



EUROPEAN COMMISSION  
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL  
Directorate D - Food Safety: production and distribution chain  
**D3 - Chemicals, Contaminants and Pesticides**

Cypermethrin  
SANCO/4333/2000 final  
15 February 2005

Review report for the active substance **cypermethrin**  
finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on  
15 February 2005  
in view of the inclusion of cypermethrin 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 cypermethrin, 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<sup>(1)</sup> 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<sup>(2)</sup>, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Cypermethrin 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, Cyanamid International on 25 June 1993, Stefes Agro GmbH on 20 July 1993, United Phosphorus Ltd on 26 July 1993, Zeneca Agrochemicals on 27 July 1993, Gharda Chemicals Ltd on 19 July 1993, Cequisa on 23 July 1993, Mitchell Cotts Chemical Ltd on 14 July 1993, Barclay Chemicals on 27 July 1993, ACI International on 30 July 1993, FMC Europe NV on 27 September 1993, Iberotam on 26 July 1993, Elf Atochem on 26 July 1993, Portman Agrochemicals on 26 July 1993, Helm AG on 23 July 1993, Calliope SA on 21 July 1993, Industrias Afrasa on 27 July 1993, Ellagret SA on 29 July 1993 and B.V. Luxan on 21 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance cypermethrin 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<sup>(3)</sup>, as last amended by Regulation (EC) No 2230/95<sup>(4)</sup>, designated Belgium as rapporteur Member State to carry out the assessment of cypermethrin on the basis of the dossier/s submitted by the notifier/s. In the same Regulation,

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<sup>1</sup> OJ No L 366, 15.12.1992, p.10.

<sup>2</sup> OJ No L 259, 13.10.2000, p.27.

<sup>3</sup> OJ No L 107, 28.04.1994, p.8.

<sup>4</sup> OJ No L 225, 22.09.1995, p.1.

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 cypermethrin this deadline was 31 October 1995.

Only Cyanamid Agro, Gharda Chemicals Ltd. and Mitchell Cotts Ltd submitted in time a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore Cyanamid Agro, Gharda Chemicals Ltd. and Mitchell Cotts Ltd were considered to be the main data submitters. Information has furthermore been submitted by third parties Sanachem, Elf Atochem and Barclay.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Belgium submitted on 25 October 1999 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 cypermethrin 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 cypermethrin from Gharda Chemicals Ltd. and Mitchell Cotts Ltd, on 10 May 2001.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the Commission forwarded for consultation the draft assessment report to all the Member States on 28 January 2000 as well as to Cyanamid Agro, Gharda Chemicals Ltd. and Mitchell Cotts Ltd being the main data submitters, on 8 February 2000.

On 25 September 2000 Cyanamid Agro (now BASF) withdrew its application.

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 July 2001.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States on 27 June 2001 and the main data submitters on 25 August 2001 for comments and further clarification.

Following the publication of Commission Decision 2001/810/EC of 21 November 2001 (concerning the decision on the possible inclusion of certain active substances into Annex I to Directive 91/414/EEC), only Mitchell Cotts Ltd. communicated an undertaking to ensure that its dossier would satisfy the requirements of Annexes II and III of Directive 91/414/EEC.

On 8 March 2004 Mitchell Cotts Ltd transferred its registration dossier to Chimac Agriphar which thus remains the sole notifier for this active substance.

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 July 2001 to December 2004, and was finalised in the meeting of the **Standing Committee** on 15 February 2005.

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

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, has been developed and finalised in support of the Directive 2005/53/EC<sup>5</sup> concerning the inclusion of cypermethrin in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing cypermethrin 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.

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<sup>5</sup> OJ No L 241, 17.09.2005, p. 51-56

### **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 cypermethrin 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 cypermethrin containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the main data submitter and mentioned in the list of uses supported by available data (attached as Appendix IV to this Review Report).

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

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI; excluding water and products of animal origin) for a 60 kg adult is 0.5 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). Additional intake from water and products of animal origin are not expected to give rise to intake problems.

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

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

### **4. Identity and Physical/chemical properties**

The main identity and the physical/chemical properties of cypermethrin 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 Chimac Agriphar (previously Mitchell Cotts), none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

In accordance with the provisions of Article 13(5) of Directive 91/414/EEC, Belgium is of the opinion that the currently available information does not allow to conclude unequivocally that the substances notified by the other data submitters (Cyanamid Agro, Gharda Chemicals Ltd, Sanachem, Elf Atochem and Barclay) do not, in the meaning of Article 13(2) and (5) of the

Directive, differ significantly in degree of purity and nature of impurities from the composition registered in the dossier submitted by the main data submitter.

## **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 were identified during the re-evaluation process. 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 cypermethrin**

On the basis of the proposed and supported uses (as listed in Appendix IV), 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 must pay particular attention to the protection of aquatic organisms, bees and non-target arthropods. Conditions of authorisation should include risk mitigation measures, where appropriate.

Member States must pay particular attention to the operator safety. Conditions of authorisation should include protective measures, where appropriate.

## **7. List of studies to be generated**

No further studies were identified which were at this stage considered necessary in relation to the inclusion of cypermethrin 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

New validation report (in accordance with provisions of SANCO/3030/99) for Chimac Agriphar impurities 6 and 7.

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.

## **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**

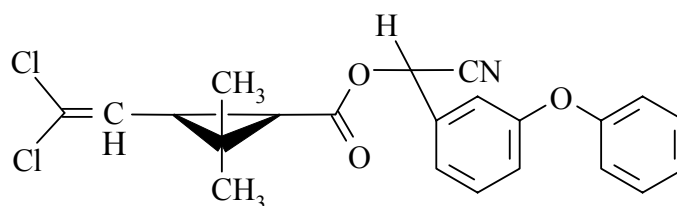
The technical information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. 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 cypermethrin in Annex I of the Directive.

## APPENDIX I

## Identity, physical and chemical properties

## CYPERMETHRIN

<b>Common name (ISO)</b>	Cypermethrin
<b>Chemical name (IUPAC)</b>	(RS)- $\alpha$ -cyano-3 phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate  (4 isomer pairs : cis-1, cis-2, trans-3, trans-4)
<b>Chemical name (CA)</b>	cyano(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylate
<b>CIPAC No</b>	332
<b>CAS No</b>	[52315-07-8]
<b>EEC No</b>	EINECS : 257-842-9
<b>FAO SPECIFICATION</b>	332/TC/S/F dd. 1993
<b>Minimum purity</b>	900 g/kg with a cis-isomer content between 40% min. and 60% max. (FAO) (insecticide activity : cis-2 isomer pair)
<b>Molecular formula</b>	C <sub>22</sub> H <sub>19</sub> Cl <sub>2</sub> NO <sub>3</sub>
<b>Molecular mass</b>	416.3
<b>Structural formula</b>	



