



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E – Food Safety: plant health, animal health and welfare, international questions
E1 - Plant health

Molinate
SANCO/3047/99-Final
3 June 2003

Review report for the active substance **molinate**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 4 July 2003 in view of the inclusion of molinate 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 molinate, 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. Molinate 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, Herbex Produtos Quimicos Lda. on 10 February 1993, Zeneca Agrochemicals Regulatory Affairs Department (now Syngenta Limited) on 27 July 1993, OXON Italia SpA on 20 July 1993 and Chemol Benelux Ltd on 23 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance molinate in Annex I to the Directive.

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

¹ OJ No L 366, 15.12.1992, p.10.

² OJ No L 259, 13.10.2000, p.27.

³ OJ No L 107, 28.04.1994, p.8.

⁴ OJ No L 225, 22.09.1995, p.1.

Only Zeneca Agrochemicals (now Syngenta Limited) and OXON Italia SpA submitted in time a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore Zeneca Agrochemicals (now Syngenta Limited) and OXON Italia SpA were considered to be main data submitters. Herbex Produtos Quimicos Lda did not submit a complete dossier. Chemol Benelux Ltd did not submit a dossier. Herbex Produtos Quimicos Lda withdrew its support of molinate on 23 December 2002.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Portugal submitted on 30 November 1998 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 molinate 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 molinate from Zeneca Agrochemicals (now Syngenta Limited) and OXON Italia SpA, on 15 March 1999.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the Commission forwarded for consultation the draft assessment report to all the Member States on 16 June 1999 as well as to Zeneca Agrochemicals (now Syngenta Limited) and OXON Italia SpA being main data submitters, on 26 June 1999.

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

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

The meetings for this consultation were organised on behalf of the Commission by the Pesticide Safety Directorate (PSD) in York, United Kingdom, November 1999 to July 2000.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States on 15. June 2001 as well as to the main data submitters on 01 June 2001 for comments and further clarification.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the dossier, the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications on the remaining issues, received after the peer review were referred to the Standing Committee on the Food Chain and Animal Health, and specialised working groups of this Committee, for final examination, with participation of experts from the 15 Member States. This final examination took place from November 2002 to July 2003, and was finalised in the meeting of the Standing Committee on 4 July 2003.

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 2003/81/EC⁵ concerning the inclusion of molinate in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing molinate 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 molinate 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 molinate 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).

⁵ OJ No L 224, 06.09.2003, p.29.

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 4(1) and of the uniform principles laid down in Annex VI of Directive 91/414/EEC.

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI; excluding water and products of animal origin) for a 60 kg adult is 0,12 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). Estimates of acute dietary exposure of adults revealed that the Acute Reference Dose (ARfD) is not exceeded for rice. 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 molinate are given in Appendix I.

As there is no FAO specification, the active substance shall comply with the specification of minimum purity, which is given in Appendix I of this report.

The review has established that for the active substance notified by the main data submitters Zeneca Agrochemicals (now Syngenta Limited) and OXON Italia SpA, none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

5. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 4(1) of Directive 91/414/EEC and the uniform principles laid down in Annex VI of that Directive, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in Appendix II.

6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing molinate

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 soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate.
- Member States should pay particular attention to the possibility of short-range transport of the active substance in air.

7. List of studies to be generated

No further studies were identified which were at this stage considered necessary in relation to the inclusion of molinate in Annex I under the current inclusion conditions.

Some 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.

In view of the remaining doubts about the volatilisation potential and/or atmospheric transport further studies may be required. Member States may require these as soon as appropriate schemes have been developed and internationally agreed guidance is available for assessing these environmental risks.

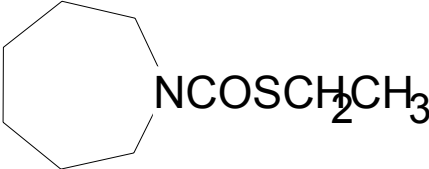
8. Information on studies with claimed data protection

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 molinate in Annex I of the Directive.

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

Common name (ISO)	Molinate
Chemical name (IUPAC)	S-ethyl azepane-1-carbothioate; S-ethyl perhydroazepine-1-carbothioate; S-ethyl perhydroazepine-1-thiocarboxilate
Chemical name (CA)	S-ethyl hexahydro-1H-azepine-1-carbothioate (9CI)
CIPAC No	235
CAS No	2212-67-1
EEC No	218-661-0
FAO SPECIFICATION	Not allocated
Minimum purity	950 g/kg
Molecular formula	C ₉ H ₁₇ NOS
Molecular mass	187.3
Structural formula	

Melting point	Freezing point: < -25°C (99.9%)
Boiling point	277.5 – 278.5 °C (99.9%)
Appearance	Pale yellow liquid (99.9%)
Relative density	1.0643 (99.9%)
Vapour pressure	0.5 Pa at 25°C
Henry's law constant	0.687 Pa m ³ mol ⁻¹ at 25°C
Solubility in water	pH unbuffered: 1.10 g/l values at other pH not required
Solubility in organic solvents	Miscible with chlorobenzene, ethanol, kerosene xylene, n-octanol, acetone, ethyl acetate, dichloromethane, hexane, methanol and toluene (20°C)
Partition co-efficient (log P_{ow})	pH 7.85 – 7.94: 2.86 (23°C)
Hydrolytic stability (DT₅₀)	pH 5: >1 year pH 7: >1 year pH 9: > 1 year
Dissociation constant	No dissociation occurs
Quantum yield of direct photo-transformation in water at λ >290 nm	Not required
Flammability	Not flammable
Explosive properties	Not explosive
UV/VIS absorption (max.)	λ max. ≅ 200 nm no absorption at λ > 290 nm
Photostability in water (DT₅₀)	Not required

APPENDIX II

END POINTS AND RELATED INFORMATION

MOLINATE

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	>80% within 48h
Distribution:	Widely distributed, highest concentrations in blood
Potential for accumulation:	No evidence of accumulation
Rate and extent of excretion:	Nearly complete excretion within 48 hours, mainly in urine
Toxicologically significant compounds:	Molinate and metabolites
Metabolism in animals:	Nearly completely metabolised <u>rats</u> : major pathway is S-oxidation to sulfoxide, followed by hydrolysis (hexamethyleneimine) or conjugation (mercapturate) <u>human</u> : major pathway is ring hydroxylation followed by conjugation with glucuronic acid (minor route of metabolism in rat)

Acute toxicity

Rat LD ₅₀ oral:	483 mg/kg bw
Rat LD ₅₀ dermal:	4350 mg/kg bw
Rat LC ₅₀ inhalation:	1.39 mg/l, (4h, nose-only, aerosol)
Skin irritation:	Non-irritant
Eye irritation:	Non-irritant
Skin sensitization (test method used and result):	Skin sensitiser (M&K): no further data required

Short term toxicity

Target / critical effect:	Testes, kidney, liver & adrenals in the rat Central nervous system and red blood cells in the dog
Lowest relevant oral NOAEL / NOEL:	1 mg/kg bw/d (90-day rat, 1-year dog)
Lowest relevant dermal NOAEL / NOEL:	No data; none required

Lowest relevant inhalation NOAEL /
NOEL:

No data; none required

Genotoxicity

No evidence of genotoxicity

Long term toxicity and carcinogenicity

Target / critical effect:

Degenerative changes in the nervous system, ovaries
and testes

Lowest relevant NOAEL:

2 mg/kg bw/d (40 ppm) (2-year rat study)

Carcinogenicity:

Kidney tumors (benign and malignant) in the rat

Reproductive toxicity

Target / critical effect - Reproduction:

Decreased fertility

Lowest relevant reproductive NOAEL /
NOEL:

0.8 mg/kg bw/d (10 ppm)

Target / critical effect - Developmental
toxicity:

Foetotoxicity at maternally toxic levels
No evidence of teratogenicity

Lowest relevant developmental NOAEL /
NOEL:

20 mg/kg bw/d (rabbit study)

Delayed neurotoxicity

No delayed neurotoxicity, neurohistopathological lesions
following an acute dose; NOAEL 200 mg/kg bw/d

Other toxicological studies

Relevant biochemical differences between species and
significant metabolic differences in rodents and humans.

Medical data

Monitoring data shows no effect on the fertility of male
workers (closed manufacturing system). No evidence of
skin sensitisation in agricultural workers.

Summary

	Value	Study	Safety factor
ADI:	0.008 mg/kg bw/d	multigeneration study	100
AOEL systemic:	0.008 mg/kg bw bw/d	multigeneration study	100
ARfD (acute reference dose):	0.1 mg/kg bw	sperm morphology (rat study)	100

Dermal absorption

GR formulation: 2.2% (Data derived value)

2 Fate and behaviour in the environment

Note: Because of specific use of molinate to rice paddy fields non standard (Annex II and Annex III to 91/414/EEC Directive) studies have been performed.

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:

0.96% (30 days, T°C 30°C)

Non-extractable residues after 100 days:

2.39% (30 days, T°C 30°C)

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

water: molinate sulfoxide: max 6.58% (14 d) HMI: max: 8.96% (7d) soil: molinate sulfoxide: max 1.91% (30 d) HMI: max: 0.66% (30d)
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Supplemental studies

Anaerobic:

Nitrogen atmosphere (365d, T°C 30°C): Oxidation of the ring producing hydroxy and oxo derivatives and of the ethyl group producing alcohol and molinate acid, followed by decarboxilation and reductive processes; none of the compounds represented individually more than 3% AR. Max. 45.5%AR as CO ₂ at 365DAT.
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Soil photolysis:

No data submitted. Not required

Remarks:

None

Rate of degradation

Laboratory studies

DT_{50lab} (20 °C, aerobic):

DT _{50lab} (30°C, aerobic, flooded soil): 28 days,

DT_{90lab} (20 °C, aerobic):

DT _{90lab} (20°C, aerobic): not reached
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DT_{50lab} (10 °C, aerobic):

DT _{50lab} (10°C, aerobic): no data submitted
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DT_{50lab} (20 °C, anaerobic):

DT _{50lab} (20°C, anaerobic, N ₂ atm., flood soil): 159 days
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Field studies (country or region)

DT_{50f} from soil dissipation studies:

USA California, Arkansas and Texas field dissipation studies on rice paddy fields.
DT_{50f} soil pre-flood: 3 – 7 days
DT_{50f} soil post-flood: 5 – 35 days

DT_{90f} from soil dissipation studies:

USA California, Arkansas and Texas field dissipation studies on rice paddy fields.
DT_{90f} soil post-flood: 90 – 115 days
Molinate residues confined to 40 cm depth but mainly in the top 0 to 10 cm, at max. 0.52 to 1.7 mg/kg. No metabolites were detectable in soil.

Italy Pavia, Milan, Novara and Vercelli field dissipation (residue) studies on rice paddy fields. At 0 to 5 cm depth maximums of 0.010 to 0.30 mg a.s./kg were measured. maximums of 0.1 mg/kg were measured at 5 – 20 cm depth. In water, maximums of 0.03 to 2.6 mg/l were measured one DAT and decreased to 0.008 to 1.3 mg/l by 4 DAT. At 42 DAT levels were of 0.001 to 0.007 mg a.s./l.
Metabolites were not investigated.

Soil accumulation studies:

No data submitted. Not required

Soil residue studies:

No data submitted. Not required

Remarks:

e.g. effect of soil pH on degradation rate

None

Adsorption/desorptionK_f / K_{oc}:

K_{oc} (a.s.): 121, 158, 195 (clay), 206 (clay loam), 252 dm³/kg; mean K_{oc}: 190 dm³/kg
 K_{oc} (molinate sulfoxide): 93, 151, 171 (clay loam), 195, 234 (clay) dm³/kg
 K_{oc} (HMI): 226, 375, 410, 517 (clay loam), 603 (clay) dm³/kg

K_d:

K_d (a.s): 0.74, 1.35, 1.57, 1.95, 2.04
 K_d (molinate sulfoxide): 0.78, 1.86, 1.88, 2.26, 2.81
 K_d (HMI): 1.64, 4.51, 5.62, 5.69, 7.23

pH dependence:

No pH dependence

Mobility**Laboratory studies:**

Column leaching:

No data submitted. Not required

Aged residue leaching:

No data submitted. Not required. The metabolites are not relevant under laboratory or field conditions

Field studies:

Lysimeter/Field leaching studies:

No data submitted. Not required

Remarks:

None

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:

pH 5, T° 25°C, 40°C: no significant hydrolysis
pH 7, T° 25°C, 40°C: no significant hydrolysis
pH 9, T° 25°C, 40°C: no significant hydrolysis

Major metabolites:

No major metabolites

Photolytic degradation:

No significant photolysis at pH 7 and T° 25°C
Under field conditions 5 – 10% dissipation of a.s. was attributed to photolysis

Major metabolites:

No major metabolites

Biological degradation

Readily biodegradable:

No data submitted. Not required

Water/sediment study:

USA California, Arkansas and Texas field trials.

