



Fenarimol
6847/VI/97-final
5 January 2007

Review report for the active substance **fenarimol**

finalised in the Standing Committee on the Food Chain and Animal Health at its
meeting on 3 March 2006
in view of the inclusion of fenarimol 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 fenarimol, 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 3600/92¹ 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 1199/97², has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Fenarimol 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, DowElanco Europe on 28 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance fenarimol 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 933/94³, as last amended by Regulation (EC) No 2230/95⁴, designated the United Kingdom as rapporteur Member State to carry out the assessment of fenarimol 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 fenarimol this deadline was 30 April 1995.

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¹ OJ No L 366, 15.12.1992, p.10

² OJ No L 170, 28.6.1997, p.19

³ Commission Regulation (EC) No 933/94 of 27 April 1994 laying down the active substances of plant protection products and designating the rapporteur Member States for the implementation of Commission Regulation (EEC) No 3600/92. OJ No L 107, 28.4.1994, p.8.

⁴ OJ No L 225, 22.9.1995, p.1

DowElanco Europe submitted a dossier to the rapporteur Member State which was considered as complete. Information has furthermore been submitted by the European Federation of Agricultural Workers and the European Chemical Bureau.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, the United Kingdom submitted on 30 April 1996 to the Commission the report of its examination, hereafter referred to as the monograph, including, as required, a recommendation concerning the possible inclusion of fenarimol 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 fenarimol from DowElanco Europe, on 26 August 1996.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the Commission forwarded for consultation the monograph to all the Member States as well as to DowElanco Europe being the main data submitter, on 24 June 1996.

The Commission organised an intensive consultation of technical experts from a certain number of Member States, to review the monograph 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 September to December 1996.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the main data submitter on 19 January 1997 for comments and further clarification.

In accordance with the provisions of Article 6(4) of Directive 91/414/EEC the Commission organised a tripartite meeting with the main data submitter and the rapporteur Member State for this active substance on 11 November 1997.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the dossier, the monograph, 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 Plant 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 2000 to September 2004, and was finalised in the meeting of the Standing Committee on 3 March 2006.

The documents and information were also submitted to the Scientific Committee for Plants for a separate independent consultation.

The Scientific Committee was asked to comment on the interpretation of the multi-generation studies and to consider the aromatase inhibition effects of fenarimol. In addition their opinion was sought on the establishment of a reliable ADI and AOEL for fenarimol. In its opinion⁵ the Committee concluded that the effects of fenarimol on male fertility seen in rats had to be considered relevant for human risk assessment although man is less sensitive than rats to the effects of aromatase inhibition by fenarimol. The SCP also concluded that the effects of fenarimol on parturition in rats could be considered as not relevant for human risk assessment. It was further concluded that, apart from male-mediated reduced fertility and effects associated with delayed parturition, there was no convincing evidence for other adverse reproductive effects associated with aromatase inhibition by fenarimol. The Committee concluded that the toxicological studies submitted for fenarimol permitted a reliable ADI and AOEL to be established. The SCP agreed with the proposed ADI of 0.01 mg/kg bw and suggested that an AOEL of 0.02 mg/kg bw be established. The conclusions of the Scientific Committee were taken into account in this Review Report.

The SCP was also consulted on the approach taken to calculate Predicted Environmental Concentrations (PEC) in soil. In its opinion⁶ the Committee proposed an alternative approach in which (a) the fraction of the applied amount which stays exposed at the soil or plant surfaces disappears so fast that it does not contribute to the longterm accumulation, and (b) the disappearance of the remaining fraction which penetrates into the soil is derived from the laboratory studies. The observations of the Scientific Committee were taken into account during the examination process.

Dow AgroSciences (formerly Dow Elanco Europe) divested fenarimol to Margarita Internacional. Margarita Internacional took over the all the obligations of Dow AgroSciences as notifier in the EU review. This transfer was formally notified to the Commission by letter dated 22 March 2002 and the change noted at the June 2002 meeting of the Working Group (Legislation).

The present review report contains the conclusions of this final examination; given the importance of the monograph, 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 2006/134/EC concerning the inclusion of fenarimol in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing fenarimol 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.

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⁵ Opinion of the Scientific Committee on Plants on regarding the possible inclusion of fenarimol in Annex I of Directive 91/414/EEC concerning the placing of plant protection products on the market (SCP/FENARI/005-final). (Opinion adopted by the Scientific Committee on Plants on May 18, 1999).

⁶ Opinion of the Scientific Committee on Plants on a specific question from the Commission concerning the evaluation of fenarimol in the context of Council Directive 91/414/EEC. SCP/FENARI-bis/002-Final (Opinion adopted by the Scientific Committee on Plants on 8 November 2001).

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 fenarimol 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 fenarimol 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).

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; for a 60 kg adult is 12% of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). National Estimates of Dietary Exposure using the UK diet do not exceed the ADI. Additional intake from water are not expected to give rise to intake problems. Estimates of acute dietary exposure of adults and toddlers are below the Acute Reference Dose (ARfD).

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 fenarimol 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 submitter Margarita Internacional, 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 as identified during the re-evaluation process are set out under point 1 above. These endpoints are listed in Appendix II.

6. Particular conditions to be taken into account on short term basis

On the basis of the proposed and supported uses, 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:

Therefore, Member States must pay particular attention to the protection of:

- aquatic organisms. Where relevant, an appropriate distance must be kept between treated areas and surface water bodies. This distance may depend of the application or not of drift reducing techniques or devices;
- earthworms. Conditions of authorisation shall include risk mitigation measures, such as the selection of the most appropriate combination of numbers and timing of applications, rates of application, and, if necessary, the degree of concentration of the active substance;
- birds and mammals. Conditions of authorisation shall include risk mitigation measures, such as a judicious timing of the application and the selection of those formulations which, as a result of their physical presentation or the presence of agents that ensure an adequate avoidance, minimise the exposure of the concerned species;
- operators, who must wear suitable protective clothing, in particular gloves, coveralls, rubber boots and face protection or safety glasses during mixing, loading, application and cleaning of the equipment, unless the exposure to the substance is adequately precluded by the design and construction of the equipment itself or by the mounting of specific protective components on such equipment;
- workers, who must wear suitable protective clothing, in particular gloves, if they must enter a treated area before the specific re-entry period has expired.

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 fenarimol in Annex I under the current inclusion conditions.

However, further studies shall be required by the Member States to address the potential endocrine disrupting properties of fenarimol within two years after the adoption of the Test Guidelines on endocrine disruption by the Organisation for Economic Cooperation and Development (OECD).

Member States must ensure that the authorisation holders report at the latest on 31 December of each year on incidences of operator health problems, require sales data

and a survey of use patterns so that a realistic picture of the use conditions and the possible toxicological impact of fenarimol can be obtained.

8. Information on studies with claimed data protection

For information of any interested parties, Appendix III lists the studies for which the main data 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. This list 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.

