



beta-Cyfluthrin

6841/VI/97-final

2 December 2002

Review report for the active substance *beta*-cyfluthrin

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 3 December 2002 in view of the inclusion of *beta*-cyfluthrin 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 *beta*-cyfluthrin, made in the context of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

Commission Regulation (EEC) No 3600/92⁽¹⁾ laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, as last amended by Regulation (EC) No 2266/2000⁽²⁾, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. *beta*-cyfluthrin 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, Bayer AG on 21 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance *beta*-cyfluthrin 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 Germany as rapporteur Member State to carry out the assessment of *beta*-cyfluthrin on the basis of the dossier submitted by the notifier. 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 *beta*-cyfluthrin this deadline was 30 April 1995.

¹ OJ No L 366, 15.12.1992, p.10.

² OJ No L 259, 13.10.2000, p.27.

³ OJ No L 107, 28.04.1994, p.8.

⁴ OJ No L 225, 22.09.1995, p.1.

Only Bayer AG submitted in time a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore Bayer AG was considered to be the main data submitter. No information has furthermore been submitted by third parties.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Germany submitted on 4 November 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 *beta*-cyfluthrin 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 *beta*-cyfluthrin from Bayer AG, on 22 January 1997.

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 Bayer AG being the main data submitter, on 13 November 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 January to April 1997.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the main data submitter on 10 April 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 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 September 1998 to December 2002, and was finalised in the meeting of the Standing Committee on 3 December 2002.

The draft assessment report and further information were also submitted to the Scientific Committee for Plants for separate consultation. The Committee was asked to comment on the appropriate dietary risk assessment to be used and to confirm that the available ecotoxicological data supports uses only in glasshouses and for seed treatment. In its opinion⁵ the Committee suggested that in addition to a long-term dietary intake risk assessment, as routinely carried out

⁵ Opinion of the scientific Committee on Plants regarding the inclusion of beta-cyfluthrin in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market. (Opinion expressed by the Scientific Committee on Plants, 28 January 2000)

for plant protection products, *beta*-cyfluthrin should also undergo a short-term acute dietary risk assessment due to its potential neurotoxicity properties. The Committee confirmed that uses as seed dressing and in greenhouses (except where beneficial arthropods are used) can be considered safe for non-target terrestrial and aquatic organisms, due to the specific circumstances of these applications and the immobility of *beta*-cyfluthrin in soil. The Committee supported the conclusions reached by Member States that field spray applications have not been shown to be sufficiently safe. Following the opinion of the Committee the short term dietary risk assessment was subsequently provided and discussed with the Member States.

The present review report contains the conclusions of the final examination; given the importance of the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications submitted after the peer review as basic information for the final examination process, these documents are considered respectively as background documents A, B and C to this review report and are part of it.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, have been developed and finalised in support of the Directive **2003/31/EC**⁶ concerning the inclusion of *beta*-cyfluthrin in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing *beta*-cyfluthrin 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.

⁶ OJ N° L101, 23.4.03, p. 3.

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 *beta*-cyfluthrin 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 *beta*-cyfluthrin 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:

- insecticide for ornamentals in greenhouse
- seed treatments

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. Indeed the evaluation concluded that uses of *beta*-cyfluthrin other than ornamentals in greenhouses and seed treatments are currently not adequately supported and have not shown to be acceptable under the criteria required by Annex VI. To support authorisations for such uses, data and information to prove their acceptability to human consumers and the environment will have to be generated and submitted to the Member States. This will be the case in particular for data to assess in all detail the risks of outdoor foliar uses of *beta*-cyfluthrin and the dietary risks of foliar treatments in edible crops.

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 *beta*-cyfluthrin 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 Bayer AG none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

5. Endpoints and related information

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

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

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 should pay particular attention to the protection of non-target arthropods. Conditions of authorisation should include adequate risk mitigation measures.

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 *beta*-cyfluthrin in Annex I under the current inclusion conditions.

To support authorisations for use under certain conditions and any expansion of the use range evaluated, additional studies will have to be generated or submitted to the Member States. This will be the case in particular for data to assess in all detail the environmental risks of outdoor foliar uses and the dietary risks of foliar treatments in edible crops. As for other pyrethroids confirmatory data to further address concerns related to potential developmental neurotoxicity should be generated, when internationally agreed testing protocols are available.

Further, the following points were identified, which may require the submission of additional information:

- Further improved analytical methods for body fluids, surface water and air.

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.

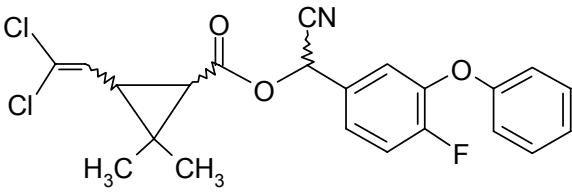
9. Updating of this review report

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 *beta*-cyfluthrin in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

beta-CYFLUTHRIN

Common name (ISO)	<i>beta</i> -Cyfluthrin
Chemical name (IUPAC)	(1 <i>R</i> ,3 <i>R</i> ; <i>S</i> ;1 <i>R</i> ,3 <i>S</i>)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylic acid (<i>S</i>)- α -cyano-(4-fluoro-3-phenoxy-phenyl)methyl ester
Chemical name (CA)	3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylic acid cyano-(4-fluoro-3-phenoxyphenyl)methyl ester
CIPAC No	482
CAS No	68359-37-5 (unstated stereochemistry)
EEC No	269-855-7
FAO SPECIFICATION	In print
Minimum purity	965 g/kg
<p><u>Ratio of Isomers</u></p> <p>Beta-cyfluthrin is a mixture of four diastereomers and the ratio of the diastereomers - normalised on the sum of the four diastereomers - shall be:</p> <p>Diastereomer I (1<i>R</i>,3<i>R</i>,α<i>R</i> + 1<i>S</i>,3<i>S</i>,α<i>S</i> = 1:1; <i>cis</i>): max. 2.0 %</p> <p>Diastereomer II (1<i>R</i>,3<i>R</i>,α<i>S</i> + 1<i>S</i>,3<i>S</i>,α<i>R</i> = 1:1; <i>cis</i>): 30.0 – 40.0 %</p> <p>Diastereomer III (1<i>R</i>,3<i>S</i>,α<i>R</i> + 1<i>S</i>,3<i>R</i>,α<i>S</i> = 1:1; <i>trans</i>): max. 3.0 %</p> <p>Diastereomer IV (1<i>R</i>,3<i>S</i>,α<i>S</i> + 1<i>S</i>,3<i>R</i>,α<i>R</i> = 1:1; <i>trans</i>): 57.0 – 67.0 %</p>	
Impurities	No relevant impurities specified
Molecular formula	C ₂₂ H ₁₈ Cl ₂ FNO ₃
Molecular mass	434.3
<p>Structural formula</p>  <p>Diastereoisomer II (1<i>R</i>,3<i>R</i>, α<i>S</i> + 1<i>S</i>,3<i>S</i>, α<i>R</i> = 1:1; <i>cis</i>)</p> <p>Diastereoisomer IV (1<i>R</i>,3<i>S</i>, α<i>S</i> + 1<i>R</i>,3<i>S</i>, α<i>R</i> = 1:1; <i>trans</i>)</p>	

Melting point	Isomer II: 80.7 °C Isomer IV: 106.2 °C
Boiling point	Decomposition above 210 °C
Appearance	Both isomers: colourless crystals
Relative density	1.346
Vapour pressure	Isomer II: $1.4 \cdot 10^{-8}$ Pa at 20 °C Isomer IV: $8.5 \cdot 10^{-8}$ Pa at 20 °C
Henry's law constant	Isomer II: $3.2 \cdot 10^{-3}$ Pa·m ³ ·mol ⁻¹ Isomer IV: $1.3 \cdot 10^{-2}$ Pa·m ³ ·mol ⁻¹
Solubility in water	At 20 °C (pH unspecified but not important due to low solubility): Isomer II: 2.1 µg/l Isomer IV: 1.2 µg/l
Solubility in organic solvents	toluene: > 200 g/l (Isomer II) 100 - 200 g/l (Isomer IV) n-hexane: 10 - 20 g/l (Isomer II) 1 - 2 g/l (Isomer IV) 2-propanol: 5 - 10 g/l (Isomer II) 5.10 g/l (Isomer IV) dichloromethane: > 200 g/l (both isomers)
Partition co-efficient (log P_{ow})	Isomers II and IV: 5.9 at 22 °C
Hydrolytic stability (DT₅₀)	pH 4, 20°C: > 1 year (all isomers) pH 7, 20°C: 270 d (diastereomers I + II) 160 d (diastereomers III + IV) pH 9, 20°C: 42 h (diastereomers I + II) 33 h (diastereomers III + IV)
Dissociation constant	Not applicable.
Quantum yield of direct photo-transformation in water at λ >290 nm	0.0052
Flammability	not flammable
Explosive properties	not explosive
UV/VIS absorption (max.)	All isomers: final absorption only. No absorption above 290 nm.
Photostability in water (DT₅₀)	in water (pH 5, 1 % acetonitrile): DT50: 12.2 d (medium-pressure mercury lamp) DT50: < 1d (natural sunlight, August/September, Kansas, 38°49' North)