<b>Melting point</b>	Melting endotherm : onset 41.2°C, peak 47.3°C (98.3%)
<b>Boiling point</b>	Not applicable (decomposition)
<b>Appearance</b>	White powder, mild chemical odour (98.3%) Yellow to brown viscous liquid/semi-solid, mild chemical odour (96.5%)
<b>Relative density</b>	$D_4^{20} = 1.303$ (98.3%)
<b>Vapour pressure</b>	$2.3 \times 10^{-7}$ Pa at 20 °C (98.4%)
<b>Henry's law constant</b>	$H = 0.024$ Pa.m <sup>3</sup> .mol <sup>-1</sup> at 20°C
<b>Solubility in water</b>	< 9 µg/L at 20°C (99.5% pure)
<b>Solubility in organic solvents</b>	ethyl acetate : > 2000 g/L at 20°C hexane : 142 g/L at 20°C o-xylene : > 450 g/L at 20°C methanol : > 450 g/L at 20°C ethanol : > 450 g/L at 20°C dimethylformamide : > 450 g/L at 20°C chloroform : > 450 g/L at 20°C acetone : > 450 g/L at 20°C
<b>Partition co-efficient (log P<sub>ow</sub>)</b>	log P <sub>ow</sub> range of discrete isomer pairs : 5.3 to 5.6 at 25°C
<b>Hydrolytic stability (DT<sub>50</sub>)</b>	at 25 °C : pH 3 : cis : DT <sub>50</sub> = 1302 d trans : DT <sub>50</sub> = 923 d pH 7 : cis : DT <sub>50</sub> = 221 d trans : DT <sub>50</sub> = 136 d pH 8 (river water) : cis : DT <sub>50</sub> = 21.2 d trans : DT <sub>50</sub> = 5.1 d pH 11 : cis : DT <sub>50</sub> = 38 min trans : DT <sub>50</sub> = 23 min
<b>Dissociation constant</b>	No dissociation of the a.s.
<b>Quantum yield of direct photo-transformation in water at λ &gt;290 nm</b>	0.0308
<b>Flammability</b>	Not flammable (no flash point up to 110°C) Auto-ignition temperature = 400°C
<b>Explosive properties</b>	No potential for explosion
<b>UV/VIS absorption (max.)</b>	in methanol, unadjusted pH : absorption maxima : 204 nm, ε = 43217 L.mol <sup>-1</sup> .cm <sup>-1</sup> 278 nm, ε = 2368 L.mol <sup>-1</sup> .cm <sup>-1</sup> absorption at λ > 290 nm : 290 nm, ε = 839 L.mol <sup>-1</sup> .cm <sup>-1</sup> 295 nm, ε = 411 L.mol <sup>-1</sup> .cm <sup>-1</sup> 304 nm, ε = 332 L.mol <sup>-1</sup> .cm <sup>-1</sup> 314 nm, ε = 316 L.mol <sup>-1</sup> .cm <sup>-1</sup>
<b>Photostability in water (DT<sub>50</sub>)</b>	pH 4, 20°C : DT <sub>50</sub> between 12.4 and 14.8 summer sunlight days (net photolysis data calculated by RMS from irradiated sample and dark control data)

# APPENDIX II

## END POINTS AND RELATED INFORMATION

### CYPERMETHRIN

## 1 Toxicology and metabolism

### Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	50% within 24 h
Distribution:	Large; highest residue in fat and skin
Potential for accumulation:	High accumulation in fat
Rate and extent of excretion:	90-100% within 72 h (56-66% in urine; 27-28% in faeces)
Toxicologically significant compounds:	Parent compound
Metabolism in animals:	± 50 %, via hydrolytic cleavage of ester bound

### Acute toxicity

Rat LD <sub>50</sub> oral:	<i>Cis/trans</i> ratio : 51/49 287 mg/kg bw (corn oil)
Rat LD <sub>50</sub> dermal:	>2000 mg/kg bw (40/60)
Rat LC <sub>50</sub> inhalation:	3.28 mg/l (40/60)
Skin irritation:	Non-irritant
Eye irritation:	Non-irritant
Skin sensitization (test method used and result):	Not sensitising (M&K)

### Short term toxicity

Target / critical effect:	Neurotoxicity , liver
Lowest relevant oral NOAEL / NOEL:	90-day dog study: 500 ppm (12.5 mg/kg bw/d )
Lowest relevant dermal NOAEL / NOEL:	15 doses/3wk rabbit study : 20 mg/kg bw/d
Lowest relevant inhalation NOAEL / NOEL:	No data required

### Genotoxicity

No genotoxic potential
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**Long term toxicity and carcinogenicity**

Target / critical effect:	Decreased bw and food consumption
Lowest relevant NOAEL:	24 month rat study: 100 ppm (5 mg/kg bw/d)
Carcinogenicity:	No carcinogenic potential

**Reproductive toxicity**

Target / critical effect - Reproduction:	Reduced litter size and pup weight at parental toxic doses
Lowest relevant reproductive NOAEL / NOEL:	100 ppm (10 mg/kg bw/d)
Target / critical effect - Developmental toxicity:	No effect at maternal toxic doses
Lowest relevant developmental NOAEL / NOEL:	Rat: >70 mg/kg bw/d

**Delayed neurotoxicity**

Rat acute study : NOAEL=20 mg/kg bw (corn oil) Rat study ,1dose/day; 5d /week, 4 week : NOAEL = 37.5 mg/kg bw/d (DMSO)
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**Other toxicological studies**

Weak liver enzyme inducer
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**Medical data**

Paresthesiae and peripheral sensory phenomena; irritation of respiratory tract
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**Summary**

	Value	Study	Safety factor
ADI:	0.05 mg/kg bw/d	Rat, 2 y study	100
AOEL systemic:	0.06 mg/kg bw/d	Dog, 90 d study	100/ 0.50 (50% absorption)
AOEL inhalation:	Not applicable, use systemic AOEL	-	-
AOEL dermal:	Not applicable, use systemic AOEL	-	-
ARfD (acute reference dose):	0.20 mg/kg bw/d	Rat, acute neurotoxicity study	100

**Dermal absorption**

10% default value
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## 2 Fate and behaviour in the environment

### 2.1 Fate and behaviour in soil

#### Route of degradation

##### Aerobic:

Mineralization after 100 days:

20-47% at d 168 (cis-isomers of cypermethrin, both labels)  
48-61% at d 168 (trans-isomers of cypermethrin, both labels)

Non-extractable residues after 100 days:

21-57% at d 168 (cis-isomers of cypermethrin, both labels)  
26-45% at d 168 (trans-isomers of cypermethrin, both labels)

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

No metabolite > 10%  
(3-phenoxybenzoic acid is found in one clay soil at level of 23-48% at d 364)

#### Supplemental studies

##### Anaerobic:

Half-lives under aerobic and anaerobic conditions are similar.  
Formation of metabolite 3-phenoxybenzoic acid (67.6 % at d 120), bound residue (11% at d 120), no mineralisation

##### Soil photolysis:

DT50 ( first order, light, assuming equivalent summer sunlight conditions at 30° N) = 34.2-38.2 d;  
DT50 (first order, dark) = 39.8-55.8 d  
[<sup>14</sup>C phenoxy] and  
[<sup>14</sup>C cyclopropane] labels

Metabolites in irradiated soil samples:  
carboxamide derivative of cypermethrin (19% AR after 7-9 days continuous irradiation), 3-phenoxybenzoic acid (3% AR at day 15) and DCVC acid ((2,2-dichlorovinyl)- 2,2-dimethylcyclopropanecarboxylic acid) (6% AR at day 15). Bound residue (12.8-21.9 % AR at day 15), mineralisation (5.4-6.2 % AR at day 15)

Metabolites in dark samples : 3-phenoxybenzoic acid (24% AR at day 15) and DCVC acid (13 %AR); carboxamide derivative of cypermethrin (5% AR at day 15). Bound residue (10.6-10.7% AR at day 15), mineralisation (0.2-2.5 % AR at day 15)

**Remarks:**

none

**Rate of degradation****Laboratory studies**DT<sub>50lab</sub> (20 °C, aerobic):

DT<sub>50lab</sub> (20-22°C, aerobic):  
 cis-isomers (3 soils) = 31-107 d, median = 88 d  
 trans-isomers (3 soils) = 13-58 d, median = 48 d  
 Another study of lower quality gave similar figures

DT<sub>90lab</sub> (20 °C, aerobic):

DT<sub>90lab</sub> (20-22°C, aerobic):  
 cis-isomers (3 soils) = 102-792 d, median = 354 d  
 trans-isomers (3 soils) = 69-251 d, median = 191 d

DT<sub>50lab</sub> (10 °C, aerobic):DT<sub>50lab</sub> (10°C, aerobic): -DT<sub>50lab</sub> (20 °C, anaerobic):DT<sub>50lab</sub> (20°C, anaerobic): 31d, 1 soil**Field studies (country or region)**DT<sub>50f</sub> from soil dissipation studies:

Graphical interpretation  
 DT<sub>50f</sub>: = <14-199 d, median = 16 d, 19  
 measurements,  
 France, Spain (2-year studies in 2 locations) , UK  
 (3-year studies in 2 locations), Germany

DT<sub>90f</sub> from soil dissipation studies:

DT<sub>90f</sub>: = 28-375 d, median = 126 d, 19  
 measurements,  
 France, Spain (2-year studies in 2 locations) , UK  
 (3-year studies in 2 locations), Germany

Soil accumulation studies:

No data required

Soil residue studies:

No data required

**Remarks:**

e.g. effect of soil pH on degradation rate

Not relevant

**Adsorption/desorption** $K_f / K_{oc}$ : $K_d$ :

pH dependence:

Alpha-cypermethrin study :

 $K_{oc} = 26492-144652$  $K_d = 821-1042$ 

No

**Mobility****Laboratory studies:**

Column leaching:

Aged residue leaching:

Not required

No residue is found in the leachate (limit of determination 0.2 µg/l)

3-phenoxybenzoic acid not recovered in the leachate

**Field studies:**

Lysimeter/Field leaching studies:

Not required

**Remarks:**

none

## 2.2 Fate and behaviour in water

### Abiotic degradation

Hydrolytic degradation:

pH3, 25°C (cis-isomers of cypermethrin): 1302d (trans-isomers of cypermethrin): 923d
pH7, 25°C (cis-isomers of cypermethrin): 221d (trans-isomers of cypermethrin): 136d
pH8, 25°C (cis-isomers of cypermethrin): 21.2d (trans-isomers of cypermethrin): 5.1d
pH11, 25°C (cis-isomers of cypermethrin): 38 min (trans-isomers of cypermethrin): 23 min

Photolytic degradation:

Major metabolites:

<p><i>Degradation rate, assuming first order kinetics (expressed as equivalent summer sunlight days) :</i></p> <p>irradiated : <math>k = 0.0783 \text{ d}^{-1}</math>; <math>t_{1/2} = 8.85 \text{ d}</math> (<sup>14</sup>C phenoxy)</p> <p><math>k = 0.0976 \text{ d}^{-1}</math>; <math>t_{1/2} = 7.10 \text{ d}</math> (<sup>14</sup>C cyclopropane) (cis-isomers are degraded 1.3 to 1.7 times faster than trans-isomers)</p> <p>dark control : <math>k = 0.0314 \text{ d}^{-1}</math>; <math>t_{1/2} = 22.1 \text{ d}</math> (<sup>14</sup>C phenoxy)</p> <p><math>k = 0.0419 \text{ d}^{-1}</math>; <math>t_{1/2} = 16.5 \text{ d}</math> (<sup>14</sup>C cyclopropane) ⇒ sunlight accelerates the rate of degradation</p> <p><i>Major photolysis products (&gt; 10% of applied radioactivity) :</i></p> <p>DCVC acid (18% after 100 hrs, <sup>14</sup>C cyclopropane label);</p> <p>3-phenoxybenzoic acid (15% after 100 hrs, <sup>14</sup>C phenoxy label);</p> <p>3-phenoxybenzaldehyde (3% after 100 hrs, <sup>14</sup>C phenoxy label); in addition, a further 16 unidentified photolytic degradation products (&lt; 10% at any time point) were detected</p> <p><i>Proposed degradation pathway :</i></p> <p>Photolysis of Cypermethrin proceeds via cleavage of the ester linkage to form DCVC acid and 3-phenoxybenzaldehyde, and subsequent oxidation of the CHO group resulting in 3-phenoxybenzoic acid. The DCVC acid is further degraded into unidentified polar compounds and subsequently to CO<sub>2</sub>.</p>
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### Biological degradation

Readily biodegradable:

No
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**Water/sediment study:**DT<sub>50</sub> water:

3 d

DT<sub>90</sub> water:

10 d

DT<sub>50</sub> whole system:

17 d

DT<sub>90</sub> whole system:

92 d

Distribution in water / sediment systems  
(active substance)

up to 42% in sediment at d 2

Distribution in water / sediment systems  
(metabolites)

3 phenoxybenzoic acid (up to 30% at d 7 in whole system), unidentified metabolite (up to 25% at d 14)

Accumulation in water and/or sediment:

Not applicable

**Degradation in the saturated zone****Remarks:**

none

## 2.3 Fate and behaviour in air

### Volatility

Vapour pressure:

$2.3 \times 10^{-7}$ Pa at 20 °C (98.4%)
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Henry's law constant:

$H = 0.024$ Pa.m <sup>3</sup> .mol <sup>-1</sup> at 20°C
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### Photolytic degradation

Direct photolysis in air:

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Photochemical oxidative degradation in air

DT <sub>50</sub> : 3.47 h
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DT<sub>50</sub>:

Volatilisation:

from plant surfaces: not available
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from soil: not available
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**Remarks:**

none
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### 3 Ecotoxicology

#### Terrestrial Vertebrates

Acute toxicity to mammals:	LD50 (rat) = 287 mg a.s./kg bw
Acute toxicity to birds:	LD50 (Anas platyrhynchos) > 10000 mg a.s./kg bw
Dietary toxicity to birds:	LC50 (Colinus virginianus, 5d) > 5620 mg a.s./kg feed or > 1376 mg a.s./kg bw/d,
Reproductive toxicity to birds:	NOEC (Colinus virginianus, 21 weeks) = 1000 mg a.s./kg feed or 92.0 mg a.s./kg bw/d
Long term oral toxicity to mammals:	NOAEL (2 gen., rat) = 100 mg/kg food

