EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate D – Food Safety: Production and distribution chain
D3 – Chemicals, contaminants and pesticides

Etoxazole

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

Review report for the active substance **etoxazole**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 3 December 2004 in view of the inclusion of etoxazole in Annex I of Directive 91/414/EEC.

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of the new active substance etoxazole, made in the context of the work provided for in Articles 5 and 6 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.

In accordance with the provisions of Article 6(2) of Directive 91/414/EEC, the French authorities received on 21 April 1998 an application from Sumitomo Chemical Agro Europe SA, hereafter referred to as the applicant, for the inclusion of the active substance etoxazole in Annex I to the Directive. The French authorities indicated to the Commission on 03 September 1998 the results of a first examination of the completeness of the dossier, with regard to the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive. Subsequently, and in accordance with the requirements of Article 6(2), a dossier on etoxazole was distributed to the Member States and the Commission.

The Commission referred the dossier to the Standing Committee on the Food Chain and Animal Health in the meeting of the working group 'legislation' thereof on 15 October 1998, during which the Member States confirmed the receipt of the dossier.

In accordance with the provisions of Article 6(3), which requires the confirmation at Community level that the dossier is to be considered as satisfying, in principle, the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive and in accordance with the procedure laid down in Article 20 of the Directive, the Commission confirmed in its Decision 1999/43/EC[1] of 22 December 1998 that these requirements were satisfied.

[1] OJ No L14, 19.01.1999, p.30

Within the framework of that decision and with a view to the further organisation of the works related to the detailed examination of the dossier provided for in Article 6(2) and (4) of Directive 91/414/EEC, it was agreed between the Member States and the Commission that France would, as rapporteur Member State, carry out the detailed examination of the dossier and report the conclusions of its examination accompanied by any recommendations on the inclusion or non-inclusion and any conditions relating thereto, to the Commission as soon as possible and at the latest within a period of one year.

The France submitted to the Commission on 8 October 2001 the report of its detailed scientific examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of etoxazole in Annex I to the Directive.

On receipt of the draft assessment report, the Commission forwarded it for consultation to all the Member States as well as to Sumitomo Chemical Agro Europe SA being the sole applicant on 9 October 2001.

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

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

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

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the sole applicant on 11 September 2002.

The dossier, draft assessment report and the peer review report (i.e. full report) including in particular an outline resumé of the remaining technical questions, were referred to the Standing Committee on the Food Chain and Animal Health, and specialised working groups of this Committee, for final examination, with participation of experts from all Member States. This final examination took place from May 2003 to December 2004 and was finalised in the meeting of the Standing Committee on 3 December 2004.

The present review report contains the conclusions of this 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.

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

2. Purposes of this review report

This review report, including the background documents and appendices thereto, have been developed and finalised in support of the Directive 2005/34/EC concerning the inclusion of etoxazole in Annex I to Directive 91/414/EEC[2], and to assist the Member States in decisions on individual plant protection products containing etoxazole 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 parallel with the provisions of Article 7(6) of Regulation 3600/92 for existing active substances, the Commission and the 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 the applicant.

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 possession of 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 etoxazole 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 etoxazole 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 sole data submitter and mentioned in the list of uses supported by available data (attached as Appendix IV to this Review Report).

Extension of the use pattern beyond those described above will require 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.

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[2] OJ No L125,18.05.05, p. 5-7

4. Specific conclusions which are highlighted in this evaluation

4.1 Residues of etoxazole in foodstuffs

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) for a 60 kg adult is 0.3% of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). This low intake value reflects the current limited use pattern for this active substance.

4.2 Exposure of operators, workers and bystanders

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

4.3 Ecotoxicology

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 7 of this report.

5. Identity and Physical/chemical properties

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

The active substance shall have a minimum purity of 948 g/kg technical product.

The review has established that for the active substance notified by the applicant (Sumitomo Chemical Agro Europe SA), none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

6. 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 evaluation process are listed in Appendix II.

