Food and Agriculture Organization
of the United Nations

FAO SPECIFICATIONS AND EVALUATIONS

FOR AGRICULTURAL PESTICIDES

PROPICONAZOLE

(2RS,4RS;2RS,4SR)-1-[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole

2019

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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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[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

PROPICONAZOLE

PROPICONAZOLE

INFORMATION

ISO common name: Propiconazole (ISO 1750, published)

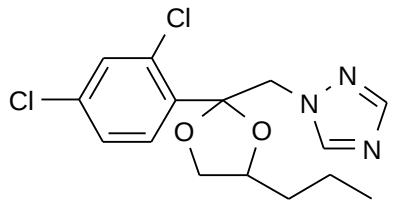
Chemical names:

IUPAC, (2*RS*,4*RS*;*2RS*,4*SR*)-1-[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1*H*-1,2,4-triazole

CA 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole

Synonym: CGA64250

Structural formula:



Molecular formula: $C_{15}H_{17}Cl_2N_3O_2$

Molecular mass: 342.2

CAS Registry number: 60207-90-1 (unstated stereochemistry)

CIPAC number: 408

Identity tests: IR spectrum, GC retention time

PROPICONAZOLE TECHNICAL MATERIAL

FAO Specification 408 / TC (June 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 (408/2018). It should be applicable to technical materials produced by 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 TC produced by other manufacturers. The evaluation report (408/2018), as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of propiconazole together with related manufacturing impurities, in the form of a yellowish viscous liquid/solid and shall be free from visible extraneous matter and added modifying agents.

2 Active ingredient

2.1 **Identity tests** (CIPAC/5150) (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 **Propiconazole content** (CIPAC/5150) (Note 1)

The propiconazole content shall be declared (not less than 940 g/kg) and when determined, the average measured content shall not be lower than the declared minimum content.

Note 1 The results of the collaborative validation of the capillary GC method for determination of propiconazole in TC and EC were presented at the 2018 CIPAC Meeting in Panama and the method was provisionally adopted. It became a full method in 2019. Prior to the publication of the method in one of the next Handbooks, copies of the method can be obtained through the CIPAC prepublishment scheme, https://www.cipac.org/index.php/methods-publications/pre-published-methods

* 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/

PROPICONAZOLE EMULSIFIABLE CONCENTRATE

FAO Specification 408 / EC (June 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 (408/2018). It should be applicable to emulifiable concentrates produced by 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 EC produced by other manufacturers. The evaluation report (408/2018), as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of technical propiconazole, complying with the requirements of FAO specification 408/TC (June 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/5150) (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 **Propiconazole content** (CIPAC/5150) (Note 1)

The propiconazole 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 following tolerances:

Declared content in g/kg or g/l at 20 ± 2 °C	**Tolerance**
up to 25	± 15% of the declared content
above 25 up to 100	± 10% of the declared content
above 100 up to 250	± 6% of the declared content
above 250 up to 500	± 5% of the declared content
above 500	± 25 g/kg or g/l
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/ps/en/

3. Physical properties

3.1 **Emulsion stability and re-emulsification** (MT 36.3, CIPAC Handbook K) (Note 3)

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: 0.4 mL
2.0 h	"Cream", maximum: 1 mL "Free oil", maximum: trace
24 h	Re-emulsification complete
24.5 h	"Cream", maximum: 0.4 mL "Free oil", none
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 5)

Maximum: 60 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 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, CIPAC Handbook K, p. 137, p. 2003)

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 clause for:

- emulsion stability and re-emulsification (3.1)

Note 1 The results of the collaborative validation of the capillary GC method for determination of propiconazole in TC and EC were presented at the 2018 CIPAC Meeting in Panama and the method was provisionally adopted. It became a full method in 2019. Prior to the publication of the method in one of the next Handbooks, copies of the method can be obtained through the CIPAC prepublishment scheme, https://www.cipac.org/index.php/methods-publications/pre-published-methods

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

Note 3 As outlined in CIPAC MT 36.3, the test concentrations should be based on those in the recommended directions for use supplied with the product. Where several concentrations are recommended, the highest and lowest concentrations within the scope of the method should be used.

Note 4 Limits given based on a 1% test concentration. Limits may vary depending on the testing concentration. A maximum of 40% (of the volume added) cream separation is accepted after 0.5 hour.

