

REGISTRATION REPORT

Part A

Risk Management

Product code: -

Product name(s): BOTECTOR

Active Substance(s):

Aureobasidium pullulans strains DSM 14940

2.5 10⁹ CFU/g

Aureobasidium pullulans strains DSM 14941

2.5 10⁹ CFU/g

Interzonal and

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(label extension)

Applicant: : SAN Agrow Holding GmbH

Date: 6 November 2025

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.....	5
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 product.....</i>	<i>6</i>
2.3	PRODUCT USES.....	7
3	RISK MANAGEMENT.....	20
3.1	REASONED STATEMENT OF THE OVERALL CONCLUSIONS TAKEN IN ACCORDANCE WITH THE UNIFORM PRINCIPLES.....	20
3.1.1	<i>Physical and chemical properties.....</i>	<i>20</i>
3.1.2	<i>Methods of analysis.....</i>	<i>20</i>
3.1.3	<i>Mammalian Toxicology.....</i>	<i>20</i>
3.1.3.6	RELEVANCE OF METABOLITES.....	21
3.1.4	<i>Residues and Consumer Exposure.....</i>	<i>21</i>
3.1.5	<i>Environmental fate and behaviour.....</i>	<i>21</i>
3.1.6	<i>Ecotoxicology.....</i>	<i>22</i>
3.1.7	<i>Efficacy.....</i>	<i>22</i>
3.2	CONCLUSIONS ARISING FROM FRENCH ASSESSMENT.....	23
3.3	SUBSTANCES OF CONCERN FOR NATIONAL MONITORING.....	23
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.....	23
3.4.1	<i>Post-authorisation monitoring.....</i>	<i>23</i>
3.4.2	<i>Post-authorisation data requirements.....</i>	<i>23</i>
3.4.3	<i>Label amendments.....</i>	<i>23</i>
	APPENDIX 1 – COPY OF THE FRENCH DECISION.....	24
	APPENDIX 2 – COPY OF THE DRAFT PRODUCT LABEL AS PROPOSED BY THE APPLICANT.....	24
	APPENDIX 3 – LETTER(S) OF ACCESS.....	29

PART A – Risk Management

The company SAN Agrow Holding GmbH has requested a marketing authorisation in France for the product BOTECTOR, containing 2.5 10⁹ CFU/g minimum of *Aureobasidium pullulans* strains DSM 14940 and 2.5 10⁹ CFU/g minimum of *Aureobasidium pullulans* strains DSM 14941 for use as a fungicide for 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 BOTECTOR where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of SAN Agrow Holding GmbH have been made using endpoints agreed in the EU peer review(s) of *Aureobasidium pullulans* strains DSM 14940 and *Aureobasidium pullulans* strains DSM 14941.

This document describes the specific conditions of use and labelling required for France for the registration of BOTECTOR.

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 SAN Agrow Holding GmbH's application submitted on 31/08/2023 (2023-2938) for a label extension of the product BOTECTOR in France (product uses described under point 2.3). France acted as a zonal (zRMS) and an interzonal Rapporteur Member State (izRMS) for this request and assessed the application submitted for the label extension of this product in France and in other Member States (MSs) of the European Union.

1.2 Active substance approval

Aureobasidium pullulans (strains DSM 14940 and DSM 14941)

Commission Implementing Regulation (EU) No 827/2013 of 29 August 2013 approving the active substance *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941), 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 540/2011 were as follows :

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941), and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941) is to be considered as a potential sensitizer. Conditions of use shall include risk mitigation measures, where appropriate.

An EFSA conclusion is available (EFSA Journal 2013;11(4):3183).

A Review Report is available (SANCO/11104/2013 rev 1 16 July 2013).

1.3 Regulatory approach

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

The French Order of 4th May 2017¹ 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 1107/2009², 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 546/2011³, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Moreover, the French Order of 12 April 2021⁴ 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 extrapolation⁵ is to supply “minor” crops with registered plant protection products.

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

Finally, the French Order of 20 November 2021⁶ on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless otherwise stated in the product authorisation, use on attractive crop⁷ when in flower and on foraging area is forbidden. Specific conditions of application on flowering crops should be respected. As consequences specific SPE 8 may include reference to this order.

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

¹ 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>

² REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

³ 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

⁴ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

⁵ SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

⁶ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734>

⁷ List of culture considered as unattractive to bees and other pollinators insects defined by French Agricultural ministry and published in Bulletin Officiel du ministère chargé de l'agriculture.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of BOTECTOR, 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

Not necessary: the applicant is the owner of the active substance.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	BOTECTOR
Authorisation number	2120082
Function	Fungicide
Applicant	SAN AGROW HOLDING GmbH
Composition	<i>Aureobasidium pullulans</i> souche DSM 14940, 2.5 10 ¹² UFC/kg <i>Aureobasidium pullulans</i> souche DSM 14941 2.5 10 ¹² UFC/kg
Formulation type (code)	Water-dispersible granule [WG]
Packaging	Packaging not changed

2.2 Classification and labelling

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

Classification not changed.

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

The authorisation of the product is linked for professional uses only to the following conditions:

SP 1	Do not contaminate water with the product or its container. Do not clean application equipment near surface water. Avoid contamination via drains from farmyards and roads.
SPe 3	To protect aquatic organisms respect an unsprayed buffer zone of 5 meters ⁸ to surface water bodies for in-field and walk-in tunnel uses.
SPe 2	To protect aquatic organisms do not discharge waste water from soil-less greenhouses directly into surface water.

2.2.3 Other phrases linked to the product

Wear suitable personal protective equipment ⁹ : refer to the Decision in Appendix 1 for the details
Re-entry period ¹⁰ : - field uses: 6 hours - indoor uses: 8 hours
Pre-harvest interval ¹¹ : Not necessary
Other mitigation measures: - Contains <i>Aureobasidium pullulans</i> . Micro-organisms may have the potential to provoke sensitising reactions - the product should not be used by subjects affected by immunodeficiency or in treatment with immunosuppressive agents
The label may include the following recommendations: The label must reflect the conditions of authorisation.

⁸ in consistency with French Order of 4 May 2017 (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), modified by the French Order of 27 December 2019.

⁹ If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

¹⁰ 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]

¹¹ 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.

Remarks:

PPP (product name/code):	< BOTECTOR / BOTECTOR	Formulation type:	WG ^(a, b)
Active substance 1:	< <i>Aureobasidium pullulans</i> strains DSM 14940 >	Conc. of as 1:	2.5 x 10 ¹² CFU/Kg ^(c)
Active substance 2:	< <i>Aureobasidium pullulans</i> strains DSM 14941 >	Conc. of as 2:	2.5 x 10 ¹² CFU/Kg ^(c)
Applicant:	SAN AGROW HOLDING GmbH	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	Zonal (southern) and interzonal ^(d)	Non professional use:	<input type="checkbox"/>
Verified by MS:	yes		
Field of use:	fungicide		

GAP rev. 0, date: 2025-11

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 CONCLUSION
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/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	Apricots <i>Prunus armeniaca</i> (PRNAR)	F	<i>Monilia spp.</i> (1MONIG) <i>Botrytis cinerea</i> (BOTRCI) <i>Colletotrichum spp.</i> (COLLSP)	Foliar spray	BBCH 61-89	a) 6 b) 6	7 days	a) 1 b) 6	a) 5 10 ¹² CFU/ha (1000 g/ha) b) 15 10 ¹² CFU/ha (6000 g/ha)	200- 1000	-Not neces sary	Acceptable (*)
2	FR	Cherries <i>Prunus avium</i>	F	<i>Monilia spp.</i> (1MONIG)	Foliar spray	BBCH 61-89	a) 6 b) 6	7 days	a) 1	a) 5 10 ¹² CFU/ha (1000	200- 1000	Not neces	Acceptable (*)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ⁽⁶⁾	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ⁽⁶⁾ RMS CONCLUSION
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
		(PRNAV) / <i>Prunus cerasus</i> (PRNCE)		<i>Botrytis cinerea</i> (BOTRCI) <i>Colletotrichum spp.</i> (COLLSP)					b) 6	g/ha b) 30 10 ¹² CFU/ha (6000 g/ha)		sary	
3	: FR	Peaches <i>Prunus persica</i> (PRNPS) / <i>Prunus persica</i> var. nucipersica (PRNPN)	F	<i>Monilia spp.</i> (1MONIG) <i>Botrytis cinerea</i> (BOTRCI) <i>Colletotrichum spp.</i> (COLLSP)	Foliar spray	BBCH 61-89	a) 6 b) 6	7 days	a) 1 b) 6	a) 5 10 ¹² CFU/ha (1000 g/ha) b) 30 10 ¹² CFU/ha (6000 g/ha)	200- 1000	Not neces sary	Acceptable (*)
4	zRMS: FR	Plums <i>Prunus domestica</i> (PRNDO)	F	<i>Monilia spp.</i> (1MONIG) <i>Botrytis cinerea</i> (BOTRCI) <i>Colletotrichum spp.</i> (COLLSP)	Foliar spray	BBCH 61-89	a) 6 b) 6	7 days	a) 1 b) 6	a) 5 10 ¹² CFU/ha (1000 g/ha) b) 30 10 ¹² CFU/ha (6000 g/ha)	200- 1000	Not neces sary	Acceptable (*)
5	zRMS: FR	Almonds <i>Prunus dulcis</i> (PRNDU)/ <i>Prunus dulcis</i> var. <i>amara</i> (PRNDA)	F	<i>Monilia spp.</i> (1MONIG) <i>Botrytis cinerea</i> (BOTRCI) <i>Colletotrichum spp.</i> (COLLSP)	Foliar spray	BBCH 61-89	a) 6 b) 6	7 days	a) 1 b) 6	a) 5 10 ¹² CFU/ha (1000 g/ha) b) 30 10 ¹² CFU/ha (6000 g/ha)	1000 L/100 00 m ² L WA	Not neces sary	Acceptable (*)
6	zRMS: FR	Canefruits Blackberries <i>Rubus fruticosus</i> (RUBFR) Dewberries <i>Rubus</i> <i>caesius</i> (RUBCA)	F	<i>Botrytis cinerea</i> (BOTRCI)	Spray	BBCH 51-89	a) 6 b) 6	7 days	a) 1 b) 6	a) 5 10 ¹² CFU/ha (1000 g/ha) b) 30 10 ¹² CFU/ha	200- 1000	Not neces sary	Acceptable (*)

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, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f) RMS CONCLUSION
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
		Raspberries <i>Rubus idaeus</i> (RUBID)								(6000 g/ha)			
7	FR	Others small fruits and berries Blueberries <i>Vaccinium corymbosum</i> (VACCO) Cranberries <i>Vaccinium oxycoccos</i> (VACOX) Currants (black, red and white) <i>Ribes sp.</i> (RIBSS) Gooseberries (green, red and yellow) <i>Ribes uva-crispa</i> (RIBUC) Rose hips <i>Rosa canina</i> (ROSCN) Mulberries (black and white) <i>Morus alba</i> (MORAL) Azaroles/Mediterr anean medlars <i>Crataegus azarolus</i> (CSCAZ) Elderberries <i>Sambucus nigra</i> (SAMNI)	F	<i>Botrytis cinerea</i> (BOTRCI)	Spray	BBCH 51-89	a) 6 b) 6	7 days	a) 1 b) 6	a) 5 10 ¹² CFU/ha (1000 g/ha) b) 30 10 ¹² CFU/ha (6000 g/ha)	200- 1000	Not neces sary	Acceptable (*)

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, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f) RMS CONCLUSION
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
8	zRMS: FR	Spinaches and similar leaves 3CHEC <i>Spinach Spinacia oleracea</i> (SPQOL), Purlanes <i>Portulaca oleracea</i> (POROL), Chard/beet leaves <i>Beta vulgaris subsp. vulgaris var. cicla</i> (BEAVV)	F	<i>Botrytis cinerea</i> (BOTRCI) <i>Bremia lactucae</i> (BREMLA) <i>Sclerotinia</i> (1SCLEG)	Spray	BBCH 13-49	a) 5 b) 5	7 days	a) 1 b) 5	a) 5 10 ¹² CFU/ha (1000 g/ha) b) 25 10 ¹² CFU/ha (5000 g/ha)	700 1000 L/ha	Not neces sary	Not acceptable (efficacy)
9	zRMS: FR	Grape leaves and similar species <i>Vitis vinifera</i> (VITVI)	F	<i>Botrytis cinerea</i> (BOTRCI) <i>Bremia lactucae</i> (BREMLA) <i>Sclerotinia</i> (1SCLEG)	Spray	BBCH 13-49	a) 5 b) 5	7 days	a) 1 b) 5	a) 5 10 ¹² CFU/ha (1000 g/ha) b) 25 10 ¹² CFU/ha (5000 g/ha)	700 1000 L/ha	Not neces sary	Not acceptable (efficacy)
10	zRMS: FR	Watercresses <i>Nasturtium officinale</i> (NAAOF)	F	<i>Botrytis cinerea</i> (BOTRCI) <i>Bremia lactucae</i> (BREMLA) <i>Sclerotinia</i> (1SCLEG)	Spray	BBCH 13-49	a) 5 b) 5	7 days	a) 1 b) 5	a) 5 10 ¹² CFU/ha (1000 g/ha) b) 25 10 ¹² CFU/ha (5000 g/ha)	700 1000 L/ha	Not neces sary	Acceptable
11	zRMS: FR	Witloofs/Belgian endives	F	<i>Botrytis cinerea</i> (BOTRCI)	Spray	BBCH 13-49	a) 5 b) 5	7 days	a) 1 b) 5	a) 5 10 ¹² CFU/ha (1000	700 1000	Not neces	Not acceptable (efficacy)

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 CONCLUSION
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
		<i>Cichorium intybus</i> var. <i>foliosum</i> (CICIF)		<i>Bremia lactucae</i> (BREMLA) <i>Sclerotinia</i> (1SCLEG)						g/ha b) 25 10 ¹² CFU/ha (5000 g/ha)	L/ha	sary	
12	zRMS: FR	Herbs and edible flowers 3HERC <i>Anthriscus</i> <i>cerefolium</i> (ANRCE), <i>Allium</i> <i>schoenoprasum</i> (ALLSC), <i>Apium graveolens</i> (APUGV), <i>Petroselinum</i> <i>crispum</i> (PARCR), <i>Salvia officinalis</i> (SALOF) <i>Salvia</i> <i>rosmarinus</i> (RMSOF) <i>Thymus praecox</i> (THYPR) <i>Ocimum</i> <i>basilicum</i> (OCIBA) and edible flowers <i>Laurus nobilis</i> (LURNO) <i>Artemisia glauca</i> (ARTGL) Others	F	<i>Botrytis cinerea</i> (BOTRCI) <i>Bremia lactucae</i> (BREMLA) <i>Sclerotinia</i> (1SCLEG)	Spray	BBCH 13-49	a) 5 b) 5	7 days	a) 1 b) 5	a) 5 10 ¹² CFU/ha (1000 g/ha) b) 25 10 ¹² CFU/ha (5000 g/ha)	700 1000 L/ha	Not neces sary	Acceptable
13	zRMS: FR	Cucurbits with edible peel	F	<i>Botrytis cinerea</i> (BOTRCI)	Spray	BBCH 51-89	a) 5 b) 5	7 days	a) 1 b) 5	a) 5 10 ¹² CFU/ha (1000	700 1000	Not neces	Acceptable (*)

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, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f) RMS CONCLUSION
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
		3FCVC cucumber crops (CUMSC) gherkin crops (CUMSG) Courgettes <i>Cucurbita pepo</i> (CUUPG) Others		<i>Sclerotinia</i> (1SCLEG)						g/ha b) 25 10 ¹² CFU/ha (5000 g/ha)	L/ha	sary	
14	zRMS: FR	cucurbits with inedible peel 3FCVC Melons <i>Cucumis melo</i> (CUMME), Pumpkins <i>Cucurbita pepo</i> (CUUPE), Watermelons <i>Citrullus lanatus</i> (CITLA)	F	<i>Botrytis cinerea</i> (BOTRCI) <i>Sclerotinia</i> (1SCLEG)	Spray	BBCH 51-89	a) 5 b) 5	7 days	a) 1 b) 5	a) 5 10 ¹² CFU/ha (1000 g/ha) b) 25 10 ¹² CFU/ha (5000 g/ha)	700 1000 L/ha	Not neces sary	Acceptable (*)
15	zRMS: FR	Sweet peppers/bell peppers <i>Capsicum</i> (1CPSG)	F	<i>Botrytis cinerea</i> (BOTRCI) <i>Sclerotinia</i> (1SCLEG)	Spray	BBCH 51-89	a) 5 b) 5	7 days	a) 1 b) 5	a) 5 10 ¹² CFU/ha (1000 g/ha) b) 25 10 ¹² CFU/ha (5000 g/ha)	700 1000 L/ha	Not neces sary	Acceptable (*)
16	zRMS: FR	Lettuces and salad plants 3LETC Lamb's lettuce <i>Valerianella</i>	F	<i>Botrytis cinerea</i> (BOTRCI) <i>Bremia lactucae</i> (BREMLA) <i>Sclerotinia</i> (1SCLEG)	Spray	BBCH 13-49	a) 5 b) 5	7 days	a) 1 b) 5	a) 5 10 ¹² CFU/ha (1000 g/ha) b) 25 10 ¹²	700 - 1000 L/ha	Not neces sary	Acceptable

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, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f) RMS CONCLUSION
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
		<i>locusta</i> (VLLLO), Lettuce <i>Lactuca sativa</i> (LACSA), <i>Lactuca sativa</i> var. <i>capitata</i> (LACSC), <i>Lactuca sativa</i> var. <i>crispa</i> (LACSP), <i>Lactuca sativa</i> var. <i>longifolia</i> (LACSO), <i>Lactuca serriola</i> (LACSE), cress and rocket crops (3CRRC) Red mustards <i>Brassica juncea</i> (BRSJU) Baby leaf crops								CFU/ha (6000 g/ha)			
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	zRMS: FR	Canefruits Blackberries <i>Rubus fruticosus</i> (RUBFR) Dewberries <i>Rubus caesius</i> (RUBCA) Raspberries <i>Rubus idaeus</i> (RUBID)	G	<i>Botrytis cinerea</i> (BOTRCI)	Spray	BBCH 51-89	a) 6 b) 6	7 days	a) 1 b) 6	a) 5 10 ¹² CFU/ha (1000 g/ha) b) 30 10 ¹² CFU/ha (6000 g/ha)	1000 L/ha	Not neces sary	Acceptable (*)
2	zRMS:	Others small	G	<i>Botrytis cinerea</i>	Spray	BBCH 51-89	a) 6	7 days	a) 1	a) 5 10 ¹²	1000	Not	Acceptable (*)

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, Fpn G, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f) RMS CONCLUSION
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
	FR	fruits and berries Blueberries <i>Vaccinium corymbosum</i> (VACCO) Cranberries <i>Vaccinium oxycoccos</i> (VACOX) Currants (black, red and white) <i>Ribes sp.</i> (RIBSS) Gooseberries (green, red and yellow) <i>Ribes uva-crispa</i> (RIBUC) Rose hips <i>Rosa canina</i> (ROSCN) Mulberries (black and white) <i>Morus alba</i> (MORAL) Azaroles/Mediterr anean medlars <i>Crataegus azarolus</i> (CSCAZ) Elderberries <i>Sambucus nigra</i> (SAMNI)		(BOTRCI)			b) 6		b) 6	CFU/ha (1000 g/ha) b) 30 10 ¹² CFU/ha (6000 g/ha)	L/ha	neces sary	

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ⁽⁶⁾	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 ⁽⁶⁾ RMS CONCLUSION
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
3	zRMS: FR	Lettuces and salad plants 3LETC Lamb's lettuce <i>Valerianella</i> <i>locusta</i> (VLLLO) , Lettuce <i>Lactuca sativa</i> (LACSA), <i>Lactuca sativa</i> <i>var. capitata</i> (LACSC), <i>Lactuca sativa</i> <i>var. crispa</i> (LACSP), <i>Lactuca sativa</i> <i>var. longifolia</i> (LACSO), <i>Lactuca serriola</i> (LACSE) cress and rocket crops (3CRRC) Red mustards <i>Brassica juncea</i> (BRSJU) Baby leaf crops	G	<i>Botrytis cinerea</i> (BOTRCI) <i>Bremia lactucae</i> (BREMLA) <i>Sclerotinia</i> (1SCLEG)	Spray	BBCH 13-49	a) 5 b) 5	7 days	a) 1 b) 5	a) 5 10 ¹² CFU/ha (1000 g/ha) b) 25 10 ¹² CFU/ha (5000 g/ha)	700 1000 L/ha	Not neces sary	Acceptable
4	zRMS: FR	Spinaches and similar leaves 3CHEC <i>Spinach Spinacia</i> <i>oleracea</i> (SPQOL), Purlanes <i>Portulaca</i>	G	<i>Botrytis cinerea</i> (BOTRCI) <i>Bremia lactucae</i> (BREMLA) <i>Sclerotinia</i> (1SCLEG)	Spray	BBCH 13-49	a) 5 b) 5	7 days	a) 1 b) 5	a) 5 10 ¹² CFU/ha (1000 g/ha) b) 25 10 ¹² CFU/ha (5000 g/ha)	700 - 1000 L/ha	Not neces sary	Not acceptable (efficacy)

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, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f) RMS CONCLUSION
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
		<i>oleracea</i> (POROL), Chard/beet leaves <i>Beta vulgaris</i> <i>subsp. vulgaris</i> <i>var. cicla</i> (BEAVV)											
5	zRMS: FR	Grape leaves and similar species <i>Vitis vinifera</i> (VITVI)	G	<i>Botrytis cinerea</i> (BOTRCI) <i>Bremia lactucae</i> (BREMLA) <i>Sclerotinia</i> (1SCLEG)	Spray	BBCH 13-49	a) 5 b) 5	7 days	a) 1 b) 5	a) 5 10 ¹² CFU/ha (1000 g/ha) b) 25 10 ¹² CFU/ha (5000 g/ha)	700 - 1000 L/ha	Not neces sary	Not acceptable (efficacy)
6	zRMS: FR	Watercresses <i>Nasturtium</i> <i>officinale</i> (NAAOF)	G	<i>Botrytis cinerea</i> (BOTRCI) <i>Bremia lactucae</i> (BREMLA) <i>Sclerotinia</i> (1SCLEG)	Spray	BBCH 13-49	a) 5 b) 5	7 days	a) 1 b) 5	a) 5 10 ¹² CFU/ha (1000 g/ha) b) 25 10 ¹² CFU/ha (5000 g/ha)	700 - 1000 L/ha	Not neces sary	Acceptable
7	zRMS: FR	Witloofs/Belgian endives <i>Cichorium</i> <i>intybus</i> var. <i>foliosum</i> (CICIF)	G	<i>Botrytis cinerea</i> (BOTRCI) <i>Bremia lactucae</i> (BREMLA) <i>Sclerotinia</i> (1SCLEG)	Spray	BBCH 13-49	a) 5 b) 5	7 days	a) 1 b) 5	a) 5 10 ¹² CFU/ha (1000 g/ha) b) 25 10 ¹² CFU/ha (5000 g/ha)	700 - 1000 L/ha	Not neces sary	Not acceptable (efficacy)

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 CONCLUSION
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
8	zRMS: FR	Herbs and edible flowers 3HERC Anthriscus cerefolium (ANRCE) Allium schoenoprasum (ALLSC) Apium graveolens (APUGV) Petroselinum crispum (PARCR) Salvia officinalis (SALOF) Salvia rosmarinus (RMSOF) <i>Thymus praecox</i> (THYPR) <i>Ocimum basilicum</i> (OCIBA) and edible flowers <i>Laurus nobilis</i> (LURNO) <i>Artemisia glauca</i> (ARTGL) Others	G	<i>Botrytis cinerea</i> (BOTRCI) <i>Bremia lactucae</i> (BREMLA) <i>Sclerotinia</i> (1SCLEG)	Spray	BBCH 13-49	a) 5 b) 5	7 days	a) 1 b) 5	a) 5 10 ¹² CFU/ha (1000 g/ha) b) 25 10 ¹² CFU/ha (5000 g/ha)	700 - 1000 L/ha		Acceptable
9	zRMS: FR	Cucurbits with edible peel 3FCVC cucumber crops (CUMSC) gherkin crops (CUMSG)	G	<i>Botrytis cinerea</i> (BOTRCI) <i>Sclerotinia</i> (1SCLEG)	Spray	BBCH 51-89	a) 5 b) 5	7 days	a) 1 kg/ha b) 5 kg/ha	a) 5 10 ¹² CFU/ha (1000 g/ha) b) 25 10 ¹² CFU/ha (5000 g/ha)	700 - 1000 L/ha	Not neces sary	Acceptable (*)

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 CONCLUSION
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
		<i>Cucurbita pepo</i> (CUUPG) Others											
10	zRMS: FR	Cucurbits with inedible peel 3FCVC <i>Cucumis melo</i> (CUMME) <i>Cucurbita pepo</i> (CUUPE) <i>Citrullus lanatus</i> (CITLA)	G	<i>Botrytis cinerea</i> (BOTRCI) <i>Sclerotinia</i> (1SCLEG)	Spray	BBCH 51-89	a) 5 b) 5	7 days	a) 1 b) 5	a) 5 10 ¹² CFU/ha (1000 g/ha) b) 25 10 ¹² CFU/ha (5000 g/ha)	700 - 1000 L/ha	Not neces sary	Acceptable (*)
11	zRMS: FR	Sweet peppers/bell peppers <i>Capsicum</i> (1CPSG)	G	<i>Botrytis cinerea</i> (BOTRCI) <i>Sclerotinia</i> (1SCLEG)	Spray	BBCH 51-89	a) 5 b) 5	7 days	a) 1 b) 5	a) 5 10 ¹² CFU/ha (1000 g/ha) b) 25 10 ¹² CFU/ha (5000 g/ha)	700 - 1000 L/ha	Not neces sary	Acceptable (*)

* The application is possible during the flowering period in line with the application of the French Order of November 20, 2021 (arrêté du 20 novembre 2021 relatif à la protection des abeilles et des autres insectes pollinisateurs et à la préservation des services de pollinisation lors de l'utilisation des produits phytopharmaceutiques).

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 | 1 | Numeration necessary to allow references | 7 | Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application |
| columns: | 2 | Use official codes/nomenclatures of EU Member States | 8 | The maximum number of application possible under practical conditions of use must be provided. |
| | 3 | For crops, the EU and Codex classifications (both) should be used; when relevant, the situation should be described (e.g. fumigation of a structure) | 9 | Minimum interval (in days) between applications of the same product |
| | 4 | F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application | 10 | For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products. |
| | 5 | Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named. | 11 | The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha). |
| | 6 | Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated. | 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

Already assessed in first market authorisation.

3.1.2 Methods of analysis

Already assessed in first market authorisation.

3.1.2.1 Analytical method for the formulation

Already assessed in first market authorisation.

3.1.2.2 Analytical methods for residues

Already assessed in first market authorisation.

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

BOTECTOR containing 5×10^9 CFU/g *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941) has a low oral, inhalation, and dermal toxicity, is not an eye irritant and is not irritating to the skin.

In addition, the label should include the phrase: “The product contains *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941). Micro-organisms may have the potential to provoke sensitising reactions.” 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 toxicity, infectivity and pathogenicity potential in the available toxicological studies the setting of toxicological reference values for the microorganism has not been considered necessary (EFSA 2013¹², *Review Report 2013*¹³). Therefore, no unacceptable risk for operators is expected following the intended uses.

Since *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941) may be responsible for opportunist infection in immunodeficient subjects, the product should not be used by immunodeficient subjects or subjects under treatment with immunosuppressant agents.

Taking into account that microorganisms are considered as potential sensitisers, adequate personal protective equipment is necessary as a condition of use.

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

¹² European Food Safety Authority (EFSA) Conclusion on the peer review of the pesticide risk assessment of the active substance *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941) EFSA Journal 2013;11(4):3183

¹³ Final Review report for the active substance *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941) SANCO/11104/2013 rev 1 13 July 2013

3.1.3.3 Bystander and Resident Exposure

Based on the lack of toxicity, infectivity and pathogenicity potential in the available toxicological studies the setting of toxicological reference values for the microorganism has not been considered necessary (EFSA 2013¹⁴, *Review Report 2013*¹⁵). Therefore, no unacceptable risk for bystander and resident is expected following the intended uses.

3.1.3.4 Worker Exposure

Based on the lack of toxicity, infectivity and pathogenicity potential in the available toxicological studies the setting of toxicological reference values for the microorganism has not been considered necessary (EFSA 2013¹⁶, *Review Report 2013*¹⁷). Therefore, no unacceptable risk for worker is expected following the intended uses.

Taking into account that microorganisms are considered as potential sensitisers, adequate personal protective equipment is necessary as a condition of use.

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

3.1.3.6 Relevance of metabolites

Not required.

3.1.4 Residues and Consumer Exposure

The intended uses of *A. pullulans* DSM 14940 and DSM 14941 do not represent a risk for the consumer.

Indeed, based on the toxicity studies it was concluded at EU level (EFSA, 2013) that the setting of dietary toxicological values were not required, and therefore that a quantitative risk assessment was not necessary for *Aureobasidium pullulans*, and then *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 were included in Annex IV of Regulation (EC) No 396/2005.

Since *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 are included in Annex IV of Regulation (EC) No 396/2005, it is considered that the risk of residue on treated crops can be considered as negligible. Consequently, it can be concluded that the intended uses of BOTECTOR (stone fruits, almonds, cane fruits, other small fruits and berries, lettuces and salad plants, spinaches and similar leaves, grape leaves and similar species, watercresses, witloofs/belgian endives, herbs and edible flowers, cucurbits with edible and inedible peel and sweet peppers and bell peppers) do not represent a risk for the consumer.

As *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 are included in Annex IV of Regulation (EC) No 396/2005, it is considered that the setting of a PHI is not considered necessary for the intended uses.

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment of the formulation have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusion (EFSA, 2013) were used in calculations.

Aureobasidium pullulans DSM 14940 and DSM 14941 strains are naturally present in the environment (EFSA, 2013).

For uses under permanent greenhouse with soil-less culture, no exposure assessment for all environmental compartments is needed.

For others intended uses, PEC_{SOIL} and PEC_{SW} derived for the active substance are used for the ecotoxicological risk assessment and mitigation measures are proposed.

¹⁴ European Food Safety Authority (EFSA) Conclusion on the peer review of the pesticide risk assessment of the active substance *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941) EFSA Journal 2013;11(4):3183

¹⁵ Final Review report for the active substance *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941) SANCO/11104/2013 rev 1 13 July 2013

¹⁶ European Food Safety Authority (EFSA) Conclusion on the peer review of the pesticide risk assessment of the active substance *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941) EFSA Journal 2013;11(4):3183

¹⁷ Final Review report for the active substance *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941) SANCO/11104/2013 rev 1 13 July 2013

No risk to groundwater contamination for the micro-organism is considered needed 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 and its metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Based on the guidance documents, the risks for birds, aquatic organisms, mammals, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants are acceptable for the intended uses in the conditions of uses described under 2.5.

3.1.7 Efficacy

For the following uses, the effectiveness data are sufficient to conclude. The effectiveness levels of the product BOTECTOR is considered variable and partial. However, these effectiveness levels are considered acceptable for this type of micro-organism-based product, given the nature of the active substance:

- *Monilia spp.* and *Botrytis cinerea* on Almond, Apricot, Cherry, Nectarine, Plum, Peach;
- *Botrytis cinerea* and *Sclerotinia spp.* on lettuce and salad plants, and by extrapolation (based on BOTRCI on strawberry, tomato, grape, lettuce) on spinaches and similar leaves, watercresses, witloofs, herbs and edible flowers, cucurbits with edible or inedible peel, grape leaves, sweet peppers and bell peppers.
- Botrytis cinerea* on canefruits, others small fruits and berries.

Given the lack of data or absence of possible extrapolation, the assessment of the level of effectiveness of product BOTECTOR for these uses cannot be finalised or not acceptable for:

- against *Colletotrichum spp.* for Almond, Apricot, Cherry, Nectarine, Plum, Peach**
- against *Bremia lactucae* on lettuces and salad plants, spinaches and similar leaves, watercresses, witloofs, and herbs and edible flowers;**

The phytotoxicity level of BOTECTOR is considered negligible for requested uses.

The risks of negative impact on yield, quality, propagation, succeeding crops and adjacent crops are considered negligible.

In the absence of specific data, a particular attention should be paid to the use conditions of the product as part of an IPM programme, in terms of biological compatibility with fungicides products or with biological control agents.

The risk of resistance to *Aureobasidium pullulans* strains DSM 14941 and 14940 is considered low and does not require a monitoring for requested uses.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation **can be granted** as proposed in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

No further information is required.

3.4.2 Post-authorisation data requirements

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

No further information is required.

3.4.3 Label amendments

The draft label proposed by the applicant in appendix 2 may be corrected with consideration of any new element under points 2.2.1 (or 2.2.2), 2.2.3 and 2.2.4.

The label shall reflect the detailed conditions stipulated in the Decision.

Appendix 1 – Copy of the French Decision



BOTECTOR_PMAJ_20
23-2938_D.pdf

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

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.

BOTECTOR®

Fongicide de biocontrôle contre pourriture grise sur fraisier, tomate, aubergines et vigne.

Quantité nette : 0.4 kg, 1.0 kg, 1.2 kg

Granulés dispersables (WG)

Numéro d'AMM: 2120082

Mode d'action: action préventive par antagonisme (compétition pour espace et nourriture)

RESERVÉ À UN USAGE EXCLUSIVEMENT PROFESSIONNEL

Utilisable en agriculture biologique conformément au règlement CE n°848/2018.



Classification selon Fongicide Resistance Action Committee (FRAC): FRAC Code: NC.

Le traitement des vergers durant la période de floraison ne représente pas une menace pour les insectes pollinisateurs.

Contenant: 2.5x10⁹ UFC/g *Aureobasidium pullulans* souche DSM 14940 et 2.5x10⁹ UFC/g *Aureobasidium pullulans* souche DSM 14941.

DISCRIPTION DU PRODUIT

Tableau des usages autorisés

Culture	Maladie (Traitement des parties aériennes)	Nombre maximum d'applications	Utilisation	Délai avant récolte	Dose maximale d'emploi
Fraisier	Pourriture grise (<i>Botrytis cinerea</i>)	6/an. Entre les stades BBCH 61 et 89.	F	1 jour	1 kg/ha
Tomate, aubergine	Pourriture grise (<i>Botrytis cinerea</i>)	5/an. Entre les stades BBCH 51 et 89.	F	1 jour	1 kg/ha
Vigne	Pourriture grise (<i>Botrytis cinerea</i>)	4/an et par parcelle Entre les stades BBCH 68 et 89.	F	3 jours	1 kg/ha pour une application sur l'ensemble de la végétation. 0.4 kg/ha pour une application dirigée sur les grappes.
Pêcher Abricotier Prunier Amandier	Moniliose, Pourriture grise (<i>Botrytis cinerea</i>), Antracnose (<i>Colletotrichum</i> spp.)	6/an (Intervalle min. entre applications : 7 Jours) BBCH 61-89	F	-	1 kg/ha (Le taux d'application et le volume d'eau doivent être adaptés au système de culture, à la densité de la culture et au stade de développement.)
Cerisier	Moniliose, Antracnose (<i>Colletotrichum</i> spp.)	6/an (Intervalle min. entre applications : 7 Jours) BBCH 61-89	F	-	1 kg/ha (Le taux d'application et le volume d'eau doivent être adaptés au système de culture, à la densité de la culture et au stade de développement.)
Framboisier Cassissier	Pourriture grise (<i>Botrytis cinerea</i>)	6/an (Intervalle min. entre applications : 7 Jours) BBCH 51-89	F, G	-	1Kg/ha

Laitue, Chicorée de Bruxelles, Epinard Vigne Cresson de fontaine Fines Herbes	Mildiou, pourriture grise (<i>Botrytis cinerea</i>), Sclérotinioses	5/an (Intervalle min. entre applications : 7 Jours) BBCH 13-49	F, G	-	1Kg/ha
Cucurbitacées à peau non comestible et à peau comestible	Pourriture grise (<i>Botrytis cinerea</i>), Sclérotinioses	5/an (Intervalle min. entre applications : 7 Jours) BBCH 51-89	F, G	-	1Kg/ha
Poivron	Pourriture grise (<i>Botrytis cinerea</i>), Sclérotinioses	5/an (Intervalle min. entre applications : 7 Jours) BBCH 51-89	F, G	-	1Kg/ha

Le délai avant récolte est fixé à 3 jours pour l'usage sur « vigne » et à 1 jour pour les usages sur « fraiser » et « tomate », conformément à la réglementation en vigueur et pour limiter l'exposition potentielle des consommateurs immunodéprimés ou sous traitement immunodépresseur.

Délai de rentrée en application de l'arrêté du 4 mai 2017 : 6 heures.

Recommandations d'utilisation :

Précautions d'emploi

L'efficacité du produit état variable et partielle, veuillez suivre les recommandations ci-après :

- 1- Nettoyer le pulvérisateur avant utilisation.
- 2- Nous recommandons d'éviter un pré-mélange fortement concentré de BOTECTOR®.
- 3- Ajoutez la quantité totale d'eau dans le réservoir. Ne pas utiliser d'eau chaude pour préparer la suspension de pulvérisation.
- 4- BOTECTOR® doit être ajouté à l'eau sous agitation.

Maintenir l'agitation pendant l'application. Utiliser la suspension dans les 8 heures. Ne pas conserver un reste dans la cuve. L'application de certains fongicides contre d'autres maladies sur le verger peut diminuer l'efficacité de la préparation BOTECTOR®. Pour plus d'informations, un tableau de compatibilité est disponible sur : www.san-agrow.com. Pour des produits qui ne sont pas miscibles, veuillez respecter un intervalle de sulfatage de 3 jours avant et après le traitement avec BOTECTOR® pendant la période de mûrissement.

Stockage et manipulation du produit:

Stocker dans un endroit frais et sec. Conservation au moins 18 mois en-dessous de 20°C, conservation en stockage réfrigéré au moins 30 mois en-dessous de 8°C.

Ne pas utiliser par des personnes fortement immunodéprimées ou sous traitement immunosuppresseur.

EN CAS D'URGENCE

**Composer le 15 ou le 112 ou contacter
le centre anti-poison le plus proche**

Puis signalez vos symptômes au réseau Phyt'attitude, n° vert 0800 887 887 (appel gratuit depuis un poste fixe).

Premiers soins :

S'éloigner de la zone dangereuse.

En cas de contact cutané : Enlever tout vêtement souillé. Laver aussitôt les parties atteintes avec beaucoup d'eau et du savon. Si les troubles se prolongent, consulter un médecin.

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

En cas d'inhalation : Amener la victime à l'air libre. Si les troubles se prolongent, consulter un médecin.

En cas d'ingestion : Rincer immédiatement la bouche avec de l'eau. Ne PAS faire. Consulter immédiatement un médecin et lui montrer l'emballage ou l'étiquette.

Dans tous les cas, si les symptômes persistent ou en cas de malaise, consulter un médecin et lui présenter l'étiquette et/ou la Fiche de Données de Sécurité.

En cas d'intoxication animale : Contacter votre vétérinaire.

Avertissement:

Toute reproduction totale ou partielle de cette étiquette est interdite.

Les recommandations et les informations que nous avons données sont le résultat de tests et d'études très détaillés et approfondis. Toutefois, lors de l'utilisation, plusieurs facteurs, qui sont hors de notre contrôle, entrent en jeu (la préparation des mélanges, le mode d'utilisation, les conditions atmosphériques, etc.). C'est pour cela que nous portons la responsabilité uniquement de la qualité permanente du produit, selon sa spécification. Le risque de dommages éventuels (l'absence d'efficacité, la toxicité, la qualité des mélanges des réservoirs, etc.), résultat d'une utilisation incorrecte ou inadéquate ou provoqués par des facteurs hors de notre contrôle (comme par exemple une mauvaise conservation) relève uniquement de la responsabilité de l'utilisateur. Nous déclinons également toute responsabilité, dans le cadre permis par les articles de la loi, des conséquences ou des dommages directs ou indirects.

Détenteur de l'AMM : SAN Agrow Holding GmbH, Industriestraße 21, 3130 Herzogenburg, Autriche,
Tel : +43 2782 833 00, www.san-agrow.com

N° de lot et de date de fabrication: voir indication sur la boîte

BOTECTOR est une marque déposée du groupe SAN Group GmbH (IR-1008746)

Appendix 3 – Letter(s) of access

Not applicable.