



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Metiram

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FINAL

Review report for the active substance **metiram**

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 metiram 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 metiram, made in the context of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

Commission Regulation (EEC) No 3600/92⁽¹⁾ laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, as last amended by Regulation (EC) No 2266/2000⁽²⁾, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Metiram 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, BASF AG on 13 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance metiram in Annex I to the Directive.

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

¹ OJ No L 366, 15.12.1992, p.10.

² OJ No L 259, 13.10.2000, p.27.

³ OJ No L 107, 28.04.1994, p.8.

⁴ OJ No L 225, 22.09.1995, p.1.

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 metiram this deadline was 30 April 1995.

Only BASF AG submitted in time a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore BASF AG was 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 22 August 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 metiram 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 metiram from BASF AG, on 19 September 2000.

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

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

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

The meetings for this consultation were organised on behalf of the Commission by the Biologische Bundesanstalt für Land und Forstwirtschaft (BBA) in Braunschweig, Germany, from November 2001 to July 2002.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the main data submitter on 11 September 2002 for comments and further clarification.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the dossier, the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications on the remaining issues, received after the peer review were referred to the **Standing Committee on the Food Chain and Animal Health**, and specialised working groups of this Committee, for final examination, with participation of experts from all Member States. 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.

This final examination took place from July 2002 to September 2004, and was finalised in the meeting of the Standing Committee on 3 June 2005.

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

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

2. Purposes of this review report

This review report, including the background documents and appendices thereto, has been developed and finalised in support of the Directive 2005/72/EC⁵ concerning the inclusion of metiram in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing metiram 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 metiram will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each metiram containing plant protection product for which Member States will grant or review the authorisation.

⁵ OJ No L 279, 22.10.2005, p. 63-69

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 17% of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). Additional intake from water and products of animal origin are not expected to give rise to intake problems.

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

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

4. Identity and Physical/chemical properties

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

For metiram a FAO specification does not exist as defined in Appendix I of this report.

The active ingredient shall have a minimum purity of 840 g/kg technical product.

The manufacturing impurity ETU(ethylene thiourea) is considered to be of toxicological concern and must not exceed 0.5% of the active substance.

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 metiram

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 aquatic organisms, non target arthropods, birds and mammals. Conditions of authorisation must 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.

They shall ensure that the notifiers at whose request metiram 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 metiram in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

METIRAM

Common name	METIRAM
Chemical name (IUPAC)	Zinc ammoniate ethylenebis(dithiocarbamate) – poly[ethylenebis(thiuramdisulfide)].
Chemical name (CA)	Tris[amine[ethylenebis(dithiocarbamate)]Zinc(II) [tetrahydro-1,2,4,7-dithiadiazocine-3,8-dithione], polymer.
CIPAC No	478
CAS No	9006-42-2
EEC No	Not assigned.
FAO SPECIFICATION	FAO specification does not exist.
Minimum purity	840 g/kg The manufacturing impurity ethylene thiourea is considered to be of toxicological concern and must not exceed 0.5% of the active substance.
Molecular formula	$(C_{16}H_{33}N_{11}S_{16}Zn_3)_x$
Molecular mass	$(1088.6)_x$
Structural formula	$\left[\left[\begin{array}{c} \text{H} \quad \text{S} \\ \quad \\ \text{CH}_2 - \text{N} - \text{C} - \text{S} - \\ \\ \text{CH}_2 - \text{N} - \text{C} - \text{S} - \text{Zn}(\text{NH}_3) - \\ \quad \\ \text{H} \quad \text{S} \end{array} \right]_3 \begin{array}{c} \text{H} \quad \text{S} \\ \quad \\ \text{CH}_2 - \text{N} - \text{C} - \text{S} - \\ \\ \text{CH}_2 - \text{N} - \text{C} - \text{S} - \\ \quad \\ \text{H} \quad \text{S} \end{array} \right]_x$

Melting point	156 °C (901 g/kg)
Boiling point	Not applicable. Metiram (901 g/kg) does not boil or sublime below the decomposition temperature of about 156 °C.
Appearance	Solid consisting of a light-yellow powder (901 g/kg).
Relative density	1.860 kg/l (purity: 861 g/kg) at 20°C.
Vapour pressure	The vapour pressure of Metiram (purity: 856 g/kg) at 20° and 25°C is less than 1×10^{-5} Pa.
Henry's law constant	$<5.4 \times 10^{-3}$ Pa m ³ mol ⁻¹ at 20 °C.
Solubility in water	≤ 2 mg/l at 20°C
Solubility in organic solvents	Less than 0.1 g/l at 25 °C in n-hexane, toluene, dichloromethane, methanol, isopropanol, acetone, ethyl acetate.
Partition co-efficient (log P_{ow})	pH 5: 1.9 pH 7: 1.76 pH 9: 0.32
Hydrolytic stability (DT₅₀)	pH 5, 22°C: half – life 22.5 h pH 7, 22°C: half life 17.4 h pH 9, 22°C: half life 115.1 h
Dissociation constant	Neither acidic nor basic properties.
Quantum yield of direct photo-transformation in water at λ >290 nm	Strong absorption for metiram dissolved in DMSO up to about 400 nm, extinction coefficients exceed 10 l mol ⁻¹ cm ⁻¹ by orders of magnitude. The quantum yield was estimated to be at least equal to 0.001.
Flammability	No burning was observed. Metiram TK 85 is not classified as highly flammable.No self-heating was observed when tested for 24 hours at 140 °C.
Explosive properties	Metiram contains no moiety in its molecule which could render it potentially explosive.
UV/VIS absorption (max.)	λ =259 nm ⇒ ε = 6.4 x 10 ⁴ (l x Mol ⁻¹ x cm ⁻¹) λ =281 nm ⇒ ε = 4.8 x 10 ⁴ (l x Mol ⁻¹ x cm ⁻¹) λ =295 nm ⇒ ε = 3.0 x 10 ⁴ (l x Mol ⁻¹ x cm ⁻¹)
Photostability in water (DT₅₀)	It was not possible to determine the photolytic half lives of metiram, since metiram is not stable and not soluble in water (confer hydrolysis results). The photolysis of the solvolysis products of metiram was studied. The kinetics of the solvolysis process of the suspended metiram were experimentally demonstrated. Carbimid and EBIS are degraded within one day, ETU builds up and is stable under sterile conditions.

APPENDIX II

END POINTS AND RELATED INFORMATION

METIRAM

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	Rapid, 60%, based on urinary and biliary excretion within 48 h.
Distribution:	Widely distributed, highest residues in thyroid and kidneys.
Potential for accumulation:	No potential for accumulation.
Rate and extent of excretion:	Rapid, > 99% within 7 d.
Toxicologically significant compounds:	Parent compound and metabolites (especially ETU and CS ₂).
Metabolism in animals:	Extensively metabolised, mainly hydrolysis and ring formation (ETU).

Acute toxicity

Rat LD ₅₀ oral:	> 5000 mg/kg bw
Rat LD ₅₀ dermal:	> 2000 mg/kg bw
Rat LC ₅₀ inhalation:	> 5.7 mg/l (head/nose exposure).
Skin irritation:	Not irritant.
Eye irritation:	Not irritant.
Skin sensitization (test method used and result):	Sensitiser (M & K).

Short term toxicity

Target / critical effect:	Thyroid (inhibition of thyroid peroxidase, hyperplasia/hypertrophy), liver (increased weight), atrophy of hindlimb muscles in rats.
Lowest relevant oral NOAEL / NOEL:	80 ppm = 2.6 mg/kg bw/d (1-year, dog).
Lowest relevant dermal NOAEL / NOEL:	>250 mg/kg bw/d (21-d, rabbit).
Lowest relevant inhalation NOAEL / NOEL:	20 mg/m ³ air (90-d, rat).

Genotoxicity

Overall no genotoxic potential in vivo.

Long term toxicity and carcinogenicity

Target / critical effect:

Thyroid (inhibition of thyroid peroxidase, hyperplasia/hypertrophy), atrophy of hindlimb muscles in rats.

Lowest relevant NOAEL:

NOAEL 3.1 mg/kg b.w. rat (2 years).

Carcinogenicity:

No evidence of oncogenic potential in rats and mice.
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Reproductive toxicity

Target / critical effect - Reproduction:

No reproductive toxic effects at parentally toxic dose levels.
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Lowest relevant reproductive NOAEL / NOEL:

40 ppm, ca 2.7 mg/kg bw/d (systemic toxicity). 320 ppm, ca. 21 mg/kg bw/d (reproductive toxicity).

Target / critical effect - Developmental toxicity:

Decreased litter size and foetal weights at maternally toxic dose levels.

Lowest relevant developmental NOAEL / NOEL:

Rabbit: 40 mg/kg bw/d.

Delayed neurotoxicity

90-day, rat: no evidence of neurotoxicity from microscopic examination of nervous system.

Other toxicological studies

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

Medical data

In case of eye contact conjunctivitis, in case of skin contact: redness, itching and blistering. Suspected contact allergy to Metiram could neither be proved nor totally be excluded (publication).