DT₅₀ water:

DT₅₀ water: 2 – 5 days

DT₉₀ water:

DT₅₀ soil pre-flood: 3 – 7 days

DT₅₀ whole system:

DT₅₀ soil post-flood: 5 – 35 days

DT₉₀ whole system:

DT₉₀ soil post-flood: 90 – 115 days

Distribution in water / sediment systems
(active substance)

Distribution in the paddy field systems:
Molinate residues in flood water dissipated rapidly to levels near or below the LOD after 15 days.
Molinate residues in flooded soil were confined to 40 cm depth but mainly in the top 10 cm soil layer

Distribution in water / sediment systems
(metabolites)

Distribution in the paddy field systems:
No metabolites were detected in soil whereas molinate sulfoxide, HMI and molinate acid were detected in two of the four trials in the paddy water only in the first 2 DAT decreasing to LOD by the end of the experimental periods.
see also point for Rate of Degradation in Soil – Field Studies

Accumulation in water and/or sediment:

No data submitted. Not required

Degradation in the saturated zone

Remarks:

No data submitted. Not required

2.3 Fate and behaviour in air

Volatility

Vapour pressure:

0.5 Pa at 25°C

Henry's law constant:

0.687 Pa m ³ mol ⁻¹ at 25°C

Photolytic degradation

Direct photolysis in air:

No data submitted

Photochemical oxidative degradation in air

Atkinson's method: DT ₅₀ = 4.2 hours

DT₅₀:

Volatilisation:

<p>From plant surfaces: No data submitted</p> <p>from soil: No data submitted</p> <p>from water:</p> <p>Flux of 51.5 ng.cm⁻².h⁻¹.ppm⁻¹ (EXAMS)</p> <p>Flux of 62.8 ng.cm⁻².h⁻¹.ppm⁻¹ (climatic chamber, equiv. to 0.02 h⁻¹ volatilisation rate)</p> <p>35% loss (field experiment)</p> <p>DT₅₀ (dissipation): 1.6 – 7.2 days (computer controlled aquatic microcosm)</p> <p>DT₅₀ (dissipation): 6 days (field study)</p>

Remarks:

None

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	LD50 = 483 mg a.s./kg b.w. (rat)
Acute toxicity to birds:	LD50 (21 d) = 389 mg a.s./kg b.w. (<i>A. platyrhynchos</i>)
Dietary toxicity to birds:	LC50 (12 d) = 2500 mg a.s./kg food (<i>A. platyrhynchos</i>)
Reproductive toxicity to birds:	NOEC (21 weeks) = 200 mg a.s./kg food (<i>A. platyrhynchos</i>)
Short term oral toxicity to mammals:	1 mg/kg bw/d (90-day rat, 1-year dog)

Aquatic Organisms

	Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Acute toxicity fish:	<i>O. mykiss</i>	a.s.	96 h	LC50	16
		EC 72.6%	96 h	LC50	15
		GR 7.5%	96 h	LC50	100
Long term toxicity fish:	<i>O. mykiss</i>	a.s.	73 d	NOEC	0.39
Bioaccumulation fish:	-	-	-	-	-
Acute toxicity invertebrate:	<i>D. magna</i>	a.s.	48 h	EC50	14.9
		EC 91.2%	48 h	EC50	5.3
		GR 7.5%	48 h	EC50	190
Chronic toxicity invertebrate:	<i>D. magna</i>	a.s.	21 d	NOEC	0.38
Acute toxicity algae:	<i>S. capri-cornutum</i>	a.s.	96 h	EbC50/ErC50	0.22/0.5
		EC 91.2%	72 h	EbC50/ErC50	0.41/0.85
		GR 7.5%	72 h	EbC50/ErC50	1.4/2.5
Chronic toxicity sediment dwelling organism:	-	-	-	-	-
Acute toxicity aquatic plants:	<i>L. gibba</i>	a.s.	14 d	EC50frond/ EbC50	3.3/ 7.7

Honeybees

Acute oral toxicity:	LD50 > 11 µg/bee
Acute contact toxicity:	No data submitted. Not relevant

Other arthropod species*Test species*

Laboratory tests

*T. pyri**P. cupreus**P. cupreus**P. cupreus**Pardosa* sp.*A. rhopalosiphi**C. carnea**T. cacoeciae*

Field or semi-field tests

Stage	Test substance	Dose (kg as/ha)	Endpoint	% Effect
protony mph	a.s.	4.5	mortality	100%
adults	EC 96%	4.5	mortality	3%
adults	EC 72.6%	5.0	mortality	0% (35.3% subleth. effects)
adults	GR 7.5%	5.0	mortality	0% (46.9% subleth. effects)
adults	EC 96%	4.5	mortality	55%
adult females	EC 96%	4.5	mortality	95%
larvae	EC 72,6%	5.0	mortality/ reproducti on	36.1%
adults	EC 72.6%	5.0	parasitism	28% reduction
No data submitted.				

Earthworms

Acute toxicity:

LC50 (14 d) = 289 mg a.s./kg substrate
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Reproductive toxicity:

No data submitted. Not relevant

Soil micro-organisms

Nitrogen mineralization:

No prolonged adverse effects at rates up to 10 kg a.s./ha

Carbon mineralization:

No prolonged adverse effects at rates up to 10 kg a.s./ha

APPENDIX IIIA**MOLINATE**

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
ZENECA				
IIA, 2/01	Goodman M A	1993	Molinate - Aqueous Solubility. Western Research Centre Report No. RR93-067B GLP. Unpublished.	
IIA, 2/02	Goodman M A	1994	Molinate - Certain Physical/Chemical Properties. Western Research Centre Report No. RR94-061B GLP. Unpublished.	
IIA, 2/03	Myers H W	1987a	Molinate - Physical Properties. Western Research Centre Report No. RR87-55. Not GLP. Unpublished.	
IIA, 2/04	Myers H W	1987b	Molinate - The Density, Vapour Pressure, Octanol/Water Partition Coefficient and Henry's Law Constant. Western Research Centre Report No. RRC 87-100. GLP. Unpublished.	
IIA, 2/05	Myers H W	1988	Molinate - Oxidising or Reducing Action, Flammability, Explodability, Storage Stability, Viscosity, Miscibility and Corrosion Characteristics. Western Research Centre Report No. RRC88-33. GLP. Unpublished.	

