FAO SPECIFICATIONS AND EVALUATIONS FOR AGRICULTURAL PESTICIDES

Triadimefon

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

FOOD AND AGRICULTURE ORGANIZATION of THE UNITED NATIONS

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TRIADIMEFON

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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.

Since 1999 the development of FAO specifications follows the **New Procedure**, described in the 5th edition of the "Manual on the development and use of FAO specifications for plant protection products" (FAO Plant Production and Protection Page No. 149). This **New Procedure** follows a formal and transparent evaluation process. It describes the minimum data package, the procedure and evaluation applied by FAO and the Experts of the FAO/WHO Joint Meeting on Pesticide Specifications (JMPS). [Note: prior to 2002, the Experts were of the FAO Panel of Experts on Pesticide Specifications, Registration Requirements, Application Standards and Prior Informed Consent, which now forms part of the JMPS, rather than the JMPS.]

FAO Specifications now only apply to products for which the technical materials have been evaluated. Consequently from the year 2000 onwards the publication of FAO specifications under the **New Procedure** has changed. Every specification consists now of two parts namely the specifications and the evaluation report(s):

PART ONE: **The Specification** of the technical material and the related formulations of the plant protection product in accordance with chapter 4, 5 and 6 of the 5th edition of the "Manual on the development and use of FAO specifications for plant protection products".

PART TWO: **The Evaluation Report(s)** of the plant protection product reflecting the evaluation of the data package carried out by FAO and the JMPS. The data are to be provided by the manufacturer(s) according to the requirements of Appendix A, Annex 1 or 2 of the "Manual on the development and use of FAO specifications for plant protection products" and supported by other information sources. The Evaluation Report includes the name(s) of the manufacturer(s) whose technical material has been evaluated. Evaluation reports on specifications developed subsequently to the original set of specifications are added in a chronological order to this report.

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

Specifications bear the date (month and year) of publication of the current version. Dates of publication of the earlier versions, if any, are identified in a footnote. Evaluations bear the date (year) of the meeting at which the recommendations were made by the JMPS.

*NOTE: publications are available on the internet at *http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmps/en/*
or in hardcopy from the Plant Protection Information Officer.

PART ONE

SPECIFICATIONS

TRIADIMEFON

PART ONE

TRIADIMEFON

INFORMATION

ISO common name

Triadimefon (ISO 1750 published)

Chemical names

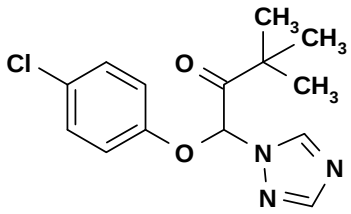
IUPAC (*RS*)-1-(4-chlorophenoxy)-3,3-dimethyl-1-(1*H*-1,2,4-triazol-1-yl)butan-2-one

CA 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1*H*-1,2,4-triazol-1-yl)-2-butanone

