

## **REGISTRATION REPORT**

### **Part A**

### **Risk Management**

**Product code: SBM 10/094**

**Product name: BELEM EV**

**Active substance:**

**cypermethrin, 2g/kg**

**COUNTRY: FRANCE**

**Southern Zone**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(Label extension)**

**Applicant: SBM DÉVELOPPEMENT**

**Date: 03/03/2020**

## Table of Contents

|          |  |           |
|----------|--|-----------|
| <b>1</b> | <b>DETAILS OF THE APPLICATION.....</b>   | <b>3</b>  |
| 1.1      | APPLICATION BACKGROUND .....   | 3         |
| 1.2      | ACTIVE SUBSTANCE APPROVAL.....   | 3         |
| 1.3      | REGULATORY APPROACH .....  | 3         |
| 1.4      | DATA PROTECTION CLAIMS .....   | 5         |
| 1.5      | LETTER(S) OF ACCESS .....  | 5         |
| <b>2</b> | <b>DETAILS OF THE AUTHORISATION .....</b>  | <b>5</b>  |
| 2.1      | PRODUCT IDENTITY .....   | 5         |
| 2.2      | CLASSIFICATION AND LABELLING.....  | 5         |
| 2.2.1    | <i>Classification and labelling in accordance with Regulation (EC) No1272/2008.....</i>  | 5         |
| 2.2.2    | <i>Other phrases in compliance with Regulation (EU) No 547/2011.....</i>   | 5         |
| 2.2.3    | <i>Other phrases linked to the preparation.....</i>  | 5         |
| 2.3      | PRODUCT USES.....  | 7         |
| <b>3</b> | <b>RISK MANAGEMENT.....</b>  | <b>10</b> |
| 3.1      | REASONED STATEMENT OF THE OVERALL CONCLUSIONS TAKEN IN ACCORDANCE WITH THE UNIFORM PRINCIPLES.....   | 10        |
| 3.1.1    | <i>Physical and chemical properties .....</i>  | 10        |
| 3.1.2    | <i>Methods of analysis .....</i>   | 10        |
| 3.1.3    | <i>Mammalian Toxicology.....</i>   | 10        |
| 3.1.4    | <i>Residues and Consumer Exposure .....</i>  | 10        |
| 3.1.5    | <i>Environmental fate and behaviour.....</i>   | 11        |
| 3.1.6    | <i>Ecotoxicology.....</i>  | 12        |
| 3.1.7    | <i>Efficacy .....</i>  | 12        |
| 3.2      | CONCLUSIONS ARISING FROM FRENCH ASSESSMENT .....   | 13        |
| 3.3      | SUBSTANCES OF CONCERN FOR NATIONAL MONITORING .....  | 13        |
| 3.4      | FURTHER INFORMATION TO PERMIT A DECISION TO BE MADE OR TO SUPPORT A REVIEW OF THE CONDITIONS AND RESTRICTIONS<br>ASSOCIATED WITH THE AUTHORISATION ..... | 13        |
| 3.4.1    | <i>Post-authorisation monitoring .....</i>   | 13        |
| 3.4.2    | <i>Post-authorisation data requirements .....</i>  | 13        |
| 3.4.3    | <i>Label amendments .....</i>  | 13        |
|          | <b>APPENDIX 1 – COPY OF THE FRENCH DECISION .....</b>  | <b>14</b> |
|          | <b>APPENDIX 2 – COPY OF THE DRAFT PRODUCT LABEL AS PROPOSED BY THE APPLICANT .....</b>   | <b>21</b> |
|          |  | <b>21</b> |

## **PART A – Risk Management**

The company SBM DÉVELOPPEMENT has requested extension of the marketing authorisation in France for the product BELEM EV (product code: SBM 10/094; marketing authorisation n° 2150116), containing 2g/kg cypermethrin, for use as an insecticide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate the 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 BELEM EV (SBM 10/094) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of BELEM EV (SBM 10/094) have been made using endpoints agreed in the EU peer review of cypermethrin.

This document describes the specific conditions of use and labelling required for France for the registration of BELEM EV (SBM 10/094).

Appendix 1 of this document provides a copy of the French Decision.

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

### **1 DETAILS OF THE APPLICATION**

#### **1.1 Application background**

The present registration report concerns the evaluation of SBM DÉVELOPPEMENT's application to market BELEM EV (SBM 10/094) 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 label extension of this product in France and in other MSs of the Southern zone.

#### **1.2 Active substance approval**

##### **Cypermethrin**

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.

Specific provisions of Regulation (EU) No 540/2011 were as follows:

##### **PART A**

Only uses as insecticide may be authorised.

##### **PART B**

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on cypermethrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 February 2005 shall be taken into account. In this overall assessment:

- Member States must pay particular attention to the protection of aquatic organisms, bees and non-target arthropods. Conditions of authorisation should include risk mitigation measures, where appropriate,
- Member States must pay particular attention to the operator safety. Conditions of authorisation should include protective measures, where appropriate.

