Food and Agriculture Organization
of the United Nations

FAO SPECIFICATIONS AND EVALUATIONS

FOR AGRICULTURAL PESTICIDES

TRIADIMENOL

(1RS, 2RS; 1RS, 2SR)-1-(4-chlorophenoxy)-3,3-dimethyl-1- (1H-1,2,4-triazol-1-yl)butan-2-ol

2019

TABLE OF CONTENTS

TRIADIMENOL

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.

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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, the development of FAO specifications follows the **New Procedure**, described in the 1st edition of "Manual for Development and Use of FAO and WHO Specifications for Pesticides" (2002) - currently available as 3rd revision of the 1st edition (2016) - , 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 development and use of FAO and WHO specifications for pesticides".

Part Two: The Evaluation Report(s) of the pesticide, reflecting the evaluation of the data package carried out by FAO and the JMPS. The data are provided by the manufacturer(s) according to the requirements of chapter 3 of the "FAO/WHO Manual on Pesticide Specifications" and supported by other information sources. The Evaluation Report includes the name(s) of the manufacturer(s) whose technical material has been evaluated. Evaluation reports on specifications developed subsequently to the original set of specifications are added in a chronological order to this report.

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

Specifications bear the date (month and year) of publication of the current version.

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

PART ONE

SPECIFICATIONS

TRIADIMENOL

TRIADIMENOL

INFORMATION

ISO common name

Triadimenol (ISO 1750 published)

Chemical name(s)

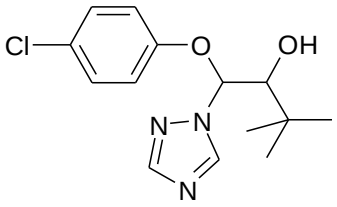
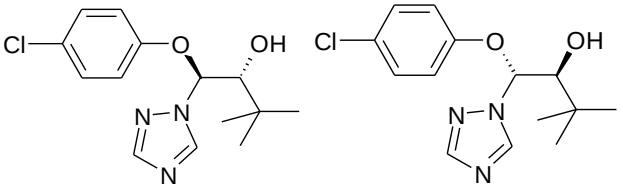
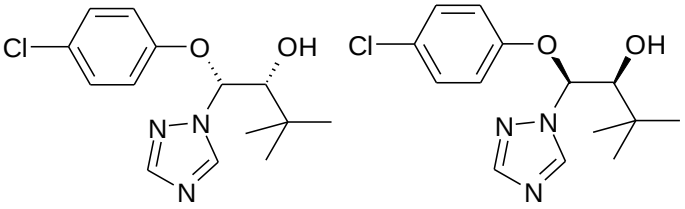
IUPAC (1*RS*, 2*RS*; 1*RS*, 2*SR*)-1-(4-chlorophenoxy)-3,3-dimethyl-1-(1*H*-1,2,4-triazol-1-yl)butan-2-ol

CA 1*H*-1,2,4-triazole-1-ethanol, β-(4-chlorophenoxy)-α-(1,1-dimethylethyl)- (unstated stereochemistry).

Synonyms

KWG 0519

Structural formulae

Name	*Structural formula*	*Proportions*
Triadimenol		100%
Diastereoisomer A *(RS + SR)*		78 – 88 %
Diastereoisomer B *(RR + SS)*		12 - 22 %

Molecular formula

$C_{14}H_{18}ClN_3O_2$

Relative molecular mass

295.8

CAS Registry numbers

55219-65-3 (unstated stereochemistry)

89482-17-7 (diastereoisomer A)

82200-72-4 (diastereoisomer B)

89497-66-5 ($\alpha R,\beta S$) enantiomer

89497-63-2 ($\alpha S,\beta R$) enantiomer

89497-64-3 ($\alpha R,\beta R$) enantiomer

89497-65-4 ($\alpha S,\beta S$) enantiomer

CIPAC number

398

Identity tests

Retention times in GC, mass spectra (from GC/MS), IR spectrum, ^{1}H-NMR-spectra of diastereomer A and B, respectively

Identity tests

Isomers A –^{1}H NMR

Required parameters are missing or incorrect.

Isomers B – ^{1}H NMR

Required parameters are missing or incorrect.

TRIADIMENOL TECHNICAL MATERIAL

FAO Specification 398 / TC (April 2019*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation reports (398/2010 & 398/2019). It should be applicable to technical meterials of this manufacturer 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 reports (398/2010 & 398/2019) as PART TWO form an integral part of this publication.

1 Description

The material shall consist of triadimenol together with related manufacturing impurities, and shall be a white to greyish or yellowish grained powder free from visible extraneous matter and added modifying agents.

2 Active ingredient

2.1 **Identity tests** (CIPAC 398/TC/M/2, CIPAC Handbook N, p. 135, 2012)

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 **Triadimenol content** (CIPAC 398/TC/M/3, CIPAC Handbook N, p. 135, 2012)

The triadimenol 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.

2.3 **Ratio of isomers** (CIPAC 398/TC/M/3, CIPAC Handbook N, p. 135, 2012)

Triadimenol is a mixture of diastereomers *RS* + *SR* and *RR* + *SS*. The ratio of these isomers shall be:

Diastereomer *RS* + *SR*, range: 78 to 88 %

Diastereomer *RR* + *SS*, range: 12 to 22 %

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

TRIADIMENOL WETTABLE POWDER

FAO Specification 398 / WP (April 2019*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation reports (398/2010 & 398/2019). It should be applicable to wettable powders of this manufacturer but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation reports (398/2010 & 398/2019) as PART TWO form an integral part of this publication.

1 Description

The material shall consist of an homogeneous mixture of technical triadimenol, complying with the requirements of FAO specification 398/TC (April 2019), together with filler(s) and any other necessary formulants. 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 398/WP/M/2, CIPAC Handbook N, p. 138, 2012)

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

2.2 **Triadimenol content** (CIPAC 398/WP/M/3, CIPAC Handbook N, p. 138, 2012)

The triadimenol 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 at 20 ± 2°C	Tolerance
up to 25	± 25% of the declared content
above 25 up to 100	± 10% or of the declared content
above 100 up to 250	± 6% or of the declared content
Note: the upper limit is included in the range	

3 Physical properties

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

Maximum: 2 % retained on a 75 µm test sieve.

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

3.2 **Suspensibility** (MT 184.1) (Notes 1 & 2)

A minimum of 60 % of the triadimenol content found under 2.2 shall be in suspension after 30 min in CIPAC Standard Water D at 25 ± 5°C (Notes 3 & 4).

3.3 **Persistent foam** (MT 47.3, Handbook O, p. 177, 2017) (Note 5)

Maximum: 20 mL after 1 min.

3.4 **Wettability** (MT 53.3, Handbook F, p. 164, 1995)

The formulation shall be completely wetted in 2 min without swirling.

4 Storage stability

4.1 **Stability at elevated temperature** (MT 46.3, 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:

- Wet sieve test (3.1),
- Suspensibility (3.2),
- Wettability (3.4).

Note 1 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 2 MT 184.1 is the revised version of MT 184 and was adopted at the 2018 CIPAC Meeting in Panama. Prior to its publiction in an next Handbook, copies of the method can be obtained through https://www.cipac.org/index.php/methods-publications/pre-published-methods

Note 3 This test will normally only be carried out after the heat stability test 4.1.

Note 4 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, simpler methods such as gravimetric and solvent extraction determination may be used on a routine basis provided that these methods have been shown to give equal results to those of chemical assay. In case of dispute, chemical assay shall be the "referee method".

Note 5 The mass of sample to be used in the test should be at the highest rate of use recommended by the supplier. The test is to be conducted in CIPAC standard water D.

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

TRIADIMENOL WATER DISPERSIBLE GRANULES

FAO Specification 398 / WG (April 2019*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation reports (398/2010 & 398/2019). It should be applicable to water dispersible granules of this manufacturer 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 reports (398/2010 & 398/2019) as PART TWO form an integral part of this publication.

1 Description

The material shall consist of a homogeneous mixture of technical triadimenol, complying with the requirements of the FAO specification 398/TC (April 2019) together with carriers and any other necessary formulants. It shall be in the form of light to dark beige irregular granules for application after disintegration and dispersion in water. The formulation shall be dry, free-flowing, essentially non-dusty, and free from visible extraneous matter and hard lumps.

2 Active ingredient

2.1 **Identity tests** (CIPAC 398/WG/M2, CIPAC Handbook N, p. 140, 2012)

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 Triadimenol content (CIPAC 398/WG/M3, CIPAC Handbook N, p. 140, 2012)

The triadimenol 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**
above 25 up to 100	± 10 % of the declared content
Note In each range the upper limit is included	

3 Physical properties

3.1 **Wettability** (MT 53.3, CIPAC Handbook F, p. 164, 1995)

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

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

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

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

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

Dispersibility: minimum 70 % after 1 minute of stirring.

3.4 **Suspensibility** (MT 184.1) (Notes 1, 2 & 3)

A minimum of 60 % shall be in suspension after 30 min in CIPAC Standard Water D at 25 ± 2°C.

3.5 **Persistent foam** (MT 47.3, Handbook O, p. 177, 2017) (Note 4)

Maximum: 20 mL after 1 minute.

3.6 **Dustiness** (MT 171.1), (Notes 5 & 6)

Essentially non-dusty

3.7 **Flowability** (MT 172.2) (Note 7)

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

3.8 **Attrition resistance** (MT 178.2, Handbook K, p. 140, 2003)

Minimum: 98 % attrition resistance.

4 Storage stability

4.1 **Stability at elevated temperature** (MT 46.3, 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 6) and the formulation shall continue to comply with the clauses for:

- Wet sieve test (3.2),
- Degree of dispersion (3.3),
- Suspensibility (3.4),
- Dustiness (3.6),
- Attrition resistance (3.8).

Note 1 MT 184.1 is the revised version of MT 184 and was adopted at the 2018 CIPAC Meeting in Panama. Prior to its publiction in an next Handbook, copies of the method can be obtained through https://www.cipac.org/index.php/methods-publications/pre-published-methods

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

Note 3 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, simpler methods such as 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, the chemical method shall be the “referee method”.