7. 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 etoxazole

On the basis of the proposed and supported uses, the following particular issues have been identified as requiring particular and short term (within 12 months at the latest) attention from the Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

In this overall assessment, Member States should pay particular attention to the protection of aquatic organisms.

Risk mitigation measures should be applied where appropriate.

8. List of studies to be generated

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

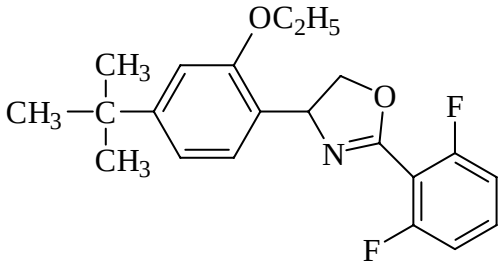
9. Updating of this review report

The technical information in this report may require periodic updating 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 etoxazole in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

ETOXAZOLE

Common name (ISO)	Etoxazole
Development Code (for new actives only)	S-1283
Chemical name (IUPAC)	(*RS*)-5-*tert*-butyl-2-[2-(2,6-difluorophenyl)-4,5-dihydro-1,3-oxazol-4-yl] phenetole
Chemical name (CA)	2-(2,6-difluorophenyl-4-[4-(1,1-dimethylethyl)-2-ethoxyphenyl]-4,5-dihydrooxazole
CIPAC No	623
CAS No	153233-91-1
EEC No	Not allocated
FAO SPECIFICATION	Not applicable
Minimum purity	948 g/kg
Molecular formula	$C_{21}H_{23}F_2NO_2$
Molecular mass	359.42
Structural formula	

Melting point	101.5 - 102.5°C (99.85% purity)
Boiling point	Not applicable (solid with high melting point)
Appearance	Pure: White free flowing crystalline powder(99.85% purity) Active substance as manufactured: white lumpy powder
Relative density	1.24 (99.85% purity)
Vapour pressure	7.0 x 10^{-6} Pascal at 25°C (99.85% purity)
Henry's law constant	3.6 x 10^{-2} Pa m^3/mole at 20 – 25°C (calculation)
Solubility in water	7.04 x 10^{-5} g/l in distilled water at 20°C (99.85% purity) 6.69 x 10^{-5} g/l in distilled water at 30°C The effect of pH was not determined as the test material has no ionisable groups or dissociation constant
Solubility in organic solvents	Acetone: 309 g/l at 20°C 1,2-dichloroethane: 402 g/l at 20°C Ethyl acetate: 249 g/l at 20°C n-heptane: 18.7 g/l at 20°C Methanol: 104 g/l at 20°C Xylene: 252 g/l at 20°C
Partition co-efficient (log P_{ow})	Log P_{ow} = 5.52 ± 0.58 at 20°C (99.85% purity) The effect of pH was not determined as the test material has no ionisable groups or dissociation constant
Hydrolytic stability (DT_{50})	PH 5 : 9.6 days @ 20°C PH 7 : 161 – 147* days @ 20°C PH 9 : 165 – 217* days @ 20°C * determined by extrapolation of Arrhenius plot
Dissociation constant	Not measurable
Quantum yield of direct photo-transformation in water at λ >290 nm	0.026 molxeinstein^{-1}
Flammability	Not flammable
Explosive properties	Not explosive
UV/VIS absorption (max.)	Neutral: λmax = 220 nm ε = 17379 lxmol^{-1}xcm^{-1} Acidic: λmax = 222 5 nm ε = 16670 lxmol^{-1}xcm^{-1} Alkaline: λmax = 272.5 nm ε = 3993 lxmol^{-1}xcm^{-1} No absorption between 300 and 350 nm
Photostability in water (DT_{50})	[^{14}C-oxazole]etoxazole: Half-life = 15.9 days summer sunlight equivalents at latitude 40°N, pH 9 [^{14}C-*t*-butylphenyl]etoxazole: Half-life = 17.4 days summer sunlight equivalents at latitude 40°N, pH 9

