



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Ethofumesate
SANCO/6503/VI/99-final
15 May 2002

Review report for the active substance **ethofumesate**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on
26 February 2002
in view of the inclusion of ethofumesate 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 ethofumesate, made in the context of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

Commission Regulation (EEC) No 3600/92⁽¹⁾ laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, as last amended by Regulation (EC) No 1972/99⁽²⁾, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Ethofumesate 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, Pen-Tsao-Materia Medica Center GmbH on 14 July 1993, Feinchemie Schwebda GmbH on 11 June 1993, Stefes Research GmbH on 9 July 1993, Hoechst Schering AgrEvo GmbH on 27 July 1993, Kemira Agro Benelux on 5 July 1993, B.V. Luxan on 21 July 1993, Barclay Chemicals Manufacturing Exports Ltd on 27 June 1993, Helm AG on 23 July 1993 and Phytorus SA on 26 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance ethofumesate in Annex I to the Directive.

In accordance with the provisions of Article 5 of Regulation (EEC) No 3600/92, the Commission, by its Regulation (EEC) No 933/94⁽³⁾, as last amended by Regulation (EC) No 2230/95⁽⁴⁾, designated Sweden as rapporteur Member State to carry out the assessment of

¹ OJ No L 366, 15.12.1992, p.10.

² OJ No L 244, 16.09.1999, p.41.

³ OJ No L 107, 28.04.1994, p.8.

⁴ OJ No L 225, 22.09.1995, p.1.

ethofumesate 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 ethofumesate this deadline was 31 October 1995.

Hoechst Schering AgrEvo GmbH, Feinchemie Schwebda GmbH, Barclay Chemicals Manufacturing Exports Ltd and Phytorus SA submitted a dossier to the rapporteur Member State. Hoechst Schering AgrEvo GmbH and Feinchemie Schwebda GmbH were the main data submitters, with a joint dossier which did not contain substantial data gaps, taking into account the supported uses. Barclay Chemicals Manufacturing Exports Ltd and Phytorus SA did not submit complete dossiers. Pen-Tsao-Materia Medica Center GmbH is not responsible for the notification any more. Griffin (Europe) S.A., Pen Tsao's agent in the EU, represents Pen Tsao's interest in the EU review process. Griffin (Europe) is still a notifier, but they did not submit a complete dossier. Stefes Research GmbH is not a notifier any more, as they have not answered Spain (earlier RMS) before the deadline on their interest to still be a notifier. Kemira Agro Benelux have withdrawn their notification after that AgrEvo have bought Ethofumesate from them. Kemiras documentation is included in the documentation of AgrEvo. B.V. Luxan is not considered any more to be a notifier since Sweden did not receive any documents from them. Helm AG has withdrawn their notification. Information has not been submitted by third parties.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Sweden submitted on 2 October 1998 to the Commission the report of its examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of ethofumesate 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 ethofumesate from Hoechst Schering AgrEvo GmbH and Feinchemie Schwebda GmbH, on 10 March 1999.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the Commission forwarded for consultation the draft assessment report to all the Member States on 14 December 1998 as well as to Hoechst Schering AgrEvo GmbH and Feinchemie Schwebda GmbH being the main data submitters, on 15 December 1998.

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

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

The meetings for this consultation were organised on behalf of the Commission by the Biologische Bundesanstalt für Land und Forstwirtschaft (BBA) in Braunschweig, Germany, from March to October 1999.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the main data submitters on 14 March 2000 for comments and further clarification.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the dossier, the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications on the remaining issues, received after the peer review were referred to the Standing Committee on the Food Chain and Animal Health, and specialised working groups of this Committee, for final examination, with participation of experts from the 15 Member States. This final examination took place from October 2000 to February 2001, and was finalised in the meeting of the Standing Committee on 26 February 2002.

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.

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 2002/37/EC⁵ concerning the inclusion of ethofumesate in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing ethofumesate they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

This review report provides also for the evaluation required under Section A.2.(b) of the above mentioned uniform principles, as well as under several specific sections of part B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the active substance in Annex II of the directive, submitted for the purpose of inclusion of the active substance in Annex I, as well as the result of the evaluation of those data.

In accordance with the provisions of Article 7(6) of Regulation (EEC) No 3600/92, Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request. Moreover the Commission will send a copy of this review report (not including the background documents) to all operators having notified for this active substance under Article 4(1) of this Regulation.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC. It is therefore recommended that this review report would not be accepted to support any registration outside

⁵ OJ L 117, 04.05.2002, p10

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

Furthermore, these conclusions were reached within the framework of the following uses which were proposed and supported by the main data submitter:

- herbicide on sugarbeets, fodderbeets, beans, peas, red beets and tobacco

The maximum amount of active substance per season per hectare must not exceed 1.0 kg. every 3 years.

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

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI; excluding water and products of animal origin) for a 60 kg adult is 0.162 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). Additional intake from water and products of animal origin are not expected to give rise to intake problems.

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

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

4. Identity and Physical/chemical properties

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

The review has established that for the active substance notified by the main data submitters Hoechst Schering AgrEvo GmbH and Feinchemie Schwebda GmbH none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

In accordance with the provisions of Article 13(5) of Directive 91/414/EEC, Sweden is also satisfied, on the basis of the information currently available, that the substances notified by the other data submitters (Barclay Chemicals Manufacturing Exports Ltd, Phytorus SA and Griffin (Europe) S.A.) do not, in the meaning of Article 13(2) and (5) of the Directive, differ significantly in degree of purity and nature of impurities from the composition registered in the dossier submitted by the main data submitter. The manufacturing processes described by AgrEvo, Barclay Chemicals Ltd, Griffin (Europe) S.A. and Phytorus S.A. are identical as far as starting material and reaction path-way concerns.

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 by Member States in relation to the granting of authorisations of plant protection products containing ethofumesate

On the basis of the proposed and supported uses, the following particular issue has 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:

- Leaching to groundwater: Particular attention should be given to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climate conditions and risk mitigation measures should be applied where appropriate.

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 ethofumesate in Annex I under the current inclusion conditions.

8. Information on studies with claimed data protection

For information of any interested parties, Appendix III gives information about the studies for which the main data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion. This information is only given to facilitate the operation of the provisions of Article 13 of Directive 91/414/EEC in the Member States. It is based on the best information available to the Commission services at the time this review report was prepared; but it does not prejudice any rights or obligations of

Member States or operators with regard to its uses in the implementation of the provisions of Article 13 of the Directive 91/414/EEC neither does it commit the Commission.

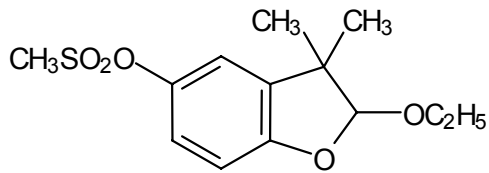
9. Updating of this review report

The technical information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Such adaptations will be examined and finalised in the Standing Committee on the Food Chain and Animal Health, in connection with any amendment of the inclusion conditions for ethofumesate in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

ETHOFUMESATE

Common name (ISO)	Ethofumesate
Chemical name (IUPAC)	(±)-2-ethoxy-2,3-dihydro-3,3-dimethylbenzofuran-5-ylmethanesulfonate
Chemical name (CA)	5-Benzofuranol, 2-ethoxy-2,3-dihydro-3,3-dimethyl-, methanesulfonate, (.+-.)-
CIPAC No	233
CAS No	26225-79-6
EEC No	247 525-3
FAO SPECIFICATION	Not available
Minimum purity	960 g/kg
Molecular formula	C ₁₃ H ₁₈ O ₅ S
Molecular mass	286.3
Structural formula	

Melting point	69.6 - 70.7 °C
Boiling point	Ethofumesate decomposes before reaching the boiling point.
Appearance	White crystalline solid
Relative density	1.3 (20 °C)
Vapour pressure	6.5×10^{-4} Pa (25 °C)
Henry's law constant	6.8×10^{-4} Pa·m ³ ·mol ⁻¹ (25 °C)
Solubility in water	pH 3 - 11: 39 - 44 mg/l (technical material; 20.0 ± 0.5 °C) pH 7.7: 50 mg/l (25.0 ± 0.5 °C) pH 7.7: 57mg/l (30.0 ± 0.1 °C)
Solubility in organic solvents	at 25 °C: acetone, dichloromethane, dimethylsulphoxide, ethyl acetate: > 600 g/l toluene and p-xylene: 300-600 g/l methanol: 120-150 g/l ethanol: 60-75 g/l
Partition co-efficient (log P_{ow})	pH 6.4 (20 °C): 2.7 pH 6.4 (25 °C): 2.7
Hydrolytic stability (DT₅₀)	pH 5 (35 °C, 36 d): 2.68% of NC 8493 were detected after 36 d. Half-life is 940 d. Ethofumesate is stable to hydrolysis. pH 5 (25 °C, 36 d): 1.57% of NC 8493 were detected after 36 d. Half-life is 2050 d. Ethofumesate is stable to hydrolysis. pH 7 (35 °C, 36 d): stable to hydrolysis pH 9 (25 °C, 36 d): stable to hydrolysis
Dissociation constant	According to the chemical structure ethofumesate is not expected to dissociate in water.
Quantum yield of direct photo-transformation in water at ε >290 nm	$9.5 - 11 \times 10^{-5}$
Flammability	Not flammable.
Explosive properties	Not explosive.
UV/VIS absorption (max.)	ε at 230 nm: 6650 ε at 282 nm: 2520 ε at 228 nm: 7090 ε at 282 nm: 2790 Abs. max at 230 nm and 282 nm, with a tailing of low absorbance between 290 and 300 nm. Absorption of sunlight is only expected at a narrow range between 290 and 300 nm.

Photostability in water (DT₅₀)	8 - 13 d: 12 h of sunlight exposure per day; extrapolated to environmental conditions results in 37 – 62 d: during summer at 40°N to 60°N in Europe 4.6 d: whole year - central Europe 2.6 d: month May
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APPENDIX II

END POINTS AND RELATED INFORMATION

ETHOFUMESATE

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	Up to 100 % absorbed. Urine and biliary excretion are the same. Value based on oral and iv. dosing.
Distribution:	Widely distributed.
Potential for accumulation:	No evidence of accumulation
Rate and extent of excretion:	Rapid and almost complete within 24 h. Mainly via urine (approximately 90 %)
Toxicologically significant compounds:	Parent compound and metabolites
Metabolism in animals:	Extensively metabolised. Hydrolysis, oxidation and ring opening.

Acute toxicity

Rat LD ₅₀ oral:	> 5 000 mg/kg bw
Rat LD ₅₀ dermal:	> 2 000 mg/kg bw
Rat LC ₅₀ inhalation:	> 0.3 mg/l (whole-body exposure, dust aerosol)
Skin irritation:	Non-irritant.
Eye irritation:	Non-irritant.
Skin sensitization (test method used and result):	Non-sensitising (M&K, Buehler).

Short term toxicity

Target / critical effect:	Increased liver and kidney weights
Lowest relevant oral NOAEL / NOEL:	250 mg/kg bw/d (90-day oral study in dog)
Lowest relevant dermal NOAEL / NOEL:	1 000 mg/kg bw/d (21-day dermal study in rabbit)
Lowest relevant inhalation NOAEL / NOEL:	Data not required.

Genotoxicity

No genotoxic potential. One test was positive but was <u>not</u> done according to OECD Guidelines. All other

tests were negative (15 tests).

Long term toxicity and carcinogenicity

Target / critical effect:	Liver
Lowest relevant NOAEL:	7 mg/kg bw/d; 2-year feeding study in rat
Carcinogenicity:	No carcinogenic potential

Reproductive toxicity

Target / critical effect - Reproduction:	Decreased pup weight at parental toxic dose levels
Lowest relevant reproductive NOAEL / NOEL:	78 mg/kg bw/d; multigeneration study in rat (Tesh-1980)
Target / critical effect - Developmental toxicity:	Foetotoxicity. Increased incidences of resorption at maternal toxic dose levels. Increase in the delayed ossification is not significant at litter toxic dose levels.
Lowest relevant developmental NOAEL / NOEL:	300 mg/kg bw/d (developmental study in rabbit)

Delayed neurotoxicity

Data not required. No indication from other studies.
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Other toxicological studies

Data not required.

