REGISTRATION REPORT

Part A

Risk Management

Product name: LALSTOP G46 WG

Active Substance(s):

***Clonostachys rosea* strain J1446**

(*Gliocladium catenulatum* strain J1446),

minimum 1.10^9 CFU/g ; 900 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: Danstar Ferment AG

Date: 16/01/2024

Table of Contents

PART A – Risk Management

The company Danstar Ferment AG has requested a marketing authorisation in France for the product LALSTOP G46 WG, containing minimum 1.10^9 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 LALSTOP G46 WG where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of LALSTOP G46 WG have been made using endpoints agreed in the EU peer review of *Clonostachys rosea* strain J1446 (*Gliocladium catenulatum* strain J1446).

This document describes the specific conditions of use and labelling required for France for the registration of LALSTOP G46 WG.

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 LALSTOP G46 WG in France as a fungicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

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.
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 application (2023-0071) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[1] – the highest application rates over the Southern Zone. 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 12 April 2021[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.

Finally, the French Order of 20 November 2021[7] 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

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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 https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456

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

7 https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734

product authorisation, use on attractive crop[8] 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.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of LALSTOP G46 WG, 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.

[8] 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.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	LALSTOP G46 WG
Authorisation number	2230771
Function	fungicide
Applicant	DANSTAR FERMENT AG
Composition	900 g/kg (minimum of 1.10^9 CFU/g) *Clonostachys rosea* strain J1446
Formulation type (code)	Water-dispersible granule (WG)
Packaging	PET/ALU/PE-laminate (5 g, 10 g, 50 g, 100 g, 200 g, 500 g, 1 kg, 2 kg)

2.2 Classification and labelling

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

Physical hazards	None	
Health hazards	No classification for aquatic organisms	
Environmental hazards	Not classified	
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 *Clonostachys rosea* strain J1446. Micro-organisms may have the potential to provoke sensitising reactions.

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.
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres[9] to surface water bodies

[9] The legal basis for this is **Titre III Article 12** 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]

	for the uses on vineyard and strawberry.

2.2.3 Other phrases linked to the preparation

Wear suitable personal protective equipment[10]: refer to the Decision in Appendix 1 for the details
Re-entry period[11]: 6 hours
Pre-harvest interval[12]: not applicable
Other mitigation measures: - The formulation LALSTOP G46 WG can be stored up 18 months at 4°C and up to 12 months between 4-25°C - Authorised use during flowering and during honeydew production outside the presence of bees. (according to French Order of 28 November 2003)
The label may include the following recommendations: - Contains *Clonostachys rosea*. Microorganisms may have the potential to provoke sensitising reactions. - Specify conditions of use to : o - ensure uniform application and proper operation of spray equipment. o - guarantee product efficacy when other fungicides are used on the crop. o - ensure optimum efficacy, as efficacy is variable and partial. The label must reflect the conditions of authorisation.

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

[11] 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]

[12] 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 zRMS. 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: 2024-january -16

PPP (product name):	**LALSTOP G46 WG**	**Formulation type:**	**WG**
active substance:	***Clonostachys rosea* strain J1446**	**Conc. of as 1:**	**minimum 1x10^9 CFU/g ; 900 g/kg**
safener:	-	**Conc. of safener:**	-
synergist:	-	**Conc. of synergist:**	-
Applicant:	**Danstar Ferment AG**	**professional use:**	☒
Zone(s):	**southern**	**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) RMS CONCLUSION**
					Type (d-f)	**Conc. of as (i)**	**method kind (f-h)**	**growth stage & season (j)**	**number min max (k)**	**interval between applications (min)**	**kg product/ha min max**	**g a.s./ha min max**	**water L/ha min max**		
Grapevine VITVI	FR	LALS TOP G46 WG	F	Grey mould *(Botrytis cinerea)* BOTRCI	WG	900 g/kg (1*10^9)	Foliar spraying	End of flowering to grape harvest; foliar spray onto full leaf wall area BBCH 67-89	4	6 days	0.5	450	400-800	1	**Acceptable**
Strawberry FRAAN	FR	LALS TOP G46 WG	F	Grey mould *(Botrytis* sp.) BOTRCI	WG	900 g/kg (1*10^9)	Foliar spraying	At full balloon stage and at flowering BBCH 59-73	4	6 days	0.25	225	1	-	**Acceptable** Efficacy shown on *Botrytis cinerea*

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

Authorised packaging: PET-Alu-LDPE laminated bags (5g, 10g, 50g, 100g, 200g, 500g, 1kg, 2kg).

LALSTOP 46 WG is a 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 a brown granules, with characteristic odour. It is not explosive and has no oxidising properties. The product is not flammable. In aqueous solution (1% aqueous dispersion), it has a pH value 6.98 at ambient temperature.

The shelf-life study proves viability for at least 18 months when LALSTOP G46 WG is stored at +4°C in its original container both in normal and vacuum packaging. The shelf-life study when LALSTOP G46 WG is stored at 20-25°C in its original container proves viability for at least 18 months when stored in vacuum packing and 12 months when stored in normal packaging.
According to recent storage stability study (GLP, Buccella 202a&b) LALSTOP G46 WG is stable for 18 months when stored at +4°C and at least 12 months when stored at +20°C, in normal packaging (PET/aluminium/LDPE bag). Physico chemical properties were also provided after storage 12 and 18 months at 4°C and 12 months at 20°C.

According to the overall available data, a shelf life of 12 months at 20-25°C and 18 months at 4°C can be granted. However, it should be mention on the label that the product must be stored between 4 and 25°C.

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 is missing. The applicant provided the following justification: *"Data has been provided in this dossier to demonstrate lack of ability of C. rosea strain J1446 to produce gliotoxin or other relevant secondary metabolites / toxins. Consequently, EFSA and EC data gaps related to gliotoxin as well as zRMS study request for gliotoxin before and after storage are not considered valid for LALSTOP G46 WG S anymore. No further data needed for this data point/data request."* Determination of gliotoxin is missing after storage. However, new data have been provided and confirm that the strain is not able to produce gliotoxin (see tox section).

Its technical characteristics are acceptable for a WG formulation.

As the wet sieve test and suspensibility are outside the acceptable limits, an evidence must be submitted in order to demonstrate the slurry may be satisfactorily applied through appropriate application equipment with no blockage using stored batches (12 months at 4°C and 12 months at 20/25°C) **and remains homogeneous during the application. Without these evidences, the assessment cannot be finalised. Those data are required in the framework of a dossier for modification of use conditions.**

Implications for labelling:
The formulation LALSTOP G46 WG can be stored up 18 months at 4°C and up to 12 months between 4 and 25°C

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 of microbial contaminants according to SANCO 12116/2012 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).

3.1.2.1 Analytical method for the formulation

Analytical methods for the determination of microbial active substance and relevant impurity (gliotoxin) in the formulation are validated.

3.1.2.2 Analytical methods for residues

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

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

LALSTOP G46 WG containing $1x10^9$ CFU/g (corresponding 900 g/kg) Clonostachys rosea J1446 has a low oral, inhalation, and dermal toxicity, is not an eye irritant and is not irritating. Microorganisms 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

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 and resident Exposure

Following the above given reasons for abstaining from an estimation of operator risks, this also applies to bystanders and resident exposure. With regard to the application method, bystander exposure is supposed to be negligible for field 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 operators, refer to the Decision in Appendix 1.

3.1.3.6 Relevance of metabolites

In the EFSA conclusion (EFSA Journal 2017; 15(7): 4905, published 26 July 2017) the point of possible production of gliotoxin was raised. However, the Literature search did not identify any reports of *Clonostachys rosea* producing gliotoxin. Gliotoxin was not detected using HPLC with an LOQ of 50 µg/kg, in unformulated cell mass powder, culture broth samples or mineral wool cultivation pots (Guy, 2020a and validated in Guy, 2020b). In addition, in the final renewal report for Clonostachys rosea J1446 finalised in the Standing Committee on Plants, Animals, Food and Feed (SANTE/11655/2017 Rev 3), the data gaps reported by EFSA were not regarded as a critical concern.

Furthermore, a new study submitted to the RMS in May 2020 (Guy, 2020a and validated in Guy, 2020b according to SANCO 3030/99 rev. 5 with a quantification limit of 20 µg/ml), determined the amount of gliotoxin in three formulations based on C. rosea J1446: Lalfresh S, LALSTOP G46 WG and Prestop WP. The study showed no gliotoxin in the formulations, < 1.00 % µg/l in the solutions and < 20 µg/kg in the formulation.

A genomic screening study was also performed on the genome of Clonostachys Rosea J1446 for presence of gene clusters encoding for secondary metabolites (Brader G 2021). This screening confirmed the absence of genes encoding for substances of concern for human health like gliotoxins and trichothecenes. In addition, the strain does not produce

any antibiotics or antimycotics used in human or veterinary medicine. It was also confirmed that none of the secondary metabolites, which according to genome sequence analysis can be potentially produced by Clonostachys rosea J1446, are of toxicological relevance or concern for human health, non-target organisms or the environment according to scientific peer-reviewed open literature (Seehase 2021)

In conclusion based on the submitted information the data gaps reported by EFSA are not regarded as a critical concern including the potential of gliotoxin production.

3.1.4 Residues and Consumer Exposure

In the framework of the first inclusion of the active substance Clonostachys rosea strain J1446 (formely Gliocladium catenulatum strain J1446), the strain was temporaly included in annex IV to regulation (EC) n°395/2005 for which it is not necessary to set MRLs (Reg (UE) 839/2008).

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

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

Considering that:

- an EU data GAP was identified with regard to the potential of production of secondary metabolite; New reliable data has been provided in this updated draft Registration Report to address this EU data gap. No relevant secondary metabolites or toxins are possibly produced by Clonostachys rosea J1446 and hence this data gap is not regarded as critical concern or valid anymore.
- no spraying treatment after stage BBCH 19 on strawberry, neither treatment on grapes was considered among the representative uses of the review report.

In a recent study, the genome of C. rosea strain J1446 was screened for presence of gene clusters encoding for secondary metabolites (Brader (2021)). This screening confirmed absence of genes encoding for substances of concern for human health like gliotoxins and trichothecenes. In addition, the strain does not produce any antibiotics or antimycotics used in human or veterinary medicine. It was also confirmed that none of the secondary metabolites, which according to genome sequence analysis can be potentially produced by Clonostachys rosea J1446, are according to scientific peer-reviewed open literature of toxicological relevance or concern for human health, non-target organisms or the environment.

According to C. rosea J1446 metabolite studies, no relevant secondary metabolites or toxins are possible produced by this strain. It can therefore be concluded that no residues and consumer health risks / concerns exists related to possible non-viable residues or in situ production of toxins / metabolites on treated crops after LALSTOP G46 WG applications.

According to new data provided in this updated dRR dossier, the data gaps identified by EFSA and EC related to viable residues and to gliotoxin and other secondary metabolites of toxicological concerns are not considered valid for the active substance or the end product LALSTOP G46 WG anymore.

This new data is considered relevant and reliable to support the conclusion that approvals for LALSTOP G46 WG can be granted for all proposed intended product uses in concerned Member States, including uses on edible plant parts.

Data on absence of viable residues and (relevant) secondary metabolites or toxins of concern produced by Clonostachys rosea J1446 also supports and qualify the listing of C. rosea J1446 on Annex IV of Regulation (EC) 396/2005 (ref. Commission Regulation (EU) 2019/977 of 13 June 2019).

Therefore, the intended uses on strawberry (until BBCH 73) and grapevine (until BBCH 89) for LALSTOP G46 WG can be recommended.

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009.

The endpoints established in the EU conclusions (EFSA, 2017) were used in calculations.
PECSOIL and PECSW derived for the active substance are used for the eco-toxicological risk assessment.
No unacceptable risk of groundwater contamination is expected for the intended uses.

3.1.6 Ecotoxicology

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance 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

The level of efficacy of product LALSTOP G46 WG is considered variable and partial for the uses claimed. However, it is considered acceptable for this type of microorganism-based product.
The phytotoxicity level of product LALSTOP G46 WG is considered negligible for all the uses claimed.
The risks of negative impact on yield, quality, the winemaking process and multiplication are considered negligible.
The risks of negative impact on succeeding and adjacent crops can be considered negligible.
According to the data provided, particular attention should be paid to the conditions of use of the product in the context of an integrated biological protection program, in terms of biological compatibility with other plant protection products.
The risk of resistance to Clonostachys rosea strain J1446 is considered very low.

3.2 Conclusions arising from French assessment

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

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

No further information is required.

3.4.2 Post-authorisation data requirements

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 ***LALSTOP G46 WG***

de la société	*DANSTAR FERMENT AG*
enregistrée sous le	*n° 2023-0071*

Vu les conclusions de l'évaluation de l'Anses du 16 octobre 2023,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France, sous réserve du respect de la composition du produit autorisée dans les conclusions de l'évaluation, pour les usages et dans les conditions précisés dans la présente décision et son annexe.

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

Avertissement :

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

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AGENCE NATIONALE DE SÉCURITÉ SANITAIRE de l'alimentation, de l'environnement et du travail

Informations générales sur le produit	
Nom du produit	LALSTOP G46 WG
Type de produit	Produit de référence
Titulaire	DANSTAR FERMENT AG Poststrasse 30 CH-6300 ZOUG Suisse
Formulation	Granulé dispersable (WG)
Contenant	1.10⁹ UFC/g - *Clonostachys rosea* souche J1446
Numéro d'intrant	9972-2023.01
Numéro d'AMM	2230771
Fonction	Fongicide
Gamme d'usage	Professionnel
Mention particulière	Produit à faible risque au sens de l'article 47 du règlement (CE) n° 1107/2009

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 mars 2035.

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 16/01/2024

DocuSigned by:
Charlotte Grastilleur
AE281A955A42454...

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 : 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**
Sachets en polyéthylène téréphtalate / aluminium / polyéthylène basse densité	5 g ; 10 g ; 50 g ; 100 g ; 200 g ; 500 g ; 1 kg
Sacs en polyéthylène téréphtalate / aluminium / polyéthylène basse densité	2 kg

Classification du produit
La classification retenue est la suivante : Sans classement.
Pour les phrases P se référer à la règlementation en vigueur. **Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.**

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêté du 20/11/2021)
16553201 Fraisier*Trt Part.Aer.*Pourriture grise et sclérotinioses	**0,25 kg/ha**	**4/an**	entre les stades BBCH 59 et BBCH 73	1	5	-	-	Emploi possible
	Efficacité montrée sur *Botrytis cinerea* Intervalle minimum entre les applications : 6 jours.							
12703205 Vigne*Trt Part.Aer.*Pourriture grise	**0,5 kg/ha**	**4/an**	entre les stades BBCH 67 et BBCH 89	1	5	-	-	Non concerné
	Intervalle minimum entre les applications : 6 jours.							

Emploi possible ou interdit = usage autorisé ou interdit durant la floraison et sur les zones de butinage, pour les cultures attractives en plein champ ou sous abri ouvert, dans les conditions fixées par l'arrêté du 20/11/2021.

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Conditions d'emploi du produit

Stockage et manipulation du produit

- Stocker le produit à une température de 4 °C pour une durée n'excédant pas 18 mois, ou à une température comprise entre 4 °C et 25 °C pour une durée n'excédant pas 12 mois.

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 à l'aide d'un pulvérisateur à rampe

• pendant le mélange/chargement

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité ;
- Protections respiratoires certifiées : demi-masque certifié (EN 140) équipé d'un filtre P3 (EN 143) ou A2P3 (EN 14387) ;

• pendant l'application

Si application avec tracteur avec cabine

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;

Si application avec tracteur sans cabine

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;
- En cas d'exposition aux gouttelettes pulvérisées, porter un demi-masque filtrant à particules (EN 149) ou un demi-masque (EN 140) équipé d'un filtre à particules P3 (EN 143) ;

• pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité.

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

• **pendant le mélange/chargement**

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité ;
- Protections respiratoires certifiées : demi-masque certifié (EN 140) équipé d'un filtre P3 (EN 143) ou A2P3 (EN 14387) ;

• **pendant l'application**

Si application avec tracteur avec cabine

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;

Si application avec tracteur sans cabine

- Combinaison de protection de catégorie III type 4 avec capuche ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;
- En cas d'exposition aux gouttelettes pulvérisées, porter un demi-masque filtrant à particules (EN 149) ou un demi-masque (EN 140) équipé d'un filtre à particules P3 (EN 143) ;

• **pendant le nettoyage du matériel de pulvérisation**

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité.

Pour le travailleur, porter

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 et, en cas de contact avec la culture traitée, des gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A).

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

- 6 heures

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. Éviter la contamination *via* les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

Protection de la faune

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.

- Peut être dangereux pour les abeilles. Application possible durant la floraison et sur les zones de butinage, pour les cultures attractives, selon les conditions fixées par l'arrêté du 20 novembre 2021 pour les usages caractérisés par « emploi possible ».

Recommandations relatives à l'étiquette du produit

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

- Contient du *Clonostachys rosea* souche J1446. Peut provoquer des réactions de sensibilisation.

Préciser les conditions d'utilisation afin :

- d'assurer l'homogénéité de l'application et le bon fonctionnement des dispositifs de pulvérisation.
- de garantir l'efficacité du produit dans le cas d'utilisation d'autres produits fongicides sur la culture.
- d'assurer un niveau d'efficacité optimal, l'efficacité étant variable et partielle.

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

LALSTOP® G46 WG

FONGICIDE DE BIOCONTROLE

Substance active : *Clonostachys rosea* J1446 ; $1*10^9$ UFC/g
Type de formulation : WG (Granulés dispersibles)
N° d'enregistrement : XXXX
Titulaire de l'agrément : Danstar Ferment AG, Poststrasse 30, CH-6300 Zug, Suisse.
Poids net : 5 g - 2 kg

Pour éviter tout risque pour l'homme et l'environnement, veuillez-vous conformer aux instructions d'utilisation. LALSTOP G46 WG contient du *Clonostachys rosea* J1446. Les micro-organismes peuvent provoquer des réactions de sensibilisation.
Usage professionnel.

SSCL SANS CLASSEMENT

Éviter de respirer les poussières. 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

LALSTOP G46 WG est un fongicide de biocontrôle destiné à la lutte contre la pourriture grise (*Botrytis)* des plants de vigne et de fraisier.

RESTRICTIONS D'UTILISATION

Le fongicide de biocontrôle LALSTOP G46 WG s'utilise en préventif. Ce produit convient à la lutte intégrée contre les parasites. Contactez le titulaire de l'agrément pour recevoir davantage d'informations sur sa compatibilité. Ce produit est inoffensif pour l'objet traité. Ne mélangez pas LALSTOP G46 WG 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.

INSTRUCTIONS D'UTILISATION

Culture	Pathogène(s) / cible(s)	Doses	Méthode d'application
Vigne	Pourriture grise (*Botrytis cinerea*)	0,25 – 0,5 kg/ha	Pulvérisation foliaire
Fraisier	Pourriture grise (*Botrytis* sp.)	0,125 – 0,25 kg/ha	Pulvérisation foliaire

INSTRUCTIONS DE PRÉPARATION ET PULVÉRISATION

Le fongicide de biocontrôle LALSTOP G46 WG est utilisé en suspension aqueuse. Mélangez d'abord LALSTOP G46 WG avec une petite quantité d'eau (env. 1 litre). Agitez avec précaution jusqu'à ce que la suspension soit homogène. Diluez ensuite jusqu'à la concentration souhaitée. La suspension aqueuse LALSTOP G46 WG est appliquée par pulvérisation, jusqu'à presque atteindre le ruissellement, en veillant à couvrir entièrement la culture. Ne mélangez pas le produit avec d'autres pesticides ni avec des solutions d'engrais concentrées.

DOSAGES ET STADES D'APPLICATION

Vigne Pulvériser LALSTOP G46 WG sur toute la surface du feuillage de la vigne à une dose de 0,25 à 0,5 kg par hectare, en solution dans 400 à 800 litres d'eau, en une application. Répéter le traitement par pulvérisation de la vigne, avec 2 applications si la maladie est modérément répandue, et jusqu'à 4 applications si la présence de la maladie est forte, entre les stades BBCH 67 (70 % chute des capuchons floraux), BBCH 77 (début de la fermeture de la grappe), BBCH 81 (début de la maturation) et BBCH 89 (baies mûres pour la vendange).

Fraisier : Pulvériser LALSTOP G46 WG sur le feuillage des plants à une dose de 0,125 à 0,25 kg par hectare, en solution dans 1000 litres d'eau maximum, en une application. Si le volume d'eau augmente, la dose appliquée doit augmenter proportionnellement. Trois à cinq applications sont recommandées, à une semaine d'intervalle, aux stades BBCH > 59 (stade ballon, avant l'ouverture des premières fleurs). LALSTOP G46 WG peut également être utilisé dans le cadre de la lutte intégrée contre les parasites, en remplaçant un ou deux traitements chimiques par LALSTOP G46 WG.

STOCKAGE

LALSTOP G46 WG est une préparation biologique contenant des spores et du mycélium fongiques, vivants et séchés. LALSTOP G46 WG 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.

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

Appendix 3 – Letter(s) of Access

Provided upon request.