Food and Agriculture Organization
of the United Nations

FAO SPECIFICATIONS AND EVALUATIONS FOR AGRICULTURAL PESTICIDES

TRIFLOXYSTROBIN

methyl (*E*)-(methoxyimino){α-({[(*E*)-1-(α,α,α-trifluoro-*m*-tolyl)ethylidene]amino}oxy)-*o*-tolyl}acetate

2024

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TRIFLOXYSTROBIN

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.

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[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 1999 onward, the development of FAO specifications follows the New Procedure, described first in the fifth edition of the "Manual on the development and use of FAO specifications for plant protection products" and later in the first edition of the “Manual on Development and Use of FAO and WHO Specifications for Pesticides” (2002) – currently available as ”Manual on the development and use of FAO and WHO specifications for chemical pesticides” second edition (2022) – 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 JMPM, 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 the development and use of FAO and WHO specifications for chemical 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 “ Manual on the development and use of FAO and WHO specifications for chemical pesticides” 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. 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 (https://www.fao.org/pest-and-pesticide-management/guidelines-standards/faowho-joint-meeting-on-pesticide-specifications-jmps/pesticide-specifications/pesticide-specifications-list/en/) or in hardcopy from the plant protection information officer.

PART ONE

SPECIFICATIONS

TRIFLOXYSTROBIN

TRIFLOXYSTROBIN

INFORMATION

ISO common name

trifloxystrobin (ISO 1750 (published))

Chemical name(s)

IUPAC:

methyl (*E*)-(methoxyimino){α-({[(*E*)-1-(α,α,α-trifluoro-*m*-tolyl)ethylidene]amino}oxy)-*o*-tolyl}acetate (1979 Rules)

or

methyl (2*E*)-(methoxyimino)(2-{[({(1*E*)-1-[3-(trifluoromethyl)phenyl]ethylidene} amino)oxy]methyl}phenyl)acetate

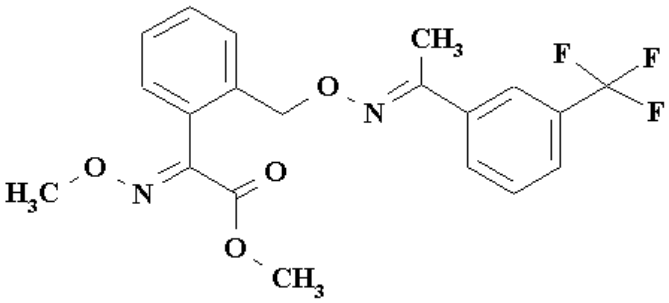
CA:

methyl (α*E*)-α-(methoxyimino)-2-[[[[(1*E*)-1-[3-(trifluoromethyl)phenyl]ethylidene] amino]oxy]methyl]benzeneacetate

Synonyms

CGA 279202

Structural formula



Molecular formula

$C_{20}H_{19}F_3N_2O_4$

Relative molecular mass

408.4

CAS Registry number

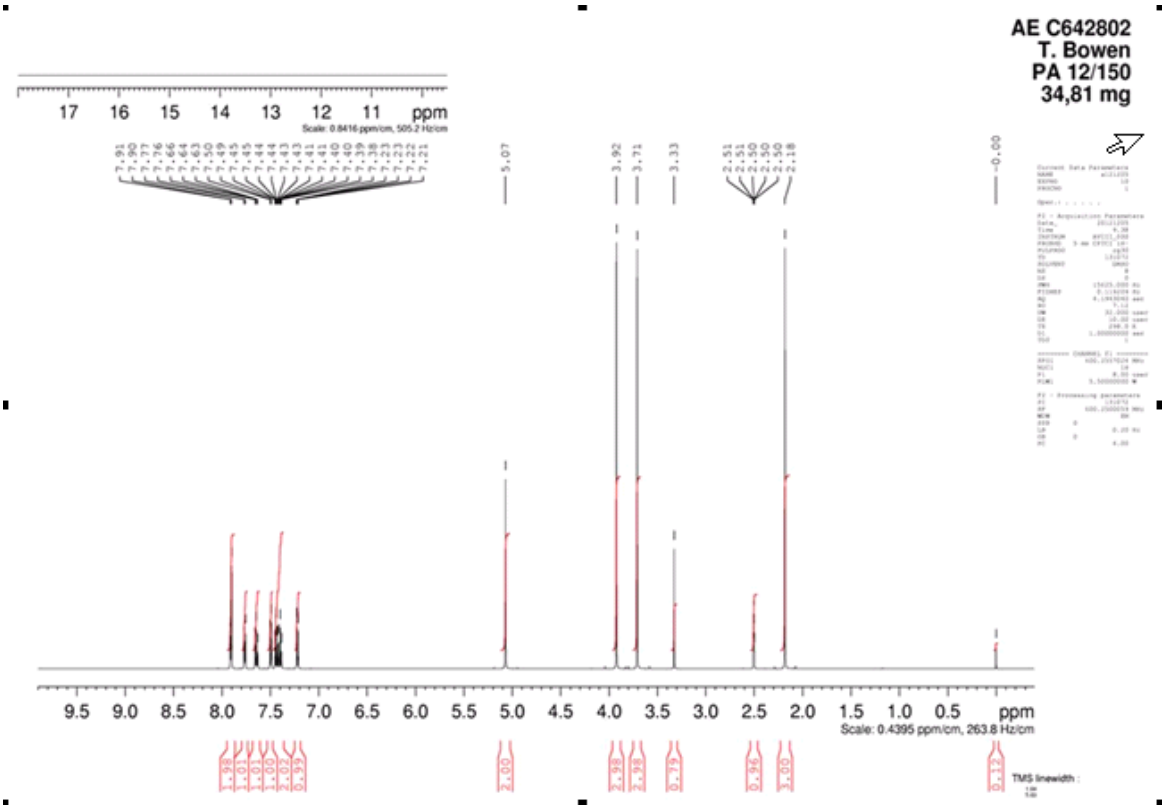
141517-21-7

CIPAC number

617

Identity tests

^{1}H NMR spectrum


AE C642802
T. Bowen
PA 12/150
34,81 mg
17 16 15 14 13 12 11 ppm
Scale: 0.8416 ppm/cm, 505.2 Hz/cm
7.91 7.90 7.77 7.76 7.66 7.64 7.63 7.50 7.49 7.45 7.44 7.44 7.43 7.43 7.41 7.41 7.40 7.40 7.39 7.38 7.23 7.23 7.22 7.21
5.07
3.92 3.71
3.33
2.51 2.51 2.50 2.50 2.50 2.18
-0.00
9.5 9.0 8.5 8.0 7.5 7.0 6.5 6.0 5.5 5.0 4.5 4.0 3.5 3.0 2.5 2.0 1.5 1.0 0.5 ppm
Scale: 0.4395 ppm/cm, 263.8 Hz/cm
1.98 1.01 1.01 1.00 2.02 0.99
2.00
2.98 2.98 0.79 0.96 3.00
3.12
TMS linewidth :

FAO Specification 617/TC (June 2024*)

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 (617/2024). It should be applicable to relevant products of this manufactuer, but it is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for TC produced by other manufacturers. The evaluation report (617/2024), as PART TWO, forms an integral part of this publication.