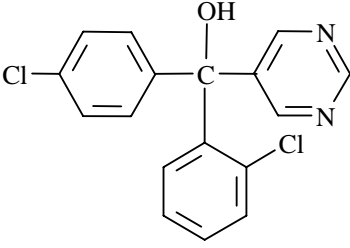
9. Updating of this review report

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 Plant Health, in connection with any amendment of the inclusion conditions for fenarimol in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

FENARIMOL

Active substance (ISO Common Name)	Fenarimol
Function (e.g. fungicide)	Fungicide
Rapporteur Member State	UK
Identity (Annex IIA, point 1)	
Chemical name (IUPAC)	(±)-2,4'-dichloro-α-(pyrimidin-5-yl) benzhydryl alcohol
Chemical name (CA)	(±)-α-(2-chlorophenyl)-α-(4-chlorophenyl)-5-pyrimidinemethanol
CIPAC No	380
CAS No	60168-88-9 (unstated stereochemistry)
EEC No (EINECS or ELINCS)	262-095-7
FAO Specification (including year of publication)	None established
Minimum purity of the active substance as manufactured (g/kg)	98%
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	None
Molecular formula	C ₁₇ H ₁₂ Cl ₂ N ₂ O
Molecular mass	331.2
Structural formula	

Melting point (state purity)	117 - 119°C		
Boiling point (state purity)	Not required for solids		
Temperature of decomposition	240°C		
Appearance (state purity)	Off-white crystals		
Relative density (state purity)	$D_4^{23} = 1.40$		
Surface tension	not relevant		
Vapour pressure (in Pa, state temperature)	6.5×10^{-5} Pa at 25°C		
Henry's law constant (Pa m ³ mol ⁻¹)	7.0×10^{-4} Pa m ³ /mol		
Solubility in water (g/l or mg/l, state temperature)	at 25°C		
	pH3	14.6 mg/l	
	pH7	13.7 mg/l	
	pH10	13.8 mg/l	
Solubility in organic solvents (in g/l or mg/l, state temperature)	n-Heptane	At 20°C 0.92 g/L	
	Xylene	33.3 g/L	
	Dichloromethane	>250g/L	
	Methanol	98.0 g/L	
	Acetone	151 g/L	
	Methyl-t-butyl ether	49.5 g/L	
	Ethyl acetate	73.3 g/L	
	Acetonitrile	29.5 g/L	
	n-Octanol	50.6 g/L	
	Partition co-efficient (log P _{OW}) (state pH and temperature)	Log K _{OW} = 3.69	
pH_____:			
pH_____:			
Hydrolytic stability (DT ₅₀) (state pH and temperature)	Hydrolytically stable at all pH		
	pH_____:		
	pH_____:		
Dissociation constant	No titratable group in DMF between pH 3.5 and 13.5		
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	Solution	λ_{max} (nm)	ε (l/mol/cm)
	Methanolic	205.8	3.37×10^4
	Acidic	204.8	3.59×10^4
	Basic	221.0	1.90×10^4
Photostability (DT ₅₀) (aqueous, sunlight, state pH)	Photolabile DT ₅₀ of 12 hours was determined in distilled water under natural sunlight and clear sky conditions at 40°N in mid-summer.		

APPENDIX II

END POINTS AND RELATED INFORMATION

FENARIMOL

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals (Annex IIA, point 5.1)

Rate and extent of absorption:	Oral rat – 80% within 24 hours*
Distribution:	Extensive (including neonatal brain)*
Potential for accumulation:	Half-life in blood 11 – 17 hours*
Rate and extent of excretion:	65 – 83% in urine and bile in 24 hours*
Metabolism in animals	Main metabolites – fenarimol N-oxide; metabolite K*
Toxicologically significant compounds (animals, plants and environment)	Parent compound and metabolites

Acute toxicity (Annex IIA, point 5.2)

Rat LD ₅₀ oral	approximately 2500 mg/kg*
Rat LD ₅₀ dermal	> 2000 mg/kg*
Rat LC ₅₀ inhalation	No toxicity at 2 mg/L/1 hour*
Skin irritation	Not classified*
Eye irritation	Not classified*
Skin sensitization (test method used and result)	Not classified (Magnusson & Kligman)*

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect	Liver/fatty change*
Lowest relevant oral NOAEL / NOEL	12.5 mg/kg, 1 year dog*
Lowest relevant dermal NOAEL / NOEL	>1000 mg/kg, rabbit
Lowest relevant inhalation NOAEL / NOEL	Not determined

Genotoxicity (Annex IIA, point 5.4)

Negative*

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect

Liver/fatty change*

Lowest relevant NOAEL / NOEL

1.3 mg/kg, rat*

Carcinogenicity

Not carcinogenic*

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect

Reduced fertility and parturition effects (rat and mouse).

Lowest relevant reproductive NOAEL / NOEL

2 mg/kg bw/day (rat)

Developmental target / critical effect

Increased hydronephrosis (rat) without maternal toxicity and extra ribs (rabbit) with maternal toxicity . (These minor effects of delayed development are not of particular concern.)

Lowest relevant developmental NOAEL / NOEL

13 mg/kg bw/day (rat)

Neurotoxicity / Delayed neurotoxicity (Annex IIA, point 5.7)

Evidence for fertility effects being mediated via central nervous system control of male sexual behaviour .

No specific studies of delayed neurotoxicity performed or considered relevant.

Other toxicological studies (Annex IIA, point 5.8)

Mechanistic studies indicate that aromatase inhibition causes both reduced fertility (apparently involving altered male sexual behaviour) and parturition effects.

Medical data (Annex IIA, point 5.9)

No evidence of adverse health effects apart from 4 cases of minor transient effects (irritation, nausea).

Summary (Annex IIA, point 5.10)

ADI

AOEL systemic

Drinking water limit

ARfD (acute reference dose)

Value	Study	Safety factor
0.01 mg/kg**	2 year rat	100
0.02 mg/kg/day**	Rat multigen	100
0.02 mg/kg/day	Rat multigen	100

Dermal absorption (Annex IIIA, point 7.3)

2.6%

* = endpoint entry agreed at ECCO 8

** = endpoint as proposed by the SCP

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralisation after 100 days	< 1%
Non-extractable residues after 100 days	3 – 10%
Relevant metabolites - name and/or code, % of applied (range and maximum)	Several minor metabolites, none of which exceeded 5% AR

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation	Little degradation occurs; >90% parent compound remained 52 weeks after treatment; no metabolites were identified.
Soil photolysis	62% of applied fenarimol was lost (proposed to be by photolysis) in a 100 day winter natural sunlight experiment in Indiana USA. No individual metabolite in the soil accounted for >6%AR. In another experiment (summer natural sunlight experiment in Indiana USA) there was a 32% loss of radioactivity proposed to be by photolysis within 18 hours. No individual metabolite in the soil accounted for >3%AR.

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Method of calculation	Linear regression or graphical estimate
Laboratory studies (range or median, with n value, with r^2 value)	<p>DT_{50lab} (20°C, aerobic): 473, 436, 542, 1360 (average = 703) days at 100 g/ha 917, 889, 1204, 1833 (average = 1211) days at 500 g/ha Calculated by first-order linear regression analysis</p> <p>DT_{90lab} (20°C, aerobic): Not calculated due to slow degradation</p> <p>DT_{50lab} (10°C, aerobic): 1406 days at 100 g/ha, 2422 days at 500 g/ha assuming Q10 of 2.2</p> <p>DT_{50lab} (20°C, anaerobic): >> One year</p> <p>degradation in the saturated zone: No information provided none required.</p>
Field studies (state location, range or median with n value)	<p>DT_{50f}: 123, 95, 14, 21, 60, 130 (average = 74) days Calculated by graphical estimation. Using linear regression and $\sqrt{1}$st order curve the longest DT50 estimated was 120 days. A median pseudo first order DT50 for use in FOCUS modelling calculated using a median DT90 (see below) of 580 days / 3.3 is 174 days. The mean value estimated in the same way is 149 days.</p> <p>DT_{90f}: >610, >610, 550, 120, 489, >609 days All six sites in Germany. Calculated by graphical estimation.</p>
Soil accumulation and plateau concentration	No field data available but theoretical calculations using the longest dissipation rate from the German field studies ($\sqrt{1}$ st order DT50 120 days) indicate soil residues will plateau after 3 years of intended use on turf (4x1500 g/ha) at 0.74mg/kg or 1.18x the concentration after a single years use assuming 50% crop interception. With a more realistic 90% crop interception this value is 0.15mg/kg (still 1.18x the concentration after a single years use).

