



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate D - Food Safety: production and distribution chain
D3 - Chemicals, Contaminants and Pesticides

Thiophanate-methyl

5030/VI/98 final

15 February 2005

Review report for the active substance **thiophanate-methyl**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on
15 February 2005
in view of the inclusion of thiophanate-methyl 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 thiophanate-methyl, 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. Thiophanate-methyl 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, Nisso Chemical Europe on 16 June 1993, United Phosphorus Ltd on 26 July 1993, Cequisa on 23 July 1993, ACI International on 30 July 1993, Helm AG on 23 July 1993, Ellagret SA on 29 July 1993 and B.V. Luxan on 21 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance thiophanate-methyl 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 Germany as rapporteur Member State to carry out the assessment of thiophanate-methyl on the basis of the dossier submitted by the notifier. 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 thiophanate-methyl this deadline was 31 October 1995.

¹ OJ No L 366, 15.12.1992, p.10.

² OJ No L 259, 13.10.2000, p.27.

³ OJ No L 107, 28.04.1994, p.8.

⁴ OJ No L 225, 22.09.1995, p.1.

Only Nisso Chemical Europe, represented by SCC GmbH, submitted in time a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore Nisso Chemical Europe was considered to be the main data submitter. No information has furthermore been submitted by third parties.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Germany submitted on 21 November 1997 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 thiophanate-methyl 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 thiophanate-methyl from Nisso Chemical Europe, on 16 January 1998.

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 as well as to Nisso Chemical Europe being main data submitter, on 9 December 1997.

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 March to July 1998 and from February to September 2003.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the main data submitter on 4 September 1998 for comments and further clarification.

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 July 1998 to December 2004, and was finalised in the meeting of the **Standing Committee** on 15 February 2005.

These documents were also submitted to the Scientific Committee on Plants for separate consultation. The report of this Committee was formally adopted on 23 March 2001 (SCP/BENOMY/002 – final, SCP/CARBEN/002 – final, SCP/THIOPHAN/002 - final⁵).

⁵ Opinion of the Scientific Committee on Plants regarding the inclusion of thiophanate-methyl in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market

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 2005/53/EC⁶ concerning the inclusion of thiophanate-methyl in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing thiophanate-methyl 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.

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 thiophanate-methyl 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 thiophanate-methyl containing plant protection product for which Member States will grant or review the authorisation.

⁶ OJ No L 241, 17.09.2005, p. 51-56

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 46 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). The calculation was done with the ADI of carbendazim and on basis of the intended uses of thiophanate-methyl only. 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 thiophanate-methyl 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.

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

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 thiophanate-methyl

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 protection of aquatic organisms, earthworms and other soil macro-organisms.

Conditions of authorisation should include risk mitigation measures, 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 thiophanate-methyl in Annex I under the current inclusion conditions.

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.

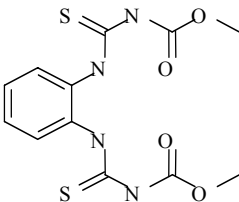
9. Updating of this review report

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 thiophanate-methyl in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

THIOPHANATE-METHYL

Common name (ISO)	Thiophanate-methyl
Chemical name (IUPAC)	Dimethyl 4,4'-(o-phenylene)bis(3-thioallophanate)
Chemical name (CA)	Dimethyl [1,2-phenylenebis (iminocarbonothioyl)] biscarbamate
CIPAC No	262
CAS No	23564-05-8
EEC No	EEC: 006-069-00-3; EINECS: 245-740-7
FAO SPECIFICATION	AGP: CP/331 (1995); 950 ± 20 g/kg;
Minimum purity	950 g/kg
Molecular formula	C ₁₂ H ₁₄ N ₄ O ₄ S ₂
Molecular mass	342.4
Structural formula	 <p>The image shows the chemical structure of Thiophanate-methyl. It consists of a central benzene ring with two nitrogen atoms at the 1 and 2 positions. Each nitrogen atom is double-bonded to a sulfur atom and single-bonded to a methyl carbamate group (-N-C(=O)-O-CH₃).</p>

Melting point	Not determined, decomposes at 165 °C
Boiling point	Not required, test substance decomposes before melting
Appearance	Pure a.s.: white crystalline powder without odour; Techn. a.s. (970 g/kg): pale brown powder with faint sulfuric odour
Relative density	1.45 (20 °C)
Vapour pressure	< 9.4 x 10 ⁻⁶ Pa (9.5 °C) < 8.8 x 10 ⁻⁶ Pa (19.6 °C) < 9.5 x 10 ⁻⁶ Pa (29.8 °C)
Henry's law constant	8.1 x 10 ⁻⁵ Pa·m ³ ·mol ⁻¹
Solubility in water	0.02 g/L at ambient temperature and pH range 4 – 7.5. (One value (from 1992) obtained with the purest material is 0.04 g/L at 25 °C)
Solubility in organic solvents	In g/L at 25 °C: n-hexane: 0.00047 xylene: 0.11 n-octanol: 0.18 dichloromethane: 0.73 ethyl acetate: 8.40 methanol: 7.80 acetone: 29.00
Partition co-efficient (log P_{ow})	pH range 4 - 7: 1.45 ± 0.5
Hydrolytic stability (DT₅₀)	pH 5: > 1 y (25 °C) pH 7: 36 d (25 °C) pH 9: 0.7 d (25 °C)
Dissociation constant	pK _a : 7.28 (25 °C) - Species not identified
Quantum yield of direct phototransformation in water at λ >290 nm	5.97 x 10 ⁻³
Flammability	Not highly flammable
Explosive properties	Contains no moiety in its molecule which could render it potentially explosive due to theoretical reasons
UV/VIS absorption (max.)	λ max.: 268 nm; ε max: 19046 l·mol ⁻¹ ·cm ⁻¹ ; shoulder: 305 nm
Photostability in water (DT₅₀)	2.2 d (pH 5)

APPENDIX II**END POINTS AND RELATED INFORMATION****THIOPHANATE-METHYL****1 Toxicology and metabolism****Absorption, distribution, excretion and metabolism in mammals**

Rate and extent of absorption:	Rapidly absorbed; ca 70 % based on urinary excretion within 96 h (low dose).
Distribution:	Widely distributed
Potential for accumulation:	No potential for accumulation
Rate and extent of excretion:	Rapidly excreted, ca. 70 % via urine, ca. 30 % via faeces within 96 h (low dose)
Toxicologically significant compounds:	Parent compound and metabolites especially carbendazim (MBC)
Metabolism in animals:	Predominantly metabolised (71-88 %), major metabolites 5-OH-MBC-sulfate, 5-OH-MBC and 4-OH-thiophanate-methyl, MBC

Acute toxicity

Rat LD ₅₀ oral:	> 5000 mg/kg bw
Rat LD ₅₀ dermal:	> 2000 mg/kg bw
Rat LC ₅₀ inhalation:	1.7 mg/L air
Skin irritation:	Not irritant
Eye irritation:	Not irritant
Skin sensitization (test method used and result):	Sensitising (maximisation test)

Short term toxicity

Target / critical effect:	Liver, thyroid, kidney (increased weight, histopathological changes, changed clinicochemical parameters), anaemia
Lowest relevant oral NOAEL / NOEL:	1-y, dog: 8 mg/kg bw/d
Lowest relevant dermal NOAEL / NOEL:	21-d, rabbit: 300 mg/kg bw/d
Lowest relevant inhalation NOAEL / NOEL:	Not required.

Genotoxicity

Genotoxic due to the weak aneugenic potential; threshold concentration for aneugenic activity in vitro: 6 µg/mL; NOEL in vivo: 50 mg/kg bw (based on carbendazim data)
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Long term toxicity and carcinogenicity

Target / critical effect:

Thyroid (rat: follicular hypertrophy, hyperplasia, tumours), liver (mouse: tumours), anaemia (rat)
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Lowest relevant NOAEL:

2-y, rat: 200 ppm (8.8 mg/kg bw/d)

Carcinogenicity:

The tumours (see above) do not lead to classification with regard to carcinogenicity.

Reproductive toxicity

Target / critical effect - Reproduction:

Reduced pup weight

Lowest relevant reproductive NOAEL / NOEL:

200 ppm (15 mg/kg bw/d)

Target / critical effect - Developmental toxicity:

Slight skeletal variation at maternal toxic doses in rabbits
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Lowest relevant developmental NOAEL / NOEL:

Rabbit: 20 mg/kg bw/d

Delayed neurotoxicity

No data, but no evidence for a neurotoxic potential in other studies
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Other toxicological studies

Non-MBC metabolites: low acute toxicity and no mutagenic potential in the Ames test; Induction of metabolising enzymes and hormonal changes in the pituitary-thyroid-axis (rat)
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Medical data

No detrimental effects on health of participating personnel in manufacturing of thiophanate-methyl
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Summary

Thiophanate-methyl

	Value	Study	Safety factor
ADI *:	0.08 mg/kg bw	1-y dog study supported by 2-y rat study	100
AOEL systemic:	0.08 mg/kg bw/d	1-y dog study	100
ARfD (acute reference dose) *:	0.2 mg/kg bw	Developmental toxicity study, rabbit	100

* Note: These reference doses were derived from toxicological studies with thiophanate-methyl. However, since plant and food residues are expressed as carbendazim (MBC), the ADI and ARfD established for that compound must be taken into consideration (see below).

Carbendazim

	Value	Study	Safety factor
ADI:	0.02 mg/kg bw	based on developmental studies in rats and rabbits	500
ARfD (acute reference dose):	0.02 mg/kg bw	based on developmental studies in rats and rabbits	500

Dermal absorption

10 %

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:

After 120 d:	25.7 % in silt loam 7.6 % in clay loam 7.3 % in sandy loam
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Non-extractable residues after 100 days:

≈ 40 % -73 % for all 3 soil types after 120 d

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

Carbendazim (MBC): max. 75.8 % in silt loam (after 7 d) max. 62.8 % in clay loam (after 3 d) max. 66.1 % in sandy loam (after 3 d)

Study: Völkl 2002; SCC Doc. No.: 721-004, RD-02149, RCC 815051; BOD2002-462
Evaluated in Addendum 7 (31.03.2003)

Supplemental studies

Anaerobic:

Similar to aerobic conditions Main metabolite: carbendazim (MBC) Water: max. 60.58 % of total applied activity Soil: max. 42.95 % of total applied activity Mineralisation: 4.07 % after 12 month Bound residues in soil: 83.68 % after 12 month

Soil photolysis:

Some data submitted: photolysis of minor significance
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Remarks:

none

Rate of degradation

Laboratory studies

DT₅₀lab (20 °C, aerobic):

<u>Thiophanate-methyl</u> 0.61 d (n = 3) range: 0.48 – 0.74 d r ² = 0.999
<u>Metabolite carbendazim</u> 39.8 d (n = 3)* range: 23.1 – 57.8 d * calculated from the studies with thiophanate-methyl

DT₉₀lab (20 °C, aerobic):Thiophanate-methyl2.05 d (n = 3)
range: 1.60 – 2.44 d
r² = 0.999Metabolite carbendazim133 d (n = 3)*
range: 77 - 192 d
* calculated from the studies with thiophanate-methylDT₅₀lab (10 °C, aerobic):

Not submitted, not required

DT₅₀lab (20 °C, anaerobic):

< 1 d (0.02 d)

Study: Völkl 2002; SCC Doc. No.: 721-004, RD-02149, RCC 815051; BOD2002-462
Evaluated in Addendum 7 (31.03.2003)**Field studies (country or region)**DT_{50f} from soil dissipation studies:Not submitted due to DT_{50 lab} for thiophanate-methyl and the main metabolite carbendazim < 60 dDT_{90f} from soil dissipation studies:

Not submitted, see above

Soil accumulation studies:

Not required.

Soil residue studies:

Not submitted, not required

Remarks:

e.g. effect of soil pH on degradation rate

none

Adsorption/desorptionK_f / K_{oc}:Values selected from n = 6,
according to the highest 1/nK_d:0.27 - 0.66 / 225 - 189 (TM)
0.45 - 4.47 / 375 - 1090 (MBC)

pH dependence:

Yes, stronger in acidic soils.

Mobility**Laboratory studies:**

Column leaching:

7.6 - 7.7 % (TM, measured as MBC)
in 3 German standard soils
0.2 / 11.4 / 32.6 / 43.7 % (active substance)
in 4 Japanese soils

Aged residue leaching:

1.1 % radioactivity (neither TM nor MBC) in
German standard soil (after 31 d incubation)
7 % (probably MBC) in Japanese sandy loam
(after 2 d incubation)

Field studies:

Lysimeter/Field leaching studies:

Not submitted. RMS: Not required.

Remarks:

none

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:

pH 5: 867 d (25 °C)
pH 7: 36 d (25 °C)
pH 9: 0.7 d (25 °C)

Major metabolites:

Carbendazim

Photolytic degradation:

DT₅₀ = 2.2 d in natural sunlight at pH 5

Major metabolites:

MBC: 50 %, DX-105: 4 % after 5.5 d

Biological degradation

Readily biodegradable:

Not required.

Water/sediment study:

RiverPondDT₅₀ water:2.9 d
(1st order; r² = 0.999)DT₉₀ water:9.7 d
(1st order; r² = 0.999)DT₅₀ whole system:1.8 d (
1st order; r² = 0.999)3.7 d
(1st order; r² = 0.994)DT₉₀ whole system:5.8 d
1st order; r² = 0.999)12.3 d
(1st order; r² = 0.994)Distribution in water / sediment systems
(active substance)

Thiophanate-methyl: water/sediment

<u>Day</u>	<u>River</u>	<u>Pond</u>
0	103.2 % / 0 %	98.4 % / 0 %
8	0 % / 0.4 %	9.7 % / 8.1 %
100	0 % / 0 %	0 % / 0 %

Distribution in water / sediment systems
(metabolites)

Carbendazim: water/sediment

<u>Day</u>	<u>River</u>	<u>Pond</u>
0	2.8 % / 0 %	2.7 % / 0 %
8	39.0 % / 42.6 %	34.3 % / 28.4 %
100	2.3 % / 33.0 %	2.6 % / 30.2 %

Accumulation in water and/or sediment:

No accumulation expected.

Degradation in the saturated zone not required

Remarks:

none

2.3 Fate and behaviour in air

Volatility

Vapour pressure:

< 9.4×10^{-6} Pa (9.5 °C)
< 8.8×10^{-6} Pa (19.6 °C)
< 9.5×10^{-6} Pa (29.8 °C)

Henry's law constant:

8.1×10^{-5} Pa·m ³ ·mol ⁻¹

Photolytic degradation

Direct photolysis in air:

No data provided

Photochemical oxidative degradation in air

DT₅₀:

Latitude: Season:DT ₅₀ :
1.6 – 4.7 h (AOP)

Volatilisation:

from plant surfaces: not submitted , not required
from soil: no volatilisation

Remarks:

none

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:

Long term toxicity to mammals:

Acute toxicity to birds:

Dietary toxicity to birds:

Reproductive toxicity to birds:

LD ₅₀ 2270 mg/kg bw
NOEL 200 ppm
LD ₅₀ > 4640 mg/kg bw
LC ₅₀ > 10000 ppm
NOEL 500 ppm

Aquatic Organisms

Test substance: **thiophanate-methyl**

	Species	Time Scale	Toxicity (mg / l)	Endpoint
Acute toxicity fish:	<i>Oncorhynchus mykiss</i>	96 h (fl)	11.0	LC ₅₀
	<i>Cyprinus carpio</i>	72 h	> 75.0	LC ₅₀
	<i>Salmo gairdneri</i>	96 h (st)	1.07	LC ₅₀
Long term toxicity fish:	<i>Salmo gairdneri</i>	28 d (fl)	0.32	NOEC
Bioaccumulation fish:	-	-	-	-
Acute toxicity invertebrate:	<i>Daphnia magna</i>	48 h (fl)	5.4	EC ₅₀
Chronic toxicity invertebrate:	<i>Daphnia magna</i>	21 d (ss)	1.8	NOEC mortality
			0.18	NOEC reproduction
Acute toxicity algae:	<i>Pseudokirchneriella subcapitata</i>	72 h (st)	>25.4 12.0	E _r C ₅₀ E _b C ₅₀
Chronic toxicity sediment dwelling organism:	<i>Chironomus riparius</i>	28 d (st)	1.0	NOEC development
			0.5	NOEC emergence
Sewage sludge	<i>P. putida</i>	17 h	> 2000	EC ₅₀

Test substance: Metabolite **carbendazim**

	Species	Time Scale	Toxicity (mg / L)	Endpoint
Acute toxicity fish:	<i>Oncorhynchus mykiss</i>	96 h (st)	0.83	LC ₅₀
	<i>Cyprinus carpio</i>	72 h (st)	0.44	LC ₅₀
Long term toxicity fish:	<i>Oncorhynchus mykiss</i>	79 d (fl)	0.011	NOEC embryo mortality
Bioaccumulation fish:	-	-	-	-
Acute toxicity invertebrate:	<i>Daphnia magna</i>	48 h (st)	0.15	EC ₅₀
Chronic toxicity invertebrate:	<i>Daphnia magna</i>	21 d (ss)	0.0015	NOEC reproduction
Acute toxicity algae:	<i>Scenedesmus subspicatus</i>	72 h (st)	> 8.0	E _b C ₅₀
Chronic toxicity sediment dwelling organism:	<i>Chironomus riparius</i>	28 d (st)	0.0133	NOEC development
			0.0133	NOEC emergence

Honeybees

Acute oral toxicity:

LD₅₀ >100 µg/bee (48 h)

Acute contact toxicity:

LD₅₀ >100 µg/bee (48 h)**Other arthropod species**

Test species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect
<i>Trichogramma cacoeciae</i>	adult	SC 700 g as/L	0.14	Parasitisation	< 50 %
<i>Amblyseius potentillae</i>	nymphs, adults	SC 700 g as/L	0.14	Mortality	100 %
<i>Typhlodromus pyri</i>	nymphs, adults	SC 500 g as/L	0.07	Mortality	4 %
<i>Chrysopa carnea</i>	larvae	SC 500 g as/L	0.07	Mortality	28 %
<i>Syrphus vitripennis</i>	larvae	SC 700 g as/L	0.105	Mortality	50 – 79 %
<i>Episyrphus balteatus</i>	larvae	BAS32511F	0.210	Mortality	0 %
		SC 500 g	0.500		4 %
		as/L	1.500		27 %

<i>Test species</i>	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect
<i>Typhlodromus pyri</i>	Nymphs, adults	SC 500 g as/L	3 x 0.525	Abundance 1 week after last application	32 %
<i>Typhlodromus pyri</i>	Nymphs, adults	BAS32511F SC 500 g as/L	0.15 0.27 0.485 0.875 1.575	Mortality/ Fertility	4.8 %/ - 14.7 %/ - 24.6 %/ 29.0 % 28.6 %/ 23.0 % 24.6 %/ 44.0 %* LR50/ER50 > 1.575 kg a.s./ha
<i>Aphidius rhopalosiphi</i>	adults	BAS32511F SC 500 g as/L	0.175 0.525 1.575	Parasitization	1 % 72 % 74 %
<i>Aphidius rhopalosiphi</i>	adults on natural substrate	BAS32511F SC 500 g as/L	0.100 0.500 1.500	Parasitization	2 % 14 % 45 %
<i>Poecilus cupreus</i>	adults	BAS32511F SC 500 g as/L	0.525	Mortality Food uptake	0 % 0 %
*) only 2 of 3 replicates were analysed for reproduction, because 1 replicate had no female					

Field / Semi-field tests

Typhlodromus pyri

Two field studies were conducted for populations on apple trees with 1 to 3 applications of app. 0.525 kg as/ha and drift rates of app. 0.105 kg as/ha formulated as BAS32511F (500 g as/L) each. Final check of populations was done 26 days after the final application and effects were calculated acc. to Henderson & Tilton. No unacceptable effects were reported neither for max. field rates with effects < 20 %, nor drift rates with effects < 10 %. This study is not valid, because 7 days after beginning one fungicide and one insecticide were applied.

