

REGISTRATION REPORT

Part A

Risk Management

Product code: SEIBS 701

Product name: FUNGISEI

Active substance:

***Bacillus subtilis* strain IAB/BS03, 10 g/L**

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: SEIPASA S.A.

Date: 07/04/2021

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PART A – Risk Management

The company SEIPASA S.A. has requested the marketing authorisation in France for the product FUNGISEI (product code: SEIBS 701), containing a minimum of $1\ 10^8$ CFU¹/mL minimum of *Bacillus subtilis* strain IAB/BS03 (10 g/L of technical product), for use as a fungicide for professional use. *Bacillus subtilis* strain IAB/BS03 is a low risk active substance and is the only active substance of FUNGISEI (SEIBS 701), therefore FUNGISEI (SEIBS 701) shall be authorised as a low risk plant protection product if compliant with article 47.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report (RR), 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 FUNGISEI (SEIBS 701) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of FUNGISEI (SEIBS 701) have been made using endpoints agreed in the EU peer review of *Bacillus subtilis* strain IAB/BS03.

This document describes the specific conditions of use and labelling required for France for the registration of FUNGISEI (SEIBS 701).

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 SEIPASA SA's application to market FUNGISEI (SEIBS 701) in France as a fungicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for field uses and as interzonal Rapporteur Member State (izRMS) for greenhouse uses and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone for field uses and of the European Union for greenhouse uses.

1.2 Active substance approval

Bacillus subtilis strain IAB/BS03

Commission Implementing Regulation (EU) No 2019/1605 of 27 September 2019 approving the low-risk active substance *Bacillus subtilis* strain IAB/BS03, 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.

Specific provisions of Regulation (EU) No 2019/1605 were as follows:

In this overall assessment Member States shall pay particular attention to:

- a) the specification of the technical material as commercially manufactured used in plant protection products, including full characterisation of relevant secondary metabolites;
- b) the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers, and ensuring that adequate personal protective equipment is included as a condition of use.

Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in OECD Issue Paper on Microbial Contaminant Limits for Microbial Pest Control Products, contained in the Working Document SANCO/12116/2012.

¹ CFU: Colony-forming unit

Conditions of use shall include risk mitigation measures, where appropriate.

An EFSA conclusion is available (EFSA Journal 2018;16(6):5261, 13 April 2018).

A Review Report is available (SANTE/2019/10318 rev3, 17 July 2019).

1.3 Regulatory approach

The present application (2019-6306) 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 for field uses and of the European Union for greenhouse uses, taking into account the worst-case uses (“risk envelope approach”)² – the highest application rates over the Southern Zone and European Union. When risk mitigation measures were necessary, they are adapted to the situation in France.

According to the French law and procedures, specific conditions of use are set out in the Decision letter.

The French Order of 4 May 2017³ 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 1107/2009⁴, 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 546/2011⁵, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014⁶ 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 extrapolation⁷ is to supply “minor” crops with registered plant protection products.

² 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.

³ Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjutants 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/AGR1632554A/jo/texte;https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

⁴ 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.

⁵ 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.

⁶ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGR1407093A/jo>

⁷ SANCO document “guidance document: Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9.

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.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of FUNGISEI (SEIBS 701), 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 a letter of access for active substance and PPP data.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	FUNGISEI (SEIBS 701).
Authorisation number	N/A : no marketing authorisation granted
Low risk product (article 47)	Yes.
Function	Fungicide.
Applicant	SEIPASA S.A.
Composition	1.10 ⁸ CFU/mL minimum, <i>Bacillus subtilis</i> strain IAB/BS03
Formulation type (code)	SL – soluble concentrate (requested) – see § 3.1.1.
Packaging	HDPE (500 mL, 1 L, 5 L, 10 L, 20 L).

2.2 Classification and labelling

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

No health or environmental classification.

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

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

N/A : no marketing authorisation granted.

2.2.3 Other phrases linked to the preparation

N/A : no marketing authorisation granted.

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 for field uses and izRMS for greenhouse uses. 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.

PPP (product name/code):		FUNGISEI (SEIBS 701)		Formulation type:		GAP 2021/04/07	
Active substance 1:		<i>Bacillus subtilis</i> strain IAB/BS03		Conc. of a.s. 1:		SL requested; SC proposed ^(a, b)	
Safener:		No		Conc. of safener:		Min. 1 x 10 ⁸ CFU/mL (10 g/L) ^(c)	
Synergist:		No		Conc. of synergist:		/	
Applicant:		SEIPASA S.A.		Professional use:		<input checked="" type="checkbox"/>	
Zone(s):		Southern and interzonal ^(d)		Non-professional use:		<input type="checkbox"/>	
Verified by MS:		Yes					
Field of use:		Fungicide					

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	CFU/ha (g a.s./ha) a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	CFU/ha (g a.s./ha) a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	Tomato and eggplant (aubergine)	F	Grey mould (<i>Botrytis cinerea</i>)	Spraying	BBCH 61-89	5	5 days	a) 3 b) 15	a) 3×10^{11} (30) b) 1.5×10^{12} (150)	500- 1000	Not necess ary	Not acceptable (Lack of efficacy data)
2	FR	Pepper	F	Grey mould (<i>Botrytis cinerea</i>)	Spraying	BBCH 61-89	5	5 days	a) 3 b) 15	a) 3×10^{11} (30) b) 1.5×10^{12} (150)	700- 1000	Not necess ary	Not acceptable (Lack of efficacy data)
3	FR	Celery and celery branch	F	Grey mould (<i>Botrytis cinerea</i>)	Spraying	BBCH 12-49	5	5 days	a) 3 b) 15	a) 3×10^{11} (30) b) 1.5×10^{12} (150)	200- 1000	Not necess ary	Not acceptable (Lack of efficacy data)
4	FR	Baby leaf crops (including <i>Brassica</i> species)	F	Grey mould (<i>Botrytis cinerea</i>)	Spraying	BBCH 12-49	5	5 days	a) 3 b) 15	a) 3×10^{11} (30) b) 1.5×10^{12} (150)	800- 1000	Not necess ary	Not acceptable (Lack of efficacy data)
5	FR	Herbs and edible flowers (chervil, celery leaves, parsley, sage, rosemary, thyme, basil and edible flowers, bay leaves, tarragon, others)	F	Grey mould (<i>Botrytis cinerea</i>)	Spraying	BBCH 12-67	5	5 days	a) 3 b) 15	a) 3×10^{11} (30) b) 1.5×10^{12} (150)	400- 1000	Not necess ary	Not acceptable (Lack of efficacy data)
6	FR	Grapes	F	Grey mould (<i>Botrytis cinerea</i>)	Spraying	BBCH 68-89	5	5 days	a) 3 b) 15	a) 3×10^{11} (30) b) 1.5×10^{12} (150)	200- 1000	Not necess ary	Not acceptable (Lack of efficacy data)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	CFU/ha (g a.s./ha) a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
7	FR	Flowering and head brassica	F	Grey mould (<i>Botrytis cinerea</i>)	Spraying	BBCH 14-47	5	5 days	a) 3 b) 15	a) 3×10^{11} (30) b) 1.5×10^{12} (150)	800- 1000	Not necess ary	Not acceptable (Lack of efficacy data)
8	FR	Lettuce	F	Downy mildew (<i>Bremia</i> spp.)	Spraying	BBCH 12-49	5	5 days	a) 3 b) 15	a) 3×10^{11} (30) b) 1.5×10^{12} (150)	400- 1000	Not necess ary	Not acceptable (Lack of efficacy data)
9	FR	Globe artichoke	F	Downy mildew (<i>Bremia</i> spp.)	Spraying	BBCH 11-59	5	5 days	a) 3 b) 15	a) 3×10^{11} (30) b) 1.5×10^{12} (150)	400- 1000	Not necess ary	Not acceptable (Lack of efficacy data)
10	FR	Spinach and similar leaves (spinaches purslanes, chards/beets leaves, rape leaves and similar species, other)	F	Downy mildew (<i>Bremia</i> spp.)	Spraying	BBCH 12-49	5	5 days	a) 3 b) 15	a) 3×10^{11} (30) b) 1.5×10^{12} (150)	400- 1000	Not necess ary	Not acceptable (Lack of efficacy data)
11	FR	Celery and celery branched	F	Downy mildew (<i>Bremia</i> spp.)	Spraying	BBCH 12-49	5	5 days	a) 3 b) 15	a) 3×10^{11} (30) b) 1.5×10^{12} (150)	400- 1000	Not necess ary	Not acceptable (Lack of efficacy data)
12	FR	Baby leaf crops (including <i>Brassica</i> species)	F	Downy mildew (<i>Bremia</i> spp.)	Spraying	BBCH 12-49	5	5 days	a) 3 b) 15	a) 3×10^{11} (30) b) 1.5×10^{12} (150)	400- 1000	Not necess ary	Not acceptable (Lack of efficacy data)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	CFU/ha (g a.s./ha) a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
