

REGISTRATION REPORT

Part A

Risk Management

Product code: TM0005

Product name: FLYPACK CERASI

**Chemical active substance:
deltamethrin, 0.015 g/trap**

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: SEDQ

Date: 07/05/2019

Table of Contents

| | | |
|----------|---|-----------|
| 1 | Details of the application | 4 |
| 1.1 | Application background..... | 4 |
| 1.2 | Letters of Access..... | 5 |
| 1.3 | Justification for submission of tests and studies | 5 |
| 1.4 | Data protection claims | 5 |
| 2 | Details of the authorisation decision | 5 |
| 2.1 | Product identity | 5 |
| 2.2 | Conclusion | 5 |
| 2.3 | Substances of concern for national monitoring | 6 |
| 2.4 | Classification and labelling..... | 6 |
| 2.4.1 | Classification and labelling under Regulation (EC) No 1272/2008 | 6 |
| 2.4.2 | Standard phrases under Regulation (EU) No 547/2011 | 6 |
| 2.4.3 | Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009) | 6 |
| 2.5 | Risk management..... | 6 |
| 2.5.1 | Restrictions linked to the PPP | 7 |
| 2.5.2 | Specific restrictions linked to the intended uses | 8 |
| 2.6 | Intended uses (only NATIONAL GAP) | 9 |
| 3 | Background of authorisation decision and risk management | 11 |
| 3.1 | Physical and chemical properties (Part B, Section 2) | 11 |
| 3.2 | Efficacy (Part B, Section 3) | 11 |
| 3.3 | Methods of analysis (Part B, Section 5)..... | 11 |
| 3.3.1 | Analytical method for the formulation | 11 |
| 3.3.2 | Analytical methods for residues..... | 11 |
| 3.4 | Mammalian toxicology (Part B, Section 6) | 12 |
| 3.4.1 | Acute toxicity..... | 12 |
| 3.4.2 | Operator exposure | 12 |
| 3.4.3 | Worker exposure | 13 |
| 3.4.4 | Bystander and resident exposure | 13 |
| 3.5 | Residues and consumer exposure (Part B, Section 7)..... | 14 |
| 3.6 | Environmental fate and behaviour (Part B, Section 8) | 14 |
| 3.7 | Ecotoxicology (Part B, Section 9) | 15 |
| 3.8 | Relevance of metabolites (Part B, Section 10) | 15 |
| 4 | Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009) | 15 |
| 5 | Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation..... | 15 |
| 5.1.1 | Post-authorisation monitoring..... | 15 |

| | | |
|-------------------|--|-----------|
| 5.1.2 | Post-authorisation data requirements | 15 |
| Appendix 1 | Copy of the product authorisation | 16 |
| Appendix 2 | Copy of the product label..... | 21 |
| Appendix 3 | Letter of Access | 24 |

PART A

RISK MANAGEMENT

1 Details of the application

The company SEDQ has requested marketing authorisation in France for the product FLYPACK CERASI (formulation code: TM0005), containing 0.015g deltamethrin/trap for use as an insecticide (professional uses).

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum/addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to FLYPACK CERASI (TM0005) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of FLYPACK CERASI (TM0005) have been made using endpoints agreed in the EU peer review of deltamethrin.

This document describes the specific conditions of use and labelling required for France for the registration of FLYPACK CERASI (TM0005).

Appendix 1 of this document provides a copy of the product authorisation.

Appendix 2 of this document contains a copy of the product label (draft as proposed by the applicant).

Appendix 3 of this document contains a copy of the Letter(s) of Access.

Appendix 4 of this document provides the list of data considered for national authorisation.

1.1 Application background

The present registration report concerns the evaluation of SEDQ's application to market FLYPACK CERASI (TM0005) in France as an insecticide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

The present application (2017-1954) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")¹ – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

The current document (RR) based on Anses assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009², implementing regulations, and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail.

¹ SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev.5.

² REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011³, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

1.2 Letters of Access

The applicant has provided Letter(s) of Access for PPP data.

1.3 Justification for submission of tests and studies

According to the applicant: FLYPACK CERASI (TM0005) is “*a new product never registered in Europe. All studies presented in this dossier are deemed necessary to support the registration in France*”.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of FLYPACK CERASI (TM0005), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

| | |
|---|---|
| Product code | TM0005 |
| Product name in MS | FLYPACK CERASI |
| Authorisation number | 2190253 |
| Low risk (article 47) | No. |
| Function | Insecticide. |
| Applicant | SEDQ. |
| Active substance(s) (incl. content) | Deltamethrin, 0.015g/trap. |
| Formulation type | Ready to use trap. |
| Packaging | Polypropylene bags (containing 1 unit*, 2 units, 5 units, 20 units, 240 units). |
| Coformulants of concern for national authorisations | - |
| Restrictions related to identity | - |
| Mandatory tank mixtures | None. |
| Recommended tank mixtures | None. |

*1 unit = 1 trap with a top and base in PP.

2.2 Conclusion

The evaluation of the application for FLYPACK CERASI (TM0005) resulted in the decision **to grant** the

³ COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products.

authorisation.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

| | |
|-------------------------------|--|
| Hazard class(es), categories: | Hazardous to the aquatic environment, Acute Hazard, Category 1. Hazardous to the aquatic environment, Chronic Hazard, Category 1. |
| Hazard pictograms: |  |
| Signal word: | Warning |
| Hazard statement(s): | H400 : Very toxic to aquatic life. H410 : Very toxic to aquatic life with long-lasting effects. |
| Precautionary statement(s): | <i>For the P phrases, refer to the extant legislation</i> |
| Additional labelling phrases: | The product FLYPACK CERASI (TM0005) contains deltamethrin. It may cause paresthesia. According to the French Order of 9 November 2004 ⁴ , it should be mentioned on the label to avoid contact with skin. |

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

| | |
|------|---|
| SP 1 | Do not contaminate water with the product or its container. |
| | For other restrictions refer to 2.5. |

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017⁵ provides that:

⁴ The legal basis of this is *Arrêté du 9 novembre 2004 modifiant l'arrêté du 20 avril 1994 relatif à la déclaration, la classification, l'emballage et l'étiquetage des substances*, <https://www.legifrance.gouv.fr/eli/arrete/2004/11/9/SOCT0412154A/jo>.

⁵ Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGR1632554A/jo/texte>.

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres;
- unless formally stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, drift buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

Finally, the French Order of 26 March 2014⁶ provides that:

- an authorisation granted for a “reference” crop applies also for “linked” crops, unless formally stated in the Decision
- the “reference” and “linked” crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “linked” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those “linked” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁷ is to supply “minor” crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

2.5.1 Restrictions linked to the PPP

The authorisation of the PPP is linked to the following conditions:

| | |
|---|---|
| Operator protection: | |
| - | refer to the Decision in Appendix 1 for the details. |
| Worker protection: | |
| - | refer to the Decision in Appendix 1 for the details. |
| Integrated pest management (IPM)/sustainable use: | |
| | - |
| Environmental protection | |
| | Remove traps at harvest at the latest. |
| Other specific restrictions | |
| Re-entry period | Not applicable. |
| Storage | The formulation must be stored in a room where temperature remains below 40°C |
| Risk mitigation measure | - |

⁶ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGR1407093A/jo>.

⁷ SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9.

| | |
|------------------------------|---|
| Agricultural recommendations | - |
|------------------------------|---|

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.

| | | | | | | | | GAP rev. 1, date: 2019-05-07 | | | | |
|--------------------------|-------------------------|-----------------------|-------------------------------------|--|--|--|--|------------------------------|--|--|--|--|
| PPP (product name/code): | TM0005 / FLYPACK CERASI | Formulation type: | Ready-to-use trap ^(a, b) | | | | | | | | | |
| Active substance 1: | deltamethrin | Conc. of a.s. 1: | 0.015 g/trap ^(c) | | | | | | | | | |
| Safener: | - | Conc. of safener: | - ^(c) | | | | | | | | | |
| Synergist: | - | Conc. of synergist: | - ^(c) | | | | | | | | | |
| Applicant: | SEDQ | Professional use: | <input checked="" type="checkbox"/> | | | | | | | | | |
| Zone(s): | southern ^(d) | Non-professional use: | <input type="checkbox"/> | | | | | | | | | |
| Verified by MS: | Yes | | | | | | | | | | | |
| Field of use: | insecticide | | | | | | | | | | | |

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|---|--------------------|---|---|---|--|---|---|--|--|---|------------------------------|---------------|--|
| Use- No. ^(e) | Member state(s) | Crop and/ or situation (crop destination/purpose of crop) | F, Fn, Fpn G, Gn, Gpn or I | Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group) | Application | | | | Application rate | | | PHI (days) | Remarks: e.g. g safener/synergist per ha ^(f) |
| | | | | | Method/ Kind | Timing/Growth stage of crop & season | Max. number a) per use b) per crop/ season | Min. interval between applications (days) | No. of trap/ha a) max. rate per appl. b) max. total rate per crop/season | g a.s./ha a) max. rate per appl. b) max. total rate per crop/season | Water L/ha min/ max | | |
| Zonal uses (field or outdoor uses, certain types of protected crops) | | | | | | | | | | | | | |
| 1 | FR | Cherry PRNAV | F | <i>Rhagoletis cerasi</i> RHAGCE | Attract and kill trap /Traps hang manually in trees | Post-flowering (from BBCH 70) At fly flight start | a) 1 b) 1 | n/a | a) 100 traps/ha b) 100 traps/ha | a) 1.5 g/ha b) 1.5 g/ha | n/a | n/a | Acceptable Efficacy shown on <i>Rhagoletis cerasi</i> |

Remarks table heading: (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR).
 (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008.
 (c) g/kg or g/l.
 (d) Select relevant.
 (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.
 (f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

- 1 Numeration necessary to allow references.
- 2 Use official codes/homelacatures of EU Member States.
- 3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure).
- 4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
- 5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
- 6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
- 7 Growth stage at first and 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.
- 8 The maximum number of application possible under practical conditions of use must be provided.
- 9 Minimum interval (in days) between applications of the same product.
- 10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
- 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
- 12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
- 13 PHI - minimum pre-harvest interval.
- 14 Remarks may include: Extent of use/economic importance/restrictions.

3 Background of authorisation decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

FLYPACK CERASI (TM0005) is a “trap with Attract and Kill technology” [applicant’s citation]. All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a fly trap with a yellow or orange base (PP) and a clear top (PP). The inner surface of the top is impregnated with deltamethrin. It is dry to the touch, with no odour. It is not flammable or explosive and has no oxidising properties. The top portion was chemically stable after 14 days’ storage at 54°C, but the attractant lost mass (due to the instability of ammonium carbonate at temperature > 58°C; a mass loss of the attractant of about 28% was noticed after two weeks). The attractant is stable at 40°C for eight weeks in packets. The ambient temperature shelf-life study is on-going and should be provided post-authorisation. The formulation’s technical characteristics are acceptable for a trap.

The formulation is not classified for the physico-chemical aspect.

The formulation must be stored in a room where temperature remains below 40°C.

3.2 Efficacy (Part B, Section 3)

The efficacy level of FLYPACK CERASI (TM0005) traps is considered satisfactory for the requested use.

No phytotoxicity is expected with the use of FLYPACK CERASI (TM0005) traps since there is no contact between the crop and the active substance contained in the device (no foliar spraying).

For the same reason, no risk of negative impact is expected on yield, quality, propagation and adjacent crops.

The risk of resistance appearing or developing to deltamethrin, under the conditions of use in a trap, is considered to be low and does not require any monitoring.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical methods for the determination of the active substance and the attractant in the formulation are available and validated. As the active substance deltamethrin does not contain any relevant impurity, no analytical method is required.

3.3.2 Analytical methods for residues

FLYPACK CERASI (TM0005) constitutes an entirely ‘off-crop’ use of deltamethrin in which the active substance is impregnated into the inner surface of a plastic trap deployed in orchards. The insecticide thus has no contact with plants and the environment. Analytical methods for the determination of residues of deltamethrin in foodstuffs of plants or animal origin, in soil, water, air and in body fluids are not

necessary.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

| Active substance: deltamethrin | | |
|---------------------------------------|--|--|
| ADI | 0.01 mg/kg bw/d | EU (2003) |
| ARfD | 0.01 mg/kg bw | |
| AOEL | 0.0075 mg/kg bw/d | |
| AAOEL | - (re-registration not performed yet) | |
| Dermal absorption | Default value according to guidance on dermal absorption (Efsa 2012) | Concentrate (used in formulation) 100% |
| | | |
| | Dermal absorption endpoints % | |
| Oral absorption | 75 % based on urine and bile excretion in a low oral dose and an intravenous dose study in rat | |

3.4.1 Acute toxicity

FLYPACK CERASI (TM0005) is a disposable closed trap made of plastic and ready to use. Such a device cannot be tested on animals for its toxicological properties.

It is considered that no risk is anticipated when the device is correctly used. Opening of the device should not be forced in order not to enter into contact with the active substance (inner surface of the top portion) or the attractant.

3.4.2 Operator exposure

Summary of critical use patterns (worst cases):

| Crop type | F/G ¹⁰ | Equipment Application method | Maximum application rate (g a.s. /ha) | Minimum volume water (L/ha) |
|--------------|-------------------|---|--|-----------------------------------|
| Cherry trees | F | Not applicable (ready-to-use device) | 100 traps/ha (1.5 g deltamethrin/ha) | Not applicable |

Additional information provided by the applicant for the attractant ammonium carbonate and the possibility of exposure for the farmer:

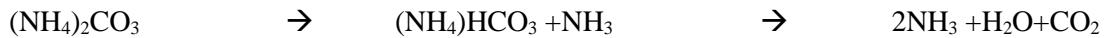
⁸ Referring to physico-chemical properties of deltamethrin (molecular mass and log Pow).

⁹ Not relevant for FLYPACK CERASI (TM0005). As the trap is a closed ready to use device, there is no possibility for the operator or the worker to be in contact with deltamethrin.

¹⁰ Open field or glasshouse.

The attractant ammonium carbonate is released from the sachet at low rates (0.087g per day over the 150-day operational life of the trap).

Ammonium carbonate is a non-lethal attractant for male and female cherry flies (*Rhagoletis cerasi*). The attractant sachet contains ammonium carbonate, which, when in contact with water vapour, releases ammonia. The latter will attract *Rhagoletis cerasi*:



Analytical studies have been submitted to determine emission of attractants and a comparison with their atmospheric background levels (Roura (2017)/SEDQ-A-2014024). The detailed study is provided in section 8 (environmental fate) of Registration Report Part B.

Ammonium carbonate is used in the pharmaceutical and cosmetic industries, as an acidity regulator in food, and in agriculture as a fertiliser.

Ammonia is naturally present in air, soil and water. The major source of ammonia in soils is through anthropogenic inputs of fertiliser, although the decomposition of animal and plant material and the decay of nitrogen-fixing bacteria are also significant sources (ATSDR, 2004). Ammonia does not persist for long in the environment as it is rapidly recycled by natural pathways (ATSDR, 2004). The additional ammonia loading to the environment from the volatilisation of ammonium carbonate in FLYPACK CERASI (TM0005) is considered negligible compared with natural and anthropogenic sources, and hence of no concern.

FLYPACK CERASI (TM0005) is a ready-to-use (already assembled) dispenser containing 20 g ammonium carbonate. No dermal exposure to deltamethrin is expected. Moreover, deltamethrin is not volatile (vapour pressure: 1.24×10^{-8} Pa at $25^\circ C$). Therefore, no exposure by inhalation is expected either.

Considering the proposed use, the formulation and the application mode of the product, estimation of operator systemic exposure was not considered necessary.

Gloves are recommended when of handling, to prevent any dermal exposure.

The attractant substance ammonium carbonate (co-formulant) releases ammonia. The release is slow and results in atmospheric concentrations below the natural background in agricultural areas. The risk from ammonia is therefore considered acceptable.

3.4.3 Worker exposure

FLYPACK CERASI (TM0005) is in the form of closed and ready-to-use trap device. There is no possibility for the worker to be in contact with deltamethrin. Moreover, deltamethrin is not volatile (see above). Therefore, no exposure by inhalation is expected either. Worker exposure estimation is considered to be not relevant.

The attractant substance ammonium carbonate (co-formulant) releases ammonia. The release is slow and results in atmospheric concentrations below the natural background in agricultural areas. The risk from ammonia is therefore considered acceptable.

3.4.4 Bystander and resident exposure

As FLYPACK CERASI (TM0005) is in the form of dispensers containing a non-volatile active substance, deltamethrin (see above), no drift by volatilisation is expected. Therefore, bystander and resident

exposure estimation is considered to be not relevant.

The attractant substance ammonium carbonate (co-formulant) releases ammonia. The release is slow and results in atmospheric concentrations below the natural background in agricultural areas. The risk from ammonia is therefore considered acceptable.

3.5 Residues and consumer exposure (Part B, Section 7)

The data available are considered sufficient for risk assessment. Any exceedence of the current MRL of 0.1mg/kg for deltamethrin on cherries as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and short-term intakes of deltamethrin residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, France (zRMS) agrees with the authorisation of the intended uses.

According to the available data, no specific mitigation measures should apply.

Summary for deltamethrin

| Use No.* | Crop | Plant metabolism covered? | Sufficient residue trials? | PHI sufficiently supported? | Sample storage covered by stability data? | MRL compliance Reg. (EU) 2018/832 | Chronic risk for consumers identified? | Acute risk for consumers identified? | Comments |
|----------|--------|---------------------------|----------------------------|-----------------------------|---|-----------------------------------|--|--------------------------------------|----------|
| 1 | Cherry | Not required | Not required | Not required | Not required | Not applicable | No | No | - |

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

FLYPACK CERASI (TM0005) is a trap with “Attract and Kill technology” for the control of *R. cerasi* in cherry tree crops. It represents an entirely off-crop use of deltamethrin and the selected attractant chemical. At no point in the use of the product will there be any contact between the chemical components and any part of the crop.

Based on the specific mode of application, it was not considered necessary to assess the effects of processing on residues, residues in succeeding crops and the effect on dietary burden.

Summary for FLYPACK CERASI (TM0005)

| Crop | PHI for FLYPACK CERASI (TM0005) requested by applicant | PHI/withholding period* sufficiently supported for | | PHI for FLYPACK CERASI (TM0005) proposed by zRMS | zRMS Comments (if different PHI proposed) |
|----------|--|--|----|--|---|
| | | deltamethrin | | | |
| Cherries | NR | NR | NR | NR | - |

NR: not relevant

* Purpose of withholding period to be specified

3.6 Environmental fate and behaviour (Part B, Section 8)

Considering the intended use for the product FLYPACK CERASI (TM0005), exposure of environmental

compartments to the active substance is considered negligible. Consequently, no risk assessment for environment and non-target organisms is deemed necessary.

3.7 Ecotoxicology (Part B, Section 9)

Considering the intended use for the product FLYPACK CERASI (TM0005), exposure of environmental compartments to the active substance is considered negligible. Consequently, no risk assessment for birds, aquatic organisms, mammals, earthworms, other soil macro-organisms, micro-organisms and terrestrial plants is deemed necessary.

The risk for bees and other non-target arthropods is considered acceptable when the following mitigation is respected: remove traps at harvest at the latest, to avoid unnecessary exposure of pollinators.

3.8 Relevance of metabolites (Part B, Section 10)

Not relevant.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

The active substance deltamethrin is not approved as a candidate of substitution, therefore a comparative assessment is not foreseen.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

When the conclusions of the assessment is « Not acceptable », please refer to relevant summary under point 3 “Background of authorisation decision and risk management”.

5.1.1 Post-authorisation monitoring

None.

5.1.2 Post-authorisation data requirements

The French Decision requests the submission of post-authorisation confirmatory pieces of information within 24 months regarding:

- The two-year ambient temperature storage shelf-life study report.

Appendix 1 Copy of the product authorisation



Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) N° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et réglementaire,

*Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique **FLYPACK CERASI***

de la société Sociedad Española de Desarrollos Químicos, S.L.
enregistrée sous le n°2017-1954

Vu les conclusions de l'évaluation de l'Anses du 18 avril 2019,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France, sous réserve du respect de la composition du produit autorisée dans les conclusions de l'évaluation, pour les usages et dans les conditions précisés dans la présente décision et ses annexes.

La présente décision s'applique sans préjudice des autres dispositions applicables.

Avertissement :

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.



Informations générales sur le produit

| | |
|-------------------------|---|
| Nom du produit | FLYPACK CERASI |
| Type de produit | Produit de référence |
| Titulaire | Sociedad Española de Desarrollos Químicos, S.L. Avda. Diagonal, 352, entlo 08013 BARCELONE Espagne |
| Formulation | Piège prêt à l'emploi |
| Contenant | 0,015 g/piège - deltaméthrine |
| Numéro d'intrant | 646-2017.01 |
| Numéro d'AMM | 2190253 |
| Fonction | Insecticide |
| Gamme d'usage | Professionnel |

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 octobre 2020.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) 1107/2009, dans les trois mois suivant le renouvellement de l'approbation de la substance active, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance de la durée nécessaire pour mener à bien l'examen et adopter une décision sur le renouvellement.

La présente décision peut être retirée ou modifiée avant cette échéance si des éléments le justifient.

A Maisons-Alfort le, 07 MAI 2019

Caroline BEMAILLE

Directrice générale déléguée

en charge du pôle produits réglementés

Agence nationale de sécurité sanitaire de

l'alimentation, de l'environnement et du travail (ANSES)



ANNEXE I : Modalités d'autorisation du produit

Vente et distribution

Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :

| Emballage | Contenance |
|-----------------------|--------------------------------------|
| Sacs en polypropylène | 1 ; 2 ; 5 ; 20 ou 240 pièges par sac |

Classification du produit

La classification retenue est la suivante :

| Catégorie de danger | Mention de danger |
|--|---|
| Dangers pour le milieu aquatique - Danger aigu, catégorie 1 | H400 : Très toxique pour les organismes aquatiques |
| Dangers pour le milieu aquatique - Danger chronique, catégorie 1 | H410 : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme |

Pour les phrases P se référer à la réglementation en vigueur.

Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.



Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

| Usages | Dose maximale d'emploi | Nombre maximum d'applications | Stade d'application BBCH | Délai avant récolte (jours) | Zone Non Traitée aquatique (mètres) | Zone Non Traitée non cibles (mètres) | Mention abeilles |
|---|------------------------|-------------------------------|--------------------------|-----------------------------|-------------------------------------|--------------------------------------|------------------|
| 12203101 Cerisier*Trt. Part.Aer.* Mouches | 100 pièges/ha | 1/an | à partir de BBCH 70 | Non applicable | - | - | - |



Conditions d'emploi du produit

Stockage et manipulation du produit

- Ne pas stocker le produit dans un local où la température peut dépasser 40°C.
- Le produit contient de la deltaméthrine, susceptible de provoquer des paresthésies, il conviendra de mentionner sur l'étiquette d'éviter le contact avec la peau conformément à l'arrêté du 9 novembre 2004.

Protection de l'opérateur et du travailleur

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections individuelles
- le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage).
- les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

Pour l'opérateur, porter

Dans le cadre de la manipulation du piège

- Gants en nitrile certifiés EN 374-3.

Délai de rentrée en application de l'arrêté du 4 mai 2017

- Non pertinent pour ce type d'application.

Respect des limites maximales de résidus (LMR)

Pour chaque usage figurant dans la liste des usages autorisés, les conditions d'utilisation du produit permettent de respecter les limites maximales de résidus.

Protection de l'environnement (milieux, faune et flore)

Protection de l'eau

- SP 1 : Ne pas polluer l'eau avec le produit ou son emballage.

Protection de la faune

- Retirer les pièges au plus tard au moment de la récolte des fruits.

Exigences complémentaires post-autorisation

A défaut de transmission de ces données dans les délais impartis à compter de la date de la présente décision, la présente décision pourra être retirée ou modifiée.

| Détail de la demande post autorisation | Délai (mois) | Référence (mois) |
|--|--------------|------------------|
| Fournir les résultats de l'étude en cours de réalisation, concernant la stabilité au stockage pendant 2 ans, à température ambiante. | 24 | - |

Appendix 2 Copy of the product label

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.

FLYPACK® Cerasi PROJET DE TEXTE D'ETIQUETTE

SIDE1

FLYPACK® Cerasi

Contient 0.015 g/Unité deltaméthrine
20 g/Unité carbonate d'ammonium

Piégeage de la mouche de la cerise

Carton de 20 unités individuelles

RESERVE A UN USAGE EXCLUSIVEMENT PROFESSIONNEL

SIDE2

Ce produit est utilisé pour le contrôle de la mouche de la cerise par piégeage massive.

Tableaux des usages :

| Traitement des parties aériennes | Cibles / Usages | Doses | DAR (en jours) |
|----------------------------------|---|----------------------|----------------|
| Cerisier | Mouche de la cerise : <i>Rhagoletis cerasi</i> | 50 - 100 pièges / ha | NA |

Limites maximales en résidus de substances actives : se reporter aux LMR en vigueur au niveau de l'Union Européenne et consultables à l'adresse : http://ec.europa.eu/sanco_pesticides/public/index.cfm

Mode d'emploi

Les pièges à usage unique sont livrés prêts à l'emploi. Ils sont utilisables en agriculture conventionnelle et biologique.

• Préparation des pièges

- Porter des gants pendant la manipulation
- Sortir les pièges de leur emballage

• Dose(s) préconisée(s)

- Le nombre de diffuseurs conseillé est de 50 à 100 par hectare.

• Conditions de traitement (époque, stade, seuil d'intervention)

- Suspendre les pièges sur les branches des arbres à une hauteur de 1,60 à 2,00 m du sol.
- Les pièges doivent être répartis régulièrement en quinconce dans la parcelle
- Augmenter la densité en périphérie des grandes parcelles
- Les pièges doivent être installés à partir du début de la période à risque.
- La durée de diffusion est de 150 jours.
- Respecter les époques et les doses d'emploi.

Nouveau catalogue des usages (arrêté du 26 mars 2014): L'utilisation de ce produit est préconisée uniquement sur les cultures et cibles précisées dans les préconisations et usages homologués. La société décline en conséquence toute responsabilité en cas d'utilisation du produit sur des cultures ou contre des cibles non préconisées

Attention : en cas de recours à des techniques culturales nouvellement mises en œuvre par l'utilisateur ou présentant une quelconque spécificité, l'utilisateur doit en informer son fournisseur avant toute utilisation du produit, afin que ce dernier puisse en vérifier la faisabilité avec le fabricant du produit.

SIDE 3

Fllypack® Cerasi AMM N°:
0.015 g/Unité de deltaméthrine
20 g/Unité carbonate d'ammonium

Autres composants dangereux : Non concerné

Pictogramme :



Mention d'avertissement : Attention

Mentions de danger :

H410 - Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.

Conseils de prudence :

P273 - Eviter le rejet dans l'environnement.
P280 - Porter des gants de protection .
P501 - Eliminer le contenu/récipient au point de collecte des déchets dangereux ou spéciaux.

Respectez les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement.

SIDE 4

Précautions à prendre :

- Pour le stockage

- Conserver les pièges dans leur emballage d'origine, à une température comprise entre 10 et 25 °C, à l'abri du soleil, dans des locaux fermés à clé, à l'écart de tout aliment et boisson y compris ceux pour les animaux, et hors de portée des enfants. Les locaux doivent être frais et ventilés.

- Pour l'emploi

- Porter des gants appropriés pour la manipulation des pièges.
- Eviter le contact avec la peau, les yeux et les vêtements

- Pour l'élimination du produit et de l'emballage

En fin de campagne, les pièges utilisés seront éliminés via une collecte organisée par les distributeurs partenaires de la filière Adival ou un autre service de collecte spécifique.

Délai de rentrée des travailleurs sur la parcelle : Sans délais de rentrée.

Premiers secours

Conseils généraux

En cas d'accident ou de malaise, consulter immédiatement un médecin (si possible, lui montrer l'étiquette).

Inhalation

Amener la victime à l'air libre. Si les symptômes persistent ou si le moindre doute existe, il faut consulter un médecin.

Contact avec la peau

Oter immédiatement les vêtements et les chaussures contaminés. Laver immédiatement et abondamment avec de l'eau et du savon. Faire appel à une assistance médicale en cas d'apparition d'une irritation qui persiste.

Contact avec les yeux

Rincer immédiatement et abondamment à l'eau, y compris sous les paupières, pendant au moins 15 minutes. Faire appel à une assistance médicale en cas d'apparition d'une irritation qui persiste.

Ingestion :

Ne PAS faire vomir. Rincer la bouche. Garder la personne au calme. Appeler un médecin.

En cas de perte de la Fiche de données de sécurité, celle-ci peut vous être à nouveau fournie sur simple appel au 0 800 25 35 45 ou être consultée sur les sites internet : www.bayer-agri.fr et www.quickfds.com.

En cas d'urgence, appeler le 15 ou le centre antipoison puis signalez vos symptômes au réseau "Phyt'attitude" n° vert 0 800 887 887 (appel gratuit depuis un poste fixe).

Date de fabrication/n° de lot : voir sur l'emballage

Important

Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduisez sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces...

Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de vente du Ministère de l'Agriculture.

Compte tenu de la diversité des législations existantes, il est recommandé, dans le cas où les denrées issues des cultures protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur.

Appendix 3 Letter of Access

Letter(s) of access and, if necessary, an argumentation according to art. 62.4 of Reg (UE) No 1107/2009 have been submitted and are available under request.