APPENDIX II

END POINTS AND RELATED INFORMATION

ETOXAZOLE

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	Rapid, about 60 %, based on recovery in bile, urine and carcass within 48 h
Distribution:	Widely distributed, highest residues in liver
Potential for accumulation:	No potential for accumulation
Rate and extent of excretion:	8-17 % via urine, 77-88 % via faeces (40-54 % in bile) within 7 days
Toxicologically significant compounds:	Parent compound
Metabolism in animals:	Extensively metabolised, principally by hydroxylation of the 4,5-dihydrooxazole ring followed by cleavage of the molecule and hydroxylation of the tertiary-butyl side chain

Acute toxicity

Rat LD_{50} oral:	>5000 mg/kg bw
Rat LD_{50} dermal:	>2000 mg/kg bw
Rat LC_{50} inhalation:	>1.09 mg/l (whole body, max. attainable concentration)
Skin irritation:	Not irritating
Eye irritation:	Not irritating
Skin sensitization (test method used and result):	Not sensitising

Short term toxicity

Target / critical effect:	Liver (indications of liver toxicity); prostate (atrophy) in dogs
Lowest relevant oral NOAEL / NOEL:	90-d & 1-yr, dog: 200 ppm (equivalent to ca. 5 mg/kg bw/d
Lowest relevant dermal NOAEL / NOEL:	28-d, rat: 100 mg/kg bw/d
Lowest relevant inhalation NOAEL / NOEL:	Not required

Genotoxicity

Positive mouse lymphoma test; negative in vivo tests (micronucleus and UDS). Overall no genotoxic concern.

Long term toxicity and carcinogenicity

Target / critical effect:	Liver (indications of liver toxicity); abnormal amelogenesis (incisors) and hyperplasia of bone tissue in rats at high doses (≥5000 ppm)
Lowest relevant NOAEL:	2-y rat : 4mg/kg bw/d
Carcinogenicity:	No carcinogenic potential

Reproductive toxicity

Target / critical effect - Reproduction:	Slight decrease of viability and body weight of pups at parental toxic dose level
Lowest relevant reproductive NOAEL / NOEL:	400 ppm (equivalent to ca. 38 mg/kg bw/d)
Target / critical effect - Developmental toxicity:	Fetotoxic (increased incidence of 13th rib) at maternal toxic dose level in rabbits
Lowest relevant developmental NOAEL / NOEL:	Rabbit: 200 mg/kg bw/d

Delayed neurotoxicity

No concern - not required

Other toxicological studies

Metabolites R-3 and R-7: LD_{50} rat, oral >5000 mg/kg bw (R-3 and R-7 HCl salt) Not mutagenic in bacteria

Medical data

Limited; new compound

Summary

	Value	Study	Safety factor
ADI:	0.04 mg/kg bw/d	2-yr, rat	100
AOEL systemic:	0.03 mg/kg bw/d	90-d & 1-yr, dog oral absorption 60%	100
AOEL inhalation:	Not allocated, use systemic AOEL		
AOEL dermal:	Not allocated, use systemic AOEL		
ARfD (acute reference dose):	Not allocated - not necessary		

Dermal absorption	10 % default

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:	t-butylphenyl : 7.0 % (90 d) - 15.8 % (269 d) difluorophenyl : 48.0 % (90 d) - 56.4 % (269 d) (soil biomass still significant after 269 d)
Non-extractable residues after 100 days:	t-butylphenyl : 18.6 % (90 d) - 27.5 % (269 d) difluorophenyl : 25.5 % (90 d) - 23.0 % (269 d)
Major metabolites above 10 % of applied active substance: name and/or code % of applied rate (range and maximum)	R-3 max. 10.4 % (61 d) R-4 max. 11.9 % (30 d) R-7 max. 21.6 % (7 d) R-8 max. 44.8 % (60d) R-13 max. 19.1 % (180 d)