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

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports⁶ on previous use in granting national authorizations
IIA, 2/06	Jackon W A	1998	Determination of Certain Physical and Chemical Properties of Molinate Hazard Test Reference HT 987185. GLP. Unpublished	
IIA, 2.5/01	Anonimous	1988	Molinate: NMR, IR and Mass Spectra with Interpretation. ICI Americas Inc. Letter Report: February 1988 (RIC0260) Not GLP. Unpublished.	
IIA, 2.5/02	Goodman M A	1993	Molinate: UV Spectra and Molar Extinction Coefficient. ICI Americas Inc. Letter Report: RIC2116 Not GLP. Unpublished.	
IIA, 2.9.1/ 01	Lee K S	1988	Molinate - Hydrolysis Study. Western Research Centre Report No. RR88-46. Not GLP. Unpublished.	
IIA, 2.13/01	Tremain S P	2001	Molinate – Technical grade active ingredient: Determination of Explosive Properties. SPL Project No. 12927010. GLP. Unpublished.	
OXON				
IIA, 2.1- 3/01	Flack I	1996	Molinate Technical: physical, chemical and technical properties. Report OXN 23/942155 Huntingdon Research Centre, UK GLP. Unpublished.	
IIA, 2.2	Flack I	1996	Molinate Technical physical, chemical and technical properties. Report OXN 23/942155 Huntingdon research Centre, UK GLP. Unpublished.	
IIA, 2.3.1-2	Flack I	1996	Molinate Technical physical, chemical and technical properties. Report OXN 23/942155 Huntingdon research Centre, UK GLP. Unpublished.	
IIA, 2.4.1- 2./01	Flack I	1996	Molinate Technical physical, chemical and technical properties. Report OXN 23/942155 Huntingdon research Centre, UK GLP. Unpublished.	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports⁶ on previous use in granting national authorizations
IIA; 2.4.1-2/02	Flack I	1995	Molinate (technical) Physical and chemical properties (Appearance) Report OXN 144/950437 Huntingdon Research Centre. GLP. Unpublished.	
IIA, 2.5.1-2	Flack I	1996	Molinate Technical physical, chemical and technical properties. Report OXN 23/942155 Huntingdon research Centre, UK GLP. Unpublished.	
IIA, 2.6 - 2.10	Flack I	1996	Molinate Technical physical, chemical and technical properties. Report OXN 23/942155 Huntingdon research Centre, UK GLP. Unpublished.	
IIA, 2.11- 15	Flack I	1994	Molinate Technical physical, chemical and technical properties Report OXN 24/942335 Huntingdon Research Centre, UK GLP. Unpublished.	
ZENECA				
IIA, 4.1/01	Thorndycraft M D	1994	The Determination of Molinate in Ordram 15-G Selective Herbicide Formulations by Capillary Gas Chromatography. ZENECA Analytical Method RRC 86-110 Not GLP. Unpublished.	
IIA, 4.2.1/ 01	Alferness P L	1994	Ordram [®] : Determination of 4- Hydroxymolinate and Molinate Acid in Rice Grain and Straw by Gas Chromatography and Mass-Selective Detection. Western Research Center Report No. RR 94-015B GLP. Unpublished.	
IIA, 4.2.1/ 02	Storoni H R	1991	Molinate: Analytical Method Validation in Rice Grain and Straw. Western Research Center Report No. RR 91-025B GLP. Unpublished.	
IIA, 4.2.1/ 03	Weber H and Pelz S	2001	Validation of the DFG method S19 (extended revision) for the determination of residues of molinate in rice (grain and straw). Specht & Partner Project No. SYN-0102V. GLP. Unpublished.	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports⁶ on previous use in granting national authorizations
IIA, 4.2.2/01	Curry K K	1988	Determination of Molinate Residues in Soil by Capillary Gas Chromatography. Western Research Center Report No. WRC 88-74 Not GLP. Unpublished.	
IIA, 4.2.3/04	Pangburn T G	1998	Molinate: Validation of Method to Determine Molinate in Surface Water Matrix by Gas Chromatography Western Research Center Report No. WRC 98-070 GLP. Unpublished	
IIA, 4.2.3/05	Pangburn T G	1998	Determination of Molinate in Surface Water by Gas Chromatography Western Research Center Report No. WRC 98-157 Not GLP. Unpublished	
IIA, 4.2.4/01	Leung S	1993	Molinate: Validation of an Analytical Method for the Determination of Molinate in Air at High Sampling Flow Rate. Western Research Center Report No. RR 92-067B 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
ZENECA				
IIA, 5.1/06	Batten P L <i>et al</i>	1992	Molinate: Metabolism in Man Following a Single Oral Dose. Report No. CTL/R/1099 Not GLP. Unpublished.	
IIA, 5.4/01	Callander R.D.	1988	Molinate: An Evaluation in the <i>Salmonella</i> Mutation Assay. Report No. CTL/P/2246 (C2.6/04) GLP. Unpublished.	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA, 5.9.3/ 03	Checkoway H, Matanoski G, Marsh G M and Savitz D A	1995	An Assessment of Fertility in Male Workers Exposed to Molinate at the Stauffer Chemical Company - Executive Summary and Comments (Main Epidemiology Report CTL/C/3097, 13 July 1995). Report No. CTL/C/3098 Not GLP. Unpublished.	
IIA, 5.8.2/ 04	Ellis M K and Farnworth M J	1999	First revision to molinate: Effects of molinate and molinate metabolites following seven days administration on testis and sperm morphology in the rat. Report No. CTL/R/8608 GLP. Unpublished	
IIA, 5.8.2/ 05	Ellis M K and Farnworth M J	1999	First revision to molinate: Investigation in to the mode of action in the rat Leydig cells in vitro. Report No. CTL/R/8609 GLP. Unpublished	
IIA, 5.8.2/ 06	Ellis M K and Farnworth M J	1999	First revision to molinate: Effects of molinate and molinate metabolites on plasma and testicular interstitial fluid hormone concentrations in the rat in vivo. Report No. CTL/R/8610 GLP. Unpublished	
IIA, 5.6/01	Gilles P A and Richter A G	1989	A Two-Generation Reproduction Study in Female Rats with R-4572. Report No. T-13218 (C2.5/02) (Volumes 1-2) GLP. Unpublished.	
IIA, 5.2/02	Hext P M	1989	Molinate: 4-Hour Acute Inhalation Toxicity Study in the Rat. Report No. CTL/P/2412 (C2.1/02) GLP. Unpublished.	
IIA, 5.5/02	Hodge M C E	1993	Report Supplement: Histopathological Re-evaluation of the Ovarian Thecal/Interstitial Cell Vacuolation/Hypertrophy. Report No. CTL/P/4115 (C2.4/03 - Supplement) GLP. Unpublished.	
