



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate D - Food Safety: Production and distribution chain
Unit D.3 - Chemicals, contaminants and pesticides

Maneb

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EU RESTRICTED

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THE VIEWS OF THE COMMISSION SERVICES**

FINAL

Review report for the active substance **maneb**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on
3 June 2005
in view of the inclusion of maneb 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 maneb, 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. Maneb 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, Rohm & Haas France SA on 21 July 1993, Barclay Chemicals on 27 July 1993, ACI International on 30 July 1993, Procida SA on 26 July 1993, Elf Atochem Agri SA on 26 July 1993, Kocide Chem. Corp on 27 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 maneb in Annex I to the Directive.

In accordance with the provisions of Article 4 of Regulation (EEC) No 3600/92, Elf Atochem Agri SA and Rohm and Haas France SA notified to the Commission on 14 March 2001 of their wish to secure the inclusion of the active substance maneb in Annex I to the Directive.

¹ OJ No L 366, 15.12.1992, p.10.

² OJ No L 259, 13.10.2000, p.27.

In accordance with the provisions of Article 5 of Regulation (EEC) No 3600/92, the Commission, by its Regulation (EEC) No 933/94⁽³⁾, as last amended by Regulation (EC) No 2230/95⁽⁴⁾, designated Italy as rapporteur Member State to carry out the assessment of maneb on the basis of the dossier/s submitted by the notifier/s. 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 maneb this deadline was 30 April 1995.

Only Elf Atochem Agri SA and Rohm & Haas France SA submitted in time a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore Elf Atochem Agri SA and Rohm & Haas France SA were considered to be the main data submitters. (Elf Atochem Agri SA submitted its dossier on 19 April 1995. On 12 October 1995, the Italian RMS informed them that the dossier had been examined. No formal completeness check was done).

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Italy submitted on 29 November 2000 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 maneb in Annex I to the Directive.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the Commission forwarded for consultation the draft assessment report to all the Member States on 31 January 2001, as well as to Elf Atochem Agri SA and Rohm & Haas France SA being the main data submitters, on 26 January 2001.

The Commission organised a tripartite meeting with the main data submitters and the rapporteur Member State for this active substance on 6 April 2001 in order to discuss further data to be submitted.

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 Biologische Bundesanstalt für Land und Forstwirtschaft (BBA) in Braunschweig, Germany, from November 2001 to July 2002.

In June 2001 Rohm and Haas France SA was bought by Dow Agro Sciences and notified its willing not to support maneb annex I listing inclusion anymore in December 2001

³ OJ No L 107, 28.04.1994, p.8.

⁴ OJ No L 225, 22.09.1995, p.1.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the main data submitter on 11 September 2002 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 all Member States. This final examination took place from July 2002 to September 2004. In November 2003 the United Kingdom was asked to participate with Italy in preparing refinements to the avian and mammalian risk assessment. Acceptable avian and mammalian risk assessments were completed by June 2004 and submitted as part of an Addendum to the draft assessment report. The evaluation was finalised in the meeting of the Standing Committee on 3 June 2005.

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

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

2. Purposes of this review report *Journal officiel n° L 279 du 22/10/2005 p. 0063 - 0069*

This review report, including the background documents and appendices thereto, has been developed and finalised in support of the Directive 2005/72/EC⁵ concerning the inclusion of maneb in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing maneb 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 maneb 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 maneb 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 submitters 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 a **careful** 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 39 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994).

Estimates of acute dietary exposure for adults and toddlers revealed that the Acute Reference Dose (ARfD) would not be exceeded for the relevant commodities potato and onion: with maximum 2 % or 6% for respectively adults or toddlers. Additional intake from water and products of animal origin is 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 maneb 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 Elf Atochem Agri SA, 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 maneb

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 for groundwater contamination, when the active substance is applied in regions with vulnerable soils and/or extreme climatic conditions.
- Member States must pay particular attention to the residues in food and evaluate the dietary exposure of consumers.
- Member States must pay particular attention to the protection of birds, mammals aquatic organisms and non target arthropods and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures.

7. List of studies to be generated

Member States shall request the submission of further studies to confirm the risk assessment for birds and mammals and for developmental toxicity.

They shall ensure that the notifiers at whose request maneb has been included in Annex I of Council Directive 91/414/EEC provide such studies to the Commission within 2 years from the entry into force of the Directive of inclusion.

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 studies to assess the consumer risks of uses in edible crops other than those supported by available data.

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 submitters have 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 maneb in Annex I of the Directive.

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

Common name (ISO)	MANEB
Chemical name (IUPAC)	manganese ethylenebis (dithiocarbamate) (polymeric)
Chemical name (CA)	[1,2-ethanediylbis[carbamo(dithio)ato](2-)]manganese (9CI) [ethylenebis(dithiocarbamate)manganese] (8CI)
CIPAC No	61
CAS No	12427-38-2
EEC No	006-077-00-7 (EINECS)
FAO SPECIFICATION	AGP: CP/82 of 1979. Minimum purity: 860 g/kg.
Minimum purity	860 g/kg
Molecular formula	(C ₄ H ₆ MnN ₂ S ₄) _x
Molecular mass	(265.3) _x
Structural formula	<p>[-SCS.NHCH₂CH₂NHCS.S-Mn-]_x</p> <p>Maneb is a polymeric complex of the monomer illustrated</p>

Notifier A:

Melting point	Not measurable as the product decomposes before melting (purity 89.7 %).
Boiling point	Not applicable, decomposes before melting.
Appearance	Light to greyish yellow fine powder with a faint cabbage and fishy smell (purity 86%).
Relative density	1.99 g/ml at 20°C (purity not specified).
Vapour pressure	1.4×10^{-5} Pa at 20 °C.
Henry's law constant	$2.08 \times 10^{-5} \text{ Pa m}^3 \text{ mol}^{-1}$
Solubility in water	pH 5: 259 mg/l at 20°C.
	pH 7: 178 mg/l at 20°C.
	pH 9: 257 mg/l at 20°C.
Solubility in organic solvents	Methanol : < 10 mg/l at 20°C.
	Ethyl acetate : < 10 mg/l at 20°C.
	Toluene: < 10 mg/l.
	1,2-dichloromethane: < 10 mg/l.
	Acetonitrile : < 10 mg/l at 20°C.
	Xylene : < 10 mg/l at 20°C.
	Heptane : < 10 mg/l at 20°C.
	Acetone : < 10 mg/l at 20°C.
n-Octanol : < 1.4 mg/l at 20°C.	
Partition co-efficient (log P_{ow})	pH 5: logP _{ow} < -0.17 at 20° C.
	pH 7: LogP _{ow} < -0.45 at 20°C.
	pH 9: LogP _{ow} < -1 at 20° C.
Hydrolytic stability (DT₅₀)	pH 5: DT ₅₀ 10.8 h at 20°C.
	pH 7: DT ₅₀ 208 h at 20°C.
	pH 9: DT ₅₀ 33 h at 20°C.
Dissociation constant	Not applicable.
Quantum yield of direct photo-transformation in water at λ >290 nm	Quantum yield cannot be calculated for maneb because the measured photodegradation rate was negligible.
Flammability	Maneb technical is not flammable in the sense of the method EEC A10.
Explosive properties	On the basis of the theoretical evaluation of the chemical structure, possible decomposition reactions and energies, and the decomposition products of the substance, no potential explosive properties are expected.

UV/VIS absorption (max.)	λ max = 285 nm As Maneb is a polymer of unknown chain length and product properties, no technique allows to establish an absolute molecular weight. And Maneb is not soluble in water or organic solvents without decomposition. The calculation of ϵ for Maneb is therefore not possible.
Photostability in water (DT₅₀)	Stable to aqueous photolysis (pH 7; 25°C; artificial light source): hydrolytic degradation occurs both in samples exposed to the light and in the dark controls.

APPENDIX II

END POINTS AND RELATED INFORMATION

MANEB

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	Rapid, 60% based on urinary excretion.
Distribution:	Widely distributed, highest residues in thyroid.
Potential for accumulation:	Low potential.
Rate and extent of excretion:	Rapid, approximately 80% within 120 h (29% faeces and 51% urine).
Toxicologically significant compounds:	Parent compound and metabolite (ETU).
Metabolism in animals:	Extensively metabolised, the main steps are hydrolysis and ring formation.

Acute toxicity

Rat LD ₅₀ oral:	> 5000 mg/kg bw
Rat LD ₅₀ dermal:	> 2000 mg/kg bw
Rat LC ₅₀ inhalation:	5.34 mg/l (males).
Skin irritation:	Non irritant.
Eye irritation:	Irritant.
Skin sensitization (test method used and result):	Sensitiser (M & K).

Short term toxicity

Target / critical effect:	Thyroid (inhibition of thyroid peroxidase, hyperplasia/hypertrophy)
Lowest relevant oral NOAEL / NOEL:	80 ppm=5 mg/kg bw/d (90-d, rat)
Lowest relevant dermal NOAEL / NOEL:	100 mg/kg bw/d (21-d, rabbit)
Lowest relevant inhalation NOAEL / NOEL:	10 mg/m ³ (90-d, rat)

Genotoxicity

The overall body of toxicological data coming from a number of <i>in vitro</i> and <i>in vivo</i> assays indicates that there is no concern.
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Long term toxicity and carcinogenicity

Target / critical effect:

Thyroid (inhibition of thyroid peroxidase, hyperplasia/hypertrophy), liver (mice).
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Lowest relevant NOAEL:

60 ppm=8.6 mg/kg bw/d (18-month mice)

Carcinogenicity:

Liver adenomas in mice.