APPENDIX II

END POINTS AND RELATED INFORMATION

beta-CYFLUTHRIN

1 Toxicology and metabolism

* = studies were performed with cyfluthrin

Absorption, distribution, excretion and metabolism in mammals (*)

Rate and extent of absorption:	Rapid and almost complete (90% after 2 days)
Distribution:	Highest residues: fat, liver and kidney
Potential for accumulation:	No accumulation
Rate and extent of excretion:	Efficiently eliminated within 2 days via urine (64 %) and faeces (32 %)
Toxicologically significant compounds:	Parent compound; main metabolites identified in plants were also found in animals.
Metabolism in animals:	Extensively metabolized (>80%), basic metabolic steps are the same in animal species under investigation; main metabolite in rat: conjugate of FCR 3145, its free form and COE 538/78; cleavage of ester bond, oxidation-, hydroxylation- and conjugation reactions.

Acute toxicity

Rat LD ₅₀ oral	77 mg/kg bw
Rat LD ₅₀ dermal	>5000 mg/kg bw
Rat LC ₅₀ inhalation	0.081 mg/l air (aerosol) 0.70 mg/l air (dust)
Skin irritation	Non-irritant
Eye irritation	Non-irritant
Skin sensitization (test method used and result)	Non sensitizer (Magnusson & Kligman)

Short term toxicity

Target / critical effect:	CNS / General behavioural disturbances; axonal degeneration
Lowest relevant oral NOAEL / NOEL:	90-d dog: 60 ppm (1.5 mg/kg bw/d)
Lowest relevant dermal NOAEL / NOEL:	3-wk rabbit: 340 mg/kg bw/d *
Lowest relevant inhalation NOAEL / NOEL:	3-mo rat: 0.09 µg/l (0.0243 mg/kg bw/d)*

Genotoxicity

No genotoxic potential

Long term toxicity and carcinogenicity (*)

Target/critical effect:	Retardation in growth, alopecia
Lowest relevant NOAEL / NOEL:	24-mo oral rat: 50 ppm (2 mg/kg bw/d)*
Carcinogenicity:	No evidence of a carcinogenic potential

Reproductive toxicity (*)

Target / critical effect - Reproduction:	Reduced viability index and growth retardation of offspring at parental toxic doses, coarse tremors of pups during lactation
Lowest relevant reproductive NOAEL / NOEL:	Rat: 50 ppm (3.3 mg/kg bw/d)*
Target / critical effect - Developmental toxicity:	Miscarriage and post-implantation resorptions (rabbit) delayed ossification and decreased foetal weights (rat); effects observed only at maternal toxic doses in both species.
Lowest relevant developmental NOAEL / NOEL:	Rat: 10 mg/kg bw/d

Neurotoxicity / Delayed neurotoxicity (Annex IIA, point 5.7)

Critical effects:	Clinical signs indicative of a neurological disorder and a reversible axonal degeneration. No evidence of delayed neurotoxicity in hens.
NOAEL (acute oral neurotoxicity, rat)	2 mg/kg bw/d (aqueous vehicle)
NOAEL (90-d oral neurotoxicity, rat)	30 ppm (2 mg/kg bw/d)

Other toxicological studies (*)

Metabolites: weak acute oral toxicity, no point mutations

Medical data

Skin symptoms (paresthesia) in applicators

Summary

	Value	Study	Safety factor
ADI:	0.003 mg/kg bw	pharmacological study in mice (same endpoint as used by EMEA)	100
AOEL systemic:	0.02 mg/kg bw/d	90-d & acute oral neurotoxicity rat	100
AOEL inhalation:	0.000243 mg/kg bw/d	13-wk inhalation study in rats *	100
ARfD (acute reference dose):	0.02 mg/kg bw/d	Acute oral neurotoxicity rat (in the same order as the ADI)	100

Dermal absorption

Default value of 10 %

Remarks:

beta-cyfluthrin and cyfluthrin have the same toxicological profile. *beta*-cyfluthrin has an approximately 2 to 5 times higher acute toxicity than cyfluthrin. The NOELs of subacute and subchronic studies are in the same range. For this reason it is possible to renounce further investigations with *beta*-cyfluthrin, especially for testing long term toxicity/carcinogenicity, reproduction toxicity and neurotoxicity

* = Studies were conducted with cyfluthrin

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:

Up to 36 % after 190 d
(day 84: up to 23 %)

Non-extractable residues after 100 days:

Up to 42 % after 190 d
(day 84: up to 34 %)
(Non-extractable residues may be higher as no data were available with compound labelled in the cyclopropyl group. However, they will certainly be less than the trigger of 70 %.)

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

3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylic acid (DCVA, permethric acid): >10 %

4-fluoro-3-phenoxybenzoic acid (FPBacid): up to 10 % after 28 d (up to 31 % after 118 d under "dry" conditions)

Supplemental studies

Anaerobic:

Anaerobic conditions were imposed 30 d after aerobic conditions (18 - 22°C)
(100 % = radioactivity after 30 d of preincubation)

Mineralization: not significant

Non-extractables: up to 64 % after (30 +) 60 d

FPBacid: up to 19 % after (30 +) 30 d

DCVA: The formation of DCVA is expected, however, the percentage is unknown as no data were available with compound labelled in the cyclopropyl group.

Soil photolysis:**Sunlight:**

- Non-extractables: up to 14 % after 6 d
- 4-fluoro-3-phenoxybenzaldehyde (FPBald):
up to 18 % after 6 d
(mineralization: up to 13 % after 7 d artificial irradiation)

DT₅₀: 1st phase: 2 d
2nd phase: 7 - 16 d

Remarks:

All results from investigations with cyfluthrin.

Rate of degradation**Laboratory studies**

DT_{50lab} (20 °C, aerobic):

Active substance:

All results from investigations with cyfluthrin:

DT_{50lab} (18 - 20°C, aerobic):
48 – 54 d at > 13 % soil water content
(mean: 51 d, median: 51 d, n=4, r² = 0.918 – 0.989, kinetics of higher order: 1.5th, 2nd, root function 1.5th)

16 and 35 d at 9 - 11 % soil water content
(mean: 26 d, median: 26 d, n=2, r² = 0.982 – 0.998, kinetics of higher order: root functions 1.5th and 2nd)

DT_{50lab} (28°C, aerobic):
4 and 10 d at 60 % MWHC
(mean: 7 d, median: 7 d, n=2, r² = 0.977 – 0.978, kinetics of higher order: root functions 1st and 1.5th)

Metabolite DCVA:

DT_{50lab} (25°C, aerobic): 12 – 62 d at 40 % MWHC
(mean: 24 d, median: 16 d, 2 soils, 4 isomers, 1st order kinetics)

Metabolite FPBacid:

There was insufficient sampling for calculation, but an estimation was possible:

DT₅₀ (FPBacid) < DT₅₀ (DCVA)

DT_{90lab} (20 °C, aerobic):Active substance:

All results from investigations with cyfluthrin:

DT_{90lab} (18 - 20°C, aerobic):

253 – 1664 d at > 13 % soil water content

(mean: 611 d, median: 363 d, n=4, r² = 0.918 – 0.989, kinetics of higher order: 1.5th, 2nd, root function 1.5th)

950 and >>1000 d at 9 - 11 % soil water content

(mean and median: not determinable, n=2, r² = 0.982 – 0.998, kinetics of higher order: root functions 1.5th and 2nd)DT_{90lab} (28°C, aerobic):

53 and 139 d at 60 % MWHC

(mean: 96 d, median: 96 d, n=2, r² = 0.977 – 0.978, kinetics of higher order: root functions 1st and 1.5th)Metabolites DCVA and FPBacid: no data availableDT_{50lab} (10 °C, aerobic):DT₅₀ for cyfluthrin = 20 days
(45 d for isomer I, 29 d for isomer II,
12 d isomer III and 19 d for isomer IV)DT_{50lab} (20 °C, anaerobic):Not possible to define DT₅₀**Field studies****(country or region)**DT_{50f} from soil dissipation studies:5 –21 d (*beta*-cyfluthrin, Germany, n = 2)

26 - 40 d (cyfluthrin, Germany, n = 2)

Total residues (cyfluthrin, DCVA, FPBacid):
mean 6 d (2 - 10 d; n = 3; USA)DT_{90f} from soil dissipation studies:- < 70 d (*beta*-cyfluthrin, Germany, n = 2)

- 133 d (cyfluthrin, Germany, n = 2)

- Total residues (cyfluthrin, DCVA, FPBacid):
mean 68 d (26 - 116 d; n = 3; USA)

Higher order degradation kinetics

Soil accumulation studies:

Not required

Soil residue studies:

Not required

Remarks

e.g. effect of soil pH on degradation rate

No significant dependency

Adsorption/desorptionK_f / K_{oc}:K_d

pH dependence:

<u>Active substance:</u> K _{oc} : 64300				
sandy loam, pH 5.1, 2.4 % OC				
Active substance (cyfluthrin; additional results):				
K _{oc} :	180290	124000	117946	73484
Soil:	Loamy Sand	Silt loam	Loamy sand	Clay loam
pH:	5.9	8.1	6.7	6.5
OC(%):	0.69	0.90	1.12	2.44
pH dependence: No				
<u>Metabolite DCVA:</u> calculated K _{oc} : 53.4				
Experimental results:				
K _{oc} :	31	14	356	
Soil type:	Sand	clay loam	sandy loam	
pH:	6.9	8.1	5.1	
OC(%):	0.59	1.6	0.8	
The adsorption depends strongly on the soil pH-value as expected.				
Metabolite FPBacid: no data available, not required				

Mobility**Laboratory studies**

Column leaching:

Aged residue leaching:

Field studies:

Lysimeter/Field leaching studies:

Remarks:

Soil-TLC:Rf values: 0.05 - 0.06 without ageing, 0.02 - 0.04 after previous incubation over 36 d.
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Soil-TLC: DCVA: Rf values: 0.29 - 0.87 FPBacid: Rf values: 0.18 - 0.73

In leachate: 1 % cyfluthrin 3.5 % FPBacid
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DCVA: The adsorption depends strongly on the soil pH-value as expected: DCVA has to be considered as being mobile in alkaline soils and being immobile in acid soils.

Ageing period: 30 and 60 d In leachate: ≤ 1 % cyfluthrin < 1 % FPBacid
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DCVA: The adsorption depends strongly on the soil pH-value as expected: DCVA has to be considered as being mobile in alkaline soils and being immobile in acid soils.

Not required

All results from investigations with cyfluthrin.
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2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:

Relevant metabolites:

Photolytic degradation:

Relevant metabolites:

Active substance: at 20 °C: DT ₅₀ at pH 4: > 1 year (all isomers) 7: 270 d (diastereomers I + II) 160 d (diastereomers III + IV) 9: 42 h (diastereomers I + II) 33 h (diastereomers III + IV)
FPBald: 11 % at pH 7 after 35 d 89 % at pH 9 after 14 and 21 d DCVA: Half-life at 25 °C > 1 year at pH 4, 7, 9 FPBald: A further hydrolytic degradation is not expected under sterile conditions because of the molecular structure.
DT50: 12.2 d (medium-pressure mercury lamp) DT50: < 1d (natural sunlight, August/September, Kansas, 38°49' North)
Up to 37 % FPBacid and 12 % FPBald after 14 d DCVA: > 10 % assumed, DT ₅₀ : 22 d (cis), 33 d (trans)

Biological degradation

Ready biological degradability:

Water/sediment study:

DT₅₀ water:

DT₉₀ water:

DT₅₀ whole system:

DT₉₀ whole system:

DT₅₀ water:

DT₅₀ water:

DT₉₀ water:

DT₅₀ sediment:

DT₉₀ sediment:

DT₅₀ whole system:

DT₉₀ whole system:

Distribution in water / sediment systems
(active substance)

- residues in the water phase (% of applied)
maximum at day
at the end of the study at day....
- residues in the sediment (% of applied)
maximum at day....
at the end of the study at day....

Distribution in water / sediment systems
(metabolites)

- residues in the water phase (% of applied)
maximum at day
at the end of the study at day....
- residues in the sediment (% of applied)
maximum at day....
at the end of the study at day....

Mineralization after 70 days

Non-extractable residues after 70 days

Distribution in water / sediment systems
(active substance)

- residues in the water phase (% of applied)
maximum at day
at the end of the study at day....

Not required as cyfluthrin is considered to be not readily biodegradable.

- [fluorophenyl-UL-¹⁴C]cyfluthrin:

DT₅₀ (water) < 1 d

DT₉₀ (water) < 1 d

DT₅₀ (whole system) 0.22 – 0.36 d

DT₉₀ (whole system) 6.1 – 9.9 d

FPBacid: ca. 10 d, estimated

- [cyclopropane-1-¹⁴C]cyfluthrin:

DT₅₀ (water) 2.4 – 3.8 h

DT₉₀ (water) 26.6 – 41.7 h

DT₅₀ (sediment) 3.3 – 12.4 d

DT₉₀ (sediment) 90 d

DT₅₀ (whole system) 2.5 – 3.5 d

DT₉₀ (whole system) 56.6 – 66.8 d

- [fluorophenyl-UL-¹⁴C]cyfluthrin:

0.5 % at day 1 <1.1 % at day 11
n.d. at day 70

20 % at day 1
1.1 % at day 70

FPBald

FPBacid

1.1 % at day 1 29 % at day 11
n.d. at day 70 n.d. at day 70

16 % at day 1 24 % at day 1
0.4 % at day 70 0.7 % at day 70

61 – 67 %
20 – 29 %

- [cyclopropane-1-¹⁴C]cyfluthrin:

24.3 – 40.5 % at 0.5 h (maximum), 4 – 17.3 % at
day 1
n.d. at day 100

- residues in the sediment (% of applied)
maximum at day....
- at the end of the study at day....

Distribution in water / sediment systems
(metabolites)

- residues in the water phase (% of applied)
maximum at day
- at the end of the study at day....
- residues in the sediment (% of applied)
maximum at day....
- at the end of the study at day....

Mineralization after 100 days

Non-extractable residues after 100 days

Accumulation in water and/or sediment:

63 – 68.4 % at 6 h (maximum)

7.1 – 15.9 % at day 100

DCVA:

32.2 – 36.0 % at day 28/2 (maximum)

11.2 – 25.6 % at day 100

8.0 – 23.7 % at day 100 (maximum)

14 – 37 %

12 – 26 %

No

Degradation in the saturated zone

Not required

Remarks:

Nearly all results from investigations with cyfluthrin, excepting hydrolysis.

2.3 Fate and behaviour in air

Volatility

Vapour pressure:

Isomer II: $1.4 \cdot 10^{-8}$ Pa at 20 °C

Isomer IV: $8.5 \cdot 10^{-8}$ Pa at 20 °C

Henry's law constant:

Isomer II: $0.0032 \text{ Pa}\cdot\text{m}^3\cdot\text{mol}^{-1}$ at 20 °C

Isomer IV: $0.013 \text{ Pa}\cdot\text{m}^3\cdot\text{mol}^{-1}$ at 20 °C

Photolytic degradation

Direct photolysis in air:

No data available; not (yet) required according to Annex II

Photochemical oxidative degradation in air
DT₅₀:

Tropospheric half-life: 17.8 h

Chemical lifetime in troposphere: 25.7 h

(according to Atkinson, reaction with OH radicals,
concentration: $5 \cdot 10^5 \text{ OH}/\text{cm}^3$)

Volatilisation:

Volatilization under field conditions within 24 h
after application:

plant (wheat)/soil system: 0 - 32 % (mean: 7 %)

Remarks:

No remarks

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	LD ₅₀ = 77 - 1369 mg/kg bw (rat, depending on vehicle)
Long-term toxicity to mammals:	NOEL = 50 ppm (cyfluthrin; rat, reproduction)
Acute toxicity to birds:	LD ₅₀ > 2000 mg/kg bw (bobwhite quail, Japanese quail) LD ₅₀ = ca. 100 mg/kg bw (canary)
Dietary toxicity to birds:	LC ₅₀ > 5000 ppm (cyfluthrin; bobwhite quail and mallard duck)
Reproductive toxicity to birds:	NOEL = 250 ppm (cyfluthrin; mallard duck) NOEL = 1000 ppm (cyfluthrin; bobwhite quail)
Short-term oral toxicity to mammals:	not required.

Aquatic Organisms

Acute toxicity fish:	LC ₅₀ = 0.068 µg/l (<i>Oncorhynchus mykiss</i> ; 96 h); β-cyfluthrin LC ₅₀ = 0.28 µg/l (<i>Lepomis macrochirus</i> ; 96 h); β-cyfluthrin
Long term toxicity fish:	NOEC = 0.01 µg/l (<i>Oncorhynchus mykiss</i> ; 58 d; cyfluthrin) NOEC = 0.14 µg/l (<i>Pimephales promelas</i> ; 307 d; cyfluthrin)
Bioaccumulation fish:	BCF = 506; CT ₅₀ = 9 d; CT ₉₀ = 28 d (cyfluthrin)
Acute toxicity invertebrate:	EC ₅₀ = 0.29 µg/l (<i>Daphnia magna</i> ; 48 h, β-cyfluthrin)
Chronic toxicity invertebrate:	NOEC = 0.02 µg/l (<i>Daphnia magna</i> ; 21 d; cyfluthrin)
Acute toxicity algae:	EC ₅₀ > 10 mg/l (<i>Scenedesmus subspicatus</i> ; 96 h), β-cyfluthrin
Chronic toxicity sediment dwelling organism:	EC ₁₅ = 0.36 µg/l (<i>Chironomus riparius</i> ; 28 d), β-cyfluthrin EC ₅ = 0.32 µg/l (<i>Chironomus riparius</i> ; 28 d), β-cyfluthrin EC ₅₀ = 0.45 µg/l (<i>Chironomus riparius</i> ; 28 d), β-cyfluthrin
Mesocosm study	NOEC _{community} = 10 ng cyfluthrin/l EAC = 50 ng cyfluthrin/l

Honeybees

Acute oral toxicity:

LD₅₀ ~ 0.05 µg/bee

Acute contact toxicity:

LD₅₀ ~ 0.001 µg/bee

Other arthropod species

Test species	% Effect
Aphidius rhopalosiphi - extended lab test on natural substrate	Mortality: LR ₅₀ 17 g as/ha (BULLDOCK EC 025)
<i>Aphidius rhopalosiphi</i> / Pupae - extended lab test on natural substrate	Mortality 100 % (1,675 g as/ha; BULLDOCK SC 025)
<i>Typhlodromus pyri</i> – extended lab test on natural substrate	Mortality: The LR ₅₀ 0.24 g as/ha (BULLDOCK EC 025)
<i>Seiulus tiliarium</i> - test using native populations	Abundance: 0% reduction (299 DAT) (675 ml/ha BULLDOCK EC 025)
<i>Coccinella septempunctata</i> - extended lab test on natural substrate	Mortality: LR ₅₀ 0.0261 g as/ha (BULLDOCK EC 025)
<i>Coccinella septempunctata</i> - aged residue test on natural substrate	Mortality: 100 % (test start first day after application of 450 ml/ha BULLDOCK EC 025) Mortality: 28 % (test start 3 weeks after application of 450 ml/ha BULLDOCK EC 025) Reproduction: reduced by 48 % Mortality: 0 % (test start 7 weeks after application of 450 ml/ha BULLDOCK EC 025), Reproduction: reduced by 5 %
<i>Poecilus cupreus</i> - semi-field test	Sublethal effects: 100 % in adults 3 DAT (12.5 g as/ha, EC-formulation: 25 g as/l)
Aleochara bilineata - extended lab test using natural soil	Mortality: 25.4 % Parasitisation rate: 20 % reduction (14.2 g as/ha, BULLDOCK EC: 25 g as/l)
<i>Chrysoperla carnea</i> – lab tests on glass plates	Mortality: 100 % effect on larvae (9.1 g as/ha, EC: 120 g as/l)

Earthworms

Acute toxicity:

LC ₅₀ > 1000 mg as/kg

Reproductive toxicity:

NOEC > 1.887 kg EC-formulation (cyfluthrin 53g/l)/ha - corresponds to 0133 mg as/kg soil or 100 g cyfluthrin/ha; Since logP _{ow} > 2 toxicity data are corrected by the factor of 2, therefore, the NOEC amounts to > 0.94 kg formulation/ha or 0.067 mg as/kg.

Soil micro-organisms

Nitrogen mineralization:

No negative effects up to 0.24 mg as/kg dry soil (⇔ 0.18 g as/ha)
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Carbon mineralization:

No negative effects up to 0.24 mg as/kg dry soil (⇔ 0.18 g as/ha)
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APPENDIX IIIA***beta*-CYFLUTHRIN**

List of studies for which the main submitter has claimed data protection and which during the re-evaluation process were considered as essential for the evaluation with a view to Annex I inclusion.

This list is valid for Cyfluthrin and *beta*-Cyfluthrin. The additional references for *beta*-Cyfluthrin are in bold print.

**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 ⁸ on previous use in granting national authorizations
All 1.11 /02	Werner, T.	1995	Analytical material balance: Supplement to study "The composition of Baythroid" of February 29, 1984. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: PC 721. GLP or GEP: yes Published: no	
All 1.11 /03b	Haustein, M.	1995	GLP Final Report - Analytical Material Balance β-Cyfluthrin (FCR 4545) Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: PC 975. GLP or GEP: yes Published: no	

⁸ Entries are based on information received from the Notifier(s) and in certain cases Member States. Neither the Commission nor the Member States are responsible for the completeness or validity of this information received.

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ⁸ on previous use in granting national authorizations
All 2.2 /02b	Weber	1988	Determination of the density of FCR 4545 Generated by: Bayer AG Submitted by: Bayer AG Bayer file No.: PC 124 (translation). GLP or GEP: no Published: no	
All 2.3.2 /01	Krohn, J.	1987	Calculation of the Henry law constant of cyfluthrin. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: PC 182. GLP or GEP: no Published: no	
All 2.7 /01	Krohn, J.,	1994	Solubility of Cyfluthrin in Representative Organic Solvents. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: PC 362, (revised report) (Translation of PC 183) GLP or GEP: no Published: no	
All 2.9.1 /04	Krauskopf, B.	1994	Cyfluthrin: Statement concerning the behaviour of the metabolite 3-phenoxy-4-fluoro-benzoic acid in soil and differences in results of hydrolysis studies. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: M 1069 GLP or GEP: no Published: no	
All 2.9.1 /05	Krohn, J.	1997	Hydrolysis of cyfluthrin and beta-cyfluthrin as a function of pH.. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: 145000926 GLP or GEP: yes Published: no	
All 2.9.2 /02	Westphal, C.	1984	Report on studies to investigate photodegradation of cyfluthrin. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: M 2034. GLP or GEP: no Published: no	

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	Reports⁸ on previous use in granting national authorizations
All 2.9.2 /05	Gronberg, R.R.	1987	Photodecomposition of [Phenyl-UL- ¹⁴ C]BAYTHROID™ in Aqueous Solution by Sunlight. Generated by: Mobay Chemical Corporation, Submitted by: Bayer AG, Bayer file No.: MR 88598 (revised report). GLP or GEP: no Published: no	
All 2.9.3 /01	Hellpointner, E.	1991	Determination of the quantum yield and assessment of the environmental half-life of the direct photo-degradation of cyfluthrin in water. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: PF 3555. GLP or GEP: yes Published: no	
All 2.9.4 /02b	Krohn, J.	1994	Dissociation constant of <i>beta</i>-cyfluthrin. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: PC 473, (translation of PC129) GLP or GEP: no Published: no	
All 2.10 /01	Hellpointner, E.	1992	Calculation of the chemical lifetime of <i>beta</i>-cyfluthrin in the troposphere. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: PF 3766. GLP or GEP: no Published: no	
All 2.11.2/02b	Mix, K.-H.	1995	Bestimmung der sicherheitstechnischen Kennzahlen von FCR 4545 (Bulldock Techn.). Generated by Bayer AG, Submitted by Bayer AG, Bayer file No.: PC 669. GLP or GEP: yes Published: no	

