EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
**Pesticides and biocides**

Lambda-cyhalothrin
SANCO/12282/2014 Rev 5
11 December 2015[1]
17 July 2020[2]

**Final** Review report for the active substance lambda-cyhalothrin
finalised in the Standing Committee on Plants, Animals, Food and Feed
at its meeting on 11 December 2015
in view of the renewal of the approval of lambda-cyhalothrin as active substance
in accordance with Regulation (EC) No 1107/2009[3]

## 1. Procedure followed for the re-evaluation process

This review report has been established as a result of the evaluation of lambda-cyhalothrin, in accordance with Regulation (EC) No 1107/2009[4] and Commission Regulation (EU) No 1141/2010[5] following the submission of an application to renew the approval of this active substance expiring in June 2016.

Commission Regulation (EU) No 1141/2010, as amended by Commission Implementing Regulation (EU) No 380/2013[6], lays down the procedure for the renewal of the second group of active substances in Annex I to Directive 91/414/EEC[7] and includes lambda-cyhalothrin.

Lambda-cyhalothrin 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 2000/80/EC[8]. Lambda-cyhalothrin 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[9].

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1 On 29 May 2015, the Standing Committee on Plant Animal Food and Feed took note of the updated toxicological reference values for lambda-cyhalothrin, as significantly revised in the EFSA Conclusion published in March 2015. Considering that EFSA received a mandate from the Commission to update by 6 months all MRLs where reference values have changed, the Committee decided to take note of the toxicological reference values before voting any proposal for possible renewal or withdrawal of lambda-cyhalothrin. This procedure was considered as exceptional and it is followed in this particular case to avoid delays with the review of the MRLs by EFSA. The revised toxicological reference values are listed in Appendix II, point 1 of this report.

2 On 17 July 2020, the Standing Committee on Plants, Animals, Food and Feed took note of the revision of the review report for the active substance lambda-cyhalothrin, after the finalisation of the confirmatory data as referred to in point 7 of this report (cf. infra).

3 Does not necessarily represent the views of the Commission.

4 OJ L 309, 24.11.2009, p. 1.

5 OJ L 322, 8. 12.2010, p. 10.

6 OJ L 116, 26.4.2013, p.4.

7 OJ L 230, 19.8.1991, p. 1.

8 OJ L 309, 19.12.2000, p. 14.

9 OJ L 153, 11.6.2011, p. 1.

In accordance with the provisions of Article 5 of Directive 91/414/EEC, seven companies and task forces notified to the Commission of their wish to renew the approval of the active substance lambda-cyhalothrin.

Commission Directive 2015/1885[10] extended until 30 June 2016 the period of approval of lambda-cyhalothrin to allow the completion of its review.

Commission Regulation (EU) No 1141/2010 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 lambda-cyhalothrin the rapporteur Member State was Sweden and the co-rapporteur Member State was Spain.

Sweden finalised in February 2013 its examination, in the form of a renewal assessment report. This Report was sent to the Commission and the European Food Safety Authority on 28 February 2013 and included a recommendation concerning the decision to be taken with regard to the renewal of the approval of lambda-cyhalothrin for the supported uses.

In accordance with Article 16 of Commission Regulation (EU) No 1141/2010, the Commission requested the EFSA to arrange an expert consultation on the rapporteur Member State's renewal assessment report and to deliver its conclusions.

Therefore, 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 11 March 2015. This conclusion refers to background document A (renewal assessment report and additional report) and background document B (EFSA peer review report).

According to the provisions of Article 17 of Regulation (EU) No 1141/2010, the Commission referred a draft review report on the renewal of approval to the Standing Committee on Plants, Animals, Food and Feed, for final examination on 9 October 2015. The draft review report on renewal of approval was finalized in the meeting of the Standing Committee on 11 December 2015 and further updated on 17 July 2020 in light of the assessment of confirmatory information submitted.