IIA, 5.6/02	Hodge M C E	1993	Report Supplement to T-13218: Histopathological Re-evaluation of the Ovarian Thecal/Interstitial Cell Vacuolation Hypertrophy. Report No. CTL/P/4175 GLP. Unpublished.	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA, 5.8/02	Hodge M C E	1993	Molinate: Sperm Morphology in the Rat. Report No. CTL/P/4102 (C2.2/02) GLP. Unpublished.	
IIA, 5.8.2/ 07	Horner S A	1996	Molinate: Developmental neurotoxicity study in rats. Report No. CTL/P/4994 GLP. Unpublished	
IIA, 5.4/02	Howard C A and Richardson C R	1988	Molinate: An Evaluation in the <i>in vitro</i> Cytogenetic Assay in Human Lymphocytes. Report No. CTL/P/2402 (C2.6/05) GLP. Unpublished.	
IIA, 5.1/05	Jones B K	1987	Molinate: Excretion and Blood Kinetics in the Monkey. Report No. CTL/L/4432 Not GLP. Unpublished.	
IIA, 5.8/01	Killinger J M <i>et al</i>	1981	Ordram: Fertility Study in Male Rats Mechanism/Site of Action. Report No. T-10421 (C2.5/21) GLP. Unpublished	
IIA, 5.8.2/08	Lovatt C	2000	Molinate: Effect on rat ovarian esterase activity. Report No. CTL/00A120/RESEARCH/REPORT GLP. Unpublished	
IIA, 5.8.2/09	Lovatt C	2000	Molinate: Effect on rat testicular esterase activity and testosterone levels. Report No. CTL/00A121/RESEARCH/REPORT GLP. Unpublished	
IIA, 5.8.2/10	Lovatt C	2000	Molinate: Metabolism by sulphoxidation in the rat. Report No. CTL/00A122/RESEARCH/REPORT GLP. Unpublished	
IIA, 5.4/03	Majeska J B	1984	Ordram Technical: Mutagenicity Evaluation in Mouse Lymphoma Multiple Endpoint Test - Forward Mutation Assay. Report No. T-11840 (C2.6/02) GLP. Unpublished.	
IIA, 5.4/05	Majeska J B	1983	Ordram Technical Mutagenicity Evaluation in Bone Marrow Micronucleus. Report No. T-11820 (C2.6/03) GLP. Unpublished.	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA, 5.2/01	Miller J L	1981	Summary of Richmond Toxicology Laboratory Report - Ordram Technical. Report No. T-6632 (C2.1/05) Not GLP. Unpublished.	
IIA, 5.6/07	Minor J L	1990	A Teratology Study in CD Rats with R-4572 Technical. Report No. T-13266 (C2.5/04) GLP. Unpublished.	
IIA,5.6/08	Minor J L <i>et al</i>	1985	A Teratology Study in New Zealand White Rabbits with Ordram. Report No. T-11866 (C2.5/01) GLP. Unpublished.	
IIA,5.6/03	Moxon M E	1997	Molinate: Two Generation Reproduction Study in the Rat. Zeneca Central Toxicology Laboratory Report No. CTL/P/5409. GLP. Unpublished.	
IIA, 5.2/03	Mutter L C	1985	Dermal Sensitisation Test with Ordram Technical. Report No. T-12007 (C2.1/01) GLP. Unpublished.	
IIA, 5.3/02	Pettersen J C and Richter A G	1990	Two-year Chronic Toxicity/ Oncogenicity Study with R-4572 in Rats. Report No. T-13023 (C2.4/03) (Volumes 1-5) GLP. Unpublished.	
IIA, 5.5/01	Pettersen J C and Richter A G	1990	Two-Year Chronic Toxicity/ Oncogenicity Study with R-4572 in Rats. Report No. T-13023 (C2.4/03) (Reference included under 5.3 above) GLP. Unpublished.	
IIA, 5.3/04	Pettersen J C and Wadsworth P F	1991	One Year Toxicity Study with R-4572 in Beagle Dogs. Report No. T-13236 (C2.4/02) GLP. Unpublished.	
IIA, 5.5/03	Potrepka R F and Morrissey R L	1991	18-Month Dietary Mouse Oncogenicity Study with R-4572. Report No. T-13211 (C2.4/04) (Volumes 1-4) GLP. Unpublished.	
IIA, 5.1/01	Ritter J C	1991a	R-4572 Metabolism Study in Rats, Single Dose Excretion and Tissue Levels. Report No. T-13267*A (C2.7/01) GLP. Unpublished.	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA, 5.1/02	Ritter J C	1991b	R-4572 Metabolism Study in Rats, Repeat Dose (10 mg/kg) Excretion and Tissue Levels. Report No. T-13267 (C2.7/01) GLP. Unpublished.	
IIA, 5.1/03	Ritter J C	1991c	R-4572 Metabolism Study in Rats, Intravenous Dose (1 mg/kg) Excretion and Tissue Levels. Report No. T-13267* (C2.7/01) GLP. Unpublished.	
IIA, 5.1/04	Ritter J C	1991d	R-4572 Biotransformation in the Rat. Report No. T-13267*B (C2.7/01) GLP. Unpublished.	
IIA, 5.7/01	Sprague G L	1983	Acute Delayed Neurotoxicity Study with Ordram Technical in Adult Hens. Report No. T-10510 (C2.8/01) Not GLP. Unpublished.	
IIA, 5.9.3/ 01	Taves <i>et al</i> (Summary by Paddle G M)	1983	Epidemiologic Assessment of Fertility in Male Workers Exposed to Ordram at the Stauffer Chemical Company Plant at Little Rock, Arkansas; Cold Creek, Alabama and Richmond, California, USA. Report No. CTL/C/2411-4 Not GLP. Unpublished.	
IIA, 5.9.3/ 02	Tomenson J and Northrop H L	1995	An Assessment of Fertility in Male Workers Exposed to Molinate at Stauffer Chemical Company. Report No. CTL/C/3097 Not GLP. Unpublished.	
IIA, 5.4/04	Trueman R W	1989	Molinate: Assessment for the Induction of Unscheduled DNA Synthesis in Primary Rat Hepatocyte Cultures. Report No. CTL/P/2484 (C2.6/06) GLP. Unpublished.	
IIA, 5.1/07	Wickramaratne G A de S <i>et al</i>	1997	Species Comparison in the Metabolism of the Herbicide Molinate. Report No. CTL/R/1355 Not GLP. Unpublished.	
IIA,5.6/05	Wickramaratne G A de S <i>et al</i>	1997	Molinate: Elucidation of the Processes Underlying the Reproductive Effects in the Male Rat. Zeneca Central Toxicology Laboratory Report No. CTL/R/1336 Not GLP. Unpublished.	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA,5.6/06	Wickramaratne G.A. de S. <i>et al</i>	1997	Molinate: Rodent Reproduction Toxicity and its Relevance to Humans: A Review. Report No. CTL/R/1335 Not GLP. Unpublished.	
IIA, 5.8/03	Wickramaratne G A de S <i>et al</i>	1997	The Morfological Effects of the Thiocarbamate Herbicide, Molinate, on the Ovary, Adrenal and Testis of the Sprague-Dawley Rat. Zeneca Central Toxicology Laboratory Report No. CTL/R/1343 Not GLP. Unpublished.	
IIA, 5.6/04	Williams J	1997	Molinate: An Evaluation of Vaginal Opening in Rat Pups. Zeneca Central Toxicology Laboratory Report No. CTL/P/5583 GLP. Unpublished.	
IIA, 5.3.1/01	Dickhaus S.	1979	Report on a preliminary study of 4 weeks for a 3-month subacute toxicity in the species rat with molinate as a feed admixture. Report 2-4-175-79 Pharmatox-Vogtei-Ruthe Strasse 26-Sehnde 13- FRG No GLP. Unpublished.	
IIA, 5.3.2	Dickhaus S.	1980	Three month subacute toxicity with molinate as feeding study in the species rat. Report 2-4-176-79 Pharmatox-Vogtei-Ruthe Strasse 26-Sehnde 13- FRG No GLP. Unpublished.	