#### Aquatic Organisms

	Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Acute toxicity fish:	Salmo gairdneri	a.s.	96 h	LC50	0.0028
	Salmo gairdneri	(2,2-dichlorovinyl)-2,2-dimethyl cyclopropane carboxylic acid	96 h	LC50	180
	Salmo gairdneri	m-phenoxybenzoic acid	96 h	LC50	>10
Long term toxicity fish:	Pimephales promelas	a.s.	34 d	NOEC	0.00003
Bioaccumulation fish:	Salmo gairdneri	a.s.	-	BCF	1204
Acute toxicity invertebrate:	Daphnia magna	a.s.	48 h	EC50	0.0003
	Daphnia magna	(2,2-dichlorovinyl)-2,2-dimethyl cyclopropane carboxylic acid	48 h	EC50	32
Chronic toxicity invertebrate:	Daphnia magna	a.s.	21 d	NOEC	0.00004
Acute toxicity algae:	Selenastrum capricornutum	a.s.	96 h	EC50	> 0.1
	Selenastrum capricornutum	(2,2-dichlorovinyl)-2,2-dimethyl cyclopropane carboxylic acid	96 h	EC50	110
Chronic toxicity sediment dwelling organism:	No data required				
Outdoor mesocosm	Aquatic invertebrates and algae	a.s.	105 d	EAC	0.00005

## Honeybees

Acute oral toxicity:

Technical a.s. : 0.035 µg a.s./bee  
CYTHRINE (EC 100 g/l) : 3.2 µg/bee

Acute contact toxicity:

Technical a.s. : 0.020 µg a.s./bee  
CYTHRINE (EC 100 g/l) : 0.88 µg/bee

## Other arthropod species

*Test species*

% Effect
No laboratory tests
Field or semi-field tests
<p>field trial in winter wheat located in Damerham, Hampshire, UK</p> <p>The trial was of a randomised block design with four treatments (control, Cyperkill 10 EC at field rate, Cyperkill 10 EC at drift rate, dimethoate), 4 replicates of one hectare for each treatment.</p> <p>Cypermethrin (2 applications of 25 g a.s./ha at 14 days interval) significantly depleted numbers of Carabidae beetles (adults), Linyphiidae spiders, predatory diptera, Braconidae/ Ichneumonidae + Aphidius sp., other parasitica, gamebird-chick food at 0-4 days after 2<sup>nd</sup> application. Collembola level increases at 0-4 days after 2<sup>nd</sup> application (probably due to a decrease of their predators). All the taxonomic groups observed in this study have recovered at 38-40 days after 2<sup>nd</sup> application.</p> <p>Cypermethrin (2 applications of 0.595 g a.s./ha at 14 days interval, equivalent to drift rate) significantly depleted numbers of Carabidae beetles (adults), Staphylinidae beetles (adults), Linyphiidae spiders, predatory diptera, other parasitica at 0-4 days after 2<sup>nd</sup> application. Collembola level increases at 0-4 days after 2<sup>nd</sup> application. All the taxonomic groups observed in this study have recovered at 38-40 days after 2<sup>nd</sup> application.</p> <p>The effects observed in this study are considered to be acceptable since a full population recovery of non target arthropods occurred within the same crop-growing season (within 40 days post treatment)</p>

## Earthworms

Acute toxicity:

LC50 > 100 mg a.s./kg soil

LC50 (Cyperkill 10 (EC, 100 g a.s./l) = 575 mg/kg  
LC50 (Cyperkill 40, (EC, 400 g a.s./l) = 240 mg/kg

Reproductive toxicity:

No effect observed in a field test realized at 100 g a.s./ha

## Soil micro-organisms

Nitrogen mineralization:

Effects less than 25% after 28 days, at 30 and 150 g a.s./ha

Carbon mineralization:

Effects less than 25% after 28 days, at 30 and 150 g a.s./ha

**APPENDIX IIIA****CYPERMETHRIN**

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.

**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**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports<sup>6</sup> on previous use in granting national authorizations</b>
IIA 2.1.1 IIA 2.1.2 IIA 2.2 IIA 2.3.2 IIA 2.6 IIA 2.8	Bates, M.	2002a	Cypermethrin <i>cis:trans</i> 40:60 (purified active substance) : Evaluation of the physico-chemical properties Generated by : Covance Laboratories Ltd Submitted by : Mitchell Cotts Chemicals Report N° : 40/30-D2149 (CYP/C65) 16 May 2002a GLP, not published	No previous use (generated during the review process)
IIA 2.7 IIA 2.11.2 IIA 2.12 IIA 2.13 IIA 2.15	Bates, M.	2002b	Cypermethrin <i>cis:trans</i> 40:60 (technical active substance) : Evaluation of the physico-chemical properties Generated by : Covance Laboratories Ltd Submitted by : Mitchell Cotts Chemicals Report N° : 40/33-D2149 (CYP/C63) 25 April 2002b GLP, not published	No previous use (generated during the review process)
IIA 2.5.1 IIA 2.9.3/02	Greenwood, J.	2004	Cypermethrin <i>cis:trans</i> /40:60 (purified active substance) : Evaluation of spectroscopic properties Covance Laboratories Ltd., Report N° 0040/056-D2149 GLP, unpublished	No previous use (generated during the review process)

<sup>6</sup> 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 <sup>6</sup> on previous use in granting national authorizations
IIA 2.9.2	Swales, S.	2003	(14C)-Cypermethrin : Photodegradation in sterile, aqueous solution Covance Laboratories Ltd., Report N° 40/35 (Company file CYP/M70) GLP, unpublished	No previous use (generated during the review process)
IIA, 2.9.3/01 IIA, 2.10	Greenwood, J. Maudsley, L.	2003	Cypermethrin <i>cis:trans</i> /40:60 (purified active substance) : Quantum yield analysis Covance Laboratories Ltd., Report N° 40/34 (Company file CYP/C71) GLP, unpublished	No previous use (generated during the review process)
IIA 1.11 IIA 4.1.1 IIA 4.1.2 (< doc. J)	Bates, M.	2002	Cypermethrin <i>cis:trans</i> 40:60 technical active substance : five batch analysis Generated by : Covance Laboratories Ltd Submitted by : Mitchell Cotts Chemicals Report N° 40/29-D2149 (CYP/C66) GLP, unpublished	No previous use (generated during the review process)
IIA, 1.11 IIA, 4.1.1 IIA, 4.1.2 (< doc. J)	Bates, M	2003	Cypermethrin <i>cis:trans</i> /40:60 (technical active substance) : Five batch analysis – Supplementary analyses Covance Laboratories Ltd., Report N° 40/54 (Company file CYP/C76) GLP, unpublished	No previous use (generated during the review process)
IIA, 4.1.2 (< doc. J)	Riley, J.	1999	Method validation for the determination of impurities in Cypermethrin by Gas Chromatography Mitchell Cotts Chemicals Ltd., Report N° 166/014/SR/99 non-GLP, Unpublished	No previous use (generated during the review process)
IIA, 4.2.1/01	Wimbush, J.	2002a	Cypermethrin : Validation of the DFG Multi Residue method S23 for the determination and confirmation of residues in oilseed rape (seed, oil and straw) and wheat (grain and straw). Covance Laboratories Ltd., report N° 40/037-D2149 (Company file CYP/C67) Unpublished, GLP	No previous use (generated during the review process)

