



EUROPEAN COMMISSION  
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL  
Directorate D - Food Safety: Production and distribution chain  
**Unit D.3 - Chemicals, contaminants and pesticides**

Mancozeb

SANCO/4058/2001 - rev. 4.4

July 2009<sup>1</sup>

## EU RESTRICTED

**COMMISSION WORKING DOCUMENT - DOES NOT NECESSARILY REPRESENT THE  
VIEWS OF THE COMMISSION SERVICES**

**FINAL**

Review report for the active substance **mancozeb**

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 mancozeb 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 mancozeb, 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<sup>(2)</sup> 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<sup>(3)</sup>, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Mancozeb 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, Stefes Research GmbH on 09.07.03, Indofil Chemicals C on 12.07.93, United Phosphorus Ltd on 26.07.93, Rohm & Haas France on 21.07.93, Barclay Chemicals on 27.07.93, ACI International on 30.07.9, Bakelite Italia on 13.07.93, AgriChem on 15.07.93, Elf Atochem on 26.07.93, Portman Agrochemicals on 26.07.93, Helm AG on 23.07.93, B.V. Luxan Registration Department on 21.07.93 and Dupont De Nemours SA on 23.07.93 notified to the Commission of their wish to secure the inclusion of the active substance mancozeb in Annex I to the Directive.

<sup>1</sup> On July 2009 the Standing Committee on Food Chain and Animal Health took note of this amended revision 4.4 which includes the results of the confirmatory studies required by the inclusion Directive.

<sup>2</sup> OJ No L 366, 15.12.1992, p.10.

<sup>3</sup> 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<sup>(4)</sup>, as last amended by Regulation (EC) No 2230/95<sup>(5)</sup>, designated Italy as rapporteur Member State to carry out the assessment of mancozeb on the basis of the dossiers submitted by the notifiers. In the same Regulation, the Commission specified furthermore the deadline for the notifiers with regard to the submission to the rapporteur Member States of the dossiers required under Article 6(2) of Regulation (EEC) No 3600/92, as well as for other parties with regard to further technical and scientific information; for mancozeb this deadline was 31.10.1995. B.V. Luxan Registration Department on 19.12.1994, Stefes Research GmbH on 23.01.1995, Helm A.G. on 18.03.1995, AgriChem on 25.04.1995 and Bakelite Italia on 15.05.1997, withdrew their notification on mancozeb.

Among the other notifiers, only Rohm & Haas France S.A., Elf Atochem Agri S.A., Dow AgroSciences submitted in time a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Indofil Chemicals Company although did not submit in time a complete dossier was allowed to submit further data to complete the dossier, taking into account a lack of information made available to the company about the procedure. However the dossier is not considered complete even though the submitted information was assessed by RMS in its Draft Assessment Report. Furthermore, following the take-over of Rohm and Haas Agriculture Business by Dow Agrosciences, the new company (Dow Agrosciences) on 10.10.2001, decided to refer to the dossier developed by Rohm and Haas as to the one submitted for EU review. Therefore Rohm And Haas France S.A. (Dow Agrosciences), Elf Atochem Agri S.A., were considered to be the main data submitter.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Italy submitted on 3 October 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 mancozeb 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 mancozeb from Rohm & Haas France S.A., Elf Atochem Agri S.A., Dow AgroSciences and Indofil Chemicals Company, on 11.09.2000.

The Commission organised a tripartite meeting with the main data submitters and the rapporteur Member State for this active substance on 06.04.2001 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.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the main data submitter on 11.11.2002 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

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<sup>4</sup> OJ No L 107, 28.04.1994, p.8.

<sup>5</sup> OJ No L 225, 22.09.1995, p.1.

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.

On July 2009, the **Standing Committee on the Food Chain and Animal Health**, took note of the present revision 4.4. in which the results of the confirmatory study on developmental neurotoxicity have been included in Appendix II with respect to the new endpoint and data of the study.

## 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/EC**<sup>6</sup> concerning the inclusion of mancozeb in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing mancozeb 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 mancozeb will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive

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6 OJ No L 279, 22.10.2005, p. 63-69

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 mancozeb containing plant protection product for which Member States will grant or review the authorisation.

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

Extension of the use pattern beyond those described above will require 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 apple, tomato, potato and grape: with maximum 23% or 41% 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 mancozeb are given in Appendix I.

The technical material on which the evaluation has been made has a degree of purity of at least 80%. This minimum purity is not in conformity with the tentative FAO specification of 1980, which was 85% but the technical material used in the evaluation is considered to present a higher stability.

The review has established that for the active substance notified by the main data submitter Rohm & Haas France S.A. (now Dow AgroSciences), Elf Atochem Agri S.A., and Indofil Chemicals Company none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

In accordance with the provisions of Article 13(5) of Directive 91/414/EEC, Italy is also satisfied, on the basis of the information currently available, that the substances notified by the other data submitters (Elf Atochem Agri S.A., and Indofil Chemicals Company) do not, in the meaning of Article 13(2) and (5) of the Directive, differ significantly in degree of purity and nature of impurities from the composition registered in the dossier submitted by the main data submitter.

## **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 mancozeb**

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

- Member States should pay particular attention to the 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 mancozeb 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 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 mancozeb in Annex I of the Directive.

## APPENDIX I

## Identity, physical and chemical properties

## MANCOZEB

<b>Common name (ISO)</b>	MANCOZEB
<b>Chemical name (IUPAC)</b>	manganese ethylenebis (dithiocarbamate) (polymeric) complex with zinc salt
<b>Chemical name (CA)</b>	[1,2-ethanediybis[carbomodithioato](2-)] manganese mixture with [1,2-ethanediybis [carbomodithioato] (2-)] zinc (9Cl)[ethylenebis(dithiocarbamato)]manganese mixture with [ethylenebis(dithiocarbamato)]zinc (8Cl)
<b>CIPAC No</b>	34
<b>CAS No</b>	8018-01-7 (formerly 8065-67-5)
<b>EEC No</b>	006-076-00-1
<b>FAO SPECIFICATION</b>	Tentative, 1980
<b>Minimum purity</b>	800 g/kg
<b>Molecular formula</b>	$(C_4H_6MnN_2S_4)_x(Zn)_y$
<b>Molecular mass</b>	271.3
<b>Structural formula</b>	$\left[ \begin{array}{c} S \\    \\ S-C-NH-CH_2-CH_2-NH-C-S-Mn \end{array} \right]_x Zn_y$ <p>Mancozeb is a polymeric complex of the monomer illustrated which contains 20% manganese and 2.5% zinc</p>

<b>Melting point</b>	Not measurable as the product decomposes without melting.
<b>Boiling point</b>	Not applicable, decomposes before melting.
<b>Appearance</b>	Yellowish powder (80%)
<b>Relative density</b>	density: 1.9938 g/ml at 20°C (81.5%) relative density: 1.976 g/ml at 22°C. (80%)
<b>Vapour pressure</b>	$1.33 \times 10^{-5}$ Pa
<b>Henry's law constant</b>	(a) Henry's law constant is calculated from the vapour pressure value and water solubility. $KD < 5.9 \times 10^{-4}$ Pa x $m^3 \times mol^{-1}$ (not volatile).
<b>Solubility in water</b>	2 - 20 mg/l
<b>Solubility in organic solvents</b>	Mancozeb is practically insoluble in organic solvents.
<b>Partition co-efficient (log P<sub>ow</sub>)</b>	K <sub>ow</sub> 1.8 (first partitioning), and 21.4 (second partitioning of octanol vs fresh water) Indicative Log P <sub>ow</sub> = 1.33 ETU: Kow (1 ppm ETU in octanol): 0.15. Kow(10 ppm ETU in octanol): 0.14. (indicative values) Indicative Log P <sub>ow</sub> = -0.85
<b>Hydrolytic stability (DT<sub>50</sub>)</b>	< 1 day
<b>Dissociation constant</b>	At 25°C, the typical pKa value for Mancozeb is 10.3.
<b>Quantum yield of direct photo-transformation in water at λ &gt;290 nm</b>	Quantum yield cannot be calculated for mancozeb because the measured photodegradation rate was negligible.
<b>Flammability</b>	Mancozeb technical is not flammable in the sense of the method EEC A 10.
<b>Explosive properties</b>	The chemical structure, possible decomposition reactions and energies, and the decomposition products of the substance have been studied. No potential explosive properties are expected. Therefore, on the basis of this theoretical evaluation, it is not necessary to perform the test for explosive properties.
<b>UV/VIS absorption (max.)</b>	The EBDC ion from the soluble disodium salt absorbs at 280.5 - 285 nm (227 nm shoulder) with molar absorbance of $6 \times 10^4$ in water and at 296 nm with molar absorbance of $2.9 \times 10^4 \pm 0.8 \times 10^4$ in DMSO. The test substance has the same spectrum in DMSO as the soluble EBDC ion. In UV B with a maximum at 310 nm (10% NaOH, pH 9.8).
<b>Photostability in water (DT<sub>50</sub>)</b>	Mancozeb decomposes completely with 3 hours at pH 8.8. Irradiated and dark control samples showed similar decomposition behaviour indicating that the major routes were hydrolysis and oxidation not photolysis. Four main decomposition products were observed: EBIS, ETU, EDA and EU.

## APPENDIX II

### END POINTS AND RELATED INFORMATION

#### MANCOZEB

## 1 Toxicology and metabolism

### Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	Rapid, 50% based on urinary excretion.
Distribution:	Widely distributed, the highest residues in thyroid.
Potential for accumulation:	No potential for accumulation.
Rate and extent of excretion:	Rapid, > 95% within 4 d.
Toxicologically significant compounds:	Parent compound and metabolite (ETU).
Metabolism in animals:	Extensively metabolised, reactions of hydrolysis, conjugation and ring formation (ETU).

### Acute toxicity

Rat LD <sub>50</sub> oral:	> 5000 mg/kg bw.
Rat LD <sub>50</sub> dermal:	> 2000 mg/kg bw.
Rat LC <sub>50</sub> inhalation:	> 5.14 mg/l, whole body exposure
Skin irritation:	Non irritant.
Eye irritation:	Slightly irritant, no classification needed.
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:	7 mg/kg bw/d (overall NOAEL, 90-d rat, 90-d & 1-year dog)
Lowest relevant dermal NOAEL / NOEL:	>1000 mg/kg bw/day (28-d & 90-d, rat:)
Lowest relevant inhalation NOAEL / NOEL:	36 mg/m <sup>3</sup> (respirable concentration) (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, hypertrophy/hyperplasia); retinopathy at high doses.
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Lowest relevant NOAEL:

125 ppm (4.8 mg/kg bw/d) (2-years rat).
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Carcinogenicity:

Thyroid adenomas and carcinomas in rats at high doses.
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## Reproductive toxicity

Target / critical effect - Reproduction:

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

150 ppm (about 7 mg/kg bw/d) (two-generation study in rat).
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Target / critical effect - Developmental toxicity:

Malformations at high doses in rats; embryo-/fetotoxicity (delayed ossification, abortions) at lower maternally toxic doses in rats and rabbits.
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Lowest relevant developmental NOAEL / NOEL:

Rat: 60 mg/kg bw/d.
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## Delayed neurotoxicity

There is no evidence from toxicology studies for <u>delayed</u> neurotoxicity.
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## Other toxicological studies

Neurotoxicity study, 90-d, rat: clinical signs and histopathology; NOAEL 125 ppm (8.2 mg/kg bw/d).
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An oral developmental neurotoxicity study of mancozeb in rats has been submitted in 2008. No test related effects on any of the F1 litter parameters investigated in this study. NOAEL 30 mg/Kg /day the highest dose tested. <sup>1</sup>
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## Medical data

Human studies of manufacturing workers exposed to mancozeb have detected the presence of mancozeb in urine but, with the exception of sporadic reports of sensitisation by skin contact; no evidence of thyroid effects; evidence of increased chromosomal aberrations in manufacturing workers in one report
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<sup>1</sup> The SCFCAH took note of revision 4.4. of this review report in July 2009. The study as required by the directive of inclusion has been submitted in 2008. Oral developmental neurotoxicity study of mancozeb in rats; WIL research laboratories. Ashland OH 44805-8946.