Supplemental studies

Anaerobic:	Slow degradation, same pathway as under aerobic conditions R-8 max. 24.2 % (120 d) R-11 max. 38.2 % (120 d) CO_2 negligible, non-extractable 4.2-12.4 % (120 d)
Soil photolysis:	DT_{50} 23 d sunlight equivalent (latitude 40° N) R-3 and R-11 max. 12 % each (29 d sunlight equivalent)) DT_{50} dark 90 d (mean of 2 labels)
Remarks:	None

Rate of degradation

Laboratory studies

DT_{50}lab (20 °C, aerobic):	Etoxazole (20° C, 40 % WHC) Soil type / OC (%) / pHw / DT50 sandy loam 2.0 5.6 10.2 d sand (2.1) 0.6 6.7 15.0 d loamy sand (2.2) 2.1 6.7 29.0 d clay loam 1.3 7.4 52.0 d mean 26.6 d normal. DT_{50} (20° C, pF 2) : 9.8-33.2 d (mean 21.1 d) Metabolites R-7 and R-8 (Modelmaker, data from parent studies, 20° C, 40 % WHC) Soil type / DT50 (R-7) / DT50 (R-8) sandy loam 17.2 d 282 d sand 11.9 d 187 d loamy sand 110 d 119 d clay loam - 100 d mean 46.4 d 172 d normalized DT_{50} (20° C, pF 2) R-7 : 9.7-110 d (mean 45.0 d) R-8 : 63.9-251.8 d (mean 146.7 d) Metabolite R-3 : DT_{50} = 33.3-95 d (mean 54.7 d) for 3 soils (pH 4.8-7.7, 20° C, 45 % WHC), slower degradation at the lowest pH, normalized DT_{50} (20° C, pF 2) = 31.3-93.1 d (mean 53.4 d) Metabolite R-4 : DT_{50} = 6.5-19.4 d (mean 14.1 d), same soils and conditions, normalized DT_{50} (20° C, pF 2) = 6.1-19.0 d (mean 13.9 d) Metabolite R-13 : DT_{50} = 86.7-182 d (mean 128 d), same soils and conditions. Metabolite R-11 : Expected to be transient in the parent studies, DT_{50} = 5.7-17.2 d (2 soils, 24° C, pF 2 assumed), normalized DT_{50} (20° C, pF 2) = 7.7-23.2 d
DT_{90}lab (20 °C, aerobic):	DT_{90lab} (20°C, 40 or 45 % WHC, aerobic): Etoxazole : 34.1-172 d (mean 88 d) R-3 : 111-315 d (mean 183 d) R-4 : 22-64 d (mean 47 d) R-7 : 40-365 d (mean 154 d) R-8 : 332-936 d (mean 571 d) R-11 : 26-77 d (mean 51 d), pF 2 assumed R-13 : 288-604 d (mean 425 d)
DT_{50}lab (10 °C, aerobic):	DT_{50lab} (10°C, aerobic): 48 d (sandy loam)
DT_{50}lab (20 °C, anaerobic):	DT_{50lab} (20°C, anaerobic): 102 d (sandy loam)

Field studies (country or region)