1 Description

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

2 Active ingredient

2.1 Identity tests (617/TC/M2, CIPAC Handbook O, p. 162, 2017)

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 Trifloxystrobin content (617/TC/M3, CIPAC Handbook O, p. 162, 2017)

The trifloxystrobin 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.

3 Relevant impurities

3.1 methyl (2*E*)-[2-(chloromethyl)phenyl](methoxyimino)acetate (CGA 344605 or AE1344136; CAS Reg No.:189813-45-4) (CIPAC 5289/m) (Note 1)

Max. 4 g/kg

Note 1 Method available at https://www.cipac.org/images/pdf/relevant%20impurities/5289m_method_imp_CGA_344605_in_trifloxystrobin_free.pdf (https://www.cipac.org/index.php/m-p/free-methods/freerelevant-impurities-methods)

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* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: https://www.fao.org/pest-and-pesticide-management/guidelines-standards/faowhojoint-meeting-on-pesticide-specifications-jmps/pesticide-specifications/en/

FAO Specification 617/EC (June 2024*)

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 (617/2024). It should be applicable to relevant products of this manufactuer, but it 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. The evaluation report (617/2024), as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of technical trifloxystrobin, complying with the requirements of FAO specification 617/TC (March 2024), in the form of white to beige powder, dissolved in suitable solvents, together with any other necessary formulants. It shall be in the form of a stable homogeneous liquid, free from visible suspended matter and sediment, to be applied as an emulsion after dilution in water.

2 Active ingredient

2.1 Identity tests (617/EC/M2, CIPAC Handbook O, p. 166, 2017)

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 Trifloxystrobin content (617/EC/M3, CIPAC Handbook O, p. 166, 2017)

The trifloxystrobin content shall be declared (g/kg or g/l at 20 ± 2°C, Note 1) and, when determined, the average content measured shall not differ from that declared by more than the following tolerances:

Declared content in g/kg or g/l at 20 ± 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: In each range the upper limit is included	

3 Relevant impurities

3.1 methyl (2*E*)-[2-(chloromethyl)phenyl](methoxyimino)acetate (CGA 344605 or AE1344136; CAS Reg No.:189813-45-4) (CIPAC 5289/m, Note 2)

Maximum 0.4% of the trifloxystrobin content found under 2.2.

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* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: https://www.fao.org/pest-and-pesticide-management/guidelines-standards/faowhojoint-meeting-on-pesticide-specifications-jmps/pesticide-specifications/en/

4 Physical properties

4.1 Emulsion stability and re-emulsification (MT 36.3, CIPAC Handbook K, p.137, 2003) (Notes 3 & 4)

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

Time after dilution	Limits of stability, MT 36.3
0 h	Initial emulsification complete
0.5 h	"cream" or “sediment”, maximum: 2 ml, “free oil”, maximum: 1 ml
2.0 h	"cream", or “sediment”, maximum: 2 ml “free oil”, maximum: 1 ml
24 h	re-emulsification complete
24.5 h	"cream", or “sediment”, maximum: 2 ml “free oil”, maximum: 1 ml
Note: tests after 24 h are required only where results at 2 h are in doubt.	

4.2 Persistent foam (MT 47.3, CIPAC Handbook O, p.177, 2017) (Note 5)

Maximum: 60 ml after 1 min.

5 Storage stability

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

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

5.2 Stability at elevated temperature (MT 46.4, CIPAC Handbook P, p.232, 2021)

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:

- emulsion stability and re-emulsification (4.1)

Note 1 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 2 Method available at https://www.cipac.org/images/pdf/relevant%20impurities/5289m_method_imp_CGA_344605_in_trifloxystrobin_free.pdf (https://www.cipac.org/index.php/m-p/free-methods/freerelevant-impurities-methods)

Note 3 This test will normally only be carried out after the heat stability test 5.2.

Note 4 As outlined in CIPAC MT 36.3, the test concentrations should be based on those in the recommended directions for use supplied with the product. Where several concentrations are recommended, the highest and lowest concentrations within the scope of the method should be used.

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 at 25 ± 5°C.

Note 6 Samples of the formulation taken before and after the storage stability test may be analyzed concurrently after the test in order to reduce the analytical error.

FAO Specification 617/SC (June 2024*)

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 (617/2024). It should be applicable to relevant products of this manufactuer, but it 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. The evaluation report (617/2024), as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of a suspension of fine particles of technical trifloxystrobin, complying with the requirements of FAO specification 617/TC (March 2024), in the form of white to beige powder, 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 (617/SC/M2, CIPAC Handbook O, p. 168, 2017)

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 Trifloxystrobin content (617/SC/M3, CIPAC Handbook O, p. 168, 2017)

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

Declared content in g/L or g/kg	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: In each range the upper limit is included	

3 Relevant impurities

3.1 methyl (2*E*)-[2-(chloromethyl)phenyl](methoxyimino)acetate (CGA 344605 or AE1344136; CAS Reg No.:189813-45-4) (CIPAC 5289/m, Note 3)

Maximum 0.4% of the trifloxystrobin content found under 2.2.

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* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: https://www.fao.org/pest-and-pesticide-management/guidelines-standards/faowhojoint-meeting-on-pesticide-specifications-jmps/pesticide-specifications/en/

4 Physical properties

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

Maximum "residue": 5 %

4.2 Spontaneity of dispersion (MT 160.1, Notes 4 & 5)

Spontaneity of dispersion: minimum 80% after 5 min in CIPAC standard water D at 25 ± 5°C. (Note 5)

4.3 Suspensibility (MT 184.1, CIPAC Handbook P, p.245, 2021) (Note 5)

Suspensibility: minimum 70 % after 30 min in CIPAC standard water D at 25 ± 5°C.