Summary

	Value	Study	Safety factor
ADI:	0.03	2-years-rat	100
AOEL systemic:	0.016	1-year, dog correction for 60% oral absorption	100
AOEL inhalation:	Not necessary (Vapor pressure < 1x 10 ⁻⁵ Pa)		
AOEL dermal:	Not necessary		

ARfD (acute reference dose):

Metiram: Not necessary – Not allocated ETU 0.05 mg/kg bw/d.
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Dermal absorption

1%

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:

28-41% (90-365 d).

Non-extractable residues after 100 days:

38-65% (90-365 d).

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

ETU (max 12% AR on d 4)
EBIS (max 57% AR on d 0)
Carbimid (max 14.9% AR on d 0)
TDIT (max 13.5% AR on d 0)
Unknown (max. 13.2% on d 7)

Supplemental studies

Anaerobic:

Parent compound degraded with pathway similar to aerobic conditions; lower mineralization observed (up to 16% AR).

Up to 36% AR ETU+EU detected (d 1).

Soil photolysis:

Degradation of Metiram only slightly influenced by light.

Initial gradual influence of light on the degradation of ETU.

Remarks:

None.

Rate of degradation

Laboratory studies

DT₅₀lab (20 °C, aerobic):

median 1 d (7 soils: 0.5, <0.7, 0.8, 1.0, 1.0, 2.7. and 19 d).

ETU 0.2 - 2.0 d, median 0.75 d, n=6

EBIS 0.09 - 0.8 d, median 0.33 d, n=6

TDIT 0.3 - 0.9 d, median 0.6 d, n=2

Carbimid 0.008 - 0.9 d, median 0.01 d, n=4

DT₉₀lab (20 °C, aerobic):

Metiram 1.8 - 3.2 d, n=2 ETU 0.7 - 6.6 d, n=2 TDIT 0.9 - 2.8 d, =2 EBIS 0.29 -1.6 d, n=2 Carbimid 0.026 - 0.051 d, n=3
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DT₅₀lab (10 °C, aerobic):

<1.6, 1.8, 2.2, 6.0 and 42 d (5 soils).

DT₅₀lab (20 °C, anaerobic):

6 d (recalculated by RMS).

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

(2 locations, Princeton, NJ, and Champaign, IL, USA): < 7 d, <7 d (metiram) ~7 d, <7 d (ETU)
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DT_{90f} from soil dissipation studies:

< 14 d (a.s.) <14 d (ETU)

Soil accumulation studies:

Accumulation studies in soil were not performed due to the fast degradation of metiram and degradation products.
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Soil residue studies:

Soil residue studies in soil were not performed due to the fast degradation of metiram and degradation products.
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Remarks:

e.g. effect of soil pH on degradation rate

None.

Adsorption/desorption

K_f / K_{oc} :

K_d :

pH dependence:

Metiram is almost insoluble in water and very unstable in soil. For this reason no adsorption/desorption study has been carried out with the parent compound, but column leaching studies have been directly undertaken. Like the other EBDCs metiram can be considered low mobile in soil.

ETU:

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

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

No for parent and ETU

Mobility

Laboratory studies:

Column leaching:

No leaching of metiram observed (max application rate covered, only 1.9% of applied found in one out of 3 soils).

Aged residue leaching:

Aging for 30 d (study 1) and 17 h (study 2)
study 1: 1.9% of applied found in the leachate
study 2: a.s. and ETU were not detected in leachate.

Field studies:

Lysimeter/Field leaching studies:

Not required since metiram is unstable in soil and insoluble in water.

Remarks:

None.

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:

Due to the fact that metiram is insoluble in water, an aqueous suspension was produced by ultrasonification. DT₅₀ values:

pH 5, 22°C: 22.5 h

pH 7, 22°C: 17.4 h

pH 9, 22°C: 115.1 h

Major metabolites:

ETU is formed, which is stable at pH 5, 7 and 9 at 25°C.

Photolytic degradation:

Extinction coefficient > 10 l mol⁻¹ cm⁻¹, quantum yield estimated to be > 0.001 (derived at 300 nm, a.s. completely dissolved in DMSO:water 1:1) lead to calculated environmental half-life in the upper layer of aquatic ecosystems < 6.3 h (continuous irradiation) or < 0.6 calendar day (Central Europe scenario, application in March, daylength 11.6 h).

Major metabolites:

Three experiments (A, B, C) of the same study have shown: half-life 27.5 d for photolysis of suspended a.s., major degradates: ETU (stable), carbimid (short lasting), hydantoin, unid. fraction up to 13% (see attached document).

DT₅₀ values ETU: 358 d (non sensitised, corrected for the dark control)
(2.3 d sensitized by acetone).

Biological degradation

Readily biodegradable:

No (34 % COD 28 d, 20-25°C).

Water/sediment study:

DT₅₀ water:

Metiram: 0.8 and 0.6 d; ETU: 5.4 and 5.4 d

DT₉₀ water:

Metiram: 2.7 and 1.9 d; ETU: 18 and 18 d

DT₅₀ whole system:

Metiram: 3.4 and 3.4 d; ETU: 6.5 and 5.9 d

DT₉₀ whole system:

Metiram: 11 and 11 d; ETU: 21 and 20 d

Distribution in water / sediment systems (active substance)

Max. in sediment 21-24 % (d 0), 2.3-4.5% after 105 d.

Distribution in water / sediment systems (metabolites)

ETU:

Max. in water 41-49% (d 0.25)

Max. in sediment 6.4-7.6% (d 7).

Accumulation in water and/or sediment:

No remarks.

Degradation in the saturated zone

Not relevant.

Remarks:

None.

2.3 Fate and behaviour in air

Volatility

Vapour pressure:

The vapour pressure of Metiram (purity: 856 g/kg) at 20° and 25°C is less than 1×10^{-5} Pa.

Henry's law constant:

$<5.4 \times 10^{-3}$ Pa m³ mol⁻¹ at 20°C.

Photolytic degradation

Direct photolysis in air:

Not relevant.

Photochemical oxidative degradation in air

DT₅₀:

Metiram is immediately decomposed: therefore the metabolite formed in soil directly after treatment (EBIS) is tested.

DT₅₀ EBIS: <0.043 d.

Volatilisation:

From plant surfaces: not relevant (vapour pressure metiram $<10^{-5}$ Pa).

From soil: not relevant (vapour pressure metiram $<10^{-5}$ Pa).

Remarks:

None.

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:

Rat, male and female: LD₅₀ > 6500 mg/kg bw
ETU LD50: >5000 mg /kg bw/d.

Acute toxicity to birds:

LD₅₀ > 2150 mg a.s./kg bw (quail).

Dietary toxicity to birds:

LC₅₀: 3250 mg/kg diet = 853 mg a.s./kg/d.

Reproductive toxicity to birds:

NOEC: 50 mg/kg diet = 7.9 mg a.s./bw/d (duck);
100 mg/kg diet (quail).

Subchronic and reproductive toxicity
(Higher tier - pulse dose)

NOEC: 150 mg/kg diet = 25.5 mg a.s./kg bw/d
(duck).

Short term oral toxicity to mammals:

Not relevant.

Aquatic Organisms

Acute toxicity fish:

Group	Test substance	Time-scale	Endpoint	Toxicity (mg as/l)
<i>Rainbow trout</i>	formulation	96h flow-through	LC ₅₀ (initial measured) # (mean measured)	0.39 0.333
<i>Rainbow trout</i>	ETU	96 h static	LC ₅₀ NOEC	>490 490
<i>Rainbow trout</i>	ETU	96 h static	LC ₅₀ NOEC	>500 200
<i>Rainbow trout</i>	EU	96 h static	LC ₅₀ NOEC	> 122 122
<i>Stickleback</i>	formulation	96 h, flow through	LC ₅₀ NOEC	>57.4 11.72
<i>Carp</i>	formulation	96 h, flow through	LC ₅₀ NOEC	16.3 2.67
<i>Golden Orf</i>	formulation	96 h, flow through	LC ₅₀ NOEC	25.3 16.0
<i>Fathead Minnow</i>	formulation	96 h, flow through	LC ₅₀ NOEC	12.3 6.85
Long term toxicity fish: <i>Rainbow trout</i>	formulation	28 days flow Through	NOEC (nominal) [§]	0.022
<i>Rainbow trout</i>	formulation	Chronic, 28 days Juvenile Growth Test	LOEC NOEC	0.22 0.07
Bioaccumulation fish:	Not relevant log Pow <3			

Acute toxicity invertebrate:

