EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Pesticides and biocides

Alpha-cypermethrin
SANTE-2018-11525 Rev 3
17 July 2019

Final Renewal report for the active substance **alpha-cypermethrin**

finalised in the Standing Committee on Plants, Animals, Food and Feed
at its meeting on 17 July 2019
in view of the renewal of the approval of the active substance **alpha-cypermethrin** as a candidate for substitution,
in accordance with Regulation (EC) No 1107/2009[1]

1. Procedure followed for the re-evaluation process

This renewal report has been established as a result of the evaluation of alpha-cypermethrin, in accordance with Regulation (EC) No 1107/2009[2] and Commission Implementing Regulation (EU) No 844/2012[3] following the submission of an application to renew the approval of this active substance expiring in July 2020.

Alpha-cypermethrin is a substance that was included in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market, by Commission Directive 2004/58/EC[4]. Alpha-cypermethrin is deemed to have been approved under Regulation (EC) No 1107/2009 and is listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011[5].

An application for renewal of the approval of **alpha-cypermethrin** was submitted by BASF Agro B.V. in accordance with Article 1 of Regulation No 844/2012.

Commission Implementing Regulation (EU) No 1197/2012[6] extended until 31 July 2017 the period of approval of alpha-cypermethrin to allow the completion of its review.

Commission Implementing Regulation (EU) 2017/841[7] extended until 31 July 2018 the period of approval of alpha-cypermethrin to allow the completion of its review.

Commission Implementing Regulation (EU) 2018/917[8] extended until 31 July 2019 the period of approval of alpha-cypermethrin to allow the completion of its review.

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1 Renewal Report established in accordance with Art. 14 of Regulation (EU) No 844/2012; does not necessarily represent the views of the European Commission.
2 OJ L 309, 24.11.2009, p. 1.
3 OJ L 252, 19.9.2012, p. 26.
4 OJ L 120,24.42004, p.26.
5 OJ L 153, 11.6.2011, p. 1.
6 OJ L 342, 14.12.2012, p. 27.
7 OJ L 125, 18.5.2017, p. 12.

Commission Implementing Regulation (EU) 2019/707[9] extended until 31 July 2020 the period of approval of alpha-cypermethrin to allow the completion of its review.

Commission Implementing Regulation (EU) No 686/2012[10] designated the rapporteur Member States and the co-rapporteur Member States which had to submit the relevant renewal assessment reports and recommendations to the European Food Safety Authority (EFSA).

For alpha-cypermethrin the rapporteur Member State was Belgium and the co-rapporteur Member State was Greece.

Belgium finalised in May 2017 its examination, in the form of a renewal assessment report. This Report was sent to the Commission and the European Food Safety Authority on 7 May 2017 and included a recommendation concerning the decision to be taken with regard to the renewal of the approval of alpha-cypermethrin for the supported uses.

In accordance with Article 13 of Implementing Regulation (EU) No 844/2012, the EFSA organised an intensive consultation of technical experts from Member States, to review the renewal assessment report and the comments received thereon (peer review).

The EFSA sent to the Commission its conclusion on the risk assessment (Conclusions regarding the peer review of the pesticide risk assessment of the active substance)[11] on 7 August 2018. This conclusion refers to several background documents: the renewal assessment report including its revisions and the EFSA peer review report.

According to the provisions of Article 14 of Implementing Regulation (EU) No 844/2012, the Commission referred a draft renewal report on the renewal of approval to the Standing Committee on Plants, Animals, Food and Feed, for examination on 24-25 January 2019. The draft renewal report was finalised in the meeting of the Standing Committee on 17 July 2019.

The present renewal report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of the EFSA, and its background documents, these documents are also considered to be part of this renewal report.

2. Purposes of this renewal report

This renewal report, including the background documents and appendices hereto, has been developed and finalised in support of **Commission Implementing Regulation (EU) 2019/1690**[12] concerning the renewal of approval of **alpha-cypermethrin** as active substance under Regulation (EC) No 1107/2009, and to assist the Member States in decisions on individual plant protection products containing **alpha-cypermethrin** they have to take in accordance with the provisions of that Regulation, and in particular the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011[13].

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8 OJ L 163, 28.6.2018, p. 13.
9 OJ L 120, 8.5.2019, p. 16.
10 OJ L 200, 27.7.2012, p. 5.
11 EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance alpha-cypermethrin EFSA Journal 2018;16(8):5403.
12 OJ L 259, 10.10.2019, p. 2.
13 OJ L 155, 11.6.2011, p. 127.