B.7 Residue data

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
ZENECA				
IIA, 6.1.1/ 01	Goldsby G P	1991	(¹⁴ C)-Molinate Metabolism in Rice. WRC Report No. RR90-109B (D3.1/02) GLP. Unpublished.	
IIA, 6.2.1/ 01	Goldsby G and Kan H	1993	¹⁴ C-Molinate Metabolism in Lactating Goats. WRC Report No. RR93-035B (D4.1/01) (+ additional data RR 93-035B Res 1) GLP. Unpublished.	
IIA, 6.2.1/ 02	Miller M	1993	¹⁴ C-Molinate: Metabolism in Laying Hens. WRC Report No. RR-93-052B (D4.1/02) (+ additional data RR 93-052B Res 1) GLP. Unpublished.	
IIA, 6.3.2.1/12	Adelson B and Ott K	1990j	Phase 3 Reformat of MRIDS 46548, 94720, 111345 and 41237601 and Related MRIDS 152310 and 40980201: Molinate Post-Emergence, Water-Run Magnitude of Residue on Rice. WRC Report No. RR-90-317B GLP. Unpublished.	
IIA, 6.3.2.1/13	Alferness P and Storoni H	1993	Molinate: Magnitude of the Residue on Rice Grain and Straw for Trials Conducted in the USA in 1992. WRC Report No. RR93-047B (D3.2.6/04) GLP. Unpublished.	
IIA, 6.3.3/ 01	McKay J C	1989	Molinate - Storage Stability Study: Crops and Soil Storage Stability Validation for Molinate in Raw Agricultural Commodities and Soil. WRC Report No. RRC88-63 (D2.3/01) GLP. Unpublished.	
IIA, 6.5/01	Curry K K and Grant K L	1991	Ordram (Molinate) - Magnitude of the Residue Study on Processed Rice Products. WRC Report No. RR-90-440B (D3.3.6/01) GLP. Unpublished.	
IIA, 6.6/01	Heath J	1991	Molinate: Confined Crop Rotation. WRC Report No. RR91-013B (D3.4/01) GLP. Unpublished.	

OXON				
IIA, 6.3	Fraschini C	1995	Analysis of compound Molinate residues on rice straw. Report N° SIP 1015 SIPCAM GLP. Unpublished.	
IIA, 6.3	Fraschini C	1995	Analysis of compound Molinate residues on rice grains. Report N° SIP 1016 SIPCAM GLP. Unpublished.	
IIA, 6.3	Fraschini C	1995	Analysis of compound Molinate residues on polished rice grains. Report N° SIP 1017 SIPCAM GLP. Unpublished.	
IIA, 6.3	Fraschini C	1996	Analysis of compound Molinate residues on rice straw. Report N° SIP 1060 SIPCAM GLP. Unpublished.	
IIA, 6.3	Fraschini C	1988	Analysis of compound Molinate residues on rice grains. Report N° SIP 1061 SIPCAM GLP. Unpublished.	
IIA, 6.3	Fraschini C	1996	Analysis of compound Molinate residues on polished rice grains. Report N° SIP 1062 SIPCAM GLP. Unpublished.	

