



EUROPEAN COMMISSION

DIRECTORATE-GENERAL HEALTH & CONSUMER PROTECTION

Directorate E - Public, animal and plant health

Unit E1 Legislation relating to crop products and animal nutrition

lambda-cyhalothrin

7572/VI/97-final

25 January 2001

Review report for the active substance *lambda*-cyhalothrin

Finalised in the Standing Committee on Plant Health at its meeting on 19 October 2000
in view of the inclusion of *lambda*-cyhalothrin 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 *lambda*-cyhalothrin, 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 1972/99², has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. *lambda*-Cyhalothrin 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, Zeneca Agrochemicals on 27 July 1993 and Stefes Pflanzenschutz GmbH on 9 and 20 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance *lambda*-cyhalothrin 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 *lambda*-cyhalothrin 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

¹ OJ No L 366, 15.12.1992, p.10.

² OJ No L 244, 16.9.1999, p. 41.

³ OJ No L 107, 28.04.1994, p.8.

⁴ OJ No L 225, 22.09.1995, p.1.

Regulation (EEC) No 3600/92, as well as for other parties with regard to further technical and scientific information; for *lambda*-cyhalothrin this deadline was 30 April 1995.

Only Zeneca Agrochemicals submitted a dossier to the rapporteur Member State which was considered as complete. Stefes Pflanzenschutz GmbH did not submit a dossier.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Sweden submitted on 12 June 1996 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 *lambda*-cyhalothrin 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 *lambda*-cyhalothrin from Zeneca Agrochemicals, on 31 July 1996.

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 as well as to Zeneca Agrochemicals 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 draft assessment report and the comments received thereon (peer review), in particular on each of the following disciplines:

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

The meetings for this consultation were organised on behalf of the Commission by the Pesticide Safety Directorate (PSD) in York, United Kingdom, 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 13 January 1997 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 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 February 1998 to August 2000, and was finalised in the meeting of the Standing Committee on 19 October 2000.

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.

These documents were also submitted to the Scientific Committee for Plants for separate consultation. The report of this Committee was formally adopted on 29 February 2000⁵).

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 2000/80/EC concerning the placing of plant protection products on the market, so as to consolidate that Annex and include a further active substance (*lambda*-cyhalothrin), and to assist the Member States in decisions on individual plant protection products containing *lambda*-cyhalothrin they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

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

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

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC. It is therefore recommended that this review report would not be accepted to support any registration outside the context of Directive 91/414/EEC, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.

3. Overall conclusion in the context of Directive 91/414/EEC

The overall conclusion from the evaluation is that it may be expected that plant protection products containing *lambda*-cyhalothrin 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 *lambda*-cyhalothrin containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of a range of uses, which were proposed and supported by the main data submitter, as outlined in Background document C of this report.

⁵ Opinion of the scientific Committee on Plants regarding the inclusion of *lambda*-cyhalothrin in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market. SCP/LAMBDA/002-Final.

Extension of the use pattern beyond those reviewed 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 30 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). Provisional estimates of acute dietary exposure of adults and toddlers revealed that the Acute Reference Dose (ARfD) might be exceeded for few, individual commodities⁶. These possible exceedances should be addressed in the framework of Council Directive 90/642/EEC on the setting of maximum residues of pesticides in fruit and vegetables.

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 *lambda*-cyhalothrin are given in Appendix I.

The active substance shall comply with the FAO specification and there seem not to be reasons for deviating from that specification; the FAO specification is given in Appendix I of this report.

The review has established that for the active substance notified by the main data submitter Zeneca Agrochemicals, 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 Adults: Spinach; Toddlers: Apples, pears, grapes, spinach. Worst case estimates on the basis of provisional residue data.

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 *lambda*-cyhalothrin

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:

- Member States in granting authorisations must pay particular attention to the operator safety and must ensure that the conditions of authorisation include appropriate protective measures.
- Member states should observe the acute dietary exposure situation of consumers in view of future revisions of Maximum Residue Levels.
- For the protection of aquatic organisms, risk mitigation measures should be applied where appropriate.
- For the protection of bees Member States should prescribe appropriate risk mitigation measures (e.g. buffer zones) if products containing *lambda*-cyhalothrin are applied at high doses.
- Depending on crop and application rate, Member States should prescribe appropriate risk mitigation measures to avoid unacceptable effects on non-target arthropods when authorisations are granted for plant protection products containing this active substance.

7. List of studies to be generated

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

Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions. This may particularly be the case for

- residue data supporting the current critical GAP, and
- further laboratory and/or field studies on bees and non-target arthropods.

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.

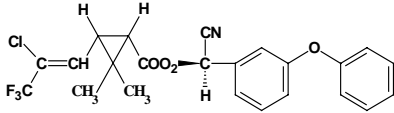
9. Updating of this review report

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 Plant Health, in connection with any amendment of the inclusion conditions for *lambda*-cyhalothrin in Annex I of the Directive.

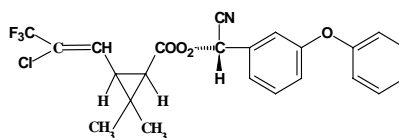
APPENDIX I

Identity, physical and chemical properties

lambda-CYHALOTHRIN

Common name (ISO)	<i>lambda</i> -Cyhalothrin
Chemical name (IUPAC)	A 1:1 mixture of: (<i>S</i>)- α -cyano-3-phenoxybenzyl (<i>Z</i>)-(1 <i>R</i> ,3 <i>R</i>)-3-(2-chloro-3,3,3-trifluoropropenyl)-2,2-dimethylcyclopropane-carboxylate, and (<i>R</i>)- α -cyano-3-phenoxybenzyl (<i>Z</i>)-(1 <i>S</i> ,3 <i>S</i>)-3-(2-chloro-3,3,3-trifluoropropenyl)-2,2-dimethylcyclopropane-carboxylate
Chemical name (CA)	[1- α (<i>S</i> [*]), 3- α (<i>Z</i>)]-(\pm)-cyano(3-phenoxyphenyl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate
CIPAC No	463
CAS No	91465-08-6
EEC No	Not allocated
FAO SPECIFICATION	The technical material shall consist of lambda-cyhalothrin together with related manufacturing impurities and shall be a viscous brown/green semi-solid mass, which is liquid at 50°C and contains not more than a trace of insoluble material, and shall be free from extraneous matter and added modifying agents. (Draft FAO Specification, May 2000.)
Minimum purity	810 g/kg
Molecular formula	C ₂₃ H ₁₉ ClF ₃ NO ₃
Molecular mass	449.9
Structural formula	<p>(<i>R</i>) (<i>Z</i>) - (1<i>S</i>) - cis - isomer:</p> 

(S) (Z) - (1R) - cis - isomer



Melting point	49.2 °C (322.4 K)
Boiling point	No measurable boiling point (decomposes)
Appearance	Beige solid without any characteristic odour (technical grade)
Relative density	1.33 g/cm ³ (1330 kg/m ³) at 25 °C
Vapour pressure	2 · 10 ⁻⁷ Pa at 20 °C (extrapolated)
Henry's law constant	0.02 Pa·m ³ ·mol ⁻¹ at 20 °C
Solubility in water	At 20 °C: pH 5: 4 · 10 ⁻³ mg/l pH 6.5: 5 · 10 ⁻³ mg/l pH 9.2: 4 · 10 ⁻³ mg/l
Solubility in organic solvents	At 21 °C: hexane, toluene, dichloromethane, methanol, acetone and ethyl acetate: > 500 g/l
Partition co-efficient (log P_{OW})	log P _{OW} = 7.0
Hydrolytic stability (DT₅₀)	There is no significant hydrolysis at pH 5.2 and 6.9. After 7 days at pH 9.0, 43 – 45 % of PP321 remains intact, thus half-life is approximately 7 days.
Dissociation constant	Not applicable
Quantum yield of direct photo-transformation in water:acetonitrile	0.092 (at wavelengths 270-290 nm)
Flammability	Flammability, in terms of flash point: 83 ± 2°C (substance heated before test)
Explosive properties	Not explosive (expert judgement based on structure)
UV/VIS absorption (max.)	Two absorption maxima, at 210 nm and 275-280 nm, with an absorption tail up to 300 nm.
Photostability (DT₅₀)	Indicated DT ₅₀ in water 13 days (latitudes 40 and 50°N). Average quantum yield at 270-290 nm 0.092. Calculated DT ₅₀ in European waters 5 days (summer) to 75 days (winter). Calculated photochemical oxidative DT ₅₀ in air 4.1 h.

APPENDIX II

END POINTS AND RELATED INFORMATION

lambda-CYHALOTHRIN

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	Oral, < 2 d man, 50 %
Distribution:	Wide, with concentration in adipose tissue
Potential for accumulation:	Half-life: 23 d
Rate and extent of excretion:	2 d, 90 %
Toxicologically significant compounds:	Parent
Metabolism in animals:	Mainly by cleavage of ester bond and further transformation to conjugated metabolites

Acute toxicity

Rat LD ₅₀ oral:	LD ₅₀ = 56 (f) - 79 (m) mg/kg bw	R25
Rat LD ₅₀ dermal:	LD ₅₀ = 632 (m) – 696 (f) mg/kg bw	R21
Rat LC ₅₀ inhalation:	LC ₅₀ = 0.06 mg/l	R26
Skin irritation:	Slight irritation. Non-irritant according to criteria.	
Eye irritation:	Slight irritation. Non-irritant according to criteria.	
Sensitisation (test method used and result):	Not sensitising at a 1% challenge dose. Higher doses not possible due to paraesthesia Guinea pig maximisation test	

Short term toxicity

Target / critical effect:	Organs liver, CNS
Lowest relevant oral NOAEL / NOEL:	0.5 mg/kg bw/d, oral, 1 y dog
Lowest relevant dermal NOAEL / NOEL:	No study available

Lowest relevant inhalation NOAEL / NOEL:

No study available

Genotoxicity

Negative

Long term toxicity and carcinogenicity

Target / critical effect:

Liver

Lowest relevant NOAEL:

NOEL 1.7 mg/kg bw/d, 2 y rat (cyhalothrin)

Carcinogenicity:

Negative

Reproductive toxicity

Target / critical effect - Reproduction:

Negative. Parental, slightly reduced bw gain and slightly reduced bw gain of the pups.

Lowest relevant reproductive NOAEL / NOEL:

NOEL 1.5 mg/kg bw/d (parental)

NOEL 1.5 mg/kg bw/d (foetal)

Target / critical effect - Developmental toxicity:

Negative. No treatment related embryotoxic or teratogenic effects were observed.

Lowest relevant developmental NOAEL / NOEL:

NOEL 10 mg/kg bw/d based on maternal toxicity (decreased bw gain and loss of limb coordination).