Synonyms

Bayleton

Structural formula



Molecular formula

$C_{14}H_{16}ClN_3O_2$

Relative molecular mass

293.7

CAS Registry number

43121-43-3

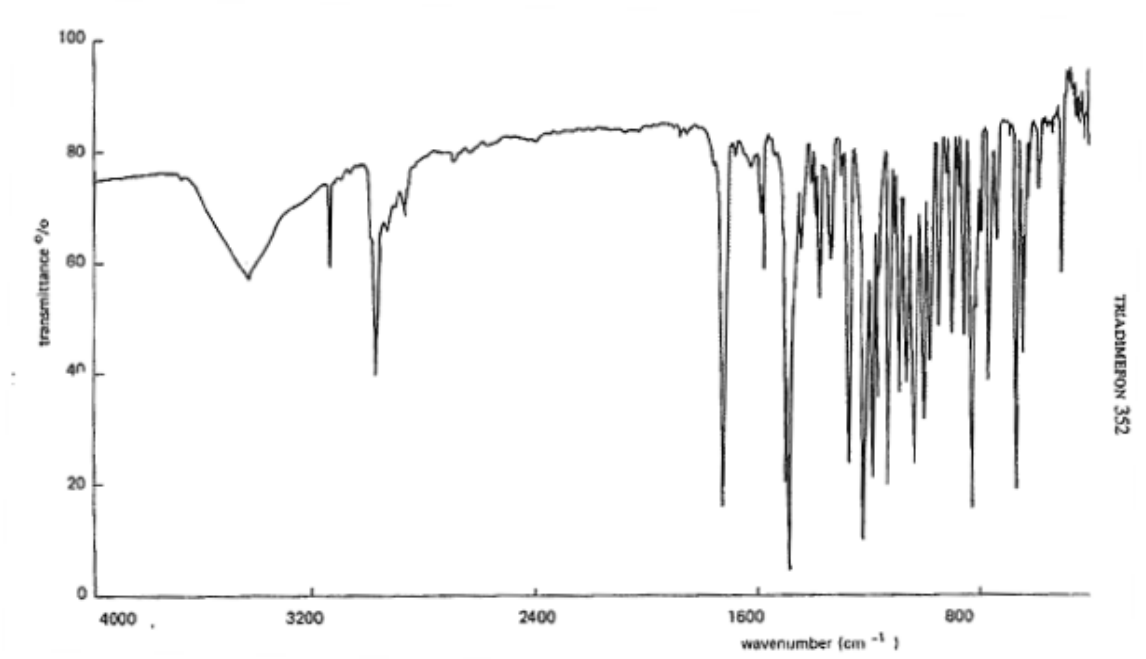
CIPAC number

352

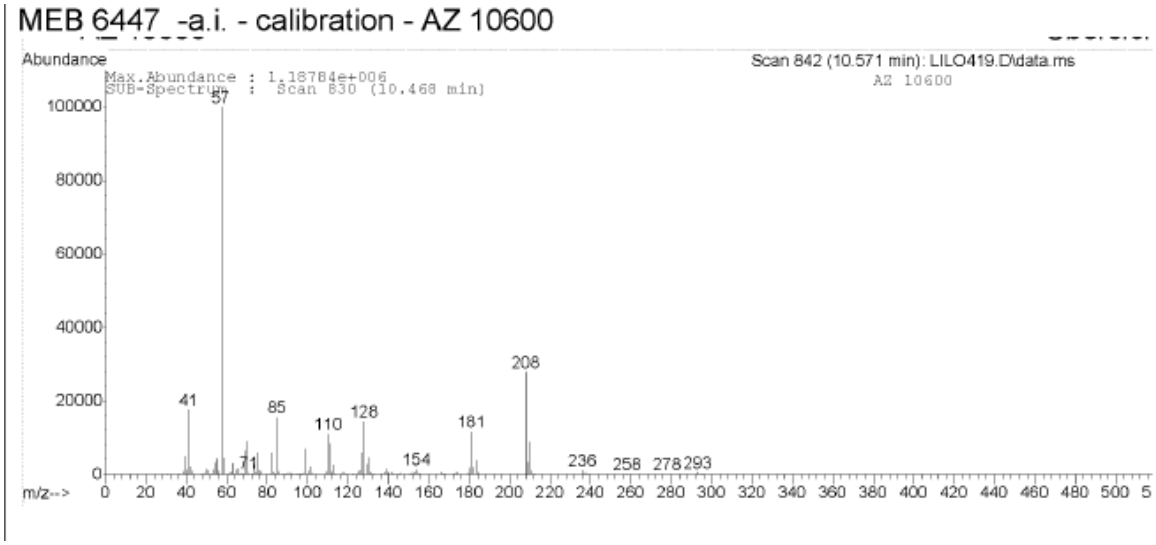
Identity tests

Retention time in HPLC, IR spectrum, EI-MS from GC-MS

IR spectrum of triadimefon



Electron ionisation (EI) mass spectrum of triadimefon (from GC-MS)



TRIADIMEFON TECHNICAL MATERIAL

FAO SPECIFICATION 352/TC (October 2011*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose names are listed in the evaluation report (352/2011). It should be applicable to TC produced by this manufacturer but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for TC produced by other manufacturers. The evaluation report 352/2011, as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of triadimefon 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 (352/TC/M/2, CIPAC Handbook 1C, p. 2236, 1985)
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 Triadimefon content (352/TC/M/3, CIPAC Handbook 1C, p. 2237, 1985)

The triadimefon content shall be declared (not less than 960 g/kg) and, when determined, the average measured content shall not be lower than the declared minimum content.

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

TRIADIMEFON EMULSIFIABLE CONCENTRATE

FAO specification 352/EC (October 2011*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation report (352/2011). 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 specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation report (352/2011) as PART TWO forms an integral part of this publication.

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1 Description

The material shall consist of technical triadimefon, complying with the requirements of FAO specification 352/TC (October 2011), dissolved in suitable solvents, together with any other necessary formulants. It shall be in the form of a stable homogeneous clear liquid with light chestnut to brown color, free from visible suspended matter and sediment, to be applied as an emulsion after dilution in water.

2 Active ingredient

2.1 Identity tests (352/EC/(M)/-, Note 1)

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

2.2 Triadimefon content (352/EC/(M)/-, Note 1)

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

Declared content in g/kg or g/L at 20 ± 2°C (Note 2)	Tolerance
above 25 up to 100	±10% of the declared content
above 100 up to 250	± 6% of the declared content
above 250 up to 500	± 5% of the declared content
Note: In each range the upper limit is included	

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

3 Physical properties

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

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

Time after dilution	Limits of stability, MT 36.3
0 h	Initial emulsification complete
0.5 h	"Cream", 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 MT 36.3, tests after 24 h are required only where results at 2 h are in doubt	

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

Maximum: 50 mL after 1 min.

4 Storage stability

4.1 Stability at 0 °C (CIPAC 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 4) and the formulation shall continue to comply with the clauses for:
- emulsion stability and re-emulsification (3.1).

Note 1 The extension of the scope of CIPAC method 352 (CIPAC/4689) for the determination of the content of triadimefon in EC, WG and GR formulations was accepted as a full CIPAC method in 2010. Prior to their publication in Handbook N, copies of the methods may be obtained through the CIPAC website, http://www.cipac.org/prepubme.htm.

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

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

TRIADIMEFON GRANULES

FAO Specification 352/GR (October 2011*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation report (352/2011). 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 specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation report (352/2011) as PART TWO forms an integral part of this publication.

1 Description

The material shall consist of granules containing technical triadimefon, complying with the requirements of FAO/WHO specification 352/TC (October 2011), together with suitable carriers and any other necessary formulants. It shall be dry, free from visible extraneous matter and hard lumps, free-flowing, essentially non-dusty and intended for application by machine.

2 Active ingredient

2.1 Identity tests (352/EC/(M)/-, Note 1)

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

2.2 Triadimefon content (352/EC/(M)/-, Note 1)

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

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

3 Physical properties

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

Not less than 975 g/kg of the formulation shall be within the size range 250 to 2000 µm.

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

Essentially non-dusty (Note 2).

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

* 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/

Minimum 98 % attrition resistance.

4 Storage stability

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

After storage at 54 ± 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:

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

Note 1 The extension of the scope of CIPAC method 352 (CIPAC/4689) for the determination of the content of triadimefon in EC, WG and GR formulations was accepted as a full CIPAC method in 2010. Prior to their publication in Handbook N, copies of the methods may be obtained through the CIPAC website, http://www.cipac.org/prepubme.htm.

Note 2 The optical method, MT 171.2, usually shows good correlation with the gravimetric method, MT 171.1, and can, therefore, be used as an alternative where the equipment is available. Where the correlation is in doubt, it must be checked with the formulation to be tested. In case of dispute the gravimetric method shall be used.

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

TRIADIMEFON WATER DISPERSIBLE GRANULES

FAO specification 352/WG (October 2011*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation report (352/2011). 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 specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation report (352/2011) as PART TWO forms an integral part of this publication.

1 Description

The material shall consist of a homogeneous mixture of technical triadimefon, complying with the requirements of the FAO specification 352/TC (October 2011), together with carriers and any other necessary formulants. It shall be in the form of granules, generally from beige to light brown 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 (352/WG/(M)/-, Note 1)

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

2.2 Triadimefon content (352/WG/(M)/-, Note 1)

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

Declared content in g/kg	Tolerance
above 250 up to 500	± 5% 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: 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/pm/jmps/ps/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, Handbook K, p. 142, 2003) (Note 2)

A minimum of 70 % shall be in suspension after 30 min in CIPAC Standard Water D at 30 ± 2 °C.

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

Maximum: 20 mL after 1 minute.

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

Essentially non-dusty.

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

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

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

Minimum: 98 % attrition resistance.

4 Storage stability

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

After storage at 54 ± 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:
- Wet sieve test (3.2),
- Degree of dispersion (3.3),
- Suspensibility (3.4),
- Dustiness (3.6),
- Attrition resistance (3.8)

Note 1 The extension of the scope of CIPAC method 352 (CIPAC/4689) for the determination of the content of triadimefon in EC, WG and GR formulations was accepted as a full CIPAC method in 2010. Prior to their publication in Handbook N, copies of the methods may be obtained through the CIPAC website, http://www.cipac.org/prepubme.htm.

