on the internet through the FAO and WHO web sites. 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 pesticide in accordance with chapters 4 to 9 of the “Manual on development and use of FAO and WHO specifications for pesticides”.

Part Two: The Evaluation Report(s) of the pesticide, reflecting the evaluation of the data package carried out by FAO and the JMPS. The data are provided by the manufacturer(s) according to the requirements of chapter 3 of the “FAO/WHO Manual on Pesticide Specifications” 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 developed 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

THIACTOPRID

	Page
THIACTOPRID INFORMATION	3
THIACTOPRID TECHNICAL MATERIAL (MAY 2010)	4
THIACTOPRID AQUEOUS SUSPENSION CONCENTRATE (MAY 2010)	5
THIACTOPRID SUSPO-EMULSION (MAY 2010)	8
THIACTOPRID OIL-BASED SUSPENSION CONCENTRATE (MAY 2010)	11
THIACTOPRID WATER DISPERSIBLE GRANULES (MAY 2010)	14

THIACTOPRID

INFORMATION

ISO common name

thiacloprid (BSI, E-ISO)

Chemical name(s)

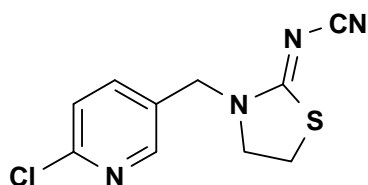
IUPAC N-{(2Z)-3-[(6-Chloro-3-pyridinyl)methyl]-1,3-thiazolan-2-ylidene}cyanamide

CAS Cyanamide, N-[(2Z)-3-[(6-chloro-3-pyridinyl)methyl]-2-thiazolidinylidene]-

Synonyms

YRC 2894

Structural formula



Molecular formula

C₁₀H₉ClN₄S

Relative molecular mass

252.7

CAS Registry number

111988-49-9

CIPAC number

631

Identity tests

HPLC retention time; ¹H NMR spectrum

THIACTOPRID TECHNICAL MATERIAL

FAO specification 631/TC (MAY 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 (631/2007). It should be applicable to TC produced by this manufacturer 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 TC produced by other manufacturers. The evaluation report (631/2007), as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of thiacloprid together with related manufacturing impurities, in the form of a white to light brown coloured crystalline powder, free from visible extraneous matter and added modifying agents.

2 Active ingredient

2.1 Identity tests (631/TC/M/2, CIPAC Handbook M, p. 199)

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 Thiacloprid content (631/TC/M/3, CIPAC Handbook M, p. 199)

The thiacloprid content shall be declared (not less than 975 g/kg) and, when determined, the average measured content shall not be lower than the declared minimum content.

*NOTE: publications are available on the internet at
<http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmps/en/>

THIACTOPRID AQUEOUS SUSPENSION CONCENTRATE

FAO specification 631/SC (MAY 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 report (631/2007). It should be applicable to relevant products of this manufacturer, and those of any other formulators who use only TC from the evaluated source. 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 (631/2007), as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of a suspension of fine particles of technical thiacloprid, complying with the requirements of FAO specification 631/TC (2010), in the form of a light brown suspension, in an aqueous phase together with suitable formulants. After gentle agitation the material shall be homogeneous (Note 1) and suitable for further dilution in water.

2 Active ingredient

2.1 Identity tests (631/SC/M/2, CIPAC Handbook M, p. 203)

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 Thiacloprid content (631/SC/M/3, CIPAC Handbook M, p. 203)

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

Declared content, g/kg or g/l at $20 \pm 2^\circ\text{C}$	Tolerance
above 100 up to 250	$\pm 6\%$ of the declared content
above 250 up to 500	$\pm 5\%$ of the declared content
Note. the upper limit is included in each range	

3 Physical properties

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

Maximum "residue": 3%.

3.2 Spontaneity of dispersion (MT 160, CIPAC Handbook F, p.391, 1995) (Note 5)

A minimum of 85% of the thiacloprid content found under 2.2 shall be in

* 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/en/>

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 85% of the thiacloprid 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. 148, 2003)

Maximum: 0.2% 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 5)

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 the 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 6) 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 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 3 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 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 6 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.

THIACTOPRID AQUEOUS SUSPO-EMULSION

FAO specification 631/SE (MAY 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 report (631/2007). It should be applicable to relevant products of this manufacturer, and those of any other formulators who use only TC from the evaluated source. 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 (631/2007), as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of a suspension of fine particles of technical thiacloprid combined with an emulsion of fine droplets of technical thiacloprid or another active substance in solution in an oil, complying with the requirements of FAO specification 631/TC (2010), in the form of a light brown suspension, in an aqueous phase, together with other suitable formulators. After gentle agitation, the material shall be homogeneous (Note1), and be suitable for further dilution in water.

2 Active Ingredient

2.1 Identity tests (631/SE/M/2, CIPAC Handbook M, p. 204)

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 Thiacloprid content (631/SE/M/3, CIPAC Handbook M, p. 204)

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

Declared content, g/kg or g/l at $20 \pm 2^\circ\text{C}$	Tolerance
Above 100 up to 250	$\pm 6\%$ of the declared content
Note: the upper limit is included in the range	

3 Physical properties

3.1 Pourability (MT 148.1, CIPAC Handbook J, p. 133, 2000)

Maximum "residue": 5%.