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

PROPICONAZOLE

PROPICONAZOLE

FAO/WHO EVALUATION REPORT 408/2018

Recommendation

The Meeting recommended that:

i) the FAO specifications for propiconazole TC and EC developed under the old procedure should be withdrawn

ii) the specifications for propiconazole TC and EC, proposed by Syngenta Crop Protection AG and as amended, should be adopted by FAO, subject clarification of some points.

Appraisal

The Meeting considered a data package submitted by Syngenta Crop Protection AG (Syngenta) in October 2017 in support of the conversion of “old procedure” FAO specifications for propiconazole TC and EC formulation into the corresponding "new procedure" reference specifications.

Propiconazole is not under patent. The compound was evaluated by the FAO/WHO JMPR and WHO/IPCS in 1987 and again in 2004 for toxicology. The conclusions in the 2004 evaluations were:

"Propiconazole has moderate acute oral toxicity in rats and mice (LD_{50} values, about 1500 mg/kg bw) and low acute dermal (LD50 values, > 4000 mg/kg bw) and inhalation toxicity (LC50, > 5 mg/l of air). Propiconazole is not an eye irritant in rabbits, but is irritating to rabbit skin and is a skin sensitizer in guineapigs in the Magnusson and Kligman test. (...) Propiconazole was not teratogenic in rabbits.

The Meeting established an ADI of 0–0.07 mg/kg bw based on the NOAEL of 7 mg/kg bw per day in a multigeneration study of reproductive toxicity in rats and a 100-fold safety factor. (...) An ARfD of 0.3 mg/kg bw was established based on the NOAEL of 30 mg/kg bw per day in the study of developmental toxicity in rats and a 100-fold safety factor."

JMPS was provided with commercially confidential information on the manufacturing process, the analysis of 5 typical batches and analytical methods. Syngenta's propiconazole TC is produced at two sites - one in Europe and one in South-East Asia. A final purification step of the TC for both production sites is carried out at the European site only.

The data submitted allowed a detailed comparison of the composition of the finished TC stemming from the two sites. The two sources produced according to the same manufacturing specification. The European site was nevertheless considered as the reference source and the Asian source was deemed equivalent by the Meeting.

Five batch analytical data (reports February, 2014) on impurities present at or above 1g/kg in the TC and their manufacturing limits in the samples produced at both the manufacturing sites had been provided.

Mass balances ranged from 994 to 1006 g/kg. The Meeting concluded that none of the impurities present below or above 1 g/kg should be considered as relevant.

The impurities and their specification limits were the same as those submitted to Tukes (Finnish Safety and Chemicals Agency), Helsinki, as the rapporteur for the EU renewal. A letter of access had been provided by Syngenta and been confirmed by Tukes.

The physical state of propiconazole technical material varies between a viscous liquid and solid depending on the storage conditions. Partial crystallization may occur to yield a mixture of liquid and solid (crystalline) phases. Propiconazole TC is a liquid at normal temperature. It is moderately volatile and has a medium solubility in water. It is not readily hydrolized and shows a moderate octanol-water partition coefficient of 3.7 at pH 6.6.

The propiconazole molecule carries two asymmetric carbon atoms in the dioxolan moiety. It therefore consists of two pairs of diastereomers. The manufacturing process is not expected lead to enantiomeric excesses in the two diastereomers. The typical ratio of *cis* to *trans* diastereomers is in the range of 1.25 - 1.6. The physical properties, the methods for testing them and the limits proposed for the EC formulations, comply with the requirements of the FAO/WHO Manual (March 2016 3rd revision of the 1st edition).

The analytical method for determination of the content of propiconazole in TC and EC is a meanwhile full CIPAC method based on capillary GC method with internal standardization. Organic impurities are determined using GC FID.

Issues identified with the TC specification:
The Meeting noted that the suggested minimum purity based on the 5-batch data, was 940 g/kg was considered low and requested Syngenta to provide QC data to corroborate the minimum purity. The company explained that the minimum purity given under the old procedure specification was 880 g/kg (1993). However, it was clear that with this data call-in that there would be a need to increase the minimum purity to a limit that was appropriate according to the GLP 5-batch data as representative of routine manufacture. On the basis of the 5-batch data, Syngenta therefore proposed a proportionate increase to 940 g/kg from the original specification minimum purity of 880 g/kg. Syngenta further commented, that a further increase in purity to more than 940 g/kg minimum would lead to a higher number of batches that would be non-compliant with a further increased minimum purity. The Meeting accepted the justification and the minimum purity of 940 g/kg.