DT_{50f} from soil dissipation studies:	<u>European sites</u> : 275 g as/ha (5 x max. rate), bare soil, 4 northern and southern french sites (LOQ 0.01 mg/kg, about 5 % for etoxazole and 8 % for R-8) <u>Soil type</u> (location) <u>OC (%)</u> <u>pH</u> <u>DT50</u> silty clay loam (Tours, N) 0.52 4.2 8 d clay loam (Montauban S) 0.52 7.1 8 d clay loam (Provence, S) 1.22 7.2 4 d silt loam (Alsace, N) 0.70 5.4 9 d Metabolite R-8 never detected. Others not looked for. DT_{50f} for FOCUS gw modelling (1^{st} order) Etoxazole : mean 7.3 d (2 N and 2 S French scenarios) <u>US sites</u> : 2x150 g/ha (21 d interval), bare soil, 3 sites (California, Idaho, Mississipi, pH 6.4-7.2), LOD 0.01 mg/kg (about 4.5 % of the total measured rate 249-261 g/ha for etoxazole, R-3, R-4, R-7 and R-13 , 6.8 % for R-8 , 10.3 % for R-11) Etoxazole : DT_{50} = 8.3-17.8 d (mean 12.6 d) Metabolite R-3 : low concentrations for short periods of time; max. 0.017 mg/kg (about 7.3 %) 10 DALA, not detected (< 4.5 %) 92 DALA; no tendency to accumulate Metabolite R-4 : not detected Metabolite R-7 : max. 0.054-0.099 mg/kg (about 23-42.7 %), not detected 29-136 DALA Metabolite R-8 : not detected despite formation from major and transient R-7 Metabolite R-11 : detected once (0.01 mg/kg, about 10.3 %) 10 DALA; too high LOD. Metabolite R-13 : low concentrations (0.01 mg/kg, about 4.5 %) within 10 DALA; no tendency to accumulate. The metabolites are not expected to persist or accumulate
DT_{90f} from soil dissipation studies:	DT_{90f}: same conditions European sites : 28 d, 27 d, 13 d, 31 d
Soil accumulation studies:	No data, not required
Soil residue studies:	No data, not required

Remarks: e.g. effect of soil pH on degradation rate	None

Adsorption/desorption

K_f / K_{oc}:	Etoxazole : Kf = 66-131, 1/n = 0.87-1.01 (mean 0.93), Kfoc = 4910-11000 (mean 6650) for 4 soils (OC 0.6-2.4 %, pH 4.3-7.4)
K_d:	Metabolite R-3 : Kf = 47-183, 1/n = 0.92-0.96 (mean 0.94), Kfoc = 3359-6295 (mean 5266) for 3 soils (OC 1.4-3.4 %, pH 4.8-6.6)
pH dependence:	Metabolite R-4 : Kf = 3.02-10.4, 1/n = 0.90-0.93 (mean 0.92), Kfoc = 216-360 (mean 294) for 3 soils (OC 1.4-3.4 %, pH 4.8-6.6)
	Metabolite R-7 : Kf = 14-98, 1/n = 0.87-0.93 (mean 0.90), Kfoc = 1125-7540 (mean 3665) for 3 soils (OC 0.6-2.4 %, pH 4.3-7.4)
	Metabolite R-8 : Kf = 1.24-4.56, 1/n = 0.79-0.86 (mean 0.83), Kfoc = 103-351 (mean 220) for 3 soils (OC 0.6-2.4 %, pH 4.3-7.4)
	Metabolite R-11 : Kf = 0.32-1.34, 1/n = 0.65-0.92 (mean 0.75), Kfoc = 23-46 (mean 32.6) for 3 soils (OC 1.4-3.4 %, pH 4.8-6.6)
	Metabolite R-13 : Kf = 82-1082, 1/n = 0.72-1.00 (mean 0.85), Kfoc = 13670-83230 (mean 44480) for 3 soils (OC 0.6-2.4 %, pH 4.3-7.4)

Mobility

Laboratory studies:

Column leaching:	No data, not required
Aged residue leaching:	No data, not required

Field studies:

Lysimeter/Field leaching studies:	No data, not required

Remarks:	None

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:	pH 5 (20° C) DT_{50} 9.6 d , metabolite R-7 (65 %, 21 d) pH 7 (20° C) DT_{50} 161 d , metabolite R-4 (14 %, 30 d) pH 9 (20° C) DT_{50} 165 d , metabolite R-4 (16.9 %, 30 d)
Major metabolites:	Metabolites R-7 and R-4
Photolytic degradation:	pH 9 (20° C) DT_{50} 130 h continuous artificial light (16.7 d summer sunlight equivalent 40° N) metabolites R-3 (12 %, end) ; R-11 (64 %, end); R-12 (30.6 %, end) ; R-15 (29.5 %, end), stable
Major metabolites:	Metabolites R-3, R-11, R-12 and R-15