There is an EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance (EFSA Journal 2018;16(8):5402).

A Review Report is available (SANCO/4333/2000 final - 15 February 2005).

#### **1.3 Regulatory approach**

The present applications (2015-5781 for extension of use and 2017-2805 for post-authorisation follow-up of the

previous evaluation (2012-1137)) were 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”)<sup>1</sup> – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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>2</sup> provides that:

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

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009<sup>3</sup>, 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.

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

Finally, the French Order of 26 March 2014<sup>5</sup> 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 extrapolation<sup>6</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.

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

<sup>1</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>2</sup> Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjoints 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>.

<sup>3</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>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.

<sup>5</sup> <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGR1407093A/jo>.

<sup>6</sup> SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9.

#### 1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of BELEM EV (SBM 10/094), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

#### 1.5 Letter(s) of Access

Not necessary: the applicant is the owner of the active substance and plant protection product data.

## 2 DETAILS OF THE AUTHORISATION

#### 2.1 Product identity

|                                |                       |
|--------------------------------|-----------------------|
| <b>Product name (code)</b>     | BELEM EV (SBM 10/094) |
| <b>Authorisation number</b>    | 2150116               |
| <b>Function</b>                | Insecticide           |
| <b>Applicant</b>               | SBM DÉVELOPPEMENT     |
| <b>Composition</b>             | 2g/kg cypermethrin    |
| <b>Formulation type (code)</b> | Granule (GR)          |
| <b>Packaging</b>               | Packaging not changed |

#### 2.2 Classification and labelling

##### 2.2.1 Classification and labelling in accordance with Regulation (EC) No 1272/2008

Classification not changed.

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

##### 2.2.2 Other phrases in compliance with Regulation (EU) No 547/2011

The authorisation of the preparation is linked for professional uses only to the following conditions:

|       |  |
|-------|--|
| SP 1  | Do not contaminate water with the product or its container. Do not clean application equipment near surface water. Avoid contamination via drains from farmyards and roads.      |
| SPe 3 | To protect aquatic organisms, respect a planted buffer zone of 20 metres to surface water bodies for the uses on carrots, other root and tuber vegetables, turnips and beetroot. |

##### 2.2.3 Other phrases linked to the preparation

|   |
|---|
| Wear suitable personal protective equipment <sup>7</sup> : refer to the Decision in Appendix 1 for the details.   |
| Re-entry period <sup>8</sup> : 6 hours.   |
| Pre-harvest interval for carrots, other root and tuber vegetables and turnips: 120 days.  |
| The label must include the following recommendations:   |
| <ul style="list-style-type: none"><li>- It should be pointed out that the efficacy level of BELEM EV (SBM 10/094) is variable and partial.</li><li>- Contains cypermethrin (pyrethrinoïde), may cause paresthesia. According to the French Order of 9 November 200411, avoid contact with skin.</li></ul> |

<sup>7</sup> If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture.

<sup>8</sup> The legal basis for this is **Titre I Article 3** of the French Order of 4 May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides].

The label must reflect the conditions of authorisation.

## 2.3 Product uses

**Please note:** The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.

When the conclusion is “not acceptable”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.

GAP rev. , date: 2020/03/03

|                         |                       |  |                      |                                     |
|-------------------------|-----------------------|--|----------------------|-------------------------------------|
| PPP (product name/code) | BELEM EV / SBM 10/094 |  | Formulation type:    | Granule (GR)                        |
| active substance        | cypermethrin          |  | Conc. of a.s. :      | 2g/kg                               |
| Applicant:              | SBM DÉVELOPPEMENT     |  | professional use     | <input checked="" type="checkbox"/> |
| Zone(s):                | Southern EU           |  | non-professional use | <input type="checkbox"/>            |
| Verified by MS:         | yes                   |  |                      |                                     |

| Crop and/or situation<br>(a) | Zone | Name code<br>(Product code)<br>(b) | F<br>G<br>or<br>I | Pests or<br>Group of pests<br>controlled<br>(c) | Formulation   |                                   | Application             |                                    |                             |  | Application rate per treatment |                             |                         | PHI<br>(days)<br>(l) | Remarks:<br>(m) |  |
|------------------------------|------|------------------------------------|-------------------|---|---------------|-----------------------------------|-------------------------|------------------------------------|-----------------------------|--|--------------------------------|-----------------------------|-------------------------|----------------------|-----------------|--|
|                              |      |                                    |                   |   | Type<br>(d-f) | Conc.<br>of a.s.<br>(g/kg)<br>(i) | method<br>kind<br>(f-h) | growth<br>stage &<br>season<br>(j) | number<br>min<br>max<br>(k) | interval<br>between<br>applications<br>(min) | kg<br>a.s./hL<br>min<br>max    | water<br>L/ha<br>min<br>max | g a.s./ha<br>min<br>max |                      |                 |  |
|                              |      |                                    |                   |   |               |                                   |                         |                                    |                             |  |                                |                             |                         |                      |                 |  |