Note 2 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, the simpler gravimetric method, MT 168, may be used on a routine basis provided that it has been shown to give equal results to those of chemical assay. In case of dispute, chemical assay shall be the "referee method".

Note 3 The mass of sample to be used in the test should correspond to the highest rate of use recommended by the supplier. The test is to be conducted in CIPAC standard water D.

Note 4 Measurement of dustiness must be carried out on the sample "as received" and, where practicable, the sample should be taken from a newly opened container, because changes in the water content of samples may influence dustiness significantly. The optical method, MT 171.2, usually shows good correlation with the gravimetric method, MT 171.1, and can, therefore, be used as an alternative where the equipment is available. Where the correlation is in doubt, it must be checked with the formulation to be tested. In case of dispute the gravimetric method shall be used.

Note 5 Analysis of the formulation, before and after the storage stability test, should be carried out concurrently (i.e. after storage) to reduce analytical error.

TRIADIMEFON WETTABLE POWDER

FAO specification 352/WP (October 2011*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation report (352/2011). 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 specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation report (352/2011) as PART TWO forms an integral part of this publication.

1 Description

The material shall consist of a homogeneous mixture of technical triadimefon, complying with the requirements of FAO specification 352/TC (October 2011), together with filler(s) and any other necessary formulants. It shall be in the form of a white to beige fine powder free from visible extraneous matter and hard lumps.

2 Active ingredient

2.1 Identity tests (352/WP/M/2, CIPAC Handbook 1C, p. 2236, 1985)

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 Triadimefon content (352/WP/M/3, CIPAC Handbook 1C, p. 2239, 1985)

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

Declared content in g/kg	Tolerance
above 25 up to 100	±10% of the declared content
above 100 up to 250	± 6% of the declared content
above 250 up to 500	± 5% of the declared content
Note: In each range the upper limit is included	

3 Physical properties

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

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

3.2 Suspensibility (MT 184, CIPAC Handbook K, p.142, 2003) (Note 1)

* 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 60 % of the triadimefon content found under 2.2 shall be in suspension after 30 min in CIPAC Standard Water D at 30 ± 2 °C (Note 2).

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

Maximum: 10 mL after 1 min.

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

The formulation shall be completely wetted in 120 sec. without swirling.

4 Storage stability

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

After storage at 54 ± 2 °C for 14 days, the determined average active ingredient content must not be lower than 95 % relative to the determined average content found before storage (Note 4) and the formulation shall continue to comply with the clauses for:

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

Note 1 This test will normally only be carried out after the heat stability test 4.1.

Note 2 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 3 The mass of sample to be used in the test should be at the highest rate of use recommended by the supplier.

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

PART TWO

EVALUATION REPORTS

TRIADIMEFON

TRIADIMEFON

FAO/WHO EVALUATION REPORT 352/2011

Recommendations

The Meeting recommended that

(i) the specifications for triadimefon TC, EC, GR, WG and WP proposed by Bayer CropScience, as amended, should be adopted by FAO

(ii) the existing FAO specifications for triadimefon TC, TK, EC, GR, DP, WG and WP (1995) should be withdrawn.

Appraisal

The data for triadimefon were evaluated in support of the review of existing FAO specifications for TC, EC, GR, WP and WG, which were developed in 1995 (FAO, 1995).

Triadimefon is no longer under patent.

Triadimefon was last evaluated by the JMPR in 2007 for residues (JMPR, 2007) and in 2004 for toxicology (JMPR, 2004). Triadimefon has been reviewed several times since the first evaluation in 1979. In addition, it was reviewed by the US EPA in 2006 (EPA, 2006). Triadimefon is registered and sold in Africa, Europe (outside EU community), the Americas and Asia.

The new draft specifications and the supporting data were provided by Bayer CropScience in 2009. The 2010 JMPS meeting considered the data on triadimefon in support of proposed new FAO specifications for triadimefon TC, EC, GR, WG and WP, and concluded that some additional data was required to support the specifications. The proposer submitted the required data and revised specifications, and the specifications were considered again in the 2011 JMPS Meeting and adopted.

Triadimefon is a solid with a melting point of 78-82°C. The compound has a rather low water solubility - 64 mg/L at 20°C – showing no pH-dependence. It is highly soluble in medium polarity organic solvents like dichloromethane. It has a low vapour pressure; therefore significant volatilization is not expected to occur. Triadimefon is stable to hydrolysis at pH 5-9 and 25˚C and it is slowly degraded by photolysis.

Triadimefon is manufactured as a racemate. The CIPAC method published in Handbook 1C and extended to GR, WG and EC in 2009 is based on reversed phase HPLC on a ODS column with a mixture of acetonitrile/water as eluent and UV detection at 276 nm. Triadimefon elutes under these conditions as single peak with a retention time of approx. 2 min.

The Meeting was provided with commercially confidential information on the manufacturing process and five batch analysis data on all impurities present at or above 1 g/kg and their manufacturing limits in the TC. Mass balances ranged from 990.5 to 995.5 g/kg in the five batches. None of the manufacturing byproducts has to be considered, on the basis of information available, as a relevant impurity. The impurities and their maximum limits in the

manufacturing specification were considered to be equivalent to the triadimefon purity and impurity profile provided to China authorities for registration.

The FAO specifications developed under old procedure (1995) included clauses to limit the concentrations of 3 impurities: 4-chlorophenol (maximum 5 g/kg), water (maximum 5 g/kg) and material insoluble in acetone (maximum 5 g/kg). The Meeting discussed the issue of impurities and concluded that none of these impurities, in the light of the rules of the FAO and WHO Manual (2nd revision 2010) with lowered limits in the actual manufacturing specification have to be considered as relevant.

The technical material revealed a certain potential to cause dermal sensitisation in the Magnusson-Kligman maximization test, while the purified triadimefon did not. The animals were exposed by intradermal as well as topical administration to technical triadimefon (purity 954 g/kg) in the induction phase, whereas either technical or purified triadimefon was used in the challenging exposure after 13 days of rest.

The proposer has revised the classification under GHS to include clauses in risk and safety phrases for skin sensitization.

The draft specifications were submitted broadly in accordance with the requirements of the Specification manual (FAO/WHO, 2006.) The Meeting noted the following points:

TC: The draft specification included a clause for acidity. The company explained that, in the old procedure specification, the acidity clause had the intention of controlling the hydrolysis of the triazole moiety in triadimefon. The meeting concluded that aqueous hydrolysis is slow and not pH dependent and therefore the acidity clause was considered not to be justified. The company agreed to remove the clause from the specification. Subsequently, the clauses for pH or acidity, respectively, were also removed from the specifications for the formulations.

