REGISTRATION REPORT

Part A

Risk Management

Product code: SBM 14/001

Product name: SUCCESS SOL

Chemical active substance:

spinosad, 1 g/kg

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application and label extention)

Applicant: SBM Développement

Date: 2019/11/26

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PART A
RISK MANAGEMENT

1 Details of the application

The company SBM Développement has requested a marketing authorisation in France for the product SUCCESS SOL (formulation code: SBM 14/001), containing 1 g/kg spinosad, as an insecticide for non-professional uses.

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 addenda for France. The information, data and assessments provided in the Registration Report, Part B include assessment of further data or information as required at national registration by EU regulations. It also includes assessment of data and information related to SUCCESS SOL (SBM 14/001) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of SUCCESS SOL (SBM 14/001) have been made using endpoints agreed in the EU peer review of spinosad.

This document describes the specific conditions of use and labelling required for France for the registration of SUCCESS SOL (SBM 14/001).

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

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

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

1.1 Application background

The present registration report concerns the evaluation of SBM Développement's application to market SUCCESS SOL (SBM 14/001) in France as an insecticide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation and the label extension of this product in France and in other MSs of the Southern zone.

The present applications (2017-0502 for marketing authorisation, 2018-1557 for extension of use (additional crops) and 2019-1140 to change the applicant's address) 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")[1] – the highest application rates applied for in the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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[2], 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.

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

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

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011[3], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

1.2 Letters of Access

The applicant has provided a letter of access for active substance data.

1.3 Justification for submission of tests and studies

According to the applicant: "*The submission of the dossier SUCCESS SOL (SBM 14/001)concerns a registration of the formulation. The tests and studies submitted were necessary to the current registration as some of them were not evaluated for the registration of this formulation*."

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of SUCCESS SOL (SBM 14/001), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

Product code	SBM 14/001.
Product name in MS	SUCCESS SOL.
Authorisation number	2190760
Low risk (article 47)	No.
Function	Insecticide.
Applicant	SBM Développement.
Active substance(s) (incl. content)	spinosad, 1 g/kg.
Formulation type	Granule (GR).
Packaging	0.5 L – 1 L – 1.5 L – 2 L HDPE bottles. Non-professional user.
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None.
Recommended tank mixtures	None.

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

2.2 Conclusion

The evaluation of the application for SUCCESS SOL (SBM 14/001) 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:	-
Hazard pictograms:	Hazardous to the aquatic environment - Chronic Hazard, category 3.
Signal word:	-
Hazard statement(s):	H412: Harmful to aquatic life with long-lasting effects.
Precautionary statement(s):	***For the P phrases, refer to the extant legislation***
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use [EUH401].

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

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

	Do not dispose of unused product in the sink, gutter or any other water point.
	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[4] 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

[4] Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte

is 5 metres;

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.

Finally, the French Order of 26 March 2014[5] 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 "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[6] is to supply "minor" crops with registered plant protection products.

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

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

2.5.1 Restrictions linked to the PPP

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

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection:	
	-
Other specific restrictions:	
Re-entry period	Not applicable.
Agricultural recommendations	The limited efficacy of the product against Wireworms must be indicated on the label.

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

[5] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

[6] SANCO document "guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs": SANCO/ 7525/VI/95 - rev.9

2.5.1 (mandatory labelling):

None.

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, 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.

GAP rev. 1, date: 2019-11-26

PPP (product name/code):	SUCCESS SOL/SBM 14/001	Formulation type:	GR [a, b]
Active substance 1:	spinosad	Conc. of a.s. 1:	1 g/kg [c]
Applicant:	SBM Développement	Professional use:	☐
Zone(s):	southern Zone [d]	Non-professional use:	☒
Verified by MS:	yes		
Field of use:	insecticide		

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FRANCE

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
Zonal uses (field uses)													
1	FR	Potatoes Beetroot (minor use)	Fn	Wireworms *(Agriotes* spp.*)*	Application in furrow. Granules buried into the planting furrow.	At planting	a) 1 b) 1	-	48 corresponding to 48 g/10 m²	~~0.048~~ 48 g/ha, corresponding to 0.048 g/10 m²	Not applicable	F	**Acceptable**
3	FR	Part of group root and tuber vegetables (minor uses) Carrots [DAUCS] Horseradish Celeriac Parsnips Parsley root ~~Radishes~~ ~~Turnips~~ ~~Swedes~~ Salsifies Jerusalem artichoke	Fn	Carrot fly *(Psila rosae)* [PSILRO] Wireworms *(Agriotes spp.)* [AGRISP]	Application in furrow. Granules buried into the seed bed.	At sowing BBCH 00	a) 1 b) 1	-	48 corresponding to 48 g/10 m²	~~0.048~~ 48 g/ha, corresponding to 0.048 g/10 m²	Not applicable	F	**Acceptable**

Yellow shading: modified by zRMS
~~Crossed~~ crops: not requested in the national application form. Crops added (beetroot..) to correspond to the national uses.