<i>Daphnia magna</i>	formulation	48 h, static	LC ₅₀ (nominal) (initial measured)# (mean measured)	0.77 0.264 0.110
<i>Daphnia magna</i>	ETU	48 h, static	EC ₅₀	49
<i>Daphnia magna</i>	ETU	48 h, static	EC ₅₀ EC ₀	21.6 6.25
<i>Daphnia magna</i>	EU	48 h, static	EC ₅₀ NOEC	> 985 589
<i>Physa acuta</i>	formulation	48 h, static	EC ₅₀ NOEC	>1.77 ≥1.77
<i>Cyclopoida</i>	formulation	48 h, static	EC ₅₀ NOEC	0.66 0.43
<i>Chydorus sphaericus</i>	formulation	48 h, static	EC ₅₀ NOEC	0.6 0.12
<i>Ostracoda</i>	formulation	48 h, static	EC ₅₀ NOEC	>1.77 ≥1.77
<i>Simocephalus vetulus</i>	formulation	48 h, static	EC ₅₀ NOEC	2.09 0.12
Chronic toxicity invertebrate: <i>Daphnia magna</i>	formulation	21 d, flow-through	NOEC (mean measured) ^{#+}	0.0043
<i>Daphnia magna</i>	ETU	21 d, flow-through	NOEC	2.0
<i>Daphnia magna</i>	formulation	28 d	NOEC	0.2
Acute toxicity algae: <i>Pseudokirchneriella subcapitata</i>	formulation	72h, static	EC ₅₀ (nominal) [^]	0.063
<i>Pseudokirchneriella subcapitata</i>	ETU	72 h, static	EC ₅₀	93.8
<i>Chlorella pyrenoidosa</i>	ETU	96 h, static	NOEC	6600
<i>Pseudokirchneriella subcapitata</i>	EU	96 h, static	EC ₅₀ NOEC	>119 119
<i>Chironomus riparius</i>	formulation	28 d, static	EC ₅₀ NOEC	>2.1 0.22
<i>Ankistrodesmus bibraianus</i>	formulation	72 h, static	E _r C ₅₀ E _r C ₁₀	1.365 0.079
<i>Euglena gracilis</i>	formulation	72 h, static	E _r C ₅₀ E _r C ₁₀	4.612 0.436
<i>Tetraedron caudatum</i>	formulation	72 h, static	E _r C ₅₀ E _r C ₁₀	0.812 0.050

<i>Desmodesmus subspicatus</i>	formulation	72 h, static	E _r C ₅₀ E _r C ₁₀	0.891 0.183
<i>Anabaena flos-aquae</i>	formulation	72 h, static	E _r C ₅₀ E _r C ₁₀	0.189 0.037
<i>Navicula pelliculosa</i>	formulation	72 h, static	E _r C ₅₀ E _r C ₁₀	>0.206 0.039
<i>Cosmarium praemorsum</i>	formulation	72 h, static	E _r C ₅₀ E _r C ₁₀	0.157 0.013
<i>Staurastrum tetracerum</i>	formulation	72 h, static	E _r C ₅₀ E _r C ₁₀	0.170 0.002
<i>Corcontochrysis noctivaga</i>	formulation	72 h, static	E _r C ₅₀ E _r C ₁₀	0.232 0.031
<i>Ochromonas danica</i>	formulation	72 h, static	E _r C ₅₀ E _r C ₁₀	0.210 0.068
<i>Staurastrum gracile</i>	formulation	72 h, static	E _r C ₅₀ E _r C ₁₀	0.519 0.020
<i>Anabaena cylindrica</i>	formulation	72 h, static	E _r C ₅₀ E _r C ₁₀	0.360 0.180
<i>Pseudokirchneriella subcapitata</i>	formulation	72 h, static	E _r C ₅₀ E _r C ₁₀	0.191 0.049

measured concentrations were below 80% of the nominal concentrations.

§ measured concentrations were within the 80% of the nominal concentrations.

+ not possible to extrapolate NOEC from initial measured concentrations.

^ No analytical measures were performed.

Honeybees

Acute oral toxicity:

No effect (72h) at 80 µg a.s/bee

Acute contact toxicity:

No effect (72h) at 80 µg as/bee

Other arthropod species

Test species	Test Substance	Dose (kg /ha)	Endpoint	Effect
<i>A. rhopalosiphi (adult)</i>	formulation BASF 222 28 F (70% s.a.)	4	Lethal effects Sub-lethal effect	14% -41%
<i>T. pyri (protonymphs)</i>	formulation BASF 222 28 F (70% s.a.)	0.7-2.8	Lethal effects	100%
<i>C. carnea (eggs, larvae, adult)</i>	formulation BASF 222 28 F (70% s.a.)	4	Lethal effects Sub-lethal effect	-55.8% no effects
<i>Pardosa spec. (adult)</i>	formulation BASF 222 28 F (70% s.a.)	8	Lethal effects	5%

Field or semi-field tests

Typhlodromus pyri

7 high-tiered field studies have been performed on *T. pyri*. A reduction in the population has been observed in all trials. However the effect became evident after the 5th treatment, suggesting for most supported crops (max. 4 treatments) that this event is unlikely.

Based on the level and the duration of effects shown in the aged residue trial combining realistic exposure scenarios with standardized laboratory bioassays, it can be shown that no long lasting effects are to be expected for field populations of predatory mites even under in-crop exposure scenarios. This is confirmed by the results of the additional field trials.

Earthworms

Acute toxicity:

AS: LC₅₀ (14 d): > 1000 mg a.s./kg soil

EP: LC₅₀ (14 d) > 1000 mg/kg soil

ETU: LC₅₀ (14 d) > 1000* mg/kg soil

Reproductive toxicity:

Not triggered (DT90f < 100 d).

Soil micro-organisms

Nitrogen mineralization:

Metiram:

AS: transient reduction returning to control values at 49 d (1.6 kg/ha, 5.3 mg/kg sandy loam) and 70 d (8 kg/ha 26.5 mg/kg sandy loam). No effects on microbial biomass content at any time.

EP : transient reduction (80%) up to 7 d at 4kg/ha (sandy loam soil, 5.3 mg/kg soil) returning to control values at 21 d. Delayed recovery 35 d to control values for the highest dose (48 kg/ha, 64 mg/kg soil). For sandy loam soil recovery of the activity to control values was further delayed (28 and 56 d for 2 rates).

ETU:

No effects on soil microflora at dosage 0.42-4.2 kg/ha (0.56-5.6 mg/kg soil).

Carbon mineralization:

Metiram:

AS: transient reduction up to 14 d, dose dependent, returning to control values at 28 d in 2 soils (loam and loamy sand). Soil respiration is inhibited at the highest dose (8 kg/ha, 26.4 mg/kg soil) up to 14 d returning to control values at 28 d.

EP: only negligible effects up to 48 kg /ha (64 mg/kg soil).

ETU:

No effects on soil microflora at dosage 0.42-4.2 kg/ha (0.56-5.6 mg/kg soil).

APPENDIX IIIA**METIRAM**

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

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

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports⁶ on previous use in granting national authorizations
II A 2.3.2 /2.4	Ohnsorge U.	1995	Henry's law constant for Metiram BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. # 95/10144 GLP: not applicable Unpublished	F
II A 2.5 /2.5	Türk, W.	1995	Spectra of Metiram TK 85 BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. # 95/10069 Addendum: BASF Reg. Doc. # 95/10211 27 February 1995 GLP, Unpublished	F
II A 2.5 /2.6	Türk, W.	1995	Spectra of ETU BASF Aktiengesellschaft , Limburgerhof, Germany BASF Reg. Doc. # 95/10273 GLP, Unpublished	F

⁶ Entries are based on information received from the Notifier(s) and in certain cases Member States. Neither the Commission nor the Member States are responsible for the completeness or validity of this information received.

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ⁶ on previous use in granting national authorizations
II A 2.11 /2.10	Löffler, U.	1993	Metiram-Premix TK 85; Evaluation of physical and chemical properties for crop protection products BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc.# 93/10688 GLP, Unpublished	F
II A 2.14 /2.11	Kröhl, T.	1994	Physical and chemical properties report for BAS 222 29 F BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. # 94/10792 GLP, Unpublished	F
III A 2.2.2 /2.2	Redeker, J	1992	BAS 222 28 F. Determination of the oxidizing and reducing action. Physical properties report for Polyram DF BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. # 92/10749 GLP, Unpublished	
II A 2 III A 2.7.1 /01	Kästel R.	2002	Physical and chemical properties of the formulation BAS 222 28 F BASF Aktiengesellschaft, Limburgerhof, Germany BASF DocID 2002/1014101 GLP Unpublished	
II A 2 III A 2.7.1./02 II A 2 III A 2.8.6.3./ 01	Kästel R.	2002	A.I content before and after accelerated storage of the formulation BAS 222 28 F BASF Aktiengesellschaft, Limburgerhof, Germany BASF DocID 2002/10141013 GLP Unpublished	
II A 3.9 /3.4	Schenk W.	1995	Possible procedures for the decontamination of water from metiram BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg.Doc.# 95/10272 Unpublished	F