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports<sup>6</sup> on previous use in granting national authorizations</b>
IIA, 4.2.1/01	Devine, H.C.	2003a	Independent laboratory validation of Covance method 0040/037-03R for residues of Cypermethrin in oilseed rape (seed) and wheat (grain) CEM Analytical Services Ltd., report N° CEMS-1932 (Company file CYP/C72) Unpublished, GLP	No previous use (generated during the review process)
IIA, 4.2.1/01	Devine, H.C.	2003b	Independent laboratory validation of Covance method 0040/037-03RO for residues of Cypermethrin in oilseed rape (oil) CEM Analytical Services Ltd., report N° CEMS-1933 (Company file CYP/C73) Unpublished, GLP	No previous use (generated during the review process)
IIA, 4.2.1/02	Wimbush, J.	2003a	Cypermethrin : Validation of an analytical method for the determination and confirmation of residues in products of animal origin (milk, liver, kidney, muscle, fat and eggs) Covance Laboratories Ltd., report N° 40/041-2149 (Company file CYP/C68) Unpublished, GLP	No previous use (generated during the review process)
IIA, 4.2.1/02	Devine, H.C.	2003c	Independent laboratory validation of Covance method CLE 0040/041-01R for residues of Cypermethrin in bovine muscle, fat and hen eggs CEM Analytical Services Ltd., report N° CEMS-1934 (Company file CYP/C75) Unpublished, GLP	No previous use (generated during the review process)
IIA, 4.2.1/02	Devine, H.C.	2003d	Independent laboratory validation of Covance method CLE 0040/041-02R.M for residues of Cypermethrin in bovine milk CEM Analytical Services Ltd., report N° CEMS-1935 (Company file CYP/C74) Unpublished, GLP	No previous use (generated during the review process)

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports<sup>6</sup> on previous use in granting national authorizations</b>
IIA, 4.2.2/01	Wimbush, J.	2003b	Cypermethrin : Validation of an analytical method for the determination and confirmation of residues in soil and sediment Covance Laboratories Ltd., report N° 40/039-D2149 (Company file CYP/C70) Unpublished, GLP	No previous use (generated during the review process)
IIA, 4.2.3/01	Wimbush, J.	2002b	Cypermethrin : Validation of an analytical method for the determination and confirmation of residues in surface water Covance Laboratories Ltd., report N° 40/040-D2149 (Company file CYP/C69) Unpublished, GLP	No previous use (generated during the review process)

### B.6 Toxicology and metabolism

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports on previous use in granting national authorizations</b>
			No protection claim	

### B.7 Residue data

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports on previous use in granting national authorizations</b>
IIA 6.0/01	Wimbush J., Irlam S.	2003	Cypermethrin : The evaluation of residue stability in Oil Seed Rape (seed) under deep freeze storage conditions. Covance Laboratories Ltd., Report N° 0040/042-D2149. Company File CYP/R79 GLP, unpublished	No previous use (generated during the review process)

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports on previous use in granting national authorizations</b>
IIA 6.0/02	Wimbush J., Irlam S.	2003	Cypermethrin : The evaluation of residue stability in Wheat Grain under deep freeze storage conditions. Covance Laboratories Ltd., Report N° 0040/043-D2149. Company File CYP/R80 GLP, unpublished	No previous use (generated during the review process)
IIA 6.4/01	Heal, B.	2003	Cypermethrin : Residues in milk and edible tissues following repeated oral (dietary) administration to dairy cattle. Covance Laboratories Ltd., Report N° 0040/031-D6154. (Company file CYP/C78) GLP, unpublished	No previous use (generated during the review process)

#### B.8 Environmental fate and behaviour

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports on previous use in granting national authorizations</b>
IIA, 7.1.1.1.2	Swales, S.	2003	( <sup>14</sup> C)-cypermethrin: Photodegradation on a soil surface (Swales, S., 2003) Covance Laboratories Ltd., Report N° 40/44-D2149 (Company file CYP/M71) GLP, unpublished	No previous use (generated during the review process)
IIA 7.2.1.2 IIA 2.9.2	Swales, S.	2003	( <sup>14</sup> C)-Cypermethrin : Photodegradation in sterile, aqueous solution Covance Laboratories Ltd., Report N° 40/35 (Company file CYP/M70) GLP, unpublished	No previous use (generated during the review process)

**B.9 Ecotoxicology**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports on previous use in granting national authorizations</b>
IIA, 8.1.2	Gallagher et al.	2002	Cypermethrin: A dietary LC50 study with the Northern bobwhite quail Wildlife International Ltd. (Company file CYP/T324) GLP, unpublished	No previous use (generated during the review process)
IIA, 8.1.3	Frey L.	2003	Cypermethrin: Reproduction study with the northern bobwhite quail Wildlife International Ltd. (Company file CYP/T329) GLP, unpublished	No previous use (generated during the review process)
IIA, 8.1.3	Martin K.	2003	Analytical method verification for the determination of cypermethrin in avian diet Wildlife International Ltd. (Company file CYP/C77) GLP, unpublished	No previous use (generated during the review process)
IIA 8.2; IIIA 10.2	Schnöder F, Kroos M.	2003	Evaluation of direct and indirect effects of Cyperkill 10 on aquatic organisms in outdoor enclosures (multi-site study) Covance Laboratories GmbH, Münster, Germany, (Company file CYP/T331) GLP, unpublished	No previous use (generated during the review process)
IIA 8.3.2; IIIA 10.5	Halsall N.	2003	A field trial to determine the effects of Cyperkill 10EC (100 g/l cypermethrin) on the non-target arthropod fauna of a winter wheat crop, following two applications during May and June Mambo-Tox Ltd. (Company file CYP/T326) GLP, unpublished	No previous use (generated during the review process)
IIA 8.3.2; IIIA 10.5	Halsall N.	2003	A field evaluation of the effects of Cyperkill 10EC (100 g/l cypermethrin) on the protected life-stage (mummies) of <i>Aphidius rhopalosiphum</i> De Stefani-Perez (Hymenoptera: Braconidae) Mambo-Tox Ltd. (Company file CYP/T328) GLP, unpublished	No previous use (generated during the review process)

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports on previous use in granting national authorizations</b>
IIIA 10.6.2	Vinall S.	2003	A field trial to determine the effects of Cyperkill 10EC (100 g/l cypermethrin) on the invertebrate soil meso- and macrofauna Mambo-Tox Ltd. (Company file CYP/T325) GLP, unpublished	No previous use (generated during the review process)
IIIA 10.6.2	Vinall S.	2003	A field trial to determine the effects of Cyperkill 10EC (100 g/l cypermethrin) on the decomposition of organic materials enclosed in litter bags Mambo-Tox Ltd. (Company file CYP/T327) GLP, unpublished	No previous use (generated during the review process)
IIA 8.6	Mills H.	2002	Cypermethrin – literature search: phytotoxic effects on non-target flora Covance Laboratories Ltd., (Company file CYP/T322) unpublished	No previous use (generated during the review process)
IIA 8.7	Bealing DJ.	2002	Cypermethrin – Determination of inhibition of respiration of activated sludge Covance Laboratories Ltd., (Company file CYP/T323) yes, unpublished	No previous use (generated during the review process)

**APPENDIX IIIB****CYPERMETHRIN**

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**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>
IIA 1.11 IIA 4.1.1 IIA 4.1.2 (< doc. J)	Bates, M.	2002	Cypermethrin <i>cis:trans</i> 40:60 technical active substance : five batch analysis Generated by : Covance Laboratories Ltd Submitted by : Mitchell Cotts Chemicals Report N° 40/29-D2149 (CYP/C66) GLP, unpublished
IIA 1.11 IIA 4.1.1 IIA, 4.1.2 (< doc. J)	Bates, M	2003	Cypermethrin <i>cis:trans</i> /40:60 (technical active substance) : Five batch analysis – Supplementary analyses Covance Laboratories Ltd., Report N° 40/54 (Company file CYP/C76) GLP, unpublished
IIA 2.1.1 IIA 2.1.2 IIA 2.2 IIA 2.3.2 IIA 2.6 IIA 2.8	Bates, M.	2002a	Cypermethrin <i>cis:trans</i> 40:60 (purified active substance) : Evaluation of the physico-chemical properties Generated by : Covance Laboratories Ltd Submitted by : Mitchell Cotts Chemicals Report N° : 40/30-D2149 (CYP/C65) 16 May 2002a GLP Unpublished
IIA 2.1.1	Waghmare, S.V.	2000a	Physical and chemical characteristics of cypermethrin (50:50) : Melting point Generated by : Gharda Chemicals Ltd Submitted by : Gharda Chemicals Ltd Report N° : SAL114PC1 File N° : C.CMO.039 24 October 2000a GLP Unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 2.1.2	Sonawane, K.K.	2001a	Physical and chemical characteristics of cypermethrin (50:50) : Boiling point Generated by : Gharda Chemicals Ltd Submitted by : Gharda Chemicals Ltd Report N° : SAL14PC38 File N° : C.CMO.060 17 April 2001a GLP Unpublished
IIA 2.2	Waghmare, S.V.	2000b	Physical and chemical characteristics of cypermethrin (50:50) : Relative density Generated by : Gharda Chemicals Ltd Submitted by : Gharda Chemicals Ltd Report N° : SAL14PC2 File N° : C.CMO.040 24 October 2000b GLP Unpublished
IIA 2.3.1	Waghmare, S.V.	2000c	Physical and chemical characteristics of cypermethrin (50:50) : Vapour pressure Generated by : Gharda Chemicals Ltd Submitted by : Gharda Chemicals Ltd Report N° : SAL14PC3 File N° : C.CMO.041 24 October 2000c GLP Unpublished
IIA 2.3.2	Waghmare, S.V.	2000d	Physical and chemical characteristics of cypermethrin (50:50) : Relative density Generated by : Gharda Chemicals Ltd Submitted by : Gharda Chemicals Ltd Report N° : SAL14PC4 File N° : C.CMO.042 24 October 2000d GLP Unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 2.4.1 IIA 2.4.2	Waghmare, S.V.	2000e	Physical and chemical characteristics of cypermethrin (50:50) : Appearance (colour, odour, physical state) Generated by : Gharda Chemicals Ltd Submitted by : Gharda Chemicals Ltd Report N° : SAL14PC5 File N° : C.CMO.043 24 October 2000e GLP Unpublished
IIA 2.4.1 IIA 2.4.2	Waghmare, S.V.	2000f	Physical and chemical characteristics of cypermethrin (tech) (50:50) : Appearance (colour, odour, physical state) Generated by : Gharda Chemicals Ltd Submitted by : Gharda Chemicals Ltd Report N° : SAL14PC20 File N° : C.CMO.057 28 August 2000f GLP Unpublished
IIA 2.5.1 IIA 2.9.3/02	Greenwood, J.	2004	Cypermethrin <i>cis:trans</i> /40:60 (purified active substance) : Evaluation of spectroscopic properties Covance Laboratories Ltd., Report N° 0040/056-D2149 GLP, unpublished
IIA 2.6	Waghmare, S.V.	2000g	Physical and chemical characteristics of cypermethrin (50:50) : Solubility in water Generated by : Gharda Chemicals Ltd Submitted by : Gharda Chemicals Ltd Report N° : SAL14PC7 File N° : C.CMO.044 24 October 2000g GLP Unpublished
IIA 2.7 IIA 2.11.2 IIA 2.12 IIA 2.13 IIA 2.15	Bates, M.	2002b	Cypermethrin <i>cis:trans</i> 40:60 (technical active substance) : Evaluation of the physico-chemical properties Generated by : Covance Laboratories Ltd Submitted by : Mitchell Cotts Chemicals Report N° : 40/33-D2149 (CYP/C63) 25 April 2002b GLP Unpublished

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>
IIA 2.7	Sonawane, K.K.	2001b	Physical and chemical characteristics of cypermethrin (50:50) : Solubility in organic solvent Generated by : Gharda Chemicals Ltd Submitted by : Gharda Chemicals Ltd Report N° : SAL14PC8 File N° : C.CMO.058 17 April 2001b GLP Unpublished
IIA 2.8	Waghmare, S.V.	2000h	Physical and chemical characteristics of cypermethrin (50:50) : n-Octanol/water partition coefficient Generated by : Gharda Chemicals Ltd Submitted by : Gharda Chemicals Ltd Report N° : SAL14PC9 File N° : C.CMO.045 24 October 2000h GLP Unpublished
IIA 2.9.2	Waghmare, S.V.	2000i	Physical and chemical characteristics of cypermethrin (50:50) : Direct phototransformation of cypermethrin in water Generated by : Gharda Chemicals Ltd Submitted by : Gharda Chemicals Ltd Report N° : SAL14PC11 File N° : C.CMO.047 24 October 2000i GLP Unpublished
IIA 2.9.2	Swales, S.	2003	(14C)-Cypermethrin : Photodegradation in sterile, aqueous solution Covance Laboratories Ltd., Report N° 40/35 (Company file CYP/M70) GLP, unpublished
IIA 2.9.3/01 IIA 2.10	Greenwood, J. Maudsley, L.	2003	Cypermethrin cis:trans/40:60 (purified active substance) : Quantum yield analysis Covance Laboratories Ltd., Report N° 40/34 (Company file CYP/C71) GLP, unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 2.11.1	Waghmare, S.V.	2000j	Physical and chemical characteristics of cypermethrin (tech) (50:50) : Flammability Generated by : Gharda Chemicals Ltd Submitted by : Gharda Chemicals Ltd Report N° : SAL14PC14 File N° : C.CMO.051 24 October 2000j GLP Unpublished
IIA 2.11.2	Waghmare, S.V.	2000k	Physical and chemical characteristics of cypermethrin (tech) (50:50) : Self-ignition temperature (auto-flammability) Generated by : Gharda Chemicals Ltd Submitted by : Gharda Chemicals Ltd Report N° : SAL14PC15 File N° : C.CMO.052 24 October 2000k GLP Unpublished
IIA 2.12	Waghmare, S.V.	2000l	Physical and chemical characteristics of cypermethrin (tech) (50:50) : Flash point Generated by : Gharda Chemicals Ltd Submitted by : Gharda Chemicals Ltd Report N° : SAL14PC14 File N° : C.CMO.050 24 October 2000l GLP Unpublished
IIA 2.12	Sonawane, K.K.	2001c	Physical and chemical characteristics of cypermethrin technical : Flash point Generated by : Gharda Chemicals Ltd Submitted by : Gharda Chemicals Ltd Report N° : SAL14PC14 File N° : C.CMO.061 4 September 2001c GLP Unpublished

