

# **REGISTRATION REPORT**

## **Part A**

### **Risk Management**

**Product code: XP21CSPR1CRYGNI / XP CRYPTO PRO PRESS**

**Product name(s): CRYPTO PRO PRESS**

**Chemical active substance:**

**(Z)-11-hexadecenal, 70 g/kg**

**Southern Zone**

**Zonal Rapporteur Member State: FRANCE**

**NATIONAL ASSESSMENT (authorization)**

**Applicant: M2i Biocontrol**

**MS Finalisation date: 2025 08 18**

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## PART A

# RISK MANAGEMENT

## 1 Details of the application

The company M2I BIOCONTROL has requested a marketing authorisation in France for the product XP CRYPTO PRO PRESS (formulation code: XP21CSPR1CRYGNI / XP CRYPTO PRO PRESS), containing 70 g/kg of (Z)-11-hexadecenal<sup>1</sup> as a mating disruptor for professional uses.

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).

### 1.1 Application background

The present registration report concerns the evaluation of M2I BIOCONTROL's application submitted on 30/01/2023 to market CRYPTO PRO PRESS (XP21CSPR1CRYGNI / XP CRYPTO PRO PRESS) in France (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 Member States (MSs) of the southern zone.

The present application (2023-0857) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009<sup>2</sup>, the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone for field uses, taking into account the worst-case uses ("risk envelope approach")<sup>3</sup>. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of CRYPTO PRO PRESS (XP21CSPR1CRYGNI / XP CRYPTO PRO PRESS) has been made using endpoints agreed in the EU peer review of (E,E)-8,10-dodecadien-1-ol. It also includes assessment of data and information related to CRYPTO PRO PRESS (XP21CSPR1CRYGNI / XP CRYPTO PRO PRESS) where those data have not been considered in the EU peer review process.

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. The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011<sup>4</sup>, and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

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<sup>1</sup> COMMISSION IMPLEMENTING REGULATION (EU) 2022/1251 of 19 July 2022 renewing the approval of the active substances Straight Chain Lepidopteran Pheromones (acetates) as low-risk active substances, and Straight Chain Lepidopteran Pheromones (aldehydes and alcohols) in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

<sup>2</sup> 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

<sup>3</sup> 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](#)

<sup>4</sup> 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

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This document also describes the specific conditions of use and labelling required for France for the registration of CRYPTO PRO PRESS (XP21CSPR1CRYGNI / XP CRYPTO PRO PRESS).

## 1.2 Letters of Access

The applicant is members of the Joint SCLP Renewal Task Force, a letter of access to SCLP data (protected studies) is provided.

## 1.3 Justification for submission of tests and studies

According to the applicant: « XP21CSPR1CRYGNI / XP CRYPTO PRO PRESS/ Crypto Pro Press is a new product never registered in Europe for the proposed use.

*All studies presented in this dossier are deemed necessary to support the registration.*

*The Crypto Pro Press product has the same composition as the Box T Pro Press product (granted in France under MA n° 2189998). A certificate of identical composition between the 2 products is provided in the administrative part. The only difference between these 2 products lies in their use (different target crop and pest). This is why the physico-chemical and stability studies presented in the dossier are those that were carried out under the product name Box T Pro Press.*

*- Along this dossier, M2i Biocontrol is referring to EFSA document, to RAR SCLP reports to justify the data provided on the active substance (Z)-11-hexadecenal and also justify that no further studies have to be carried out.*

*- Physico-chemical studies to define precisely the product and to be able to present classification and write the label.*

*- A package of GEP efficacy trials reports is submitted to demonstrate the efficiency of (Z)-11-hexadecenal against *Cryptoblabes gnidiella* on vineyards.*

*-A complete report describing the full manufacturing process of XP21CSPR1CRYGNI / XP CRYPTO PRO PRESS/ Crypto Pro Press product is provided. This report detailed thus the main characteristic of the product regarding risk minimization (encapsulation, integrity of the microcapsules all along their life, ..).*

*- Stability Study of XP21CSPR1CRYGNI / XP CRYPTO PRO PRESS/ Crypto Pro Press 2 years at 20°C is provided.*

*- the XP21CSPR1CRYGNI / XP CRYPTO PRO PRESS/ Crypto Pro Press release-rate duration report is provided to ensure the product properties to market and it is a basis for the provided report on the comparison of the active substance exposure assessment using XP21CSPR1CRYGNI / XP CRYPTO PRO PRESS/ Crypto Pro Press and the natural backgrounds level in case of *Cryptoblabes gnidiella* females infestation, in accordance of the Guidance Document on semiochemical active substances and plant protection product.».*

## 1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of CRYPTO PRO PRESS (XP21CSPR1CRYGNI / XP CRYPTO PRO PRESS), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

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## 2 Details of the authorisation decision

### 2.1 Product identity

|  |  |
|--|--|
| Product code   | XP21CSPR1CRYGNI / XP CRYPTO PRO PRESS  |
| Product name in MS                                     | CRYPTO PRO PRESS   |
| Authorisation number                                   | 2250271  |
| Kind of use  | Professional use   |
| Low risk product (article 47)                          | No (The product is not compliant with Article 47 of Regulation (EC) no 1107/2009 due to the presence of a co-formulant identified as a substance of concern and currently evaluated under the REACH program) |
| Function   | Semiochemical based product for mating disruption  |
| Applicant  | M2i Biocontrol   |
| Active substance(s)<br>(incl. content)                 | (Z)-11 hexadecenal ; 70 g/kg   |
| Formulation type                                       | Capsule Suspension (CS)  |
| Packaging  | Multilayers bag made of PEBD/PE/Polyamide/PET/aluminium (250g)   |
| Coformulants of concern for<br>national authorisations | -a preservative identified as a substance of concern and currently being assessed<br>under the REACH program   |
| Restrictions related to identity                       | -  |
| Mandatory tank mixtures                                | not applicable   |
| Recommended tank mixtures                              | not applicable   |

### 2.2 Conclusion

The evaluation of the application for CRYPTO PRO PRESS (XP21CSPR1CRYGNI / XP CRYPTO PRO PRESS) resulted in the decision **to grant** the 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: | Skin sensitisation, category 1<br>Hazardous to the aquatic environment - Chronic Hazard, category 2 |
|-------------------------------|---|

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|                               |  |
|-------------------------------|--|
| Hazard pictograms:            | <br>GHS07               |
| Signal word:                  | Warning  |
| Hazard statement(s):          | H317: May cause an allergic skin reaction.<br>H411: Toxic to aquatic life with long-lasting effects.     |
| Precautionary statement(s):   | <b><i>For the P phrases, refer to the existing legislation</i></b>                                       |
| Additional labelling phrases: | -  |
|                               | a preservative identified as a substance of concern and currently being assessed under the REACH program |

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. Avoid contamination via drains from farmyards and roads). |
|      | 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 2017<sup>5</sup> provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres for products applied through spraying or dusting;
- unless otherwise 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, non-spraying buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

Moreover, the French Order of 12 April 2021<sup>6</sup> provides that:

- an authorisation granted for a “reference” crop applies also for “related” crops, unless formally stated in the Decision

<sup>5</sup> 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, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRGI632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

<sup>6</sup> <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

- the “reference” and “related” 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 “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation<sup>7</sup> 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.

Finally, the French Order of 20 November 2021<sup>8</sup> on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless otherwise stated in the product authorisation, use on attractive crop<sup>9</sup> when in flower and on foraging area is forbidden. Specific conditions of application on flowering crops should be respected. As consequences specific SPe 8 may include reference to this order.

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                          |  |
| -   | -  |
| Other specific restrictions                       |  |
| Re-entry period                                   | Not applicable for this type of application          |
| Storage   | Protect from frost                                   |
| SPa 1   | -  |

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

<sup>8</sup> <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734>

<sup>9</sup> List of culture considered as unattractive to bees and other pollinators insects defined by French Agricultural ministry and published in Bulletin Officiel du ministère chargé de l'agriculture.



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|                              |  |
|------------------------------|--|
| Risk mitigation measures     | For people with multiple chemical sensitivity (MCS) <sup>10</sup> symptoms, wearing an A2P3 mask is recommended during application phase, and when re-entering the field <sup>11</sup> . |
| Risk mitigation measures     | -  |
| 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.

<sup>10</sup> RAPPORT d'étude de l'Anses relatif au syndrome d'intolérance aux odeurs chimiques (SIOC) ou hypersensibilité chimique multiple, 2023.

<sup>11</sup> Recommendations made following Phyt'attitude reports of adverse events occurring during handling or contact with SCLP-based products during the period 1997-2022

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## 2.6 Intended uses (only NATIONAL GAP)

GAP rev. 01, date: 2025 08 18

PPP (product name/code): XP21CSPR1CRYGNI / XP CRYPTO PRO PRESS/ Crypto Pro Press

Formulation type: Capsule Suspension (CS)

Active substance 1: Z-11-hexadecenal

Conc. of as 1: 70 g/kg <sup>(c)</sup>

Applicant: M2i Biocontrol

Professional use: X

Zone(s): South Zone France, Italy, Spain

Non professional use: ☐

Verified by MS: yes

Field of use: semiochemical based product for mating disruption

| 1                          | 2                  | 3   | 4   | 5   | 6                | 7  | 8  | 9   | 10  | 11   | 12                                | 13            | 14  |
|----------------------------|--------------------|---|---|---|------------------|--|--|---|---|--|-----------------------------------|---------------|---|
| Use-<br>No. <sup>(e)</sup> | Member<br>state(s) | Crop and/<br>or situation<br><br>(crop destination<br>/ purpose of<br>crop) | F,<br>Fn,<br>Fpn<br>G,<br>Gn,<br>Gpn<br>or<br>I | Pests or Group of pests<br>controlled<br><br>(additionally: develop-<br>mental stages of the pest<br>or pest group) | Application      |  |  |   | Application rate  |  |                                   | PHI<br>(days) | Remarks:<br><br>e.g. g<br>safener/synergist<br>per ha<br><sup>(f)</sup><br><br>RMS conclusion |
|                            |                    |   |   |   | Method /<br>Kind | Timing / Growth<br>stage of crop &<br>season | Max. num-<br>ber<br>a) per use<br>b) per crop/<br>season | Min. in-<br>terval be-<br>tween ap-<br>plications<br>(days) | kg or L product /<br>ha<br>a) max. rate per<br>appl.<br>b) max. total rate<br>per crop/season | g or kg as/ha<br>a) max. rate per appl.<br>b) max. total rate per<br>crop/season | Water<br>L/ha<br><br>min /<br>max |               |   |

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| Zonal uses (field or outdoor uses, certain types of protected crops) |              |   |   |  |  |   |              |    |                          |                                |    |                       |   |
|--|--------------|---|---|--|--|---|--------------|----|--------------------------|--------------------------------|----|-----------------------|---|
| 1  | France,<br>I | Grapevine<br>( <i>Vitis vinifera</i> )<br>Table grape and<br>wine grape | F | <i>Cryptoblabes gnidiella</i><br>(Honeydew moth)<br><br>EPPO Code : CRYBGN<br><br>Developmental stages of<br>the pest: adult moths | Treatment of<br>aerial parts of<br>the vine stock<br>Deposit of<br>the<br>formulation<br>on a support<br>such as posts<br>or wine<br>stocks using<br>a specific<br>application<br>device | From the first<br>captures (May) to<br>before G2 (July) | a) 1<br>b) 1 | NA | a) 1 kg/ha<br>b) 1 kg/ha | a) 70 g as/ha<br>b) 70 g as/ha | NA | Not<br>neces-<br>sary | Acceptable<br><br><b>Restricted use to</b><br><i>Cryptoblabes</i><br><i>gnidiella</i> |
| 2  | France,      | Persimmon ( <i>Di-<br/>ospyros kaki</i> )                               | F | <i>Cryptoblabes gnidiella</i><br>(Honeydew moth)<br><br>EPPO Code : CRYBGN<br><br>Developmental stages of<br>the pest: adult moths | Treatment of<br>aerial parts.<br>Deposit of<br>the<br>formulation<br>on a support<br>such as posts<br>or tree trunks<br>using a<br>specific<br>application<br>device                     | From the first<br>captures (May) to<br>before G2 (July) | a) 1<br>b) 1 | NA | a) 1 kg/ha<br>b) 1 kg/ha | a) 70 g as/ha<br>b) 70 g as/ha | NA | not<br>neces-<br>sary | Acceptable<br><br><b>Restricted use to</b><br><i>Cryptoblabes</i><br><i>gnidiella</i> |
| 3  | France,      | Pomegranate<br>( <i>Punica gran-<br/>atum</i> )                         | F | <i>Cryptoblabes gnidiella</i><br>(Honeydew moth)<br><br>EPPO Code : CRYBGN<br><br>Developmental stages of<br>the pest: adult moths | Treatment of<br>aerial parts.<br>Deposit of<br>the<br>formulation<br>on a support<br>such as posts<br>or tree trunks<br>using a<br>specific<br>application<br>device                     | From the first<br>captures (May) to<br>before G2 (July) | a) 1<br>b) 1 | NA | a) 1 kg/ha<br>c) 1 kg/ha | a) 70 g as/ha<br>b) 70 g as/ha | NA | not<br>neces-<br>sary | Acceptable<br><br><b>Restricted use to</b><br><i>Cryptoblabes</i><br><i>gnidiella</i> |

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|                               |     |  |     |  |
|-------------------------------|-----|--|-----|--|
| <b>Remarks table heading:</b> | (a) | e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)   | (d) | Select relevant  |
|                               | (b) | Catalogue of pesticide formulation types and international coding system CropLife  | (e) | Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1  |
|                               | (c) | International Technical Monograph n°2, 6th Edition Revised May 2008<br>g/kg or g/l   | (f) | No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.   |
| <b>Remarks columns:</b>       | 1   | Numeration necessary to allow references   | 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        |
|                               | 2   | Use official codes/nomenclatures of EU Member States   | 8   | The maximum number of application possible under practical conditions of use must be provided.   |
|                               | 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)   | 9   | Minimum interval (in days) between applications of the same product  |
|                               | 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   | 10  | For specific uses other specifications might be possible, e.g.: g/m <sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products. |
|                               | 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. | 11  | The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).   |
|                               | 6   | Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench<br>Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.  | 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)**

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of homogeneous white opaque paste with a characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. In aqueous solution, it has a pH value around 7.4 at 20.1 °C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active in-gredient content nor the technical properties were changed. The stability study at 20°C is currently ongoing for 24 months in the expected commercial packaging (4 layers pouches made of PE/Polyamide/PET/aluminium). Its technical characteristics are acceptable for this type of formula-tion. Nevertheless, the shelf-life study and the demonstration of the integrity of capsule before and after storage should be provided at post-authorisation level.

#### **3.2 Efficacy (Part B, Section 3)**

Considering the data provided :

- CRYPTO PRO PRESS (XP21CSPR1CRYGNI / XP CRYPTO PRO PRESS) efficacy level is considered acceptable for the control of the honeydew moth *Cryptoblabes gnidiella* in grapevine, persimmon and pomegranate.
- CRYPTO PRO PRESS (XP21CSPR1CRYGNI / XP CRYPTO PRO PRESS) phytotoxicity level is considered as negligible.
- The risks of adverse effects on yield, quality, wine making process, propagation and adjacent crops are considered as negligible.
- The risk of resistance to (Z)-11-Hexadecenal does not require to set up a monitoring on the claimed uses.

#### **3.3 Methods of analysis (Part B, Section 5)**

##### **3.3.1 Analytical method for the formulation**

The analytical method for the determination of the active substance in the product has been provided and considered as validated. An analytical method for the determination of the stabilizer BHT in the product has been provided and considred as validated.

##### **3.3.2 Analytical methods for residues**

No residue definition is available for (Z)-11-Hexadecenal, therefore no methods are presented.

### **3.4 Mammalian toxicology (Part B, Section 6)**

#### **3.4.1 Acute toxicity**

CRYPTO PRO PRESS (XP21CSPR1CRYGNI / XP CRYPTO PRO PRESS), containing 70 g/kg (Z)-11-hexadecenal, has a low acute oral, inhalation and dermal toxicity and is not irritating to the skin or eye. It is considered to be a skin sensitiser.

#### **3.4.2 Operator exposure**

Considering the mode of application, characteristics of the product CRYPTO PRO PRESS (XP21CSPR1CRYGNI / XP CRYPTO PRO PRESS) (vapour releasing product containing microencapsulated active substance), the low toxicity of the active substance, and the level of emission which is comparable to the natural background level, no unacceptable risk is expected.

For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

#### **3.4.3 Worker exposure**

Considering the mode of application, characteristics of the product CRYPTO PRO PRESS (XP21CSPR1CRYGNI / XP CRYPTO PRO PRESS) (vapour releasing product containing microencapsulated active substance), the low toxicity of the active substance, and the level of emission which is comparable to the natural background level, no unacceptable risk is expected.

For details of personal protective equipment for workers, refer to the Decision in Appendix 1.

#### **3.4.4 Bystander exposure**

Considering the mode of application, characteristics of the product CRYPTO PRO PRESS (XP21CSPR1CRYGNI / XP CRYPTO PRO PRESS) (passive vapour releasing product containing microencapsulated active substance), the low toxicity of the active substance, and the level of emission which is comparable to the natural background level, no unacceptable risk is expected.

#### **3.4.5 Resident exposure**

Considering the mode of application, characteristics of the product CRYPTO PRO PRESS (XP21CSPR1CRYGNI / XP CRYPTO PRO PRESS) (passive vapour releasing product containing microencapsulated active substance), the low toxicity of the active substance, and the level of emission which is comparable to the natural background level, no unacceptable risk is expected.

#### **3.4.1 Combined exposure**

Not relevant.

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

The data available are considered sufficient for risk assessment. SCLPs including (Z)-11-hexadecenal are included in Annex IV of Regulation (EC) No 396/2005 that regroups active substances for which no MRL are necessary.

The chronic and the short-term intakes of SCLPs residues are unlikely to present a public health concern. As far as consumer health protection is concerned, zRMS FR agrees with the authorization of the intended uses.

#### Summary for XP21CSPR1CRYGNI / XP CRYPTO PRO PRESS

##### Information on XP21CSPR1CRYGNI / XP CRYPTO PRO PRESS (KCA 6.8)

| Crop             | PHI for<br>XP18CSPR1CYD<br>/ XP18 CS<br>CYDIA<br>proposed by ap-<br>plicant | PHI/ Withholding period* sufficiently<br>supported for | PHI for<br>XP18CSPR1CYD<br>/ XP18 CS<br>CYDIA<br>proposed by<br>zRMS | zRMS Comments<br>(if different PHI<br>proposed) |
|------------------|---|--|--|---|
|                  |   | (E,E)-8,10-dodecadien-1-ol                             |  |   |
| Grape-<br>vine   | NR  | NR   | NR   |   |
| Persim-<br>mon   | NR  | NR   | NR   |   |
| Pome-<br>granate | NR  | NR   | NR   |   |

NR: not relevant

\* Purpose of withholding period to be specified

#### Waiting periods before planting succeeding crops

Not relevant.

### 3.6 Environmental fate and behaviour (Part B, Section 8) and Ecotoxicology (Part B, Section 9)

The fate and behaviour in the environment and ecotoxicology sections have been evaluated according to the requirements of Guidance document on semiochemicals (SANTE/12815/2014).

No unacceptable risk for the environment and non-target organisms is expected from the use of the product CRYPTO PRO PRESS (XP21CSPR1CRYGNI / XP CRYPTO PRO PRESS)(gel containing the encapsulated active substance, exposure via vapour phase only) according to the intended uses.

### 3.7 Relevance of metabolites (Part B, Section 10)

Not required. Please refer to environmental fate and behaviour above.

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

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The active substance SCLP is not approved as a candidate for 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**

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## **Appendix 1    Copy of the product authorisation**





CRYPTOPROP\_PAM  
M\_2023-0857\_D2.pd

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## 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.

|  |   |  |
|--|---|--|
| <b>Crypto Pro Press®</b> - insecticide de Biocontrôle - AMM N° <b>XXXX</b> - M2i Biocontrol<br><b>Confusion sexuelle pour lutter contre la pyrale du Daphné (<i>Cryptoblabes gnidiella</i>)</b><br><b>Produit diffuseur de vapeur (VP) - 70 g/kg de (Z)-11-hexadecenal (7% w/w)</b><br><b>XXXg</b>   |   |  |
| <b>USAGE EXCLUSIVEMENT PROFESSIONNEL.</b>  |   |  |
| <p><b>H317</b> Peut provoquer une allergie cutanée<br/> <b>H411</b> <u>Toxique</u> pour les organismes aquatiques, entraîne des effets néfastes à long terme.</p> <p><b>Conseils de prudence</b></p> <p><b>P273</b> Éviter le rejet dans l'environnement.<br/> <b>P280</b> Porter des gants de protection/des vêtements de protection<br/> <b>P302+P352</b> EN CAS DE CONTACT AVEC LA PEAU : Laver abondamment à l'eau.<br/> <b>P391</b> Recueillir le produit répandu<br/> <b>P501</b> Eliminer le contenu/réceptacle dans un centre de collecte de déchets dangereux ou spéciaux, conformément à la réglementation locale, régionale, nationale et /ou internationale</p> <p><b>EUH401</b> Pour éviter les risques pour la santé humaine et l'environnement, respectez les instructions d'utilisation.</p> <p><b>SP1</b> Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Eviter la contamination via les systèmes d'évacuation des eaux à partir des cours de fermes ou des routes.</p> <p>Délai de rentrée des travailleurs sur la parcelle (DRE) : <b>non applicable.</b></p> |   | <br>GHS07 <br>GHS09  |
| <p><b>EN CAS D'URGENCE,</b><br/> <b>Composer le 15 ou le 112</b><br/> <b>ou contacter le centre antipoison le plus proche</b></p> <p>Puis signalez vos symptômes au réseau <b>Phyt'attitude</b> : <b>0800 887 887</b> ou contacter le centre antipoison le plus proche</p>   |   | <p>Détenteur de l'Autorisation de Mise sur le <u>Marché</u>: M2i Biocontrol—1 rue royale, 112 bureaux de la Colline 92210 Saint-Cloud Cedex</p> <p>Fiche de données de sécurité disponible sur Internet : <a href="http://www.m2i-lifesciences.com/fds-tds-">www.m2i-lifesciences.com/fds-tds-</a></p> |
| <p><b>PREMIERS SOINS</b></p> <p><b>S'éloigner de la zone dangereuse.</b></p> <ul style="list-style-type: none"> <li>- <b>En cas de contact cutané</b> : enlever tout vêtement souillé, rincer immédiatement et abondamment la peau sous l'eau du robinet.</li> <li>- <b>En cas d'irritation ou éruption cutanée</b>, consulter un spécialiste.</li> <li>- <b>En cas de projection dans les yeux</b> : rincer immédiatement pendant 15 à 20 minutes sous un filet d'eau paupières ouvertes. Consulter un spécialiste.</li> <li>- <b>En cas d'inhalation</b> : en cas de trouble respiratoire, contacter sans délai les secours : le 112 ou un centre antipoison.</li> <li>- <b>En cas d'ingestion</b> : rincer immédiatement la bouche avec de l'eau. Ne pas faire vomir sans avis médical. Contacter sans délai les secours : le 112 ou un centre antipoison.</li> <li>- <b>En cas d'intoxication animale</b> : contactez votre vétérinaire.</li> <li>- Dans tous les cas, si les symptômes persistent ou en cas de malaise, consulter un médecin et lui présenter l'étiquette et/ou la Fiche de Données de Sécurité.</li> </ul>                             |   |  |
| <p><b>PRODUITS POUR LES PROFESSIONNELS : UTILISEZ LES PRODUITS PHYTOPHARMACEUTIQUES AVEC PRECAUTION. AVANT TOUTE UTILISATION, LIRE L'ETIQUETTE ET LES INFORMATIONS CONCERNANT LE PRODUIT.</b></p>  |   |  |
| <p><b>STOCKAGE:</b> Stocker dans un endroit bien ventilé à température ambiante. Tenir à l'abri du gel et de la chaleur.</p> <p><b>ELIMINATION:</b> Conserver dans l'emballage d'origine chez le distributeur partenaire</p> <p>Ré-emploi de l'emballage interdit.</p>   | <p>Code <u>emballeur</u>:</p> <p>N° de lot/date de fabrication : voir sur l'avant de la poche</p> | <p>Code barre (code EAN) :</p>   |

**Crypto Pro Press®** - insecticide de Biocontrôle - AMM N° **XXXX** - M2i Biocontrol  
**Confusion sexuelle pour lutter contre la pyrale du Daphné (*Cryptoblabes gnidiella*)**  
**Produit diffuseur de vapeur (VP)** - 70 g/kg de (Z)-11-hexadecenal (7% w/w)

**DESCRIPTIF DU PRODUIT**

**Conditions d'application**

Dose : Crypto Pro Press® s'utilise dans les vignes, kakis et grenadiers à une dose maximale conseillée de 1 kg/ha (4 poches/ha), correspondant à 500 points de diffusion/ha, soit 125 points/poche. Une application par saison est nécessaire.

| Usages                     | Cible                         | Dose max. conseillée     | Max. number of appl. | Timing   |
|----------------------------|-------------------------------|--------------------------|----------------------|--|
| Vigne<br>Kaki<br>Grenadier | <i>Cryptoblabes gnidiella</i> | 1 kg/ha<br>(4 poches/ha) | 1                    | Application de mai<br>(1ères captures) à<br>juillet (avant G2) |

**RECOMMANDATIONS D'EMPLOI**

**Surface minimale** : 2 hectares minimum. Pour des surfaces inférieures, consultez votre conseiller technique.

**Précautions d'emploi :**

En première année de confusion sexuelle, l'utilisation de traitements insecticides peut être nécessaire en fin de saison (G3), pour réduire les populations de ravageurs dans la parcelle.

Les années suivantes, poursuivre les traitements insecticides selon les pratiques habituelles (en particulier sur la G3) en adaptant selon la pression historique, les bulletins régionaux type BSV et les niveaux de dégâts/piégeages de l'année en cours. Se référer à votre conseiller pour affiner le nombre et le positionnement des traitements nécessaires par an.

En cas de forte pression du ravageur (niveau élevé de piégeage des pyrales et/ou seuil de dégâts inacceptable pour le producteur), un traitement complémentaire peut être appliqué pour réduire les populations à un niveau compatible avec la confusion sexuelle.

Veiller à ne pas appliquer le produit en cas de pluie supérieure à 8 mm dans les 24 heures suivant la pose.

**Positionnement des points de diffusion**

Disposer homogènement les 500 points de diffusion/ha. Une répartition en quinconce sur la parcelle est préférable pour assurer une couverture uniforme. Le renforcement des bordures de la parcelle à protéger est préconisé. Répartir les diffuseurs selon les spécificités de la parcelle et doubler le nombre de diffuseurs sur les bordures.

**Vigne** : Les points de diffusion doivent être appliqués dans la zone de la grappe : sur le cep ou le piquet de palissage par exemple (sans contact avec le raisin) à l'aide d'un dispositif d'application spécifique. En cas d'application sur le cep, il doit être positionné soit sur une coupe, soit entre deux vieilles branches, à l'abri du soleil (préférer une orientation nord). Lorsqu'il est appliqué sur un piquet de palissage, il doit être positionné au niveau de la zone des grappes, en privilégiant une orientation nord.

**Kaki, grenadier** : Les points de diffusion doivent être appliqués dans le tiers supérieur de la canopée de l'arbre, en privilégiant les zones ombragées. S'assurer que le diamètre du bois soit suffisant pour poser le point de diffusion.

**Suivi des vols**

La méthode de lutte par confusion sexuelle, s'utilise dans le cadre d'un programme de protection intégrée, et doit être associé à la surveillance des papillons, du début de la saison jusqu'à la récolte.

En début de saison, des pièges à phéromones doivent être placés à l'intérieur de la parcelle pour contrôler l'efficacité du traitement (idéalement 3 pièges), et à l'extérieur de la parcelle (zone non confusée, espacée d'environ 100 m), pour suivre chaque semaine le vol des papillons (1 piège).

**Préparation de Crypto Pro Press®**

Crypto Pro Press® est une préparation directement prête à l'emploi. Ne pas diluer dans l'eau. Il est recommandé d'utiliser le dispositif d'application prévu pour ce produit.

**Mélanges et compatibilité**






Crypto Pro Press® s'applique seul.

XP21CSPR1CRYGNI / XP CRYPTO PRO PRESS/ Crypto Pro Press  
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## MISE EN ŒUVRE ET BONNES PRATIQUES

### Protection de l'opérateur et du travailleur

| Caractéristiques des EPI<br>▼  |   | PROTECTION DE L'OPÉRATEUR PENDANT<br>LES PHASES DE :                              |   |
|--|---|---|---|
|  |   | CHARGEMENT/<br>DECHARGEMENT   | APPLICATION   |
| GANT SÉNITIF NF EN ISO 27065/A1<br>ou à usage unique NF EN ISO 374-2 (types A) |  |  | À usage unique  |
| EPI VESTIMENTAIRE<br>conforme à la norme NF EN ISO 27065/A1                    |  |  |  |

## AVERTISSEMENT

Toute reproduction totale ou partielle de cette étiquette est interdite.

Le fabricant garantit la qualité du produit vendu dans son emballage d'origine et stocké selon les conditions préconisées, ainsi que sa conformité à l'Autorisation de Mise sur le Marché délivrée par les autorités compétentes françaises.

Les conditions d'utilisation du produit ont été déterminées suivant des tests et des essais rigoureux. Toutefois, il est impossible de prendre en compte toutes les variables et éliminer tous les risques associés à son utilisation. Des blessures ou des dommages peuvent résulter des conditions en dehors du contrôle du fabricant. Le fabricant garantit seulement que ce produit est conforme à sa composition apparaissant sur l'emballage et qu'il est considéré être raisonnablement adapté aux finalités dont il est fait allusion sous des conditions normales d'utilisation. En aucun cas le fabricant ne doit être tenue responsable de dommages indirects ou particuliers résultant de l'utilisation ou la manipulation du produit. Toute dérogation à la présente garantie ne peut être valable que si elle est délivrée par écrit par un représentant légal autorisée du fabricant.