|           |    |                       |   |   |   |   |   |                                     |   |                |  |    |   |   |
|-----------|----|-----------------------|---|---|---|---|---|-------------------------------------|---|----------------|--|----|---|---|
| Potatoes  | FR | BELEM EV (SBM 10/094) | F | Wireworms ( <i>Agriotes</i> sp.)                                    | G | 2 | Band application in furrow.<br>Granules buried into the seed bed. | At planting<br>Planting depth: 8 cm | 1 | Not applicable | Not applicable, product applied as a dry granule | 96 | F | Acceptable<br>Application without any fishtail diffuser |
| Tomatoes  | FR | BELEM EV (SBM 10/094) | F | Cutworms ( <i>Agrotis</i> spp.)<br>Wireworms ( <i>Agriotes</i> spp) | G | 2 | Band application in furrow.<br>Granules buried into the seed bed. | At planting<br>Planting depth: 8 cm | 1 | Not applicable | Not applicable, product applied as a dry granule | 96 | F | Acceptable<br>Application without any fishtail diffuser |
| Aubergine | FR | BELEM EV (SBM 10/094) | F | Cutworms ( <i>Agrotis</i> spp.)<br>Wireworms ( <i>Agriotes</i> spp) | G | 2 | Band application in furrow.<br>Granules buried into the seed bed. | At planting<br>Planting depth: 8 cm | 1 | Not applicable | Not applicable, product applied as a dry granule | 96 | F | Acceptable<br>Application without any fishtail diffuser |

| Crop and/<br>or situation<br>(a)      | Zone | Name code<br>(Product<br>code) | F<br>G<br>or<br>I<br>(b) | Pests or<br>Group of pests<br>controlled<br>(c)                              | Formulation   |                                   | Application   |                                       |                             |  | Application rate per treatment                         |                             |                         | PHI<br>(days)<br>(l)  | Remarks:<br>(m) |
|---------------------------------------|------|--------------------------------|--------------------------|--|---------------|-----------------------------------|---|---------------------------------------|-----------------------------|--|--|-----------------------------|-------------------------|---|-----------------|
|                                       |      |                                |                          |  | Type<br>(d-f) | Conc.<br>of a.s.<br>(g/kg)<br>(i) | method<br>kind<br>(f-h)   | growth<br>stage &<br>season<br>(j)    | number<br>min<br>max<br>(k) | interval<br>between<br>applications<br>(min)<br>min<br>max | kg<br>a.s./hL<br>min<br>max                            | water<br>L/ha<br>min<br>max | g a.s./ha<br>min<br>max |   |                 |
| Carrots                               | FR   | BELEM<br>EV (SBM<br>10/094)    | F                        | Carrot fly ( <i>Psila<br/>rosae</i> )<br>Wireworms<br>( <i>Agriotes</i> sp.) | G             | 2                                 | Band application in<br>furrow.<br>Granules buried into<br>the seed bed. | At<br>sowing<br>Sowing depth:<br>2 cm | 1                           | Not<br>applicable  | Not applicable,<br>product applied<br>as a dry granule | 96                          | 120                     | Acceptable<br>Application<br>without any<br>fishtail diffuser<br>Buffer zone of<br>20 m |                 |
| Other root and<br>tuber<br>vegetables | FR   | BELEM<br>EV (SBM<br>10/094)    | F                        | Carrot fly ( <i>Psila<br/>rosae</i> )<br>Wireworms<br>( <i>Agriotes</i> sp.) | G             | 2                                 | Band application in<br>furrow.<br>Granules buried into<br>the seed bed. | At<br>sowing<br>Sowing depth:<br>2 cm | 1                           | Not<br>applicable  | Not applicable,<br>product applied<br>as a dry granule | 96                          | 120                     | Acceptable<br>Application<br>without any<br>fishtail diffuser<br>Buffer zone of<br>20 m |                 |
| Beetroot                              | FR   | BELEM<br>EV (SBM<br>10/094)    | F                        | Wireworms<br>( <i>Agriotes</i> sp.)  | G             | 2                                 | Band application in<br>furrow.<br>Granules buried into<br>the seed bed. | At<br>sowing<br>Sowing depth:<br>2 cm | 1                           | Not<br>applicable  | Not applicable,<br>product applied<br>as a dry granule | 96                          | Not<br>applicable       | Acceptable<br>Application<br>without any<br>fishtail diffuser<br>Buffer zone of<br>20 m |                 |
| Turnips                               | FR   | BELEM<br>EV (SBM<br>10/094)    | F                        | Cabbage Root fly<br>( <i>Chamaepsila<br/>rosae</i> )                         | G             | 2                                 | Band application in<br>furrow.<br>Granules buried into<br>the seed bed. | At<br>sowing<br>Sowing depth:<br>2 cm | 1                           | Not<br>applicable  | Not applicable,<br>product applied<br>as a dry granule | 96                          | 120                     | <b>Not acceptable</b><br>for flies<br>(Lack of<br>efficacy data)                        |                 |

| Crop and/<br>or situation<br>(a) | Zone | Name code<br>(Product<br>code) | F<br>G<br>or<br>I<br>(b) | Pests or<br>Group of pests<br>controlled<br>(c)            | Formulation   |                                   | Application   |                                       |                             |  | Application rate per treatment                         |                             |                         | PHI<br>(days)<br>(l)   | Remarks:<br>(m) |
|----------------------------------|------|--------------------------------|--------------------------|--|---------------|-----------------------------------|---|---------------------------------------|-----------------------------|--|--|-----------------------------|-------------------------|--|-----------------|
|                                  |      |                                |                          |  | Type<br>(d-f) | Conc.<br>of a.s.<br>(g/kg)<br>(i) | method<br>kind<br>(f-h)   | growth<br>stage &<br>season<br>(j)    | number<br>min<br>max<br>(k) | interval<br>between<br>applications<br>(min)<br>min<br>max | kg<br>a.s./hL<br>min<br>max                            | water<br>L/ha<br>min<br>max | g a.s./ha<br>min<br>max |  |                 |
| Turnips                          | FR   | BELEM<br>EV (SBM<br>10/094)    | F                        | Wireworms<br>( <i>Agriotes</i> sp.)                        | G             | 2                                 | Band application in<br>furrow.<br>Granules buried into<br>the seed bed. | At<br>sowing<br>Sowing depth:<br>2 cm | 1                           | Not<br>applicable  | Not applicable,<br>product applied<br>as a dry granule | 96                          | 120                     | Acceptable<br>for soil pests<br>(wireworms)<br><br>Application<br>without any<br>fishtail diffuser<br>Buffer zone of<br>20 m               |                 |
| Radish                           | FR   | BELEM<br>EV (SBM<br>10/094)    | F                        | Cabbage Root fly<br>( <i>Chamaepsila</i><br><i>rosae</i> ) | G             | 2                                 | Band application in<br>furrow.<br>Granules buried into<br>the seed bed. | At<br>sowing<br>Sowing depth:<br>2 cm | 1                           | Not<br>applicable  | Not applicable,<br>product applied<br>as a dry granule | 96                          | 120                     | Not acceptable<br>for flies<br>(Lack of<br>efficacy data)<br><br>Application<br>without any<br>fishtail diffuser<br>Buffer zone of<br>20 m |                 |

**Remarks:**

- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure).
- (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I).
- (c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds.
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR).
- (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989.
- (f) All abbreviations used must be explained.
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench.
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

- (i) g/kg or g/l.
- (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application.
- (k) The minimum and maximum number of application possible under practical conditions of use must be provided.
- (l) PHI - minimum pre-harvest interval.
- (m) Remarks may include: Extent of use/economic importance/restrictions.

### 3 RISK MANAGEMENT

#### 3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

##### 3.1.1 Physical and chemical properties

The physico-chemical properties of the formulation have been evaluated and considered acceptable during the evaluation for authorisation of this formulation. The intended concentrations requested for the extension of use(s) (ready-to-use GR formulation) are covered by the concentrations authorised during the previous authorisation of this formulation (2012-1137).

The completed two-year formulation storage stability study at ambient temperature, identified as a requirement at the time of the previous evaluation for marketing authorisation, has been submitted and evaluated (reference 2017-2805). These new data comply with regulatory requirements.

##### 3.1.2 Methods of analysis

The analytical methods for the determination of the active substance residues in matrices (plants and foodstuffs of animal origin) submitted at European level and in the dossier of the preparation meet the regulatory requirement.

The new uses claimed by SBM for the product BELEM EV (SBM 10/094) are covered by the analytical methods which were previously submitted in the initial dossier for this preparation. Therefore section 2 that was previously evaluated by France has not been re-evaluated in the frame of this new submission.

##### 3.1.3 Mammalian Toxicology

Unchanged from the previous evaluation (2012-1137).

##### 3.1.4 Residues and Consumer Exposure

###### 3.1.4.1 Residues

The preparation BELEM EV (SBM 10/094) contains cypermethrin.

**Table 1 Summary for cypermethrin**

| Use-No.* | Crop                            | Plant metabolism covered? | Sufficient residue trials? | PHI sufficiently supported? | Sample storage covered by stability data? | MRL compliance Reg. 2017/626 | Chronic risk for consumers identified? | Acute risk for consumers identified? | Comment |
|----------|---------------------------------|---------------------------|----------------------------|-----------------------------|---|------------------------------|--|--------------------------------------|---------|
| 1        | Potatoes                        | Yes                       | Yes                        | Yes                         | Yes                                       | Yes                          | No                                     | No                                   | -       |
| 2        | Tomatoes                        | Yes                       | Yes                        | Yes                         | Yes                                       | Yes                          |  | No                                   | -       |
| 3        | Aubergine                       | Yes                       | Yes                        | Yes                         | Yes                                       | Yes                          |  | No                                   | -       |
| 4        | Carrots                         | Yes                       | Yes                        | Yes                         | Yes                                       | Yes                          |  | No                                   | -       |
| 5        | Other root and tuber vegetables | Yes                       | Yes                        | Yes                         | Yes                                       | Yes                          |  | No                                   | -       |
| 6        | Beetroot                        | Yes                       | Yes                        | Yes                         | Yes                                       | Yes                          |  | No                                   | -       |
| 7        | Turnips                         | Yes                       | Yes                        | Yes                         | Yes                                       | Yes                          |  | No                                   | -       |
| 8        | Radish                          | Yes                       | Yes                        | Yes                         | Yes                                       | Yes                          |  | No                                   | -       |

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

**Table 2 Information on BELEM EV (SBM 10/094)**

| Crop                            | PHI for BELEM EV (SBM 10/094) requested by applicant | PHI/withholding period* sufficiently supported for | PHI for BELEM EV (SBM 10/094) proposed by zRMS | zRMS Comments (if different PHI proposed) |
|---------------------------------|--|--|--|---|
|                                 |  | cypermethrin                                       |  |   |
| Potatoes                        | F*   | Yes  | F*   | -   |
| Tomatoes                        | F*   | Yes  | F*   | -   |
| Aubergine                       | F*   | Yes  | F*   | -   |
| Carrots                         | 120 days   | Yes  | 120 days                                       | -   |
| Other root and tuber vegetables | 120 days   | Yes  | 120 days                                       | -   |
| Beetroot                        | F*   | Yes  | F*   | -   |
| Turnips                         | 120 days   | Yes  | 120 days                                       | -   |
| Radish                          | 120 days   | Yes  | 120 days                                       | -   |

NR: not relevant

\* Purpose of withholding period to be specified

\*\* F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

### 3.1.4.2 Consumer exposure

The data available are considered sufficient for risk assessment. Any exceedance of the current MRL for cypermethrin as laid down in Regulation (EU) No 396/2005 is not expected.

The chronic and short-term intakes of cypermethrin residues resulting from the uses proposed in the framework of this application are unlikely to present a public health concern.

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

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

### 3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate predicted environmental concentration (PEC) values for the active substance cypermethrin and its metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC values of cypermethrin and its metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PECsoil and PECsw values derived for cypermethrin and its metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PECgw values for cypermethrin and its metabolites do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009 and guidance document SANCO 221/2000 on the relevance of metabolites in groundwater. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

Based on vapour pressure, information on volatilisation from plants and soil, and DT<sub>50</sub> calculation, no significant contamination of the air compartment is expected for the intended uses.

### 3.1.6 Ecotoxicology

#### 3.1.6.1 Effects on Terrestrial Vertebrates

Unchanged from the previous evaluation (2012-1137).

#### 3.1.6.2 Effects on Aquatic Species

The risk assessment for aquatic organisms was carried out according to the Guidance Document on Aquatic Ecotoxicology (Sanco/3268/2001) and considering the EU agreed endpoints of cypermethrin.

Among the tested aquatic organisms, fish and aquatic invertebrates were the most sensitive to the active substance and the preparation. Considering the nature of the application, no drift of granules or granular dust is expected during precision application because of the precise nature of the application method. Therefore exposure to the aquatic environment will only be via drainage and run-off.

Toxicity data on metabolites indicated a lower toxicity. Mesocosm studies have been provided for cypermethrin and lead to a Regulatory Acceptable Concentration (RAC) at 0.01µg a.s./L with a safety factor of 1. This mesocosm covers the risk to aquatic organisms.

The TER values using PECsw FOCUS STEP 3 exceed the relevant triggers, indicating that the risk to aquatic organisms is acceptable for all the uses without mitigation measures, except for root vegetables. For root vegetables, with a 20m planted buffer strip, the risk is acceptable for aquatic communities.

#### 3.1.6.3 Effects on Bees and Other Arthropod Species

Unchanged from the previous evaluation (2012-1137).

#### 3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms

Unchanged from the previous evaluation (2012-1137).

#### 3.1.6.6 Effects on Soil Non-target Micro-organisms

Unchanged from the previous evaluation (2012-1137).

#### 3.1.6.7 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna)

Unchanged from the previous evaluation (2012-1137).