Medical data

General survey of accessible literature: no adverse effects in humans exposed.
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Summary

	Value	Study	Safety factor
ADI:	0.07 mg/kg bw/d	2-y rat (Suresh-95)	100
AOEL systemic:	2.5 mg/kg bw/d	90-d dog (Brownlie-94)	100
AOEL inhalation:	Not required		
AOEL dermal:	Not required		-
ARfD (acute reference dose):	Not required		

Dermal absorption

No data. Default value of 10% is used for calculations .
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2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:

Range 6 - 13%; median 8.7%; n=5

Non-extractable residues after 100 days:

Range 16 - 34%; median 31%; n=5

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

All less than 6%

Supplemental studies

Anaerobic:

Not relevant because of very slow transformation

Soil photolysis:

DT₅₀ two studies :

14 d; =290nm, 24 h light, 1.5 kg a.s./ha
65 days; 300-800 nm, light 12h per day, 15 mg as/kg.

Remarks:

None

Rate of degradation

Laboratory studies

DT₅₀lab (20 °C, aerobic):

40 - 75% WHC:
range 47 – 211 d; mean 97 d; median 84 d; n=10

DT₉₀lab (20 °C, aerobic):

40 - 75% WHC:
range 210 – 701 d; median 331 d; n=10

DT₅₀lab (10 °C, aerobic):

No study.
Calculation of DT₅₀, 10°C carried out on eight DT₅₀ laboratory tests (20-21°C, aerobic) using Q₁₀=2.2.

Result: DT₅₀, (10°C, aerobic) (calc.) = 198 d

DT₅₀lab (20 °C, anaerobic):

Very slow transformation: 90-100% unaltered after 60 d; n=2

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

Germany: One dose range 0.8 - 6.5 kg as/ha: range 15 - 250 d; median 65 d; n=10. Not dose related

UK: One dose 1.5 kg as/ha: 36 and 56 d; mean 46 d; n=2

California, USA: 2.1 kg as/ha: 75 d. n=1
Calculated mean of all = 77 d; median = 56 d; n=13

DT_{90f} from soil dissipation studies:

Germany: One dose range 0.8 - 6.5 kg as/ha: range 3 months - >3 years; median ca. 11 months; n=11.

UK: One dose 1.5 kg as/ha: 4 and 4.6 months, mean 4.3 months; n=2

Soil accumulation studies:

No relevant data.

Calculated based on a field DT₅₀ = 119 days

a) Application of 1.0 kg as/ha and year, a plateau concentration of 114% of maximum PECsoil reached after 3 years. Plateau concentration 1.5 mg as/kg soil.

b) Application 1.0 kg as/ha each third year. There was no significant accumulation. Three years after applic. 0.1% of dose remained.

Soil residue studies:

Data not required.

Remarks:

e.g. effect of soil pH on degradation rate

None.

Adsorption/desorptionK_f / K_{oc}:

K_{oc}: range 97 - 245; mean = 147; median 132; n=11

K_d

K_d: range 0.73 – 6.2; mean = 2.7; median 2.3; n=11

pH dependence:

Not pH dependent.

Mobility

Laboratory studies:

Column leaching:

According to BBA Guideline (200 mm over 2 d):
n.d.-2.9% as; n=9
Other method (508 mm over 15 - 20 d): 4.2-67%
of applied radioactivity; n=4

Aged residue leaching:

Three different methods: n.d.-4.2% of applied
initial radioactivity; n=5

Field studies:

Lysimeter/Field leaching studies:

Two studies according to BBA guideline:

1. Three lysimeters with loamy sand soil.
Lysimeter with a surface area of 0.5 m² and a
depth of 1.0 m. One dose of 1.25 kg as/ha
applied pre-emergence to sugar beet on silty
sand in April 1992. An approximate mean
rainfall of 857 mm/year. Terminated after 2
years.
LOD = 0.1 µg/L
2. Two lysimeters with a sandy soil. Lysimeter
with a surface area of 1.0 m² and a depth of
1.2m. One dose of 1.5 kg as/ha applied to
fodder beet on sandy soil in both lysimeters
in May year 1 and additionally to one soil in
May year 2. Total rainfall (4 years) 3280 mm.
Terminated after 3 years.
LOD = 0.01 µg/L

Results: No detected active substance or
metabolite in leachate in any of the lysimeters.

Remarks:

None.

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:

pH 5.0, 7.0, 9.2: Negligible

Major metabolites:

None.

Photolytic degradation:

Artificial light: (greatly variable results)
37-62 d (summer, 40-60°N)
4.6 d (on a year basis) / 2.6 d (for month May)

Major metabolites:

None identified.

Biological degradation

Readily biodegradable:

Not readily biodegradable; n=3

Water/sediment study:

Calculations: 3 out of 5 according to first order kinetics, 2 out of 5 according to 1.5th order kineticsDT₅₀ water:Study 1: 13 days, n=1 (1st order)
Study 2: 11 and 19 days, n=2 (1st and 1.5th order)
Study 3: 7 and 50 days, n=2 (root of 1st order)DT₉₀ water:Study 1: -
Study 2: 121 and 212 days, n=2
Study 3: -DT₅₀ whole system:Study 1: 125 days, n=1, (1st order)
Study 2: 105 and 153 days, n=2 (1st and 1.5th order)
Study 3: 242 and 285 days, n=2 (root of 1st order)DT₉₀ whole system:Study 1: -
Study 2: 507 and 550 days, n=2
Study 3: -

Distribution in water / sediment systems (active substance)

Study 1: After 84 days, 14% of applied radioactivity as parent compound in water / 51% in sediment, n=1. Maximum 53% parent compound in the sediment after 63 days of incubation. No DT₅₀ calculated for the sediment.