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 ⁶ on previous use in granting national authorizations
II A 5.2.4 III A 12.3 /7.4	Rossbacher R., Kirsch P.	1993	Study on the acute dermal irritation/corrosion of BAS 222 28 F in the rabbit BASF Aktiengesellschaft, Ludwigshafen, Germany BASF Reg. Doc. #93/11000 GLP, Unpublished	
III A 10.2.1 /10.2	Munk, R.	1994	Acute toxicity study on the Rainbow trout (Oncorhynchus Mykiss W.) of BAS 222 28 F BASF Aktiengesellschaft, Ludwigshafen, Germany BASF Reg. Doc. #94/10920 GLP, Unpublished	
III A 10.2.1 10.4	Jatzek, H.J.	1994	Determination of the acute toxicity of BAS 222 28 F to the waterflea Daphnia magna Straus BASF Aktiengesellschaft, Ludwigshafen, Germany BASF Reg. Doc. #94/10671 GLP, Unpublished	
II A 4.2.1.1 /4.2/A	Weber, H.	1999	Validation of DFG method S 15 for the Determination of Metiram in various plant materials Dr. Specht und Partner, Chem. Laboratorien, Germany BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. # 99/12032 GLP, Unpublished	
II A 4.2.1.1 /01	Tilting N.	2002	Validation of Analytical Method 525/0 for the determination of BAS 222 F (metiram) in muscle, milk and egg (confirmatory method) BASF AG, Agricultural Center Limburgerhof, Limburgerhof, Germany BASF RegDoc# 2002/1014144 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 ⁶ on previous use in granting national authorizations
II A 4.2.1.2	Tilting N.	2000	Adaptation of Method 135 to Additional Matrices: Determination of Mancozeb and Metiram as CS2. BASF AG. BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep. unpublished BASF RegDoc# 2000/1017115 GLP Unpublished	
II A 4.2.1.2	Möllerfeld J	1999	Independent Lab Validation of BASF Analytical Method No. 159/2: Determination of Ethylenethiourea in Potatoes (Christa) and Tomatoes. BASF AG Labor Dr. Möllerfeld GmbH, Wörrstadt, Germany Fed. Rep. unpublished BASF RegDoc# 1999/10240 GLP Unpublished	
II A 4.2.1.2	Sasturain J., Mackenroth C	2000	Validation of BASF Method No. 159/2: Determination of Ethylenethiourea in tobacco matrices. BASF AG. BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep. unpublished BASF RegDoc# 2000/1000237 GLP Unpublished	
II A 4.2.1.2	Sasturain J., Mackenroth C	2000	Validation of BASF Method No. 373/0: Determination of Ethylenethiourea in potato. BASF AG. BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep. unpublished BASF RegDoc# 2000/1000238 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 ⁶ on previous use in granting national authorizations
II A 4.2.1.2	Möllerfeld J.	2001	Independent Lab Validation of BASF Analytical Method No. 373/1: Determination of Ethylenethiourea in Potatoes, Apples, Grapes, Melons (fruit and pale), Lettuce, Tomatoes and Wine. BASF AG. Labor Dr. Möllerfeld GmbH, Wörrstadt, Germany Fed. Rep. unpublished BASF RegDoc# 2001/1015054 GLP Unpublished	
II A 4.2.1.2	Benz A., Mackenroth C	2002	Validation of BASF Method No. 373/2: Determination of ETU (Ethylenethiourea, Reg. No. 146099) in various Plant Matrices. BASF AG. BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed. Rep. unpublished BASF RegDoc# 2002/1004090 GLP Unpublished	
II A 4.2.1.3 /4.20	Larese J.	1988	Storage stability of metiram and ethylenethiourea in frozen apples Enviro-Bio-Tech Ltd., Bernville – USA BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. # 88/5093 GLP, Unpublished.	F
II A 4.2.1.3 /4.21	Larese J.	1989	Storage stability of metiram and ethylenethiourea in frozen apples, Addendum: Twelve months ethylenethiourea and metiram stability Enviro-Bio-Tech Ltd., Bernville – USA BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. # 89/5082 GLP, Unpublished	F

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 ⁶ on previous use in granting national authorizations
II A 4.2.1.3 /4.22	Larese J.	1988	Storage stability of metiram and ethylenethiourea in frozen apples processed commodities Enviro-Bio-Tech Ltd., Bernville – USA BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. # 88/5022 GLP, Unpublished	F
II A 4.2.1.3 /4.23	Larese J.	1988	Storage stability of metiram and ethylenethiourea in frozen apples, Addendum: Three month ethylenethiourea stability in apple sauce Enviro-Bio-Tech Ltd., Bernville – USA BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. # 88/5538 GLP, Unpublished	F
II A 4.2.1.3 /4.24	Larese J.	1988	Storage stability of metiram and ethylenethiourea in frozen apples processed commodities - Addendum: Metiram and ethylenethiourea stability up to three and six months in apple juice Enviro-Bio-Tech Ltd., Bernville – USA BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. # 88/5537 GLP, Unpublished	F
II A 4.2.1.3 /4.25	Larese J.	1988	Storage stability of metiram and ethylenethiourea in frozen apples processed commodities - Addendum: Metiram and ethylenethiourea stability in wet and dry apple pomace Enviro-Bio-Tech Ltd., Bernville – USA BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. # 88/5536 GLP, Unpublished	F

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 ⁶ on previous use in granting national authorizations
II A 4.2.1.3 /4.26	Larese J.	1988	Storage stability of metiram and ethylenethiourea in frozen apples processed commodities - Addendum: Metiram and ethylenethiourea stability up to one year in wet and dry apple pomace Enviro-Bio-Tech Ltd., Bernville – USA BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. # 89/5055 GLP, Unpublished	F
II A 4.2.1.3 /4.27	Larese J.	1988	Storage stability of metiram and ethylenethiourea in frozen apples processed commodities - Addendum: Metiram and ethylenethiourea stability up to one year in aple juice, sauce and baby food Enviro-Bio-Tech Ltd., Bernville – USA BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. # 89/5083 GLP, Unpublished	F
II A 4.2.1.4 /4.28	Larese J.	1988	Storage stability of metiram and ethylenethiourea in frozen potatoes Enviro-Bio-Tech Ltd., Bernville – USA BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. # 88/5087 GLP, Unpublished	F
II A 4.2.1.4 /4.29	Larese J.	1989	Storage stability of metiram and ethylenethiourea in frozen potatoes – Addendum: Twelve months ethylenethiourea and metiram stability Enviro-Bio-Tech Ltd., Bernville – USA BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. # 89/5086 GLP, Unpublished	F

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 ⁶ on previous use in granting national authorizations
II A 4.2.1.5 /4.30	Larese J.	1988	Storage stability of metiram and ethylenethiourea in frozen tomatoes Enviro-Bio-Tech Ltd., Bernville – USA BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. # 88/5090 GLP, Unpublished	F
II A 4.2.1.5 /4.31	Larese J.	1989	Storage stability of metiram and ethylenethiourea in frozen tomatoes – Addendum: Twelve months metiram and ethylenethiourea stability Enviro-Bio-Tech Ltd., Bernville – USA BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. # 89/5085 GLP, Unpublished	F
II A 4.2.1.5 /4.32	Mamouni, A.	1994	Storage stability of metiram in white grapes RCC Umweltchemie AG, Itingen, Switzerland BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. # 94/11068 GLP, Unpublished	F
II A 4.2.1	Novak R.A.	1988	Metiram and ethylenethiourea: summary of storage stability in Frozen Raw Agricultural commodities and processed commodities. Metiram Task Force BASF RegDoc# 88/5101 GLP: Yes Unpublished	
II A 4.2.5.3 /4.39	Christman, P.J.	1988	Determination of storage stability of metiram and ethylenethiourea in/on animal products Hazleton Laboratories America Inc., Madison USA BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. # 88/5100 GLP, Unpublished	F

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 ⁶ on previous use in granting national authorizations
II A 4.2.5.3 /4.40	Christman, P.J.	1988	Determination of the Stability of Metiram and ETU residues in/on Animal Products Hazleton Laboratories America Inc., Madison USA BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. # 88/5127 Addendum: to BASF Reg. Doc #88/5100 GLP, Unpublished.	F
II A 4.2.1.4	Benz, A. et al	2002	Storage stability study of incurred ETU residues in potatoes. BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1004096 GLP: Yes Unpublished	
II A 4.2.1.6	Benz, A. et al	2002	Storage stability study of incurred ETU residues in grapes. BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1004089 GLP: Yes Unpublished	
II A 4.2.1.6 III A 8.2	Benz A:	2002	Storage stability of incurred ETU residues in grapes BASF Aktiengesellschaft, Ludwigshafen, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1012093 2002	
II A 4.2.2 /01	Zangmeister W.	2002	Validation of Analytical Method No. 509 for the Determination of BAS 222 F (Reg.No. 250284) in Standard Soil 2.2 and 2.3. BASF AG, Agricultural Center Limburgerhof, Germany BASF RegDoc# 2002/1005333 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 ⁶ on previous use in granting national authorizations
II A 4.2.3 /01	Kerkdijk, H.	2002	Validation of Analytical Methods for the determination of ETU in surface and tap water. TNO Nutrition and Food Research, Zeist, The Netherlands. BASF AG, Agricultural Center Limburgerhof, Germany BASF RegDoc# 2002/1012956 GLP Unpublished	
II A 4.2.4 /01	Zangmeister W.	2002	Validation of Analytical Methods 418/1 and 418/2: Determination of BAS 222 28 F (Polyram DF) in air using Tenax (418/1) or IOM Sampler (418/2) by HPLC-ECD. BASF AG, Agricultural Center Limburgerhof, Germany BASF RegDoc# 2002/1005332 GLP Unpublished	
II A 4.2.4 /4.3/A	Zangmeister, W.	1998	Analytical procedure No.418 determination of BAS 222 F (Metiram) in air BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. # 99/10067 GLP, Unpublished	
II A 4.2.4 /4.4/A	Zangmeister, W.	1999	Validation of Analytical Method No.418 determination of BAS 222 F (Metiram) in air by GC/MS BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. # 99/10067 GLP, Unpublished	