B.8 Environmental fate and behaviour

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
ZENECA				
IIA, 7.1/01	Barnes J P	1991	Hexamethyleneimine: Adsorption/ Desorption on Four Soils and One Aquatic Sediment. Report No. RR91-018B (F3.2/01) GLP. Unpublished.	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA, 7.1/02	Curry K K <i>et al</i>	1989a	Ordram 8-E Aquatic Field Dissipation Study for Aquatic Use Post-Flood, Molinate, California 1988. Report No. RR89-025B (F3.3/05) Not GLP. Unpublished.	
IIA, 7.1/03	Curry K K <i>et al</i>	1989b	Ordram 15 G Aquatic Field Dissipation Study for Aquatic Use Post-Flood, Molinate, California 1988. Report No. RR89-055B (F3.3/04) Not GLP. Unpublished.	
IIA, 7.1/04	Dohn D R	1988	Molinate Adsorption/Desorption on Four Soils and One Aquatic Sediment. Report No. RRC 88-05 (F3.2/01) GLP. Unpublished.	
IIA, 7.7	Hayes S E	1994	Calculation of Half Life by Reaction with Atmospheric Hydroxyl Radicals. non GLP; Unpublished	
IIA, 7.1/05	Lay M M	1990	Aerobic Aquatic Metabolism of Molinate with Stockton Adobe Clay. Report No. RR89-034B (F4.2/01) GLP. Unpublished.	
IIA, 7.1/06	Meyers T J	1987a	Molinate - Field Dissipation Studies for Aquatic Food Crop Uses - Arkansas. Report No. RR86-121 (F3.3/02) Not GLP. Unpublished.	
IIA, 7.1/07	Meyers T J	1987b	Molinate - Field Dissipation Studies for Aquatic Food Crop Uses - Texas. Report No. RR87-72 (F3.3/03) Not GLP. Unpublished.	
IIA, 7.1/08	Subba-Rao R V	1991	Soil/Sediment Adsorption-Desorption of ¹⁴ C-Molinate Sulfoxide. Report No. RR91-017B (F3.2/03) GLP. Unpublished.	
OXON				
IIA, 7.1.12.2	Fraschini C	1995	Analysis of compound Molinate residues on rice paddy soil. Report N° SIP 1013 SIPCAM GLP. Unpublished.	
IIA, 7.1.12.2	Fraschini C	1996	Analysis of compound Molinate residues on rice paddy soil. Report N° SIP 1058 SIPCAM. 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, 7.1.13.2	Fraschini C	1995	Analysis of compound Molinate residues on rice paddy water. Report N° SIP 1014 SIPCAM GLP. Unpublished.	
IIA, 7.1.13.2	Fraschini C	1996	Analysis of compound Molinate residues on rice paddy water. Report N° SIP 1059. SIPCAM GLP. Unpublished.	

B.9 Ecotoxicology

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
ZENECA				
IIA, 8.1/02	Fletcher D W	1987	21-day acute oral toxicity study with Ordram Technical in Mallard duck. Biolife Report No. T-12557 (G2.1/03) GLP. Unpublished.	
IIA, 8.1/03	Sauerhoff M W	1987	Twelve-day dietary LC ₅₀ study with Ordram Technical in mallard ducklings. Biolife Report No. T-12558 (G2.1/02) GLP. Unpublished.	
IIA, 8.1.3	Frey L T et al	2001	A Reproduction study with the Mallard Wildlife International Ltd Proj. no. 528-103 Report no. WINO 2965 GLP. Unpublished	
IIA, 8.2/01	Farrelly E and Hamer M J	1988	Molinate: An investigation of the toxicity of the technical material to first instar <i>Daphnia magna</i> . Report No. RJ0687B (G6.1/02) GLP. Unpublished.	
IIA, 8.2/02	Forbis A D	1987	Chronic toxicity of ¹⁴ C-Ordram to <i>Daphnia magna</i> under flow-through conditions. Report No. T-12562 (G6.2/02) GLP. Unpublished.	
IIA, 8.2/03	Kent S J et al	1994a	Molinate: Acute toxicity to Rainbow trout (<i>Oncorhynchus mykiss</i>). Report No. BL5139/B (G5.1/18) 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, 8.2/04	Kent S J <i>et al</i>	1994b	Molinate: Acute toxicity to Bluegill sunfish (<i>Lepomis macrochirus</i>). Report No. BL5179/B GLP Unpublished.	
IIA, 8.2/05	Kent S J <i>et al</i>	1994c	Molinate: Acute toxicity to Mysid shrimp (<i>Mysidopsis bahia</i>). Report No. BL5130/B (G6.1/09) GLP. Unpublished.	
IIA, 8.2/06	Kent S J <i>et al</i>	1994d	Molinate: Acute toxicity to larvae of the Pacific oyster (<i>Crassostrea gigas</i>). Report No. BL5149/B (G6.1/10) GLP. Unpublished.	
IIA, 8.2/07	McAllister W A	1987	Early life stage toxicity of ¹⁴ C-Ordram to Rainbow trout (<i>Salmo gairdneri</i>) in a flow-through system. Report No. T-12563 (G5.2/01) GLP. Unpublished.	
IIA, 8.2/08	Smyth D V <i>et al</i>	1990	Molinate: Determination of toxicity to the green alga <i>Selenastrum capricornutum</i> . Report No. BL3837/B (G8.1/01) GLP. Unpublished.	
IIA, 8.2/09	Smyth D V <i>et al</i>	1994	Molinate: Determination of Toxicity to the Marine Alga (<i>Skeletonema costatum</i>). ICI Group Environmental Laboratory Report No. BL3858/B [G8.1/02]. GLP. Unpublished.	
IIA, 8.2/10	Smyth D V <i>et al</i>	1990	Molinate: Determination of Toxicity to the Freshwater Diatom (<i>Navicula pelliculosa</i>). ICI Group Environmental Laboratory Report No. BL3866/B [G8.1/03]. GLP. Unpublished.	
IIA, 8.2/11	Smyth D V <i>et al</i>	1990	Molinate: Determination of Toxicity to the Blue-Green Alga (<i>Anabaena flos-asquea</i>). ICI Group Environmental Laboratory Report No. BL3863/B [G8.1/04]. GLP. Unpublished.	
IIA, 8.2/12	Smyth D V <i>et al</i>	1998	Molinate Technical Toxicity to the Green Alga (<i>Scenedesmus subspicatus</i>). Brixham Environmental Laboratory ZENECA Limited Report No. BL6311/B [AF0010/B]. 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, 8.2/13	Thompson R S <i>et al</i>	1990	Molinate: Determination of Toxicity to the Duckweed (<i>Lemma gibba</i>). ICI Group Environmental Laboratory Report No. BL3882/B [G8.1/05]. GLP. Unpublished.	
IIA, 8.3	Brown K C <i>et al</i>	1995	The Effects of molinate on the Predatory mite <i>Typhlodromus pyri</i> Report No. 95.17 GLP. Unpublished	
IIA, 8.4/01	Coulson J M	1994	Molinate: Toxicity to the earthworm <i>Eisenia foetida</i> . Report No. RJ1614B (G4.3/01) GLP. Unpublished.	
IIA, 8.5/01	Mason G <i>et al</i>	1995	Molinate: Study on microbial activities in soil. Report No. RJ1759B GLP. Unpublished.	
IIA, 8.6/01	Cole J	1995	Effects on Other Non-target Organisms. Data summary. Not GLP. Unpublished.	
IIA, 8.6/02	Porch J R <i>et al</i>	2002	ZA-4572(A12897A) : A Toxicity Test to Determine the Effects of a Formulation of Molinate (ORDRAM 8 E) on Seedling Emergence of Ten Species of Plants Wildlife International Ltd Proj. no. 528-137 Syngenta no. 2013643 GLP, Unpublished	
IIA, 8.6/03	Porch J R <i>et al</i>	2002	ZA-4572(A12897A) : A Toxicity Test to Determine the Effects of a Formulation of Molinate (ORDRAM 8 E) on Vegetative Vigor of Ten Species of Plants Wildlife International Ltd Proj. no. 528-138 Syngenta no. 2013642 GLP, Unpublished	
OXON				
IIA, 8.1.1.	Rodgers M H	1996	Molinate technical: acute oral toxicity to the Bobwhite quail Report OXN 65/A/950885 Huntingdon Research Centre Ltd, UK 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.	Johnson A I	1997	Molinate technical: dietary LC ₅₀ to the Bobwhite quail OXN 216/970812 Huntingdon Life Sciences Ltd, UK GLP. Unpublished.	
IIA, 8.1.3	Teunissen M S	2002	Reproduction Study in Mallard duck with molinate technical (by dietary admixture) Notox Proj no. 307687 GLP, Unpublished	
IIA, 8.2.5.	Bell G <i>et al</i>	1996	Molinate technical: Acute toxicity to daphnia magna. Report OXN 103A(b)/950714 Huntingdon Research Centre Ltd, UK GLP. Unpublished.	
IIA, 8.2.6	Bell G and Smith B	1996	Algal growth inhibition test Report OXN 103(a)/950715 Huntingdon Research Centre Ltd, UK GLP. Unpublished.	
IIA, 8.5	Carter J N, Thomas F J and Jackson P D	1995	Molinate technical. Effects on soil non-target microorganisms Report OXN 89A/951355 Huntingdon Research Centre UK GLP. Unpublished.	
IIA, 8.7	Kelly G, Malcomber I N and Flatman, D I R	1997	Molinate Technical - Effects on the respiration of activated sewage sludge. Report OXN 217/971350 Huntingdon Life Sciences, UK GLP. Unpublished.	