This renewal report provides also for the evaluation required under part I, Section A.2(b) of the above mentioned uniform principles, as well as under several specific sections of chapter 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 requirements of Regulation (EU) No 283/2013[14], submitted for the purpose of (renewal of) approval of the active substances, as well as the result of the evaluation of those data.

This renewal report will be made available to the public.

The information in this renewal report is, at least partly, based on information which is confidential and/or protected under the provisions of Regulation (EC) No 1107/2009. It is therefore recommended that this renewal report would not be accepted to support any registration outside the context of that Regulation, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this renewal report is based.

3. Overall conclusion in the context of Regulation (EC) No 1107/2009

The overall conclusion from the evaluation is that it may be expected that plant protection products containing **alpha-cypermethrin** will still fulfil the safety requirements laid down in Article 4(1) to (3) of Regulation (EC) No 1107/2009. 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 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, for each alpha-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 applicant and mentioned in the list of uses supported by available data (attached as Appendix II to this renewal report). Not all initially proposed uses are included in Appendix II because the data submitted were not sufficient to conclude on acceptable use with respect to the risk to consumers or non-target organisms.

The following reference values have been finalised as part of this evaluation:

ADI: 0.00125 mg/kg bw per day,
ARfD: 0.00125 mg/kg bw,
AOEL: 0.0005 mg/kg bw per day,
AAOEL: 0.0005 mg/kg bw.

It should be noted that the ADI, ARfD and AOEL are significantly lower than the previously agreed values.

EFSA did not identify any critical area of concern, and concluded that the representative uses on cereals and winter oilseed rape are acceptable.

The Theoretical Maximum Daily Intake (TMDI) for all considered consumer groups is max. 67% of the Acceptable Daily Intake (ADI), based on EFSA PRIMo Model rev.2. The International

[14] Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market Text with EEA relevance (OJ L 93, 3.4.2013, p. 1).

Estimated Short-Term Intake (IESTI) is max. 38% of the Acute Reference Dose (ARfD) for barley and 5.3% for oilseed rape, based on the same model.

The review has identified several acceptable exposure scenarios for operators, workers, residents, bystanders and groundwater 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 uses listed in Appendix II there are no unacceptable effects on the environment, as provided for in Article 4(3)(e) of Regulation (EC) No 1107/2009, provided that certain conditions are taken into account as detailed in section 6 of this 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 29(1) of Regulation (EC) No 1107/2009 and of the uniform principles laid down in Regulation (EU) No 546/2011.

Preliminary results of the consumer risk assessment showed potential acute intake concern for the uses for cucumber, courgette, lettuce and leafy brassica (kales). Hence, these proposed uses are not included in the Appendix II. Therefore, Member States must carefully consider the acute dietary intake to identify consumer risk from alpha-cypermethrin and its metabolites when carrying out evaluations of plant protection products for these or any other uses. Also, if Member States consider any product containing alpha-cypermethrin for these uses, they must carefully consider the risk to aquatic organism, as even taking into account mitigation measures, a high risk was identified for the proposed rates of application of 2 x 10g as/ha for the use by field spray application. The risk to non-target arthropods must also be carefully considered for use on lettuce and leafy brassicas.

As regards the new criteria to identify endocrine disrupting properties introduced by Commission Regulation (EU) 2018/605[15] which became applicable on 10 November 2018, alpha-cypermethrin is unlikely to be an endocrine-disruptor (ED) based on the available scientific information summarised in the EFSA conclusion as compared to other effects, there are no or very weak endocrine disruptive effects and no endocrine mode of action. However, in order to increase the confidence in this conclusion, the applicant will be requested to provide an updated assessment as regards the new ED-criteria within two years after publication of the implementing regulation renewing the approval of alpha-cypermethrin in line with the recently adapted guidelines.

Given that the ARfD and AOEL are significantly lower than those of the majority of the approved active substances within the groups of substances, **alpha-cypermethrin** meets the conditions of indent 1 of point 4 of Annex II and therefore shall be approved pursuant to Article 24 of Regulation (EC) No 1107/2009 as a candidate for substitution.

The following points could not be finalised by EFSA (2018):

– *The consumer dietary risk assessment cannot be finalised as for the provisional residue definitions for risk assessment in plants and animal commodities (pending finalisation of the assessment of the toxicity for the group of related metabolites bearing the 3-phenoxybenzoyl moiety, the genotoxic potential of metabolites 3-PBA and the relative toxicity of the*

15 Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. (OJ L 101, 20.4.2018, p. 33).

individual cypermethrin isomers, in particular the enantiomer (1S cis αR) and the identified data gaps for additional residue trials on cucumbers, kales, lettuces and barley. Furthermore an acute intake concern was identified for cucumbers (IESTI: 131% of ARfD, Dutch child), courgettes (IESTI: 104% of ARfD, UK toddler), kales (IESTI: 2541% of ARfD, Dutch child) and for lettuces (IESTI: 1248% of ARfD, German child) (see Section 3.1).

As a consequence, EFSA, in its Conclusion, pointed at the following issues to be further investigated when Member States authorise the plant production products containing alpha_cypermethrin:

1. EFSA states that all metabolites bearing the 3-phenoxybenzoyl moiety such as 3-PBA and 4-OH-PBA can be considered as unlikely to be genotoxic. Some of those metabolites are common to several pyrethroid active substances, including lambda-cyhalothrin and gamma-cyhalothrin. Similarly to the assessment of alpha-cypermethrin, EFSA could not finalise the risk assessment in those cases, and confirmatory data evaluations are ongoing; EFSA Technical Reports have already been or will be published in due course. To ensure a consistent and robust approach in the consideration of these common metabolites, the applicant of alpha-cypermethrin will also be requested to provide for confirmatory information to further address the toxicity of the metabolites.

2. More clarification is needed as regards the potential relative toxicity of individual cypermethrin isomers, in particular the enantiomer (1S cis αR) relevant to consumer exposure. Confirmatory information will be requested from the applicant to further address the toxicity of the isomers taking into account future developments in guidance in this area.

3. Overall, EFSA concluded that alpha-cypermethrin is unlikely to be genotoxic. However, the Conclusion points at a toxicity study in rabbits (Belgium, 2018) which showed positive results with a subsequent assessment of micronuclei formation in blood.

   Concerning point 3, Member States are strongly recommended to coordinate via the zonal system of authorisation, the evaluation of any new and necessary data during renewal or first authorisation of a plant protection product to ensure a harmonised approach and avoid duplication of work.

– *The consumer risk assessment is not finalised with regard to the unknown nature of residues that might be present in drinking water, consequent to water treatment following abstraction of surface water that might contain alpha-cypermethrin and its metabolites.*

At the time of submission of the dossier, there was no agreed guidance for assessing the effects of water treatment processes on residues that may occur in drinking water. There are no indications from the existing data that harmful by-products would be formed, nevertheless, further information is requested as confirmatory information once pertinent guidance becomes available.

4. Identity and Physical/chemical properties

The main identity of **alpha-cypermethrin** is given in Appendix I.

The active substance shall have a minimum purity of 980 g/kg.

The manufacturing impurity hexane is of toxicological, ecotoxicological and/or environmental concern.

The following maximum limit shall apply to this impurity in the active substance as manufactured:

– hexane: 1g/kg.

5. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in the conclusion of the EFSA.

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 alpha-cypermethrin

On the basis of the proposed and supported uses (as listed in Appendix II), the following 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:

– the protection of operators, ensuring that conditions of use prescribe the application of adequate personal protective equipment;
– the consumer risk assessment;
– the protection of aquatic organisms, bees and non-target arthropods.

Conditions of use shall include risk mitigation measures, where appropriate.

7. List of studies to be generated

The applicant shall submit confirmatory information as regards:

1. the toxicological profile of the metabolites bearing the 3-phenoxybenzoyl moiety;
2. the potential relative toxicity of individual cypermethrin isomers, in particular the enantiomer (1S cis αR) relevant to consumer exposure;
3. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater is abstracted for drinking water.
4. As regards Points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605 an updated assessment of the information already submitted and, where relevant, further information to confirm the absence of androgenic endocrine activity shall be submitted.

The applicant shall submit the information to the Commission, the Member States and the Authority:

- in point 1 by 30 October 2020;
- in point 2 within two years from the date of publication, by the Commission of a guidance document on evaluation of isomer mixtures;
- in point 3 within two years from the date of publication, by the Commission of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater;

- in point 4 by 30 October 2021 in accordance with Commission Regulation (EU) No 2018/605 and the joint guidance document to identify endocrine disrupting substances as adopted by EFSA and ECHA.

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.

