REGISTRATION REPORT

Part A

Risk Management

Product code: VINTEC

Product name(s): VINTEC

Active Substance:

***Trichoderma atroviride* strain SC1, 1 x 10^{10} CFU/g min**

(150 g/kg)

COUNTRY: FRANCE

Southern zone

Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(major extension of use)

Applicant: BI-PA SA

Date: 2019-12-31

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 5
1.5 LETTER(S) OF ACCESS 5

2 DETAILS OF THE AUTHORISATION 5

2.1 PRODUCT IDENTITY 5
2.2 CLASSIFICATION AND LABELLING 5
2.2.1 Other phrases in compliance with Regulation (EU) No 547/2011 5
2.2.2 Other phrases linked to the preparation 5
2.3 PRODUCT USES 6

3 RISK MANAGEMENT 8

3.1 REASONED STATEMENT OF THE OVERALL CONCLUSIONS TAKEN IN ACCORDANCE WITH THE UNIFORM PRINCIPLES 8
3.1.1 Physical and chemical properties 8
3.1.2 Methods of analysis 8
3.1.3 Mammalian Toxicology 8
3.1.4 Residues and Consumer Exposure 9
3.1.5 Environmental fate and behaviour 9
3.1.6 Ecotoxicology 10
3.1.7 Efficacy 10
3.2 CONCLUSIONS ARISING FROM FRENCH ASSESSMENT 10
3.3 SUBSTANCES OF CONCERN FOR NATIONAL MONITORING 10
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 10
3.4.1 Post-authorisation monitoring 10
3.4.2 Post-authorisation data requirements 10
3.4.3 Label amendments 10

APPENDIX 1 – COPY OF THE FRENCH DECISION 11

APPENDIX 2 – COPY OF THE DRAFT PRODUCT LABEL AS PROPOSED BY THE APPLICANT 16

APPENDIX 3 – LETTER(S) OF ACCESS 21

PART A – Risk Management

The company BI-PA SA has requested the extension of use in France for the product VINTEC (marketing authorisation n° 2169998), containing 1.10^{10} CFU/g of *Trichoderma atroviride* strain SC1 (150 g/kg technical product) 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 VINTEC where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of VINTEC have been made using endpoints agreed in the EU peer review(s) of *Trichoderma atroviride* strain SC1.

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

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 BI-PA SA's application to market VINTEC 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 label extension of this product in France and in other MSs of the Southern zone. *Trichoderma atroviride* strain SC1 is a low risk active substance and is the only active substance of VINTEC, therefore VINTEC shall be authorized as a low risk plant protection product if compliant with article 47.

1.2 Active substance approval

Trichoderma atroviride strain SC1

COMMISSION IMPLEMENTING REGULATION (EU) 2016/951 of 15 June 2016 approving the low-risk active substance *Trichoderma atroviride* strain SC1, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.
Specific provisions of Regulation (EU) No 540/2011 were as follows : For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on *Trichoderma atroviride* strain SC1, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that microorganisms are considered as potential sensitizers. Conditions of use shall include risk mitigation measures, where appropriate. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer.
An EFSA conclusion is available (EFSA Journal 2015; 13(4): 4092) A Review Report is available (SANCO/10389/2016 rev 1, 22 March 2016).

1.3 Regulatory approach

The present application (2018-1865) for extension of use 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 26 March 2014[5] provides that:
- an authorisation granted for a "reference" crop applies also for "linked" crops, unless formally stated in the Decision
- the "reference" and "linked" crops are defined in Appendix 1 of that French Order.

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

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

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

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

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

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

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

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

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

1.4 Data protection claims

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

1.5 Letter(s) of Access

Not necessary: the applicant is the owner of data which support the approval of the active substance.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	VINTEC
Authorisation number	2169998
Function	Fungicide
Low risk (art 47)	yes
Applicant	BI-PA SA
Composition	1 x 10^{10} CFU/g or 150 g/kg
Formulation type (code)	Water-dispersible granule (WG)

2.2 Classification and labelling

Classification not changed (see first market authorization).

