

REGISTRATION REPORT

Part A

Risk Management

Product name: LALFRESH S

Active substance:

***Clonostachys rosea* strain J1446,
minimum 1 10⁹ CFU/g (900 g/kg)**

COUNTRY: FRANCE

Interzonal

Inter-Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: Danstar Ferment AG

Date: 2021-01-22

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PART A – Risk Management

The company Danstar Ferment AG has requested a marketing authorisation and label extension in France for the product LALFRESH S according to article 51 Regulation (EC) No 1107/2009¹, containing 1x10⁹ CFU/g ; 900 g/kg *Clonostachys rosea* strain J1446 (*Gliocladium catenulatum* strain J1446) 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 LALFRESH S where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of LALFRESH S have been made using endpoints agreed in the EU peer review of *Clonostachys rosea* strain J1446.

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

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 Danstar Ferment AG's application to market LALFRESH S in France as a fungicide (product uses described under point 2.3). France acted as a interzonal Rapporteur Member State (izRMS) for this request and assessed the application submitted for the first authorisation and the label extension of this product in France and in other MSs of the European Union.

1.2 Active substance approval

Clonostachys rosea strain J1446 (*Gliocladium catenulatum* strain J1446).

Commission Implementing Regulation (EU) 2019/151 of 30 January 2019 renewing the approval of the active substance *Clonostachys rosea* strain J1446 as a low-risk active substance 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 :

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

- the specification of technical material as commercially manufactured in plant protection products, including full characterisation of potential metabolites of concern;
- the protection of operators and workers, taking into account that microorganisms are considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use;
- the studies or information from the scientific literature recently made available in relation to antifungal susceptibility of *Clonostachys rosea* J1446.

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 microbial contamination as referred to in the Working Document SANCO/12116/2012(*).

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

¹ 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

An EFSA conclusion is available (EFSA Journal 2017;15(7):4905)

A Renewal Report is available (SANTE/11655/2017 Rev 3, 13 December 2018).

1.3 Regulatory approach

The present applications (2019-3431 ; 2019-6331) were 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”)² – 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 2017³ provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight hours for indoor uses.

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

The current document (RR) based on Anses’s assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009⁴, implementing regulations, and French regulations.

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

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011⁵, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014⁶ provides that:

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

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “linked” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those “linked” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁷ is to supply “minor” crops with registered plant protection products.

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

² SANCO document “risk envelope approach”, European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the “risk envelope approach”; SANCO/11244/2011 rev. 5

³ Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs 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>

⁴ REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

⁵ COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

⁶ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRGI407093A/jo>

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

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

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of LALFRESH S, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

The applicant has provided a letter of access for active substance.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	LALFRESH S
Authorisation number	N/A : no marketing authorisation granted
Function	fungicide
Applicant	Danstar Ferment AG
Composition	900 g/kg (minimum of 1.10^9 CFU/g) <i>Clonostachys rosea</i> strain J1446
Formulation type (code)	Water-dispersible granule (WG)
Packaging	N/A : no marketing authorisation granted

2.2 Classification and labelling

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

Physical hazards	None	
Health hazards	None	
Environmental hazards	Not classified	
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

N/A : no marketing authorisation granted

2.2.3 N/A : no marketing authorisation granted Other phrases linked to the preparation

N/A : no marketing authorisation granted

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated by France as izRMS.. When the conclusion is “not acceptable”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.

GAP rev. 0, date: 2021-01-22

PPP (product name): LALFRESH S
 active substance: *Clonostachys rosea* strain J1446
 safener: -
 synergist: -
 Applicant: Danstar Ferment AG
 Zone(s): EU
 Verified by MS: yes

Formulation type: WG
 Conc. of as: minimum 1x10⁹ CFU/g ; 900 g/kg
 Conc. of safener: -
 Conc. of synergist: -
 professional use: ☒
 non-professional use: ☐

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)	g product/kg fruits min max	g a.s./kg of fruits min max	water L/kg min max		
Stone fruits	FR	-	G I	Post-harvest storage diseases <i>Monilia sp.</i> (MONILA, MONIFC, MONIFG)	WG	900 g/kg (1.10 ⁹ CFU/g)	Spraying of fruits	After fruit harvest BBCH 87-89	1	-	9 g / 1000 kg fruits	8.1 g / 1000 kg fruits (9E9 CFU/1000 kg)	3 L / 1000 kg fruits	-	Not acceptable (Risk for consumers cannot be excluded)
Minor use according to article 51															
Cherries (PRNCE)	FR	-	G I	Post-harvest storage diseases	WG	900 g/kg (1.10 ⁹ CFU/g)	Dipping of fruits	After fruit harvest BBCH 87-89	1	-	1 g / L water		-	-	Not acceptable (risk for consumers cannot be excluded)

- 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 sucking 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

LALFRESH S is water-dispersible granules. All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is brown granules with a characteristic odour. It is not explosive, has no oxidising properties, and is not flammable. In aqueous solution (1 % aqueous dispersion), it has a pH value of 6.98 at ambient temperature. The product is stable for 12 months at 4 °C and for 12 months at 25 °C in aluminum bag packaging; neither the active ingredient content nor the technical properties were changed. As physical and chemical properties were not provided after 12 months at 25 °C, these data should be provided in post-authorisation.

The relevant metabolite gliotoxin was determined in five batches and its content is lower than the acceptable limit (50 µg/kg). The content of gliotoxin and of microbial contaminants before and after storage is missing and should be provided in post-authorisation for confirmation.

Its technical characteristics are acceptable for a WG formulation.

As the wet sieve test is outside the acceptable limits, an evidence must be submitted in post-authorisation showing that the preparation may be satisfactorily applied through appropriate application equipment with no blockage using stored batches (12 months at 4 °C and 12 months at 25 °C).

Implications for labelling:

The formulation LALFRESH S must be stored between 4 °C and 25 °C for 12 months maximum.

The formulation must be shaken during the application in accordance with good agricultural practices.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

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

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

According to Regulation (EU) 2019/151, the maximal content of gliotoxin should be 50 µg/kg in MPCA. The gliotoxin content was determined in 5 batches of the product LALFRESH S using a validated method and were provided in the framework of the equivalence report (See France equivalence report June 2020).

3.1.2.2 Analytical methods for residues

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

3.1.3 Mammalian Toxicology

The derivation of reference values were not needed based on the absence of toxicity, infectivity and pathogenicity indications of the microorganism.

3.1.3.1 Acute Toxicity

LALFRESH S has a low acute oral, inhalational and dermal toxicity. It is not irritating to the rabbit skin or eye. However, no classification is warranted.

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

3.1.3.2 Operator Exposure

The EFSA model is not suitable for calculating a risk assessment for operators on the base of a not existing dose-effect relation.

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

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

3.1.3.3 Bystander Exposure

Following the above given reasons for abstaining from an estimation of operator risks, this also applies to bystanders. As regard the application method, bystander exposure is not considered relevant for indoor uses.

3.1.3.4 Worker Exposure

The microorganism is neither toxic nor infectious nor pathogenic in mammals, thus an unacceptable risk is not expected for the worker wearing appropriate protection equipment.

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

3.1.3.5 Resident Exposure

Following the above given reasons for abstaining from an estimation of operator risks, this also applies to residents. With regard to the application method, residential exposure is not considered relevant for indoor uses.

3.1.3.6 Relevance of metabolites

The possible production of the potential metabolite of concern, gliotoxin, was highlighted by EFSA because it is known to interfere with DNA synthesis and may have a genotoxic effect. However, as noted in the EFSA conclusion, no reports were identified of gliotoxin being produced by the *Clonostachys* genus. The gliotoxin content was determined in five batches and its content is lower than the acceptable limit (50 µg/kg).

Therefore, the data gap reported by EFSA is not regarded as a critical concern that would preclude renewal of approval.

3.1.4 Residues and Consumer Exposure

In the framework of the first inclusion of the active substance *Clonostachys rosea* strain J1446 (formerly *Gliocladium catenulatum* strain J1446), the strain was temporally included in Annex IV to Regulation (EC) No 395/2005 for which it is not necessary to set MRLs (Regulation (EU) 839/2008).

However, during the renewal of the active substance, the question of the production of toxins/metabolites was considered open by EFSA (2017).

Therefore, only limited uses were recommended in the Renewal report (SANTE/11655/2017 Rev 3 of 13 December 2018).

EC, 2018:

“Extension of the use pattern beyond those described above [Appendix II of review report] will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the Requirements of Article 29(1) of Regulation (EC) No 1107/2009 and of the uniform principles laid down in Regulation (EU) No 546/2011. This might in particular be the case for the risk to consumers from metabolites produced after application of the active substance, which is considered low for the uses supported by available data on the decline of the microorganism after application, but might be different for uses where last applications are closer to the time of harvest and for which the setting of a pre-harvest interval (PHI) is recommended by EFSA (2017) to ensure that viable counts at the time of harvest are negligible.”

Considering that:

- **an EU data GAP was identified with regard to the potential of production of secondary metabolites;**

- no new data were submitted to address the EU GAP;
- no post-harvest use were considered among the representative uses of the review report, meaning that the intended uses are not covered;

the consumer risk cannot be assessed.

Therefore, despite the previous inclusion of *Clonostachys rosea* strain J1446 in Regulation (EC) No 839/2008, the intended uses after harvest cannot be recommended.

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. 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.

Considering the intended use for the product LALFRESH S (post-harvest treatment on stone fruits; indoor use), exposure of environmental compartments to the active substance *Clonostachys rosea* strain J1446 is considered negligible. Consequently, no risk assessment for environment and non-target organisms is deemed necessary.

3.1.6 Ecotoxicology

Please refer to Part 3.1.5.

3.1.7 Efficacy

- The efficacy level of LALFRESH S is considered as partial and variable for all the claimed uses. However it is considered acceptable considering the kind of product based on microorganisms.
- Concerning cherries use, according to Article 51 of Regulation (EC) No 1107/2009, the efficacy assessment and the absence of any phytotoxicity risk on this crop is not necessary.
- The risk of negative impact on quality is considered negligible.
- Considering the data provided, a specific attention should be paid to the conditions of use of the product in the frame of IPM practices, particularly in terms of biological compatibility with fungicide products.
- The risk of resistance development or appearance to *Clonostachys rosea* strain J1446 is considered very low.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, **an authorisation cannot be granted**. A copy of the decision issued can be found in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

N/A : no marketing authorisation granted

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

3.4.1 Post-authorisation monitoring

N/A : no marketing authorisation granted

3.4.2 Post-authorisation data requirements

- None

3.4.3 Label amendments

N/A : no marketing authorisation granted

Appendix 1 – Copy of the French Decision



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

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

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

Vu la demande d'autorisation de mise sur le marché et la demande associée du produit phytopharmaceutique
LALFRESH S

de la société DANSTAR FERMENT AG

enregistrées sous les n°2019-3431 et 2019-6331

Vu les conclusions de l'évaluation de l'Anses du 25 septembre 2020,

Considérant qu'un risque d'effet nocif pour le consommateur, lié à l'utilisation du produit, ne peut être exclu,

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

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

Informations générales sur le produit	
Nom du produit	LALFRESH S
Type de produit	Produit de référence
Titulaire	DANSTAR FERMENT AG Postrasse 30, CH-6300 ZUG, Suisse
Formulation	Granulé dispersable (WG)
Contenant	1.10 ⁹ UFC/g - <i>Clonostachys rosea</i> souche J1446
Numéro d'intrant	256-2019.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usage	Professionnel

A Maisons-Alfort, le 22 JAN. 2021

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

ANNEXE I : Conditions de mise sur le marché demandées

Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai après traitement (jours)
12564201 Fruits à noyau*Trt Prod. Réc.* Maladies de conservation	9 g/t	1/an	-
Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet nocif pour le consommateur.			
Cerisier*Trt Prod. Réc.* Maladies de conservation	1 g/L	1/an	-
Motivation du refus : L'usage revendiqué pour une utilisation par trempage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet nocif pour le consommateur.			

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

Draft Master Label
LALFRESH S dRR, Section 1 – EU zone (post-harvest / indoor)
Jan 2019 / MiB – v2 FRA

LALFRESH® S

FONGICIDE DE BIOCONTROLE

Substance active : *Clonostachys rosea* J1446 ; 1*10⁹ UFC/g
Type de formulation : WG (Granulés dispersibles)
N° d'enregistrement : XXXX
Poids net : 90g, 180g, 450 g, 900g, 1800g.

Pour éviter tout risque pour l'homme et l'environnement, veuillez-vous conformer aux instructions d'utilisation. LALFRESH® S contient du *Clonostachys rosea* J1446. Les micro-organismes peuvent provoquer des réactions de sensibilisation.

Usage professionnel.

SSCL SANS CLASSEMENT

Éviter tout contact avec les yeux, la peau ou les vêtements. Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage (avec filtre FFP2 ou FFP3). Éliminer le contenu/le contenant conformément à la réglementation locale. Ne pas contaminer l'eau avec le produit ou son récipient / ne pas nettoyer l'équipement d'application près des eaux de surface.

UTILISATION PRÉVUE

LALFRESH® S est un fongicide de biocontrôle à utiliser en post-récolte, destiné à la lutte contre les maladies de conservation des fruits à noyau (prunes, pêches et nectarines) causées par différentes espèces de *Monilia*.

RESTRICTIONS D'UTILISATION

Le fongicide de biocontrôle LALFRESH® S s'utilise en préventif. Ne mélangez pas LALFRESH® S avec des pesticides chimiques ni avec des solutions d'engrais concentrées.

PROTECTION INDIVIDUELLE

Porter des gants (p. ex. en nitrile), un vêtement approprié et un masque respiratoire pendant les phases de mélange, chargement et application. En cas de ventilation insuffisante ou de la possibilité de formation de poussière, portez un équipement respiratoire adapté (masque filtrant avec filtre FFP2 ou FFP3).

PRÉCAUTIONS ENVIRONNEMENTALES

L'élimination du contenu et de son contenant doit être conforme aux réglementations locales et nationales en vigueur. Jetez les emballages vides avec les déchets ménagers.

N° de lot : 00000
Date limite de conservation: XX-XX-XXXX

INSTRUCTIONS D'UTILISATION

Culture	Pathogène(s) / cible(s)	Méthode d'application	Doses	Volume d'application / pulvérisation
Fruits à noyau (produits récoltés)	<i>Monilia</i> sp.	Pulvérisation	9 g / 1 000 kg fruits	3 L / 1 000 kg fruits
Cerises (usages mineurs)	<i>Monilia</i> sp.	Trempage	1 g / 1 L eau	10 L / 1 kg cerises

INSTRUCTIONS DE PRÉPARATION ET PULVÉRISATION

Le fongicide de biocontrôle LALFRESH® S doit être utilisé en suspension dans une solution aqueuse et appliqué par pulvérisation sur des fruits à noyau récoltés. La dose d'utilisation recommandée est de 9 g / 1 000 kg de fruits dans un volume d'eau de 3 L / 1 000 kg de fruits. Diluer LALFRESH® S dans un volume d'eau adéquate et agiter soigneusement jusqu'à ce que la suspension soit homogène. Pour assurer une efficacité maximale, il est important que la pulvérisation soit homogène sur l'ensemble de la surface des fruits.

LALLEMAND propose une machinerie d'application qui permet de pulvériser LALFRESH® S de manière automatique lors du conditionnement des fruits. Pour plus d'informations sur l'achat de ce matériel contactez LALLEMAND (coordonnées Importateur sur cette étiquette).

Si d'autres types d'équipements de pulvérisation sont utilisés, veuillez également contacter LALLEMAND pour évaluer l'utilisation de LALFRESH® S à l'aide de ces derniers

DOSAGES ET STADES D'APPLICATION

Après récolte des fruits à noyau, pulvériser LALFRESH® S via un équipement spécifique à la dose de 9gr / 1000 kg de fruits dilué dans 3L d'eau / 1000kg de fruits.

Après stockage des fruits à basse température (réfrigérateur) garder les fruits à température ambiante quelques minutes afin d'éviter de pulvériser LALFRESH® S sur des fruits trop humide.

INSTRUCTIONS POUR LE TREMPAGE DES CERISES (USAGES MINEURS)

« Pour les usages mentionnés ci-après l'extension d'autorisation de mise sur le marché a été obtenue dans le cadre de l'article 51 du règlement (CE) n° 1107/2009 (extension des autorisations de mise en marché pour les usages mineurs). L'attention de l'utilisateur est attirée sur les risques éventuels de phytotoxicité ou de manque d'efficacité. Au regard des données à sa disposition, le titulaire de l'autorisation de mise sur le marché décline toute responsabilité sur ces éventuels risques. Avant tout emploi du produit, il est recommandé à l'utilisateur de s'assurer de son efficacité ou de l'absence de risques éventuels de phytotoxicité sur la culture. »

LALFRESH® S doit être utilisé dans une solution aqueuse pour le trempage des cerises. La dose d'utilisation recommandée est de 1 g de LALFRESH® S / 1 L d'eau (1 kg de cerises dans 10 L d'eau, par exemple). Diluer LALFRESH® S dans un volume d'eau adéquat et agiter soigneusement jusqu'à ce que la suspension soit homogène. Pour assurer une efficacité maximale, il est important de tremper les fruits dans la solution aqueuse pendant 1 minute. Cela permettra une couverture complète de la surface des cerises.

STOCKAGE

LALFRESH® S est une préparation biologique contenant des spores et du mycélium fongiques, vivants et séchés. LALFRESH® S peut être conservé pendant 18 mois à température ambiante (+25°C) dans son emballage sous vide non ouvert, ou en chambre froide (+4°C) dans les sacs/emballages sous vide non ouverts. Il est recommandé d'utiliser la totalité du contenu des sacs dès leur ouverture.

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Appendix 3 – Letter(s) of Access

Provided upon request.