### 3.1.7 Efficacy

Considering the data submitted:

- The efficacy level of BELEM EV (SBM 10/094) is considered variable and partial for the requested uses on soil pests (*Agriotes sp.* and *Agrotis sp.*) and carrot fly (*Psila rosae*). However, it may be considered acceptable in a context where the control solutions against these pests are limited.
- As regards to vegetable flies on turnip and radish, **considering the absence of data on *Delia sp.*, or possible extrapolation, the evaluation cannot be finalised.**
- The phytotoxicity level of BELEM EV (SBM 10/094) is considered negligible for all the requested uses.
- The risks of negative impact on yield, quality, propagation, succeeding and adjacent crops are considered negligible.
- The risk of resistance developing or appearing to cypermethrin is considered to not require monitoring for the requested uses.

### **3.2 Conclusions arising from French assessment**

Taking into account the above assessment, an authorisation **can be granted** as proposed in Appendix 1 – Copy of the product Decision, except for use against flies (*Delia* sp.) on radish and turnips.

### **3.3 Substances of concern for national monitoring**

No information stated.

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

#### **3.4.1 Post-authorisation monitoring**

No further information is required.

#### **3.4.2 Post-authorisation data requirements**

No further information is required.

#### **3.4.3 Label amendments**

The draft label proposed by the applicant in Appendix 2 must be corrected with consideration of any new element under points 2.2.1 (or 2.2.2), 2.2.3 and 2.2.4.

The label shall reflect the detailed conditions stipulated in the Decision.

## Appendix 1 – Copy of the French Decision



### Décision relative à une demande d'extension d'usages 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'extension d'usage majeur et les données complémentaires fournies suite à une exigence post-autorisation du produit phytopharmaceutique BELEM EV*

de la société **SBM DEVELOPPEMENT**  
enregistrées sous les n°2015-5781 et 2017-2805

*Vu les conclusions de l'évaluation de l'Anses du 2 décembre 2019,*

L'autorisation de mise sur le marché du produit référencé ci-après **est étendue** aux usages décrits dans la présente décision.

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

|                         |  |
|-------------------------|--|
| <b>Nom du produit</b>   | BELEM EV   |
| <b>Type de produit</b>  | Produit de référence                             |
|                         | SBM DEVELOPPEMENT                                |
| <b>Titulaire</b>        | 60 chemin des Mouilles<br>69130 Ecully<br>France |
| <b>Formulation</b>      | Granulé (GR)                                     |
| Contenant               | 2 g/kg - cyperméthrine                           |
| <b>Numéro d'intrant</b> | 2150221  |
| <b>Numéro d'AMM</b>     | 2150116  |
| <b>Fonction</b>         | Insecticide                                      |
| <b>Gamme d'usage</b>    | Professionnel                                    |

L'échéance de validité de la présente décision correspond à celle de l'autorisation du produit.

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

A Maisons-Alfort le, **03 MARS 2020**

**Caroline SEMAILLE**  
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

### Liste des nouveaux 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 arthropodes non cibles (mètres) | Zone Non Traitée plantes non cibles (mètres) | Mention abeilles |
|--|------------------------|-------------------------------|--------------------------|-----------------------------|-------------------------------------|--|--|------------------|
| <b>16172104</b><br>Betterave potagère*Trt Sol*<br>Ravageurs du sol | <b>48 kg/ha</b>        | <b>1/an</b>                   |                          |                             |                                     |  |  |                  |
|  |                        |                               |                          |                             |                                     |  |  |                  |
|  |                        |                               |                          |                             |                                     |  |  |                  |
|  |                        |                               |                          |                             |                                     |  |  |                  |
| <b>16202101</b><br>Carotte*Trt Sol*Mouches                         | <b>48 kg/ha</b>        | <b>1/an</b>                   |                          |                             |                                     |  |  |                  |
|  |                        |                               |                          |                             |                                     |  |  |                  |
|  |                        |                               |                          |                             |                                     |  |  |                  |
|  |                        |                               |                          |                             |                                     |  |  |                  |
| <b>01108018</b><br>Carotte*Trt Sol*Ravageurs du sol                | <b>48 kg/ha</b>        | <b>1/an</b>                   |                          |                             |                                     |  |  |                  |
|  |                        |                               |                          |                             |                                     |  |  |                  |
|  |                        |                               |                          |                             |                                     |  |  |                  |
|  |                        |                               |                          |                             |                                     |  |  |                  |



### Liste des nouveaux 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 anthropodes non cibles (mètres) | Zone Non Traitée plantes non cibles (mètres) | Mention abeilles |
|--|------------------------|-------------------------------|--------------------------|-----------------------------|-------------------------------------|--|--|------------------|
| 16772101<br>Noyer*Trit Sol*<br>Ravageurs du sol          | 48 kg/ha               | 1/an                          | -                        | 120<br>(dont DVP 20)        | 20                                  | -  | -  | -                |
|  |                        |                               |                          |                             |                                     |  |  |                  |
|  |                        |                               |                          |                             |                                     |  |  |                  |
| 15652103<br>Pomme de terre*Trit Sol*<br>Ravageurs du sol | 48 kg/ha               | 1/an                          | -                        | F                           | -                                   | -  | -  | -                |
|  |                        |                               |                          |                             |                                     |  |  |                  |
|  |                        |                               |                          |                             |                                     |  |  |                  |
| 16952101<br>Tomate*Trit Sol*<br>Ravageurs du sol         | 48 kg/ha               | 1/an                          | -                        | F                           | -                                   | -  | -  | -                |
|  |                        |                               |                          |                             |                                     |  |  |                  |
|  |                        |                               |                          |                             |                                     |  |  |                  |

DVP : Dispositif Végétalisé Permanent.

BELEM EV  
AMM n°2150116



| Liste des usages refusés          |               |                               |                             |
|-----------------------------------|---------------|-------------------------------|-----------------------------|
| Usages                            | Dose d'emploi | Nombre maximum d'applications | Délai avant récolte (jours) |
| 16772102<br>Navet*Ttr Sol*Mouches | 48 kg/ha      | 1/an                          | 120                         |

**Motivation du refus :**  
L'usage est refusé en raison d'un manque de données d'efficacité.



BELEM EV  
AMM n°2150116



## Conditions d'emploi du produit

### Stockage et manipulation du produit

Le produit contenant de la cyperméthrine (pyréthrinoïde), susceptible de provoquer des paresthésies, il conviendra d'éviter le contact avec la peau, conformément à l'arrêté du 9 novembre 2004.

### Protection de l'opérateur et du travailleur

Les équipements de protection individuelle ci-après sont applicables à tous les usages du produit.

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*

##### **• pendant le chargement du matériel d'épandage (ex : microgranulateur)**

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m<sup>2</sup> ou plus avec traitement déperlant (combinaison ou ensemble veste + pantalon) ;
- Blouse ou tablier à manches longues de catégorie III type 3 (PB) porté sur la combinaison de travail ;

##### **• pendant l'épandage**

- Gants en nitrile certifiés EN 374-2 à usage unique en cas d'intervention sur semoir, épandeur à engrains ou microgranulateur ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m<sup>2</sup> ou plus avec traitement déperlant (combinaison ou ensemble veste + pantalon) ;

##### **• pendant le nettoyage du matériel d'épandage**

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m<sup>2</sup> ou plus avec traitement déperlant (combinaison ou ensemble veste + pantalon) ;
- Combinaison catégorie III Type 5/6 ou blouse ou tablier à manches longues de catégorie III type 3 (PB).

#### *Pour le travailleur, porter*

- Une combinaison de travail (cotte en coton/polyester 35 %/ 65 % - grammage d'au moins 230 g/m<sup>2</sup>) avec traitement déperlant et, en cas de contact avec la culture traitée, des gants en nitrile certifiés EN 374-3.

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

- 6 heures.

#### **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. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

#### ***Protection de la faune***

- SPe 3 : Pour protéger les organismes aquatiques, respecter un dispositif végétalisé permanent non traité d'une largeur de 20 mètres en bordure des points d'eau pour les usages sur "carotte", "navet" et "betterave potagère".

### **Recommandations relatives à l'étiquette du produit**

Il est recommandé de faire figurer l'information suivante sur l'étiquette :

- L'efficacité du produit étant variable et partielle, préciser les conditions optimales d'utilisation.

**Appendix 2 – Copy of the draft product label as proposed by the applicant**



**BELEM EV®**

**Granule multicrop insecticide**

**Effective against wireworms, cutworms and vegetable flies**

Contains 0.2% of cypermethrin

Formulation Granules (GR)

*Producer:*

**SBM Développement**

160 Route de la Valentine - CS 70052  
13374 Marseille cedex 11  
France

® Registered SBM Développement, France

Manufacturing date: XXXXX  
Sample: XXXXX

### Statutory information

Respect usage instructions to avoid risks for the man, animals and environment.

- **WARNING** Dangerous to the environment  
H410 Very Toxic to aquatic life with long lasting effects.

Do not get on skin.

Wear protective gloves and protective clothing.

Eliminate product and its container like toxic rubbish.

Do not throw away in the environment. Follow MSDS instructions.

Do not contaminate water with product or its container. Do not clean application equipment near surface water. Avoid contaminations via drains from farmyards or roads.

To protect aquatic organisms,

- respect a vegetated buffer strip of 20 m to surface water bodies for crops of carrots, beetroots, turnips, radish, and other root and tuber vegetables;
- respect a vegetated buffer strip of 5 m to surface water bodies for crops potatoes, tomatoes, aubergines and grass/turf

### Container

Wash out container thoroughly, empty washings into spray tank and dispose of container safely.

### Mode of action

BELEM EV contains cypermethrin, active substance belonging to the synthetic pyrethroids' family. Synthetic pyrethroids are neuropoisons acting on the axons in the peripheral and central nervous system of insects by interacting with sodium channels causing hyperactivity and paralysis. Cypermethrin acts mainly by contact but also by ingestion; its persistence of activity in the soil varies depending on the more or less important quantity of light. Persistence of BELEM EV varies from 1.5 to 2 months.

Cypermethrin is taken part in group 3 of IRAC classification:

« The repeated use, on the same plot, of mixtures with active substances of the same chemical family or having the same mode of action can lead to make resistant organisms.

To reduce this risk, it is advised to take turns or split, on the same plot, mixtures composed with active substances coming from different chemical families or with different mode of actions.”

### Uses and doses

| Crop      | Pests  | Doses    | Application   | PHI | Buffer Zone |
|-----------|--|----------|---|-----|-------------|
| Potatoes  | Wireworms ( <i>Agriotes spp</i> )                  | 48 kg/ha | 1 application in furrow<br>Granule buried into the seed bed | -   | -           |
| Tomatoes  | Wireworms ( <i>Agriotes spp</i> )                  | 48 kg/ha | 1 application in furrow<br>Granule buried into the seed bed | -   | -           |
|           | Cutworms<br>( <i>Agrotis ipsilon, A. segetum</i> ) |          |   |     |             |
| Aubergine | Wireworms ( <i>Agriotes spp</i> )                  | 48 kg/ha | 1 application in furrow<br>Granule buried into the seed bed | -   | -           |
|           | Cutworms<br>( <i>Agrotis ipsilon, A. segetum</i> ) |          |   |     |             |

|            |  |          |   |          |      |
|------------|--|----------|---|----------|------|
| Carrot     | Wireworms ( <i>Agriotes spp</i> )                  | 48 kg/ha | 1 application in furrow<br>Granule buried into the seed bed | 120 days | 20 m |
|            | Carrot fly ( <i>Psila rosae</i> )                  |          |   |          |      |
| Beetroots  | Wireworms ( <i>Agriotes spp</i> )                  | 48 kg/ha | 1 application in furrow<br>Granule buried into the seed bed | -        | 20 m |
| Turnip     | Wireworms ( <i>Agriotes spp</i> )                  | 36 kg/ha | 1 application in furrow<br>Granule buried into the seed bed | 120 days | 20 m |
|            | Turnip fly<br>( <i>Delia floralis, D.radicum</i> ) |          |   |          |      |
| Radish     | Turnip fly<br>( <i>Delia floralis, D.radicum</i> ) | 36 kg/ha | 1 application in furrow<br>Granule buried into the seed bed | 120 days | 20 m |
| Grass/Turf | Cutworms<br>( <i>Agrotis ipsilon, A. segetum</i> ) | 24 kg/ha | 1 broadcast application<br>Granule buried into the seed bed | -        | -    |

#### Directions for use

BELEM EV is a granule soil insecticide which contains cypermethrin, a non mobile active substance. BELEM EV must be applied at seeding or planting, in localisation in the seeding row. BELEM EV has to be homogeneously spread in both sides of the seeding furrow.

#### Classification

|                        |   |   |
|------------------------|---|---|
| Hazard symbols:        |  |   |
| Indications of danger: | <b>Signal word : WARNING</b><br><b>Dangerous to the environment</b>                 |   |
| Risk phrases:          | H410  | Very Toxic to aquatic life with long lasting effects.   |
| Safety phrases:        | P262<br>P273<br>P280<br>P391<br>P501<br>EUH401<br><br>SP1<br>SPe 3                  | Do not get on skin.<br>Avoid release to the environment.<br>Wear protective gloves and protective clothing<br>Collect spillage<br>Dispose of contents/container as hazardous waste<br>To avoid risks to human health and the environment, comply with the instructions for use.<br>Do not pollute the water with the product or its packaging<br>To protect aquatic organisms,<br>- respect a vegetated buffer strip of 20 m to surface water bodies for crops of carrots, beetroots, turnips, radish, and other root and tuber vegetables; |

|  |  |   |
|--|--|---|
|  |  | - respect a vegetated buffer strip of 5 m to surface water bodies for crops potatoes, tomatoes, aubergines and grass/turf |
|--|--|---|

**Important**

Preserve the uses, doses, conditions and the safety precautions marked on the packing. They were determined based on the product characteristics and applications for which it is recommended.

Crop and applications must be managed according good agricultural practices, under your responsibility, taking into consideration the specific parameters of your farm, such as the soil type, weather conditions...

The manufacturer guarantees the quality of the product sold in its original packing as well as its accordance to its registration.