Study 2: After 103 days, 13-18% of applied radioactivity as parent compound in water / 37-41% in sediment. Maximum 48 – 49 % of applied as parent compound in the sediment after 30 days of incubation. Thereafter DT₅₀ in the sediment 170 – 270 days.

Study 3: After 225 and 234 days, 21 and 1.5% of applied radioactivity as parent compound in water / 30 and 53% in sediment. No DT₅₀ calculated for the sediment.

Distribution in water / sediment systems (metabolites)	Maximum of 4 unknown metabolites, altogether up to 17% of applied radioactivity.
Accumulation in water and/or sediment:	Considered not relevant since active substance is applied every third year.
Rate of mineralisation	6-9%
Non-extractable residues	27%
Degradation in the saturated zone	Degradation in the saturated zone: No study. Not required.
Remarks:	None.

2.3 Fate and behaviour in air

Volatility

Vapour pressure:

6.5 x 10 ⁻⁴ Pa (25 °C)

Henry's law constant:

6.8 x 10 ⁻⁴ Pa·m ³ ·mol ⁻¹ (25 °C)

Photolytic degradation

Direct photolysis in air:

Data not required.

Photochemical oxidative degradation in air

2.1 h, calc. according to Meyland and Howard (AOP)
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DT₅₀:

4.1 h, calc. According to Atkinson

Volatilisation:

From plant surfaces:

22% lost from plant surface during 24 hours

From soil:

15% lost from soil surface during the first 24 hours
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Remarks:

No remarks.

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	LD50 > 5000 mg/kg bw (rat)
Acute toxicity to birds:	LD50 > 2000 mg/kg bw (mallard duck, quail)
Dietary toxicity to birds:	LC50 > 5200 mg/kg feed (mallard duck, quail) NOEC = 2600 mg/kg feed
Reproductive toxicity to birds:	NOEL >406 mg/kg bw per day (>3000 mg/kg feed)
Reproductive toxicity to mammals:	NOAEL 300 mg as/kg bw, rabbit, teratogenicity, foetal

Aquatic Organisms

Acute toxicity fish:	LC50 = 11 mg as/l (96 h; <i>Cyprinus carpio</i>) LC50 ≈ 13 mg as/l (Betanal Progress; 96 h; <i>Cyprinus carpio</i>) LC50 ≈ 26 mg as/l, based on mean measured concentration (Tramat 500; 96 h; <i>Cyprinus carpio</i>)
Long term toxicity fish:	NOEC = 0.8 mg as/l (21 d; <i>Oncorhynchus mykiss</i>)
Bioaccumulation fish:	144 (based on total radioactivity)
Acute toxicity invertebrate:	EC50 = 14 mg as/l (48 h; <i>Daphnia magna</i>) EC50 ≈ 30 mg as/l (Tramat 500; 48 h; <i>Daphnia magna</i>)
Chronic toxicity invertebrate:	NOEC = 0.32 mg as/l (21 d; <i>Daphnia magna</i>)
Acute toxicity algae:	EC50 = 3.9 mg as/l (96 h; <i>Scenedesmus subspicatus</i>) EC50 = 6.7 mg as/l (Ethofumesate 50SC; 96 h; <i>Scenedesmus subspicatus</i>)
Chronic toxicity sediment dwelling organism:	NOEC > 5.0 mg as/l (28 d; <i>Chironomus riparius</i>)
Acute toxicity aquatic plants:	EC50 > 50 mg as/l (14 d; <i>Lemna minor</i>) NOEC = 4.3 mg as/l (14 d; <i>Lemna minor</i>)
Remarks	* Betanal Progress is a formulation containing ethofumesate plus two other active substances

Honeybees

Acute oral toxicity:

>50 µg/bee

Acute contact toxicity:

>50 µg/bee

Other arthropod species

	% Effect
<i>Aleochoa bilineata</i>	No effects (adult; mortality, egg production and viability; Tramat 500; 1.25 kg as/ha)
<i>Poecilus cupreus</i>	No effects (adult; mortality; Tramat 500; 2.0 kg as/ha)
<i>Chrysoperla carnea</i>	No adverse effects (larvae; mortality, egg production and viability; Tramat 500; 2 % solution, ca 2.0 kg as/ha)
<i>Chrysoperla carnea</i>	Slight reduction (larvae; mortality, egg production and viability; * Betanal Progress; 3 % solution, 0.8 kg etho- fumesate/ha)
<i>Coccinella septempunctata</i>	No effects (larvae; mortality; *Betanal Progress; 3% solution, 0.8 kg ethofumesate/ha)
<i>Syrphus corollae</i>	Slightly reduced performance of treated larvae (larvae; mortality, pupation, hatching, viable offspring; *Betanal Progress; 2 % solution)
<i>Poecilus cupreus</i>	No effects (adult; mortality, number of pupae fed; *Betanal Progress; 1.5 %solution, 0.8 kg ethofumesate/ha)
<i>Aleochoa bilineata</i>	No effects (adult; parasitic efficiency; *Betanal Progress; 1% solution, 0.4 kg ethofumesate/ha)
<i>Aleochoa bilineata</i>	No effects (adult; parasitic efficiency; Ethosat; 1 % solution, 1 kg as/ha)
Remarks	* Betanal Progress is a formulation containing ethofumesate plus two other active substances

Earthworms

Acute toxicity:

LC50 = 134 mg/kg soil (*Eisenia andrei*; 14 d)

Reproductive toxicity:

NOEL > 25 mg/kg soil (*Eisenia foetida*; 56 d)

Soil micro-organisms

Nitrogen mineralization:

Max 28% inhibition 14 days after treatment with Betanal Progress at normal field rate (6.5 mg/kg) in a 60 days study. No treatment related effects in majority of studies at 4 – 20 kg as/ha.

Carbon mineralization:

Slight effect at maximum recommended field rate (2.0 mg kg soil) in one study. No treatment related effects in majority of studies.

APPENDIX IIIA**ETHOFUMESATE**

List of studies for which the main submitter has claimed data protection and which during the re-evaluation process were considered as essential for the evaluation with a view to Annex I 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(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ² on previous use in granting national authorizations
IIA 2.5	Audus, B.L.	1994	Ethofumesate: additional ultra-violet/visible spectral data for ethofumesate and its process impurities Company File No.: A85625/C128-2 Generated by: AgrEvo No GLP, unpublished	
IIA 2.5	Audus, B.L.	1994	Ethofumesate: additional ultra-violet/visible spectral data for ethofumesate and its process impurities Company File No.:A85635/C135-2 Generated by: AgrEvo No GLP, unpublished	
IIA 2.6	Vries de R	1994	Determination of the water solubility of ethofumesate at pH9 and 11 Company File No.: A87528/C503-1 Generated by: Notox GLP, unpublished	
IIA 4.2.5	Mckenzie, J.	1994	Validation of a plasma assay, ethofumesate in dog plasma Company File No.: A87559/C507-1 Generated by: Toxicol GLP, unpublished	

¹ List based on a detailed analysis from Sweden. All studies are owned by the Members of the task force (AgrEvo GmbH and Feinchemie Schwebda GmbH)

² Reports received from Member States at the date of finalisation of the present review report (not exhaustive).

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ² on previous use in granting national authorizations
IIA 4.2.4	Wrede-Rucker, A	1993	Analytical method for the determination of ethofumesate in air Company File No.:A83393/W139-1 Generated by: Schering GLP, unpublished	
IIA 2.1.14	Walter, D	1999	Surface tension of ethofumesate tech. Company File No: (study no 99164/01-PCST) Generated by : GAB Biotechnologie GmbH, germany GLP, unpublished	
IIA 2.9	Keirs, D C	2000	[¹⁴ C]-Ethofumesate: Aqueous photolysis Company File No.: C009667 Generated by Inveresk Research GLP, unpublished	
IIA 4.3.2	Schneider, E	1999	Validation of an analytical method for the determination of ethofumesate and ethofumesate-2-keto in surface water. Company File No: C006011 Generated by: Dr. Krebs Analytik GmbH GLP, unpublished	
IIA 4.2	Godfrey, T L	1996	Ethofumesate and metabolite analytical grades. Codes AE B049913 and AE C509607 (NC 8438 and NC 9607). Analytical method for the determination of active substance and major metabolite in sugar beet (roots and tops) by GC/MSD. Company File No: A89687 Generated by: AgrEvo UK Limited GLP, unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ² on previous use in granting national authorizations
IIA 4.1 IIIA 5.1	Johnson, M K; Lyon, C F	1997	The validation of AM 1100/29/01 for the determination of ethofumesate in the technical grade active ingredient and suspension and emulsifiable concentrate formulations by high performance liquid chromatography. Company File No: C004902 Generated by: AgrEvo UK Limited No GLP, unpublished	
IIA 4.1 IIIA 5.1	Johnson, M K	1998	The determination of ethofumesate in the technical grade active ingredient and suspension and emulsifiable concentrate formulations by high performance liquid chromatography. Company File No: C004901 Generated by: AgrEvo UK Limited No GLP, unpublished	
IIA 4.2.2	Peatman, M H	1999	Review of analytical methodology for residues in edible animal products (dairy, tissues, fat and offal) Company File No: C003328 Generated by : AgrEvo UK Limited No GLP, unpublished	
IIA 2.5	Audus, B.L.	1994	Ethofumesate: Additional ultra-violet/visible spectral data for ethofumesate and process impurities. Company file No: C128/1/A85624 and C163/2/ A85665 Generated by: AgrEvo UK Ltd No GLP, unpublished	
IIA 2.9.3	Knoch, E.	1994	Determination of the direct phototransformation of ¹⁴ C-ethofumesate in a buffered medium at pH 4. Company File No: W509/A87609 Generated by: RCC Roßdorf, Germany GLP, unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ² on previous use in granting national authorizations
IIA 4.1.2 IIIA 5.1.2	Audus, B.L.	1993	An assesment of the accuracy and precision of the analytical method AM 1100/221, for the determination of 2,6-diethoxy-3,6,7,8-tetrahydro-3,3,7-trimethyl-2H-furo[2,3-G](1)benzopyran in technical ethofumesate. Company File No: C162/A85663 Generated by : Schering Agrochemicals Ltd GLP, unpublished	
IIA 4.2.4 IIa 5.2.4	Reichert, N.	1994	Development of a method for the determination of ethofumesate and oxo-metabolite of ethofumesate in air. Company File No: C506/A87531 Generated by RCC GmbH, Roßdorf, Germany GLP, unpublished	
IIA 4.2	Wrede, A	2000	Wrede, A Validation of the Method AL 081/96 – 0 in peas and sugar beet roots by GC-MSD Company File No.: C009934 Report No.: CR00/021 Generated by: Aventis CropScience GmbH GLP, unpublished	
IIA 4.2.1	Reichert, N.	2000	Independent laboratory validation of the method of analysis for the determination of ethofumesate and metabolite NC 9607 (AE 509607) in sugarbeet and pea. Company File No.: C009953 Study No.: IF-100/30496-00 Generated by: Institut Fresenius GLP, unpublished	

B.6 Toxicology and metabolism

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 5.4	Gant, R.	1994	Bacterial mutation assay. Huntingdon Research Centre Ltd. Report No: AGV 20/941511 Company File No: T191/A83222 GLP Unpublished	
IIA 5.1	Leuschner, J.	1993	Metabolism study of ¹⁴ C-labelled ethofumesate after single and intravenous administration to Sprague-Dawley rats. LPT Laboratory of pharmacology and toxicology. Report No: 8210/1/93 GLP Unpublished	
IIA 5.5	Suresh, T.P.	1995	Combined chronic toxicity and carcinogenicity study in Wistar rats. Test compound: ethofumesate technical (FSG 03189H/27, Feb 1990). Rallis Agrochemical Research Station. Report No: TOXI-903.C.C-R Company file No.: ES-ETFS-C.C-R GLP unpublished	
IIA 5.3	Brownlie, S.-A., Davies, R.E., Wright, J.A.	1994	Ethofumesate: oral (capsule/gavage) maximum tolerated dose (mtd) and 28 day repeat dose range finding study in the dog. Toxicol Laboratories Ltd Report No. KIR/7/93 T509/A87567 GLP unpublished	
IIA 5.3	Brownlie, S.-A., Davies, R.E., Canning, M., McKenzie, J.	1994	Ethofumesate: 13 week oral (gavage) toxicity study in the dog. Toxicol Laboratories Ltd Report No. KIR/8/C T512/A87568 GLP unpublished	

B.7 Residue data

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 6.3	Old, J; Doran, A; Foster, A C; Smith, A	1999	Phenmedipham/ethofumesate residues in peas following two applications to peas in Northern/Central Europe. Company File No: C004834 Generated by : Inveresk Research, Scotland GLP, unpublished	
IIA 6.1	Miller, C A	1999	Summary of the metabolism of ethofumesate in plants. Company File No: C003349 Generated by : AgrEvo UK Ltd No GLP, unpublished	
IIA 6.2	Reynolds, C M	1999	Ethofumesate ruminant : Metabolism, distribution and nature of the residues in milk and edible tissues. Code AE B 049913 Company File No: C003362 Generated by : AgrEvo UK Ltd GLP, unpublished	
IIA 6.2	Moss, T; Reynolds, C M	1999	Poultry metabolism, distribution and nature of the residues in eggs and edible tissues. Code AE B 049913. Company File No: C002998 Generated by : AgrEvo UK Ltd GLP, unpublished	
IIA 6.3	Straszewski, A.	1993	Ethofumesate: SC (CQ1273/01): Residues of ethofumesate and its major metabolite in sugarbeets, France 1992. Company File No: A83115/R176-1 Generated by: Schering GLP, unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 6.3	Castro, L.E.	1994	Ethofumesate emulsifiable concentrate 200 g/L CR13678: At-harvest residues of ethofumesate and metabolites in rotational crops and soil following applications of Nortron EC to sugar beets, USA, 1990. Company File No: A83117/R178-1 Generated by: Nor-AM GLP, unpublished	
IIA 6.3	Wrede, A.	1995 a	Residues in sugarbeet after applications of Betanal Progress OF in France 1993. Company File No: A62042/R180-1 Generated by: Hoechst Schering AgrEvo GLP, unpublished	
IIA 6.3	Wrede, A.	1995 b	Residues in sugarbeet after applications of Betanal Progress in France 1993. Company File No: A83118/R182-1 Generated by : AgrEvo GLP, unpublished	
IIA 6.3	Carlton, R. & Cordell, P.	1993	The uptake and metabolism of ethofumesate and its soil metabolites in a confined rotational crop study. Company File No: A83396/W153-1 Generated by: Schering GLP, unpublished	

B.8 Environmental fate and behaviour

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 7.1.1.1.2	Burri, R.	1995	Photodegradation study of 14C-ethofumesate on soil. Company file No: W527/A87626 Generated by: RCC Umweltchemie AG, Itingen, Switzerland GLP unpublished	
IIA 7.1.3.1	Burgener, A.	1995	Kemifam Pro FL soil leaching in three soils. Company file No: W548/A87641 Generated by: RCC Umweltchemie AG, Itingen, Switzerland GLP unpublished	
IIA 7.1.3.3, IIIA 9.1.2.2.	Allen, R., MacKenzie, E.A., Hibbert, L., Lander, G.	1995	Ethofumesate, SC, 50% w/v, Code: CR 19035/1 and CR 18654/1. Leaching in soil lysimeters maintained under outdoor conditions. Company file No: NC 8438/W171/A89221 Generated by AgroEvo UK Limited, Environmental Sciences, Saffron Walden, England. GLP unpublished	
IIA 7.1.3.3, IIIA 9.1.2.2	Burgener, A.	1994	[14C]-Ethofumesate: Mobility and degradation in soil in outdoor lysimeters Company file No: W503/A87603 Generated by: RCC Umweltchemie AG, Itingen, Switzerland GLP unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 7.1.3.3, IIIA 9.1.2.2	Burgener, A.	1997	[14C]-Ethofumesate: Mobility and degradation in soil in outdoor lysimeters Company file No: A 91247 ETHO/W214-1 Generated by: RCC Umweltchemie AG, Itingen, Switzerland GLP unpublished	
IIA 7.1.3.3, IIIA 9.1.2.2	Burgener, A.	1997	Report amendment to [14C]-Ethofumesate: Mobility and degradation in soil in outdoor lysimeters Company file No: A 91248 ETHO/W214-2 Generated by: RCC Umweltchemie AG, Itingen, Switzerland GLP unpublished	
IIA 7.1.3.3, IIIA 9.1.2.2	Jene, B.	1999 a	Simulation of the Leaching behaviour of Ethofumesate in a Loamy Macroporous Soil of a Typical Sugar Beet Growing Area in the Paris Basin Using the MACRO Model. Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Federal Republic of Germany Code: AE B049913 Company file No: C004998 Study Identity: OE 99/094 unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 7.1.3.3, IIIA 9.1.2.2	Jene, B.	1999 b	Simulation of the Leaching behaviour of Ethofumesate with MACRO in a Loamy Macroporous Soil of a Typical Sugar Beet Growing Area in the Paris Basin Using Worst Case Half lives. Code: AE B049913 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Federal Republic of Germany. Company file No: C006227 Study Identity: OE99/137 - unpublished	
IIA 7.2.1.2	Knoch, E.	1994	Determination of the direct phototransformation of ¹⁴ C-ethofumesate in a buffered medium at pH 4. Company file No: W509/A87609 Generated by: RCC, Roßdorf, Germany GLP unpublished	
IIA 7.2.1.3.2, IIIA 9.2.2	Kellner, G.	1995	DEGRADATION AND METABOLISM OF ¹⁴ C-ETHOFUMESATE IN AQUATIC SYSTEMS Company file No: W526/A87625 Generated by: RCC, Roßdorf, Germany No GLP unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 7.2.1.3.2	Wahle, U. (and MacVicar, F. for Amendment)	1995	DEGRADATION OF ETHOFUMESATE IN AEROBIC WATER/ ANAEROBIC SEDIMENT SYSTEM Company file No: W173 (and W173 Amendment)/A83402 Generated by: Fraunhofer-Institut für Umweltchemie und Okotoxikologie; Schmollenberg; Germany GLP unpublished	
IIA 7.2.2	Vries, de R.	1994	Determination of the rate of volatilisation of ethofumesate from soil and plant surface (dwarf runner beans). Company file No: W525/A87624 Generated by: NOTOX B.V., 's-Hertogenbosch, The Netherlands GLP unpublished	

B.9 Ecotoxicology

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
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Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 8.2	Mattock, S. D.	1998	Ethofumesate Lemna minor semi static phytotoxicity test ethofumesate substance technical 97% w/w code: AE B049913 00 ID97 0002 Company file No: A 91865 ETHO/W218-1 Generated by: Dr U Noack Laboratorium, Germany GLP unpublished	
IIA 8.2	Mattock, S. D.	1998	Ethofumesate substance technical 97% w/w code: AE B049913 00 ID97 0002 chronic toxicity to the sediment dwelling organism Chironomus riparius (BBA method) Company file No: A 91783 ETHO/W215-1 Generated by: Covance laboratories Ltd, Harrogate GLP unpublished	
IIA 8.2.6	Scheerbaum, D.	1998	Ethofumesate alga growth inhibition test (Nitzschia palea), 96 (h) ethofumesate substance technical 98.8% w/w AE B049913 00 ID97 0002 Company file No: A 91866 ETHO/W219-1 Generated by: Dr U Noack Laboratorium, Germany GLP unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 8.3	Sowig, P., Gosch, H.	1999	Effects on growth and reproduction of earthworms (<i>Eisenina foetida</i>). Ethofumesate; water miscible suspension concentrate; 500 g/l. Report no CE99/016 Company File No: C003978 Hoecht Schering AgrEvo GmbH Entwicklung Umweltforschung D-65926 Frankfurt am main GLP Unpublished	
IIIA 10.3	Thuerwaechter, F.	1999	Effect of three Betanal Formulations on non-target terrestrial plants. Company file No: C005554 Generated by: Hoechst Schering AgrEvo GmbH. not GLP unpublished	
IIA 8.1.3	Frey, L.T., Beavers, J.B., Jaber, M.	2000	Ethofumesate : Mallard duck dietary reproduction study, AE B049913. Company File No.: C008193 Generated by: Wildlife International Ltd, USA Report no.: TOX/00/136-176 GLP, unpublished	

APPENDIX IIIB**ETHOFUMESATE**

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 2.1.14	Walter, D	1999	Surface tension of ethofumesate tech. Company File No: (study no 99164/01- PCST) Generated by GAB Biotechnologie GmbH, germany GLP, unpublished
IIA 2.9	Keirs, D C	2000	[¹⁴ C]-Ethofumesate: Aqueous Photolysis Inveresk Research Report No. 18951 Study No. 396835 GLP, unpublished
IIA 4.1 IIIA 5.1	Johnson, M K	1998	The determination of ethofumesate in the technical grade active ingredient and suspension and emulsifiable concentrate formulations by high performance liquid chromatography. Company File No: C004901 Generated by: AgrEvo UK Limited No GLP, unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 4.1 IIIA 5.1	Johnson, M K; Lyon, C F	1997	The validation of AM 1100/29/01 for the determination of ethofumesate in the technical grade active ingredient and suspension and emulsifiable concentrate formulations by high performance liquid chromatography. Company File No: C004902 Generated by: AgrEvo UK Limited No GLP, unpublished
IIA 4.2	Godfrey, T L	1996	Ethofumesate and metabolite analytical grades. Codes AE B049913 and AE C509607 (NC 8438 and NC 9607). Analytical method for the determination of active substance and major metabolite in sugar beet (roots and tops) by GC/MSD. Company File No: A89687 Generated by: AgrEvo UK Limited GLP, unpublished
IIA 4.2	Wrede, A.	2000	Validation of the Method AL 081/96 – 0 in peas and sugar beet roots by GC-MSD C009934 Aventis CropScience GmbH GLP, unpublished
IIA 4.2.1	Reichert, N.	2000	Independent laboratory validation of the method of analysis for the determination of ethofumesate and metabolite NC 9607 (AE 509607) in sugar beet and pea C009953 Institut Fresenius GLP, unpublished
IIA 4.3.2	Schneider, E	1999	Validation of an analytical method for the determination of ethofumesate and ethofumesate-2-keto in surface water. Company File No: C006011 AgrEvo Generated by: Dr. Krebs Analytik GmbH GLP, unpublished