4.4 Wet sieve test (MT 185.1, Note 6)

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

4.5 Persistent foam (MT 47.3, CIPAC Handbook O, p.177, 2017) (Note 7)

Maximum: 60 ml after 1 min.

5 Storage stability

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

After storage at 0 ± 2°C for 7 days, the formulation shall continue to comply with the clauses for:
- suspensibility (4.3),
- wet sieve test (4.4).

5.2 Stability at elevated temperature (MT 46.4, CIPAC Handbook P, p.232, 2021)

After storage at 40 ± 2°C for 8 weeks, the determined average active ingredient content must not be lower than 95 % relative to the determined average content found before storage (Note 8) and the formulation shall continue to comply with the clauses for:
- pourability (4.1),
- spontaneity of dispersion (4.2),
- suspensibility (4.3),
- wet sieve test (4.4).

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 or OECD 109 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 Method available at https://www.cipac.org/images/pdf/relevant%20impurities/5289m_method_imp_CGA_344605_in_trifloxystrobin_free.pdf (https://www.cipac.org/index.php/m-p/free-methods/freerelevant-impurities-methods)

Note 4 The revision of methods MT 160 (CIPAC/5323) to determine the spontaneity of dispersion of liquid formulations forming suspensions on dilution with water was accepted as full CIPAC method with the remark that MT 160.1 supersedes MT 160 (ISBN 978-1-911009-72-6). Before publication in a handbook it is available as a pre-published method. (https://www.cipac.org/index.php/m-p/pre-published-methods)

Note 5 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 6 The revision of methods MT 182 and MT 185 (CIPAC/5353) to combine into a single method for wet sieve test was accepted as provisional CIPAC method under the prerequisite that it supersedes both MT 182 and MT 185 (ISBN 978-1-911009-78-8). Before publication in a handbook it is available as a pre-published method. (https://www.cipac.org/index.php/m-p/pre-published-methods

Note 7 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 8 Samples of the formulation taken before and after the storage stability test may be analysed concurrently after the test in order to reduce the analytical error.

FAO Specification 617/WG (June 2024*)

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 (617/2024). It should be applicable to relevant products of this manufactuer, but it 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. The evaluation report (617/2024), as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of a homogeneous mixture of technical trifloxystrobin, complying with the requirements of the FAO specification 617/TC (March 2024), in the form of white to beige powder, together with carriers and any other necessary formulants. It shall be in the form of granules for application after disintegration and dispersion in water. The formulation shall be dry, free-flowing, nearly dust free or essentially non-dusty, and free from visible extraneous matter and hard lumps.

2 Active ingredient

2.1 Identity tests (617/WG/M2, CIPAC Handbook O, p. 168, 2017)

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 Trifloxystrobin content (617/WG/M3, CIPAC Handbook O, p. 168, 2017)

The trifloxystrobin content shall be declared (g/kg) and, when determined, the average content measured shall not differ from that declared by more than the appropriate tolerance, given in the following table of tolerances.

Declared content in g/kg	Tolerance
up to 25	± 25 % 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: In each range the upper limit is included	

3 Relevant impurities (CIPAC prepublished method)

3.1 methyl (2*E*)-[2-(chloromethyl)phenyl](methoxyimino)acetate (CGA 344605 or AE1344136; CAS Reg No.:189813-45-4) (CIPAC 5289/m, Note 1)

Maximum 0.4% of the trifloxystrobin content found under 2.2.

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* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: https://www.fao.org/pest-and-pesticide-management/guidelines-standards/faowhojoint-meeting-on-pesticide-specifications-jmps/pesticide-specifications/en/

4 Physical properties

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

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

4.2 Wet sieve test (MT 185.1, Note 2)

Maximum: 2 % of the formulation shall be retained on a 75 µm test sieve.

4.3 Dispersibility (MT 174, CIPAC Handbook F, p. 435, 1995)

Dispersibility: minimum 60 % after 1 minute of stirring.

4.4 Suspensibility (MT 184.1, CIPAC Handbook P, p.245, 2021) (Notes 3 & 4)

Suspensibility: minimum 60 % after 30 min in CIPAC standard water D at 25 ± 5°C.

4.5 Persistent foam (MT 47.3, CIPAC Handbook O, p.177, 2017) (Note 5)

Maximum: 60 after 1 minute in CIPAC Standard Water D.

4.6 Dustiness (MT 171.1, CIPAC Handbook P, p.235, 2021) (Note 6)

The formulation shall have a maximum collected dust of 30 mg by the gravimetric method or a maximum dust factor of 25 by the optical method of MT 171.1.

4.7 Flowability (MT 172.2, CIPAC Handbook P, p.235, 2021) (Note 7)

At least 99 % of the formulation shall pass through a 5 mm test sieve after 20 drops of the sieve.

4.8 Attrition resistance (MT 178.3, Note 8)

Minimum: 98 % attrition resistance.

5 Storage stability

5.1 Stability at elevated temperature (MT 46.4)

After storage at 40 ± 2°C for 8 weeks the determined average active ingredient content must not be lower than 95 % relative to the determined average content found before storage (Note 9) and the formulation shall continue to comply with the clauses for:

- wet sieve test (4.2),
- dispersibility (4.3),
- suspensibility (4.4),
- dustiness (4.6),
- attrition resistance (4.8),

Note 1 Method available at https://www.cipac.org/images/pdf/relevant%20impurities/5289m_method_imp_CGA_344605_in_trifloxystrobin_free.pdf (https://www.cipac.org/index.php/m-p/free-methods/freerelevant-impurities-methods)

Note 2 The revision of methods MT 182 and MT 185 (CIPAC/5353) to combine into a single method for wet sieve test was accepted as provisional CIPAC method under the prerequisite that it supersedes both MT 182 and MT 185 (ISBN 978-1-911009-78-8). Before publication in a handbook it is available as a pre-published method. (https://www.cipac.org/index.php/m-p/pre-published-methods

Note 3 The formulation should be tested at the highest and lowest rates of use recommended by the supplier, provided this does not exceed the conditions given in method MT 184.1.

Note 4 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. In case of dispute, chemical assay shall be the "referee method".

Note 5 The mass on sample to be used in the test should be specified at the highest rate recommended by the supplier. The test is to be conducted in CIPAC standard water D at 25 ± 5°C.