EC, clause for emulsion stability and re-emulsification: The Meeting noted that the draft specification referred to both CIPAC MT 36.1 and MT 36.3, and concluded it should be made clear which one is to be used. The proposer confirmed that MT 36.3 was to be used to carry out the test. Reference to MT 36.1 was therefore removed.

GR. The meeting noted that the proposed specification for nominal size range was not in compliance with the FAO/WHO Specification manual. The company agreed to change the limit to “Not less than 975 g/kg of the formulation shall be within the size range 250 to 2000 µm.”

WG and WP. The proposed specification was broadly similar to the existing specification, except for the addition of the attrition resistance clause and minor changes in other clauses, which were considered to be acceptable. The Meeting questioned the proposed limits for suspensibility of 60% and for flowability of 90%. The proposer explained that the value of suspensibility was increased from 50% (Specification 1995) to 60% for WP in a considerable effort. With regard to WG, the proposer increased the value to 70%. The proposer also raised the limit of flowability to 98% after re-evaluation. These revised limits were accepted by the Meeting.

The reversed phase HPLC analytical method for triadimefon in TC and WP became a full CIPAC method in 1995. The extension of the scope of the CIPAC method 352 (CIPAC/4689) for the determination of the content of triadimefon in EC, WG and GR formulations was accepted as a full CIPAC method in 2010. The retention time in HPLC is the primary identification method and IR and GC-EI-MS, respectively, are additional tests.

SUPPORTING INFORMATION
FOR
EVALUATION REPORT 352/2011

USES

Triadimefon is a triazole fungicide registered in more than 50 countries. Triadimefon is an ergosterol demethylation inhibitor with protective, curative and eradicant action. It is absorbed by the roots and leaves, with ready translocation in young growing tissues. Triadimefon offers i.a. control of Powdery mildew in cereals, and many permanent crops like pome fruit, stone fruit, berries and others, of *Monilinia spp.* in stone fruit; black rot of grapes; Application rates are in the range 125-500 g ai/ha for cotton, cereals, hops, coffee, and sugar beet.

IDENTITY OF THE ACTIVE INGREDIENT

ISO common name

Triadimefon (E-ISO, BSI)

Chemical name(s)

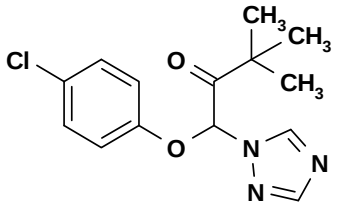
IUPAC (*RS*) 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1*H*-1,2,4-triazol-1-yl)butan-2-one

CA 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1*H*-1,2,4-triazol-1-yl)-2-butanone

Synonyms

Bayleton® (Bayer Trade name)