B.6 Toxicology and metabolism

No new information

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
IIA 6.2	Moss, T; Reynolds, C M	1999	Poultry metabolism, distribution and nature of the residues in eggs and edible tissues. Code AE B 049913. Company File No: C002998 Generated by : AgrEvo UK Ltd GLP, unpublished
IIA 6.6	Old, J; Doran, A; Foster, A C; Smith, A	1999	Phenmedipham/ethofumesate residues in peas following two applications to peas in Northern/Central Europe. Company File No: C004834 AgrEvo Generated by : Inveresk Research, Scotland GLP, unpublished
IIA 6.3	Peatman, M H	1999	MRL proposal for peas and beans following a review of available residue data from the EU. Company File No: C003327 Generated by: AgrEvo UK Ltd No GLP, unpublished
IIA 6.2	Peatman, M H; Reynolds, C M	1999	Maximum estimated dietary concentrations for poultry and cattle and rebuttal for further animal feeding studies. Company File No: C003329 Generated by : AgrEvo UK Ltd No GLP, unpublished
IIA 6.2	Reynolds, C M	1999	Ethofumesate ruminant : Metabolism, distribution and nature of the residues in milk and edible tissues. Code AE B 049913 Company File No: C003362 Generated by : AgrEvo UK Ltd GLP, unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
II A 6.1	Adcock J W, Warner P A, Challis I R	1976	The metabolism of ¹⁴ C-ethofumesate in the onion. Report METAB/76/22 Study METAB/76/22 AgrEvo M30 (A82959)
II A 6.1	Caley C. Y, Chapleo S, Haswell A	1994	The metabolism of ¹⁴ C-ethofumesate in sugar beet. Report No 10056 Document No M501 (A87553) AgrEvo
II A 6.1	Chapleo S, Hall B E	1992	The metabolism of ¹⁴ C-ethofumesate in sugar beet – a glasshouse study Report No IRI 381174 Document No M54 (A82970) AgrEvo
II A 6.1	Chapleo S, Hall B E	1992	The metabolism of ¹⁴ C-ethofumesate in annual ryegrass - a glasshouse study Report No IRI 381169 Document No M55 (A82971) AgrEvo
IIA, 6.1	Lines D., Adcock J.W.	1979	The metabolism of ethofumesate by sugar beet under field conditions. AgrEvo Registration document NC 8438/M43.
II A 6.1	Miller C A	1999	Summary of the metabolism of ethofumesate in plants. Report No: ENVIR/99/028 Study No: ENVIR/99/028 C003349 AgrEvo
IIA, 6.9	Carlton R., Cordell P.	1993	The uptake and metabolism of ethofumesate and its soil metabolites in a confined rotational crop study. NC 8438/W153 (A83396) AgrEvo Schering Agrochemicals Report No: ENVIR/93/009 (AgrEvo)

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
II A 6.1	Warner P. A Adcock J W	1977	The metabolism of 14C-ethofumesate in tobacco. Report No METAB/77/38 Study No METAB/77/38 M35 (A82963) AgrEvo
IIA 6.1	Adcock J.W., Lines D.	1978	The metabolism of ethofumesate by sugar beet under glasshouse conditions. Document No M41, report No METAB/78/57 AgrEvo

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	Terry, A.	1999	Calculated degradation rate of ethofumesate in soil at 10°C. Sent by e:mail: 01.12.1999 File name: rate_10C.doc AgrEvo Unpublished
IIA.7.1.3.3, IIIA.9.1.2.2	Burgener, A.	1997	[14C]-Ethofumesate: Mobility and degradation in soil in outdoor lysimeters Company file No: A 91247 ETHO/W214-1 Generated by: RCC Umweltchemie AG, Itingen, Switzerland AgrEvo/ Kemira GLP, Unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA.7.1.3.3, IIIA.9.1.2.2	Burgener, A.	1997	Report amendment to [14C]-Ethofumesate: Mobility and degradation in soil in outdoor lysimeters Company file No: A 91248 ETHO/W214-2 Generated by: RCC Umweltchemie AG, Itingen, Switzerland AgrEvo/ Kemira GLP, unpublished
	Jene, B.	1999a	Simulation of the Leaching Behaviour of Ethofumesate in a Loamy Macroporous Soil of a Typical Sugar Beet Growing Area in the Paris Basin Using the MACRO Model. Code: AE B049913; Study ID: OE99/094 Generated by: Hoechst Schering AgrEvo GmbH Environmental Sciences, D-65926 Frankfurt am Main, FRG. (August 1999) Unpublished
	Jene, B.	1999b	Simulation of the Leaching Behaviour of Ethofumesate with MACRO in a Loamy Macroporous Soil of a Typical Sugar Beet Growing Area in the Paris Basin Using Worst Case Half Lives. Code: AE B049913; Study ID: OE99/137 Generated by: Hoechst Schering AgrEvo GmbH Environmental Sciences, D-65926 Frankfurt am Main, FRG. (December 1999) Unpublished
	Legrand, M. F., Costentin, E. and Bruchet, A.	1991	Occurrence of 38 Pesticides in Various French Surface and Ground Waters. Published in : Environmental Technology, Vol.12. pp. 985-996. Publication Division Selper Ltd. 1991.
		1999	Monitoring data from Anglia, surface and groundwater. List of data.

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
IIA 8.1.3	Frey, L T, Beavers, J B, Jarber, M	2000	Ethofumesate: Mallard duck dietary reproduction study, AE B049913 Company file No.: IF-100/30496-00 Generated by: Institut fresenius Task Force Ethofumesate GLP, unpublished
IIA, 8.2	Bellmann, W	1992	Final Report on the Alga Growth Inhibition Test according to OECD Guideline 201. Test article Ethofumesate Project No 40730.315-201 TUV Sudwest, Sudwestdeutschland Feinchemie GLP, unpublished
IIA, 8.2	Scheerbaum, D	1998	Ethofumesate Substance Technical 98.8% w/w: Alga, Growth Inhibition test (Nitschia palea 96 h) ENVIR/98/23 AgrEvo Dr U NOACK Laboratorium, Sarstedt, Germany GLP, unpublished
IIA, 8.2	Scheerbaum, D	1998	Ethofumesate Substance Technical 98.8% w/w: Lemna minor: Semi Static Phytotoxicity Test ENVIR/98/22 Dr U NOACK Laboratorium, Sarstedt, Germany AgrEvo GLP, unpublished
IIA, 8.2	Mattock, S.D.	1998	Ethofumesate Substance Technical 98.8% w/w: Chronic toxicity to the sediment dwelling organism Chironomus riparius (BBA method) ENVIR/98/06 Covance Laboratories Ltd, North Yorkshire, UK AgrEvo GLP, unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA, 8.2	Bellmann, W	1992	21 d Daphnia-Reproduction test according to OECD Guideline 202, Part II. Test article Ethofumesate Project No 40730.315-202-II TUV Sudwest, Sudwestdeutschland Feinchemie GLP, unpublished
IIA, 8.3.3	Sowig, P. and Gosch, H.	1999	Effects on growth and reproduction of earthworms (<i>Eisenia fetida</i>). Ethofumesate; water miscible suspension concentrate; 500 g/l. Report No CE99/016 Hoechst Schering AgrEvo GmbH Entwicklung Umweltforschung D-65926 Frankfurt am Main GLP, unpublished
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