REGISTRATION REPORT

Part A

Risk Management

Product code: SBM 10/051

Product name: SUCCESS GR

Active Substance(s):

spinosad, 4 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: **SBM DEVELOPPEMENT**

Date: **5 décembre 2017**

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PART A – Risk Management

The company SBM DEVELOPPEMENT has requested marketing authorisation in France for the product SUCCESS GR (formulation code: SBM 10/051), containing 4 g/kg spinosad 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 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(s) 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 French Decision.

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

Appendix 3 of this document is a copy of the letter(s) of Access.

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of SBM DEVELOPPEMENT'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 first authorisation of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Spinosad

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 spinosad, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 July 2006 shall be taken into account. In this overall assessment Member States — must pay particular attention to the protection of aquatic organisms; — must pay particular attention to the risk to earthworms when the substance is used in glasshouses. Conditions of use shall include risk mitigation measures, where appropriate.
There is no definitive EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance. A Review Report is available (SANCO/1428/2001 rev. final, 14 July 2006).

1.3 Regulatory approach

The present application (2015-6177) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[1] – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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 [2] 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[3], 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[4], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

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 "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[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.

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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 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

3 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

4 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

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

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of SUCCESS GR (SBM 10/051), 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

The applicant has provided the supporting data in Document K; the ownership of the data is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7. A copy of the letter(s) of access is reproduced in Part A, Appendix 3.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	SUCCESS GR (SBM 10/051)
Authorisation number	2171089
Function	insecticide
Applicant	SBM DEVELOPPEMENT
Composition	4 g/kg spinosad
Formulation type (code)	granule (GR)
Packaging	Kraft/polyethylene multilayer bag (5 kg, 10 kg, 12 kg, 25 kg)

2.2 Classification and labelling

2.2.1 Classification and labelling in accordance with Regulation (EC) No1272/2008

Physical hazards	-	
Health hazards	-	
Environmental hazards	Hazardous to the aquatic environment — Chronic Hazard, Category 2	
Hazard pictograms		
Signal word	-	
Hazard statements	H411	H411 Toxic to aquatic life with long lasting effects.[1]
Precautionary statements –	***For the P phrases, refer to the extant legislation***	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	-	-

[1] By calculation in agreement with 1272/2008 regulation and 286/2011.

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 an untreated area of 20 meters in relation to water points including an untreated permanent vegetated strip of 20 meters to surface water bodies.
SPe 6	To protect bird and wild mammals remove spillage.

2.2.3 Other phrases linked to the preparation

Wear suitable personal protective equipment[7]: refer to the Decision in Appendix 1 for the details		
Re-entry period[8]: Not applicable		
Pre-harvest interval[9]:	Maize	F - At sowing
	Sweet corn	F - At sowing
Other mitigation measures: -		
The label may include the following recommendations: - It should be mentioned on the label that the level of efficacy is partial, then, optimal conditions of uses should be precised. The label must reflect the conditions of authorisation.		

[7] If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

[8] The legal basis for this is **Titre I Article 3** of the French Order of 4th 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]

[9] According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

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.
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. 2, date: 2017-december-05

PPP (product name/code) **SUCCESS GR / SBM 10/051**
active substance 1 **spinosad**
Applicant: **SBM DEVELOPPEMENT**
Zone(s): **southern**
Verified by MS: **yes**

Formulation type: **GR**
Conc. of as 1: **4 g/kg**
professional use ☒
non professional use ☐

Crop and/ or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg product/ha min max	kg as/ha min max	water L/ha min max		
Maize* : millet, moha, miscanthus and sorghum	FR	SBM 10/051	F	Wireworms *(Agriotes spp.)*	GR	4 g/kg	Application in furrow. Granules buried into the seed bed	BBCH 00 (At Sowing)	1	-	12	0.048	Not applicable, product applied as a dry granule	F	**Acceptable** (but with a partial efficacy)
Sweet corn	FR	SBM 10/051	F	Wireworms *(Agriotes spp.)*	GR	4 g/kg	Application in furrow. Granules buried into the seed bed	BBCH 00 (At Sowing)	1	-	12	0.048	Not applicable, product applied as a dry granule	F	**Acceptable** (but with a partial efficacy)

* According to the French catalogue of uses, the use "maize" also includes the following minor crops: millet, moha, miscanthus and sorghum.

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 suckling 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

SUCCESS GR (SBM 10/051) is a granule (GR). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is white/beige micro-granules. The formulation is not explosive and has no oxidising properties. It is not flammable and has no self-ignition temperature up to 400°C. In aqueous solution (1% dilution), it has a pH value of 7.39 at 21.1 °C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in paper bag.

The formulation's technical characteristics are acceptable for a GR formulation and it is not classified for the physico-chemical aspect.

3.1.2 Methods of analysis

3.1.2.1 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 analytical method is required.

3.1.2.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report (DAR) and in this dossier and are validated for the determination of residues of spinosad in plants (high water content matrices and dry commodities), soil, water (surface and drinking) and air. **To update the dossier, the ratio of isomer in batch SBM13/040, before and after storage, is required in post-authorization**.

The active substance is neither toxic nor very toxic, hence no analytical method is required for the determination of residues in biological fluids and tissues.

3.1.3 Mammalian Toxicology

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="4">EU (2007)</td></tr>
<tr><td>ARfD</td><td colspan="2">Not pertinent</td></tr>
<tr><td>AOEL short-term*</td><td colspan="2">0.024 mg/kg bw/d</td></tr>
<tr><td></td><td colspan="2"></td></tr>
<tr><td rowspan="3">Dermal absorption</td><td colspan="3">Default value according to guidance on dermal absorption (Efsa 2012):</td></tr>
<tr><td></td><td>Concentrate
(used in formulation)
4 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 have been 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.

The composition of the reference preparation is too different from the SUCCESS GR (SBM 10/051) 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 ≤ 5 % active substance.

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

3.1.3.1 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 sensitiser.

The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.2.2.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G[10]	Equipment	Application rate kg/L product/ha (g as/ha)	Spray dilution (L/ha)	Model
Maize	F	Microgranular applicator	12 kg product/ha (48 g spinosad/ha)	-	PHED

Considering the proposed uses, operator systemic exposure was estimated using the PHED model:

Crop	Equipment	PPE and/or working coverall	% AOEL spinosad
Maize	Microgranular applicator	Working coverall and gloves during mixing/loading and application	5.5

According to the model calculations, it can 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.

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

3.1.3.3 Bystander Exposure

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

3.1.3.4 Resident Exposure

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

[10] Open field or glasshouse

3.1.3.5 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.

3.1.4 Residues and Consumer Exposure

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 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, zRMS (France) agrees with the authorisation of the intended uses on sweet corn and maize.

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

Storage stability data for dry commodities are required in post-authorization.

Summary of the evaluation

The preparation SUCCESS GR (SBM 10/051) contains spinosad.

Summary for spinosad

Table 1: Summary for spinosad

Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg (EU) No 2015/603	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
Sweet corn	Yes	Yes	Yes	Yes	Yes	No	NR	/
Maize	Yes	Yes	Yes	Yes	Yes		NR	Post-authorisation data: storage stability data for dry commodities

NR: Not Relevant

As residues of spinosad do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Summary for SUCCESS GR (SBM 10/051)

Table 2: Information on 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		
Sweet corn	F**	Yes	F**	/
Maize	F**	Yes	F**	/

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).

Waiting periods before planting succeeding crops are not relevant.

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 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 [11]. 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.

3.1.6 Ecotoxicology

3.1.6.1 Effects on Terrestrial Vertebrates

Use of SUCCESS GR (SBM 10/051) on the range of supported crops is not expected to pose an acute or a reproductive risk to avian and mammalian species.

3.1.6.2 Effects on Aquatic Species

The TER values for the active substance and metabolites spinosyn B and N-demethylated spinosyn D are greater than the trigger of 10, indicating that application of SUCCESS GR (SBM 10/051) according to the proposed label uses poses acceptable long-term risk to aquatic invertebrates **with the respect of a 20 meters vegetated buffer**.

3.1.6.3 Effects on Bees and Other Arthropod Species

[11] 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.

As the product SUCCESS GR (SBM 10/051) is a soil granular insecticide applied at sowing in the furrow and since the active substance is not systemic, only soil dwelling non-target arthropods can be exposed to this product. As recommended by Guidance Document SANCO 10329/2002, studies were conducted with the product SUCCESS GR (SBM 10/051) on *Hypoaspis aculeifer* and *Folsomia candida* that are considered as representative for the non-target arthropods for such a use.

The TER_{LT} for both species were above the trigger of 5 indicating an acceptable chronic risk for these species. Consequently, the risk of SUCCESS GR (SBM 10/051) is considered as acceptable for non-target arthropods when it is applied according to Good Agricultural Practice.

3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms

All the acute and long-term TER values are higher than the acute trigger values of 10 and 5, respectively, indicating that SUCCESS GR (SBM 10/051) poses acceptable acute and chronic risk to earthworms when applied according to the proposed use rate.

3.1.6.6 Effects on Soil Non-target Micro-organisms

The effects of SUCCESS GR (SBM 10/051) on nitrogen turnover and carbon respiration of soil micro-organisms do not show deviation lower or higher than 25 % to control. Moreover, the NOEC of 3.582 mg/kg and 1.928 mg/kg for spinosyn B and N-demethylated spinosyn D, respectively, are approximately 15 and 37 times higher than the maximum PEC_S of 0.232 mg/kg and 0.0516 mg/kg, respectively. Consequently, the risk of SUCCESS GR (SBM 10/051) to micro-organisms is acceptable when the product is applied according to the Good Agricultural Practice.

3.1.6.7 Effects on Non-target Terrestrial Plants

Considering the requested use and application, the exposure of non-target plants to the product SUCCESS GR (SBM 10/051) is negligible; no risk assessment is performed. The risk is expected to be acceptable following applications of SUCCESS GR (SBM 10/051) according to the Good Agricultural Practice.

3.1.7 Efficacy

Considering the data submitted:

- The efficacy level of SUCCESS GR (SBM 10/051) is considered as variable and partial (around 30-35% of efficacy in average) for the control of wireworms in maize (and related minor crops[12]) and sweet maize 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 to be negligible for the claimed uses.
- The risks of negative impact on yield, quality, propagation, succeeding crops and adjacent crops are considered to be negligible.
- For wireworms, the risk of resistance development or appearance to spinosad does not require any monitoring for the claimed use.

[12] According to the French catalogue of uses, the use « maize » also includes the following minor crops: millet, moha, miscanthus, sorghum.

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.

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

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

- The ratio of isomer in batch SBM13/040, before and after storage.
- Residues stability data in dry commodities.

3.4.3 Label amendments

The draft label proposed by the applicant in appendix 2 may 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

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agence nationale de sécurité sanitaire alimentation, environnement, travail

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 la demande associée du produit phytopharmaceutique ***SUCCESS GR***

de la société *SBM DEVELOPPEMENT*

enregistrées sous les *n°2015-6177 et 2015-6235*

Vu les conclusions de l'évaluation de l'Anses du 24 octobre 2017,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France 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 GR
AMM n°2171089

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Informations générales sur le produit	
Noms du produit	SUCCESS GR MUSDO GR
Type de produit	Produit de référence
Titulaire	SBM DEVELOPPEMENT 160, route de la Valentine CS 70052 13374 MARSEILLE Cedex 11 FRANCE
Formulation	Granulé (GR)
Contenant	4 g/kg - spinosad
Numéro d'intrant	815-2015.01
Numéro d'AMM	2171089
Fonction	Insecticide
Gamme d'usages	Professionnel

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 30 avril 2019.

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

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

A Maisons-Alfort, le 05 DEC. 2017

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)

SUCCESS GR
AMM n°2171089

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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**
Sacs multicouches en papier / polyéthylène	5 kg ; 10 kg ; 12 kg ; 25 kg

Classification du produit		
La classification retenue est la suivante :		
Catégorie de danger		**Mention de danger**
Dangers pour le milieu aquatique - Danger chronique, catégorie 2		H411 : Toxique pour les organismes aquatiques, entraîne des effets 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.**		

SUCCESS GR
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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
16662105 Maïs doux*Trt Sol*Ravageurs du sol	**12 kg/ha**	**1/an**	BBCH 00 Au semis	F (BBCH 00)	20 (dont DVP 20)	-	-	-
	Efficacité montrée sur taupins. Application dans la raie de semis.							
15552102 Maïs*Trt Sol*Ravageurs du sol	**12 kg/ha**	**1/an**	BBCH 00 Au semis	F (BBCH 00)	20 (dont DVP 20)	-	-	-
	Efficacité montrée sur taupins. Application dans la raie de semis.							

DVP : Dispositif Végétalisé Permanent.

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

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- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 20 mètres par rapport aux points d'eau comportant un dispositif végétalisé permanent non traité d'une largeur de 20 mètres en bordure des points d'eau.

Exigences complémentaires post-autorisation

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

Détail de la demande post autorisation	Délai (mois)	Récurrence (mois)
Fournir les résultats de l'étude en cours de réalisation, concernant la stabilité au stockage pendant 8 mois sur matrice sèche.	24	-
Fournir le ratio d'isomères avant et après stockage dans le lot SBM13/040, utilisé dans les études de stabilité.	24	-

Recommandations relatives à l'étiquette du produit

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

SUCCESS® GR

SUCCESS® GR est un insecticide du sol pour le maïs et le maïs doux.

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

Réservé 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 culturale 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)
Maïs Maïs doux	Larves de taupins	12 kg/ha	1	Au semis : application dans la raie de semis	- *

*** Non pertinent : usage au semis, 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, sur toute la hauteur de la raie de semis.
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.
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 MATÉRIEL

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(s) of Access

Dow AgroSciences

Dow AgroSciences S.A.S
6, Rue Jean-Pierre Timbaud – 78067 St Quentin en Yvelines – France – Tél. : 33 (0)1 30 23 13 13 – Fax : 33 (0)1 30 23 13 14

Anses-DEPR-SCUD
ACI-COP-4-030
14 Rue Pierre et Marie Curie
94701 Maisons-Alfort Cedex

Montigny le Bretonneux, 14 October 2016

Letter of Access

On behalf of Dow AgroSciences, I confirm that we supply the active substance spinosad to SBM Développement, 160 Route de la Valentine – C.S. 70052 - 13374 MARSEILLE Cedex 11, for incorporation into the soil insecticide plant protection product (PPP) <<SUCCESS GR>> which is the subject of a request for authorisation (registration) from SBM Développement (dossier n° 2015-6177).

Dow AgroSciences agrees that the data on the active substance spinosad, submitted by Dow AgroSciences for its inclusion in Annex I to the Directive 91/414/EEC, may be used by the authority ANSES in order to support the registration application for the placing on the market of the granular soil insecticide product: << SUCCESS GR >> Containing 4 g/kg Spinosad, received from the applicant SBM Développement, subject to the condition that the active substance spinosad contained in the product << SUCCESS GR >> is supplied solely by Dow AgroSciences.

On behalf of Dow AgroSciences, I also confirm that SBM Développement has data access rights to the following studies:

Dow AgroSciences

This Letter of Access shall not be construed as authorisation to consider said Dow AgroSciences data, directly or indirectly, in support of any other application submitted by SBM Développement, its affiliated companies, representatives, agents or customers, without limitation, for new or amended registrations for any formulations based on spinosad. This letter does not permit release of this data and/or information to the applicant.

This Letter of Access is only applicable to Dow AgroSciences data; any other data required in support of their products will be supplied by SBM Développement, its affiliated companies, representatives, agents or customers.

For, and on behalf of, Dow AgroSciences

Nora O' CARROLL
Country Registration Specialist

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