Structural formula



Molecular formula

C_{14} H_{16} Cl N_3 O_2

Relative molecular mass

293.7

CAS Registry number

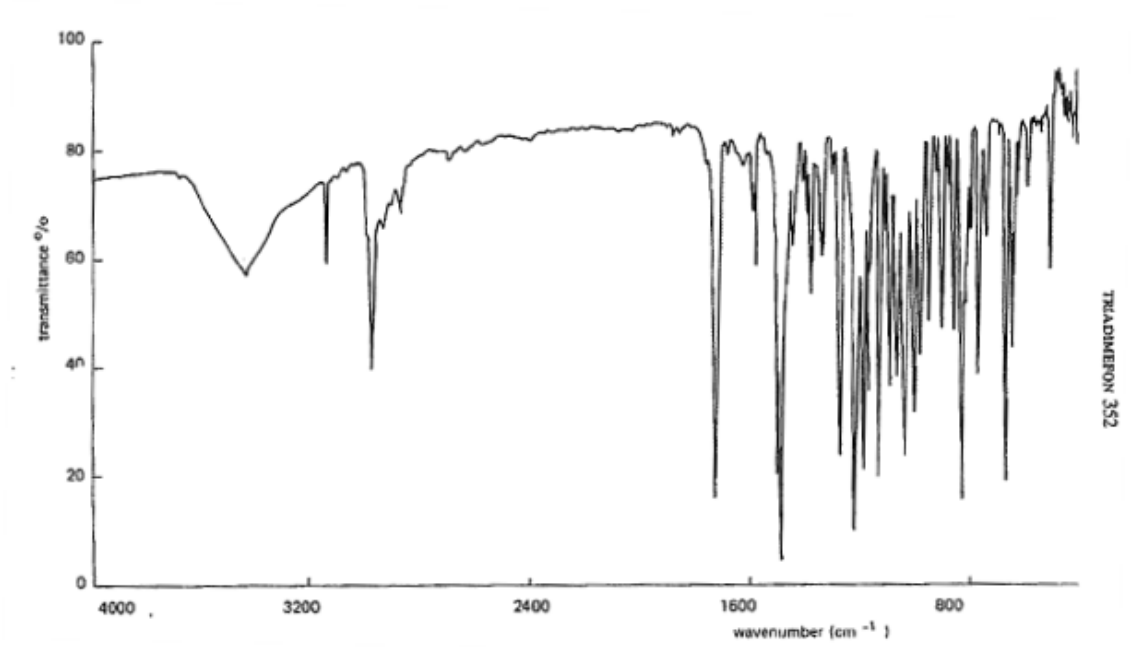
43121-43-3

CIPAC number

352

Identity tests

IR/NMR



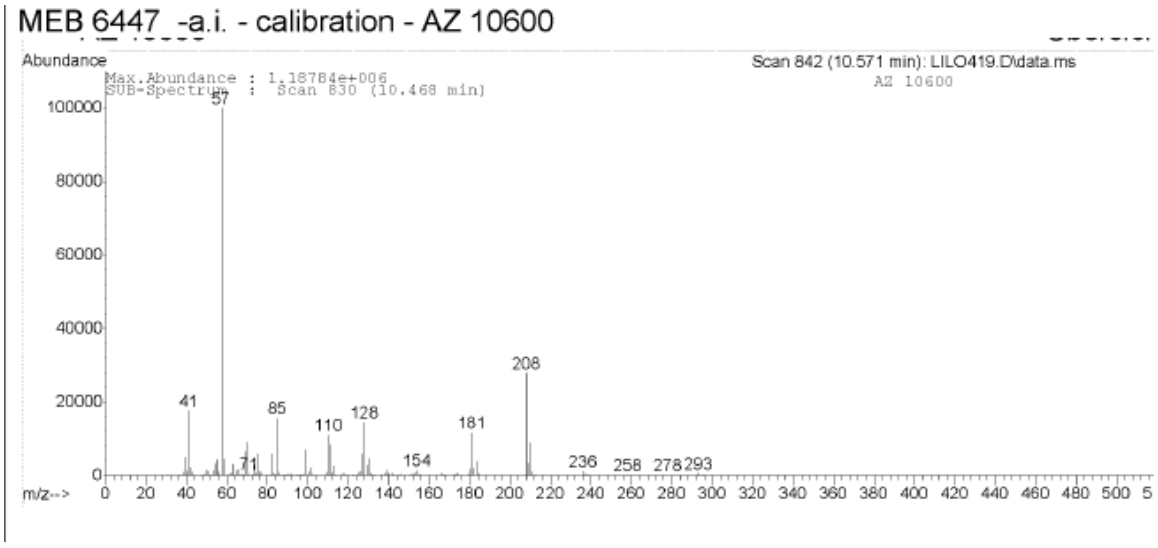


Table 1. **Physico-chemical properties of pure triadimefon**

Parameter	Value(s) and conditions	Purity %	Method	Reference
Vapour pressure	2×10^{-5} Pa at 20 °C 6×10^{-5} Pa at 25 °C	99.6	OECD 104 (vapour pressure balance method)	M-023477-01-1
Melting point	Melting point: 78 and 82 °C (two crystal modifications)	99.6	Differential scanning calorimetry	M-023448-01-1
Temperature of decomposition	Decomposition temperature: > 150 °C	99.6	OECD 113	M-023565-01-2
Solubility in water	6.4×10^{-2} g/L at 20 °C	99.6	OECD 105 (shake flask method)	M-023519-01-2
Octanol-water partition coefficient	log P_{OW} = 3.11 at 22 °C	99.6	OECD 107 EEC A8	M-023543-01-1
Hydrolysis characteristics	Stable at pH 5, 7 and 9 (sterile aqueous buffers in the dark) and 25 °C. Percent triadimefon remaining after 30 days: 92.8 %, 91.2 % and 93.5 % at pH 5, 7 and 9 respectively.	Radiochemical purity 98.2	EPA 161-1	M-020484-01-2
Photolysis characteristics	Under simulated sunlight at 25 °C, the experimental half-life is 7.6 hours. Sterile aqueous solution of 5.4 mg/L. Under photosensitized (humic acid) conditions at 24 °C, the experimental half-life is 10.9 hours. Photolysis products were identified.	Radiochemical purity > 99.0	EPA 161-2	M-020624-01-1 M-020637-01-1
Dissociation characteristics	Triadimefon is a very weak base, which can only be completely protonated in non-aqueous systems in the presence of very strong acids. So It is not possible to specify a pK_a value	99.6	OECD 112	M-023497-01-1

Parameter	Value(s) and conditions	Purity %	Method	Reference
Solubility in organic solvents	6.3 g/L n-hexane at 20 °C > 200 g/L dichloromethane at 20 °C 99 g/L 2-propanol at 20 °C > 200 g/L toluene at 20 °C 84 g/L n-octanol at 20 °C > 200 g/L acetone at 20 °C > 200 g/L acetonitrile at 20 °C > 200 g/L dimethylformamide at 20°C > 200 g/L ethylene glycol at 20°C > 200 g/L dimethylsulfoxide at 20 °C	99.6	OECD 105	M-023536-01-1

Table 2. **Chemical composition and properties of triadimefon 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 in the range from 990.5 to 995.5 g/kg.
Declared minimum triadimefon content	960 g/kg
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	75-82 °C	99.6	OECD 102 (DSC)	M-023448-01-1

HAZARD SUMMARY

Triadimefon was evaluated by the JMPR first in 1979, several times since then and most recently 2008. The 2004 JMPR established an ADI of 0-0.03 mg/kg bw and an ARfD of 0.08 mg/kg bw.

The WHO hazard classification of triadimefon is class III, slightly hazardous (WHO 2002).

Classification and labelling of triadimefon according to the EU Commission Regulation (EC) No 790/2009 is as follows.

Acute toxicity: Category 4

H302 Harmful if swallowed.

Skin sensitization: Category 1

H317 May cause an allergic skin reaction.

Chronic aquatic toxicity: Category 2

H411 Toxic to aquatic life with long lasting effects.

FORMULATIONS AND CO-FORMULATED ACTIVE INGREDIENTS

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

Triadimefon may be co-formulated with other fungicides like carbendazim, tebuconazole and trifloxystrobin, or with insecticides like fenamiphos,

These formulations are registered and sold in Africa, Europe (outside EU community), the Americas and Asia.

METHODS OF ANALYSIS AND TESTING

The analytical method for the active ingredient (including identity tests) is CIPAC 352/TC. The methods for TC and WP are published in Handbook 1C, and method extensions to cover EC, GR and WG formulations were presented at the 2009 CIPAC Meeting in El Salvador and were adopted as full CIPAC Methods in 2010 Prior to the publication in one of the next CIPAC Handbooks, copies of the methods are available through www.cipac.org. Triadimefon is determined by reversed phase HPLC on a 5 μm ODS column using acetonitrile/water as mobile phase and UV detection at 276 nm with external standardization.

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

PHYSICAL PROPERTIES

The physical properties, the methods for testing them and the limits proposed for the TC and EC, GR, WG and WP formulations, comply with the requirements of the FAO/WHO Specification manual (FAO and WHO, 2010).

CONTAINERS AND PACKAGING

No special requirements for containers and packaging have been identified.

EXPRESSION OF THE ACTIVE INGREDIENT

The active ingredient triadimefon is expressed as triadimefon in g/L for liquid formulations and as g/kg for solid formulations.

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

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

Spe-cies	Test	Duration, conditions, guide-line adopted,	Purity % Note[2]	Result	Reference
Rat, m & f	oral	Single dose, no guideline	93.4%	LD_{50} = 568 mg/kg bw (m) LD_{50} = 363 mg/kg bw (f) JMPR 2004 p 346 LD_{50} = 568-1245 mg/kg bw (m) LD_{50} = 363-793 mg/kg bw (f)	M-056052-01-1
Rat, m & f	oral	Single dose, no guideline	92.6%	LD_{50} = 1855 / 1020 mg/kg bw (m/f, fasted) 1245 / 793 mg/kg bw (m/f, un-fasted) JMPR 2004 p346 fasted LD_{50} = 1855 mg/kg bw (m) LD_{50} = 1020 mg/kg bw (f)	M-055766-01-1
Rat, m & f	oral neuro-toxicity	Single dose, 0, 2, 35, 600/450 m/f mg/kg bw FIFRA 81-8(SS), Addendum 10, EPA 540/09-91-123, PB 91-154617	95.8%	NOAEL: 2 mg/kg bw JMPR 2004: NOAEL: 2 mg/kg bw per day.	M-061772-01-1

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

Spe-cies	Test	Duration, conditions, guide-line adopted,	Purity % Note[3]	Result	Reference
Rat, m	dermal	Single application, 7 days exposure, no guideline	93.4%	LD_{50} > 1000 mg/kg bw	M-056052-01-1
Rat, m&f	dermal	Single application, 24 h exposure, no guideline	92.6%	LD_{50} > 5000 mg/kg bw (JMPR reported)	M-055766-01-1
Rat, m&f	inhalation	Liquid aerosol, inhalation for 1 h and 4 h, no guideline	93.4%	LC_{50} > 439 / 480 mg/m³ (1h) LC_{50} > 472 / 455 mg/m^3 (4h) (m/f)	M-056052-01-1
Rat, m&f	inhalation	Inhalation for 4 h, dust, nose-only exposure, OECD 403, FIFRA: 81-3, 40 CFR 798.1150, JMAFF: 59 NohSan No. 4200	95.0%	LC_{50} > 3270 mg/m^3 (3.27 mg/L in JMPR)	M-062519-01-1
Rabbit, m&f	Skin irrita-tion	No information on form of test material, type of dressing, dose and duration of exposure, no guideline	93.4%	Not irritating	M-056052-01-1
Rabbit, m&f	Skin irrita-tion	4 h exposure OECD 404, FIFRA: 81-5,40 CFR 798.4470, JMAFF: 59 NohSan No. 4200	94.6%	Slightly irritating, classification not triggered	M-062558-01-1
Rabbit, m&f	Eye irrita-tion	5 minutes / 24 h exposure, no guideline cited	93.4%	Slightly irritating, classification not triggered	M-056052-01-1

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

Species	Test	Duration, conditions, guideline adopted,	Purity % Note[4]	Result	Reference
Rabbit, m&f	Eye irritation	Single application, no eye-wash, OECD 405, FIFRA: 81-4, 40 CFR 798.4500, JMAFF: 59 NohSan No. 4200	94.6%	Slightly irritating, classification not triggered	M-062586-01-1
Guinea pig, male	Skin sensitization	Buehler Patch test, OECD 406, FIFRA: 81-6, 40 CFR 798.4100, JMAFF: 59 NohSan No. 4200	94.6%	Sensitizing	M-062508-01-1
Guinea pig, male	Skin sensitization	Maximization test, OECD 406, EC Directive 84/449: EEC B.6., FIFRA: 81-6	a) technical: 95.4%, b) purified: 99.6%,	a) Triadimefon technical: sensitizing b) pure triadimefon: not sensitizing	M-062483-01-1

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

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

Spe-cies	Test	Duration and conditions or guideline adopted	Purity % Note[5]	Result	Refer-ence
Rat, m&f	oral, gavage	30 days 0, 3, 10, 30 mg/kg bw/day no guideline	not specified	NOAEL: 30 mg/kg bw NOEL liver enzyme induction: 3 / 10 mg/kg bw/day (m/f)	M-056007-01-1
Rat, m&f	oral, gavage	4 weeks + 4 weeks recov-ery 0, 1, 5, 25 mg/kg bw/day no guideline	97.0 %	NOAEL: 25 mg/kg bw/day NOEL liver enzyme induction: 1 mg/kg bw/day	M-056443-01-1
Rat, m&f	dermal	3 weeks, 5 days/week, 0, 100, 300, 1000 mg/kg bw/day OECD 410, FIFRA: 82-2, JMAFF: 59 NohSan No. 4200	95.9%	NOAEL: 1000 / 300 mg/kg bw/day (m/f) JMPR 2004 NOAEL: 300 mg/kg bw per day	M-077447-01-1
Rabbit, m&f	dermal	4 weeks, 5 days/week, 0, 50, 250 mg/kg bw/day no guideline	not specified	NOAEL: 250 mg/kg bw/day	M-055921-01-1
Rat, m&f	inhalation	3 weeks, 5 days/week, 0, 78.7, 307 mg/m^3 air no guideline	not specified	NOAEL: 78.7 mg/m³ (21.2 mg/kg bw/day)	M-056007-01-1

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

Spe-cies	Test	Duration and conditions or guideline adopted	Purity % Note[5]	Result	Refer-ence
Rat, m&f	oral, gavage	30 days 0, 3, 10, 30 mg/kg bw/day no guideline	not specified	NOAEL: 30 mg/kg bw NOEL liver enzyme induction: 3 / 10 mg/kg bw/day (m/f)	M-056007-01-1
Rat, m&f	Sub-chronic feeding	12 weeks 0, 50, 200, 800, 2000 ppm no guideline	not specified	NOAEL: 800 ppm (40 mg/kg bw/day) JMPR 2004 NOAEL 150 mg/kg bw per day	M-056560-01-1
Rat, m&f	Sub-chronic feeding	12 weeks, 0, 170, 500, 1500, 4500 ppm FIFRA 82-1	94.6%	NOAEL: 170 ppm (13.6 / 14.1 mg/kg/day, m/f) JMPR 2004: study not reported 4500 ppm concentration	M-071081-01-1
Rat, m&f	Sub-chronic dietary neuro-toxicity	13 weeks + 4 / 10 weeks recovery 0, 50, 800, 2200 ppm FIFRA 82-5(b)	95.8 – 95.9%	NOAEL: 50 ppm (3.4 / 4.3 mg/kg bw/day, m/f) NOAEL: irreversible effects on the nervous system: 2200 ppm (150 / 190 mg/kg bw/day, m/f).	M-061688-01-1
Dog, m&f	Sub-chronic feeding	13 weeks, 0, 150, 600, 2400 ppm no guideline	99.6%	NOAEL: 600 ppm (15 mg/kg bw/day) NOEL liver enzyme induction: 150 ppm (3.75 mg/kg bw/day)	M-055428-01-1
Dog, m&f	Chronic feed-ing	2 years 0, 100, 330, 1000 (to week 54) 2000 (after week 54) ppm no guideline	88.9% and 92.7%, respectively	NOAEL: 330 ppm (11.4 mg/kg bw/day) JMPR 2004 NOAEL: 600 ppm (17.3 mg/kg bw per day)	M-055557-02-1

Spe-cies	Test	Duration and conditions or guideline adopted	Purity % Note[5]	Result	Refer-ence
Rat, m&f	oral, gavage	30 days 0, 3, 10, 30 mg/kg bw/day no guideline	not specified	NOAEL: 30 mg/kg bw NOEL liver enzyme induction: 3 / 10 mg/kg bw/day (m/f)	M-056007-01-1
Rat, m&f	Chronic feed-ing / carcino-genicity	24 months 0, 50, 500, 5000 ppm no guideline	93.1%	NOAEL: 50 ppm (2.4 / 3.2 mg/kg bw/day, m/f) No tumours up to 500 ppm (24 / 33 mg/kg bw/day, m/f)	M-056567-01-1
Rat, m&f	Chronic feed-ing / carcino-genicity	105 weeks, 0, 50, 300, 1800 ppm FIFRA 83-1	94.4%	NOAEL: 300 ppm (16.4 / 22.5 mg/kg bw/day, m/f)	M-062044-03-1
Mouse, m&f	Chronic feed-ing / carcino-genicity	24 months 0, 50, 300, 1800 ppm no guideline cited; accor-dance to OECD 451	97,0%	NOAEL: 300 ppm (60.5 / 75.6 mg/kg, m/f)	M-056399-02-1
Mouse, m&f	Chronic feed-ing / carcino-genicity	21 months 0, 50, 300, 1800 ppm OECD 451, FIFRA 83-1	90,0%	NOAEL: 50 ppm (13.5 / 19.6 mg/kg bw/day, m/f) JMPR 2004 NOAEL: 13.5 mg/kg bw per day	M-061976-01-1
Rat, m&f	Multigenera-tion study (3-generations)	0, 50, 300, 1800 ppm, no guideline cited, accor-dance to OECD 416	not specified	NOAEL parental: 300 ppm (15 mg/kg bw/day) NOAEL reproduction: 50 ppm (2.5 mg/kg bw/day) JMPR 2004 NOAEL: 3.75 mg/kg bw per day	M-055966-01-1

Spe-cies	Test	Duration and conditions or guideline adopted	Purity % Note[5]	Result	Refer-ence
Rat, m&f	oral, gavage	30 days 0, 3, 10, 30 mg/kg bw/day no guideline	not specified	NOAEL: 30 mg/kg bw NOEL liver enzyme induction: 3 / 10 mg/kg bw/day (m/f)	M-056007-01-1
Rat, m&f	Two-generation study	0, 50, 1800 ppm OECD 416	92.6%	NOAEL parental: 50 ppm (2.5 mg/kg bw/day) NOAEL reproduction: 50 ppm (2.5 mg/kg bw/day) JMPR 2004 NOAEL: 3.75 mg/kg bw per day	M-056450-01-1
Rat, f	Developmen-tal, oral, gavage	Days 6 – 15 of gestation, 0, 10, 30, 100 mg/kg bw/day and 0, 50, 75, 100 mg/kg bw/ day no guideline	not specified	NOAEL maternal: 10 mg/kg bw/day, NOAEL developmental: 50 mg/kg bw/day No NOAEL reported in 2004 JMPR	M-055321-01-1
Rat, f	Developmen-tal, oral, ga-vage	Days 6 – 15 of gestation, 0, 10, 30, 90 mg/kg bw/day no guideline	93.2%	NOAEL maternal: 30 mg/kg bw/day NOAEL developmental: 30 mg/kg bw/day No NOAEL reported in 2004 JMPR	M-056068-01-1
Rat, f	Developmen-tal, oral, gavage	Days 6 – 15 of gestation, 0, 10, 25, 50, 100 mg/kg bw/day no guideline	97.0%,	NOAEL maternal: 10 mg/kg bw/day NOAEL developmental: 25 mg/kg bw/day No NOAEL reported in 2004 JMPR	M-073193-01-1
Rat, f	Developmen-tal, inhalation	Days 6 – 15 of gestation, 0, 14, 33, 114 mg/m^3 air no guideline	not stated	NOAEL maternal: 14 mg/m³ (3.8 mg/kg bw/day) NOAEL developmental: 114 mg/m³ (30.8 mg/kg bw/day) No NOAEL reported in 2004 JMPR	M-055872-01-1

Spe-cies	Test	Duration and conditions or guideline adopted	Purity % Note[5]	Result	Refer-ence
Rat, m&f	oral, gavage	30 days 0, 3, 10, 30 mg/kg bw/day no guideline	not specified	NOAEL: 30 mg/kg bw NOEL liver enzyme induction: 3 / 10 mg/kg bw/day (m/f)	M-056007-01-1
Rabbit, f	Developmen-tal, oral, ga-vage	Days 6 – 18 of gestation, 0, 5, 15, 50 mg/kg bw/day no guideline	not stated	NOAEL maternal/ developmental: 50 mg/kg bw/day 2004 JMPR reported the lowest NOAEL for offspring toxicity was 20 mg/kg bw.	M-055308-01-1
Rabbit, f	Developmen-tal, oral, ga-vage	Days 6 – 18 of gestation, 0, 10, 30, 100 mg/kg bw/day no guideline	93.5%	NOAEL maternal: 10 mg/kg bw/day NOAEL developmental: 30 mg/kg bw/day	M-055950-01-1
Rabbit, f	Developmen-tal, oral, ga-vage	Days 6 – 18 of gestation, 0, 20, 50, 120 mg/kg bw/day OECD 414, FIFRA 83-3	94.3%	NOAEL maternal: 50 mg/kg bw/day NOAEL developmental: 20 mg/kg bw/day	M-062642-02-1
Rabbit, f	Developmen-tal, oral, gavage	Days 6 – 18 of gestation, 0, 40, 60, 80 mg/kg bw/day OECD 414, FIFRA 83-3	92.9%	NOAEL maternal: 20 mg/kg bw/day NOAEL developmental: 20 mg/kg bw/day (interpreted together with M-062642-01-1)	M-061785-01-1

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

Species	Test	Purity % Note[6]	Guideline, duration, doses and conditions	Result	Reference
Salmonella typhimurium (TA1535, TA100, TA1537, TA1538, TA98)	Reverse mutation assay	not specified	FIFRA 84-2	negative[7]	M-062696-01-1
Saccharomyces yeast (S138 and S211c)	Reverse mutation assay	not specified	no guideline specified	negative[7]	M-056201-01-1
Salmonella typhimurium (TA1535, TA1537, TA98, TA100) *Bacillus subtilis* [NIG 17 (rec^+) and NIG 45 (rec^-)]	Reverse mutation assay Rec assay	97.0%	no guidelines specified	negative[7]	M-055511-01-1
Salmonella typhimurium (TA1535, TA100, TA1537, TA1538, TA98) *Escherichia coli*, (WP2 hcr strain) *Bacillus subtilis* [H-17 (rec^+) and M-45 (rec^-)]	Reverse mutation assay Rec assay	97.0%	guidelines not specified	negative[7]	M-052644-01-1
Salmonella typhimurium (TA100, TA98,) Bacillus subtilis [H-17 (rec^+) and M-45 (rec^-)]	Reverse mutation assay Rec assay	97.0%	guidelines not specified	negative[7]	M-056176-01-1

[6] Note: Purity is the content of pure active ingredient in the technical material, expressed as a percentage.
[7] Agrees with result reported in JMPR Evaluations, 2004.