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>
IIA 2.13	Waghmare, S.V.	2000 m	Physical and chemical characteristics of cypermethrin (tech) (50:50) : Explosivity Generated by : Gharda Chemicals Ltd Submitted by : Gharda Chemicals Ltd Report N° : SAL14PC16 File N° : C.CMO.053 24 October 2000m GLP Unpublished
IIA 2.15	Waghmare, S.V.	2000n	Physical and chemical characteristics of cypermethrin (tech) (50:50) : Oxidizing properties Generated by : Gharda Chemicals Ltd Submitted by : Gharda Chemicals Ltd Report N° : SAL14PC18 File N° : C.CMO.055 24 October 2000n GLP Unpublished
IIA 4.1.2	Sonawane, K.K.	2001	Validation of method for the estimation of impurity 3, impurity 4 cis and impurity 4 trans in cypermethrin technical Generated by : Gharda Chemicals Ltd Submitted by : Gharda Chemicals Ltd Report N° SAL SP 0109 File N° C.CMO.062 12 September 2001 GLP Unpublished
IIA 4.1.2	Anonymous	-	Determination of impurity 7 content in cypermethrin technical by gas liquid chromatography (internal standard method) Generated by : Gharda Chemicals Ltd Submitted by : Gharda Chemicals Ltd Report N° : - File N° C.CMO.063 Date not specified Not GLP Unpublished
IIA 4.1.2 (< doc. J)	Riley, J.	1999	Method validation for the determination of impurities in Cypermethrin by Gas Chromatography Mitchell Cotts Chemicals Ltd., Report N° 166/014/SR/99 non-GLP, Unpublished

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>
IIA 4.2.1	Chen, A.W. Fink, J.M. Letinski, D.J.	1996	Analytical methods to determine residual cypermethrin and its major acid metabolites in bovine milk and tissues J. Agric. Food Chem., 44, 3534-3539, 1996 Submitted by : Gharda Chemicals Not GLP Published
IIA 4.2.1	French, W.M.	1996	Cypermethrin residue studies in rapeseed and winter wheat 1995 Generated by : Mitchell Cotts Chemicals Ltd. Submitted by : Mitchell Cotts Chemicals Ltd. Report/file No. : - 20 December 1996 GLP Unpublished
IIA 4.2.1	French, W.M.	1997	Cypermethrin residue studies in rapeseed and winter wheat 1996 Generated by : Mitchell Cotts Chemicals Ltd. Submitted by : Mitchell Cotts Chemicals Ltd. Report/file No. : - 26 March 1997 GLP Unpublished
IIA 4.2.1/01	Wimbush, J.	2002a	Cypermethrin : Validation of the DFG Multi Residue method S23 for the determination and confirmation of residues in oilseed rape (seed, oil and straw) and wheat (grain and straw). Covance Laboratories Ltd., report N° 40/037-D2149 (Company file CYP/C67) Unpublished, GLP
IIA 4.2.1/01	Devine, H.C.	2003a	Independent laboratory validation of Covance method 0040/037-03R for residues of Cypermethrin in oilseed rape (seed) and wheat (grain) CEM Analytical Services Ltd., report N° CEMS-1932 (Company file CYP/C72) Unpublished, GLP
IIA 4.2.1/01	Devine, H.C.	2003b	Independent laboratory validation of Covance method 0040/037-03RO for residues of Cypermethrin in oilseed rape (oil) CEM Analytical Services Ltd., report N° CEMS-1933 (Company file CYP/C73) Unpublished, GLP

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 4.2.1/02	Wimbush, J.	2003a	Cypermethrin : Validation of an analytical method for the determination and confirmation of residues in products of animal origin (milk, liver, kidney, muscle, fat and eggs) Covance Laboratories Ltd., report N° 40/041-2149 (Company file CYP/C68) Unpublished, GLP
IIA 4.2.1/02	Devine, H.C.	2003c	Independent laboratory validation of Covance method CLE 0040/041-01R for residues of Cypermethrin in bovine muscle, fat and hen eggs CEM Analytical Services Ltd., report N° CEMS-1934 (Company file CYP/C75) Unpublished, GLP
IIA 4.2.1/02	Devine, H.C.	2003d	Independent laboratory validation of Covance method CLE 0040/041-02R.M for residues of Cypermethrin in bovine milk CEM Analytical Services Ltd., report N° CEMS-1935 (Company file CYP/C74) Unpublished, GLP
IIA 4.2.2/01	Wimbush, J.	2003b	Cypermethrin : Validation of an analytical method for the determination and confirmation of residues in soil and sediment Covance Laboratories Ltd., report N° 40/039-D2149 (Company file CYP/C70) Unpublished, GLP
IIA 4.2.3	Alawi, M.A. Gharaibeh, S. Al-Shureiki, Y	1990	Rueckstandsuntersuchungen auf Fenitrothion und Pyrethroide in wasser, boden und pflanzen nach der heuschreckenbekaempfung in Jordanien 1989 Chemosphere, Vol. 20, Nos. 3/4, 443-447, 1990 Submitted by : Gharda Chemicals Not GLP Published
IIA 4.2.3	Muir, D.C.G. Rawn, G.P. Townsend, B.E. Lockhart, W.L. Greenhalgh, R.	1985	Bioconcentration of cypermethrin, deltamethrin, fenvalerate and permethrin by <i>Chironomus tentans</i> larvae in sediment and water Environmental Toxicology and Chemistry, Vol. 4, 51-61, 1985 Submitted by : Gharda Chemicals Not GLP 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
IIA 4.2.3	van der Hoff, G.R. Pelusio, F. Brinkman, U.A.Th. Baumann, R.A. van Zoonen, P.	1996	Automated solid-phase extraction coupled to gas chromatography with electron-capture detection : combination of extraction and clean-up of pyrethroids in the analysis of surface water J. Chromatogr. A, 719, 59-67, 1996 Submitted by : Gharda Chemicals Not GLP Published
IIA 4.2.3/01	Wimbush, J.	2002b	Cypermethrin : Validation of an analytical method for the determination and confirmation of residues in surface water Covance Laboratories Ltd., report N° 40/040-D2149 (Company file CYP/C69) Unpublished, GLP
IIIA 1.4 (< doc. J)	Corman, C.	2001	Confidential composition Cythrine (CA701348) Generated by : Chimac Agriphar Submitted by : Chimac Agriphar for Gharda Chemicals Ltd. 12 June 2001 Not GLP, unpublished
IIIA 2.2.1	Licata-Messana, L.	2000a	Cypermethrin 100 g/L EC : Determination of the explosive properties Generated by : SEPC Submitted by : Gharda Chemicals Report N° 99-903017-9 14 March 2000a GLP Unpublished
IIIA 2.2.1 IIIA 2.2.2 IIIA 2.3 IIIA 2.5.2 IIIA 2.5.3 IIIA 2.6.1 IIIA 2.7.2 IIIA 2.8.2	Bates, M.	2002c	Cyperkill 10 (Formulation containing 100 g/L cypermethrin cis:trans 40:60) : Evaluation of the physico-chemical properties Generated by : Covance Laboratories Ltd Submitted by : Mitchell Cotts Chemicals Report N° : 40/36-D2149 18 April 2002c GLP Unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIIA 2.2.2	van Rijsbergen, L.M.	2001	Statement on the oxidizing properties of Cypermethrin 100 EC Generated by : NOTOX Submitted by : Gharda Chemicals NOTOX Project N° 332437 21 August 2001 GLP Unpublished
IIIA 2.3 IIIA 2.4.1 IIIA 2.4.2 IIIA 2.5.1 IIIA 2.5.3 IIIA 2.6.1 IIIA 2.7.1 IIIA 2.7.2 IIIA 2.8.2 IIIA 2.8.7.2	Bernes, A.	1999	Physical and chemical properties and storage stability tests of CYTHRINE 10EC (cypermethrin 100 g/L) Generated by : Chimac-Agriphar Submitted by : Gharda Chemicals P.J./B.A.9217/Ch.1663/1998/180 9 February 1999 GLP Not published
IIIA 2.3	Licata-Messana, L.	2000b	Cypermethrin 100 g/L EC : Determination of the relative self-ignition temperature <i>Liquids</i> Generated by : SEPC Submitted by : Gharda Chemicals Report N° 99-903017-10 14 March 2000b GLP Unpublished
IIIA 2.4.2 IIIA 2.7.1 IIIA 2.7.3 IIIA 2.8.7.2 IIIA 4.1.3	Parsons, A.H.	1998	Cyperkill 10 storage stability trial Generated by : Mitchell Cotts Chemicals Ltd. Submitted by : Mitchell Cotts Chemicals Ltd. Study No. J 9884 6 March 1998 GLP Not published
IIIA 2.7.1	Taylor, A.J.	2002	Justification for the storage stability of Mitchell Cotts Chemicals Cyperkill 10 at 40°C for 8 weeks Generated by : Mitchell Cotts Chemicals Submitted by : Mitchell Cotts Chemicals Doc. N° : AJT/HW/9148/02 20 March 2002 no GLP unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIIA 2.8.7.2	Szimjonka, M.	2001	Chemical and physico-chemical analysis of Cypermethrin 100 g/L EC and accelerated storage stability Generated by : Chimac-Agriphar Submitted by : Gharda Chemicals Report N° 01-A-04 20 March 2001 GLP Unpublished
IIIA 2.8.7.2	Beardshall, R.	2002	Emulsifiability of Mitchell Cotts Chemicals Cyperkill 10 in CIPAC water A Generated by : Mitchell Cotts Chemicals Submitted by : Mitchell Cotts Chemicals Doc. N° : RB/AJT/9189/02 15 May 2002 no GLP unpublished
IIIA 4.1.3	Anonymous	-	Stability study of Cypermethrin 10EC Generated by : Gharda Chemicals Submitted by : Gharda Chemicals Report/file No. and date : - Not GLP Unpublished