Reproductive toxicity

Target / critical effect - Reproduction:

Decreased pup body weight gain at parentally toxic dose level.
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Lowest relevant reproductive NOAEL / NOEL:

– Reproductive: 300 ppm (20 mg/kg bw/d) – Systemic: 75 ppm (5.6 mg/kg bw/d).

Target / critical effect - Developmental toxicity:

Malformations at high dose levels in rats; embryo-/fetotoxicity (delayed ossification, reduced fetal weight, resorptions) at lower maternally toxic dose levels in rats and rabbits.
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Lowest relevant developmental NOAEL / NOEL:

Rat: 20 mg/kg bw/d.

Delayed neurotoxicity

NOEL: 75 ppm corresponding to 5 and 6 mg/kg bw/d for males and females, respectively.

Maneb did not show any potential of neurotoxicity in rats.
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Other toxicological studies

Metabolite EBIS: oral LD ₅₀ in rats is 240 mg/kg bw; effects on thyroid, evidence of neurotoxicity in rats and mice.

Medical data

The great majority of publications report on cases of allergic contact dermatitis (eczemas, irritation, sensitisation).

Urinary monitoring studies of workers using ETU or manganese as indicators of exposure suggest that the resulting exposures are generally within the acceptable limits.

A monitoring study showed that the main body part exposed of workers was hands. No biologically significant change was observed for the blood concentrations of T3, T4 and TSH.

Three clinical cases were associated with the use of maneb (2 cases of acute renal failure, 1 with reversible neurological reactions), but details on exposure are missing. One case of Parkinson Disease was reported after chronic exposure, and other studies hypothesize an association between occupational exposure to pesticides containing Mn and intoxication of the CNS. The overall available evidence is still inconclusive, and further research is needed.

Summary

	Value	Study	Safety factor
ADI:	0.05 mg/kg bw/d	multi-generation study in rat (supported by 90-d rat)	100
AOEL systemic:	0.03 mg/kg bw/d	90-d rat 60 % oral absorption	100
AOEL inhalation:	0.027 mg/kg bw/d	90-d inhalation study in rats	100
AOEL dermal:	1 mg/kg bw/d	21-d dermal study in rabbit	100
ARfD (acute reference dose):	Maneb: 0.2 mg/kg bw/d (based on the NOEL of 20 mg/kg bw/d teratogenicity in rats) ETU 0.05 mg/kg bw/d		

Dermal absorption

0.4% (*in vivo* rat, 8-hour exposure)

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:

16-23% AR after 30-32 d.

Non-extractable residues after 100 days:

62-88% AR after 30-32 d.

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

EU: 36.1-63.8 %

ETU: 9.6-20.4 %

EBIS: 4.1-12.8 %

Unidentified: 6.0-10.9%

Supplemental studies

Anaerobic:

Results of anaerobic degradation studies gives similar results to that under aerobic conditions.

Soil photolysis:

Not relevant.

Remarks:

None.

Rate of degradation

Laboratory studies

DT₅₀lab (20 °C, aerobic):

DT₅₀lab (20°C, aerobic):

Maneb ≤ 2.5, ≤ 3.5 and ≤ 2 hours (3 soils)

ETU: estimated in 2 hours, n=1

0.3 d, 1d; (2 Dutch soils)

from literature data (mean value on 4 soils): 1.2 d.

EU: 4.8 to 7.6 days. Average: 6.2, n=3, r²>0.94.

from literature data (mean value on 3 soils): 4.9 d.

EBIS: 0.09 to 0.15 days. Average: 0.12 d, n=3, r²=0.968.

DT ₉₀ lab (20 °C, aerobic):	DT ₉₀ lab (20°C, aerobic): ≤ 8, ≤ 7 and ≤ 7 weeks (3 soils) ETU: estimated in less than 2 d, n=1 EU: 16.0 to 25.2 d. Average: 20.6 d, n=3 EBIS: 0.29 to 0.50 d. Average: 0.41 d, n=3
DT ₅₀ lab (10 °C, aerobic):	DT ₅₀ lab (10°C, aerobic): evaluated for maneb with a Q ₁₀ of 2.2: 4.4 to 7.7 hours. ETU: DT ₅₀ lab (10°C, aerobic): 0.7, 1.3, 2.2 and 4.5 d (5 soils).
DT ₅₀ lab (20 °C, anaerobic):	DT ₅₀ lab (20°C, anaerobic): no significant differences are shown in degradation patterns of maneb under anaerobic conditions in comparison with aerobic conditions.
Field studies (country or region)	
DT _{50f} from soil dissipation studies:	USA Keystone silt loam soil: Maneb DT ₅₀ : <1 week (1 st sampling) ETU DT ₅₀ : <1 week (1 st sampling)
DT _{90f} from soil dissipation studies:	8.5 d.
Soil accumulation studies:	Not required as DT ₅₀ is well below 1 d. (2-3.5 h) which is far below 1 third of the time between application and harvest.
Soil residue studies:	Not required.
Remarks: e.g. effect of soil pH on degradation rate	None.

Adsorption/desorption

K_f / K_{oc} :

K_{oc} maneb: 2127, 1028, 1211 and 874 L/kg (resp. 1/n: 0.871, 0.881, 0.872 and 0.932 L/kg) (4 soils), (purity ^{14}C -maneb 65%). Due to the rapid degradation of maneb, results have to be referred to a mixture of parent compound and degradates.

K_{oc} ETU: 146, 41.9, 57 and 34 L/kg (resp. 1/n: 0.522, 0.469, 0.327 and 0.406 L/kg) (shake flask, 4 soils).

K_{oc} ETU: 2.6 and 5.2 L/kg (column study, 2 soils)

K_d :

K_d EU : 0.1-0.44 L/kg.

K_{oc} EU : 5.4-44.1 L/kg (2shake flask, 2 soils).

pH dependence:

Not for parent and ETU.

Mobility

Laboratory studies:

Column leaching:

9.5-32% of applied RA recovered in leachate of 4 soils (no ETU and CS_2 -generating products in 2 soils with highest % RA in leachate).

Aged residue leaching:

<2% AR recovered at 10cm depth;

1.8% AR (of which 1.5% EU) recovered in leachate of loamy sand treated with 30-d aged residue of maneb.

Study validity questioned, new study required.

Results of the new study (1 humic sand soil) :

Total recovery of AR = 83.6 %

Unextractable radioactivity : 65.2 % of applied

Only the application layer contained more than 10 % of the AR (74.4 %). The leachates contain 4.2 % of AR.

Field studies:

Lysimeter/Field leaching studies:

NL field leaching study (Boland et al, 1995: average ETU concentration under 32 potatoes fields 0.11 mg/l, 90th percentile 0.27 mg/l (LOQ 0.05 mg/l). Relationship between soil type and concentrations measured (higher in sandy/peat versus clay/loam) can be hypothesized. Application rates <1.5 kg as/ha for 63% and from 1.5 to 2 kg as/ha for 22% of all fields, 7 d interval mostly adopted: cumulative applied dose rate/No. of applications higher than the GAPs Sampled depth 0-1 m. 1993 extremely wet year (flooded plots).

3 Swedish potatoes sandy soil sites, sampled for 1 year (1992-93) at 12-16.8 kg a.i/ha/year, supplementary irrigation 175-200 mm, rainfall 511-803 mm, LOQ 0.1 µg/l, 2 pipes for each site at 2.5 and 5 m depth, no data on pH.

ETU < 0.1 µg/l

Remarks:

None.

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:

DT₅₀ (25°C): less than 1 day at pH 3, 5, 7 and 9

Major metabolites:

Hydrolysis products: *EU, ETU, EBIS*.
ETU hydrolytically stable at pH 5, 7 and 9.

Photolytic degradation:

Negligible photolytic degradation of maneb and ETU.

Major metabolites:

Negligible photolytic degradation of maneb and ETU.

Biological degradation

Readily biodegradable:

No

Water/sediment study:

DT₅₀ water:

DT₅₀ (water, 20°C) maneb: 2.4 - 14.4 h
DT₅₀ (water, 20°C) ETU: 4.0 - 11.1 d
DT₅₀ (water, 20°C) EU: <20 d
DT₅₀ (water, 20°C) EBIS: <1 d

DT₉₀ water:

DT₉₀ (water, 20°C) ETU: 13.3 - 36.7d
DT₉₀ (water, 20°C) maneb: 2.0 - .6 d
DT₉₀ (water, 20°C) EU: <29 d
DT₉₀ (water, 20°C) EBIS: <7 d

DT₅₀ whole system:

DT₅₀ (system, 20°C) maneb: 2.4 - 14.4 h
DT₅₀ (system, 20°C) ETU: 7.4 - 7.6 d
DT₅₀ (system, 20°C) EU: <20 d
DT₅₀ (system, 20°C) EBIS: <1 d

DT₉₀ whole system:

DT₉₀ (system, 20°C) maneb: 2.0 - 6.6 d
DT₉₀ (system, 20°C) ETU: 24.6 - 25.3 d
DT₉₀ (system, 20°C) EU: <29d
DT₉₀ (system, 20°C) EBIS: <7 d

Distribution in water / sediment systems
(active substance)

Water/sediment % applied radioactivity (river system): 83.9 (sum of complexed fractions)/0.3 on d 0, n.d./3.8 on d 105.
water/sediment % applied radioactivity (pond system): 84.3 (sum of complexed fractions)/0.2 on d 0, n.d./6.2 on d 105.
Active ingredient concentration – not relevant in sediment.

