FAO SPECIFICATIONS AND EVALUATIONS FOR AGRICULTURAL PESTICIDES

IMIDACLOPRID

1-(6-Chloro-3-pyridinylmethyl)-*N*-nitroimidazolidin-2-ylideneamine

FOOD AND AGRICULTURE ORGANIZATION of THE UNITED NATIONS

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DISCLAIMER[1]

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/ag/agp/agpp/pesticid/)

OR IN HARDCOPY FROM THE PLANT PROTECTION INFORMATION OFFICER.

PART ONE

SPECIFICATIONS

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IMIDACLOPRID

INFORMATION

ISO common names

Imidacloprid (BSI, E-ISO), imidaclopride ((m) draft F-ISO)

Synonyms

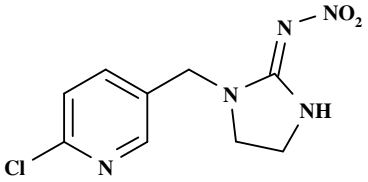
BAY NTN 33 893

Chemical names

IUPAC 1-(6-chloro-3-pyridinylmethyl)-*N*-nitroimidazolidin-2-ylideneamine

CA 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine

Structural formula



Empirical formula

$C_9H_{10}ClN_5O_2$

Relative molecular mass

255.7

CAS Registry number

138261-41-3

CIPAC number

582

Identity tests

HPLC retention time, IR and ^{1}H-NMR spectra.

IMIDACLOPRID TECHNICAL MATERIAL

FAO specification 582/TC (April 2006*)

*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 (*582/2004*). It should be applicable to relevant products of these manufacturers but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation report (*582/2004*) as PART TWO forms an integral part of this publication.*

1 Description

The material shall consist of imidacloprid together with related manufacturing impurities and shall be a beige powder, free from visible extraneous matter and added modifying agents.

2 Active ingredient

2.1 **Identity tests** (582/TC/M/2, CIPAC Handbook K, p.70, 2003)

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 **Imidacloprid content** (582/TC/M/3, CIPAC Handbook K, p.70, 2003)

The imidacloprid content shall be declared (not less than 970 g/kg) and, when determined, the average measured content shall not be lower than the declared minimum 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/ag/agp/agpp/pesticid/.

IMIDACLOPRID GRANULES

FAO specification 582/GR (May 2006 and June 2008*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturers whose names are listed in the evaluation reports (582/2004 and 582/2008). It should be applicable to relevant products of these manufacturers but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation report (582/2004) as PART TWO forms an integral part of this publication. The evaluation report (582/2008) as an addendum to PART TWO forms an integral part of this publication

1 Description

The material shall consist of granules containing technical imidacloprid, complying with the requirements of FAO specification 582/TC (MAY 2006) together with suitable carriers and any other necessary formulants, in the form of rounded beige or colored granules. It shall be dry, free from visible extraneous matter and hard lumps, free-flowing, nearly dust free and intended for application by machine.

2 Active ingredient

2.1 Identity tests (582/GR/M/2, CIPAC Handbook H, p.190, 1998)

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 Imidacloprid content (582/GR/M/3, CIPAC Handbook, p.190, 1998)

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

Declared content, g/kg	Tolerance
up to 25 above 25 up to 100 Note: the upper limit is included in the range	± 25% of the declared content ± 10% of the declared content

3 Relevant impurities

3.1 Water (MT 30.5, CIPAC Handbook J, p.120, 2000)

Maximum: 1 g/kg.

4. Physical properties

4.1 Pour and tap density (MT 186, CIPAC Handbook K, p.151, 2003)

Pour density: 1.4 to 1.6 g/ml.

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.fao.org/ag/agp/agpp/pesticid/.

Tap density: 1.5 to 1.7 g/ml.

4.2 Nominal size range (MT 58, CIPAC Handbook F, p.173, 1995)

Not less than 950 g/kg of the formulation shall be within the size range 300 to 900 µm.

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

Nearly dust free (Note 1).

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

Minimum: 99% attrition resistance.

5 Storage stability

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

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 2) and the formulation shall continue to comply with the clauses for:

– nominal size range (4.2);

– dustiness (4.3)

– attrition resistance (4.4).

Note 1 The optical method, MT 171, usually shows good correlation with the gravimetric method 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 2 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.

IMIDACLOPRID WATER DISPERSIBLE POWDER FOR SLURRY SEED TREATMENT

FAO specification 582/WS (April 2006*)

*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 (*582/2004*). It should be applicable to relevant products of these manufacturers but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation report (*582/2004*) as PART TWO forms an integral part of this publication.*

1 Description

The material shall consist of an homogeneous mixture of technical imidacloprid, complying with the requirements of FAO specification 582/TC (April 2006), together with carriers and any other necessary formulants, including colouring matter (Note 1). It shall be in the form of a fine powder, free from visible extraneous matter and hard lumps.

2 Active ingredient

2.1 **Identity tests** (CIPAC 582/WS/M2, CIPAC Handbook K, p.70, 2003)

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 **Imidacloprid content** (CIPAC 582/WS/M3, CIPAC Handbook K, p.70, 2003)

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

Declared content, g/kg	Tolerance
above 250 up to 500	± 5% of the declared content
above 500	± 25 g/kg
Note: the upper limit is included in the lower range	

3 Relevant impurities

3.1 **Water** (MT 30.5, CIPAC Handbook J, p.120, 2000)

Maximum: 20 g/kg.

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.fao.org/ag/agp/agpp/pesticid/.

4 Physical properties

4.1 **Wet sieve test** (MT 185, CIPAC Handbook K, p.148, 2003) (Note 2)

Maximum: 0.1% of the formulation shall be retained on a 75 µm test sieve.

4.2 **Persistent foam** (MT 47.2, CIPAC Handbook F, p.152, 1995) (Note 3)

Maximum: 20 ml after 1 min.

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

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

5 Storage stability

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

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 clause for:

- wet sieve test (4.1).

Note 1 The formulation shall contain a dye or pigment that permanently colours the seed after treatment (red is recommended) and cannot be removed by washing with water. 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 to be used as livestock feeding stuffs.

Note 2 This test should be performed at the application concentration.

Note 3 The mass of sample to be used in the test should be specified at the highest rate of use recommended by the supplier.

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.

IMIDACLOPRID WATER DISPERSIBLE GRANULES

FAO specification 582/WG (April 2006*)

*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 (*582/2004*). It should be applicable to relevant products of these manufacturers but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation report (*582/2004*) as PART TWO forms an integral part of this publication.*

1 Description

The material shall consist of an homogeneous mixture of technical imidacloprid, complying with the requirements of the FAO specification 582/TC (April 2006), together with carriers and any other necessary formulants. It shall be in the form of spherical granules, with a nominal size range of 0.1 to 0.8 mm and an average of approximately 0.4 to 0.5 mm, for application after disintegration and dispersion in water. The formulation shall be dry, free-flowing, essentially non-dusty, and free from visible extraneous matter and hard lumps.

2 Active ingredient

2.1 **Identity tests** (CIPAC 582/WG/M2, CIPAC Handbook K, p.70, 2003)

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 **Imidacloprid content** (CIPAC 582/WG/M3, CIPAC Handbook K, p.70, 2003)

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

Declared content, g/kg	Tolerance
above 500	± 25 g/kg

3 Physical properties

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

The formulation shall be completely wetted in 5 seconds, without swirling.

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

Maximum: 0.1% retained on a 75 µm test sieve.

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* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.fao.org/ag/agp/agpp/pesticid/.

3.3 **Degree of dispersion** (MT 174, CIPAC Handbook F, p.435, 1995)

Dispersibility: minimum 80% after 1 minute of stirring.

3.4 **Suspensibility** (MT 184, CIPAC Handbook K, p.142, 2003) (Notes 1 & 2)

A minimum of 95% after 10 min and a minimum of 90% after 30min shall be in suspension in CIPAC standard water D at 30 ± 2℃.

3.5 **Persistent foam** (MT 47.2, CIPAC Handbook F, p.152, 1995) (Note 3)

Maximum: 20 ml after 1 minute.

3.6 **Dustiness** (MT 171, CIPAC Handbook F, p.425, 1995) (Note 4)

Nearly dust free.

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

At least 95 % 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, CIPAC Handbook J, p.128, 2000)

After storage at 54 ± 2°C for 14 days, the determined average active ingredient content must not be lower that 97%, relative to the determined average content found before storage (Note 5) and the formulation shall continue to comply with the clauses for:

- wet sieve test (3.2);
- degree of dispersion (3.3);
- suspensibility (3.4);
- dustiness (3.6)
- flowability (3.7).

Note 1 The formulation should be tested at the highest and lowest rates of use recommended by the supplier.

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 The mass of sample to be used in the test should be specified at the highest rate recommended by the supplier.

Note 4 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, usually shows good correlation with the gravimetric method 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 5 Analysis of the formulation, before and after the storage stability test, should be carried out concurrently (i.e. after storage) to reduce analytical error.

IMIDACLOPRID AQUEOUS SUSPENSION CONCENTRATE

FAO specification 582/SC (April 2006*)

*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 (*582/2004*). It should be applicable to relevant products of these manufacturers but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation report (*582/2004*) as PART TWO forms an integral part of this publication.*

1 Description

The material shall consist of a whitish suspension of fine particles of technical imidacloprid, complying with the requirements of FAO specification 582/TC (April 2006), 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** (582/SC/M/2, CIPAC Handbook K, p.70, 2003)

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 **Imidacloprid content** (582/SC/M/3, CIPAC Handbook K, p.70, 2003)

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

Declared content, g/kg or g/l at 20 ± 2ºC	Tolerance
up to 25	± 15% of the declared content
above 25 up to 100	± 10% of the declared content
above 100 up to 250	± 6% of the declared content
above 250 up to 500	± 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": 4%.

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.fao.org/ag/agp/agpp/pesticid/.

3.2 **Spontaneity of dispersion** (MT 160, CIPAC Handbook F, p.391, 1995) (Note 3)

A minimum of 90% of the imidacloprid content found under 2.2 shall be in suspension after 5 minutes in CIPAC Standard Water D at 30 ± 2°C.

3.3 **Suspensibility** (MT 184, CIPAC Handbook K, p.142, 2003) (Notes 3 & 4)

A minimum of 95% of the imidacloprid content found under 2.2 shall be in suspension after 30 min in CIPAC Standard Water D at 30 ± 2°C.

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

Maximum: 0.1% retained on a 75 µm test sieve.

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

Maximum: 40 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 ± 2°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 ± 2°C for 14 days, the determined average active ingredient content must not be lower than 97% relative to the determined mean content found before storage (Note 5) 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 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, the simpler gravimetric method, MT 168, may be used on a routine basis provided that it has been shown to give equal results to those of chemical assay. In case of dispute, chemical assay shall be the "referee method".

Note 4 The mass of sample to be used in the test should be at the highest rate of use recommended by the supplier.

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.

IMIDACLOPRID SUSPENSION CONCENTRATE FOR SEED TREATMENT

FAO specification 582/FS (April 2006*)

*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 (*582/2004*). It should be applicable to relevant products of these manufacturers but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation report (*582/2004*) as PART TWO forms an integral part of this publication.*

1 Description

The material shall consist of a suspension of fine particles of technical imidacloprid, complying with the requirements of FAO/WHO specification 582/TC (April 2006), in an aqueous phase together with suitable formulants, including colouring matter (Note 1). After gentle stirring or shaking, the material shall be homogeneous (Note 2) and is intended for use without dilution.

2 Active ingredient

2.1 **Identity tests** (582/FS/M/2, CIPAC Handbook K, p.70, 2003)

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 **Imidacloprid content** (582/FS/M/3, CIPAC Handbook K, p.70, 2003)

The imidacloprid content shall be declared (g/kg or g/l at 20 ± 2ºC, Note 3) and, when determined, the average measured content shall not differ from that declared by more than the following tolerances:

Declared content, g/kg or g/l at 20 ± 2ºC	Tolerance
above 25 up to 100	± 10% of the declared content
above 100 up to 250	± 6% of the declared content
above 250 up to 500	± 5% of the declared content
Note: the upper limit is included in each range	

3 Physical properties

3.1 **pH range** (MT 75.3, CIPAC Handbook J, p.131, 2000)

The pH of the undiluted aqueous suspension shall be 5 to 9.

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

Maximum "residue": 4%.

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* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.fao.org/ag/agp/agpp/pesticid/.

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

Maximum: 0.1 % retained on a 75 µm test sieve.

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

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

- wet sieve test (3.3).

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

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

- pH range (3.1);
- pourability (3.2)
- wet sieve test (3.3).

Note 1 The formulation shall contain a dye or pigment that permanently colours the seed after treatment (red is recommended) and cannot be removed by washing with water. 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 to be used 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 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 The test is conducted with the undiluted product.

Note 5 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 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.

IMIDACLOPRID OIL-BASED SUSPENSION CONCENTRATE

FAO specification 582/OD (April 2006*)

*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 (*582/2004*). It should be applicable to relevant products of these manufacturers but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation report (*582/2004*) as PART TWO forms an integral part of this publication.*

1 Description

The material shall consist of a stable brownish suspension of fine particles of technical imidacloprid, complying with the requirements of FAO specification 582/TC (April 2006), in an oil phase together with suitable formulants. After shaking or stirring of the sample, the material shall be homogeneous (Note 1) and suitable for dilution in water.

2 Active ingredient

2.1 Identity tests (582/OD/M/2, CIPAC Handbook, 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 Imidacloprid content (582/OD/M/2, CIPAC Handbook, Note 2)

The imidacloprid content shall be declared (g/kg or g/l at 20 ± 2ºC, Note 3) and, when determined, the average measured content shall not differ from that declared by more than the following tolerances:

Declared content, g/kg or g/l at 20 ± 2ºC	Tolerance
above 100 up to 250	± 6% of the declared content
above 250 up to 500	± 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”: 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/ag/agp/agpp/pesticid/.

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

The formulation, when diluted at 30 ± 2°C (Note 4) 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 "Free oil", maximum: trace "Sediment", maximum: 0.1 ml
24 h	Re-dispersion complete
24.5 h	"Cream", maximum: 1 ml "Free oil", maximum: trace "Sediment", maximum: 0.25 ml

3.3 **Wet sieve test** (MT 185, CIPAC Handbook K, p.148, 2003) (Note 5)

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 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 ± 2°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 ± 2°C for 14 days, the determined average active ingredient content must not be lower that 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);
- 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, 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 2 Extension of the methods for the identification and determination of imidacloprid content in OD were adopted by CIPAC in 2004 but are not yet published in a Handbook. The basic method for determination of imidacloprid (in TC, WG, SC, WS, FS) was published in CIPAC Handbook K (2003). Prior to publication of the Handbook, copies of the methods may be obtained through the CIPAC website, http://www.cipac.org/prepubme.htm or from the CIPAC Secretary, Dr László Bura (mail to bura.laszlo@ntksz.ontsz.hu).

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 The formulation should be tested at 2% dilution or, alternatively, at the highest and lowest rates of use recommended by the supplier.

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 be at the highest rate of use recommended by the supplier.

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.

IMIDACLOPRID SOLUBLE CONCENTRATE

FAO specification 582/SL (April 2006*)

*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 (*582/2004*). It should be applicable to relevant products of these manufacturers but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation report (*582/2004*) as PART TWO forms an integral part of this publication.*

1 Description

The material shall consist of technical imidacloprid, complying with the requirements of FAO specification 582/TC (April 2006), dissolved in suitable solvents, together with any other necessary formulants. It shall be in the form of a clear or opalescent liquid, free from visible suspended matter and sediment, to be applied as a true solution of the active ingredient in water.

2 Active ingredient

2.1 Identity tests (CIPAC 582/SL/M2, CIPAC Handbook, 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 Imidacloprid content (CIPAC 582/SL/M3, CIPAC Handbook, Note 1)

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

Declared content, g/kg or g/l at 20 ± 2ºC	Tolerance
above 25 up to 100	± 10% of the declared content
above 100 up to 250	± 6% of the declared content
Note: the upper limit is included in each range	

3 Physical properties

3.1 Solution stability (MT 41, CIPAC Handbook F, p.131, 1995)

The formulation, after the stability test at 54ºC (clause 4.2) and following dilution (Note 3) with CIPAC standard water D and standing at 30 ± 2ºC for 18 h, shall give a clear or opalescent solution, free from more than a trace of sediment and visible solid particles. Any visible sediment or particles produced shall pass through a 45 µm test sieve.

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* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.fao.org/ag/agp/agpp/pesticid/.

3.2 **Persistent foam** (MT 47.2, CIPAC Handbook F, p.152, 1995) (Note 3)

Maximum: 5 ml after 1 minute.

4 Storage stability

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

After storage at 0 ± 2°C for 7 days, the volume of solid and/or liquid which separates shall not be more than 0.1 ml.

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

After storage at 54 ± 2°C for 14 days, the determined average active ingredient content must not be lower than 97 % relative to the determined average content found before storage (Note 5).

Note 1 Extension of the methods for the identification and determination of imidacloprid content in OD were adopted by CIPAC in 2004 but are not yet published in a Handbook. The basic method for determination of imidacloprid (in TC, WG, SC, WS, FS) was published in CIPAC Handbook K (2003). Prior to publication of the Handbook, copies of the methods may be obtained through the CIPAC website, http://www.cipac.org/prepubme.htm or from the CIPAC Secretary, Dr László Bura (mail to bura.laszlo@ntksz.ontsz.hu).

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 concentration used for the test should not be higher than the highest concentration recommended in the instructions for 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.

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.

PART TWO

EVALUATION REPORTS

IMIDACLOPRID

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2004	**FAO/WHO evaluation report** based on submission of information from Bayer CropScience (TC, GR, WS, WG, SC, FS, OD, SL)	**22**
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IMIDACLOPRID

FAO/WHO EVALUATION REPORT 582/2004

Recommendations

The Meeting recommended the following.

(i) The specifications for imidacloprid TC, GR, WG, WS, SC, FS, OD and SL, proposed by Bayer CropScience AG, as amended, should be adopted by FAO.

(ii) The manufacturer should resubmit a draft specification for imidacloprid DT when validated test methods and agreed guidelines become available for tablet integrity.

Appraisal

The Meeting considered data on imidacloprid, submitted by Bayer AG/Bayer CropScience AG, for the development of new FAO specifications for TC, GR, WS, WG, SC, FS, OD and SL. A draft specification for DT was also submitted but, in the absence of suitable test methods and agreed characteristics for tablet integrity, this was not considered further. The data and proposed specifications were broadly in accordance with the requirements of the FAO/WHO manual.

Imidacloprid is under patent till 2006.

Imidacloprid is an off-white powdered solid, of very low volatility. It has slight solubility in water, which is not influenced by pH, but is not fat-soluble. It is not measurably acidic or basic; it is stable at pH 4 and 7 and only very slowly hydrolyzed at pH 9. In contrast, it is subject to very rapid photolysis, which forms a major route of dissipation in the environment.

Confidential information on the method of manufacture, the technical specification and data from the analysis of production batches was presented to the meeting. Mass balances in the batch analyses were high (99.6-99.7%). The data presented were confirmed as identical to those submitted for registration in Europe (Germany is rapporteur member state for the re-evaluation and authorization of imidacloprid in the European Union under the provisions of directive 91/414/EEC).

The Meeting agreed that none of the impurities should be considered as relevant.

Analytical methods for imidacloprid (including identity tests) in TC, GR, WG, WS, SC, FS, OD, SL are full CIPAC methods. The method for GR was published in CIPAC Handbook H. The methods for TC, WG, WS, SC, FS were published in CIPAC handbook K and extensions to OD and SL were adopted by CIPAC 2004 but are not yet published. In these methods, imidacloprid is determined by reversed-phase HPLC, using external standardization and detection at 260 nm.

The method for determination of impurities was also based on reversed-phase HPLC, using isocratic elution, UV-detection and external standardization with authentic standards.

Test methods for determination of physico-chemical properties of the technical active substance were OECD, USEPA, EC, while those for the formulations were for example, CIPAC, as indicated in the specifications.

The physical properties, the methods for testing them and the limits proposed for the GR, WS, WG, SL, SC and OD specification, as amended following discussions between the Meeting and manufacturer, comply with the requirements of the FAO/WHO Manual.

The proposed specification for FS did not incorporate a clause for suspensibility, because the manufacturer explained that the product is not intended for dilution with water before use. The Meeting agreed that the clause was inappropriate in this case, that the description clause should be amended to reflect this, and that the test for persistent foam should be conducted on the undiluted product. The manufacturer noted that the red dye in the undiluted FS tends to make the exact determination of persistent foam more difficult than is usual with method MT 47.2 but stated that the product does comply with the specification.

SUPPORTING INFORMATION
FOR
EVALUATION REPORT 582/2004

Uses

Imidacloprid is a chloronicotinyl (also known as neonicotinoid) insecticide with a broad spectrum of contact and ingestion activity against insects but with no activity against spider mites or nematodes. It is used against sucking insects (such as aphids, whiteflies, leaf-hoppers, thrips, scales, mealy bugs, psyllids, phylloxera), phytophagous coleoptera (such as Colorado beetles, rice water weevils, wireworms, beetle grubs, flea beetles), and various other pests (such as lepidopterous leaf-miners, some dipterous pests, termites, locusts and fleas). It is systemic in plants, has significant residual activity, and controls pests which are resistant to other classes of insecticide.

Imidacloprid interferes with the transmission of nerve impulses in insects. As with the naturally occurring signal-transmitter acetylcholine, imidacloprid stimulates nerve cells by acting on a receptor protein. In contrast to acetylcholine, which is quickly degraded by the enzyme acetylcholine-esterase, imidacloprid is inactivated either very slowly or not at all. Pest feeding activity ceases within minutes to hours and death occurs usually within 24-48 hours but can take up to a few days.

Identity of the active ingredient

ISO common names

Imidacloprid (BSI, E-ISO), imidaclopride ((m) draft F-ISO)

Synonyms

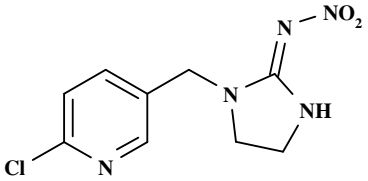
BAY NTN 33 893

Chemical names

IUPAC 1-(6-chloro-3-pyridinylmethyl)-*N*-nitroimidazolidin-2-ylideneamine

CA 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine

Structural formula



Empirical formula

$C_9H_{10}ClN_5O_2$

Relative molecular mass

255.7

CAS Registry number

138261-41-3

CIPAC number

582

Identity tests

HPLC retention time, IR and ^{1}H-NMR spectra.

Physical and chemical properties

Table 1. Physicochemical properties of pure imidacloprid

Characteristic	Value	Purity, %	Method	Reference
Vapour pressure	4 x 10^{-10} Pa at 20ºC 9 x 10^{-10} Pa at 25ºC	99.9	OECD 104, by extrapolation	PC313
Melting point	144ºC	99.9	OECD 102	PC312
Boiling point	Not measurable	-	-	PC14376
Decomposition temperature	DTA-measurement: No exothermic decomposition occurred belov ℃. TGA-measurement: Above 230 ℃, a weight loss was observed both under air and under a nitrogen atmosphere. Imidacloprid is thermally stable at room temperature.	99.5	OECD 113	PC339
Solubility in water	0.61 g/l at 20℃ Solubility is not influenced by pH in the range pH 4 to 9.	97.2	EEC A6 OECD 105	PC320
Octanol:water partition coefficient	P_{OW} = 3.7 Log P_{OW} = 0.57 at 21℃ Effect of pH not investigated because pH (4-9) does not influence water solubility.	99.8	EEC A8 OECD 107	PC337
Hydrolysis	Imidacloprid was found to be stable with a half-life > 1 year at pH 5 and 7. Slow hydrolysis with a half-life of approx. 1 year occurred at pH 9.	>99.8	EPA 161-1	NR1276
Photolysis	Half-life = 57 min. at 5.4 mg/l, 23 to 24.5℃, sterile conditions, irradiated with xenon lamp and UV-glass filter (cut-off 290 nm). The corresponding rate constant was 0.012 min^{-1}. Environmental half-life in surface water calculated as 4.2 h, at 50° latitude (e.g. N. Germany) and at the equinox.	>99.8	EPA 161-2	PF3517
Dissociation characteristics	Imidacloprid shows very weakly basic properties. Complete protonation can be achieved only in non-aqueous solutions in presence of very strong acids. It is not possible to determine a pK value in pure aqueous systems.	99.8	OECD 112	PC317

Table 2. Chemical composition and properties of imidacloprid 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 99.6 – 99.7%.
Declared minimum imidacloprid content:	970 g/kg
Relevant impurities ≥ 1 g/kg and maximum limits for them:	None
Relevant impurities < 1 g/kg and maximum limits for them:	None

Table 2. Chemical composition and properties of imidacloprid technical material (TC)

Stabilizers or other additives and maximum limits for them:	None
Melting temperature range (TC)	142-144 °C

Background information on toxicology/ecotoxicology

Bayer CropScience confirmed that the toxicological and ecotoxicological data included in Annex 1, below, were derived from imidacloprid having impurity profiles similar to those referred to in Table 2, above.

Imidacloprid was evaluated for toxicology by the FAO/WHO JMPR in 2001, which set the reference doses: ADI: 0.06 mg/kg bw/day; acute RfD: 0.4 mg/kg bw. Imidacloprid was evaluated for residues by the FAO/WHO JMPR in 2002, which recommended MRLs for 51 food commodities and assessed the dietary risks from long- and short-term intake of residues as "unlikely to present a public health concern".

Imidacloprid was evaluated by the U.S. EPA in 1992/93 and the results (imidacloprid compound (BAY NTN 33893 Techn.) – Registry No. EPA 3125-414, approval March 18, 1994) were published in the U.S. Federal Register in 1994. Residue tolerances were established (USEPA 1996).

The Bayer CropScience hazard phrases and classification are:

Harmful if swallowed
Harmful to aquatic organisms
Do not breathe dust
Classification: Xn: harmful
Harmful to honeybees by direct contact, but no problems expected when not sprayed into flowering crop or when used as seed treatment.

The WHO hazard classification of imidacloprid is Class II, moderately hazardous (WHO 2002).

Formulations

Imidacloprid is registered and marketed world-wide for use in more than 120 countries and on over 160 crops. The main formulation types are SL, SC, WG, WS and FS.

Methods of analysis and testing

The analytical methods for imidacloprid (including identity tests) in TC, GR, WG, WS, SC, FS, OD, SL are full CIPAC methods. The method for GR was published in CIPAC Handbook H. The methods for TC, WG, WS, SC, FS were published in CIPAC handbook K; extensions to OD and SL were adopted by CIPAC 2004 but are not yet published. In these methods, imidacloprid is determined by reversed-phase HPLC, using external standardization and detection at 260 nm.

The analytical method for determination of impurities (Bayer method 2201-0308702-98) is also based on reversed-phase HPLC, using isocratic elution and UV-detection

with certified reference substances for external standard calibration. Validation reports were provided.

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

Containers and packaging

No special requirements for containers and packaging have been identified.

Expression of active ingredient

The active ingredient is expressed as imidacloprid, in g/kg in solid formulations, and in g/kg or g/l at 20 ± 2C in liquid formulations.

ANNEX 1

HAZARD SUMMARY PROVIDED BY THE PROPOSER

Note: The proposer provided written confirmation that the toxicological and ecotoxicological data included in the following summary were derived from imidacloprid having impurity profiles similar to those referred to in Table 2, above.

Table A. Toxicology profile of the imidacloprid technical material, based on acute toxicity, irritation and sensitization

Species	Test	Duration and conditions	Result	Reference
Rat (m,f)	oral	single application; OECD 401, purity: 94.2%	LD_{50} = 424 mg/kg bw (m) 450 mg/kg bw (f)	18594
Rat	dermal	single application 24 h; OECD 402, purity: 94.2%	LD_{50} >5000 mg/kg bw	18594
Rat	inhalation	dust, 4 h exposure; OECD 403, purity: 95.3%	LC_{50} >5323 mg/m^3	16777
Rabbit	skin irritation	OECD 404, duration of exposure: 4 hours, purity: 94.2%	non-irritating	16455
Rabbit	eye irritation	OECD 405, duration of exposure: 24 hours, purity: 94.2%	non-irritating	16456
Guinea pig	skin sensitization	Maximization test, purity: 94.2%	non-sensitizing	16533

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

Species	Test	Duration and conditions	Result	Reference
Rabbit	sub-acute, dermal	OECD 410, purity: 95.0%	NOAEL = 1000 mg/kg bw/day	19152
Rat	sub-acute, inhalation	OECD 412, purity: 95.2%	NOAEC = 5.5 mg/m^3 air	18199
Dog	sub-acute, feeding	OECD 409, 4 weeks, purity: 92.8%	NOAEL = 7.3 mg/kg bw/day	R4196
Rat	sub-chronic, feeding	OECD 408, 13 weeks, purity: 92.8%	NOAEL = 11 mg/kg bw/day	17279
Rat	sub-chronic, feeding	OECD 408, 13 weeks, purity: 95.3%	NOAEL = 14 mg/kg bw/day	18187
Mouse	sub-chronic, feeding	OECD 408, 13 weeks, purity: 92.8%	NOAEL = 17 mg/kg bw/day	17280
Dog	sub-chronic, feeding	OECD 409, 13 weeks, purity: 95.3%	NOAEL = 7.8 mg/kg bw/day	18732
Rat	chronic/oncogenicity, feeding	OECD 453, 24 months, purity: 94.3-95.3%	NOAEL = 5.7 mg/kg bw/day Not carcinogenic	19925
Mouse	oncogenicity, feeding	OECD 451, 24 months, purity: 95.3%	NOAEL = 65.5 mg/kg bw/day Not carcinogenic	19931; 20769
Dog	chronic, feeding	OECD 452, 52 weeks, purity: 94.9%	NOAEL = 15 mg/kg bw/day	R4856
Rat	2-generation reproduction toxicity	OECD 416, purity: 94.4-95.3%	NOAEL parents = 6.7 mg/kg bw/day, NOAEL developmental = 12.5 mg/kg bw/day	R5097
Rat (f)	developmental toxicity	OECD 414, purity: 94.2%	NOAEL maternal = 10 mg/kg bw/day, NOAEL developmental = 30 mg/kg bw/day, Not teratogenic	R5442

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

Species	Test	Duration and conditions	Result	Reference
Rabbit (f)	developmental toxicity	OECD 414, purity: 94.2%	NOAEL maternal = 8 mg/kg bw/day, NOAEL developmental = 24 mg/kg bw/day, Not teratogenic	R5443

Table C. Mutagenicity profile of imidacloprid technical material based on *in vitro* and *in vivo* tests

Species	Test	Conditions	Result	Reference
Salmonella microsome	Reverse mutation, *in vitro*	OECD 471, doses: 0-20-100-500-2500-12500 µg/plate, purity: 95.0%	negative	17577
Salmonella microsome	Reverse mutation, *in vitro*	OECD 471, doses: 0-8-40-200-1000-5000 µg/plate, purity: 96.0-96.3%	negative	20090
Salmonella microsome	Reverse mutation, *in vitro*	OECD 471, doses: 0-8-40-200-1000-5000 µg/plate, purity: 97.4%	negative	21775
Salmonella microsome	Reverse mutation, *in vitro*	OECD 471, doses: 0-312.5-625-1250-2500-5000 µg/plate, purity: 93.7%	negative	RA91002
Bacillus subtilis	Recombinant assay, *in vitro*	in compliance with MAFF (59 Nousan No. 4200), doses: 0-312.5-625-1250-2500-5000 µg/plate, purity: 94.7%	negative	RA90016
CHO-HGPRT	*in vitro*	OECD 476, doses: up to 125 µg/ml with S-9 mix and 1222 µg/ml without S-9 mix, purity: 95.2%	negative	17578
Saccharomyces cerevisiae	Mitotic recombination, *in vitro*	OECD 480, doses: 0-625-1250-2500-5000-10000 µg/ml, purity: 95.3%	negative	16832
Rat primary hepatocytes	UDS test, *in vitro*	OECD 482, doses: 750 µg/ml to 5.00 µg/ml, purity: 95.2%	negative	R4631
Chinese hamster ovary cells	Sister chromatid exchange, *in vitro*	OECD 473, doses: up to and including 5000µg/ml, purity: 95.2%	weakly positive	R4407
Chinese hamster ovary cells	Sister chromatid exchange, *in vitro*	OECD 473, doses: up to 400 µg/ml without S-9 mix and up to 1250 µg/ml with S-9 mix, purity: 95.2%	negative	BC1149
Human lymphocyte	Cytogenetic study, *in vitro*	OECD 473, up to 5200 µg/ml, purity: 95.2%	positive	18092
Chinese hamster bone marrow	Cytogenetic study, *in vivo*	OECD 475, dose: 2000 mg/kg, purity: 94.6%	negative	18557
Mouse bone marrow	Micronucleus test, *in vivo*	OECD 474, dose: 80 mg/kg, purity: 95.3%	negative	16837
Chinese hamster bone marrow	Sister chromatid exchange, *in vivo*	OPPTS 8705915, doses: 500-1000-2000 mg/kg, purity: 95.0%	negative	18093
Mouse germ-cell	Cytogenetic study, *in vivo*	OECD 483, dose: 80 mg/kg	negative	R5063

Table D. Ecotoxicology profile of imidacloprid technical material

Species	Test	Duration and conditions	Result	Reference
Leuciscus idus melanotus (golden orfe)	acute	96h, 21°C, purity: 95.3%	LC_{50} = 237 mg a.s./l	FO-1042
Oncorhynchus mykiss (rainbow trout)	acute	96h, 21°C, purity: 95.3%	LC_{50} = 211 mg a.s./l	FF-210
Daphnia magna (water flea)	acute	48h, 20°C static, purity: 95.4%	EC_{50} = 85 mg/l	100245
Daphnia magna (water flea)	chronic	21 d, 20°C static renewal, purity: 95.4%	NOEC = 1.8 mg/l	100247
Chironomus riparius (midge larvae)	chronic	28 d, 20°C static, purity: 98.4%	EC_{15} = 0.00225 mg/l	DOM 21035
Selenastrum capricornutum (green alga)	chronic	72h, 23°C, static, purity: 98.6%	ErC_{50} >100 mg/l LOEC <100 mg/l	DOM 20018
Earthworm	acute toxicity	14d, 22°C, purity: 92.8%	LC_{50} = 10.7 mg/kg dry soil	HBF/RG 63
Earthworm	chronic toxicity	reproduction, 8 wks, purity: 98.6%	NOEC ≥ 0.178 mg/kg (5 % O.M.)	HBF/RG 301
Apis mellifera (honey bee)	acute oral toxicity	48h, purity: 98.6% 48h and 96h, purity: 99.4% 48h, purity: 99.8%	LD_{50} >21 ng/bee LD_{50} = 40.9 ng/bee LD_{50} = 3.7 ng/bee	AH99.4.22.4 6400036 BAY 158/901384
Apis mellifera (honey bee)	acute contact toxicity	72h, purity: 98.6% 48h, 99.8%	LD_{50} = 129 ng/bee LD_{50} = 81 ng/bee	AH99.4.22.3 BAY 158/901384
Bobwhite quail	acute toxicity	14d, single dose, purity: 97.4%	LD_{50} = 152 mg a.s./kg bw	100059
Bobwhite quail	sub-acute toxicity	5d, purity: 98.4%	LC_{50} = 2225 ppm feed (14d) LC_{50} >5000 ppm feed (adult)	SXR/VB 57
Bobwhite quail	sub-chronic toxicity	20 wks, reproduction, purity: 94.8%	NOEC = 126 ppm feed	101203
Mallard duck	acute oral toxicity	14d, single dose, purity: 96.6%	LD_{50} = 283 mg a.s./kg b.w.	107354
Mallard duck	sub-acute toxicity	5d, purity: 97.4%	LC_{50} >4797 ppm feed	100238
Mallard duck	sub-chronic toxicity	20 wks, reproduction, purity: 95.8%.	NOEC = 128 ppm feed	103813-1
Japanese quail	acute oral toxicity	14d, single dose, purity: 95.3%	LD_{50} = 31 mg a.s./kg b.w.	VW-123
Japanese quail	sub-acute toxicity	5d, purity: 97.2%	LC_{50} = 392 ppm feed	GMU/VW-177

Annex 2. References

Bayer CropScience document number	Year and title of report or publication details
100059	1990. Technical NTN 33893: An acute oral LD_{50} with Bobwhite quail.
100238	1990. Technical NTN 33893: A subacute dietary LC_{50} with Mallard ducks.
100245	1990. Acute Toxicity of NTN 33893 to *Daphnia magna.*
100247	1990. 21-Day Chronic Static Renewal Toxicity of NTN 33893 to *Daphnia magna.*
101203	1991. Technical NTN 33893: A One Generation Reproduction Study with Bobwhite Quail.
103813-1	1993. Technical NTN 33893: A One Generation Reproduction Study With Mallard Ducks.
107354	1996. NTN 33893 Technical: An acute oral LD_{50} with Mallards.
16455	1988. NTN 33893 - Study for irritant/corrosive potential on the skin (rabbit) according to OECD guideline no. 404.
16456	1988. NTN 33893 - Study for irritant/corrosive potential on the eye (rabbit) according to OECD guideline no. 405.
16533	1988. NTN 33893 technical - Study for skin sensitising effect on guinea pigs (maximisation test).
16777	1988. NTN 33893 - Study for acute inhalation toxicity in the rat in accordance with OECD guideline no. 403.
16832	1988. NTN 33893 - Test on S. cerevisiae D7 to evaluate for induction of mitotic recombination..
16837	1988. NTN 33893 - Micronucleus-test on the mouse to evaluate for clastogenic effects.
17279	1988. NTN 33893 - Pilot range-finding study for a chronic toxicity study on Wistar rats (ninety-eight day feeding study).
17280	1988. NTN 33893 - Pilot range-finding study for a cancerogenesis study on B6C3F1 mice (one hundred seven day feeding study).
17577	1989. NTN 33893 - Salmonella/microsome test to evaluate for point mutagenic effects.
17578	1989. NTN 33893 - Mutagenicity study for the detection of induced forward mutations in the CHO-HGPRT assay in vitro.
18092	1989b. NTN 33893 - In vitro cytogenetic study with human lymphocytes for the detection of induced clastogenic effects.
18093	1989. NTN 33893 - Sister chromatid exchange in bone marrow of chinese hamsters in vivo.
18187	1989. NTN 33893 - Subchronic toxicity study on wistar rats (administration in the feed for 96 days).
18199	1989. NTN 33893 (proposed common name: Imidacloprid) - Subacute inhalation toxicity study on the rat according to OECD guideline no. 412.
18557	1989. NTN 33893 - In vivo cytogenetic study of the bone marrow in chinese hamster to evaluate for induced clastogenic effects.
18594	1989. NTN 33893 - Study for acute oral toxicity to rats.
18732	1990. NTN 33893 technical - Subchronic toxicity study on dogs in oral administration (thirteen-week feeding study).
19152	1990. NTN 33893 techn. - Study for subacute dermal toxicity in the rabbit.
19925	1991. NTN 33893 (proposed c.n.: Imidacloprid) - Chronic toxicity and cancerogenicity studies on Wistar rats (administration in food over 24 months).
19931	1991. NTN 33893 (proposed common name Imidacloprid) - Carcinogenicity study on B6C3F1 mice (administration in the food for 24 months).
20090	1991. NTN 33893 AMP - Salmonella/microsome test.

Bayer CropScience document number	Year and title of report or publication details
20769	1991. NTN 33893 (proposed common name: Imidacloprid) - Carcinogenicity study in B6C3F1 mice (supplementary MTD testing for study T5025710 with administration in diet over a 24-month period).
21775	1992. NTN 33893 AMP W - Salmonella/microsome test.
6400036	1999. Laboratory Testing for Toxicity (Acute Oral LD50) of NTN 33893 on Honey Bees *(Apis mellifera* L.) (Hymenoptera, Apidae).
AH99.4.22.3	1999. Honeybee *(Apis mellifera L.*) Contact Toxicity Study in the Laboratory with Imidacloprid techn.
AH99.4.22.4	1999. Honeybee *(Apis mellifera L.*) Oral Toxicity Study in the Laboratory with Imidacloprid techn.
BAY 158/901384	1990. The Acute Oral and Contact Toxicity to Honey Bees of Compound NTN 33893 Technical.
BC1149	1989. BAY NTN 33893 - Sister chromatid exchange assay in chinese hamster ovary cells.
CIPAC H	Dobrat, W. and Martijn, A. Eds. (1998): CIPAC Handbook volume H, Analysis of technical and formulated pesticides. Collaborative International Pesticides Analytical Council, Harpenden, U.K.
CIPAC K	Dobrat, W. and Martijn, A. Eds. (2003). CIPAC Handbook volume K, Analysis of technical and formulated pesticides. Collaborative International Pesticides Analytical Council, Harpenden, U.K.
DOM 20018	2000. Imidacloprid - Influence on the Growth of the Green Alga, *Selenastrum capricornutum*.
DOM 21035	2001. Influence of Imidacloprid (tech.) on Development and Emergence of Larvae of *Chironomus riparius* in a Water-Sediment System.
FAO/WHO 2002	Manual of the development and use of FAO and WHO specifications for pesticides. FAO plant production and protection paper 173. FAO, Rome, 2002.
FF-210	1988b. The acute toxicity of NTN 33893 techn. to Rainbow trout (*Salmo gairdneri*) in a static test.
FO-1042	1987. The Acute Toxicity of NTN 33893 techn. to Golden Orfe (*Leuciscus idus melanotus*) in a Static Test.
GMU/VW-177	1996. NTN 33893 techn.: 5-Day Dietary LC50 to Japanese quail.
HBF/Rg 301	1999. Influence of Low Concentrations of Imidacloprid (tech.) on the Reproduction of Earthworms (*Eisenia fetida)*.
HBF/Rg 63	1986. Acute toxicity of NTN 33893 (tech.) to earthworms.
NR1276	1989. Hydrolysis of NTN 33893.
PC1437	1996. Boiling Point of Imidacloprid (NTN 33893).
PC312	1993. Melting Point of Imidacloprid
PC313	1993. Vapour Pressure Curve of Imidacloprid.
PC317	1990. Dissociation constant of NTN 33893.
PC320	1993. Water solubility of Imidacloprid.
PC337	1989. Octanol/Water partition coefficient of NTN 33893.
PC339	1998. Thermal stability of the active ingredient NTN 33893.
PF3517	1988. Photodegradation of NTN 33893 in water.
R4196	1987. 28-day oral range-finding toxicity (feeding) study with NTN 33893 tech. in the dog.
R4407	1988. Clastogenic evaluation of NTN 33893 in an in vitro cytogenetic assay measuring sister chromatid exchange in chinese hamster ovary (CHO) cells.
R4631	1988. Mutagenicity test on NTN 33893 in the rat primary hepatocyte unscheduled DNA synthesis assay.
R4856	1989. 52-week oral toxicity (feeding) study with NTN 33893 technical in the dog.
R5063	1990. Mouse germ-cell cytogenetic assay with NTN 33893.

Bayer CropScience document number	Year and title of report or publication details
R5097	1990. Multiple generation reproduction study with NTN 33893 technical in rats.
R5442	1998. Embryotoxicity study (including teratogenicity) with NTN 33893 technical in the rat.
R5443	1988. Embryotoxicity study (including teratogenicity) with NTN 33893 technical in the rabbit.
RA90016	1990. NTN 33893 - Rec-assay with spores in the bacterial System.
RA91002	1991. NTN 33893 - Reverse mutation assay (Salmonella typhimurium and Escherichia coli).
SXR/VB 57	1996. Age-related five day dietary toxicity of imidacloprid to Bobwhite quail.
USEPA 1996	Pesticide tolerances. Imidacloprid. Federal Register, February 14, 1996, Vol. 61, No. 31 [Rules and Regulations], pages 5711 ff.
VW-123	1988. Acute oral LD_{50} of NTN 33893 to Japanese quail.
WHO 2002	The WHO recommended classification of pesticides by hazard and guidelines to classification 2000-2002. WHO, Geneva, 2002.

Addendum Report

(FAO Specification 582/GR/2008)

(CIPAC number 582)

Explanation

Imidacloprid data were provided in 2004 by Bayer CropScience to support specifications for imidacloprid TC, GR, WS, WG, SC, FS, OD, SL. The FAO specifications were published in 2006.

Supporting data for the extension of an existing specification (imidacloprid GR) were provided by Cheminova A/S in 2007.

The Cheminova A/S granular formulations are prepared from Bayer CropScience technical material that complies with FAO specifications.

The Cheminova A/S granular formulations do not meet the existing GR specifications in two respects:

- colour of the granules; and
- upper limits for pour and tap density.

Data were provided to support proposed changes to the existing specifications for imidacloprid granules.

Recommendations

The Meeting recommended that:

- the specifications for imidacloprid GR be amended to include coloured granules and to accommodate wider ranges for pour and tap density.

Appraisal

Imidacloprid specifications for TC, GR, WS, WG, SC, FS, OD and SL were published in 2006 after a data submission from Bayer CropScience. In 2007, Cheminova A/S requested an extension of the imidacloprid GR specification and provided supporting data.

The extension involves a change in description from "beige granules" to "beige or coloured" granules and to allow a wider range in pour and tap densities (upper limits to increase by 0.1 g/ml).

The granules from both manufacturers are manufactured from the same source of TC, but possibly different carrier materials, which may influence the density. The colouring is to assist observation of the granules on soil.

Neither change should influence the product performance.

SUPPORTING INFORMATION

Formulations and co-formulated active ingredients

The main formulation types available are SL, SC, WG, GR, FS and WS.

In GR formulations, imidacloprid may be formulated alone or co-formulated with other active ingredients, such as organophosphate and pyrethroid insecticides.

Cheminova's imidacloprid GR formulations are registered and sold in Great Britain.

Methods of analysis and testing

Analytical methods for the active ingredient are based on the methods and testing described in existing FAO specification for imidacloprid GR formulations (FAO Specification 582/GR (May 2006)) following the new procedure.

Test methods for determination of physico-chemical properties of the technical active ingredient were not applicable as TC utilized by Cheminova A/S for GR formulations originate from a manufacturer whose specification is already approved, 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 GR formulations, comply with the requirements described in the existing FAO specification for imidacloprid GR formulations (FAO Specification 582/GR (May 2006)) following the new procedure, with the following exceptions:

Colour

In the existing FAO specification for imidacloprid GR formulations (FAO Specification 582/GR (May 2006)) the material is described as "beige granules" (Refer to "1. Description", line 4 of FAO Specification 582/GR (May 2006)).

It is proposed to change the wording to "beige or coloured granules".

Justification for change: granule formulations consist of a carrier material, such as silica, coated with imidacloprid. One of the uses is for soil treatment, where a colouring of the granules will help identify treated areas.

Density

In the existing FAO specification for imidacloprid GR formulations (FAO Specification 582/GR (May 2006)) the density range of the formulations is stated as:

Pour density: 1.4 to 1.5 g/ml
Tap density: 1.5 to 1.6 g/ml

when determined in compliance with CIPAC MT 186, Handbook K, p. 151, 2003.

It is proposed to extend the limits to:

Pour density: 1.4 to 1.6 g/ml
Tap density: 1.5 to 1.7 g/ml

when determined in compliance with CIPAC MT 186, Handbook K, p. 151, 2003.

Justification for change: The density of the formulation will to a high degree depend on the carrier material, such as silica. The density of these materials can vary. The limits in the existing FAO specification for imidacloprid GR formulations (FAO Specification 582/GR (May 2006)) are narrow, and the suggested extension will allow for additional suitable carriers to be available for formulation purposes.

Containers and packaging

No special requirements for containers and packaging have been identified.