Issues identified with the EC specification:
The Meeting noted that a pH range had been proposed for the EC. As propiconazole is not readily hydrolyzed, the necessity of the clause was questioned. As Syngenta could not provide a justification for the pH clause that seemed plausible to the Meeting, the clause was removed.

SUPPORTING INFORMATION

FOR

EVALUATION REPORT 408/2018

USES

Propiconazole is a systemic triazole fungicide with curative and protective action, acting essentially by inhibiting the C_{14}-demethylase in sterol biosynthesis of sensitive pathogens and exhibits a broad range of activity against diseases caused by *Erysiphe graminis*; *Leptosphaeria nodorum*; *Pseudocerosporella herpotrichoides*; *Puccinia* spp.; *Pyrenophora teres*; *Rhynchosporium secalis* and *Septoria* spp.

IDENTITY OF THE ACTIVE INGREDIENT

ISO common name: Propiconazole (ISO 1750, published)

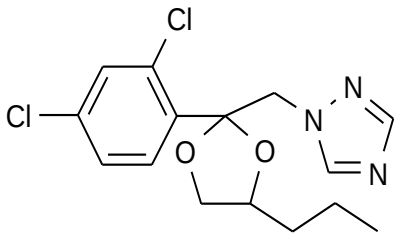
Chemical names:

IUPAC, (2*RS*,4*RS*;2*RS*,4*SR*)-1-[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1*H*-1,2,4-triazole

CA 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole

Synonym: CGA64250

Structural formula:



Molecular formula: $C_{15}H_{17}Cl_2N_3O_2$

Molecular mass: 342.2

CAS Registry number: 60207-90-1 (unstated stereochemistry)

CIPAC number: 408

Identity tests: IR spectrum, GC retention time

Table 1. Physico-chemical properties of pure propiconazole

Parameter	Value(s) and conditions	Purity %	Method reference (and technique if the reference gives more than one)	Study number
Vapour pressure	0.056 mPa at 25 °C	99.1	OECD 104 EEC A4 gas saturation method	CGA64250/2087 (1988)
Melting point.	At room temperature (22 °C) the substance is a mixture of a crystalline part and a liquid part (proportion about 1:1). Using slow cooling down (scan rate 10 °C/min or 1.25 °C/min) a melting point is observed at +53.8 to +53.9 °C for the crystalline part and a freezing point (glass transition temperature) is observed for the liquid part at -23.6 to -23.5 °C. Using rapid cooling down (scan rate 320 °C/min) only a freezing point is observed at -22.4 to -22.6 °C.	98.8	EEC A1 DSC method	CGA64250/2441 (1994)
Temperature of decomposition	Thermal decomposition begins around 355°C	99.1	OECD 103 EEC A2 DSC method	CGA64250/2290 (1993)
Solubility in water	100 mg/L in pure water at pH 6.9 at 20 °C	99.1	OECD 105 EEC A6 flask method	CGA64250/2085 (1987)
Octanol/ water partition coefficient	log P_{OW} 3.72 at pH 6.6 at 25 °C	99.1	OECD 107 EEC A8 shake flask method	CGA64250/2086 (1987)
Hydrolysis characteristics	Triazole-^{14}C-label, 2.05 MBq/mg, radiochemical purity > 98.5% w/w. 10 mg/L propiconazole in sterile aqueous buffers in the dark propiconazole is hydrolytically stable (mean recovery 99.6%) at pH 4, 5, 7, 9 at 50 ± 1 °C for at least 5 days.	98.5	OECD 111 EPA 161-1 Japan MAFF 12 Noshan no 8147	CGA64250/4697 (2004)