2.2.1 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 m to surface water bodies for outdoor uses.

2.2.2 Other phrases linked to the preparation

Wear suitable personal protective equipment[7]: refer to the Decision in Appendix 1 for the details
Re-entry period[8]: 6 hours
Pre-harvest interval[9]: 21 days
Other mitigation measures: -

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

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

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

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.

GAP rev., date: 2019-12-31

PPP (product name/code):	**VINTEC**	Formulation type:	**WG** [a, b]
Active substance 1:	*Trichoderma atroviride* strain SC1	Conc. of as 1:	**150 g/kg (10 10^{13} cfu/kg)** [c]
Applicant:	**BI-PA SA**	Professional use:	☒
Zone(s):	Southern zone [d]	Non professional use:	☐
Verified by MS:	yes		
Field of use:	fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f] **RMS Conclusions**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	France	Grapevine (VITVI)	F	*Botrytis cinerea*	Spray appli-cation	From BBCH 68 (80% of flowerhoods fallen) until PHI	a) 4 b) 4	7 days	a) 0.2 b) 0.8	a) 2×10^{12} CFU/ha b) 8×10^{12} CFU/ha	100 – 1000	21	**Acceptable** For this use 2 to 4 applications are recommended at the following stages BBCH 68; BBCH 77-79 ; BBCH 81; 3 weeks before harvest

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/L
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

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

3 RISK MANAGEMENT

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

3.1.1 Physical and chemical properties

The physico-chemical properties of the formulation have been evaluated and considered acceptable during the registration of this formulation.

The concentrations of uses claimed for this extension of uses (concentration from 0.01 % to 0.03 %) are not covered by this previously assessment.
Nevertheless, the relevant tests of physical and chemical properties for WG formulation (suspensibility, spontaneity of dispersion, wet sieve test, persistent foam) evaluated in the initial dossier cover the maximum use concentration of the extension of use.

3.1.2 Methods of analysis

3.1.2.2 Analytical methods for residues

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

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

Active substance	**ADI** mg/kg bw/d	**ArfD** mg/kg bw	**AOEL** mg/kg bw/d	**Classification**
Trichoderma atroviride SC1	Not relevant for microorganisms			Not classified Micro-organisms may have the potential to provoke sensitising reactions.

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

3.1.3.1 Acute Toxicity

VINTEC containing 150 g/ kg *Trichoderma atroviride* SC1 (1.10^{10} CFU/g) has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye.

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 equipment is worn (gloves, coverall and respiratory mask), the preparation is considered safe for operators based on the low toxicity profile and the application.
Since *Trichoderma atroviride* SC1 may be responsible for opportunist infection in sever immunocompromised people, the product should not be used by people affected by immunodeficiency or in treatment with immunosuppressive agents.
For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

3.1.3.3 Bystander and residential Exposure

Following the above given reasons for abstaining from an estimation of operator risk assessment, this also applies with regard to bystanders and residents. As regard the application method, bystander and residential exposure is supposed to be negligible for field uses.

3.1.3.4 Worker Exposure

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

3.1.4 Residues and Consumer Exposure

The intended uses of *Trichoderma atoviride* SC1 do not represent a risk for the consumer.

Indeed *Trichoderma atroviride* is a wide-spread, ubiquitous and common soil-borne fungus, which is found at substantial numbers in all agricultural soils, in particular in the rhizosphere, and in wood decay. Despite its ubiquity, no strain of *Trichoderma atroviride* is mentioned in any paper related to human infection or secondary infection cases.

T. atroviride produced no metabolite of known toxicological concern.
At EU level, due to the lack of significant toxicity, infectivity or pathogenicity of the microorganism and the absence of growth at 35°C and above, it was considered not necessary to derive reference values for *Trichoderma atroviride* strain SC1. Consequently *Trichoderma atroviride* strain SC1 was included in Annex IV of Regulation (EC) No 396/2005.

Considering that *Trichoderma atroviride* strain SC1 is included in Annex IV of Regulation (EC) No 396/2005 it is considered that the risk of residue on tomatoes can be considered as negligible and that no further information is considered necessary. Therefore, a PHI should not be necessary depending on national requirement and applicant proposal.

Consequently it can be concluded that the intended uses of VINTEC do not represent a risk for the consumer.

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 PEC of the active substance in soil, and surface water have been assessed according to FOCUS guidance documents, and the endpoints established in the EU conclusions.

Trichoderma atroviride strain SC1 is a low-risk active substance (See Commission Regulation (EC) No 2016/951).

PEC soil and PECsw derived for the active substance are used for the ecotoxicological risk assessment. No unacceptable risk of groundwater contamination is expected for all 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.

Trichoderma atroviride strain SC1 is a low-risk active substance (See Commission Regulation (EC) No 2016/951).

Based on the guidance documents, the risks for birds, mammals, aquatic organisms, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms are acceptable for the intended uses.

3.1.7 Efficacy

Considering the data submitted:

- The efficacy level of VINTEC is considered as partial for the claimed use. However, it is considered as acceptable considering the kind of product based on micro-organisms.
- The phytotoxicity level of VINTEC is considered as negligible for the claimed use.
- The risks of negative impact on yield, quality, propagation, succeeding crops, adjacent crops are considered as negligible.
- The risk of resistance development or appearance to *Trichoderma atroviride* SC1 is considered as very low.

3.2 Conclusions arising from French assessment

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

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

No further information is required.

3.4.2 Post-authorisation data requirements

The French Decision requests the submission of post-authorisation confirmatory pieces requested in the first authorisation dated on July 24th, 2017.

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'extension d'usage 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'extension d'usage majeur du produit phytopharmaceutique ***VINTEC***

de la société *BI-PA SA*

enregistrée sous le *n°2018-1865*

Vu les conclusions de l'évaluation de l'Anses du 17 septembre 2019,

Vu la décision du Directeur général de l'Anses du 23 octobre 2019,

Vu le recours gracieux formé le 9 décembre 2019 par la société BI-PA SA,

L'autorisation de mise sur le marché du produit référencé ci-après **est étendue** aux usages décrits dans la présente décision.

La présente décision abroge et remplace la décision du 23 octobre 2019 et 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.

VINTEC
AMM n°2169998

Page 1 sur 5

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Informations générales sur le produit	
Nom du produit	VINTEC
Type de produit	Produit de référence
Titulaire	BI-PA SA Technologielaan 7 - Industriepark 1840 Londerzeel Belgique
Formulation	Granulé dispersable (WG)
Contenant	10^{10} UFC/g (équivalent à 150 g/kg) - *Trichoderma atroviride* SC1
Numéro d'intrant	040-2015.02
Numéro d'AMM	2169998
Fonction	Fongicide
Gamme d'usage	Professionnel
Mention particulière	Produit à faible risque au sens de l'article 47 du règlement (CE) 1107/2009

L'échéance de validité de la présente décision correspond à celle de l'autorisation du produit.

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

A Maisons-Alfort le, 31 DEC. 2019

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)

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ANNEXE I : Modalités d'autorisation du produit

Liste des nouveaux 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)	Mention abeilles
12703205 Vigne*Trt Part.Aer.* Pourriture grise	**0,2 kg/ha**	**4/an**	à partir du stade BBCH 68	21	5	-	-	-
	Intervalle minimum entre les applications : 7 jours.							

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Conditions d'emploi du produit

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 à l'aide d'un pulvérisateur à jet porté ou traîné, à rampe ou pneumatique

• pendant le mélange/chargement

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

• pendant l'application

Si application avec tracteur avec cabine

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 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 EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;
- Demi-masque filtrant anti-aérosols certifié (EN 149) de classe FFP3 ou demi-masque certifié (EN 140) équipé d'un filtre anti-aérosols certifié (EN143) de classe P3 ;

• pendant le nettoyage du matériel de pulvérisation

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

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Pour le travailleur, porter
- Une combinaison de travail (cotte en coton/polyester 35 %/65 % - grammage d'au moins 230 g/m²) avec traitement déperlant et, en cas de contact avec la culture traitée, des gants en nitrile certifiés EN 374-3.

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

Protection de l'environnement (milieux, faune et flore)

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.

VINTEC
AMM n°2169998

Page 5 sur 5

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

Vintec®

A bio-control FUNGICIDE to protect vines against pathogens related to wood diseases (Esca, BDA and Eutypa) and grey mould

Water dispersible granule (WG) formulation containing 1 x 10^{10} colony forming units (CFU)/g of *Trichoderma atroviride* SC1

FOR PROFESSIONAL USE ONLY

DO NOT STORE AT TEMPERATURES HIGHER THAN 4°C – DO NOT FREEZE

® Registered trademark of Bi-PA NV/SA

Contents: 50g

Batch number and production date: see packaging
Authorization number : 2169998

® Registered trademark of Bi-PA NV/SA

VINTEC® .Authorization N°. 2169998

Contains 1 x 10^{13} CFU/kg of *Trichoderma atroviride* strain SC1
Water dispersible granule (WG)

P-phrases: P261 Avoid breathing dust - **P280** Wear protective gloves - **P285** In case of inadequate ventilation wear respiratory protection - **P501** Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation

EUH401 To avoid risks to human health and the environment, comply with the instructions for use.

Product contains *Trichoderma atroviride*. Could provoke sensitizing reactions. The product should not be used by subjects affected by immunodeficiency or under treatment with immunosuppressive agents

SP1: 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).
SPe3: To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres to surface water bodies for outdoor uses.

Re-entry interval: 8 hours for indoor application (not applicable for outdoor uses),or, in case of earlier return, wear a half-mask particulate filter certified according to EN 149 standard or a half mask certified EN 140 with a particle filter P3 (certified EN 143).

Safety data sheet available on the website www.quickfds.com

Distributed by : **Belchim Crop Protection France S.A.**
Parc Tertiaire de Bois Dieu | 3 allée des Chevreuils | 69380 LISSIEU | Tel. +33 4 78 83 40 66

IN CASE OF EMERGENCY : Call for help by dialing 15 or 112 or contact the nearest poison control center, then report your symptoms to the Phyt'Attitude network, free number 0 800 887 887 (free dial from a landline).

bi-pa
Biological Products for Agriculture

Authorization holder : **Bi-PA NV/SA**
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www.Bi-PA.com

BELCHIM
CROP PROTECTION

Distributed by: **Belchim Crop Protection France S.A.**
Parc Tertiaire de Bois Dieu
3 allée des Chevreuils
69380 LISSIEU
www.belchim.fr

First Aid

- After inhalation : Remove person to fresh air and keep comfortable for breathing.
- After skin contact : Wash skin with plenty of water.
- After eye contact : Rinse eyes with water as a precaution.
- After ingestion : Call a poison center or a doctor if you feel unwell.

In any case, if the symptoms persist or when feeling unwell, consult a doctor and show him the label and/or the safety data sheet.

BIO-CONTROL FUNGICIDE for use in grapevines against pathogens related to wood diseases (Esca, BDA and Eutypa) and grey mould

USES AND DOSE RATES

Authorized uses	Dose rate	Maximum number of treatments	Time of application	Preharvest interval (PHI)
Vine*Treatment of plant cuttings*Esca and black dead arm	0.2 kg/hl	4/year	Use during production of plants (operations of cutting, grafting, planting, etc.)	F
Vine*Treatment of aerial parts*Esca and black dead arm	0.2 kg/ha	2/year	BBCH00 (dormancy) – before the swellingof the buds. Treatment after pruning.	F
Vine*Treatment of aerial parts*Eutypa	0.2 kg/ha	2/year	BBCH00 (dormancy) – before the swellingof the buds. Treatment after pruning.	F
Vine*Treatment of aerial parts*Grey mould	0.2 kg/ha	4/year	BBCH68 until PHI	F

The use of Vintec® for these authorized uses is only recommended for the crops mentioned in the table above. As a consequence, Belchim Crop Protection denies all responsibility in case of uses of the product on crops or for targets that are not recommended.

Maximum residu levels (MRL) : see MRL's defined at EU level, searchable at the following address: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database

CONDITIONS OF USE

Vintec® is a bio-control fungicide for use in vines (cuttings and established vines) against Botrytis cinerea (gray mould) and the pathogens Phaemoniella chlamydospora and Phaeoacremonium aleophilum, related to Esca, against pathogens related to Black Dead Arm (BDA) and against Eutypa lata, pathogen related to Eutypa.
The product can be used in conventional and organic agriculture;

For the use as dipping or drenching treatment during the nursery process
Details of use:

Time of application	Type of treatment
After preparation of the root stocks and scions, before cold storage	Soaking of root stocks and scions
During rehydration, before grafting	Soaking of root stocks and scions
At stratification	Irrigation of grafted plants
Before transplant	Soaking of extremities of the plant (callus, young roots)

For the use in established vineyards (ESCA, BDA, Eutypa)

- After pruning, apply Vintec® on the pruning wounds during the winter dormancy period (before bud swelling) as soon as the temperature reaches 10°C.
- For an optimal result, ensure that the application is followed by a period of 24 hours without rain or frost.
- Vintec® can be applied using a backpack sprayer or towed sprayer adapted to target the pruning wounds. Use an amount of water sufficient to cover all the pruning wounds without surpassing the runoff point.
- Vintec® is more effective when used in combination with cultural prophylactic measures (late pruning, coppicing and limitation of inoculum in surroundings of the treated parcels by by elimination of dead woods and vines).

For the use in established vineyards (gray mould)

- Preventive treatment against Botrytis cinerea: recommended dose rate is 200 g/ha. For this use, between 2 and 4 applications are recommended on the following stages: BBCH68, BBCH77-79, BBCH81, 3 weeks before harvest.

Storage : Store the product only in the original container, away from moisture, from light and frost, away from food, drinks including those for animals.
Vintec® contains living organisms:

- Storage temperature between 0 and 4°C
- Do not freeze
- Do not expose Vintec® to prolonged direct sunlight.
- Do not store under wet conditions.
- Shelf life under these conditions : 24 months

Where packages have been opened, they may be stored in the refrigerator for 1 month maximum.

IMPLEMENTATION AND GOOD PRACTICES
It should be recalled that the use of suitable and maintained equipment and the implementation of collective protection is the first measure of prevention of professional risk, before the introduction of additional protections such as individual protections.
In any case, the wearing of a dedicated working suit or PPE must be associated with hygienic reflexes (e.g.: hand washing, shower at the end of treatment) and a rigorous behaviour (e.g. dressing / undressing procedure). The methods of cleaning and storage of work suits and reusable PPE must comply with their instructions for use.

Wear work suits and the following personal protective equipment (PPE):

PPE properties ▼		PROTECTION OF THE USER DURING THE PHASES OF : MIXING/LOADING	TREATMENT : WITH BACKPACK SPRAYER	TREATMENT : DIPPING ROOTSTOCKS AND SCIONS IN THE NURSERY (IN GREENHOUSE)	CLEANING	WORKER PROTECTION
NITRILE gloves re-usable (certified EN 374-3) or single use(certified EN 374-2)		Reusable	Single use	Reusable	Reusable	Reusable(**)
Protective clothing (***) 65 %polyester / 35 %cotton >= 230 g/m² + water repellent				PPE protective clothing AND PPE partial coverall		
Partial PPE blouse apron with long sleeves categorie III type PB3 certified EN 14605+A1						
Protective coveralls categorie III type 3 or 4 certified EN 14605+A1:2009		Type 4	Type 4 with hood		Type 4	
Respiratory protection certified anti-aerosol filtering half-mask (EN 149) of class FFP3		or	or	or		
Respiratory protection certified half-mask (EN 140:1998) equipped with a certified anti-aerosol filter of class P3 (EN143:2008)						
BOOTS certified EN 13 832-3:2008						

PPE properties ▼		PROTECTION OF THE USER DURING THE PHASES OF : MIXING/LOADING	TREATMENT : TRACTOR-MOUNTED BOOM SPRAYER TRACTOR-MOUNTED BROADCAST AIR ASSISTED SPRAYER, ATOMISER TRACTOR WITH CABIN	TRACTOR WITHOUT CABIN	CLEANING	WORKER PROTECTION
NITRILE gloves re-usable (certified EN 374-3) or single use(certified EN 374-2)		Reusable	Single use (*)	Single use	Reusable	Reusable(**)
Protective clothing (***) 65 %polyester / 35 %cotton >= 230 g/m² + water repellent		PPE protective clothing AND PPE partial coverall			PPE protective clothing AND PPE partial coverall	
Partial PPE blouse apron with long sleeves categorie III type PB3 certified EN 14605+A1						
Protective coveralls categorie III type 3 or 4 certified EN 14605+A1:2009				Type 4 with hood		
Respiratory protection certified anti-aerosol filtering half-mask (EN 149) of class FFP3		or		or	or	
Respiratory protection certified half-mask (EN 140:1998) equipped with a certified anti-aerosol filter of class P3 (EN143:2008)						

* These gloves need only be worn outside the cabin and must be stored outside the cabin after use
** In case of contact with the crop or treated parts
*** This recommended garment may be replaced by any other clothing PPE, specific to plant protection products, which comply with the essential health and safety requirements of Directive 89/686 / EEC.

PREPARATION OF THE SOLUTION
Use Vintec® in clean tanks and spraying equipment, cleaned with a product such as Phytnet (if the tank and the sprayer have been in contact with other plant protection products). Residues of products used before application of Vintec® can have a negative effect on the survival of the microorganism *Trichoderma atroviride* SC1.
The use of water containing disinfectant substances is not recommended.

Shake/homogenise the solution before and during application.
Prepare the solution based on Vintec® before use. Put the required dose of Vintec® in a tank or sprayer partially filled with water, then homogenise the solution by mixing with an agitation system or with a stick (not by hand). A water temperature between 5 and 15°C is recommended. The solution should be used within 48 hours.

MIXTURES
Do not mix Vintec® with other plant protection products.
However Vintec® can be combined with Mycorrhiza and *Bacillus* spp.

ELIMINATION OF THE PRODUCT AND THE CONTAINERS:
To eliminate the non-used product, take contact with the authorized company to collect and eliminate dangerous products.
Do not re-use the empty container. Eliminate the empty containers via the organized collection by a specific collection service.

IMPORTANT
- Respect the uses, dose rates, conditions and precautions for use mentioned on the packaging, which were determined by the characteristics of the product and the applications for which it is recommended.
- Run, on this basis, the cultivation and the treatments according to the good agricultural practice and the recommendations from your distributor taking into account, under your responsibility, all particular factors concerning your farm, such as the nature of the soil, the weather conditions, cultivation methods, plant varieties, types of grape variety, species resistance ...
- The manufacturer guarantees the quality of its products sold in their original packaging and their compliance with the marketing authorization of the Ministry of Agriculture.

WARRANTY
The seller makes no warranty, expressed or implied, with regard to the use of the product other than that indicated on the label. The purchaser and user shall assume all risk associated with use and/or handling and/or the storage of the product, if this use and/or handling and/or storage are carried out contrary of the instructions on the label.

RESPONSIBILITIES
Buyer's or user's exclusive remedy for damages, breach of warranty, or negligence, shall be limited to the direct damage, and shall not exceed the purchase price of the product, and shall not include any incidental or consequential damages.

The origin of this invention is the result of research by Fondazione Edmund Mach and Trentino Sviluppo.

Appendix 3 – Letter(s) of Access

Not necessary.