Remarks table heading:

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

Remarks columns:	1	Numeration necessary to allow references	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		
	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)	8	The maximum number of application possible under practical conditions of use must be provided.
	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	9	Minimum interval (in days) between applications of the same product
			10	For specific uses other specifications might be possible, e.g.: g/m^3 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).
			12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	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)

SUCCES SOL (SBM 14/001) is a granule formulation (code GR). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is that of heterogeneous beige granules. By extrapolation from the formulation 10/051, the formulation SBM 14/001 is not considered explosive nor to have oxidising properties. The product is not flammable. It has a self-ignition temperature up to 400 °C. In aqueous solution (1 %), it has a pH value around 7 at 21 °C. There is no effect of high temperatures on the stability of the formulation, since after 14 days at 54 °C, neither the active substance content nor the technical properties were changed. The stability data indicate a shelf life of at least two years at ambient temperature when stored in polyethylene (PE) bags inside a cardboard box, or in HDPE packaging.

The technical characteristics are acceptable for a GR formulation.

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

- The efficacy level of SUCCESS SOL (SBM 14/001) is considered satisfactory for the control of carrot flies. The efficacy level is limited on wireworms but considered acceptable in a context of limited availability of products or alternative methods for this use.
- The phytotoxicity level of SUCCESS SOL (SBM 14/001) is considered negligible for the requested uses.
- The risks of negative impact on quality, propagation, following and adjacent crops are considered negligible.
  The risk of resistance developing or appearing to spinosad does not require monitoring for the requested uses.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

An analytical method for the determination of the active substance in the formulation is available and validated. As the active substance spinosad does not contain any relevant impurity, no pertinent analytical method is required.

3.3.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report (DAR) and in this dossier and validated for the determination of residues of spinosad in plants (high-water-content matrices), soil, water (surface and drinking) and air.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

<table>
<tr><td colspan="4">Active substance: spinosad</td></tr>
<tr><td>ADI</td><td colspan="2">0.024 mg/kg bw/d</td><td rowspan="3">EU (2007)</td></tr>
<tr><td>ARfD</td><td colspan="2">not applicable</td></tr>
<tr><td>AOEL short-term*</td><td colspan="2">0.024 mg/kg bw/d</td></tr>
<tr><td rowspan="3">Dermal absorption</td><td colspan="3">Based on default values according to guidance on dermal absorption (Efsa 2012):</td></tr>
<tr><td></td><td>Concentrate (used in formulation) 1 g/kg</td><td>Spray dilution (used in formulation)</td></tr>
<tr><td>Dermal absorption endpoints %</td><td>50</td><td>-</td></tr>
</table>

*In the review report on spinosad (SANCO/1428/2001-rev. final 2006), a long-term AOEL of 0.012 mg/kg bw/d was also proposed based the 24-month rat study with 50 % correction for oral absorption. However, the short-term AOEL of 0.024 mg/kg bw/d based on the 90-day dog study (including 50 % correction for oral absorption) seems to be more appropriate for the risk assessment of operators.

Dermal absorption values have been determined according to the EFSA Guidance on dermal absorption (EFSA Journal 2012;10(4):2665).

Based on an evaluation of agreed dermal absorption values for a range of concentrated pesticide formulation and their dilutions, the following default values are recommended:

- A default dermal absorption value of 25 % may be applied for products containing > 5 % (50 g/kg for solids or 50 g/L for liquids) active substance.
- A default value of 75 % should be used for products or in use dilutions containing ≤ 5 % active substance.

However, if oral absorption is less than 75 %, this can be used as a surrogate dermal absorption value for the concentrate. As the oral absorption is 50 %, this value can be used as default dermal absorption value.

3.4.1 Acute toxicity

SBM 14/001 (SUCCESS SOL), containing 1 g/kg spinosad, has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitiser.

The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.4.1.

3.4.2 Operator exposure

Summary of critical use patterns (worst cases):

Crop	F/G[7]	Equipment	Application rate kg product/ha (g a.s./ha)	Spray dilution (L/ha)	Model
Risk envelope Potatoes	F	Flexible canister with a single dispenser hole with a diameter of 2 to 2.5 mm. Application in row. Granules buried into the seed bed.	48 g SBM 14/001 / 10 m^2 (0.048 g spinosad /10 m^2)	-	Amateur use model (puffer pack model)

Considering the proposed uses, operator systemic exposure was estimated using the amateur use model (puffer pack):

Crop	Equipment	PPE and/or working coverall	% short-term AOEL spinosad
Potatoes	Application in row Granules buried into the planting furrow	Without personal protection equipment	5.2

According to the model calculations, it may be concluded that the risk for the operator (user) using SBM 14/001 is acceptable without personal protection equipment.

3.4.3 Worker exposure

SBM 14/001 is applied in the sowing row; no work is expected to be practised after application. Therefore, worker exposure estimation is considered not relevant.

3.4.4 Bystander and resident exposure

In the context of use by non-professionals, it is considered that the assessment of risk for bystanders is not necessary.

It may be concluded that there is no unacceptable risk to the resident exposed to SUCCESS SOL (SBM 14/001).

Residential children exposure was assessed by the applicant according to the amateur-use guidance. Exposure is estimated to be 0.0214 % of the short-term AOEL of spinosad. It may be concluded that there is no unacceptable risk to the resident exposed to SBM 14/001.

[7] Open field or glasshouse

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

Overall conclusion

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

The chronic and short-term intakes of spinosad 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 of the intended use.

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

Data gaps

Noticed data gaps for the a.s. are:

- Metabolism studies representative for soil applications of spinosad.
- Rotational metabolism studies conducted with spinosyn D (EFSA, 2018).

Data required post-authorisation: none.

Summary for SBM 14/001

Table 1: Information on SBM 14/001 (KCA 6.8)

Crop	PHI for SBM 14/001 requested by applicant	PHI sufficiently supported for spinosad	PHI for SBM 14/001 proposed by zRMS	zRMS Comments (if different PHI proposed)
Potatoes	F*	Yes	F*	-
Carrots	F*	Yes	F*	-
Whole group root and tuber vegetables	F*	Yes	F*	-

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

Waiting periods before planting succeeding crops

Not relevant.

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

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 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 spinosad and its metabolites in soil 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. Considering the granular formulation and the intended non-professional use, the PEC values in surface water are not required.

PECsoil values derived for the active substance and its metabolites are used for the ecotoxicological risk assessment.

PECgw values for spinosad and its metabolites do not occur at levels exceeding those mentioned in Regulation (EC) No 546/2011. 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_{50} calculation, no significant contamination of the air compartment is expected for the intended uses.

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance and its metabolites were used 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.

Based on the guidance documents, the risks for birds, aquatic organisms, mammals, bees and other non-target arthropods, earthworms, other soil macro- and micro-organisms and terrestrial plants are acceptable for the intended uses.

3.8 Relevance of metabolites (Part B, Section 10)

Not relevant.

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

The active substance spinosad 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

None

Appendix 1 Copy of the product authorisation

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

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

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

Vu la demande d'autorisation de mise sur le marché et les demandes associées du produit phytopharmaceutique ***SUCCESS SOL***

de la société *SBM DEVELOPPEMENT*

enregistrées sous les *n°2017-0502, 2018-1557 et 2019-1140*

Vu les conclusions de l'évaluation de l'Anses du 17 octobre 2019,

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

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

Avertissement :

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

SUCCESS SOL
AMM n°2190760

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Informations générales sur le produit	
Nom du produit	SUCCESS SOL
Type de produit	Produit de référence
Titulaire	SBM DEVELOPPEMENT 60 chemin des Mouilles 69130 Ecully France
Formulation	Granulé (GR)
Contenant	1 g/kg - spinosad
Numéro d'intrant	161-2017.01
Numéro d'AMM	2190760
Fonction	Insecticide
Gamme d'usage	Amateur / emploi autorisé dans les jardins

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 30 avril 2021.

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

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

Attention : à compter du 01/01/2019, la mise sur marché, la délivrance, l'utilisation et la détention des produits de la gamme d'usages « amateur » sont exclusivement réservées aux utilisateurs professionnels, en application de l'article L. 253-7-III du Code rural et de la pêche maritime, à l'exception des produits de la gamme amateurs inscrits sur la liste des produits de biocontrôle, des produits utilisables en agriculture biologique ou des produits à faible risque. Cette interdiction ne s'applique pas aux traitements et mesures nécessaires à la destruction et à la prévention de la propagation des organismes nuisibles mentionnés à l'article L. 251-3, en application de l'article L. 251-8 du même Code.

A Maisons-Alfort le, 26 NOV. 2019

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)

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ANNEXE I : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	**Contenance**
Bouteilles en polyéthylène haute densité	0,5 L ; 1 L ; 1,5 L ; 2 L d'un poids net de 600 g, 1100 g ou 2100 g

Les emballages en carton avec sachet refermable sont refusés car ils ne sont pas en mesure de garantir une exposition minimale de l'utilisateur non professionnel.

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	**Mention de danger**
Dangers pour le milieu aquatique - Danger chronique, catégorie 3	H412 : Nocif pour les organismes aquatiques, entraîne des effets néfastes à long terme
Pour les phrases P se référer à la règlementation en vigueur. **Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.**	

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Liste des usages autorisés
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
16172104 Betterave potagère* Trt Sol*Ravageurs du sol	**48 g/10 m²**	**1/an**	BBCH 00	F (BBCH 00)	-	-	-	-
	Uniquement sur betterave potagère. Efficacité montrée sur taupin.							
16202101 Carotte* Trt Sol*Mouches	**48 g/10 m²**	**1/an**	BBCH 00	F (BBCH 00)	-	-	-	-
	-							
01108018 Carotte* Trt Sol*Ravageurs du sol	**48 g/10 m²**	**1/an**	BBCH 00	F (BBCH 00)		-	-	-
	Efficacité montrée sur taupin.							
15652103 Pomme de terre* Trt Sol*Ravageurs du sol	**48 g/10 m²**	**1/an**	BBCH 00	F (BBCH 00)	-	-	-	-
	Efficacité montrée sur taupin.							

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anses
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Conditions d'emploi du produit

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
Ne pas rejeter dans l'évier, le caniveau ou tout autre point d'eau les fonds de bidon non utilisés.

Recommandations relatives à l'étiquette du produit

Il est recommandé de faire figurer l'information suivante sur l'étiquette :
- L'efficacité du produit étant limitée contre les ravageurs du sol, préciser les conditions optimales d'utilisation.

Appendix 2 Copy of the product label

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

SUCCESS® SOL

SUCCESS® SOL est un insecticide du sol contre les taupins de la pomme de terre

Autorisation de Mise sur le Marché (A.M.M.) N° XXXXXXX
Nom commercial : SUCCESS® SOL
Détenteur de l'A.M.M. : SBM Développement (160 Route de la Valentine, 13374 Marseille, France)
Type d'action : Insecticide (Traitement du sol)
Emploi autorisé dans les jardins

Granulés (GR) - 1 g/kg (0.1% m/m) de spinosad (CAS N°168316-95-8)

PRODUIT UTILISABLE EN AGRICULTURE BIOLOGIQUE, conformément au Règlement (CE) N° 834/2007

SUCCESS® SOL

H412	**Nocif pour les organismes aquatiques, entraîne des effets néfastes à long terme.**
P101	En cas de consultation d'un médecin, garder à disposition le récipient ou l'étiquette
P102	Tenir hors de portée des enfants
P270	Ne pas manger, boire ou fumer en manipulant le produit
P273	Éviter le rejet dans l'environnement.
P501	Eliminer le contenu/récipient dans une déchetterie ou par un organisme agréé.
EUH401	Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.
SP1	Ne pas polluer l'eau avec le produit ou son emballage.

Fabricant :
SBM Développement
160 Route de la Valentine - CS 70052
13374 Marseille cedex 11 - France

En cas d'urgence, appelez le 15 ou le centre anti-poison.

Fiche de Données de Sécurité disponible sur demande.

N° de lot et date de fabrication : voir emballage
XX kg e

Emploi autorisé dans les jardins.

LIRE L'ÉTIQUETTE AVANT L'EMPLOI. NE PAS UTILISER POUR UN AUTRE USAGE QUE CELUI PRÉCONISÉ. RESPECTER LES BONNES PRATIQUES PHYTOSANITAIRES.

RECOMMANDATIONS D'EMPLOI

IMPORTANT : Lire attentivement les instructions de cette section afin de garantir une utilisation sûre et efficace de ce produit.

MODE D'ACTION

Dans le système nerveux, le spinosad provoque l'excitation en activant les récepteurs de l'acétylcholine des nerfs, menant à des contractions musculaires involontaires, des tremblements puis une paralysie chez les insectes traités. Les insectes cessent de s'alimenter.
A base de spinosad, SUCCESS® SOL agit par contact et par ingestion. Il agit sur un grand nombre d'insectes du sol, en particulier sur les taupins.

Le spinosad appartient au groupe 5 de l'IRAC (Insecticide Action Resistance Committee).

TABLEAU DES USAGES

Culture	Organisme nuisible	Dose d'emploi de SBM 14/001	Nombre maximal de traitements par an	Conditions d'emploi	Délai avant récolte (DAR)
Pomme de terre	Taupins	48 g / 10 m²	1	A la plantation : application dans la raie de plantation	Application à la plantation, le délai avant récolte est couvert par le cycle de la culture
Pomme de terre	Taupins	48 g / 10 m²	1	A la plantation : application dans la raie de plantation	Application à la plantation, le délai avant récolte est couvert par le cycle de la culture
Carotte	Mouche de la carotte	48 g / 10 m²	1	Au semis : application dans la raie de semis	Application au semis, le délai avant récolte est couvert par le cycle de la culture
Betterave Potagère, Raifort, Céleri-rave, Topinambour, Panais, Persil à grosse racine, Radis, Salsifis, Navets	Taupins Mouche de la carotte	48 g / 10 m²	1	Au semis : application dans la raie de semis	Application au semis, le délai avant récolte est couvert par le cycle de la culture

APPLICATION

SUCCESS® SOL se présente sous la forme de granulés prêts à l'emploi et s'applique sans dilution lors de la plantation des pommes de terre, sur toute la hauteur de la raie de plantation ou du trou de plantation.

Veiller à bien répartir les granulés sur toute la hauteur de la raie de plantation ou du trou de plantation afin de créer une barrière de protection autour du tubercule puis de la plantule de pomme de terre. Bien reboucher le trou ou s'assurer de la bonne fermeture du sillon pour que la barrière à insectes soit en place et garantir une bonne protection du sol.

PRÉCONISATIONS D'EMPLOI

Ne pas traiter sur un terrain risquant un entraînement vers un point d'eau : ruisseau, étang, mare, puits… en particulier si le terrain est en pente.
Ne pas traiter en présence d'abeilles.
Attention : ce produit peut porter atteinte à la faune auxiliaire.

STOCKAGE

Toujours conserver le produit dans son emballage d'origine. Le stocker à l'abri du gel et de la chaleur et de la lumière solaire directe.

ÉLIMINATION DU PRODUIT ET DE SON EMBALLAGE

Réemploi de l'emballage interdit. Ne pas jeter dans les poubelles ménagères, mais éliminer l'emballage avec ou sans reliquat de produit en déchetterie ou via un organisme agréé.

PREMIER SECOURS

En cas d'urgence, appelez le 15 ou le centre anti-poison.

En cas d'inhalation :

Transporter la victime à l'air libre et la garder au chaud et au repos. Si la respiration est irrégulière ou arrêtée, pratiquer la respiration artificielle et faire appel à un médecin. Ne rien faire ingérer à la victime.

En cas de contact avec les yeux :

Laver abondamment avec de l'eau douce et propre durant 15 minutes en maintenant les paupières écartées.

En cas de contact avec la peau :

Enlever les vêtements/chaussures imprégnés et laver soigneusement la peau avec de l'eau et du savon ou utiliser un nettoyant connu. Ne pas utiliser de solvants ou de diluants.

En cas d'ingestion :

En cas d'ingestion, si la quantité est peu importante, (pas plus d'une gorgée), rincer la bouche avec de l'eau et consulter un médecin.
Si la quantité est plus importante, appeler un médecin pour juger de la nécessité d'un traitement/suivi en milieu hospitalier. Si nécessaire montrer l'étiquette.

AVERTISSEMENT

Toute reproduction totale ou partielle de cette étiquette est interdite.
Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage. Ils ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. 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.

Appendix 3 Letter of Access

Provided upon request.