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_f / K_{oc}	K_f : 1.5, 5.1, 8.1, 11.9 (average = 6.7) L/kg
K_d	1/n 0.86-0.9 (average=0.87)
pH dependence (yes / no) (if yes type of dependence)	K_{foc} : 500, 634, 810, 992 (average = 734) L/kg K_d : Not calculated pH dependence: None observed

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching	<0.5% applied radioactivity in leachate and >90% in top 10 cm in a clay loam soil treated at 1 kg/ha and leached with 64 cm water over 2-4 days
Aged residues leaching	<0.4% applied radioactivity in leachate and remainder in top 12 cm in a sandy loam soil containing 30 day aged residues and leached with 51 cm water
Lysimeter/ field leaching studies	No data available

2.2 Fate and behaviour in water

Hydrolysis of active substance and relevant metabolites (DT ₅₀) (state pH and temperature)	Hydrolytically stable at all pH
	pH_____:
	pH_____:
Photolytic degradation of active substance and relevant metabolites	Photolabile DT ₅₀ of 12 hours was determined for fenarimol in distilled water under natural sunlight and clear sky conditions at 40°N in mid-summer. Major photoproduct accounting for up to 19% applied radioactivity was 2'-chloro-2-(5-pyrimidyl)-4-chloro-benzophenone.
Readily biodegradable (yes/no)	Not readily biodegradable
Degradation in water/sediment - DT ₅₀ water - DT ₉₀ water - DT ₅₀ whole system - DT ₉₀ whole system	DT ₅₀ water :1 - <7 days DT ₉₀ water: <7 - 14 days DT ₅₀ whole system : 486 - 3048 days DT ₉₀ whole system : Not calculated due to slow degradation. Will not accumulate in water. Potential to accumulate in sediment
Mineralisation	minimal
Non-extractable residues	3-16% AR at 100 days
Distribution in water / sediment systems (active substance)	Approx. 90% partitioned into sediment within 14 days
Distribution in water / sediment systems (metabolites)	No major metabolites formed

2.3 Fate and behaviour in air

Direct photolysis in air	No data available
Quantum yield of direct phototransformation	0.05
Photochemical oxidative degradation in air	No data available
Volatilisation	from plant surfaces: Up to 1.5% AR lost after 24 hours
	from soil: <0.2% AR lost after 24 hours

3 Ecotoxicology

Terrestrial Vertebrates

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Acute toxicity to mammals	Rat oral LD50 2500 mg/kg
Reproductive toxicity to mammals	NOEC from multigeneration study 12.5 ppm
Acute toxicity to birds	Bobwhite quail LD50 >2000 mg/kg
Dietary toxicity to birds	Bobwhite quail and Mallard LC50 >6250 ppm
Reproductive toxicity to birds	Mallard NOEC 250 ppm Bobwhite quail NOEC 300 ppm.

Aquatic Organisms

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Laboratory tests				
Fish (Rainbow Trout)	fenarimol	96 hours	LC50	4.1
<i>Daphnia magna</i>	fenarimol	48 hours	EC50	6.8
Alga	fenarimol	14-days	EC50	1.48
Fish (Rainbow Trout)	Rubigan EC	96 hours	LC50	6.8
<i>Daphnia magna</i>	Rubigan EC	48 hours	EC50	1.5
Alga	Rubigan EC	72 hours	EbC50	6.3
Fish	Rubigan SC	96 hours	LC50	42
<i>Daphnia magna</i>	Rubigan SC	48 hours	EC50	12
Fish (Rainbow Trout)	fenarimol	69-days	NOEC	0.43
Fish (Fathead Minnow)	fenarimol	266-day	NOEC	0.085
<i>Daphnia magna</i>	fenarimol	21-days	NOEC	0.113
<i>Sediment dwelling invertebrates</i>	fenarimol	28-days	EC50 NOEC emergence NOEC development	1.45 0.625 0.625
Microcosm or mesocosm tests				
None submitted				

Honeybees

Acute oral toxicity

48 h oral LD50 > 10 µg/bee

Acute contact toxicity

48 h contact LD₅₀ > 100 µg/bee

Other arthropod species

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect	Annex VI Trigger
Laboratory tests						
<i>T. pyri</i>	nymphs	Rubigan 12EC	32 and 64 g a.s./ha	Mortality and eggs/female	At 32 g/ha = 30% mortality, at 64 g/ha = 34% mortality Control mortality = 12%. Eggs per female = 8.49, 6.40 and 5.43 in the 32, 64 g/ha and control treatments respectively.	30%
<i>Aphidius rhopalosiphi</i>	adults	Rubigan 12EC	32 and 64 g a.s./ha	Mortality	Mortality at 32 and 64 g/ha = 100%.	30%
<i>Aphidius rhopalosiphi</i>	adults	Rubigan 12EC	80 and 120 g a.s./ha	Mortality	Mortality at 80 and 120 g/ha = 0 and 6.7% respectively. Control mortality = 0%	30%
<i>Poecilus cupreus</i>	adults	Rubigan 12EC	80 and 120 g a.s./ha	Mortality	Mortality at 80 and 120 g/ha = 0%	30%
<i>Chrysolperla carnea</i>	larvae and pupae	Rubigan 12EC	32 and 64 g a.s./ha	Mortality and egg production	Mortality at 32 g/ha was 12% and 4.5% for larvae and pupae. At 64 g/ha there was 3.9% and 0% mortality for larvae and pupae. No of eggs = 17.62, 30.2, 30.12 in the control, 32 and 64 g/ha treatments respectively.	30%
Field or semi-field tests						
<p>A study was conducted to investigate the effects of repeated applications of 'Rubigan 12 EC' on <i>T.pyri</i>. Fenarimol was applied at the rate of 36 g a.s./ha (i.e. 3.6 g a.s./hl and 1000 l of water applied). This was applied four times with between 12 and 15 days between applications. Water was applied as a control.</p> <p>The experiment was of randomized block design with five replicates. Mite populations were assessed</p>						

shortly before the first application of treatments, six days after the first, third and fourth applications and 21 and 42 days after the fourth application. Twenty- five leaves were collected evenly from the vines within each plot. The number of mite adults, juveniles and eggs observed on each leaf was recorded. There were no statistical differences between the fenarimol treatment and the control at any of the sample dates.

Earthworms

Acute toxicity

No effects at concentrations up to 100 mg a.s./kg soil.

Reproductive toxicity

No adverse effects at rates of 378 and 1890 g a.s./ha in a study using 120g/L EC formulation.

Soil micro-organisms

Nitrogen mineralization

No significant effect at up to 7 kg a.s./ha.

Carbon mineralization

Soil respiration and soil microbial activity

Soil macro-organisms

No significant effect at up to 168 kg/ha.

A litter bag study indicated that there was no evidence of any adverse effects on components of organic matter degradation arising from treatment with fenarimol applied at 525 g a.s./ha and 6000 g a.s./ha.

Appendix IIIA

FENARIMOL

List of studies for which the main data 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 inclusion¹.