* 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/en/>

3.2 Dispersion stability (MT 180, CIPAC Handbook H, p.310, 1998) (Note 3)

The formulation, when diluted at $30 \pm 2^\circ\text{C}$ (Note 3) with CIPAC Standard Waters A and D, shall comply with the following:

Time after allowing the dispersion to stand	Limits of stability
0 h	Initial dispersion complete
0.5 h	"Cream", maximum: 0.5 ml
2.0 h	"Cream", maximum: 0 ml "Free oil" maximum: 0.05 ml "Sediment" maximum: 0.05 ml
24 h	Re-dispersion complete
24.5 h	"Cream", maximum: 0.5 ml "Free oil" maximum: 0.05 ml "Sediment" maximum: 0.05 ml

3.3 Wet sieve test (MT 185, CIPAC Handbook K, p. 148, 2003) (Note 4)

Maximum: 0.2% of the formulation shall be retained on a 75 μm test sieve.

3.4 Persistent foam (MT 47.2, CIPAC Handbook F, p. 152, 1995) (Note 5)

Maximum: 30 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 the clauses for:

- dispersion stability (3.2),
- wet sieve test (3.3).

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 6) and the formulation shall continue to comply with the clause for:

- pourability (3.1),
- dispersion stability (3.2),
- wet sieve test (3.3).

Note 1 Before sampling to verify formulation quality, inspect the commercial container carefully. On standing, suspo-emulsions usually develop a concentration gradient which may result in the appearance of a clear layer at either the top or the bottom of the container. A sediment layer may also form at the bottom of the container, which can be detected by probing with a glass rod. 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).

After this procedure the container should not contain a sticky layer of non-dispersed matter at the bottom (if the suspo-emulsion has flocculated it may not be possible to redisperse this sticky layer). All the physical and chemical tests must be carried out on a laboratory sample taken after the recommended homogenization procedure.

- 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 This test will normally be carried out after the test of stability at elevated temperature (4.2). The formulation should be tested at the highest and lowest recommended rates of use.
- Note 4 The formulation should be tested at the highest and lowest recommended rates of use. Following the CIPAC MT185, weigh an appropriate quantity of the sample into a beaker and add tap water. Allow to stand for 60 s, then stir with the magnetic stirrer for 5 min, making no deliberate attempt to break up any lumps. After the magnetic stirring step (5'), the slurry is allowed to stand for up to 5' before the sieving step.
- Note 5 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 6 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.

THIACTOPRID OIL-BASED SUSPENSION CONCENTRATE

FAO specification 631/OD (MAY 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 report (631/2007). It should be applicable to relevant products of this manufacturer, and those of any other formulators who use only TC from the evaluated source. 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 (631/2007), as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of a stable suspension of fine particles of technical thiacloprid, complying with the requirements of FAO specification 631/TC (2010), in the form of a white to light brown suspension, in a non-aqueous fluid together with suitable formulators. After shaking or stirring of the sample, the material shall be homogeneous (Note 1).

2 Active Ingredient

2.1 Identity tests (631/OD/M/2, CIPAC Handbook M, p. 205)

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

2.3 Thiacloprid content (631631/OD/M/3, CIPAC Handbook M, p. 205)

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

Declared content, g/kg or g/l at $20 \pm 2^\circ\text{C}$	Tolerance
Above 25 up to 100	$\pm 10\%$ of the declared content
Above 100 up to 250	$\pm 6\%$ of the declared content
Note: the upper limit is included in each range	

3 Physical properties

3.1 Pourability (MT 148.1, CIPAC Handbook J, p. 133, 2000)

Maximum "residue": 5%.

* 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/en/>

3.2 Dispersion stability (MT 180, CIPAC Handbook H, p.310, 1998) (Note 3)

The formulation, when diluted at $30 \pm 2^\circ\text{C}$ with CIPAC Standard Waters A and D, shall comply with the following:

Time after allowing the dispersion to stand	Limits of stability
0 h	Initial dispersion complete
0.5 h	"Cream", maximum: 0.5 ml
2.0 h	"Cream", maximum: 0 ml "Free oil" maximum: 0.05 ml "Sediment" maximum: 0.05 ml
24 h	Re-dispersion complete
24.5 h	"Cream", maximum: 0.5 ml "Free oil" maximum: 0.05 ml "Sediment" maximum: 0.05 ml

3.3 Wet sieve test (MT 185, CIPAC Handbook K, p. 148, 2003)

Maximum: 0.2% of the formulation shall be retained on a 75 μm test sieve.

3.4 Persistent foam (MT 47.2, CIPAC Handbook F, p. 152, 1995) (Note 4)

Maximum: 20 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 the clauses for:

- dispersion stability (3.2),
- wet sieve test (3.3).

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 5) and the formulation shall continue to comply with the clause for:

- pourability (3.1),
- dispersion stability (3.2),
- wet sieve test (3.3).

Note 1 Before sampling to verify the formulation quality, inspect the commercial container carefully. On standing, oil-based suspension concentrates (OD) 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 gently 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 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 test should be carried out at 2% dilution or, alternatively, at the highest and lowest recommended rates of use.

Note 4 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 5 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.

THIACTOPRID WATER DISPERSIBLE GRANULES

FAO specification 631/WG (MAY 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 report (631/2007). It should be applicable to relevant products of this manufacturer, and those of any other formulators who use only TC from the evaluated source. 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 (631/2007), as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of a homogeneous mixture of technical thiacloprid, complying with the requirements of the FAO specification 631/TC (2010), in the form of a light brown powder together with carriers and any other necessary formulators. It shall be in the form of granules 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 (631/WG/M/2, CIPAC Handbook M, p. 201)

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

2.4 Thiacloprid content (631/WG/M/3, CIPAC Handbook M, p. 202)

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

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

3 Physical properties

3.1 Wettability (MT 53.3, CIPAC Handbook F, p. 165, 1995)

The formulation shall be completely wetted in 1 min without swirling.

3.2 Wet sieve test (MT 185, CIPAC Handbook K, p. 148, 2003)

Maximum: 1% retained on a 75 µm test sieve.

* 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/en/>

- 3.3 **Degree of dispersion** (MT 174, CIPAC Handbook F, p. 435, 1995)
Dispersibility: minimum 90% after 1 minute of stirring.
- 3.4 **Suspensibility** (MT 184, CIPAC Handbook K, p. 142, 2003) (Note 1)
A minimum of 80% shall be in suspension after 30 minutes in CIPAC Standard Water D at $30 \pm 2^\circ\text{C}$.
- 3.5 **Persistent foam** (MT 47.2, CIPAC Handbook F, p. 152, 1995) (Note 2)
Maximum: 40 ml after 1 min.
- 3.6 **Dustiness** (MT 171, CIPAC Handbook F, p. 425, 1995) (Note 3)
Nearly dust-free.
- 3.7 **Flowability** (MT 172, CIPAC Handbook F, p. 430, 1995)
At least 99% of the formulation shall pass through a 5 mm test sieve after 20 drops of the sieve.
- 3.8 **Attrition resistance** (MT 178.2, CIPAC Handbook K, p. 140, 2003)
Minimum: 98% 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 clause for:
- wet sieve test (3.2),
 - degree of dispersion (3.3),
 - suspensibility (3.4),
 - dustiness (3.6),
 - attrition resistance (3.8).

Note 1 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 2 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 3 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 4 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

THIACTOPRID

	Page
2010 FAO/WHO evaluation report on thiacloprid	17
Supporting information	19
Annex 1: hazard summary provided by the proposer	22
Annex 2: references	28

THIACTOPRID

FAO/WHO EVALUATION REPORT 631/2010

Recommendations

The Meeting recommended that:

- (i) the specifications for thiacloprid TC, SC, SE, OD and WG, proposed by Bayer CropScience and as amended, should be adopted by FAO.

Appraisal

The meeting considered data submitted by Bayer CropScience in support of proposed new FAO specifications for thiacloprid TC, SC, SE, OD and WG. The data and proposed specifications were broadly in accordance with the requirements of the FAO/WHO manual [M-360693-02-1].

Thiacloprid is not under patent.

Thiacloprid has recently been evaluated by the FAO/WHO JMPR for residues and toxicology [M-364878-01-1]. It has been reviewed by the U.S. EPA and the European Commission and was included in Annex I of Council Directive 91/414/EEC in October 2004. The WHO hazard classification is class II, 'moderately hazardous' (category II) (04).

Thiacloprid is a yellowish crystalline solid of very low volatility. It is slightly soluble in water, the solubility is not influenced by pH in the range between 4 to 9 and it has no acidic or basic properties in aqueous solution. Its octanol/water partition coefficient ($\log P_{ow} = 1.26$) shows that the molecule is not lipophilic. Thiacloprid is hydrolytically stable in the pH range 5 to 9 and undergoes photolysis only very slowly.

The Meeting noted that thiacloprid is inadequately described by the IUPAC and CA names, which do not distinguish whether thiacloprid is the *E*-isomer at the C=N group, or the *Z*-isomer, or a mixture of the two. The manufacturer stated that thiacloprid is the *Z*-isomer and have provided the new IUPAC and CA names.

The Meeting was provided with commercially confidential information on the manufacturing process and 5-batch analysis data on all impurities present at or above 1g/kg and their manufacturing limits in the TC. Mass balances ranged from 997.2-1001.09 g/kg. These data were confirmed as identical to those submitted for registration in Greece.

The Meeting questioned whether or not *N*-nitrosamines could be formed during the production of thiacloprid. The manufacturer explained that according to their manufacturing process, the generation of nitrosamines is highly unlikely. The Meeting agreed that *N*-nitrosamines did not qualify as relevant impurities in thiacloprid. The Meeting agreed that none of the impurities should be designated as relevant for specification purposes.

The physical properties, the methods for testing them and the limits proposed for the SC, SE, OD, WG formulation, generally complied with the requirements of the FAO/WHO manual but the Meeting considered the following issues.

SC, SE, OD, WG. Clauses for pH range were proposed but thiacloprid is resistant to hydrolysis and the manufacturer agreed that they were not essential quality criteria for SC and WG formulations.

SE. The manufacturer stated that two different SE products were covered by the specification, both containing thiacloprid in particulate form. However, one also contains emulsified thiacloprid and the other contains a second active ingredient in the form of an emulsion.

SE, OD. The Meeting noted that the proposed limits for “free oil” and “sediment” in the dispersion stability clause were 0.05 ml and questioned whether the CIPAC method was capable of measuring such small volumes. The manufacturer provided evidence to show that the method is indeed capable of providing such measurements.

Analytical methods for the identification and quantification of thiacloprid in the TC and SC, SE, OD and WG formulations were adopted by CIPAC with provisional status in 2006, were later promoted to full methods and are in the meantime published in CIPAC Handbook M which appeared in 2009.

SUPPORTING INFORMATION
FOR
EVALUATION REPORT 631/2010

Uses

Thiacloprid is a chloronicotinyl insecticide for the control of a wide range of insects. It acts as an agonist of nicotinic acetylcholine receptors (nAChR) and it is therefore effective against insects resistant to acetylcholinesterase inhibitors (e.g. organophosphorus and carbamate insecticides). It is used for control of Homoptera (especially aphids) and Coleoptera in cereals, oilseed rape, potato, sugar beet, pome and stone fruits, fruiting vegetables, cucurbits, brassica vegetables, lettuce and pulses and many others.