## Summary

	Value	Study	Safety factor
ADI:	0.05 mg/kg bw/d	2-years, rat	100
AOEL systemic:	0.035 mg/kg bw/d	overall short-term NOAEL in rats and dogs; correction for 50 % oral absorption	100
AOEL inhalation:	not necessary (Vapor Pressure $1.33 \times 10^{-5}$ Pa)		
AOEL dermal:	not necessary (28-day dermal NOEL > 1000 mg/kg bw/d)		
ARfD (acute reference dose):	Mancozeb: 0.6 mg/kg bw/d (based on teratogenicity NOEL of 60 mg/kg bw/d in rat) ETU 0.05 mg/kg bw/d.		

## Dermal absorption

0.11% by 8 hours (high level dose formulation)  
0.24% by 8 hours (low level dose formulation)  
based on the results of in vivo rat dermal absorption study.

## 2 Fate and behaviour in the environment

### 2.1 Fate and behaviour in soil

#### Route of degradation

##### Aerobic:

Mineralization after 100 days:

After 93-103 d:	31.5-51.8% for Mancozeb 32.2-58.2% for ETU
After 28 d:	47.2% for EU

Non-extractable residues after 100 days:

After 93 d:	46.1% for Mancozeb 46.0% for ETU.
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Major metabolites above 10 % of applied active substance: name and/or code % of applied rate (range and maximum)

No major metabolites (> 10%) ethylene-thiourea (ETU), max. 3.1% ethyleneurea (EU), max. 8.5% ethylenebisisothiocyanide sulfide (EBIS), max. 8.2% ethylene thiuram disulphide (ETD) was detected but in such a low amount that the interpretation of spectrum was rather uncertain.
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#### Supplemental studies

##### Anaerobic:

Metabolic pathway: Mancozeb - ETU - EU - CO <sub>2</sub> Major metabolite: EU (up to 30%) and ETU (12%). CO <sub>2</sub> : 5% in 31 d. Bound residues: 49.2% after 31 d.
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##### Soil photolysis:

Mancozeb does not photodegrade in dry soil. In wet soils, oxidative processes induce a degradation of Mancozeb that is much more rapid than the photo-degradation process. Soil photolysis is overlapped by other degradation processes.
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##### Remarks:

No remarks.
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## Rate of degradation

### Laboratory studies

DT<sub>50lab</sub> (20 °C, aerobic):

DT <sub>50lab</sub> (20°C; aerobic): Mancozeb: estimated in 1 to 3 hours. Average: 1.8. n=5 ETU: estimated in 2 hours. n=2 0.3 to 1d; (2 Dutch soils) EU: 4.8 to 7.6 d. Average: 6.2. n=3, r <sup>2</sup> >0.94.
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DT<sub>90lab</sub> (20 °C, aerobic):

DT <sub>90lab</sub> (20°C; aerobic): Mancozeb: 2 - 25 hours. ETU: estimated in less than 2 d. n=2 EU: 16.0 to 25.2 days. Average: 20.6 d. n=3
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DT<sub>50lab</sub> (10 °C, aerobic):

DT <sub>50lab</sub> (10°C; aerobic): evaluated for mancozeb with a Q <sub>10</sub> of .2.2/2.3 to 8.4 hours.
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DT<sub>50lab</sub> (20 °C, anaerobic):

DT <sub>50lab</sub> (20°C; anaerobic) : 11 d.
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### Field studies (country or region)

DT<sub>50f</sub> from soil dissipation studies:

not required as DT <sub>50</sub> is far less than 60 d (1 to 3 hours).
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DT<sub>90f</sub> from soil dissipation studies:

Not relevant.
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Soil accumulation studies:

not required as DT <sub>50</sub> is well below 1 d (1-3 hours) which is far below 1 third of the time between application and harvest.
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Soil residue studies:

Not relevant.
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### Remarks:

e.g. effect of soil pH on degradation rate

No remarks.
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## Adsorption/desorption

$K_f / K_{oc}$ :

parent:  $K_{oc}$ : 363 –2334 L/kg; n=4; average: 997.5  
1/n= 0.686 - 0.777

$K_f$ : 7.26 -11.67 L/kg

ETU:  $K_{oc}$ : 34 –146 L/kg ; n=4;  
average: 70 (shake flask)  
1/n= 0.5522, 0.469, 0.327, 0.406  
 $K_{oc}$ : 5.2 and 2.6 L/kg (column study, 2  
soils) 1/n: 0.9 (standard value)

$K_f$ : 0.73, 0.67, 1.14, 0.51

$K_d$ :

parent:  $K_d$ : 7.26 – 11.67 L/kg. Average: 9.74

ETU:  $K_d$ : 0.006 – 0.051 L/kg. Average: 0.035;  
(2 Dutch soils)

pH dependence:

no for parent and ETU.

## Mobility

### Laboratory studies:

Column leaching:

No guidelines.  
2.5 cm H<sub>2</sub>O/week (375 ml) for 9 weeks  
Two out of 5 soils leaching was observed (the clay  
leachate contained radioactivity comprising 2 to 5%  
of the applied material), all other leachates were  
free of detectable radioactivity.

## Aged residue leaching:

Guideline: US-EPA 163.

Aged for 24 hours, 2320 ml deionised water applied continuously.

Elution time varying from 1 d (sandy loam and Washington silt loam) to 8 d (Lawrenceville silt loam) to 34 d (incomplete elution for clay loam).

78-99% of applied dose was found in soil with 57-84% in the top 2.5 cm; the leachate varies from 4.2 to 19% of the applied activity. No volatile residues are observed.

Guideline: SETAC and draft OECD

Mancozeb applied at 4x the field application rate to a humic sand soil and aged for one half-life, 52.6 hours, as determined in a preliminary test ca. 250 mL of 0.01 M CaCl<sub>2</sub> (200 mm of artificial rainfall) over a period of 48 hours.

Total percentage in the leachate was 4.2-4.7 % of the applied radioactivity (corresponding to ETU, EU and others); >91% of the recovered radioactivity remained in either the application layer or the first column segment after leaching.

$K_d > 4.5$  L/kg

$K_{om} > 438$  L/kg.

## Field studies:

## Lysimeter/Field leaching studies:

The Netherlands. Monitoring of ETU in the uppermost groundwater.

NL field leaching study (Boland et al, 1995: average ETU concentration under 32 potatoes fields 0.11 —g/l, 90th percentile 0.27 —g/l (LOQ 0.05 —g/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 field, 7 day interval mostly adopted. Sampled depth 0-1 m. 1993 extremely wet year.

Gärds-Köpinge, Sweden. Occurrence of ETU in Swedish groundwaters and drinking waters.

3 Swedish potatoes sandy soil sites, sampled for 1 year (1992-93). No detections (LOQ 0.1 µg/L) in samples of groundwater collected at 2.5 and 5 m depth and in tap water from 96 m depth from a site with light-textured sandy soil treated with mancozeb at a total seasonal dose of 10.4 kg as/ha.

## Remarks:

No remarks

## 2.2 Fate and behaviour in water

### Abiotic degradation

Hydrolytic degradation:

<p>pH 5 :                  Mancozeb: two studies at 25 °C. DT<sub>50</sub> (linear regression) 2.2 and 36 hours.</p> <p>pH 7:                  Mancozeb: two studies at 25 °C. DT<sub>50</sub> (linear regression) 5.5 and 55 hours.</p> <p>pH 9:                  Mancozeb: two studies at 25 °C. DT<sub>50</sub> (linear regression) 14.1 and 16 hours.</p>
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Major metabolites:

<p>pH 5 :                  Metabolites: ETU (major), EU and EBIS (traces)                  ETU: hydrolytically stable.</p> <p>pH 7:                  Metabolites: ETU and EBIS (major), EU (traces)                  ETU: hydrolytically stable.</p> <p>pH 9:                  Metabolites: ETU, EU, EBIS                  ETU: hydrolytically stable.</p>
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Photolytic degradation:

<p>Mancozeb: the major decomposition routes for the a.i. are hydrolysis and oxidation, not photolysis.</p>
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Major metabolites:

<p>ETU: pH 7. Non sensitised: DT<sub>50</sub> (photolysis)= 358 d; (sensitised: DT<sub>50</sub> (photolysis)= 2.3 d).</p>
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### Biological degradation

Readily biodegradable:

Water/sediment study:

DT<sub>50</sub> water:

DT<sub>90</sub> water:

DT<sub>50</sub> whole system:

DT<sub>90</sub> whole system:

Distribution in water / sediment systems  
 (active substance)

Distribution in water / sediment systems  
 (metabolites)

Accumulation in water and/or sediment:

### Degradation in the saturated zone

Remarks:

No
<p><u>Aquatic</u> (20°C, 4 systems):</p> <p><i>mancozeb major fraction:</i>                  DT<sub>50</sub>= 0.6-14.4 hours; average 4.7 hours                  DT<sub>90</sub> = 6.6-158 hours; average 57.4 hours;</p> <p><i>mancozeb sum of complexed fraction:</i>                  DT<sub>50</sub>= 0.1-0.9 d; average 12 hours                  DT<sub>90</sub> = 1.3-4.9 d; average 3.1 d.</p> <p><i>ETU:</i>                  DT<sub>50</sub>= 11.1, 6.1, 4.0, 6.3 d; average 6.9 d.                  DT<sub>90</sub>= 36.7, 20.4, 13.3, 21.0 d; average 22.3 d.</p> <p><u>Whole system</u> (20°C, 4 systems):  <i>Mancozeb:</i> see aquatic as no a.i. was detected in sediment.  <i>ETU:</i>                  DT<sub>50</sub>= 11.1, 6.7, 7.4, 7.6 d; average 8.2 d.                  DT<sub>90</sub>= 36.7, 22.4, 24.6, 25.3 d; average 27.2 d.</p> <p>Mancozeb. No mancozeb was detected in sediment</p> <p>Water                  ETU: max 48.5% at d 1                  EU: max 37.5 at d 14                  EBIS: max 30.9% at d 0</p> <p>Sediments                  ETU: max 8.1% AR at 7 d                  EU: max 9.1% after 30 d                  EBIS: max 3.8% after 2 d.</p>
No remarks.

No data submitted and no data required.

No remarks.

