

REGISTRATION REPORT

Part A

Risk Management

Product name: LALSTOP G46 WG

Active substance:

***Clonostachys rosea* strain J1446**

(*Gliocladium catenulatum* strain J1446),

minimum 1 10⁹ CFU/g ; 900 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: Danstar Ferment AG

Date: January 2021

Table of Contents

1	DETAILS OF THE APPLICATION.....	3
1.1	APPLICATION BACKGROUND.....	3
1.2	ACTIVE SUBSTANCE APPROVAL.....	3
1.3	REGULATORY APPROACH	4
1.4	DATA PROTECTION CLAIMS	4
1.5	LETTER(S) OF ACCESS	5
2	DETAILS OF THE AUTHORISATION	6
2.1	PRODUCT IDENTITY	6
2.2	CLASSIFICATION AND LABELLING.....	6
2.2.1	<i>Classification and labelling in accordance with Regulation (EC) No1272/2008.....</i>	6
2.2.2	<i>Other phrases in compliance with Regulation (EU) No 547/2011</i>	6
2.2.3	<i>Other phrases linked to the preparation</i>	6
2.3	PRODUCT USES.....	7
3	RISK MANAGEMENT.....	9
3.1	REASONED STATEMENT OF THE OVERALL CONCLUSIONS TAKEN IN ACCORDANCE WITH THE UNIFORM PRINCIPLES.....	9
3.1.1	<i>Physical and chemical properties</i>	9
3.1.2	<i>Methods of analysis</i>	9
3.1.3	<i>Mammalian Toxicology.....</i>	9
3.1.4	<i>Residues and Consumer Exposure</i>	10
3.1.5	<i>Environmental fate and behaviour.....</i>	11
3.1.6	<i>Ecotoxicology.....</i>	11
3.1.7	<i>Efficacy</i>	11
3.2	CONCLUSIONS ARISING FROM FRENCH ASSESSMENT	12
3.3	SUBSTANCES OF CONCERN FOR NATIONAL MONITORING	12
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	12
3.4.1	<i>Post-authorisation monitoring</i>	12
3.4.2	<i>Post-authorisation data requirements</i>	12
3.4.3	<i>Label amendments</i>	12
	APPENDIX 1 – COPY OF THE FRENCH DECISION	13
	APPENDIX 2 – COPY OF THE DRAFT PRODUCT LABEL AS PROPOSED BY THE APPLICANT	16
	APPENDIX 3 – LETTER(S) OF ACCESS	18

PART A – Risk Management

The company Danstar Ferment AG has requested a marketing authorisation in France for the product LALSTOP G46 WG, containing minimum 1 10⁹ 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 (2018-3659) 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 2017² provides that:

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

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

The current document (RR) based on Anses’s assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009³, implementing regulations, and French regulations.

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

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011⁴, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014⁵ provides that:

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

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “linked” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those “linked” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁶ is to supply “minor” crops with registered plant protection products.

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

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

1.4 Data protection claims

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

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, modifié par l'arrêté du 27 décembre 2019.

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/AGR1407093A/jo>

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

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)	LALSTOP G46 WG
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 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 zRMS.. When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.

PPP (product name):	LALSTOP G46 WG				Formulation type:	WG				GAP rev. 1, date: 2021-01-21			
active substance:	<i>Clonostachys rosea</i> 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:	<input checked="" type="checkbox"/>							
Zone(s):	southern				non-professional use:	<input type="checkbox"/>							
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) (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 (<i>Botrytis cinerea</i>) 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	-	Not acceptable (Risk for consumers, aquatic organisms)
Strawberry FRAAN	FR	LALS TOP G46 WG	F	Grey mould (<i>Botrytis</i> 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	max 1000	-	Not acceptable (Risk for consumers, aquatic organisms)

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

LALSTOP G46 WG 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 secondary 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 LALSTOP G46 WG 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 LALSTOP G46 WG 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

LALSTOP G46 WG has a low acute oral, inhalational and dermal toxicity and is not irritating to the rabbit skin. It is moderately eye irritating and is moderately sensitizing for skin. 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. 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 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 supposed to be negligible for field 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 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 included in Annex IV to Regulation (EC) No 395/2005 for which it is not necessary to set MRLs (Regulation (UE) 2019/977 of 13 June 2019).

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 spraying treatment after stage BBCH 19 on strawberry, neither treatment on grapes was considered among the representative uses of the review report, meaning that the intended uses are not covered;

the intended uses on grapevine until BBCH 89 and on strawberry until BBCH 73 are not acceptable.

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. Appropriate endpoints from the EU conclusions were used to calculate PEC values for the active substance 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.

The endpoints established in the EU conclusions (EFSA, 2017) were used in calculations. PEC_{SOIL} and PEC_{SW} 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 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, mammals, bees, other non-target arthropods, earthworms, soil microorganisms and plants are acceptable for the intended uses.

For aquatic organisms, the risk assessment cannot be finalized for vineyard and strawberry uses.

3.1.7 Efficacy

Considering the data provided:

- the efficacy level of LALSTOP G46 WG is considered partial and variable for all the claimed uses. However it is considered acceptable considering the kind of product based on microorganisms;
- the phytotoxicity level of LALSTOP G46 WG is considered negligible for all the claimed uses;
- the risks of negative impact on yield, quality, wine making processes, propagation, succeeding crops and adjacent crops are 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* 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

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

- None.

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



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 du produit phytopharmaceutique **LALSTOP G46 WG***

de la société DANSTAR FERMENT AG

enregistrée sous le n°2018-3659

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 également qu'un risque d'effet inacceptable pour les organismes aquatiques, 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.

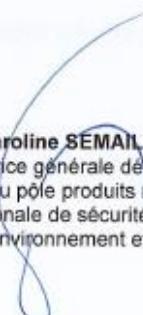
Informations générales sur le produit

Nom du produit	LALSTOP G46 WG
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	789-2018.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usage	Professionnel

La demande en cours d'instruction, enregistrée sous le numéro suivant : 2020-0222, devient sans objet.

A Maisons-Alfort, le

26 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 avant récolte (jours)
16553201 Fraisier*Ttr Part.Aer.* Pourriture grise et sclérotinioses	0,25 kg/ha	4/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, ni d'exclure un risque d'effet inacceptable pour les organismes aquatiques.	
12703205 Vigne*Ttr Part.Aer.* Pourriture grise	0,5 kg/ha	4/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, ni d'exclure un risque d'effet inacceptable pour les organismes aquatiques.	

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*10⁹ 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 (<i>Botrytis cinerea</i>)	0,25 – 0,5 kg/ha	Pulvérisation foliaire
Fraisier	Pourriture grise (<i>Botrytis</i> 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.