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	Title of study	Reports on previous use in granting national authorizations
IIA 1.10	Moreland, J. Knowles, S. Iosson, I. Comb, A.	Characterisation of Fenarimol Fungicide, (Batch 272M/5 Ex Lonza) Date: 1995a (ref A23)	
IIA 1.10	Moreland, J. Knowles, S. Iosson, I. Comb, A.	Characterisation of Fenarimol Fungicide, (Batch RMM 1636 Ex Tippecanoe) Date: 1995b (Ref A24)	
IIA 1.10	Smith, A.	Analysis of product samples for active ingredient and impurities in fenarimol technical. (ref A34)	
IIA 1.11	Comb, A. L.	5-Batch Characterisation of Fenarimol Fungicide, (batches 99, 101, 102 132 and 134 Ex Lonza) Date: 1995 (ref A25)	
IIA 2.2	Comb, A.	Fenarimol: Determination of Physico-Chemical Properties (Relative Density) (ref A33)	
IIA 2.3	Olive, C.	Determination of Auto-Ignition Temperature (Liquids and gases) of Fenarimol 120 g/L EC, EAF-457 (ref MA28)	

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

Annex point/ reference number	Author	Title of study	Reports on previous use in granting national authorizations
IIA 2.3.1	Cowlyn, T. C.	Fenarimol (pure): Determination of Physico-Chemical Properties (Vapour Pressure) Date: 1992a (ref A21)	
IIA 2.5	Knowles, S.	Generation of UV-Vis Spectral Data for Fenarimol (Pure), TSN100304 (ref A26)	
IIA 2.7	Gilbert, G.	Fenarimol Technical: Solubility in various organic solvents (ref A27)	
IIA 2.11 2.13 2.15	Cowlyn, T. C.	Fenarimol (technical): Determination of Physico-Chemical Properties (Flammability, Auto-flammability, Explosive and Oxidising Properties) Date: 1992 (ref A22)	
IIA 3.6	Hewitt, H.G.	A Review of the Resistance Status of the Pathogens <i>Podosphaera leucotricha</i> , <i>Uncinula necator</i> and <i>Sphaerotheca fuliginea</i> to Fenarimol and other DMI Fungicides. (ref S30)	
IIA 4.1	Butler, R	Analytical Method: Fenarimol Fungicidal Chemical Date: 1994 (ref O16)	
IIA 4.2 (6.3)	Khoshab, A Coombe, N.	Independent laboratory confirmation of Dowelanco analytical method ERC 94.3 for the determination of fenarimol in melon peel and pulp (ref OR33)	
IIA 4.2 (6.6)	Khoshab, A.	Determination of Residues of Fenarimol in Cucumbers and Courgettes (ref OR30)	
IIA 4.2 (6.6)	Khoshab, A Coombe, N.	Independent laboratory confirmation of Dowelanco analytical method ERC 95.25 for the determination of fenarimol in cucumbers and courgettes (ref OR32)	
IIA 4.2 (IIA 6.6)	Reeves, G.L.	Determination of Fenarimol in Peppers (ref OR37)	

Annex point/ reference number	Author	Title of study	Reports on previous use in granting national authorizations
IIA 4.2.1	Perkins, J. Knowles, S.	Re-Assay, Fenarimol pyrimidinethanol analog (Metabolite B), TSN 100091 (ref A28)	
IIA 4.2.1	Perkins, J.	Analysis of fenarimol metabolite C, TSN 101567 (ref A29)	
IIA 4.2.1	Butcher, S. M.	Determination of Residues of Fenarimol in Tomatoes, Peaches and Melons Date: 1994 (ref OR24)	
IIA 4.2.1	Reeves, G.L.	Multi-crop Confirmatory Determination of Fenarimol Residues. (ref OR38)	
IIA 4.2.4	Rawle, N. W.	Determination of Fenarimol in Air	

B.6 Toxicology and metabolism

Annex point/ reference number	Author	Title of study	Reports on previous use in granting national authorizations
IIA 5.1 6.2	Prout, M. S.	The Dissipation of ¹⁴ C-Fenarimol in the Lactating Goat Date: 1994 (ref H17)	
IIA 5.2.4	Jones, J. R.	Fenarimol Technical: Acute Dermal Irritation Test in the Rabbit Date: 1994a (ref B05)	
IIA 5.2.5	Jones, J. R.	Fenarimol Technical: Acute Eye Irritation Test in the Rabbit Date: 1994b (ref B06)	
IIA 5.9	Twenty, J.	Medical Response regarding Allergic Contact Sensitization. Date: 1995 (ref G02)	

B.7 Residue data

Annex point/ reference number	Author	Title of study	Reports on previous use in granting national authorizations
IIA 6.3	Butcher, S. Wood, S.	Residues of Fenarimol in Peaches at intervals following Application of RUBIGAN 4 (EAF216), - Southern France 1993 Date: 1994d (ref NG07)	
IIA 6.3	Butcher, S. M.	Residues of Fenarimol in Tomatoes at Intervals Following Application of RUBIGAN 12EC (EAF 457), Spain 1993 Date: 1994f (ref NE08)	
IIA 6.3	Anon	Residue Study - Melons —France (ref NB21)	
IIA 6.3	Anon	Residue Study - Melons —France (ref NB22)	
IIA 6.3	Butcher, S.	Residues of Fenarimol in Melons at Intervals following Multiple Applications of Rubigan 12SC (EAF-383), Spain 1994 (ref NB31)	
IIA 6.3	Butcher, S.	Residues of Fenarimol in Melons at Harvest following Multiple Applications of Rubigan 12SC (EAF-383), Italy 1994 (ref NB32)	
IIA 6.3	Gale, D.	Residues of Fenarimol in Cucumbers at Harvest Grown under Covered Conditions Following multiple Applications of RUBIGAN 12SC (EAF-383), UK – 1996 (ref NB34)	
IIA 6.3	Gale, D.	Residues of Fenarimol in Cucumbers at Harvest Grown under Covered Conditions Following multiple Applications of RUBIGAN 12SC (EAF-383), Netherlands – 1996 (ref NB35)	
IIA 6.3	Gale, D.	Residues of Fenarimol in Melons at Intervals Following multiple Applications of RUBIGAN 12SC (EAF-383), Italy – 1996 (ref NB36)	

Annex point/ reference number	Author	Title of study	Reports on previous use in granting national authorizations
IIA 6.3	Gale, D.	Residues of Fenarimol in Cucumbers at Harvest following Multiple Applications of RUBIGAN 12SC (EAF-383), Greece – 1998 (ref NB37)	
IIA 6.3	Gale, D.	Residues of Fenarimol in Cucumbers at Harvest following Multiple Applications of RUBIGAN 12SC (EAF-383), Italy – 1998 (ref NB38)	
IIA 6.3	Gale, D.	Residues of Fenarimol in Cucumbers at Intervals under Covered Conditions following Multiple Applications of RUBIGAN 12SC (EAF-383), Belgium – 1998 (ref NB39)	
IIA 6.3	Gale, D.	Residues of Fenarimol in Cucumbers at Intervals grown under Covered Conditions following Multiple Applications of RUBIGAN 12SC (EAF-383), UK – 1998 (ref NB40)	
IIA 6.3	Gale, D.	Residues of Fenarimol in Peppers at Harvest Grown under covered conditions following Multiple Applications of RUBIGAN 12SC (EAF-383), Spain - 1996 (ref NE15)	
IIA 6.3	Gale, D.	Residues of Fenarimol in Peppers at Harvest Grown under covered conditions following Multiple Applications of RUBIGAN 12SC (EAF-383), Greece - 1996 (ref NE16)	
IIA 6.3	Gale, D.	Residues of Fenarimol in Tomatoes at Harvest Grown under covered conditions following Multiple Applications of RUBIGAN 12SC (EAF-383), UK - 1996 (ref NE17)	

Annex point/ reference number	Author	Title of study	Reports on previous use in granting national authorizations
IIA 6.3	Gale, D.	Residues of Fenarimol in Peppers at Intervals Grown under covered conditions following Multiple Applications of RUBIGAN 12SC (EAF 383), UK – 1996 (ref NE18)	
IIA 6.3	Gale, D.	Residues of Fenarimol in Peppers at Harvest grown under Covered Conditions following Multiple Applications of RUBIGAN 12SC (EAF-383), Netherlands – 1996 (ref NE19)	
IIA 6.3	Gale, D.	Residues of Fenarimol in Tomatoes at Harvest grown under Covered Conditions following Multiple Applications of RUBIGAN 12SC (EAF-383), Netherlands – 1996 (ref NE20)	
IIA 6.3	Gale, D.	Residues of Fenarimol in Peppers at Intervals grown under Covered Conditions following Multiple Applications of RUBIGAN 12SC (EAF-383), Italy – 1996 (ref NE21)	
IIA 6.3	Gale, D.	Residues of Fenarimol in Tomatoes at Intervals under covered conditions following Multiple Applications of RUBIGAN 12SC (EAF-383), UK - 1998 (ref NE23)	
IIA 6.3	Gale, D.	Residues of Fenarimol in Tomatoes at Harvest under Covered Conditions following Multiple Applications of Rubigan 12 SC (EAF-383), Netherlands - 1998. (ref NE25)	
IIA 6.3	Gale, D.	Residues of Fenarimol in Peppers at Intervals under Covered Conditions following Multiple Applications of Rubigan 12 SC (EAF-383), Netherlands - 1998. (ref NE26)	