Biological degradation

Readily biodegradable:	No
Water/sediment study:	
DT_{50} water:	1.2 - 1.7 d (bi-exponential, $R^2 > 0.90$)
DT_{90} water:	38 - 40 d (decrease to < 55 % within 1 d then DT_{50} < 16.2 d)
DT_{50} whole system:	56 - 103 d (bi-exponential)
DT_{90} whole system:	343 - 369 d each value is mean of 2 labels
Distribution in water / sediment systems (active substance)	Etoxazole max. 80 % in sediment after 7 d (DT_{50} 9 - 149 d, mean of 2 labels, $R^2 > 0.86$)
Distribution in water / sediment systems (metabolites)	no major metabolite in water R-13 max. 16.7 % in sediment (100 d) R-4 max. 5.6 % in water (100 d) and 3.1 % in sediment (60 d) R-7 max. 0.8 % in water and 2 % in sediment
Accumulation in water and/or sediment:	No accumulation in water and/or sediment:

Degradation in the saturated zone

Remarks:

none

2.3 Fate and behaviour in air

Volatility

Vapour pressure:	7.0 x 10^{-6} Pascal at 25°C (99.85% purity)
Henry's law constant:	3.6 x 10^{-2} Pa m^3/mole at 20 – 25°C (calculation)

Photolytic degradation

Direct photolysis in air:	No data, not required
Photochemical oxidative degradation in air DT_{50}:	1.5 h (Atkinson)
Volatilisation:	No data

Remarks:	None

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	LD50 > 5 000 mg/kg bw (rat, acute oral)
Acute toxicity to birds:	LD50 > 2 000 mg/kg bw (Mallard duck)
Dietary toxicity to birds:	LC50 > 5 200 mg/kg diet (Bobwhite quail)
Reproductive toxicity to birds:	NOEC = 1 000 mg/kg diet (Bobwhite quail)
Short term oral toxicity to mammals:	NOEC = 400 mg/kg diet (rat, reproduction)

Aquatic Organisms

	Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Acute toxicity fish:	Fish (Rainbow trout)	Etoxazole	acute	LC50	2.8
	Fish (Bluegill sunfish)	Etoxazole	acute	LC50	1.4 (1)
	Fish (Bluegill sunfish)	R-3, R-4, R-7, R-8, R-13 (metabolites)	acute	LC50	> 0.96 - 1 (1)
Long term toxicity fish:	Fish (Rainbow trout)	Etoxazole	chronic (ELS 89 d)	NOEC	0.015 (1)
Bioaccumulation fish:	2500-3300 whole fish most of the residues is the parent compound				
Acute toxicity invertebrate:	Daphnid	Etoxazole	acute	EC50	0.0071
	Daphnid	BORNEO	acute	EC50	0.002 mg as/l (1)
	Daphnid	R-3, R-4, R-7, R-8, R-13 (metabolites)	acute	EC50	> 0.96 - 1 (1)
Chronic toxicity invertebrate:	Daphnid	Etoxazole	chronic (21 d)	NOEC	0.0002 (1)
Acute toxicity algae:	Alga	Etoxazole	(72 h)	EbC50 / ErC50	> 10 (1)
Acute/Chronic toxicity sediment dwelling organism:	*Chironomus Sp*	Etoxazole	10 d	NOEC 10d	25 mg/kg (sed.)

(1) values used in the TER calculations

Honeybees

Acute oral toxicity:	LD50 > 200 µg as/bee (technical as) LD50 > 100 µg as/bee (SC 110 g as/l)
Acute contact toxicity:	LD50 > 200 µg as/bee (technical as) LD50 > 100 µg as/bee (SC 110 g as/l)