Earthworms

Acute toxicity:

Reproductive toxicity:

Field test - effects on reproduction /
long termLC₅₀: > 13.2 mg as/kg d.w. substrate (14 d)EC₁₀: 0.64 kg as /ha (56 d)
(corresponds to 0.85 mg as/kg)EC₁₀: 0.17 kg as/ha (11 months)

Soil micro-organisms

Nitrogen mineralization:

No effects up to 5 kg as/ha

Carbon mineralization:

No effects up to 5 kg as/ha

APPENDIX IIIA**THIOPHANATE-METHYL**

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.⁷

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) Company⁸ report no. GLP or GEP status (where relevant), published or not BBA registration number	Reports⁹ on previous use in granting national authorizations
AIIA-1.8	Watanabe, I.	1986	Thiophanate-methyl - Description of beginning materials and manufacturing process. NPS RD-8664 SCC Doc. No.: 121-001 not GLP, unpublished CHE96-00457	-
AIIA-1.9; AIIA-1.10	Iguchi, K.	1990	Thiophanate-methyl - Certification of ingredient limits. NPS NIPPON SODA REG.: RD-9021. SCC-Doc. No: 131-001 GLP, unpublished CHE96-00458.	-

⁷ Prepared by RMS, without further analysis, on the basis of a list provided by the main data submitter

⁸ Only notifier listed

⁹ Reports received from Member States at the date of finalisation or the present review report (not exhaustive)

Annex point/ reference number	Author(s)	Year	Title source (where different from company) Company ⁸ report no. GLP or GEP status (where relevant), published or not BBA registration number	Reports ⁹ on previous use in granting national authorizations
AIIA-1.10; AIIA-1.11	Anonym	1992	Analytical Method for 2,3-Diaminophenazine and 2-Amino-3-hydroxy-phenazine in Thiophanate-methyl Technical and the results of Determination NPS NIPPON SODA REG.: RD-9201. SCC Doc. No.: 411-001 not GLP, unpublished CHE96-00463	-
AIIA-1.10 AIIA-1.11	Anonym	1993	Analytical Method for Phenazine Derivatives in Thiophanate-methyl TC and Results of Determination. NPS SCC Doc. No.: 411-003 NIPPON SODA REG.: RD-9309 not GLP, unpublished CHE96-00464 (identical with CHE96-00461)	-
AIIA-1.10 AIIA-1.11	Iguchi, K.	1990	Thiophanate-methyl - Analytical methods to verify certified limits. NPS NIPPON SODA REG.: RD-9022 SCC Doc. No.: 411-004 GLP, unpublished CHE96-00465	-
AIIA-1.11	Anonym	1993	Analytical method for phenazine derivatives in thiophanate-methyl TC and results of Determination. NPS NIPPON SODA REG.: RD-9309. SCC Doc. No.: 411-003 not Glp, unpublished CHE96-00461 (identical with CHE96-00464)	-
AIIA-1.11	Iguchi, K.	1990	Thiophanate-methyl - Preliminary analysis of product samples. NPS RD-9020. SCC Doc. No.: 131-002 GLP, unpublished CHE96-00460	-

Annex point/ reference number	Author(s)	Year	Title source (where different from company) Company ⁸ report no. GLP or GEP status (where relevant), published or not BBA registration number	Reports ⁹ on previous use in granting national authorizations
AIIA-2.1	Nakayama, K.	1992	Thiophanate-methyl, pure: melting point. NPS NIPPON SODA REG.: RD-9216. SCC Doc. No.: 112-001 GLP, unpublished CHE96-00435	-
AIIA-2.2	Nakayama, K.	1992	Thiophanate-methyl, pure: specific gravity. NPS NIPPON SODA REG.: RD-9217. SCC Doc. No.: 113-001 GLP, unpublished CHE96-00436	-
AIIA-2.3.1	Anonym	1981	Vapor pressure and volatility of Thiophanate-methyl. NPS RD-8136 SCC Doc. No.: 115-001 not GLP, unpublished LUF95-00141	-
AIIA-2.3.1	Soeda, J. and Nomura, O.	1986	Thiophanate-methyl - Vapor pressure. NPS RD-8657 ! NISSO EC-60 SCC Doc. No.: 115-004 not GLP, unpublished LUF95-00142	-
AIIA-2.4	Nakayama, K.	1990	Thiophanate-methyl: physical state. NPS NIPPON SODA REG.: RD-9024 SCC Doc. No.: 111-001 GLP, unpublished CHE96-00438.	-
AIIA-2.4	Nakayama, K.	1992	Thiophanate-methyl, pure: colour NPS NIPPON SODA REG.: RD-9213 SCC Doc. No.: 111-004 GLP, unpublished CHE96-00439	-

Annex point/ reference number	Author(s)	Year	Title source (where different from company) Company ⁸ report no. GLP or GEP status (where relevant), published or not BBA registration number	Reports ⁹ on previous use in granting national authorizations
AIIA-2.4	Nakayama, K.	1992	Thiophanate-methyl, pure: physical state NPS NIPPON SODA REG.: RD-9214 SCC Doc. No.: 111-006 GLP, unpublished CHE96-00437	-
AIIA-2.4	Nakayama, K	1992	Thiophanate-methyl, pure: odour NPS NIPPON SODA REG.: RD-9215 SCC Doc., No.: 111-005 GLP, unpublished CHE96-00441	-
AIIA-2.5	Matsumoto, M.	1995	Thiophanate-methyl: Pure; Molar Extinction Coefficient at the Relevant Wavelength of 268. RD9530 SCC Doc., No.: 117-002 not GLP, unpublished CHE96-00444.	-
AIIA-2.5	Seriyaama, Y. Takase, M.	1995	Spectra of minor impurities (DAP and HAP) of Thiophanate-methyl technical. NPS NIPPON SODA REG.: RD-9523. SCC Doc., No.: 157-001 not GLP, unpublished CHE96-00462	-
AIIA-2.6	Gomy, T.Makoto, H.	1996	Thiophanate-methyl - Solubility in Water NPS NCAS 95-168, RD-9629 SCC Doc. No.: 114-002 GLP, unpublished CHE96-00522	-
AIIA-2.6	Nakayama, K.	1992	Thiophanate-methyl, pure: solubility NPS NIPPON SODA REG.: RD-9219. SCC Doc. No.: 114-003 GLP, unpublished CHE96-00447	-

Annex point/ reference number	Author(s)	Year	Title source (where different from company) Company ⁸ report no. GLP or GEP status (where relevant), published or not BBA registration number	Reports ⁹ on previous use in granting national authorizations
AIIA-2.8	Shiotani, H.	1992	Thiophanate-methyl-octanol/water partition coefficient (Kow) NPS RD-9212 SCC Doc. No.: 114-005 GLP, unpublished CHE96-00450	-
AIIA-2.8	Tetsuya, T.	1996	Thiophanate-methyl - Partition Coefficient NPS NCAS 95-167. NIPPON SODA REG.: RD-9630 SCC Doc. No.: 114-008 GLP, unpublished CHE96-00523	-
AIIA-2.9.1; AIIA-7.2.1.1; AIIA-7.2.1.4	Priester, T.M.	1995	Hydrolysis of Carbendazim [2-14C]. AVO A52842 ! AMR-265-84 not GLP, unpublished WAS95-00185	-
AIIA-2.9.2; AIIA-7.2.1.2	Schwab, W.	1992	HOE 017411-(Carbendazim)-14C, Photoabbau im Wasser. AVO A47539 ! CB92/017 not GLP, unpublished WAS95-00187	-
AIIA-2.9.4	Appel, M.	1988	HOE 017411/Carbendazim - Determination of the dissociation constants (pK values). AVO A42938 ! OC 01-88 not GLP, unpublished WAS95-00188	-
AIIA-2.10; AIIA-7.2.2	Denkler, M.	1995	Estimation of the rate of photochemical transformation in the atmosphere under tropospheric conditions. NPS SCC 146-004 SCC Doc. No.: 782-001not GLP, unpublished LUF96-00042	-

Annex point/ reference number	Author(s)	Year	Title source (where different from company) Company ⁸ report no. GLP or GEP status (where relevant), published or not BBA registration number	Reports ⁹ on previous use in granting national authorizations
AIIA-2.11	Krips, H.J	1996	Determination of the Flammability of Thiophanate-methyl NPS NOTOX PROJECT 168323. NIPPON SODA REG.: RD-9657. SCC Doc. No.: 142-001 GLP, unpublished CHE96-00524	-
AIIA-2.11	Krips, H.J	1996	Determination of the relative Self-Ignition temperature of Thiophanate-methyl NPS NOTOX PROJECT 168334. NIPPON SODA REG.: RD-9658. SCC Doc. No.: 142-002 GLP, unpublished CHE96-00525	-
AIIA-3.7	Anonym	1995	Material Safety Data Sheet for NF-44 (thiophanate-methyl), technical grade NPS SCC Doc. No.: 953-001 not GLP, unpublished CHE96-00452	-
AIIA-4.2.1	Gomyo, T.	1988	Analytical method for thiophanate-methyl and its related compounds in animal organs and milk; NPS Nippon Soda EC-137 SCC Doc. No.: 433-001 not GLP, unpublished MET96-00110	-
AIIA-4.2.1	Soeda, Y. and Gomyo, T.	1988	Thiophanate-methyl - analytical method for onion; Nippon Soda EC-145. NPS NIPPON SODA REG.: RD-8855. SCC Doc. No.: 432-002 not GLP, unpublished MET96-00107	-

Annex point/ reference number	Author(s)	Year	Title source (where different from company) Company⁸ report no. GLP or GEP status (where relevant), published or not BBA registration number	Reports⁹ on previous use in granting national authorizations
AIIA-4.2.1	Soeda, Y. and Gomyo, T.	1988	Thiophanate-methyl - analytical method for celery; Nippon Soda EC-146. NPS NIPPON SODA REG.: RD-8856. SCC Doc. No.: 432-003 not GLP, unpublished MET96-00	-
AIIA-4.2.1	Tokieda, M:	1988	Residue analysis of thiophanate-methyl and its metabolite (MBC) in canola; NPS Nippon Soda EC-150. NIPPON SODA REG.: RD-8862. MET96-00108	-
AIIA-4.2.4	Gomyo, T. and Kobayashi, S.	1994	Development of analytical method for determination of thiophanate-methyl and its degradate (MBC) in air NPS Nippon Soda EC-539 SCC Doc. No.: 436-002 not GLP, unpublished MET96-0011	-

Codes of company

AVO: Hoechst Schering AgrEvo GmbH Zulassung Pflanzenschutz
 BAS: BASF AG, Ludwigshafen
 NPS: Nisso Chemicals Europe
 SCC: SCC GmbH

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 BBA registration number	Reports on previous use in granting national authorizations
AIIA-5.1	Nabetani, M. and Mori, H.	1993	Metabolism of 14C-thiophanate-methyl in mice. NPS PROJECT ID NISSO EC-363 ! RD-9246 SCC Doc. No.: 512-003 GLP, unpublished TOX95-51650	-
AIIA-5.1	Tanoue, T. et. al.	1992	Thiophanate-methyl - Metabolism in rats. Supplemental report to Nisso EC-338 (TOX 95-51648). NPS PROJECT ID NISSO EC-395 ! RD-9247 SCC Doc. No.: 512-005 GLP, unpublished TOX95-51649	-
AIIA-5.1	Walters, K.A. and James, V.J.	1993	In vitro skin penetration of thiophanate-methyl. NPS REPORT NO: RPUK/2/93/R2 ! RD-9336 SCC Doc. No.: 511-002 GLP, unpublished TOX95-51644	-
AIIA-5.2.4	Nishibe, T.	1986	Thiophanate-methyl: Primary dermal irritation study in rabbits NPS NISSO TXR 0218 ! RD-8692 SCC Doc. No.: 565-002 GLP, unpublished TOX95-51655	Evaluated and used in the UK to grant/ maintain national authorisations during national review conducted 1992 UK ref: SC9089/42
AIIA-5.2.6	Nishibe, T. and Mochizuki, N.	1993	Topsin M: Skin sensitization study in guinea-pigs NPS REPORT NO. G-09300 ! RD-9347 SCC Doc. No.: 567-002 GLP, unpublished TOX95-51658	-

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 BBA registration number	Reports on previous use in granting national authorizations
AIIA-5.4.1	Marshall, R.	1996	Thiophanate methyl technical: Induction of micronuclei in cultured human peripheral blood lymphocytes NPS REPORT NO.: 68/151-1052 ! RD-9728 SCC Doc. No.: 557-001 GLP, unpublished TOX97-50340	-
AIIA-5.4.1	Marshall, R.	1996	Thiophanate methyl technical: Study to determine the threshold of action for the induction of aneuploidy in cultured human peripheral blood lymphocytes NPS REPORT NO.: 68/154-1052 ! RD-9729 SCC Doc. No.: 557-002 GLP, unpublished TOX97-50339	-
AIIA-5.4.2	Proudlock, R.J.	1999	Thiophanate-methyl – Mouse Micronucleus Test. NPS NOD 024/983714 SCC Doc. No.: 557-007 GLP, unpublished TOX1999-479	-
AIIA-5.5	Takoari, H.	1993	Thiophanate-methyl – Combined chronic toxicity/oncogenicity study in rats NPS PROJECT NO. 0566 ! REP. NO. RD-9327 SCC Doc. No.: 537-001 GLP, unpublished TOX95-52662	-
AIIA-5.5	Tompkins, E.C.	1992	18-month dietary oncogenicity study in mice with Topsin M NPS STUDY NO.: WIL-75024 ! REP. NO. RD-9328 SCC Doc. No.: 555-001 not GLP, unpublished TOX95-52663	-

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 BBA registration number	Reports on previous use in granting national authorizations
AIIA-5.6.1	Müller, W.	1993	Topsin M - Two generation oral (dietary administration) reproduction toxicity study in the rat (with one litter in the P and two litters in the F1 generation) NPS HD PROJ. NO.: 683-004 ! REP. NO. RD-9329 SCC Doc. No.: 553-002 not GLP, unpublished TOX95-52664.	-
AIIA-5.6.1	Muler, W. and Singer, A.	1995	Final addendum histopathology report and peer review pathology report to MRID 42899101. Topsin-M - Two generation oral (dietary administration) reproduction toxicity study in the rat (with one litter in the P and two litters in the F1 generation) NPS PROJECT NO.: 683-004 ! RD-9525 SCC Doc. No.: 553-001 GLP, unpublished TOX97-50341	-
AIIA-5.8.1	Anonym	1988	Toxicity of thiophanate-methyl and its related compounds (impurities and metabolites) NPS RD-8779N SCC Doc. No.: 563-001 not GLP, unpublished TOX95-51684	-
AIIA-5.8.1	Nishibe, T.	1988	DX-105, DX-189, FH-613: Acute oral toxicity study in rats NPS NISSO TXR 0256 ! RD-8867 SCC Doc. No.: 521-001 GLP, unpublished TOX95-51680	-

Codes of company

NPS: Nisso Chemicals Europe

SCC: SCC GmbH

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 BBA registration number	Reports on previous use in granting national authorizations
AIIA-6.1	Alam, F.; Dedmore, M.; Jalal, M.A.F.	1994	Nature of the Residues of 14C-Thiophanate-Methyl in Spray Treated Apples. NPS RD-99125 BR-93-29 SCC-Doc. No.: 632-2001 GLP, unpublished RIP2000-220	-
AIIA-6.1	Alam, F.; Dedmore, M.; Jalal, M.A.F.	1994	Nature of the Residues of 14C-Thiophanate-Methyl in Spray Treated Apples. NPS RD- 93292 SCC-Doc. No.: 632-2003 GLP, unpublished	-
AIIA-6.1	Davis, M.L.; Malik, N.S.A. and Lofthouse, T.J.	1992	Metabolism of the Fungicide Thiophanate-methyl in Spray-treated Spring Wheat. NPS SC900053 , BR-90-17 SCC Doc. No.: 611-004 GLP, unpublished RIP2002-701	-
AIIA-6.2; AIIA-6.4	Eldeib, Ph.D.D., Harris, C., Patterson, C., Bielefeld, T. and Hurshman, B.	1995	Isolation, characterization and identification of unknown metabolite(s) for goat liver treated with 14C-Thiophanate-methyl. NPS RD-9519 ! BR-93-34 SCC Doc. No.: 612-001 not GLP, unpublished RIP95-00970	-
AIIA-6.2; AIIA-6.4	Fegert, A. und Fuchs, A.	1993	Prüfung des Rückstandsverhaltens von Cercobin FL (BAS 325 10 F) an Winterraps unter Freilandbedingungen. NPS / BAS BER.NR. 3289 ! BASF 93/11485 SCC Doc. No.: 634-4002 GLP, unpublished RIP95-00980	-

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 BBA registration number	Reports on previous use in granting national authorizations
AIIA-6.2; AIIA-6.4	Hanlon, C.M. and Norris, K.J.	1995	Metabolism of the fungicide 14C-Thiophanate-methyl in lactating goats. NPS RD-9518 ! BR-90-16 SCC Doc. No.: 612-002 GLP, unpublished RIP95-00969	-
AIIA-6.2; AIIA-6.4	Wright, M.C.	1995	14C-Thiophanate-methyl nature of the residue in laying hens. NPS RD-9516 ! BR-90-15 SCC Doc. No.: 612-003 GLP, unpublished RIP95-00968	-
AIIA-6.3	de Vos, R.H. and Peet, E.W.	1973	Residues of thiophanate-methyl and its metabolite MBC in onions. NPS R 4212 SCC Doc. No.:633-1201 not GLP, unpublished RIP96-00158	-
AIIA-6.3	de Vos, R.H. and Peet, E.W.	1973	Residues of thiophanate-methyl and its metabolite MBC in gherkins. NPS R 4089 SCC Doc. No.: 633-2301 not GLP, unpublished RIP96-00159	-
AIIA-6.3	de Vos, R.H. and Peet, E.W.	1973	Residues of thiophanate-methyl and its metabolite MBC in wheat. NPS R4022 SCC Doc. No.: 634-4001 not GLP, unpublished RIP96-00156	-
AIIA-6.3	de Vos, R.H. and Peet E.W.	1973	Residues of thiophanate-methyl and its metabolite MBC in Brussels sprouts. NPS R 4216 SCC Doc. No.: 633-3201 not GLP, unpublished RIP96-00160	-

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 BBA registration number	Reports on previous use in granting national authorizations
AIIA-6.3	Kimer, K.	1991	DETERMINATION OF RESIDUE OF THIOPHANATE-METHYL AND CARBENDAZIM IN SPRING RAPE. NPS 2-1991 SCC Doc. No.: 634-4005 not GLP, unpublished RIP96-00155	-
AIIA-6.3	Maurer, T.	1995	Residue data summary from supervised trials in pome fruit with Thiophanate-methyl. NPS SCC 146-001-6 (2) SCC Doc. No.: 632-2901 not GLP, unpublished RIP95-00972	-
AIIA-6.3	Maurer, T.	1995	Residue data summary from supervised trials in stone fruit with Thiophanate-methyl. NPS SCC 146-001-6 (3) SCC Doc. No.: 632-3901 not GLP, unpublished RIP95-00973	-
AIIA-6.3	Maurer, T.	1995	Residue data summary from supervised trials in fruiting vegetable (gherkins) with Thiophanate-methyl. NPS SCC 146-001-6 (5) SCC Doc. No.: 633-2302 not GLP, unpublished RIP95-00975	-
AIIA-6.3	Maurer, T.	1995	Residue data summary from supervised trials in legume vegetable (peas) with Thiophanate-methyl. NPS SCC 146-001-6 (7) SCC Doc. No.: 633-5201 GLP, unpublished RIP95-00977	-

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 BBA registration number	Reports on previous use in granting national authorizations
AIIA-6.3	Maurer, T.	1995	Residue data summary from supervised trials in potatoes with Thiophanate-methyl. NPS SCC 146-001-6 (9) SCC Doc. No.:634-1101 not GLP, unpublished RIP95-00979	-
AIIA-6.3	Maurer, T.	1995	Residue data summary from supervised trials in oil seeds with Thiophanate-methyl. NPS SCC 146-001-6 (8) SCC Doc. No.: 634-0901 GLP, unpublished RIP95-00978	-
AIIA-6.3	Maurer, T.	1995	Residue data summary from supervised trials in brassica vegetables (brussels sprouts) with Thiophanate-methyl. NPS SCC 146-001-6 (6) SCC Doc. No.: 633-3901 not GLP, unpublished RIP95-00976	-
AIIA-6.3	Maurer, T.	1995	Residue data summary from supervised trials in bulb vegetable (onions) with Thiophanate-methyl. NPS SCC 146-001-6 (4) SCC Doc. No.: 633-1202 not GLP, unpublished RIP95-00974	-
AIIA-6.3	Maurer, T.	1995	Residue data summary from supervised trials in cereals with Thiophanate-methyl. NPS SCC 146-001-6 (1) SCC Doc. No.: 634-4901 not GLP, unpublished RIP95-00971	-

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 BBA registration number	Reports on previous use in granting national authorizations
AIIA-6.3	Mestres, R.	1977	Residus de Methyl Thiophanate sur pommes de terre - Compte-rendu des essais sur pomme de terre. NPS SCC Doc. No.: 634-1103not GLP, unpublished RIP95-00982	-
AIIA-6.3	Mestres, R.	1978	Analyse de residus. NPS - SCC Doc. No.: 635-002 not GLP, unpublished RIP95-00984	-
AIIA-6.3	Mestres, R.	1977	Residus de Methyl Thiophanate sur pommes de terre. NPS - SCC Doc. No.:634-1104 not GLP, unpublished RIP95-00983	-
AIIA-6.3	Mestres, R.	1977	Residus de Methyl Thiophanate sur pommes de terre. NPS - SCC Doc. No.:634-1102 not GLP, unpublished RIP95-00981	-
AIIA-6.3	Sarrazin, J.F. and Beaubois, G.	1988	REPORT ON PESTICIDE RESIDUE TRIAL: PART A FIELD REPORT OF CHERRIES. NPS F 90 A 0288/1 SCC Doc. No.: 632-3101 not GLP, unpublished RIP96-00157	-
AIIA-6.3	Sarrazin, J.F. and Capron, C.	1992	REPORT ON PESTICIDE RESIDUE TRIAL: PART A – FIELD REPORT OF PEAS. NPS F11A.01.92 SCC Doc. No.: 633-5202 not GLP, unpublished RIP96-00161	-

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 BBA registration number	Reports on previous use in granting national authorizations
AIIA-6.3	Sarrazin, J.F. and Magnier, F.	1992	REPORT ON PESTICIDE RESIDUE TRIAL: PART A – FIELD REPORT OF RAPE. NPS F04A.02.92 SCC Doc. No.: 634-0602 not GLP, unpublished RIP96-00162	-

Codes of company

BAS: BASF AG, Ludwigshafen
NPS: Nisso Chemicals Europe
SCC: SCC GmbH

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 BBA registration number	Reports on previous use in granting national authorizations
AIIA-7.1.1.2.1; AIIIA-9.1.1.1	Gildemeister, H., Jordan, H.J. and Remmert, U.	1981	Behaviour of the plant protection product HOE 17411 OF AT 102 (Carbendazim) in soil SS 2.2 at 15°C, 20°C and 25°C. AVO A47457 ! (B) 125/81 not GLP, unpublished BOD95-00446	-
AIIA-7.1.1.2.2; AIIIA-9.1.1.2	Krebs, B. und Baedelt, H.	1990	Untersuchung des Abbaues im Boden unter Freilandbedingungen. AVO A42438 ! DEU88F10611 not GLP, unpublished BOD95-00450	-
AIIA-7.1.1.2.2; AIIIA-9.1.1.2	Krebs, B. und Baedelt, H.	1990	Untersuchung des Abbaues im Boden unter Freilandbedingungen. AVO A42437 ! DEU88F10621 not GLP, unpublished BOD95-00449	-
AIIA-7.1.1.2.2; AIIIA-9.1.1.2	Krebs, B. und Baedelt, H.	1990	Untersuchung des Abbaues im Boden unter Freilandbedingungen. AVO A42436 ! DEU88F10631 not GLP, unpublished BOD95-00448	-
AIIA-7.1.1.2.2; AIIIA-9.1.1.2	Krebs, B. und Baedelt, H.	1990	Untersuchung des Abbaues im Boden unter Freilandbedingungen. AVO A42435 ! DEU88F10641 not GLP, unpublished BOD95-00447	-
AIIA-7.1.2	Görlitz, G. and Klöckner, Ch.	1986	HOE 017411, Adsorption/desorption in the soil/water system. AVO A40783 ! (B)136/85 not GLP, unpublished BOD95-00451	-

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 BBA registration number	Reports on previous use in granting national authorizations
AIIA-7.1.2	Shiotani, H.	1992	Thiophanate-methyl - Batch equilibrium (adsorption/desorption on soils). NPS RD-9204 ! NISSO EC-362 SCC Doc. No.: 731-002 GLP, unpublished BOD95-00653	-
AIIA-7.1.3.1; AIIIA-9.1.2.1	Gorbach, S. and Thier, W.	1989	Leaching of 2-Amino-benzimidazole, possible metabolite of Thiophanate-methyl. NPS RD-8973 ! (B) 63/77 SCC Doc. No.: 732-003 not GLP, unpublished BOD95-00490	-
AIIA-7.2.1.1	Görlitz, G. and Klöckner, Ch.	1982	Behaviour of plant protection agents in water. AVO A47455 ! (B) 63/82 not GLP, unpublished WAS95-00192	-
AIIA-2.9.1; AIIA-7.2.1.1; AIIA-7.2.1.4	Priester, T.M.	1995	Hydrolysis of Carbendazim [2-14C]. AVO A52842 ! AMR-265-84 not GLP, unpublished WAS95-00185	-
AIIA-7.2.1.2	Gottesbüren, B.	1995	Estimation of the Transformation Coefficients of Thiophanate-methyl and DX-105 during Photometabolism. NPS 95/11148 ! CALC-16 SCC Doc. No.: 782-002 not GLP, unpublished LUF96-00043	-
AIIA-2.9.2; AIIA-7.2.1.2	Schwab, W.	1992	HOE 017411-(Carbendazim)-14C, Photoabbau im Wasser. AVO A47539 ! CB92/017 not GLP, unpublished WAS95-00187	-

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 BBA registration number	Reports on previous use in granting national authorizations
AIIA-7.2.1.3.2	Gildemeister, D.	1988	Degradation of Carbendazim (HOE 017411) in Two Aerobic Aquatic Systems. AVO A37801 ! RCC 088132 ! 88/0150 not GLP, unpublished WAS95-00191	-
AIIA-2.10; AIIA-7.2.2	Denkler, M.	1995	Estimation of the rate of photochemical transformation in the atmosphere under tropospheric conditions. NPS SCC 146-004 SCC Doc. No.: 782-001 not GLP, unpublished LUF96-00042	-
AIIA 7.2.2	Shiotani, H.	1992	Thiophanate-methyl - Laboratory volatility from soil. NPS RD-9221 ! NISSO EC-381 SCC Doc. No.: 742-001 GLP, unpublished LUF95-00193	-

Codes of company

AVO: Hoechst Schering AgrEvo GmbH Zulassung Pflanzenschutz

NPS: Nisso Chemicals Europe

SCC: SCC GmbH

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 BBA registration number	Reports on previous use in granting national authorizations
AIIA-8.2.1	Bettencourt, M. J.	1993	Thiophanate-methyl Acute toxicity to rainbow trout (<i>Oncorhynchus mykiss</i>) under flow-through conditions NPS RD-9330 SCC Doc. No.: 821-001 GLP, unpublished WAT95-50821	-
AIIA-8.2.1	Kosaka, Sh. and Gotoh, K.	1983	Acute toxicity study of Thiophanate-methyl in rainbow trout NPS/BAS BASF 83/10061. SCC Doc. No.:821-002 not GLP, unpublished WAT-50309	-
AIIA-8.2.4	Putt, A. E.	1992	Thiophanate-methyl Acute toxicity to daphnids (<i>Daphnia magna</i>) under flow-through conditions (FIFRA Guideline no.: 72-2) NPS RD-9229. SCC Doc. No.: 822-004 GLP, unpublished WAT95-50820	-
AIIA-8.2.6	Nishibe, T., Saiko, O.	1983	Toxicity study of Thiophanate-methyl in green algae NPS/BAS BASF 83/10062 SCC Doc. No.: 823-002 Not GLP, unpublished WAT-50305	-
AIIA-8.4.1	Dohmen, G. P.	1996	Effect of thiophanate-methyl on the mortality of the earthworm <i>Eisenia foetida</i> NPS / BAS 33850. SCC Doc. No.: 833-001 GLP, unpublished ARW96-00126	-

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 BBA registration number	Reports on previous use in granting national authorizations

Codes of company

BAS: BASF AG, Ludwigshafen
NPS: Nisso Chemicals Europe
SCC: SCC GmbH

APPENDIX III B

THIOPHANATE-METHYL

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 the 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 BBA registration number
AIIA-2.3.1	Higashida, S. and Kobayashi, H.	1999	Vapor Pressure of Thiophanate-methyl. NPS RD-IIM001, NCAS 99-145 SCC Doc. No.: 115-005 GLP, unpublished LUF2000-27
AIIA-2.9.2	Soeda, Y. and Shiotani, H.	1987	Thiophanate-methyl - Photodegradation in Water. NPS NISSO EC-74 SCC Doc. No.: 712-001 not GLP, unpublished LUF2000-542
AIIA-2.9.4	Ishihara, K.	1998	Thiophanate-methyl - Dissociation Constant. NPS RD-9857, EC-225 SCC Doc. No.: 115-003 not GLP, unpublished WAS1999-44
AIIA-2.14	Tanaka, T.	2001	Measurement of Surface Tension of Thiophanate-methyl Technical NPS RD-II 01069. 116-001 GLP, unpublished CHE2002-297

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 BBA registration number
AIIA-3.8	Ishihara, Kanji	1985	Thiophanate-methyl - Pyrolysis study. NPS RD-9856 SCC Doc. No.:141-001 not GLP, unpublished CHE1999-682
AIIA-4.1; AIIIA-5.1	Fries, J.	2001	Gehaltsbestimmung von 2,3-Diaminophenazin und 2-Hydroxy-3-aminophenazin in BAS 325 11 F mittels HPLC. BAS 422-001 / 2001/1003811 / SCC Doc. No.:422-001 not GLP, unpublished CHE2002-100
AIIA-4.2.1; AIIIA-5.2.1	Brewin, S.	2001	Thiophanate-methyl and Carbendazim; development and validation of methodology for the determination of residues in melon whole fruit and flesh; NPS RD-II01024. SCC 432-009 GLP, unpublished MET2002-93
AIIA-4.2.1; AIIIA-5.2.1	Brewin, S.	2001	Thiophanate-methyl and Carbendazim; development and validation of methodology for the determination of residues in winter wheat NPS RD-II01023. SCC 432-008 GLP, unpublished MET2002-94
AIIA-4.2.1; AIIIA-5.2.1	Brewin, S.	2001	Thiophanate-methyl and Carbendazim; development and validation of methodology for the determination of residues in oilseed rape; NPS RD-II01025. SCC 432-010 GLP, unpublished MET2002-92

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 BBA registration number
AIIA-4.2.1; AIIIA-5.2.1	Brewin, S.	2001	Thiophanate-methyl and Carbendazim; Validation of methodology for the determination of residues in apples; NPS RD-II01308. SCC 432-011 GLP, unpublished MET2002-91
AIIA-4.2.1; AIIIA-5.2.1	Gomyo, T.	1987	Fortified Recovery Test for Thiophanate-methyl and Its Degradad Compound (MCB) in Crops. NPS RD-8767 SCC Doc. No.: 432-005 not GLP, unpublished MET1999-1132
AIIA-4.2.1	Mayer, J.	2001	Independent laboratory validation of a proposed analytical method for the appropriate metabolites of Thiophanate-methyl in meat, milk and eggs NPS NIPPON SODA REG.: RD-II01307 SCC Doc. No.: 433-002 GLP, unpublished
AIIA-4.2.1; AIIIA-5.2.1	Melkebeke, I.T.	1997	Validation of an analytical method for residues of thiophanate-methyl in grapes. NPS SCC Doc. No.:432-006 GLP, unpublished MET1999-1133
AIIA-4.2.2; AIIIA-5.2.2	Saito, S.	2001	Validation study of the analytical method for the determination of Thiophanate-methyl and its degradation product MBC in soil NPS RD-II01020. SCC 434-004 not GLP, unpublished MET2002-90

Codes of company

BAS: BASF AG, Ludwigshafen

NPS: Nisso Chemicals Europe
SCC: SCC GmbH

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 BBA registration number
AIIA-5.3.1 AIIA-5.6.2	York	1997	Oral (Stomach tube and dietary) dosage-range developmental toxicity study of Thiophanate-methyl in rabbits NPS RD-9769 SCC Doc. No.: 551-004 GLP, unpublished
AIIA-5.3.1 AIIA-5.6.2	York	1997	Oral (Stomach tube) developmental toxicity study of Thiophanate-methyl in rabbits NPS RD-9770 SCC Doc. No.: 551-005 GLP, unpublished
AIIA-5.4.2	Proudlock, R.J.	1999	Thiophanate-methyl – Mouse Micronucleus Test. NPS NOD 024/983714 SCC Doc. No.:557-007 GLP, unpublished TOX1999-479
AIIA-5.6.2	Christian	1997	Critical review of two developmental (embryo-fetal toxicity/teratogenicity) toxicity study of Thiophanate-methyl in rabbits NPS RD-9771 SCC Doc. No.: 551-001 GLP, unpublished
AIIA-5.10	Poth, A.	2001	Thiophanate-methyl – Summary and evaluation of thresholds of the toxicological effects under consideration of the established ADI and AOEL. NPS 146-003-01/1 SCC Doc. No.: 581-002 not GLP, unpublished TOX2001-1161

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 BBA registration number
AIIA-5.9.3 AIIIA-7.2.3.1	Heidemann, A.	1998	Thiophanate-methyl – Risk assessment for the operator, bystander and consumer with special regard of MBC-generation. NPS SCC PROJECT NO.: 146-003-98/3 SCC Doc. No.: 581-001 not GLP, unpublished TOX98-51473

Codes of company

NPS: Nisso Chemicals Europe
SCC: SCC GmbH

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 BBA registration number
AIIA-6	Brewin, S.	1999	Thiophanate-Methyl and Carbendazim, The determination of storage stability in rape seed, dry peas, grapes and wheat grain over a 12 month period stored at approximately – 18°C NPS NOD/181 SCC Doc. No.:645-002 not GLP, unpublished RIP2002-734
AIIA-6	Brewin, S.	2002	Thiophanate-Methyl and Carbendazim, The determination of storage stability in rape seed, dry peas, grapes and wheat grain over a 12 month period stored at approximately – 18°C NPS NOD 181/023745 SCC-Doc. No.: 645-003 GLP, unpublished
AIIA-6	Lucas, L. T.	2000	Thiophanate Methyl Frozen Storage Stability of Residues in/on Whole Apples. NPS BR-95-09 SCC Doc. No.:645-001 GLP, unpublished RIP2000-2050
AIIA-6.1	Alam, F.; Dedmore, M.; Jalal, M.A.F.	1994	Nature of the Residues of 14C-Thiophanate-Methyl in Spray Treated Apples. NPS RD-99125 BR-93-29 SCC-Doc. No.: 632-2001 GLP, unpublished RIP2000-220
AIIA-6.1	Alam, F.; Dedmore, M.; Jalal, M.A.F.	1994	Nature of the Residues of 14C-Thiophanate-Methyl in Spray Treated Apples. NPS RD- 93292 SCC-Doc. No.: 632-2003 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 BBA registration number
AIIA-6.1	Davis, M.L.; Malik, N.S.A. and Lofthouse, T.J.	1992	Metabolism of the Fungicide Thiophanate-methyl in Spray-treated Spring Wheat. NPS SC900053 , BR-90-17 SCC Doc. No.:611-004 GLP, unpublished RIP2002-701
AIIA-6.1	Eder, M.	2001	Thiophante-methyl, Finally revised cGAPs for Southern and Northern Europe. NPS Dok-Nr.: 671-001 not GLP, unpublished RIP2002-165
AIIA-6.1	Malik, N.S.A. and Wright, M.C.	1992	14C-Thiophanate-Methyl nature of the residue in spray treated lima beans. NPS BR-90-19 , RD-II02140 SCC Doc. No.: 611-003 GLP, unpublished RIP2002-706
AIIA-6.1	Malik, N.S.A. and Wright M.C.	1992	14C-Thiophanate-Methyl Nature of the Residue in Spray Treated Sugar Beets. NPS BR-90-18 , RD-II01232 SCC Doc. No.: 633-0001 GLP, unpublished RIP2002-711
AIIA-6.3; AIIA-6.5	de Vries, R.	1998	Residue analysis of thiophanate-methyl in grapes and wine after application of thiophanate-methyl 70 % WP in Portugal, 1997. NPS Project 205763 SCC Doc. No.: 632-4001 GLP, unpublished RIP1999-272

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 BBA registration number
AIIA-6.3	Fraschini, C.	1997	Residue analysis of thiophanate-methyl and metabolite Carbendazim in barley (grain). NPS SIP 1035 SCC Doc. No.:634-4301 GLP, unpublished RIP1999-274
AIIA-6.3; AIIA-6.5	Fraschini, C.	1997	Residue analysis of thiophanate-methyl and metabolite Carbendazim in apricot (fruit). NPS SIP 1039 SCC Doc. No.:632-3001 GLP, unpublished RIP1999-273
AIIA-6.3	Grolleau, G.	2001	Magnitude of the residue of Thiophante-methyl in Open Field Tomato Raw Agricultural Commodity. NPS SCC Doc-No.: 633-2002; Study No.: EA000162 GLP, unpublished RIP2002-157
AIIA-6.3	Grolleau, G.	2001	Magnitude of the residue of Thiophante-methyl in Protected Pepper Raw Agricultural Commodity. NPS SCC Doc-No.: 633-2101; Study No.: EA000155 GLP, unpublished RIP2002-159
AIIA-6.3	Grolleau, G.	2001	Magnitude of the residue of Thiophante-methyl in Protected Tomato Raw Agricultural Commodity. NPS SCC Doc-No.: 633-2001; Study No.: EA000157 GLP, unpublished RIP2002-161
AIIA-6.3	Grolleau, G.	2001	Magnitude of the residue of Thiophante-methyl in Plum Raw Agricultural Commodity. NPS SCC Doc-No.: 632-3301; Study No.: EA000152 GLP, unpublished RIP2002-162

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 BBA registration number
AIIA-6.3	Grolleau, G.	2001	Magnitude of the residue of Thiophante-methyl in Peach Raw Agricultural Commodity. NPS SCC Doc-No.: 632-3201; Study No.: EA000151 GLP, unpublished RIP2002-163
AIIA-6.3	Grolleau, G.	2001	Magnitude of the residue of Thiophante-methyl in AppleRaw Agricultural Commodity. NPS SCC Doc-No.: 632-2002; Study No.: EA000153 GLP, unpublished RIP2002-164
AIIA-6.3	Grolleau, G.	2002	Magnitude of the Residue of Thiophanate-methyl in Fresh Beans Raw Agricultural Commodity. NPS EA010155 , RD-II02138 SCC Doc. No.: 633-5102 GLP, unpublished RIP2002-687
AIIA-6.3	Grolleau, G.	2002	Magnitude of the Residue of Thiophanate-methyl in Fresh Peas Raw Agricultural Commodity. NPS EA010154 , RD-II02139 SCC Doc. No.: 633-5204 GLP, unpublished RIP2002-688
AIIA-6.3	Grolleau, G.	2002	Magnitude of Thiophanate-methyl in Cherry Raw Agricultural Commodity and Processed Fractions. NPS EA010144 , RD-II02125 SCC Doc. No.:632-3104 GLP, unpublished RIP2002-689

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 BBA registration number
AIIA-6.3	Grolleau, G.	2002	Magnitude of the Residue of Thiophanate-methyl in Protected Pepper Raw Agricultural Commodity. NPS EA010146 , RD-II02141 SCC Doc. No.:633-2102 GLP, unpublished RIP2002-707
AIIA-6.3	Grolleau, G.	2002	Magnitude of the Residue of Thiophanate-methyl in Open Field Melon Raw Agricultural Commodity. NPS EA010150 , RD-II02129 SCC Doc. No.: 633-2502 GLP, unpublished RIP2002-708
AIIA-6.3	Grolleau, G.	2002	Magnitude of the Residue of Thiophanate-methyl in Protected Melon Raw Agricultural Commodity. NPS EA010149 , RD-II02128 SCC Doc. No.: 633-2503 GLP, unpublished RIP2002-709
AIIA-6.3	Grolleau, G.	2002	Magnitude of the Thiophanate-methyl in Plum Raw Agricultural Commodity and Processed Fractions. NPS EA010143 , RD-II02124 SCC Doc. No.: 632-3302 GLP, unpublished RIP2002-710
AIIA-6.3	Grolleau, G.	2002	Amendment to EAS final Report: Magnitude of the Residue of Thiophanate-methyl in OpenField Tomato Raw Agricultural Commodity; RIP2002-698. NPS EA000162 SCC Doc. No.: 633-2002 GLP, unpublished RIP2002-713

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 BBA registration number
AIIA-6.3	Grolleau, G.	2002	Amendment to EAS Final Report: Magnitude of the Residue of Thiophanate-methyl in Oildees Rape Raw Agricultural Commodity; RIP2002-695. NPS EA000161 SCC Doc. No.: 634-0604 GLP, unpublished RIP2002-714
AIIA-6.3	Grolleau, G.	2002	Amendment to EAS Final Report: Magnitude of the Residue of Thiophanate-Methyl in Grapevine Raw Agricultural Commodity; RIP 2002-691. NPS EA000160 SCC Doc. No.: 632-4002 GLP, unpublished RIP2002-715
AIIA-6.3	Grolleau, G.	2002	Amendment to EAS Final Report: Magnitude of the Residue of Thiophanate-Methyl in Winter Barley Raw Agricultural Commodity; RIP2002-692. NPS EA000159 SCC Doc. No.: 634-4302 GLP, unpublished RIP2002-717
AIIA-6.3	Grolleau, G.	2002	Amendment to EAS final Report: Magnitude of the Residue of Thiophanate-methyl in Winter Wheat Raw Agricultural Commodity; RIP2002-696. NPS EA000158 SCC Doc. No.: 634-4003 GLP, unpublished RIP2002-718
AIIA-6.3	Grolleau, G.	2002	Amendment to EAS Final Report: Magnitude of the Residue of Thiophanate-Methyl in Protected Tomato Raw Agricultural Commodity; RIP2002-697. NPS EA000157 SCC Doc. No.:633-2001 GLP, unpublished RIP2002-719

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 BBA registration number
AIIA-6.3	Grolleau, G.	2002	Amendment to EAS Final Report: Magnitude of the Residue of Thiophanate-Methyl in Protected Melon Raw Agricultural Commodity; RIP2002-709. NPS EA000156 SCC Doc. No.: 633-2501 GLP, unpublished RIP2002-726
AIIA-6.3	Grolleau, G.	2002	Amendment to EAS Final Report: Magnitude of the Residue of Thiophanate-methyl in Protected Pepper Raw Agricultural Commodity; RIP2002-707. NPS EA000155 SCC Doc. No.: 633-2101 GLP, unpublished RIP2002-727
AIIA-6.3	Grolleau, G.	2002	Amendment to EAS Final Report: Magnitude of the Residue of Thiophanate-methyl in Apple Raw Agricultural Commodity; RIP2002-699. NPS EA000153 SCC Doc. No.: 632-2002 GLP, unpublished RIP2002-728
AIIA-6.3	Grolleau, G.	2002	Amendment to EAS Final Report: Magnitude of the Residue of Thiophanate-methyl in Peach Raw Agricultural Commodity; RIP2002-690. NPS EA000151 SCC Doc. No.: 632-3201 GLP, unpublished RIP2002-732
AIIA-6.3	Grolleau, G.	2002	Magnitude of the Residue of Thiophanate-methyl in Peach Raw Agricultural Commodity and Processed Fractions. NPS EA010142 , RD-II02123 SCC Doc. No.: 632-3202 GLP, unpublished RIP2002-690

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 BBA registration number
AIIA-6.3	Grolleau, G.	2002	Magnitude of the Residue of Thiophanate-methyl in Wine and Table Grapes Raw Agricultural Commodity and Processed Fractions. NPS EA010145 , RD-II02143 SCC Doc. No.: 632-4003 GLP, unpublished RIP2002-691
AIIA-6.3	Grolleau, G.	2002	Magnitude of the Residue of Thiophanate-methyl in Spring and Winter Barley Raw Agricultural Commodity and Processed Fractins. NPS EA010156 , RD-II02144 SCC Doc. No.: 634-4304 GLP, unpublished RIP2002-692
AIIA-6.3	Grolleau, G.	2002	Magnitude of the Residueof Thiophanate-methyl in Dry Beans Raw Agriculture Commodity. NPS EA010153 , RD-II02131 SCC Doc. No.: 633-8001 GLP, unpublished RIP2002-693
AIIA-6.3	Grolleau, G.	2002	Magnitude of the Residue of Thiophanate-methyl in Dry Peas Raw Agricultural Commodity. NPS EA010152 , RD-II02142 SCC Doc. No.: 633-8201 GLP, unpublished RIP2002-694
AIIA-6.3	Grolleau, G.	2002	Magnitude of the Residue of Thiophanate-methyl in Oilseed Rape Raw Agricultural Commodity. NPS EA010151 , RD-II02130 SCC Doc. No.: 634-0606 GLP, unpublished RIP2002-695

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 BBA registration number
AIIA-6.3	Grolleau, G.	2002	Magnitude of the Residue of Thiophanate-methyl in Open Field Tomato Raw Agricultural Commodity and Processed Fractions. NPS EA010148 , RD-II02127 SCC Doc. No.: 633-2004 GLP, unpublished RIP2002-698
AIIA-6.3	Grolleau, G.	2002	Magnitude of the Residue of Thiophanate-methyl in Apple Raw Agricultural Commodity and Processed Fractions. NPS EA010140 , RD-II02140 SCC Doc. No.: 632-2005 GLP, unpublished RIP2002-699
AIIA-6.3	Grolleau, G.	2002	Magnitude of the Residue of Thiophanate-methyl in Pear Raw Agricultural Commodity. NPS EA010141 , RD-II02122 SCC Doc. No.: 632-2101 GLP, unpublished RIP2002-700
AIIA-6.3	Grolleau, G.	2001	Magnitude of the residue of Thiophante-methyl in Protected Melon Raw Agricultural Commodity. NPS SCC Doc-No.: 633-2501; Study No.: EA000156 GLP, unpublished RIP2002-160
AIIA-6.3	Grolleau, G.	2001	Magnitude of the residue of Thiophante-methyl in Grapevines Raw Agricultural Commodity. NPS SCC Doc-No.: 632-4002; Study No.: EA000160 GLP, unpublished RIP2002-158

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 BBA registration number
AIIA-6.3	Grolleau, G.	2001	Magnitude of the residue of Thiophante-methyl in Winter Barley Raw Agricultural Commodity. NPS SCC Doc-No.: 634-4302; Study No.: EA000159 GLP, unpublished RIP2002-156
AIIA-6.3	Grolleau, G.	2001	Magnitude of the residue of Thiophante-methyl in Winter Wheat Raw Agricultural Commodity. NPS SCC Doc-No.: 634-4003; Study No.: EA000158 GLP, unpublished RIP2002-155
AIIA-6.3	Grolleau, G.	2001	Magnitude of the residue of Thiophante-methyl in Oilseed Rape Raw Agricultural Commodity. NPS SCC Doc-No.: 634-0604; Study No.: EA000161 GLP, unpublished RIP2002-154
AIIA-6.3	Grolleau, G.	2001	Magnitude of the residue of Thiophante-methyl in cherry raw agricultural commodity and processed fractions. NPS SCC Doc-No.: 632-3102; Study No.: EA000150 GLP, unpublished RIP2002-153
AIIA-6.3	Grolleau, G.	2002	Amendment to EAS Final Report: Magnitude of the Residue of Thiophanate-methyl in Cherry Raw Agricultural Commodity and Processed Fractions; RIP2002-689. NPS EA000150 SCC Doc. No.: 632-3102 GLP, unpublished RIP2002-733

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 BBA registration number
AIIA-6.3	Grolleau, G.	2002	Amendment to EAS Final Report: Magnitude of the Residue of Thiophanate-methyl in Plum Raw Agricultural Commodity; RIP2002-710. NPS EA000152 SCC Doc. No.: 632-3301 GLP, unpublished RIP2002-730
AIIA-6.3	Grolleau, G.	2002	Magnitude of the Residue of Thiophanate-methyl in Protection Tomato Raw Agriculture Commodity and Processed Fractions. NPS EA010147 , RD-II02126 SCC Doc. No.: 633-2003 GLP, unpublished RIP2002-697
AIIA-6.3	Grolleau, G.	2002	Magnitude of the Residue of Thiophanate-methyl in Winter Wheat Raw Agricultural Commodity. NPS EA010157 , RD-II02132 SCC Doc. No.: 634-4005 GLP, unpublished RIP2002-696
AIIA-6.3	Muller, M.A.	1996	Residue analysis of thiophanate-methyl observed in colza (rape) grain samples. NPS 95-731 SCC Doc. No.: 634-0603 GLP, unpublished RIP1999-277
AIIA-6.3	Muller, M.A.	1996	Residue analysis of thiophanate-methyl observed in pea grain samples. NPS 95-733 SCC Doc. No.: 633-5203 GLP, unpublished RIP1999-275

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 BBA registration number
AIIA-6.3	Riches, N.T.	1997	Residue analysis of thiophanate-methyl observed in bean samples. NPS 96-745 SCC Doc. No.: 633-5101 GLP, unpublished RIP1999-276
AIIA-6.4	Castro, L.	1997	Residues of Thiophanate-methyl and its major metabolites in the eggs and tissue of laying hens following daily oral dosing with Thiophanate-methyl. NPS KP-96-05 SCC Doc. No.: 631-002 GLP, unpublished RIP1999-279
AIIA-6.4	Castro, L.	1997	Magnitude of the residue of Thiophanate-methyl in milk and tissue of lactating dairy cattle. NPS KP-96-04 SCC Doc. No.: 631-001 GLP, unpublished RIP1999-278
AIIA-6.5	Fraschini, C.	1997	Residue analyses of Thiophanate-methyl and metabolite Carbendazim in apricot (jam). NPS SIP 1042 SCC Doc. No.: 638-004 GLP, unpublished RIP1999-283
AIIA-6.5	Fraschini, C.	1997	Residue analyses of Thiophanate-methyl and metabolite Carbendazim in apricot (puree). NPS SIP 1043 SCC Doc. No.:638-003 GLP, unpublished RIP1999-282

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 BBA registration number
AIIA-6.5	Fraschini, C.	1997	Residue analyses of Thiophanate-methyl and metabolite Carbendazim in apricot (preserve). NPS SIP 1041 SCC Doc. No.: 638-002 GLP, unpublished RIP1999-281
AIIA-6.5	Fraschini, C.	1997	Residue analyses of Thiophanate-methyl and metabolite Carbendazim in apricot (juice). NPS SIP 1040 SCC Doc. No.: 638-001 GLP, unpublished RIP1999-280
AIIA-6.6	Kim-Kang, H.	1997	Addendum Report #2 (14C) Thiophanate-Methyl Nature of the Residues in Rotational Crops. NPS RD-99124 BR-90-14 SCC Doc. No.: 637-001 GLP, unpublished RIP2000-202
AIIA-6.6	Malik, N. S .A. and Wright, M. C.	1993	14C-Thiophanate Methyl Nature of the Residues in Rotational Crops. NPS RD-99123 BR-90-14 SCC Doc. No.: 637-001 GLP, unpublished RIP2000-201

Codes of company

NPS: Nisso Chemicals Europe

SCC: SCC GmbH

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 BBA registration number
AIIA-7.1.1.1.2	Dykeman, R.G.	1986	Thiophanate-Methyl - Anaerobic Aquatic Metabolism. NPS RD-99122, WT-1-82 SCC Doc. No.: 715-001 not GLP, unpublished BOD2000-66
AIIA-7.1.1.2.1	Schnurr, S.	2002	Assessment of the Influences on Degradation of Carbendazim in Soil. NPS SCC 146-003-02/2 SCC Doc. No.: 781-002 not GLP, unpublished BOD2002-463
AIIA-7.1.1.2.1	Völkl, S.	2002	14C-Thiophanate-methyl: Degradation and Metabolism in Three Soils Incubated under Aerobic Conditions. NPS SCC Doc. No.: 721-004, RD-02149, RCC 815051 GLP, unpublished BOD2002-462
AIIA-7.1.2	Koch Singles, S.	2000	Adsorption/Desorption of IN-JS940 (a Metabolite of Famoxadone) in Four Soils. CTF Du-Pont-3834 GLP, unpublished BOD2000-1406
AIIA-7.1.3.1; AIIA-7.1.3.2	Anthe, M.	1998	Summary on the Mobility of Thiophanate-methyl in Sandy Acidic Soils. NPS SCC 146-003 SCC Doc. No.: 781-001 not GLP, unpublished BOD98-01086

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 BBA registration number
AIIA-7.1.3.1	Schnurr, S.	2002	Estimation of the Leaching Potential of Thiophanate-methyl aistits Major Metabolite Carbendazim by Model Calculations with FOCUS PELMO (Pesticide Leaching Model). NPS SCC 146-003-02/4 SCC Doc. No.: 782-005 not GLP, unpublished BOD2002-465
AIIA-7.2.1.3.2	Völkl, S	2001	14C-thiophanate-methyl: Route and rate of degradation in aerobic aquatic systems. NPS 735063 SCC Doc. No.:714-001 GLP, unpublished WAS2002-236 (identisch mit WAS2002-109)
AIIA-7.2.1.3.2	Völkl, S.	2001	14C-Thiophanate-methyl: Routre and Rate of Degradation in Aerobic Aquatic Systems. NPS RD-II 01057, 714-001, RCC 735063 SCC Doc. No.: 714-001 GLP, unpublished WAS2002-109 (identisch mit WAS 2002-236)

Codes of company

CTF: Carbendazim Task Force
NPS: Nisso Chemicals Europe
SCC: SCC GmbH

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 BBA registration number
AIIA-8.1.3	Pedersen, C.A. and Solatycki, A.M.	1993	Thiophanate-methyl: Toxicity and reproduction study in bobwhite quail. NPS BLAL 106-014-07 SCC Doc. No.: 813-001 GLP, unpublished AVS2000-26
AIIA-8.2	Eder	2001	Final report, Assessment of the aquatic risk from Thiophanate-methyl NPS SCC, 146-003-01/3 SCC-Doc. No.: 882-002 not GLP, unpublished
AIIA-8.2.6	Saito, S.	2002	Thiophanate-methyl: inhibition of growth to the alga pseudokirchneriella subcapitata. NPS NCAS 02-160 SCC Doc. No.: 823-003 GLP, unpublished WAT2003-28
AIIA-8.2.6	Anthe, M.	1998	Addendum Report: Toxicity of Thiophanate-methyl to green algae: Calculation of E _b C ₅₀ - and E _r C ₅₀ -values NPS SCC Project no.: 146-003 SCC Doc. No.: 782-003 not GLP, unpublished
AIIA-8.2.7	Eder, M.	2002	Assessment of the aquatic risk from Thiophanate-methyl and Carbendazim to sediment dwelling organisms NPS 146-003-02/3 SCC-Doc. No.: 881-005 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 BBA registration number
AIIA-8.2.7	Mimmert, U.	2002	Effects of ¹⁴ C-Thiophanate-methyl on the development of sediment-dwelling larvae of <i>Chironomus riparius</i> in a water-sediment system. NPS 831148 ! SCC Doc. No.: 828-001 ! RD-II 02133GLP, unpublished WAT2002-317
AIIA-8.3.2; AIIIA-10.5.1	Becker, R.	2001	Effect of BAS 325 11 F on the parasitoid <i>Aphidius rhopalosiphii</i> (Hymenoptera: Braconidae) in an extended laboratory trial. BAS 107771 SCC Doc. No.: 834-009 GLP, unpublished ANA2002-136
AIIA-8.3.2; AIIIA-10.5.1	Bühler, A.	2001	Effects of BAS 325 11 F on the predatory mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae) in the laboratory trial -dose response-. BAS 110811 SCC Doc. No.: 834-005 GLP, unpublished ANA2002-135
AIIA-8.3.2; AIIIA-10.5.1	Bühler, A.	2001	Effect of BAS 325 11 F on the ground dwelling predator <i>Poecilus cupreus</i> (Coleoptera, Carabidae) in the laboratory trial. BAS 107759 SCC Doc. No.: 834-007 GLP, unpublished ANA2002-133
AIIA-8.3.2; AIIIA-10.5.2	Müther, J.	2001	A field study to evaluate the effects of BAS 325 11 F against predatory mites in apple. BAS 20011102/G1-NFTp SCC Doc. No.: 834-010 GLP, unpublished ANA2002-134

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 BBA registration number
AIIA-8.3.2; AIIIA-10.5.1	Stäbler, P.	2001	BAS 325 11 F: Acute toxicity to the hoverfly, <i>Episyrphus balteatus</i> DEG. (Diptera, Syrphidae) in the laboratory. BAS 20011102/01-NLEb SCC Doc. No.: 834-008 GLP, unpublished ANA2002-132
AIIA-8.3.2; AIIIA-10.5.1	Vinall, S.	2001	A laboratory test to determine the effects of BAS 325 11 F on the parasitic wasp, <i>Aphidius rhopalosiphi</i> . BAS BASF-01-8 SCC Doc. No.: 834-006 GLP, unpublished ANA2002-137
AIIA-8.4.2; AIIIA-10.6.1.2	Petto, R.	1998	Effects of thiophanate-methyl on reproduction and growth of earthworms <i>Eisenia fetida</i> (Savigny 1826) in artificial soil. NPS Proj.: 3600022 SCC Doc. No.: 833-005 not GLP, unpublished ARW2000-27
AIIA-8.6; AIIIA-10.8	Anonymous	2002	The impact of Thiophanate-methyl on non-target flora and fauna (IIA 8.6)NPS SCC Doc. No.: 851-001 IRD-II02074 not GLP, unpublished PFL2002-112
AIIIA-10.6.1.3; AIIIA-10.6.2 AIIA-8.4	Brandt, S.	2001	Assessment of the Risk for Soil Dwelling Organisms from Thiophanate-Methyl. NPS 146-003-01/4 SCC Doc. No.: 882-001 not GLP, unpublished ARW2002-33

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 BBA registration number
AIIIA-10.6.1.3 AIIA-8.4	Ehlers, H. A.	2001	Field Study to Evaluate the Effects of Cercobin FL on Earthworm. NPS 5901023 SCC Doc. No.: 833-008 GLP, unpublished ARW2002-31
AIIIA-10.6.1.3 AIIA-8.4	Ehlers, H. A.	2001	Evaluation of the Earthworm Population in the Orchard treated with Cercobin FL. NPS 5904023 SCC Doc. No.:833-010 GLP, unpublished ARW2002-30
AIIA-8.4 AIIIA-10.6.1.3 AIIIA-10.6.2	Meinerling, M. and Herrmann, S.	2001	Determination of the Deposition Rate of Thiophanate-Methyl in a Field Application of Cercobin FL. NPS 5903100 SCC Doc. No.: 833-007 GLP, unpublished ARW2002-32
AIIA-8.4 AIIIA-10.6.2	Meister, A.	2001	Effects of Cercobin FL on the Decomposition of Organic Material enclosed in Litter Bags in the Field. NPS 5902081 SCC Doc. No.: 835-002 GLP, unpublished ARW2002-34

Codes of company

BAS: BASF AG, Ludwigshafen

NPS: Nisso Chemicals Europe

SCC: SCC GmbH

APPENDIX IV**List of uses supported by available data****THIOPHANATE-METHYL**

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 (days)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Oilseed rape	EU (North & South)		F		SC	500 g/L	Spraying	79	1		0.223	350	0.781	49	
Cereals (Winter barley, winter wheat)	EU (North & South)		F		SC	500 g/L	Spraying	71	1		0.223	350	0.781	42	
Pome fruit (Apples, pears)	EU (North & South)		F		SC	500 g/L	Spraying	60-69 85-87	2		0.068	1250	0.844	3	
Stone fruit (Plums, cherries)	EU (North & South)		F		SC	500 g/L	Spraying	60-69 85-87	2		0.068	1250	0.844	14	
Stone fruit (Peaches)	EU (South)		F		SC	500 g/L	Spraying	60-69 85-87	2		0.068	1250	0.844	3	
Tomatoes/ Peppers	EU (North & South)		G		SC	500 g/L	Spraying	89	3	7	0.092	1150	1.063	3	
Dry (combining) peas	EU (North & South)		F		SC	500 g/L	Spraying	Last treatment: 71	2	14	0.268	350	0.938	28	
Fresh peas outdoors	EU (North & South)		F		SC	500 g/L	Spraying	Last treatment: 71-79	2	14	0.268	350	0.938	14	
Dry beans	EU (North & South)		F		SC	500 g/L	Spraying	Last treatment: 71	2	14	0.268	350	0.938	28	

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 (days)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Fresh beans with pods outdoors	EU (North & South)		F		SC	500 g/L	Spraying	Last treatment: 71-79	2	14	0.268	350	0.938	14	
Melons	EU (North & South)		G		SC	500 g/L	Spraying	drip irrigation: 69-72 spraying: 81-89	3	14	drip irrigation: 0.281 2. + 3. applic. 0.0844	1000	drip irrigation: 2.81 2. + 3. applic. 0.844	3	
Melons	EU (South)		F		SC	500 g/L	Spraying		2	14	0.0844	1000	0.844	3	

- (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 suckling 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 plant - 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) Indicate the minimum and maximum number of application possible under practical conditions of use
- (l) PHI - minimum pre-harvest interval
- (m) Remarks may include: Extent of use/economic importance/restrictions