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 ⁸ on previous use in granting national authorizations
All 2.14/01	Krohn, J.	1994	Surface tension of <i>beta</i> -cyfluthrin Generated by: Bayer AG Submitted by: Bayer AG Bayer file No.: PC 472, (translation of PC178). GLP or GEP: no Published: no	
All 4.1 /04	Kulinna, G.	1994	Baythroid, Industrial Active Component, Secondary Components - Capillary Gas Chromatography. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: 2201-0281801-94. GLP or GEP: no Published: no	
All 4.1 /05	Haustein, M.	1996	Cyfluthrin: Bisacylbenzaldehyde hydrate - HPLC, External Standard. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: 2201-0281703-96. GLP or GEP: no Published: no	
All 4.1 /06	Haustein, M.	1997	Validation of HPLC-Method 2201-0281703-96. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: VB1-2201-0281703. GLP or GEP: no Published: no	
All 4.1 /07b	Teller, M.G.	1995	Determination of <i>beta</i> -Cyfluthrin in formulations: Assay - GLC - internal standard. Bayer AG, Report No.: 2001-0040501-95. GLP or GEP: no Published: no	
All 4.1 /08b	Haustein, M.	1997	Validation of HPLC-Method 2201-0243001-92 Bayer AG, Report No.: VB1-2201-0243001. GLP or GEP: no Published: no	
All 4.1 /09b	Sutor, P.	1997	Validation of GLC-Method 2001-0040501-95. Bayer AG, Report No.: VB1-2001-0040501, GLP or GEP: no Published: no	

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 ⁸ on previous use in granting national authorizations
All 4.2.5 /03	Maasfeld, W.	1989	Method for the gas-chromatic determination of residues of BAYOFLY in bovine tissues and milk. Bayer AG, Report No.: Dr. Mf/ RA - 653, Method 00553 GLP or GEP: no Published: no	
AIIA-4.2.2	Werren, R.D.; Pelz, S.	1999	Validation of DFG method S 19 with modified extraction for the determination of residues of cyfluthrin in soil; Specht & Partner No.: BAY-9906V, Az. M7706/99 GLP: yes Published: no	
AIIA-4.2.3	Sommer, H.	1999	Enforcement and confirmatory method for determination of Cyfluthrin in surface water by GC/ECD; Method 00587 / MR-334/99 GLP: yes Published: no	
AIIA-4.2.4	Hellpointer, E.	1999	Confirmatory Method for the Determination of Cyfluthrin in Air (Confirmed method 00309); Report-No.: MR-390/99; Method No. 00309; Bayer AG Study Number P 625 9 6002 GLP: yes Published: no	

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	Reports² on previous use in granting national authorizations
All 5.1.1 /01 = 6.3.1.1 /01	Eben, A., Thyssen, J.	1981	Thiocyanate excretion in rats' urine after intraperi-toneal administration of FCR 1272 and decamethrin in comparable doses and after exposure to defined FCR 1272 concentrations in the inhalation air. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: PH10130. GLP or GEP: no Published: no	
All 5.2.1 /11c	Heimann, K.G.	1987	FCR 1272 (c.n. cyfluthrin) / study for acute oral toxicity to rats (formulation acetone and peanut oil). Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: 15847. GLP or GEP: yes Published: no	
All 5.2.6 /03c	Iyatomi, A.	1983	Report of acute toxicity - B. Generated by: Nihon Tokushu Noyaku Seizo K.K., Submitted by: Bayer AG. GLP or GEP: no Published: no	
All 5.3.3.4 /02c	Pauluhn, J.	1987b	FCR 1272 (common name: cyfluthrin, the active ingredient of Baythroid) / study of the subchronic inhalation toxicity in accordance with OECD guideline No. 413 (addendum to 5.3.3.4 /01). Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: 15469. GLP or GEP: yes Published: no	
All 5.3.3.4 /03c	Pauluhn, J.	1987c	FCR 1272 (common name: cyfluthrin, the active ingredient of Baythroid) / study of the subchronic inhalation toxicity in accordance with OECD guideline No. 413 (addendum to 5.3.3.4 /01). Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: 15469 A. GLP or GEP: no Published: no	

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	Reports² on previous use in granting national authorizations
All 5.5.1 /01	Hoffmann, K., Schilde, B.	1983	FCR 1272 (Proposed common name cyfluthrin) / chronic toxicity to dogs on oral administration. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: 11983. GLP or GEP: yes Published: no	
All 5.5.2 /01	Suberg, H., Löser, E.	1983a	FCR 1272 (cyfluthrin, the active ingredient of Baythroid) / chronic toxicity study on rats (2-year feeding experiment). Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: 11949. GLP or GEP: no Published: no	
All 5.5.3 /01	Suberg, H., Löser, E.	1983b	FCR 1272 (common name: cyfluthrin) / chronic toxicological study on mice (feeding study over 23 months). Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: 12035. GLP or GEP: no Published: no	
All 5.6.1 /01	Löser, E., Eiben, R.	1983	FCR 1272 (proposed common name: cyfluthrin) / multigeneration study on rats. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: 11870. GLP or GEP: no Published: no	
All 5.6.2.2 /04	Schmidt, U.	1993	FCR 1272 - determination of the FCR 1272 concentration in the plasma of rats following inhalative exposure. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: 22726 GLP or GEP: yes Published: no	
All 5.8.4 /02	Watanabe, M., Iyatomi, A.	1984	FCR 1272 / antidotal test, Generated by: Nihon Tokushu Noyaku Seizo K.K., Submitted by: Bayer AG, Bayer file No.: 271. GLP or GEP: no Published: no	

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	Reports² on previous use in granting national authorizations
All 5.8.5 /03	Polacek, I.	1985	CNS safety pharmacology study with Bay VI 1704 on oral application. Generated by: Toxikologisches Institut Regensburg, Submitted by: Bayer AG, Bayer file No.: R3459. GLP or GEP: no Published: no	

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	Reports² on previous use in granting national authorizations
AIIA-6.6; AIIIA-8.5	Leslie, W.L.	1988	Baythroid – Residues in field rotational cereal crops. Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file No.: MR98429. GLP or GEP: no Published: no	
AIIA-6.6; AIIIA-8.5	Leslie, W.L.	1989	Baythroid – residues in field rotational cereal crops – addendum No. 1 to 6.2 /02 Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file No.: MR98429-2 GLP or GEP: no Published: no	
AIIA-6.4; AIIIA-8.3	Shaw II, H.R.	1983a	Residue of Baythroid in bovine milk. Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file No.: MR86040. GLP or GEP: no Published: no	
AIIA-6.4; AIIIA-8.3	Shaw II, H.R.	1983b	Residues of Baythroid in cattle tissues. Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file No.: MR86039. GLP or GEP: no Published: no	
AIIA-6.4; AIIIA-8.3	Chopade, H.M.	1983	Residues of Baythroid in chicken tissues. Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file No.: MR86033. GLP or GEP: no Published: no	
AIIA-6.4; AIIIA-8.3	Chopade, H.M., Gentile, C.C.	1983a	Residues of Baythroid in chicken eggs. Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file No.: MR86034. GLP or GEP: no Published: no	
AIIA-6.4; AIIIA-8.3	Anonymous	1984	Bovine residue feeding study (28 day). Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file No.: MR86218. GLP or GEP: no Published: no	
AIIA-6.4; AIIIA-8.3	Chopade, H.M.	1984	A 28 day Baythroid poultry feeding study. Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file No.: MR86658. GLP or GEP: no Published: no	

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	Reports² on previous use in granting national authorizations
AIIA-6.4; AIIIA-8.3	Harbin, A.M.	1985	28 day residue feeding study. Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file No.: MR90387. GLP or GEP: no Published: no	
AIIA-6.4; AIIIA-8.3	Ernst, V.J.	1985	Residue cattle feeding study (28 days). Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file No.: MR90386. GLP or GEP: no Published: no	
AIIA-6.4; AIIIA-8.3	Lemke, V.J.	1994	Cyfluthrin – A 28-day dairy cattle feeding study. Generated by: Miles Inc., Submitted by: Bayer AG, Bayer file No.: MR106628. GLP or GEP: no Published: no	
AIIA-6.4; AIIIA-8.3	Maasfeld, W.	1989	Method for the gas-chromatic determination of residues of BAYOFLY in bovine tissues and milk. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: Dr. Mf/ RA – 653. GLP or GEP: no Published: no	
AIIA-6.3; AIIIA-8.2	Anonymous (residue form)	1988	Residue trials with Baythroid 050 SL in apples in South Africa. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: 311/88379/W113A, 311/88379/W113B, 311/88379/W113C, 311/88379/W113D, 311/88379/W113E. GLP or GEP: no Published: no	
AIIA-6.3; AIIIA-8.2	Heinemann, O., Seym, M.	1996	Determination of residues of Baythroid 050 EC in/on apple following spray application in France. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: RA 2025-94 (0107-94, 0108-94, 0109-94, 0110-94). GLP or GEP: yes Published: no	

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	Reports² on previous use in granting national authorizations
AIIA-6.3; AIIIA-8.2	Heinemann, O., Seym, M.	1996	Determination of residues of Baythroid 050 EC on apple following spray application in France. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: RA 2000-95 (0125-95, 0409-95, 0410-95, 0411-95). GLP or GEP: yes Published: no	
AIIA-6.3; AIIIA-8.2 and AIIA-6.5; AIIIA-8.4	Heinemann, O., Seym, M.	1996	Determination of residues of Baythroid 050 EC on processed apple products.. Generated by: Bayer AG Submitted by: Bayer AG Bayer file Nos.: RA-3000-95 (0125-95) 0411-95). GLP or GEP: yes Published: no	
AIIA-6.3; AIIIA-8.2	Anonymous (residue form)	1986	Residue trials with Baythroid 050 EC in plums in South Africa. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: 311/88094/D31A, 311/88094/D31B. GLP or GEP: no Published: no	
AIIA-6.3; AIIIA-8.2	Seym, M.	1996	Determination of residues of Baythroid 050 EC on plum following spray application in France. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: RA 2026-94 (0111-94, 0112-94). GLP or GEP: yes Published: no	
AIIA-6.3; AIIIA-8.2	Seym, M.	1997	Determination of residues of Baythroid 050 EC in/on plum in France. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: RA 2002-95 (0124-95, 0415-95, 0416-95, 0417-95, 0418-95, 0420-95) GLP or GEP: yes Published: no	
AIIA-6.3; AIIIA-8.2	Anonymous (residue form)	1990	Residue trials with Baythroid 050 EC in peaches in South Africa. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: 311/88073/H173A, 311/88073/H173B, 311/88832/G175A, 311/88832/G175B. GLP or GEP: no Published: no	

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
AIIA-6.3; AIIIA-8.2	Heinemann, O., Seym, M.	1996	Determination of residues of Baythroid 050 EC in/on peach following spray application in southern France. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: RA 2024-94 (0102-94, 0104-94, 0105-94, 0106-94). GLP or GEP: yes Published: no	
AIIA-6.3; AIIIA-8.2	Seym, M.	1997	Determination of residues of Baythroid 050 EC following spray application on peach in France. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: RA 2001-95 (0123-95, 0412-95, 0413-95, 0414-95). GLP or GEP: yes Published: no	
AIIA-6.3; AIIIA-8.2	Anonymous (residue form)	1990	Residue trials with Baythroid 050 SC in grapes in South Africa. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: 311/88009/U13A, 311/88009/U13B, 311/88009/U13C, 311/88009/U13D, 311/88009/U13E, 311/88009/U13F 311/88009/U13G, 311/88009/U13H, 311/88009/U13I, 311/88009/U13J, 311/88009/U13K, 311/88009/U13L. GLP or GEP: no Published: no	
AIIA-6.3; AIIIA-8.2	Seym, M.	1997	Determination of residues of Bulldock (025 SC) on grape following spray application in Portugal. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: RA 2007-95 (0172-95, 0427-95). GLP or GEP: yes Published: no	
AIIA-6.3; AIIIA-8.2	Seym, M.	1997	Determination of residues of Bulldock 025 SC and Bulldock 025 EC on tomato in Spain, Italy, France and Portugal. Generated by: Bayer AG Submitted by: Bayer AG Bayer file Nos.: RA 2018-96 (0193-96, 0196-96, 0422-96, 0424-96, 0854-96) GLP or GEP: yes Published: no	

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AIIA-6.3; AIIIA-8.2	Seym, M.	1997	Determination of residues of Bulldock SC and Bulldock 025 EC on tomato in Spain, Italy, France and Portugal. Generated by: Bayer AG Submitted by: Bayer AG Bayer file Nos.: RA 2017-96 (0194-96, 0195-96, 0423-96, 0425-96) GLP or GEP: yes Published: no	
AIIA-6.3; AIIIA-8.2	Seym, M.	1997	Determination of residues of Bulldock 025 SC and Bulldock 025 EC on alfalfa in Spain and Italy. Generated by: Bayer AG Submitted by: Bayer AG Bayer file Nos.: RA 2016-96 (0067-96, 0429-96) GLP or GEP: yes Published: no	
AIIA-6.3; AIIIA-8.2	Seym, M.	1997	Determination of residues of Baythroid 050 EC in/on sweet corn in France in Italy. Generated by: Bayer AG Submitted by: Bayer AG Bayer file Nos.: RA-2012-96 (0022-96, 0315.96) GLP or GEP: yes Published: no	
AIIA-6.3; AIIIA-8.2	Seym, M.	1997	Determination of residues of Baythroid 050 EC on sweet corn following spray application in France. Generated by: Bayer AG Submitted by: Bayer AG Bayer file Nos.: RA-2013-96 (0282-96, 0367-96) GLP or GEP: yes Published: no	
AIIA-6.3; AIIIA-8.2	Anonymous (residue form)	1992 / 1993	Residue trials with Baythroid 050 EC in peppers in Spain. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: RA 2035-92 (0505-92, 0506-92, 0508-92, 0509-92); RA2017-93 (0115-93, 0116-93, 0117-93, 0118-93). GLP or GEP: yes Published: no	

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AIIA-6.3; AIIIA-8.2	Seym, M. (residue form)	1992	Determination of residues of Bulldock 025 SC in/on tomato and pepper under actual use conditions in Spain. Residue trials with Bulldock 025 SC in tomatoes. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: RA 2039-92 (0136-92, 0137-92, 0138-92). GLP or GEP: yes Published: no	
AIIA-6.3; AIIIA-8.2	Seym, M. (residue form)	1992	Determination of residues of Bulldock 025 SC in/on tomato and pepper under actual use conditions in Spain. Residue trials with Bulldock 025 SC in peppers. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: RA 2039-92 (0139-92, 0140-92, 0141-92). GLP or GEP: yes Published: no	
AIIA-6.3; AIIIA-8.2	Seym, M.	1997	Determination of residues of Bulldock 025 EC and Bulldock 025 SC on tomato in Spain. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: RA 2005-95 (0174-95, 0175-95). GLP or GEP: yes Published: no	
AIIA-6.3; AIIIA-8.2	Anonymous (residue form)	1989	Residue trials with Baythroid 050 EW in zucchini in Italy. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: 0073-89. GLP or GEP: no Published: no	
AIIA-6.3; AIIIA-8.2	Anonymous (residue form)	1992 / 1993	Residue trials with Baythroid 050 EC in cucumbers in Spain. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: RA 2035-92 (0498-92), RA2017-93 (0109-93, 0110-93, 0111-93). GLP or GEP: yes Published: no	

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	Reports² on previous use in granting national authorizations
AIIA-6.3; AIIIA-8.2	Anonymous (residue form)	1986	Residue trials with Baythroid 050 EC in cauliflower in the UK. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: TCR 299 (25/86, 26/86) GLP or GEP: no Published: no	
AIIA-6.3; AIIIA-8.2	Anonymous (residue form)	1986	Residue trials with Baythroid 050 EC in white cabbage in the UK. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: TCR 299 (23/86, 24/86). GLP or GEP: no Published: no	
AIIA-6.3; AIIIA-8.2	Anonymous (residue form)	1984 / 1985 / 1988	Residue trials with Baythroid 050 EC in peas in the UK. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: TCR 253 (16/84, 17/84), TCR 285 (24/85, 25/85), TCR 345 (55/88). GLP or GEP: no Published: no	
AIIA-6.3; AIIIA-8.2	Anonymous (residue form)	1993	Experimentations residus legumes 1993. Baythroid en application foliaire sur haricot. Generated by: Ministère de l'agriculture, de la pêche et de l'alimentation, (SPV). Submitted by: Bayer AG, Bayer file Nos.: RHARI1/93/03 (R-HAR-93-3501 RHA-9305-0201). GLP or GEP: no Published: no	
AIIA-6.3; AIIIA-8.2	Anonymous (residue form)	1996	Baythroid against corn moth on French beans. Bayer France. Generated by: Ministère de l'agriculture, de la pêche et de l'alimentation, (SPV). Submitted by: Bayer AG, Bayer file Nos.: RHARI194/01 (R-HARI-94-00201, R-HARI-94-03501, R-HARI-94-06201, R-HARI-94-06202). GLP or GEP: no Published: no	

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
AIIA-6.3; AIIIA-8.2	Anonymous (residue form)	1996	Baythroid against maize pyralid on French beans (sampling during harvest). Bayer France. Generated by: Ministère de l'agriculture, de la pêche et de l'alimentation, (SPV), Submitted by: Bayer AG, Bayer file Nos.: RHARI195/88 (R-HARI-95-03501). GLP or GEP: no Published: no	
AIIA-6.3; AIIIA-8.2	Anonymous (residue form)	1996	Baythroid against maize pyralid on French beans (degradation curve). Bayer France. Generated by: Ministère de l'agriculture, de la pêche et de l'alimentation, (SPV), Submitted by: Bayer AG, Bayer file Nos.: RHARI195/30 (R-HARI-95-03502, 30125). GLP or GEP: no Published: no	
AIIA-6.3; AIIIA-8.2	Heinemann, O., Seym, M.	1997	Determination of residues of Baythroid 50 EC on bean following spray application in France and Italy. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: RA 2021-96 (0439-96, 0440-96, 0441-96, 0442-96). GLP or GEP: yes Published: no	
AIIA-6.3; AIIIA-8.2	Anonymous (residue form)	1982 / 1987	Residue trials with Baythroid 240 EC in cotton. Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file No.: MR84361, MR84362, MR84363, MR84364, MR84365, MR83366, MR84367, MR84368, MR84369, MR84370, MR84371, MR84372, MR84380, MR98405 A, MR98405 B, MR98405 C, MR98405 D. GLP or GEP: no Published: no	
AIIA-6.3; AIIIA-8.2	Anonymous (residue form)	1989	Residue trials with Bulldock 125 SC in cotton in Brazil. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: 38920 B, 38920 C. GLP or GEP: no Published: no	

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AIIA-6.3; AIIIA-8.2	Seym, M.	1997	Determination of residues of Bulldock 025 EC and Bulldock 025 SC on cotton in Spain. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: RA 2006-95 (0177-95, 0178-95, 0426-95, 0428-95). GLP or GEP: yes Published: no	
AIIA-6.3; AIIIA-8.2	Anonymous (residue form)	1982 / 1984	Residue trials with Baythroid 240 EC in soybean. Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file No.: MR98398 A, MR98398 B, MR98398 C, MR98398 D, MR98398 E, MR98398 F, MR98398 G, MR898398 H, MR98398 I, MR98398 J, MR98398 K, MR98398 L. GLP or GEP: no Published: no	
AIIA-6.3; AIIIA-8.2	Anonymous (residue form)	1989	Residue trials with Baythroid 050 EW in soybeans in Italy. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: 0070-89. GLP or GEP: no Published: no	
AIIA-6.3; AIIIA-8.2	Anonymous (residue form)	1986	Residue trials with Baythroid 050 EC in potatoes in France. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: DP86-5, DP86-6. GLP or GEP: no Published: no	
AIIA-6.3; AIIIA-8.2	Seym, M.	1997	Determination of residues of Bulldock 025 EC and Bulldock 025 SC on potato in Portugal and Spain. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: RA 2004-95 (0179-95, 0180-95, 0425-95). GLP or GEP: yes Published: no	

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
AIIA-6.3; AIIIA-8.2	Schmidt, B. (residue form)	1990	Versuche zum Rückstandsverhalten von FCR 4545 & R2170 in Getreide. Residue trials with Enduro 258 EC in barley in Germany. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: PF 3743 (0534-90). GLP or GEP: yes Published: no	
AIIA-6.3; AIIIA-8.2	Seym, M. (residue form)	1991	Determination of residues of FCR 4545 & R 2170 in/on common oat, spring barley and spring wheat under actual use conditions in the Federal Republic of Germany. Residue trials with Enduro 258 EC in barley. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: RA 2055-91 (0090-91). GLP or GEP: yes Published: no	
AIIA-6.3; AIIIA-8.2	Schmidt, B. (residue form)	1990	Versuche zum Rückstandsverhalten von FCR 4545 & R2170 in Getreide. Residue trials with Enduro 258 EC in oat in Germany. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: PF 3743 (0535-90). GLP or GEP: yes Published: no	
AIIA-6.3; AIIIA-8.2	Seym, M. (residue form)	1991	Determination of residues of FCR 4545 & R 2170 in/on common oat, spring barley and spring wheat under actual use conditions in the Federal Republic of Germany. Residue trials with Enduro 258 EC in oat. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: RA 2055-91 (0089-91). GLP or GEP: yes Published: no	

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	Reports² on previous use in granting national authorizations
AIIA-6.3; AIIIA-8.2	Schmidt, B. (residue form)	1990	Versuche zum Rückstandsverhalten von FCR 4545 & R2170 in Getreide. Residue trials with Enduro 258 EC in wheat in Germany. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: PF 3743 (0532-90, 0533-90). GLP or GEP: yes Published: no	
AIIA-6.3; AIIIA-8.2	Seym, M. (residue form)	1991	Determination of residues of FCR 4545 & R 2170 in/on common oat, spring barley and spring wheat under actual use conditions in the Federal Republic of Germany. Residue trials with Enduro 258 EC in wheat. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: RA 2055-91 (0091-91, 0092-91). GLP or GEP: yes Published: no	
AIIA-6.3; AIIIA-8.2	Anonymus (residue form)	1990	Residue trials with Enduro 258 EC in wheat in France. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: 0573-90, 0695-90. GLP or GEP: no Published: no	
AIIA-6.3; AIIIA-8.2	Anonymous (residue form)	1985	Residue trials with Tamaron B 525 EC in maize in Spain. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: 6802-85. GLP or GEP: no Published: no	
AIIA-6.3; AIIIA-8.2	Seym, M.	1997	Determination of residues of Baythroid 050 EC in/on sweet corn in France. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: RA 2003-95 (0182-95, 0421-95, 0423-95, 0424-95). GLP or GEP: yes Published: no	

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
AIIA-6.3; AIIIA-8.2	Seym, M. (residue form)	1991	Determination of residues of Bulldock 25 EC in/on sugar beet under actual use conditions in the Federal Republic of Germany. Residue trials with Bulldock 25 EC in sugar beets. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: RA 2013-91 (0001-91, 0002-91). GLP or GEP: yes Published: no	
AIIA-6.3; AIIIA-8.2	Schmidt, B. (residue form)	1990	Versuche zum Rückstandsverhalten von FCR 4545 & R2170 in Zuckerrüben. Residue trials with Enduro 258 EC in sugar beets in Germany. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: PF 3744 (0528-90, 0529-90, 0530-90, 0531-90). GLP or GEP: yes Published: no	
AIIA-6.3; AIIIA-8.2	Ohs, P. (residue form)	1991	Determination of residues of FCR 4545 & R 2170 258 EC in/on fodder and sugar beet under actual use conditions in the Federal Republic of Germany. Residue trials with Enduro 258 EC in beets. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: RA 2054-91 (0085-91, 0086-91, 0087-91, 0088-91). GLP or GEP: yes Published: no	
AIIA-6.3; AIIIA-8.2	Seym, M.	1997	Determination of residues of Bulldock 025 SC on alfalfa in Spain. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file Nos.: RA 2008-95 (0181-95, 0429-95). GLP or GEP: yes Published: no	
AIIA-6; AIIIA-8	Lemke, V.J.	1987	Storage stability of Baythroid in bovine liver. Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file No.: MR94303. GLP or GEP: no Published: no	

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	Reports² on previous use in granting national authorizations
AIIA-6; AIIIA-8	Lemke, V.J.	1987	Storage stability of FPB-aldehyde (Baythroid Metabolite) in bovine liver. Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file No.: MR94304. GLP or GEP: no Published: no	
AIIA-6; AIIIA-8	Delk, J.L.	1988	Baythroid – Storage stability of residue in various frozen crops. Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file No.: MR98334. GLP or GEP: no Published: no	
AIIA-6; AIIIA-8	Grace, T.J.	1989	Freezer storage stability of cyfluthrin in hops. Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file No.: MR99203. GLP or GEP: no Published: no	
AIIA-6; AIIIA-8	Minor, R.G., Freeseaman, P.L.	1989	Freezer storage stability of cyfluthrin in apples, cotton, potatoes and soybeans. Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file No.: MR99631 GLP or GEP: no Published: no	
AIIA-6; AIIIA-8	Minor, R.G., Freeseaman, P.L.	1992	Freezer storage stability of cyfluthrin in corn green forage, head lettuce, and wheat green forage Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file No.: MR 102608. GLP or GEP: yes Published: no	
AIIA-6; AIIIA-8	Wiedmann, J.L., Amato, S.L., Koch, D.A.	1992	Storage stability of cyfluthrin in crops and processing fractions. Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file No.: MR103821. GLP or GEP: yes Published: no	
AIIA-6; AIIIA-8	Wiedmann, J.L., Amato, S.L., Koch, D.A.	1994	Storage stability of cyfluthrin in crops and processed products. Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file No.: MR103821-1. GLP or GEP: yes Published: no	

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	Reports² on previous use in granting national authorizations
AIIA-6.5; AIIIA-8.4	Wiedmann, J.L., Jablonski, J.E.	1990	Cyfluthrin (2 EC Formulation) – Magnitude of the residue in apple processed products. Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file No.: MR100203. GLP or GEP: part Published: no	
AIIA-6.5; AIIIA-8.4	Leslie, W.L.	1988	Baythroid – Magnitude of the residue in tomato processed products. Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file No.: MR98399. GLP or GEP: no Published: no	
AIIA-6.3; AIIIA-8.2	Anonymous (residue form)	1983	Residue trials with Baythroid 240 EC in cotton in USA Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file Nos.: MR84368. GLP or GEP: no Published: no	
AIIA-6.5; AIIIA-8.4	Burger, R.N., Lenz, C.A.	1992	Cyfluthrin (2 EC Formulation) – Magnitude of the residue on processed soybean commodities. Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file No.: MR103825. GLP or GEP: yes Published: no	
AIIA-6.5; AIIIA-8.4	Leslie, W.L.	1989	Baythroid – Magnitude of the residue on unprocessed whole corn and corn processed products. Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file No.: MR98509. GLP or GEP: yes Published: no	

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	Reports² on previous use in granting national authorizations
All 7.1.1.2.1 /02	Anonymous	1983	Residue recovery report. Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file No.: MR 84342. GLP or GEP: no Published: no	
All 7.1.1.2.1 /04	Anonymous	1983	Residue recovery report: Generated by: Mobay Corporation, Submitted by: Bayer AG Bayer file No.: MR 84373. GLP or GEP: no Published: no	
All 7.1.1.2.2 /02	Wagner, K.	1983 revis- ed 1988	Verhalten der Pflanzenbehandlungsmittelwirkstoffe im Boden Wirkstoff: Cyfluthrin. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: RR5621/82. GLP or GEP: no Published: no	
All 7.1.1.2.2 /06	Riegner, K.	1997	Aerobic degradation of Cyfluthrin in soil at low temperature according to EC requirements. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: PF4241. GLP or GEP: yes Published: no	
All 7.1.1.2.2 /07	Jersch-Schmitz, S.	1997	Calculation of DT50- and DT90-values of cyfluthrin isomers in soil. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: M9677. GLP or GEP: no Published: no	
All 7.1.1.2.3 /10	Anonymous (soil residue form)	1983	Baythroid, Loamy Sand, Florida/USA. Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file No.: MR84350. GLP or GEP: no Published: no	
All 7.1.1.2.4 /01	Anonymous	1983b	Effect of frozen storage at 0 to -10 degrees Fahrenheit on residues. Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file No.: MR84376. GLP or GEP: no Published: no	

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All 7.1.1.2.4 /02	Grace, T.J.	1990	Freezer storage stability of FPB-acid and DCVA in soil. Generated by: Mobay Corporation, Submitted by: Bayer AG, Bayer file No.: MR100153. GLP or GEP: yes Published: no	
All 7.1.2 /04	Burhenne, J.	1996	Adsorption/desorption of cyfluthrin on soils. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: IM 1972 GLP or GEP: yes Published: no	
All 7.1.2 /05	Slangen, P.J.	1999	Adsorption/desorption of FCR 1272-permethric acid on soil. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: IM 1983 GLP or GEP: yes Published: no	
All 7.1.3 /06, AIII 9.1.3	Schad, T.	1998	Predicted environmental concentrations of cyfluthrin in soil based on calculations using PELMO. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: MR-675/98 GLP or GEP: no Published: no	
All 7.2.1.1 /05	Krohn, J.	1997	Hydrolysis of permethric acid as a function of pH.. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: 145000921 GLP or GEP: yes Published: no	
All 7.2.1.1 /06	Krohn, J.	1997	Hydrolysis of cyfluthrin and beta-cyfluthrin as a function of pH. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: 145000926 GLP or GEP: yes Published: no	
All 7.2.1.3 /06	Sneikus, J.	2000	Aerobic aquatic degradation and metabolism of cyfluthrin in the water-sediment system. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: 268/00 GLP or GEP: yes Published: no	

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All 7.2.1.3, AIII 9.2.3 /01b	Schaefer, H.	2001	Predicted environmental concentrations of beta-cyfluthrin in surface water based on calculations with EXAMS. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: MR-573/00 GLP or GEP: yes Published: no	
All 7.2.1.3, AIII 9.2.3 /04c	Schaefer, H.	2001	Predicted environmental concentrations of cyfluthrin in surface water based on calculations with EXAMS. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: MR-572/00 GLP or GEP: yes Published: no	

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	Reports² on previous use in granting national authorizations
All 8.2.1 /04c	Gagliano	1994	Acute toxicity of ¹⁴ C-Cyfluthrin to the bluegill (<i>Lepomis macrochirus</i>) under flow-through conditions. Generated by: Miles Inc. Submitted by Miles Inc. Bayer file No.: 106774. GLP or GEP: yes Published: no	
All 8.2.1 /08b	Surprenant, D. C.	1994	Acute toxicity of FCR 4545 technical to Rainbow trout (<i>Oncorhynchus mykiss</i>) under flow-through conditions. Generated by: Springborn Bionomics, Submitted by: Bayer AG, Bayer file No.: 103231. GLP or GEP: yes Published: no	
All 8.3.1.1 /02c	Davies, L. G., Carlisle, W. R., Bratby, P.	1985	Report on a laboratory investigation into the toxicity of cyfluthrin (Baythroid) to honey bees (<i>Apis Mellifera</i>). Generated by: Department of Life Science, Nottingham, Submitted by: Bayer AG, Bayer file No.: TOX 1368. GLP or GEP: no Published: no	
All 8.3.2.1 /01c	Heimbach, F.	1985	Toxicity of cyfluthrin to Carabid beetles. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: HBF/CA 01. GLP or GEP: no Published: no	
All 8.3.2.1 /10b	Schmuck, R.	1993	Acute effects of a spray application of Bulldock EC 025 on Carabid beetles (<i>Poecilus cupreus</i>) under semifield conditions. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: SXR/HF 63. GLP or GEP: yes Published: no	
All 8.3.6 /02c	Müller	1994	Studies on the ecological behaviour of Cyfluthrin. Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: 478 A/94. GLP or GEP: yes Published: no	

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
All 10.2.1 /01c	Bowman, J. H.	1989b	Acute flow-through toxicity of Tempo 2 EC to bluegill (<i>Lepomis macrochirus</i>). Generated by: Analytical Bio-Chemistry Laboratories, Submitted by: Bayer AG, Bayer file No.: 99787. GLP or GEP: yes Published: no	
All 10.2.1 /02c	Bowman, J. H.	1989a	Acute flow-through toxicity of ¹⁴ C-Tempo 2 EC to rainbow trout (<i>Oncorhynchus mykiss</i>). Generated by: Analytical Bio-Chemistry Laboratories, Submitted by: Bayer AG, Bayer file No.: 99843. GLP or GEP: yes Published: no	
All 10.2.2 /01c	Burgess, D.	1989	Acute flow-through toxicity of ¹⁴ C-Tempo (cyfluthrin) to <i>Daphnia magna</i> . Generated by: Analytical Bio-Chemistry Laboratories, Submitted by: Bayer AG, Bayer file No.: 99848. GLP or GEP: yes Published: no	

APPENDIX IIIB*beta-Cyfluthrin*

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

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

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

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

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