Note 4 The mass of sample to be used in the test should be specified at the highest rate recommended by the supplier. The test is to be conducted in CIPAC standard water D.

Note 5 Measurement of dustiness must be carried out on the sample "as received" and, where practicable, the sample should be taken from a newly opened container, because changes in the water content of samples may influence dustiness significantly. The optical submethod of MT 171, usually shows good correlation with the gravimetric submethod, MT 171, and can, therefore, be used as an alternative where the equipment is available. Where the correlation is in doubt, it must be checked with the formulation to be tested. In case of dispute the gravimetric method shall be used.

Note 6 MT 171.1 is the corrected and amended version of MT 171. Prior to its publication in a next Handbook, copies of the method may be downloaded from the CIPAC website https://www.cipac.org/index.php/methods-publications/errata

Note 7 The revised flowability method MT 172.2 was provisionally adopted at the 2018 CIPAC Annual Meeting in Panama. Prior to its publication in a next Handbook, copies of the method may be obtained through the CIPAC prepublication scheme https://www.cipac.org/index.php/methods-publications/pre-published-methods

Note 8 Analysis of the formulation, before and after the storage stability test, may be carried out concurrently (i.e. after storage) to reduce analytical error.

TRIADIMENOL SUSPENSION CONCENTRATE

FAO Specification 398 / SC (April 2019*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation reports (398/2010 & 398&2019). It should be applicable to suspension concentrates of this manufacturer but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation report (398/2010 & 398&2019) as PART TWO form an integral part of this publication.

1 Description

The material shall consist of a suspension of fine particles of triadimenol, complying with the requirements of FAO specification 398/TC (April 2019), 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** (CIPAC 398/SC/M/2, CIPAC Handbook N, p. 141, 2012)

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 **Triadimenol content** (CIPAC 398/SC/M/3, CIPAC Handbook N, p. 141, 2012)

The triadimenol content shall be declared (g/kg or g/L at 20 ± 2ºC, 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/kg or g/L at 20 ± 2°C	**Tolerance**
above 250 up to 500	± 5% or of the declared content
Note: the upper limit is included in the range	

3 Physical properties

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

Maximum "residue": 4 %.

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

A minimum of 70 % of the triadimenol content found under 2.2 shall be in suspension after 5 min in CIPAC Standard Water D at 25 ± 2°C.

3.3 **Suspensibility** (MT 184.1) (Note 3)

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

A minimum of 85 % of the triadimenol content found under 2.2 shall be in suspension after 30 min in CIPAC Standard Water D at 25 ± 5°C.

3.4 **Wet sieve test** (MT 185, Handbook K, p. 149, 2003)

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

3.5 **Persistent foam** (MT 47.3, Handbook N, p. 177, 2017) (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 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 95 % relative to the determined average 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 MT 184.1 is the revised version of MT 184. The method was adopted as provisional CIPAC method at the 2018 CIPAC Meeting in Panama. Prior to its publication in a next Handbook, copies of the method may be obtained through the CIPAC prepublishment scheme, http://www.cipac.org/prepubme.htm

Note 4 The mass of sample to be used in the test should be specified at the highest rate recommended by the supplier. The test is to be conducted in CIPAC standard water D.

Note 5 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.

TRIADIMENOL SUSPENSION CONCENTRATE FOR SEED TREATMENT

FAO Specification 398 / FS (April 2019*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation reports (398/2010 & 398/2019). It should be applicable to relevant products of this manufacturer 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 reports (398/2010 & 398/2019) as PART TWO form an integral part of this publication.

1 Description

The material shall consist of a suspension of fine particles of technical triadimenol, complying with the requirements of FAO specification 398/TC (April 2019), 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 suitable for further dilution with water if necessary.

2 Active ingredient

2.1 **Identity tests (**CIPAC 398/FS/M/2, CIPAC Handbook N, p. 141, 2012)
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 **Triadimenol content** (CIPAC 398/FS/M/3, CIPAC Handbook N, p. 142, 2012)
The triadimenol content shall be declared (g/kg or g/l at 20 ± 2ºC, Note 3) 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 or g/L at 20 ± 2°C	**Tolerance**
above 25 up to 100	± 10% or of the declared content
above 100 up to 250	± 6% or of the declared content
above 250 up to 500	± 5% or of the declared content
Note: the upper limit is included in the range	

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

3 Physical properties

3.1 **Pourability** (MT 148.1, CIPAC Handbook J, p. 133, 2000)
Maximum "residue": 4 %.

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

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

3.3 **Persistent foam** (MT 47.3, CIPAC Handbook N, p. 177, 2017)

If the product is intended to be used after dilution, persistent foam is to be measured at a concentration of 30 % in water. In those conditions, the maximum is 40 mL after 1 min.
This clause is not applicable where the product is used undiluted.

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 (3.2).

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

- Pourability (3.1),
- Wet sieve test (3.2).

Note 1 The influence of treatment on germination is of major importance but it is not the subject of a specification clause because no test method is applicable to all types of seeds. To avoid adverse effects, users should apply the formulation strictly according to the recommendations of the manufacturer and should not treat seeds for which effect on germination is not known. Treated seeds should be stored in a suitable container and should be protected from excessive temperature and moisture. Normally, the formulation shall contain a dye or pigment that permanently colours the seed after treatment (red is recommended, but other colours are possible). In some countries, there may be a legal requirement that a specific colour shall be used. The same colour must not be used for denaturing seeds intended for use as livestock feeding stuffs.

Note 2 Before sampling to verify the formulation quality, inspect the commercial container carefully. On standing, suspension concentrates usually develop a concentration gradient from the top to the bottom of the container. This may even result in the appearance of a clear liquid on the top and/or sediment on the bottom. Therefore, before sampling, homogenize the formulation according to the instructions given by the manufacturer or, in the absence of such instructions, gently shake the commercial container (for example by inverting the closed container several times, large containers must be opened and stirred adequately). After this procedure, the container should not contain a sticky layer of non-dispersed matter at the bottom. A suitable and simple method of checking for a non-dispersed sticky layer ("cake") is by probing with a glass rod or similar device adapted to the size and shape of the container. All the physical and chemical tests must be carried out on a laboratory sample taken after the recommended homogenization procedure.

Note 4 Unless homogenization is carried out carefully, it is possible for the sample to become aerated. This can lead to errors in the determination of the mass per millilitre, and in calculation of the active ingredient content (in g/L) if methods other than MT 3.3 are used. If the buyer requires both g/kg and g/L at 20°C, then in case of dispute the analytical results shall be calculated as g/kg.

Note 5 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.

TRIADIMENOL EMULSIFIABLE CONCENTRATE

FAO Specification 398 / EC (April 2019*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation reports (398/2010 & 398/2019). It should be applicable to emulsifiable concentrates of this manufacturer 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 reports (398/2010 and 398/2019) as PART TWO form an integral part of this publication.

1 Description

The material shall consist of technical triadimenol, complying with the requirements of FAO specification 398/TC (April 2019), 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** (CIPAC 398/EC/M/2, CIPAC Handbook N, p. 140, 2012)
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 **Triadimenol content** (398/EC/M3, CIPAC Handbook N, p. 140, 2012)
The triadimenol content shall be declared (g/kg or g/L at 20 ± 2ºC, Note 1) and, when determined, the average content measured shall not differ from that declared by more than the appropriate tolerance, given in the following table.

Declared content in g/kg or g/L at 20 ± 2°C	Tolerance
above 25 up to 100	± 10% or of the declared content
Note: the upper limit is included in the range	

3 Physical properties

3.1 **Emulsion stability and re-emulsification** (MT 36.3, CIPAC Handbook K, p. 137, 2003)

The formulation, when diluted at 25 ± 2°C with CIPAC Standard Waters A and D, shall comply with the following:

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

Time after dilution	Limits of stability, MT 36.3
0 h	Initial emulsification complete
0.5 h	"Cream", maximum: 1 mL
2.0 h	"Cream", maximum: 1 mL "Free oil", maximum: 0.1 mL
24 h	Re-emulsification complete
24.5 h	"Cream", maximum: 1 mL "Free oil", maximum: 0.1 mL
Note: in applying 36.3, tests after 24 h are required only where results at 2 h are in doubt	

3.2 **Persistent foam** (MT 47.3, CIPAC Handbook O, p. 177, 2017) (Note 2)
Maximum: 50 mL after 1 min.

4 Storage stability

4.1 **Stability at 0°C** (MT 39.3 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.

4.2 **Stability at elevated temperature** (MT 46.3, 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 3) and the formulation shall continue to comply with the clauses for:

- emulsion stability and re-emulsification (3.1).

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 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 3 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.

TRIADIMENOL DISPERSIBLE CONCENTRATE

FAO Specification 398 / DC (April 2019*)

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 (398/2010 &398/2019). 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 reports (398/2010 &398/2019) as PART TWO forms an integral part of this publication.

1 Description

The material shall consist of technical triadimenol, complying with the requirements of FAO specification 398/TC (April 2019), 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 a dispersion after dilution in water.

2 Active ingredient

2.1 **Identity tests** (CIPAC 398/EC/M/2, CIPAC Handbook N, p. 140, 2012)
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 **Triadimenol content** (CIPAC 398/EC/M/3, CIPAC Handbook N, p. 140, 2012) (Note 1)
The triadimenol content shall be declared (g/kg or g/L at 20 ± 2ºC, Note 2) and, when determined, the 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 or g/L at 20 ± 2°C	Tolerance
above 100 up to 250	± 6% or of the declared content
Note: the upper limit is included in the range	

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

3 Physical properties

3.1 Dispersion stability (MT 180, CIPAC Handbook O, p. 192, 2017) (Note 3)

The formulation, when diluted at 25 ± 2°C with CIPAC Standard Waters A and D, shall comply with the following:

Time after allowing the dispersion to stand	Limits of stability
1h	Cream or oil, maximum: 0.25 mL Sediment, maximum: 0.5 mL

3.2 Wet sieve test (MT 185, CIPAC Handbook K, p. 149, 2003) (Note 4)

Maximum: 1 % of the formulation shall be retained on a 75 µm test sieve, at the dilutions specified.

3.3 Persistent foam (MT 47.3, CIPAC Handbook N, p. 177, 2017) (Note 5)

Maximum: 50 mL after 1 min.