## 2.3 Fate and behaviour in air

### Volatility

Vapour pressure:

1.33 x 10 <sup>-5</sup> Pa.
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Henry's law constant:

Henry's law constant is calculated from the vapour pressure value and water solubility. $KD < 5.9 \times 10^{-4} \text{ Pa} \times \text{m}^3 \times \text{mol}^{-1}$ (not volatile).
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### Photolytic degradation

Direct photolysis in air:

No data.
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Photochemical oxidative degradation in air

No data.
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DT<sub>50</sub>:

Volatilisation:

Neither mancozeb nor ETU are volatile.
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Remarks:

No remarks.
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### 3 Ecotoxicology

#### Terrestrial Vertebrates

Acute toxicity to mammals:

LD<sub>50</sub>>5000 mg /kg bw  
ETU: Rat LD<sub>50</sub> oral > 5000 mg/kg bw

Acute toxicity to birds:

LD<sub>50</sub>>2000 mg./kg bw

Dietary toxicity to birds:

LC<sub>50</sub>>5200 ppm (860 mg/kg bw/d)

Reproductive toxicity to birds:

NOEL: 125 ppm (18.8 mg/kg bw/d)  
Based on marked effects on reproductive performance at 1000 ppm.

Reproductive toxicity to mammals:

NOEL: 55 mg/kg bw/d  
(rabbit developmental NOEL)  
based on decreased maternal body weight, increased abortions, decreased number of litters at 80 mg a.s./kg bw/day. No foetal developmental effects.

ETU: NOEL 150 ppm (two generation study in rat).

#### Aquatic Organisms

##### Toxicity data for aquatic species

Acute toxicity fish:

Group	Test substance	Time-scale	End-point	Toxicity (mg/l)
Laboratory tests				
Rainbow trout	Mancozeb tech	96h	LC <sub>50</sub>	<b>0.074*</b> 0.088**
Rainbow trout	Mancozeb 80% WP	96h	LC <sub>50</sub>	0.11 mg product/l (0.088 mg as/L)**
Rainbow trout	Penncpzeb 80 WP	96h	LC <sub>50</sub>	0.18 mg product/l (0.15 mg as/L)
Rainbow trout	ETU	96h	LC <sub>50</sub>	>490
Long term toxicity fish:	Rainbow trout	Sancozeb 800 WP	Prolonged tox. test 14 days	NOEC 0.66 mg as/L**
	Fathead minnow	Dithane M - 45	early life stage 34 d	NOEC 0.00219*
Bioaccumulation fish:	Not requested: logPow = 1.38			

Acute toxicity invertebrate:	<i>Daphnia magna</i>	Mancozeb tech	48h	EC <sub>50</sub>	<b>0.073*</b>
	<i>Daphnia magna</i>	Mancozeb 80% wdp	24h	EC <sub>50</sub>	0.014 mg product /l (0.011 mg as/l)**
	<i>Daphnia magna</i>	Penncozeb 80 WP	48h	EC <sub>50</sub>	0.47 mg product/l (0.39 mg as/l)**
Chronic toxicity invertebrate:	<i>Daphnia magna</i>	ETU	48h	EC <sub>50</sub>	21.6
	<i>Daphnia magna</i>	Mancozeb tech	21 days chronic	NOEC	<b>0.0073*</b>
	<i>Daphnia magna</i>	Sancozeb 800 WP	21 days chronic	NOEC	0.029 mg as/l**
	<i>Daphnia magna</i>	ETU	21 days chronic	NOEC	2
Acute toxicity algae:	<i>Chlorella P.</i>	ETU	96h	ErC <sub>50</sub>	6600
	<i>Selenastrum capricornutum</i>	Dithane M - 45	120h	EC <sub>50</sub>	<b>0.044***</b>
	<i>Pseudo-kirchneriella s.</i>	ETU	72h static	ErC <sub>50</sub>	93.8
	<i>Xenopus leavis</i>	ETU	Metamorphosis assay 28 d Semi static	NOEC	10
Chronic toxicity sediment dwelling organism:	Not requested				
Higher tier studies	Rainbow trout	Dithane M - 45	Fish Species Sensitivity Distribution Study <sup>+</sup> 96 h	LC <sub>50</sub>	<b>0.073 mg as/l</b> 0.050 mg as/l)
	Invertebrates and phytoplankton	Penncozeb 80 WP	Invertebrate Phytoplankton Mesocosm	EAC	<b>0.032 mg as/l</b>
	<i>Brachionus calyciflorus</i>	Penncozeb 80 WP	Acute 24 h	EC <sub>50</sub>	0.11 mg as/L
	<i>Lymnae stagnalis</i>	Penncozeb 80 WP	Acute 48 h	EC <sub>50</sub>	>113 mg as/L
	<i>Gammarus sp.</i>	Penncozeb 80 WP	Acute 48 h	EC <sub>50</sub>	3.0 mg as/L
	<i>Asellus sp.</i>	Penncozeb 80 WP	Acute 48 h	EC <sub>50</sub>	4.4 mg as/L

\*Mean measured concentration at the end of the test.

\*\*Nominal, analytically confirmed concentration > 80% recovery.

\*\*\*Initial measured concentration.

Values in **Bold** were used for risk assessment

**Fish Species Sensitivity Distribution Study**

10 species of freshwater fish were tested for 96 hours acute toxicity in shallow (30 cm), static sediment/water microcosms. Test material (Dithane M-45) was applied once in 5 test concentrations under the water surface. Analytical confirmation indicated that all initial concentrations were >80% of nominal, therefore, results were expressed as nominal initial concentrations.

The most sensitive fish species was rainbow trout 96 hours LC<sub>50</sub> = 0.073 mg as/L (NOEC=0.050 mg as/L). Results in the other species of fish were (96 hr LC50's mg as/L): fathead minnow 0.57; channel catfish 0.68; bluegill sunfish 0.84; three-spined stickleback 0.93; zebra fish 0.95; largemouth bass 1.0; guppy 1.3; golden medaka 1.4; common carp 1.7.

**Invertebrate/Phytoplankton Microcosm study**

No NOEC community could be derived because there were still long term effects at the lowest tested concentration (reduction of the abundance of clams). The study was conducted at pH 5.5-7: mancozeb hydrolysed very fast in acid environment and much slower under alkaline conditions. For this reason the study can be use in a risk evaluation of mancozeb in more or less acid surface waters.

**Invertebrate/Phytoplankton Mesocosm study**

The study is adequate for risk evaluation for phyto- and zoo-plancton communities and aquatic diptera. The Ecological Acceptable Concentration is 32 µg as/l applicable to aquatic risk assessment scenarios involving 8 or fewer applications.

**Honeybees**

Acute oral toxicity:

LD50 140.6 µg as/bee

Acute contact toxicity:

LD50 161.7 µg as/bee

**Other arthropod species****Effects on other arthropod species**

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect %	Annex VI Trigger
<i>Chrysoperla carnea</i> *	larvae	Dithane M45	1.8	Mortality	9.4	30%
<i>Episyrphus balteatus</i> *	larvae	Dithane M45	1.8	Mortality	12.5	30%
<i>Trichogramma cacoeciae</i> *	adult	Dithane M45	1.8	Parasitic capacity	>50	30%
<i>Cydnodromus californicus</i> °	adult	Dithane M45	2	Mortality	0	30%
<i>Amblyseius andersoni</i> *	adult	Mancozeb tech	200 g/hl	Long term effect	<b>37.89</b>	30%
<i>Amblyseius andersoni</i> (S and R)°°	adult	Polyram c80	40	Short term effects (mortality and fecundity)	25.36 (for R) <b>73.45</b> (for S)	30%
				Long term effect (mortality and fecundity)	31.82 (for R) 67.87 (for S)	

<i>Typhlodromus pyri</i>	Adult	Mancozeb tech	3.6	Long term effect	>75%	30%
<i>Aphidius rhopalosiphi</i> <sup>°</sup>	adult	Manex II	2.6	Mortality Reduced beneficial capacity	-0.4 36	30
<i>Poecilus cupreus</i> <sup>°</sup>	adult	Manex II	2.4	Mortality	0	30
<i>Chrysoperla carnea</i> <sup>°</sup>	larvae	Manex II	2.4	Mortality Reproduction rate	-0.3 12.2	30
<i>Coccinella septempunctata</i> <sup>°</sup>	larvae	Pencozeb 80	2-3	Mortality Reproduction rate	33.8 2.01	30
<i>Aphidius rhopalosiphi</i> <sup>°</sup>	adult	Sancozeb 800 wp	3.5	Mortality Reduced beneficial capacity	<b>64.9</b> <b>52.8</b>	30
<b>Field study</b>						
<i>Cydnodromus californicus</i> <sup>°°</sup> <i>P.ulmi</i>	adult	Dithane M 45	1.28 (0.16 kg a.i./hl)	Population reduction	40 (after 17 days) -100 (after 38 days)	none
<i>Typhlodromus pyri</i> <sup>°°</sup>	adult	Dithane Ultra WG	2x2.0, 2x3.0 4x2.0, 2x3.0	Population reduction	16.7 36.7	none

Semi field test

<sup>°</sup>Laboratory test<sup>°°</sup>Field test

## Earthworms

Acute toxicity:

LC <sub>50</sub> > 299.1 mg as/kg soil ETU: LC <sub>50</sub> > 1000* mg/kg soil. 14 d
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Reproductive toxicity:

NOEC: 161 mg as/kg (mortality) NOEC: 20 mg as/kg (reproduction)
--

## Soil micro-organisms

Nitrogen mineralization:

no effects on soil microflora at 4 kg as/ha (6.68 mg as/kg dry soil) ETU: no effects on soil microflora at concentrations = 0.56 – 5.6 mg/kg (equivalent to 0.42-4.2 kg as/ha)
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Carbon mineralization:

no effects on soil microflora at 4 mg as/ha (6.68 mg as/kg dry soil) ETU: no effects on soil at concentrations = 0.56 – 5.6 mg/kg (equivalent to 0.42-4.2 kg as/ha)
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## APPENDIX IIIA

### MANCOZEB

List of studies for which the main submitters have 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	Reports <sup>1</sup> on previous use in granting national authorizations
IIA 1.1	Grandcolas, D.	1995	Dithane M-45: Analytical profile of Batches Lauterbourg Plant-Rohm and Haas FranceEuropean Region Agricultural Delivery System Laboratory Dow AgroSciences Report n°ER Ref. 87.8 GLP, Unpublished	
IIA 1.4	Olive, C.	2002	Determination of the Relative self- ignition of Dithane M-45 Huntingdon Life Science Dow AgroSciences Report n°GHE-P-9874 (ER Ref. 105.15) GLP, Unpublished	
IIA 2.1	Thomas D.M.	1994 a	The Melting Temperature of Dithane <sup>®</sup> M-45 Huntingdon Research Centre, Ltd. Dow Agro Sciences Report n°ER Ref No. 76.9 (APR-94- 248) GLP, Unpublished	

<sup>1</sup> 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	Reports <sup>1</sup> on previous use in granting national authorizations
IIA 2.2	Thomas D.M.	1994 b	The Relative Density of Dithane <sup>®</sup> M-45 Huntingdon Research Centre, Ltd. Dow AgroSciences Report n°ER Ref No. 76.7 (APR-94-250) GLP, Unpublished	
IIA 2.4	Wasser, C	1995 b	Determination of the Appearance of Technical and Pure Mancozeb Anadiag S.A., Haguenau, France Dow Agro Sciences Report n°RF 4124 04 GLP, Unpublished	
IIA 2.5	Wasser, C	1995 c	Determination of the UV/Visible Spectrum of Mancozeb Anadiag S.A., Haguenau, France Dow Agro Sciences Report n°RF 4124 05 01 GLP, Unpublished	
IIA 2.5.1	Thomas D.M.	1994 c	The Infra-red Absorption Spectrum of Dithane <sup>®</sup> M-45 Huntingdon Research Centre, Ltd. Dow Agro Sciences Report n°ER Ref No. 76.8 (APR-94-249) GLP, Unpublished	
IIA 2.5.2	Meyer A.L.	1994	Spectral Data for Ethylenethiourea Dow AgroSciences Report n°ER Ref No. 76.11 (APR 94-074) No GLP, Unpublished	
IIA 2.6	Wasser, C	1995 e	Determination of the Solubility of Mancozeb in Water Anadiag S.A., Haguenau, France Dow AgroSciences Report n°RF 4124 06 GLP, Unpublished	