Distribution in water / sediment systems
(metabolites)

ETU

River system:

Max. in water 31.9% (d 1), <0.1% at d 59.
Max. in sediment 7% (d 7), 0.4% at d 30 Pond system.

Max. in water 47.9% (d 2), 0.1% at d 105.
Max. in sediment 13.7% (d 7), 1.7% at d 59

EU

River system:

Max. in water 20.6% (d 14), 1.7% at d 59.

Max in sediment 5.1% (d 14), 0.4% at d 30, pond system.

Max. in water 23.4% (d 30), 2.5% at d 105.

Max. in sediment 7.3% (d 30), 1 % at d 59.

EBIS

River system

Max in water 45.5% (d 0), 0.2% at d 7.

Max in sediment 2.6% (d 7), 0.5% at d 30, pond system.

Max. in water 41.5% (d 0), 0.2% at d 7.

Max. in sediment 0.7% (d 7), 0.1% at d 30.

Accumulation in water and/or sediment:

Not required.

Degradation in the saturated zone

Not required.

Remarks:

None.

2.3 Fate and behaviour in air

Volatility

Vapour pressure:

1.4 x 10 ⁻⁵ Pa at 20 °C.

Henry's law constant:

2.08 x 10 ⁻⁵ Pa.m ³ .mol ⁻¹
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Photolytic degradation

Direct photolysis in air:

Not applicable.

Photochemical oxidative degradation in air

Not applicable.

DT₅₀:

Volatilisation:

Not provided.

Remarks:

None.

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	LD ₅₀ rat > 5000 mg/kg bw
Acute toxicity to birds:	LD ₅₀ mallard duck >1467 mg/kg bw
Dietary toxicity to birds:	LC ₅₀ mallard duck > 5000 ppm
Reproductive toxicity to birds:	NOEC 100 ppm mallard duck
Short term oral toxicity to mammals:	NOEL (rat 2 generation) 75 ppm NOEL (ecol.) 300ppm (22.4 mg a.s. bw/d)

Aquatic Organisms

Toxicity data for aquatic species (most sensitive species of each group) – Maneb.

Group	Test substance	Time-scale	Endpoint	Toxicity (mg a.s./L)
Laboratory tests				
Rainbow trout	Maneb 80 WP (purity 80%)	96 h (static)	LC ₅₀ (initial measured) (mean measured)	0.23 0.16
Fathead minnow	Maneb (purity 87.3%)	35 d (flow-through)	NOEC (initial measured) (mean measured)	0.0065 0.0061
<i>Daphnia magna</i>	Maneb 80 WP (purity 80%)	48 h (static)	LC ₅₀ (initial measured) (mean measured)	0.31 0.25
<i>Daphnia magna</i>	Maneb (purity 87.3%)	21 d flow-through	NOEC (initial measured) (mean measured)	0.0023 0.0021
<i>Selenastrum capricornutum</i>	Maneb (purity 87.3%)	120h – static grow inhibition	EC ₅₀ (initial measured)# (mean measured)	0.011 0.007
Mesocosm study: a) bridging study (indoor, multispecies, on effects on planctonic community) that supports the comparability of effects between mancozeb and maneb; b) outdoor mesocosm on mancozeb (8 treatments with 7 day intervals, 3 controls, no replicates), effects observed below 125 µg/l considered transient and acceptable effects (recovery occurred), EAC of 32 µg/l (as a. i.) proposed, valid also for maneb.				

initial measured concentrations within 80% of the nominal concentrations.

Toxicity data for aquatic species (most sensitive species of each group) – Metabolites

Group	Test substance	Time-scale	Endpoint	Toxicity (mg a.s./L)
Laboratory tests				
Rainbow trout	ETU	96 h static	LC ₅₀ NOEC	>500* 200
<i>Daphnia. Magna</i>	ETU	48 h static	EC ₅₀ EC ₀	21.6* 6.25
<i>Daphnia. Magna</i>	ETU	21 d flow-through	NOEC	2.0
<i>Pseudokirchneriella subcapitata</i>	ETU	72 h static	EC ₅₀	93.8*
<i>Chlorella pyrenoidosa</i>	ETU	96 h static	NOEC	6600
<i>Xenopus laevis</i>	ETU	28 d semi-static	NOEC	10*
Rainbow trout	EU	96 h static	LC ₅₀ NOEC	>122* 122
<i>Daphnia magna</i>	EU	48 h static	EC ₅₀ NOEC	>985* 589
<i>Pseudokirchneriella subcapitata</i>	EU	96 h static	EC ₅₀ NOEC	>119* 119

*New studies (2001/2002)

Bioaccumulation fish:

Not required (log P 0.14)			
Chronic toxicity invertebrate:	Not required.		
Acute toxicity algae:	Not relevant.		
Chronic toxicity sediment dwelling organism:	Not required.		
Acute toxicity aquatic plants: (for herbicides only)	Not relevant.		

Honeybees

Acute oral toxicity:

LD₅₀: > 89.49 µg/bee.

Acute contact toxicity:

LD₅₀ > 100 µg/bee.**Other arthropod species**

Species	Stage	Test Substance	Dose (kg a.s./ha)	Endpoint	Effect	Annex VI Trigger
Laboratory tests						
<i>Coccinella septempunctata</i> L.	-	Trimangol 80	1.6	mortality	9.4%	30%
<i>Coccinella septempunctata</i> L.	-	Maneb	3.2	total effect (mortality+ reproduction)	39.4 %	30%
<i>Coccinella septempunctata</i> L.	-	Maneb 80 WP	Dose response	LD50:	1813 g a.s./ha	-
<i>Poecilus cupreus</i>	-	Trimangol 80	1.6	mortality	0%	30%
<i>Chrysoperla carnea</i>	-	Maneb	1.6	mortality total effect	40.6%	30%
<i>Chrysoperla carnea</i>	-	Maneb 80 WP	Dose response	LD50:	≥ 3075 g a.s./ha	30 %
Extended laboratory study						
<i>Aphidius rhopalosiphi</i>	-	Maneb 75 WG	Dose response	Mortality fecundity	LR50 > 1500 g a.s./ha	-
<i>Typhlodromus pyri</i>	-	Maneb 80 WP	Dose response	Mortality Reproduction Escape rate	Corrected mortality (dead mites) 120 < LR ₅₀ < 600 g a.s./ha High repellent effect during the test.	-

Extended Lab study with aged residue						
<i>Typhlodromus pyri</i>	-	Maneb 80 WP	0.24 (4 applications)	Mortality Reproduction Escape rate	No effect on mortality and reproduction at the off-crop rate (24 g a.s./ha) 7 d after the last application. High repellent effect with freshly applied residue.	30 %
			2.4 (4 applications)		Effects on mortality and reproduction up to 35 d after the last application at the max recommended rate of 2400 g a.s./ha. High repellent effect up to 42 d.	

Earthworms

Acute toxicity:

LC₅₀ (14 d): 840 ppm, NOEC 200 ppm.

Reproductive toxicity:

NOEC 6 kg a.s./ha, equivalent to 8.0 mg a.s./
kg soil.

Soil micro-organisms

Nitrogen mineralization:

no effects up to 28 d at 2 and 20 kg a.s./ha (study 1).
higher ammonium content in one soil at both rates (3.6 kg a.s./ha and 10x) still at d 90 (>50% than the control), but whole N mineralized differed <20%, normal levels in the other soil (study 2).

Carbon mineralization:

no effects up to 28 d. at 2 and 20 kg a.s./ha (study 1).
slight (<20%) and transient effect at 3.6 kg a.s./ha, slighter at the 10x in one soil (study 2).

APPENDIX IIIA**MANEB**

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

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

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports¹ on previous use in granting national authorizations
IIA 2.1.1.	KOOL P.	1995	Melting point of Maneb Elf Atochem Agri BV Rotterdam-NL GLP Unpublished	
IIA 2.2.	HEUGENS R.	1994	Density of the test substance Maneb Elf Atochem Agri BV Rotterdam-NL GLP Unpublished	
IIA 2.3	DIEPENHORST P.C.	1987	Vapour Pressure of the Test Substance Maneb Elf Atochem Agri BV Rotterdam-NL GLP Unpublished	
IIA 2.4.	DIEPENHORST P.C.	1995	Appearance of Maneb active substance Elf Atochem Agri BV Rotterdam-NL GLP Unpublished	
IIA 2.5.1/01.	KOOL P	1990	Maneb Technical : UV- & IR-spectra Elf Atochem Agri BV Rotterdam-NL Non GLP Unpublished	

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

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports¹ on previous use in granting national authorizations
IIA 2.5.1/02	TAS A.C.	2000	Acquisition of a mass spectrum of Maneb TC TNO Nutrition & Food Research – NL Elf Atochem Agri BV Rotterdam-NL GLP Unpublished	
IIA 2.6./01	DIEPENHORST P.C.	1992	Solubility of Maneb. Elf Atochem Agri BV Rotterdam-NL GLP Unpublished	
IIA 2.11.1 IIA 2.11.2.	BAL E.A.	1995	Physico-chemical properties of Maneb TC (Flammability EEC A 10, and autoflammability EEC A 16). TNO Defence Research, NL, Elf Atochem Agri BV Rotterdam-NL GLP Unpublished	
IIA 2.16.	MERRITT M.	2000	Thermal Stability Test Report for Maneb TC Chilworth Technology – UK Elf Atochem Agri BV Rotterdam-NL GLP Unpublished	
IIA 4.1/03	Diepenhorst, P.C.	1993	Ethylenebis(dithiocarbamates) : Determination of Sulphate Elf Atochem Agri BV Rotterdam-NL Not GLP. Unpublished	
IIA 4.1/04	Diepenhorst, P.C.	1986	Ethylenebis(dithiocarbamates): HPLC determination of DIDT and Sulphur Elf Atochem Agri BV Rotterdam-NL Not GLP. Unpublished	
IIA 4.1/05	Diepenhorst, P.C.	1987	Ethylenebis(dithiocarbamates): Determination of soluble manganese Elf Atochem Agri BV Rotterdam-NL 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 ¹ on previous use in granting national authorizations
IIA 4.1/06	Diepenhorst, P.C.	1990	Ethylenebis(dithiocarbamates): determination of Sulphide Elf Atochem Agri BV Rotterdam-NL Not GLP. Unpublished	
IIA 4.1/07	Diepenhorst, P.C.	1990	Ethylenebisdithiocarbamate: determination of Sodium Elf Atochem Agri BV Rotterdam-NL Not GLP. Unpublished	
IIA 4.1/08	Kool, P.	1991	Ethylenebis(dithiocarbamates): determination by HPTLC of ETD Elf Atochem Agri BV Rotterdam-NL Not GLP. Unpublished	
IIA 4.1/09	Diepenhorst, P.C.	XXX	Ethylenebis (Dithiocarbamates): Determination of Zinc by AAS Elf Atochem Agri BV Rotterdam-NL Not GLP. Unpublished	
IIA 4.1/10	Diepenhorst, P.C.	1986	Hexamine: Spectrometric determination in Ethylene 1,2 bis dithiocarbamates Elf Atochem Agri BV Rotterdam-NL Not GLP. Unpublished	
IIA 4.1/11	Diepenhorst, P.C.	1994	Ethylene bis dithiocarbamates: HPLC determination of lignosulfonates Elf Atochem Agri BV Rotterdam-NL Not GLP. Unpublished	
IIA 4.2.1/01	Westberg, G. L.	1989	Determination of Ethylene bis dithiocarbamates (EBDC's) in meat Morse Laboratories, inc, sacramento, CA 95825 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 ¹ on previous use in granting national authorizations
IIA 4.2.5/03	Rogers, E. et al.	1989	Determination of Ethylene Thiourea in meat. Morse Laboratories, inc, sacramento, CA 95825 Not GLP Unpublished	
IIA 4.2.1/02	Reed, R.L	2000	Validation of the Residue Analytical Method for Ethylenethiourea (ETU) in Meat, Protocol No.: MLI-00-03 Rept. No. 34-00-102 (ER Ref 95.1) Morse Laboratories, Inc. August 21st, 2000 GLP Unpublished	
IIA 4.2.1/01	Clayton, B	2000	ILV of Analytical Method No. ETU-89AM-002, Determination of Ethylene Bis Dithiocarbamates (EBDC's) in Meat, Protocol ID No.: 00-0023 Rept. No. TR34-00-99 (ER Ref. 95.3) EN CAS Laboratories June 10th, 2000 GLP Unpublished	
IIA 4.2.5/02	Westberg, G. L.	1989	Determination of Ethylene Bis Dithiocarbamates (EBDC's) in Milk Morse Laboratories, inc, sacramento, CA 95825 Not GLP Unpublished	
IIA 4.2.5/04	Rogers, E. et al.	1989	Determination of Ethylene Thiourea in milk. Morse Laboratories, inc, sacramento, CA 95825 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 ¹ on previous use in granting national authorizations
IIA 4.2.1/03	Reed, R.L	2000	Validation of the Residue Analytical Method for Ethylenethiourea (ETU) in Milk, Protocol No.: MLI-00-04 Rept. No. TR34-00-101 (RE Ref. 95.2) Morse Laboratories, Inc. September 25th, 2000 GLP Unpublished	
IIA 4.2.1/05	Clayton, B	2001	ILV of Analytical Method No#Meth-128, Original, Determination of Ethylene Thiourea in Milk, Protocol ID No.: 00-0026 Rept. No. TR34-00-104 (ER Ref. 95.8) EN CAS Laboratories February 28th, 2000 GLP, Unpublished	
IIA 4.2.3/01	Diepenhorst, P.C.	1992	Ethylenethiourea (ETU) residue, determination by GC-MS in drinking water / ground water. Elf Atochem Agri BV Rotterdam-NL Not GLP. Unpublished	
IIA 4.2.2.	Russell GOTTSCHALK	2002	Validation of the Method for the Analysis of Ethylenethiourea (ETU) in SOIL by LC/MS/MS, using 2 European soils Source: Enviro-Test Lab ETL Report N° 02CER01 Company : Mancozeb consortium GLP Not Published	

B.6 Toxicology and metabolism

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 5.1/01	Puhl, J.	1985	Metabolism of radiolabeled Maneb in Rats Hazleton Laboratories America, Inc Madison, WI 53707 Cerexagri (Formerly Elf Atochem Agri) report n° 6181-101 Not GLP Unpublished	
IIA 5.1/02	Craine, E.M.	1991	A dermal radiotracer absorption study in Rat with 14C-Maneb WIL Research Laboratories, Inc Ashland, Ohio 44805-9281. Cerexagri (Formerly Elf Atochem Agri) report n°WIL-134010 Not GLP Unpublished	
IIA 5.1/03	Puhl, J.	1985	Dermal absorption of radiolabelled Maneb in Male Rats Hazleton Laboratories America, Inc. 3301 Kinsman Boulevard Madison, Wisconsin 53704 Cerexagri (Formerly Elf Atochem Agri) report n°NA Not GLP Unpublished	
IIA 5.2.1/01	Naas, D.J..	1989	Acute oral toxicity (LD50) study in albinos rats with Maneb technical WIL Research Laboratories, Inc Ashland OH 44805-9281 USA Cerexagri (Formerly Elf Atochem Agri) report n° WIL-134003 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 5.2.2/01	Naas, D.J..	1989	Acute dermal toxicity (LD50) study in albinos rats with Maneb technical WIL Research Laboratories, Inc Ashland OH 44805-9281 USA Cerexagri (Formerly Elf Atochem Agri) report n° WIL-134004 Not GLP Unpublished	
IIA 5.2.3/01	Terrill, J.B.	1990	Acute Inhalation Toxicity Study with Maneb in the Rat. Hazleton Laboratories America, Inc Cerexagri (Formerly Elf Atochem Agri) report n° HLA 2567-100 Not GLP Unpublished	
IIA 5.2.5/01	Naas, D.J..	1989	Primary eye irritation study in albino rabbits with Maneb technical WIL Research Laboratories, Inc Ashland OH 44805-9281 USA Cerexagri (Formerly Elf Atochem Agri) report n° WIL-134006 Not GLP Unpublished	
IIA 5.2.5/02	Naas, D.J..	1989	Primary dermal irritation study in albino rabbits with Maneb technical WIL Research Laboratories, Inc Ashland OH 44805-9281 USA Cerexagri (Formerly Elf Atochem Agri) report n° WIL-134005 Not GLP Unpublished	
IIA 5.2.6/01	Naas, D.J..	1989	Skin sensitization study in Albino guinea pigs with Maneb technical WIL Research Laboratories Inc. Ashland, Ohio 44805-9281 Cerexagri (Formerly Elf Atochem Agri) report n° HLA 2567-134007 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 5.3.1/01	Trutter, J.A.	1989	28-day dose range finding study with Maneb technical in the rat Hazleton Laboratories America, Inc. Cerexagri (Formerly Elf Atochem Agri) report n° 153-157 Not GLP Unpublished	
IIA 5.3.2/01	Trutter, J.A.	1988	Subchronic toxicity study with Maneb technical in the rat. Hazleton Laboratories America, Inc. Cerexagri (Formerly Elf Atochem Agri) report n° 153-140 Not GLP Unpublished	
IIA 5.3.2/02	Allen, T.R. et al.	1989	13-week oral toxicity (feeding) study with Maneb technical in the dog. RCC Ltd Ch - 4452 ITINGEN Cerexagri (Formerly Elf Atochem Agri) report n°206605 Not GLP Unpublished	
IIA 5.3.3/01	Terrill, J.B.	1991	A 4-week inhalation study in rat to determine the lung tissue residues and effect upon thyroid function with Maneb. Hazleton Laboratories America, Inc 1330-B Piccard Drive Rockville, Maryland 20850-4373 Cerexagri (Formerly Elf Atochem Agri) report n° HLA 2567-101 Not GLP Unpublished	
IIA 5.3.3/02	Cutler, R.N.	1986	13-week subchronic inhalation toxicity study on Maneb in rats International Research and Development Corporation Mattawan Michigan USA 49071 (Addendum) Task Force n° 550-001 (Final report) 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 5.3.3/03	Ulrich, C.E.	1987	13-week subchronic inhalation toxicity study on Maneb in rats International Research and Development Corporation Mattawan Michigan USA 49071 (Addendum) Task Force n° IRDC 550-001 Not GLP Unpublished	
IIA 5.3.3./04	Trutter, J.A.	1988	21-day dermal toxicity study in rabbits with Maneb technical Hazleton Laboratories America Inc. 9200 Leesburg Turpike Vienna, Virginia 22180- USA Cerexagri (formerly Elf Atochem Agri) report n° 153-139 Not GLP Unpublished	
IIA 5.4.1/01	Loveday, K.S. and Thomas, M.	1985	Salmonella/microsome mutagenesis assay on technical grade Maneb American Biogenics Corporation 225 Wildwood avenue Woburn, MA 01801 Cerexagri (formerly Elf Atochem Agri) report n° 840014-40 Not GLP Unpublished	
IIA 5.4.1/02	Loveday, K.S. and Thomas, M.	1986	CHO/HGPRT in vitro mammalian cell mutation Assay on technical grade Maneb American Biogenics Corporation 225 Wildwood avenue Woburn, MA 01801 Cerexagri (formerly Elf Atochem Agri) report n°840014-10 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 5.4.1/03	Loveday, K.S. and Thomas, M.	1986	In vitro unscheduled DNA synthesis assay in Rat hepatocytes: the effect of technical grade Maneb American Biogenics Corporation 225 Wildwood avenue Woburn, MA 01801 Cerexagri (formerly Elf Atochem Agri) report n°850047-20 Not GLP Unpublished	
IIA 5.4.1/04	Coleman, D.	2002	In vitro mammalian chromosomeaberration test in human lymphocytes HLS, Woolley Road, Alconbury, Huntingdon, Cambridge, PE28 4HS, England Cerexagri report N° EFA 039/014312 GLP Unpublished	
IIA 5.4.1./05	L. ALLAIS	2002	MANEB TECHNICAL : In Vitro Mammalian Chromosome Aberration Test in Human Lymphocytes Huntingdon Life Sciences – UK ; Cerexagri (formerly Elf Atochem Agri) Report N° EFA 039/014312, GLP Not published	
IIA 5.4.2/01	Ivett, J.L.	1985	Clastogenic evaluation of Maneb technical, lot MT 01 in the rat bone marrow cytogenic assay Litton Bionetics, Inc 5516 Nicholson lane Kensington, MARYland 20895 Cerexagri (formerly Elf Atochem Agri) report n° 7892 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 5.5/02	Tompkins, E.C.	1992	18-month dietary oncogenicity study in Mice with Maneb technical WIL Research Laboratories Inc. Ashland, OH 44805-9281 USA Cerexagri (formerly Elf Atochem Agri) report n° 134008 Not GLP Unpublished	
IIA 5.5/03	Corney, S.J. et al.	1992	52-week oral toxicity (feeding) study with Maneb technical in the dog Research & Consulting Company Ltd CH - 4452 ITIGEN Cerexagri (formerly Elf Atochem Agri) report n° 206616 Not GLP Unpublished	
IIA 5.6.1/01	Ryle, P.R. et al.	1991	A study of the effect of Maneb (technical) on reproductive function of 2 generations in the rat HRC, England Cerexagri (formerly Elf Atochem Agri) report n° 1/9072 MNB/1 Not GLP Unpublished	
IIA 5.6.2/01	Kapp, R.W.	1991	Prenatal toxicity study of Maneb in Rats BASF Gewerbehygiene und Toxicologie Ludwigshaven, Germany Cerexagri (formerly Elf Atochem Agri) report n° 88/522-88/523-88/524 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 5.6.2/02	Nemec, M.D.	1992	A developmental Toxicity Study of Maneb Technical in Rats WIL Research Laboratories, Inc 1407 Mantomery Twp. Rd 805 Ashland, OH 44805-9281 Cerexagri (formerly Elf Atochem Agri) report n° WIL-134011 Not GLP Unpublished	
IIA 5.8.1/01	Briffaux, J.P.	1991	ETU 13 week oral (dietary) toxicity study in the Beagle Dog HAZLETON FRANCE (HF) Les Oncins - BP 0118 69593 L'ARBRESLE CEDEX France Cerexagri (formerly Elf Atochem Agri) report n° NA Not GLP Unpublished	
IIA 5.8.1/02	Schmid, H. et al.	1992	104 week chronic toxicity (feeding) study with ETHYLENE THIOUREA (ETU) in the Rat. RCC, Research and Consulting Company Ltd and RCC Umweltchemie AG P.O. Box, CH 4452 ITINGEN / SWITZERLAND Cerexagri (formerly Elf Atochem Agri) report n° 256803 Not GLP Unpublished	
IIA 5.8.1/03	Briffaux, J.P.	1992	ETU 52 week oral (dietary) toxicity study in the Beagle Dog. HAZLETON FRANCE (HF) Les Oncins - BP 0118 69593 L'ARBRESLE CEDEX France Cerexagri (formerly Elf Atochem Agri) report n° 616-505 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 5.8.1/04	Dotti, A. et al.	1992	Two-generation reproduction study with ETHYLENE THIOUREA (ETU) in the Rat. RCC, Research and Consulting Company AG P.O. Box, CH 4452 ITINGEN SWITZERLAND Cerexagri (formerly Elf Atochem Agri) report n°252360 Not GLP Unpublished	
IIA 5.8.1/05	Leuschner, J.	2001	Acute skin irritation test (patch test) of ETU (ethylene thiourea) in rabbits, according to EC guideline B.4 and OECD guideline 405 LPT Laboratory of Pharmacology Cerexagri (formerly Elf Atochem Agri) report n° GP01-004 GLP Unpublished	
IIA 5.8.1/06	Leuschner, J.	2001	Acute eye irritation study of ETU (ethylene thiourea) by instillation into the conjunctival sac of rabbits, according to EC guideline B.5 and OECD guideline 405 LPT Laboratory of Pharmacology Cerexagri (formerly Elf Atochem Agri) report n° GP01-005 GLP Unpublished	
IIA 5.8.1/07	Leuschner, J.	2001	Acute toxicity study of ETU (ethylene thiourea) in Sprague-Dawley rats by dermal administration, according to EC guideline B.3 and OECD guideline 402 LPT Laboratory of Pharmacology Cerexagri (formerly Elf Atochem Agri) report n° GP01-003 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 5.9	W. Vogel	1990	Dermal and inhalation exposure to workers involved in the manufacturing of EBDC fungicides Source: RCC Company: Cerexagri Report N°238860 GLP Not published	
IIIA 7.3	Kemp, L.	2002	14C – Maneb : In Vivo Dermal Absorption study in the male rat Huntingdon Life Sciences, Woolley Road, Alconbury, Huntingdon, Cambridge, PE28 4HS, England Cerexagri, Report n° EFA 040/022611 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 6.1/01	Malik, N. & Wright, J.	1992	Maneb: Nature of the residue in potatoes. Hazleton Laboratories America, Inc 3301 Kinsman Boulevard Madison, Wisconsin 53704 and Xenobiotic Laboratories Inc PO Box 3205 Princeton, NJ 08543-3205 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 6.1/02	Wright, M. & Ussary, J.P.	1993	Maneb: Nature of the residue in potatoes. Hazleton Laboratories America, Inc 3301 Kinsman Boulevard Madison, Wisconsin 53704 and Xenobiotic Laboratories Inc PO Box 3205 Princeton, NJ 08543-3205. GLP Unpublished	
IIA 6.1/03	Ballantine, L.G.	1992	Maneb: nature of the residue in Lettuce. Hazleton Laboratories America, Inc 3301 Kinsman Boulevard Madison, Wisconsin 53704 GLP Unpublished	
IIA 6.2/01	Merricks, D.L.	1989	Metabolism feeding study in goat using 14C-Maneb Agriseach Incorporated 26 Water Street Frederick, MD 21701 GLP Unpublished	
IIA 6.2/02	Christman, P.J.	1990	Determination of Maneb and Ethylenethiourea in Milk and Tissues of goat dosed with 14C-Maneb. Hazleton Laboratories America Inc. 3301 Kinsman Boulevard Madison, Wisconsin 53704 GLP Unpublished	
IIA 6.2/03	Wu, J.	1990	Metabolism of 14-Maneb in lactating goats - Analysis and quantitation of metabolites and/or the corresponding natural product in milk and tissues. Xenobiotic Laboratories Inc. P.O. Box 3205 Princeton, NJ 08543-3205 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 6.2/04	Merricks, D.L.	1989	Metabolism feeding study in laying hens using 14C-Maneb Agriseach Incorporated 26 Water Street Frederick, MD 21701 GLP Unpublished	
IIA 6.2/05	Christman, P.J.	1989	Determination of Ethylenethiourea in Eggs and Tissues of Hens dosed with 14C-Maneb. Hazleton Laboratorie America Inc. 3301 Kinsman Boulevard Madison, Wisconsin 53704 GLP Unpublished	
IIA 6.2/06	Wu, J.	1990	Metabolism of 14C-Maneb in laying hens - Analysis and quantitation of metabolites and/or the corresponding natural products in eggs and tissues Xenobiotic Laboratories, Inc. PO Box 3205 Princeton, NJ 08543-3205 GLP Unpublished	
IIA 6.3/01	W.M. WAALKENS & L. CASTRO	2002	Determination of the Magnitude of the residues of Maneb, Mancozeb & Ethylene-Thio-Urea (ETU) in / on Potatoes after applications of Trimangol 75 DG and Penncozeb 75 DG to ware potatoes in The Netherlands & Germany, 1999. Source : De Bredelaar BV Company : Cerexagri Report N R99-22-NG-01 GLP, Not Published	
IIA 6.3/02	.Y. Communal	1997	Determination of Mancozeb, Maneb & Ethylenethiourea Residues in Potato samples. Source : ADME Company : Cerexagri Report N 96081 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
IIA 6.3/03	P.Y. Communal	1997	Residues analyses of Mancozeb, Maneb & Ethylenethiourea (ETU) residues in Potato samples. Source : ADME Company : Cerexagri Report N 95065 GLP, Not Published	
IIA 6.3/04	P.Y. Communal	1997	Residue Analyses of Mancozeb, Maneb & Ethylenethiourea Residues in Potato samples Source : ADME Company : Cerexagri Report N 95071 GLP, Not Published	
IIA 6.3/05	I. Geuijen	1996	Magnitude of residues of CS2 and ETU on Potato after applications of Trimangol DG, Penncozeb DG and Pennfluid, the Netherlands, 1995 Source : Company : Cerexagri Report N 139837 GLP, Not Published	
IIA 6.3/06	HOUBIERS	1995	Residues of Maneb & ETU in Horse Beans, Sugar Beets & Cutting Celery after treatment with Trimangol Granulat. Source : REDENED B.V. Company : Cerexagri Report N° G12-94 to G17-94 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
IIA 6.3/07	Jay, P. & Derly, G.	2001	Residues determination of maneb in sugar beets following 4 applications of Trimangol DG. Study carried out in United Kingdom, Germany, France, Italy and Spain in year 2000. BIOTEK Agriculture-BKA/676/00/RES- France, Eurotrial Group Study. Cerexagri report n° EU-GLP/218 GB- F-I-E/00/SB GLP Unpublished	
IIA 6.3/08	Jay, P. & Derly, G.	2002	Residues determination of maneb in sugar beets following applications of Trimangol DG. Study carried out in France, Italy and Spain in year 2001. BIOTEK Agriculture-BKA/608/01/RES- France, Eurotrial Group Study. Cerexagri report n° EU-GLP/23 1-F-I-E/01/SB GLP Unpublished	
IIA 6.3/09	P.Y. Communal	1997	Residue Analyses of Mancozeb, Maneb & Ethylenethiourea in Wheat (grain and straw) samples. Source : ADME Company :Cerexagri Report N 95062 GLP, Not Published	
IIA 6.3/10	P.Y. Communal	1997	Determination of Mancozeb, Maneb & Ethylenethiourea Residues in Wheat (grain and straw) samples. Source : ADME Company :Cerexagri Report N 96071 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
IIA 6.3/11	T.H. Byast	1996	Determination of Residues in samples of Oilseed Rape, Winter Barley & Winter Oats, Grain & Straw treated with Penncozeb 75 DG & Trimangol 75 DG. Source OAT Company : Cerexagri Report N° OA00138/R52706 GLP, Not Published	
IIA 6.4/01	Predmore	1986	Field aged Mancozeb on $\alpha\alpha$ Hay feeding studies, in lactating dairy cows. ABC Biochemical Laboratory. PO box 1097 Columbia. Missouri 65205 GLP Unpublished	
IIA 6.4/02	Predmore	1986	Residues of Mancozeb and ETU in Eggs and Edible tissues from hens fed field aged Mancozeb residues. ABC PO Box 1097 Columbia Missouri 65205 GLP Unpublished	
IIA 6.5/01	Pitt, J.L	1989	Maneb and its metabolite Ethylene Thiourea; Magnitude of the Residue in Processed Apple Fractions Field : Alton, NY USA Processing : ACDS 1649 Lester Road Phelps, NY 14532 USA Analysis: Morse Laboratories, inc. 1525 Fulton Avenue Sacramento, CA 95825 USA 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 6.5/02	Bookbinder, M.G.	1988	<p>Maneb and ETU: Residues in Commodities Processed from snap beans treated by ground equipment in New York, 1987.</p> <p>Field : ACDS 1649 Lester Road Phelps, NY 14532 - USA Analysis : Morse Laboratories, Inc. 1525 Fulton Avenue Sacramento, CA 95825 – USA National Food Laboratory Suite 400 1401 New York Ave. Washington, D.C. – USA</p> <p>GLP Unpublished</p>	
IIA 6.5/03	Bookbinder, M.G.	1988	<p>Maneb and ETU: Residues in Commodities Processed from grapes treated by ground equipment in California, 1987.</p> <p>Field: Chular Canyon ranch supply P.O. Box 906 Chular, CA 93926 -USA Analysis: Morse Laboratories, Inc. 1525 Fulton Avenue Sacramento, CA 95825 – USA</p> <p>GLP Unpublished</p>	
IIA 6.5/04	Bookbinder, M.G.	1988	<p>Maneb and ETU: Residues in Commodities Processed from Sugar beet roots treated by ground equipment in California,</p> <p>Analysis : Morse Laboratories, Field : Research for hire 1696 S Leggett Street Porterville, CA 93257 – USA Inc. 1525 Fulton Avenue Sacramento, CA 95825 - USA McKenzie Laboratories 734 A East Spouthern Pacific Dr. Phoenix, AZ 85034 –USA American crystal Sugar Co. 1700 North 11th St. Moorhead, MN 56560 – USA</p> <p>GLP Unpublished</p>	

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 6.5/05	Bookbinder, M.G.	1988	Maneb and ETU: Residues in Commodities Processed from Tomatoes treated by ground equipment in California, 1987. Field: Research for hire 1696 S Leggett Street Porterville, CA 93257 - USA Analysis: Morse Laboratories, inc. 1525 Fulton Avenue Sacramento, CA 95825 – USA GLP Unpublished	
IIA 6.6/01	Merrick, L.	1993	14C-Maneb confined rotational crop study Agriseach Inc. 26 Water street Frederick, MD 21701 – USA GLP 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 7.1	Dressel, J	2001	Compilation of aerobic soil half lives and soil adsorption of ETU, EU, EBIS, Carbimide and EDA (metabolites of EBDC Fungicides) December 7th, 2001, Not GLP Unpublished	
IIA 7.1.1/01	Herrchen, M.	1987	Aerobic biodegradation in soil of the EBDC-fungicide Maneb Fraunhofer-Institut für Umweltchemie und Ökotoxikologie-5948 Schmalleberg Grafschaft 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 7.1.1/02	Herrchen, M.	1987	Anaerobic biodegradation in soil of the EBDC-fungicide Maneb Fraunhofer-Institut für Umweltchemie und Ökotoxikologie-5948 Schmallenberg Grafschaft Not GLP Unpublished	
IIA 7.1.1/03	Todt, K. & Conradt, H.	1991	Degradation of Maneb in soil I. NATEC Institut, HAMBURG Not GLP Unpublished	
IIA 7.1.1/04	Herrchen, M.	1987	Soil photolysis study of Maneb Fraunhofer-Institut für Umweltchemie und Ökotoxikologie-5948 Schmallenberg Grafschaft. Not GLP Unpublished	
IIA 7.1.1./06	Dressel, J	2001	Compilation of aerobic soil half lives and soil adsorption of ETU, EU, EBIS, Carbimide and EDA (metabolites of EBDC Fungicides) December 17th, 2001 Not GLP, Unpublished	
IIA 7.1.1	M.C. WRIGHT	2000	Aerobic Soil Metabolism Degradation Rate Determination for ETU on Soil. Report of Degradation Rate Determination for ETU on New York Silt Loam Soil at 70% and 40% Normal Moisture Holding Capacity and 25°C. Source XenoBiotec Lab Company: Mancozeb Consortium Report RPTOO598 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
IIA 7.1.1	H.Q.M. de Vette	1999	Determination of the rate of degradation of N,N'-ethylene urea (EU ; metabolite of mancozeb) in 3 soils (CTB guideline section G.1.1.3, BBA Guideline IV, 4-1, and OECD Draft Guideline) Source: TNO Company: Cerexagri Report V99.137 GLP Not Published	
IIA 7.1.2.	Paul CONNOLLY	2002	Ethylene Urea : (E U) Adsorption / Desorption of Ethylene Urea on European Soils Source: Exygen Research Company: Mancozeb consortium Report 009-013 GLP Not Published	
IIA 7.1.3/01	Warren, J. & Connor, S.	1986	Leaching characteristics of parent 14C-Maneb ABC Laboratories Inc. 7200 East ABC Lane Columbia Missouri 65205 Not GLP Unpublished	
IIA 7.1.3/02	Herrchen, M.	1987	Soil leaching studies after 30 days of aging of the EBDC fungicide Maneb Fraunhofer-Institut für Umweltchemie und Ökotoxikologie D-5948 Schmallenberg Grafschaft 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 7.1.3/04	Boland, J. & al.	1995	Monitoring of ETU in the uppermost groundwater below flowerbulb and potato fields in the Netherlands in 1993. RIVM, Laboratory for Soil and Groundwater Research (LBG) and RIVM Laboratory for Organic-Analytical Chemistry (LOC)A. v. Leeuwenhoeklaan 93721 MA Bilthoven The Netherlands. GLP Unpublished	
IIA 7.2	Kuenemann, P	2001	Risk of ETU ground water contamination further to application of EBDC fungicides Relevance of Dutch study to EU conditions December 17th, 2001, Not GLP Unpublished	
IIA 2.9.1. IIA 7.2.1/02	Rüdel, H.	1990	Hydrolysis of Maneb at pH 5, 7, and 9 Fraunhofer Institut für Umweltchemie und Ökotoxikologie D - 5948 Schmallenberg Germany Not GLP Unpublished	
IIA 7.2.1/03	Rüdel, H.	1990	Water photolysis of Maneb at pH 7 Fraunhofer Institut für Umweltchemie und Ökotoxikologie D - 5948 Schmallenberg Germany Not GLP Unpublished	
IIA 7.2.1/04	Herrchen, M.	1987	Hydrolysis of the EBDC fungicide Maneb Fraunhofer Institut für Umweltchemie und Ökotoxikologie D - 5948 Schmallenberg Germany 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 7.2.1/05	Herrchen, M.	1987	Water photolysis of the EBDC fungicide Maneb Fraunhofer Institut für Umweltchemie und Ökotoxikologie D - 5948 Schmallenberg Germany Not GLP Unpublished	
IIA 7.2.2	Völkel W.	1995	[14C]-Mancozeb : Degradation and metabolism in Aquatic Systems Source RCC Company Cerexagri Report N° 361462 GLP Not Published	
IIA 7.2.2/01	Müller-Kallert H.M.	1995	[14C]-Maneb : Degradation and metabolism in aquatic systems RCC Umweltchemie AG PO BOX CH-4452 Itingen/BL Switzerland Not 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 8.1.2/01	Fletcher, D.W.	1988	Maneb Technical : 8-day acute dietary LC50 in Mallard ducklings. Bio-Life Associates Ltd. Route 3, Box 156 Neillsville Wisconsin 54456 – USA 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 8.1.2/02	Fletcher, D.W.	1988	Maneb Technical : 21-day acute oral LD50 study in Bobwhite quail16 Bio-life Associates Ltd Route 3, Box 156 Neillsville Wisconsin 54456 – USA Not GLP Unpublished	
IIA 8.1.3/01	Fletcher, D.W. & Pederson, C.A.	1989	Maneb technical : Toxicity and Reproduction study in the Mallard Duck Bio-Life Associates Ltd. Route 3 Box 156 Neillsville Wisconsin 54456 – USA Not GLP Unpublished	
IIA 8.1.3/02	Fletcher, D.W. & Pederson, C.A.	1989	Maneb technical : Toxicity and Reproduction study in the Bobwhite Quail Bio-Life Associates Ltd. Route 3 Box 156 Neillsville Wisconsin 54456 – USA Not GLP Unpublished	
IIA 8.2.1	Zok, S.	2001	Ethylene ThioUrea : Acute toxicity study on the rainbow trout (Oncorhynchus mykiss Walbaum 1792) in a static system (96 hours), Project Number 12F0533/005042. Non GLP, Unpublished	
IIA 8.2.1	S.J. Palmer, T.Z. Kendall and H.OI Krueger	2001	Ethylene Urea: A 96-Hour Static Acute Toxicity Test with the Rainbow Trout (Oncorhynchus mykiss) Project Number 299A-116, January 29, 2001. GLP, Unpublished	
IIA 8.2.3/01	McAllister, W.A.	1989	Early life-stage toxicity of Maneb to Fathead Minnow (Pimephales promelas) under flow-through conditions ABC Laboratories Inc. Environmental Toxicology 7200 E. ABC Lane PO Box 1097 Columbia, Missouri 65205 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 8.2.5/01	Adema, D.M.M.	1982	The acute toxicity of "Trimangol technisch" to Daphnia magna T.N.O. P.O. Box 217 NL - 2600 AE Delft The Netherlands TNO CL/82/103, 28 July 1982 Not GLP Unpublished	
IIA 8.2.5/02	Hisgen	2000	Ethylene ThioUrea : Determination of the acute effect on the swimming ability of the water flea Daphnia magna STRAUS, Report Number 00/0533/50/1, October 27, 2000. GLP, Unpublished	
IIA 8.2.5/03	S.J. Palmer, T.Z. Kendall and Ho.Ol Krueger	2001	Ethylene Urea: A 48-Hour Static Acute Toxicity Test with the Cladoceran, Project Number 299A-14, January 26, 2001. GLP, Unpublished	
IIA 8.2.6/01	Burgess, D. et al.	1989	Chronic toxicity of Maneb to Daphnia magna under flow-through test condition Analytical Bio-Chemistry Laboratories, Inc. Aquatic Toxicology Division 7200 East ABC Lane PO Box 1097 Columbia, Missouri 65205 Not GLP Unpublished	
IIA 8.2.7/01	Forbis, A.D. et al.	1988	Acute toxicity of Maneb to Selenastrum capricornutum Printz Analytical Bio-chemistry Laboratories, Inc. Aquatic Toxicology Division 7200 East ABC Lane P.O. Box 1097 Columbia, Missouri 65205 USA Not GLP Unpublished	
IIA 8.2.7/02	Reuschenbach	2000	Ethylene ThioUrea : Determination of the inhibitory effect on the cell multiplication of unicellular green algae; Report Number 00/0533/60/1 November 14, 2000. GLP, Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company), Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 8.2.7/03	S.J. Palmer, T.Z. Kendall and H.O. Krueger	2001	Ethylene Urea: A 96-Hour Toxicity Test with the Freshwater Alga (<i>Selenastrum capricornutum</i>); Project Number 299A- 115, January 29, 2001. GLP, Unpublished	
IIIA 10.2.2./01 IIA 8.2.6/02 IIA 8.2.7/02	U. Memmert	1999	Ecological Effects of Penncozeb 80 WP in a Freshwater Mesocosm study Source: RCC Company: Cerexagri Report N°681030 GLP Not Published	
IIA 8.2	Zok,S	2002	Ethylene ThioUrea : <i>Xenopus laevis</i> Metamorphosis Assay Project No: 99F0533/005076 January 8th, 2002 GLP Unpublished	
IIA 8.3.1/02 IIIA 10.5.1/01	Kühner, C.	1991	Assessment of the side-effects of Trimangol 80 on the Lady bird, <i>Coccinella septempunctata</i> L. (Laboratory test) Institut für Umweltanalytik und Biotechnologie Eutingen Strasse 24 D - 7532 Niefern Report n°089/02-Cs, 21 p.,8 April 1991 Not GLP Unpublished	
IIA 8.3.1/03 IIIA 10.5.1/02	Römbke, J.	1990	A study of the acute toxicity for <i>Poecilus cupreus</i> (carabidae) – Trimangol Battelle Europe BAttelle-Institut e.V.Am Römerhof 35 D-6000 Frankfurt am Main Germany Report n°BE-E-94-89-01-CAK 2, March 21, 1990 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 8.3.2/01 IIIA 10.6.1.1	Kühner, C.	1991	Acute toxicity of Trimangol 80 to earthworms, Eisenia foetida using an artificial soil test. Institut für Umweltanalytik und Biotechnologie Eutingen Strasse 24 D - 7532 Niefern-Öschelbronn Report n°089/01-EF, 19 p., 8 April 1991 Not GLP Unpublished	
IIA 8.3.2.	F. STAAB	2001	Effect of metabolite ETU on the mortality of the Earthworm Eisenia foetida. Source BASF Company Mancozeb Consortium Report N°96317 GLP Not Published	
IIA 8.3.2.	F. STAAB	2001	Effect of BF 222-EU on the mortality of the Earthworm Eisenia foetida. Source BASF Company Mancozeb Consortium Report N°99457 GLP Not Published	
IIA 8.3.3/01 IIIA 10.7	Danneberg, G.	1990	Investigation of the effects of Trimangol on the activity of the soil microflora Battele Project N° V-67 545, EPA 164-4, March 90 Not GLP Unpublished	
IIA 8.3.3	W. KRIEG	2001	Effect of BF 222-ETU on Nitrogen Transformation of the Soil Microflora Source BASF Company Mancozeb consortium Report N°97481 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
IIA 8.3.3	W. KRIEG	2001	Effect of BF 222-ETU on Carbon Transformation of the Soil Microflora Source BASF Company Mancozeb consortium Report N°97479 GLP Not Published	
IIA 8.3.3	W. KRIEG	2001	Effect of BF 222-EU on Nitrogen Transformation of the Soil Microflora Source BASF Company Mancozeb consortium Report N° GLP Not Published	
IIA 8.3.3	W. KRIEG	2001	Effect of BF 222-EU on Carbon Transformation of the Soil Microflora Source BASF Company Mancozeb consortium Report N°99453 GLP Not Published	
IIA 8.3.3	Krieg,W	2001	Effect of BF 222-ETU on Carbon Transformation of Soil Microflora. Study Code 97479 (ER Ref 97.9) February 9, 2001 GLP, Unpublished	
IIA 8.3.3	Krieg,W	2001	Effect of BF 222-ETU on Carbon Transformation of Soil Microflora. Study Code 99453 (ER Ref 97.10) February 9, 2001 GLP, Unpublished	
IIA 8.3.3	Krieg,W	2001	Effect of BF 222-ETU on Nitrogen Transformation of Soil Microflora. Study Code 97481 (ER Ref 97.8) January 12, 2001 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 8.3.3	Krieg,W	2001	Effect of BF 222-ETU on Nitrogen Transformation of Soil Microflora. Study Code 97455 (ER Ref 97.11) January 12, 2001 GLP, Unpublished	
IIA 8.3.2	Staab, F	2001	Effect of metabolite ETU on the mortality of the earthworm Eisenia foetida. Study Code 96317 (ER Ref 97.2) January 17, 2001 GLP, Unpublished	
IIA 8.3.2	Staab, F	2001	Effect of metabolite BF 222-ETU on the mortality of the earthworm Eisenia foetida. Study Code 99457 (ER Ref 97.3) January 17, 2001 GLP, Unpublished	

APPENDIX IIIB

MANEB

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

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

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 2.11.2	Bremble P.	2000	Test report for Maneb TC Chilworth Technology Report N° 25300 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
IIA 2.14/1	van Beijnen A.J.M.	2002	MANEB TK, Surface tension (of aqueous solution) (860 g/kg) CEREXAGRI Report N°DL02-022 GLP, Unpublished
IIIA 2.1, 2.4.2, 2.6.2, 2.7.1.1, 2.7.1.3, 2.8.1, 2.8.2, 2.8.3.1, 2.8.5.2, 2.8.6.1	Diepenhorst, P.C	2003	Maneb 80 WP, physical, chemical and technical properties acc to Dir 94/37/EC Annex II. Cerexagri report n° DL 02-087 GLP, Unpublished
IIA 4.2.1/4	Crofts, D., Clayton, B.	2000	ILV of Analytical Method No. ETU-89AM-002, Determination of Ethylene Bis Dithiocarbamates (EBDC's) in Meat Source: EN CAS Laboratories Company: Mancozeb Consortium Report No.: TR 34-10-99 GLP, Unpublished
IIA 4.2.1/6	Reed, R.L.	2000	Validation of Residue Analytical Method for Ethylenethiourea (ETU) in Meat, Protocol No. MLI-00-03, Source: Morse Laboratories, Inc. Company: EBDC Task Force Report No.: TR-34-00-01 GLP, Unpublished
IIA 4.2.1/7	Clayton, B.	2001	Independent Laboratory Validation (ILV) Analytical Method # Meth-127, Original, "Determination of ETU in Meat " Source: EN-CAS Analytical Lab Study N° # 00-0024 Company: EBDC Task Force Report No.: TR-34-00-101 GLP, Unpublished
IIA 4.2.1/9	Crofts, D., Clayton, B.	2000	ILV of Analytical Method No. ETU-89AM-003, Determination of Ethylene Bis Dithiocarbamates (EBDC's) in Milk Protocol No. 00-0025 Source: EN CAS Laboratories Company: EBDC Task Force Report No.: TR 34-00-100 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
IIA 4.2.1/11	Reed, R.L., Westberg, G.	2000	Validation of the Residue Analytical Method for Ethylenethiourea (ETU) in Milk, Protocol No. MLI 00-04, Source: Morse Laboratories, Inc. Company: EBDC Task Force Report No.: TR-34-00-001 GLP, Unpublished
IIA 4.2.1/12	Clayton, B.	2000	ILV of Analytical Method No. Meth-128, Original, Determination of Ethylenethiourea in Milk Source: EN CAS Laboratories Company: EBDC Task Force Report No.: TR-34-00-104 GLP, Unpublished
IIA 4.2.2/1	Gottschalk R	2003	Validation of the Analytical Method MS 270 for the Analysis of Maneb in Soil. Enviro-Test Lab (ETL) Report N°- ETL02CER02 Cerexagri GLP, Unpublished
IIA 4.2.2/2	Gottschalk R.	2002	Validation of the Method for the Analysis of Ethylenethiourea (ETU) in SOIL by LC/MS/MS, using 2 European soils Source: Enviro-Test Lab ETL Report N° 02CER01 Company : Mancozeb consortium GLP Not Published
IIA 4.2.3/2	Gottschalk R	2003	Validation for the analysis of Maneb in Water Enviro-Test Lab (ETL) Cerexagri Report N° 03CER03.REP GLP, Unpublished
IIA 4.2.3/4	James J. W.	2000	Independent Laboratory Validation of Analytical Method "DETERMINATION OF ETHYLENE THIOUREA IN WATER, Meth-119, Revision #2" EN-CAS Analytical Labs Report N°00-0006 GLP, Unpublished
IIA 4.2.4/1	Krainz A.	2003	Development and Validation of a Residue Analytical Method for Maneb in Air RCC Report N°848100 Cerexagri GLP, Unpublished
IIA 5.4.1/07	Allais L.	2002	In vitro mammalian chromosome aberration test in human lymphocytes HLS, Woolley Road, Alconbury, Huntingdon, Cambridge, PE28 4HS, England Cerexagri report N° EFA 039/014312 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
IIA	Redondi, S.	2002	Maneb Mutagenicity Response to ECCO 118 Annex 4, Comment V, of Annex 4 Position Paper Non GLP, Unpublished
IIA 5.7/1	Mark D. Nemec	1995	A Subchronic (13-week) neurotoxicity study in Maneb Technical in rats WIL Research Labs Cerexagri Report N°WIL-134016 GLP, Unpublished
IIA 5.8 1/1	Leuschner. J	2001	Acute Toxicity study of ETU (Ethylene Thiourea) in Sprague-Dawley Rats by Dermal Administration LPT Lab – Hamburg Report N°13986 / 01 GLP, Unpublished
IIA 5.8 1/2	Leuschner. J	2002	Acute inhalation toxicity study of milled Ethylene Thiourea (ETU) in Sprague-Dawley rats LPT Laboratory of Pharmacology and Toxicology KG Report N°15283/02 GLP, Unpublished
IIA 5.8 1/3	Leuschner. J	2001	Acute Skin irritation test (Patch Test) of ETU (Ethylene Thiourea) in Rabbits LPT Lab – Hamburg Report N°13987 / 01 GLP, Unpublished
IIA 5.8.1/4	Leuschner. J	2001	Acute Eye Irritation study of ETU (Ethylene Thiourea) by instillation into conjunctival sac of rabbits LPT Lab – Hamburg Report N°13988 / 01 GLP, Unpublished
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Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
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APPENDIX IV

List of uses supported by available data

MANEB

Name of the active substance: maneb (fungicide)	Name of the company: CEREXAGRI
Name of the product: Trimangol 80 WP	Concentration of the a.s. (active substance) in the product: 800 g/kg
Type of formulation: WP	Other a.s. in the product (name and concentration): --

Crop		F, G or I (1)	Pest controlled	Application				Application rate per treatment			PHI (days)	Remarks
				method kind	growth stage & season	Number min max	interval between applications	kg as/hL min max	water L/ ha min max	kg as/ha min max		

Ware potatoes SOLTU	N	F	<i>Phytophthora infestans</i>	downw. spr.	BBCH 95	8-10	7		200-400	1.6	7	
	S	F	<i>Phytophthora infestans</i>	downw. spr.	BBCH 95	4-6	7		200-400	1.6	7	
Onion ALLCE	N	F	<i>Peronospora destructor</i> <i>Botrytis squamosa</i>	Downw. Spr.	Full growth	4-8	7-14		400	1.6-2.0	28	
	S	F	<i>Puccinia allii</i>	Downw. Spr.	Full growth	4-6	7-14		400	2.0	28	
Sugar beet BETVU	N	F	<i>Cercospora betae</i>	downw. spr.	Full growth	2	10-14		200-400	1.6	28	
	S	F	<i>Cercospora betae</i>	downw. spr.	Full growth	4	10-14		200-400	2.0	28	

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