B.6 Toxicology and metabolism

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
II A 5.2.2	Leuschner, J.	2001	Acute toxicity study of ETU (ethylene thiourea) in Sprague-Dawley rats by dermal administration LPT, Germany ETU-Task Force BASF RegDoc# 2001/1014630 GLP Published:No	*
II A 5.2.2	Donato Di, L.J., Longacre, S.L.	1987	Ethylene thiourea: Dermal/oral absorption study in male rats Protocol No. 85P-419, Report No. 85R-206 Rohm and Haas Company BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 1987/10466 GLP Published:No	
II A 5.2.3	J. Leuschner	2002	Acute Inhalation Toxicity Study of Ethylene Thiourea (ETU) in Sprague-Dawley Rats LPT Laboratory of Pharmacology and Toxicology, Hamburg, Germany EBDC-Task Force BASF RegDoc# 2002/1005548 GLP Published:No	*
II A 5.2.4	Leuschner, J	2001	Acute skin irritation (patch test) of ETU (ethylene thiourea) in rabbits LPT, Germany ETU-Task Force BASF RegDoc# 2001/1014631 GLP Published:No	*

* Study of the EBDC-Task-Force

* Study of the EBDC-Task-Force

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
II A 5.2.4	Cotton H.	2002	C14 - Metiram technical (Reg. No. 250284): Rates of Penetration through rat and human skin using an in vitro system Covance Laboratories, Harrogate, Great Britain BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1005547 GLP Unpublished	
II A 5.2.4	Remmele M. et al	2002	Report Metiram technical (synonym: Metiram TC or BAS 222 29F) Acute dermal irritation/corrosion in rabbits BASF Aktiengesellschaft, Ludwigshafen, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1005292 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
II A 5.2.5	Remmele M. et al	2002	<p>BASF DocID Report Metiram technical (synonym: Metiram TC or BAS 222 29F) Acute eye irritation in rabbits BASF Aktiengesellschaft, Ludwigshafen, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1005291 GLP Unpublished</p> <p>Amendement no.1 to the report Report Metiram technical (synonym: Metiram TC or BAS 222 29F) Acute eye irritation in rabbits BASF Aktiengesellschaft, Ludwigshafen, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1006988 GLP Unpublished</p>	
II A 5.2.5	Leuschner, J	2001	<p>Acute eye irritation study of ETU (ethylene thiourea) by instillation into the conjunctival sac of rabbits LPT, Germany ETU-Task Force BASF RegDoc# 2001/1014629 GLP Published:No</p>	*
II A 5.3.1.3 /5.24	Mellert W., Hildebrand B.	1992	<p>Report: Study of the oral toxicity of Metiram Premix 95% in Wistar rats. Administration in the diet for 3 months including the examination of neurotoxicology ("Neurofunctional Observational Battery") BASF Aktiengesellschaft, Ludwigshafen, Germany BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. #92/11224 GLP Published:No</p>	

* Study of the EBDC-Task-Force

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
II A 5.3.2.2 /5.25	Mellert W., Hildebrand B.	1992	Report on the study of the oral toxicity of Metiram Premix 95% in B6C3F1 mice. Administration in the diet for 3 months BASF Aktiengesellschaft, Ludwigshafen, Germany BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. #92/11223 GLP Published:No	
II A 5.4.1	Schulz, V.	2001	Statement on the requirement for a chromosome aberration study in vitro with metiram (CAS No. 9006-42-2) BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2001/1003804 GLP: Not applicable Unpublished	
II A 5.4.1	Schulz, V.	2001	Toxicological assessment of metiram – mutagenicity and genotoxicity BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2001/1010568 GLP:Not applicable Unpublished	
II A 5.5.1	Allen, T.R. et al.	1989	19-week oral toxicity (feeding) study with Metiram Premix 95% in the dog RCC Switzerland BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 1989/5128 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
II A 5.5.1/5.46	Corney S. J. et al.	1991	52-week oral toxicity (feeding) study with metiram premix 95% in the dog RCC, Itingen, CH BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. #91/10786 GLP Published:No	
II A 5.5.1	Briffaux, J.P.,	1992	ETU: 52 Week Oral (Dietary) Toxicity Study in the Beagle Dog Project ID. No. 616/505 Hazleton Laboratories, Lyon, France EBDC/ETU Task Force Yes No	*
II A 5.5.2	Schmid, H.; Tennekes, H	1992	104 Week Chronic Toxicity (feeding) Study with Ethylenethiourea (ETU) in the Rat RCC, Itingen Switzerland EBDC/ETU Task Force Yes No	*
II A 5.6.1	Dotti, A.	1992	Ethylene Thiourea (ETU): Two-generation Study in the Rat RCC Project No. 252360, Research and Consulting Company, Itingen, Switzerland EBDC/ETU Task Force Yes No	*
II A 5.5 /02.	Tenneskes H	2002	Evaluation of the validity of the long term toxicity and carcinogenicity study with metiram in the rat BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1011511 Unpublished	

* Study of the EBDC-Task-Force

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
II A 5.9	Pallapies D.	2002	Statement on Metiram , experiences in humans BASF Aktiengesellschaft, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1005490 GLP: not applicable Unpublished	
III A 7.2.2	Ravitz, S.J., Bookbinder, M.G	1988	Dislodgeable foliar residues of Polyram 80 WP fungicide applied to apples in California Orius Associates Inc BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF RegDoc# 1990/5009 GLP Unpublished	
III A 7.2.3	Stauber, F.	2001	Metiram – Substantiation of safe uses with respect to operator and worker exposure for the purpose of the subsequent Annex I listing of the active substance Revised version BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2001/1009900 GLP: Not applicable Unpublished	

B.7 Residue data

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 6.1 /6.13	Merricks, D.L., Lantz L.	1991	¹⁴ C-metiram Confined rotational crop study Agriseach Inc. Frederick, MD, USA BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. #91/5096 GLP, Unpublished	B, F
II A 6.2.1 /6.15	Wu J.	1989	Metabolism of [14 C]-metiram complex in lactating goats – Analysis and quantitation of metabolites and/or the corresponding natural products in milk and tissues Xenobiotic Laboratories Inc. Princeton, USA BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg.Doc. #89/10487 GLP: Yes Unpublished	
IIA 6.3 IIIA 8.2 IIA 6.5 IIIA 8.4 /6.39	Mamouni, A.	1994	Determination of residues of Metiram (CS ₂ and ETU) in Grapes following treatment with Polyram DF (BAS 222 28 F) under Field Conditions in Italy, 1992 and in Industrial grape processing products RCC Umweltschmie AG, Itingen, Switzerland BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. #94/10693 GLP, Unpublished	B, F
IIA 6.3 IIIA 8.2 IIA 6.5 IIIA 8.4 /6.2-A	Schulz, H.	1998	Determination of the Residues of Metiram and ETU in Grapes and in processing products following treatment with BAS 222 28 F under Field conditions in Spain, 1997 Institut Fresenius, Chem. u. Biologischen Laboratorien BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. #98/11226 GLP, Unpublished	

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IIA 6.3 IIIA 8.2 IIA 6.5 IIIA 8.4 /6.3-A	Schulz, H.	1998	Determination of the Residues of Metiram and ETU in Red Wine Grapes and in processing products following treatment with BAS 222 28 F under Field conditions in France, 1997 Institut Fresenius, Chem. u. Biologischen Laboratorien BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. #98/11226 GLP, Unpublished	
IIA 6.3 IIIA 8.2 /6.4-A	Meumann, H.	2000	Study on the residue behavior of BAS 500 F and Metiram in grapes after treatment with BAS 518 00 F, BAS 500 00 F and BAS 222 28 F under Field conditions in Germany, France and Spain, 1999 BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. #2000/1000242 GLP, Unpublished	
IIA 6.3 /6.7-A	Slesinski, R., Leparulo, M.	1990	Grape and Apple Storage Stability Study Technical Assessment, Inc., USA EBDC/ETU Task Force BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. #90/5086 GLP, Unpublished	
II A 6.3	Larese J.	1989	Storage stability of metiram and ethylenethiourea in frozen potato processed commodities: metiram and ethylenethiourea stability in wet and dry potato peel Metiram Task force BASF RegDoc#89/5058 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
II A 6.3	Larese J.	1989	Storage stability of metiram and ethylenethiourea in frozen potato processed commodities:ADDENDUM: twelve month metiram and ethylenethiourea stability: potato chips and granules Metiram Task force BASF RegDoc#89/88 GLP: Yes Unpublished	
II A 6.3 III A 8.2	Treiber, S	2001	Study on the residue behavior of metiram in grapes after treatment with BAS 222 28 F under field conditions in Germany, France and Spain, 2000 BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2001/1000990 GLP: Yes Unpublished	
II A 6.3 III A 8.2	Raunft, E.	2001	Study on the residue behavior of metiram in potato after treatment with BAS 222 28 F under field conditions in Germany, 2000 BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep. BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2001/1000993 GLP: Yes Unpublished	
II A 6.3 III A 8.2	Blaschke, U.	2000	Determination of the magnitude of the residue of BAS 222 28 F in/on potato raw agricultural commodity specimens from supervised field trials in Northern and Southern France in 2000 Huntingdon Life Sciences Ltd., Huntingdon, England BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2001/1000924 GLP: 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
II A 6.3 III A 8.2	Schulz, H.	2001	Determination of the residues of metiram and ETU in potatoes following treatment with BAS 222 28 F (Polyram DF) under field conditions in Italy and Spain 2000 Chemische und Biologische Laboratorien GmbH, Taunusstein, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2001/1009072 GLP: Yes Unpublished	
II A 6.3 III A 8.2	Raunft, E	2002	Study on the residue behaviour of metiram in grapes after application of BAS 222 28 F under field conditions in Germany, France and Spain, BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1004086 GLP: Yes Unpublished	
II A6.3 III A 8.2	Gehl, J.,	2002	Determination of the residues of Metiram and ETU in grapes following treatment with BAS 222 28 F (Polyram DF) under field conditions in Southern Europe, 2001 Arbeitsgemeinschaft GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, Niefern-Öschelbronn, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1004067 GLP: Yes Unpublished	