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports<sup>1</sup> on previous use in granting national authorizations</b>
IIA 2.7	Wasser, C	1995f	Determination of the Solubility of Mancozeb in Organic Solvents Anadiag S.A., Haguenau, France Dow AgroSciences Report n°RF 4124 07 GLP, Unpublished	
IIA 2.8	Wasser, C	1995g	Determination of the n-octanol/water Partition Coefficient "Flask Method" Anadiag S.A., Haguenau, France Dow AgroSciences Report n°RF 4124 08 GLP, Unpublished	
IIA 2.9	Wasser, C	1995h	Determination of the Stability of Mancozeb in Water-Influence of the pH on the Stability Anadiag S.A., Haguenau, France Dow AgroSciences Report n°RF 4124 09 GLP, Unpublished	
IIA 2.10	Wasser, C	1995i	Determination of the Stability of Mancozeb in Air Anadiag S.A., Haguenau, France Dow AgroSciences Report n°RF 4124 10 GLP, Unpublished	
IIA 2.11.1	Thomas D.M.	1994d	The Flammability (solids) of Dithane <sup>®</sup> M-45 Huntingdon Research Centre, Ltd. Dow AgroSciences Report n°ER Ref No. 76.5 (APR-94- 252) GLP, Unpublished	
IIA 2.11.2	Thomas D.M.	1994e	The Relative Self-Ignition Temperature of Dithane <sup>®</sup> M-45 Huntingdon Research Centre, Ltd. Dow AgroSciences Report n°ER Ref No. 76.6 (APR-94- 251) 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 <sup>1</sup> on previous use in granting national authorizations
IIA 2.13	Thomas D.M.	1994f	Dithane <sup>®</sup> M45 Explosive Properties Huntingdon Research Centre, Ltd. Dow AgroSciences Report n°ER Ref No. 83.3 (APR-95-109) GLP, Unpublished	
IIA 2.14	Comb,C.L.	2000	Dithane M-45 Surface Tension Study Report Research Laboratory Huntingdon Life Sciences Ltd Dow AgroSciences Report n° ER 92.1 GLP, Unpublished	
IIA 2.15	Thomas D.M.	1994g	Dithane <sup>®</sup> M45 Oxidizing Properties Huntingdon Research Centre, Ltd. Dow AgroSciences Report n°ER Ref No. 83.2 (APR-95-110) GLP, Unpublished	
IIA 4.1	Eisenschmied, M. A.	1994	Validation of the ETU Dithane <sup>®</sup> Method for Dithane <sup>®</sup> RD Formulation. Dow AgroSciences Report n°ER File No. 85.4 (US File No. 13-94-050TR) No GLP, Unpublished	
IIA 4.2.1	Crotts, D and Clayton, B	2000	EN-CAS Laboratories -ILV of Analytical Method No. ETU-89AM-002, Determination of Ethylene Bis Dithiocarbamates (EBDC's) in Meat, Protocol ID No.: 00-0023 EN CAS Laboratories Mancozeb Task Force Report n° TR34-00-99 (ER Ref. 95.3) 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 <sup>1</sup> on previous use in granting national authorizations
IIA 4.2.1	Crotts, D and Clayton, B	2000	EN-CAS Laboratories - ILV of analytical Method No.: ETU-89AM-003, Determination of Ethylene Bis Dithiocarbamates (EBDC's) in Milk, Protocol ID No.: 00-0025. EN CAS Laboratories Mancozeb Task Force Report n° TR34-00-100 (ER Ref 95.4) GLP, Unpublished	
IIA 4.2.1	Reed, R.L	2000	Validation of the Residue Analytical Method for Ethylenethiourea (ETU) in Meat, Protocol No.: MLI-00-03 Morse Laboratories, Inc. EDBC/ETU Task Force Report n° 34-00-102 (ER Ref 95.1) GLP, Unpublished	
IIA 4.2.1	Reed, R.L Westeberg, G.	2000	Validation of the Residue Analytical Method for Ethylenethiourea (ETU) in Milk, Protocol No.: MLI-00-04 Morse Laboratories, Inc. EDBC/ETU Task Force Report n° TR34-00-101 (RE Ref. 95.2) GLP, Unpublished	
IIA 4.2.2	Hanauer R.	2001	Validation of the method: determination of mancozeb in surface water LOQ 0.1 ppb (µg/Liter) Morse Laboratories Mancozeb consortium Report N° TR 34-00-112 (ER Ref 97.4) GLP Unpublished	
IIA 4.2.2	James J. W.	2000	Independent Laboratory Validation of Analytical Method "DETERMINATION OF ETHYLENE THIOUREA IN WATER EN CAS Laboratories EDBC/ETU Task Force Report n°- GLP Unpublished	

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports<sup>1</sup> on previous use in granting national authorizations</b>
IIA 4.2.2	Gottschalk, R.	2002	Validation of the analytical MS 270 for the analysis of mancozeb in soil Enviro-Test Laboratory Mancozeb Consortium Report n°02MTF01.REP (ER Ref 106.3) GLP, Unpublished	
IIA 4.2.2	Gottschalk, R.	2002	Validation of the method for analysis of ethylenethiourea (ETU) in soil by LC/MS/MS, using 2 European soils Enviro-Test Laboratory Mancozeb Task Force Report n°02CER01.REP ER Ref 102.17) GLP, Unpublished	
IIA 4.2.3	Purghart, V.	2002	Validation of analytical method for the determination of Dithane M-45 (as CS <sub>2</sub> ) in grass, sand and Poecilus cupreus by GC/MS Springborn Laboratory (Europe) AG Mancozeb Task Force Report No.: 01RC-0238 (ER Ref 103.1) GLP, Unpublished	
IIA 4.2.3 IIIA 5.2.3	Anonymous	1994	The HPLC analysis of ethylenethiourea in ground water. RIVM, Bilthoven, The Netherlands Mancozeb Consortium Report n°ER File No. 84.3 (US File No.: SOP LOC/125/01) No GLP, Unpublished	
IIA 4.2.4 IIIA 5.2.4	Mueller-Kallert, M.	1995	Analytical Method for the Determination of Mancozeb and its Metabolite ETU in Air RCC Umweltchemie AG, P.O. Box CH-4452, Itingen/BL, Switzerland. Mancozeb Consortium Report n°83.5 (TR34-94-160) GLP, Unpublished	

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports<sup>1</sup> on previous use in granting national authorizations</b>
IIA 4.2.5	Clayton, B.	2001	ILV of Analytical Method No#Meth-127, Original, Determination of Ethylene Thiourea in Meat, Protocol ID No.: 00-0024  EN CAS Laboratories EDBC/ETU Task Force Report n°TR34-00-103(ER Ref. 95.7) GLP, Unpublished	

**B.6 Toxicology and metabolism**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports on previous use in granting national authorizations</b>
IIA 5.4	Arce, G.T.	2002	Mancozeb Mutagenicity Response to ECCO 118 Annex 5, Comment V, Point 4.1, and Point 4.2 Mancozeb Task Force Report n°P02015 (ER Ref. 105.14) Position Paper Non GLP, Unpublished	
IIA 5.4.1	Riach, CG	1996	Mancozeb 800WP Mouse Lymphoma Mutation Assay Inveresk Research, Scotland Dow Agro Sciences Report N°12146 GLP, Unpublished	
IIA 5.4.2	Holmstrom, LM, Innes, DC	1997	Sanachem Mancozeb 85% Technical Micronucleus Test in Bone Marrow of CD-1 Mice Inveresk Research, Scotland Mancozeb Consortium Report N°14823 (ER Ref. 113.06) 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	Dybowski, J. A.	2002	Mancozeb is not a developmental toxicant" Mancozeb Task Force Report n°GHC 5446 (ER Ref. 105.13) Position Paper Non GLP, Unpublished	
IIA 5.8.1	J. Leuschner	2001	Acute toxicity study of ETU (ethylene thiourea) in Sprague-Dawley rats by dermal administration LPT Laboratory of Phamacology EDBC/ETU Task Force Report n°LPT 13986/01 (ER Ref. 103.4) GLP, Unpublished	
IIA 5.8.1	J. Leuschner	2001	Acute skin irritation (patch test) of ETU (ethylene thiourea) in rabbits LPT Laboratory of Phamacology EDBC/ETU Task Force Report n°LPT 13987/01 (ER Ref. 103.2) GLP, Unpublished	
IIA 5.8.1	J. Leuschner	2001	Acute eye irritation study of ETU (ethylene thiourea) by instillation into the conjunctival sac of rabbits LPT Laboratory of Phamacology EDBC/ETU Task Force Report n°LPT 13988/01 (ER Ref. 103.3) GLP, Unpublished	
IIA 5.8.1	J. Leuschner	2001	Acute Inhalation Toxicity Study of Milled Ethylene Thiourea (ETU) in Sprague-Dawley Rats LPT Laboratory of Pharmacology EDBC/ETU Task Force Report N°LPT 15283/02 (ER Ref. 103.5) GLP, Published/Unpublished	
IIA 5.8.2	Ollinger, J.	2002	Carbon disulfide is not a toxicologically significant metabolite of mancozeb. Discussion on toxicologically significant animal metabolites Mancozeb Task Force Report n°MZ-JO0202 (ER Ref. 105.12) Position Paper Non GLP, Unpublished	

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports on previous use in granting national authorizations</b>
IIA 5.10	Billington, R., Redondi, S., and Dybowski, J.	2004	Mancozeb – an ARfD and R63 are not triggered by developmental toxicity Position paper of the Mancozeb Consortium, Mancozeb Consortium Report n°ER Ref 112.04 Non-GLP, Unpublished	
IIA 5.10	Ollinger, J.	2002	Definition of the appropriate ADI for ETU EDBC/ETU Task Force Position Paper Report N° ETU JO0201 (ER Ref 105.11) Non-GLP, Unpublished	
IIA 5.12.2	Fisher, L.	2002	[ <sup>14</sup> C]-Mancozeb In Vivo dermal absorption study in the male rat. Huntingdon Life Sciences Mancozeb Task Force Report n°041/022683 (ER Ref.106.4) GLP, Unpublished	