Identity of the active ingredient

ISO common name

thiacloprid (BSI, E-ISO)

Chemical name(s)

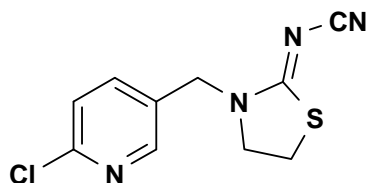
IUPAC N-{(2Z)-3-[(6-Chloro-3-pyridinyl)methyl]-1,3-thiazolan-2-ylidene}cyanamide

CAS Cyanamide, N-[(2Z)-3-[(6-chloro-3-pyridinyl)methyl]-2-thiazolidinylidene]-

Synonym

YRC 2894

Structural formula



Molecular formula

C₁₀H₉ClN₄S

Relative molecular mass

252.7

CAS Registry number

111988-49-9

CIPAC number

631

Identity tests

HPLC retention time; ¹H NMR spectrum

Physico-chemical properties of thiacloprid

Table 1. Physico-chemical properties of pure thiacloprid

Parameter	Value(s) and conditions	Purity %	Method	Reference
Vapour pressure	3 x 10 ⁻⁷ mPa at 20°C 8 x 10 ⁻⁷ mPa at 25°C	99.7	OECD 104	M-000646-01-1
Melting point	136°C	99.3	OECD 113	M-000646-01-1
Boiling point	Not measurable	99.3	OECD 113	M-000646-01-1
Decomposition temperature	>270°C	99.3	OECD 113	M-000646-01-1
Solubility in water	0.185 g/l at 20°C, not influenced by pH in the range 4 to 9	99.3	OECD 105	M-001134-01-1
Octanol/water partition coefficient	log P _{OW} = 1.26 at 20°C	99.3	OECD 107	M-000646-01-1
Hydrolysis characteristics	Stable at pH 5, 7 and 9 During 30-d incubation at 25°C, max. 2% of applied radioactivity recovered as reaction products. Extrapolated DT ₅₀ >1 year	Radio-chemical >98	US EPA: CFR 40, Series 161-1	M-001109-01-1
Photolysis characteristics	Under 18 d continuous irradiation at 25°C with simulated sunlight in a Suntest® unit, average intensity about 945 W/m ² (corresponding to approx. 73 solar d in Phoenix, USA) thiacloprid degraded very slowly with half-life = 79.7 d. Corresponding to environmental half-life approx. 324 solar d in Phoenix, USA	Radio-chemical >98	US EPA: CFR 40, Series 161-2	M-001134-01-1
Dissociation characteristics	Titration with NaOH or HCl showed no potential jumps corresponding to neutralization reactions of acidic or basic centres in the molecule.	99.3	OECD 112	M-000646-01-1

Table 2. Physico-chemical properties of thiacloprid technical material (TC)

Manufacturing process, maximum limits for impurities ≥1 g/kg, 5 batch analysis data	Confidential information supplied and held on file by FAO. Mass balances were 99.72-100.10%.
Declared minimum thiacloprid content	975 g/kg
Relevant impurities ≥ 1 g/kg and maximum limits for them	None
Relevant impurities < 1 g/kg and maximum limits for them	None
Stabilizers or other additives and maximum limits for them	None
Melting temperature range	135-136°C

Hazard summary

Thiacloprid has been evaluated by the FAO/WHO JMPR [M-364878-01-1], which set an ADI of 0-0.01 mg/kg bw and an ARfD of 0.03 mg/kg bw. The JMPR concluded that the increased tumour incidences associated with exposure to thiacloprid are

threshold phenomena and unlikely to pose a carcinogenic risk to humans at exposure levels relevant to residues found in food.

Thiacloprid up to now is not classified and labelled by the European Chemicals Bureau (ECB). However, on a national level in most of the European countries thiacloprid is classified as a carcinogen category 3; harmful after acute oral and inhalation exposure as well as dangerous for the environment and harmful to aquatic organisms. Currently, thiacloprid is under evaluation in the ECHA process for classification and labelling as a biocide.

Thiacloprid has been reviewed by the U.S. EPA and the European Commission and it was included in Annex I of Council Directive 91/414/EEC in October 2004. The EC concluded there was no evidence of genotoxicity in a standard battery of *in vitro* and *in vivo* tests (data included in the DAR for EU registration).

The WHO hazard classification is class II, 'moderately hazardous' (category II).

Formulations

The main formulation types available are SC, SE, OD and WG. Thiacloprid may be co-formulated with beta-cyfluthrin, buprofezin, deltamethrin and ethiprole.

The formulations are registered and sold in more than 70 countries of Europe, North America, South America, Asia and Africa.

Methods of analysis and testing

The analytical method for the determination of the active ingredient (including identity tests) is based on reversed-phase HPLC with gradient elution, UV-detection at 225 nm and external standardization. The method was adopted with provisional status by CIPAC in 2007 and was promoted to a full CIPAC method in 2008. The method is published in Handbook M. This method also forms the primary means for identification but the identity may also be confirmed using ¹H-NMR.

The method(s) for determination of impurities were HPLC-UV and GC-FID.

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

Containers and packaging

No extraordinary container or package issues need to be considered.

Expression of the active ingredient

The active ingredient is expressed as thiacloprid, in g/kg or in g/l.

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 thiacloprid having impurity profiles similar to those referred to in Table 2, above.

Table A. Toxicology profile of technical thiacloprid, based on acute toxicity, irritation and sensitization

Species	Test	Duration and conditions, purity	Result	Reference
Rat (m,f)	Acute oral	Single application, OECD 401, purity 97.3%	LD ₅₀ = 836 mg/kg bw (m) 444 mg/kg bw (f)	M-000796-01-1
Rat (m,f)	Acute dermal	Single application 24 h, occlusive conditions, OECD 402, purity 97.3%	LD ₅₀ >2000 mg/kg bw (m,f)	M-000808-01-1
Rat (m,f)	Acute inhalation	Solid aerosol (dust), 4 h exposure, OECD 403, purity 97.2%	LC ₅₀ = >2535 mg/m ³ (m) ~1233 mg/m ³ (f)	M-000815-01-1
Rabbit	Skin irritation	4 h exposure, OECD 404, purity 97.3%	non-irritating	M-000708-03-1
Rabbit	Eye irritation	24 h exposure, OECD 405, purity 97.3%	non-irritating	M-000708-03-1
Guinea pig	Skin sensitization	Maximization test, OECD 406, purity 97.3%	non-sensitizing	M-003836-02-1

Thiacloprid is classified by the EU for oral and inhalation toxicity as harmful by inhalation (R20) and if swallowed (R22).

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

Species	Test	Duration and conditions, purity	Result	Reference
Rat	Sub-acute, dermal	OECD 410, 4 weeks (22 x 6 h) exposure, 2 weeks recovery, 0, 100, 300, 1000 mg/kg bw/d & 0, 1000 mg/kg bw/d (recovery), purity 97.2%	NOAEL = 300 mg/kg bw/d	M-000824-01-1
Rat	Sub-acute, inhalation	OECD 403, 412, 4 weeks (5 x 6 h/week), 0, 2.0, 18.2, 143.4 mg/m ³ air, purity 97.2%	NOAEC = 18.2 mg/m ³ air	M-241815-01-1
Rat	Sub-acute, inhalation	Mainly to OECD 403, 412, 1 week (5 x 6 h), 0, 1.97, 19, 205 mg/m ³ air, purity 97.2%	NOAEC = 19 mg/m ³ air	M-000725-02-1
Rat	Sub-acute, gavage	Mainly to OECD 407, 2 weeks, 0, 5, 10, 20, 60, 120 mg/kg bw/d, purity 98.3%	NOAEL = 20 mg/kg bw/d	M-000703-01-4
Rat	Sub-acute, feeding	Mainly to OECD 407, 2 weeks, 0, 25, 100, 500, 2000 ppm, purity 98.6%	NOAEL = 11.2 mg/kg bw/d (100 ppm)	M-000785-02-1
Rat	Sub-acute, feeding	OECD 407, 3 weeks, 0, 25, 100, 400, 1600 ppm, purity 96.8%	NOAEL = 9.0 mg/kg bw/d (100 ppm)	M-030427-03-1
Dog	Sub-acute, feeding	Mainly to OECD 409, 10 weeks, 0, 100, 300, 1000 ppm; dietary 1000 ppm increased to 1250 ppm from day 19 on, to 1600 ppm from day 26 on and to 2500 ppm from day 38 on to end of study); satellite group: 2500 ppm for 4 weeks; purity 98.6%	NOAEL = 9.6 mg/kg bw/d (300 ppm)	M-003816-02-1

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

Species	Test	Duration and conditions, purity	Result	Reference
Mouse	Sub-acute, feeding	Mainly to OECD 407, 3 weeks; 0, 100, 1000, 10000 ppm; purity 98.6%	NOAEL = 30.1 mg/kg bw/d (100 ppm)	M-000688-01-1
Mouse	Sub-acute, feeding	Mainly to OECD 407, 2 weeks, 0, 50, 200, 2000, 10000 ppm; purity 98.6%	NOAEL = 84.3 mg/kg bw/d (200 ppm)	M-000821-01-1
Rat	Sub-chronic, feeding	OECD 408, US EPA FIFRA § 82-1, 13 weeks & 5 weeks recovery, 0, 25, 100, 400, 1600 ppm & 0, 1600 ppm (recovery); purity 98.6%	NOAEL = 7.3 mg/kg bw/d (100 ppm)	M-000863-01-1
Mouse (m,f)	Sub-chronic, feeding	OECD 408, US EPA FIFRA § 82-1, 14 weeks, 0, 50, 250, 1250, 6250 ppm, purity 98.6–98.7%	NOAEL = 19.9 mg/kg bw/d (m) (50 ppm) No NOAEL could be set in females	M-000697-02-1
Dog	Sub-chronic, feeding	OECD 409, 15 weeks, 0, 250, 1000, 2000 ppm (high dose group: day 1 to 4: 4000 ppm; due to severe clinical signs treatment-free period (days 5-14), day 15 to the end of study: 2000 ppm); purity 96.8-97.2%	NOAEL = 8.5 mg/kg bw/d (250 ppm)	M-003814-01-1
Rat (m,f)	Chronic toxicity/ oncogenicity, feeding	OECD 453, US EPA FIFRA § 83-5, 2 years; 0, 25, 50, 500, 1000 ppm; purity 96.8-97.2%	NOAEL = 1.23 mg/kg bw/d (m), 3.3 mg/kg bw/d (f) (25 ppm (m), 50 ppm (f)) Tumour incidences: thyroid follicular cell adenoma in males: 0, 0, 2, 10, 16.3% (up to 5.1/14.7% covered by Bayer internal/ external historical controls) uterine adenocarcinoma in females: 12, 6, 6, 28, 34% (up to 24/28% covered by Bayer internal/ external historical controls)	M-003817-01-1
Mouse (m,f)	Oncogenicity, feeding	OECD 451, US EPA FIFRA 83-2, 2 years; 0, 30, 1250, 2500 ppm purity 96.8-97.2%	NOAEL = 5.7 mg/kg bw/d (m), 10.9 mg/kg bw/d (f) (30 ppm (m,f)) Tumour incidences: ovarian luteoma in females: 0, 2, 10, 13% (up to 6% covered by historical controls)	M-003819-02-1