Species	Test	Purity % Note[6]	Guideline, duration, doses and conditions	Result	Reference
Salmonella typhimurium (TA98, TA100, TA1535, TA1537, TA1538, TA1950)	Reverse mutation assay	97.0%	no guidelines specified	negative[7]	M-056552-01-1
Chinese hamster ovary cells	Gene mutation in mammalian cells (CHO/HGPRT)	93.1%	FIFRA: 84-2	negative[7]	M-062898-01-1
Human peripheral blood lymphocytes	Cytogenetic study	93.0%	FIFRA: 84-2	negative[7]	M-062967-01-1
Rat hepatocytes	Unscheduled DNA synthesis	96.4%	FIFRA: 84-4	negative[7]	M-062849-01-1
Escherichia coli	DNA repair test (Pol test on E. coli)	86.0%	no guidelines specified	negative[2]	M-055776-01-1
In vivo					
Mouse, m&f	Micronucleus test	not specified	Oral dose, gavage, 2×200 mg/kg bw, 24 h interval no guidelines	negative[2]	M-055249-01-1
Mouse, m	Dominant lethal test	95.9%	Dose, single, oral, gavage 200 mg/kg bw no guideline	negative[2]	M-055506-01-1

[2] Agrees with result reported in JMPR Evaluations, 2004.

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

Species	Test	Purity % Note[1]	Guideline, duration, doses and conditions	Result	Study reference
Daphnia magna (water flea)	acute toxicity, static	96.8	48h Batch No. 000-6019/1030139, FIFRA guideline 72-2	EC_{50} = 7.16 mg/L	M-068888-01-1
Oncorhynchus mykiss (rainbow trout)	acute toxicity, static renewal	96.8	96h Batch No. 000-6019/1030139, FIFRA guideline 72-1	LC_{50} = 4.08 mg/L	M-068883-01-1
Lepomis macrochirus (bluegill)	acute toxicity, static renewal	96.8	96h Batch No. 000-6019, FIFRA guideline 72-1	LC_{50} = 10.0 mg/L	M-068898-01-1
Selenastrum capricor-nutum (green alga)	effect on growth, static	96.8	120h Batch No. 000-6019/1030139,, FIFRA guideline 123-2	EC_{50} = 2.01 mg/L NOEC = 1.2 mg/L	M-137141-02-1
Earthworm	chronic toxicity	96.0	56 days, artificial soil Pt 203080030, ISO guideline 11268-2	NOEC = 30.3 mg/kg dry soil	M-116580-01-1
Bobwhite quail	acute toxicity	95.0	dosing via gelatine capsules on day 1 Batch No. 0-00-6021,, FIFRA guideline 163.71-1	LD_{50} = 2000 mg/kg bw	M-088810-01-1
Bobwhite quail	short-term toxicity	93.0	subchronic, 5 day dietary Batch No. 5030047 isomer ratio not specified no guideline stated	LC_{50} = >4640<10000 mg/kg diet	M-088825-01-1

Species	Test	Purity % Note[1]	Guideline, duration, doses and conditions	Result	Study reference
Daphnia magna (water flea)	acute toxicity, static	96.8	48h Batch No. 000-6019/1030139, FIFRA guideline 72-2	EC_{50} = 7.16 mg/L	M-068888-01-1
Mallard duck	short-term toxicity	93.0	subchronic, 5 day dietary Batch No. 5030047, isomer ratio not specified no guideline stated	LC50 = >10000 mg/kg diet	M-089096-01-1

ANNEX 2

REFERENCES

Study number	Author(s)	year	Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study.
M-088825-01-1		1977	Eight-day dietary LC_{50} - Bobwhite quail - Bayleton technical. BCS Doc ID: M-088825-01-1. Unpublished.
M-089096-01-1		1977	Eight-day dietary LC_{50} - mallard duck - Bayleton technical. BCS Doc ID: M-089096-01-1. Unpublished.
M-061976-01-1		1986	MEB 6447 (common name: triadimefon, the active ingredient of Bayleton) - Carcinogenicity study on NMRI mice (21-month administration in the feed). BCS Doc ID: M-061976-01-1. Unpublished.
M-056567-01-1		1978	MEB 6447 - Chronic toxicity study on rats (two-year feeding experiment). BCS Doc ID: M-056567-01-1. Unpublished.
M-056399-02-1		1980	MEB 6447 - Chronic toxicity study on mice (two-year feeding experiment). BCS Doc ID: M-056399-02-1. Unpublished.
M-062044-03-1		1991	MEB 6447 - Chronic toxicity and carcinogenicity studies on Wistar rats with administration in diet over a period of 105 weeks. BCS Doc ID: M-062044-03-1. Unpublished.
M-068883-01-1		1994	Acute toxicity of Bayleton technical to the rainbow trout (Oncorhynchus mykiss) under static renewal conditions. BCS Doc ID: M-068883-01-1. Unpublished.
M-068888-01-1		1994	Acute toxicity of Bayleton technical to the waterflea (Daphnia magna) under static conditions. BCS Doc ID: M-068888-01-1. Unpublished.
M-137141-02-1		1994	Acute toxicity of Bayleton technical to the green alga (Selenastrum capricornutum). BCS Doc ID: M-137141-02-1. Unpublished.
M-068898-01-1		1994	Acute toxicity of Bayleton technical to the bluegill (Lepomis macrochirus) under static-renewal conditions. BCS Doc ID: M-068898-01-1. Unpublished.
M-062849-01-1		1991	MEB 6447 - mutagenicity test on unscheduled DNA synthesis in rat liver primary cell cultures in vitro. BCS Doc ID: M-062849-01-1. Unpublished.
M-020484-01-2		1991	Stability of triadimefon in sterile aqueous buffer solutions. Mobay Corp, USA. Study BL072401. Report 101291. BCS Doc ID: M-020484-01-2. Unpublished
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