**B.7 Residue data**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports on previous use in granting national authorizations</b>
IIA 6.1	Ross, J.W.	2002	Detailed Assessment of Mancozeb Plant Metabolism Studies Mancozeb Task Force Report n°JWR TF-02-001 (ER Ref. 105.8) Position Paper Unpublished	
IIA 6.2 IIA 6.4	Ollinger, J.	2002	Available metabolism and feeding studies in livestock are sufficient to cover ETU and mancozeb levels from processed feeding products Mancozeb Task Force Report n°JO MZ0203 (ER Ref. 105.9) Position Paper Non 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 6.3	Perny, A.	1997	CS <sub>2</sub> : Magnitude of the residues in melons harvested at different dates after treatment with the preparation Sancozeb <sup>®</sup> (mancozeb) and at maturity in France. Anadiag S.A., Haguenau, France Dow Agro Sciences Report No. ID R 6081 DE (ER ref R119.5) GLP, Unpublished	
IIA 6.3 6.3/03	Perny, A.	1997	CS <sub>2</sub> : Magnitude of the residues in grapes harvested at different dates after treatment with the preparation Sancozeb <sup>®</sup> (mancozeb) and at maturity in France. Anadiag S.A., Haguenau, France Mancozeb Consortium Report No. / Study ID R 6089 DE (ER Ref. R119.2) GLP, Unpublished	
IIA 6.3 6.3/04	Perny, A.	1997	CS <sub>2</sub> : Magnitude of the residues in potatoes harvested at different dates after treatment with the preparation Sancozeb <sup>®</sup> (mancozeb) and at maturity in France. Anadiag S.A., Haguenau, France Dow AgroSciences Report No. / Study ID R 6079 DE (ER Ref. R119.7) GLP, Unpublished	
IIA 6.3 6.3/06	Perny, A.	1997	CS <sub>2</sub> : Magnitude of the residues in sugar beets harvested at different dates after treatment with the preparation Sancozeb <sup>®</sup> (mancozeb) and at maturity in France. Dow AgroSciences Anadiag S.A., Haguenau, France Report No. / Study ID R 6085 DE (ER Ref. R119.6) 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 6.3 6.3/07	Perny, A.	1997	CS <sub>2</sub> : Magnitude of the residues in tomatoes harvested at different dates after treatment with the preparation Sancozeb <sup>®</sup> (mancozeb) and at maturity in France.  Anadiag S.A., Haguenau, France Mancozeb Consortium Report No. / Study ID R 6087 DE (ER Ref. R119.3) GLP, Unpublished	
IIA 6.3 6.3/08	Puy, E.	1996	Magnitude of residues of mancozeb (as CS <sub>2</sub> ) & of ETU in grapes and in samples coming from vinification process after treatment of vine plots with Sancozeb under field conditions in France in 1995. (Degradation curves). Field part of the study.  Anadiag S.A., Haguenau, France Mancozeb Consortium Report No. / Study ID R 95023-ES (ER Ref. R119.4) GLP, Unpublished	
IIA 6.3 6.3/09	Puy, E.	1996	Mancozeb (as CS <sub>2</sub> ) magnitude of the residues in samples of grapes, must and wine coming from vines treated with Sancozeb in France in 1995.  Anadiag S.A., Haguenau, France Mancozeb Consortium Report No. / Study ID R 5042 (ER Ref. R119.4) GLP, Unpublished	
IIA 6.3	Harris, C.	2002	Summary of Dow Agrosiences mancozeb residue trials data on potatoes in response to ECCO 120 point 5.6 Mancozeb Mancozeb Task Force Report n°do03702 (ER Ref. R117.10) Position Paper Non 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 6.3 IIIA 8.2.	Barney, W.P.	2002	Magnitude of Mancozeb Residues from Application of Dithane M-45 Agricultural Fungicide to Bananas in Martinique (France). RCC Laboratories, Switzerland Mancozeb Consortium Report n° 785790 (ER Ref. 117.6) GLP. Unpublished	
IIA 6.3 IIA 6.5	Freedlander, R.S.	2002	Metabolites of toxic concern formed during processing requirement- Mancozeb Mancozeb Task Force Report n°KP-2002-35 (ER Ref. 105.10) Position paper GLP, Unpublished	
IIA 6.3 IIIA 8.2.	Galy, H	2001	Determination of Mancozeb (as CS2) residues in grapes raw agricultural commodity following treatments with the preparations Dithane M-45, Dithane DG, Dithane DG NT under field conditions in Europe in 1999. Mancozeb Consortium Report n° 9062. (ER Ref. R117.3 / 117.4 / 117.5) GLP. Unpublished	
IIA 6.3 6.3/03a	Rohm and Haas France	1995	Title: Apples France North 1989- 1990 Generated by : Rohm and Haas France Submitted by : Rohm and Haas France Ref. n. R78.14-R78.50 GLP, Unpublished	
IIA 6.3 6.3/03b	Rohm and Haas France	1995	Title: Apples France South 1989- 1990 Generated by : Rohm and Haas France Submitted by : Rohm and Haas France Ref. n. R73.18 – R73.15 –R79.4 – R73.17 – R73.21 – R78.12 – R73.13 – R73.14 GLP, Unpublished	
IIA 6.3 6.3/05	Rohm and Haas France	1995	Title: Apples Italy 1990 Generated by : Rohm and Haas France Submitted by : Rohm and Haas France Ref. n. R75.5 – R72.5	

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports on previous use in granting national authorizations</b>
IIA 6.3 6.3/22a	Rohm and Haas France	1995	Title: Grapes France North 1988-1989- 1990- 1991-1993 Generated by : Rohm and Haas France Submitted by : Rohm and Haas France Ref. n. R78.46 – R78.65 – R78.66 – R78.68 – R79.50 – R78.44 – R78.57	
IIA 6.3 6.3/22b	Rohm and Haas France	1995	Title: Grapes France South 1988-1989- 1990-1991-1993 Generated by : Rohm and Haas France Submitted by : Rohm and Haas France Ref. n. R78.64 – R78.71 – R79.8 – R79.13 – R79.16 – R78.94 – R78.62 – R79.5 – R79.26 – R79.30 – R79.65 – R79.73 – R79.45 – R80.13 – R80.24 – R80.34 – R85.21	
IIA 6.3 6.3/22c	Rohm and Haas France	1995	Title: Grapes (wine only) France N/S Generated by : Rohm and Haas France Submitted by : Rohm and Haas France Ref. n. R79.1 – R78.89 – R78.78 – R78.2 – R78.85 –	
IIA 6.3 6.3/24a	Rohm and Haas France	1995	Title: Grapes Italy 1989 – 1990 Generated by : Rohm and Haas France Submitted by : Rohm and Haas France Ref. n: R72.1 – R75.1	
IIA 6.3 6.3/24b	Rohm and Haas France	1999	Title: Grapes Italy 1996-1997 Generated by : Rohm and Haas France Submitted by : Rohm and Haas France Ref. n: R98.6-R107.3-R108.1-R106.1	
IIA 6.3 6.3/25a	Rohm and Haas France	1995	Title: Grapes Portugal 1991 Generated by : Rohm and Haas France Submitted by : Rohm and Haas France Ref. n. R80.27	
IIA 6.3 6.3/25b	Rohm and Haas France	1999	Title: Grapes Portugal 1998 Generated by : Rohm and Haas France Submitted by : Rohm and Haas France Ref. n. R98.8	

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 6.3/25 bis	Rohm and Haas France	1999	Title: Grapes Spain 1998 Generated by : Rohm and Haas France Submitted by : Rohm and Haas France Ref. n. R98.7	
IIA 6.3 6.3/35	Rohm and Haas France	1995	Title: Potatoes France 1990 – 1991 – 1992 Generated by : Rohm and Haas France Submitted by : Rohm and Haas France Ref. n. R79.27 – R78.4 – R78.6 – R78.10 – R78.22 – R78.23 – R78.25 – R78.24 – R78.27 - R78.28 – R78.29 – R78.60 – R78.61 – R79.55 – R79.58 – R84.20 – R84.3 – R84.2 – R78.26	
IIA 6.3 6.3/40a	Rohm and Haas France	1995	Title: Tomatoes France 1973 – 1990 – 1991 – 1992 (open field) Generated by : Rohm and Haas France Submitted by : Rohm and Haas France Ref. n. R69.16 – R79.44 – R77.41 – R78.53 – R80.8 – R79.43 – R85.7	
IIA 6.3 6.3/40b	Rohm and Haas France	1997	Title: Tomatoes France 1995 (open field) Generated by : Rohm and Haas France Submitted by : Rohm and Haas France Ref. n. R95.5	
IIA 6.3 6.3/40c	Rohm and Haas France	1995	Title: Tomatoes France 1992 (glasshouse) Generated by : Rohm and Haas France Submitted by : Rohm and Haas France Ref. n. R85.7	
IIA 6.3 6.3/43	Rohm and Haas France	1995	Title: Tomatoes Portugal 1990 Generated by : Rohm and Haas France Submitted by : Rohm and Haas France Ref. n. R79.53 – R79.54	

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 6.3/44a	Rohm and Haas France	1995	Title: Tomatoes Spain 1990 – 1991 – 1992 Generated by : Rohm and Haas France Submitted by : Rohm and Haas France Ref. n. R80.30 – R83.3 – R83.4 – R79.20- R79.19	
IIA 6.3 6.3/44b	Rohm and Haas France	1997	Title: Tomatoes Spain 1996 Generated by : Rohm and Haas France Mancozeb Consortium Ref. n. R97.1 GLP, Unpublished	
IIA 6.3 6.3/45	Wais, A	1997	Title: Determination of residues of RH-117281 and mancozeb in/on potatoes (RAC tubers) following treatment with RH-7281 2F and Dithane/RH-117,281 75 DG blend from field trials in Germany:1997 Generated by : RCC Project No. 652252 Submitted by : Rohm and Haas France Ref. n. R64.4	
IIA 6.3 6.3/46	Wais, A	1997	Title: Determination of residues of RH-117281 and mancozeb in/on potatoes (RAC tubers) following treatment with RH-7281 2F and Dithane/RH-117,281 75 DG blend from field trials in the U.K. :1997 Generated by : RCC Project No. 652263 Submitted by : Rohm and Haas France Ref. n. R65.5	
IIA 6.3 6.3/47	Wais, A	1998	Title: Determination of residues of RH-117281 and mancozeb in/on potatoes (RAC tubers) following treatment with Dithane/RH-117,281 75 DG blend (8:1) and Dithane/RH-117,281 75 WP blend (8:1) from two field trials in Germany; 1998 Generated by : RCC Project No. 688904 Submitted by : Rohm and Haas France Ref. n. R68.1	