13	FR	Herbs and edible flowers (chervil, celery leaves, parsley, sage, rosemary, thyme, basil and edible flowers, laurel/bay leaves, tarragon, others)	F	Downy mildew (<i>Bremia</i> spp.)	Spraying	BBCH 12-67	5	5 days	a) 3 b) 15	a) 3×10^{11} (30) b) 1.5×10^{12} (150)	400-1000	Not necessary	Not acceptable (Lack of efficacy data)
14	FR	Salad plants (Lamb's lettuce/corn salad, escaroles/broad-leaved endives, watercress and other sprouts and shoots, land cress, roman rocket/rucola, red mustards)	F	Downy mildew (<i>Bremia</i> spp.)	Spraying	BBCH 12-49	5	5 days	a) 3 b) 15	a) 3×10^{11} (30) b) 1.5×10^{12} (150)	400-1000	Not necessary	Not acceptable (Lack of efficacy data)
16	FR	Cucumber, courgette and squash	F	Powdery mildew (<i>Erysiphe</i> spp., <i>Sphaerotheca</i> spp.)	Spraying	BBCH 12-89	5	5 days	a) 3 b) 15	a) 3×10^{11} (30) b) 1.5×10^{12} (150)	500-1000	Not necessary	Not acceptable (Lack of efficacy data)
17	FR	Melon, watermelon, pumpkin	F	Powdery mildew (<i>Erysiphe</i> spp., <i>Sphaerotheca</i> spp.)	Spraying	BBCH 12-89	5	5 days	a) 3 b) 15	a) 3×10^{11} (30) b) 1.5×10^{12} (150)	400-1000	Not necessary	Not acceptable (Lack of efficacy data)
18	FR	Tobacco	F	Powdery mildew (<i>Erysiphe</i> spp., <i>Sphaerotheca</i> spp.)	Spraying	BBCH 12-59	5	5 days	a) 3 b) 15	a) 3×10^{11} (30) b) 1.5×10^{12} (150)	400-1000	Not necessary	Not acceptable (Lack of efficacy data)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	CFU/ha (g a.s./ha) a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
19	FR	Apple, pear, quince, medlar, loquat/Japanese medlar and other fruit trees	F	Scab (<i>Venturia</i> spp.)	Spraying	BBCH 57-89	7	5 days	a) 3 b) 21	a) 3×10^{11} (30) b) 2.1×10^{12} (210)	300-1000	Not necessary	Not acceptable (Lack of efficacy data)
20	FR	Sweet almond tree	F	Scab (<i>Venturia</i> spp.)	Spraying	BBCH 51-89	7	5 days	a) 3 b) 21	a) 3×10^{11} (30) b) 2.1×10^{12} (210)	300-1000	Not necessary	Not acceptable (Lack of efficacy data)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	CFU/ha (g a.s./ha) a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
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)													
21	FR	Tomato and eggplant	G	Grey mould (<i>Botrytis cinerea</i>)	Spraying	BBCH 61-89	5	5 days	a) 3 b) 15	a) 3×10^{11} (30) b) 1.5×10^{12} (150)	500- 1000	Not necess ary	Not acceptable (Lack of efficacy data)
22	FR	Pepper	G	Grey mould (<i>Botrytis cinerea</i>)	Spraying	BBCH 61-89	5	5 days	a) 3 b) 15	a) 3×10^{11} (30) b) 1.5×10^{12} (150)	700- 1000	Not necess ary	Not acceptable (Lack of efficacy data)
23	FR	Celery and celery branch	G	Grey mould (<i>Botrytis cinerea</i>)	Spraying	BBCH 12-49	5	5 days	a) 3 b) 15	a) 3×10^{11} (30) b) 1.5×10^{12} (150)	200- 1000	Not necess ary	Not acceptable (Lack of efficacy data)
24	FR	Baby leaf crops (including <i>Brassica</i> species)	G	Grey mould (<i>Botrytis cinerea</i>)	Spraying	BBCH 12-49	5	5 days	a) 3 b) 15	a) 3×10^{11} (30) b) 1.5×10^{12} (150)	800- 1000	Not necess ary	Not acceptable (Lack of efficacy data)
25	FR	Herbs and edible flowers (chervil, celery leaves, parsley, sage, rosemary, thyme, basil and edible flowers, bay leaves, tarragon, others)	G	Grey mould (<i>Botrytis cinerea</i>)	Spraying	BBCH 12-67	5	5 days	a) 3 b) 15	a) 3×10^{11} (30) b) 1.5×10^{12} (150)	400- 1000	Not necess ary	Not acceptable (Lack of efficacy data)
26	FR	Cucumber, courgette and squash	G	Powdery mildew (<i>Erysiphe</i> spp., <i>Sphaerotheca</i> spp.)	Spraying	BBCH 12-89	5	5 days	a) 3 b) 15	a) 3×10^{11} (30) b) 1.5×10^{12} (150)	500- 1000	Not necess ary	Not acceptable (Lack of efficacy data)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	CFU/ha (g a.s./ha) a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
27	FR	Melon, watermelon, pumpkin	G	Powdery mildew (<i>Erysiphe</i> spp., <i>Sphaerotheca</i> spp.)	Spraying	BBCH 12-89	5	5 days	a) 3 b) 15	a) 3×10^{11} (30) b) 1.5×10^{12} (150)	400- 1000	Not necess ary	Not acceptable (Lack of efficacy data)

* As some standards may have undergone changes, it is the responsibility of the applicant to update the reference.

Remarks table heading:

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

Remarks columns:

- 1 Numeration necessary to allow references
- 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/m³ 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

* PPE personal protective equipment, As some standards may have undergone changes, it is the responsibility of the applicant to update the reference.

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

FUNGISEI (SEIBS 701) was stated by the applicant to be a soluble concentrate (SL). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a slightly yellow homogeneous liquid, with a characteristic odour. It is not explosive and has no oxidising properties. The product has a flash point higher than 143 °C. It has a self-ignition temperature of 395.4 °C. In aqueous solution (1 %), it has a pH value of 7.23 at ambient temperature. The product is stable for 14 days at 54 °C and for two years at 20 °C in plastic bottles (500 mL tested); neither the active substance content nor the technical properties were changed. The technical characteristics are acceptable for a soluble concentrate formulation.

The formulation is not classified for the physico-chemical aspect.

The product should not be stored at a temperature higher than 20 °C and no longer than two years.

As the packaging tested in the stability test had a capacity of 500 mL, and, taking into account the composition of the product, interaction between packaging and the product cannot be excluded. Therefore the 250 mL packaging cannot be accepted.

For high-volume packaging (200 L and 1000 L), as no information is available on the possibility of stirring the product before use, these packaging volumes cannot be accepted.

The details of packaging type used in the stability study should be indicated (“plastic bottle” is not sufficient).

The product cannot be considered a soluble concentrate (SL), but a suspension concentrate (SC). Physico-chemical properties specific to SC products before and after storage should be provided post-registration.

Furthermore, as the suspensibility information is not available yet, the following mitigation measure should be added to the label: “Shake before use”.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methodology for the determination of the microbial active substance in the formulation is available and validated.

Nevertheless, no validation data were provided. The % RSD was calculated by the zRMS from the results obtained in the five-batch analysis; no indication of the negative and positive controls is available in the study. Furthermore, no indication of the date of the production of batches was provided, therefore the determination of active substance and microbial contaminants in five recent batches should be provided post-authorisation, or additional data, to complete the data gaps in the initial study provided.

Analytical methods for the determination of microbial contaminants according to OECD 65 are available and validated.

3.1.2.2 Analytical methods for residues

Analytical methods for the determination of residues are not necessary as there is no residue definition.

3.1.3 Mammalian Toxicology

Active substance	ADI mg/kg bw/d	ARfD mg/kg bw	AOEL mg/kg bw/d	Classification

<i>Bacillus subtilis</i> strain IAB/BS03	Not relevant for micro-organisms.	Not classified. Micro-organisms may have the potential to provoke sensitising reactions.
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The derivation or reference values was not needed, based on the absence of toxicity, infectivity and pathogenicity indications of the micro-organism.

3.1.3.1 Acute Toxicity

FUNGISEI (SEIBS 701), containing 10 g/L (min. 1 x 10⁸ CFU/mL) *Bacillus subtilis* strain IAB/BS03, has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitiser.

The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.2.

3.1.3.2 Operator Exposure

The EFSA model is not suitable for calculating a risk assessment for operators, on the basis of a non-existent dose-effect relationship.

When the potential sensitising properties are considered and appropriate protection equipment is worn (gloves, coverall and respiratory mask), the product is considered safe for operators, based on the low toxicity profile and the application method.

Since *Bacillus subtilis* may be responsible for opportunist infection in severely immunocompromised people, the product should not be used by immunocompromised subjects or those under treatment with immunosuppressant agents.

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

3.1.3.3 Bystander and resident Exposure

The aforementioned reasons for not undertaking an operator risk assessment also apply to bystanders and residents. Given the application method, bystander and residential exposure is considered to be negligible for field uses.

Estimation of bystander and resident exposure is considered unnecessary for greenhouse uses.

3.1.3.4 Worker Exposure

As the micro-organism is not toxic, infectious or pathogenic in mammals, no unacceptable risk is expected for workers wearing appropriate protective equipment.

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

3.1.3.6 Relevance of metabolites

Not relevant.

3.1.4 Residues and Consumer Exposure

Bacillus subtilis strain IAB/BS03 was approved under Reg. (EU) 2019/1605. The active substance is included in the list of low-risk substances (EU database, 10/03/2020), and in Annex IV of Reg. (EU) 396/2005 (SANTE/11822/2019).

Estimation of consumer risk is not considered necessary for *Bacillus subtilis* strain IAB/BS03. Consequently, no risk is expected for consumers for the intended uses of the product FUNGISEI (SEIBS 701).

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 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 endpoints established in the EU conclusions (EFSA, 2018) were used in calculations. PECsoil and PECsw values derived for the active substance are used for the ecotoxicological risk assessment.

The assessment of groundwater contamination by *Bacillus subtilis* strain IAB/BS03 related to the use of FUNGISEI (SEIBS 701) is not considered relevant.

No unacceptable risk of groundwater contamination is expected for the intended uses.

3.1.6 Ecotoxicology

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 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, mammals, aquatic organisms, bees, other non-target arthropods, earthworms, soil micro-organisms and plants are acceptable for all intended uses.

3.1.7 Efficacy

Considering the data submitted:

- The evaluation of the efficacy level of FUNGISEI (SEIBS 701) **could not be finalised, due to the level of uncertainty about the results provided (infection levels, efficacy calculations, tested rates...).**
- The phytotoxicity level of FUNGISEI (SEIBS 701) is considered negligible for all the requested uses.
- The risks of negative impact on yield, quality, propagation, succeeding and adjacent crops are considered negligible.
- Specific attention should be paid to the conditions of use of the product for integrated pest management practices, particularly in terms of biological compatibility with fungicide products.
- The risk of resistance developing or appearing to the strain IAB/BS03 of *Bacillus subtilis* is considered to be very low.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, **an authorisation cannot be granted**. A copy of the decision issued can be found 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

N/A : no marketing authorisation granted.

3.4.2 Post-authorisation data requirements

N/A : no marketing authorisation granted.

3.4.3 Label amendments

N/A : no marketing authorisation granted.

Appendix 1 – Copy of the French Decision



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 **FUNGISEI***

de la société SEIPASA SA

enregistrée sous le n°2019-6306

Vu les conclusions de l'évaluation de l'Anses du 8 décembre 2020,

Considérant que les données disponibles ne permettent pas de déterminer l'efficacité du produit,

Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 sont respectées,

La mise sur le marché du produit phytopharmaceutique désigné ci-après n'est pas autorisée en France.



Informations générales sur le produit

Nom du produit	FUNGISEI
Type de produit	Produit de référence
Titulaire	SEIPASA SA C/ Almudévar, 2 22240 Tardienta (Huesca) Espagne
Formulation	Concentré soluble (SL)
Contenant	1.10 ⁸ UFC/mL - <i>Bacillus subtilis</i> souche IAB/BS03
Numéro d'intrant	921-2019.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usage	Professionnel

A Maisons-Alfort, le

07 AVR. 2021

Caroline SEMAILLE
Directrice générale déléguée
en charge du pôle produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)



ANNEXE I : Conditions de mise sur le marché demandées

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12103205 Amandier*Ttr Part.Aer.*Tavelure(s)	3 L/ha	7/an	-
16103202 Artichaut*Ttr Part.Aer.*Mildiou(s)	3 L/ha	5/an	-
16253204 Céleris*Ttr Part.Aer.*Mildiou(s)	3 L/ha	5/an	-
16253206 Céleris*Ttr Part.Aer.* Pourriture grise et sclérotinioses	3 L/ha	5/an	-
00516049 Choux feuillus*Ttr Part.Aer.*Mildiou(s)	3 L/ha	5/an	-

FUNGISEI
AMM n°

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Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
00516052 Choux feuillus*Trt Part.Aer.* Pourriture grise et sclerotiniose	3 L/ha	5/an	-
16403203 Choux*Trt Part.Aer.* Pourriture grise et sclerotiniose	3 L/ha	5/an	-
16323203 Concombre*Trt Part.Aer.* Ordium(s)	3 L/ha	5/an	-
16463201 Cresson aérien*Trt Part.Aer.* Mildiou(s)	3 L/ha	5/an	-
16473201 Cresson de fontaine*Trt Part.Aer.* Mildiou(s)	3 L/ha	5/an	-
16503204 Epinard*Trt Part.Aer.* Mildiou(s)	3 L/ha	5/an	-

FUNGISEI
AMM n°



Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
19153202 Fines Herbes*Trit Part.Aer.* Mildiou(s)	3 L/ha	5/an	-
16823204 Fines Herbes*Trit Part.Aer.* Pourriture grise et sclerotinioses	3 L/ha	5/an	-
16603207 Laitue*Trit Part.Aer.* Mildiou(s)	3 L/ha	5/an	-
16603201 Laitue*Trit Part.Aer.* Pourriture grise et sclerotinioses	3 L/ha	5/an	-
16753205 Melon*Trit Part.Aer.* Oïdium(s)	3 L/ha	5/an	-
16863201 Polivron*Trit Part.Aer.* Pourriture grise et sclerotinioses	3 L/ha	5/an	-

FUNGISEI
AMM n°:

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Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12603203 Pommier*Trt Part.Aer.* Tavelure(s)	3 L/ha	7/an	-
Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas de déterminer l'efficacité du produit.			
15853201 Tabac*Trt Part.Aer.* Oidium(s)	3 L/ha	5/an	-
Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas de déterminer l'efficacité du produit.			
16953203 Tomate*Trt Part.Aer.* Pourriture grise et sclérotinioses	3 L/ha	5/an	-
Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas de déterminer l'efficacité du produit.			
12703205 Vigne*Trt Part.Aer.* Pourriture grise	3 L/ha	5/an	-
Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas de déterminer l'efficacité du produit.			

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

Uniquement pour les utilisateurs professionnels
Lire attentivement le mode d'emploi avant utilisation

FUNGISEI

Formulation : Concentré soluble (SL)

Substance active : *Bacillus subtilis* strain IAB/BS03 (10 g/L – 0.81 % p/p)

Classification :

FUNGISEI est un produit de Biocontrôle à faible risque et non classé.

EUH208 : Contient *Bacillus subtilis* strain IAB/BS03. Peut produire une réaction allergique.

En cas d'urgence, appeler le 15 ou le centre antipoison (01.40.05.48.48), puis signaler les symptômes au réseau Phyt'attitude (N° vert : 0 800 887 877 – service et appel gratuit).

Emballage : XXL

Lot N° : XXXXX

N° d'AMM : XXXXX

Titulaire de l'autorisation :

SEIPASA S.A.

C/ Almudévar, 2

22240 Tardienta (Huesca)

Espagne

Distributeur en France : XXXXX

Date de fabrication : indiqué sur l'emballage

Date d'expiration : 2 ans à compter de la date de fabrication

Usages autorisés :

Culture	Cible	Dose d'emploi	Nombre d'applications maximum	Intervalle entre les applications	Période d'application	Délai avant récolte
Tomate, aubergine, poivron (En plein champs et sous serre)	Pourriture grise	3 L/ha	5	5-7 jours	BBCH 61-89	-
Céleri-rave, céleri-branches, cultures à petites feuilles (laitues, chicorées – scaroles, chicorées – frisées, mâche, roquette et autres salades, choux feuillus, choux verts, choux chinois et autres) (En plein champs et sous serre)	Pourriture grise	3 L/ha	5	5-7 jours	BBCH 12-49	-

Culture	Cible	Dose d'emploi	Nombre d'applications maximum	Intervalle entre les applications	Période d'application	Délai avant récolte
Fins herbes (plantes liliacées dont la ciboule et la ciboulette, plantes apiacées dont persil, cerfeuil, feuilles de fenouil, angelique et carvi et plantes lamiacées comme basilic, thym et sauge) (En plein champs et sous serre)	Pourriture grise	3 L/ha	5	5-7 jours	BBCH 12-67	-
Vigne (En plein champs)	Pourriture grise	3 L/ha	5	5-7 jours	BBCH 69-89	-
Choux, choux à inflorescences (Choux fleurs, brocoli et autres), choux feuillus (choux verts (type non pommeés), choux chinois et autres), choux pommeés, choux de Bruxelles et autres, choux-raves (En plein champs)	Pourriture grise	3 L/ha	5	5-7 jours	BBCH 14-47	-
Laitues, chicorées – scaroles, chicorées – frisées, mâche, roquette et autres salades, épinard, feuilles de bettes, poupier, céleri-rave, céleri-branches, cresson alenois, cresson de fontaine, cultures à petites feuilles (laitues, chicorées – scaroles, chicorées – frisées, mâche, roquette et autres salades, choux feuillus, choux verts, choux chinois et autres) (En plein champs)	Mildiou	3 L/ha	5	5-7 jours	BBCH 12-49	-
Artichaut (En plein champs)	Mildiou	3 L/ha	5	5-7 jours	BBCH 11-59	-
Fins herbes (plantes liliacées dont la ciboule et la ciboulette, plantes apiacées dont persil, cerfeuil, feuilles de fenouil, angelique et carvi et plantes lamiacées comme basilic, thym et sauge) (En plein champs)	Mildiou	3 L/ha	5	5-7 jours	BBCH 12-67	-
Concombre, courgette, cornichon et autres cucurbitacées à peau comestible, melon, pastèque, potiron et autres cucurbitacées à peau non comestible	Oïdium	3 L/ha	5	5-7 jours	BBCH 12-89	-
Tabac	Oïdium	3 L/ha	5	5-7 jours	BBCH 12-59	-

Culture	Cible	Dose d'emploi	Nombre d'applications maximum	Intervalle entre les applications	Période d'application	Délai avant récolte
Pommier, poirier, cognassier, nèfles, nashi, pommette	Tavelure	3 L/ha	7	5-7 jours	BBCH 57-89	-
Amandier	Tavelure	3 L/ha	7	5-7 jours	BBCH 51-89	-

Préparation de la bouille :

Toujours mélanger le produit FUNGISEI dans un pulvérisateur/conteneur propre. Remplir le réservoir jusqu'à la moitié de son volume avec de l'eau propre, ajouter la quantité nécessaire de produit sous agitation, puis remplir complètement le réservoir et bien mélanger. Ajuster le pH de la bouillie à 5-7.

Mélange : Respecter la réglementation en vigueur et les recommandations des guides de bonnes pratiques officiels disponibles sur le site : <http://e-phv.agriculture.gouv.fr>

PRECAUTIONS :

Stockage : le produit FUNGISEI doit être stocké dans son emballage d'origine fermé de manière étanche, dans un endroit bien ventilé et sous clef, hors de portée des enfants.

Pour l'utilisateur : Eviter le contact du produit avec les yeux, la peau et les voies respiratoires. En cas d'incident en cours d'application, arrêter l'application, ne pas porter les mains ou les gants souillés à la bouche. Après l'application, rincer les équipements de protection, se laver les gants puis les mains, prendre une douche. Ne pas réutiliser l'emballage du produit.

Équipement de protection individuelle pour la préparation et les manipulations avec le produit :

Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur à rampe :

- Pendant le mélange/chargement :
 - Gants en nitrile certifiés EN 374-3 ;
 - Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
 - EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3B) à porter par-dessus la combinaison précitée ;
- Pendant l'application - Pulvérisation vers le bas :
 - Si application avec tracteur avec cabine :
 - Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
 - Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;
 - Si application avec tracteur sans cabine :
 - Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
 - Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;
- Pendant le nettoyage du matériel de pulvérisation :
 - Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;

- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3B) à porter par-dessus la combinaison précitée.

Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur pneumatique :

- Pendant le mélange/chargement :
 - Gants en nitrile certifiés EN 374-3 ;
 - Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
 - EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3B) à porter par-dessus la combinaison précitée ;
- Pendant l'application - Pulvérisation vers le haut :
 - Si application avec tracteur avec cabine :
 - Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
 - Gants en nitrile certifiés EN 374-3 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;
 - Si application avec tracteur sans cabine :
 - Combinaison de protection de catégorie III type 4B avec capuche ;
 - Gants en nitrile certifiés EN 374-3 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;
- Pendant le nettoyage du matériel de pulvérisation :
 - Gants en nitrile certifiés EN 374-3 ;
 - Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
 - EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3B) à porter par-dessus la combinaison précitée ;

Dans le cadre d'une application effectuée à l'aide d'une lance (usage sous abri)

- Pendant le mélange/chargement :
 - Gants en nitrile certifiés EN 374-3 ;
 - Combinaison de protection de catégorie III type 4 ou 3 (selon le niveau de protection recommandé pendant la phase d'application) ;
- OU
- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3B) à porter par-dessus la combinaison précitée ;
- Pendant l'application : sans contact intense avec la végétation
 - Culture basse (< 50 cm)
 - Gants en nitrile certifiés EN 374-3 ;
 - Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
 - Bottes de protection certifiées EN 13 832-3 ;
 - Culture haute (> 50 cm)
 - Gants en nitrile certifiés EN 374-3 ;
 - Combinaison de protection de catégorie III type 4 avec capuche ;
 - Bottes de protection certifiées EN 13 832-3 ;
- Pendant l'application : contact intense avec la végétation, cultures hautes et basses

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de protection de catégorie III type 3 avec capuche ;
- Bottes de protection certifiées EN 13 832-3 ;
- Pendant le nettoyage du matériel de pulvérisation :
 - Gants en nitrile certifiés EN 374-3 ;
 - Combinaison de protection de catégorie III type 4 ou 3 (selon le niveau de protection recommandé pendant la phase d'application) ;

OU

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse) de catégorie III et de type PB (3B) à porter par-dessus la combinaison précitée

Porter une combinaison de travail (cotte en coton/polyester 35%/65% - grammage d'au moins 230 g/m²) avec traitement déperlant et, en cas de contact avec la culture traitée, des gants en nitrile certifiés EN 374-3.

Après utilisation : Eliminer les emballages via les collectes organisées, en accord avec la réglementation en vigueur.

IMPORTANT : PRODUIT POUR LES PROFESSIONNELS. Respecter les usages, doses, conditions et recommandations 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 tel 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 mise sur le marché délivrée par les autorités françaises compétentes. SEIPASA S.A. ne saurait être en aucun cas tenu pour responsable des conséquences inhérentes à toute copie de cette étiquette, totale ou partielle et la diffusion ou à l'utilisation non autorisée de cette dernière.

Appendix 3 – Letter(s) of Access

Provided upon request.