APPENDIX IIIB**MOLINATE**

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
ZENECA			
IIA, 2.13/01	Tremain S P	2001	Molinate – Technical grade active ingredient: Determination of Explosive Properties. SPL Project No. 12927010. GLP. Unpublished.
IIA, 4.2.1/03	Weber H and Pelz S	2001	Validation of the DFG method S19 (extended revision) for the determination of residues of molinate in rice (grain and straw). Specht & Partner Project No. SYN-0102V. GLP. Unpublished.
OXON			
IIA, 4.2.1/07	Freschi G	2002	Applicability and validation of a multiresidues analytical method on herbicides (lenacil, diuron, terbuthylazine, linuron and molinate) in cereal crops (rice grain) Research Centre “E. Gagliardini” Project No. UAR/001/2002. No 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
IIA, 5.8.2/ 04	Ellis M K and Farnworth M J	1999	First revision to molinate: Effects of molinate and molinate metabolites following seven days administration on testis and sperm morphology in the rat. Report No. CTL/R/8608 GLP. Unpublished
IIA, 5.8.2/ 05	Ellis M K and Farnworth M J	1999	First revision to molinate: Investigation in to the mode of action in the rat Leydig cells in vitro. Report No. CTL/R/8609 GLP. Unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA, 5.8.2/ 06	Ellis M K and Farnworth M J	1999	First revision to molinate: Effects of molinate and molinate metabolites on plasma and testicular interstitial fluid hormone concentrations in the rat in vivo. Report No. CTL/R/8610 GLP. Unpublished
IIA, 5.8.2/ 07	Horner S A	1996	Molinate: Developmental neurotoxicity study in rats. Report No. CTL/P/4994 GLP. Unpublished
IIA, 5.8.2/08	Lovatt C	2000	Molinate: Effect on rat ovarian esterase activity. Report No. CTL/00A120/RESEARCH/REPORT GLP. Unpublished
IIA, 5.8.2/09	Lovatt C	2000	Molinate: Effect on rat testicular esterase activity and testosterone levels. Report No. CTL/00A121/RESEARCH/REPORT GLP. Unpublished
IIA, 5.8.2/10	Lovatt C	2000	Molinate: Metabolism by sulphoxidation in the rat. Report No. CTL/00A122/RESEARCH/REPORT GLP. Unpublished

B.7 Residue data

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
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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
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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
SYNGENTA			

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA, 8.1.3	Frey L T et al	2001	A Reproduction study with the Mallard Wildlife International Ltd Proj. no. 528-103 Report no. WINO 2965 GLP. Unpublished
IIA, 8.6/02	Porch J R et al	2002	ZA-4572(A12897A) : A Toxicity Test to Determine the Effects of a Formulation of Molinate (ORDRAM 8 E) on Seedling Emergence of Ten Species of Plants Wildlife International Ltd Proj. no. 528-137 Syngenta no. 2013643 GLP, Unpublished
IIA, 8.6/03	Porch J R et al	2002	ZA-4572(A12897A) : A Toxicity Test to Determine the Effects of a Formulation of Molinate (ORDRAM 8 E) on Vegetative Vigor of Ten Species of Plants Wildlife International Ltd Proj. no. 528-138 Syngenta no. 2013642 GLP, Unpublished
OXON			
IIA, 8.1.3	Teunissen M S	2002	Reproduction Study in Mallard duck with molinate technical (by dietary admixture) Notox Proj no. 307687 GLP, Unpublished

APPENDIX IV

List of uses supported by available data

MOLINATE

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		
Rice/ paddy fields	France, Greece, Italy, Spain, Portugal	ORDRAM	F	Grass weeds, namely <i>Echinochloa</i> spp. and <i>Glyceria</i> spp.	GR	75 g/kg	By hand, by tractor	pre-plant incorporation or post-flood, pre-emergence of rice or post-flood, post emergence of rice	1	-	-	-	4,875	-	
		MOLINAM 7.5 G	F		GR	75 g/kg	Overall distribution using fertilizer distributor	pre-sowing of rice or after sowing (2-3 leaves stage of rice and <i>Echinochloa</i> at latest)	1	-	-	-	2.5-5	-	

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)
e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
- (c) e.g. wetttable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (d) GCPF Codes - GIFAP Technical Monograph No 2, 1989
- (e) All abbreviations used must be explained
- (f) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
- (g) 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