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	Ross, J.W.	2002	Assessment of Mancozeb Crop Storage Stability Studies. Mancozeb Task Force Report n°JWR TF-02-002 (ER Ref. R117.9) Position Paper Non GLP, Unpublished	
IIA 6.3 IIA 6.5 IIIA 8.4	Wais, A.	2001	Determination of residues of Mancozeb and ETU in/on Potato (RAC Tubers) following treatment with Dithane M-45 fungicide from one field trial (harvest trial) in Germany; 2000. RCC Laboratories, Switzerland Mancozeb Consortium Study n° RCC 771761 (ER Ref. R112.1) GLP, Unpublished	
IIA 6.3	Purghart, V.	2002	Residual analysis of grass samples and <i>Poecilus cupreus</i> treated with Dithane M-45. Springborn Laboratories study number 1007.075.252, Mancozeb Consortium Report N°01RC-0230. (ER Ref. 104.4) GLP, unpublished	
IIA 6.3 IIA 6.5 IIIA 8.4	Wais, A.	2001	Determination of residues of Mancozeb and ETU in/on Potato (RAC Tubers) following treatment with Dithane M-45 fungicide from three field trials (harvest trials) in UK; 2000. RCC Laboratories, Switzerland Mancozeb Consortium Study n° RCC 771772 (ER Ref. 110.7) GLP, Unpublished	
IIA 6.3 IIA 6.5 IIIA 8.4	Wais, A.	2001	Determination of residues of Mancozeb and ETU in/on Potato (RAC Tubers) following treatment with dithane m-45 fungicide from two field trials (harvest trials) in Italy; 2000. RCC Laboratories, Switzerland Mancozeb Consortium Study n° RCC 771794 (ER Ref. R112.2) 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 6.3	Harris, C	2002	Summary of Dow Agrosiences mancozeb residue trials data with additional storage/processing information. Response to ECCO 120 Point 5.5. Mancozeb Task Force Report n°do03702 (ER Ref. R117.8) Non GLP, Unpublished	
IIA 6.5 IIIA 8.4 6.5/01	Johnson, G.E.	1990	EBDC/ETU Consumer Practice Study. Rohm and Haas Study # ETU 90-02. Generated by: EN-CAS Analytical Laboratories Submitted by: Rohm and Haas Co. Report/file No.: ER Ref No. R 84.50 Report/file No.: ETU 90-02 Date of report: September 7, 1990. GLP, Unpublished	
IIA 6.5 IIIA 8.4 6.5/03	Ollinger, J., Lyman, W.R., and Larkin, R.H.	1986	Food Processing Studies for Potatoes Treated with Mancozeb. Rohm and Haas Technical Report # 31O-86-16. Generated by: National Food Laboratory, Inc. Submitted by: Rohm and Haas Co. Report/file No.: ER Ref No. R 63.4 Report/file No.: 31O-86-16 GLP(part yes), Unpublished	
IIA 6.5 IIIA 8.4 6.5/06	Ollinger, J., Lyman, W.R., and Larkin	1986	Food Processing Studies for Grapes Treated with Mancozeb. Rohm and Haas Technical Report # 31O-86-15. Generated by: National Food Laboratory, Inc. Submitted by: Rohm and Haas Co. Report/file No.: ER Ref No. R 63.1 Report/file No.: 31O-86-15 GLP(part yes), 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 IIIA 8.4 6.5/12	Ollinger, J., Lyman, W.R., and Larkin, R.H.	1986	Food Processing Studies for Tomatoes Treated with Mancozeb. Rohm and Haas Technical Report # 31O-86-14.  Generated by: National Food Laboratory, Inc.  Submitted by: Rohm and Haas Co.  Report/file No.: ER Ref No. R 63.3 Report/file No.: 31O-86-14  GLP(part yes), Unpublished	
IIA 6.5 IIIA 8.4 6.5/13	Slesinski, R.S.	1990	EBDC/ETU National Food Survey, Fourth Quarter and Final Report. Report # ETU 90-09.  Generated by: Morse Laboratories, Inc., McKenzie Laboratories, Inc., EN-CAS Analytical Laboratories  Submitted by: Atochem North America, Inc., BASF Corporation, E.I. DuPont de Nemours and Company, Inc, and Rohm and Haas Company. The independent research contractor who conducted the survey was Technical Assessment Systems, Inc., Washington, DC.  Report/file No.: ER Ref No. R 84.50 Report/file No.: ETU 90-09  GLP, Unpublished	
IIA 6.5.2 6.5.2/01	Puy, E.	1996	Magnitude of residues of mancozeb (as CS <sub>2</sub> ) & of ETU in samples coming from vinification process after treatment of vine plots with Sancozeb under field conditions in France in 1995. Wine processing.  Anadiag S.A., Haguenau, France  Mancozeb Consortium  Report No. / Study ID R 95023-VN (ER Ref, R119.4)  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 6.5.2 6.5.2/02	Puy, E.	1996	Mancozeb (as CS <sub>2</sub> ) magnitude of the residues in samples of grapes, must and wine coming from vines treated with Sancozeb in France in 1995. Anadiag S.A., Haguenau, France Mancozeb Consortium Report No. / Study ID R 5042 (ER Ref. R119.4) GLP, Unpublished	
IIA 6.5.2 6.5.2/03	Puy, E.	1996	ETU - Magnitude of the residues & of ETU in samples of must and wine. Anadiag S.A., Haguenau, France Mancozeb Consortium Report No. / Study ID R 5043 (ER Ref R119.4) GLP, Unpublished	
IIA, 6.6 6.6/01	Merricks D.L.	1993	14C-Maneb confined rotational crop study. Agriseach Incorporated 26 Water Street Frederik MD. Cerexagri s.a. Report n°CRX_28C8-VXAW GLP, Unpublished	
IIA 6.1 IIIA 8.1.1 8.1.1/8	Hanauer, R.	1996	Metabolism and Degradation of 14C-mancozeb in Field Treated Potatoes Generated by: Rohm and Haas Co. Mancozeb Consortium Report/file No.: ER Ref No. 88.1 Report/file No.: 3495142 Unpublished	
IIA 6.5 IIIA 8.4 8.4/6	Anonymous	1994	Title: Determination of the Magnitude of the Residue due to Mancozeb and ETU in Potato Processed Fractions Generated by: Rohm and Haas Company Submitted by: Rohm and Haas Company Report/file No.: ER Ref No. R 92.6 Report/file No.: 348915 Unpublished	

**B.8 Environmental fate and behaviour**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports on previous use in granting national authorizations</b>
IIA 7.1.1	de Vette H.Q.M., van Hasten, J.G., and Hanstueit, A.O.	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). TNO Nutrition and Food Mancozeb Consortium Report n°V99.137 (ER ref 113.01) GLP, Unpublished	
IIA 7.1.1.2.1/ IIIA 9.1.1.1.1	Dressel, J	2001	Compilation of aerobic soil half lives and soil adsorption of ETU, EU, EBIS, Carbimide and EDA (metabolites of EBDC Fungicides) December 17 <sup>th</sup> , 2001 Mancozeb Consortium Report No. CALC-288 (ER Ref. 104.6) Not GLP, Unpublished	
IIA 7.1.1	Kuenemann, P.	2002	Position paper on the relevance of ETD Mancozeb Task Force Report n°ER Ref. 104.11 Not GLP, Unpublished	
IIA 7.1.1	Kuenemann, P.	2002	Position paper on the relevance of EBIS Mancozeb Task Force Report n°ER Ref. 104.14 Not GLP, Unpublished	
IIA 7.1.1	Ollinger, J.	2002	2-imidazole is not a relevant mancozeb metabolite under anaerobic soil conditions Mancozeb Task Force Report n°MZCONS-0201 (ER Ref. 104.14) Position paper Not GLP, Unpublished	
IIA 7.1.1 IIIA 9.1.1	Wright, M.C	2000	Aerobic soil metabolism degradation rate determination for ethylenethiourea (ETU) on soil. Mancozeb Consortium Report n°RPT00643 (ER Ref. 103.6) 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 7.1.2	Connolly, P.	2002	Ethylene urea Final report-Tier I. Adsorption/desorption of ethylene urea on European soils EDBC/ETU Task Force Report n°009-013 (ER Ref. 103.7) GLP, Unpublished	
IIA 7.1.3.3 IIIA 9.1.2.2	J. Boland, S.Q. Broerse, A.A. Cornelese, A.M.A. van der Linden, R.A. Baumann, W. de Graaf, H.A.G. Heusinkveld	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) - The Netherlands Mancozeb Consortium Report n°CRX_L2N0-TXH8 (ER Ref 83.1) GLP, Unpublished	
IIA 7.2.1.3.1	Ectors, A	1995	Biodegradation Study of Sancozeb 800WP CO <sub>2</sub> Evolution Test LISEC, Genk, Belgium Mancozeb Consortium Report n°ID WB-04-071 GLP, Unpublished	
IIA 7.2.1.3.2	Müller-Kallert, H.-M.	1994	<sup>14</sup> C-Mancozeb: Degradation and Metabolism in Aquatic Systems. RCC Umweltchemie AG- Switzerland Dow Agro Sciences Report n°ER Ref No. 69.3 GLP, Unpublished	

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports on previous use in granting national authorizations</b>
IIIA 9.1.1	Cornelese, A.A., de Jong, P.G.H., van der Linden, A.M.A. Baumann, R.A.	1994	Behaviour of ETU in soil from two Dutch Fields. RIVM, Laboratory for Soil and Groundwater Research and for Organic Analytical Chemistry, Ministry of Public Health and Environmental protection, A. v. Leeuwenhoek laan 9, 3721 Bilthoven - Holland, Project No. 715802 Mancozeb Consortium Report n°82.15 (US Ref No. 94RC-1099) GLP, Unpublished	
IIIA 9.2.1	Dressel, J	2001	Predicted Environmental Concentrations (PEC) of metabolite ETU in Groundwater after application of Mancozeb formulations to different crops. EDBC/ETU Task Force Report n°CALC-296 (ER Ref. 104.13) Not GLP, Unpublished	
IIIA 9.2.2	Buerge, I.	2000	Dithane® M-45: Activated sludge respiration inhibition test. Springborn Laboratories (Europe) AG Mancozeb Consortium Report n°92.7 (US Ref No. 99RC-0234) GLP, Unpublished	