Annex point/ reference number	Author	Title of study	Reports on previous use in granting national authorizations
IIA 6.3	Gale, D.	Residues of Fenarimol in Tomatoes at Intervals under Covered Conditions following Multiple Applications of Rubigan 12 SC (EAF-383), Belgium - 1998. (ref NE27)	
IIA 6.3	Butcher, S. Wood, S.	Residues of Fenarimol in Peaches at intervals following Application of RUBIGAN 4 (EAF216), - Southern France 1993 (ref NG07)	
IIA 6.3	Butcher, S. Wood, S.	Residues of Fenarimol in Peaches at intervals following Application of RUBIGAN 12SC (EAF383), Italy – 1993 (ref NG08)	
IIA 6.3	Gale, D.	Residues of Fenarimol in Peaches at Harvest Following Multiple Applications of RUBIGAN 12SC (EAF-383), Spain - 1998. (ref NG13)	
IIA 6.3	Gale, D.	Residues of Fenarimol in Peaches at Intervals Following Multiple Applications of RUBIGAN 12SC (EAF-383), Greece - 1998. (ref NG14)	
IIA 6.3	Gale, D.	Residues of Fenarimol in Peaches at Harvest Following Multiple Applications of RUBIGAN 12SC (EAF-383), Greece - 1998. (ref NG15)	
IIA 6.3	Gale, D.	Residues of Fenarimol in Peaches at Harvest Following Multiple Applications of RUBIGAN 12SC (EAF-383), Italy - 1998. (ref NG16)	
IIA 6.6	Gale, D.	A Rotational Crop Study: Residues of Fenarimol in Peppers, Soil, and a Follow-on Crop of Courgettes, following multiple Applications of RUBIGAN 12SC (EAF-383) to Pepper Plants, Italy, 1996. (ref NE14)	

B.8 Environmental fate and behaviour

Annex point/ reference number	Author	Title of study	Reports on previous use in granting national authorizations
IIA 7.1.1	Jackson, R. Lewis, C.	The Metabolism of ¹⁴ C Fenarimol in Soil Date: 1994 (ref K41)	
IIA 7.1.1 7.2	Havens, P.L. Davis, J.D.	Soil Accumulation and Groundwater Predicted Environmental Concentrations of Fenarimol When Applied Under Worst-case European Conditions. (ref K50)	
IIA 7.1.1.2.2	Gale, D.	Residues of Fenarimol in Soil under Grapevines following repeated multiple applications of Formulations containing Fenarimol, Spain – 1998 (ref NK07))	
IIA 7.1.1.2.2	Khoshab, A. Gale, D. McLaughlin, E.	Determination of Residues of Fenarimol in Soil. (ref OR39)	
IIA 7.2	Yon, D. Maycock, R. Clements, B.	Groundwater Predicted Environmental Concentrations of Fenarimol and 2-chlorobenzoic acid by FOCUS PELMO modelling (submitted to SCP)	
IIA 7.2	Jackson, R.	Letter Report: The Predicted Environmental Concentration of Fenarimol in Sediment and Surface Water. (ref K51)	
IIA 7.2.1.3	Jackson, R. Lewis, C.	The Degradation and Retention of ¹⁴ C Fenarimol in Water-Sediment Systems. Date: 1994a (ref K42)	
IIA 7.2.3	Day, S. R.	The Evaporation Behaviour of Fenarimol from Soil and Leaf Surfaces Following Application of Rubigan 12 EC (EAF 457). Date: 1993 (ref K43)	

B.9 Ecotoxicology

Annex point/ reference number	Author	Title of study	Reports on previous use in granting national authorizations
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Annex point/ reference number	Author	Title of study	Reports on previous use in granting national authorizations
IIA 8.2.2.3	Dionne, E.	Fenarimol – The Chronic Toxicity to the Fathead Minnow (<i>Pimephales promelas</i>) during a full life-cycle exposure Date: 2003 (ref 12791.6106)	
IIA 8.2.6	Douglas, M. T. Bell, G. MacDonald, I.A.	The Algistatic Activity of Fenarimol Technical Date: 1991 (ref J22)	
IIA 8.2.7	Kelly, C.	Fenarimol Technical: Toxicity to the sediment phase of the midge <i>Chironomus riparius</i> . (ref J26)	
IIA 8.3.1	Bell, G.	Fenarimol: Acute Toxicity to Honey Bees (<i>Apis mellifera</i>) Date: 1994 (ref J24)	
IIA 8.3.2	Miles, M. Fullick, K. Day, E.	An Extended Laboratory Test to Evaluate the Side Effects of Rubigan 12EC on the Parasitic Wasp <i>Aphidius rhopalosiphi</i> . (ref MJ10)	
IIA 8.3.2	Austin, H. M.	A Laboratory Study to Evaluate the Effects of RUBIGAN 12EC on the Carabid Beetle, <i>Poecilus cupreus</i> . (ref MJ11)	
IIA 8.3.2	Austin, H. M.	A Laboratory Study to Evaluate the Effects of RUBIGAN 12EC on the Parasitic Wasp, <i>Aphidius rhopalosiphi</i> . (ref MJ12)	
IIA 8.3.2	Nickless, A.	A Laboratory Study to Evaluate the Effects of RUBIGAN 12EC on the Green Lacewing, <i>Chrysoperla carnea</i> . (ref MJ13)	
IIA 8.3.2	Gill, A.	Laboratory Study to Evaluate the Effects of RUBIGAN 12EC on the Predatory Mite, <i>Typhlodromus Pyri</i> . (ref MJ14)	
IIA 8.3.2	Miles, M.	Interpretive Summary on the Side Effects of the Fungicide Fenarimol to Non-target Arthropods; Studies to Address EU Directive EU 91/414 – Letcombe Glasshouse. (ref MJ15)	

Annex point/ reference number	Author	Title of study	Reports on previous use in granting national authorizations
IIA 8.3.2	Miles, M.	A Field Experiment to Determine the Effects of EF-1303, EF-1295 and RUBIGAN on the Predatory Mite <i>Typhlodromus Pyri</i> in Vines in France (ref MJ16)	

APPENDIX IIIB**FENARIMOL**

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	Author	Title	GLP	Pub
IIA 1.10	Smith, A.	Analysis of product samples for active ingredient and impurities in fenarimol technical Study report: .FOR00007 Date: 2000	Yes	No
IIA 2.2	Comb, A.	Fenarimol: Determination of Physico-Chemical Properties (Relative Density) Study report: DWC976/983841 GHE-P-7783 Date: 1999	Yes	No
IIA 2.3	Olive, C.	Determination of Auto-Ignition Temperature (Liquids and gases) of Fenarimol 120 g/L EC, EAF-457 Study report: GHE-P-8276 Date: 2000	Yes	No
IIA 2.5	Knowles, S.	Generation of UV-Vis Spectral Data for Fenarimol (Pure), TSN100304 Study report: GHE-P-5219 Date: 1996	Yes	No
IIA 2.7	Gilbert, G.	Fenarimol Technical: Solubility in various organic solvents Study report: GHE-P-5672 Date: 1996	Yes	No