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II A 6.3 III A 8.2	Schroth, E.,	2002	Determination of residues in/on potatoes following multiple applications of BAS 222 28 F (metiram) under field conditions in Spain, Italy and France, 2001. Agrología S.L., Palomares, Sevilla, Spain BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1004066 GLP: Yes Unpublished	
II A 6.5	Raunft, E. et al	2002	Study on the residue behaviour of metiram in grapes and grape process fractions after application of BAS 222 28 F under field conditions in Germany, 2001 BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1004093 GLP: Yes Unpublished	
II A 6.5.1	Hassink J.	2002	Hydrolysis of BAS 222 F at 90°C, 100°C and 120°C BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1005307 GLP Unpublished	
II A 6.7	Bross M.	2002	Metiram: Summary Of Residue Data Including MRL Proposals and Dietary Risk Assessment Supporting the Safe Uses in Potatoes and Grapes BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1004104	

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
Reference to BASF RegDoc# 2002/100 4104	Raunft, E. et al	2001	Study on the residue behaviour of metiram in potatoes after treatment with BAS 222 28 F under field conditions in Belgium, Germany and the Netherlands, 1999 BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2000/1014866	

B.8 Environmental fate and behaviour

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
II A 7.1.1.1.1 /01	Staudenmaier H.	2002a	Aerobic Metabolism of BAS 222 F (Metiram) in Cashmere Soil BASF Aktiengesellschaft, Ludwigshafen, Germany BASF AG Agrarzentrum, Limburgerhof, Germany BASF RegDoc# 2002/1011913 GLP Unpublished	
II A 7.1.1.1.1 /02	Staudenmaier H.	2002b	Aerobic Metabolism of BAS 222 F (Metiram) in Soil BASF Aktiengesellschaft, Ludwigshafen, Germany BASF AG Agrarzentrum, Limburgerhof, Germany BASF RegDoc# 2002/1012954 GLP Unpublished	
II A 7.1.1.1.1 /03	Staudenmaier H.	2003	EBIS and TDIT, metabolites of Metiram (BAS 222 F) in soil BASF Aktiengesellschaft, Ludwigshafen, Germany BASF AG Agrarzentrum, Limburgerhof, Germany BASF RegDoc# 2003/1000983 Position paper Unpublished	
II A 7.1.1.2 7.1/A	Cornelese, A.A., et al.	1995	Behaviour of ETU in soil from two Dutch Fields RIVM, Laboratory for Soil and Groundwater Research and RIVM, Laboratory for Organic-Analytical Chemistry BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. # 95/10772 GLP Unpublished	*

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II A 7.1.1.2.1	De Vette HQM	2002	V4012/01 A study on the rate of degradation of carbimide (metabolite of BAS 222 F, Metiram) in three aerobic soils) TNO, Delft, Netherlands BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1000223 and amendment BASF RegDoc# 2002/1004290 GLP, Unpublished	
II A 7.1.1.2.1	de Vette, H. Q. M., J. G. van Asten, A. O. Hanstveit	1999	Determination of the rate of degradation of N,N'-ethylene urea (EU; metabolite of mancozeb) in three soils, TNO Nutrition and Food Research Institute, TNO study no. IMW-98-0134-01, Delft, The Netherlands	*
II A 7.1.1.2.1	Wright, M. C.	2000	Aerobic soil metabolism degradation rate determination for ethylenethiourea (ETU) on soil	*
II A 7.1.1.2.1	Dressel, J	2001	Compilation of aerobic soil half lives and soil adsorption of ETU, EU, Carbimide and EDA (Metabolites of EBCD Fungicides) BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2001/1010672 GLP:Not applicable Unpublished	*
II A 7.1.1.2.1 III A 9.1.1.1 /04	de Vette H.Q.M	2002a	A study on the rate of degradation of CARBIMID (metabolite of BAS 222 F, Metiram) in three aerobic soils BASF Aktiengesellschaft, Ludwigshafen, Germany BASF AG Agrarzentrum, Limburgerhof, Germany BASF RegDoc# 2002/1004290 GLP Unpublished	

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II A 7.1.1.2.1 III A 9.1.1.1 /05	de Vette H.Q.M.	2002b	Amendment I to report V4012/01. A study on the rate of degradation of CARBIMID (metabolite of BAS 222 F, Metiram) in three aerobic soils BASF Aktiengesellschaft, Ludwigshafen, Germany BASF AG Agrarzentrum, Limburgerhof, Germany BASF RegDoc# 2002/1000223 GLP Unpublished	
II A 7.1.1.2.1 III A 9.1.1.1 /03	de Vette H.Q.M., Cremers R.K.H	2002	A study on the rate of degradation of EBIS (metabolite of BAS 222 F, Metiram) in three aerobic soils BASF Aktiengesellschaft, Ludwigshafen, Germany BASF AG Agrarzentrum, Limburgerhof, Germany BASF RegDoc# 2002/1005335 GLP Unpublished	
II A 7.2.1.3.2	Ebert D.	2003	Degradation of BAS 222 F (Metiram) in Water/Sediment Systems Under Aerobic Conditions BASF Aktiengesellschaft, Ludwigshafen, Germany BASF AG Agrarzentrum, Limburgerhof, Germany BASF RegDoc# 2003/1001011 GLP Unpublished	
II A 7.1.2 III A 9.1.2 /01	Richter Th.	2002a	Study for the adsorption/desorption determination of Metiram-metabolite 243959 (BF 222-EBIS) on 5 European soils BASF Aktiengesellschaft, Ludwigshafen, Germany BASF AG Agrarzentrum, Limburgerhof, Germany BASF RegDoc# 2002/1005329 GLP Unpublished	

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II A 7.1.2 II A 7.1.2 III A 9.1.2 /02	Richter Th.	2002b	Study for the adsorption/desorption determination of Metiram-metabolite 251072 (BF 222-CARBIMID) on 5 European soils BASF Aktiengesellschaft, Ludwigshafen, Germany BASF AG Agrarzentrum, Limburgerhof, Germany BASF RegDoc# 2002/1005327 GLP Unpublished	
II A 7.2.1.2 7.3/A II A 2.9.3,	Von Götz, N.	2000	Photochemical Oxidative Degradation of EBIS, a Degradation Product of Metiram (BAS 222 F) (QSAR estimates) BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. # 2000/1000148 GLP Unpublished	
II A 7.1.2 7 7.1 /A	Yeh, S.M	.1987	Batch Soil Adsorption/Desorption Study on Ethylenethiourea ETU Task-Force BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. #1986/5201 Unpublished	*
III A 9.2.1 5.5 5.1/A	Von Götz, N.	2000	Predicted Environmental Concentrations (PEC) of Metiram and its metabolite ETU in Surface Water after Application of Metiram Formulations to different crops BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. # 2000/1000132 Unpublished	
III A 9.1.3 5.2/A	Von Götz, N	. 2000	Predicted Environmental Concentrations (PEC) of Metiram and its metabolite ETU in Soil after Application of Metiram Formulations to different crops BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. # 2000/1004064 Unpublished	

