



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E – Food Safety: plant health, animal health and welfare, international questions
E1 - Plant health

Propiconazole
SANCO/3049/99-Final
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THE VIEWS OF THE COMMISSION SERVICES**

Review report for the active substance **propiconazole**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 15 April 2003 in view of the inclusion of propiconazole in Annex I of Directive 91/414/EEC

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of propiconazole, made in the context of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

Commission Regulation (EEC) No 3600/92⁽¹⁾ laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, as last amended by Regulation (EC) No 2266/2000⁽²⁾, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Propiconazole is one of the 90 existing active substances covered by this Regulation.

In accordance with the provisions of Article 4 of Regulation (EEC) No 3600/92, Ciba-Geigy Ltd. on 7 July 1993, Sanachem GmbH on 25 April 1995, Makhteshim Agan on 20 July 1993 and Barclay Chemicals (R&D) Ltd. on 25 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance propiconazole in Annex I to the Directive.

¹ OJ No L 366, 15.12.1992, p.10.

² OJ No L 259, 13.10.2000, p.27.

In accordance with the provisions of Article 5 of Regulation (EEC) No 3600/92, the Commission, by its Regulation (EEC) No 933/94⁽³⁾, as last amended by Regulation (EC) No 2230/95⁽⁴⁾, designated Finland as rapporteur Member State to carry out the assessment of propiconazole on the basis of the dossiers submitted by the notifiers. In the same Regulation, the Commission specified furthermore the deadline for the notifiers with regard to the submission to the rapporteur Member States of the dossiers required under Article 6(2) of Regulation (EEC) No 3600/92, as well as for other parties with regard to further technical and scientific information; for propiconazole this deadline was 30 April 1996.

Ciba-Geigy Ltd (subsequently Novartis Crop Protection AG, now Syngenta), Sanachem GmbH (subsequently Dow AgroScience), Makhteshim Agan and Barclay Chemicals (R&D) Ltd. submitted each a dossier to the rapporteur Member State. Novartis Crop Protection AG submitted in time a dossier which did not contain substantial data gaps, taking into account the supported uses. Therefore Novartis Crop Protection AG was considered to be the main data submitter. Sanachem GmbH and Barclay Chemicals (R&D) Ltd. did not submit sufficiently complete dossiers, Makhteshim Agan has right to refer to the dossier submitted by Novartis Crop Protection AG. No information has further been submitted by third parties.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Finland submitted on 30 November 1998 to the Commission the report of its examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of propiconazole in Annex I to the Directive. Moreover, in accordance with the same provisions, the Commission and the Member States received also the summary dossier on propiconazole from Novartis Crop Protection AG, on 25 October 1999.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the Commission forwarded for consultation the draft assessment report to all the Member States on 30 August 1999 as well as to Novartis Crop Protection AG being the main data submitter, on 08 September 1999.

The Commission organised an intensive consultation of technical experts from a certain number of Member States, to review the draft assessment report and the comments received thereon (peer review), in particular on each of the following disciplines:

- identity and physical /chemical properties ;
- fate and behaviour in the environment ;
- ecotoxicology ;
- mammalian toxicology ;
- residues and analytical methods ;
- regulatory questions.

The meetings for this consultation were organised on behalf of the Commission by the Pesticide Safety Directorate (PSD) in York, United Kingdom, from November 1999 to June 2000.

³ OJ No L 107, 28.04.1994, p.8.

⁴ OJ No L 225, 22.09.1995, p.1.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States on 15 June 2001 as well as to the main data submitter (now Syngenta) on 01 June 2001 for comments and further clarification.

According to Commission Decision of 14 February 2001 concerning the decision on the possible inclusion of certain active substances into Annex I to Council Directive 91/414/EEC⁵ a deadline of 31.10.2001 for submission of further studies was established.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the dossier, the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications on the remaining issues, received after the peer review were referred to the Standing Committee on the Food Chain and Animal Health, and specialised working groups of this Committee, for final examination, with participation of experts from the 15 Member States. This final examination took place from September 2002 to February 2003 and was finalised in the meeting of the Standing Committee on 15 April 2003.

The review did not reveal any open questions or concerns which would have required a consultation of the Scientific Committee on Plants.

The present review report contains the conclusions of the final examination; given the importance of the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications submitted after the peer review as basic information for the final examination process, these documents are considered respectively as background documents A, B and C to this review report and are part of it.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, has been developed and finalised in support of the Directive 2003/70/EC⁶ concerning the inclusion of propiconazole in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing propiconazole they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

This review report provides also for the evaluation required under Section A.2.(b) of the above mentioned uniform principles, as well as under several specific sections of part B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the active substance in Annex II of the directive, submitted for the purpose of inclusion of the active substance in Annex I, as well as the result of the evaluation of those data.

In accordance with the provisions of Article 7(6) of Regulation (EEC) No 3600/92, Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request. Moreover the Commission will send a copy of this review report (not including the background documents) to all operators having notified for this active substance under Article 4(1) of this Regulation.

⁵ OJ No L 49, 20.02.2001, p.13.

⁶ OJ No L 184, , p.19.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC. It is therefore recommended that this review report would not be accepted to support any registration outside the context of Directive 91/414/EEC, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.

3. Overall conclusion in the context of Directive 91/414/EEC

The overall conclusion from the evaluation is that it may be expected that plant protection products containing propiconazole will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each propiconazole containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the main data submitter and mentioned in the list of uses supported by available data (attached as Appendix IV to this Review Report).

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 4(1) and of the uniform principles laid down in Annex VI of Directive 91/414/EEC.

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI; excluding water and products of animal origin) for a 60 kg adult is 2.3 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). Additional intake from water and products of animal origin are not expected to give rise to intake problems.

The review has identified several acceptable exposure scenarios for operators, workers and bystanders, which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4 (1) (b) (iv) and (v) of Directive 91/414/EEC, provided that certain conditions are taken into account as detailed in section 6 of this report.

4. Identity and Physical/chemical properties

The main identity and the physical/chemical properties of propiconazole are given in Appendix I.

The active substance shall comply with the FAO specification and there seem not to be reasons for deviating from that specification; the FAO specification is given in Appendix I of this report. However the minimum purity should be 920 g/kg.

The review has established that for the active substance notified by the main data submitter Novartis Crop Protection AG, none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

In accordance with the provisions of Article 13(5) of Directive 91/414/EEC, Finland is also satisfied, on the basis of the information currently available, that the substances notified by two data submitters (Sanachem GmbH and Makhteshim Agan) do not, in the meaning of Article 13(2) and (5) of the Directive, differ significantly in degree of purity and nature of impurities from the composition registered in the dossier submitted by the main data submitter. Barclay Chemicals (R&D) Ltd. did not submit sufficient data on degree of purity and nature of impurities.

5. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 4(1) of Directive 91/414/EEC and the uniform principles laid down in Annex VI of that Directive, the most important endpoints as identified during the re-evaluation process are set out under point 1 above. These endpoints are listed in Appendix II.

6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing propiconazole

On the basis of the proposed and supported uses (as listed in Appendix IV), the following particular issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

- Member States should pay particular attention to the protection of non-target arthropods and aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate.
- Member States should pay particular attention to the protection of soil organisms for applications rates exceeding 625 g a.i./ha (e.g. uses in turf). Conditions of authorisation should include risk mitigation measures (e.g. spotwise application scheme), where appropriate.

7. List of studies to be generated

No further studies were identified which were at this stage considered necessary in relation to the inclusion of propiconazole in Annex I under the current inclusion conditions.

Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions. This may particularly be the case for:

- Higher tier studies on the predatory mite *Typhlodromus pyri*.

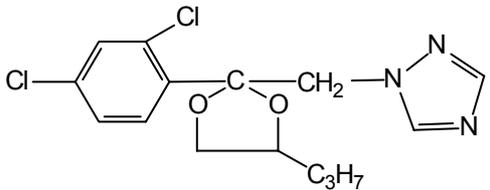
8. Information on studies with claimed data protection

For information of any interested parties, Appendix III gives information about the studies for which the main data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion. This information is only given to facilitate the operation of the provisions of Article 13 of Directive 91/414/EEC in the Member States. It is based on the best information available to the Commission services at the time this review report was prepared; but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 13 of the Directive 91/414/EEC neither does it commit the Commission.

9. Updating of this review report

The technical information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Such adaptations will be examined and finalised in the Standing Committee on the Food Chain and Animal Health, in connection with any amendment of the inclusion conditions for propiconazole in Annex I of the Directive.

APPENDIX I**Identity, physical and chemical properties****PROPICONAZOLE**

Common name (ISO)	Propiconazole
Chemical name (IUPAC)	(±)-1-[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
Chemical name (CA)	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl] methyl]-1H-1,2,4-triazole
CIPAC No	408
CAS No	60207-90-1
EEC No	EINECS: 262-104-4
FAO SPECIFICATION	AGP: CP/330, (1995); min. 880 g/kg
Minimum purity	920 g/kg
Molecular formula	C ₁₅ H ₁₇ Cl ₂ N ₃ O ₂
Molecular mass	342.2
Structural formula	

Melting point	-23 °C (98.8% pure)
Boiling point	No boiling point, decomposition begins around 355 °C.
Appearance	Clear, viscous liquid
Relative density	1.32 at 20 °C (99.8 % pure)
Vapour pressure	$5.6 \cdot 10^{-5}$ Pa at 25 °C (99.1% pure)
Henry's law constant	$9.2 \cdot 10^{-5}$ Pa · m ³ · mol ⁻¹
Solubility in water	150 mg/l at 20 °C (pH 5.2)
Solubility in organic solvents	Acetone, dichloromethane, methanol, ethyl acetate and xylene completely miscible at 20 °C n-heptane 1.585 g/l at 20 °C
Partition co-efficient (log P_{ow})	3.72 at 25 °C and pH 6.6
Hydrolytic stability (DT₅₀)	DT ₅₀ = 25 - 85 days in whole system
Dissociation constant	PK _a = 1.09 at 20 °C
Quantum yield of direct photo-transformation in water at λ >290 nm	No absorption > 290 nm.
Flammability	Not classified as highly flammable.
Explosive properties	Not explosive.
UV/VIS absorption (max.)	λ _{max} : 220 nm, ε _{max} : 11666 l mol ⁻¹ cm ⁻¹
Photostability in water (DT₅₀)	DT ₅₀ = 47 - 984 days at 30 - 50 °N latitude

APPENDIX II

ENDPOINTS AND RELATED INFORMATION

PROPICONAZOLE

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	86% within 48 h
Distribution:	Widely distributed; highest residues in liver and kidneys
Potential for accumulation:	No evidence of accumulation
Rate and extent of excretion:	95% in 48 h, in about equal amounts in urine and feces (enterohepatic re-circulation)
Toxicologically significant compounds:	Parent compound and metabolites (animals). Triazolyl alanine and triazolyl acetic acid formed only in plants; not toxicologically significant
Metabolism in animals:	Extensively metabolised (>20 metabolites identified in rat urine)

Acute toxicity

Rat LD ₅₀ oral:	Appr. 1500 mg/kg bw
Rat LD ₅₀ dermal:	>4000 mg/kg bw
Rat LC ₅₀ inhalation:	>5.8 mg/l/4 h, nose-only
Skin irritation:	Not irritating
Eye irritation:	Not irritating
Skin sensitization (test method used and result):	Skin sensitizer (Maximisation test)

Short term toxicity

Target / critical effect:	Liver toxicity (mice)
Lowest relevant oral NOAEL / NOEL:	20 ppm (2.7 mg/kg bw/day; 17 week, mice)
Lowest relevant dermal NOAEL /NOEL:	200 mg/kg bw/day (21 day, rabbit)
Lowest relevant inhalation NOAEL /	21 mg/m ³ (90 days rat; 6 h head-only/day)

NOEL:

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Genotoxicity

No genotoxic effects

Long term toxicity and carcinogenicity

Target / critical effect:

Liver in rats and mice

Lowest relevant NOAEL:

100 ppm (3.6 mg/kg bw/day)

Carcinogenicity:

Liver tumors (benign and malignant) in male mice

Reproductive toxicityTarget / critical effect -
Reproduction:Reduced litter size, pup weight and viability.
Effects at dose levels causing parental toxicityLowest relevant reproductive
NOAEL / NOEL:

Rat: 100 ppm (8 mg/kg bw/day)

Target / critical effect -
Developmental toxicity:Slight increase in cleft palate in rat, also
increased visceral and skeletal variations at dose
levels causing marked maternal toxicityLowest relevant developmental
NOAEL / NOEL:

Rat: 30 mg/kg bw/day

Delayed neurotoxicity

No further data required

Other toxicological studies

Triazolyl alanine and triazolyl acetic acid were studied for toxicokinetics, acute toxicity, short-term toxicity and genotoxicity (also reproductive toxicity of triazolyl alanine). No adverse effects were observed. Studies on tumor promotion and induction of drug metabolising enzymes showed that propiconazole is a promoter of proliferative changes and causes induction of hepatic enzymes.

Medical data

Surveillance of manufacturing plant personnell reports four cases of compound related adverse effects (skin reactions, allergenic in one case) during handling of formulations.

Dermal testing of 20 human volunteers with epicutaneous doses up to 1% caused no dermal reactions in any of the test subjects. Three occupational exposure cases involving Tilt are reported. The occupationally exposed showed no sensitisation reactions, but chest pain and local skin reactions were observed.

A literature search for publications between 1975 and 2000 has been performed using 32 different data bases. No studies indicating possible health effects in humans attributable to the use of propiconazole was found.

Summary

	Value	Study	Safety factor
ADI:	0.04 mg/kg bw/day	Chronic rat study	100
AOEL systemic:	0.1 mg/kg bw/day	2-generation rat study	100
AOEL inhalation:	Not relevant	Not relevant	Not relevant
AOEL dermal:	Not relevant	Not relevant	Not relevant
ARfD (acute reference dose):	0.3 mg/kg bw/day	Developmental study in rat	100

Dermal absorption

The estimated dermal absorption in humans is 0.9%, 1.6% and 2.4% at exposure to undiluted product or to typical field crop or stone fruit treatment dilutions, respectively, based on an *in vivo* study in rat and a comparative *in vitro* dermal penetration study using rat and human skin.

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:

Propiconazole:
-CO₂ evolved 0.2 - 0.5% (triazole labelled; 84 d and 105 d), 2.0 % (triazole labelled; 120 d) and 29.3 - 35.4 % (phenytring labelled; 84 d) of AR

-1,2,4-triazole (was used as a starting substance):
CO₂ evolved 0.9 - 48.8 % of AR (84 - 168 d), 1.6 - 32.2 % of AR (120 d)

-CGA 118 245 CO₂ 0.1 - 0.2 % of AR (3 soils, 5 d)

Non-extractable residues after 100 days:

Propiconazole:
-triazole labelled 14.1 - 15.5 % of AR (84 d), 47.3 % of AR (120 d)
-phenytring labelled 23.3 - 27.3 % of AR (84 d)
-triazole labelled 3.4 - 24.6 % of AR (105 days) in different conditions

-1,2,4-triazole (was used as a starting substance):
52.7 % of AR (84 d), 41.8 - 66.2 % of AR (3 soils, 120 d)

-CGA 118 245 non-extractables 9.8 - 12.3 % of AR (3 soils, 5 d)

Major metabolites above 10 % of applied active substance: name and/or code % of applied rate (range and maximum)

-1,2,4-triazole (CGA 71019) 24 % and 43 % of AR
-CGA 118 245 (U3) 22 %

Supplemental studies

Anaerobic:

- triazole labelled propiconazole: CO₂ evolved \leq 0.1 % of AR and non-extractable residues 9.1 % of AR (84d)
- triazole labelled propiconazole: CO₂ evolved 0.4 % of AR and non-extractable residues 20.2 % of AR (119 d)

Soil photolysis:

not significant; 91.5 – 97.5 % of AR as propiconazole (24 hours)
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Remarks:

None

Rate of degradation**Laboratory studies**DT_{50lab} (20 °C, aerobic):

Propiconazole: DT _{50lab} (20 – 25 °C, aerobic): 29 - 70 days (n = 9) and 316 days (n = 1) at low moisture (30 % FC)
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1,2,4-triazole: DT _{50lab} 2 – 12 days (20 °C) (n = 3) DT _{50lab} 98 days (25 °C) (n = 1) (high application rate, 1 mg/kg)
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-CGA 118 245: DT ₅₀ , DT ₉₀ < 1 d

DT_{90lab} (20 °C, aerobic):

-Propiconazole: DT _{90lab} (20 - 25 °C, aerobic): 97 - 336 days (n = 7)

-1,2,4-triazole DT _{90lab} 41 – 202 (20 °C, 3 soils)
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DT_{50lab} (10 °C, aerobic):

-Propiconazole: DT _{50lab} (10 °C, aerobic): 430 days (n = 1); DT _{90lab} (10 °C, aerobic): 1430 days. Both values extrapolations.
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DT _{50lab} (13.5 °C, aerobic): 80 days (n = 1)

DT_{50lab} (20 °C, anaerobic):

-Propiconazole, 1,2,4-triazole: DT _{50lab} (20 °C, anaerobic): not determined

Field studies (country or region)DT_{50f} from soil dissipation studies:

Propiconazole: DT _{50f} : Switzerland, 28 days (n = 1) USA, 20 - 103 days (n = 4) Switzerland, 120 - 140 days (n = 2) Germany, 17 - 411 days (n = 6)

DT_{90f} from soil dissipation studies:

Propiconazole: DT _{90f} : 192 – 2099 days (n = 13) DT _{90f} longer than one year cannot be excluded

Soil accumulation studies:

- France: maximum residues of propiconazole were < 0.02 – 0.12 mg/kg and 1,2,4-triazole < 0.01 mg/kg within 6 – 7 years of annual 2 x 125 g a.i./ha use
- Switzerland: maximum residues of propiconazole were < 0.02 – 0.06 mg/kg and 1,2,4-triazole < 0.01 – 0.05 mg/kg within 10 years of annual 2 – 3 x 125 g a.i./ha
- Canada: maximum residues of propiconazole were 0.03 mg/kg - 0.1 mg/kg (250 g a.i./ha/year) and 0.03 – 0.17 mg/kg (500 g a.i./ha/year) within two years; 1,2,4-triazole was not found above detection limit of 0.1 ppm
- Canada: maximum residues of propiconazole were 0.03 mg/kg - 0.09 mg/kg (cumulative use rate 250 – 375 g a.i./ha within two years) and 0.04 – 0.18 mg/kg (cumulative use rate 500 – 750 g a.i./ha) within three years; 1,2,4-triazole was found at trace amounts in higher use rate plots
- Finland: the residues of propiconazole were 0.01 – 0.06 mg/kg (0- 20 cm, 7 fields) except one residue of 0.26 after many years use

Soil residue studies:

See above

Remarks:

e.g. effect of soil pH on degradation rate

No data

Adsorption/desorption K_f / K_{oc} :

Propiconazole:
 K_{oc} 382 – 1789 (9 soils)
 1,2,4-triazole:
 K_{oc} 43 – 202 (5 soils)
 CGA 118 245:
 K_{oc} 101 – 166 (3 soils)

 K_d

Propiconazole:
 K_d 455 – 2279 (9 soils)

pH dependence:

No

Mobility

Laboratory studies:

Column leaching:

Propiconazole:

< 0.5 % of the applied radioactivity found in the leachate (4 soils, after 2 days of 200 ml watering)

Aged residue leaching:

Propiconazole:

1. After 6 months of ageing and 16 days irrigation of 200 mm, 0.9 - 1.6 % of AR was found in leachates (2 soils)
 2. After 30 days of ageing and 16 days irrigation of 200 mm, 0.4 - 0.6 % of AR was found in leachates (2 soils)
 3. After 30 days of ageing and irrigation of 45 days of 571 mm, 2.8 - 7.5 % of AR was found in leachates (2 soils)
- 2 metabolites found in leachates, triazole acetic acid and another unidentified; concentrations not given.

1,2,4-triazole:

1. After 31 – 32 days of ageing and 79 days of irrigation of 521 mm, 42 – 46 % of AR was found in leachates (2 soils)

Field studies:

Lysimeter/Field leaching studies:

Norway:

- field lysimeters: 36 plots covered with grass, barley or no vegetation; application dose not clear; first year propiconazole was not found in the leachates, second year found in the leachate from plots without vegetation and plots with barley (cumulative leaching 0.002 - 0.014 % of the applied dose). Concentrations not given.

Remarks:

None

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:	Propiconazole (pH 1 - 13): 94 – 106 % of the radioactivity found after 28 days (70 °C)
Major metabolites:	Not relevant
Photolytic degradation:	Propiconazole: not significant (DT ₅₀ 94 - 249 days)
Major metabolites:	Not relevant

Biological degradation

Readily biodegradable:	Not readily biodegradable
Water/sediment study: DT ₅₀ water:	DT _{50water} 5.4 days (1 Rhine river + sediment, 175 day study) DT _{50water} 6.4 days (1 pond water + sediment, 175 day study)
DT ₉₀ water:	Not estimated
DT ₅₀ whole system:	DT ₅₀ whole system 636 days (1 Rhine river + sediment, 175 days study) DT ₅₀ whole system 485 days (1 pond water + sediment, 175 study)
DT ₉₀ whole system:	Not estimated
Distribution in water / sediment systems (active substance)	96.5 – 98.1 % of AR in water at the beginning of the study and 7.1 – 8.4 % of AR in water at the end of the study (175 days); respective amounts in the sediment were 2.0 and 83.0 – 87.5 % of AR (175 days); non-extractable residues were found at the end of the study 7.6 –9.1 %; mineralisation 0.4 % of AR (1 Rhine water and 1 pond water)
Distribution in water / sediment systems (metabolites)	Eight metabolites were found CGA 217 495 2.8 – 2.9 %; CGA 91305 3.1 – 5.0 %; M3 (unknown) 3.1 – 4.4 %; 1,2,4-triazole 2.1 – 2.3 % after 90 to 175 days. Others were found at concentrations below 1.3 % (1 Rhine water and 1 pond water)
Accumulation in water and/or sediment:	No data

Degradation in the saturated zone Degradation in the saturated zone: not available

Remarks: None

2.3 Fate and behaviour in air

Volatility

Vapour pressure: $5.6 \cdot 10^{-5}$ Pa at 25 °C (99.1% pure)

Henry's law constant: $9.2 \cdot 10^{-5}$ Pa · m³ · mol⁻¹

Photolytic degradation

Direct photolysis in air: No photolysis

Photochemical oxidative degradation in air: 3.4 - 14 hours (calculated with Atkinson method)

DT₅₀:

Volatilisation: From plant surfaces: about 30 % (20 °C, 24 hours)
From soil: not significant

Remarks: None

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	Propiconazole: Acute toxicity LD ₅₀ > 1490 mg a.i./kg body weight Long-term toxicity NOEL 500 ppm
Acute toxicity to birds:	Propiconazole: LD ₅₀ > 2510 mg a.i./kg body weight (mallard duck, bobwhite quail)
Dietary toxicity to birds:	Propiconazole: LC ₅₀ > 5620 mg a.i./kg food (mallard duck, bobwhite quail)
Reproductive toxicity to birds:	Propiconazole: NOEC > 300 mg a.i./kg food (mallard duck)
Short term oral toxicity to mammals:	Lowest relevant oral NOAEL/NOEL 20 ppm (2.7 mg/kg bw/day; 17 week, mice)

Aquatic Organisms

	Group	Test substance	Time - scale	End point	Toxicity (mg/l)
Acute toxicity fish:	Leiostomus xanthurus	Propiconazole	96 h	LC ₅₀	2.6
	Oncorhynchus mykiss	Metabolite, CGA 217 495	96 h	LC ₅₀	> 100
	Lepomis macrochirus	Tilt 250 EC (A 6097 K)	96 h	LC ₅₀	6.7
Long term toxicity fish:	Cyprinodon variegatus	Propiconazole	100 d	NOEC	0.068
Bioaccumulation fish:	116 (bluegill); 98 % of propiconazole has been eliminated during 14 day depuration period				
Acute toxicity invertebrate:	Daphnia magna	Propiconazole	48 h	EC ₅₀	10.2
	Daphnia magna	Metabolite, CGA 217 495	48 h	EC ₅₀	> 100
	Daphnia magna	Tilt 250 EC (A 6097 K)	48 h	EC ₅₀	6.9
	Mysidopsis bahia	Propiconazole	96 h	LC ₅₀	0.51
	Crassostrea virginica	Propiconazole	96 h	EC ₅₀	1.7
Chronic toxicity invertebrate:	Daphnia magna	Propiconazole	21 d	NOEC	0.31
Acute toxicity algae:	Pseudokirchneriella subcapitata	Metabolite, CGA 217 495	72 h	E _r C ₅₀	94.0
	Scenedesmus				

Chronic toxicity sediment dwelling organism:	subspicatus	Tilt 250 EC (A 6097 G)	72h	EC ₅₀	0.23
	Selenastrum capricornutum	Tilt 250 EC (A 6097 K)	72 h	E _r C ₅₀	17.0
	Navicula seminulum	Propiconazole	11 d	EC ₅₀	0.093
	Chironomus riparius	Propiconazole	28 d	Emergence, NOEC Development, NOEC	8.0 (water) 25.0 (sed.) 4.0 (water) 50.0 (sed.)

Honeybees

Acute oral toxicity:

LD₅₀ > 100 ug/ai/bee (propiconazole)

Acute contact toxicity:

LD₅₀ > 100 µg/ai/bee (propiconazole)

Other arthropod species

Test species

% Effect

Coccinella septempunc.

4% mortality
 - 15 % reproductivity increased
 (125 g ai/ha, A 6097 G)

Syrphus corollae

45 % mortality
 49 % fertility
 72 % beneficial capacity
 (125 g ai/ha, A 6097 G)

Typhlodromus pyri

49.5, 85.9, 91.4 % mortality
 81.9 % benefical capacity
 (18.8, 94, 250 g ai/ha, A 6097 K)

Poecilus cupreus

0 % (Mortality)
 (18.8, 94, 250 g ai/ha, A 6097 K)

Chrysoperla carnea

- 8.6 %, - 8.6% and 0 % (Mortality)
 3.4 %, 19.6 % and 23.0 % (Reproduction)
 (18.8, 94, 250 g ai/ha, A 6097 K)

Aphidius rhopalosiphi

2.5 %, 0 % and 0 % (Mortality)
25.9 %, 24.4 and – 24.1 % (Beneficial capacity)
(18.8, 94, 250 g ai/ha, A 6097 K)

Aphidius rhopalosiphi

0 % (Mortality)
- 17 %, 23 % and 11 % (Fecundity)
(18.8, 94, 250 g ai/ha, A 6097 K)

Typhlodromus pyri

100 % beneficial capacity
(1 or 2 times 125 g ai/ha, Sanazole 250 EC)

Aphidius rhopalosiphi

90 % and 100 % (Mortality)
(125 g ai/ha, 250 g ai/ha, Sanazole 250 EC)

Euseius stipulatus

No statistically significant difference compared to the control in Portuguese apricot field (250 – 575 g ai/ha, A 6097 K)

Earthworms

Acute toxicity:

-Propiconazole : LC₅₀ 686 mg/kg
-Tilt 250 EC: LC₅₀ 1000 mg/kg (250 mg a.i./kg)
1,2,4-triazole: LC₅₀ > 1000mg/kg
- CGA 118 245 LC₅₀ > 1000 mg/kg

Reproductive toxicity:

- A 6097 K: No statistically significant differences were found at the concentrations corresponding to use rates of 125, 250 and 625 g a.i./ha

Soil micro-organisms

Nitrogen mineralization:

- Tilt 250 EC (A 6097 G): Difference in NH₄-N, NO₂-N and NO₃-N concentrations at dose levels of 0.67 mg/kg and 6.7 mg/kg compared to the control were below 25 % after 28 days exposure
- CGA 71019: differences in the soil respiration and nitrification rates were not significant

Carbon mineralization:

- Tilt 250 EC (A 6097 G): Difference in dehydrogenase activity at dose levels of 0.67 mg/kg and 6.7 mg/kg compared to the control were below 25 % after 28 days exposure
- there was no statistically significant effects of propiconazole containing product EC 250

(A 6097 K) in the decomposition rates of
organic material in the litter bag test

APPENDIX IIIA**PROPICONAZOLE**

List of studies for which the main submitter has claimed data protection and which during the re-evaluation process were considered as essential for the evaluation with a view to Annex I inclusion.

B.1 Identity, B.2 Physical and chemical properties, B.3 Data on application and further information, B.4 Proposals for classification and labelling, B.5 Methods of analysis

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports¹ on previous use in granting national authorizations
IIA 2.9.3	Abildt U.,	1995	Estimation of the environmental photochemical half-life of CGA 64250 in surface water, Ciba-Geigy Ltd., Basle, Rep.N°46/94, 24.01.1995 GLP, not published Novartis File No CGA64250/2563	
IIA 2.15	Angly, H.	2000	Oxidizing properties (liquid) of CGA 64250 tech. Institute of Safety and Security, Testing Laboratory, Basle, Switzerland. Study Report No. 2000.4012.OPL GLP, not published Novartis File No CGA64250/4299	
IIA 1.8.	Burkhard N.	1995	Manufacturing process - CGA 64250 Ciba-Geigy Ltd., Basle, Process Description, 15.02.1995 Non GLP, not published Novartis File No CGA64250/2593	
IIA 1.9	Burkhard N.	1995	Purity and by-products of techn. A.I. , Ciba-Geigy Ltd., Basle, Data Sheet, 06.02.1995 Non GLP, not published Novartis File No CGA64250/1986	

¹ Entries are based on information received from the Notifier(s) and in certain cases Member States. Neither the Commission nor the Member States are responsible for the completeness or validity of this information received.

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports¹ on previous use in granting national authorizations
IIA 1.11	Burkhard N.	1995	Analytical certificates of technical propiconazole used for the determination of physico-chemical properties Ciba-Geigy Ltd., Basle, 20.02.1995 GLP, not published Novartis File No -	
IIA 2.3	Burkhard N.	1994	Henry's Law Constant, Ciba-Geigy Ltd., Basle, Data Sheet, 12.09.1994 Non GLP, not published Novartis File No CGA64250/2403	
IIA 2.1.2	Das R.	1993	Report on boiling point/boiling range, Ciba-Geigy Munchwilen AG, Munchwilen, Rep N° 16313, 08.11.1993 GLP, not published Novartis File No CGA64250/2290	
IIA 2.2	Das R.	1993	Report on density, Ciba-Geigy Munchwilen AG, Munchwilen, Rep N° 16314, 08.11.1993 GLP, not published Novartis File No CGA64250/2289	
IIA 2.4	Das R.	1994	Report on general physico-chemical properties (pure active ingredient), Ciba-Geigy Munchwilen AG, Munchwilen, Rep N° 20751, 22.03.1994 GLP, not published Novartis File No CGA64250/2334	
IIA 2.4	Das R.	1993	Report on general physico-chemical properties (technical grade active ingredient), Ciba-Geigy Munchwilen AG, Munchwilen Rep N° 16311, 08.11.1993 GLP, not published Novartis File No CGA64250/2083	
IIA 2.9.2	Das Y.T	1990	Photodegradation of [Phenyl(U)- ¹⁴ C] propiconazole in aqueous solution buffered at pH 7 under artificial sunlight, Innovative Scientific Services Inc., Piscataway NJ, USA, Rep. N° ISSI 90070, 26.11.1990 GLP, not published Novartis File No CGA64250/1825	
IIA 4.2.2	Formica, G.	1991	CGA 64250, Determination of free 1,2,4-triazole by high performance liquid chromatography, soil, Ciba-Geigy Ltd., Basel, Rep.No. REM-130-03, 13.09.1991 Non GLP, not published Novartis File No CGA64250/1983	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports¹ on previous use in granting national authorizations
IIA 4.2.2	Formica, G.	1992	Determination of free 1,2,4-triazole by high performance liquid chromatography, soil, Ciba-Geigy Ltd., Basel, Rep.No. REM-130-04, 09.04.1992 Non GLP, not published Novartis File No CGA64250/2024	
IIA 4.2.1	Formica, G.	1992	CGA 64250, Determination of total residues of CGA 64250 as 1,2,4-triazole by high performance liquid chromatography, plant material and soil, Ciba-Geigy Ltd., Basel, Rep.No. REM-130-05, 22.05.1992 Non GLP, not published Novartis File No CGA64250/2027	
IIA 4.2.1	Forrer, K.	1991	CGA 64250, Gas chromatographic determination of residues of parent compound, plant material and Soil, Ciba-Geigy Ltd., Basel, Rep.No. REM-130-02, 09.07.1991 Non GLP, not published Novartis File No CGA64250/1973	
IIA 2.1.1	Geoffroy, A.	1994	Report on freezing temperature, Ciba-Geigy Ltd., Basle, Rep N° PP-94/37P.MPR, 29.09.1994 GLP, not published Novartis File No CGA64250/2441	
IIA 2.9.4	Jäkel, K.	1990	Report on dissociation constant in water, Ciba-Geigy Ltd., Basle, Rep.N° EA-133549, 08.08.1990 GLP, not published Novartis File No CGA64250/2287	
IIA 2.8	Jäkel, K.	1987	Report on partition coefficient, Ciba-Geigy Ltd., Basle, Rep.N° AG-87-22P, 20.11.1987 GLP, not published Novartis File No CGA64250/2086	
IIA 2.6	Jäkel, K.	1987	Report on water solubility, Ciba-Geigy Ltd., Basle, Rep.N° AG-87-22P, 19.11.1987 GLP, not published Novartis File No CGA64250/2085	
IIA 1.11	Kreuzer, A.	1995	Report on chemical composition (nitrosamines) Ciba-Geigy Mönchwilten AG, Mönchwilten, Rep. N° 30011, 15.02.1995 GLP, not published Novartis File No CGA64250/2594	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports¹ on previous use in granting national authorizations
IIA 1.11	Käser, W.	1995	Report on chemical composition (5 batches) Ciba-Geigy Mönchwilen AG, Mönchwilen, Rep. N° 30040, 15.02.1995 GLP, not published Novartis File No CGA64250/2088	
IIA 2.1.1	Käser, W.	1989	Purification Report, Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep. N° AMS-181-106, 09.05.1989 Non GLP, not published Novartis File No CGA64250/2410	
IIA 2.5	Käser, W.	1994	Report on spectra, Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep.N° 28042, 20.12.1994, GLP, not published Novartis File No CGA64250/2097	
IIA 3.9	Käser, W.	1995	CGA 64250 - Statement on emergency measures in case of an accident, Ciba-Geigy Mönchwilen AG, Mönchwilen, Statement, 18.01.1995, Non GLP, not published Novartis File No CGA64250/2526	
IIA 3.8	Käser, W.	1995	CGA 64250 - Statement on procedures for destruction or decontamination, Ciba-Geigy Mönchwilen AG, Mönchwilen, Statement, 18.01.1995, GLP, not published Novartis File No CGA64250/2525	
IIA 4.1	Käser, W.	1995	Analytical Method CGA 64250 (propiconazole) by-products Ciba-Geigy Mönchwilen AG, Mönchwilen, Met. N° AK-88/6, 13.02.1995 Non GLP, not published Novartis File No CGA64250/2092	
IIA 4.1	Käser, W.	1995	Method validation for impurities in technical active substances Ciba-Geigy Mönchwilen AG, Mönchwilen, Met. N° AK-88/6, 13.02.1995 GLP, not published Novartis File No CGA64250/2093	
IIA 4.1	Käser, W.	1987	Method Validation for technical active substance Ciba-Geigy Ltd., Basel, Met. N° AW-88/4, 05.03.1987 GLP, not published Novartis File No CGA64250/2091	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports¹ on previous use in granting national authorizations
IIA 1.10	Käser, W.	1995	List of by-products (codes, names, formulae), Ciba-Geigy Münchwilen AG, Münchwilen, Overview, 21.02.1995 Non GLP, not published Novartis File No CGA64250/2596	
IIA 4.1, IIIA 5.1	Käser, W.	1991	Analytical method CGA 64250 in formulation (A-6097 K) Ciba-Geigy Ltd., Basel, Switzerland Study Report No. AF-1017/1, 26.06.1991 Non GLP, not published Novartis File No CGA64250/2850	
IIA 4.1, IIIA 5.1	Käser, W.	1991	Method validation for formulated products AF-1017/1 (A-6097 K) Ciba-Geigy Ltd., Basel, Switzerland Study Report No. AF-1017/1, 18.06.1991 Non GLP, not published Novartis File No CGA64250/2851	
IIA 4.2.5	Maffezzoni, M. and Pointurier, R.	2000	Residue method: AGR/MOA/PROPIC-1 validated with meat, liver, kidney, fat, milk and egg. Determination of propiconazole by GC/MS. ADME Bioanalyses, Vergèze, France 2000. Study Report No. AGR/MOA/PROPIC-1, 29.12.1991 GLP, not published Novartis File No CGA64250/4386	
IIA 1.11	Maier, W.	1995	Purity of test material used in toxicity tests Ciba-Geigy Ltd., Basle, 12.01.1995 Non GLP, not published Novartis File No -	
IIA 4.2.3	Manuli, P.J.	1992	Analytical method for the determination of propiconazole in water by capillary gas chromatography, Ciba-Geigy Corp., USA, Rep.No. AG-561, 23.03.1992 Non GLP, not published Novartis File No CGA64250/2025	
IIA 4.2.5	Pointurier, R. and Duchêne, P.	2001	Validation of analytical method AGR/MOA/ PROPIC-1 for propiconazole in animal tissues. ADME Bioanalyses, Vergèze, France 2001. Study Report No. NOV/PRO/00063, 10.01.2001 GLP, not published Novartis File No CGA64250/4405	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports¹ on previous use in granting national authorizations
IIA 4.3.2	Pointurier, R. and Duchêne, P.	2000	Propiconazole in drinking and surface water, validation of method REM 10/86 with GC/MS. ADME Bioanalyses, Vergèze, France 2000. Study Report No. NOV/PRO/00061, 28.12.2000 GLP, not published Novartis File No CGA64250/4387	
IIA 4.3.3	Pointurier, R. and Duchêne, P.	2000	Propiconazole in air: Development of a confirmatory technique with GC/MS. ADME Bioanalyses, Vergèze, France 2000. Study Report No. NOV/PRO/00062, 28.12.2000 GLP, not published Novartis File No CGA64250/4388	
IIA 2.3	Rordorf, B.F.	1988	Report on vapor pressure curve, Ciba-Geigy Ltd., Basle, Rep.N° AG-88-02P, 15.06.1988 GLP, not published Novartis File No CGA64250/2087	
IIA 2.14	Ryser, M.	1994	Report on surface tension of aqueous solutions, Ciba-Geigy Ltd., Basle, Rep N° PP-94/21T.SUR, 19.09.1994 GLP, not published Novartis File No CGA64250/2413	
IIA 2.11	Schürch, H.	1994	Report on auto-flammability of liquids, Ciba-Geigy Ltd., Basle, Rep N° PP-94/10T.AFG, 18.04.1994 GLP, not published Novartis File No CGA64250/2338	
IIA 2.12	Schürch, H.	1994	Report on determination of flash-point, Ciba-Geigy Ltd., Basle, Rep. N° PP-94/10T.FLP, 18.04.1994 GLP, not published Novartis File No CGA64250/2336	
IIA 2.13	Schürch, H.	1994	Report on explosive properties, Ciba-Geigy Ltd., Basle, Rep N° PP-94/10T.EXP, 18.04.1994 GLP, not published Novartis File No CGA64250/2337	
IIA 2.10	Stamm, E.	1994	Rate estimation of the hydroxyl radical oxidation of propiconazole - CGA 64250, Ciba-Geigy Ltd., Basle, Statement, 31.05.1994 Non GLP, not published Novartis File No CGA64250/2358	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports¹ on previous use in granting national authorizations
IIA 2.9.4	Stulz, J.	1994	Propiconazole - Dissociation constant, Ciba-Geigy Munchwilen AG, Munchwilen, Statement, 26.10.1994 Non GLP, not published Novartis File No CGA64250/2455	
IIA 2.7	Stulz, J.	1994	Report on solubility in organic solvents, Ciba-Geigy Munchwilen AG, Munchwilen, Rep N° 20752, 15.03.1994 GLP, not published Novartis File No CGA64250/2084	
IIA 4.2.2	Tribolet, R.	2001	Residue method: REM 130.10. Propiconazole (CGA 64250) Soil determination of metabolite CGA 118245 by LC-LC-MS/MS. Syngenta Crop Protection AG, Residue Analysis, Basel, Switzerland. Study Report REM 130.10, 23.10.2001 Non GLP, not published Novartis File No.CGA64250/4431.	
IIA 4.2.4	Tribolet, R.	1992	Sampling of air and determination of residues of parent compound by high performance liquid chromatography incl. validation, Ciba-Geigy Ltd., Basel, Rep. Nr. REM-130-07, 14.12.1992 GLP, not published Novartis File No CGA64250/2110	

B.6 Toxicology and metabolism

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 5.1.1 / 04	Ballantine, L. and Simoneaux, B.	1983	Dermal absorption of triazole ¹⁴ C-CGA 64250 by rats., Ciba-Geigy Corp., Greensboro, NC, USA. Rep.Nr. ABR-82068, 11.05.1983 Owned by Ciba-Geigy Ltd. Basle, Switzerland Submitted by Ciba-Geigy Ltd. Basle, Switzerland Non-GLP, not published Novartis File N° 64250/1551	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 5.1.1 / 05	Ballantine, L. Murphy, T. Brown, K. Doornheim, D. Marco, G.	1986	Dermal absorption of ¹⁴ C-propiconazole in rats after a ten hour exposure period., Ciba-Geigy Corp., Greensboro, NC, USA, Rep.Nr. ABR-86053, 08.04.1986 Owned by Ciba-Geigy Ltd. Basle, Switzerland Submitted by Ciba-Geigy Ltd. Basle, Switzerland Non-GLP, not published Novartis File N° 64250/1552	
IIA 5.8 / submitted later	Beilstein, P.	1998	Effects on biochemical parameters in the liver following administration to male mice Novartis Crop Protection AG, Basel, Switzerland Study report N0.CB 97/22, 07.04.1998 GLP, not published Novartis File No.CGA64250/3359	
IIA 5.1.1 / 03	Bissig, R.	1992	Biliary excretion, absorption, and distribution kinetics of [U- ¹⁴ C]phenyl CGA 64250 in the rat after oral administration., Ciba-Geigy Ltd., Basle, Switzerland, Rep.Nr. 11PTO1, 14.01.1992 Owned by Ciba-Geigy Ltd. Basle, Switzerland Submitted by Ciba-Geigy Ltd. Basle, Switzerland GLP, not published Novartis File N° 64250/1988	
IIA 5.6.1 /01	Borders, Ch.K., Salamon, C.M., Mayhew; D.A.	1985	Two-generation reproduction study in albino rats with CGA 64250 technical., ToxiGenics, Rep.Nr. 450-1202, 12.03.1985 Owned by Ciba-Geigy Ltd. Basle, Switzerland Submitted by Ciba-Geigy Ltd. Basle, Switzerland GLP, not published Novartis File N° 64250/1591	
IIA 5.1.1 / 02	Cresswell, D.G., Hopkins, R.	1989	Absorption, distribution, metabolism and excretion in the rat., Hazleton Laboratories, UK, Rep.Nr. HUK 380-105, 08.06.1989 Owned by Ciba-Geigy Ltd. Basle, Switzerland Submitted by Ciba-Geigy Ltd. Basle, Switzerland GLP, not published Novartis File N° 64250/1553	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 5.4.2 / submitted later	De Parade, E.	1999	CGA 64250 tech. - Micronucleus test, mouse Novartis Crop Protection AG, Basel, Switzerland Study Report No. 993100, 14.12.1999 GLP, not published Novartis File N° CGA64250/4268	
IIA 5.1.3 / 02b	Doweyko, A.M.	1990	Metabolism of phenyl ¹⁴ C- propiconazole in goats., Environ. Health Center, Farmington, USA, Rep. Nr. F-00052, 31.07.1990 Owned by Ciba-Geigy Ltd. Basle, Switzerland Submitted by Ciba-Geigy Ltd. Basle, Switzerland Non-GLP, not published Novartis File N° 64250/2021	
IIA 5.1.3 / 04b	Doweyko, A.M.	1990	Metabolism of [phenyl ¹⁴ C]-propiconazole in chickens., Environ. Health Center, Farmington, USA, Rep. Nr. F-00051, 14.06.1990 Owned by Ciba-Geigy Ltd. Basle, Switzerland Submitted by Ciba-Geigy Ltd. Basle, Switzerland GLP, not published Novartis File N° 64250/2022	
IIA 5.9.1 / 02	Fuchs, Th.	1991	Epicutaneous Test with propiconazole in 20 human volunteers. Centre for Dermatology and Venereology. Hospital of the Georg-August University Göttingen, Germany, August 1, 1991 Submitted by Ciba-Geigy Ltd. Basle, Switzerland GLP not applicable Novartis File N° 64250/2137	
IIA 5.5 / submitted later	Gerspach, R.	1997	18-Months oncogenicity study in mice Novartis Crop Protection AG, Stein, Switzerland Study report No.943126, 26.03.1997 GLP, not published Novartis File N° CGA64250/3142	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 5.5 / 04	Hardisty, J.	1991	Reexamination of the liver tumor response in male and female mice (Pathology report), Experimental Pathology Laboratories Inc., Research Triangle Park NC/USA, Rep.Nr. CBG/196/81827, 06.05.1991 Owned by Ciba-Geigy Ltd. Basle, Switzerland Submitted by Ciba-Geigy Ltd. Basle, Switzerland GLP, not published Novartis File N° 64250/2033	
IIA 5.2.3 / 01	Hartmann, H.R. Gfeller, W.	1988	Acute aerosol inhalation toxicity in the rat, Ciba-Geigy Ltd, Stein, Switzerland, Rep.Nr. 871471, 14.01.1988 Owned by Ciba-Geigy Ltd. Basle, Switzerland Submitted by Ciba-Geigy Ltd. Basle, Switzerland GLP, not published Novartis File N° 64250/1533	
II A 5.12 / submitted later	Hassler, S.	2000	The in vitro percutaneous absorption of [Phenyl-U-14] CGA 64250 formulated as TILT 250 EC (A-6097 K) through rat and human epidermis. Novartis Crop Protection AG, Basel, Switzerland Study Report No. 044AM02, 04.01.2000 GLP, not published Novartis File N° CGA64250/4276	
II A 5.12 / submitted later	Hassler, S.	2000	Dermal absorption of [Phenyl-U-14C] CGA 64250 formulated as Tilt 250 EC (A-6097 K) in the rat Novartis Crop Protection AG, Basel, Switzerland Study Report No. 044AM01, 09.02.2000 GLP, not published Novartis File N° CGA64250/4292	
IIA 5.9.1 / 01	Jaque, B.	1991	Industrial Health Record CGA 64'250 Propiconazole, Medical Surveillance, Monthey, Switzerland, October 1991 Owned by Ciba-Geigy Ltd. Basle, Switzerland Submitted by Ciba-Geigy Ltd. Basle, Switzerland GLP not applicable Novartis File N° 64250/2172	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 5.6.2 / 02	Mallows, S. Levy, E., Giknis, M.L.A., Yau, E.T.	1987	A modified teratology (Segment II) study in albino rats, CGS-Ciba-Geigy Corp., Summit NJ, USA, Rep.Nr. MIN 862244, 06.02.1987 Owned by Ciba-Geigy Ltd. Basle, Switzerland Submitted by Ciba-Geigy Ltd. Basle, Switzerland GLP, not published Novartis File N° 64250/1587	
IIA 5.6.2 / 01	Marcisin, J.F., Wimbert, K.V., Giknis, M.L.A., Arthur, A.T., Yau, E.T.	1987	Teratology (Segment II) study in rats, CGS-Ciba-Geigy Corp., Summit NJ, USA, Rep.Nr. MIN 852148, 28.01.1987 Owned by Ciba-Geigy Ltd. Basle, Switzerland Submitted by Ciba-Geigy Ltd. Basle, Switzerland GLP, not published Novartis File N° 64250/1586	
IIA 5.3.2 / 03	Potrepka, R.F. Turnier, J.C.	1991	Subchronic dietary toxicity study with CGA 64250 in mice, Ciba-Geigy Corp., Farmington, CT, USA, Rep.Nr. F-00098, 30.04.1991 Owned by Ciba-Geigy Ltd. Basle, Switzerland Submitted by Ciba-Geigy Ltd. Basle, Switzerland GLP, not published Novartis File N° 64250/2020	
IIA 5.3.2 / 04	Potrepka, R.F. Turnier, J.C.	1991	13-week dietary toxicity study with CGA 64250 in male mice, Ciba-Geigy Corp. Farmington, CT, USA, Rep.Nr. F-00107, 30.04.1991 Owned by Ciba-Geigy Ltd. Basle, Switzerland Submitted by Ciba-Geigy Ltd. Basle, Switzerland GLP, not published Novartis File N° 64250/2019	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 5.6.2 / 03	Raab, D.M. Youreneff, M.A., Giknis, M.L.A., Arthur, A.T., Yau, E.T.	1986	A teratology study (Segment II) in New Zealand white rabbits, CGS-Ciba-Geigy Corp., Summit NJ, USA, Rep.Nr. MIN 852172, 01.08.1986 Owned by Ciba-Geigy Ltd. Basle, Switzerland Submitted by Ciba-Geigy Ltd. Basle, Switzerland GLP, not published Novartis File N° 64250/1589	
IIA 5.2.6 / submitted later	Sommer, E.	1999	CGA 64250 tech. - Skin sensitization in the Guinea Pig (Maximization test) Novartis Crop Protection AG, Stein, Switzerland Study Report No. 993101, 07.09.1999 GLP, not published Novartis File N° CGA64250/4197	
IIA 5.8 / submitted later	Weber, E.	1999	CGA64250 – Assessment of hepatic cell proliferation in male mice Novartis Crop Protection AG, Basel, Switzerland Final Report 97/23, 01.09.1999 GLP, not published Novartis File No.CGA64250/4200	

B.7 Residue data

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 6.6 / submitted later	Argento, J.C.	1994	CGA 64250 + CGA 114900 + Tebuconazole (CGA 197505), EC 625, A-9232 A, Barley (Grains and Straw), France Rep. No OF94107, 8.9.94 GLP, not published Novartis File No CGA64250/2451	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 6.6 /254	Bodnaruk, K.P.	1993	CGA 64250, TILT 250 EC (A 6097 K), Avocados, aerial application, Australia, CGA-Ciba-Geigy Ltd., Australia, Rep.Nr. 93/10/1425, 26.10.1993 GLP, not published Novartis File No CGA64250/2296	
IIA 6.6 /257	Bull, M.S	1989	The determination of residues of propiconazole in pineapples at harvest following an application of the fungicide TILT at planting, CGA-Ciba-Geigy Ltd., Australia, Rep.Nr. 89-4-1238, 05.04.1989 Non GLP, not published Novartis File No CGA64250/982	
IIA 6.6 /197	Cheung, M.W.	1986	CGA 64250, 3.6E, nectarines, USA, Ciba- Geigy Corp., USA, Rep.Nr. AG-A-9170-01, 29.09.1986 Non GLP, not published Novartis File No CGA64250/850	
IIA 6.6 /194	Cheung, M.W.	1987	CGA 64250, 3.6E, apricots, USA, Ciba- Geigy Corp., USA, Rep.Nr. AG-A-8959-01, 31.03.1987 Non GLP, not published Novartis File No CGA64250/538	
IIA 6.6 /195	Cheung, M.W.	1987	CGA 64250, 3.6E, apricots, USA, Ciba- Geigy Corp., USA, Rep.Nr. AG-A-9063-01, 30.04.1987 GLP, not published Novartis File No CGA64250/539	
IIA 6.6 /199	Cheung, M.W.	1987	CGA 64250, 3.6E, nectarines, USA, Ciba- Geigy Corp., USA, Rep.Nr. AG-A-9346-01, 30.04.1987 Non GLP, not published Novartis File No CGA64250/851	
IIA 6.6 /200	Cheung, M.W.	1987	CGA 64250, 3.6E, nectarines, USA, Ciba- Geigy Corp., USA, Rep.Nr. AG-A-10049- 01, 30.01.1989 GLP, not published Novartis File No CGA64250/853	
IIA 6.6 /198	Cheung, M.W.	1987	CGA 64250, nectarines, USA, Ciba-Geigy Corp., USA, Rep.Nr. AG-A-9371-01, 31.03.1987 Non GLP, not published Novartis File No CGA64250/852	
IIA 6.6 /164	Cheung, M.W.	1988	Propiconazole - peanuts, magnitude of residue, USA, Ciba-Geigy Corp., USA, Rep.Nr. ABR-88068, 06.05.1988 GLP, not published Novartis File No CGA64250/955	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 6.7 /003	Darnow, J.N.	1990	Determination of extract storage stability for total propiconazole residues in weathered crops, corn silage and soybean, RI-SS-002-90, 30.03.1990 GLP, not published Novartis File No CGA64250/1860	
IIA 6.6 /236	Dharmalingam, K.	1994	CGA 64250, TILT 250EC, tea, India 1994, School of Biotechnology, Madurai Kamaraj University, Madurai, India, PP93 Season 3, 03.12.1994 Non GLP, not published Novartis File No CGA64250/2528	
IIA 6.6 /237	Dharmalingam, K.	1994	CGA 64250, TILT 250EC, tea, India 1994, School of Biotechnology, Madurai Kamaraj University, Madurai, India, PP93 Season 2, 03.12.1994 Non GLP, not published Novartis File No CGA64250/2528	
IIA 6.6 /238	Dharmalingam, K.	1994	CGA 64250, TILT 250EC, tea, India 1994, School of Biotechnology, Madurai Kamaraj University, Madurai, India, PP93 Season 1, 03.12.1994 Non GLP, not published Novartis File No CGA64250/2528	
IIA 6.3 / submitted later	Eudy, L.W.	1997	Stability of propiconazole fortified into crops and processed fractions under freezer storage conditions. Novartis Crop Protection Inc., Greensboro, United States. Study report No.ABR-97039, 30.09.1997. GLP, not published Novartis File No CGA64250/3400	
IIA 6.6 /258	Hauck, M.	1992	CGA 64250, guava, Bangladesh, Ciba-Geigy Ltd., Basle, Rep.Nr. 2019-91, 13.08.1992 GLP, not published Novartis File No CGA64250/2049	
IIA 6.6 /182	Hauck, M.	1992	CGA 64250, rice, Italy, Ciba-Geigy Ltd., Basle, Rep.Nr. 2084-91, 07.09.1992 GLP, not published Novartis File No CGA64250/2069	
IIA 6.6 /183	Hauck, M.	1992	CGA 64250, rice, Italy, Ciba-Geigy Ltd., Basle, Rep.Nr. 2083-91, 07.09.1992 GLP, not published Novartis File No CGA64250/2068	
IIA 6.6 /184	Hauck, M.	1992	CGA 64250, rice, Italy, Ciba-Geigy Ltd., Basle, Rep.Nr. 2078-91, 07.09.1992 GLP, not published Novartis File No CGA64250/2067	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 6.6 /185	Hauck, M.	1992	CGA 64250, rice, Italy, Ciba-Geigy Ltd., Basle, Rep.Nr. 2077-91, 07.09.1992 GLP, not published Novartis File No CGA64250/2066	
IIA 6.6 /165	Hauck, M.	1993	CGA 64250, TILT 250EC, rapeseed, Canada, Ciba-Geigy Ltd., Basle, Rep.Nr. 2106/92, 12.07.1993 GLP, not published Novartis File No CGA64250/2244	
IIA 6.6 /166	Hauck, M.	1993	CGA 64250, TILT EC 250, rapeseed, Canada, Ciba-Geigy Ltd., Basle, Rep.Nr. 2108/92, 27.08.1993 GLP, not published Novartis File No CGA64250/2256	
IIA 6.6 submitted later	Maffezzoni, M.	1994	CGA 114900 + CGA 197505 + CGA 64250, EC 625, A-9233 B, Barley (Grain and Straw), France Rep. N° OF94112, 28.9.94 GLP, not published Novartis File No CGA64250/3268	
IIA 6.6 submitted later	Maffezzoni, M.	1994	CGA 64250 + CGA 114900 + Tebuconazole (CGA 197505), EC 625, A- 9233 B, Wheat (Grain and Straw), France Rep. No OF94111, 5.9.94 GLP, not published Novartis File No CGA64250/2450	
IIA 6.4 / submitted later	Maffezzoni, M.	1998	Residue study with CGA 64250 and CGA 197505 in or on malting spring barley in France (north), ADME - Bioanalysis, Aigues-Vives, France Study Report No. 9715203, 30.09.1998 GLP, not published Novartis File N° CGA64250/3433	
IIA 6.4 / submitted later	Maffezzoni, M.	1998	CGA 64250 + CGA 197505, EC 500, A- 9232 A, Winter barley, France (North). ADME - Bioanalysis, Aigues-Vives, France. Study Report No. 9711703, 05.10.1998. GLP, not published Novartis File No CGA64250/3420	
IIA 6.4 / submitted later	Maffezzoni, M.	1998	CGA 64250 + CGA 197505, EC 500, A- 9232 A, Springr barley, France (North). ADME - Bioanalysis, Aigues-Vives, France. Study Report No. 9715201, 30.09.1998. GLP, not published Novartis File No CGA64250/3432	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 6.4 / submitted later	Maffezzoni, M.	1998	CGA 64250 + CGA 197505, EC 500, A-9232 A, Winter barley, France (North). ADME - Bioanalysis, Aigues-Vives, France. Study Report No. 9711701, 30.09.1998. GLP, not published Novartis File No CGA64250/3419	
IIA 6.6 submitted later	Pointurier, R.	1994	CGA 64250 + Tebuconazole (CGA 197505), EC 625, A-9232 A, Wheat, (Grains and Straw), France Rep. No OF94106, 30.8.94 GLP, not published Novartis File No CGA64250/2452	
IIA 6.6 /146	Ramsteiner K.	1987	CGA 64250, coffee beans, India, Ciba-Geigy Ltd., Basle, Rep.Nr. RR-2115-87, 24.08.1987 Non GLP, not published Novartis File No CGA64250/732	
IIA 6.6 /147	Ramsteiner K.	1987	CGA 64250, coffee beans, India, Ciba-Geigy Ltd., Basle, Rep.Nr. RR-2114-87, 24.08.1987 Non GLP, not published Novartis File No CGA64250/731	
IIA 6.6 /233	Sack, St.	1994	CGA 64250, TILT 250EC, tea, Bangladesh 1992, Ciba-Geigy Ltd., Basle, Rep.Nr. 2007/92, 26.04.1994 GLP, not published Novartis File No CGA64250/2348	
IIA 6.6 /234	Sack, St.	1994	CGA 64250, TILT 250EC, tea, Bangladesh 1992, Ciba-Geigy Ltd., Basle, Rep.Nr. 2006/92, 26.04.1994 GLP, not published Novartis File No CGA64250/2347	
IIA 6.6 /235	Sack, St.	1994	CGA 64250, TILT 250EC, tea, Bangladesh 1992, Ciba-Geigy Ltd., Basle, Rep.Nr. 2005/92, 26.04.1994 GLP, not published Novartis File No CGA64250/2346	
IIA 6.6/ submitted later	Schulz, H.	1997	Determination of the residues of CGA 64250 and CGA 219417 in Winter wheat and in processing products following treatment with CGD 20570F under field conditions in Germany 1996. Institut Fresenius, Germany. Study Report No. IF-96/07964-00, 29.01.1997. GLP, not published Novartis File No CGA64250/3141	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 6.1 / submitted later	Swain, W.E.	1997	Uptake and metabolism of CGA 64250 in greenhouse grown spring wheat after spray treatment with Phenyl- ¹⁴ C-CGA64250 Novartis Crop Protection Inc., Greensboro, United States. Study report No.ABR-97039, 02.09.1997. GLP, not published Novartis File No CGA64250/3393	

B.8 Environmental fate and behaviour

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 7.2.1.2 /05	Abildt, U.	1994	Estimation of the Environmental Photochemical half life of CGA 64250 in Surface water; CIBA-GEIGY Ltd., Basle; Project Report 46/94; January 24, 1994. GLP, not published Novartis File No CGA64250/2563	
IIA 7.1.2 / submitted later	Adam, D.	2000	Adsorption/Desorption of CGA 118245 in various soils. Novartis Crop Protection AG, Basel, Switzerland. Study Report No. 99DA09, 11.05.2000. GLP, not published. GLP, not published Novartis File No CGA64250/-	
IIA 7.1.1.1.1	Adam, D.	2000	Rate of degradation of ¹⁴ C-triazole labelled CGA 118 245 in various soil under aerobic conditions at 20 ° C. Novartis Crop Protection AG, Basel, Switzerland Study Report No. 00DA04, 26.9.2000 GLP, not published Novartis File No CGA64250/0006	
IIA 7.1.1.1.	Adam, D.	2001	Metabolism of ¹⁴ C-triazolering labelled CGA 64250 under aerobic and aerobic/ anaerobic laboratory conditions in one soil at 20 °C. Syngenta Crop Protection AG, Basel, Switzerland Study Report No. 00DA06, 4.4.2001 GLP, not published Novartis File No CGA64250/4413	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
Analytical report 5252/00. IIA 7.1.1.2.2	-	-	Determination of residues of propiconazole and free triazole in soil from Finland. Syngenta AG/ Residue Analysis, Basel Switzerland. Analytical Report No. 513/01. GLP, not published.	
IIA 7.2.1.3.1 /01	Bader, U.	1990	Report on the test for ready biodegradability in the modified Sturm test of CGA 64250. CIBA-GEIGY LTD., Basle, Test No.: 901111. 24/04/90. GLP, not published Novartis File No CGA64250/230	
IIA 7.1.1.1.1 /05	Baranowski, D. and Galicia, H.	1992	¹⁴ C-Propiconazole (CGA 64250): Degradation and metabolism in one soil incubated under aerobic conditions. RCC Umweltchemie, CH-4452 Itingen; RCC Project No.217484.March 03, 1992 GLP, not published Novartis File No CGA64250/2005	
IIA 7.2.1.3.2 /05	Das, Y.T.	1992	Metabolism of (Phenyl(U)- ¹⁴ C)Propiconazole under anaerobic aquatic soil conditions. Innovative Scientific Services, Inc. (ISSI), 515 Blue Ridge Avenue, Piscataway, N.J. 08854. ISSI-No. 90072, CIBA-GEIGY Protocol Number 87-90. July 20, 1992. GLP, not published Novartis File No CGA64250/2081	
IIA 7.1.3 / submitted later	Huber, A.	2000	Leaching behaviour of CGA 64250 (propiconazole) and its major metabolite 1,2,4-triazole (CGA 71019) under northern european soil and climate conditions. Novartis Crop Protection AG, Basel, Switzerland. Study report No.Mod00AH15, 11.05.2000. Non GLP, not published Novartis File No CGA64250/-	
IIA 7.2.2.1 /01	Krauss, J.H.	1992	Volatilization of CGA 64250 from Plant and soil after postemergent spray application of [¹⁴ C-Phenyl]labelled material on wheat under indoor conditions. Ciba-Geigy Ltd., Basle, Metabolism Report 10/92, May 19, 1992. GLP, not published Novartis File No CGA64250/2032	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 7.1.1.2.1 /03	Müller-Kallert, H.-M.	1992	Degradation of ¹⁴ C-CGA 64250 in one soil incubated under various experimental conditions. RCC Project 255971; RCC Umweltchemie AG, CH-4452 Itingen/BL.; 22.04.1992. GLP, not published Novartis File No CGA64250/2031	
IIA 7.1.1.2.2 /16	Offizorz, P.	1994	Determination of Propiconazole in field soil and rotational crops (sugar beet) - Exp. No. CGD 14-90. RCC Project 275117; RCC, In den Leppsteinwiesen 19, D-6101 Roßdorf. 31.05.1994. GLP, not published Novartis File No CGA64250/2612	
IIA 7.1.1.2.2 /16	Offizorz, P.	1994	Determination of Propiconazole in field soil and rotational crops (rape) - Exp. No. CGD 15-90. RCC Project 275128; RCC, In den Leppsteinwiesen 19, D-6101 Roßdorf. 31.05.1994. GLP, not published Novartis File No CGA64250/2613	
IIA 7.1.1.2.2 /16	Offizorz, P.	1994	Determination of Propiconazole in field soil and rotational crops (rape) - Exp. No. CGD 16-90. RCC Project 275130; RCC, In den Leppsteinwiesen 19, D-6101 Roßdorf. 31.05.1994. GLP, not published Novartis File No CGA64250/2614	
IIA 7.1.1.2.2 /16	Offizorz, P.	1994	Determination of Propiconazole in field soil and rotational crops (sugar beet) - Exp. No. CGD 17-90. RCC Project 275141; RCC, In den Leppsteinwiesen 19, D-6101 Roßdorf. 31.05.1994. GLP, not published Novartis File No CGA64250/2615	
IIA 7.1.1.1.3 /04	Regetta, R.C. and Zogorski, W.J.	1992	A random soil survey for 1,2,4-Triazole content in California. Rohm and Haas Company, 727 Norriston Road, Spring House, PA 19477; Technical Report No. 34-92-30; 25.03.1992. Originated by: Rohm and Haas Company Co-owned by: CIBA-GEIGY Limited GLP, not published Novartis File No 71019/11	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 7.1.1.2 / submitted later	Reiling, H.	1999	Statement: "Evaluation of Validity of results from an Adsorption/Desorption Study with 1,2,4-triazole (A. Keller, 1983)", 20.10.90. Novartis Crop Protection AG, Basel, Switzerland. Non GLP, not published Novartis File No CGA64250/-	
IIA 7.2.1.3.2 / submitted later	Reischmann, F.J.	1999	Metabolism of ¹⁴ C-triazole labelled CGA 64250 in two aerobic aquatic systems under laboratory conditions. Novartis Crop Protection AG, Basel, Switzerland Study Report No. 98RF03, 02.11.1999. GLP, not published. Novartis File No CGA64250/4247	
IIA 7.1.1.2.2 /26	Sack, S.	1994	Long-term Residue Study: Propiconazole (Reports of the 1st to 6th year). Novartis Crop Protection AG, CH - 4002 Basle, Switzerland. Rep. No. 2400/87 – 92. GLP, not published Novartis File No CGA64250/2051	
IIA 7.1.1.2.2 /27	Sack, S.	1994	Long-term Residue Study: Propiconazole (Reports of the 1st to 7th year). Novartis Crop Protection AG, CH - 4002 Basle, Switzerland. Rep. No. 2401/86 – 92. GLP, not published Novartis File No CGA64250/2052	
IIA 7.1.1.2.2 /24	Sack, S.	1997	Long-term Residue Study: Propiconazole (Reports of the 1st to 10th year). Novartis Crop Protection AG, CH - 4002 Basle, Switzerland. Rep. No. 2155/85 – 94. GLP, not published Novartis File No CGA64250/1964	
IIA 7.1.1.2.2 /25	Sack, S.	1997	Long-term Residue Study: Propiconazole (Reports of the 1st to 10th year). Novartis Crop Protection AG, CH - 4002 Basle, Switzerland. Rep. No. 2156/85 – 94. GLP, not published Novartis File No CGA64250/1965	
IIA 7.1.2.1 /02	Saxena, A. M.	1988	The adsorption and desorption of ¹⁴ C-Propiconazole on representative agricultural soils. Halzleton Laboratories America Inc., 3301 Kinsman Boulevard, Madison, Wisconsin 53704; HLA 6117-140; July 27, 1988. GLP, not published Novartis File No CGA64250/247	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 7.1.1.2.1/ submitted later	Scholz, K., Leicht, W.	2000	"Dependence of the half life of 1,2,4- triazole on its concentration in soil", 17.01.2000. Bayer AG Germany, Non GLP, not published Novartis File No CGA64250/-	
IIA 7.1.1.2.1/ submitted later	Slangen, P.J.	2000	Degradation of 1,2,4-triazole in three soils under aerobic conditions – Draft report. Notox Project 278336, 03.05.2000-08-17 GLP, not published Novartis File No CGA64250/-	

B.9 Ecotoxicology

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 8.3.6.1 /01	Bader, U.	1990	Report on the test for inhibitory concentration on aerobic bacteria CGA 64250, Ciba-Geigy Ltd., Basel, CH, Rep. N° 901112, 28.03.1990 GLP, not published Novartis File No CGA64250/188	
IIA 8.1.3 /02	Beavers, J.B.	1982	One-generation reproduction study - Bobwhite quail, CGA 64250 technical, Wildlife International Ltd., Solitude Creek Farm, St. Michaels, Maryland, US, Rep. N° 108-202, 05.04.1982 GLP, not published Novartis File No CGA64250/200	
IIA 8.2.2.3 /01	Breteler, R.J.	1988	The chronic toyesicity of CGA-64250 technical (Propiconazole) to sheepshead minnow (<i>Cyprinodon variegatus</i>), Springborn Life Sciences, Inc., Wareham, Massachusetts, US, Rep. N° 88-04-2685, 18.07.1988 GLP, not published Novartis File No CGA64250/210	
IIA 8.4.1	Bätscher, R.	2000	Acute toxicity of CGA 118245 (metabolite of CGA 64250) to the earthworm (<i>Eisenia foetida</i>) in a 14 day test RCC AG, Itingen, Switzerland Study Report No. 747088, 13.04.2000 GLP, not published Novartis File N° CGA118245/0001	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 8.2.7 / submitted later	Grade, R.	1999	Toxicity test of CGA 64250 tech. on sediment-dwelling Chironomus riparius under static conditions. Novartis Crop Protection AG, Basel, Switzerland Study Report No. 983985, 07.05.1999 GLP, not published Novartis File No CGA64250/4169	
IIA 8.2.4 / submitted later	Grade, R.	1999	Acute toxicity test of CGA 64250 techn. to the Cladoceran Daphnia magna Straus in the static system Novartis Crop Protection AG, Basel, Switzerland Study Report No. 983985, 21.07.1999 GLP, not published Novartis File No CGA64250/4294	
IIA 8.2.1 / submitted later	Gries, Th.	1999	CGA 217495 (metabolite of CGA 64250): static acute toxicity test with rainbow trout (Oncorhynchus mykiss) Springborn Lab., Horn, Switzerland Study Report No. 1047.024.103, 11.03.1999. GLP, not published Novartis File No CGA217495/0003	
IIA 8.2.6 / submitted later	Gries, Th.	1999	CGA 217495 (metabolite of CGA 64250): static toxicity test with the freshwater algae Pseudokirchneriella subcapitata Springborn Lab., Horn, Switzerland Study Report No. 1047.024.430, 12.03.1999 GLP, not published Novartis File No CGA217495/000	
IIA 8.2.4 / submitted later	Gries, Th.	1999	CGA 217495 (metabolite of CGA 64250): static acute toxicity test with daphnids (Daphnia magna) Springborn Lab., Horn, Switzerland Study Report No. 1047.024.110, 12.03.1999 GLP, not published Novartis File No CGA217495/0002	
IIA 9.2.1	Huber, A.	2000	Leaching behaviour of CGA 64250 (Propiconazole) and its major metabolite 1,2,4-triazole (CGA 71019) under northern European climate conditions. Novartis Crop Protection AG, Basel, Switzerland Study Report No. Mod00AH15, 11.5.2000 Non GLP, not published Novartis File N° -	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 9.2.1	Huber, A.	2000	Leaching Behaviour of CGA 118245 (Metabolite of Propiconazole, CGA 64250) under Northern European Climate Conditions. Novartis Crop protection AG, Basel Switzerland Report No. Mod00AH26., 15.8.2000 Non GLP, not published Novartis File N° CGA 64250/0005	
IIA 9.2.1	Huber, A.	2001	Leaching Behaviour of CGA 64250 (Propiconazole) and its Major Metabolite 1,2,4-triazole (CGA 71019) under the Conditions of the FOCUS Leaching Scenarios. Syngenta Crop Protection AG, Basel, Switzerland Report No. Mod01AH08, 31.8.2001. Non GLP, not published Novartis File N° CGA 64250/4428	
IIA 8.3.4 /01	Mumma, R.O. and Bogus, E.R.	-	Effects of CGA-64250 on the degradation of 14C-cellulose, 14C-protein, and 14C-starch in soil, Pesticide Research Laboratory and Graduate Study Center, The Pennsylvania State University, PA, US Non GLP, not published Novartis File No CGA64250/228	
IIA 8.4.1/ submitted later	Nienstedt, K.M.	1999	A 14-day acute toxicity test with the Earthworm (<i>Eisenia fetida</i>). Springborn Lab., Horn, Switzerland. Study Report No. 1047.070.630, 09.12.1999 GLP, not published Novartis File No CGA64250/4258	
IIA 8.2.1 / submitted later	Rufli, H.	1999	Acute toxicity test of CGA 64250 techn. to Rainbow Trout (<i>Oncorhynchus mykiss</i>) under static conditions Novartis Crop Protection AG, Basel, Switzerland Study Report No. 983986, 09.08.1999 GLP, not published Novartis File No CGA64250/4196	
IIA 8.2.2.2 /01	Surprenant, D.C.	1987	The toxicity of CGA-64250 (Propiconazole) to fathead minnow (<i>Pimephales promelas</i>) embryos and larvae, Springborn Life Sciences, Inc., Wareham, MA, US, Rep. N° 87-8-2476, 10.11.1987 GLP, not published Novartis File No CGA64250/209	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company), Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 8.2.2.1 /01	Wüthrich, V.	1991	Propiconazol: 21-day prolonged toxicity study in the rainbow trout under flow-through conditions, RCC Umweltchemie AG, Itingen, CH, Rep. N° 227272, 22.01.1991 GLP, not published Novartis File No CGA64250/2653	
IIA 8.5	Völkel, W.	2000	The effects of CGA 71019 on soil respiration and nitrification. RCC Ltd., Itingen, Switzerland Study Report No. 763367, 16.5.2000 GLP, not published Novartis File N° 2003502	

APPENDIX IIIB**PROPICONAZOLE**

List of studies which were submitted during the evaluation process and were not cited in the draft assessment report:

B.1 Identity, B.2 Physical and chemical properties, B.3 Data on application and further information, B.4 Proposals for classification and labelling, B.5 Methods of analysis

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 2.15	Angly, H.	2000	Oxidizing properties (liquid) of CGA 64250 tech. Institute of Safety and Security, Testing Laboratory, Basle, Switzerland. Study Report No. 2000.4012.OPL GLP, not published Novartis File No CGA64250/4299
IIA 4.1, IIIA 5.1	Käser, W.	1991	Analytical method CGA 64250 in formulation (A-6097 K) Ciba-Geigy Ltd., Basel, Switzerland Study Report No. AF-1017/1, 26.06.1991 Non GLP, not published Novartis File No CGA64250/2850
IIA 4.1, IIIA 5.1	Käser, W.	1991	Method validation for formulated products AF-1017/1 (A-6097 K) Ciba-Geigy Ltd., Basel, Switzerland Study Report No. AF-1017/1, 18.06.1991 Non GLP, not published Novartis File No CGA64250/2851
IIA 4.2.1 IIA 4.2.5	Lin, K.	1995	Investigations into the methylation of 2,4-dichlorobenzoic acid as a part of analytical methods AG-517 and AG-454B. Novartis Crop Protection Inc., Greensboro, United States Study report No. ABR-94065, 18.10.1995 GLP, not published Novartis File No CGA64250/2961
IIA 4.2.5	Lin, K.	1997	Determination of total residues of propiconazole in meat, milk and eggs as 2,4-dichlorobenzoic acid methyl ester by capillary gas chromatography. Novartis Crop Protection Inc., Greensboro, United States Study report No. AG-629, 10.10.1997 GLP, not published Novartis File No CGA64250/3396

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 4.2.1	Lin, K.	1997	Validation of analytical method AG-626 for determination of total residues of Propiconazole in wheat Novartis Crop Protection Inc., Greensboro, United States Study report No. ABR-97092, 10.10.1997 GLP, not published Novartis File No CGA64250/3398
IIA 4.2.1	Lin, K.	1997	Determination of total residues of Propiconazole in crops as 2,4-dichlorobenzoic acid methyl ester by capillary gas chromatography. Novartis Crop Protection Inc., Greensboro, United States Study report No. AG-626, 10.10.1997 GLP, not published Novartis File No CGA64250/3399
IIA 4.2.5	Lin, K.	1997	Validation of analytical method AG-626 and AG-629 for determination of total residues of Propiconazole in crops and in meat, milk and eggs as 2,4-dichlorobenzoic acid methyl ester capillary gas chromatography. Novartis Crop Protection Inc., Greensboro, United States Study report No. ABR-95061, 10.10.1997 GLP, not published Novartis File No CGA64250/3397
IIA 4.2.5	Maffezzoni, M. and Pointurier, R.	2000	Residue method: AGR/MOA/PROPIC-1 validated with meat, liver, kidney, fat, milk and egg. Determination of propiconazole by GC/MS. ADME Bioanalyses, Vergèze, France 2000. Study Report No. AGR/MOA/PROPIC-1, 29.12.2000 GLP, not published Novartis File No CGA64250/4386
IIA 4.2.5	Pointurier, R. and Duchêne, P.	2001	Validation of analytical method AGR/MOA/ PROPIC-1 for propiconazole in animal tissues. ADME Bioanalyses, Vergèze, France 2001. Study Report No. NOV/PRO/00063, 10.01.2001 GLP, not published Novartis File No CGA64250/4405
IIA 4.3.2	Pointurier, R. and Duchêne, P.	2000	Propiconazole in drinking and surface water, validation of method REM 10/86 with GC/MS. ADME Bioanalyses, Vergèze, France 2000. Study Report No. NOV/PRO/00061, 28.12.2000 GLP, not published Novartis File No CGA64250/4387
IIA 4.3.3	Pointurier, R. and Duchêne, P.	2000	Propiconazole in air: Development of a confirmatory technique with GC/MS. ADME Bioanalyses, Vergèze, France 2000. Study Report No. NOV/PRO/00062, 28.12.2000 GLP, not published Novartis File No CGA64250/4388
IIA 4.2.1	Sack, S.	1999	Validation of analytical procedures No.180 Novartis Crop Protection AG, Basel, Switzerland Study Report 215/99, 23.11.1999 GLP, not published Novartis File No.CGA64250/4252

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 4.2.1	Sack, S.	1999	Validation of REM 130.05 Novartis Crop Protection AG, Basel, Switzerland Study Report 216/99, 23.11.1999 GLP, not published Novartis File No.CGA64250/4251
IIA 4.2.2	Tribolet, R.	2001	Residue method: REM 130.10. Propiconazole (CGA 64250) Soil determination of metabolite CGA 118245 by LC-LC-MS/MS. Syngenta Crop Protection AG, Residue Analysis, Basel, Switzerland. Study Report REM 130.10, 23.10.2001 Non GLP, not published Novartis File No.CGA64250/4431.

B.6 Toxicology and metabolism

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 5.9	-	2000	Overview/summary data of: 1) Medical surveillance on manufacturing plant personnel 2) Direct observations, e.g. clinical cases and poisoning incidents 3) Diagnosis of poisoning 4) First aid measures Novartis Crop Protection AG, Switzerland Study Report No. - , 2000 Non GLP, not published Novartis File No.CGA64250/2941
IIA 5.8	Beilstein, P.	1998	Effects on biochemical parameters in the liver following administration to male mice Novartis Crop Protection AG, Basel, Switzerland Study report N0.CB 97/22, 07.04.1998 GLP, not published Novartis File No.CGA64250/3359
IIA 5.4.2	Deperate, E.	1999	CGA 64250 tech. - Micronucleus test, mouse Novartis Crop Protection AG, Basel, Switzerland Study Report No. 993100, 14.12.1999 GLP, not published Novartis File No CGA64250/4268
IIA 5.14.	EUROPOEM	1996	The development, maintenance and dissemination of a European predictive operator exposure model (EUROPOEM) database. A EUROPOEM Database and Harmonised Model, AIR3 CT93-1370, final draft 1996. Non GLP, published

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 5.5	Gerspach, R.	1997	18-Months oncogenicity study in mice Novartis Crop Protection AG, Stein, Switzerland Study report No.943126, 26.03.1997 GLP, not published Novartis File No CGA64250/3142
IIA 5.12	Hassler, S.	2000	Dermal absorption of [Phenyl-U-14C] CGA 64250 formulated as TILT 250 EC (A-6097 K) in the rat. Novartis Crop Protection AG, Switzerland Study report No.044AM01, 2000 GLP, not published Novartis File No.CGA64250/4292
IIA 5.12	Hassler, S.	2000	The <i>in vitro</i> percutaneous absorption of [Phenyl-U-14C] CGA 64250 formulated as TILT 250 EC (A-6097 K) through rat and human epidermis. Novartis Crop Protection AG, Switzerland Study report No.044AM02, 2000 GLP, not published Novartis File No.CGA64250/4276
IIA 5.14.	Krebs, B. Maasfeld, W. Schrader, J. Wolf, R.	1995	Uniform principles for safeguarding the health of workers re-entering crop growing areas after application of plant protection products. Non GLP, not published
IIA 5.14.	Krieger, R.I. Ross, J.H. Thonsinthusak T.	1992	Assessing Human Exposures to Pesticides. <i>Rev. Environ. Contam. Toxicol.</i> Vol. 128. pp. 1-15. Non GLP, published
IIA 5.2.6	Sommer, E.	1999	CGA 64250 tech. - Skin sensitization in the Guinea Pig (Maximization test) Novartis Crop Protection AG, Stein, Switzerland Study Report No. 993101, 07.09.1999 GLP, not published Novartis File No CGA64250/4197
IIA 5.8	Weber, E.	1999	CGA64250 – Assessment of hepatic cell proliferation in male mice Novartis Crop Protection AG, Basel, Switzerland Final Report 97/23, 01.09.1999 GLP, not published Novartis File No.CGA64250/4200

B.7 Residue data

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
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Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 6.3	Eudy, L. W.	1997	Stability of propiconazole fortified into crops and processed fractions under freezer storage conditions Novartis Crop Protection Inc., Greensboro, United States Study report No.ABR-97039, 30.09.1997 GLP, not published Novartis File No.CGA64250/3400
IIA 6.1	Gentile, B.	2000	CGA 64250/propiconazole – Statement on extractability in Metabolism studies Novartis Crop Protection AG, Basel, Switzerland Study report No. statement, 28.04.2000 Non GLP, not published Novartis File No.CGA64250/ -
IIA 6.4	Maffezzoni, M.	1998	Residue study with CGA 64250 and CGA 197505 in or on malting spring barley in France (north), ADME - Bioanalysis, Aigues-Vives, France Study Report No. 9715203, 30.09.1998 GLP, not published Novartis File N° CGA64250/3433
IIA 6.4	Maffezzoni, M.	1998	Residue study with CGA 64250 and CGA 197505 in or on malting spring barley in France (north), ADME - Bioanalysis, Aigues-Vives, France Study Report No. 9715201, 30.09.1998 GLP, not published Novartis File N° CGA64250/3432
IIA 6.4	Maffezzoni, M.	1998	Residue study with CGA 64250 and CGA 197505 in or on malting spring barley in France (north), ADME - Bioanalysis, Aigues-Vives, France Study Report No. 9711703, 05.10.1998 GLP, not published Novartis File N° CGA64250/3420
IIA 6.4	Maffezzoni, M.	1998	Residue study with CGA 64250 and CGA 197505 in or on malting spring barley in France (north), ADME - Bioanalysis, Aigues-Vives, France Study Report No. 9711701, 30.09.1998 GLP, not published Novartis File N° CGA64250/3419
IIA 6.3	Sack, S.	2000	Residue Study with Propiconazole (CGA 64250) in or on Rice in Italy Novartis Crop Protection AG, Basel, Switzerland Study Report No. 2077/99, 13.04.2000 GLP, not published Novartis File N° CGA64250/4301
IIA 6.3	Sack, S.	2000	Residue Study with Propiconazole (CGA 64250) in or on Rice in Italy Novartis Crop Protection AG, Basel, Switzerland Study Report No. 2078/99, 13.04.2000 GLP, not published Novartis File N° CGA64250/4302
IIA 6.3	Sack, S.	2000	Residue Study with Propiconazole (CGA 64250) in or on Rice in Italy Novartis Crop Protection AG, Basel, Switzerland Study Report No. 2079/99, 13.04.2000 GLP, not published Novartis File N° CGA64250/4303

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 6.3	Schulz, H.	1997	Determination of the residues of CGA 64250 and CGA 219417 in Winter rye following treatment with CGD 20570F under field conditions in Germany 1996. Institut Fresenius, Taunusstein, Germany Study Report No. IF-96/07966-00, 24.02.1997 GLP, not published Novartis File N° CGA64250/3169
IIA 6.3	Schulz, H.	1997	Determination of the Residues of CGA 64250 and CGA 219417 in winter wheat and processing products following treatment with CGD 20570 F under Field Conditions in Germany 1996 (north). Institut Fresenius, Taunusstein, Germany Study Report No. IF-96/07964-00, 29.01.1997 GLP, not published Novartis File N° CGA64250/3141
IIA 6.1	Swain, W.E.	1997	Uptake and metabolism of CGA 64250 in greenhouse grown spring wheat after spray treatment with Phenyl-14C-CGA64250 Novartis Crop Protection Inc., Greensboro, United States Study report No.ABR-97039, 02.09.1997 GLP, not published Novartis File No.CGA64250/3393
IIA 6.3	Walser, M.	1995	Determination of residues of cyprodinil (CGA219417) and propiconazole (CGA 64250) in rye – Field trial 2148/95. Ciba-Geigy Ltd., Basel, Switzerland Study Report No. gr 12595, 15.12.1995 GLP, not published Novartis File N° CGA64250/601

B.8 Environmental fate and behaviour

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 7.1.1.1.1	Adam, D.	2000	Rate of degradation of ¹⁴ C-triazole labelled CGA 118 245 in various soil under aerobic conditions at 20 ° C. Novartis Crop Protection AG, Basel, Switzerland Study Report No. 00DA04, 26.9.2000 GLP, not published Novartis File No CGA64250/0006
IIA 7.1.2	Adam, D.	2000	Adsorption/Desorption of CGA 118245 in various soils Novartis Crop Protection AG, Basel, Switzerland Study Report No. 99DA09, 11.05.2000 GLP, not published Novartis File N° CGA64250/

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 7.1.1.1.	Adam, D.	2001	Metabolism of ¹⁴ C-triazolering labelled CGA 64250 under aerobic and aerobic/ anaerobic laboratory conditions in one soil at 20 °C. Syngenta Crop Protection AG, Basel, Switzerland Study Report No. 00DA06, 4.4.2001 GLP, not published Novartis File No CGA64250/4413
Analytical report 5252/00. IIA 7.1.1.2.2	-	-	Determination of residues of propiconazole and free triazole in soil from Finland. Syngenta AG/ Residue Analysis, Basel Switzerland. Analytical Report No. 513/01. GLP, not published.
IIA 7.2.1	Huber, A.	2000	Leaching behaviour of CGA 64250 (propiconazole) and its major metabolite 1,2,4-triazole (CGA 71019) under northern european soil and climate conditions Novartis Crop Protection AG, Basel, Switzerland Study report No.Mod00AH15, 11.05.2000 Non GLP, not published
IIA 7.1.2	Reiling, H.	1999	Statement: "Evaluation of Validity of results from an Adsorption/Desorption Study with 1,2,4-triazole (A. Keller, 1983)", 20.10.90 Novartis Crop Protection AG, Basel, Switzerland Non GLP, not published
IIA 7.2.1.3.2	Reischmann, F.J.	1999	Metabolism of ¹⁴ C-triazole labelled CGA 64250 in two aerobic aquatic systems under laboratory conditions Novartis Crop Protection AG, Basel, Switzerland Study Report No. 98RF03, 02.11.1999 GLP, not published Novartis File N° CGA64250/4247
IIA 7.1.1.2.1	Scholz, K., Leicht, W.	2000	Statement: "Dependence of the half-life of 1,2,4-triazole on its concentration in soil", 17.01.2000 Bayer AG, Germany Non GLP, not published
IIA 7.1.1.2.1	Slangen, P.J.	2000	Degradation of 1,2,4-triazole in three soils under aerobic conditions – Draft report Notox Project 278336, 03.05.2000-08-17 GLP, not published

B.9 Ecotoxicology

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 8.4.1	Bätscher, R.	2000	Acute toxicity of CGA 118245 (metabolite of CGA 64250) to the earthworm (<i>Eisenia foetida</i>) in a 14 day test RCC AG, Itingen, Switzerland Study Report No. 747088, 13.04.2000 GLP, not published Novartis File N° CGA118245/0001

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 8.2.7	Grade, R.	1999	Toxicity test of CGA 64250 tech. on sediment-dwelling Chironomus riparius under static conditions Novartis Crop Protection AG, Basel, Switzerland Study Report No. 983985, 07.05.1999 GLP, not published Novartis File N° CGA64250/4169
IIA 8.2.4	Grade, R.	1999	Acute toxicity test of CGA 64250 techn. to the Cladoceran Daphnia magna Straus in the static system Novartis Crop Protection AG, Basel, Switzerland Study Report No. 983985, 21.07.1999 GLP, not published Novartis File N° CGA64250/4294
IIA 8.2.1	Gries, Th.	1999	CGA 217495 (metabolite of CGA 64250): static acute toxicity test with rainbow trout (Oncorhynchus mykiss) Springborn Lab., Horn, Switzerland Study Report No. 1047.024.103, 11.03.1999 GLP, not published Novartis File N° CGA217495/0003
IIA 8.2.6	Gries, Th.	1999	CGA 217495 (metabolite of CGA 64250): static toxicity test with the freshwater algae Pseudokirchneriella subcapitata Springborn Lab., Horn, Switzerland Study Report No. 1047.024.430, 12.03.1999 GLP, not published Novartis File N° CGA217495/000
IIA 8.2.4	Gries, Th.	1999	CGA 217495 (metabolite of CGA 64250): static acute toxicity test with daphnids (Daphnia magna) Springborn Lab., Horn, Switzerland Study Report No. 1047.024.110, 12.03.1999 GLP, not published Novartis File N° CGA217495/0002
IIA 9.2.1	Huber, A.	2000	Leaching behaviour of CGA 64250 (Propiconazole) and its major metabolite 1,2,4-triazole (CGA 71019) under northern European climate conditions. Novartis Crop Protection AG, Basel, Switzerland Study Report No. Mod00AH15, 11.5.2000 Non GLP, not published Novartis File N° -
IIA 9.2.1	Huber, A.	2000	Leaching Behaviour of CGA 118245 (Metabolite of Propiconazole, CGA 64250) under Northern European Climate Conditions. Novartis Crop protection AG, Basel Switzerland Report No. Mod00AH26., 15.8.2000 Non GLP, not published Novartis File N° CGA 64250/0005
IIA 9.2.1	Huber, A.	2001	Leaching Behaviour of CGA 64250 (Propiconazole) and its Major Metabolite 1,2,4-triazole (CGA 71019) under the Conditions of the FOCUS Leaching Scenarios. Syngenta Crop Protection AG, Basel, Switzerland Report No. Mod01AH08, 31.8.2001. Non GLP, not published Novartis File N° CGA 64250/4428

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 8.4.1	Nienstedt, K.M.	1999	A 14-day acute toxicity test with the Earthworm (<i>Eisenia fetida</i>) Springborn Lab., Horn, Switzerland Study Report No. 1047.070.630, 09.12.1999 GLP, not published Novartis File N° CGA64250/4258
IIA 8.2.1	Rufli, H.	1999	Acute toxicity test of CGA 64250 techn. to Rainbow Trout (<i>Oncorhynchus mykiss</i>) under static conditions Novartis Crop Protection AG, Basel, Switzerland Study Report No. 983986, 09.08.1999 GLP, not published Novartis File N° CGA64250/4196
IIA 8.5	Völkel, W.	2000	The effects of CGA 71019 on soil respiration and nitrification. RCC Ltd., Itingen, Switzerland Study Report No. 763367, 16.5.2000 GLP, not published Novartis File N° 2003502

APPENDIX IV

List of uses supported by available data

PROPICONAZOLE

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks : (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/ha min max	water l/ha min max	kg as/ha min - max		
Barley	EU-N/S		F	Erysiphe graminis, Septoria, Puccinia spp., Rhynchosporium secalis			foliar	Until stage 65	1 2				0.125 0.25	30	
Oat	EU-N/S		F	Erysiphe, Septoria, Puccinia Rhynchosporium spp.			foliar	Preventative and on first signs of disease	1 2				0.125 0.25	28-30	
Rice	EU-S		F	Helminthosporium spp.			foliar	At first signs of disease	1 2				0.1 - 0.3	42	
Rye	EU-N/S		F	Erysiphe, Septoria, Puccinia, Cladosporium, Cercospora, Rhynchosporium, Fusarium spp.			foliar	Preventative and on first signs of disease	1 2				0.125 0.25	30	
Triticale	EU-N/S		F	Erysiphe, Septoria, Puccinia, Cladosporium, Cercospora, Rhynchosporium, Fusarium spp.			foliar	Preventative and on first signs of disease	1 2				0.125 0.25	30	
Wheat	EU-N/S		F	Erysiphe graminis, Septoria, Puccinia, Cladosporium, Pseudocercospora,			foliar	Preventative and on first signs of disease	1 2				0.125 0.25	30-35	

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/ha min max	water l/ha min max	kg as/ha min max		
Sugar-beet	EU-N/S		F	Cercospora, Erysiphe betae			foliar	At first signs of disease	1 2				0.125 0.25	21	
Stone fruits	EU-S		F	Monilinia spp.			foliar	F stage- at flowering	1 3 1 2				0.0940.282 0.09 0.18	14	
Grass seed / grass / turf	EU-N/S		F	Erysiphe graminis, Septoria, Puccinia spp., Rhynchosporium secalis			foliar		2				0.25		
Lawn	EU-N/S		F	Helminthosporium spp.			foliar	On disease occurrence	1 2				0.4 2		

- Remarks:**
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
 - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
 - (c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
 - (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 - (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
 - (f) All abbreviations used must be explained
 - (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
 - (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
 - (i) g/kg or g/l
 - (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
 - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
 - (l) PHI - minimum pre-harvest interval
 - (m) Remarks may include: Extent of use/economic importance/restrictions