Annex point	Author	Title	GLP	Pub
IIA 3.6	Hewitt, H.G.	A Review of the Resistance Status of the Pathogens <i>Podospaera leucotricha</i> , <i>Uncinula necator</i> and <i>Sphaerotheca fuliginea</i> to Fenarimol and other DMI Fungicides. Study report: GH-4685 Date: 1995	No	No
	Perkins, J. Knowles, S.	Re-Assay, Fenarimol pyrimidinemethanol analog (Metabolite B), TSN 100091 Study report: GHE-P-4895 Date: 1998	Yes	No
	Perkins, J.	Analysis of fenarimol metabolite C, TSN 101567 Study report: GHE-P-5069 Date: 1998	Yes	No
IIA 4.2 (IIA 6.3)	Khoshab, A Coombe, N.	Independent laboratory confirmation of Dowelanco analytical method ERC 94.3 for the determination of fenarimol in melon peel and pulp Study report: GHE-P-5228 Date: 1996	Yes	No
IIA 4.2 (IIA 6.6)	Khoshab, A.	Determination of Residues of Fenarimol in Cucumbers and Courgettes Study report: ERC 95.25 Date: 1996	Yes	No
IIA 4.2 (IIA 6.6)	Khoshab, A Coombe, N.	Independent laboratory confirmation of Dowelanco analytical method ERC 95.25 for the determination of fenarimol in cucumbers and courgettes Study report: GHE-P-5228 Date: 1996	Yes	No
IIA 4.2 (IIA 6.6)	Reeves, G.L.	Determination of Fenarimol in Peppers Study report: ERC 96.29 Date: 1996	Yes	No
IIA 4.2.1	Reeves, G.L.	Multi-crop Confirmatory Determination of Fenarimol Residues. Study report: ERC 96.32 Date: 1997	Yes	No

Annex point	Author	Title	GLP	Pub
IIA 4.2.4	Rawle, N. W.	Determination of Fenarimol in Air Study report: ERC 98.12 Date: 1998	Yes	No

B.6 Toxicology and metabolism**None**

B.7 Residue data

Annex point	Author	Title	GLP	Pub
IIA 6.3	Anon	Residue Study - Melons —France Study report: F80-730 Date: 1980	No	No
IIA 6.3	Anon	Residue Study - Melons —France Study report: F80-73A Date: 1980	No	No
IIA 6.3	Anon	Residue Study - Melons —France Study report: F80-735 Date: 1980	No	No
IIA 6.3	Butcher, S.	Residues of Fenarimol in Melons at Intervals following Multiple Applications of Rubigan 12SC (EAF-383), Spain 1994 Study report: GHE-P-4011 Date: 1995	Yes	No
IIA 6.3	Butcher, S.	Residues of Fenarimol in Melons at Harvest following Multiple Applications of Rubigan 12SC (EAF-383), Italy 1994 Study report: GHE-P-4013 Date: 1995	Yes	No
IIA 6.3	Gale, D.	Residues of Fenarimol in Melons at Intervals Following multiple Applications of RUBIGAN 12SC (EAF- 383), Italy – 1996 Study report: GHE-P-6724 Date: 1998	Yes	No
IIA 6.3	Anon	Residue Study - Cucumber — UK Study report: FG76-016 Date: 1976	No	No
IIA 6.3	Gale, D.	Residues of Fenarimol in Cucumbers at Harvest Grown under Covered Conditions Following multiple Applications of RUBIGAN 12SC (EAF- 383), UK – 1996 Study report: GHE-P-6726 Date: 1997	Yes	No

Annex point	Author	Title	GLP	Pub
I/A 6.3	Gale, D.	Residues of Fenarimol in Cucumbers at Harvest Grown under Covered Conditions Following multiple Applications of RUBIGAN 12SC (EAF-383), Netherlands – 1996 Study report: GHE-P-6834 Date: 1998	Yes	No
I/A 6.3	Gale, D.	Residues of Fenarimol in Cucumbers at Harvest following Multiple Applications of RUBIGAN 12SC (EAF-383), Greece – 1998 Study report: GHE-P-7410R Date: 1998	Yes	No
I/A 6.3	Gale, D.	Residues of Fenarimol in Cucumbers at Harvest following Multiple Applications of RUBIGAN 12SC (EAF-383), Italy – 1998 Study report: GHE-P-7406 Date: 1998	Yes	No
I/A 6.3	Gale, D.	Residues of Fenarimol in Cucumbers at Intervals under Covered Conditions following Multiple Applications of RUBIGAN 12SC (EAF-383), Belgium – 1998 Study report: GHE-P-7409 Date: 1999	Yes	No
I/A 6.3	Gale, D.	Residues of Fenarimol in Cucumbers at Intervals grown under Covered Conditions following Multiple Applications of RUBIGAN 12SC (EAF-383), UK – 1998 Study report: GHE-P-7408 Date: 1998	Yes	No
I/A 6.3	Khoshab, A.	Residues of Fenarimol in Cucumbers at Harvest Following multiple Applications of RUBIGAN 12SC (EAF-383), Glasshouse Trials, Italy - 1995. Study report: GHE-P-5163 Date: 1996	Yes	No
I/A 6.3	Anon	Residue Study - Tomatoes— Italy Study report: I79-251 Date: 1979	No	No

Annex point	Author	Title	GLP	Pub
I/A 6.3	Butcher, S. M.	Residues of Fenarimol in Tomatoes at Intervals Following Application of RUBIGAN 12EC (EAF 457), Spain 1993 Study report: GHE-P-3653 Date: 1994	Yes	No
I/A 6.3	Gale, D.	Residues of Fenarimol in Tomatoes at Harvest Grown under covered conditions following Multiple Applications of RUBIGAN 12SC (EAF-383), UK - 1996 Study report: GHE-P-6727 Date: 1997	Yes	No
I/A 6.3	Gale, D.	Residues of Fenarimol in Tomatoes at Harvest grown under Covered Conditions following Multiple Applications of RUBIGAN 12SC (EAF-383), Netherlands – 1996 Study report: GHE-P-6836 Date: 1998	Yes	No
I/A 6.3	Gale, D.	Residues of Fenarimol in Tomatoes at Intervals under covered conditions following Multiple Applications of RUBIGAN 12SC (EAF-383), UK - 1998 Study report: GHE-P-7417 Date: 1998	Yes	No
I/A 6.3	Gale, D.	Residues of Fenarimol in Tomatoes at Harvest under Covered Conditions following Multiple Applications of Rubigan 12 SC (EAF-383), Netherlands - 1998. Study report: GHE-P-7416 Date: 1999	Yes	No
I/A 6.3	Gale, D.	Residues of Fenarimol in Tomatoes at Intervals under Covered Conditions following Multiple Applications of Rubigan 12 SC (EAF-383), Belgium - 1998. Study report: GHE-P-7415R Date: 1999	Yes	No

Annex point	Author	Title	GLP	Pub
I/A 6.3	Khoshab, A.	Residues of Fenarimol in Tomatoes at Harvest Following Multiple Applications of RUBIGAN 12SC (EAF-383), Italy - 1995. Study report: GHE-P-5161 Date: 1996	Yes	No
I/A 6.3	Gale, D.	Residues of Fenarimol in Peppers at Intervals Grown under covered conditions following Multiple Applications of RUBIGAN 12SC (EAF 383), UK – 1996 Study report: GHE-P-6725R Date: 1998	Yes	No
I/A 6.3	Gale, D.	Residues of Fenarimol in Peppers at Intervals grown under Covered Conditions following Multiple Applications of RUBIGAN 12SC (EAF-383), Italy – 1996 Study report: GHE-P-6723 Date: 1998	Yes	No
I/A 6.3	Anon	Residue Study – Pepper — Italy Study report: I79-250 Date: 1979	No	No
I/A 6.3	Gale, D.	Residues of Fenarimol in Peppers at Harvest grown under Covered Conditions following Multiple Applications of RUBIGAN 12SC (EAF-383), Netherlands – 1996 Study report: GHE-P-6835 Date: 1998	Yes	No
I/A 6.3	Gale, D.	Residues of Fenarimol in Peppers, grown outdoors, at harvest following multiple applications of RUBIGAN 12SC (EAF-383), Italy, 1998 Study report: GHE-P-7405R Date: 1998	Yes	No
I/A 6.3	Gale, D.	Residues of Fenarimol in Peppers, Grown outdoors, at Harvest following Multiple Applications of RUBIGAN 12SC (EAF-383), Greece - 1998 Study report: GHE-P-7414 Date: 1999	Yes	No

Annex point	Author	Title	GLP	Pub
I/A 6.3	Gale, D.	Residues of Fenarimol in Peppers at Harvest Grown under covered conditions following Multiple Applications of RUBIGAN 12SC (EAF-383), Spain - 1996 Study report: GHE-P-6517 Date: 1997	Yes	No
I/A 6.3	Gale, D.	Residues of Fenarimol in Peppers at Harvest Grown under covered conditions following Multiple Applications of RUBIGAN 12SC (EAF-383), Greece - 1996 Study report: GHE-P-6837 Date: 1997	Yes	No
I/A 6.3	Butcher, S.	The Stability of Fenarimol in Fortified Peaches, Tomatoes and Melons under Frozen Storage Conditions. Study report: GHE-P-4318 Date: 1995	Yes	No
I/A 6.3	Gale, D.	Residues of Fenarimol in Peppers at Intervals under Covered Conditions following Multiple Applications of Rubigan 12 SC (EAF-383), Netherlands - 1998. Study report: GHE-P-7413 Date: 1999	Yes	No
I/A 6.3	Butcher, S.	Residues of Fenarimol in Peaches at Harvest following Multiple Applications of RUBIGAN 4 (EAF-216), Southern France – 1994 Study report: GHE-P-4062 Date: 1995	Yes	No
I/A 6.3	Butcher, S.	Residues of Fenarimol in Peaches at harvest following multiple Application of RUBIGAN 12SC (EAF-383), Italy – 1994 Study report: GHE-P-4014 Date: 1995	Yes	No

Annex point	Author	Title	GLP	Pub
I/A 6.3	Butcher, S. Wood, S.	Residues of Fenarimol in Peaches at intervals following Application of RUBIGAN 4 (EAF216), - Southern France 1993 Study report: GHE-P-3652 Date: 1994	Yes	No
I/A 6.3	Butcher, S. Wood, S.	Residues of Fenarimol in Peaches at intervals following Application of RUBIGAN 12SC (EAF383), Italy – 1993 Study report: GHE-P-3626 Date: 1994	Yes	No
I/A 6.3	Gale, D.	Residues of Fenarimol in Peaches at Harvest Following Multiple Applications of RUBIGAN 12SC (EAF-383), Spain - 1998. Study report: GHE-P-7306 Date: 1998	Yes	No
I/A 6.3	Gale, D.	Residues of Fenarimol in Peaches at Intervals Following Multiple Applications of RUBIGAN 12SC (EAF-383), Greece - 1998. Study report: GHE-P-7411 Date: 1998	Yes	No
I/A 6.3	Gale, D.	Residues of Fenarimol in Peaches at Harvest Following Multiple Applications of RUBIGAN 12SC (EAF-383), Greece - 1998. Study report: GHE-P-7412R Date: 1998	Yes	No
I/A 6.3	Gale, D.	Residues of Fenarimol in Peaches at Harvest Following Multiple Applications of RUBIGAN 12SC (EAF-383), Italy - 1998. Study report: GHE-P-7404R Date: 1998	Yes	No

Annex point	Author	Title	GLP	Pub
IIA 6.6	Gale, D.	A Rotational Crop Study: Residues of Fenarimol in Peppers, Soil, and a Follow-on Crop of Courgettes, following multiple Applications of RUBIGAN 12SC (EAF-383) to Pepper Plants, Italy, 1996. Study report: GHE-P-6516 Date: 1997	Yes	No

B.8 Environmental fate and behaviour

Annex point	Author	Title	GLP	Pub
IIA 7.1.1 IIA 7.2	Havens, P.L. Davis, J.D.	Soil Accumulation and Groundwater Predicted Environmental Concentrations of Fenarimol When Applied Under Worst-case European Conditions. Study report: GH-C-4842R (revised) Date: 2000	No	No
IIA 7.1.1 IIA 7.2	Yon, D. Maycock, R. Clements, B.	Groundwater Predicted Environmental Concentrations of Fenarimol and 2-chlorobenzoic acid by FOCUS PELMO modelling Study report: None Date: 2001	-	-
IIA 7.1.1.2.2	Gale, D.	Residues of Fenarimol in Soil under Grapevines following repeated multiple applications of Formulations containing Fenarimol, Spain – 1998 Study report: GHE-P-7407 Date: 1998	Yes	No
IIA 7.1.1.2.2	Khoshab, A. Gale, D. McLaughlin, E.	Determination of Residues of Fenarimol in Soil. Study report: ERC 97.05 Date: 1997	Yes	No
IIA 7.2	Jackson, R.	Letter Report: The Predicted Environmental Concentration of Fenarimol in Sediment and Surface Water. Study report: None Date: 1999	No	No

B.9 Ecotoxicology

Annex point	Author	Title	GLP	Pub
IIA 8.2.7	Kelly, C.	Fenarimol Technical: Toxicity to the sediment phase of the midge Chironomus riparius. Study report: DWC 839/972312 Date: 1997	Yes	No

Annex point	Author	Title	GLP	Pub
I/A 8.3.2	Miles, M.	A Field Experiment to Determine the Effects of EF-1303, EF-1295 and RUBIGAN on the Predatory Mite Typhlodromus Pyri in Vines in France Study report: GHE-P-5783 Date: 1998	Yes	No
I/A 8.3.2	Miles, M. Fullick, K. Day, E.	An Extended Laboratory Test to Evaluate the Side Effects of Rubigan 12EC on the Parasitic Wasp Aphidius rhopalosiphi. Study report: GHE-P-5638 Date: 1996	Yes	No
I/A 8.3.2	Austin, H. M.	A Laboratory Study to Evaluate the Effects of RUBIGAN 12EC on the Carabid Beetle, Poecilus cupreus. Study report: GHE-P-6712 Date: 1996	Yes	No
I/A 8.3.2	Austin, H. M.	A Laboratory Study to Evaluate the Effects of RUBIGAN 12EC on the Parasitic Wasp, Aphidius rhopalosiphi. Study report: GHE-P-6713 Date: 1996	Yes	No
I/A 8.3.2	Nickless, A.	A Laboratory Study to Evaluate the Effects of RUBIGAN 12EC on the Green Lacewing, Chrysoperla carnea. Study report: GHE-P-6714 Date: 1997	Yes	No
I/A 8.3.2	Gill, A.	Laboratory Study to Evaluate the Effects of RUBIGAN 12EC on the Predatory Mite, Typhlodromus Pyri. Study report: GHE-P-6711 Date: 1996	Yes	No
I/A 8.3.2	Miles, M.	Interpretive Summary on the Side Effects of the Fungicide Fenarimol to Non-target Arthropods; Studies to Address EU Directive EU 91/414 - Letcombe Glasshouse. Study report: GHE-P-6996 Date: 1998	Yes	No

Annex point	Author	Title	GLP	Pub
	Mallett, M. J.	The Acute Toxicity of EAF-383 to the Earthworm <i>Eisenia foetida</i> Study report: GHE-T-964 Date: 1999	Yes	No
IIIA 10.6.2	Walker, H.M.	A Field Evaluation of the Effects of EAF-383 (120 g fenarimol l ⁻¹) in a Suspension Concentrate (SC) Formulation on the Degradation of Buried Leaf Material Study report: ER-00-KCB110 Date: 2000	Yes	No

Product (Annex III) data

Annex point	Author	Title	GLP	Pub
IIIA 2.1	Olive, C.	Letter Report: Odour of Fenarimol 6WP Fungicide – EAF-219 Study report: Klp97006 Date: 2000	No	No
IIIA 2.2.2 IIIA 2.5.3 IIIA 2.5	Olive, C.	Determination of Physico-Chemical Properties of Fenarimol 120 g/L EC, EAF-457. Study report: GHE-P-8134 Date: 2000	Yes	No
IIIA 2.4.2 IIIA 2.7.3 IIIA 2.8.2	Turri, E Olive, C.	Package Storage Stability Study for Fenarimol 6WP Fungicide, EAF-219 Study report: GHE-P-6645 Date: 2000	Yes	No
IIIA 2.5.3 IIA 2.1	Olive, C.	Determination of Physico-Chemical Properties of Fenarimol 120 g/L SC, EAF-383 Study report: GHE-P-8135 Date: 2000	Yes	No
IIIA 2.7.2 IIIA 2.7.3	Turri, E. Olive, C.	Packaging Storage Stability Trial for Fenarimol 120 g/l SC Fungicide, EAF-383 Study report: GHE-P-4564 Date: 1995	Yes	No
IIIA 4.1	Curle, P.	Summary of European packaging Study report: None Date: 1994	No	No

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APPENDIX IV

List of uses supported by available data

FENARIMOL

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) (k)	Remarks (l)
					Type (d-f)	Conc. of a.s. (i)	Method Kind (f-h)	Growth stage (j)	Number min max	Interval between apps. (min)	kg a.s./hl min max	water (l/ha) min max	kg a.s./ha min max		
Apples	NMS	Rubigan	F	Foliar and fruit fungi	SC	120	MV	BBCH85	6		0.04	>200	.080	14	
Apples	SMS	Rubigan	F	Foliar and fruit fungi	EC/SC	120	HV	BBCH85	3		.0048	1500	.072	14	
Pears	NMS	Rubigan	F	Foliar and fruit fungi	WP	60	HV	BBCH81	5	7 - 10 days	.0051	1500	.076	21	
Pears	SMS		F	Foliar and fruit fungi	SC/WP	120/60	HV	BBCH81	6		.0048	1500	.072	14	
Peaches	SMS		F	Foliar and fruit fungi	SC/EC	120	HV	BBCH85	3		.0048	1200	.006	7	
Table Grapes	SMS			Foliar and fruit fungi	SC/EC	120	HV	BBCH85	3		.0036	1200	.043	21	
Wine Grapes	NMS		F	Foliar and fruit fungi	SC	120	MV	BBCH81	4	-	.020	>200	.040	21	
Wine Grapes	SMS		F	Foliar and fruit fungi	SC/WP	120/60	HV	BBCH83	7	7 - 15 days	0.0036	1000	0.036	21	

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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) (k)	Remarks (l)
					Type (d-f)	Conc. of a.s. (i)	Method Kind (f-h)	Growth stage (j)	Number min max	Interval between apps. (min)	kg a.s./hl min max	water (l/ha) min max	kg a.s./ha min max		
Tomatoes	NMS		G	FUNGI	SC	120	HV	BBCH79	5	7 - 10 days	.0048	1500	.072	3	
Tomatoes	SMS		F	Fungi	SC/EC	120	HV	BBCH79	3		.0048	1200	.058	7	Glasshouse covered by north trials
Peppers	NMS		G	Fungi	SC	120	HV	BBCH79	5	7 - 10 days	.0024	1500	.036	3	
Peppers	SMS		G	Fungi	SC/EC	120	HV	BBCH79	3		.006	1200	.072	7	
Aubergines	SMS		F	Fungi	SC/WP	120/60	HV	BBCH79	3	8 - 12 days	.0048	800	.038	7	
Cucumbers	NMS		G	Fungi	EC	40	HV	BBCH79	5	7 days	.003	1500	.045	3	
Cucumbers	SMS	Rubigan	G	Fungi	SC/EC	120	HV	BBCH79	2	10 - 14 days	.0048	1000	.048	7	
Melons	SMS	Rubigan	F/G	Fungi	EC7SC	120	HV	BBCH79	2	10 - 14 days	.0048	1000	<u>0.048</u>	<u>7</u>	or
		Rubigan 4	F	Fungi	EC	40	M-HV	BBCH87	1-5	7 - 14 days	.0024-.012	200-1000	<u>0.024</u>	<u>2</u>	
Turf	France	Rimidin	F	Diseases	SC	120 g/L	Broadcast spraying medium volume	Establ. grass all year long	1-4	21 days	0.24	250 to 500	0.6 to 1.2	N/A	Grass clippings are left on soil surface of intensive turf
Turf	UK	Rimidin	F	Turf diseases	SC	120 g/l	overall	Year round	1-4	3 weeks	0.3	500	0.6-1.5	N/A	

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) (k)	Remarks (l)
					Type (d-f)	Conc. of a.s. (i)	Method Kind (f-h)	Growth stage (j)	Number min max	Interval between apps. (min)	kg a.s./hl min max	water (l/ha) min max	kg a.s./ha min max		
Turf	Ireland	Rimidin	F	Turf diseases	SC	120 g/l	overall	Year round	1-4	3 weeks	0.12	500	0.6-1.5	N/A	
Turf	Spain	Rimidin	F	Turf diseases	SC	120 g/l	overall	Year round	1-4	10	0.075	400	0.3	N/A	Protectant
Roses	UK	Rubigan	F	Powdery mildew	SC	120 g/l	overall	Year round	-	10 days	Max 0.004	1000	0.04	N/A	Maximum concentration must not exceed 33 ml in 100 litres water
Roses	Ireland	Rubigan	F	Powdery mildew	SC	120 g/l	overall	Year round	-	10 days	Max 0.004	1000	0.04	N/A	Maximum concentration must not exceed 33 ml in 100 litres water
Roses	Germany	Rubigan EC	F	Powdery mildew	EC	120	overall	-	1 to 8	10 - 14 days	0.0036	max. 1500	max. 0.054	N/A	
Roses	Netherlands	Rugigan 12SC	G	Spherotheca spp	SC	120	Overall	All year	3 to 6	7 - 10 days	0.0042	1000	0.042	N/A	
Ornamentals	Netherlands	Rugigan 12SC	G	Spherotheca spp	SC	120	Overall	All year	3 to 6	7 - 10 days	0.0042	1000	0.042	N/A	
Nursery trees	Netherlands	Rugigan 12SC	F	Erysiphe spp	SC	120	Overall	All year	1 to 3	7 - 10 days	0.006	600	0.036	N/A	
Perennial plants	Netherlands	Rugigan 12SC	F	Erysiphe spp	SC	120	Overall	All year	1 to 3	7 - 10 days	0.0048	600	0.028	N/A	

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) (k)	Remarks (l)
					Type (d-f)	Conc. of a.s. (i)	Method Kind (f-h)	Growth stage (j)	Number min max	Interval between apps. (min)	kg a.s./hl min max	water (l/ha) min max	kg a.s./ha min max		
Ornamentals	Spain	Rubigan 12	F/G		EC	120	Overall	All year	-	7-14 days					Rates and no. of apps. to be confirmed, but within GAP of other countries
Ornamentals	Spain	Rubigan Flow	F/G		SC	120	Overall	All year	-	7-14 days					

- Remarks:
- | | | | |
|-----|--|-----|--|
| (a) | The EU and Codex classifications (both) should be used. | (g) | Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench |
| (b) | Outdoor or field use (F), glasshouse application (G) or indoor application (I) | (h) | Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants |
| (c) | e.g. biting and sucking insects, soil borne insects, foliar fungi, weeds | (i) | g/kg or g/l |
| (d) | e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) | (j) | Growth stage at last treatment |
| (e) | GIFAP Codes - GIFAP Technical Monograph No. 2, 1989 | (k) | PHI - Pre-harvest interval |
| (f) | All abbreviations must be explained | (l) | Remarks may include: Extent of use/ economic importance/restrictions (e.g. feeding/grazing)/minimal intervals between applications |