Parameter	Value(s) and conditions	Purity %	Method reference (and technique if the reference gives more than one)	Study number
Photolysis characteristics	Phenyl-^{14}C-label, 40 µCi/mg, radiochemical purity > 95.5% w/w. 10.8 mg/L propiconazole in sterile aqueous buffer exposed to artificial sunlight (12 h light, 12 h darkness) for 30 d (360 h). DT50 = 249 days at pH 7 at 25±1 °C Parent decline of 97.9% to 88.4% TAR after 30 days.	95.5	EPA 161-2 EC Dir. 95/36/EC	CGA64250/1825 (1990)
Dissociation characteristics	pK_b = 12.91 for propiconazole at 20 °C, describing: propiconazole + H_2O ↔ propiconazole-H^+ + OH^- pKa = 1.09 for propiconazole-H^+ at 20°C, describing: propiconazole-H^+ + H_2O ↔ propiconazole + H_3O^+ At pH < 3.1 both the neutral and the protonated form are present; at pH > 3.1 propiconazole is predominantly present as the neutral form.	99.1	OECD 112 spectrophotometric titration at 233.5nm	CGA64250/2287 (1990) CGA64250/2455 (1994)
Solubility in organic solvents	47 g/L in n-hexane at 25°C completely miscible in toluene, ethanol, n-octanol, acetone, ethyl acetate, dichloromethane at 25°C	92.4	OECD 105 EEC A6 flask method	CGA64250/2084 (1994)

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

Manufacturing process, maximum limits for impurities ≥ 1 g/kg, 5 batch analysis data	Confidential information supplied and held on file by FAO. Mass balances were 99.4 – 100.6% and percentages of unknowns were 0.1 – 0.6%.
Declared minimum propiconazole content	940 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 number
Melting temperature range of the TC and/or TK	Not measured, propiconazole TC is a liquid at normal temperature.	---	---	---
Solubility in organic solvents	47 g/L in n-hexane at 25°C completely miscible in toluene, ethanol, n-octanol, acetone, ethyl acetate, dichloromethane at 25°C	92.4	OECD 105 EEC A6 flask method	CGA64250/2084 (1994)

FORMULATIONS AND CO-FORMULATED ACTIVE INGREDIENTS

The present submission is for EC formulation only.

METHODS OF ANALYSIS AND TESTING

The capillary GC method using internal standard (CIPAC/5150) for the determination of propiconazole in TC and EC formulations was adopted as a full CIPAC method at the 2019 CIPAC Meeting in Braunschweig, with the note that acetone can also be used instead of methyl isobutyl ketone (MIBK).

The method for determination of impurities is according to the analytical method SB-73/1, by gas chromatography (GC) with internal standard calibration, and flame ionization detection (FID).

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

CONTAINERS AND PACKAGING

No special requirements for containers and packaging have been identified.

EXPRESSION OF THE ACTIVE INGREDIENT

The content of the active ingredient propiconazole is expressed as propiconazole.

ANNEX 1

HAZARD SUMMARY PROVIDED BY THE PROPOSER

Notes.

(i) The proposer confirmed that the toxicological data included in the summary below were derived from propiconazole having impurity profile similar to those referred to in the table above.

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

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

Species	Test	Purity %[2]	Guideline, duration, doses and conditions	Result	Study number
Rat (Tif:RAIf); (male and female)	oral	93	No guideline non-GLP Dose levels 500, 1000, 3000 or 4000 mg/kg 14 day observation period	LD_{50} = 1517 mg/kg bw	CGA64250/1528
Mouse (Tif:MAG); (males and females)	oral	93	No guideline non-GLP Dose levels 800, 1500, 2500 or 3000 mg/kg 14 day observation period	LD_{50} = 1490 mg/kg bw	CGA64250/1529
Rat (Tif:RAIf); (male and female)	dermal	93	No guideline non-GLP Dose levels 3000 or 4000 mg/kg 14 day observation period	LD_{50} = >4000 mg/kg bw	CGA64250/1531
Rabbit (NZW); (male and female)	dermal	93	No guideline non-GLP Dose levels 2000 or 6000 mg/kg 14 day observation period	LD_{50} = >6000 mg/kg bw	CGA64250/1532
Rat (Tif:RAIf); (male and female)	inhalation	91	OECD 403 (1981); GLP 4h nose only exposure; MMAD approx.2.6 µm	LC_{50} = >5 mg/m^3	CGA64250/1533
Rabbit	skin irritation	93	No guideline, non-GLP 7 day observation period	Moderate irritant	CGA64250/1535
Rabbit	eye irritation	93	No guideline, non- GLP	Minimal irritant	CGA64250/1536
Guinea pigs	skin sensitisation	92.4	Magnusson and Kligman maximisation test	Skin sensitiser*	CGA64250/4197

***** The skin sensitisation classification for propiconazole is: Skin Sensitiser, Category 1, H317 (May cause an allergic skin reaction).

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

Table 4. Toxicology profile of propiconazole technical material, based on acute toxicity, irritation and sensitization (Additional acute toxicity data)

Species	Test	Purity %[3]	Guideline, duration, doses and conditions	Result	Study number
Rat	Acute Oral	95.2	OECD 425, GLP RjHan: WI female rats 2000, 550 or 175 mg/kg bw	LD_{50} 550 mg/kg bw	CGA064250_10710
Rat	Acute Dermal	95.2	OECD 402, GLP RjHan: WI (5/sex/group) 5000 mg/kg bw	LD_{50} >5000 mg/kg bw	CGA064250_10706
Rabbit	Skin Irritation	95.2	OECD 404, GLP NZW 3 male 0.5g	Mild irritant	CGA064250_10705
Rabbit	Eye Irritation	95.2	OECD 405, GLP NZW 3 male 0.1 mL	Mild irritant	CGA064250_10711

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

Table 5. Toxicology profile of propiconazole technical material based on repeated administration (subacute to chronic)

Species	Test	Purity % [4]	Guideline, duration, doses and conditions	Result	Study number
Mouse (m)	Short term toxicity	92	No guideline 90 d dietary oral CD1 (ICR) BR mice Dose Levels: 0, 20, 500, 850, 1450, 2500 ppm	NOAEL = 71 mg/kg bw/d	CGA64250/2020
Mouse (m+f)	Short term toxicity	92	No guideline 17 w dietary oral CD1 (ICR) BR mice Dose Levels: 0, 20, 500, 850, 1450, 2500 ppm (males); 0, 20, 500, 2500 ppm (females)	NOAEL = 65 mg/kg bw/d	CGA64250/2019
Rat (m+f)	Short term toxicity	91.9	No guideline 28 d oral gavage RAIf rats Dose Levels: 0, 50, 150, 450 mg/kg bw/day	NOAEL = 150 mg/kg bw/d	CGA64250/1596
Rat (m+f)	Short term toxicity	90	OECD 408 (1981) 90 d dietary oral Tif:RAIf rats Dose Levels: 0, 240, 1200, 6000 ppm	NOAEL = 76 mg/kg bw/d	CGA64250/1538
Dog (m+f)	Short term toxicity	90	No guideline, non-GLP 90 d dietary oral Beagle dogs (4/sex/group) Dose Levels: 0, 50, 250, 1250 ppm	NOAEL = 6.9mg/kg bw/d	CGA64250/1539
Dog (m+f)	Short term toxicity	90.2	OECD 452 (1981) 1 year dietary oral Beagle dogs (5/sex/group) Dose Levels: 0, 5, 50, 250 ppm	NOAEL = 8.4 mg/kg bw/d	CGA64250/1544

Species	Test	Purity % [4]	Guideline, duration, doses and conditions	Result	Study number
Rabbit (m+f)	Short term dermal toxicity	91.9	OECD 410 (prior to GLP) 21 d dermal NZW rabbits (10 males/ 10 females) Dose Levels: 0, 200, 1000 or 5000mg/kg bw/ day	NOAEL = 200 mg/kg bw/d	CGA64250/1595
Rats (m+f)	Short term toxicity inhalation	91.9	OECD 413 (prior to GLP) 90 d inhalation RAIf rats (5/sex/group) Dose Levels: 0, 21, 85,191 mg/m^3	NOAEC = 85 mg/m^3	CGA64250/1593
Mice (m+f)	Carcinogenicity	92	No guideline given 104 w dietary oral CD1 mice Dose Levels: 0, 100, 500, 2500 ppm	NOAEL = 10 mg/kg bw/d (non-neoplastic effects) NOAEL = 49 mg/kg bw/d (tumours)	CGA64250/1542
Mice (m)	Carcinogenicity	92.4	Not conducted to OECD guideline 18 months dietary oral Crl:CD1 (ICR) BR (5/sex/group) 0, 500, 850 ppm	NOAEL = 11 mg/kg bw/d (non-neoplastic effects) NOAEL = 59 mg/kg bw/d (tumours)	CGA64250/3142
Rats (m+f)	Carcinogenicity	91.9	OECD 453 109 w dietary oral CD Sprague-Dawley Dose Levels: 0, 100, 500, 2500 ppm	NOAEL = 18 mg/kg bw/d (non-neoplastic effects) NOAEL = 96 mg/kg bw/d (tumours)	CGA64250/1540
Rats (f)	Reproductive toxicity- 2 generation study	89.7	OECD 416 (1983) Dietary, oral Dose levels: 0, 100, 500, 2500 ppm	Maternal: 7mg/kg/bw/d Reproductive: 35 mg/kg bw/day Offspring: 7 mg/kg bw/day	CGA64250/1591
Rats	Developmental toxicity	91.9	No guideline Oral gavage Tif:RaIf rats Dose levels: 0, 30, 100, 300 mg/kg bw/day	Level of detail insufficient to derive NOAEL	CGA64250/1585

Species	Test	Purity % [4]	Guideline, duration, doses and conditions	Result	Study number
Rats	Developmental toxicity	92.1	OECD 414 (1981) Oral gavage Crl:COBS CD(SD) BR VAF/plus rats Dose levels: 0, 30, 90, 360/300 mg/kg bw/day	Maternal NOAEL: 90 mg/kg bw/day Developmental NOAEL: 30 mg/kg bw/day	CGA64250/1586
Rats	Developmental toxicity	92.1	No guideline requirement conducted to GLP Oral gavage Crl:COBS CD(SD) BR VAF/plus rats Dose levels: 0,300 mg/kg bw/day	Study was not designed to determine a NOAEL	CGA64250/1587
Rabbits	Developmental toxicity	92.1	OECD 414 (1981) Oral gavage Crl:COBS CD(SD) BR VAF/plus rats Dose levels: 0, 100, 250, 400 mg/kg bw/day	Maternal NOAEL: 100 mg/kg bw/day Developmental NOAEL: 250 mg/kg bw/day	CGA64250/1589

Table 6. Toxicology profile of propiconazole technical material based on repeated administration (subacute to chronic) - Additional data

Species	Test	Purity (%)[4]	Guideline, duration, doses and conditions	Result [(isomer/form)]	Study number
Rats	28 day dermal toxicity	92.4	OECD 410, GLP Hanlbm:WIST 10/sex/group Dose levels: 0, 10, 100, 1000 mg/kg bw/day	NOAEL: 1000 mg/kg bw/day	CGA64250/4412
Rats	Acute neurotoxicity	95.2	OECD 424, GLP Alpk:APfSD 10/sex/group Dose levels: 0, 30, 100, 300 mg/kg bw	NOAEL: 100 mg/kg bw/day	CGA64250/4839
Rats	90 day neurotoxicity	95.2	OECD 424, GLP Crl:CD(SD) 12/sex/group Dose levels: 0, 200, 600, 3500 ppm males 0, 200, 600, 1500 ppm females	NOAEL: 3500ppm (222 mg/kg/day) males and 1500ppm (111 mg/kg/day (females)	CGA06425_51255

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

Table 7. Mutagenicity profile of propiconazole technical material based on *in vitro* and *in vivo* tests

Species	Test	Purity %[5]	Guideline, duration, doses and conditions	Result	Study number
(*Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537, TA1538)	Bacterial Reverse Gene Mutation (in vitro)	90.7	20- 5120 µg/plate +/- S9 DMSO No guideline, non-GLP	Negative +/-S9	CGA64250/1571
Mouse lymphoma L5178Y Tk +/- cells	Mammalian Gene Mutation (in vitro)	90.7	7.8-125 µg/mL +/-S9 in DMSO No guideline, non-GLP	Negative +/-S9	CGA64250/1583
BALB 3T3 mouse embryo cells	Cell transformation (in vitro)	89.7	1.2-18.5 µg/mL +/-S9 in DMSO No guideline, non-GLP	Negative +/-S9	CGA64250/1582
Human peripheral lymphocytes	Chromosomal aberration (in vitro)	89.7	1-180 µg/mL +/-S9 in DMSO No guideline, GLP	Negative +/-S9	Strasser and Arni (1984) CGA64250/1576
Tif:RAIf rat hepatocytes	Unscheduled DNA synthesis (in vitro)	90.7	0.7-83 ng/mL+/-S9 in DMSO OECD guideline 482 (1986), GLP	Negative	CGA64250/1581
Chinese hamster	Micronucleus formation (in vivo)	90.7	0, 307, 615 or 1230 mg/kg bw by gavage in arachis oil. 8 animals per sex per group OECD 474 (1997), GLP	Negative	CGA64250/860359 CGA64250/1584

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

Species	Test	Purity %[5]	Guideline, duration, doses and conditions	Result	Study number
Mice (Ico:CD1)	Micronucleus formation (in vivo)	92.4	0, 80, 1600, 3200 mg/kg bw by gavage in arachis oil 5 animals per sex per group OECD guideline 474 (1997), GLP	Negative	CGA 64250/4268
Mice (Tif:MAGf (SPF))	Dominant lethal mutation	90.7	0, 165, 495 mg/kg bw by gavage in methyl cellulose. Males	Negative	CGA64250/1569 CGA064250_10740

Table 8. Mutagenicity profile of the technical material based on *in vitro* tests (Additional data)

Species	Test	Purity % [6]	Guideline, duration, doses and conditions	Result [(isomer/form)]	Study number
Salmonella typhimurium (TA1535, TA1537, TA98, TA100) and *Escherichia coli* (WP2 (pKM101), WP2 uvrA)	Salmonella typhimurium and Escherichia coli reverse mutation assay	94.1	OECD 471, GLP 0 to 5000 µg/plate, +/- activation	Negative	CGA064250_10884
Mouse L5178Y/TK cells	L5178Y/TK +/- mouse lymphoma mutagenicity test *in vitro*	94.1	0 to 90 µg/ml, - activation 0 to 70 µg/ml, + activation	Negative	CGA064250_10886

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

Table 9. Ecotoxicology profile of propiconazole technical material

Species	Test	Purity % [7]	Guideline, duration, doses and conditions	Result	Study number
Anas platyrhynchos [Mallard duck]	Acute toxicity	89.5	FIFRA Subdivision E, Section 71-1 and EPA Series 850. 398, 631, 1000, 1590 and 2510 mg/kg body weight	LD50 > 2510 mg a.i./kg body weight	CGA64250/0191
Colinus virginianus [Bobwhite quail]	Acute toxicity	89.5	FIFRA Subdivision E, Section 71-1 and EPA Series 850. 398, 631, 1000, 1590 and 2510 mg/kg body weight	LD50 ≥ 2510 mg a.i./kg body weight	CGA64250/0193
Anas platyrhynchos [Mallard duck]	Chronic toxicity	90.7	Guideline not reported 20 week reproductive study equivalent to OECD 206 25, 100, 300 and 1000 mg/kg	NOEL = 300 mg/kg	CGA64250/0197
Colinus virginianus [Bobwhite quail]	Chronic toxicity	90.7	Guideline not reported 20 week reproductive study equivalent to OECD 206 25, 100, 300 and 1000 mg/kg	NOEL = 1000 mg/kg	CGA64250/0200
Leiostomus xanthurus [Spot]	Acute toxicity	90.7	EG&G Bionomics Marine Research Laboratory Protocol 96 hr acute test equivalent to OECD 203 0.53, 0.93, 1.52, 2.84 and 5.02 mg/l	LC50 = 2.6 mg/L	CGA64250/0207
Oncorhynchus mykiss [rainbow trout]	Acute toxicity	92.4	OECD 203 96 hr acute test 1.0, 1.8, 3.2, 5.8 and 10 mg/L	LC50 = 4.3 mg/L	CGA64250/4196
Cyprinodon variegatus [sheepshead minnow]	Chronic toxicity	91.7	U.S. EPA Pesticide Registration Guidelines “Life-Cycle-Tests with Fish”, Ref.No. 72-5; 100d fish full life cycle 0.016, 0.038, 0.068, 0.15, 0.29 and 0.55 mg/l	NOEC = 0.068 mg/L	CGA64250/0210
Pimephales promelas [fathead minnow]	Chronic toxicity	95.2	Adapted from OPPTS Draft Guideline 850.1500 and OECD draft proposal for fish two generation test guideline (2002) 253d fish full life cycle 0.0079, 0.021, 0.063, 0.188 and 0.558 mg/L	NOAEC = 0.188 mg/L	CGA064250_10944

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

Species	Test	Purity % [7]	Guideline, duration, doses and conditions	Result	Study number
Pimephales promelas [fathead minnow]	Chronic toxicity	95.2	OECD Guidelines for Testing of Chemicals, Section 2 - Effects on Biotic Systems, Method 229: Fish Short Term Reproduction Assay (7 September 2009) US EPA Endocrine Disruptor Screening Program Test Guidelines, OPPTS 890.1350: Fish Short-Term Reproduction Assay (Public Draft, October 2009) 21d short term reproduction assay 0.010, 0.12 and 1.0 mg a.s./L	NOEC > 0.12 mg/L (screening study* not suitable for risk assessment)	CGA064250_10739
Xenopus laevis [African clawed frog]	Chronic toxicity	95.2	OECD Guideline for the Testing of Chemicals. No. 231. Amphibian Metamorphosis Assay. OECD, 2009. Endocrine Disruptor Screening Program Test Guidelines OPPTS 890.1100 Amphibian Metamorphosis (Frog). EPA 740-C-09-002. October 2009. 21d metamorphosis assay 0.0056, 0.056 and 0.57 mg a.i./L	NOEC > 0.056 mg/L (screening study* not suitable for risk assessment)	CGA064250_50878
Daphnia magna [water flea]	Acute toxicity	92.4	48 hr acute toxicity OECD 202 0.5, 1.0, 2.0, 4.0, 8.0 and 16 mg/L	EC50 = 10.2 mg/L	CGA64250/4294
Mysidopsis bahia [mysid shrimp]	Acute toxicity	90.7	Guideline not reported; 96 hr acute toxicity study 0.16, 0.46, 0.75, 1.42 and 2.9 mg/L	LC50 = 0.51 mg/L	CGA64250/0215
Procambarus sp [crayfish]	Acute toxicity	90.7	Methods for acute toxicity tests with fish, macroinvertebrates and amphibians" (US EPA, Ecological Research Series (EPA-660/3-75-009, 61 pp., 1975). 96 hr acute toxicity study 22, 36, 60 and 100 mg/L	LC50 = 42 mg/L	CGA64250/0211
Daphnia magna	Chronic toxicity	90.7	Methods for acute toxicity tests with fish, macroinvertebrates and amphibians" (US EPA, Ecological Research Series (EPA-660/3-75-009, 61 pp., 1975); 21d reproduction study 0.05, 0.14, 0.31, 0.69 and 1.3 mg/L	NOEC = 0.31 mg/L	CGA64250/0214

Species	Test	Purity % [7]	Guideline, duration, doses and conditions	Result	Study number
Daphnia magna	Chronic toxicity	95.2	OECD 211; 21d reproduction study 0.18, 0.37, 0.73, 1.5 and 2.9 mg/L	NOEC = 0.37 mg/L	CGA064250_51265
Mysidopsis bahia [mysid shrimp]	Chronic toxicity	90.7	Guideline not reported; 28d chronic toxicity test 0.054, 0.114, 0.205, 0.507 and 0.882 mg/L	NOEC = 0.114	CGA64250/0216
Crassostrea virginica [eastern oyster]	Chronic toxicity	90.7	Guideline not reported; 96 hr growth inhibition study 0.5, 1.0, 2.0, 4.0 and 8.0 mg/L	EC50 = 1.7 mg/L	CGA64250/0217
Chironomus riparius [midge]	Chronic toxicity	92.4	OECD Guideline For Testing Of Chemicals, Proposal For Toxicity Test With Chironomidae, May 1998 [equivalent to OECD 216/217]; 28d chronic toxicity test a) 0.25, 0.50, 1.0, 2.0, 4.0, 8.0 and 16.0 mg/L b) 25, 50, 100, 200 and 400 mg/kg sediment	NOEC development = 4.0 mg/L water NOEC emergence = 25 mg/kg sediment	CGA64250/4169
Pseudokirchneriella subcapitata [green algae]	Chronic toxicity	95.2	OECD 201; 96 hr algal growth inhibition assay. 0.042, 0.13, 0.46, 1.37, 4.63 and 14.7 mg/L	96hr ErC50 = 1.0 mg/L	CGA064250_10713
Eisenia fetida [earthworm]	Acute toxicity	94.9	OECD 207; 14d acute toxicity test 62.5, 125, 250, 500 and 1000 mg/kg dry soil	LD50 = 686 mg/kg	CGA64250/4258
Activated sludge	Respiration inhibition test	99.2	Guideline not reported; equivalent to OECD 209 1.05, 4.5, 12.0, 32.0 and 116.0 mg/L	EC50 >100 mg/L	CGA64250/2588

* Screening studies with only 3 test concentrations and wide spacing factors (10x) therefore NOECs do not represent accurate values for risk and/or hazard assessment.

ANNEX 2

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