**B.9 Ecotoxicology**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports on previous use in granting national authorizations</b>
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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	Reports on previous use in granting national authorizations
IIA, 8.1 8.1.3/01	Hakin, B. Johnson, A.J. Chanter, D.O.	1990	The effects of dietary inclusion of mancozeb on reproduction in the mallard duck.  Generated by:Huntingdon Research Centre Submitted by:Rohm and Haas Company ER Company file No.:77.1 GLP, Unpublished	
IIA, 8.1 8.1.3/02	Beavers, J.B. Marselas, G. Smith, G.J. Jaber, M.J	1990	Mancozeb:A one-generation reproduction study with the mallard ( <i>Anas platyrhynchos</i> ).  Generated by:Wildlife International Submitted by:Rohm and Haas Company ER Company file No.: 78.1 GLP, Unpublished	
IIA, 8.1 8.1.3/03	Hakin, B. Johnson, A.J. Chanter, D.O.	1990	The effects of dietary inclusion of mancozeb on reproduction in the bobwhite quail.  Generated by:Huntingdon Research Centre Submitted by:Rohm and Haas Company ER Company file No.: 78.3 GLP, Unpublished	
IIA 8.2 IIIA 10.2	Dohmen G	2002	Risk assessment for ethylenethiourea (ETU) a common metabolite of EBDC fungicides BASF Aktiengesellschaft, Limburgerhof, Germany EDBC/ETU Task Force Report n°2002/1006139 (ER Ref. 106.7) Position Paper	
IIA 8.2.1	Palmer S. J. et al.	2001	Ethylene Urea: A 96-hour static acute toxicity test with the rainbow trout ( <i>Oncorhynchus mykiss</i> ) Wildlife International Ltd., USA EBDC/ETU Task Force Report n°2001/5000987 (ER Ref. 97.5) GLP, Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 8.2.1	Rhodes, J.E.	2000	Acute toxicity study of Dithane M-45 to the Rainbow Trout ( <i>Ocorhynchus mykiss</i> ) determined under flow-through test conditions. ABC laboratories Dow AgroSciences Report n°00RC-0114 (ER Ref. 94.1) GLP, Unpublished	
IIA 8.2.1	Rhodes, J.E.	2000	Acute Toxicity of Dithane M-45 to the Bluegill Sunfish ( <i>Lepomis macrochirus</i> ) determined under Flow-Through Test Conditions. Dow AgroSciences Report n°00RC-0115, (ER Ref. 94.2) GLP, Unpublished	
IIA 8.2.1	Zok, S.	2001	Acute toxicity study on the rainbow trout ( <i>Oncorhynchus mykiss</i> WALBAUM 1792) in a static system (96 hours). BASF Aktiengesellschaft, Ludwigshafen, Germany EDBC/ETU Task Force Report n°2001/1001877 (ER Ref. 97.1) GLP, Unpublished	
IIA, 8.2 8.2.5/02	Graves, D. Mank, M. Swigert, J.	1995	A flow-through life-cycle toxicity test with the cladoceran ( <i>Daphnia magna</i> ) Generated by: Wildlife International, Inc. Submitted by: Rohm and Haas Company ER Company file No.:85.14 No GLP, Published	
IIA, 8.2 8.2.5/01a 8.2.6/01b	Burgess, D.	1988	Chronic toxicity of Dithane® M-45 to <i>Daphnia magna</i> under flow-through test conditions. Generated by: ABC Submitted by: Rohm and Haas Company ER Company file No.:M45-5-1 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 8.2.2	Zok, S.	2002	Xenopus laevis metamorphosis assay (ETU) BASF Aktiengesellschaft, Ludwigshafen, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany EDBC/ETU Task Force Report n°2002/1003402 (ER Ref. 104.3) GLP, Unpublished	
IIA, 8.2 8.2.6/02a 8.2.7/01b	Forbis, A.	1990	Acute toxicity of Dithane® M-45 Fungicide to <i>Selenastrum capricornutum</i> Printz. Generated by:ABC Submitted by: Rohm and Haas Company ER Company file No.: 77.12 GLP, Unpublished	
IIA 8.2.3	Rhodes J.E., Downing J., Bielefeld T	1994	Early life-stage toxicity of Mancozeb to Fathead Minnow ( <i>Pimephales promelas</i> ) under flow-through conditions ABC Laboratories Inc. Environmental Toxicology - Missouri 65205 Mancozeb consortium Report n°CRX_GPYS-FNNG (ER Ref. 78.2) GLP, Unpublished	
IIA 8.2.4	Rhodes, J.E.	2000	Acute Toxicity of Dithane M-45 to the Water Flea, <i>Daphnia magna</i> , determined Under Flow-Through Test Conditions Dow AgroSciences Report n°00RC-0116 (ER Ref. 94.3) GLP, Unpublished	
IIA, 8.1.2 8.1.2/01	Roberts, N. Hakin, B.	1989	The dietary toxicity (LC50) of Mancozeb technical to the Bobwhite quail Huntingdon Research Centre Ltd. Huntingdon Cambs, PE 18 6ESEngland Elf Atochem Agri 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 8.1.2/02	Roberts, N. Hakin, B.	1989	The dietary toxicity (LC50) of Mancozeb technical to the Mallard duck Huntingdon Research Centre Ltd. Huntingdon Cambs, PE 18 6E England Elf Atochem Agri GLP, Unpublished	
IIA, 8.2.1 8.2.1/01	Douglas M.T., Handley J.W. and McDonald I.A. a	1988	The acute toxicity of Mancozeb Technical to Rainbow trout ( <i>Salmo gairdneri</i> ) Huntingdon Research Centre Ltd. Huntingdon Cambs PE18 6ES England Elf Atochem Agri GLP, Unpublished	
IIA, 8.2.1 8.2.1/02	Douglas M.T., Handley J.W. and McDonald I.A. b	1988	The acute toxicity of Mancozeb Technical to Bluegill sunfish ( <i>Lepomis macrochirus</i> ) Huntingdon Research Centre Ltd. Huntingdon Cambs PE18 6ES England Elf Atochem Agri GLP, Unpublished	
IIA, 8.4 8.3.3.1	Roberts, N. Hakin, B.	1986	The acute toxicity (LC50) of Dithane <sup>®</sup> M-45 to the earthworm <i>Eisenia foetida</i> . Generated by: Huntingdon Research Centre Submitted by: Rohm and Haas Company ER Company file No.: M45-38-5 No GLP, Unpublished	
IIA, 8.1.3 8.1.3/01	Johnson, A.J.	1993	Mancozeb - Reproduction in the Bobwhite Quail Huntingdon Research Centre Ltd. P.O. Box 2 Huntingdon Cambs, PE18 6ES The UK Elf AtoChem Agri 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 8.3.2/01	Kühner, C.	1993	Assessment of side effects (initial toxicity) of Dithane® Ultra WG on the larvae of the green lacewing, <i>Chrysoperla carnea</i> Steph. (Neuroptera, Chrysopidae) under semi-field conditions.  Generated by:GAB Biotechnologie Mancozeb consortium ER Company file No.:M45-68-8 GLP, Unpublished	
IIA, 8.3.2 8.3.2/03	Kühner, C.	1994	Assessment of side effects (persistent toxicity) of Dithane® Ultra WG on adults of <i>Trichogramma cacoeciae</i> Marchal (Hymenoptera, Trichogrammatidae) as a representative of the microhymenoptera under semi-field conditions.  Generated by:GAB Biotechnologie Mancozeb consortium ER Company file No.:M45-68-7 GLP, Unpublished	
IIA, 8.3.2 8.3.2/02	Tornier, I.	1993	Assessment of side effects (initial toxicity) of Dithane® Ultra WG on the larvae of the hoverfly, <i>Episyrphus balteatus</i> DEG (Diptera, Syrphidae) under semi-field conditions.  Generated by: GAB Biotechnologie Mancozeb consortium ER Company file No.:M45-68-6 GLP, Unpublished	
IIA, 8.6 8.3.5/02	Musco, V.	1994	Herbicide screening test with Dithane® M-45.  Generated by:Rohm and Haas Company Mancozeb consortium ER Company file No:79.4 No 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	Hisgen, M.	2000	Determination of the acute effect on the swimming ability of the water flea <i>Daphnia magna</i> STRAUS. BASF Aktiengesellschaft, Ludwigshafen, Germany EDBC/ETU Task Force Report n°2000/1017216 (ER Ref. 95.5) GLP, Unpublished	
IIA 8.2.5	Palmer S. J. et al..	2001	Ethylene Urea: A 48-hour static acute toxicity test with the cladoceran ( <i>Daphnia magna</i> ) Wildlife International Ltd., USA EDBC/ETU Task Force Report n°2001/5000988 (ER Ref. 97.7) GLP, Unpublished	
IIA, 8.2.5 8.2.5/02	Douglas M.T., Handley J.W., and McDonald I.A. c	1988	The acute toxicity of Mancozeb technical to <i>Daphnia magna</i> Huntingdon Research Centre Ltd. Huntingdon Cambs PE18 6ES England Elf Atochem Agri GLP, Unpublished	
IIA 8.2.7	Palmer, S. et al.	2001	Ethylene Urea: A 96-hour toxicity test with the freshwater alga ( <i>Selenastrum capricornutum</i> ) Wildlife International Ltd., USA EDBC/ETU Task Force Report n°2001/5000986 (ER Ref. 97.6) GLP, Unpublished	
IIA 8.2.7	Reuschen-bach P.	2000	Determination of the inhibitory effect on the cell multiplication of unicellular green algae BASF, Aktiengesellschaft, Ludwigshafen, Germany EDBC/ETU Task Force Report n°2000/1017191 (ER Ref. 95.6) GLP, Unpublished	
IIA 8.4.1	Staab, F.	2001	Effect of BF 222-EU on the mortality of the earthworm <i>Eisenia fetida</i> BASF Aktiengesellschaft, Limburgerhof, Germany EDBC/ETU Task Force Report n°2001/1000881 (ER Ref. 97.3) 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 8.5	Krieg, W.	2001	Effect of BF 222-ETU on carbon transformation of the soil microflora BASF Aktiengesellschaft, Limburgerhof, Germany EDBC/ETU Task Force Report n°2001/1000909 (ER Ref. 97.9) GLP, Unpublished	
IIA 8.5	Krieg, W.	2001	Effect of BF 222-ETU on nitrogen transformation of the soil microflora BASF Aktiengesellschaft, Limburgerhof, Germany EDBC/ETU Task Force Report n°2001/1000109 (ER Ref. 97.8) GLP, Unpublished	
IIA 8.5	Krieg, W.	2001	Effect of BF 222-EU on carbon transformation of the soil microflora BASF Aktiengesellschaft, Limburgerhof, Germany EDBC/ETU Task Force Report n°2001/1000910 (ER Ref. 97.11) GLP, Unpublished	
IIA 8.5	Krieg, W.	2001	Effect of BF 222-EU on nitrogen transformation of the soil microflora BASF Aktiengesellschaft, Limburgerhof, Germany EDBC/ETU Task Force Report n°2001/1000108 (ER Ref. 97.10) GLP, Unpublished	
IIA 8.5	Ramsay, R.	1994	Insecticidal activity of Dithane <sup>®</sup> M-45N. Mancozeb Consortium Report n°ER Ref. 79.5 No GLP, Unpublished	
IIIA 10.1.1	Leopold, MA, van Dreumel, IF	1995	Acute Oral Toxicity Study in Japanese Quail with Sancozeb 800WP NOTOX, 's-Hertogenbosch, The Netherlands Mancozeb Consortium Report n°WE-14-001 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
IIIA 10.2.1	Brouwers, T	1995	Acute Toxicity of Sancozeb 800WP for fish, <i>Brachydanio rerio</i> LISEC, Genk, Belgium Dow AgroSciences LISEC Study No. WE-03-126 GLP, Unpublished	
IIIA 10.2.1	Brouwers, T	1995	Acute Toxicity of Sancozeb 800WP for <i>Daphnia magna</i> LISEC, Genk, Belgium Dow AgroSciences Report n°WE-01-165 GLP, Unpublished	
IIIA 10.2.1	Brouwers, T	1995	Alga, growth inhibition test – effect of Sancozeb 800WP on the growth of <i>Selenastrum capricornutum</i> LISEC, Genk, Belgium Dow AgroSciences Report n°WE-06-095 GLP, Unpublished	
IIIA 10.2.1	Purghart, V	2002	Residual analysis of grass samples and <i>Poecilus cupreus</i> treated with Dithane M-45. Springborn Laboratories study number 1007.075.252 Mancozeb Consortium Report n°01RC-0230. (ER Ref. 104.4) GLP, unpublished	
IIIA 10.2.1	Wuthrich V. a	1993	Penncozeb 80 WP : 96-hours acute toxicity study in the Rainbow Trout under flow-through conditions RCC Umweltchemie AG. Switzerland Cerexagri s.a. Report n°CRX_BDFP-1ITH GLP, Unpublished	
IIIA 10.2.1	Wuthrich V. b	1993	Penncozeb 80 WP : 96-hours acute toxicity study in the Mirror Carp under flow-through conditions RCC Umweltchemie AG, Switzerland Cerexagri s.a. Report n°CRX_53C4-5BFL 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
IIIA 10.2.1	Wuthrich V. c	1993	48-hour acute toxicity of Penncozeb 80 WP to <i>Daphnia magna</i> (OECD-immobilization test) RCC Umweltchemie AG, Switzerland Cerexagri s.a. Report n°CRX_TG4J-O3YS GLP, Unpublished	
IIIA 10.2.2	Madsen, T.J.	2002	Mancozeb: Static acute toxicity tests conducted with ten species of freshwater fish exposed in a sediment-water system. Mancozeb Consortium, unpublished report. ABC Laboratories Mancozeb Consortium Report n°47737 (ER Ref. 106.9) GLP, Unpublished	
IIIA 10.2.2	Peither A.	2002 a	Acute toxicity of Penncozeb 80 WP to the rotifer species <i>Brachyonus calyciflorus</i> in a 24-hour immobilization test. RCC, Environmental Chemistry and Pharmanalytics Division, CH-4452 Itingen/Switzerland Mancozeb Consortium Report n°837527 ; (ER Ref. 104.2) GLP, unpublished	
IIIA 10.2.2 Addendum 2 (January 2003)	Peither A.	2002 b	Acute toxicity of Penncozeb 80 WP to the freshwater snail <i>Lymnea stagnalis</i> in a 48-hour immobilization test RCC, Environmental Chemistry and Pharmanalytics Division, CH-4452 Itingen/Switzerland Mancozeb Consortium Report n°837450 (ER Ref. 103.10) GLP, unpublished	
IIIA 10.2.2	Peither A.	2002 c	Acute toxicity of Penncozeb 80 WP to crustacean species <i>Gammarus sp</i> in a 48-hour immobilization test. RCC, Environmental Chemistry and Pharmanalytics Division, CH-4452 Itingen/Switzerland Mancozeb Consortium Report n°837483 (ER Ref. 103.11) 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
IIIA 10.2.2	Peither A.	2002 d	Acute toxicity of Penncozeb 80 WP to crustacean species <i>Asellus sp.</i> in a 48-hour immobilization test. RCC, Environmental Chemistry and Pharamanalytics Division, CH-4452 Itingen/Switzerland Mancozeb Consortium Report n°837505 (ER Ref. 104.1) GLP, unpublished	
IIIA 10.2.4	Brouwers, T	1995	Fish Prolonged Toxicity Test with Sancozeb 800WP LISEC, Genk, Belgium Dow Agro Sciences Report n°WE-04-002 GLP, Unpublished	
IIIA 10.2.4	Brouwers, T	1995	Effect of Sancozeb 800WP on the Reproduction of <i>Daphnia magna</i> LISEC, Genk, Belgium Dow Agro Sciences Report n°WE-02-038 GLP, Unpublished	
IIIA 10.4.1	Schmitzer, S	1995	Laboratory Testing for Toxicity (Acute, Contact and Oral LD50) of Mancozeb 800WP to Honey Bees ( <i>Apis mellifera</i> L.) (Hymenoptera, Apidae) IBACON, Rossdorf, Germany Mancozeb Consortium Report n°400036 GLP, Unpublished	
IIIA 10.4.1	Tornier, I.	1995	Assessment of side effects of Manex II to the honey bee, <i>Apis mellifera</i> L. in the laboratory following EPPO guideline No. 170. GAB Biotechnologie GmbH, Bericht Nr. 94115/01-BLEU. Dow Agro Sciences Report n°ER Ref 86.21 (US Ref No: 95RC-1047) 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
IIIA 10.5.1	Klepka, S	1995	Effects of Sancozeb 800WP on <i>Aphidius rhopalosiphi</i> (Hymenoptera, Aphidiidae) in the Laboratory IBACON, Rossdorf, Germany Project No. 600003 GLP, Unpublished	
IIIA 10.5.1	Kuhner, C. a	1995	Assessment of Side Effects of Manex II SC on the aphid parasitoid, <i>Aphidius rhopalosiphi</i> (Hymenoptera, Aphididae) in the laboratory. GAB Biotechnologie GmbH, Bericht Nr. 94115/01-NLAp. Dow Agro Sciences Report n°ER Ref 86.24 (US Ref No: 95RC-1050) GLP, Unpublished	
IIIA 10.5.1	Kuhner, C. b	1995	Assessment of Side Effects of Manex II SC on the ground beetle, <i>Poecilus cupreus</i> L. (Coleoptera Carabidae) in the laboratory. GAB Biotechnologie GmbH, Bericht Nr. 94115/01-NLPc. Dow Agro Sciences Report n°ER Ref 86.23 (US Ref No: 95RC-1049) GLP, Unpublished	
IIIA 10.5.1	Kuhner, C. c	1995	Assessment of Side Effects of Manex II SC on the green lacewing, <i>Chrysoperla carnea</i> Steph. (Neuroptera, Chrysopidae) in the laboratory, 12.04.1995 GAB Biotechnologie GmbH, Bericht Nr. 94115/01-NLCC. Dow Agro Sciences Report n°ER Ref 86.22 (US Ref No: 95RC-1048) GLP, Unpublished	
IIIA 10.6.1.1	Van Erp, YHM	1995	Acute Toxicity Study in the Earthworm with Sancozeb 800WP NOTOX, 's-Hertogenbosch, The Netherlands LISEC, Genk, Belgium Dow Agro Sciences Report n°WE-08-001 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
IIIA 10.6.1.2	Nienstedt, K.	1999	A chronic toxicity and reproduction test exposing the earthworm <i>Eisenia foetida</i> to Dithane® M-45 in OECD artificial soil. Springborn Laboratories (Europe) AG Study No. 1007.054.630 Mancozeb consortium Report n°ER Ref 92.4 (US Ref No. 99RC-0124) GLP, Unpublished	
IIIA 10.7.1	Ectors, A	1995	Effect of Sancozeb 800WP on the Nitrification in Soil LISEC, Genk, Belgium Dow Agro Sciences Report n°WE-12-001 GLP, Unpublished	
IIIA 10.7.1	van der Kolk, J.	1998	Dithane® M-45: Determination of the effects on soil microflora activity. Springborn Laboratories (Europe) AG, Horn, Switzerland Mancozeb consortium Report n°97-061-1007 (ER Ref. 90.21) GLP, Unpublished	

Mancozeb Consortium = DowAgroSciences and Cerexagri s.a.

EDBC/ETU Task Force = DowAgroSciences and Cerexagri s.a. and BASF AG and Du Pont de Nemours

Mancozeb Task Force = DowAgroSciences and Cerexagri s.a. and Du Pont de Nemours

**APPENDIX IIIB****MANCOZEB**

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**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>
IIA, 1.1	Rohm and Haas Company	1994	Material Safety Data Sheet
IIA, 1.1	Tennant, T.	1994	Laboratory Report Report No: 107994-001 ONEIDA RESEARCH SERVICE, INC.
95/8	Clayton, B.	2000	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 GLP, Unpublished
	Wright, M.C.	2000	Extraction Recovery for Ethylenethiourea (ETU) in soil

**B.6 Toxicology and metabolism**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>
IIA 5.4	Leconte, F.	2002	Position paper regarding comments made by ECCO meeting 118 on genotoxicity of Mancozeb technical - Chromosomal aberration STUDY (Mukherjee, 1999)
IIA 5.4	Dr R. S. Banerjee	2002	Clarifications about Report n. 1812 entitled "Chromosomal aberration study of Mancozeb technical in mice". Jay Research Foundation

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>
IIA 5.6	Manish V. Patel, R. S. Banerjee	2002	Explanation/clarification on NOAEL for maternal toxicity". Jay Research Foundation
IIA 5.6	Leconte, F.	2002	Position paper regarding comments made by ECCO meeting 118 on point 5.4.2 reproductive toxicity of Mancozeb technical - Teratology study (Manish V. Patel)"

**B.7 Residue data**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>
IIA 6.3 IIA 6.5 6.31	Jay, P., Derly, G.	2002	Residue Determination of Mancozeb in raw and processed tomato fruits (washed canned peeled, puree, ketchup, juice and pomace) following 5 applications of mancozeb 75% WG formulation. Study carried out in Northern and Southern France and Italy in year 2001. Source: BIOTEK Agriculture Company: Mancozeb Consortium Report No. EU-GLP/227 F-1/01/TM ER Ref. R117.7 GLP, Unpublished
IIA 6.3 IIA 6.5 IIIA 8.4 6.5/14	Satterthwaite, S.T.	1986	Analytical Reports of Mancozeb and ETU residues for processed apple samples. Submitted by Dow Agrosciences Technical report n° 310-86-12 No GLP, Unpublished
IIA 6.3 IIA 6.5 6.5/19	Marshall, W.	1977	Thermal decomposition of Ethylenbisditithiocarbamate Fungicides to Ethylenethiourea in Aqueous Media J. Agric. Food Chem. 25 (2), 357 (1977) Published
IIA 6.3 IIIA 8.2 6.3/50	Waiss, A.	2001	Determination of Residues of Mancozeb and ETU in/on Potatoes (RAC tubers) Following Treatment with Dithane M-45 Fungicide from Two Field Trial (Harvest Trials) in Spain; 2000. Source: RCC, Ltd., Switzerland Company: Mancozeb Consortium Report No.: 771783 ER Ref. No. R112.3 GLP, Unpublished

**B.8 Environmental fate and behaviour**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>
IIIA 9.2.1/ 9.2.3	Kuenemann, P	2001	Risk of ETU ground water contamination further to application of EBDC fungicides Relevance of Dutch study to EU conditions December 17 <sup>th</sup> , 2001, Not GLP, Unpublished
IIA 7.2.1	Krieger, M. S.	2002	Calculation of the half-life of EBIS in water-sediment systems. (position paper)
IIA 7.1.3.2; IIIA 9.1.2.1	Bogaards J.J.P., Hanstveit A.O., Mol J.G.J., van Schöll I.	2002	Determination of leaching of aged residues of Mancozeb on a soil column. (SETAC-Europe, OECD Draft) TNO Rept No. 4084/01(ER Ref. 106.6) GLP, Unpublished

**B.9 Ecotoxicology**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>
IIA, 8.4.1	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
IIIA, 10.2.1	Kramer,V  POSITION PAPER	2002	A refined higher tier risk assessment on the effects of mancozeb fungicide used in orchards, vineyards and field crops on the terrestrial vertebrates in Europe Lab Rept Code GHE-P-9646 February 6 <sup>th</sup> , 2002 Non GLP, Unpublished
-	Zedet, S  POSITION PAPER	2001	"Mancozeb Endocrine Disruption Issues". October 2001 Non GLP, Unpublished
II A 8.2 III A 10.2	Dohmen,P  POSITION PAPER	2001	Risk Assessment for Ethenethiourea (ETU) a common metabolite of EBDC fungicides <i>BASF DocID 2001/1019902</i> Non GLP, Unpublished

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>
-	Kramer, V.J POSITION PAPER	2002	Mancozeb, and its degradation intermediate ETU, do not cause endocrine disruption in the aquatic environment, January 10, 2002. Non GLP, Unpublished

## APPENDIX IV

## List of uses supported by available data

## MANCOZEB

Crop and/or situation	Member State or Country	Product name	F G or I	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks:	
					Type	Conc.of as	method kind	growth stage & season	number min max	interval between appl. (min)	kg as/hL min max	water L/ha min max	kg as/ha min max			
Apple	N		F	Fungi	WP	800	air-assisted		1			0.48	500	2.4	28	
	S		F	Fungi	WP	800	air-assisted		1			0.16	1500	2.4	28	
Potato	N+S		F	Fungi	WP	800	hydraulic nozzle		8	7		0.8	200	1.6	7	
Tomato	N+S		F	Fungi	WP	800	hydraulic nozzle low water volume		5	7		0.32	500	1.6	3	
							hydraulic nozzle high water volume		5	7		0.16	1000	1.6	3	
Grape	N		F	Fungi	WP	800	air-assisted high water volume		2	7-10		0.16	1000	1.6	56	
			F	Fungi	WP	800	air-assisted low water volume		2	7-10		0.28	500	1.4	28	
	S		F	Fungi	WP	800	air-assisted high water volume		2	7-10		0.16	1000	1.6	28	
			F	Fungi	WP	800	air-assisted low water volume		2	7-10		0.32	500	1.6	28	

- Remarks:**
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
  - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
  - (c) e.g. biting and 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 plants - type of equipment used must be indicated
  - (i) g/kg or g/l
  - (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
  - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
  - (l) PHI - minimum pre-harvest interval
  - (m) Remarks may include: Extent of use/economic importance/restrictions

