

REGISTRATION REPORT

Part A

Risk Management

Product code: PM13-151

Product name(s): SUNBO PRO

Chemical active substance(s):

Ferric phosphate, 24.2 g/kg

Interzonal

And Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: De Sangosse SAS

Date: 27/03/2024

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PART A

RISK MANAGEMENT

1 Details of the application

The company De Sangosse SAS has requested a marketing authorisation in France for the product SUNBO PRO (product code: PM13-151), containing 24.2 g/kg ferric phosphate anhydrous¹ as a molluscicide for professional uses.

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

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

1.1 Application background

The present registration report concerns the evaluation of De Sangosse SAS's application submitted on 24/10/2022 to market SUNBO PRO (PM13-151) in France (product uses described under point 2.3). France acted as a interzonal and zonal Rapporteur Member State for this request and assessed the application submitted for the first authorisation of this product in France and in other Member States (MSs) of the European Union.

Ferric phosphate is a low risk active substance, therefore SUNBO PRO (PM13-151) shall be authorised as a low risk plant protection product where compliant with Article 47 of Regulation (EC) no 1107/2009.

The present application (2022-2763) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009², the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone for field uses and for all MSs of the European Union for uses under protection, taking into account the worst-case uses ("risk envelope approach")³. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of SUNBO PRO (PM13-151) has been made using endpoints agreed in the EU peer review of ferric phosphate. It also includes assessment of data and information related to SUNBO PRO (PM13-151) where those data have not been considered in the EU peer review process.

This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail. The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

¹ COMMISSION IMPLEMENTING REGULATION (EU) 2015/1166 of 15 July 2015 renewing the approval of the active substance ferric phosphate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

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

³ 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](#)

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The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011⁴, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

This document also describes the specific conditions of use and labelling required for France for the registration of SUNBO PRO (PM13-151).

1.2 Letters of Access

Not necessary: the applicant has provided equivalent studies to those essential for approval/renewal of the active substance ferric phosphate via a data matching table (DMT).

1.3 Justification for submission of tests and studies

According to the applicant: “Not required.”

1.4 Data protection claims

2 Where protection for data is being claimed for information supporting registration of LUCIO PRO (PM13-150), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7. » ou par « There is no new data submitted with this application
Details of the authorisation decision

2.1 Product identity

Product code	PM13-151
Product name in MS	SUNBO PRO
Authorisation number	2240107
Kind of use	Professional use
Low risk product (article 47)	Yes SUNBO PRO is compliant with Article 47 of Regulation (EC) no 1107/2009.
Function	Molluscicide
Applicant	De Sangosse SAS
Active substance(s) (incl. content)	Ferric phosphate; 24.2 g/kg
Formulation type	Granular Bait [GB]
Packaging	Bag in paper (5 kg, 10 kg, 12 kg, 15 kg, 16 kg, 18 kg, 20 kg, 25 kg) Big Bags in PP ⁵ (200 kg, 300 kg, 400 kg, 500 kg, 1000 kg)

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 PP : polypropylen

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Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion DAMM

The evaluation of the application for SUNBO PRO (PM13-151) 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:	Not classified
Hazard pictograms:	None
Signal word:	None
Hazard statement(s):	None
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation</i>
Additional labelling phrases:	None

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 4 May 2017⁶ provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres for products applied through spraying or dusting;
- unless otherwise stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, non-spraying buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

Finally, the French Order of 12 April 2021⁷ provides that:

- an authorisation granted for a “reference” crop applies also for “related” crops, unless formally stated in the Decision
- the “reference” and “related” crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁸ is to supply “minor” crops with registered plant protection products.

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

Finally, the French Order of 20 November 2021⁹ on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless otherwise stated in the product authorisation, use on attractive crop⁹ when in flower and on foraging area is forbidden. Specific conditions of application on flowering crops should be respected. As consequences specific SPe 8 may include reference to this order

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

2.5.1 Restrictions linked to the PPP

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

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	

⁶ Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRGI632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

⁷ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

⁸ SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

⁹ Arrêté du 20 novembre 2021 relatif à la protection des abeilles et des autres insectes pollinisateurs et à la préservation des services de pollinisation lors de l'utilisation des produits phytopharmaceutiques - Légifrance (legifrance.gouv.fr)

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-	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.
Storage	The formulation should be stored in a dry place.
Risk mitigation measures	-
Risk mitigation measures	-
Agricultural recommendations	-

2.5.2 Specific restrictions linked to the intended uses

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

None.

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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 12 April 2021 (highlighted in green), evaluated and concluded as safe uses by France as izRMS. 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. 1, date: 2024-03-27

PPP (product name/code): SUNBO PRO / PM13-151
Active substance 1: Ferric phosphate anhydrous
Safener: -
Synergist: -
Applicant: De Sangosse SAS
Zone(s): Zonal and Interzonal ^(d)
Verified by MS: Yes
Field of use: Molluscicide

Formulation type: GB ^(a, b)
Conc. of a.s. 1: 24.2 g/kg ^(c)
Conc. of safener: - ^(c)
Conc. of synergist: - ^(c)
Professional use:
Non-professional use:

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop or situation (crop destination/purpose of crop)	F, Fn, 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) RMS CONCLUSION
					Method/Ki nd	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/ma x		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	All situations, crop and non-crop	F	Slugs and snails	Spreading Broadcast	At any time	a) 1 b) 4	5	a) 7 b) 28	a) 169.4 b) 677.6	n/a	1	Acceptable also permitted under shelter
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop 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) RMS CONCLUSION
					Method/Ki nd	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/ma x		
1	FR	All situations, crop and non-crop	G	Slugs and snails	Spreading Broadcast	At any time	a) 1 b) 4	5	a) 7 b) 28	a) 169.4 b) 677.6	n/a	1	Acceptable also permitted under shelter

Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(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	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m 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).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
		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)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a homogeneous orange cylindrical pellet. It is not explosive and has no oxidising properties. In 1% aqueous solution, it has a pH value around 5 at ambient temperature (20°C). The stability data indicate a shelf life of at least 2 years at ambient temperature in paper packaging (extrapolable to PP packaging). Its technical characteristics are acceptable for a ready to use bait formulation.

3.2 Efficacy (Part B, Section 3)

Considering the data submitted :

- The efficacy level of SUNBO PRO (PM13-151) is considered as satisfactory for the claimed use.
- The phytotoxicity level of SUNBO PRO (PM13-151) is considered as negligible for the claimed use.
- The risks of negative impact on yield, quality, transformation processes, propagation, succeeding crops, adjacent crops are considered as negligible.
- The risk of resistance development to ferric phosphate does not require a monitoring for the claimed use.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical methods for the determination of the active substance ferric phosphate in the formulation are available and validated.

Analytical methods for the determination of relevant impurities (lead, cadmium and mercury) of ferric phosphate in the formulation are available and validated.

3.3.2 Analytical methods for residues

Ferric phosphate as active substance on Annex IV of EC Regulation no 396/2005 is exempt from MRL setting.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

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Agreed EU endpoints	
Active substance	Ferric phosphate 24.2 g/kg (equivalent to 8.96 g iron/kg)
AOEL systemic	0.4 mg/kg de pc/jour (iron)
AAOEL	-
Oral absorption	50%
Vapour pressure	Non-volatile
Reference	SANTE/10385/2015 Rev 1 EFSA Journal 2015;13(1):3973
Dermal absorption	10%

3.4.1 Acute toxicity

SUNBO PRO (PM13-151) containing 24.2 g/kg ferric phosphate (anhydrous) has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is not a skin sensitiser.

3.4.2 Operator exposure

Considering proposed uses, operator systemic exposure was estimated using the EFSA model¹⁰:

Model data		Ferric phosphate
	Level of PPE	% AOEL
Application : Broadcast application or in furrow applications of granules		
Outdoor		
Application rate: 7 kg SUNBO PRO (PM13-151) /ha		0.0627 kg iron / ha
Granule application EFSA Model (PEHD; 75th percentile) Body weight: 60 kg	Working coverall and gloves during mix/loading and application	0.32
Application : Manual application of granules		
Outdoor		
Application rate: 7 kg SUNBO PRO (PM13-151) /ha		0.0627 kg iron / ha
Granule application EFSA Model (PEHD; 75th percentile) Body weight: 60 kg	Working coverall and gloves during mix/loading and application	2.67
Application : Manual application of granules		
Indoor		
Application rate: 7 kg SUNBO PRO (PM13-151) /ha		0.0627 kg iron / ha
Granule application EFSA Model (PEHD; 75th percentile) Body weight: 60 kg	Working coverall and gloves during mix/loading and application	2.67

¹⁰ AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014;12 (10):3874)

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According to the model calculations, it can be concluded that the risk for the operator using SUNBO PRO (PM13-151) is acceptable with a working coverall and gloves during mixing/loading and application.

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

3.4.3 Worker exposure

Considering that the product is a granular bait formulation the worker exposure evaluation is not relevant.

3.4.4 Bystander exposure

SUNBO PRO (PM13-151) is a granular bait formulation; no drift is expected. Therefore, bystander exposure estimation is considered not relevant.

3.4.5 Resident exposure

According to the intended uses (ready-to-use bait pellet applied on bare soil), no spray drift, no fall out are expected. Therefore, the resident exposure assessment is not relevant

3.4.6 Combined exposure

Not relevant, the product contains only one active substance.

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

The data available are considered sufficient for risk assessment. Ferric phosphate is included in Annex IV of Regulation (CE) No 396/2005 that regroups active substances for which no MRL are necessary.

Summary for SUNBO PRO (PM13-151)

Crop	PHI for SUNBO PRO (PM13-151) proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for SUNBO PRO (PM13-151) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Ferric phosphate		
All situations, crop and non-crop	3 days for FR uses	NR	3 days (edible crops)	-

NR: not relevant

* Purpose of withholding period to be specified

Waiting periods before planting succeeding crops

Not relevant.

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

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The fate and behaviour in the environment of the formulation has been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review were used to calculate PECs for the active substance for the intended use patterns.

Due to the natural occurrence in the environment of ferric phosphate and its dissociation products (iron ions and phosphate ions), no specific study to address the fate and behaviour of active substance in environment is needed.

PECsoil derived for the active substance are used for the ecotoxicological risk assessment.

For the aquatic risk assessment the maximum solubility in water (1.86×10^{-12} g/L) is used.

Due to the nature of the active substance, no unacceptable risk of groundwater contamination by ferric phosphate is expected for the intended uses.

Ferric phosphate is a non-volatile active substance.

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 review for active substances and their metabolites were used for the intended use patterns. In cases where deviations from the EU agreed end-points 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, mammals, aquatic organisms, bees and other non-target arthropods, earthworms and other soil macro-organisms, micro-organisms are acceptable for the intended uses on field and greenhouse without the need of mitigation measures when the product SUNBO PRO (PM13-151) is applied according to the intended GAP.

3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to environmental fate and behaviour above for conclusion on the risk of groundwater contamination.

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

The active substance Ferric phosphate 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

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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.

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Appendix 1 Copy of the product authorisation DAMM

DocuSign Envelope ID: 78AD161E-843B-4A6E-AC5C-D1FF2AC3301B



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 réglementaire,

*Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique **SUNBO PRO***

de la société DE SANGOSSE S.A.S

enregistrée sous le n° 2022-2763

Vu les conclusions de l'évaluation de l'Anses du 6 février 2024,

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 son annexe.

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.

DocuSign Envelope ID: 78AD161E-843B-4A6E-AC5C-D1FF2AC3301B



Informations générales sur le produit	
Nom du produit	SUNBO PRO
Type de produit	Produit de référence
Titulaire	DE SANGOSSE S.A.S Bonnell CS 10005 47480 PONT-DU-CASSE France
Formulation	Appât prêt à l'emploi (RB)
Contenant	24,2 g/kg - phosphate ferrique
Numéro d'intrant	850-2022.01
Numéro d'AMM	2240107
Fonction	Molluscicide
Gamme d'usage	Professionnel
Mention particulière	Produit à faible risque au sens de l'article 47 du règlement (CE) n° 1107/2009

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. À titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 décembre 2031.

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 27/03/2024

DocuSigned by:

 AE281A865A42454...
 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 : 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 en papier	5 kg ; 10 kg ; 12 kg ; 15 kg ; 16 kg ; 18 kg ; 20 kg ; 25 kg
Big-bags en polypropylène	200 kg ; 300 kg ; 400 kg ; 500 kg ; 1000 kg

Classification du produit
La classification retenue est la suivante : Sans classement.
Pour les phrases P se référer à la réglementation 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)	Culture attractive en floraison (arrêté du 20/11/2021)
11012903 Traitements généraux*Trt Sol*Limaces et escargots	7 kg/ha	4/an	-	1	-	-	-	Non concerné
Egalement autorisé sous abri. Intervalle minimum entre les applications : 5 jours.								

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Conditions d'emploi du produit

Stockage et manipulation du produit

- Stocker le produit dans un endroit sec.

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 matériel d'application (ex : microgranulateur)

• pendant le chargement du matériel d'application

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité ;

• pendant l'application

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;

• pendant le nettoyage du matériel d'application

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité.

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

- 6 heures pour les usages en plein champ et 8 heures pour les applications en milieu fermé.

Respect des limites maximales de résidus (LMR)

- Le délai avant récolte est fixé à 1 jour en fonction des pratiques agricoles sur la culture et afin de limiter l'exposition potentielle des consommateurs.

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.

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Appendix 3 : 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.

Proposition d'étiquette – SUNBO® PRO
20/06/2022



SUNBO® PRO
MOLLUSCICIDE DE BIOCONTROLE
Sur toutes les cultures en plein champ et sous abri

RESERVE A UN USAGE EXCLUSIVEMENT PROFESSIONNEL

Détenteur de l'AMM, distributeur, marque déposée :
DE SANGOSSE S.A.S
Bonnell - CS 10005
47480 Pont-du-Casse
Tél. : 05 53 69 36 30
www.desangosse.fr



SUNBO® PRO
AMM N°xxxxxxxxxx
Formulation : RB - Appât prêt à l'emploi
Substance active : 2,42 % (24,2 g/Kg) Phosphate ferrique anhydre IPMAX
Conseils de prudence :
P102 : Tenir hors de portée des enfants
P270 : Ne pas manger, boire ou fumer en manipulant le produit
P273 : Eviter le rejet dans l'environnement
P280 : Porter des gants de protection
P391 : Recueillir le produit répandu
P501 : Eliminer le contenu/réceptacle conformément à la réglementation locale/nationale.
EUH401 : Respectez les instructions d'utilisation pour 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. Eviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

EN CAS D'URGENCE
Composer le 15 ou le 112 ou contacter le centre
anti poison le plus proche

Puis signaler vos symptômes au réseau Phyt'Attitude,
N° Vert : 0 800 887 887 (appel gratuit depuis un poste fixe).

PREMIERS SOINS

S'éloigner de la zone dangereuse.

En cas de contact cutané : enlever tout vêtement souillé, rincer immédiatement et abondamment la peau sous l'eau du robinet. En cas d'irritation ou éruption cutanée, consulter un spécialiste.

En cas de projection dans les yeux : rincer immédiatement pendant 15 à 20 minutes sous un filet d'eau paupières ouvertes. Consulter un spécialiste.

En cas d'inhalation : en cas de trouble respiratoire, contacter sans délai les secours : le 15, le 112 ou un centre antipoison.

En cas d'ingestion : rincer immédiatement la bouche avec de l'eau. Ne pas faire vomir sans avis médical. Contacter sans délai les secours : le 15, le 112 ou un centre antipoison.

Proposition d'étiquette – SUNBO® PRO
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Dans tous les cas, si les symptômes persistent ou en cas de malaise, consulter un médecin et lui présenter l'étiquette et/ou la fiche de données de sécurité.
 En cas d'intoxication animale, contactez votre vétérinaire.
 Fiche de données de sécurité disponible sur : www.quickfds.com.

DESCRIPTIF DU PRODUIT ET MODE D'ACTION

SUNBO®PRO est un anti-limaces biocontrôle destiné aux applications en en plein, mélange et localisé. SUNBO® PRO est un molluscicide qui fonctionne par ingestion. Une fois ingéré SUNBO® PRO bloque la digestion du ravageur.

Tableau des usages autorisés :

Pour un traitement du sol :

Cultures	Cibles	Dose maximale d'emploi	Nombre maximum d'applications	Stades d'application / Conditions d'emploi	Délai avant récolte (DAR)	Zone non traitée aquatique
Toutes cultures en plein champ et sous abri (cultures alimentaires)	Limaces et escargots	7 kg/ha	4/an	-	3 jours	5 mètres
Toutes cultures en plein champ et sous abri (cultures non alimentaires)	Limaces et escargots	7 kg/ha	4/an	-	-	5 mètres

RECOMMANDATIONS D'EMPLOI

Conditions d'application*

La décision d'appliquer un anti-limaces doit résulter de l'observation du ravageur.

L'évaluation de l'activité des limaces peut se faire de différentes façons ; DE SANGOSSE recommande l'emploi de pièges à limaces spécifiques et le suivi d'un protocole précis.

Choix de la dose à appliquer*

La dose choisie doit tenir compte du nombre de ravageurs à contrôler.

*Pour une information détaillée sur les conditions d'applications, consulter le site www.ciblage-anti-limaces.fr

Proposition d'étiquette – SUNBO® PRO



Proposition d'étiquette – SUNBO® PRO
20/06/2022



PREVENTION ET GESTION DE LA RESISTANCE

L'utilisation répétée, sur une même parcelle, de préparations à base de substances actives de la même famille chimique ou ayant le même mode d'action, peut conduire à l'apparition d'organismes résistants. Pour réduire ce risque, l'utilisateur doit raisonner en premier lieu les pratiques agronomiques et respecter les conditions d'emploi du produit. Il est conseillé d'alterner ou d'associer, sur une même parcelle, des préparations à base de substances actives de familles chimiques différentes ou à modes d'action différents, tant au cours d'une saison culturale que dans la rotation. En dépit du respect de ces règles, on ne peut pas exclure une altération de l'efficacité de cette préparation liée à ces phénomènes de résistance. De ce fait, DE SANGOSSE S.A.S décline toute responsabilité quant à d'éventuelles conséquences qui pourraient être dues à de telles résistances.

MISE EN OEUVRE REGLEMENTAIRE ET BONNES PRATIQUES

Stockage du produit

Conserver le produit uniquement dans son emballage d'origine, dans un local phytopharmaceutique conforme à la réglementation en vigueur, à l'écart des aliments et boissons, y compris ceux pour animaux. Conserver hors de la portée des enfants et des personnes non autorisées. Conserver dans un endroit sec et frais.

Protection de l'opérateur et du travailleur

Se laver les mains après toute manipulation/utilisation/intervention dans une parcelle préalablement traitée. Ne pas manger, boire, téléphoner ou fumer lors de l'utilisation du produit.

Caractéristiques des EPI	PROTECTION DE L'UTILISATEUR PENDANT LES PHASES DE :		
	MÉLANGE/ CHARGEMENT	APPLICATION	NETTOYAGE
GANTS EN NITRILE EN ISO 374-1/A1 réutilisables (EN 16523-1+A1 (type A)) (usage unique (EN ISO 374-2 (types A, B ou C)))	Réutilisables	À usage unique*	Réutilisables
PROTECTEURS OCULAIRES conforme à la norme NF EN ISO 20353 (1)	EPI vestimentaire ET EPI partiel		EPI vestimentaire ET EPI partiel

*En cas d'intervention sur semoirs, épandeurs, microgranulateurs

Rapporter les équipements de protection individuelle (EPI) usagés dans un sac translucide, à votre distributeur partenaire ECO EPI ou faire appel à une entreprise habilitée pour la collecte et l'élimination de produits dangereux.

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