Delayed neurotoxicity

Not relevant

Other toxicological studies

None

Medical data

Information supplied

Summary

	Value	Study	Safety factor
ADI:	0.005 mg/kg bw/d	1 y dog	100
AOEL systemic:	0.0025 mg/kg bw/d	1 y dog (50 % oral absorption)	100
AOEL inhalation:			
AOEL dermal:			
ARfD (acute reference dose):	0.0075 mg/kg bw	6-week oral dog study; NOEL 0.75 mg/kg bw	100

Dermal absorption

12 % EC formulation, in-use dilution: 4 %, *in vivo* rat
5 % EC formulation, in-use dilution: <0.3%, *in vivo* man
5 % EC formulation, in-use dilution: 0.055%, *in vitro* man
0.3% used for model calculations (concentrate and dilution) (See Doc. 5684/VI/97-app.4)

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:

25-59% after 90-92 days, mean 39% (n=4)
(¹⁴C-cyclopropane labelled)

Non-extractable residues after 100 days:

12-19% after 90-92 days, mean 16% (n=4)

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

Only compound XV (hydroxylated *lambda*-cyhalothrin)⁷ identified as "major": max. 11 and 12% in two different soils, after 35 and 63 days. Declined to 2-3% after 90 days.

Supplemental studies

Anaerobic:

< 1% ¹⁴CO₂ after 131 days (¹⁴C-cyclopropane labelled).

Bound residues 3% after 131 days.

Compound Ia (ester cleavage product)⁸ max. 18% after 131 days.

Soil photolysis:

Negligible

Remarks:

Major degradation is by ester cleavage to produce compound Ia and V⁹. Compound Ia detected as <10% from ¹⁴C-cyclopropane labelling. Mineralisation of V shown in studies on pyrethroids generating the same metabolite.

Rate of degradation

Laboratory studies

⁷ Compound XV: (RS)- α -cyano-3-(4-hydroxyphenoxy)benzyl-(Z)-(1RS)-cis-3-(2-chloro-3, 3, 3-trifluoropropenyl)-2, 2-dimethylcyclopropanecarboxylate. (IUPAC)

⁸ Compound Ia (cyclopropane acid): (Z)-3-(2-chloro-3, 3, 3-trifluoropropenyl)-2, 2-dimethylcyclopropanecarboxylic acid. (IUPAC)

⁹ Compound V: 3-phenoxybenzoic acid. (IUPAC)

DT ₅₀ lab (20 °C, aerobic):	29, 34, 62, 100 d, (first order, r ² 0.96-1.0) mean 56 d (n=4) Compound XV: 7, 10, 16 days (mean 11 d) ¹⁰
DT ₉₀ lab (20 °C, aerobic):	96, 113, 206, 332 d, mean 187 d (n=4)
DT ₅₀ lab (10 °C, aerobic):	63 d (n=1) (first order, r ² 0.99)
DT ₅₀ lab (20 °C, anaerobic):	101 d (n=1) (first order, r ² 0.98)
Field studies (country or region)	US and Germany: Detected in the upper 10 cm of soil, < 4 % below 5 cm depth
DT _{50f} from soil dissipation studies:	Germany: 6, 26, 28, 40 d (best fit model) US study I: 2, 37 d (best fit model) US study II: 19, 20, 21, 35 d (best fit model) Mean 23 d (n=10)
DT _{90f} from soil dissipation studies:	Germany: 68, 85, 92, 207 d (best fit model) US study I: approx. 30, > 279 d (graphical) US study II: 62, 67, 108, 117d (best fit model) Mean 112 days (n=10)
Soil accumulation studies:	Not submitted, not required
Soil residue studies:	Not submitted, not required
Remarks	US study I used ¹⁴ C-cyclopropane and ¹⁴ C-phenyl label; bound residues as 22-32% after 115 days, and as 17-27% after 279 days.
Adsorption/desorption	
K _f / K _{oc} :	K _{OC} = 38000, 47800, 199000, 345000 ml/g, mean 157000 (n=4)
K _d	K _d = 464, 1290, 1470, 5350, mean 2144 (n=4)
pH dependence:	%OC: 0.7 - 2.7, pH 6.0 - 6.6, % sand 2 – 72 No pH dependency expected Compound XV: K _{om} 36000, 39000, 39000, 42000, 46000, 61000 (mean 44000) ¹¹
Mobility	

¹⁰ DT_{50s} for soil metabolite XV inserted as agreed by Working Group Legislation, October 2000. Data provided by CTB (The Netherlands), not evaluated by the RMS. DT_{50s} in original report were 4, 3 and 4 days but recalculated into the figures in the table by CTB, assuming first order kinetics (r² 0.75-0.96).

¹¹ K_{om} values for soil metabolite XV inserted as agreed by Working Group Legislation, October 2000. Data provided by CTB (The Netherlands), not evaluated by the RMS. K_{oc} values in original report were 60000, 67000, 68000, 75000, 78000 and 110000, but recalculated into the values in the table by CTB.

Laboratory studies:

Column leaching:

No significant leaching

Aged residue leaching:

No significant leaching

Field studies:

Lysimeter/Field leaching studies:

Not submitted, not requested

No leaching in field dissipation studies

Remarks:

None

2.2 Fate and behaviour in water**Abiotic degradation**

Hydrolytic degradation:

Not significant at pH 5.2 and pH 6.9,
DT₅₀ approx. 1 week at pH 9.0

Relevant metabolites:

At pH 9.0: Compounds Ia¹² and IV¹³ identified as
"major" (>10%)

Photolytic degradation:

DT₅₀: a few weeks, expected to be negligible under
field conditions.

Relevant metabolites:

At laboratory: Compounds Ia and V¹⁴ identified as
"major" (>10%)**Biological degradation**

Ready biological degradability:

Not submitted, not requested

Water/sediment study:

at 20 °C, 2 systems, pH 7.2-7.8:
5 and 11 hDT₅₀ water:

15 and 7 days

DT₅₀ whole system:

3.3 and 4.6 days

DT₉₀ water:

151 and 45 days

DT₉₀ whole system:Distribution in water / sediment systems
(active substance)Parent compound, as % of applied radioactivity in
the two water/sed. systems:

	Day 0	Day 1	Day 7
Water	72/49	10/13	3.7/2.6
Sediment	14/30	70/30	53/43

¹² Compound Ia (cyclopropane acid): (Z)-3-(2-chloro-3, 3, 3-trifluoropropenyl)2, 2-dimethylcyclopropanecarboxylic acid. (IUPAC).

¹³ Compound IV: 3-phenoxybenzaldehyde. (IUPAC)

¹⁴ Compound V: 3-phenoxybenzoic acid. (IUPAC)

	<div>Total</div> <div>86/79</div> <div>80/43</div> <div>57/46</div>
Distribution in water / sediment systems (metabolites)	<p>Compound Ia was found at max. 18/22% of applied radioactivity days 14/30, whereof 3/11% in sediment and 14/11% in water. After 98 days compound Ia had declined to 0.4/3%.</p> <p>Compounds V, VI¹⁵, XV¹⁶ each <10%.</p> <p>Bound residues 17/24% and ¹⁴CO₂ 15/48% after 98 days.</p>
Accumulation in water and/or sediment:	Disappearance rate from water phase is even more rapid in the presence of plants, since extensive adsorption and enhanced degradation was shown in the presence of plants.
Degradation in the saturated zone	Not submitted, not requested
Remarks:	None

2.3 Fate and behaviour in air

Volatility

Vapour pressure:

$2 \cdot 10^{-7}$ Pa at 20 °C (extrapolated)

Henry's law constant:

0.02 Pa m³·mol⁻¹ at 20 °C

Photolytic degradation

Direct photolysis in air:

Not submitted and not requested, but possible theoretically due to absorption "tail" to 300 nm.

Photochemical oxidative degradation in air:

DT₅₀ 4.1 h (calculated)

Volatilisation:

Volatilisation from soil not significant, from leaves low rate of volatilisation observed (88% of applied amount remaining on leaves after 24 hours).

¹⁵ Compound VI: 3-phenoxybenzylalcohol. (IUPAC)

¹⁶ Compound XV (hydroxylated lambda-cyhalothrin): (RS)-α-cyano-3-(4-hydroxyphenoxy)benzyl-(Z)-(1RS)-cis-3-(2-chloro-3, 3, 3-trifluoropropenyl)-2, 2-dimethylcyclopropanecarboxylate. (IUPAC)

Remarks:

None

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:

Acute toxicity to birds:

Dietary toxicity to birds:

Reproductive toxicity to birds:

Short term oral toxicity to mammals:

LD ₅₀ = 20 mg/kg bw (mice)
LD ₅₀ > 3950 mg/kg bw (mallard duck)
LC ₅₀ > 5300 mg/kg food (bobwhite quail)
NOEC > 30 mg/kg food (mallard duck)
NOEL = 0.7 mg/kg bw/day (male rat, 90-day)

Aquatic Organisms

Acute toxicity fish:

Long term toxicity fish:

Bioaccumulation fish:

Acute toxicity invertebrate:

Acute toxicity algae:

Chronic toxicity sediment dwelling organism:

LC ₅₀ (96 h) = 0.21 µg/l (<i>Lepomis macrochirus</i>) <u>Major transformation products:</u> Compound Ia ¹⁷ : LC ₅₀ (96 h) > 14 mg/l, 2 species Compound V ¹⁸ : LC ₅₀ (96 h) = 13 - 36 mg/l, 2 species
NOEC (28 d) 0.25 µg/l (<i>Cyprinodon variegatus</i>) (flow-through early life stage toxicity test)
BCF: 1660-2240 (whole fish)
EC ₅₀ (48 h) = 0.36 µg/l (<i>Daphnia magna</i>) EC ₅₀ (96 h) = 0.016 µg/l (<i>Gammarus pulex</i> neonates; most sensitive life-stage tested) NOEC (96 h) = 0.006 µg/l (<i>G. pulex</i> neonates) <u>Major transformation products:</u> Compound Ia: EC ₅₀ (48 h) 105 mg/l (<i>D. pulex</i>) Compound V: EC ₅₀ (48 h) 85 mg/l, (<i>D. magna</i>)
EC ₅₀ (96 h) > 0.3 mg/l (<i>Selenastrum capricornutum</i>)
<i>Chironomus riparius</i> , 28-d studies "spiked water test": NOEC (time to emergence) 0.16 µg/l "spiked sediment test": NOEC (total emergence) 105 µg/kg

¹⁷ Compound Ia (cyclopropane acid): (Z)-3-(2-chloro-3, 3, 3-trifluoropropenyl)2, 2-dimethylcyclopropanecarboxylic acid. (IUPAC).

¹⁸ Compound V: 3-phenoxybenzoic acid. (IUPAC)

Results from mesocosm studies:

Mesocosm study I (UK):

Gammaridae most sensitive taxa:
LOEC: 4 events of overspray at 0.17 g/ha
Chironomidae, less sensitive:
NOEC: 4 events of overspray at 1.7 g/ha

Mesocosm study II (US):

Insecta most sensitive taxa:
NOAEC: 12 events of overspray at 0.017 g/ha +
6 events of run-off at 0.05 g/ha
Fish, *L. macrochirus*, and sedentary chironomids
were less sensitive:
NOEC: 12 events of overspray at 1.7 g/ha + 6
events of run-off at 5 g/ha

Honeybees

Acute oral toxicity:

LD₅₀ (48 h) = 0.91 µg/bee

Acute contact toxicity:

LD₅₀ (48 h) = 0.038 µg/bee

Field study in cereals:

Preliminary results indicate NOAEC = 20 g/ha

Other arthropod species

Foliage dwellers:

Rhopalosiphum padi

LD₅₀ (6 d) 0.004 µg/g bw, contact exposure

Leptyphantes spp. (m)

LD₅₀ (6 d) 0.097 µg/g bw, contact exposure

Leptyphantes spp. (f)

LD₅₀ (6 d) 0.132 µg/g bw, contact exposure

Bathyphantes spp. (f)

LD₅₀ (6 d) 0.012 µg/g bw, contact exposure

Oedothorax spp. (m)

LD₅₀ (6 d) 0.058 µg/g bw, contact exposure

Panonychus ulmi

LD₅₀ (48 h) 1.9 g/ha

Typhlodromus pyri

LD₅₀ (48 h) 0.2 g/ha

Episyrphus balteatus

27% larval mortality after 6 days at 9 g/ha

Soil dwellers:

Trechus quadristriatus

LD₅₀ (6 d) 12.1 µg/g bw, contact exposure

Pterostichus melanarius

23% mortality after 28 days at 7.5 g/ha

Poecilus cupreus

0-10% mortality after 28 days at 7.5 g/ha

Pardosa sp.

90% mortality after 14 days at 7.5 g/ha

Pardosa spp.

83-87% mortality after 14 days at 7.5 g/ha

Field study, autumn application in cereals, UK, at 5 g/ha:

Mean depression in abundance of affected species was 20-60% and lasted for 4-5 weeks.

Field study, summer application in cereals, UK, at 7 g/ha:

Mean depression in abundance of affected species was 75% and lasted for 27±6 days.

Field study, summer application in cereals, UK, at 2.5, 5 and 10 g/ha:

Depression in abundance of the species affected lasted for 1-7 weeks with no statistically significant effects remaining 7 weeks after spraying. Increased selectivity was seen at reduced rates.

Field studies in non-European countries:

Recovery after 3 weeks.

Earthworms

Acute toxicity:

LC₅₀ (14 d) > 1000 mg/kg soil

NOEC = 100 mg/kg soil

Reproductive toxicity:

Not submitted, not requested

Soil micro-organisms

Nitrogen mineralization:

< 21% effect on ammonification/nitrification at 1.25 kg/ha

Carbon mineralization:

No significant effects at 1.25 kg/ha

APPENDIX III

lambda-CYHALOTHRIN

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 inclusion¹⁹.

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 ²⁰ on previous use in granting national authorizations
AII 1	Duffin MR	1991	<i>lambda</i> -Cyhalothrin: Detailed Analysis of Technical Materials Representative of Established Large Scale Production. ZENECA Agrochemicals Report No. RJ0943B. GLP study Not published	
AII 2	Jackson WA	1994	Determination of some Physico-Chemical Properties of <i>lambda</i> -cyhalothrin TGAI. Report No. HT94/140. GLP study Not published	
AII 2	Wollerton C	1984	PP321: Physical-Chemical Data File. ICI, Plant Protection Division, Report No. RJ0366B. GLP not relevant Not published	Austria (18/7/91) & the Netherlands.
AII 2.3 AII 2.6 AII 2.8	Wollerton C and Husband R	1988	PP321: Water Solubility, Octanol-Water Partition Coefficient, Vapour Pressure and Henry's Law Constant. ICI Agrochemicals Report No. RJ 0699B. GLP study Not published	
AII 2.5	Tandy MJ, Duffin MR and Stanley PD	1988	PP321 and Cyhalothrin: NMR Spectra of Associated Isomers Detected in Technical Material. ICI Agrochemicals Report Series M4835B. Not GLP study Not published	Austria (18/7/91).

¹⁹ List based on a detailed analysis from Sweden in its submission of XX/XX/XX (background document C).

²⁰ Reports received from the notifier 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 ²⁰ on previous use in granting national authorizations
AII 2.9.1 AII 7.2.1.1	Collis WMD and Leahey JP	1984	PP321: Hydrolysis in Water at pH 5, 7 and 9. ICI Report series RJ 0338B. GLP study Not published	Austria (18/7/91), Germany (25/10/90), UK (14/2/1990), the Netherlands.
AII 2.9.2 AII 2.9.3 AII 7.2.1.2	Moffatt F	1994	lambda-Cyhalothrin: Environmental Half-life and Quantum Yield for Direct Phototransformation in Aqueous Solution. Zeneca Report Series RJ 1617B. GLP study Not published	
AII 2.9.2 AII 7.2.1.2	Priestley DB and Leahey JP	1988	PP321: Aqueous Photolysis at pH 5. ICI Report Series RJ 0605B. GLP study Not published	Germany (25/10/90), the Netherlands.
AII 2.10	Hayes SE	1998	Lambda-cyhalothrin - calculation of half-life by reaction with atmospheric hydroxyl radicals. Zeneca G:\AOP+lambda-cyhalothrin.AOP. GLP not relevant Not published	
AII 4.1	Duffin MR	1994	The determination of lambda-cyhalothrin and associated impurities in technical material by capillary gas chromatography. Zeneca Agrochemicals Analytical Method PAM 721/3. Not GLP study Not published	
AII 4.2	Hadfield ST, Sadler J and Bolygo E	1989	The determination of residues of PP321 in water following sampling by a solid-phase extraction technique. ICI Agrochemical Residue Analytical Method Number 125b. Not GLP study Not published	
AII 4.2	Marsh JR	1995	Determination of lambda-cyhalothrin in human blood. Zeneca Central Toxicology Laboratory Report No. CTL/R/1241. Not GLP study Not published	
AII 4.2	Ryan J and Sapiets A	1993	Lambda-cyhalothrin: Validation of a stepped model to determine residues in air. Zeneca Agrochemicals Jealott's Hill Research Station Report No. RJ1525B. GLP study Not published	

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 ²⁰ on previous use in granting national authorizations
AII 4.2	Sapiets A	1986a	The determination of residues of PP321 in products of animal origin. A gas-liquid chromatographic method using an internal standard. ICI Chemical Industries PLC, Plant Protection Division Residue Analytical Method Number 86/1. GLP study Not published	
AII 4.2	Sapiets A	1986b	The determination of residues of PP321 in soil. ICI Chemical Industries PLC, Plant Protection Division Residue Analytical Method Number 93. Not GLP study Not published	Germany (25/10/90), Italy (30/12/92).
AII 4.2	Specht and Partner	1990	Überprüfung der Anwendbarkeit der DFG Multimethode S 19. <i>Lambda</i> -cyhalothrin. RIC 2246. Dr Specht & Partner Chemische Laboratorien GMBH. Not GLP study Not published	Germany (25/10/90).
AII 4.2	Swaine H and Sapiets A	1984	The determination of residues of PP321 in crops. A gas-liquid chromatographic method using an internal standard. ICI Chemical Industries PLC, Plant Protection Division Residue Analytical Method No. 81. GLP study Not published	Submitted in all Member States except Ireland, Luxembourg, Portugal & Spain.

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
AII 5.1	Harrison MP	1981	Cyhalothrin: The disposition and metabolism of ¹⁴ C-ICI 146,814 in rats; Part I. Central Toxicology Laboratory Report No. CTL/C/1279A. Not GLP study Not published	Submitted in all Member States except Greece, Ireland, Luxembourg, Portugal & Spain.
AII 5.1	Harrison MP	1983	Cyhalothrin: The metabolism and disposition of ICI 146,814 in the rat; Part IV. Central toxicology Laboratory Report No. CTL/C/1279D. Pharmaceuticals Report No. 6/HC/005683. GLP study Not published	
AII 5.1	Harrison MP	1984a	Cyhalothrin (ICI 146,814): The metabolism and disposition of ICI-146,814 in rats; Part II. Tissue residues derived from [¹⁴ C-benzyl] or [¹⁴ C-cyclopropyl]-ICI 146,814, after a single oral dose of 1 or 25 mg/kg. Central Toxicology Laboratory Report No. CTL/C/1279B. GLP study Not published	Submitted in all Member States except Austria, Denmark, Ireland, Luxembourg, Portugal, Spain & Sweden.
AII 5.1	Harrison MP	1984b	Cyhalothrin: The metabolism and disposition of [¹⁴ C]-ICI-146,814 in rats; Part III. Studies to determine radioactive residues in the rat following 14 days repeated oral administration. Central Toxicology Laboratory Report No. CTL/C/1279C. GLP study Not published	
AII 5.1	Harrison MP	1984c	Cyhalothrin (ICI 146,814): The disposition and metabolism of [¹⁴ C]-ICI 146,814 in the dog. Central Toxicology Laboratory Report No. CTL/C/1277. Pharmaceuticals Report No. 10/HD/007328. Not GLP study Not published	
AII 5.1	Jones BK	1989a	Cyhalothrin: Tissue distribution and elimination following a single oral dose (1 mg/kg) in the rat. Central Toxicology Laboratory Report No. CTL/P/2489. GLP study Not published	

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
AII 5.1	Jones BK	1989b	Cyhalothrin: Tissue distribution and elimination following a single oral dose (25 mg/kg) in the rat. Central Toxicology Laboratory Report No. CTL/P/2490. GLP study Not published	
AII 5.1	Marsh JR, Woollen BH and Wilks MF	1994	The metabolism and pharmacokinetics of <i>lambda</i> -cyhalothrin in man. Central Toxicology Laboratory Report No. CTL/P/4208. GLP study Not published	
AII 5.1	Prout MS	1984	Cyhalothrin: Bioaccumulation in the rat. Central Toxicology Laboratory Report No. CTL/P/1014. GLP study Not published	Submitted in all Member States except Austria, Finland, Greece, Ireland, Luxembourg, Portugal & Spain.
AII 5.1	Prout MS and Howard EF	1985	PP321: Comparative absorption study in the rat (1 mg/kg). Central Toxicology Laboratory Report No. CTL/P/1214. GLP study Not published	Submitted in all Member States except Belgium, Greece, Ireland, Luxembourg, Portugal & Spain.
AII 5.2	Barber JE	1985	PP321: Acute dermal toxicity study. Central Toxicity Laboratory Report No. CTL/P/1149. GLP study Not published	Submitted in all Member States except Ireland, Luxembourg, Portugal, Spain & Sweden.
AII 5.2	Barber JE	1987	Skin sensitisation Validation: October 1979-December 1983. Central Toxicology Laboratory Report No. CTL/T/2316. Not GLP study Not published	
AII 5.2	Hext PM	1987	PP321: 4-hour acute inhalation toxicity study in the rat. Central Toxicology Laboratory report No. CTL/P/1683. GLP study Not published	Austria (18/7/91), France (2/87), Germany (19/4/89), Italy (30/12/92), Spain.
AII 5.2	Pritchard VK	1984	PP321: Skin sensitisation study. Central Toxicology Laboratory Report No. CTL/P/1054. GLP study Not published	Submitted in all Member States except Ireland, Luxembourg & Portugal.

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
AII 5.2	Pritchard VK	1985a	PP321 and cyhalothrin: Skin irritation study. Central Toxicology Laboratory Report No. CTL/P/1139. GLP study Not published	Submitted in all Member States except Ireland, Luxembourg, Portugal & Spain.
AII 5.2	Pritchard VK	1985b	PP321: Eye irritation study. Central Toxicology Laboratory Report No. CTL/P/1207. GLP study Not published	Submitted in all Member States except Ireland, Luxembourg, Portugal & Spain.
AII 5.2	Southwood J	1985	PP321: Acute oral toxicity studies. Central Toxicology Laboratory Report No. CTL/P1102. GLP study Not published	Submitted in all Member States except Ireland, Luxembourg, Portugal & Spain.
AII 5.3	Hart D, Banham PB, Chart IS, Evans DP, Gore CW, Stonard MD, Moreland S, Godley MJ and Robinson M	1985	PP321: 90-day feeding study in rats. Central Toxicology Laboratory Report No. CTL/P/1045. GLP study Not published	Submitted in all Member States except Ireland, Luxembourg, Portugal & Spain.
AII 5.3	Lindsay S, Chart IS, Godley MJ, Gore CW, Hall M, Pratt I, Robinson M and Stonard M	1981	Cyhalothrin: 90-day feeding study in rats. Central Toxicology Laboratory Report No. CTL/P/629. GLP study Not published	Submitted in all Member States except Belgium, Denmark, Finland, Greece, Ireland, Luxembourg & Portugal.
AII 5.3	Lindsay S, Doe JE, Godley MJ, Hall M, Pratt I, Robinson M and Stonard MD	1982	Cyhalothrin induced liver changes: Reversibility study in male rats. Central Toxicology Laboratory Report No. CTL/P/668. GLP study Not published	Denmark, Finland (18/1/93), France (9/5/86), Germany (19/4/89), Sweden (30/5/91), UK (14/2/90).
AII 5.3	Stonard MD	1991	First amendment to PP321: 1-year oral dosing study in dogs. Central Toxicology Laboratory Report No. CTL/P/1316. GLP study Not published	Austria (18/7/91), Denmark, Germany (19/4/89), Italy (30/12/92), the Netherlands.
AII 5.4	Callander RD	1984	PP321-An evaluation in the <i>Salmonella</i> Mutagenicity Assay. Central Toxicology Laboratory Report No. CTL/P/1000. GLP study Not published	Submitted in all Member States except Ireland, Luxembourg & Portugal.

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
AII 5.4	Cross M	1985	PP321: Assessment of mutagenic potential using L5178Y mouse lymphoma cells. Central Toxicology Laboratory Report No. CTL/P/1340. GLP study Not published	Austria (18/7/91), Denmark, Germany (19/4/89), Italy (30/12/92), the Netherlands Sweden (30/5/91).
AII 5.4	Sheldon T, Howard CA and Richardson CR	1985	PP321: A cytogenic study in human lymphocytes <i>in vitro</i> . Central Toxicology Laboratory Report No. CTL/P/1333. GLP study Not published	Submitted in all Member States except Belgium, Greece, Ireland, Luxembourg, Portugal, Spain & UK.
AII 5.4	Sheldon T, Richardson CR, Show J and Barber G	1984	An evaluation of PP321 in the Mouse Micronucleus Test. Central Toxicology Laboratory Report No. CTL/P/1090. GLP study Not published	Submitted in all Member States except Ireland, Luxembourg, Portugal & Spain.
AII 5.4	Trueman RW	1989	lambda-Cyhalothrin: Assessment for the induction of Unscheduled DNA synthesis in primary rat hepatocyte cultures. Central Toxicology Laboratory Report No. CTL/P/2707. GLP study Not published	
AII 5.5	Colley J, Dawe S, Heywood R, Almond R, Gibson WA, Gregson R and Gopinath C	1984	Cyhalothrin: Potential tumorigenic and toxic effects in prolonged dietary administration to mice. Huntingdon Research Centre Report No. ICI 395/83668/2. Central Toxicology Laboratory Report Reference Numbers CRL/C/1260 Vol. 1-3, addendum 1 & 2 & photomicrography addendum and CTL/P/1185 (Summary Report; Evans, D.P., 1984). GLP study Not published	Submitted in all Member States except Belgium, Ireland, Luxembourg, Portugal, Spain & UK.
AII 5.6	Killick ME	1981a	Cyhalothrin: Oral (gavage) teratology study in the rat. Hazleton Report No: 2661-72/208. Central Toxicology Laboratory Report No. CTL/C/1075. GLP study Not published	Submitted in all Member States except Ireland, Luxembourg & Portugal.

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
AII 5.6	Killick ME	1981b	Cyhalothrin: Oral (gavage) teratology study in the New Zealand White rabbit. Hazleton Report No: 2700-72/211. Central Toxicology Laboratory Report No. CTL/C/1072. GLP study Not published	Submitted in all Member States except Ireland, Luxembourg & Portugal.
AII 5.6	Milburn GM, Banham P, Godley MJ, Pigott G and Robinson M	1984	Cyhalothrin: Three generation reproduction study in the rat. Central Toxicology Laboratory Report No. CTL/P/906 and CTL/P/1244 (Summary report; Evans, D.P., 1984). GLP study Not published	Submitted in all Member States except Ireland, Luxembourg & Portugal.
AII 5.6	Pigott GH, Chart IS, Godley MJ, Gore CW, Hollis KJ, Robinson M, Taylor K and Tinston DJ	1984	Cyhalothrin: Two-year feeding study in rats. Central Toxicology Laboratory Report No. CTL/P/980. GLP study Not published	Submitted in all Member States except Ireland, Luxembourg, Portugal & Spain.
AII 5.2.6 AIII 7.1	Barber JE	1987	Skin sensitisation Validation: 1985. Central Toxicology Laboratory Report No: CTL/T/2439. Not GLP study Not published	
AII 5.9 AIII 7.2	Ashdown DM, Chester G and Wollen BH	1994	lambda-cyhalothrin- assessment of occupational exposure and effects on the health of workers and livestock during application of 'Karate' 5 EC to cotton in India. ZENECA Agrochemicals report No: TMF 4206B. Not GLP study Not published	
AII 5.8.2	Brammer A	1999	Lambda-cyhalothrin: Acute neurotoxicity study in rats. Zeneca Central Toxicology Laboratory Report No. CTL/P/6151. GLP study Not published	
AII 5.8.2	Horner SA	1996a	Lambda-cyhalothrin: Maximum clinically tolerated dose study in dogs. Zeneca Central Toxicology Laboratory Report No. CTL/L/7182. Not GLP study Not published	

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
AII 5.8.2	Horner SA	1996b	<i>Lambda</i> -cyhalothrin: 6 week oral toxicity study in dogs. Zeneca Central Toxicology Laboratory Report No. CTL/P/5256. GLP study 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	Reports on previous use in granting national authorizations
AII 6.1	Burke S and Sapiets A	1988	CYHALOTHRIN: - Storage Stability of the Residue in Frozen Crop and Soil Samples. Jealott's Hill Research Station Report Series M4773B. GLP study Not published	
AII 6.1	Clarke DM and Sapiets A	1990a	LAMBDA-CYHALOTHRIN: - Storage Stability of the Insecticide and its Metabolites in Frozen Dried Hops and Brewers Grains. Jealott's Hill Research Station Report Series RJ0886B. GLP study Not published	
AII 6.1	Curl EA and Leahey JP	1983	Cyhalothrin: Metabolism in Cabbage. Jealott's Hill Research Station Report No. RJ0308B. GLP study Not published	Submitted in all Member States except Belgium, Greece, Ireland, Italy, Luxembourg, Portugal & UK.
AII 6.1	French DA and Grout SJ	1990	lambda-Cyhalothrin: Quantification and Characterization of Radioactive Residues in Grain from Wheat Treated with ¹⁴ C-lambda-cyhalothrin. Jealott's Hill Research Station Report No. RJ0836B. GLP study Not published	
AII 6.1	French DA and Leahey JP	1986	PP321: Quantification of Radioactive Residues Found in Soya Beans From Plants Treated with ¹⁴ C-PP321. Jealott's Hill Research Station Report No. RJ0438B. GLP study Not published	Germany (19/4/89), Italy (30/12/92).
AII 6.1	Hall JS and Leahey JP	1979	PP564: Degradation on apples. Jealott's Hill Research Station Report No. TMJ 1728B. Not GLP study Not published	Germany (19/4/89).
AII 6.1	Leahey JP, Collis WMD and French DA	1986	PP321: Quantification and Characterization of Radioactive Residues in Cotton Leaves From Plants Treated with ¹⁴ C-Benzyl-labelled PP321. Jealott's Hill Research Station Report No. RJ0497B. GLP study Not published	Germany (19/4/89), Italy (30/12/92).

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
AII 6.1	Leahey JP and French DA	1985	PP321: Characterization of Radioactive Residues Found in Cotton Seeds From Plants Treated with ¹⁴ C-PP321, and Degradation of ¹⁴ C-PP321 Applied Directly to Cotton Seeds. Jealott's Hill Research Station Report No. RJ0393B. GLP study Not published	Germany (19/4/89), Italy (30/12/92).
AII 6.1	Leahey JP and French DA	1986a	PP321: - Quantification and Characterization of Radioactive Residues Found in Soya Leaves From Plants Treated with ¹⁴ C-PP321. Jealott's Hill Research Station Report No. RJ0507B. GLP study Not published	Germany (19/4/89), Italy (30/12/92).
AII 6.1	Leahey JP and French DA	1986b	PP321: Quantification and Characterization of Radioactive Residues found in Cotton Leaves From Plants Treated with ¹⁴ C-Cyclopropane-labelled PP321. Jealott's Hill Research Station Report No. RJ0526B. GLP study Not published	Germany (19/4/89), Italy (30/12/92).
AII 6.1	Leahey JP and Grout SJ	1990	lambda-Cyhalothrin: Quantification and Characterization of Radioactive Residues in Foliage from Wheat Treated with ¹⁴ C-lambda-cyhalothrin. Jealott's Hill Research Station Report No. RJ0889B. GLP study Not published	
AII 6.1	Leahey JP and Priestley DB	1987	PP321: Rotational crop study using ¹⁴ C-radiolabelled PP321. Jealott's Hill Research Station Report No. RJ0593B. GLP study Not published	Germany (19/4/89).
AII 6.1	Lloyd SJ, Curl EA and Leahey JP	1984	PP321: - Measurement of radioactive residues transferring into rotational crops grown in soil treated with ¹⁴ C-PP321. Jealott's Hill Research Station Report No. RJ0381B. GLP study Not published	Denmark, Finland (18/1/93), Germany (19/4/89), Italy (30/12/92), Sweden (30/5/91).
AII 6.1	Tummon OJ and Sapiets A	1988	PP321: Storage Stability in Frozen Crop Samples (Final Report). Jealott's Hill Research Station Report Series M4845B. GLP study Not published	

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
AII 6.2	Heath J and Leahey JP	1985	PP321: - Metabolism in laying hens. Jealott's Hill Research Station No. RJ0453B. GLP study Not published	France (9/5/86), Germany (19/4/89).
AII 6.2	Leahey JP, French DA and Heath J	1985	PP321: Metabolism in a goat. Jealott's Hill Research Station Report No. RJ0435B. GLP study Not published	France (9/5/86), Germany (19/4/89).
AII 6.2	Sapiets A	1985a	PP321:- Storage Stability in Deep Frozen Milk Samples. Jealott's Hill Research Station Report Series M3893B. GLP study Not published	
AII 6.2	Sapiets A	1985b	PP321:- Storage Stability in Frozen Animal Tissues. Jealott's Hill Research Station Report Series M3959B. GLP study Not published	
AII 6.3	Atger J-C, Ryan J and Sapiets A	1994	lambda-Cyhalothrin: Residue Levels in Melon from a Trial carried out in France during 1993. Jealott's Hill Research Station Report Series: RJ1687B. GLP study Not published	
AII 6.3	Benet F and Massenot F	1989	Recherche de Residus de <i>Lambda</i> cyhalothrine (ICIA0321) dans des Haricots. ICI Protection de l'Agriculture Report Series RE 8945 H. Not GLP study Not published	
AII 6.3	Benet F and Massenot F	1991	Recherche de Residus de <i>Lambda</i> -cyhalothrine dans de la Luzerne. ICI Protection de l'Agriculture Report Bernay RE-9116-E Not GLP study Not published	
AII 6.3	Bonfanti F, Ryan J and Sapiets A	1994a	lambda-Cyhalothrin: Residue Levels in Tomatoes From Trials Carried out in Italy During 1993. Jealott's Hill Research Station Report Series: RJ1626B. GLP study Not published	

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
AII 6.3	Bonfanti F, Ryan J and Sapiets A	1994b	<i>lambda</i> -Cyhalothrin: Residue Levels in Courgettes from Trials carried out in Italy during 1993. Jealott's Hill Research Station Report Series: RJ1623B. GLP study Not published	
AII 6.3	Bonfanti F, Ryan J and Sapiets A	1994c	<i>lambda</i> -Cyhalothrin: Residues Levels in Melon from a Trial carried out in Italy during 1993. Jealott's Hill Research Station Report Series: RJ1625B. GLP study Not published	
AII 6.3	Burke S and Sapiets A	1987a	PP321:-Residue Levels In Almonds From A Trial Carried Out In Italy During 1986. Jealott's Hill Report Series: M4385B. GLP study Not published	France (10/92), Italy (30/12/92).
AII 6.3	Burke S and Sapiets A	1987b	PP321: Residue Levels in Potatoes from a trial carried out in Denmark during 1986. Jealott's Hill Research Station Report Series: M4502B. GLP study Not published	Denmark (26/4/89), the Netherlands (5/2/94).
AII 6.3	Burke S, Tyldesley DJ and Sapiets A	1986	PP321: Residue Levels on Hops from Trials carried out in Germany during 1985 & Addendum. Jealott's Hill Research Station Report Series: M4315B. GLP study Not published	
AII 6.3	Clarke DM and Sapiets A	1990b	<i>lambda</i> -Cyhalothrin: Residue Levels of the Insecticide and its Metabolites in Dried Hops and Brewers Grains from Trials carried out in the Federal Republic of Germany during 1989. Jealott's Hill Research Station Report Series: M5114B, and Technical Letter 89JH152/1. GLP study Not published	
AII 6.3	Codd M, Ryan J, and Sapiets A	1994	<i>Lambda</i> -cyhalothrin: Residue Levels in Brassicae from Trials carried out in the United Kingdom During 1992-1993. Jealott's Hill Research Station Report RJ1619B. GLP study Not published	

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
AII 6.3	Culoto B	1985	Recherche de Residus de PP321 dans des Salades. ICI Protection de l'Agriculture Report Series Bernay E 7-845-P, R 12-834-P, R 4-845-P. RIC1886. Not GLP study Not published	Belgium (8/11/85), France (9/5/86), Italy (30/12/92).
AII 6.3	Grimshaw K and Sapiets A	1987a	PP321: Residue Levels in Apples from a Trial carried out in Switzerland during 1986. Jealott's Hill Report Series: M4541B. Not GLP study Not published	Austria (18/7/91).
AII 6.3	Grimshaw K and Sapiets A	1987b	PP321:- Residue Levels in Strawberries from Trials carried out in Italy during 1986. Jealott's Hill Research Station Report Series: M4547B. GLP study Not published	Austria (18/7/91), France (3/88), Italy (30/12/92).
AII 6.3	Grimshaw K and Sapiets A	1987c	PP321: Residue Levels on Alfalfa from a Trial carried out in Italy during 1987. Jealott's Hill Research Station Report Series: M4556B. GLP study Not published	France (3/88), Italy (30/12/92).
AII 6.3	Jones SD	1995a	Residue Levels in Cauliflower and Broccoli from Trials carried out in the United Kingdom during 1994. Zeneca Agrochemicals. Jealott's Hill Research Station. Report Series: RJ1833B. GLP study Not published	
AII 6.3	Jones SD	1995b	Residue Levels in Courgettes from Trials carried out in France during 1994. Zeneca Agrochemicals. Jealott's Hill Research Station. Report Series: RJ1880B. GLP study Not published	
AII 6.3	Jones SD and Atger JC	1995	Residue Levels in Melons from Trials carried out in France during 1994. Zeneca Agrochemicals. Jealott's Hill Research Station. Report Series: RJ1873B. GLP study Not published	
AII 6.3	Jones SD and Bonfanti F	1996	Residue Levels in Cherries from Trials carried out in Italy during 1995. Zeneca Agrochemicals. Jealott's Hill Research Station. Report Series: RJ2077B. GLP study Not published	

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
AII 6.3	Jones SD and Mason R	1996	Residue Levels in Cauliflower from a Trial carried out in Spain during 1995. Zeneca Agrochemicals. Jealott's Hill Research Station. Report Series: RJ2107B. GLP study Not published	
AII 6.3	Jones SD, Mason R and Hughes A	1996	Residue Levels in Lettuce from a Trial carried out in the United Kingdom during 1995. Zeneca Agrochemicals. Jealott's Hill Research Station. Report Series: RJ2133B. GLP study Not published	
AII 6.3	Jones RN and Sapiets A	1987a	PP321: Residue Levels in Carrots from a Trial carried out in Italy during 1987. Jealott's Hill Research Station Report Series: M4558B. GLP study Not published	France (3/88), Italy (30/12/92).
AII 6.3	Jones RN and Sapiets A	1987b	PP321: Residue Levels in Courgettes from a Trial carried out in Italy during 1986. Jealott's Hill Research Station Report Series: M4552B. GLP study Not published	Italy (30/12/92).
AII 6.3	Jones RN and Sapiets A	1988a	PP321: Residue Levels in Apples from a Trial carried out in Greece During 1987. Jealott's Hill Report Series: M4628B. Not GLP study Not published	Greece (2/87), Italy (30/12/92).
AII 6.3	Jones RN and Sapiets A	1988b	PP321: Residue Levels on Peaches from a Trial carried out in Greece during 1987. Jealott's Hill Research Station Report Series: M4631B. GLP study Not published	Greece (2/87), Italy (30/12/92).
AII 6.3	Jones RN and Sapiets A	1988c	PP321: - Residue Levels in Celery from Trials carried out in the United Kingdom during 1987. Jealott's Hill Research Station Report Series: M4634B. GLP study Not published	France (12/93).
AII 6.3	Jones RN and Sapiets A	1991	Lambda-cyhalothrin: Residue Levels in Cereals from Trials carried out in the United Kingdom during 1989-90. Jealott's Hill Report Series : RJ0991B. Not GLP study Not published	

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
AII 6.3	Jones SD and Tobias A	1995a	Residue Levels in Cauliflower from Trials carried out in France during 1994. Zeneca Agrochemicals. Jealott's Hill Research Station. Report Series: RJ1989B. GLP study Not published	
AII 6.3	Jones SD and Tobias A	1995b	Residue Levels in Cauliflower from Trials carried out in France during 1994 and 1995. Zeneca Agrochemicals. Jealott's Hill Research Station. Report Series: RJ1990B. GLP study Not published	
AII 6.3	Kennedy G, Murnane D and Sapiets A	1987	PP321:- Residue Levels on Oil Seed Rape from Trials carried out in Germany during 1986. Jealott's Hill Research Station Report Series M4400B. GLP study Not published	
AII 6.3	Kennedy G and Sapiets A	1986	PP321: - Residue Levels in Cauliflower From a 1985 Trial in Germany. Jealott's Hill Research Station Report Series M4226B. GLP study Not published	Italy (30/12/92).
AII 6.3	Kennedy G and Sapiets A	1987a	PP321: Residue Levels in Hazelnuts from a Trial Carried Out in Italy During 1986. Jealott's Hill Report Series: M4407B. GLP study Not published	France (10/92), Italy (30/12/92).
AII 6.3	Kennedy G and Sapiets A	1987b	PP321: Residue Levels on Strawberries from Trials carried out in the United Kingdom during 1986. Jealott's Hill Research Station Report Series: M4496B. GLP study Not published	Austria (18/7/91), France (3/88), Italy (30/12/92).
AII 6.3	Kennedy G and Sapiets A	1987c	PP321: - Residue Levels in Artichokes from a Trial carried out in Italy during 1986. Jealott's Hill Research Station Report Series: M4468B. GLP study Not published	France (3/88), Italy (30/12/92).
AII 6.3	Kennedy G, Napper J and Sapiets A	1987	PP321: Residue Levels on Grass from Trials carried out in Germany during 1986. Jealott's Hill Research Station Report Series: M4411B. GLP study Not published	Italy (30/12/92).

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
AII 6.3	Kinkaid A and Sapiets A	1986a	PP321:- Residue Levels on Plums from Trials Carried Out in Canada During 1985. Jealott's Hill Research Station Report Series: M4202B. GLP study Not published	Austria (18/7/91), France (2/87), Italy (30/12/92).
AII 6.3	Kinkaid A and Sapiets A	1986b	PP321: - Residue Levels on Grass from Trials carried out in Germany during 1985. Jealott's Hill Research Station Report Series: M4232B. GLP study Not published	Denmark (26/4/89), Sweden (30/5/91).
AII 6.3	Massenot F	1996	lambda-Cyhalothrin: Residues in plums. SOPRA. Study number 94-S015 Not GLP study Not published	
AII 6.3	Massenot F and Culoto B	1985	Recherche de Residus de PP321 dans des Raisins. ICI Protection de l'Agriculture, Bernay Report Series: E 28-EP, E 29-EP, R 29-EP. Not GLP study Not published	France (9/5/86), Greece (2/87), Italy (30/12/92), Luxembourg (2/93).
AII 6.3	Massenot F and Culoto B	1987a	Recherche de Residus de <i>Lambda</i> cyhalothrine dans des Pommes. ICI Protection de l'Agriculture, Bernay Report S 55 FP. Not GLP study Not published	Austria (18/7/91), France (2/87), Italy (30/12/92).
AII 6.3	Massenot F and Culoto B	1987b	Recherche de Residus de <i>lambda</i> cyhalothrine dans des Poireaux. ICI Protection de l'Agriculture Report Bernay E 19 GP, S 04 GP. RIC1763. Not GLP study Not published	Belgium (23/2/94), France (3/88), Italy (30/12/92).
AII 6.3	Massenot F and Culoto B	1987c	Recherche de Residus de <i>Lambda</i> cyhalothrine dans des Artichauts. ICI Protection de l'Agriculture Report Bernay S 11 GP. RIC1765. Not GLP study Not published	France (3/88), Italy (30/12/92).
AII 6.3	Massenot F and Culoto B	1988a	Recherche de Residus de <i>Lambda</i> cyhalothrine dans des Fraises. ICI Protection de l'Agriculture Report Bernay S 03 GP. Not GLP study Not published	Austria (18/7/91), Denmark (8/89), Finland (7/7/93), France (3/88), Italy (30/12/92).

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
AII 6.3	Massenot F and Culoto B	1988b	Recherche de Residus de ICIA0321 dans des Fraises. ICI Protection de l'Agriculture Report Bernay SE 042 HP. Not GLP study Not published	Finland (7/7/93), France (3/88), Italy (30/12/92).
AII 6.3	Massenot F and Culoto B	1988c	Recherche de Residus de <i>Lambda</i> cyhalothrine dans des Epinards. ICI Protection de l'Agriculture Report Series S03GP. RIC1766. Not GLP study Not published	France (3/88).
AII 6.3	Murnane D and Sapiets A	1987	PP321:- Residue Levels in Celery from a Trial carried out in Italy during 1986. Jealott's Hill Research Station Report Series: M4493B. GLP study Not published	France (3/88), Italy (30/12/92).
AII 6.3	Ruskin Y and Sapiets A	1986	PP321:- Residue Levels on Lentils from a Trial carried out in Italy during 1986. Jealott's Hill Research Station Report Series M4374B. GLP study Not published	Italy (30/12/92).
AII 6.3	Ruskin Y, Tyldesley and Sapiets A	1986	Residue Levels in Cereals from 1985 trials in Germany. ICI Plant Protection Products. Report Series: M4146B. Not GLP study Not published	
AII 6.3	Ryan J and Sapiets A	1993	<i>Lambda</i> -cyhalothrin: Residue Levels in Hops from Trials carried out in Germany during 1992. Jealott's Hill Research Station Report Series: RJ1484B. GLP study Not published	Belgium (17/3/94).
AII 6.3	Sapiets A	1984	PP321:- Residue Levels on Apricots from a 1984 Trial in Greece. Jealott's Hill Research Station Report Series: M3964B. GLP study Not published	Greece (2/87), Italy (20/5/87).
AII 6.3	Sapiets A	1985c	PP321:- Residue Levels in sugar and fodder beets from 1984 trials in Denmark. ICI Plant Protection Division Report Series: M4011B. Not GLP study Not published	Denmark, France (5/90), Italy (30/12/92).

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
AII 6.3	Sapiets A	1985d	PP321:- Residue Levels in Wheat and Barley 1984 trials in France. ICI Plant Protection Products. Report Series: M3908B. Not GLP study Not published	
AII 6.3	Sapiets A	1985e	PP321:- Residue Levels on Apples from a 1984 Trial in Greece. Jealott's Hill Research Station Report Series: M3997B. GLP study Not published	Greece (2/87), Italy (30/12/92).
AII 6.3	Sapiets A	1985f	PP321:- Residue Levels in Stone Fruits from 1984 Trials in Canada. Jealott's Hill Research Station Report Series: M4004B. GLP study Not published	France (2/87).
AII 6.3	Sapiets A	1985g	PP321: - Residue Levels on Cabbage from 1984 Trials in the United Kingdom. Jealott's Hill Research Station Report Series: M3933B. GLP study Not published	Denmark (26/4/89), Finland (18/1/93), France (9/5/86), Italy (30/12/92), Sweden (30/5/91), UK (14/2/90).
AII 6.3	Sapiets A	1985h	PP321: Residue Levels in Potatoes from a 1984 trial in Greece. Jealott's Hill Research Station Report Series: M4027B. GLP study Not published	Greece (2/87), the Netherlands (5/2/94).
AII 6.3	Sapiets A	1986a	PP321: - Residue Trials on Pears from trials carried out in the United Kingdom during 1985. ICI Plant Protection Division Report Series: M4280B. Not GLP study Not published	Denmark.
AII 6.3	Sapiets A	1986b	PP321:- Residue Levels on Apples from Trials carried out in the United Kingdom During 1985. Jealott's Hill Research Station Report Series: M4279B. GLP study Not published	Austria (18/7/91), France (2/87).
AII 6.3	Sapiets A	1986c	PP321: Residue Levels on Cabbage from a 1985 Trial in the United Kingdom. Jealott's Hill Research Station Report Series: M4278B. GLP study Not published	Denmark (26/4/89), Sweden (30/5/91).

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
AII 6.3	Sapiets A	1987a	PP321: Residue Levels in Pears from Trials carried out in Greece during 1986. ICI Plant Protection Division Report Series: M4494B. Not GLP study Not published	Greece (5/87), Italy (30/12/92).
AII 6.3	Sapiets A	1987b	PP321:-Residue Levels in Blackcurrants from Trials carried out in the United Kingdom during 1986. Jealott's Hill Report Series: M4490B. Not GLP study Not published	Austria (18/7/91), Denmark (8/89), France (3/88), Italy (30/12/92).
AII 6.3	Sapiets A	1987c	PP321: Residue Levels on Eggplant (Aubergine) from a Trial carried out in Italy during 1986. Jealott's Hill Research Station Report Series: M4392B. GLP study Not published	Italy (30/12/92).
AII 6.3	Tummon OJ and Bonfanti F	1996a	Residue Levels in Pears from Trials carried out in Italy 1994. Zeneca Agrochemicals. Jealott's Hill Research Station. Report Series: RJ2103B. GLP study Not published	
AII 6.3	Tummon OJ and Bonfanti F	1996b	Residue Levels in Cherries from a Trial carried out in Italy during 1994. Zeneca Agrochemicals. Jealott's Hill Research Station. Report Series: RJ2125B. GLP study Not published	
AII 6.3	Tummon OJ and Bonfanti F	1996c	Residue Levels in Courgettes from Trials carried out in Italy during 1994. Zeneca Agrochemicals. Jealott's Hill Research Station. Report Series: RJ2126B. GLP study Not published	
AII 6.3	Tummon OJ and Bonfanti F	1996d	Residue Levels in Melons from Trials carried out in Italy during 1994. Zeneca Agrochemicals. Jealott's Hill Research Station. Report Series: RJ2123B. GLP study Not published	
AII 6.3	Tummon OJ and Sapiets A	1987	PP321: Residue Levels on Strawberries from trials carried out in Canada during 1986. Jealott's Hill Research Station Report Series M4401B. Not GLP study Not published	Austria (18/7/91), France (3/88).

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
AII 6.3	Tummon OJ and Sapiets A	1989	<i>Lambda</i> cyhalothrin:- Residue Levels in Hops from Trials carried out in France during 1987. Jealott's Hill Research Station Report Series: M4894B GLP study Not published	France (4/91).
AII 6.3	Tummon OJ, Taylor PS and Volpi E	1996	Residue Levels in Cauliflower from a Trial carried out in Italy during 1994. Zeneca Agrochemicals. Jealott's Hill Research Station. Report Series: RJ2044B. GLP study Not published	
AII 6.3	Tummon OJ, Volpi E and Bonfanti F	1996	Residue Levels in Peaches from a Trial carried out in Italy 1994. Zeneca Agrochemicals. Jealott's Hill Research Station. Report Series: RJ2104B. GLP study Not published	
AII 6.3	Tyldesley DJ and Sapiets A	1985a	PP321: Residue Levels in Field Peas from 1984 Trials in the United Kingdom. Jealott's Hill Research Station Report Series: M4089B. GLP study Not published	Belgium (23/2/94), Denmark (26/4/89), Finland (18/1/93), Italy (30/12/92), Sweden (30/5/91), UK (14/2/90).
AII 6.3	Yearsdon C and Sapiets A	1986a	PP321: - Residue Levels on Cherries from a 1985 Trial in Germany. Jealott's Hill Research Station Report Series: M4238B. GLP study Not published	Austria (18/7/91), France (2/87), Italy (30/12/92).
AII 6.3	Yearsdon C and Sapiets A	1986b	PP321: - Residue Levels in Plums from Trials carried out in Germany during 1985. Jealott's Hill Research Station Report Series: M4284B. GLP study Not published	Austria (18/7/91), Denmark (8/89), France (2/87), Italy (30/12/92), Sweden (27/12/94).
AII 6.3	Yearsdon C and Sapiets A	1986c	PP321: - Residue Levels on Peas from Trials carried out in Germany during 1985. Jealott's Hill Research Station Report Series: M4287B. GLP study Not published	Belgium (23/2/94), Denmark (26/4/89), Sweden (30/5/91).
AII 6.4	Eckstein CL and Francis PD	1992	<i>lambda</i> -Cyhalothrin (ICIA0321): Residue Levels of the Major Metabolites in Dairy Cows fed on a Diet containing the Insecticide. Western Research Center Report Series RR 92-028B. Not GLP study Not published	

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
AII 6.4	Sapiets A	1985i	PP321: Residue Transfer Study with Dairy Cows fed on a Diet containing the Insecticide. Jealott's Hill Research Station Report Series M3936B. GLP study Not published	Austria (18/7/91), Finland (18/1/93), France (6/91), Italy (30/12/92), the Netherlands (7/4/92), Sweden (30/5/91).
AII 6.4	Sapiets A	1986d	PP321: Residue Transfer Study with Laying Hens fed on a Diet containing the Insecticide. Jealott's Hill Research Station Report Series RJ0473B. GLP study Not published	
AII 6.5	Gillespie PS	1990	ICIA0321 (<i>lambda</i> -cyhalothrin) - Magnitude of the residue study in processed tomato products. Western Research Center, Richmond, California Report Series RR 90-419B. Not GLP study Not published	
AII 6.5	Grant CL and Francis PD	1991	ICIA0321 (<i>lambda</i> -cyhalothrin) - Magnitude of the residue study on processed field corn products. Western Research Center, Richmond, California Report Series RR 91-027B. Not GLP study Not published	
AII 6.5	McKay JC	1991a	<i>lambda</i> -Cyhalothrin (ICIA0321) -Magnitude of the residue study on processed wheat products. Western Research Center, Richmond, California Report Series RR 90-424B. GLP study Not published	
AII 6.5	McKay JC	1991b	Karate ^R (<i>lambda</i> -cyhalothrin) - Magnitude of the residue study on processed sorghum products. Western Research Center, Richmond, California Report Series RR 90-426B. GLP study Not published	
AII 6.5	McKay JC	1991c	ICIA0321 (<i>lambda</i> -cyhalothrin) -Magnitude of the residue study on processed soybean products. Western Research Center, Richmond, California Report Series RR 91-048B. GLP study Not published	

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
AII 6.5	Neal J	1985	PP321 residues in the process fractions of cottonseed. ICI Americas Report Series TMU1805. Not GLP study Not published	

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
AII 7.1.1.1.1 AII 7.1.1.1.2 AII 7.1.1.2.1	Bharti H, Bewick DW and White RD	1985	PP563 and PP321: Degradation in Soil. ICI Report Series RJ 0382B GLP study Not published	Submitted in all Member States except Belgium, France, Greece, Ireland, Luxembourg, the Netherlands, Portugal & Spain.
AII 7.1.1.1.2	Parker S and Leahey JP	1986	PP321: Photodegradation on a Soil Surface. ICI Report Series RJ 0537B GLP study Not published	Denmark, Germany (25/10/90), Sweden (30/5/91).
AII 7.1.1.2.2 AIII 9.1.1.2	Bewick DW, Bartlett DW and Hendley P	1986	PP321: Fate of Radiolabelled Material in Soil under Field Conditions. ICI Report Series RJ 0529B GLP study Not published	Austria (18/7/91), Germany (25/10/90), Italy (30/12/92).
AII 7.1.1.2.2 AIII 9.1.1.2	Burke S and Sapiets A	1990	lambda-Cyhalothrin: Soil Dissipation Studies (West Germany 1989). ICI Report Series RJ 0879B GLP study Not published	Germany (25/10/90).
AII 7.1.1.2.2 AIII 9.1.1.2	Fitzpatrick RD	1985	PP321 Dissipation in US Soils -1983. ICI Report Series TMU1809 Not GLP study Not published	
AII 7.1.2	Vickers JA and Bewick DW	1986	PP321: Adsorption and Desorption in Soil. ICI Report Series RJ 0535B GLP study Not published	Austria (18/7/91), Italy (30/12/92), the Netherlands.
AII 7.1.3.1 AIII 9.1.2.1	Clarke DM and Sapiets A	1993	lambda-Cyhalothrin: Leaching of Formulated Material in Soil Columns. ICI Report Series RJ 1447B GLP study Not published	
AII 7.1.3.2	Stevens JEB and Bewick DW	1985	PP563 and PP321: Leaching of PP563 and PP321 and their Degradation Products in Soil Columns. ICI Report Series RJ 0408B GLP study Not published	Submitted in all Member States except Belgium, France, Greece, Ireland, Luxembourg, Portugal & Spain.

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
AII 7.2 AII 8.2 AII 8.3	Maund SJ	1998	<i>Lambda</i> -cyhalothrin. Response of ZENECA to National Chemicals Inspectorate (KEMI) Appendix 3 to <i>Lambda</i> -cyhalothrin 5684/VI/97 rev 5 (September 1998). Zeneca Agrochemicals Report No. RAJ0003B. GLP not relevant Not published	
AII 7.2 AII 8.2 AIII 10.2.2	Farmer D, Coulson JM, Runnalls JK, Hill SE, McIndoe EC and Hill IR	1993	<i>lambda</i> -Cyhalothrin and Cypermethrin: Evaluation and Comparison of the Impact of Multiple Drift Applications on Aquatic Ecosystems (Experimental Ponds). ICI Report Series RJ 0571B GLP study (with deviations) Not published	
AII 7.2 AII 8.2 AIII 10.2.2	Kennedy JH, Cole JFH, Ekoniak P, Hadfield ST, Sadler JK, Francis PD, Moore M and Hill IR	1988	PP321: Evaluation of the Impact of the Run-off and Spray-frift on Aquatic Ecosystems, Using USA Experimental ponds (Mesocosms). ICI Plant Protection Division Report No. RJ0614B. GLP study Not published	
AII 7.2.1.2 AII 7.2.1.3.2	Hall JS and Leahey JP	1983	Cyhalothrin: Fate in River Water. ICI Report Series RJ 0320B Not GLP study Not published	Austria (18/7/91), Denmark, Finland (18/1/93), Germany (25/10/90), the Netherlands, Sweden (30/5/91).
AII 7.2.1.3.2	Hand LH and Mehta P	1998a	<i>Lambda</i> -cyhalothrin: Degradation in an Aquatic Microcosm. Zeneca Agrochemicals Report No. RJ2730B. GLP study Not published	
AII 7.2.1.3.2	Hand LH and Mehta P	1998b	<i>Lambda</i> -cyhalothrin: Metabolism in Aquatic Plants. Zeneca Agrochemicals Report No. RJ2626B. GLP study Not published	
AII 7.2.1.3.2	Hamer MJ and Goggin UM	1997	<i>Lambda</i> -cyhalothrin: Dissipation from water in a sediment-water system. Zeneca Agrochemicals Report No. RJ2369B. GLP study Not published	
AII 7.2.1.3.2	Kuet SF	1998	<i>Lambda</i> -Cyhalothrin: Adsorption and desorption in Aquatic Plants. Zeneca Agrochemicals Report No. RJ2716B. GLP study Not published	

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AII 7.2.1.3.2	Marriott SH, Duley J, Hand L	1998	Lambda-cyhalothrin: Degradation in Water-sediment Systems Under Laboratory Conditions. Zeneca Agrochemicals Report No. RJ2640B. GLP study Not published	
AII 7.1.1.2.1	Chongtie S, Ericson J	1998	[¹⁴ C]R211133 (Ref.XV), a metabolite of LAMBDA-CYHALOTHRIN: Rate of degradation in soil under aerobic laboratory conditions (WRC-98-040B (WINo 32874). Zeneca Agrochemicals Report No. RR 98-019B GLP study Not published	Netherlands (25/9/98).
AII 7.1.2	Feeney E, Lane MCG	1998	Adsorption and desorption properties of compound XV (R211133), a soil degradate, in six soils. Zeneca Agrochemicals Report No. RJ2622B GLP study Not published	Netherlands (25/9/98).

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
AII 8.1.1	Roberts NL, Fairley C	1984	The acute oral toxicity (LD ₅₀) of PP321 to the mallard duck. Huntingdon Research Centre Report No. ICI438 BT/831011. CTL/C/1240. GLP study Not published	Submitted in all Member States except Greece, Ireland, Luxembourg & Portugal.
AII 8.1.2	Roberts NL, Fairley C, Anderson A and Dawe IS	1985	The subacute dietary toxicity of PP321 to the bobwhite quail. Huntingdon Research Centre Report No. ISN 45BT/841287. CTL/C/1358. GLP study Not published	Austria (18/7/91), Denmark, Finland (18/1/93), Germany (19/4/89), Italy (30/12/92), Sweden (30/5/91), UK (14/2/90).
AII 8.1.3	Beavers JB, Hoxter KA and Jaber MJ	1989	PP321: A one-generation reproduction study with the mallard (<i>Anas platyrhynchos</i>). Wildlife International Report No: 123-143. GLP study Not published	Germany (25/10/90).
AII 8.1.3	Gorder GW	1990	Measurement of PP321 Levels in Feed Used in a One-Generation Reproduction Study with the Mallard (<i>Anas platyrhynchos</i>). Western Research Center Report No. 89-242. RR 89-059B GLP study Not published	
AII 8.2.1	Hill RW	1984a	PP321 : Determination of acute toxicity to rainbow trout (<i>Salmo gairdneri</i>). Brixham Laboratory Report BL/B/2405. GLP study Not published	Submitted in all Member States except Greece, Ireland, Luxembourg & Portugal.
AII 8.2.1	Hill RW	1984b	PP321: Determination of acute toxicity to bluegill sunfish (<i>Lepomis macrochirus</i>). Brixham Laboratory Report BL/B/2406. GLP study Not published	Submitted in all Member States except Belgium, Greece, Ireland, Luxembourg, Portugal & Spain.
AII 8.2.1	Hill RW	1984c	PP890: Determination of the acute toxicity to rainbow trout (<i>Salmo gairdneri</i>). Brixham Laboratory Report No. BL/B/2457. GLP study Not published	Germany, the Netherlands.

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AII 8.2.1	Hill R and Young BE	1981a	Determination of the acute toxicity of 3-Phenoxybenzoic acid to Rainbow trout (<i>Salmo gairdneri</i>). ICI Brixham Laboratory report No. BL/B/2038. Not GLP study Not published	Germany, the Netherlands.
AII 8.2.1	Hill R and Young BE	1981b	Determination of the acute toxicity of 3-Phenoxybenzoic acid to Bluegill sunfish (<i>Lepomis macrochirus</i>). ICI Brixham Laboratory Report No. BL/B/2086. Not GLP study Not published	Germany, the Netherlands.
AII 8.2.1	Tapp JF and Caunter JE	1987	PP890: Determination of the acute toxicity to bluegill sunfish (<i>Lepomis macrochirus</i>). Brixham Laboratory Report No. BL/B/3029. GLP study Not published	Germany, the Netherlands.
AII 8.2.2.1	Hill RW, Caunter JE and Cumming RI	1985	PP321: Determination of the chronic toxicity to sheepshead minnow (<i>Cyprinodon variegatus</i>) embryos and larvae. Brixham Laboratory Report No. BL/B/2677. GLP study Not published	France (2/87), Germany (25/10/90).
AII 8.2.3	Hamer MJ and Hill IR	1985	Cyhalothrin : The accumulation of cyhalothrin and its degradation products by channel catfish and <i>Daphnia magna</i> in a soil/water system. ZENECA Agrochemicals Report No. RJ0427B. GLP study Not published	Denmark, Finland (18/1/93), Germany (25/10/90), Sweden (30/5/91).
AII 8.2.3	Yamauchi F	1984	PP563 (Cyhalothrin) : Accumulation in fish (carp) in a flow-through water system. MITES Report No. 58-367. RIC2139. GLP study Not published	Germany (25/10/90).
AII 8.2.4	Everett CJ, Hamer MJ and Hill IR	1983	3-Phenoxybenzoic acid: Toxicity to first instar <i>Daphnia magna</i> (II). ICI Plant Protection Division report No. RJ0318B. Not GLP study Not published	Germany, the Netherlands.
AII 8.2.4	Farrelly E, Hamer M J and Hill IR	1984	PP321 : Toxicity to first instar <i>Daphnia magna</i> . Jealott's Hill Research Station Report No RJ0359B. GLP study Not published	Submitted in all Member States except Greece, Ireland, Luxembourg, Portugal & Spain.

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AII 8.2.4	Goggin UM, Hamer MJ	1998	Lambda-Cyhalothrin. Acute toxicity of short-term exposures to <i>Gammarus pulex</i> . Zeneca Agrochemicals Report No. RJ2542B. GLP study Not published	
AII 8.2.4	Hamer MJ and Goggin UM	1998a	Lambda-cyhalothrin: Acute toxicity to different life-stages of <i>Gammarus pulex</i> . Zeneca Agrochemicals Report No. RJ2483B. GLP study Not published	
AII 8.2.4	Hamer MJ and Goggin UM	1998b	Lambda-cyhalothrin: Acute toxicity to <i>Gammarus pulex</i> in a sediment-water system. Zeneca Agrochemicals Report No. RJ2484B. GLP study Not published	
AII 8.2.4	Yamauchi F and Shigeoka T	1984	PP-563 ("Cyhalothrin acid"): Acute toxicity to <i>Daphnia magna</i> . Mitsubishi-Kasei Institute of Toxicological and Environmental Sciences (MITES) Report No. 58-367. GLP study Not published	Germany, the Netherlands.
AII 8.2.5	Farrelly E and Hamer MJ	1989	PP321 : <i>Daphnia magna</i> life-cycle study using a flow-through system. Jealott's Hill Research Station Report No RJ0764B. GLP study Not published	Germany, the Netherlands.
AII 8.2.5	Kedwards TJ	1998a	A Stage-Structured Ecological Model of the Freshwater Amphipod <i>Gammarus pulex</i> (L.). Zeneca Agrochemicals Report No. TMJ4047B. GLP not relevant Not published	
AII 8.2.5	Kedwards TJ	1998b	Lambda-cyhalothrin: Ecological modelling of effects on and recovery of <i>Gammarus pulex</i> (L.) populations. Zeneca Agrochemicals Report No. TMJ4155B. GLP not relevant Not published	
AII 8.2.6	Thompson RS and Williams TD	1985	PP321 : Toxicity to the green alga <i>Selenastrum capricornutum</i> . Brixham Laboratory Report No BL/B/2584. GLP study Not published	Denmark, Finland (18/1/93), Germany (19/4/89), the Netherlands, Sweden (30/5/91).

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AII 8.2.7	Hamer M and Gentle W	1997	Lambda-cyhalothrin: Sediment Toxicity Test with <i>Chironomus riparius</i> . Zeneca Agrochemicals Report No. RJ2227B. GLP study Not published	
AII 8.2.7	Hamer MJ and Rapley JH	1997	Lambda-cyhalothrin: BBA Toxicity Test with Sediment-dwelling <i>Chironomus riparius</i> . Zeneca Agrochemicals Report No. RJ2234B. GLP study Not published	
AII 8.2.7	Muller K, Hamer MJ, Goggin U and Lane MCG	1995	Lambda-Cyhalothrin: Bioavailability and Bioconcentration by <i>Chironomus riparius</i> in in Water-only and Sediment/Water Systems. Zeneca Agrochemicals Study No. RJ1933B. GLP study Not published	
AII 8.3.1 AIII 10.4.1	Gough HJ, Collins IG, Everett CJ and Wilkinson W	1984	PP321: Acute Contact and Oral Toxicity to Honey Bees (<i>Apis mellifera</i>). Jealott's Hill Research Station Report No. RJ0390B. GLP study Not published	Submitted in all Member States except Germany, Greece, Ireland, Luxembourg, Portugal & Spain.
AII 8.3.1 AIII 10.4.4	Gough HJ, Collins IG and Wilkinson W	1985	PP321: Field Test of Toxicity to Honey Bees (<i>Apis mellifera</i>) on Flowering Oilseed Rape (<i>Brassica napus</i>). Jealott's Hill Research Station Report No. RJ0413B. GLP study Not published	Submitted in all Member States except Germany, Greece, Ireland, Luxembourg, Portugal & Spain.
AII 8.3.1 AIII 10.4.5	Gough HJ, Collins IG and Wilkinson W	1986	PP321: Effects on Honey Bees (<i>Apis mellifera</i>) Foraging on Simulated Honeydew on Winter Wheat, 1985. Jealott's Hill Research Station Report No. RJ0464B. GLP study Not published	Greece (2/87), Italy (30/12/92), the Netherlands, Sweden (30/5/91).
AII 8.3.1 AIII 10.4.4	Nengel S	1999	Assessment of Side Effects of Karate WG on the Honey Bee (<i>Apis mellifera</i> L.) in the Field Following Application during Bee-Flight in Spain. Report code: 98139/S1-BFEU/C. GLP study Not published	
AII 8.3.2 AIII 10.5.1	Busschers M and Farrelly LC	1994a	Lambda-cyhalothrin: Laboratory Test on the Effects of 3 Different Formulations on predatory Lycosid Spiders (Lycosidae, Araneae). Jealott's Hill Research Station Report No. RJ1580B. GLP study Not published	

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AII 8.3.2 AIII 10.5.1	Busschers M and Farrelly LC	1994b	<i>Lambda-cyhalothrin</i> : Laboratory Test on the Effects of 3 Different Formulations on the Carabid Beetle <i>Poecilus cupreus</i> . Jealott's Hill Research Station Report No. RJ1579B. GLP study Not published	
AII 8.3.2 AIII 10.5.1	Deprez C and McMullin LC	1993	<i>Lambda-cyhalothrin</i> : Investigation into the Toxicity of a 5% WG Formulation to the Larvae of the Hoverfly <i>Episyrphus balteatus</i> De Geer. Jealott's Hill Research Station Report No. RJ1399B. GLP study Not published	Italy (30/12/92).
AII 8.3.2 AIII 10.5.1	Everett CJ and Cole JFH	1993a	<i>Lambda-cyhalothrin</i> : Laboratory Test on the Effects on the Ground Beetle <i>Pterostichus melanarius</i> . Jealott's Hill Research Station Report No. RJ1327B. GLP study Not published	
AII 8.3.2 AIII 10.5.1	Everett CJ and Cole JFH	1993b	<i>Lambda-cyhalothrin</i> : Laboratory Test on the Effects on Lycosid spiders. Jealott's Hill Research Station Report No. RJ1329B. GLP study Not published	
AII 8.3.2 AIII 10.5.2	McMullin LC, Everett CJ, White JS and Brown RA	1991	<i>Lambda-cyhalothrin</i> : Effects of a summer application to cereals on the beneficial arthropod fauna. Jealott's Hill Research Station Report No. RJ0956B. GLP study Not published	Italy (30/12/92).
AII 8.3.2 AIII 10.5.2	McMullin LC, Everett CJ, Canning L and Brown RA	1992	<i>Lambda-cyhalothrin</i> : The Effects of a Summer Application on the Beneficial Arthropod Fauna in Cereals Using Three Different Spray Rates. Jealott's Hill Research Station Report No. RJ1250B. GLP study Not published	Austria (18/7/91), Germany (25/10/90).
AII 8.3.2 AIII 10.5.2	Pilling ED	1995	<i>Lambda-cyhalothrin</i> : A Study of the Effects on Natural Enemies of Rice Insect pests in the Philippines. Zeneca Agrochemicals Study No. TMJ3453B. Not GLP study Not published	

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AII 8.3.2 AIII 10.5.1	Solomon MG and Fitzgerald JD	1989	Laboratory Determination of LC ₅₀ for PP321 against <i>Panonychus ulmi</i> and <i>Typhlodromus pyri</i> . Undertaken for ICI Agrochemicals. AFRC Institute of Horticultural Research Not GLP study Not published	Germany (25/10/90), Italy (30/12/92).
AII 8.3.2	White JS, Boersma AHR and Brown RA	1989	PP321: Laboratory LD ₅₀ Test on the Aphid Pest <i>Rhopalosiphum padi</i> and a Range of its Enemies. Jealott's Hill Research Station Report No. RJ0686B. GLP study Not published	Austria (18/7/91), Germany (25/10/90), Italy (30/12/92).
AII 8.3.2 AIII 10.5.2	White JS and Brown RA	1992	Lambda-cyhalothrin: Effects of application in soybean on the principal target pests and their key natural enemies. ICI Agrochemicals Report No. TMJ2969A. Not GLP study Not published	
AII 8.3.2 AIII 10.5.2	White JS, Everett CJ, Jackson DJ and Brown RA	1989	PP321 : Effects of autumn application to cereals on the beneficial arthropod fauna. Jealott's Hill Research Station Report No. RJ0728B. GLP study Not published	Austria (18/7/91), Germany (25/10/90).
AII 8.3.3	Yearsdon HA, Coulson JM and Edwards PJ	1993	Lambda-cyhalothrin: Toxicity to the Earthworm <i>Eisenia foetida</i> . Jealott's Hill Research Station Report No. TMJ3062B. Not GLP study Not published	
AII 8.3.4	Aze CJ, Tarry AR and Lewis FJ	1990	PP321: Studies on Microorganisms and their Activities in Soil. Jealott's Hill Research Station Report No. RJ0853B. GLP study Not published	Germany (25/10/90).
AII 8.3.5	Rea D, Mannion SK, Martin EA and Hill IR	1989	PP321 : Effects on the Plants in the Weed Science and Plant Growth Regulator Screens of the Biological Group. ICI Agrochemicals unpublished Report No. RJ0565B. GLP study Not published	Germany (25/10/90).

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AII 8.3.5	Rea D, Palk MS, Spinney MA and Hill IR	1990	PP321 : Effects on the Plant Pathogens and Invertebrate Pests in the Plant Pathology and Entomology Screens of the Biological Group. ICI Agrochemicals unpublished Report No. RJ0549B. GLP study Not published	