Note 6 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 of MT 171.1, 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 7 The flowability test (MT 172.2) includes the accelerated storage conditions to be used.

Note 8 The revision of methods MT 178 and MT 178.2 (CIPAC/5321) to combine into a single method for granular products and to include loosely packed tablets was accepted as full CIPAC method with the editorial changes and with the remark that MT 178.3 supersedes MT 178 and MT 178.2 (ISBN 978-1-911009-69-6).

Note 9 Samples of the formulation taken before and after the accelerated storage stability test may be analysed concurrently after the test in order to reduce the analytical error.

PART TWO

EVALUATION REPORTS

TRIFLOXYSTROBIN

FAO/WHO EVALUATION REPORT 617/2024

Recommendations

The Meeting recommended that:

(i) the specifications for trifloxystrobin TC, EC, SC and WG, proposed by Bayer CropScience, as amended, should be adapted by FAO.

Appraisal

The Meeting considered data submitted by Bayer CropScience in March 2015 for the development of new FAO specifications for TC, SC, EC and WG formulations.

The data were broadly in accordance with the requirements of the 2016 revision of the FAO/WHO manual.

Trifloxystrobin is not under patent.

Trifloxystrobin has been evaluated by the FAO/WHO JMPR (in 2004 for toxicology and residues and in 2012, 2015 and 2017 for residues) and by WHO/IPCS.

Prior to the full evaluation by JMPR in 2004, a FAO/WHO/OECD pilot project on work-sharing was conducted to test whether national and regional evaluations of pesticide residues and toxicology could be used as a basis for JMPR evaluations. The 2003 CCPR selected trifloxystrobin as the first compound for the project because it had been evaluated in Australia, Canada, the USA and by the European Commission.

Trifloxystrobin was evaluated/reviewed by the US EPA in 1999 and by the European Commission in 2003 and 2018.

The Meeting was provided with commercially confidential information on the manufacturing process and five batch analytical data on impurities present at or above 1 g/kg in the TC and their manufacturing limits. Mass balances ranged from 998 to 1005 g/kg.

The manufacturing impurity CGA 344605 or AE1344136 methyl (2*E*)-[2-(chloromethyl)phenyl](methoxyimino)acetate was considered as toxicologically relevant. The limit in the TC was set according to JMPS procedure at 4 g/kg in the TC (at this level no mutagenic hazard is detected), being also congruent with the limit set in the EU.

The impurities and their QC limits in the specification were identical to those submitted to UK.

Trifloxystrobin is a color- and odourless solid. The solubility in water is low, but it is very soluble in toluene and other organic solvents, the log $P_{o/w}$ being 4.5.

It is hydrolytically stable at pH 5 and 7, but it decomposes at pH 9. When trifloxystrobin is exposed to light an isomerization to the (*E*,*Z*), (*Z*,*E*) and (*Z*,*Z*)-isomer is observable.

The original studies were not submitted by the applicant.

The analytical method for determination of trifloxystrobin is a CIPAC method published in Handbook O. Trifloxystrobin is determined by reversed phase HPLC with UV-detection at 280 nm.

The cited method M-460723-01-1 (which was also submitted to UK) differs slightly from the CIPAC method with respect to detection wavelength (210 nm instead of 280 nm) and ratio of water/acetonitrile in the mobile phase.

The impurities are determined by HPLC with UV detection or by GC/FID.

For the relevant impurity AE1344136 CIPAC has published a peer validated method.

Specifications for formulations

The proposed specifications for EC, SC and WG were broadly in accordance with the 2016 revision of the Manual. The Meeting noted however that in most cases the default values were used in the specification and questioned this.

Clarification was also requested why the accelerate storage at 40°C is recommended in the WG and SC specifications, but at 54°C in the EC formulation. The company explained that due to the low melting point of trifloxystrobin there may be problems for solid trifloxystrobin at 54°C. The Meeting accepted this explanation.

The meaning of “sediment” in the EC specification was unclear, but no further clarification was received from the manufacturer.

The initial limit of 4 mL after 2 h was reduced to 2 mL after a request from the Meeting.

SUPPORTING INFORMATION

FOR

EVALUATION REPORT 617/2024

Uses

Trifloxystrobin is a broad spectrum contact fungicide. On the surface of the plant its primary biological mode of action is the inhibition of spore germination and germ tube extension, thereby preventing infection from taking place. In those fungi responsible for diseases such as powdery mildews, which develop close to the outer layers of the host tissues after they have penetrated, control is also expressed by the inhibition of the fungus within the plant tissues. The stages and processes which are inhibited include mycelial growth, haustoria formation and sporulation. Trifloxystrobin is a contact fungicide with penetrant properties. The active substance is not translocated in the vascular system.

Trifloxystrobin containing products are used as foliar sprays across a wide range of agricultural and horticultural crops, including cereals, vines, soft fruit, top fruit, vegetables and ornamentals, grown in open field and/or under protection.

Identity of the active ingredient

ISO common name

trifloxystrobin (accepted ISO name)

Chemical name(s)

IUPAC

methyl (*E*)-methoxyimino-{(*E*)-α-[1-(α,α,α-trifluoro-*m*-tolyl)ethylideneaminooxy]-*o*-tolyl}acetate (ISO)
(*E*,*E*)-methoxyimino-{2-[1-(3-trifluoromethyl-phenyl)-ethylidene-aminooxymethyl]-phenyl}-acetic acid methyl ester (AUN)
methyl (2*E*)-(methoxyimino)(2-{[({(1*E*)-1-[3-(trifluoromethyl) phenyl]ethylidene}amino)oxy]methyl}phenyl)acetate (ACD)

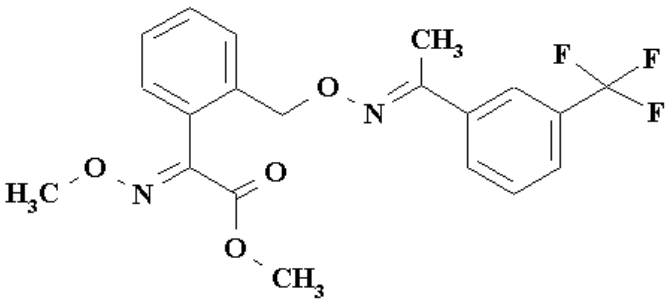
CA

Benzeneacetic acid, α-(methoxyimino)-2-[[[(*E*)-[1-[3-(trifluoromethyl) phenyl]ethylidene]amino]oxy]methyl]-, methyl ester, (α*E*)-
Methyl (α*E*)-α-(methoxyimino)-2-[[[[(1*E*)-1-[3-(trifluoromethyl)phenyl]ethylidene]amino]oxy]methyl]-benzeneacetate

Synonyms

CGA 279202

Structural formula



Molecular formula

$C_{20}H_{19}F_3N_2O_4$

Relative molecular mass

408.4 g/mol

CAS Registry number

141517-21-7

CIPAC number

617

Identity tests

^{1}H NMR spectrum

Table 1. Physico-chemical properties of pure trifloxystrobin

Parameter	Value(s) and conditions	Purity %	Method reference (and technique if the reference gives more than one)	Study reference
Vapour pressure	3.4×10^{-6} Pa at 25 °C (extrapolated)	99.7	OECD 104	M-041511-01-1
Melting point, boiling point and/or temperature of decomposition	Melting point: 72.9 °C Boiling point: approx. 312 °C at 1013 hPa Decomposition temperature: starts at about 285 °C	99.7 99.7 97.4	OECD 102 OECD 103 OECD 113	M-041431-01-1 M-041467-01-1 M-041479-01-1
Solubility in water	0.61 mg/l at 25 °C at pH 4-10	99.7	OECD 105	M-041593-01-1
Octanol/water partition coefficient	log P_{OW} = 4.5 at 25°C	99.7	OECD 107	M-041647-01-1
Hydrolysis characteristics	The hydrolysis half-lives of CGA 279202 at 20 °C are: pH k [s^{-1}] $t_{0.5}$ [days] 5 $2.56 \cdot 10^{-9}$ 3139 (8.6 y) 7 $1.00 \cdot 10^{-7}$ 80.1 (11.4 w) 9 $7.11 \cdot 10^{-6}$ 1.1 (27.1 h) The main degradation product by hydrolysis equal and above pH 5 was CGA 321113 (acid)	99.4 96.2 ^{14}C	OECD 111	M-033720-01-1
Photolysis characteristics	DT_{50}: 1.4 days DT_{50}: 0.1 days (for irradiated samples) DT_{50}: 0.4 and 0.9 days (under summer environmental conditions)	99.0 99.0	OECD 309 EPA, Subdivision N § 161-1	M-449602-01-1 M-106330-01-1
Dissociation characteristics	Trifloxystrobin does not show any acidic or basic properties in the range of pH 2 and pH 12.	99.7	OECD 112	M-041749-01-1

Solubility in organic solvents	n-hexane 1-octanol methanol toluene ethyl acetate acetone dichloromethane all at 25 °C	11 g/L 18 g/L 76 g/L 500 g/L > 500 g/L > 500 g/L > 500 g/L	97.4 or 99.9	CIPAC MT 157	M-041631-01-1

Table 2 Chemical composition and properties of trifloxystrobin 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 99.82 – 100.50 % and no unidentified impurities were reported
Declared minimum content	975 g/kg
Relevant impurities ≥ 1 g/kg and maximum limits for them	methyl (2*E*)-[2-(chloromethyl)phenyl](methoxyimino)acetate, 4 g/kg
Relevant impurities **<** 1 g/kg and maximum limits for them:	None
Stabilisers or other additives and maximum limits for them:	None

Parameter	Value and conditions	Purity %	Method reference	Study number
Melting temperature range of the TK	see table above			
Solubility in organic solvents	see table above			

Hazard Summary

Trifloxystrobin was evaluated by the WHO. The toxicological monographs and monograph addenda were prepared by a WHO Core Assessment Group that met with the FAO Panel of Experts on Pesticide Residues in Food and the Environment in a Joint Meeting on Pesticide Residues (JMPR) in 2004. This first evaluation of trifloxystrobin in the published toxicological monographs (2006) by the FAO/WHO JMPR established an ADI of 0–0.04 mg/kg bw/day, based on the parental NOAEL of 3.8 mg/kg bw/day of the two-generation study on reproductive toxicity in rats and a 100-fold safety factor.

The lowest observed adverse effect level (LOAEL) was 55 mg/kg bw/day, based on effects on body weight and food consumption and on histopathology findings in the liver and kidney. This value is supported by the NOAEL of 5 mg/kg bw/day observed in the one-year study in dogs.

Furthermore, the Meeting concluded that it was not necessary to establish an ARfD for trifloxystrobin based on its low acute toxicity.

The IPCS hazard classification of trifloxystrobin (2009[1]) is class U (unlikely to present acute hazard).

[1] The WHO Recommended Classification of Pesticides by Hazard and Guidelines to Classification 2009, ICPS, 2010. ISBN 978 92 4 154796 3.

Trifloxystrobin (CAS 141517-21-7 or EC number 604-237-6) is a pre-registered chemical compound for REACH. Trifloxystrobin is classified for health hazards (Skin.Sens.1, H317) and is hazardous to the environment (aquatic acute 1, H400 and aquatic chronic 1 H410).

The EFSA established an ADI of 0.1 mg/kg bw/day and an ARfD of 0.5 mg/kg bw.

Formulations and co-formulated active ingredients

The main formulation types available are SC and WG.

Trifloxystrobin is co-formulated with prothioconazole or tebuconazole or is not co-formulated with other pesticides.

These formulations are registered and sold in more than 150 countries.

Methods of analysis and testing

The analytical method for the active ingredient (including identity tests) is a CIPAC-method. The trifloxystrobin content is determined by high performance liquid chromatographic method (HPLC) with UV detection.

The method(s) for determination of impurities are based on a high performance liquid chromatographic method (HPLC) with UV detection or GC/FID.

The reversed phase HPLC method for the determination of trifloxystrobin in TC, EC, FS, SC, WG and AL formulations was accepted as a full CIPAC method in 2015 and is published in Handbook O.

Physical properties

The physical properties, the methods for testing them and the limits proposed for the different formulations, comply with the requirements of the FAO/WHO manual (3rd revision).

Containers and packaging

No special requirements for containers and packaging have been identified.

Expression of the active ingredient

The active ingredient is expressed as trifloxystrobin.

ANNEX 1

HAZARD SUMMARY PROVIDED BY THE PROPOSER

Notes:
(i) The proposer confirmed that the toxicological and ecotoxicological data included in the summary below were derived from trifloxystrobin having impurity profiles similar to those referred to in the table above.

(ii) The conclusions expressed in the summary below are those of the proposer, unless otherwise specified.

Table 3 Toxicology profile of the trifloxystrobin technical material, based on acute toxicity, irritation and sensitization

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study reference
Rat M F	single dose, oral	96.0%	EPA Guideline 81-1. Dose: 5,000 mg/kg bw	LD_{50} >5000 mg/kg bw	M-039034-01-1
Mouse M F	single dose, oral	96.4%	OECD 401 (1987), 92/69/EEC (1992), EPA FIFRA (1984), JMAFF (1985). Dose: 5,000 mg/kg bw	LD_{50} >5000 mg/kg bw	M-039046-02-1
Rat M F	single dose, dermal	96.4%	OECD 402; 92/69/EEC, B.3. Dose: 2000 mg/kg bw	LD_{50} >2000 mg/kg bw	M-040043-02-1
Rabbit M F	single dose, dermal	96%	EPA Guideline 81-2. Dose: 2000 mg/kg bw	LD_{50} >2000 mg/kg bw	M-039075-01-1
Rat M F	inhalation toxicity	95.9%	EPA Guidelines No. 81-3. Exposure nose only for 4 h to an aerosol at levels of 1.39 and 4.65 mg/L.	LC_{50} >4.6 mg/L	M-040049-01-1
Rabbit M F	skin irritation	96%	EPA Guideline 81-5. Dose: 0.5 g per animal	Slight irritant. All irritation cleared by the 72-h observation.	M-040053-01-1
Rabbit M F	eye irritation	96%	EPA Guideline 81-4. Dose: 0.1 mL [approx.0.047 g] of the test material	Not irritant	M-040060-01-1

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study reference
Guinea pig M F	Skin sensitization: Magnusson & Kligman Maximisation Method	96.4%	Guideline: OECD 406 Dose: 5% (intradermal induction) 50% (epidermal induction) 30% ((epidermal challenge)	Positive	M-040060-01-1 rabbit
Guinea pig M F	Skin sensitization: Buehler method	96.0%	Guidance: EPA Guideline 81-6 Dose: 0.4 g, at conc. of 25%, 50%, 75% and 100% [undiluted] w/v	Negative	M-040068-01-1
Rat M F	Acute and neurotoxicity study (Test No. 973005) 5-7weeks, oral	96.4%	Guidance: EPA Guideline Number 81-7. Dose: Range finding: 1000-3500 mg/kg bw Main test: 2000 mg/kg bw	NOAEL: < 2000 mg/kg bw/d No evidence of neurotoxicity	M-039223-03-1

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

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study number
Rat M F	28-days feeding study	96.2 %	OECD Guideline for testing of chemicals, No.407 Dose: 0, 200, 1000, 4000, 12000 ppm equivalent to: (M) 16.5, 84.4, 337, 1074 mg/kg bw (F) 16.4, 84.1, 327, 1005 mg/kg bw	NOAEL = 17/84 mg/kg bw M/ F LOAEL= 84/327 mg/kg bw M/F	M-040074-01-1
Rat M F	90-day rat, oral combined with neurotoxicity evaluations	96.2 %	FIFRA 82-1, OECD 408, EEC 87/302, FIFRA 82-7. Dose: 0, 100, 500, 2000 and 8000 (F only) ppm equivalent to (M) 6.44, 30.6 and 127 mg/kg bw (F) 6.76, 32.8, 133 and 618 mg/kg bw	NOAEL= 6.4/ 32.8 mg/kg bw/d M/F LOAEL= 30.6/133 mg/kg bw/d M/F No evidence for a neurotoxic effect	M-040135-01-1
Rat M F	24 month combined chronic / carcinogenicity study in rats	96.4%	FIFRA 83-5, OECD 453, Commission Directive 87/302/EEC,JMAFF, 59 NohSan No. 4200 Dose: 0, 50, 250, 750, 1500 ppm equivalent to (M) 1.95, 9.81, 29.7, 62.2 mg/kg bw	NOAEL: 9.8/11.4 mg/kg bw/d M/F LOAEL: 29.7/34.5 mg/kg bw M/F No carcinogenic potential	M-040512-02-1

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study number
			(F) 2.22, 11.4, 34.5, 72.8 mg/kg bw		
Rat M F	28-day, dermal	96.4%	FIFRA 82-2, OECD 410, EEC 92/69 B.9. Dose: 0, 10, 100, 1000 mg/kg bw	NOAEL = 100 mg/kg bw/d (M) NOAEL = 1000 mg/kg bw/d (F)	M-040287-01-1
Dog M F	90-days, oral (capsule)	96.4 %	OECD No. 409; FIFRA Subdivision F, 82-1; MAFF Japan Dose: 0, 5, 30, 150, 500 mg/kg bw.	NOAEL = 30 mg/kg bw LOAEL= 150 mg/kg bw	M-040184-01-1
Dog M F	12-month, oral (capsule)	96.4 %	OECD No. 452; FIFRA Subdiv. F, 83-1; MAFF Japan Dose: 0, 2, 5, 50, 200 mg/kg bw	NOAEL = 5 mg/kg bw LOAEL= 50 mg/kg bw	M-040217-01-1
Mouse M F	90-day feeding	96.2 %	OECD 408; Directive 87/322/EEC Dose: 0, 500, 2000, 7000 ppm equivalent to (M) 76.9, 315, 1275 mg/kg bw (F) 110, 425, 1649 mg/kg bw	NOAEL = 77/110 M/F mg/kg bw LOAEL= 315/425 M/F mg/kg bw	M-040129-01-2
Mouse M F	18-month carcinogenicity study, feeding	96.4%	EPA Guideline Number 83-2 Dose: 0, 30, 300, 1000, 2000 ppm equivalent to (M) 3.9, 39.4, 131.1, 274 mg/kg bw (F) 3.5, 35.7, 124.1, 246 mg/kg bw.	NOAEL: 39.4 / 35.7 mg/kg bw M/F No carcinogenic potential	M-039533-03-1
Rat M F	Reproductive toxicity (2-gen feeding study)	96.4%	OECD 416; FIFRA 83-4; JMAFF 59 NohSan no. 4200; Directive 87/302/EEC Dose: 0, 50, 750 and 1500 ppm equivalent to (M) pre-post mating: 2.28-4.36, 32.85-66.99, 73.13-146.03 mg/kg bw/ (F) pre mating: 3.43-4.05, 54.37-58.04, 114.40-123.14 mg/kg bw gestation: 3.13-3.50, 47.93-54.37, 98.03-114.40 mg/kg bw lactation: 7.17-8.00, 107.33-119.87, 219.77-242.00 mg/kg bw	Reproduction, development NOAEL: 50 ppm (2.3* or 3.8** mg/kg bw) LOAEL: 750 ppm (32.85* or 55.3** mg/kg bw)	M-039264-02-1

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study number
Rat (Tif:RAI f (SPF)) F	Developmental toxicity	96.4%	OECD 414, FIFRA 83-3, JMAFF, EC 87/302 Dose: 0, 10, 100, 1000 mg/kg bw	NOAEL maternal: 10**/100* mg/kg bw NOAEL fetal: 100 mg/kg bw No evidence for embryotoxic or teratogenic potential.	M-039420-02-1
Rabbit (RUSSIAN Chbb: HM) F	Developmental toxicity	97.1%	OECD 414, FIFRA 83-3, JMAFF, EC 87/302 Dose: 0, 10, 50, 250, 500 mg/kg bw	NOAEL maternal: 50 mg/kg bw NOAELfetal: 250 mg/kg bw No evidence for teratogenic potential.	M-039377-03-1

* EU Review Report for trifloxystrobin for Annex I inclusion (SANCO/4339/2000-Final, published 7.4.2003)

** WHO evaluated, Pesticide residues in food—2004 Toxicological evaluations (Part II—Toxicological), Rome, Italy, 20–29 September 2004

Table 5 Toxicology profile of the technical material based on Ames tests and *ex-vivo* studies

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study number
S. typhimurium (strains TA 98, TA 100, TA 102, TA 1535, TA 1537); Escherichia coli (strain WP2 uvrA).	Ames Test: Bacterial reverse mutation assay	96.4%	According to SOP No. 305003 (CIBA-GEIGY Basle, CH); The test procedure is based on:• OECD guideline, • EEC guideline, • MHW guideline, • EPA guideline 312.5 to 5000.0 µg/plate (original experiment) 61.73 to 5000.0 µg/plate (confirmatory experiment).	Negative	M-040308-01-1
Chinese hamster lung fibroblasts V79	Mammalian cell gene mutation test	96.4%	OECD 1984, EEC 1988, EPA 1987. *Pre-experiment:* 0.407 to 833.5 µg/ml (+/-S9-mix) *Original experiment:* 30.87 to 833.5 µg/ml (+S9-mix) 1.14 to 833.5 µg/ml (-S9-mix) *Confirmatory experiment:* 11.11 to 300.0 µg/ml (+S9-mix) 0.14 to 100.0 µg/ml (-S9-mix) *2nd confirmatory experiment:* 100.0 to 250.0 µg/ml (+S9-mix) 50.0 to 150.0 µg/ml (-S9-mix)	Positive at cytotoxic doses	M-040439-01-1

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study number
Chinese hamster ovary cells CHO	Mammalian chromosome aberration test	96.4%	OECD 473 (May 26, 1983), EPA § 798.5375 (May 20, 1987), EEC B.10 (December 29, 1992), MAFF Japan (January 1985). Experiments *without* metabolic activation: 18 h treatment: 0.78-3.12 µg/ml (original experiment), 0.049-0.195 µg/ml (confirmatory experiment) 42 h treatment: 0.049-0.195 µg/ml Experiments *with* metabolic activation: 3 h treatment/15 h recovery: 12.5 -50 µg/ml (original experiment); 25-100 µg/ml (confirmatory experiment) 3 h treatment/39 h recovery: 12.5-50 µg/ml	Negative	M-040332-01-1
Primary rat hepatocytes	Investigations into replicative DNA synthesis: Autoradiographic DNA Repair Test	96.4%	OECD 482 (1986), EPA § 798.5550 (1987), EEC 8.10(1988). 1st experiment: 0.39–400 µg/ml 2nd experiment: 0.39–50 µg/ml	Negative	M-040338-01-1
Mouse Bone marrow M F	Micronucleus test	96.4%	OECD (1983), EEC (1992), EPA (1987), MITI Japan (1987). Dose: 5000, 2500, 1250 mg/kg	Negative	M-040451-02-1

Table 6 Ecotoxicology profile of technical trifloxystrobin

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study number
Daphnia magna Straus (water flea)	48 h, *D. magna* acute toxicity	96.4%	Guidance document: OECD-Guideline No.: 202, Paris 1984 and FIFRA Guideline No.: 72-2, December 24, 1989.	EC_{50} = 0.016 mg/l	M-032085-01-1
Daphnia magna (water flea)	21 d, *D. magna* 21 d, *D. magna* chronic toxicity	96%	Guidance document: EPA/FIFRA Guideline No. 72-4(b).	EC50: 0.0098 mg/l NOEC: 0.0027 mg/l	M-032097-01-1
Oncorhynchus mykiss (fish)	96 h, *O. mykiss* short-term toxicity	96.4%	Guidance document: EPA Guideline No. 72-1.	LC50: 0.015 mg/l	M-032048-01-1

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study number
Oncorhynchus mykiss (fish)	95 d ELS, O. mykiss Early life-stage, long-term toxicity	96.4%	Guidance document: OECD - Guideline No.: 210; US EPA-FIFRA 72-4.	NOEC: 0.0077 mg/l	M-032080-02-1
Lepomis macrochirus bluegill sunfish (fish)	Bioaccumulation fish	4 batches at 96-97.9%	Guidance document: Environmental Fate Data Requirement 40CFR158-Subdivision N, Series 165-4 (OECD Guideline 305E)	BCF: 431	M-032004-01-1
Cophixalus riparius	28 d, *C. riparius* 28 d, *C. riparius* Chronic toxicity sediment dwelling organism	95.6%	Guidance document: Effects of Plant Protection Products on the Development of Sediment-Dwelling Larvae of Chironomus riparius in a Water-Sediment System (BBA Guideline Proposal 1995). OECD Guideline for Testing of Chemicals, Proposal for Toxicity Test with Chironomidae, November 1997. The test guideline is based on existing toxicity test protocols for Chironomus riparius and Chironomus tentans which have been developed in North America, Canada and Europe and ring-tested.	EC50: 0.45 mg/l NOEC: 0.2 mg/l	M-033988-01-1
Scenedesmus subspicatus (green alga)	72 h, *S. subspicatus* acute toxicity, growth inhibition	96.4 %	Guideline 92/69/EEC: C.3; in addition FIFRA-guideline was taken into account. Guidance document: OECD - Guideline No. 201, Paris 1984.	EbC50: 0.0053 mg/l	M-032098-01-1
Earthworm	14 days acute toxicity test	96.4 %	OECD-Guideline No: 207, 1984, Toxicity to Earthworms	LC50 14-day >1000 mg a.s./kg soil	M-034680-02-1
Carbon-and Nitrogen-transformation:	28 d test	96.4 %	BBA Guidelines, Part VI, 1-1 (2. edition) March 1990 SETAC-Europe, Procedures for Assessing the	≥13.33 mg a.s./kg dws	M-034686-01-1

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study number
			Environmental Fate and Ecotoxicity of Pesticides (March 1995) OECD Guidelines for Testing of Chemicals (Draft June 1996), Soil Microorganisms, Carbon and Nitrogen Mineralization		
Apis mellifera (honey bee)	48 h test acute oral and acute contact toxicity	96.4 %	Guidance: EPPO Guideline No. 170	LD_{50}>200 µg a.s./bee	M-032668-01-1
Bobwhite quail, (*C. virginianus/ A. platyrhynchos*) Birds	Dietary toxicity to birds	96.4%	Guidance: OECD Guideline for Testing of Chemicals number 205, entitled 'Avian Dietary Toxicity Test'	LC50 >5200 ppm;	M-032010-01-1
Bobwhite quail, *Colinus virginianus* Birds	22 weeks Reproductive toxicity to birds	96.4%	Guidance:US EPA Subdivision E Guideline 71-4.	NOEC 320 ppm	M-032013-01-1
Rat See above	Rat, 2-gen feeding study Long term toxicity to mammals,	96.4%	Guidance: OECD 416; FIFRA 83-4; JMAFF 59 NohSan no. 4200; Directive 87/302/EEC	2 gen. Repro. NOEC >1500 ppm	M-039264-02-1

ANNEX 2

REFERENCES

Study number	Author(s)	Year	Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study
M-032004-01-1	Mollova, N.	1997	[Phenyl(A)-U-14C]-CGA-279202 - Flow-through bioconcentration and metabolism study with bluegill sunfish (*Lepomis macrochirus*) Springborn Laboratories, Inc., Wareham, MA, USA GLP: yes Unpublished
M-032010-01-1	Rodgers, M. H.	1995	CGA 279202 - Subacute dietary toxicity (LC50) to the bobwhite quail Huntingdon Research Centre Ltd., Huntingdon, United Kingdom GLP: yes Unpublished
M-032013-01-1	Rodgers, M. H.	1996	CGA 279202 - Effects on reproduction in bobwhite quail after dietary administration Huntingdon Research Centre Ltd., Huntingdon, United Kingdom GLP: yes Unpublished
M-032048-01-1	Rufli, H.	1997	Acute toxicity test of CGA 279202 to rainbow trout (*Oncorhynchus mykiss*) in the flow-through system Novartis Crop Protection AG, Basel, Switzerland GLP: yes Unpublished
M-032080-02-1	Rufli, H.	1997	Early life-stage toxicity of CGA 279202 to rainbow trout (*Oncorhynchus mykiss*) using newly fertilized "green" eggs in a flow-through system Novartis Crop Protection AG, Basel, Switzerland GLP: yes Unpublished
M-032085-01-1	Neumann, C.	1997	Acute toxicity of CGA 279202 to the cladoceran *Daphnia magna* Straus under flow-through conditions Novartis Crop Protection AG, Basel, Switzerland GLP: yes Unpublished
M-032097-01-1	Boeri, R. L.; Magazu, J. P.; Ward, T. J.	1996	Chronic toxicity of CGA 279202 to the daphnid, *Daphnia magna* Wilbury Laboratories, Inc., Marblehead, MA, USA GLP: yes Unpublished
M-032098-01-1	Grade, R.	1995	Growth inhibition test of CGA 279202 tech. to green algae (*Scenedesmus subspicatus*) in a static system Ciba-Geigy Limited, Basel, Switzerland GLP: yes Unpublished
M-032668-01-1	Kleiner, R.	1995	Testing toxicity to honeybee - *Apis mellifera* L. (laboratory) according to EPPO guideline No. 170 - CGA 279202 BioChem GmbH Karlsruhe, Cunnersdorf, Germany GLP: yes Unpublished
M-033720-01-1	Kitschmann, P.	1996	Hydrolysis of (U)-^{14}C-phenyl-glyoxylate-labeled CGA 279202 under laboratory conditions Ciba-Geigy Limited, Basel, Switzerland GLP: yes Unpublished

M-033988-01-1	Grade, R.	1998	Toxicity test of CGA 279202 tech. on sediment-dwelling *Chironomus riparius* (syn. *Chironomus thummi*) under static conditions Novartis Crop Protection AG, Basel, Switzerland GLP: yes Unpublished
M-034680-02-1	Rufli, H.	1994	Report on the acute toxicity test of CGA 279202 tech. to earthworm (*Eisenia foetida foetida*) Ciba-Geigy Limited, Basel, Switzerland GLP: yes Unpublished
M-034686-01-1	Grade, R.	1998	The effect of CGA 279202 tech. on soil respiration and nitrification Novartis Crop Protection AG, Basel, Switzerland GLP: yes Unpublished
M-039034-01-1		1994	Acute oral toxicity study of CGA-279202 technical in rats Hazleton Laboratories America, Inc., Madison, WI, USA GLP: yes Unpublished
M-039046-02-1		1997	CGA 279202 tech. - Acute oral toxicity in the mouse (limit test) Ciba-Geigy Limited, Stein, Switzerland GLP: yes Unpublished
M-039075-01-1		1994	Acute dermal toxicity study of CGA 279202 technical in rabbits Hazleton Laboratories America, Inc., Madison, WI, USA GLP: yes Unpublished
M-039223-03-1		1999	CGA 279202 tech. - Acute oral neurotoxicity study in rats Novartis Crop Protection AG, Stein, Switzerland GLP: yes Unpublished
M-039264-02-1		1997	CGA 279202 Technical - Rat dietary two-generation reproduction study Novartis Crop Protection AG, Stein, Switzerland GLP: yes Unpublished
M-039377-03-1		1999	CGA 279202 technical - Rabbit oral teratogenicity Ciba-Geigy Limited, Stein, Switzerland GLP: yes Unpublished
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