Other arthropod species

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect	Annex VI Trigger
Laboratory tests						
L. dactylopii	adults	SC 110 g/l	0.055	mortality / parasitism	7.69% / 70%	30%
A. rhopalosiphi	adults	SC 110 g/l	0.055	mortality / parasitism	2.3% / 50%	30%
A. rhopalosiphi	mummies	SC 110 g/l	0.055	mortality / parasitism	18.4% / < 0%	30%
T. pyri	adults	SC 110 g/l	0.0098	mortality	11.47%	30%
T. pyri	adults	SC 110 g/l	0.055	mortality / reproduction	0% / 100%	30%
T. pyri	eggs	SC 110 g/l	0.055	mortality	100%	30%
N. californicus	adults	SC 110 g/l	0.0098	mortality / fecundity	23.75% / < 0 %	30%
C. carnea	larvae	SC 110 g/l	0.055	mortality	85%	30%
O. laevigatus	nymphs	SC 110 g/l	0.055	mortality / fecundity	79.9% / 100%	30%
A. bilineata	adults	SC 110 g/l	0.055	mortality / reproduction	10% / 14%	30%

Earthworms

Acute toxicity:	LC50 > 1 000 mg as/kg soil LC50 > 10 mg/kg soil (nominal value for metabolites R-3, R-4, R-7, R-8, R-13)
Reproductive toxicity:	No data, not required.

Soil micro-organisms

Nitrogen mineralization:	Effect < ± 25% at 0.07 mg as/kg soil
Carbon mineralization:	Effect < ± 25% at 0.07 mg as/kg soil

APPENDIX III

ETOXAZOLE

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

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

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA-1.9	Shibuya I.	2002	Preliminary evaluation of ovicidal activity against mites for optical isomers of etoxazole Yashima Chemical industry Co., Ltd. Sumitomo Chemical Co., Ltd., report No SKE-0385 Not GLP Not published
IIA-4.2.2	Tani T., Wakabayashi S., Takimoto Y., Kato T.	1996	Residue analytical method for S-1283 in soil Sumitomo Chemical Co., Ltd., report No SKA-0045 Not GLP Not published
IIA-4.2.4	Matoba Y., Takahashi M., Ohnishi J., Mikami N.	1997	Analytical method for S-1283 in air Sumitomo Chemical Co., Ltd., report No SKA-0018 Not GLP Not published

B.6 Toxicology and metabolism

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA-5.5	Anon.	2002	The explanation about effects on incisors and bones in "24-Month Oral Chronic Toxicity and Oncogenicity Study of Etoxazole in Rats" (2nd study, Study No: IET 97-0028). Sumitomo Chemical Co., Ltd. Not GLP Not published

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

none

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
IIA-7.1.1.2.2	Assaf N.	2002	Terrestrial field soil dissipation of etoxazole on bare ground in California. Valent USA Corp., USA, laboratory project n° 20271. Sumitomo Chemical Co., Ltd. report No SKR-0091. GLP Not published
IIA-7.1.1.2.2	Schreier T.	2002	Terrestrial field dissipation of etoxazole on bare ground in Idaho. Valent USA Corp., USA, laboratory project n° 22154. Sumitomo Chemical Co., Ltd. report No SKR-0092. GLP Not published
IIA-7.1.1.2.2	Schreier T.	2002	Terrestrial field soil dissipation of etoxazole on bare ground in Mississippi, Valent USA Corp., USA, laboratory project n° 22162. Sumitomo Chemical Co., Ltd. report No SKR-0093 GLP Not published

B.9 Ecotoxicology

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

none

APPENDIX IV

List of uses supported by available data

ETOXAZOLE

Crop and/or situation	Member state or country	Product name	FG 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 as (i)	Method kind (f-h)	Growth stage & season (j)	Number min max	Interval between applications	Kg as/hl min max	Water l/ha min max	Kg as/ha min max		
Grapevine	FR	Borneo	F	Spider mites	SC	110	Foliar Spray	57	1	N.A.	0.018	300	0.055	120	
Grapevine	ES, IT, GR	Borneo	F	Spider mites	SC	110	Foliar Spray	57	1	N.A.	0.004-0.018	300-1500	0.055	120	
Cotton	ES, GR	Borneo	F	Spider mites	SC	110	Foliar Spray	Remarks	1	N.A.	0.005-0.008	500-800	0.04125	n.a.	before boll opening

°Uses are note autorised yet
N.A. : not applicable

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions