

EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Directorate E – Safety of the food chain
Unit E.3 - Chemicals, contaminants and pesticides

Metalaxyl

SANCO/10476/2010 – rev.1

12 March 2010

FINAL

Review report for the active substance **metalaxyl**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on
12 March 2010
in view of the inclusion of metalaxyl 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 metalaxyl, 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 1972/99⁽²⁾, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Metalaxyl 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 23 July 1993, SANC on 23 July 1993, Makhteshim Agan on 20 July 1993, ISAGRO Srl on 22 July 1993, Industrias Químicas del Vallés on 28 July 1993, Helm AG on 23 July 93, Industrias Afrasa on 27 July 93, DeBacker & Associés on 28 July 93 and B.V. Luxan on 21 July 93 notified to the Commission of their wish to secure the inclusion of the active substance metalaxyl in Annex I to the Directive.

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 Portugal as rapporteur Member State to carry out the assessment of metalaxyl 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

¹ OJ No L 366, 15.12.1992, p.10.

² OJ No L 244, 16.09.1999, p.41.

³ OJ No L 107, 28.04.1994, p.8.

⁴ OJ No L 225, 22.09.1995, p.1.

Article 6(2) of Regulation (EEC) No 3600/92, as well as for other parties with regard to further technical and scientific information; for metalaxyl this deadline was 31 October 1995.

CIBA-GEIGY Ltd and Industrias Químicas del Vallés s.a. submitted each a dossier to the rapporteur Member State. CIBA-GEIGY Ltd. merged with Sandoz to form Novartis (now Syngenta). CIBA-GEIGY was the main data submitter, with a dossier which was considered substantially complete for the purposes of evaluation. Industrias Químicas del Vallés (IQV) did submit a dossier which was considered incomplete. Later, Novartis withdrew its support and indicated its intention not to participate in the review process for metalaxyl , by letter received at the Designated National Authority of the rapporteur Member State (DGPC) on 20 May 1998.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Portugal submitted the report of its examination (hereafter referred to as the draft assessment report) to the Commission on 26 January 2001. The report , included, as required, a recommendation concerning the possible inclusion of metalaxyl in Annex I to the Directive. On 23 April 2001 Portugal submitted to the Commission an amendment to this draft assessment report.

Since the withdrawal of Novartis was at a very late stage and as IQV maintained the interest in supporting the review of metalaxyl, the rapporteur Member State decided to carry out the detailed evaluation and the monograph. This procedure gave rise to a comparability evaluation between metalaxyl technical from both origins, concluding that both sources were equivalent. This justifies also that in the Monograph there are references to Novartis's dossier in the evaluation.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the Commission forwarded the draft assessment report to all the Member States for consultation on 27 April 2001 as well as to IQV (being the only remaining notifier), on 09 February 2001. The amended report was sent to Member States and IQV on 08 June 2001.

On the basis of the fact that the only remaining notifier did not have access to a dossier which was sufficiently complete to allow it to participate in the detailed evaluation of the dossier and assessment report under Article 7(3) of Regulation 3600/92, the Commission concluded to non include the substance and such conclusion was referred to the Standing Committee on the Food Chain and Animal Health. A decision was finalised in the meeting of the Standing Committee on 18 October 2002 and adopted with Commission Decision 2003/308/EC.

IQV appealed and the Court of Justice of the European Communities in its judgement of 18 July 2007 in Case C-326/05 P annulled Decision 2003/308/EC.

Article 233 of the Treaty requires the institution whose act has been declared void to take the necessary measures to comply with the judgement of the Court of Justice. Consequently, the Commission extended with Regulation 1313/2007 for metalaxyl the time period provided for in Regulation (EC) No 2076/2002 to allow that substance to be assessed and to allow Member States to authorise plant protection products containing that substance in the meantime. In addition, with Regulation 416/2008 the rules for the implementation of the first stage review programme were amended to permit to IQV to submit further information for metalaxyl by 31 October 2008.

The Rapporteur Member State evaluated the new studies and submitted an addendum to the original Draft Assessment Report on 12 May 2009. Moreover, in accordance with the same provisions, the Commission and the Member States received also the update summary dossier on metalaxyl from IQV.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the Commission forwarded for consultation the draft assessment report and the addendum to all the Member States on 19 June 2009 as well as to IQV on 18 June 2009.

The Commission organised a consultation of technical experts from Member States to review the draft assessment report, the addenda to that 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 report of the peer review was circulated to Member States and the notifier for comments and further clarification.

Open points were solved via written procedure and discussed in the meetings of the Working Group of Member States experts on pesticides Legislation.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the dossier, the draft assessment report, the addenda to the draft assessment report, the peer review report and the comments and clarifications on the remaining issues, received in the peer review were referred to the **Standing Committee on the Food Chain and Animal Health**, and specialised working group of this Committee, for final examination, with participation of experts from all Member States. This final examination was finalised in the meeting of the **Standing Committee on 12 March 2010**.

The review did not reveal any open questions or concerns which would have required a consultation of EFSA.

The present review report contains the conclusions of the final examination; given the importance of the draft assessment report, the addenda to the draft assessment report, the peer review report and the comments and clarifications submitted in 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 Commission Directive 2010/28/EC⁵ concerning the inclusion of metalaxyl in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing metalaxyl 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

⁵ O.J. L 104, 24.4.2010 p.57.

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.

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 metalaxyl 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 metalaxyl 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 IEDI calculation gives a value of 0,0148 mg/kg bw/day, which is about **0.30833%** of ADI. Based on the low percentage of the ADI used up through metalaxyl residues it can be concluded that wide safety margin exists for consumers.

The NEDI calculation gives a value of 0,040146 mg/kg bw/day, which is about **0.83637%** of ADI. Based on the low percentage of the ADI used up through metalaxyl residues it can be concluded that wide safety margin exists for Portuguese consumers.

Results demonstrate that in no case IESTI is higher than ARfD with the highest value in table grape resulting in 26.2% of ARfD so it can be concluded that use of metalaxyl according to the intended uses, doesn't result in an unacceptable risk with respect to adverse health effects due to acute intake of residues in food products.

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 metalaxyl 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.

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 were identified during the re-evaluation process. 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 metalaxyl

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 must pay particular attention to the potential contamination of groundwater by the active substance or its degradation products CGA 62826 and CGA 108906, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Risk mitigation measures should be applied as appropriate.”*

7. List of studies to be generated

Member States shall request the submission of the final report on the confirmatory study of validation of an analytical method for the determination of metalaxyl in air.

Some other 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 additional studies on non-target arthropods for uses other than those supported.

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.

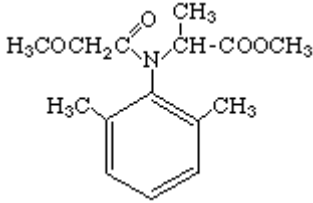
9. Updating of this review report

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 metalaxyl in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

METALAXYL

Common name (ISO)	METALAXYL
Chemical name (IUPAC)	Methyl <i>N</i> -(methoxyacetyl)- <i>N</i> -(2,6-xilylyl)-DL-alaninate
Chemical name (CA)	Methyl <i>N</i> -(2,6-dimethylphenyl)- <i>N</i> -(methoxyacetyl)-DL-alaninate
CIPAC No	365
CAS No	57837-19-1
EEC No	260-979-7
FAO SPECIFICATION	CP/329 (1995)
Minimum purity (g/kg)	950 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	2,6-dimethylaniline (max 1 g/kg)
Molecular formula	C ₁₅ H ₂₁ N O ₄
Molecular mass	279.34
Structural formula	

Melting point	72°C (95.8%); 71 -73 °C (99.9%)
Boiling point	Not applicable
Appearance	Fine crystals, colourless to white (99.8%) Powder or agglomerate, light beige (96.1%)
Relative density	1.20 (96.1%); 1.26 (99.9%)
Vapour pressure	7.5×10^{-4} Pa at 25°C
Henry's law constant	1.6×10^{-5} Pa m ³ mol ⁻¹ at 22°C
Solubility in water	pH unbuffered: pH _____ : values at other pH not required pH <u>5.2</u> : 8.4 g/l at 22°C
Solubility in organic solvents	Miscible with toluene, dichloromethane, ethanol, acetone and ethyl acetate (25°C). <i>n</i> -hexane (11 g/l at 25°C) <i>n</i> -octanol (68 g/l at 25°C)
Partition co-efficient (log P_{ow})	pH <u>?</u> : 1.75 (25°C)
Hydrolytic stability (DT₅₀)	pH 5: > 200 days (20°C) pH 7: > 200 days (20°C) pH 9: 115 days (20°C)
Dissociation constant	pKa < < 0
Quantum yield of direct photo-transformation in water at λ >290 nm	Not required (no absorption λ > 290 nm)
Flammability	Not highly flammable (96.1%) No self-ignition (96.1%)
Explosive properties	Not explosive
UV/VIS absorption (max.)	max. at λ = 206 nm no absorption at λ > 290 nm
Photostability in water (DT₅₀)	156 hours at 25°C, 10 ppm aqueous solution (pH 8.3) addition of 1% acetone: 57 minutes

APPENDIX II

END POINTS AND RELATED INFORMATION

METALAXYL

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	70% within 24 hours
Distribution:	Widely and evenly distributed
Potential for accumulation:	No accumulation
Rate and extent of excretion:	95-100% after 72 hours; slightly higher urinary excretion for females
Toxicologically significant compounds:	Parent compound.
Metabolism in animals:	Hydrolysis of the methyl ester and methyl ether groups. Oxidation of the 2-(6)-methyl group. Oxidation of the phenyl ring. N-dealkylation. Conjugation to glucuronides and sulphates.

Acute toxicity

Rat LD ₅₀ oral:	669 - 1373 mg/kg bw
Rat LD ₅₀ dermal:	> 5000 mg/kg bw
Rat LC ₅₀ inhalation:	> 3.6 mg/l air
Skin irritation:	Not irritating
Eye irritation:	Not irritating
Skin sensitization (test method used and result):	Sensitiser; optimisation test: 30% positive guinea pigs

Short term toxicity

Target / critical effect:	↗ liver weight with centrilobular hepatocellular hypertrophy (rat) and ↗ plasma AP and ALT (dog)
Lowest relevant oral NOAEL / NOEL:	0.66 mg/kg bw/day (10 ppm); -90-day rat); 7.25mg/kg bw and 8mg/kg bw in 6 months and 2 year in dog respectively
Lowest relevant dermal NOAEL / NOEL:	> 1000 mg/kg bw/day; 21-day, rabbit study

Lowest relevant inhalation NOAEL /
NOEL:

No data, not necessary

Genotoxicity

Negative

Long term toxicity and carcinogenicity

Target / critical effect:

Liver (increased liver weight and ALT in female rats)

Lowest relevant NOAEL:

9.43 mg/kg bw/day (250 ppm, 2-year rat study)

Carcinogenicity:

Not carcinogenic

Reproductive toxicity

Target / critical effect - Reproduction:

No reproductive effects at parentally toxic doses.

Lowest relevant reproductive NOAEL /
NOEL:

Reproductive: 58 mg/kg bw/day.

Target / critical effect - Developmental
toxicity:

No developmental effects at maternally toxic dose levels.

Lowest relevant developmental NOAEL
/ NOEL:

> 300 mg/kg bw/day; maternal NOAEL in rat:50mg/kg bw

Delayed neurotoxicity

No data (study not acceptable); ai not related to compounds which
may have a neurotoxic potential.

Other toxicological studies

Metalaxyl is a weak inducer of cytochrome P450.

Toxicity of metabolites:

CGA 107955 (rat)

CGA 108906(rat)

Overall LD50 > 2000 mg/kg bw/day

Medical data

Data to be submitted

Summary

	Value	Study	Safety factor
ADI:	0.08 mg/kg bw/day.	Overall NOAEL in dogs	100
AOEL	0.08 mg/kg bw/day.	Overall NOAEL in dogs	100
ARfD (acute reference dose):	0.5 mg/kg bw	NOAEL 50 mg/kg bw developmental study rat – maternal NOAEL	100

Dermal absorption

30% rat, technical metalaxyl

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:

23% - 38% AR (113DAT, T° 20°C, 60%FC, 0.1 ppm)

Non-extractable residues after 100 days:

56% AR (70% - 113DAT, T° 20°C, 60%FC, 0.1 ppm)

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

metalaxyl acid (CGA 62826)

max. 53.6% (66DAT, T° 25°C, 75% FC, 10 ppm)

range: 22.3% - 53.6%

Supplemental studies

Anaerobic:

degradation pathway similar to the pathway under aerobic conditions, i.e, cleavage of the ester bond, yielding CGA 62826, deamidation of this compound to CGA 67868 and further oxidative and hydrolytic steps with the formation of CO₂ and unextractables, however at lower rate

Soil photolysis:

stable to photolysis

Remarks:

None

Rate of degradation

Laboratory studies

regression analysis (1st order kinetics)

DT_{50lab} (20 °C, aerobic):

DT_{50lab} : 14d, 26d, 43d (r² = 0.99), 33d, 35d, 40d, 42d (calculated from raw data)

median = 36 days

DT_{90lab} (20 °C, aerobic):

DT_{90lab} (20°C, aerobic): 45d, 87d, 126d

DT_{50lab} (10 °C, aerobic):

DT_{50lab} (15°C, aerobic): 33d, 42d

DT_{90lab} (15°C, aerobic): 173d, 254d

DT_{50lab} (20 °C, anaerobic):

DT_{50lab} (20°C, anaerobic): not estimated

DT_{90lab} (20°C, anaerobic): not estimated

degradation in the saturated zone: no data submitted

Field studies (country or region)

DT_{50f} & DT_{90f} from soil dissipation studies:

DT_{50f}:

Germany: 19.5 – 86.9d, 4 values

California: 38.5 – 38.8d, 2 values

Soil accumulation studies:

Soil residue studies:

Remarks:

e.g. effect of soil pH on degradation rate

Minnesota: 113d, 1 value

North Carolina: 38.3 - 39.1d, 2 values

median: 38.7 days

DT_{90f}:

Germany: 64.7 – 288.7d, 4 values

California: 127.8 - 128.8d, 2 values

median: 128.3 days

Canada, Switzerland, The Netherlands, 3-13 appl./season,
200 - 250g/ha/appl., 8 residue trials

maximum levels in top soil: 0.13 - 0.44 mg a.s./kg soil

No relevant

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Adsorption/desorptionK_f / K_{oc}:K_d:

pH dependence:

<p>K_{oc} (a.s.): 29.6, 136.1, 199.8, 283.8dm³/kg; mean K_{oc}: 162 dm³/kg</p> <p>K_{oc} (CGA62826): 22dm³/kg</p> <p>K_d (a.s): 0.15, 0.40, 1.4, 8.0</p> <p>K_d (CGA62826): 0.3</p> <p>no pH dependence</p>
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Mobility**Laboratory studies:**

Column leaching:

Aged residue leaching:

200mm rainfall, 2 days, 4 soils: 0.4 - 92% AR in the leachate

30days ageing, 572 mm rainfall, 45 days, 2 soils: 43.1 - 69.4% AR (34-44.5% AR as a.s. + 7.8% - 22.5% AR as CGA62826)

5 months ageing, 200mm, 2 days, 1 soil: 68.9% AR (11.0% AR as a.s. + 45.2% CGA62826)
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Field studies:

Lysimeter/Field leaching studies:

4 lysimeters, appl. Rate: 330-365g a.s./ha/season:
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Concentration in the leachate of one year:
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metalaxyl: < 0.01 - 0.05 µg/l

CGA62826: 0.25 - 4.12 µg/l

CGA108906: 0.48 - 1.11 µg/l

Field leaching studies showed that metalaxyl and CGA62826 may be found at levels > 0.1 µg/l mainly when rainfall is high.

Remarks:

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2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:

pH 5, T° 25°C: no significant hydrolysis:

pH 7, T° 25°C: no significant hydrolysis:

pH 9, T° 25°C: no significant hydrolysis:

Major metabolites:

Photolytic degradation:

no significant photolysis at T° 25°C

Major metabolites:

Biological degradation

Readily biodegradable:

No

Water/sediment study:

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DT₅₀ water:

DT₉₀ water:

DT₅₀ whole system:

DT₉₀ whole system:

DT50 (a.s.) = 22.4d - 47.5d, DT50 (CGA62826) > 1 year

Distribution in water / sediment systems
(active substance)

a.s. evenly distributed in both phases

water: 0.4 - 14.2% AR (after 112 days)

sediment: 0.6 - 3.9% AR (after 112 days)

Distribution in water / sediment systems
(metabolites)

CGA62826 evenly distributed in both phases.

Water: 55.0 - 68.8% AR (after 112 days)

sediment: 12.3 - 19.0% AR (after 112 days)

Accumulation in water and/or sediment:

No

Mineralisation

max. 3% (after 112 days)

Non-extractable residues

max. 8.8% (after 112 days)

Degradation in the saturated zone No data submitted

Remarks:

None

2.3 Fate and behaviour in air

Volatility

Vapour pressure:

 7.5×10^{-4} Pa at 25°C

Henry's law constant:

 1.6×10^{-5} Pa m³ mol⁻¹ at 22°C

Photolytic degradation

Direct photolysis in air:

no data submitted

Photochemical oxidative degradation in air

DT₅₀:Vapour pressure: 3.3×10^{-3} Pa (T° 25°C);
Atkinson's method: DT50 = 4 - 6h

Volatilisation:

from plant surfaces: 35% (after 24h in glass house conditions)

from soil: 49% (35°C, 30 l/h air flow)

from water: no data

Remarks:

None

Monitoring data

Soil (indicate location and type of study)

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Surface water (indicate location and type of study)

California, Sacramento River, 1983/85: metalaxyl residues exhibited transient peaks of 0.97 to 3.5 µg/l on a monthly basis from March to September, 1984 and of 0.25 to 0.43 µg/l in February to July of 1985.

Ground water (indicate location and type of study)

Florida, North Carolina, Oregon, wells, 1983/84:

levels of metalaxyl in ground waters (12.2 - 15.2 m depth) were generally below the detection limit (<1 and later < 0.25 µg/l)

Air (indicate location and type of study)

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3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:

LD50 (mice) = 832 mg a.s./kg bw

NOAEL (3 generations, rat) > 1250 mg a.s./kg feed

Acute toxicity to birds:

LD50 (mallard duck) = 1466 mg a.s./kg bw

Dietary toxicity to birds:

LC50 (mallard duck) > 10,000 mg a.s./kg feed

Reproductive toxicity to birds:

NOEC (mallard duck) = 300 mg a.s./kg feed

Short term oral toxicity to mammals:

Aquatic Organisms

Acute toxicity fish:

Long term toxicity fish:

Bioaccumulation fish:

Acute toxicity invertebrate:

Chronic toxicity invertebrate:

Acute toxicity algae:

Microcosm or mesocosm tests

Test substance	Time-scale	Endpoint	Toxicity (mg/l)
formulated	acute	LC50 (96h)	0.96 a.s.
technical	chronic		
Metabolite TCP	chronic		
No data	No data	No data	No data
formulated	acute	EL50 (48h)	3.47 form.
Technical	chronic		
formulated			
formulated	Acute	ErC50 (72h)	0.42 a.s.
Several studies. Predicted No Effects Concentration or EAC of 0.1 µg/l.			

Bioconcentration factor (BCF)

Clearance time (CT50)

Honeybees

Acute oral toxicity:

269 µg/bee.

50.3-µg/bee.ARMETIL COBRE

Acute contact toxicity:

> 200 µg/bee.

> 100-µg/bee.ARMETIL COBRE

Other arthropod species

<i>Test species</i>	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect
<i>Typhlodromus pyri</i>	2 or 3 days old	ARMETIL COBRE (metalaxil 8% + cobre 40%)	1.8, 0.72, 0.29, 0.12 and 0.05	LR50 (7d) = 0.63 kg/ha	Dose - Resp onse
<i>Aphidius rhopalosiphi</i>	48h old	ARMETIL COBRE (metalaxil 8% + cobre 40%)	3, 1.5, 0.75, 0.38 and 0.19	LR50 (48h) = 0.38 kg/ha	Dose - Resp onse

Earthworms

Acute toxicity:

LC50 (14 d) > 1000 mg a.s./kg substrate
LC50 (14 d) > 1000 mg a.s./kg substrate N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-alanine
LC50 (14 d) = 1000 mg form./kg soil

Reproductive toxicity:

No data submitted not required

Soil micro-organisms

Nitrogen mineralization:

No prolonged adverse effects at rates up to 5.0 kg a.s./ha
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Carbon mineralization:

No prolonged adverse effects at rates up to 5.0 kg a.s./ha
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APPENDIX IIIA

METALAXYL

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	Reports⁶ on previous use in granting national authorizations
IIA 2.1.1/02 2.1.4	Hosmani, R.S	2002	Melting point/melting range and relative density of test item metalaxyl pure INDUSTRIAS QUÍMICAS DEL VALLÉS Rallis Research Centre, Study N° 3329/01 GLP, Unpublished	
IIA, 2.1.1/01	Das, R.	1993	Report on melting point/melting range CIBA-GEIGY LTD Report No: 16510 GLP. Unpublished	
IIA, 2.1.2/01	Das, R.	1994	Report on boiling point/boiling range CIBA-GEIGY LTD Report No: 26482 GLP. Unpublished	
IIA, 2.1.2/02	Bourgeois, W.	1994	Purification report CIBA-GEIGY LTD Report No: MAS-175-105 Not GLP. Unpublished	
IIA, 2.2/01	Das, R.	1993	Report on density of solids CIBA-GEIGY LTD Report No: 16511 GLP. Unpublished	
IIA, 2.3.2/02	Burkhard, N.	1994	Henry's Law Constant CIBA-GEIGY LTD Report No: Not GLP. Unpublished	

⁶ 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	Reports⁶ on previous use in granting national authorizations
IIA, 2.4.1/01	Das, R.	1994	Report on general physico-chemical properties (pure active ingredient) CIBA-GEIGY LTD Report No: 20175 GLP. Unpublished	
IIA, 2.4.1/02	Das, R.	1993	Report on general physico-chemical properties (pure active ingredient) CIBA-GEIGY LTD Report No: 16508 GLP. Unpublished	
IIA, 2.5.1/01	Bougeois, W.	1994	Report on spectra CIBA-GEIGY LTD Report No: 17935 GLP. Unpublished	
IIA, 2.7/01	Stulz, J.	1994	Report on solubility in organic solvents CIBA-GEIGY LTD Report No: 20714 GLP. Unpublished	
IIA, 2.8/01	Rodler, M.	1991	Report on octanol/water partition coefficient CIBA-GEIGY LTD Report No: EA-135744 GLP. Unpublished	
IIA, 2.9.3/01	Abildt, U.	1995	Estimation of the environmental photochemical half-life of CGA 48988 in surface water CIBA-GEIGY LTD Report No: 47/94 GLP. Unpublished	
IIA, 2.10/01	Stamm, E.	1994	Rate estimation of the hydroxyl radical oxidation of metalaxyl CIBA-GEIGY LTD Report No: not described Not GLP. Unpublished	
IIA, 2.11.1/01	Schürch, H.	1994	Report on flammability of solids. CIBA-GEIGY LTD Report No: PP-94/9T.FLS GLP. Unpublished	
IIA, 2.11.2/01	Schürch, H.	1994	Report on auto-flammability of solids. CIBA-GEIGY LTD Report No: PP-94/9T.AFS GLP. Unpublished	
IIA, 2.13/01	Schürch, H.	1994	Report on explosive properties. CIBA-GEIGY LTD Report No: PP-94/9T.EXP GLP. Unpublished	
IIA, 2.14/01	Ryser, M.	1994	Report on surface tension of aqueous solutions. CIBA-GEIGY LTD Report No: PP-94/18T.SUR GLP. Unpublished	
IIA, 2.15/01	Schürch, H.	1994	Report on oxidizing properties. CIBA-GEIGY LTD Report No: PP-94/9T.OXP GLP. Unpublished	

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	Reports⁶ on previous use in granting national authorizations
IIA, 3.7/01	Anonymous	1995	Safety data sheet of metalaxyl technical pellets CIBA-GEIGY LTD Report No: (3.7/01) Not GLP. Unpublished	
IIA, 3.8/01	Bourgeois, W.	1995a	Statement on procedures for destruction or decontamination CIBA-GEIGY LTD Report No: (3.8/01) Not GLP. Unpublished	
IIA, 3.9/01	Bourgeois, W.	1995b	Statement on emergency in case of accident CIBA-GEIGY LTD Report No: (3.9/01) Not GLP. Unpublished	
IIA 5.2.1/04	Suresh, T.P.	1991a.	Acute oral toxicity study in Wistar rats, test compound: metalaxyl technical. Rallis India Ltd., Bangalore, India, Rep. No. TOXI: RIL.1017.AOR, 12.08.1991 Owned by Rallis India Ltd., Bombay, India Submitted by Industrias Químicas del Vallés, S.A., Barcelona, Spain GLP. Unpublished	
IIA 5.2.1/05	Suresh, T.P.	1991b.	Acute oral toxicity study in Swiss albino mice, test compound: metalaxyl technical. Rallis India Ltd., Bangalore, India, Rep. No. TOXI: RIL.1018.AOM, 12.08.1991 Owned by Rallis India Ltd., Bombay, India Submitted by Industrias Químicas del Vallés, S.A., Barcelona, Spain GLP. Unpublished.	
IIA 5.2.2/03	Suresh, T.P.	1991	Acute dermal toxicity study in Wistar rats, test compound: metalaxyl technical. Rallis India Ltd., Bangalore, India, Rep. No. TOXI: RIL.1019.ADR, 12.08.1991 Owned by Rallis India Ltd., Bombay, India Submitted by Industrias Químicas del Vallés, S.A., Barcelona, Spain GLP. Unpublished.	
IIA 5.2.3/01	Hartmann, H.R.	1992	Acute inhalation toxicity in the rat. Ciba-Geigy Ltd., Stein, Switzerland, Rep. No. 923008, 09.04.1992 Owned by Ciba-Geigy Ltd. Basle, Switzerland Submitted by Ciba-Geigy Ltd. Basle, Switzerland GLP. Unpublished.	
IIA 5.2.4/02	Suresh, T.P..	1991	Primary skin irritation study in New Zealand White rabbits, test compound: metalaxyl technical. Rallis India Ltd., Bangalore, India, Rep. No. TOXI: RIL.1020.SKIN, 12.08.1991 Owned by Rallis India Ltd., Bombay, India Submitted by Industrias Químicas del Vallés, S.A., Barcelona, Spain GLP. Unpublished.	

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	Reports⁶ on previous use in granting national authorizations
IIA 5.2.5/02	Suresh, T.P..	1991	Primary eye irritation study in New Zealand White rabbits, test compound: metalaxyl technical. Rallis India Ltd., Bangalore, India, Rep. No. TOXI: RIL.1021.EYE, 12.08.1991 Owned by Rallis India Ltd., Bombay, India Submitted by Industrias Químicas del Vallés, S.A., Barcelona, Spain GLP. Unpublished.	
IIA 5.2.6/02	Arcelin, G.	1991	Contact hypersensitivity to CGA 48988 tech. in albino guinea pigs, modified Buehler method. Research and Consulting Company AG, Itingen, Switzerland, Rep. No. RCC 314504, 10.12.1991 Owned by Ciba-Geigy Ltd. Basle, Switzerland Submitted by Ciba-Geigy Ltd. Basle, Switzerland. GLP. Unpublished.	
IIA 5.4.2/02	Hertner, T. and Arni, P..	1992	Micronucleus test, mouse. Ciba-Geigy Basel, Genetische Toxikologie, Rep. No. 923096, 17.12.1992 Owned by Ciba-Geigy Ltd. Basle, Switzerland Submitted by Ciba-Geigy Ltd. Basle, Switzerland GLP. Unpublished	
IIA 4.2.2/04	Pardhasaradhi, V	2002a	Analytical method for analysis of metalaxyl residues in soil and method validation Industrias Químicas del Vallés Rallis Research Centre, Study N° 3326/01 GLP, Unpublished	
IIA 4.2.2/05	Krainz, A	2009	Development and validation of an analytical method for the determination of acid metalaxyl in soil Industrias Químicas del Vallés Harlan Laboratories study C59898 GLP, Unpublished	
IIA 4.2.3/03	Pardhasaradhi, V	2002b	Analytical method for analysis of metalaxyl residues in water and method validation Industrias Químicas del Vallés Rallis Research Centre, Study N° 3327/01 GLP, Unpublished	
IIA 4.2.3/04	Wolf, S	2009	Development and validation of an analytical method for the determination of acid metalaxyl in drinking-, ground and surface water Industrias Químicas del Vallés Harlan Laboratories study C59900 GLP, Unpublished	
IIA 4.2.4/03	Krainz, A.	2010	Metalaxyl: Validation of an analytical method for the determination of metalaxyl in air Industrias Químicas del Vallés Harlan Laboratories study C80003 draft report GLP, Unpublished	

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	Reports⁶ on previous use in granting national authorizations
IIA, 4.1/03	Bourgeois, W.	1993	Analytical method - By-products and supplementary tests Ciba-Geigy Ltd. Report No: AK-77/4 Not GLP. Unpublished	
IIA, 4.1/05	Kreuzer, A., Wyden, W.	1992	Analytical method - Nitrosamines in Agrochemicals – by chemical cleavage / Chemiluminescence detection Ciba-Geigy Ltd. Report No: AG-20/3 Not GLP. Unpublished	
IIA, 4.1/06	Bourgeois, W.	1994	Report on nitrosamines Ciba-Geigy Ltd. Report No: AG-21935 GLP. Unpublished	

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	Reports⁷ on previous use in granting national authorizations
IIA 5.2.1/04	Suresh, T.P..	1991a	Acute oral toxicity study in Wistar rats, test compound: metalaxyl technical. Rallis India Ltd., Bangalore, India, Rep. No. TOXI: RIL.1017.AOR, 12.08.1991 Owned by Rallis India Ltd., Bombay, India Submitted by Industrias Químicas del Vallés, S.A., Barcelona, Spain GLP. Unpublished	
IIA 5.2.1/05	Suresh, T.P.	1991b.	Acute oral toxicity study in Swiss albino mice, test compound: metalaxyl technical. Rallis India Ltd., Bangalore, India, Rep. No. TOXI: RIL.1018.AOM, 12.08.1991 Owned by Rallis India Ltd., Bombay, India Submitted by Industrias Químicas del Vallés, S.A., Barcelona, Spain GLP. Unpublished	
IIA 5.2.2/03	Suresh, T.P..	1991	Acute dermal toxicity study in Wistar rats, test compound: metalaxyl technical. Rallis India Ltd., Bangalore, India, Rep. No. TOXI: RIL.1019.ADR, 12.08.1991 Owned by Rallis India Ltd., Bombay, India Submitted by Industrias Químicas del Vallés, S.A., Barcelona, Spain GLP. Unpublished	
IIA 5.2.3/01	Hartmann, H.R..	1992	Acute inhalation toxicity in the rat. Ciba-Geigy Ltd., Stein, Switzerland, Rep. No. 923008, 09.04.1992 Owned by Ciba-Geigy Ltd. Basle, Switzerland Submitted by Ciba-Geigy Ltd. Basle, Switzerland GLP. Unpublished	
IIA 5.2.4/02	Suresh, T.P..	1991	Primary skin irritation study in New Zealand White rabbits, test compound: metalaxyl technical. Rallis India Ltd., Bangalore, India, Rep. No. TOXI: RIL.1020.SKIN, 12.08.1991 Owned by Rallis India Ltd., Bombay, India Submitted by Industrias Químicas del Vallés, S.A., Barcelona, Spain GLP. Unpublished	
IIA 5.2.5/02	Suresh, T.P.	1991	Primary eye irritation study in New Zealand White rabbits, test compound: metalaxyl technical. Rallis India Ltd., Bangalore, India, Rep. No. TOXI: RIL.1021.EYE, 12.08.1991 Owned by Rallis India Ltd., Bombay, India Submitted by Industrias Químicas del Vallés, S.A., Barcelona, Spain GLP. Unpublished	

⁷ 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.

IIA 5.2.6/02	Arcelin, G.	1991	Contact hypersensitivity to CGA 48988 tech. in albino guinea pigs, modified Buehler method. Research and Consulting Company AG, Itingen, Switzerland, Rep. No. RCC 314504, 10.12.1991 Owned by Ciba-Geigy Ltd. Basle, Switzerland Submitted by Ciba-Geigy Ltd. Basle, Switzerland GLP. Unpublished	
IIA 5.4.2/02	Hertner, T. and Arni, P.	1992	Micronucleus test, mouse. Ciba-Geigy Basel, Genetische Toxikologie, Rep. No. 923096, 17.12.1992 Owned by Ciba-Geigy Ltd. Basle, Switzerland Submitted by Ciba-Geigy Ltd. Basle, Switzerland GLP. Unpublished	
IIA 5.8.1/02	Hartmann, H.R..	1994	Acute oral toxicity in the rat CGA 108'906, metabolite of CGA 48'988. Ciba-Geigy Ltd., Stein, Switzerland Rep. No. 943085, 25.08.1994 Owned by Ciba-Geigy Ltd. Basle, Switzerland Submitted by Ciba-Geigy Ltd. Basle, Switzerland GLP. Unpublished	

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 6.3 /196	Bull, M.S.	1991a	CGA 48988 and copper, wine grapes, juice and wine, Australia, Ciba-Geigy Ltd., Australia, Rep.Nr. 91-11-1343, 11.11.1991 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited Not GLP. Not GEP. Unpublished.	
IIA 6.3 /196A	Bull, M.S.	1991b	CGA 48988 and copper, wine grapes, juice and wine, Australia, Ciba-Geigy Ltd., Australia, Rep.Nr. 91-11-1343, 11.11.1991 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited Not GLP. Not GEP. Unpublished	
IIA 6.2 /02	Emrani, J	1990	Metabolism of O-14-CGA 48988 in goats, Ciba-Geigy Corp.Greensboro, USA, Rep.Nr. ABR-90078, 10.10.1990 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited GLP. GEP. Unpublished	
IIA 6.2 /03	Emrani, J	1991	Supplemental report on the metabolism of O-14-CGA 48988 in goats, identification of major milk metabolite "A", Ciba-Geigy Corp.Greensboro, USA, Rep.Nr. ABR-91075, 14.11.1991 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited GLP. GEP. Unpublished	
IIA 6.4 / 02	Eudy, L.W	1991	CGA 48988 - Three level 28 day poultry study, Ciba-Geigy Corp., Greensboro NC, USA, Rep.Nr. ABR-91047, 25.11.1991 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited Not GLP. Not GEP. Unpublished	
IIA 6.3.3 /04	Eudy, L.W.	1993	Storage stability of total residues of metalaxyl in weathered crops under freezer storage conditions, Ciba-Geigy Corp, Greensboro NC, USA. Rep.Nr. ABR-93009, 27.08.1993 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited Not GLP. GEP. Unpublished	
IIA 6.2 /05	Kennedy, E.	1991	Supplemental report on the metabolism of O-14-CGA 48988 in hens, Ciba-Geigy Corp.Greensboro, USA, Rep.Nr. ABR-91077, 14.11.1991 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited GLP. GEP. Unpublished	

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 6.3 /550	Kühne, R.O.	1991n	CGA 48988, tomatoes, Argentina, Ciba-Geigy Ltd., Basle, Rep.Nr. 2015-90, 17.12.1991 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited Not GLP. GEP. Unpublished	
IIA 6.3 /396	Kühne, R.O.	1992a	CGA 48988 + copper, potatoes, Canada, Ciba-Geigy Ltd., Basle, Rep.Nr. 2071-90, 31.07.1992 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited Not GLP. GEP. Unpublished	
IIA 6.3 /397	Kühne, R.O.	1992b	CGA 48988 + copper, potatoes, Canada, Ciba-Geigy Ltd., Basle, Rep.Nr. 2072-90, 31.07.1992 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited Not GLP. GEP. Unpublished	
IIA 6.3 /398	Kühne, R.O.	1992c	CGA 48988 + copper, potatoes, Canada, Ciba-Geigy Ltd., Basle, Rep.Nr. 2075-90, 31.07.1992 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited Not GLP. GEP. Unpublished	
IIA 6.3 /399	Kühne, R.O.	1992d	CGA 48988 + copper, potatoes, Canada, Ciba-Geigy Ltd., Basle, Rep.Nr. 2076-90, 31.07.1992 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited Not GLP. GEP. Unpublished	
IIA 6.3 /395	Kühne, R.O.	19931	CGA 48988, CGA 48988, RIDOMIL PLUS 45WP, Residues in Potatoes, Canada, Ciba-Geigy Ltd., Basle, Rep.Nr. 2053-91, 04.03.1993 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited Not GLP. GEP. Unpublished	
IIA 6.3 /387	Kühne, R.O.	1993x	CGA 48988, RIDOMIL CT 81 WP, Potatoes, Spain, Ciba-Geigy Ltd., Basle, Rep.Nr. 2075/92, 11.08.1993 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited Not GLP. GEP. Unpublished	
IIA 6.3 /388	Kühne, R.O.	1993y	CGA 48988, RIDOMIL CT 81 WP, Potatoes, Spain, Ciba-Geigy Ltd., Basle, Rep.Nr. 2076/92, 11.08.1993 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited Not GLP. GEP. Unpublished	

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 6.3 /389	Kühne, R.O.	1993z	CGA 48988, RIDOMIL CT 81 WP, Potatoes, Spain, Ciba-Geigy Ltd., Basle, Rep.Nr. 2077/92, 11.08.1993 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited Not GLP. GEP. Unpublished	
IIA 6.3 /554	Kühne, R.O.	1993 aa	CGA 48988, RIDOMIL CT 81 WP, Tomatoes, Spain, Ciba-Geigy Ltd., Basle, Rep.Nr. 2074/92, 11.08.1993 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited Not GLP. GEP. Unpublished	
IIA 6.3 /556	Kühne, R.O.	1994f	CGA 48933 + Chlorothalonil, RIDOMIL CT 60, Tomatoes, Morocco, Ciba-Geigy Ltd., Basle, Rep. No. 2008/91, 28.02.1994 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited Not GLP. GEP. Unpublished	
IIA 6.3 /185	Kühne, R.O.	1994m	CGA 48988 + Folpet, Ridomil combi 50 WP, grapes, Morocco, Ciba-Geigy Ltd., Basle, Rep.Nr. 2005/91, 07.03.1994 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited Not GLP. GEP. Unpublished	
IIA 6.3 /241	Kühne, R.O.	1994n	CGA 48988 + Mancozeb, Ridomil MZ 58 WP, grapes, Morocco, Ciba-Geigy Ltd., Basle, Rep.Nr. 2036/87, 28.02.1994 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited Not GLP. GEP. Unpublished	
IIA 6.3 /242	Kühne, R.O.	1994o	CGA 48988 + Mancozeb, Ridomil MZ 58 WP, grapes, Morocco, Ciba-Geigy Ltd., Basle, Rep.Nr. 203//87, 28.02.1994 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited Not GLP. GEP. Unpublished	
IIA 6.6 /01A	McFarland, J.	1992a	Biological report for greenhouse grown tobacco grown in soil treated with 14C-CGA 48988, Ciba-Geigy Corp, Greensboro NC, USA. Rep.Nr. BIOL-90017, 28.01.1992 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited Not GLP. Not GEP. Unpublished	
IIA 6.6 /01B	McFarland, J.	1992b	Biological report for greenhouse rotational crops grown after tobacco in soil treated with 14C-CGA 48988, Ciba-Geigy Corp, Greensboro NC, USA. Rep.Nr. BIOL-90016, 28.01.1992 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited Not GLP. Not GEP. Unpublished	

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 /01C	McFarland, J.	1992c	Uptake and metabolism of metalaxyl in greenhouse rotational crops following target tobacco grown in soil treated with phenyl-14C-metalaxyl, Ciba-Geigy Corp, Greensboro NC, USA. Rep.Nr. ABR-91084, 29.01.1992 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited Not GLP. Not GEP. Unpublished	

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 7.2.1.3.2	Biever, R.C. 1992.	yes	Ridomil 2 E - An aquatic dissipation study for water seeded rice (Memphis / Tennessee), Springborn Life Science Inc., Mass., USA, Rep.Nr. SLI-91-11-4013, 21.01.1992 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basle, Switzerland GLP. Unpublished.	
IIA 7.1.1.2.2/11	Braxton, S.M. and Bird, R.McK..	1991	CGA 48988, Ridomil 2E, field dissipation, tobacco and bare soil, North Carolina, Ciba-Geigy Corp., Greensboro NC, USA, Rep.Nr. 23TBBS, 23.01.1991 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basle, Switzerland GLP. Unpublished.	
IIA 7.1.2.1	Heinis, T.	1994a	Soil adsorption of CGA 62826, Ciba-Geigy Ltd., Basel, Switzerland, Rep. Nr. 94 HT 04, 10.11.1994 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland Not GLP. Unpublished.	
IIIA 9.2.1	Hosang, J.	1994a	CGA 48988 / CGA 62826. Evaluation of accumulation, leaching and metabolism under Finnish conditions, Ciba-Geigy Ltd., Basle, Switzerland, Rep. Nr. HF94011, 13.07.1994 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland Not GLP. Unpublished.	
IIIA 9.2.1	Hosang, J.	1994b	CGA 48988 / CGA 62826. Evaluation of accumulation, leaching and metabolism under Norwegian conditions, Ciba-Geigy Ltd., Basle, Switzerland, Rep. Nr. HF94012, 13.07.1994 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland Not GLP. Unpublished.	
IIIA 9.2.1	Hosang, J.	1994c	CGA 48988 / CGA 62826. Evaluation of accumulation, leaching and metabolism under Swedish conditions, Ciba-Geigy Ltd., Basle, Switzerland, Rep. Nr. HF94013, 13.07.1994 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland Not GLP. Unpublished.	

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 7.2.2.2	Krauss, J..	1992	Volatilisation of CGA 48988 from bean leaves under indoor conditions after spray application of [14C-phenyl] labelled material, Ciba-Geigy Ltd., Basle, Rep.Nr. 12-92, 22.05.1992 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland GLP. Unpublished.	
IIA 7.1.3.3	Kubiak, R..	1993	Degradation and leaching of 14C-metalaxyl in two sand lysimeters under outdoor conditions after application to vine - Interim Report, SLFA FB Phytomedizin, Neustadt/Weinstrasse, Study No. CIBO3, 28/10/1993 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland GLP. Unpublished.	
IIA 7.1.3.3	Kubiak, R..	1995a	Degradation and leaching of 14C-metalaxyl in two sand lysimeters under outdoor conditions after application to potatoes, SLFA FB Phytomedizin, Neustadt/Weinstrasse, Study No. CIBO3, 2.1995 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland GLP. Unpublished.	
IIA 7.1.1.2.2/12	Kühne, R.O.	1992a yes	Determination of residues of metalaxyl (CGA 48988) and of metabolite CGA 62826 in soil (soil dissipation) - field experiment - Canada, Ciba-Geigy Ltd., Basle, Switzerland, Rep.Nr. 2065-90, 02.04.1992 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basle, Switzerland GLP. Unpublished.	
IIA 7.1.1.2.2/13	Kühne, R.O.	1992b	Determination of residues of metalaxyl (CGA 48988) and of metabolite CGA 62826 in soil (soil dissipation study)- field experiment - Canada, Ciba-Geigy Ltd., Basle, Switzerland, Rep.Nr. 2066-90, 02.04.1992 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basle, Switzerland GLP. Unpublished.	
IIA 7.1.1.2.2/14	Kühne, R.O.	1992c	Determination of residues of metalaxyl (CGA 48988) and of metabolite CGA 62826 in soil (soil dissipation study)- field experiment - Canada, Ciba-Geigy Ltd., Basle, Switzerland, Rep.Nr. 2067-90, 02.04.1992 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basle, Switzerland GLP. Unpublished.	

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 7.1.1.2.2/15	Kühne, R.O.	1992d	Determination of residues of metalaxyl (CGA 48988) and of metabolite CGA 62826 in soil (soil dissipation study)- field experiment - Canada, Ciba-Geigy Ltd., Basle, Switzerland, Rep.Nr. 2068-90, 02.04.1992 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basle, Switzerland GLP. Unpublished.	
IIA 7.2.1.3.2	Leech, G.N. and Wiepke, Th..	1992	Aquatic dissipation of metalaxyl (Ridomil 2 E) in Californian rice paddy, Ciba-Geigy Corp., Greensboro NC, USA, Rep.Nr. EF-90-326, 14.01.1992 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basle, Switzerland GLP. Unpublished.	
IIA 7.2.1.3.2	Morgenroth, U..	1994	14C-CGA 48988 (Metalaxyl). Degradation and metabolism in aquatic systems, RCC AG, Itingen, Switzerland, Rep. Nr. 341076, 03.03.1994, include. amendment of August 23, 1994 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland GLP. Unpublished.	
IIA 7.1.1.2.2/01	Offizorz, P. and Ressler, H.	1991a	Field soil dissipation rate determination of metalaxyl, RCC GmbH, Rossdorf, Germany, Rep. Nr. 171314, dated 13.02.1991 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basle, Switzerland Not GLP. Unpublished.	
IIA 7.1.1.2.2/02	Offizorz, P. and Ressler, H..	1991b	Field soil dissipation rate determination of metalaxyl, RCC GmbH, Rossdorf, Germany, Rep. Nr. 171325, 13.02.1991 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basle, Switzerland Not GLP. Unpublished.	
IIA 7.1.1.2.2/03	Offizorz, P. and Ressler, H.	1991c	Field soil dissipation rate determination of metalaxyl, RCC GmbH, Rossdorf, Germany, Rep. Nr. 171336, 13.02.1991 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basle, Switzerland Not GLP. Unpublished.	

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 7.1.1.2.2/04	Offizorz, P. and Ressler, H.	1991d	Field soil dissipation rate determination of metalaxyl, RCC GmbH, Rossdorf, Germany, Rep. Nr. 223209, 21.03.1991 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basle, Switzerland Not GLP. Unpublished.	
IIA 7.1.1.1.1	Schanne, C.	1991	Degradation of 14C-labelled metalaxyl in one soil incubated under various experimental conditions, RCC AG, Itingen, Switzerland, Rep.Nr. 262315, 16.12.1991 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland GLP. Unpublished.	
IIA 7.2.1.3.2	Vithala, R.	1992	Anaerobic Aquatic Metabolism of 14C-Metalaxyl, Ciba-Geigy Corp., Greensboro NC, USA, Rep.Nr. 005-001-007-89, 13.01.1992 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland GLP. Unpublished.	

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 8.2.4	Grade, R.	1994a	Report on the acute toxicity test of CGA 108906 tech. (Metabolite of CGA 48988) on Daphnia, Project Report 943524, Ecotoxicology, Ciba-Geigy, Basel, 24.06.1994 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP. Unpublished.	
IIA 8.2.6	Grade, R..	1994c	Report on the growth inhibition test of CGA 108906 tech. (Metabolite of CGA 48988) to Green Algae, Project Report 943525, Ecotoxicology, Ciba-Geigy, Basel, 24.06.1994 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP. Unpublished.	
IIA 8.3.1.1	Kleiner, R..	1994	Testing toxicity to Honeybee - Apis mellifera L. (Laboratory) According to EPPO Guideline No. 170 Report Nr. 94-10-48-056, 05.12.1994 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP. Unpublished.	
IIA 8.2.1	Memmert, U. and Knoch, E.	1991a	Acute toxicity of CGA 62826 to Rainbow trout in a semi-static test (96h), Project Report 251054, RCC GmbH, Rossdorf, Germany, 18.12, 1991 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP. Unpublished.	
IIA 8.2.4	Memmert, U. and Knoch, E.	1991b	48-hour toxicity of CGA 62826 to Daphnia magna (OECD-Immobilization -Test), Project Report 251032, RCC GmbH, Rossdorf, Germany, 18.12.1991 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP. Unpublished.	
IIA 8.2.4	Memmert U. and Knoch, E.	1991c	48-hour toxicity of CGA 67868 to Daphnia magna (OECD-Immobilization -Test), Project Report 257038, RCC GmbH, Rossdorf, Germany, 11.12.1991 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP. Unpublished.	
IIA 8.2.6	Memmert, U. and Knoch, E.	1991d	Toxicity of CGA 62826 to Scenedesmus subspectus (Algae Growth Inhibition Test), Project Report 251010, RCC GmbH, Rossdorf, Germany, 18.12.1991 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP. Unpublished.	

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 8.2.1	Memmert, U. and Knoch, E.	1992a	Acute toxicity of CGA 67868 to Rainbow trout in a semi-static test (96h), Project Report 257051, RCC GmbH, Rossdorf, Germany, 13.01. 1992 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle. GLP. Unpublished.	
IIA 8.2.6	Memmert, U. and Knoch, E.	1992b	Toxicity of CGA 67868 to Scenedesmus subspicatus (Algae Growth Inhibition Test), Project Report 257016, RCC GmbH, Rossdorf, Germany, 13.01.1992 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP. Unpublished.	
IIA 8.2.1	Rufli, H.	1994a	Report on the acute toxicity test of CGA 108906 techn. (Metabolite of CGA 48988) to Rainbow Trout, Project Report 943542, Ecotoxicology, Ciba-Geigy, Basel, 11.07.1994 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP. Unpublished.	
IIA 8.4.1	Vial, A.	1990	Acute toxicity test of CGA 48988 techn. to Earthworm (<i>Eisenia foetida foetida</i>), Ciba-Geigy Ltd., Basle, Rep.Nr. 901034, 27.04.1990 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP. Unpublished.	
IIA 8.5	Völk, S..	1992	The effects of CGA 48988-Metalaxyl on soil respiration and nitrification, RCC AG, Itingen, Switzerland, Rep.Nr. 305785, 24.02.1992 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP. Unpublished.	
IIA 8.7	Weinstock, M.	1994	Report on the test for Activated Sludge Respiration Inhibition of CGA 48988 techn., Project Report 943512, Ecotoxicology, Ciba-Geigy Basel, 24.03.1994 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP. Unpublished.	

APPENDIX IIIB

METALAXYL

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	Reports on previous use in granting national authorizations
IIIA 2.7.1/02	Hosmani, R.S	2002a	Accelerated storage stability of ARMETIL COBRE IQV Rallis Research Centre, Study N° 3404/02 GLP, Unpublished	
IIIA 2.7.3/01	Hosmani, R.S	2002b	Shelf life of ARMETIL COBRE IQV Rallis Research Centre, Study N° 3404/02 GLP, Unpublished	
IIIA 2.8.3/02	Hosmani, R.S	2004	Suspensibility and suspension stability of ARMETIL COBRE IQV Rallis Research Centre, Study N° 3406/02 GLP, Unpublished	
IIA 4.2.2/04	Pardhasaradhi, V	2002a	Analytical method for analysis of metalaxyl residues in soil and method validation IQV Rallis Research Centre, Study N° 3326/01 GLP, Unpublished	
IIA 4.2.3/03	Pardhasaradhi, V	2002b	Analytical method for analysis of metalaxyl residues in water and method validation IQV Rallis Research Centre, Study N° 3327/01 GLP, Unpublished	
IIA 4.2.4/02	Pardhasaradhi, V	2003	Analytical method for analysis of metalaxyl residues in air and method validation IQV Rallis Research Centre, Study N° 3328/01 GLP, Unpublished	

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 5.1.2 (2.7.1/01)	Hosmani, R.S	2004	Accelerated storage stability of ARMETIL COBRE IQV Rallis Research Centre, Study N° 3404/02 GLP, Unpublished	
IIA 4.2.2/05	Krainz, A	2009	Development and validation of an analytical method for the determination of acid metalaxyl in soil IQV Harlan Laboratories study C59898 GLP, Unpublished	
IIA 4.2.3/04	Wolf, S	2009	Development and validation of an analytical method for the determination of acid metalaxyl in drinking-, ground and surface water IQV Harlan Laboratories study C59900 GLP, Unpublished	
IIA 4.2.4/03	Krainz, A.	2010	Metalaxyl: Validation of an analytical method for the determination of metalaxyl in air IQV Harlan Laboratories study C80003 draft report GLP, Unpublished	

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

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

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
IIIA, 8	Terry, A.	2002	Predicted Environmental Concentrations of metelaxyl and its major metabolite in groundwater in the European Union Using the FOCUS Groundwater Scenarios. IQV	

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, 9.6.1	Kamath, H.G.	2002	Earthworm, acute toxicity test (artificial soil test) with Metalaxyl Technical. Rallis Research Centre, India. IQV, Report n° 3325/01 GLP Not published	
IIA, 9.6.1	Kamath, H.G.	2003	Earthworm, acute toxicity test (artificial soil test) with N-(2, 6-dimethylphenyl)-N-(methoxyacetyl)-alanine. Rallis Research Centre, India. IQV, Report n° 3331/01 GLP Not published	
IIIA, 9.6.3	Clayton, M.A. Hughes, J.M.	2003	Armetil Cobre Determination of Acute Toxicity (LC50) of the Armetil Cobre to Earthworms Inveresk Research, Scotland. IQV, Report n° 21969 GLP Not published	
IIIA, 9.2.5	Hargreaves, T.L. Clayton, M.A.	2003	Armetil Cobre Determination of Acute Toxicity of the Armetil Cobre to Daphnia (48h Static) Inveresk Research, Scotland. IQV, Report n° 22026 GLP Not published	
IIIA, 9.5.1	Hughes, J.M. Paterson, K.	2003a	Armetil Cobre (Metalaxyl 8% + Copper 40%) <i>Aphidius rhopalosiphi</i> Dose-Response Test (48h LR50) Inveresk Research, Scotland. IQV, Report n° 22520 GLP Not published	
IIIA, 9.5.1	Hughes, J.M. Paterson, K.	2003b	Armetil Cobre (Metalaxyl 8% + Copper 40%) <i>Typhlodromus pyri</i> Dose-Response Test (7d LR50) Inveresk Research, Scotland. IQV, Report n° 22520 GLP Not published	
IIIA, 9.4.1	Kelly, C.R. Hughes, J.M.	2002	Armetil Cobre A Laboratory Evaluation of the Acute Toxicity of a Plant Protection Product to the Honey Bee (<i>Apis mellifera</i>): 48h Contact and Oral LD50 Inveresk Research, Scotland. IQV, Report n° 20887 GLP Not 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	Reports on previous use in granting national authorizations
IIIA, 9.2.1	Knight, B. Allan, J.	2004a	Armetil Cobre Determination of Acute Toxicity (LC50) to Rainbow Trout (96h Semi-Static) Inveresk Research, Scotland. IQV, Report n° 20246 GLP Not published	
IIIA, 9.2.8	Knight, B. Allan, J.	2004b	Armetil Cobre Algae, Growth Inhibition Test (72h, EC50) Inveresk Research, Scotland. IQV, Report n° 20253 GLP Not published	

APPENDIX IV

List of uses supported by available data

METALAXYL

Summary of intended uses

Crop and/or situation	EU Area	Product name	F G O r I ¹	Pests or group of pests controlled	Formulation		Application			Application rate per treatment			PHI ² (days)	Remarks	
					type	conc. of a.s.	method kind	growth stage & season	number min max	min. interval between applications (days)	kg a.s./hl min max	Water L/ha min max			kg a.s./ha min max
Potato	S	Armetil Cobre	F	<i>Phytophthora infestans</i> (Downy mildew) <i>Alternaria solani</i> (Alternaria)	WP	8% MTX + 40% COC	High volume sprayer	First symptoms	1-3	14	0.03-0.04	500	0.15-0.20	14	
Tomato	S	Armetil Cobre	F, G	<i>Phytophthora infestans</i> (Downy mildew) <i>Alternaria solani</i> (Alternaria)	WP	8% MTX + 40% COC	High volume sprayer	Fruit set	1-4	14	0.02	800-1500	0.16-0.30	21	

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)	(i) g/kg or g/l
	(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)	(j) Growth stage at last treatment at time of application
	(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds	(k) The minimum and maximum conditions of use must be explained
	(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(l) PHI - minimum pre-harvest interval
	(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989	(m) Remarks may include: Expiry date
	(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	

¹ Outdoor or field use (F), glasshouse application (G) or indoor application (I)

² PHI - minimum pre-harvest interval