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III A 9.2.1 5.3/A	Van de Veen, J.R., Von Götz, N.	2000	Predicted Environmental Concentrations (PEC) of metabolite ETU in Groundwater after Application of Metiram Formulations to summer wheat as a worst case for different crops BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. # 2000/1004065 Unpublished	
III A 9.2.1	Dressel, J.	2001	Predicted Environmental Concentration (PEC) of Metabolite ETU in Groundwater after Application of Metiram Formulations to different Crops BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2001/1014992 Unpublished	
III A 9.2.3 5.1/A	Von Götz, N	2000	Predicted Environmental Concentrations (PEC) of Metiram and its metabolite ETU in Surface Water after Application of Metiram Formulations to different crops BASF Aktiengesellschaft, Limburgerhof, Germany Addendum to BASF Reg. Doc. # 2000/1000132 BASF DocID 2000/1004068 Unpublished	
III A 9.2.	Von Götz N., Dressel J	2001	Joint Position Paper Of Dow, Cerexagri, BASF For Mancozeb, Metiram And Maneb: Environmental Fate EBDC's: Summary Assessment Of Risk To Groundwater BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany EBDC Task Force BASF RegDoc# 2001/1020883 Unpublished	*

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B.9 Ecotoxicology

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
II A 8.1.3 8.4	Munk, R.	1992	1-Generation reproduction study with Metiram-Premix (BAS 222 29 F) on the mallard duck (<i>Anas platyrhynchos</i> L.) by administration in the diet BASF Aktiengesellschaft, Ludwigshafen, Germany BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. #92/11151 GLP Unpublished	
II A 8.1.3 8.1/A	Munk, R.	1998	BAS 222 28 F – 1 generation reproduction study on the bobwhite quail (<i>Colinus virginianus</i>) by administration in the diet BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc.#98/10719 GLP Unpublished	
II A 8.1 III A 10.1 III A 10.3	Welter K	2001	Summary and Evaluation (Document M-III, Section 6) for Metiram and the Representative Formulation BAS 222 28 F concerning Birds and Terrestrial Vertebrates other than Birds BASF Aktiengesellschaft, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2001/1007693 Unpublished	
II A 8.1 III A 10.1	Welter K	2003	BAS 222 F (Metiram) Ecologically Relevant Species (Species of Concern) and Relevant Proportions of Diet (PD) for Refined Risk Assessments on Bird and Mammals BASF Aktiengesellschaft, Ludwigshafen, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# . 2001/1014075 Unpublished	

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II A 8.1.3	Frey LT et. al	2004	Metiram: A Reproduction Study with the Mallard. WILDLIFE INTERNATIONAL, LTD., Maryland, USA BASF Aktiengesellschaft, Limburgerhof, Germany BASF DocID. 2004/1004372 GLP unpublished	
A II 8.1	Welter K.	2004	Polyram WG (BAS 222 28 F) / Metiram. Risk assessment for birds (IIIA, 10.1) and terrestrial vertebrates other than birds (IIIA, 10.3) according to Sanco 4145/2000, rev. 6, 25.09.02 BASF Aktiengesellschaft, Limburgerhof, Germany BASF Aktiengesellschaft, Limburgerhof, Germany BASF DocID. 2004/1004276 unpublished	
All 8.1 AIII 10.5.2	Tilting N	2004	Residues of metiram and ETU in potential feed items of birds and wild mammals following application of Polyram WG (BAS 222 28 F) in potatoes BASF Aktiengesellschaft, Limburgerhof, Germany BASF Aktiengesellschaft, Limburgerhof, Germany BASF DocID. 2004/1006523 GLP unpublished	
II A 8.2.1 III A 10.2.1 10.1/A	Munk, R..	1996	BAS 222 28 F Acute Toxicity Study on the Bluegill Sunfish (Lepomis macrochirus RAF.) in a flow -through system (96 h) BASF Aktiengesellschaft Ludwigshafen, Germany BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. #96/10978 GLP Unpublished	

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II A 8.2.1 III A 10.2.1 /01	Zok S	2002a	BAS 222 28 F – Acute Toxicity Study on the Common Carp (<i>Cyprinus Carpio</i>) in a Flow through System over 96 hours BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1004894 GLP Unpublished	
II A 8.2.1 III A 10.2.1 /02	Zok S	2002	BAS 222 28 F – Acute Toxicity Study on the Golden Orf (<i>Leuciscus idus</i>) in a Flow through System over 96 hours 2002/1004892 BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1004892 GLP Unpublished	
II A 8.2.1 III A 10.2.1 /03	Zok S	2002	BAS 222 28 F – Acute Toxicity Study on the Fathead Minnow (<i>Pimephales promelas</i>) in a Flow through System over 96 hours BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1004893 GLP Unpublished	
II A 8.2.1 III A 10.2.1 /04	Zok S	2002d	BAS 222 28 F – Acute Toxicity Study on the Stickleback (<i>Gasterosteus aculeatus</i>) in a Flow through System over 96 hours BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1004890 GLP Unpublished	
II A 8.2.4 III A 10.2.2 10.2/A	Maisch, R..	1997	Determination of the Acute Effect of BAS 222 28 F on the swimming ability of the water flea <i>Daphnia magna</i> Straus BASF Aktiengesellschaft Ludwigshafen, Germany BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. #97/10538 GLP Unpublished	

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II A 8.2.5 III A 10.2.1	Dohmen, G. P.	2002	Effect of BAS 222 28 F on the Population Development of <i>Daphnia magna</i> STRAUS in an Extended Laboratory Test BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1005270 GLP Unpublished	
II A 8.2.2 III A 10.2.4 /01	Junker M.	2002a	Effect of multiple applications of BAS 222 28 F on the rainbow trout (<i>Oncorhynchus mykiss</i>) in a chronic, juvenile growth test BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1005264 GLP Unpublished	
II A 8.2.4 III A 10.2.1 /05	Junker M.	2002	Effect of BAS 222 28 F on Cyclopoida in a 48 Hours Static, Acute Toxicity Test BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1005266 GLP Unpublished	
II A 8.2.4 III A 10.2.1 /06	Junker M.	2002c	Effect of BAS 222 28 F on <i>Physa acuta</i> in a 96 Hours Static, Acute Toxicity Test BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1005265 GLP Unpublished	

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II A 8.2.4 III A 10.2.1 /07	Junker M.	2002d	Effect of BAS 222 28 F on Ostracoda in a 48 Hours Static, Acute Toxicity Test BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1005268 GLP Unpublished	
II A 8.2.4 III A 10.2.1 /08	Junker M.	2002e	Effect of BAS 222 28 F on the Immobility of Chydorus sphaericus in a 48 Hours Static, Acute Toxicity Test BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1005267 GLP Unpublished	
II A 8.2.4 III A 10.2.1 /09	Junker M.	2002f	Effect of BAS 222 28 F on Simocephalus vetulus in a 48 Hours Static, Acute Toxicity Test BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1005269 GLP Unpublished	
II A 8.2.5 III A 10.2.2 10.3/A	Maisch, R..	1997	Determination of the Chronic Effect of BAS 2222 28 F on the reproduction of the water flea Daphnia magna Straus in a flow through system BASF Aktiengesellschaft Ludwigshafen, Germany BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. #97/10521 Amendment: BASF Reg. Doc. #97/10537 GLP Unpublished	

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II A 8.2.6 III A 10.2.1 /10	Kubitza J.	2002a	Effect of Metiram (applied as formulated product BAS 222 28 F on the growth of the green alga <i>Ankistrodesmus bibraianus</i>) BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1005272 GLP Unpublished	
II A 8.2.6 III A 10.2.1 /11	Kubitza J.	2002b	Effect of Metiram (applied as formulated product BAS 222 28 F on the growth of the alga <i>Euglena gracilis</i>) BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1005273 GLP Unpublished	
II A 8.2.6 III A 10.2.1 /12	Kubitza J.	2002c	Effect of Metiram (applied as formulated product BAS 222 28 F on the growth of alga <i>Tetraedron caudatum</i>) BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1005274 GLP Unpublished	
II A 8.2.6 III A 10.2.1 /13	Kubitza J.	2002d	Effect of Metiram (applied as formulated product BAS 222 28 F on the growth of the green alga <i>Desmodesmus subspicatus</i>) BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1005275 GLP Unpublished	

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II A 8.2.6 III A 10.2.1 /14	Kubitza J.	2002e	Effect of Metiram (applied as formulated product BAS 222 28 F on the growth of the blue-green alga <i>Anabaena flos-aquae</i>) BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1005276 GLP Unpublished	
II A 8.2.6 III A 10.2.1 /15	Kubitza J.	2002f	Effect of Metiram (applied as formulated product BAS 222 28 F on the growth of <i>Navicula pelliculosa</i>) BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1005277 GLP Unpublished	
II A 8.2.6 III A 10.2.1 /16	Kubitza J.	2002g	Effect of Metiram (applied as formulated product BAS 222 28 F on the growth of <i>Cosmarium praemorsum</i>) BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1005278 GLP Unpublished	
II A 8.2.6 III A 10.2.1 /17.	Kubitza J	2002h	Effect of Metiram (applied as formulated product BAS 222 28 F on the growth of <i>Staurastrum tetracerum</i>) BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1005279 GLP Unpublished	

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II A 8.2.6 III A 10.2.1 /18	Kubitza J.	2002i	Effect of Metiram (applied as formulated product BAS 222 28 F on the growth of <i>Corcontochrysis noctivaga</i>) BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1005280 GLP Unpublished	
II A 8.2.6 III A 10.2.1 /19	Kubitza J.	2002j	Effect of Metiram (applied as formulated product BAS 222 28 F on the growth of <i>Ochromonas danica</i>) BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1005281 GLP Unpublished	
II A 8.2.6 III A 10.2.1 /20	Kubitza J.	2002k	Effect of Metiram (applied as formulated product BAS 222 28 F on the growth of <i>Staurastrum gracile</i>) BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1005282 GLP Unpublished	
II A 8.2.6 III A 10.2.1 /21	Kubitza J.	2002l	Effect of Metiram (applied as formulated product BAS 222 28 F on the growth of <i>Anabaena cylindrica</i>) BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1005283 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
II A 8.2.6 III A 10.2.1 /22	Kubitza J.	2002 m	Effect of Metiram (applied as formulated product BAS 222 28 F on the growth of <i>Pseudokirchneriella subcapitata</i>) BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1005284 GLP Unpublished	
II A 8.2.6 III A 10.2.1	Kubitza J. Dohmen G. P.	2002n	High Tier Assessment on the Risk of Metiram to Aquatic Ecosystems BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1012929 GLP: not applicable Unpublished	
II A 8.2.6	Dr. G. P. Dohmen	2002	Higher Tier Assessment on the Risk of metiram to aquatic ecosystems BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1005271 GLP: not applicable Unpublished	
II A 8.2.7	Dohmen, G.P.	2001	Effect of Metiram - Applied as formulated product BAS 222 28 F - on the development of sediment dwelling larvae of <i>Chironomus riparius</i> in a water-sediment system BASF Aktiengesellschaft, Ludwigshafen, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# . 2001/1007679 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
II A 8.2.7	Dohmen G.P.	2003	Response to the Danish Comments on Ecotoxicology – 2 nd Addendum Vol. 1. Revised List of Endpoints January 2003 on Metiram from September 15 th , 2003, with Respect to Aquatic Ecotoxicology BASF Aktiengesellschaft, Ludwigshafen, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# . 2003/1014073 Unpublished	
IIA 8.3.2 IIIA 10.3.4 10.14	Schlosser, E.	1995	Effect of BAS 222 28 F on the parasitoid <i>Aphidius rhopalosiphi</i> in laboratory trials BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. #95/10277 GLP Unpublished	
IIA 8.3.2 IIIA 10.3.4 10.5/A	Suhm, M.	1995	Effects of BAS 222 28 F on the mortality of the spider Genus <i>Pardosa</i> in a laboratory test BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. #95/10326 GLP Unpublished	
II A 8.3	Ufer A.	2002	Effect of BAS 222 28 F on the predatory mite <i>typhlodromus pyri</i> (Acari: Phytoseiidae) after exposure to aged residues BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1011531 GLP: yes Unpublished	
IIA 8.3.2 IIIA 10.3.4 10.10/A	Ufer, A.	1998	Effects of BAS 222 28 F on populations of the predatory mite <i>Typhlodormus pyri</i> , Scheuten in a field study BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. #1998/11250 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 IIIA 10.3.4 10.11/A	Ipach, R.	1996	Effects of BAS 222 28 F on predatory mites (<i>Typhlodromus pyri</i>) in the field (grapevines), Germany Landes-Lehr und Forschungsanstalt, Neustadt Germany BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. #1997/10170 GLP Unpublished	
IIA 8.3.2 IIIA 10.3.4 10.12/A	Huber, B.	1997	Field Study on predatory mites – Final Report Staatliches Weinbauinstitut Freiburg, Germany BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. #1997/10171 GLP Unpublished	
IIA 8.3.2 IIIA 10.3.4 10.13/A	Ufer, A.	2000	Effect of BAS 222 28 F on the predatory mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae) in a laboratory trial (multiple dose test) BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. #2000/1011463 Unpublished	
II A 8.3.2	Ufer A	2002	Effects of BAS 222 28F on predatory mites - Summary of available data BASF Aktiengesellschaft, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF Reg.Doc. 2002/1004142 GLP: Not applicable Unpublished	
II A 8.3.2 IIIA 10.3.3.2 /01	Müther J.	2002a	A field study to evaluate the effects of BAS 222 28 F on predatory mites (Acari: Phytoseiidae) in vines (Italy) GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, Niefern-Öschelbronn, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF Reg.Doc. 2002/1013877 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
II A 8.3.2 IIIA 10.3.3.2 /02	Müther J.	2002b	A field study to evaluate the effects of BAS 222 28 F on predatory mites (Acari: Phytoseiidae) in vines (Italy) GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, Niefern-Öschelbronn, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF Reg.Doc. 2002/1013878 GLP Unpublished	
II A 8.3.2 IIIA 10.3.3.2 /03	Ufer A.	2002	Effect of BAS 222 28 F (Metiram 700 g/kg WG) on predatory mites –in crops habitants-BASF Aktiengesellschaft, Ludwigshafen, Germany BASF Reg.Doc. 2002/1011532 GLP Unpublished	
II A 8.6 III A 10.8	Oberwalder C., Schmidt O.	2000	Bas 222 28 F: Effects on non target plants in the greenhouse - A limit test BASF Aktiengesellschaft, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2000/1017171 GLP Unpublished	
II A 8.2.2.1	Zok, S.	2001	Acute toxicity study on the rainbow trout (Oncorhynchus mykiss WALBAUM 1792) in a static system (96 hours). BASF Aktiengesellschaft, Ludwigshafen, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2001/1001877 GLP Unpublished	*

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Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
II A 8.2.4	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 BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2000/1017216 GLP Unpublished	*
II A 8.2.6	Reuschenbach P.	2000	Determination of the inhibitory effect on the cell multiplication of unicellular green algae BASF Aktiengesellschaft, Ludwigshafen, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2000/1017191 GLP Unpublished	*
II A 8.2.8	Zok, S.	2002	<i>Xenopus laevis</i> metamorphosis assay (ETU) BASF Aktiengesellschaft, Ludwigshafen, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# . 2002/1003402 GLP Unpublished	*
II A 8.4.1	Staab, F.	2001	Effect of BF 222-ETU on the mortality of the earthworm <i>Eisenia fetida</i> BASF Aktiengesellschaft, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF Reg.Doc. 2001/1000882 GLP Unpublished	*

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Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
II A 8.5	Krieg, W.	2001	Effect of BF 222-ETU on carbon transformation of the soil microflora BASF Aktiengesellschaft, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2001/1000909 GLP Unpublished	*
II A 8.5	Krieg, W.	2001	Effect of BF 222-ETU on nitrogen transformation of the soil microflora BASF Aktiengesellschaft, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2001/1000109 GLP Unpublished	*
II A 8.2.2.1	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 BASF RegDoc# 2001/5000987 GLP Unpublished	*
II A 8.2.4	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 EBDC/ETU task Force BASF RegDoc# 2001/5000988 GLP Unpublished	*
II A 8.2.6	Palmer, S. et al.	2001	Ethylene Urea: A 96-hour toxicity test with the freshwater alga (<i>Selenastrum capricornutum</i>) Wildlife International Ltd., USA EBDC/ETU Task Force BASF RegDoc# 2001/5000986 GLP Unpublished	*

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Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
II A 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 BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2001/1000881 GLP Unpublished	*
II A 8.5	Krieg, W.	2001	Effect of BF 222-EU on carbon transformation of the soil microflora BASF Aktiengesellschaft, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2001/1000910 GLP Unpublished	*
II A 8.5	Krieg, W.	2001	Effect of BF 222-EU on nitrogen transformation of the soil microflora BASF Aktiengesellschaft, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2001/1000108 GLP Unpublished	*

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APPENDIX IIIB**METIRAM**

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

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

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
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none

B.6 Toxicology and metabolism

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
II A 5.6.1	Stauber F.	2002	Metiram: Evaluation on dermal absorption in rats based on in vivo data BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1008788 GLP: no Unpublished

B.7 Residue data

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
II A 6.1 II A 6.2 II A 6.6	Bross M.	2002	Metiram:Comments of the applicant concerning the animal residue definition, the storage stability of ETU in grapes and the wine processing studies BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany BASF Aktiengesellschaft, Ludwigshafen, Germany BASF RegDoc# 2002/1008788 GLP: no Unpublished
IIA 6.3 IIIA 8.2 IIA 6.5 IIIA 8.4 /6.40	Mamouni, A.	1994	Determination of residues of Metiram (CS ₂ and ETU) in Tomatoes following treatment with Polyram DF (BAS 222 28 F) under Field Conditions in Italy, 1992 and in Industrial tomatoes processing products RCC Umweltschemie AG, Itingen, Switzerland BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. #94/10418 GLP, Unpublished.

B.8 Environmental fate and behaviour

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
none			

B.9 Ecotoxicology

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
none			

APPENDIX IV

List of uses supported by available data

METIRAM

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/ha min max	water l/ha min max	kg as/ha min max		
Grape	N+S-EU	Polyram DF	F	Fungal diseases	WG	700	SPI	15-79	3	12	0.11	1000	1.1	56	
Potato	N+S-EU	Polyram DF	F	Fungal diseases	WG	700	SPI	51-87	6	7	0.126-0.21	600-1000	1.26	21	

- Remarks:**
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
 - (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