**B.6 Toxicology and metabolism**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>
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**B.7 Residue data**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>
IIA 6.0/01	Wimbush J., Irlam S.	2003	Cypermethrin : The evaluation of residue stability in Oil Seed Rape (seed) under deep freeze storage conditions. Covance Laboratories Ltd., Report N° 0040/042-D2149. Company File CYP/R79 GLP, unpublished
IIA 6.0/02	Wimbush J., Irlam S.	2003	Cypermethrin : The evaluation of residue stability in Wheat Grain under deep freeze storage conditions. Covance Laboratories Ltd., Report N° 0040/043-D2149. Company File CYP/R80 GLP, unpublished
IIA 6.4/01	Heal, B.	2003	Cypermethrin : Residues in milk and edible tissues following repeated oral (dietary) administration to dairy cattle. Covance Laboratories Ltd., Report N° 0040/031-D6154. (Company file CYP/C78) GLP, unpublished

**B.8 Environmental fate and behaviour**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>
IIA, 7.1.1.1.2	Swales, S.	2003	( <sup>14</sup> C)-cypermethrin: Photodegradation on a soil surface (Swales, S., 2003) Covance Laboratories Ltd., Report N° 40/44-D2149 (Company file CYP/M71) GLP, unpublished
IIA 7.2.1.2 IIA 2.9.2	Swales, S.	2003	( <sup>14</sup> C)-Cypermethrin : Photodegradation in sterile, aqueous solution Covance Laboratories Ltd., Report N° 40/35 (Company file CYP/M70) GLP, unpublished

**B.9 Ecotoxicology**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>
IIA, 8.1.2	Gallagher et al.	2002	Cypermethrin: A dietary LC50 study with the Northern bobwhite quail Wildlife International Ltd. (Company file CYP/T324) GLP, unpublished
IIA, 8.1.3	Frey L.	2003	Cypermethrin: Reproduction study with the northern bobwhite quail Wildlife International Ltd. (Company file CYP/T329) GLP, unpublished
IIA, 8.1.3	Martin K.	2003	Analytical method verification for the determination of cypermethrin in avian diet Wildlife International Ltd. (Company file CYP/C77) GLP, unpublished
IIA 8.2; IIIA 10.2	Schnöder F, Kroos M.	2003	Evaluation of direct and indirect effects of Cyperkill 10 on aquatic organisms in outdoor enclosures (multi-site study) Covance Laboratories GmbH, Münster, Germany, (Company file CYP/T331) GLP, unpublished
IIA 8.3.2; IIIA 10.5	Halsall N.	2003	A field trial to determine the effects of Cyperkill 10EC (100 g/l cypermethrin) on the non-target arthropod fauna of a winter wheat crop, following two applications during May and June Mambo-Tox Ltd. (Company file CYP/T326) GLP, unpublished
IIA 8.3.2; IIIA 10.5	Halsall N.	2003	A field evaluation of the effects of Cyperkill 10EC (100 g/l cypermethrin) on the protected life-stage (mummies) of <i>Aphidius rhopalosiphi</i> De Stefani-Perez (Hymenoptera: Braconidae) Mambo-Tox Ltd. (Company file CYP/T328) GLP, unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIIA 10.6.2	Vinall S.	2003	A field trial to determine the effects of Cyperkill 10EC (100 g/l cypermethrin) on the invertebrate soil meso- and macrofauna Mambo-Tox Ltd. (Company file CYP/T325) GLP, unpublished
IIIA 10.6.2	Vinall S.	2003	A field trial to determine the effects of Cyperkill 10EC (100 g/l cypermethrin) on the decomposition of organic materials enclosed in litter bags Mambo-Tox Ltd. (Company file CYP/T327) GLP, unpublished
IIA 8.6	Mills H.	2002	Cypermethrin – literature search: phytotoxic effects on non-target flora Covance Laboratories Ltd., (Company file CYP/T322) unpublished
IIA 8.7	Bealing DJ.	2002	Cypermethrin – Determination of inhibition of respiration of activated sludge Covance Laboratories Ltd., (Company file CYP/T323) yes, unpublished

## APPENDIX IV

## List of uses supported by available data

## Cypermethrin

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/ha min max	water l/ha min max	kg as/ha min max		
oilseed rape	Northern Europe	CYPERKILL	F	Coleoptera, Diptera, Aphids	EC	100	Overall spray	Infestation	1-2		0.0050 – 0.0075	400	0.020-0.030	49	
wheat (spring & winter)	Northern Europe	CYPERKILL	F	Aphids	EC	100	Overall spray	Infestation	1-2		0.0050 – 0.0075	400	0.020 – 0.030	42	

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