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

Species	Test	Duration and conditions, purity	Result	Reference
Dog	Chronic, feeding	OECD 452, 2 years; 0, 40, 100, 250, 1000 ppm; purity 96.8-97.1%	NOAEL = 8.58 mg/kg bw/d (250 ppm)	M-003818-01-1
Rat	2-Generation reproduction toxicity	OECD 416, US EPA FIFRA § 83-4; 0, 50, 300, 600 ppm; purity 96.7-97.5%	NOAEL parents = 2.6 mg/kg bw/d (50 ppm) NOAEL reproductive = 3.5 mg/kg bw/d (50 ppm) No primary reproduction toxicity	M-001304-01-1
Rat (f)	Developmental toxicity	OECD 414, US EPA FIFRA § 83-3, 0, 2, 10, 50 mg/kg bw/d from day 6-19 of gestation; purity 97.0-97.3%	NOAEL maternal = 10 mg/kg bw/d NOAEL developmental = 10 mg/kg bw/d Not teratogenic	M-000832-01-1
Rabbit (f)	Developmental toxicity	OECD 414, US EPA FIFRA § 83-3, 0, 2, 10, 45 mg/kg bw/d from gestation day 6 to 28; purity 97.3%	NOAEL maternal = 2 mg/kg bw/d NOAEL developmental = 2 mg/kg bw/d Not teratogenic	M-000780-01-1
Rat	Acute oral neurotoxicity study gavage	US EPA-FIFRA, Addendum 10, EPA 540/09-91-123, PB 91-154617 0, 20, 50, 100 mg/kg bw and 0, 3.1, 11 mg/kg bw (supplemental study) purity: 96.7-97%	NOAEL = 11 mg/kg bw (m), 3.1 mg/kg bw (f)	M-000694-01-1
Rat	Subchronic dietary neurotoxicity study feeding	US EPA-FIFRA, Addendum 10, EPA 540/09-91-123, PB 91-154617 0, 50, 400, 1600 ppm purity: 96.6-97.5%	NOAEL systemic = 2.94 mg/kg bw/day (m), 3.41 mg/kg bw/day (f) (corresponding to 50 ppm (m+f)) NOAEL neurotoxicity = 101 mg/kg bw/day (m), 115 mg/kg bw/day (f) (corresponding to 1600 ppm (m+f))	M-000903-01-1

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

Species	Test	Duration and conditions, purity	Result	Reference
Rat	Developmental neurotoxicity study feeding	US-EPA-OPPTS Guideline no. 870.6300 0, 50, 300, 500 ppm from gestation day 0 to post partum day 22 purity: 99.2%	NOAEL maternal = 4.4 mg/kg bw/day (corresponding to 50 ppm) NOAEL developmental = 4.4 / 8.2 mg/kg bw/day during gestation/lactation (corresponding to 50 ppm) NOAEL neurotoxicity = 40.8 / 82.8 mg/kg bw/day during gestation/lactation (corresponding to 500 ppm)	M-000799-01-1

Table C. Mutagenicity profile of technical thiacloprid, based on *in vitro* and *in vivo* tests

Species	Test	Duration and conditions	Result	Reference
<i>Salmonella</i> typhimurium	Reverse mutation, <i>in vitro</i> (Ames test)	OECD 471, doses 0, 16, 50, 158, 500, 1581, 5000 µg/plate, ±S-9 mix purity 97.2%	negative	M-000772-01-1
<i>Salmonella</i> typhimurium, <i>Escherichia coli</i>	Reverse mutation, <i>in vitro</i>	OECD 471, doses 0, 313, 625, 1250, 2500, 5000 µg/plate, ±S-9 mix purity 96.8%	negative	M-000790-01-1
Chinese hamster ovary cells	V79/HPRT, <i>in vitro</i>	OECD 476, doses up to 500 µg/ml, ±S-9 mix purity 96.8-97.2%	negative	M-000775-01-1
Chinese hamster ovary cells	CYT/V79, <i>in vitro</i>	OECD 473, doses 0, 75, 300, 750 µg/ml, ±S-9 mix purity 97.2%	negative	M-000894-03-1
Rat liver primary cells	UDS	OECD 482, doses: 0, 75, 150, 300, 350, 400, 450, 500 µg/ml; purity: 97.2%	negative	M-003815-01-1
Mouse bone marrow	Micronucleus, <i>in vivo</i>	OECD 474, dose 60 mg/kg bw (i.p.) purity 96.8-97.2%	negative	M-088059-01-1

Table D. Ecotoxicology profile of technical thiacloprid

Species	Test	Duration and conditions	Result	Reference
<i>Oncorhynchus mykiss</i> (rainbow trout)	Acute toxicity	OECD 203, 96 h, static, purity 97.2%	LC ₅₀ = 29.6 mg/l	M-000741-02-1

Table D. Ecotoxicology profile of technical thiacloprid

Species	Test	Duration and conditions	Result	Reference
<i>Lepomis macrochirus</i> (bluegill sunfish)	Acute toxicity	OECD 203, 96 h static, purity 97.3%	LC ₅₀ = 24.5 mg/l	M-000728-01-2
<i>Daphnia magna</i> (water flea)	Acute toxicity	OECD 202, 48 h static, purity 97.2%	EC ₅₀ >85.1 mg/l	M-000738-01-1
<i>Selenastrum subspicatus</i> (green alga)	Effect on growth	OECD 201, 72 h static, purity 96.8%	E _r C ₅₀ = 96.7 mg/ E _b C ₅₀ = 44.7 mg/	M-000731-01-1
<i>Eisenia fetida</i> (earthworm)	Acute toxicity	OECD 207, 14 d, artificial soil, purity 97.2%	LC ₅₀ >105 mg/kg d.wt. soil	M-000810-01-1
<i>Apis mellifera</i> (honey bee)	Acute toxicity	EPPO 170, 48 h, purity 97.3%	LD ₅₀ oral = 17.3 µg/bee LD ₅₀ contact = 38.8 g/bee	M-000856-01-1
<i>Gallus gallus domesticus</i> (chicken)	Acute toxicity, oral	FIFRA 71-1, purity 99.1%	LD ₅₀ >2000 mg/kg bw	M-107468-01-1
<i>Anas platyrhynchos</i> (mallard duck)	Acute toxicity, dietary	OECD 205, 5 d, purity 96.8%	LD ₅₀ >5000 mg/kg bw	M-001613-02-1
<i>Coturnix coturnix</i> (Japanese quail)	Acute toxicity, oral	EPA FIFRA 71-1, purity 97.1%	LD ₅₀ = 49 mg/kg bw	M-000769-01-1
<i>Colinus virginianus</i> (bobwhite quail)	Acute toxicity, oral	FIFRA 71-1, purity 97.2%	LD ₅₀ = 2716 mg/kg bw	M-000762-02-1
<i>Colinus virginianus</i> (bobwhite quail)	Acute toxicity, dietary	OECD 205, 5 d, purity 97.2%	LC ₅₀ >5459 mg/kg diet	M-000757-02-1

Classification and specific labelling for environmental hazard for thiacloprid in the EU: Xn - harmful; R52/53 - harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment based on ecotoxicity studies on fish, *Daphnia* and algae.

ANNEX 2. REFERENCES

Bayer Crop-Science document ID number	Year	Study. Title. Study ID number, Report ID number. GLP [If GLP] Compagny conducting the study
M-000646-01-1	1996	Physical and chemical properties of YRC 2894. GLP Bayer AG, Leverkusen, Germany Unpublished.
M-000688-01-1	1994	YRC 2894 - Pilot study on subacute toxicity in B6C3F1 mice (administration in feed over 3 weeks). None GLP Bayer AG, Wuppertal, Germany. Unpublished.
M-000694-01-1	1995	YRC 2894 - Salmonella/microsome test plate incorporation and preincubation method. GLP Bayer AG, Wuppertal, Germany. Unpublished.
M-000697-02-1	1995, amended 1998	YRC 2894 - Subchronic range-finding study for a two-year study in B6C3F1 mice (administration in feed over about 14 weeks). GLP Bayer AG, Wuppertal, Germany. Unpublished.
M-000703-01-4	1995	YRC 2894 - Pilot toxicity study on rats - acute oral toxicity to non-fasted animals - subacute oral toxicity with gavage administration over 2 weeks. None GLP Bayer AG, Wuppertal, Germany. Unpublished.
M-000708-03-1	1995 amended 1998	YRC 2894 - Study for skin and eye irritation/corrosion in rabbits. GLP Bayer AG, Wuppertal, Germany. Unpublished.
M-000725-02-1	1995 amended 1999	YRC 2894 - Pilot study on subacute inhalation toxicity in rats (exposure: 5 x 6 hours). GLP Bayer AG, Wuppertal, Germany. Unpublished.
M-000728-01-2	1995	YRC 2894 tech.: acute toxicity (96 hours) to bluegill (<i>Lepomis macrochirus</i>) in a static test. GLP Bayer AG, Leverkusen, Germany. Unpublished.
M-000731-01-1	1995	Influence of YRC 2894 on the growth of the green alga, <i>Scenedesmus subspicatus</i> . GLP Bayer AG, Leverkusen, Germany. Unpublished.
M-000738-01-1	1995	Acute toxicity of YRC 2894 (tech.) to water fleas (<i>Daphnia magna</i>). GLP Bayer AG, Leverkusen, Germany. Unpublished.
M-000741-02-1	1995	YRC 2894 tech.: acute toxicity (96 hours) to rainbow trout (<i>Oncorhynchus mykiss</i>) in a static test. GLP Bayer AG, Leverkusen, Germany. Unpublished.

Bayer Crop-Science document ID number	Year	Study. Title. Study ID number, Report ID number. GLP [If GLP] Compagny conducting the study
M-000757-02-1	1995	YRC 2894 (tech.): 5-day dietary LC50 to Bobwhite Quail. GLP Bayer AG, Leverkusen, Germany. Unpublished.
M-000762-02-1	1995	YRC 2894 tech. Acute oral toxicity to bobwhite quail. GLP Bayer AG, Leverkusen, Germany. Unpublished.
M-000769-01-1	1994	YRC 2894 (tech.), acute oral toxicity to Japanese quail, range finding test. GLP Bayer AG, Leverkusen, Germany Unpublished.
M-000772-01-1	1995	YRC 2894 - In vitro mammalian chromosome aberration test with chinese hamster V79 cells. GLP Bayer AG, Wuppertal, Germany. Unpublished.
M-000775-01-1	1995	YRC 2894 - Micronucleus test on the mouse. GLP Bayer AG, Wuppertal, Germany. Unpublished.
M-000780-01-1	1996	YRC 2894 - Developmental toxicity study in rabbits after oral administration. GLP Bayer AG, Wuppertal, Germany. Unpublished.
M-000785-02-1	1996 amended 1999	YRC 2894 - Study for subacute oral toxicity in rats (feeding study over 2 weeks). Bayer AG, GLP Wuppertal, Germany. Unpublished.
M-000790-01-1	1996	YRC 2894 - Test on unscheduled DNA synthesis in rat liver primary cell cultures in vitro. GLP Bayer AG, Wuppertal, Germany. Unpublished.
M-000796-01-1	1996	YRC 2894 - Study for acute oral toxicity in rats. GLP Bayer AG, Wuppertal, Germany Unpublished
M-000799-01-1	1996	YRC 2894 - Mutagenicity study for the detection of induced forward mutations in the V79/HPRT assay in vitro. GLP Bayer AG, Wuppertal, Germany. Unpublished.
M-000808-01-1	1996	YRC 2894 - Study for acute dermal toxicity in rats. GLP Bayer AG, Wuppertal, Germany. Unpublished.
M-000810-01-1	1994	Toxicity of YRC 2894 (tech.) to earthworms (<i>Eisenia fetida</i>) BLP Bayer AG, Leverkusen, Germany. Unpublished.

Bayer Crop-Science document ID number	Year	Study. Title. Study ID number, Report ID number. GLP [If GLP] Compagny conducting the study
M-000815-01-1	1996	YRC 2894 - Study on acute inhalation toxicity in rats according to OECD no. 403 GLP Bayer AG, Wuppertal, Germany. Unpublished.
M-000821-01-1	1997	YRC 2894 - Study for subacute oral toxicity in mice (feeding study over 2 weeks). GLP Bayer AG, Wuppertal, Germany. Unpublished.
M-000824-01-1	1997	YRC 2894 - Study for subacute dermal toxicity in rats (four-week treatment and two-week recovery period). GLP Bayer AG, Wuppertal, Germany. Unpublished.
M-000832-01-1	1997	YRC 2894 - Developmental toxicity in rats after oral administration. GLP Bayer AG, Wuppertal, Germany. Unpublished.
M-000856-01-1	1995	Assessment of side effects of YRC 2894 (tech.) to the honey bee, <i>Apis mellifera</i> L. in the laboratory following the EPPO Guideline No. 170. Non GLP GAB Biotechnologie GmbH. Unpublished.
M-000863-01-1	1997	YRC 2894 - Investigations of subchronic toxicity in Wistar rats (feeding study over 12 weeks with a subsequent recovery period over 5 weeks). GLP Bayer AG, Wuppertal, Germany. Unpublished.
M-000894-03-1	1998	An acute oral neurotoxicity study with technical grade YRC 2894 in Fischer 344 rats. GLP Bayer Corporation, Stilwell, Kansas, USA. Unpublished.
M-000903-01-1	1995	YRC 2894 - Reverse mutation assay (<i>salmonella typhimurium</i> and <i>escherichia coli</i>). GLP Nihon Bayer Agrochem K. K., Tokyo, Japan. Unpublished
M-001109-01-1	1998	Hydrolysis of YRC 2894 in sterile aqueous buffer solutions. GLP Bayer AG, Leverkusen, Germany Unpublished.
M-001134-01-1	1998	Photolysis of YRC 2894 in aqueous buffer solution. GLP Bayer AG, Leverkusen, Germany Unpublished.
M-001304-01-1	1997	A two-generation dietary reproduction study in rats using technical YRC 2894. GLP Bayer Corporation, Stilwell, KS, USA. Unpublished.

Bayer Crop-Science document ID number	Year	Study. Title. Study ID number, Report ID number. GLP [If GLP] Compagny conducting the study
M-001613-02-1	1998	Five Day Dietary Toxicity of YRC 2894 on Mallard Ducklings (Anas platyrhynchos). GLP Bayer AG, Leverkusen, Germany. Unpublished.
M-003836-02-1	1996	YRC 2894 - Study for the skin sensitization effect in guinea pigs (guinea pig maximization test method according Magnusson and Kligman) GLP Bayer AG, Wuppertal, Germany. Unpublished.
M-003814-01-1	1998	YRC 2894 - Subchronic toxicity study in Beagle dogs (feeding study for about 15 weeks). GLP Bayer AG, Wuppertal, Germany. Unpublished.
M-003815-01-1	1997	A subchronic dietary neurotoxicity screening study with technical grade YRC 2894 in Fischer 344 rats. GLP Bayer Corporation, Stilwell, Kansas, USA. Unpublished.
M-003816-02-1	1998, amended 1999	YRC 2894 - Subacute toxicity study in Beagle dogs (dose range finding study by feed admixture over at least 10 weeks) - revised final version. GLP Bayer AG, Wuppertal, Germany. Unpublished.
M-003817-01-1	1998	,YRC 2894 - Combined chronic toxicity/carcinogenicity study in Wistar rats (dietary administration over 2 years). GLP Bayer AG, Wuppertal, Germany. Unpublished.
M-003818-01-1	1998	YRC 2894 - Chronic toxicity study in beagle dogs (52 week feeding study). GLP Bayer AG, Wuppertal, Germany. Unpublished.
M-003819-02-1	1998	YRC 2894 - Oncogenicity study in B6C3F1-mice (administration in the food over 2 years). GLP Bayer AG, Wuppertal, Germany. Unpublished.
M-030427-03-1	2000	,YRC 2894 (c.n.: Thiachloprid) - Special study for subacute oral toxicity in rats (feeding study for 3 weeks). GLP Bayer AG, Wuppertal, Germany. Unpublished.
M-088059-01-1	2001	Oral (diet) developmental neurotoxicity study of YRC 2894 in CRL:CD(SD) IGS BR VAF/PLUS. GLP Argus Research Laboratories, Inc., Horsham, PA, USA. Unpublished.
M-107468-01-1	2004	Thiacloprid tech. a.s. - Acute oral toxicity for chicken (Gallus gallus domesticus). GLP Bayer CropScience AG, Monheim, Germany Unpublished.

Bayer Crop-Science document ID number	Year	Study. Title. Study ID number, Report ID number. GLP [If GLP] Compagny conducting the study
M-241815-01-1	1998	YRC 2894 Subacute inhalation toxicity on rats (Exposure 5 x 6 hour/week for 4-weeks). GLP Bayer AG, Wuppertal, Germany. Unpublished.
M-360693-02-1	2002 amended 2006	Manual on the development and use of FAO and WHO specification for pesticides, 1st edition, FAO Plant production and protection paper 173, FAO, Rome, 2002 amended in 2006
M-364878-01-1	2006	Pesticide residues in food 2006. FAO plant production and protection paper 187. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues. Rome, Italy, 3–12 October 2006. WHO and FAO, Rome, 2007.