4 Storage stability

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

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

4.2 Stability at elevated temperature (MT 46.3, 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:

- Dispersion stability (3.1).

Note 1 As DCs and ECs are true solutions of triadimenol in an organic phase (the EC with a water-immiscible solvent, the DC with a miscible one) and have the same concentration range, the CIPAC analytical method for ECs is deemed applicable to DCs as well.

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

Note 3 This test will normally be carried out after storage at elevated temperatures.

Note 4 This test detects oversize particles (e.g. caused by crystal growth) or flocs (formed between the suspension particles and the emulsion oil phase), or extraneous material, which could cause blockage of spray nozzles or filters in the spray tank.
Dispersion concentrates are much more sensitive than suspensions to the dilution used and the amount of mixing/shear they experience on dilution. Therefore more information about the dilution rates and the dispersion methods must be provided.

- The dilution rate should be that recommended for the formulation use. If a range of dilution rates is recommended, the lowest and highest rates should both be subjected to the wet sieve test.
- The degree of mixing the dilution receives must be stipulated, e.g. apply a specific number of inversions. Ideally the sample should be dispersed and then allowed to stand for a period of time before sieving (i.e. giving time for crystal growth to occur).

Note 5 The mass of sample to be used in the test should correspond to the highest rate of use recommended by the supplier. The test is to be conducted in CIPAC standard water D.

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

PART TWO

EVALUATION REPORTS

TRIADIMENOL

TRIADIMENOL

FAO EVALUATION REPORT 398 / 2019

Recommendations

The Meeting recommended that

(i) the updated specifications for triadimenol TC, WP, WG, SC, FS, DC and EC formulations should be adopted by FAO

Appraisal

The Meeting noted that the FAO Specifications for triadimenol published in 2011 needed an editorial update, as the analytical methods for triadimenol TC and formulated products had in the meantime be published in CIPAC Handbook O and were no longer available through the CIPAC prepublishment scheme.

Furthermore, several CIPAC MT methods had been revised - such as the method for determining persistent foam (MT 47.3 now replacing MT 47.2), suspensibility (MT 184.1 replacing MT 184), a corrected version of MT 171 for the determination of dust formation in granular formulations is available etc. For these reasons, the triadimenol specifications were editorially updated - in the majority of cases the newer versions of MT methods are considered equivalent and hence no changes in limits were required, e.g. when test temperature were harmonized to be at 25 ± 5 °C where required. The Meeting noted that MT 180 - Dispersion Stability of Suspo-emulsions, where an extension of the scope of the method is published in Handbook O, requests a rather narrow temperature window of 23 ± 2 °C. In that case, the the company suggested to apply the standard temperature allowance of 25 ± 5 °C and the Meeting agreed.

However, in certain cases the editorial update also needed some more modifications. This is the case for the FS formulation, where the working range of the revised method for suspensibility (MT 184.1) is exceeded: in the previous version, 30 % concentration was requested, exceeding the 20 % maximum in MT 184.1. In that case, the suspensibility clause was considered to be no longer applicable and was removed.

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TRIADIMENOL

FAO EVALUATION REPORT 398 / 2010

Recommendations

The Meeting recommended

(i) to withdraw the existing specifications for triadimenol TC, WP, DP, OL, DC, GR and WG formulations (1992 / 1995);

(ii) to adopt the new specifications for triadimenol TC, WP, WG, SC, FS, and EC formulations.

(iii) the specifications for GR and DC formulations can be published subject to adoption of the methods for determination of triadimenol in GR and DC formulations by CIPAC

Appraisal

The Meeting considered data on triadimenol submitted by Bayer CropScience (BCS) in support of review of existing FAO specifications from 1995 and specifications for additional formulation types. The data were in accordance with the requirements of the FAO/WHO Manual (2006).

Triadimenol has been reviewed several times by the FAO/WHO JMPR since the first evaluation in 1989 (Toxicology, Residues) [M-357126-01-1, M-357150-01-1 and M-357153-01-1]. Since that time, it has been reviewed in 1992 [M-356949-01-1] and in 1995 [M-357120-01-1]. The last evaluation for Residues was in 2007 [M-356947-01-1] and for Toxicology in 2004 [M-356941-01-1]. Triadimenol has been included in Annex I of the 91/414 European Directive by the European Commission in 2008 [EU 2008] and evaluated by the US EPA in 2006 (EPA-2006].

Triadimenol is a fungicide and is no longer under patent.

The Meeting was provided with commercially confidential information on the manufacturing process and batch analysis data on all impurities present at or above 1 g/kg and their manufacturing limits in the TC. The data originally submitted are similiar to those evaluated for registration in Germany and for Directive 91/414 Annex I inclusion in the EU (Rapporteur Member State UK).

New Material Accountability studies were submitted to FAO and UK (as rapporteur for EU) in November 2009 and in May 2010 (mass balance: 999.7 to 1007.8 g/kg). The Meeting concluded that none of the detected impurities should be considered as relevant. In the specification of 1992, 4-chlorophenol, water and "material insoluble in acetone" are listed as relevant impurities. The company explained that BCS now produces a TC having a higher minimal purity and lowered the manufacturing specification also with respect to 4-chlorophenol,

which brings it into a concentration range where it becomes non-relevant. Residual water and "material insoluble in acetone" will not create any adverse effects in the TC.

The analytical methods for determination of impurities at or above 1 g/kg were submitted together with appropriate validation data. Methods are based on GC –FID and titration.

The triadimenol molecule carries to asymmetrically substituted carbon atoms, C1 and C2. The synthesis of triadimenol leads to racemates at C1 and C2, which in turn leads to two diastereomers which show different chemical, physical and biological properties. For brevity, the two diastereomers carry the designation "A" (containing the RS + SR enantiomers, threo[1]) and "B" (containing the RR + SS, erythro) in the ratio (78 - 88 %): (12 - 22 %).

The manufacturing process is conducted to provide an A : B ratio around 80:20 in the TC. The reason for that is that diastereomer A carries the desired fungicidal activity by ergosterol biosynthesis inhibition in plant pathogens, whereas diastereomer B shows both a fungicidal and growth regulator activity in plants. The latter activity is less desired and therefore the amount of A is enhanced. The hazard data were elaborated in the majority of studies with a TC reflecting this diastereomer ratio.

The CIPAC method published in Handbook E allows the chromatographic separation of the two diastereomers (almost baseline separation, with a retention time difference of approx. 0.1 min). The A:B ratio can therefore easily be determined by separately integrating the peak areas produced by A and B respectively, even though the method does not explicitely provide instruction how to do so. A footnote in the TC specification was added providing instructions how the diasteromer ratio can be determined. The same method is peer-validated and the method and the evaluation are scheduled to be presented at the 2011 CIPAC Meeting in Beijing.

Triadimenol has a low vapour pressure and volatility. The water solubility is low, the octanol/water partition coefficient $\log P_{ow}$ being about 3. Triadimenol does not dissociate under environmetal pH conditions, so the water solubility is independent of the pH. Triadimenol is stable to hydrolysis with an estimated half life > one year. The photolysis is more significant with an experimental half life of 9 days which translates into an environmental half live of 48 days calculated for solar conditions of Athens, GR in summer

The Meeting considered aspects of the proposed specifications. For dustable powders (DP) and oil miscible liqiuds (OL) specifications were no longer supported. Additional specifications are proposed for emulsifiable concentrates (EC), suspension concentrates (SC) and flowable concentrates for seed treatment (FS).

Full CIPAC methods were only available for TC, WP an EC formulations. In the 1995 triadimenol specifications, the CIPAC method for WP method was also referred to the DP, WG and GR formulation specifications, respectively, and similarly the EC method also to DC and OL formulation specifications.

[1] The stereochemical descriptors "threo" and "erythro" designate the orientation of the oxygen atoms in the Fischer projection - with erythro being on the same side, threo on opposite side (see structural formula, in Information part). These terms are used here just for being complete, and the designation as diastereomers A and B is preferred for clarity.

With the replacement of the 1995 specification for triadimenol TC and formulations by specifications under new procedure, these references to analytical methods not properly validated were considered unjustified and therefore method extensions for SC, FS and EW formulations were presented in the 2009 CIPAC meeting and accepted in 2010 as full methods. No methods for GR and DC formulations were presented in 2009. The situation with GR specification is somewhat different than with the DC: whereas GR formulations need different sampling and sample preparation for analysis as compared to the adopted method for the WG formulation, the applicability of the EC analytical method for the DC formulation was reconsidered (see below).

In all specifications the proposed 95 % limit of triadimenol content after storage at elevated temperature is the default value and slightly lower than the 97% limit in the existing specifications. The specification clauses for pH, acidity and alkalinity are no longer part of the new specifications, because the company doesn´t regard these parameters as discriminent for a good quality product.

In all specifications the description of the visual appearance of the material is rather vague. BCS justified this by the broad range of products worldwide which must be covered by the description. The Meeting accepted this argument.

Specific issues for certain specifications:

TC the minimum purity was raised from 940 (± 20) g/kg in the existing specification to 970 g/kg.

WP: The limit for wetting was lowered from 3 minutes in the old specification to 2 minutes. The meeting noted that it is still higher than the generic limit of one minute without swirling. Bearing in mind the hydrophobic nature of triadimenol, the limit of 2 minutes was accepted.

SC and FS formulations: No clauses for pH, particle size distribution and viscosity are included for SC and FS. There are FS formulations with different colours and also uncoloured formulations registered. Persistant foam and suspensibilty are proposed to be determined at a concentration of 30 % in water, although the CIPAC methods are not validated for this high concentration. Nevertheless, this was considered as acceptable by the Meeting. The Meeting discussed the need for a clause for seed adhesion according to CIPAC method MT 194, but BCS answered that there was not yet sufficient data available on their different FS formulations to propose a meaningful limit. Because this specification clause was added only in the 2010 revision of the manual, this was accepted by the Meeting.

EC and DC formulations, respectively: the Meeting recommended to refer to emulsion stability MT 36.3 only for EC, because this test can be used in a wide concentration range of 0.1 to 5 %.
The Meeting questioned why only the range 25 to 100 g/l is given as concentration range, as there are EC formulations registered with a content of 250 g/l triadimenol. The company confirmed the given range, because they explained that the formulations under discussion are in fact DC formulations. This is also the reason, why BCS wanted to keep the DC specification. The Meeting regarded it as unnecessary, because EC and SC formulations are available, but

agreed to adopt it. However, BCS explained that DC formulations are still produced and registered, and the argument was accepted by the Meeting to keep the DC formulation specifications also in the new specification, which was accepted by the Meeting.

The analytical method for determination of triadimenol in the DC formulation was formally missing. However, the company made a reasoned statement that the EC method was applicable to DC formulations as well, as both formulation types are true solutions of the active ingredient in organic solvents - the EC in a water-immiscible solvent, the DC in a water miscible one. In terms of analytical method, the two formulations, which also have same range of concentration, (100 to 250 g/l) can be considered as sufficiently similar to be covered by the EC method. The solvents which are used for EC and DC respectively are compatible with the solvent system used for preparing the sample solutions for analysis by gas chromatography (toluene in the version published in Handbook E and acetone, respectively, for the method revision/extension adopted in 2009). Therefore, the data gap preventing the publication of the DC specification could be closed by referring to the EC method for triadimenol published in Handbook E.

SUPPORTING INFORMATION

FOR

EVALUATION REPORT 398 / 2010

USES

Triadimenol is a broad spectrum, systemic fungicide registered in more than 80 countries incl. Australia, Canada, EU and USA. Triadimenol is a systemic fungicide with protective, curative and eradicant action. It is absorbed by the roots and leaves, with ready translocation in young growing tissues.

Triadimenol inhibits ergosterol and gibberellin biosynthesis and hence the rate of cell division.

Triadimenol offers control of powdery mildews, rusts and Rhynchosporium in cereals, and, when applied as a seed treatment, control of bunt, smuts, Typhula spp., seedling blight, leaf stripe, net blotch and other cereal diseases. It is also used on vegetables, ornamentals, coffee, hops, vines, fruit, tobacco, sugar cane, bananas and other crops, mainly against powdery mildews, rusts and various leaf spot diseases.

Identity of the active ingredient

ISO common name

Triadimenol (ISO 1750 published)

Chemical name(s)

IUPAC

(1*RS*, 2*RS*; 1*RS*, 2*SR*)-1-(4-chlorophenoxy)-3,3-dimethyl-1-(1*H*-1,2,4-triazol-1-yl)butan-2-ol

CA

1*H*-1,2,4-triazole-1-ethanol, β-(4-chlorophenoxy)-α-(1,1-dimethylethyl)-
(unstated stereochemistry).

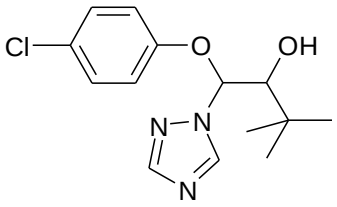
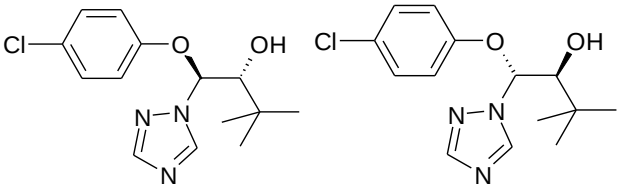
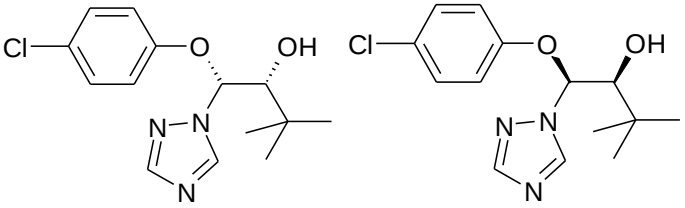
Synonyms

Baytan® (for seed treatment) and Bayfidan® (for foliar application). Both names are Bayer Trade names.

KWG 0519

AE F043694

Structural formula

Name	*Structural formula*	*Proportions*
Triadimenol		100 %
Diastereoisomer A *(RS + SR)*		78 - 88 %
Diastereoisomer B *(RR + SS)*		12 - 22 %

Molecular formula

C_{14} H_{18} Cl N_3 O_2

Relative molecular mass

295.8

CAS Registry number

55219-65-3 (unstated stereochemistry)

89482-17-7 (diastereoisomer A)

82200-72-4 (diastereoisomer B)

89497-66-5 ($\alpha R,\beta S$) enantiomer

89497-63-2 ($\alpha S,\beta R$) enantiomer

89497-64-3 ($\alpha R,\beta R$) enantiomer

89497-65-4 ($\alpha S,\beta S$) enantiomer

CIPAC number

398

Identity tests

GLC, Infrared (CIPAC 398/TC/M)

Table 1. **Physico-chemical properties of pure triadimenol**

Parameter	Value(s) and conditions	Purity %	Method reference (and technique if the reference gives more than one)	Study reference[2]
Vapour pressure	Isomer A: 6×10^{-7} Pa at 20 °C (extrapolated) 1×10^{-6} Pa at 25 °C (extrapolated) Isomer B: 4×10^{-7} Pa at 20 °C (extrapolated) 9×10^{-7} Pa at 25 °C (extrapolated) measurements at 70 ... 120 °C.	99.8 99.9	OECD 104 vapour pressure balance	M-009313-01-1
Melting point	Isomer A: 135 °C Isomer B: 133 °C	96.2 99.9	OECD 102, EEC A1 Differential Scanning Calorimetry (DSC)	M-088459-01-1 M-088465-01-1
Temperature of decomposition	No decomposition below 150 °C.	99.9	Differential Scanning Calorimetry (DSC) and Thermo gravimetric analysis (TGA)	M-009354-01-1
Solubility in water	Isomer A: 5.6×10^{-2} g/L at 20 °C Isomer B: 2.7×10^{-2} g/L at 20 °C	99.9 99.9	OECD 105 Flask method,	M-286908-01-1
Octanol/water partition coefficient	Isomer A: log P_{OW} = 3.1 at 25 °C Isomer B: log P_{OW} = 3.3 at 25 °C	99.7 98.1	OECD 107 Shaking method	M-009352-01-2
Hydrolysis characteristics	Stable at pH 4, 7 and 9 at 20 °C and 40 °C. (concentration 5 and 50 mg/l). Accountability > 97 %, no degradation after 32 days. Extrapolated half-life > 1 year for all pH values	Radiochemical purity 99.0, mixture of A and B	EPA 161-1	M-038570-01-1

Photolysis characteristics	After 12 days of irradiation in sterile aqueous buffer solution at pH 7 only 43.9 % of the applied radioactivity was recovered as unchanged parent compound. No degradation of triadimenol was observed in dark samples. The experimental half-life was determined to be 9 days, corresponding to an estimated environmental half-life of 31 days under summer solar conditions at Phoenix (USA), or of 48 days under solar conditions at Athens (EU).	Radiochemical purity 99.0 mixture of A and B	EPA 161-2	M-066950-01-1
Dissociation characteristics	Triadimenol is a very weak base, which can only be completely protonated in non-aqueous systems in the presence of very strong acids. It is not possible to specify a pKa value for water.		OECD 112	M-009342-01-2
Solubility in organic solvents	0.45 g/L n-heptane 60 g/L n-octanol 140 g/L 2-propanol > 250 g/L dichloromethane 18 g/L xylene 190 g/L acetone 60 g/L acetonitrile 150 g/L ethylacetate 71 g/L polyethyleneglycol > 250 g/L dimethylsulfoxide all at 20 °C	98.3	OECD 105	M-018058-01-1

Table 2. **Chemical composition and properties of triadimenol 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 999.7 – 1007.8 g/kg
Declared minimum content	970 g/kg
Diastereoisomer A (threo)	78 – 88 %
Diastereoisomer B (erythro)	12 - 22 %
Relevant impurities ≥ 1 g/kg and maximum limits for them	None
Relevant impurities < 1 g/kg and maximum limits for them:	None
Stabilisers or other additives and maximum limits for them:	None

Parameter	Value and conditions	Purity %	Method reference	Study reference
Melting temperature range of the TC	108 – 128 °C	98.8-100.0	OECD 102	M-345389-01-1 M-345397-01-1
Solubility in organic solvents	See Table 1			

HAZARD SUMMARY

Triadimenol was evaluated by the WHO IPCS 1989, by the FAO JMPR with regard to Toxicology in 1989 [M-357126-01-1, M-357150-01-1 and M-357153-01-1] and 2004 [M-356941-01-1].

In view of the lack of sound studies on neurotoxicity with triadimenol and since triadimenol is closely related to triadimefon in terms of chemical structure and toxicological effects, JMPR concluded that studies on neurotoxicity performed with triadimefon could serve as a basis for deducing an ADI and an ARfD for triadimenol.

JMPR established an ADI of 0-0.03 mg/kg bw based on the NOAEL of 3.4 mg/kg bw per day for hyperactivity in a 13-week feeding study on neurotoxicity with triadimefon in rats, and with a safety factor of 100.

An ARfD of 0.08 mg/kg bw was also established, based on the NOAEL of 2 mg/kg bw for hyperactivity in a study of acute neurotoxicity in rats treated with triadimefon by gavage. A safety factor of 25 was applied, because the effects were C_{max}-dependent and reversible.

In the EU evaluation of triadimenol the following values were proposed: ADI: 0.05 mg/kg bw per day; ARfD: 0.05 mg/kg bw per day and AOEL: 0.05 mg/kg bw per day.

The IPCS hazard classification of triadimenol is: Slightly hazardous

FORMULATIONS AND CO-FORMULATED ACTIVE INGREDIENTS

The main formulation types available are DC, EC, FS, GR, SC, WG and WP.

Triadimenol can be co-formulated with bitertanol, cypermethrin, disulfoton, fenamiphos, fluopyram, fuberidazole, imazalil-sulfate, imidacloprid, metalaxyl, propineb, prothioconazole, spiroxamine, sulfur, tebuconazole, thiram, triazoxide, trifloxystrobin and triflumuron.

These formulations are registered and sold in Africa, Europe, North and Latin America and Asia.

METHODS OF ANALYSIS AND TESTING

The analytical method for the active ingredient (including identity tests) is CIPAC 398/TC. The methods for TC, EC and WP including identity tests are published in Handbook E, whereas the method extension for SC, FS and WG was adopted in 2009 and became full CIPAC Methods in 2010. The method extension is not yet published in a Handbook but available through the CIPAC website, http://www.cipac/prepub.htm. The triadimenol content is determined by capillary GC with FID and internal standardisation with di-(2-ethylhexyl) phthalate. The diastereomer ratio is determined with the same method, which allows separation and quantification of diastereomers A and B, respectively.

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

PHYSICAL PROPERTIES

The methods to determine physical properties were OECD, EU or CIPAC where appropriate and comply with the FAO/WHO Manual (2010 revision).

CONTAINERS AND PACKAGING

No special requirements for containers and packaging have been identified.

EXPRESSION OF THE ACTIVE INGREDIENT

The active ingredient triadimenol is expressed as triadimenol.

ANNEX 1

HAZARD SUMMARY PROVIDED BY THE PROPOSER

Note: Bayer CropScience provided written confirmation that the toxicological data included in the following summary were derived from triadimenol having impurity profiles similar to those referred to in Table 2, above

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

Species	Test	Isomer A:B ratio	Purity % Note[3]	Guideline, duration, doses and conditions	Result	Study reference
Rat, male/female	oral	60:40	no information available	various US Government recommendations cited, single application, 25-50-100-500-750-850 (f)-1000 (f)-1250 (f)-1500-2000-2500 (m)-5000 (m) “pure technical grade KWG 0519", no information provided on batch	LD50 = 1161 mg/kg bw (m) 1105 mg/kg bw (f)	M-039739-01-1
Rat, male/female	intraperitoneal	60:40	no information available	various US Government recommendations cited, single application, 10 (f)-25 (f)-50-100-250-300 (f)-325 (f)-350-400 (f)-500-750-1000 (f)-2000 (f) “pure technical grade KWG 0519", no information provided on batch	LD50 = 367 mg/kg bw (m) 352 mg/kg bw (f)	M-039739-01-1
Mouse, male/female	oral	60:40	no information available	various US Government recommendations cited, single application, 25 (f)-50-100-250-500 (f)-1000-1250-1500-1750 (f)-2000 (m)-2500-5000 “pure technical grade KWG 0519", no information provided on batch	LD50 = 1300 mg/kg bw (m) 1267 mg/kg bw (f)	M-039739-01-1
Rat, male/female	oral	81.5:18.5	92.7	various US Government recommendations cited, single application, fasted: 250-500-600 (f)-750-1000-1500 mg/kg bw, non-fasted: 500-750-850 (f)-1000-1250 (f)-1500 (f) mg/kg bw batch no. 1616002/79	LD50 = 689/752 mg/kg bw (m/f, fasted) 1098/1037 mg/kg bw (m/f, non-fasted)	M-041641-01-1
Rat, male/female	intraperitoneal	81.5:18.5	92.7	various US Government recommendations cited, single application, 100 (f)-	LD50 = 371 mg/kg bw (m) 286 mg/kg bw (f)	M-041641-01-1

[3] Note: Purity is the content of pure active ingredient in the technical material, expressed as a percentage.

Species	Test	Isomer A:B ratio	Purity % Note[3]	Guideline, duration, doses and conditions	Result	Study reference
				250-300 (f)-350-400 (m)-500 (m) mg/kg bw batch no. 1616002/79		
Rat, male	oral	96.25:3.75 (isomer A)	99.9 or 100 (depending on the analytical method)	guideline not specified, single application, 500-750-1000-1250-1500-1750-2500 mg/kg bw, batch: from Dr. Krämer	LD50 = 579 mg/kg (isomer A)	M-041704-01-1
Rat, male	oral	1.08:98.92 (isomer B)	99.0	guideline not specified, single application, 1000-2500-3500-5000 mg/kg bw batch: from Dr. Pflugbeil	LD50 = 5000 mg/kg (isomer B)	M-041666-01-1
Rat, male	oral	60:40	no information available	guideline not specified, single application, batch 16001/78: 500-750-1000-1500-2000 mg/kg bw, batch 16010/78: 750-1000-1100-1250 mg/kg bw batches 16001/78 and 16010/78	LD50 = 819 mg/kg bw (batch 16001/78) 895 mg/kg bw (batch 16010/78)	M-041700-01-1
Rat, female	oral	86:14	97.2	OECD 423, Directive 67/548/EEC, Annex V, Method B.1.tris; US-EPA 712-C-98-190, OPPTS 870.1100, single application, 2000 g/kg bw batch no. 411407019	LD50 > 2000 mg/kg bw LD50 cut-off: 2500 mg/kg bw	M-259512-01-1
Rat, male/female	dermal	60:40	no information available	Various US Government recommendations cited, reference made to Noakes and Sanderson (1969) Brit. J. Industr. Med. 26, 59, 24h exposure, semi-occlusive conditions, 5000 mg/kg bw no information provided on batch	LD50 = > 5000 mg/kg bw	M-039739-01-1
Rat, male/female	dermal	81.5:18.5	92.7	Various US Government recommendations cited, reference made to Noakes and Sanderson (1969) Brit. J. Industr.	LD50 = > 5000 mg/kg bw	M-041641-01-1

Species	Test	Isomer A:B ratio	Purity % Note[3]	Guideline, duration, doses and conditions	Result	Study reference
				Med. 26, 59, 24h exposure, semi-occlusive conditions, 2500-5000 mg/kg bw batch no. 1616002/79		
Rat, male/female	dermal	86:14	97.2	OECD 402; Directive 67/548/EEC, Annex V, Method B.3.; US-EPA 712-C-98-192, OPPTS 870.1200, 24h exposure, semi-occlusive conditions, 2000 mg/kg bw batch no. 411407019	LD50 = > 2000 mg/kg bw	M-259092-01-1
Rat, male/female	inhalation	60:40	no information available	guideline not specified, single inhalation for 4 h, liquid aerosol, description of the exposure system implies nose-only exposure, 305 mg/m³ air batch identity not reported	LC50 = > 305 mg/m³ air	M-039739-01-1
Rat, male/female	inhalation	81.5:18.5	92.7	guideline not specified, single inhalation for 4 h, liquid aerosol, description of the exposure system implies nose-only exposure, 88, 305, 954 mg/m³ air batch no. 1616002/79	LC50 = > 954 mg/m³ air (maximum attainable concentration)	M-041641-01-1
Rabbit, human	skin irritation	60:40	no information available	US Government Dept. of Agriculture recommendations cited, rabbit: no information on dose and form of test material, type of dressing and duration of exposure, human: 4, 8 and 24 h exposure, semi-occlusive conditions, 500 mg/patch batch not reported	non-irritating	M-039739-01-1
Rabbit	skin irritation	81.5:18.5	92.7	US Government Dept. of Agriculture recommendations cited, 24 h exposure, no information on dose and form of test material and type of dressing, batch no. 1616002/79	slightly irritating, classification not triggered	M-041641-01-1

Species	Test	Isomer A:B ratio	Purity % Note[3]	Guideline, duration, doses and conditions	Result	Study reference
Rabbit, female	skin irritation	81.3:18.7	95.8	OECD 404, 4 h exposure, semi-occlusive conditions, 500 mg/patch batch no. 816176225	non-irritating	M-047568-01-1
Rabbit, male	skin irritation	82.2:17.8	97.5	Guideline not specified, 24 h exposure, occlusive conditions, 50 mg/patch batch no. P+816066128	non-irritating	M-025202-01-1
Rabbit, female	skin irritation	86:14	97.2	OECD 404; Directive 67/548EEC, Annex V, Method B.4; US- EPA 712-C-98-196, OPPTS 870.2500, 4 h exposure, semi-occlusive conditions, 500 mg/patch batch no. 411407019	non-irritating	M-259783-01-1
Rabbit	eye irritation	60:40	no information available	US Government Dept. of Health recommendations cited, 5 minutes / 24 h exposure, no information on dose available no information provided on batch	slightly irritating, classification not triggered	M-039739-01-1
Rabbit	eye irritation	81.5:18.5	92.7	US Government Dept. of Health recommendations cited, 5 minutes / 24 h exposure, no information on dose available batch no. 1616002/79	very slightly irritating, classification not triggered	M-041641-01-1
Rabbit, female	eye irritation	81.3:18.7	95.8	OECD 405, 24 h exposure, 100 µL pulverized test substance (equivalent to approx. 50 mg) batch no. 816176225	slightly irritating, classification not triggered	M-047568-01-1
Rabbit, male	eye irritation	82.2:17.8	97.5	guideline not specified, single application, eyewash after 20-30 seconds or no eyewash, 100 mg test substance batch no. P+816066128, purity	very slightly irritating, classification not triggered	M-025203-01-1

Species	Test	Isomer A:B ratio	Purity % Note[3]	Guideline, duration, doses and conditions	Result	Study reference
Rabbit, female	eye irritation	86:14	97.2	OECD 405 Directive 67/548/EEC, Annex V - Method B.5; US-EPA 712-C-98-195, OPPTS 870.2400, 24 h exposure, 100 mg pulverized test substance batch no. 411407019	non-irritating	M-261586-01-1
Guinea pig, male/female	skin sensitisation	81.5:18.5	92.7	guideline not specified, maximisation test, intradermal induction: formulation with 2.5% triadimenol, topical induction and topical test for sensitisation: formulation with 25% triadimenol batch no. 1616002/79	non-sensitizing	M-041563-01-1
Guinea pig, female	skin sensitisation	86:14	97.2	OECD 406; guideline 96/54/EC, Method B.6.; US- EPA 712-C-03-.197, OPPTS 870.2600, Buehler Patch test, 1st to 3rd topical induction and challenge: paste with 62.5% triadimenol batch no: 411407019	non-sensitizing	M-261239-01-1

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

Species	Test	Isomer A:B ratio	Purity % Note[4]	Guideline, duration, doses and conditions	Result	Study reference
Rat, male/female	oral (gavage)	60:40	98.5	no guideline stated, 28 days + 28 days recovery (all dose levels), 0-1.5–5–15-45 mg/kg bw/d, no information on batch	NOAEL = 45 mg/kg bw/d (highest dose tested)	M-039752-01-1
Rat, male/female	oral (gavage)	84.5:15.5 (batch 16010/77) 59.3:40.7 (batch 16004/77)	98.3 (batch 16010/77), 84.7 (batch 16004/77)	no guideline stated, 28 days + 28 days recovery (all dose levels), 0–15–45–100 mg/kg bw/d, KWG 0519 (80:20), batch no. 16010/77 0–45–100 mg/kg bw,/d KWG 0519 (60:40), batch no. 16004/77	NOAEL = 15 mg/kg bw/d (comparison between the two isomer ratio forms revealed only a moderate difference in the pattern of liver enzyme induction) LOAEL = 45 mg/kg bw/d	M-041594-01-1
Rat, male/female	feeding	96.25:3.75 (isomer A) 1.08:98.92 (isomer B)	97.9 (isomer A), 98.9 (isomer B)	No guideline study, 1 week, 0–1000–3000–9000 ppm (equal to 0-82.03-287.68-477.74 / 0-90.76-387.50-1518.58 mg/kg bw/d in males/females) isomer A, batch no. KTS 9701-1-1 0–1000–5000–25000 ppm (equal to 0-83.15-483.27-1529.74 / 0-90.99-650.39-no data* mg/kg bw/d in males/females), isomer B, =, batch no. KTS 9702-1-1 *: animals sacrificed on day 5	NOAEL < 82.03 mg/kg bw/d (isomer A), NOAEL < 83.15 mg/kg bw/day (isomer B)	M-075069-03-1
Rabbit, male/female	dermal	82.2:17.8	98.0	no guideline stated, 15 exposures (5 days/week, 6 h/day), 0–50–250	NOAEL: 250 mg/kg bw/d (highest dose tested)	M-039628-01-1

[4] Note: Purity is the content of pure active ingredient in the technical material, expressed as a percentage.

Species	Test	Isomer A:B ratio	Purity % Note[4]	Guideline, duration, doses and conditions	Result	Study reference
				mg/kg bw, batch no. 816066128		
Rat, male/female	inhalation	60:40	no information available	no guideline stated, 15 exposures (5 days/week, 6 hours/day), liquid aerosol, nose-only exposure, 0–30.39–68.03–229.71 mg/m³ air batch no. not specified	NOAEC: 229.71 mg/m³ (equivalent to approximately 60 mg/kg bw/d, highest concentration tested)	M-039772-01-1
Rat, male/female	feeding	58:40	98.0	no guideline stated, 13 weeks, 0–150–600–2400 ppm (equal to 0–12–49-203 / 0–17–71-287 mg/kg bw/d in males/ females), batch no. 16002/75	NOAEL = 49 / 71 mg/kg bw/d (m/f) (equivalent to 600 ppm) LOAEL = 203 / 287 mg/kg bw/d (m/f) (equivalent to 2400 ppm)	M-039765-01-1
Rat, male/female	feeding	81.3:18.7	94.0	No guideline stated, 13 weeks, 0–120–600–3000 ppm, (equal to 0–8–40-209 / 0–9–46-221 mg/kg bw/d in males/females), batch no. P+816171003	NOAEL = 8 / 9 mg/kg bw/d (m/f) (equivalent to 120 ppm) LOAEL = 40 / 46 mg/kg bw/d (m/f) (equivalent to 600 ppm)	M-025198-01-1
Mouse, male/female	feeding	80:20	97.4	OECD 408, 13 weeks, 0–160–500–1500–4500 ppm (equal to 0-25-77-235-872 / 0-31-94-297-797 mg/kg bw/d in males/females), batch no. 816176225	NOAEL = 25 / 31 mg/kg bw/day (m/f) (equivalent to 160 ppm) LOAEL = 77 / 94 mg/kg bw/d (m/f) (equivalent to 500 ppm)	M-021734-01-1
Dog, male/female	feeding	58:40	98.5	no guideline stated, 13 weeks, 0–150–600–2400 ppm (equivalent to 0-3.75-15-60 mg/kg bw/d in both sexes combined), batch no. 16002/75	NOAEL = 15 mg/kg bw/d (equivalent to 600 ppm) LOAEL = 60 mg/kg bw/d (equivalent to 2400 ppm) JMPR: overall NOAEL dog studies = 21.1 mg/kg bw/d (equivalent to 600 ppm)	M-039603-01-1

Species	Test	Isomer A:B ratio	Purity % Note[4]	Guideline, duration, doses and conditions	Result	Study reference
Dog, male/female	feeding	82.2:17.8	98.0	no guideline stated, 26 weeks, 0–10–30–100 ppm (equivalent to 0-0.25-0.75-2.5 mg/kg bw/day in both sexes combined) batch no. 816066128	NOAEL = 2.5 mg/kg bw/d (equivalent to 100 ppm, the highest dose tested)	M-039589-01-1
Dog, male/female	feeding	59.3:40.7	94.9	no guideline stated, 2 years, 0–150–600–2400 ppm (equivalent to 0-3.75-15-60 mg/kg bw/day in both sexes combined), batch no. 16004/77 Eg. 1/78	NOAEL: 15 mg/kg bw/d (equivalent to 600 ppm) LOAEL = 60 mg/kg bw/d (equivalent to 2400 ppm) JMPR: overall NOAEL dog studies = 21.1 mg/kg bw/ d (equivalent to 600 ppm)	M-039928-02-1
Rat, male/female	feeding, carcinogenicity	59.3:40.7	94.9	No guideline stated, 2 years, 0–125–500–2000 ppm (equal to 0-5-19-77 / 0-6-25-106 mg/kg bw/d in males/females), batch no. 16004/77 Eg. 1/78	NOAEL = 5 / 6 mg/kg bw/d (m/f) (equivalent to 125 ppm) LOAEL & NOAEL carcinogenicity = 77 / 106 mg/kg bw/d (m/f) (equivalent to 2000 ppm, the highest dose tested) JMPR: NOAEL: 25 mg/kg bw/d (equivalent to 500 ppm)	M-039839-02-1
Mouse, male/female	feeding, carcinogenicity	59.3:40.7	approx. 95	No guideline stated, 2 years, 0–125–500–2000 ppm (equal to 0-19-75-300 mg/kg bw/day, calculated with a default conversion factor) batch no. 16004/77 Eg. 1/78	NOAEL = 19 mg/kg bw/d (equivalent to 125 ppm) LOAEL = 75 mg/kg bw/d (equivalent to 500 ppm) NOAEL carcinogenicity = 300 mg/kg bw/d (equivalent to 2000 ppm) Incidences of hepatocellular adenoma in females: 0%–0%–8%-12%* (*: p< 0.05), the incidence at 2000 ppm is still	M-039957-02-1

Species	Test	Isomer A:B ratio	Purity % Note[4]	Guideline, duration, doses and conditions	Result	Study reference
					within the normal range of variation	
Mouse, male/female	feeding, carcinogenicity	> 70:< 30, study conduct in the 1990ies suggests an isomer ratio A:B of 80:20	96.8 - 97.6	OECD 451, 80 weeks, 0–80–400–2000 ppm (equal to 0-11-60-340 / 0-17-91-472 mg/kg bw/day in males/females), batch no. 816176225	NOAEL: 11 / 91 mg/kg bw/d (m/f) (equivalent to 80 / 400 ppm in m/f) LOAEL = 60 / 472 mg/kg bw/d (m/f) (equivalent to 400 / 2000 ppm in m/f) NOAEL carcinogenicity = 340 / 472 mg/kg bw/d (m/f) (equivalent to 2000 ppm, the highest dose tested)	M-044397-02-1
Rat, male/female	2-generation reproduction	59.3:40.7	no information available	No guideline stated, 0–125–500–2000 ppm (equivalent to 0-15-60-240 mg/kg bw/day) batch no. 16004/77 Eg. 1/78	NOAELparental, reproductive < 15 mg/kg bw/d (equivalent to < 125 ppm)	M-036765-01-2
Rat, male/female	2-generation reproduction	82.2:17.8	97.5	OECD 416, 0–20–100–500 ppm (equal to 0-1.7-9-42 / 0-2.2-11-57 (F0); 0-1.2-6-29 / 0-1.8-9-39 (F1) mg/kg bw/day in males/females), isomer ratio A:B =, batch no. 816066128	NOAEL, parental, reproductive = 6 / 9 mg/kg bw/d (equivalent to 100 ppm) LOAEL, parental, reproductive = 29 / 39 mg/kg bw/d (equivalent to 500 ppm)	M-039724-02-1
Rat, female	teratogenicity and developmental toxicity	60:40	93.7	pre-dates OECD guidelines, gestation day 6 to 15, 0–10–30–100 mg/kg bw/day, batch no. 16001/76	NOAEL maternal = 30 mg/kg bw/d LOAEL maternal & NOAEL developmental, teratogenicity = 100 mg/kg bw/d (highest dose tested)	M-039769-01-1
Rat, female	teratogenicity and developmental toxicity	80:20	97.0	OECD 414, gestation day 6 to 15, 0–30–60–120 mg/kg bw/d, batch no. 203 519 123	NOAEL maternal, developmental = 30 mg/kg bw/d LOAEL maternal, developmental = 60 mg/kg bw/d	M-039820-01-1

Species	Test	Isomer A:B ratio	Purity % Note[4]	Guideline, duration, doses and conditions	Result	Study reference
					NOAEL teratogenicity = 120 mg/kg bw/d (highest dose tested)	
Rat, female	teratogenicity and developmental toxicity	83.5:16.5	95.2	no guideline stated, gestation day 6 to 15, 0–10–30 mg/kg bw/day, batch no. 289/290	NOAEL maternal = 10 mg/kg bw/d LOAEL maternal & NOAEL developmental, teratogenicity: 30 mg/kg bw/d (highest dose tested)	M-041165-01-1
Rat, female	teratogenicity and developmental toxicity	isomer ratio not specified, study conduct in the early 1990ies suggests an isomer ratio A:B of 80:20	95.0	OECD 414, gestation day 6 to 15, 0–5–15–25–60 mg/kg bw/day, batch no. 6-03-0140	NOAEL maternal = 5 mg/kg bw/d, LOAEL maternal & NOAEL developmental = 15 mg/kg bw/d LOAEL developmental = 25 mg/kg bw/d NOAEL teratogenicity: 60 mg/kg bw/d (highest dose tested	M-045077-01-1
Rabbit, female	teratogenicity and developmental toxicity	80:20	97.0	OECD 414, gestation day 6 to 18, 0–8–40–200 mg/kg bw/day, batch no. 203 519 123	NOAEL maternal = 8 mg/kg bw/d LOAEL maternal & NOAEL developmental = 40 mg/kg bw/d LOAEL developmental & NOAEL teratogenicity: 200 mg/kg bw/d (highest dose tested) JMPR: NOAEL developmental = 40 mg/kg bw/d	M-039918-02-1
Rabbit, female	teratogenicity and developmental toxicity	isomer ratio not specified, study conduct in the	96.0	OECD 414, gestation day 6 to 18, 0–5–25–125 mg/kg bw/day, batch no. PF8741	NOAEL maternal = 25 mg/kg bw/d LOAEL maternal & NOAEL developmental, teratogenicity:	M-046281-01-1

Species	Test	Isomer A:B ratio	Purity % Note[4]	Guideline, duration, doses and conditions	Result	Study reference
		early 1990ies suggests an isomer ratio A:B of 80:20			125 mg/kg bw/day (highest dose tested)	

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

Species	Test	Isomer A:B ratio	Purity % Note[5]	Guideline, duration, doses and conditions	Result	Study reference
Salmonella typhimurium	Reverse mutation assay *in vitro*	60:40	93.7	no guideline stated, S. typhimurium: TA98, TA100, TA1535, TA1537, 4-2500 µg/plate (+/- S9 mix), batch no. 16001/76	negative	M-039614-01-1
Salmonella typhimurium, Escherichia coli, Bacillus subtilis	Reverse mutation assay *in vitro* DNA repair test *in vitro* (Rec assay)	isomer ratio not specified, study conduct in the early 1980ies suggests an isomer A:B ratio of 80:20	97.5	no guideline stated, S. typhimurium: TA98, TA100, TA1535, TA1537, TA1538, 5-5000 µg/plate (+/- S9 mix) E. coli: WP2 hcr (uvrA), 5–5000 µg/plate B. subtilis: H17 (rec+), M45 (rec-), 50–10000 µg/ plate batch not specified	negative	M-025200-01-1
Salmonella typhimurium, Escherichia coli, Bacillus subtilis	Reverse mutation assay *in vitro* DNA repair test *in vitro* (Rec assay)	82.2:17.8	97.5	no guideline stated, S. typhimurium: TA98, TA100, TA1535, TA1537, TA1538, 5 - 5000 µg/plate (+/- S9 mix) E. coli: B/r try -hcr-, 5-5000 µg/plate (+/- S9 mix) B. subtilis: NIG17 (rec+), NIG45 (rec-), 200 µg/plate batch no. 816066128	negative	M-032349-01-1

[5] Note: Purity is the content of pure active ingredient in the technical material, expressed as a percentage.

Species	Test	Isomer A:B ratio	Purity % Note[5]	Guideline, duration, doses and conditions	Result	Study reference
Mouse lymphoma cells	Gene mutation in mammalian cells *in vitro*	82.2:17.8	97.5	no guideline stated, 3.91-125.0 µg/mL (1st assay), 25.0-150.0 µg/mL (2nd assay), (+/- S9 mix) batch no. 816066128	negative	M-041584-01-1
Rat hepatocytes	Unscheduled DNA synthesis *in vitro*	82.2:17.8	97.5	no guideline stated, 0.25-250 µg/mL batch no. 816066128	negative	M-041572-01-1
Escherichia coli	DNA repair test *in vitro*	82.2:17.8	97.5	no guideline stated, E. coli: (K 12) p 3478 (pol A1-), W 3110 (pol A+), 62.5-1000 µg/plate (+/- S9 mix), isomer ratio A:B = 82.2:17.8, batch no. 816066128	negative	M-041535-02-1
Chinese hamster ovary cells	Sister chromatid exchange *in vitro*	isomer ratio not specified, study conduct in the 1980ies suggests an isomer A:B ratio of 80:20	93.0	US-EPA-FIFRA 84-2, 38-300 µg/mL (- S9 mix), 100-225 µg/mL (+ S9 mix), batch no. 0030063	negative	M-037004-01-1
Mouse, male/female	Micronucleus test *in vivo*	60:40	93.7	no guideline stated, oral administration (gavage) of 2 x 175, 2 x 350 mg/kg bw, dosing interval 24 h, batch no. 16001/76	negative	M-039622-01-1
Mouse, male/female	Micronucleus test *in vivo*	84.5:15.5	96.5	no guideline stated, oral administration (gavage) of 2 x 350, 2 x 500 mg/kg bw, dosing interval 24 h, batch no. 16010/77	negative	M-039611-01-1
Mouse, male	Dominant lethal test *in vivo*	60:40	93.7	no guideline stated, single oral administration (gavage) of 500 mg/kg bw, batch no. 16001/76	negative	M-039617-01-1

Table 6. **Ecotoxicology profile of technical triadimenol**

Species	Test	Purity % Note[6]	Guideline, duration, doses and conditions	Result	Study reference
Daphnia magna (water flea)	acute toxicity, static	96.6 isomer ratio not specified	48h batch No.: Pt. 233896349 OECD guideline 202	EC_{50} = 51 mg/L	M-036772-01-1
Leuciscus idus melanotus (golden orfe)	acute toxicity, static	94.9 isomer ratio not specified	96h batch No.: 16004/77 no guideline stated	LC_{50} = 17.4 mg/L	M-037006-01-2
Oncorhynchus mykiss (rainbow trout)	acute toxicity, static	96.3 isomer ratio not specified	96h Pt 203219536 OECD guideline 203, EEC directive 79/831/method C.1	LC_{50} = 21.3 mg/L	M-036762-01-1
Pseudokirchneriella subcapitata (green alga)	effect on growth and biomass, static water	97.3 isomer ratio not specified	72h batch No.: 233913029 OECD guideline 201, EEC directive 92/69/method C.3	EC_{50} = 38 mg/L (growth) EC_{50} = 9.6 mg/L (biomass)	M-075141-01-1

[6] Note: Purity is the content of pure active ingredient in the technical material, expressed as a percentage.

Species	Test	Purity % Note[6]	Guideline, duration, doses and conditions	Result	Study reference
Earthworm	acute toxicity	97.6 isomer ratio not specified	14d batch-No.: 233913029 OECD guideline 207	LC_{50} = 781 mg/kg dry soil	M-136962-01-1
Apis mellifera (honey bee)	[acute oral toxicity contact toxicity]	97.1 isomer ratio not specified	48h batch No.: 233913029 OECD guideline 213 and 214	LD_{50} = >224.8 µg/bee (oral) LD_{50} = >200 µg/bee (contact)	M-076757-01-1
Bobwhite quail	acute toxicity	92.0 isomer ratio not specified	Dosing via gelatine capsules on day 1 batch No.: 0030063 no guideline stated	LD_{50} = >2000 mg/kg bw	M-037221-01-1
Japanese quail	acute toxicity	purity and isomer ratio not specified	Dosing via gelatine capsules on day 1 no guideline stated	LD_{50} = >10000 mg/kg bw	M-037174-01-2
Mallard duck	short-term toxicity	92.0 isomer ratio not specified	Subchronic, 5 day dietary batch No.: 0030063 no guideline stated	LC_{50} = >5000 mg/kg diet	M-037235-01-1
Bobwhite quail	short-term toxicity	96.5% isomer ratio not specified	Subchronic, 5 day dietary batch No #82R82-109 US-EPA-FIFRA 71-2	LC_{50} = >5205 mg/kg diet	M-087993-01-1

Annex 2

References

Study number	Author(s)	year	Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study.
	FAO/WHO	2002 amended 2010	Manual on the development and use of FAO and WHO specifications for pesticides, 1st edition, FAO Plant production and protection paper 173, FAO, Rome, 2002 amended in 2006.
EPA-2006	EPA	2006	Triadimefon and Triadimenol (RED/TRED) Fact Sheet
EU-2008		2008	COMMISSION DIRECTIVE 2008/125/EC, Official Journal of the European Union L344, p. 78
M-009313-01-1		1996	Vapour pressure of Triadimenol Bayer AG, Leverkusen, Germany Unpublished
M-009342-01-2	.	1987	Dissociation constant of Triadimenol Bayer AG, Leverkusen, Germany Unpublished
M-009352-01-2		1984	Partition coefficient of Triadimenol isomer A (and isomer B) Bayer AG, Leverkusen, Germany Unpublished
M-009354-01-1		1986	Thermal stability of the agrochemical active ingredient Triadimenol (KWG 0519)l Bayer AG, Leverkusen, Germany Unpublished
M-018058-01-1		1999	Solubility in Organic Solvents and Surface Tension of Triadimenol GLP Bayer AG, Leverkusen, Germany Unpublished
M-021734-01-1		1998	KWG 0519 - Subchronic toxicity study in CD-1 mice (administration in the feed over 13 weeks) GLP Bayer AG, Germany Unpublished
M-025198-01-1	.	1983	Subacute toxicity study of KWG0519 in dietary administration to rats for 13 weeks Unpublished
M-025200-01-1		1982	Triadimenol - Microbial Mutagenicity study Unpublished
M-025202-01-1		1982	Primary skin irritation study of KWG 0519 in rabbits GLP Unpublished
M-025203-01-1		1982	Primary eye irritation study of KWG 0519 in rabbits GLP Unpublished

M-032349-01-1	.	1982	KWG 0519 - Mutagenicity test on bacterial system Unpublished
M-036762-01-1		1993	Triadimenol - Acute toxicity (96 h) to rainbow trout in a static test GLP Bayer AG, Leverkusen, Germany Unpublished
M-036765-01-2		1982	KWG 0519 - Multigeneration study on rat Bayer AG, Germany Unpublished
M-036772-01-1		1989	Acute toxicity of triadimenol (techn.) to water fleas (Daphnia magna) GLP Bayer AG, Leverkusen, Germany Unpublished
M-037004-01-1	.	1987	Baytan - Sister chromatid exchange assay in chinese hamster ovary (CHO) cells GLP Unpublished
M-037006-01-2		1979	Fish toxicity test KWG 0519 (triadimenol), golden orfe Bayer AG, Leverkusen, Germany Unpublished
M-037174-01-2		1975	KWG 0519: Acute Quail Toxicity Bayer AG, Leverkusen, Germany Unpublished
M-037221-01-1		1981	Acute oral LD50 of technical triadimenol (Baytan TM) to bobwhite quail GLP Unpublished
M-037235-01-1		1981	Acute dietary LC50 of technical triadimenol (Baytan TM) to mallard ducks and bobwhite quail GLP Unpublished
M-038570-01-1		1980	The behaviour of Baytan in sterile aqueous solutions Unpublished
M-039589-01-1		1984	KWG 0519 (c.n. triadimenol) - Second chronic study of toxicity to dogs on oral administration (six-month feeding study) Bayer AG, Wuppertal, Germany Unpublished
M-039603-01-1		1977	KWG 0519 - Subchronic toxicity study on dogs (thirteen-week feeding experiment) Bayer AG, Wuppertal, Germany Unpublished
M-039611-01-1		1979	KWG 0519 - Micronucleus test on mouse to evaluate KWG 0519 for potential mutagenic effects Bayer AG, Germany Unpublished
M-039614-01-1		1979	KWG 0519 - study no. KWG 0519/008 - Salmonella/microsome test for detection of point-mutagenic effects Bayer AG, Germany Unpublished

M-039617-01-1		1978	KWG 0519 - Dominant lethal study on male mouse to test for mutagenic effects Bayer AG, Germany Unpublished
M-039622-01-1		1978	KWG 0519 - Micronucleus test on mouse to evaluate KWG 0519 for potential mutagenic effects Bayer AG, Germany Unpublished
M-039628-01-1		1984	KWG 0519 - (suggested common name: triadimenol, the active ingredient of Baytan (TM)) - Subacute dermal toxicity study on rabbits Bayer AG, Germany Unpublished
M-039724-02-1		1984 amended 1994	KWG 0519 (proposed c.n. triadimenol) - Generation study on rats GLP Bayer AG, Germany Unpublished
M-039739-01-1	.	1976	KWG 0519 - Acute toxicity studies Bayer AG, Germany Unpublished
M-039752-01-1	.	1976	KWG 0519 - Subacute oral cumulative toxicity study on rats (four-week treatment) Bayer AG, Germany Unpublished
M-039765-01-1		1977	KWG 0519 - Subchronic toxicity study on rats (three-month feeding experiment) Bayer AG, Germany Unpublished
M-039769-01-1	.	1977	KWG 0519 - Evaluation for embryotoxic and teratogenic effects on orally dosed rats Bayer AG, Germany Unpublished
M-039772-01-1		1976	KWG 0519 - Subacute inhalation toxicity study on rats Bayer AG, Germany Unpublished
M-039820-01-1		1987	Embryotoxicity (including teratogenicity) study with KWG 0519 in the rat GLP Unpublished
M-039839-02-1		1982 amended 1994	KWG 0519 (triadimenol, the active ingredient of Baytan) - Chronic toxicity study on rats (2-year feeding experiment) GLP Bayer AG,Germany Unpublished
M-039918-02-1		1987 amended 1991	Embryotoxicity (including teratogenicity) study with KWG 0519 in the rabbit Unpublished
M-039928-02-1		1984 amended 1994	KWG 0519 (c.n. triadimenol) - First chronic study of toxicity to dogs on oral administration (two-year feeding study) GLP Bayer AG, Germany Unpublished

M-039957-02-1	1982 amended 1988	KWG 0519 (Triadimenol, Baytan active ingredient) - Chronic toxicological study on mice (feeding experiment over two years) Bayer AG, Germany Unpublished
M-041165-01-1	1984	KWG 0519 - common name: triadimenol - Study for embryotoxic effects on rats after oral administration Bayer AG, Germany Unpublished
M-041535-02-1	1981	KWG 0519 - Triadimenol, the active ingredient of Baytan - Study of DNA damage using the E. coli Pol A1 - test Bayer AG, Germany Unpublished
M-041563-01-1	1981	KWG 0519 (Triadimenol) - Study of sensitization effect on guinea pigs (Maximization test of Magnusson and Kligman) Bayer AG, Germany Unpublished
M-041572-01-1	1982	Evaluation of KWG 0519 in the primary rat hepatocyte unscheduled DNA synthesis assay - Final report Unpublished
M-041584-01-1	1982	Mutagenicity evaluation of KWG 0519 in the mouse lymphoma forward mutation assay / Final report Unpublished
M-041594-01-1	1981	KWG 0519 (Triadimenol) - Study of comparative toxicity to rats after 4-week treatment using two test compound samples Bayer AG, Germany Unpublished
M-041641-01-1	1980	KWG 0519 (triadimenol) - Acute toxicity studies (isomer ratio 80:20) Bayer AG, Germany Unpublished
M-041666-01-1	1979	KWG 0519 form B - Determination of acute toxicity (LD50): rat. p.o. Bayer AG, Germany Unpublished
M-041700-01-1	1979	KWG 0519 mixture 60:40 - Determination of acute toxicity (LD50) Bayer AG, Germany Unpublished
M-041704-01-1	1979	KWG 0519 form A - Determination of acute toxicity (LD50): rat p. o. Bayer AG, Germany Unpublished
M-044397-02-1	1998 amended 2004	KWG 0519 - Oncogenicty study on CD-1 mice. Dietary administration over 18 months. GLP Bayer AG, Germany Unpublished

M-045077-01-1	1990	Developmental toxicity study in the rat with Baytan technical GLP Unpublished
M-046281-01-1	1992	A developmental toxicity study in rabbits with Baytan technical GLP Unpublished
M-047568-01-1	1993	KWG 0519 - Study for skin and eye irritation/corrosion in rabbits GLP Bayer AG, Germany Unpublished
M-066950-01-1	2002	Photolysis of [phenyl-UL-14C]triadimenol in aqueous buffer solution GLP Bayer AG, Germany Unpublished
M-075069-03-1	2003 amended 2005	KWG 0519 (A+B Isomers) - Study for subacute oral toxicity in rats - Oral administration (diet) for 1 week GLP Bayer AG, Germany Unpublished
M-075141-01-1	2001	Triadimenol M - Alga, growth inhibition test Pseudokirchneriella subcapitata, 72 h (formerly Selenastrum capricornutum) GLP Unpublished
M-076757-01-1 .	2001	Effects of triadimenol a.i. (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory (limit test) GLP
M-087993-01-1	2003	Technical triadimenol: A subacute dietary LC 50 with northern bobwhite GLP Unpublished
M-088459-01-1	2004	Triadimenol, KWG0519 Diasteroisomer A – Melting point GLP Unpublished
M-088465-01-1	2004	Triadimenol, KWG0519 Diasteroisomer B – Melting point GLP Unpublished
M-136962-01-1	2001	Acute toxicity of triadimenol M (tech.) to earthworms (Eisenia fetida) GLP Bayer AG, Germany Unpublished
M-259092-01-1	2005	KWG 0519 - Acute toxicity in the rat after dermal application GLP Unpublished
M-259512-01-1	2005	KWG 0519 - Acute toxicity in the rat after oral administration GLP Unpublished

M-259783-01-1		2005	KWG 0519 - Acute skin irritation/corrosion on rabbits GLP Unpublished
M-261239-01-1		2005	KWG 0519 (Project: Triadimenol (KWG 0519)) - Study for the skin sensitization effect in guinea pigs (Buehler Patch Test) GLP Unpublished
M-261586-01-1		2005	KWG 0519 - Acute eye irritation on rabbits GLP Unpublished
M-286908-01-1		2007	Triadimenol A-isomer and B-isomer, Solubility in distilled water (Flask method) GLP Bayer AG, Germany Unpublished
M-345389-01-1		2009	Triadimenol (KWG 0519), : Melting point, boiling point, thermal stability GLP Unpublished
M-345397-01-1		2009	Triadimenol (KWG 0519), … : Melting point, boiling point, thermal stability GLP Unpublished
M-356484-01-1	FAO	1995	FAO specifications for plant protection products – Triadimenol (AGP: CP/334). Roma, 1995
M-356941-01-1	FAO / WHO	2004	Pesticide residues in food – 2004. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues, Rome, Italy, 2004. FAO PLANT PRODUCTION AND PROTECTION PAPER 178 WORLD HEALTH ORGANIZATION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
M-356947-01-1	FAO / WHO	2007	Pesticide residues in food 2007. Joint FAO/WHO Meeting on Pesticide Residues. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues, Geneva, Switzerland, 2007. FAO PLANT PRODUCTION AND PROTECTION PAPER 191 WORLD HEALTH ORGANIZATION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
M-356949-01-1	FAO / WHO	1992	Pesticide residues in food – 1992. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues, Rome, Italy, 1992. FAO PLANT PRODUCTION AND PROTECTION PAPER 116 WORLD HEALTH ORGANIZATION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS.

M-357120-01-1	FAO / WHO	1995	Pesticide residues in food – 1995 Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues, Geneva, Switzerland, 1995. FAO PLANT PRODUCTION AND PROTECTION PAPER 133 WORLD HEALTH ORGANIZATION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS.
M-357126-01-1	FAO / WHO	1989	Pesticide residues in food – 1989 – Report 1989 Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues, Geneva, Switzerland, 1989. FAO PLANT PRODUCTION AND PROTECTION PAPER 99 WORLD HEALTH ORGANIZATION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS.
M-357150-01-1	FAO / WHO	1989	Pesticide residues in food – 1989 – Evaluations 1989 – Part I, Residues Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues, Geneva, Switzerland, 1989. FAO PLANT PRODUCTION AND PROTECTION PAPER 100 WORLD HEALTH ORGANIZATION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS.
M-357153-01-1	FAO / WHO	1989	Pesticide residues in food – 1989 – Evaluations 1989 – Part I, Toxicology Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues, Geneva, Switzerland, 1989. FAO PLANT PRODUCTION AND PROTECTION PAPER 100/2 WORLD HEALTH ORGANIZATION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS.