REGISTRATION REPORT

Part A

Risk Management

Product name(s): DECCOFERM

Active Substance(s):

***Aureobasidium pullulans* strain DSM 14940, 1.10^{10} CFU/g (500 g/kg)**

***Aureobasidium pullulans* strain DSM 14941, 1.10^{10} CFU/g (500 g/kg)**

COUNTRY: FRANCE

Interzonal

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: **Bio- ferm GmbH**

Date: **2018-02-20**

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PART A – Risk Management

The company Bio-ferm GmbH has requested renewal of the marketing authorisation in France for the product DECCOFERM, containing 1.10^{10} CFU/g (500 g/kg) *Aureobasidium pullulans* strain DSM 14940 and 1.10^{10} CFU/g (500 g/kg) *Aureobasidium pullulans* strain DSM 14941 for use as a fungicide.

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 DECCOFERM where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of DECCOFERM have been made using endpoints agreed in the EU peer review(s) of *Aureobasidium pullulans*.

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

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 Bio-ferm GmbH's application to market DECCOFERM in France as a fungicide (product uses described under point 2.3). France acted as an 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

***Aureobasidium pullulans* strain *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 Review Report: SANCO/11104/2013 rev 1 ; (16 July 2013)

1.3 Regulatory approach

The present application (2014-2228) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) in the context of the interzonal 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 2017 [2] provides that:
- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight hours for indoor uses.

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

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009[3], implementing regulations, and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail.

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011[4], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[5] provides that:
- an authorisation granted for a "reference" crop applies also for "linked" crops, unless formally stated in the Decision
- the "reference" and "linked" crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "linked" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those "linked" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[6] is to supply "minor" crops with registered plant protection products.

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

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

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1 SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5

2 Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte

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

4 COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

5 http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

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

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of DECCOFERM 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 has provided sufficient data to show that access is not required.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	DECCOFERM
Authorisation number	2180042
Function	Fungicide
Applicant	Bio-ferm GmbH
Composition	1.10^{10} CFU/g (500 g/kg) *Aureobasidium pullulans* strain DSM 14940 1.10^{10} CFU/g (500 g/kg) *Aureobasidium pullulans* strain DSM 14941
Formulation type (code)	<Water dispersible granule > (WG)
Packaging	PEHD containers (0.5 kg - 1 kg) Polyester/aluminium/LDPE bags (0.5 kg- 1kg)

2.2 Classification and labelling

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

Physical hazards	-	
Health hazards	no classification for human health	
Environmental hazards	no classification for environment	
Hazard pictograms	None	
Signal word	None	
Hazard statements		
Precautionary statements –	***For the P phrases, refer to the extant legislation***	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)		Contains *Aureobasidium pullulans.* 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.

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

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

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).

2.2.3 Other phrases linked to the preparation

Wear suitable personal protective equipment[7]: refer to the Decision in Appendix 1 for the details
Re-entry period[8]: not applicable
Pre-harvest interval[9]: not applicable (for post-harvest treatment)
Other mitigation measures: Do not store in a room where temperature may be higher than 8°C.
The label may include the following recommendations: - Contains *Aureobasidium pullulans*. Micro-organisms may have the potential to provoke sensitising reactions. - The efficacy level of the product is considered as variable and partial, specify the optimal conditions of use The label must reflect the conditions of authorisation.

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

[8] The legal basis for this is **Titre I Article 3** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

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

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as 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., date: 2018-02-20

PPP (product name/code)	**DECCOFERM**	**Formulation type:**	**WG**
active substance 1	***Aureobasidium pullulans* strains DSM 14940 and DSM 14941**	**Conc. of as 1:**	**1.10^{10} CFU/g (500 g/kg)**
Applicant:	**Bio-ferm GmbH**	**professional use**	☒
Zone(s):	**EU**	**non professional use**	☐
Verified by MS: **yes**			

Crop and/ or situation (a)	**Zone**	**Product code**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)** (l)	**Remarks:** (m)
					Type (d-f)	**Conc. of as** (i)	**method kind** (f-h)	**growth stage & season** (j)	**number min max** (k)	**interval between applications (min)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
Citrus NNNCI	izRMS: FR cMS: FR, IT, ES	DECCOFERM	I	Post-harvest fungi	WG	DSM 14941: 1 10^{10} CFU/g (i.e. 500 g/kg) DSM 14940: 1 10^{10} CFU/g (i.e. 500 g/kg)	drenching or spraying	post-harvest treatment (BBCH 83)	a)1 b)2	-	4 10^{12} CFU/hL	-	-	-	Acceptable

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

3 RISK MANAGEMENT

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties

DECCOFERM is a light brown wettable to pink granule formulation with sweet odour. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. It is not explosive and has no oxidising properties. The product is not flammable nor auto flammable in the conditions of use.

The stability data indicate that the formulation is stable for 24 months at 8 °C in Aluminium coated bags (PE is in contact with the formulation) and HDPE packaging.

The suspensibility and the dispersibility are in acceptable limits at use concentrations.

Moreover, in storage stability studies, dispersibility is sometimes below the acceptable limit. As the diluted formulation is applied under continuous agitation according to the Good Agricultural Practices, no more data required. The formulation is nearly dust free.

3.1.2 Methods of analysis

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

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

Analytical methods for the determination of residues are not necessary as no residue definition has been set.

3.1.3 Mammalian Toxicology

Active substance	**ADI** mg/kg.bw/d	**ArfD** mg/kg.bw/d	**AOEL** mg/kg.bw/d	**Classification**
Aureobasidium pullulans strains DSM 14940 and 14941	Not relevant for microorganisms			"Micro-organisms may have the potential to provoke sensitizing reactions"

3.1.3.1 Acute Toxicity

The preparation DECCOFERM is not toxic by oral, dermal and inhalation route; is not irritating to the rabbit skin and eye. However, due to the presence of microorganism, the following phrase should be included on the label:

"DECCOFERM contains *Aureobasidium pullulans*. Micro-organisms may have the potential to provoke sensitising reactions "

Label of products should also indicate that the product should not be used by professionals or non-professionals affected by immunodeficiency, primary or secondary, or in treatment with immunosuppressive agents, which can significantly reduce the effectiveness of the immune system response.

3.1.3.2 Operator Exposure:

According to EFSA, the derivation or reference values were not needed based on the absence of toxicity, infectivity and pathogenicity indications of the micro-organism

Neither the UK Predictive Operator Exposure Model (POEM) nor the German BBA model is suitable for calculating a risk assessment for operators on the base of a not existing dose-effect relation.

When the potential sensitizing properties are considered and appropriate protection equipment is worn (gloves, coverall and respiratory mask), the preparation is considered safe for operators and worker based on the low toxicity profile of the microorganism.

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

3.1.3.3 Bystander and resident exposure

The micro-organism is neither toxic or infectious or pathogenic in mammals. Following the above given reasons for abstaining from an estimation of operator risk assessment, this also applies with regard to bystanders. As regard the application method, bystander and resident exposure is supposed to be negligible.

3.1.3.4 Worker Exposure

Involved in handling treated fruit during storage, wear coveralls (coat cotton / 35% polyester / 65% - minimum weight of 230 g / m²) water-repellent and certified nitrile gloves EN 374- 3.

The micro-organism is neither toxic or infectious or pathogenic in mammals, it is not expected an unacceptable risk for the worker.
For details of personal protective equipment for workers, refer to the Decision in Appendix 1.

3.1.4 Residues and Consumer Exposure

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

The available studies which investigated the natural occurrence of *Aureobasidium pullulans* confirm that the microorganism is widely distributed in nature and is present in varying amounts on pome trees as well as on other crops.
Applications of DECCOFERM for post-harvest treatment are not expected to increase significantly and durably the natural colonisation level of *A. pullulans* on citrus. Therefore it is assumed that applications of DECCOFERM are not expected to be concern for human safety.

At least 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.

The Annex IV includes substances for which no MRL are required and therefore it is considered that the risk of residue on citrus can be considered as negligible.

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.

Use of the formulated product DECCOFERM will be restricted to indoor use for storage facilities treatment after harvest. Contamination of the environment due to the proposed use of DECCOFERM may be precluded. Exposure of soil, groundwater and surface water and air is deemed to be negligible.

3.1.6 Ecotoxicology

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009.

No risk assessment is required for the non-target organisms. Since the product DECCOFERM or the MCPA.*Aureobasidium pullulans* (strains DSM 14940 and 14941) will be used post-harvest for the control of storage diseases in citrus fruit. For this use the application is done in closed buildings by drenching or spraying of the fruit and hence an exposure can be excluded.

3.1.7 Efficacy

Considering the data submitted:

- The efficacy level of DECCOFERM is considered as **variable and partial** for the claimed use. However, this is considered acceptable for this type of product based on micro-organisms.
- The risk of negative effect on fruit quality following the application of DECCOFERM is considered as negligible for the claimed use.
- The risk of resistance development or appearance to the DSM 14940 and DSM 14941 strains of *Aureobasidium pullulans* is considered as very low.
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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

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

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Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) N° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et règlementaire,

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

de la société	*BIO-FERM GMBH*
enregistrée sous le	*n°2014-2228*

Vu les conclusions de l'évaluation de l'Anses du 19 janvier 2018,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France pour les usages et dans les conditions précisés dans la présente décision et ses annexes.

La présente décision s'applique sans préjudice des autres dispositions applicables.

Avertissement :

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.

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Informations générales sur le produit	
Nom du produit	DECCOFERM
Type de produit	Produit de référence
Titulaire	BIO-FERM GMBH Technopark 1 3430 Tulln AUTRICHE
Formulation	Granulé dispersable (WG)
Contenant	1 10^{10} UFC/g - *Aureobasidium pullulans* souche DSM 14940 1 10^{10} UFC/g - *Aureobasidium pullulans* souche DSM 14941
Numéro d'intrant	9659-2014.01
Numéro d'AMM	2180042
Fonction	Fongicide
Gamme d'usages	Professionnel

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active qui arrivera à échéance le plus tôt. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 janvier 2025.

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

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

A Maisons-Alfort, le 20 FEV. 2018

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

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ANNEXE I : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	**Contenance**
Bidons en polyéthylène haute densité	0,5 kg ; 1 kg
Sacs multicouches en polyester / aluminium / polyéthylène basse densité	0,5 kg ; 1 kg

Classification du produit
La classification retenue est la suivante : Sans classement.
Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.

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Liste des usages autorisés

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
12054201 Agrumes*Trt Prod. Réc.* Maladies de conservation	**0,2 kg/hL**	**2/an**	F (post-récolte)	Non applicable	-	-	-	-
Efficacité montrée sur *Penicillium sp.* et *Geotrichum sp.* Application sur fruits récoltés (par trempage, douchage, etc.).								

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Conditions d'emploi du produit

Stockage et manipulation du produit

- Ne pas stocker le produit dans un local où la température peut dépasser 8°C.
- Ne pas utiliser par des personnes fortement immunodéprimées ou sous traitement immunosuppresseur.

Protection de l'opérateur et du travailleur

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections individuelles
- le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage).
- les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

Pour l'opérateur, porter

Dans le cadre d'une application effectuée par trempage ou aspersion

• pendant le mélange/chargement :

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3B) à porter par-dessus la combinaison précitée ;
- Protections respiratoires certifiées: demi-masque filtrant anti-aérosols certifié (EN 149) de classe FFP3 ou demi-masque certifié (EN 140) équipé d'un filtre anti-aérosols certifié (EN143) de classe P3.

• pendant l'application :

Si contact cutané ou respiratoire avec le produit

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3B) à porter par-dessus la combinaison précitée
- Gants en nitrile certifiés EN 374-3 ;
- Protections respiratoires certifiées: demi-masque filtrant anti-aérosols certifié (EN 149) de classe FFP3 ou demi-masque certifié (EN 140) équipé d'un filtre anti-aérosols certifié (EN143) de classe P3.

• pendant le nettoyage du matériel

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3B) à porter par-dessus la combinaison précitée ;
- Demi-masque filtrant anti-aérosols certifié (EN 149) de classe FFP3 ou demi-masque certifié 'EN 140) équipé d'un filtre anti-aérosols certifié (EN 143) de classe P3.

Pour le travailleur amené à manipuler les fruits traités au cours du stockage, porter

- Une combinaison de travail (cotte en coton/polyester 35%/65% - grammage d'au moins 230 g/m²) avec traitement déperlant et des gants en nitrile certifiés EN 374-3.

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Délai de rentrée en application de l'arrêté du 4 mai 2017 :
- Non pertinent pour ce type d'application.

Protection de l'environnement (milieux, faune et flore)
Protection de l'eau
- SP 1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface.

Exigences complémentaires post-autorisation

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

Détail de la demande post autorisation	Délai (mois)	Récurrence (mois)
Fournir le rapport final concernant les teneurs en substances actives microbiennes et en contaminants (*Escherichia coli,* etc.) dans le produit après stockage à 20°C.	24	-
Fournir une étude concernant les teneurs en substances actives microbiennes et en contaminants (*Escherichia coli,* etc.) dans le produit avant et après stockage 24 mois à 8°C.	24	-

Recommandations relatives à l'étiquette du produit

Il est recommandé de faire figurer les informations suivantes sur l'étiquette :
- Contient *Aureobasidium pullulans*. Peut provoquer des réactions de sensibilisation.
- L'efficacité du produit étant variable et partielle, préciser les conditions optimales d'utilisation.

DECCOFERM
AMM n°2180042

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

DeccoFerm®
Fongicide biotechnologique pour traitement post-récolte pour prévenir les maladies d'entreposage (Penicillium sp., Geotrichum sp. etc.) sur les agrumes.

Granulés dispersables (WG)
Capacité: 0.5 kg ; 1 kg

AMM N°: xy

Contient: 5x10⁹ cfu/g de *Aureobasidium pullulans* [souches DSM 14940 et DSM 14941]
Ce produit contient des microorganismes vivants! Prendre en compte la durée de stockage!

Culture	Agrumes (mandarinier, clémentinier, citronnier, oranger etc.)
Maladie	Maladies d'entreposage (Penicillium sp., Geotrichum sp. etc.)
Dose d'emploi	2 g/L
Périodes d'applications	traitement post-récolte
Maximum d'applications	2

Nettoyer le pulvérisateur avant utilisation. Utiliser la solution dans les 8 heures. Température de l'eau de plus de 35°C réduit la viabilité du microorganisme et par conséquent l'efficacité du produit. Agiter avant emploi. La solution doit être mélangée pendant l'application. Si le traitement des fruits avec de cire est envisagé, applique DeccoFerm antérieurement. Pour plus d'informations, recevoir la liste de compatibilité et la fiche de donnée de sécurité, voir www.bio-ferm.com.

Classement conforme à 1272/2008/EEC:
Sensibilisation respiratoire catégorie 1
Sensibilisation cutanée catégorie 1

Danger

EUH208:	Contient *Aureobasidium pullulans*. Peut produire une réaction allergique.
P101:	En cas de consultation d'un médecin, garder à disposition le récipient ou l'étiquette.
P102:	Tenir hors de portée des enfants.
P261:	Éviter de respirer les poussières/fumées/gaz/brouillards/vapeurs/ aérosols.
P270:	Ne pas manger, boire ou fumer en manipulant ce produit.
P280:	Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/ du visage.
P302+P352:	EN CAS DE CONTACT AVEC LA PEAU: laver abondamment à l'eau et au savon.
P304+P341:	EN CAS D'INHALATION: s'il y a difficulté à respirer, transporter la victime à l'extérieur et la maintenir au repos dans une position où elle peut confortablement respirer.
P333+P313:	En cas d'irritation ou d'éruption cutanée: consulter un médecin.
P342+P311:	En cas de symptômes respiratoires: appeler un CENTRE ANTIPOISON ou un médecin.
P363:	Laver les vêtements contaminés avant réutilisation.
EUH401:	Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.

Eviter tout contact inutile avec le produit. Une mauvaise utilisation du produit peut entraîner des problèmes de santé. Ne pas détourner l'emballage d'origine pour une autre utilisation.

Premiers secours:
Après inhalation: Donner de l'air frais.
Après contact avec la peau: Enlever les vêtements contaminés; se laver immédiatement avec de l'eau et du savon.
Après ingestion: Si les symptômes d'indisposition persistent, voir un médecin.
Après contact avec les yeux: Rincer abondamment avec de l'eau pendant 10 minutes. Si les symptômes d'indisposition persistent, voir un médecin.

Durée de stockage:
12 mois à température ambiante (≤20°C),
24 mois dans un endroit réfrigéré (≤8°C)

Conditions de stockage et manipulation:
Ne livrer que dans les emballages d'origine.
Entreposer les emballages dans un endroit frais, ventilé et sec.

Producteur/Homologation:
bio-ferm Biotechnologische Entwicklung und Produktion GmbH
Technopark 1
A - 3430 Tulln
Tel: +43 2272 660896-0
www.bio-ferm.com

Appendix 3 – Letter(s) of Access

Not applicable.