A complete list of studies to be generated, still ongoing or available but not peer reviewed can be found in the relevant part of the EFSA Conclusion (page 20-21).

8. Information on studies with claimed data protection

For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the applicant has claimed data protection and which during the re-evaluation process were considered as essential with a view to approval under Regulation (EC) No 1107/2009. This information is only given to facilitate the operation of the provisions of Article 62 of Regulation (EC) No 1107/2009 in the Member States. It is based on the best information available 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 62 of Regulation (EC) No 1107/2009 and neither does it commit the Commission.

9. Updating of this renewal report

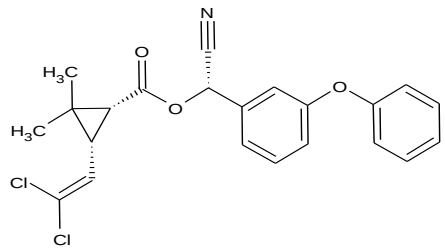
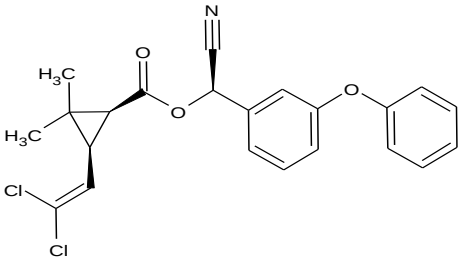
The information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 13, 21, 38, 44, 56 of Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on Plants, Animals, Food and Feed, in connection with any amendment of the approval conditions for alpha-cypermethrin**.**

APPENDIX I

Main identity

Alpha-cypermethrin

Chemical name (IUPAC)	Racemate comprising: (*R*)-α-cyano-3-phenoxybenzyl (1*S*,3*S*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (*S*)-α-cyano-3-phenoxybenzyl (1*R*,3*R*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate or (*R*)-α-cyano-3 phenoxybenzyl-(1*S*)-*cis*-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (*S*)-α-cyano-3 phenoxybenzyl-(1*R*)-*cis*-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
Chemical name (CA)	(*R*)-cyano(3-phenoxyphenyl)methyl (1*S*,3*S*)-*rel*-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate *(*Cis-*II isomeric pair of cypermethrin)*
CIPAC No	454
CAS No	[67375-30-8]
EC No (EINECS or ELINCS)	Not allocated
FAO Specification (including year of publication)	454/TC (2013) min. 930 g/kg
Minimum purity of the active substance as manufactured	980 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Hexane max. 1 g/kg
Molecular formula	$C_{22}H_{19}Cl_2NO_3$
Molar mass	416.3 g/mol

Structural formula	 [1*R cis* α*S*] +  [1*S cis* α*R*] Note: **1*R,S*** describes the configuration at the carboxyl-bearing carbon atom (C-1) of the cyclopropane ring; ***cis*/*trans*** describes the relationship to this carboxyl of the dichlorovinyl group at C-3; ***αR,S*** describes the configuration at the 'alpha' (α) position, i.e. the carbon atom bearing the nitrile (-CN, cyano) functional group. By the C.A. denomination, this configuration is described by **1*R*** or **1*S***.

APPENDIX II

List of uses supported by available data
Alpha-cypermethrin

Crop and/or situation (a)	Member State	Product Name	F G 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 a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	g a.i./hl min max (g/hl)	Water l/ha min max	a.i./ha min max (*) (g/ha)		
Cereals (barley, wheat, oats, rye, triticale)	North-/ Central-/ South-EU	FASTAC ME (BAS 310 55 I)	F	Chewing and Sucking Pests *RHOPPA* *Rhopalosiphum padi* *METODR* *Metopolophium dirhodum* *MACSAV* *Sitobion avenae* *LEMAME* *Oulema melanopus* *SITDMO* *Sitodiplosis mosellana* -All growth stages	ME	50 g/L	Spraying	BBCH 51-83	1-2	7 days	2.5 – 10	100 – 400	10	28	
Oilseed rape winter	North-/ Central-/ South-EU	FASTAC ME (BAS 310 55 I)	F	*CEUTNA* *Ceutorhynchus napi* *CEUTAS* *Ceutorhynchus assimilis* *MELIAE* *Meligethes aeneus* -Adults-	ME	50 g/L	Spraying	BBCH 51-59	1-2	7 days	2.5 – 10	100 – 400	10	28	

For uses where the column „Remarks“ in marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).

(a) For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse 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 N° 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 plant – type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).
(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) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval