

# **REGISTRATION REPORT**

## **Part A**

### **Risk Management**

**Product code: SBM 10/051**

**Product name: SUCCESS GR**

**Chemical active substance(s):**

**spinosad, 4 g/kg**

**Southern Zone**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(major label extension)**

**Applicant: SBM Développement**

**Date: 2019-04-04**

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## PART A

# RISK MANAGEMENT

### 1 Details of the application

The company SBM Développement has requested a marketing authorisation (major label extension) in France for the product SUCCESS GR (formulation code: SBM 10/051), containing 4 g/kg spinosad for use as an insecticide for 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 GR (SBM 10/051) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of SUCCESS GR (SBM 10/051) 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 GR (SBM 10/051).

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

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

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

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

#### 1.1 Application background

The present registration report concerns the evaluation of SBM Développement's application to market SUCCESS GR (SBM 10/051) 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.

The present application (2017-0529) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses (“risk envelope approach”)<sup>1</sup> – 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' assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009<sup>2</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 on the acceptability of risk are based on the criteria provided in Regulation (EU)

<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> 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

No 546/2011<sup>3</sup>, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

## 1.2 Letters of Access

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

## 1.3 Justification for submission of tests and studies

According to the applicant:

« The submission of the dossier SUCCESS GR (SBM 10/051) 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 label extension of SUCCES GR (SBM 10/051), 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 10/051
Product name in MS	SUCCESS GR
Authorisation number	2171089
Low risk (article 47)	No
Function	Insecticide
Applicant	SBM Développement
Active substance(s) (incl. content)	spinosad, 4 g/kg
Formulation type	Granule (GR)
Packaging	Packaging not changed professional user
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

<sup>3</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

## 2.2 Conclusion

The evaluation of the application for SUCCESS GR (SBM 10/051) resulted in the decision to grant the authorization.

## 2.3 Substances of concern for national monitoring

Refer to 5.1.1.

## 2.4 Classification and labelling

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

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

Hazard class(es), categories:	Hazardous to the aquatic environment — Chronic Hazard, Category 2
Hazard pictograms:	 SGH09
Signal word:	Warning
Hazard statement(s):	H411 : Toxic to aquatic life with long lasting effects.
Precautionary statement(s):	<i>For the P phrases, refer to the extant legislation</i>
Additional labelling phrases:	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

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).
	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 4th May 2017<sup>4</sup> provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres;
- 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<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 “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation<sup>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.

### 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	
SPe 3	To protect aquatic organisms, respect a 5-metre planted buffer strip to surface water bodies for uses on potatoes.
Spe 6	To protect bird and wild mammals remove spillage.
Other specific restrictions	

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

<http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo>

<sup>6</sup> SANCO document “guidance document:- Guidelines on comparability, <http://www.legifrance.gouv.fr/en/affiche/2014/3/26/ACR01401053V0>

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

Re-entry period	Not applicable
Label recommandations	<p>The level of efficacy is partial and variable, precise optimal conditions of uses.</p> <p>The label must reflect the conditions of authorisation..</p>

### **2.5.2            Specific restrictions linked to the intended uses**

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

None.

## 2.6 Intended uses (only NATIONAL GAP)

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

When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.

Use should be crossed out when the applicant no longer supports this use.

GAP rev., date: 2019-04-04

PPP (product name/code): SBM10/051 / SUCCESS GR

Formulation type: GR <sup>(a, b)</sup>

Active substance 1: spinosad

Conc. of as 1: 4 g/kg <sup>(c)</sup>

Applicant: SBM Développement

Professional use:

Zone(s): southern <sup>(d)</sup>

Non professional use:

Verified by MS: Yes

Field of use: insecticide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	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: zRMS conclusion  e.g. g safener/synergist per ha <sup>(f)</sup>
					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		
<b>Zonal uses (field or outdoor uses, certain types of protected crops)</b>													
1	FR	Potatoes	F	Wireworms ( <i>Agriotes spp.</i> )	Application in furrow. Granules buried into the planting furrow.	At planting (BBCH 00)	1	-	12	48	Not appli- cable	F	Acceptable (but with a partial efficacy)

<b>Remarks table heading:</b>	(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.
<b>Remarks columns:</b>	1 Numeration necessary to allow references 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) 4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application 5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named. 6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application 8 The maximum number of application possible under practical conditions of use must be provided. 9 Minimum interval (in days) between applications of the same product 10 For specific uses other specifications might be possible, e.g.: g/m <sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products. 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha). 12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind". 13 PHI - minimum pre-harvest interval 14 Remarks may include: Extent of use/economic importance/restrictions

### 3 Background of authorisation decision and risk management

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

The physico-chemical properties of the formulation have been evaluated and considered acceptable at the registration of this formulation. The intended concentrations requested for the extension use (preparation ready to used) are covered by the concentrations authorised at the registration of this formulation.

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

Considering the data submitted:

- The efficacy level of SUCCESS GR (SBM 10/051) is considered as limited for the control of wireworms in potato crops. However, this level of efficacy is considered acceptable in a context of limited availability of products or alternative methods on this use;
- The phytotoxicity level of SUCCESS GR (SBM 10/051) is considered negligible for the requested use;
- The risks of negative impact on yield, quality, propagation, succeeding crops and adjacent crops are considered negligible;
- For wireworms, the risk of resistance developing or appearing to spinosad does not require a monitoring for the requested use.

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

The analytical methods for the determination of the active substance residues in matrices (plants) with high water content submitted at European level and in the dossier of the preparation meet the regulatory requirements.

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

Endpoints used in risk assessment:

Active Substance: spinosad			
ADI	0.024 mg/kg bw/d	EU (2007)	
ARfD	Not pertinent		
AOEL	0.024 mg/kg bw/d (short term)*		
Dermal absorption	Default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (used in formulation) 4 g/kg	Spray dilution (used in formulation)
	<b>Dermal absorption endpoints %</b>	<b>50**</b>	-

\* The short term AOEL is used by EFSA AOEM for the operator exposure assessment (value based on a 90-day dog study using a safety factor of 100 and a correction factor for oral absorption (50%). In the review report on spinosad

(SANCO/1428/2001-rev. final 2006), a long-term AOEL of 0.012 mg/kg bw/d have been also proposed based the 24-month rat study with 50% correction for oral absorption but the short-term AOEL is more appropriate for the RA of operators.

\*\* The composition of the reference preparation is too different from the SBM 410/051 preparation. Consequently, reference is made 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  $\leq$  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 (mix/loading and application phases).**

### 3.4.1 Acute toxicity

SUCCESS GR (SBM 10/051) containing 4 g/kg spinosad has a low acute oral, inhalational and dermal toxicity. It is not irritating to the rabbit skin or eye and is not a skin sensitisier.

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 <sup>7</sup>	Equipment	Application rate kg product/ha (g as/ha)	Spray dilution (L/ha)	Model
Potatoes	F	Microgranular applicator	12 kg product/ha (48 g spinosad/ha)	-	EFSA AOEM

Considering the proposed use, operator systemic exposure was estimated using the EFSA AOEM model.

Crop	Equipment	PPE and/or working coverall	% AOEL Spinosad (0.024 mg/kg bw/d)	
Potatoes	Microgranular applicator	Working coverall and gloves during mix- ing/loading and application	5.6	

According to the model calculations, it may be concluded that the risk for the operator using SUCCESS GR (SBM 10/051) is acceptable with a working coverall (90% protection factor) and gloves during mixing/loading and application.

<sup>7</sup> Open field or glasshouse

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

### 3.4.3 Worker exposure

SUCCESS GR (SBM 10/051) is applied in the sowing row; no work is expected to be practiced after application. Therefore, worker exposure estimation is considered not relevant.

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

### 3.4.4 Bystander and resident exposure

SUCCESS GR (SBM 10/051) is applied in the sowing row; no drift is expected. Therefore, bystander exposure estimation is considered not relevant.

SUCCESS GR (SBM 10/051) is applied in the sowing row; no drift is expected. Therefore, resident exposure estimation is considered not relevant.

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

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

The chronic and the short-term intakes of spinosad residues resulting from the requested use 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.

### Summary for SUCCESS GR (SBM 10/051):

Crop	PHI for SUCCESS GR (SBM 10/051) proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for SUCCESS GR (SBM 10/051) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Spinosad		
Potatoes	Not applicable	Yes	F**	-

\* 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).

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 of spinosad 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 derived for the active substance and its metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PECgw for spinosad and its metabolites do not occur at levels exceeding those mentioned in regulation (EC) No 1107/2009 and guidance document SANCO 221/2000<sup>8</sup>. 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.

### **3.7 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-organisms and micro-organisms and terrestrial plants are acceptable for the intended use.

### **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 of substitution, therefore a comparative assessment is not foreseen.

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

<sup>8</sup> Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev10-final, 25 February 2003.

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



### Décision relative à une demande d'extension d'usage 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 du produit phytopharmaceutique **SUCCESS GR***

*de la société* **SBM DEVELOPPEMENT**  
*enregistrée sous le* n°2017-0529

*Vu les conclusions de l'évaluation de l'Anses du 12 mars 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

Noms du produit	SUCCESS GR MUSDO GR
Type de produit	Produit de référence
Titulaire	SBM DEVELOPPEMENT 60 chemin des Mouilles 69130 Ecully France
Formulation	Granulé (GR)
Contenant	4 g/kg - spinosad
Numéro d'intrant	815-2015.01
Numéro d'AMM	2171089
Fonction	Insecticide
Gamme d'usage	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,

04 AVR. 2019

**Françoise WEBER**  
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
15652103 Pomme de terre*Tit Soi'Ravageurs du sol	12 kg/ha	1/an	BBCH 00	<sup>F</sup> (BBCH 00)	5 (dont DVP 5)	-	-	-

DVP : Dispositif Végétalisé Permanent.



## Conditions d'emploi du produit

### **Protection de l'opérateur et du travailleur**

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

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

### ***Pour l'opérateur, porter***

Dans le cadre d'une application effectuée à l'aide d'un microgranulateur mécanisé

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

- Gants certifiés EN 374-3 ;
- Combinaison de travail polyester / coton 65 % / 35 % (combinaison ou ensemble veste + pantalon) ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;

#### **• pendant l'épandage**

- Gants certifiés EN 374-2 à usage unique en cas d'intervention sur semoir, épandeur à engrains ou microgranulateur ;
- Combinaison de travail polyester / coton 65 % / 35 % (combinaison ou ensemble veste + pantalon) ;

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

- Gants certifiés EN 374-3 ;
- Combinaison de travail polyester / coton 65 % / 35 % (combinaison ou ensemble veste + pantalon) ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée.

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

- Non applicable.

### **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 la faune**

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau comportant un dispositif végétalisé permanent non traité d'une largeur de 5 mètres en bordure des points d'eau pour l'usage sur pomme de terre.

- SPe 6 : Pour protéger les oiseaux et les mammifères sauvages, récupérer tout produit accidentellement répandu.

### **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 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.

### Copy of the product label

## SUCCESS® GR

### Insecticide du sol pour maïs, maïs doux et pomme de terre.

Autorisation de Mise sur le Marché (A.M.M.) N° XXXXXXXX

Détenteur de l'A.M.M. : SBM Développement (160 Route de la Valentine, 13374 Marseille, France)

Granulés (GR)

4 g/kg (0.4% m/m) de ~~spinosad~~ (CAS N°168316-95-8)

PRODUIT UTILISABLE EN AGRICULTURE BIOLOGIQUE

#### SUCCESS® GR



H411 Toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.

P273 Éviter le rejet dans l'environnement.

P280 Porter des gants de protection et des vêtements de protection.

P391 Recueillir le produit répandu.

P501 Éliminer le contenu/récipient dans un centre de collecte de déchets agréé conformément à la réglementation locale/régionale/nationale et/ou internationale.

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. 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.

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 puis signalez vos symptômes au réseau Phyt'attitude, N° vert 0 800 887 887 (appel gratuit depuis un poste fixe).

Fiche de Données de Sécurité disponible sur demande pour les professionnels.

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

Réserve à un usage exclusivement professionnel

**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® GR agit par contact et par ingestion. Il agit sur un grand nombre d'insectes du sol, en particulier sur les taupins.

#### RÉSISTANCE

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

Il existe un risque général d'apparition d'insectes résistants aux insecticides. Afin de limiter ce risque, il convient de respecter les conditions d'emploi de cette étiquette et, à chaque fois que c'est possible, de varier les substances chimiques et d'alterner avec des produits à mode d'action différent, tant au cours d'une saison culturelle que dans la rotation.

#### TABLEAU DES USAGES

Culture	Organisme nuisible	Dose d'emploi de SUCCESS® GR	Nombre maximal de traitements par an	Conditions d'emploi	Délai avant récolte (DAR)
Mais Mais doux	Larves de taupins	12 kg/ha	1	Au semis : application dans la raie de semis	- *
Pomme de Terre	Larves de taupins	12 kg/ha	1	Au semis : application dans la raie de plantation	- *

\* Non pertinent : usage au semis ou à la plantation, cela est couvert par le cycle de la culture

Délai de rentrée : non pertinent

#### LIMITES MAXIMALES DE RÉSIDUS

Les LMR sont consultables à l'adresse suivante : <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/>

#### APPLICATION

SUCCESS® GR se présente sous la forme de granulés prêts à l'emploi et s'applique sans dilution lors du semis du maïs ou de plantation de pomme de terre, sur toute la hauteur de la raie de semis ou plantation. L'application est réalisée à l'aide d'un **microgranulateur** et d'un diffuseur de type QDC DXP® visant à répartir les granulés sur tout le profil de semis afin de créer une barrière de protection autour de la semence puis de la plantule ou du tubercule. Régler soigneusement le débit de chaque élément de l'appareil de distribution, avant le début du traitement et vérifier la régularité de l'épandage pendant le travail. Nous vous recommandons de semer à une vitesse inférieure ou égale à 6 km/heure.

SUCCESS® GR est un insecticide du sol agissant essentiellement par contact, sans diffusion ni mobilité dans le sol. Pour assurer la bonne répartition des granulés autour de la graine sur tout le profil de semis, l'utilisation du diffuseur QDC DXP® doit être impérativement associée à une préparation de sol fine.

## PRÉCONISATIONS D'EMPLOI

### Avant l'application

- Stocker les produits dans un local phytosanitaire conforme et fermé à clé
- Bien lire l'étiquette et les précautions avant l'utilisation

### Pendant l'application

- Ne pas contaminer les cours d'eau et fossés en eau

## ENTRETIEN DU MATERIEL

Après chaque journée de traitement avec SUCCESS® GR, rincer soigneusement le matériel à l'eau claire additionnée d'un mouillant (recommandé pour le nettoyage des pulvérisateurs), et conformément à la législation en vigueur.

## ÉLIMINATION DU PRODUIT ET DE SON EMBALLAGE

Ne pas **ré-utiliser** l'emballage. Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux. Éliminer les emballages vides *via* une collecte organisée par un service de collecte spécifique.

## PREMIER SECOURS

### 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.

En cas d'ingestion accidentelle, appeler un médecin pour juger de la nécessité d'un traitement/suivi en milieu hospitalier. Si nécessaire montrer l'étiquette.

**Important :** Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduire sur ces bases la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous les facteurs particuliers concernant votre exploitation tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces... Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine, ainsi que leur conformité à l'autorisation de vente du Ministère de l'Agriculture. Compte tenu de la diversité des législations existantes, il est recommandé dans le cas où les denrées issues des cultures protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur.

### **Appendix 3 Letter of Access**

Provided upon request.