

REGISTRATION REPORT

Part A

Risk Management

Product code: SEIBS 701

Product name(s): FUNGISEI PRO

Active Substance(s):

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

Minimum $1 \cdot 10^8$ CFU /mL

COUNTRY: FRANCE

Interzonal and

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Non professional uses

Applicant: SEIPASA S.A.

Date: 30 October 2024 (Decision)

Table of Contents

1	DETAILS OF THE APPLICATION.....	3
1.1	APPLICATION BACKGROUND.....	3
1.2	ACTIVE SUBSTANCE APPROVAL.....	3
1.3	REGULATORY APPROACH	3
1.4	DATA PROTECTION CLAIMS	4
1.5	LETTER(S) OF ACCESS	5
2	DETAILS OF THE AUTHORISATION	6
2.1	PRODUCT IDENTITY	6
2.2	CLASSIFICATION AND LABELLING.....	6
2.2.1	<i>Classification and labelling in accordance with Regulation (EC) No1272/2008.....</i>	<i>6</i>
2.2.2	<i>Other phrases in compliance with Regulation (EU) No 547/2011.....</i>	<i>6</i>
2.2.3	<i>Other phrases linked to the preparation</i>	<i>6</i>
2.3	PRODUCT USES.....	8
3	RISK MANAGEMENT.....	13
3.1	REASONED STATEMENT OF THE OVERALL CONCLUSIONS TAKEN IN ACCORDANCE WITH THE UNIFORM PRINCIPLES.....	13
3.1.1	<i>Physical and chemical properties</i>	<i>13</i>
3.1.4	<i>Residues and Consumer Exposure</i>	<i>14</i>
3.1.5	<i>Environmental fate and behaviour.....</i>	<i>14</i>
3.1.6	<i>Ecotoxicology.....</i>	<i>14</i>
3.1.7	<i>Efficacy</i>	<i>15</i>
3.2	CONCLUSIONS ARISING FROM FRENCH ASSESSMENT	16
3.3	SUBSTANCES OF CONCERN FOR NATIONAL MONITORING	16
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	16
3.4.1	<i>Post-authorisation monitoring.....</i>	<i>16</i>
3.4.2	<i>Post-authorisation data requirements</i>	<i>16</i>
	APPENDIX 1 – COPY OF THE FRENCH DECISION	17
	APPENDIX 2 – COPY OF THE DRAFT PRODUCT LABEL AS PROPOSED BY THE APPLICANT	26
	APPENDIX 3 – LETTER(S) OF ACCESS	28

PART A – Risk Management

The company SEIPASA S.A., has requested marketing authorisation in France for the product FUNGISEI PRO (product code: SEIBS 701), containing 10 g/L *Bacillus subtilis* strain IAB/BS03 for use as a fungicide for non professional uses.

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 FUNGISEI PRO (SEIBS 701) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of FUNGISEI PRO (SEIBS 701) have been made using endpoints agreed in the EU peer review(s) of *Bacillus subtilis* strain IAB/BS03.

This document describes the specific conditions of use and labelling required for France for the registration of FUNGISEI PRO (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 S.A.'s application to market FUNGISEI PRO in France as a fungicide (product uses described under point 2.3). France acted as a zonal and interzonal Rapporteur Member State (izRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the European Union.

1.2 Active substance approval

Bacillus subtilis strain IAB/BS03

Commission Implementing Regulation (EU) No 2019/1605 of 27 September 2019 approving the 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 sensitisers, 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).

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

A Review Report is available (SANTE/2019/10318 rev 3, 17 July 2019).

1.3 Regulatory approach

The present application (2023-0744) 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 European Union, taking into account the worst-case uses (“risk envelope approach”)¹ – the highest application rates over the 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 4th May 2017² 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 1107/2009³, 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 546/2011⁴, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 12 April 2021⁵ 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 extrapolation⁶ 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.

1.4 Data protection claims

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/AGRGI632554A/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 <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

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

Where protection for data is being claimed for information supporting registration of FUNGISEI PRO, 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 letter of access for active substance and PPP data.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	FUNGISEI PRO
Authorisation number	2240506
Function	fungicide
Applicant	SEIPASA S.A.
Composition	10 g/L , <i>Bacillus subtilis</i> strain IAB/BS03, min 1 10 ⁸ CFU/mL
Formulation type (code)	Suspension Concentrate [Code: SC]
Packaging	Bottle HDPE (30 mL, 60 mL, 120 mL, 250 mL, 500 mL, 1L) with dosing cap Other packagings proposed by the applicant are not accepted by zRMS for non-professional users.

2.2 Classification and labelling

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

Physical hazards	
Health hazards	None
Environmental hazards	None
Hazard pictograms	None
Signal word	None
Hazard statements	None
Precautionary statements –	<i>For the P phrases, refer to the extant legislation</i>
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	-

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 non-professional uses only to the following conditions:

	Do not discharge into the sink, gutter or any other water source the non-used container leftovers and the sprayer washing water.
	To protect aquatic organisms apply at least 5 meters away from any surface water bodies (well, pond, stream, river...).

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 : Wait until the treated zone or plants have dried.
Pre-harvest interval ⁹ : not applicable
Other mitigation measures: -
<p>The label may include the following recommendations:</p> <ul style="list-style-type: none"> - Product contains <i>Bacillus subtilis</i>. Micro-organisms may have the potential to provoke sensitising reactions. - The product should not be used by immunocompromised subjects or subject under treatment with immunosuppressant agents. - The packaging should be rinsed at least twice according to the good agriculture practices. <p>The label must reflect the conditions of authorisation.</p>

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 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: 30 october 2024

PPP (product name/code): FUNGISEI PRO/SEIBS 701
 Active substance 1: Bacillus subtilis strain IAB/BS03
 Applicant: SEIPASA S.A.
 Zone(s): Zonal and interzonal ^(d)
 Verified by MS: yes
 Field of use: fungicide

Formulation type: SC ^(a, b)
 Conc. of as 1: 10 g/L 1 10⁸_ CFU/ml ^(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 and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f) RMS CONCLUSIONS
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	cfu/10 m2 or m2 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	Fruiting vegetables: solanacea: tomato, aubergine	Fn	Grey Mould <i>Botrytis cinerea</i>	foliar applicatio n spraying	BBCH 61 to 89	a) 5 b) 5	5	a) 3 mL/10m ² b) 15 mL/10m ²	a) 3x10 ⁸ cfu/10m ² b) 1.5x10 ⁹ cfu/10m ²	500- 1000 mL/10 m ²	Not necess ary	Acceptable
2	FR	Fruiting vegetables: solanacea: pepper	Fn	Grey Mould <i>Botrytis cinerea</i>	foliar applicatio n spraying	BBCH 61 to 89	a) 5 b) 5	5	a) 3 mL/10m ² b) 15 mL/10m ²	a) 3x10 ⁸ cfu/10m ² b) 1.5x10 ⁹ cfu/10m ²	500- 1000 mL/10 m ²		Acceptable
3	FR	Celery and Celery- branch	Fn	<i>Botrytis cinerea</i>	foliar applicatio n spraying	BBCH 12 to 49	a) 5 (5-7) b) 5 (5-7)	5	a) 3 mL/10m ² b) 15 mL/10m ²	a) 3x10 ⁸ cfu/10m ² b) 1.5x10 ⁹ cfu/10m ²	200- 1000 mL/10 m ²	Not applic able	Acceptable
4	FR	Baby leaf crops (including Brassica)	Fn	<i>Botrytis cinerea</i>	foliar applicatio	BBCH 12 to 49	a) 5 (5-7) b) 5 (5-7)	5	a) 3 mL/10m ² b) 15 mL/10m ²	a) 3x10 ⁸ cfu/10m ²	800- 1000	Not applic	Acceptable

		species)			n spraying					b) 1.5x10 ⁹ cfu/10m ²	mL/10 m ²	able	
5	FR	Herbs and edible flowers (chervil, celery leaves, parsley, sage, rosemary, thyme, basil and edible flowers, laurel/bay leave, tarragon, others)	Fn	<i>Botrytis cinerea</i>	foliar application spraying	BBCH 12 to 67	a) 5 (5-7) b) 5 (5-7)	5	a) 3 mL/10m ² b) 15 mL/10m ²	a) 3x10 ⁸ cfu/10m ² b) 1.5x10 ⁹ cfu/10m ²	400-1000 mL/10 m ²	Not applicable	Acceptable
6	FR	Grapes	Fn	Grey Mould <i>Botrytis cinerea</i>	foliar application spraying	BBCH 68 to 89	a) 5 (5-7) b) 5 (5-7)	5	a) 3 mL/10m ² b) 15 mL/10m ²	a) 3x10 ⁸ cfu/10m ² b) 1.5x10 ⁹ cfu/10m ²	200-1000 mL/10 m ²	Not applicable	Acceptable
7	FR,	Brassica vegetables: flowering and head brassica	Fn	Grey Mould <i>Botrytis cinerea</i>	foliar application spraying	BBCH 14 to 47	a) 5 (5-7) b) 5 (5-7)	5	a) 3 mL/10m ² b) 15 mL/10m ²	a) 3x10 ⁸ cfu/10m ² b) 1.5x10 ⁹ cfu/10m ²	800-1000 mL/10 m ²	Not applicable	Acceptable
8	FR	Leaf vegetables, herbs and edible flowers: lettuce	Fn	Downy Mildew <i>Bremia</i> spp.	foliar application spraying	BBCH 12 to 49	a) 5 (5-7) b) 5 (5-7)	5	a) 3 mL/10m ² b) 15 mL/10m ²	a) 3x10 ⁸ cfu/10m ² b) 1.5x10 ⁹ cfu/10m ²	400-1000 mL/10 m ²	Not applicable	Acceptable
9	FR	Artichoke	Fn	Downy Mildew <i>Bremia</i> spp.	foliar application spraying	BBCH 11 to 59	a) 5 (5-7) b) 5 (5-7)	5	a) 3 mL/10m ² b) 15 mL/10m ²	a) 3x10 ⁸ cfu/10m ² b) 1.5x10 ⁹ cfu/10m ²	400-1000 mL/10 m ²	Not applicable	Acceptable
10	FR	Leaf vegetables: Spinach and similar leaves (spinaches, purslanes, chards/beets leaves, prape leaves and similar species, others)	Fn	Downy Mildew <i>Peronospora</i> spp.	foliar application spraying	BBCH 12 to 49	a) 5 b) 5	(5-7)	a) 3 mL/10m ² b) 15 mL/10m ²	a) 3x10 ⁸ cfu/10m ² b) 1.5x10 ⁹ cfu/10m ²	400-1000 mL/10 m ²	Not applicable	Not acceptable (efficacy)
12	FR	Baby leaf crops (including Brassica species)	Fn	Downy mildew <i>Bremia</i> spp.	foliar application spraying	BBCH 12 to 49	a) 5 b) 5	(5-7)	a) 3 mL/10m ² b) 15 mL/10m ²	a) 3x10 ⁸ cfu/10m ² b) 1.5x10 ⁹ cfu/10m ²	400-1000 mL/10 m ²	Not applicable	Not acceptable (efficacy)
13	FR	Herbs and edible flowers (chervil, celery leaves, parsley, sage, rosemary, thyme,	Fn	Downy mildew <i>Bremia</i> spp.	foliar application spraying	BBCH 12 to 67	a) 5 b) 5	5	a) 3 mL/10m ² b) 15 mL/10m ²	a) 3x10 ⁸ cfu/10m ² b) 1.5x10 ⁹ cfu/10m ²	400-1000 mL/10 m ²	Not applicable	Acceptable

		basil and edible flowers, laurel/bay leave, tarragon, others)											
14	FR	Leaf vegetables, herbs and edible flowers: salad plants (Lamb's lettuce/ corn salads, Escaroles/Broad leaved endives, Cresses and other sprouts and shoots, Land Cresses, Roman rocket/rucola, Red mustards)	Fn	Downy Mildew <i>Bremia</i> spp.	foliar application spraying	BBCH 12 to 49	a) 5 b) 5	5	a) 3 mL/10m ² b) 15 mL/10m ²	a) 3x10 ⁸ cfu/10m ² b) 1.5x10 ⁹ cfu/10m ²	400-1000 mL/10 m ²	Not applicable	Acceptable
16	FR	Fruiting vegetables: cucurbits with edible peel: cucumber, courgette and squash	Fn	Powdery Mildew <i>Erysiphe</i> spp., <i>Sphaerotheca</i> spp.	foliar application spraying	BBCH 12 to 89	a) 5 b) 5	5	a) 3 mL/10m ² b) 15 mL/10m ²	a) 3x10 ⁸ cfu/10m ² b) 1.5x10 ⁹ cfu/10m ²	500-1000 mL/10 m ²	Not applicable	Acceptable
17	FR	Fruiting vegetables: cucurbits with inedible peel: melon, watermelon and pumpkins	Fn	Powdery Mildew <i>Erysiphe</i> spp., <i>Sphaerotheca</i> spp.	foliar application spraying	BBCH 12 to 89	a) 5 b) 5	5	a) 3 mL/10m ² b) 15 mL/10m ²	a) 3x10 ⁸ cfu/10m ² b) 1.5x10 ⁹ cfu/10m ²	400-1000 mL/10 m ²	Not applicable	Acceptable
18	FR	Tobacco	Fn	Powdery Mildew <i>Erysiphe</i> spp., <i>Sphaerotheca</i> spp.	foliar application spraying	BBCH 12 to 59	a) 5 b) 5	5	a) 3 mL/10m ² b) 15 mL/10m ²	a) 3x10 ⁸ cfu/10m ² b) 1.5x10 ⁹ cfu/10m ²	400-1000 mL/10 m ²	Not applicable	Acceptable
19	FR	Pome fruits: apple, pear, quinces, medlars, loquats/japanese medlars and others	Fn	Scab <i>Venturia</i> spp.	foliar application spraying	BBCH 57 to 89	a) 7 b) 7	5	a) 3 mL/10m ² b) 21 mL/10m ²	a) 3x10 ⁵ 3x10 ⁸ mLcfu/10m ² b) 2,1x10 ⁹ cfu/10m ²	300-1000 mL/10 m ²	Not applicable	Acceptable
20	FR	Sweet almond	Fn	Scab <i>Venturia</i> spp.	foliar application spraying	BBCH 51 to 89	a) 7 b) 7	5	a) 3 mL/10m ² b) 21 mL/10m ²	a) 3x10 ⁵ 3x10 ⁸ mLcfu/10m ² b) 2,1x10 ⁹ cfu/10m ²	300-1000 mL/10 m ²	Not applicable	Acceptable
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)													
1	FR	Fruiting vegetables: solanacea: tomato,	Gn	Grey Mould <i>Botrytis cinerea</i>	foliar application	BBCH 61 to 89	a) 5 b) 5	5	a) 0,3 mL/m ² b) 1,5 mL/m ²	a) 3x10 ⁸ cfu/10m ²	50-100 mL/m ²	Not applicable	Acceptable

		aubergine			n spraying					b) 1.5x10 ⁹ cfu/10m ²		able	
2	FR	Fruiting vegetables: solanacea: pepper	Gn	Grey Mould <i>Botrytis cinerea</i>	foliar application spraying	BBCH 61 to 89	a) 5 b) 5	5	a) 0,3 mL/m ² b) 1,5 mL/m ²	a) 3x10 ⁸ cfu/10m ² b) 1.5x10 ⁹ cfu/10m ²	50-100 mL/m ²	Not applicable	Acceptable
4	FR	Baby leaf crops (including Brassica species)	Gn	<i>Botrytis cinerea</i>	foliar application spraying	BBCH 12 to 49	a) 5 b) 5	5	a) 0,3 mL/m ² b) 1,5 mL/m ²	a) 3x10 ⁸ cfu/10m ² b) 1.5x10 ⁹ cfu/10m ²	40-100 mL/m ²	Not applicable	Acceptable
5	FR	Herbs and edible flowers (chervil, celery leaves, parsley, sage, rosemary, thyme, basil and edible flowers, laurel/bay leave, tarragon, others)	Gn	<i>Botrytis cinerea</i>	foliar application spraying	BBCH 12 to 67	a) 5 b) 5	5	a) 0,3 mL/m ² b) 1,5 mL/m ²	a) 3x10 ⁸ cfu/10m ² b) 1.5x10 ⁹ cfu/10m ²	40-100 mL/m ²	Not applicable	Acceptable
16	FR	Fruiting vegetables: cucurbits with edible peel: cucumber, courgette and squash	Gn	Powdery Mildew <i>Erysiphe spp.</i> , <i>Spaerotheca spp.</i>	foliar application spraying	BBCH 12 to 89	a) 5 b) 5	5	a) 0,3 mL/m ² b) 1,5 mL/m ²	a) 3x10 ⁸ cfu/10m ² b) 1.5x10 ⁹ cfu/10m ²	50-100 mL/m ²	Not applicable	Acceptable
17	FR	Fruiting vegetables: cucurbits with inedible peel: melon, watermelon and pumpkins	Gn	Powdery Mildew <i>Erysiphe spp.</i> , <i>Spaerotheca spp.</i>	foliar application spraying	BBCH 12 to 89	a) 5 b) 5	5	a) 0,3 mL/m ² b) 1,5 mL/m ²	a) 3x10 ⁸ cfu/10m ² b) 1.5x10 ⁹ cfu/10m ²	40-100 mL/m ²	Not applicable	Acceptable

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

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 PRO (SEIBS 701) is a suspension concentrate (SC). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a homogeneous liquid, slightly yellow 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 2 years at 20 °C in HDPE bottles (250 mL, 500 mL and 1L); neither the active ingredient content nor the technical properties were changed.

Technical characteristics are acceptable for a soluble concentrate formulation.

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

The packaging tested in the storage stability test has a capacity of 250 mL. Based on the composition of the product, interaction between packaging and the product cannot be excluded, therefore the packaging with lower volume than the packaging tested (0.015, 0.03, 0.06, 0.12L) cannot be accepted.

The packaging should be rinsed at least twice according to the good agriculture practices. Methods of analysis.

3.1.2.1 Analytical method for the formulation

Quantitative determination of viable *Bacillus subtilis* strain IAB/BS03 is based on counts of colony forming units evolving on nutrient broth agar after streak plating of serial dilutions of *Bacillus subtilis* strain IAB/BS03 samples.

3.1.2.2 Analytical methods for residues

The methods used for the determination of microbial contaminants in the product are international standard methods, validation data are not necessary.

According to the inclusion regulation of the active substance *Bacillus subtilis* IAB/BS03 2019/1605 and to the EFSA conclusions 2018;16(6):5261, no relevant metabolite or toxin was indicated in the technical active substance.

3.1.3 Mammalian Toxicology

The derivation or reference values were not considered necessary based on the absence of toxicity, infectivity and pathogenicity indications of the micro-organism.

3.1.3.1 Acute Toxicity

FUNGISEI PRO (SEIBS 701) containing 10 g/L / (1.10⁸ CFU/mL) *Bacillus subtilis* 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.

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

3.1.3.2 Operator Exposure

Based on the lack of significant toxicity, infectivity and pathogenicity potential in the available studies, the setting of reference values is not considered necessary (SANTE/2019/10318 rev3). Therefore, no unacceptable risk for operators is expected following the claimed uses.

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

Regarding the proposed packaging, the applicant claimed bottles of 30 mL, 60 mL, 120 mL, 250 mL, 500 mL, 1 L fitted with a dosing cap. Only these packagings are fitted with appropriate elements that limits the exposure when using the product and therefore are considered acceptable.

However, the packaging fitted with the syringe is not considered acceptable since it is not integrated in the cap and could be a source of cross contamination.

3.1.3.3 Bystander Exposure

Based on the lack of significant toxicity, infectivity and pathogenicity potential in the available studies, the setting of reference values is not considered necessary (SANTE/2019/10318 rev3). Therefore, no unacceptable risk for the bystander is expected following the claimed uses.

3.1.3.4 Worker Exposure

Based on the lack of significant toxicity, infectivity and pathogenicity potential in the available studies, the setting of reference values is not considered necessary (SANTE/2019/10318 rev3). Therefore, no unacceptable risk for workers is expected following the claimed uses.

3.1.3.5 Resident Exposure

Based on the lack of significant toxicity, infectivity and pathogenicity potential in the available studies, the setting of reference values is not considered necessary (SANTE/2019/10318 rev3). Therefore, no unacceptable risk for residents is expected following the claimed uses.

3.1.3.6 Relevance of metabolites

Not relevant.

3.1.3.7 Combined exposure

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, 18/07/2023), and in Annex IV of Reg. (EU) 396/2005 (Reg. (EU) 2021/2202).

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 PRO (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. The endpoints established in the EU conclusions (EFSA, 2018) were used in calculations.

Bacillus subtilis strain IAB/BS03 is naturally present in the environment (SANTE/2019/10318 rev3, July 2019; EFSA, 2018).

According to the intended uses, no PECSOIL calculation was required. PECSW derived for the active substance are used for the eco-toxicological risk assessment.

No risk of groundwater contamination for the microorganism and its metabolites is considered needed for the intended uses.

3.1.6 Ecotoxicology

The applicant provided the same core dossier for both preparations FUNGISEI (professional users) and FUNGISEI PRO (non professional users). The risk assessment performed in the core dossier for FUNGISEI covers the intended uses of FUNGISEI PRO (SEIBS 701).

zRMS highlights that at national level, it is considered that spray drift is the only significant route of contamination of surface water for amateur use. Consequently, the mitigation measures (vegetated filter strip or restriction relative to drained soils) proposed for agricultural use do not apply to amateur use.

3.1.7 Efficacy

The effectiveness of FUNGISEI PRO (SEIBS 701) is considered variable and partial for all the uses claimed, with the exception of use on downy mildew of cabbage and spinach. However, it is considered acceptable for this type of micro-organism-based product.

Given the absence of data or possible extrapolation for use on downy mildew on cabbage and spinach, the assessment of the effectiveness of FUNGISEI PRO (SEIBS 701) for these uses cannot be finalised.

The risk of phytotoxicity of FUNGISEI PRO (SEIBS 701) is considered negligible for all the claimed uses.

The risk of negative impact on following and adjacent crops is considered negligible.

Given the data provided, particular attention should be paid to the conditions of use of the product to ensure biological compatibility with other plant protection products.

The risk of resistance to *Bacillus subtilis* IAB/BS03 is low.

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 12 months regarding:

Results on positive and negative control of the analytical method (BT077/11) for the determination of the active ingredient content “*Bacillus subtilis* IAB/BS03” in the SC product “FUNGISEI PRO” should be provided.

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

Docusign Envelope ID: B61E8E5E-3684-4B90-B089-510A917D2AA6



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 et la demande associée du produit phytopharmaceutique **FUNGISEI PRO***

*de la société SEIPASA SA
enregistrées sous les n° 2023-0744 et 2023-2307*

Vu les conclusions de l'évaluation de l'Anses du 17 juillet 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.

Informations générales sur le produit		
Nom du produit	FUNGISEI PRO	
Type de produit	Deuxième gamme	
Titulaire	SEIPASA SA C/ Almudévar 2 22240 TARDIENTA (HUESCA) Espagne	
Formulation	Suspension concentrée (SC)	
Contenant	1.10 ⁸ UFC/mL - <i>Bacillus subtilis</i> souche IAB/BS03	
Produit de référence	Nom commercial	FUNGISEI
	N° AMM	2220430
Numéro d'intrant	142-2023.01	
Numéro d'AMM	2240506	
Fonction	Fongicide	
Gamme d'usage	Amateur / emploi autorisé dans les jardins	
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. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 20 octobre 2035.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) n° 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 30/10/2024

DocuSigned by:

 AE201A955A42454

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 : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	Contenance
Bouteilles en polyéthylène haute densité munie d'un bouchon doseur avec système anti-débordement.	30 mL ; 60 mL ; 120 mL ; 250 mL ; 500 mL ; 1 L

Les emballages de contenances inférieures à 25 mL sont refusés car les données disponibles ne permettent pas de s'assurer de la stabilité du produit dans ces emballages.

Les emballages équipés d'un bouchon sécurité enfant et d'une seringue doseuse non intégrée à la bouteille sont refusés car ils ne permettent pas de garantir une exposition minimale de l'utilisateur non professionnel.

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.

Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.

En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêté du 20/11/2021)
12103205 Amandier*Trt Part.Aer.*Tavelure(s) et polystigma	3 mL/10 m ²	7/an	entre les stades BBCH 51 et BBCH 89	3	5	-	-	Non pertinent
Intervalle minimum entre les applications : 5 jours.								
16103202 Artichaut*Trt Part.Aer.*Mildiou(s)	3 mL/10 m ²	5/an	entre les stades BBCH 11 et BBCH 59	1	5	-	-	Non pertinent
Intervalle minimum entre les applications : 5 jours.								
16203207 Carotte*Trt Part.Aer.*Pourriture grise et sclérotinioses	3 mL/10 m ²	5/an	entre les stades BBCH 12 et BBCH 49	1	5	-	-	Non pertinent
Uniquement sur céleri rave. Efficacité montrée sur <i>Botrytis cinerea</i> . Intervalle minimum entre les applications : 5 jours.								
01109004 Céleri-branche*Trt Part.Aer.*Pourriture grise et sclérotinioses	3 mL/10 m ²	5/an	entre les stades BBCH 12 et BBCH 49	1	5	-	-	Non pertinent
Efficacité montrée sur <i>Botrytis cinerea</i> . Intervalle minimum entre les applications : 5 jours.								

Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêt du 20/11/2021)
00516052 Choux feuillus*Trt Part.Aer.*Pourriture grise et sclérotinioses	3 mL/10 m ²	5/an	entre les stades BBCH 12 et BBCH 49	1	5	-	-	Non pertinent
Également autorisé sous abri. Efficacité montrée sur <i>Botrytis cinerea</i> . Intervalle minimum entre les applications : 5 jours.								
16403203 Choux*Trt Part.Aer.*Pourriture grise et sclérotinioses	3 mL/10 m ²	5/an	entre les stades BBCH 14 et BBCH 47	1	5	-	-	Non pertinent
Efficacité montrée sur <i>Botrytis cinerea</i> . Intervalle minimum entre les applications : 5 jours.								
16463201 Cresson alenois*Trt Part.Aer.*Mildiou(s)	3 mL/10 m ²	5/an	entre les stades BBCH 12 et BBCH 49	1	5	-	-	Non pertinent
Intervalle minimum entre les applications : 5 jours.								
16473201 Cresson de fontaine*Trt Part.Aer.*Mildiou(s)	3 mL/10 m ²	5/an	entre les stades BBCH 12 et BBCH 49	1	5	-	-	Non pertinent
Intervalle minimum entre les applications : 5 jours.								

Liste des usages autorisés								
En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ. En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.								
Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêté du 20/11/2021)
16323203 Cucurbitacées à peau comestible*Trt Part.Aer.*Oïdium(s)	3 mL/10 m ²	5/an	entre les stades BBCH 12 et BBCH 89	1	5	-	-	Non pertinent
	Également autorisé sous abri. Intervalle minimum entre les applications : 5 jours.							
16753205 Cucurbitacées à peau non comestible*Trt Part.Aer.*Oïdium(s)	3 mL/10 m ²	5/an	entre les stades BBCH 12 et BBCH 89	1	5	-	-	Non pertinent
	Également autorisé sous abri. Intervalle minimum entre les applications : 5 jours.							
19153202 Fines Herbes*Trt Part.Aer.*Mildiou(s)	3 mL/10 m ²	5/an	entre les stades BBCH 12 et BBCH 67	1	5	-	-	Non pertinent
	Intervalle minimum entre les applications : 5 jours. 5 applications maximum par an et par culture.							
16823204 Fines Herbes*Trt Part.Aer.*Pourriture grise et sclérotinioses	3 mL/10 m ²	5/an	entre les stades BBCH 12 et BBCH 67	1	5	-	-	Non pertinent
	Également autorisé sous abri. Efficacité montrée sur <i>Botrytis cinerea</i> . Intervalle minimum entre les applications : 5 jours. 5 applications maximum par an et par culture.							

Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
 En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêté du 20/11/2021)
12603203 Fruits à pépins*Trt Part.Aer.*Tavelure(s)	3 mL/10 m ²	7/an	entre les stades BBCH 57 et BBCH 89	3	5	-	-	Non pertinent
Intervalle minimum entre les applications : 5 jours.								
16603207 Laitue*Trt Part.Aer.*Mildiou(s)	3 mL/10 m ²	5/an	entre les stades BBCH 12 et BBCH 49	1	5	-	-	Non pertinent
Intervalle minimum entre les applications : 5 jours. 5 applications maximum par an et par culture.								
16603201 Laitue*Trt Part.Aer.*Pourriture grise et sclérotinioses	3 mL/10 m ²	5/an	entre les stades BBCH 12 et BBCH 49	1	5	-	-	Non pertinent
Également autorisé sous abri. Efficacité montrée sur <i>Botrytis cinerea</i> . Intervalle minimum entre les applications : 5 jours. 5 applications maximum par an et par culture.								
16863201 Poivron*Trt Part.Aer.*Pourriture grise et sclérotinioses	3 mL/10 m ²	5/an	entre les stades BBCH 61 et BBCH 89	1	5	-	-	Non pertinent
Également autorisé sous abri. Efficacité montrée sur <i>Botrytis cinerea</i> . Intervalle minimum entre les applications : 5 jours.								

Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.

En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêté du 20/11/2021)
15853201 Tabac*Trt Part.Aer.*Oïdium(s)	3 mL/10 m ²	5/an	entre les stades BBCH 12 et BBCH 59	Non applicable	5	-	-	Non pertinent
Intervalle minimum entre les applications : 5 jours.								
16953203 Tomate - Aubergine*Trt Part.Aer.*Pourriture grise et sclérotinioses	3 mL/10 m ²	5/an	entre les stades BBCH 61 et BBCH 89	1	5	-	-	Non pertinent
Également autorisé sous abri. Efficacité montrée sur <i>Botrytis cinerea</i> . Intervalle minimum entre les applications : 5 jours.								
12703205 Vigne*Trt Part.Aer.*Pourriture grise	3 mL/10 m ²	5/an	entre les stades BBCH 68 et BBCH 89	1	5	-	-	Non pertinent
Efficacité montrée sur <i>Botrytis cinerea</i> . Intervalle minimum entre les applications : 5 jours.								

Conditions d'emploi du produit

Stockage et manipulation du produit

- Ne doit pas être utilisé par des personnes fortement immunodéprimées ou sous traitement immunosuppresseur.

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

- Attendre le séchage complet de la zone traitée.

Respect des limites maximales de résidus (LMR)

Le délai avant récolte est fixé à 1 ou 3 jours 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

- Ne pas rejeter dans l'évier, le caniveau ou tout autre point d'eau les fonds de bidon non utilisés et les eaux de lavage du pulvérisateur.

Protection de la faune

- Pour protéger les organismes aquatiques, ne pas appliquer à moins de 5 mètres d'un point d'eau (puits, bassin, mare, ruisseau, rivière, fossé...).

Recommandations relatives à l'étiquette du produit

Il est recommandé de faire figurer l'information suivante sur l'étiquette :

- Contient du *Bacillus subtilis*. Peut provoquer des réactions de sensibilisation.

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

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

FUNGISEI PRO

Nom homologué : FUNGISEI PRO

N° d'AMM : xxxx (Emploi autorisé dans les jardins)

Détenteur de l'AMM : SEIPASA S.A., C/ Almudévar, 2, 22240 Tardienta (Huesca), Espagne

Type d'action : Fongicide

Formulation : Suspension Concentrée (SC)

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

Classification :

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

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

Emballage : XX L

Distributeur en France : XXXX

N° de lot et date de fabrication : indiqué sur l'emballage.

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

Usages autorisés :

Culture/Organisme nuisible	Dose d'emploi
Tomate, aubergine, poivron/ Pourriture grise (En plein champ et sous serre)	3 mL/10m ²
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)/pourriture grise (En plein champ et sous serre)	3 mL/10m ²
Fines herbes (plantes liliacées dont la ciboule et la ciboulette, plantes apiacées dont persil, cerfeuil, feuilles de fenouil, angélique et carvi et plantes lamiaées comme basilic, thym et sauge)/Pourriture grise (En plein champ et sous serre)	3 mL/10m ²
Vigne/Pourriture grise (En plein champ)	3 mL/10m ²
Choux, choux à inflorescences (Choux fleurs, brocoli et autres), choux feuillus (choux verts (type non pommés), choux chinois et autres), choux pommés, choux de Bruxelles et autres, choux-raves/ Pourriture grise (En plein champ)	3 mL/10m ²
Laitues, chicorées – scaroles, chicorées – frisées, mâche, roquette et autres salades, épinard feuilles de bettes, pourpier, céleri-rave, céleri-branches, cresson alénois, 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)/Mildiou (En plein champ)	3 mL/10m ²
Artichaut/Mildiou (En plein champ)	3 mL/10m ²
Fines herbes (plantes liliacées dont la ciboule et la ciboulette, plantes apiacées dont persil, cerfeuil, feuilles de fenouil, angélique et carvi et plantes lamiaées comme basilic, thym et sauge)/Mildiou (En plein champ)	3 mL/10m ²
Concombre, courgette, cornichon et autres cucurbitacées à peau comestible, melon, pastèque, potiron et autres cucurbitacées à peau non comestible/ Oïdium (sous serre)	3 mL/10m ²
Tabac / Oïdium (En plein champ)	3 mL/10m ²
Pommier, poirier, cognassier, nèfles, nashi, pommette/Tavelure (En plein champ)	3 mL/10m ²
Amandier/Tavelure (En plein champ)	3 mL/10m ²

MODE D'EMPLOI

d'incident en cours d'application, arrêter l'application, ne pas porter les mains ou les gants souillés à la bouche. Après l'ap

Elimination du produit et de l'emballage

– Lors de la dernière utilisation, rincer trois fois à l'eau,

–

près d'un point d'eau ou dans les sanitaires.

– Réemploi de l'emballage interdit. Ne pas jeter dans les poubelles ménagères.

d'urgence,

et recommandations d'emploi mentionnés sur
l'emballage qui ont été déterminés en fonction des

Appendix 3 – Letter(s) of Access

Provided upon request.