The present review report on renewal of approval contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of the EFSA, and the comments and clarifications submitted after the conclusion of the EFSA (part of background document C), these documents are also considered to be part of this review report.

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10 OJ L 276 21.10.2015 p.48.

11 EFSA (European Food Safety Authority), 2014. Conclusion on the peer review of the pesticide risk assessment of the active substance lambda-cyhalothrin. EFSA Journal 2014;12(5):3677, 170 pp. doi:10.2903/j.efsa.2014.3677.

## 2. Purposes of this review report

This review report, including the background documents and appendices hereto, has been developed and finalised in support of **Commission Implementing Regulation (EU) 2016/146**[12] concerning the renewal of approval of lambda-cyhalothrin as active substance under Regulation (EC) No 1107/2009, and to assist the Member States in decisions on individual plant protection products containing lambda-cyhalothrin they have to take in accordance with the provisions of that 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].

This review 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 544/2011[14], submitted for the purpose of (renewal of) approval of the active substances, as well as the result of the evaluation of those data.

In accordance with the provisions of Article 18 of Regulation (EU) No 1141/2010, this review report will be made available to the public.

The information in this review 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 review 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 review 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 lambda-cyhalothrin 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 lambda-cyhalothrin containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of 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 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 29(1) of Regulation (EC) No 1107/2009 and of the uniform principles laid down in Regulation (EU) No 546/2011.

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12 OJ L 30, 5.2.2016, p. 7–11.

13 OJ L 155, 11.6.2011, p. 127.

14 OJ L 155, 11.6.2011, p. 1.

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. In particular, Member States shall pay particular attention to the protection of aquatic organisms.

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

ADI: 0,0025 mg/kg bw per day,
ARfD: 0,005 mg/kg bw,
AOEL: 0,00063 mg/kg bw per day.

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) is estimated to be 10.8 % of the Acceptable Daily Intake (ADI) (WHO cluster diet B) based on EFSA PRIMo Model rev.2 and the highest International Estimated Short-Term Intake (IESTI) was calculated to be below the Acute Reference dose (ARfD).

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 following points could not be finalised or were considered as a critical area of concern by EFSA (2015) for lambda-cyhalothrin for the following reasons:

1. *Lambda-cyhalothrin is not classified or proposed to be classified as carcinogenic category 2 or toxic for reproduction category 2, in accordance with the provisions of Regulation (EC) No 1272/2008, and therefore the conditions of the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine disrupting properties are not met. However, an endocrine-mediated mode of action could not be ruled out regarding the brain morphological changes observed in the developmental neurotoxicity study (and possible sperm effects, which have to be clarified in the first place) and the potential for endocrine disrupting effects could not be finalised (see Sections 2 and 5).* As regards the current regulatory framework, lambda-cyhalothrin shall not be considered an endocrine disruptor since it does not fulfil the interim criteria to identify endocrine disruptors, as set in Annex II paragraph 3.6.5. As regards the observed brain morphological changes, these were the critical effects in a developmental neurotoxicity study for which the NOAEL was 4.9 mg/Kg bw per day. These effects are covered by the lowest relevant NOAEL (0.5 mg/Kg bw per day) seen in the multigenerational study in rats. As regards possible sperm effects, these were reported in mice in a single study in the published literature. Confirmatory data (see section 7) are requested to investigate further on the relevance and reproducibility of these effects.

2. *The consumer risk assessment could not be finalised as the proposed residue definition for risk assessment remains provisional for processed commodities and considering the uncertainties due to the identified data gaps.* The data gap identified for processed commodities regards sterilization. Acceptable processing studies on tomatoes showed that residues of relevant metabolites formed in sterilised canned tomatoes were below the LOQ (<0.01 mg/kg), which demonstrate that the use supported by the applicant is safe. The remaining data gaps regard metabolites, which are addressed by the confirmatory data required in section 7.

3. *A complete route of degradation of lambda-cyhalothrin in the aquatic compartment could not be finalised as satisfactory information to address the levels of metabolites formed from the phenoxy-14C labelled lambda-cyhalothrin when applied at doses below the water solubility is not available. Consequently, the risk to aquatic organisms from any additional pertinent metabolites could not be finalised.* Using a weight of evidence approach - which includes consideration of all available mesocosm studies submitted for the assessment of lambda-cyhalothrin and gamma-cyhalothrin for uses as plant protection products and as biocidal products - the risk to the aquatic compartment is considered acceptable. Safe uses of lambda-cyhalothrin have been demonstrated in some Member States. Member States shall pay particular attention to the risk for aquatic organisms when evaluating applications for authorization of plant protection products.

4. *The assessment of the potential for biomagnification in aquatic and terrestrial food chains could not be finalised with the available information*.
   The studies required by the data requirements have been submitted and are considered acceptable.

5. *It could not be fully demonstrated that the batches used in the toxicological and ecotoxicological studies are compliant to the proposed technical specification, as it appears that some impurities have not been tested (or not at an appropriate level) in the toxicological studies*. EFSA indicates that "*the specification for the first approval, containing significantly higher levels of impurities, was not covered by the profile of the toxicological batches at that time*". The situation is improved with respect to the first approval, where significantly higher levels of impurities were present in the technical specification. To reassess the mammalian and/or ecotoxicological data package with the aim to clarify the uncertainties linked to the presence of some impurities is considered unjustified. In light of the above and to avoid duplication of vertebrate testing, the point is considered as sufficiently addressed.

6. *A high acute and chronic risk to aquatic organisms was indicated for all representative uses, even when, where available, the risk assessment was performed using exposure estimates which assumed the maximum permissible risk mitigation according to the FOCUS Landscape and Mitigation Guidance Document (FOCUS, 2007).* Using a weight of evidence approach - which includes consideration of all available mesocosm studies submitted for the assessment of lambda-cyhalothrin and gamma-cyhalothrin for uses as plant protection products and as biocidal products - the risk to the aquatic compartment is considered acceptable. Safe uses of lambda-cyhalothrin have been demonstrated in some Member States. Member States shall pay particular attention to the risk for aquatic organisms when evaluating applications for authorization of plant protection products.

7. *A data gap was identified to address the long-term risk to mammals and the risk to off-field populations of non-target arthropods for all representative uses.* The legislative proposal includes provisions for Member States to pay particular attention to the risk for non-target organisms.

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(3)(e) of Regulation (EC) No 1107/2009, provided that certain conditions are taken into account as detailed in section 6 of this report.

Lambda-cyhalothrin was included in the list of candidates for substitution (Regulation (EU), given that:

1. the Acceptable Operator Exposure Level (AOEL) is significantly lower than those of the majority of the approved active substances within the group of insecticides;
2. lambda-cyhalothrin meets the criteria to be considered a bioaccumulative and toxic substance, Commission Implementing Regulation (EU) 2015/408).

Moreover, there are reasons for concern linked to the nature of its critical effects (developmental neurotoxic effects) and lambda-cyhalothrin may contain a significant proportion of non-active isomers.

Therefore, it shall be approved pursuant to Article 24 of Regulation (EC) No 1107/2009 as a candidate for substitution.

## 4. Identity

The main properties of lambda-cyhalothrin are given in Appendix I.

The active substance shall comply with the minimum purity of 900 g/kg (see appendix I). The FAO specification 463/TC (2013) indicates a minimum purity of 810 g/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 lambda-cyhalothrin

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.

In this overall assessment Member States shall pay particular attention to the:

a) protection of operator, worker and bystander;
b) metabolites potentially formed in processed commodities;
c) risk to aquatic organisms, mammals and non-target arthropods.

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

## 7. List of studies to be generated

Further studies were identified which were at this stage considered necessary in relation to the approval of lambda-cyhalothrin under the current approval conditions.

The concerned Member States shall request the submission of confirmatory information as regards:

1. a systematic review using guidance available (e.g. EFSA GD on Systematic Review methodology, 2010[15]) to assess the evidence available as regards potential sperm effects linked to exposure to lambda-cyhalothrin.

2. toxicological information to assess the toxicological profile of the metabolites V (PBA) and XXIII (PBA(OH)).

The applicant shall submit to the Commission, the Member States and the Authority that information by 1 April 2018.

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 23-25).

On 17 July 2020, the Standing Committee on Plants, Animals, Food and Feed took note of the revision of this review report after the assessment of the confirmatory data as referred above in this section. This assessment has been carried out in line with the 'Guidance document on the procedures for submission and assessment of confirmatory information following approval of an active substance in accordance with Regulation (EC) No 1107/2009[16], and based on the EFSA Technical Report "Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for lambda-cyhalothrin in light of confirmatory data submitted"[17].

EFSA concluded that confirmatory information as regards the systematic review is considered addressed. None of the reliable studies provided any evidence on potential sperm effects linked to the exposure to lambda-cyhalothrin.

As regards the genotoxicity profile of PBA and PBA(OH), EFSA concluded that based on the new data submitted no firm conclusion could be drawn regarding gene mutation and chromosome aberration potential of both metabolites, since some issues were identified with regard to data interpretation. Furthermore, as the additional acute toxicity studies were considered insufficient to address the relative general toxicity of the metabolites compared to the parent, a data gap was concluded on the general toxicity profile of metabolites PBA and PBA(OH).

As PBA and PBA(OH) are common metabolites to many pyrethroid substances (e.g. gamma-cyhalothrin, cypermethrins, deltamethrin), a harmonised evaluation of all data available for PBA and PBA(OH) coming from the different relevant active substances dossiers is necessary to provide consistent conclusions relevant for the active substances having PBA and PBA(OH) as common metabolites. For such an assessment a horizontal review PBA and PBA(OH) will be needed, e.g. via a mandate to EFSA.

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15 European Food Safety Authority; Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal 2010; 8(6):1637. [90 pp.]. doi:10.2903/j.efsa.2010.1637. Available online: http://www.efsa.europa.eu/en/efsajournal/pub/1637.htm.

16 Doc. SANCO/5634/2009 rev. 6.1, 13.12.2013

17 Published on 26 June 2020; http://www.efsa.europa.eu/en/supporting/pub/en-1883.

The renewal review of lambda-cyhalothrin will commence in October 2020 as the deadline for dossier submission is 30 September 2020. The Technical Report on the confirmatory information of lambda-cyhalothrin and any output of a horizontal review by EFSA on common metabolites shall be taken into account during the renewal evaluation by the Rapporteur Member State(s). Furthermore, depending on the outcome of the horizontal review of PBA and PBA(OH) by EFSA, the approval of lambda-cyhalothrin may need to be reconsidered.

## 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 review 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 lambda-cyhalothrin.

## APPENDIX I

## Identity
## LAMBDA-CYHALOTHRIN

| | |
|---|---|
| **Common name (ISO)** | Lambda-cyhalothrin |
| **Chemical name (IUPAC)** | A 1:1 mixture of:<br><br>(*R*)-α-cyano-3-phenoxybenzyl (1*S*,3*S*)-3-[(*Z*)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate and (*S*)-α-cyano-3-phenoxybenzyl (1*R*,3*R*)-3-[(*Z*)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate or of (*R*)-α-cyano-3-phenoxybenzyl (1*S*)-*cis*-3-[(*Z*)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate and (*S*)-α-cyano-3-phenoxybenzyl (1*R*)-*cis*-3-[(*Z*)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate |
| **Chemical name (CA)** | (*R*)-cyano(3-phenoxyphenyl)methyl (1*S*,3*S*)-*rel*-3-[(1*Z*)-2-chloro-3,3,3-trifluoro-1-propen-1-yl]-2,2-dimethylcyclopropanecarboxylate |
| **CIPAC No** | 463 |
| **CAS No** | 91465-08-6 |
| **EEC No** | Not allocated |
| **FAO SPECIFICATION** | FAO/WHO Specification 463/TC (2013):<br>Min. purity: 810 g/kg<br><br>The maximum acidity shall be 0.5 g/kg, calculated as $H_2SO_4$ |
| **Minimum purity** | 900 g/kg |
| **Molecular formula** | $C_{23}H_{19}ClF_3NO_3$ |
| **Molecular mass** | 449.9 g/mol |

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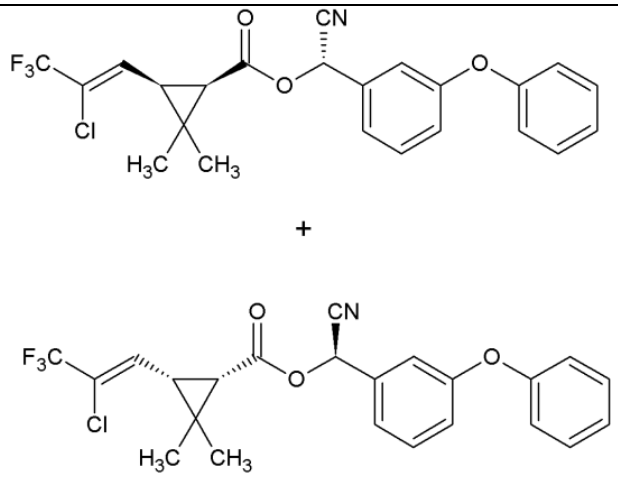
|---|---|
| **Structural formula** |  |

## APPENDIX II
## List of uses supported by available data
## LAMBDA-CYHALOTHRIN

| 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 (day) (l) | Remarks: (m) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Type (d-f) | Conc. of a.s. (i) | method kind (f-h) | growth stage & season (j) | number min max (k) | interval between applications (min) | g a.s./hL min max | water L/ha min max | g a.s./ha min max | | |
| Spring Wheat | EU-N | Karate 10CS Kaiso sorbie | F | Cereal aphids (Sitobio, Rhopalosiphon padi, Metapolophium etc)<br>Aphids as virus vectors<br>Psammotettix alienus (Wheat dwarf virus vector),<br>Zabrus, Oulemma,<br>Delia sp.,<br>Gall midges (Sitodiplosis and Contarina sp.) and thrips. | EG | 50 g/kg | foliar spray | BBCH 10-85 | 2 | 18 | 1.25-3,75 | 200-600 | 7.5 | | The last application should be made no later than at growth stage BBCH 83-85<br>STF |
| Winter Wheat | EU-N | Karate 10CS Kaiso sorbie | F | | EG | 50 g/kg | foliar spray | BBCH 10-85 | 2 | 18 | 1.25-3,75 | 200-600 | 7.5 | | |

| 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 (day) (l) | Remarks: (m) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Type (d-f) | Conc. of a.s. (i) | method kind (f-h) | growth stage & season (j) | number min max (k) | interval between applications (min) | g a.s./hL min max | water L/ha min max | g a.s./ha min max | | |
| Spring Wheat | EU-S | Karate 10CS Kaiso sorbie | F | Cereal aphids (Sitobio, Rhopalosiphon padi, Metapolophium etc)<br>Aphids as virus vectors<br>Psammotettix alienus (Wheat dwarf virus vector),<br>Zabrus, Oulemma,<br>Delia sp.,<br>Gall midges (Sitodiplosis and Contarina sp.) and thrips. | EG | 50 g/kg | foliar spray | BBCH 10-85 | 2 | 18 | 0.75-1.07 | 700-1000 | 7.5 | | The last application should be made no later than at growth stage BBCH 83-85<br>STF |
| Winter Wheat | EU-S | Karate 10CS Kaiso sorbie | F | | EG | 50 g/kg | foliar spray | BBCH 10-85 | 2 | 18 | 0.75-1.07 | 700-1000 | 7.5 | | |

| 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 (day) (l) | Remarks: (m) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Type (d-f) | Conc. of a.s. (i) | method kind (f-h) | growth stage & season (j) | number min max (k) | interval between applications (min) | g a.s./hL min max | water L/ha min max | g a.s./ha min max | | |
| Winter Wheat | EU-N | Lambda-Cyhalothrin 100 CS Lambda 50 EC | F | Aphids (Virus vectors) | EC | 50 g/L | Tractor mounted sprayer, broadcast, ground directed spray | BBCH 10 to 29 (≈ Oct./EU-N) | 1-2 | 14 | 1.875-3.75 | 200-400 | 7.5 | | RMS comment: Note that winter wheat may be treated both in Oct and Jun. TFL |
| Winter Wheat | EU-N | Lambda-Cyhalothrin 100 CS Lambda 50 EC | F | Aphids | EC | 50 g/L | Tractor mounted sprayer, broadcast, ground directed spray | BBCH 30 to 79 (≈ Jun./EU-N) | 1-2 | 14 | 0.75-1.07 | 200-400 | 7.5 | 30 | RMS comment: Note that winter wheat may be treated both in Oct and Jun. TFL |
| Spring Wheat | EU-N | Lambda-Cyhalothrin 100 CS Lambda 50 EC | F | Aphids | EC | 50 g/L | Tractor mounted sprayer, broadcast, ground directed spray | BBCH 30 to 79 (≈ Jun./EU-N) | 1-2 | 14 | 0.75-1.07 | 200-400 | 7.5 | 30 | TFL |

| 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 (day) (l) | Remarks: (m) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Type (d-f) | Conc. of a.s. (i) | method kind (f-h) | growth stage & season (j) | number min max (k) | interval between applications (min) | g a.s./hL min max | water L/ha min max | g a.s./ha min max | | |
| Winter Wheat | EU-S | Lambda-Cyhalothrin 100 CS Lambda 50 EC | F | Aphids (Virus vectors) | EC | 50 g/L | Tractor mounted sprayer, broadcast, ground directed spray | BBCH 10 to 29 (Nov./EU-S) | 1-2 | 14 | 0.75-1.07 | 200-400 | 7.5 | | RMS comment: Note that winter wheat may be treated both in Nov and May. TFL |
| Winter Wheat | EU-S | Lambda-Cyhalothrin 100 CS Lambda 50 EC | F | Aphids | EC | 50 g/L | Tractor mounted sprayer, broadcast, ground directed spray | BBCH 30 to 79 ( May/EU-S) | 1-2 | 14 | 0.75-1.07 | 200-400 | 7.5 | 30 | RMS comment: Note that winter wheat may be treated both in Nov and May. TFL |
| Spring Wheat | EU-S | Lambda-Cyhalothrin 100 CS Lambda 50 EC | F | Aphids | EC | 50 g/L | Tractor mounted sprayer, broadcast, ground directed spray | BBCH 30 to 79 ( May/EU-S) | 1-2 | 14 | 0.75-1.07 | 200-400 | 7.5 | 30 | TFL |
| | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |

| 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 (day) (l) | Remarks: (m) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Type (d-f) | Conc. of a.s. (i) | method kind (f-h) | growth stage & season (j) | number min max (k) | interval between applications (min) | g a.s./hL min max | water L/ha min max | g a.s./ha min max | | |
| | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |
| Seed Potato | EU-N | Lambda-Cyhalothrin 100 CS Lambda 50 EC | F | Aphids (Virus vectors) | EC | 50 g/L | Tractor mounted sprayer, broadcast, ground directed spray | BBCH 15-39 (≈ Apr.) | 2 | 7 | 1.25-1.875 | 400-600 | 7.5 | | RMS comment: Note that Seed Potato may be treated both in Apr and Jun-Sep. Refers to potatoes that are to be used as seed potatoes inthe next year. TFL |

| 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 (day) (l) | Remarks: (m) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Type (d-f) | Conc. of a.s. (i) | method kind (f-h) | growth stage & season (j) | number min max (k) | interval between applications (min) | g a.s./hL min max | water L/ha min max | g a.s./ha min max | | |
| Seed Potato | EU-N | Lambda-Cyhalothrin 100 CS Lambda 50 EC | F | Aphids, Colorado potato beetles | EC | 50 g/L | Tractor mounted sprayer, broadcast, ground directed spray | BBCH 40 to 85 (Jun. - Sep.) | 2 | 7 | 1.25-1.875 | 400-600 | 7.5 | 3 | RMS comment: Note that Seed Potato may be treated both in Apr and Jun-Sep. Refers to potatoes that are to be used as seed potatoes inthe next year. TFL |
| Potato | EU-N | Lambda-Cyhalothrin 100 CS Lambda 50 EC | F | Aphids, Colorado potato beetles | EC | 50 g/L | Tractor mounted sprayer, broadcast, ground directed spray | BBCH 40-85 (Jun. - Sep.) | 2 | 7 | 1.25-1.875 | 400-600 | 7.5 | 3 | RMS comment: Refers to potatoesharvested forconsumption. TFL |

| 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 (day) (l) | Remarks: (m) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Type (d-f) | Conc. of a.s. (i) | method kind (f-h) | growth stage & season (j) | number min max (k) | interval between applications (min) | g a.s./hL min max | water L/ha min max | g a.s./ha min max | | |
| Seed Potato | EU-S | Lambda-Cyhalothrin 100 CS Lambda 50 EC | F | Aphids (virus vectors) | EC | 50 g/L | Tractor mounted sprayer, broadcast, ground directed spray | BBCH 15-39 (Mar.) | 1 | | 2-5 | 400-1000 | 20 | | RMS comment: Note that Seed Potato may be treated both in Mar and May-Sep (min. 8(-10) days interval between applications). Refers to potatoes that are to be used as seed potatoes inthe next year. TFL |

| 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 (day) (l) | Remarks: (m) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Type (d-f) | Conc. of a.s. (i) | method kind (f-h) | growth stage & season (j) | number min max (k) | interval between applications (min) | g a.s./hL min max | water L/ha min max | g a.s./ha min max | | |
| Seed potato | EU-S | Lambda-Cyhalothrin 100 CS Lambda 50 EC | F | Aphids, Colorado potato beetles | EC | 50 g/L | Tractor mounted sprayer, broadcast, ground directed spray | BBCH 40-85 (May - Sep.) | 1 | | 2-5 | 400-1000 | 20 | 3 | RMS comment: Note that Seed Potato may be treated both in Mar and May-Sep. (min. 8(-10) days interval between applications). Refers to potatoes that are to be used as seed potatoes in the next year. TFL |
| Potato | EU-S | Lambda-Cyhalothrin 100 CS Lambda 50 EC | F | Aphids, Colorado potato beetles | EC | 50 g/L | Tractor mounted sprayer, broadcast, ground directed spray | BBCH 40-85 (May – Sep). | 2 | 8 | 2-5 | 400-1000 | 20 | 3 | RMS comment: Refers to potatoes harvested for consumption. TFL |
| | | | | | | | | | | | | | | | |

| 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 (day) (l) | Remarks: (m) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Type (d-f) | Conc. of a.s. (i) | method kind (f-h) | growth stage & season (j) | number min max (k) | interval between applications (min) | g a.s./hL min max | water L/ha min max | g a.s./ha min max | | |

**Remarks:**

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*eg.* fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) eg. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) eg. wettable powder (WP), watersoluble granule (WG)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, eg. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, eg. 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

(1) During the written procedure the RMS indicated that the GAP for plums should be BBCH 10-79. EFSA proposes to leave unchanged the reported NEU and SEU GAPs on plums with regard to the BBCH GS (10-85). Indeed, at the proposed earlier BBCH 10-79, the PHI value of 7 days may become inappropriate.