HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1. VOORGENOMEN BESLUIT

Op 6 maart 2018 is van

Bi-PA N.V.
Technologielaan 7
B-1840 LONDERZEEL
België

een aanvraag tot wederzijdse erkenning van een gewasbeschermingsmiddel ontvangen voor het middel

VINTEC

op basis van de werkzame stof Trichoderma atroviride strain SC1.

HET COLLEGE IS VOORNEMENS TE BESLUITEN tot toelating van bovenstaand middel.

Alle bijlagen, waaronder registratierapport deel A en deel B, vormen een onlosmakelijk onderdeel van dit besluit.

1.1 Samenstelling, vorm en verpakking

De toelating geldt uitsluitend voor het middel in de samenstelling, vorm en de verpakking als waarvoor de toelating is verleend.

1.2 Gebruik

Het middel mag slechts worden gebruikt volgens het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in deel A van het registratierapport, Appendix I.

1.3 Classificatie en etikettering

Mede gelet op de onder “wettelijke grondslag” vermelde wetsartikelen, dienen alle volgende aanduidingen en vermeldingen conform de geldende regelgeving op of bij de verpakking te worden vermeld:

- De aanduidingen, letterlijk en zonder enige aanvulling, zoals vermeld onder "verpakkingsinformatie" in bijlage I.
- Het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in deel A van het registratierapport, Appendix I.
- Overige bij wettelijk voorschrift voorgeschreven aanduidingen en vermeldingen.
- De classificatie die overeenkomstig het toelatingsbesluit is vastgesteld, moet volgens de voorschriften op de verpakking worden vermeld, zoals beschreven in bijlage II en in hoofdstuk 2 van deel A van het registratierapport.

1.4 Aflever- en opgebruiktermijn (respijtperiode)

Niet van toepassing. Het betreft een nieuwe toelating.

2. WETTELIJKE GRONDSLAG

Besluit	artikel 40 van de Verordening (EG) 1107/2009
Classificatie en etikettering	artikel 31 en artikel 65 van de Verordening (EG) 1107/2009
Gebruikt toetsingskader	Rgb d.d. 16 december 2011 en HTB 1.0 (micro-organismen)

3. BEOORDELINGEN

3.1 Fysische en chemische eigenschappen

De aard en de hoeveelheid van de werkzame stoffen en de in humaan-toxicologisch en ecotoxicologisch opzicht belangrijke onzuiverheden in de werkzame stof en de hulpstoffen zijn bepaald. De identiteit van het middel is vastgesteld. De fysische en chemische eigenschappen van het middel zijn vastgesteld en voor juist gebruik en adequate opslag van het middel aanvaardbaar geacht.

3.2 Analysemethoden

De geleverde analysemethoden voldoen aan de vereisten om de residuen te kunnen bepalen die vanuit humaan-toxicologisch en ecotoxicologisch oogpunt van belang zijn, volgend uit geoorloofd gebruik.

3.3 Risico voor de mens

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor de mens verwacht.

3.4 Risico voor het milieu

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor het milieu verwacht.

3.5 Werkzaamheid

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften verwacht dat het werkzaam is.

Voor nadere onderbouwing van de beoordelingen verwijzen wij u naar deel A en B van het Registration Report als toegevoegd aan de bijlagen van dit besluit overeenkomstig Besluit beleidsregel bekendmaken delen A en B van het Registration Report.

Zienswijzenprocedure

Ingevolge artikel 2:3 Besluit bestuursreglement regeling toelating gewasbeschermingsmiddelen en biociden Ctgb 2007 geldt dat dit ontwerpbesluit gedurende twee weken ter inzage wordt gelegd op het Ctgb; hiervan wordt mededeling gedaan in de Staatscourant. Het ontwerpbesluit wordt gedurende deze periode tevens op de website van het Ctgb geplaatst. Belanghebbenden kunnen gedurende de ter inzagenlegging schriftelijk bij het Ctgb aangeven dat zij een zienswijze zullen indienen; de zienswijze dient schriftelijk binnen twee weken na de inzagenperiode te worden ingediend.

Ede, ...

Het College voor de toelating van
gewasbeschermingsmiddelen en biociden,
voor deze:
de voorzitter,

Ir. J.F. de Leeuw

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

2.1 Aanvraaginformatie

Aanvraagnummer:	20180597 NLWERG
Type aanvraag:	aanvraag tot wederzijdse erkenning van een gewasbeschermingsmiddel
Middelnaam:	VINTEC
Verzenddatum aanvraag:	1 maart 2018
*Formele registratiedatum: **	6 april 2018
Datum in behandeling name:	5 juli 2018
Datum compliance check:	n.v.t.

* Datum waarop zowel de aanvraag is ontvangen als de aanvraagkosten zijn voldaan.

Aangezien VINTEC een voor Nederland nieuwe werkzame stof bevat (Trichoderma atroviride strain SC1, zie hieronder), is de zienswijzeprocedure zoals bedoeld in artikel 2:3 Besluit bestuursreglement regeling toelating gewasbeschermingsmiddelen en biociden Ctgb 2007 van toepassing.

2.2 Stofinformatie

Werkzame stof	Gehalte
Trichoderma atroviride strain SC1	150 g/kg

- De stof is per 6 juli 2016 goedgekeurd volgens Verordening (EU) 1107/2009 (Uitvoeringsverordening (EU) 2016/951 d.d. 15 juni 2016). De goedkeuring van deze werkzame stof expireert op 6 juli 2031.

2.3 Toelatingsinformatie

Toelatingsnummer:	15689 N
Expiratiedatum:	6 juli 2032
Afgeleide parallel of origineel:	Origineel
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Gewasbeschermingsmiddel
Gebruikers:	Professioneel

2.4 Verpakkingsinformatie

Aard van het preparaat:
Water dispergeerbaar granulaat

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BIJLAGE II Etikettering van het middel VINTEC

Professioneel gebruik
de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel:
-

Pictogram	-
Signaalwoord	-
Gevarenaanduidingen	-
Voorzorgsmaatregelen	P261 Inademing van stof/rook/gas/nevel/damp/spuitnevel vermijden. P280C Beschermende handschoenen en beschermende kleding dragen. P302 + P352 BIJ CONTACT MET DE HUID: Met veel water/... wassen. P305 + P351 + P338 + P310 BIJ CONTACT MET DE OGEN: voorzichtig afspoelen met water gedurende een aantal minuten; contactlenzen verwijderen, indien mogelijk. Blijven spoelen. Onmiddellijk een ANTIGIFCENTRUM/arts/... raadplegen. P333 + P313 Bij huidirritatie of uitslag: een arts raadplegen. P342 + P311 Bij ademhalingssymptomen: een ANTIGIFCENTRUM of een arts raadplegen. P262 Contact met de ogen, de huid of de kleding vermijden. SP 1 Zorg ervoor dat u met het product of zijn verpakking geen water verontreinigt.
Aanvullende etiketelementen	EUH401 Volg de gebruiksaanwijzing om gevaar voor de menselijke gezondheid en het milieu te voorkomen.
Kinderveilige sluiting verplicht	Nee
Voelbare gevaarsaanduiding verplicht	Nee

REGISTRATION REPORT
Part A

Risk Management

Product code: **VINTEC**
Active Substance: **1.0×10^{13} CFU *Trichoderma atroviride* SC1/kg**

Inter-Zonal

Zonal Rapporteur Member State: France

Mutual recognition to The Netherlands

Applicant: **Bi-PA nv**
Date: **September 2018**
Evaluator: **Ctgb, NL**

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PART A – Risk Management

1 Details of the application

This document describes the acceptable use conditions required for the registration of VINTEC containing *Trichoderma atroviride* SC1 for nursery uses in the EU. VINTEC was authorised in France as plant protection product for indoor and outdoor use in grapevine against *Phaeomoniella chlamydospora, Phaeoacremonium aleophilum* and *Eutypa lata* in February 2017 (N° D´AMM 2169998) under Regulation (EC) 1107/2009. Based on the decision for indoor use in vine nurseries, the applicant applies for mutual recognition of the registration for the indoor use of VINTEC to the Netherlands.

VINTEC was evaluated as the representative formulation during the EU review of *Trichoderma atroviride* SC1 as an active ingredient under Regulation (EC) No 1107/2009. It has previously been evaluated according to Uniform Principles. The risk assessment conclusions are based on the information, data and assessments provided in the Registration Report (RR), Part B Sections 1-7 and Part C. Assessments for the safe use of VINTEC have been made using endpoints provided in the DAR of *T. atroviride* SC1. All the studies included in the present RR are part of the EU evaluation dossier for *T. atroviride* SC1.

This document describes the specific conditions of use and labelling required for EU member states for the registration of VINTEC.

Appendix 1 of this document contains a copy of the proposed product label.

Appendix 2 contains the Letter of Access for the applicant for efficacy data owned by third parties.

1.1 Application background

This application is submitted by Bi-PA nv.

Applicant and future registration holder:

Name	Bi-PA nv
Address	Technologielaan 7 1840 Londerzeel Belgium

The application is for registration of VINTEC, a biological fungicide for use in vine nurseries. The product is formulated as water dispersible granules (WG) and contains 1×10^{13} CFU/kg of *Trichoderma atroviride* SC1.

Other codes or names that have been used for VINTEC, are BCP511B, SC1 WG and *Trichoderma atroviride* SC1 WG.

1.2 Annex I inclusion

The dossier was submitted to the authorities of France in November 2012. The completeness decision laying down that the dossier is in principal recognised to fulfil all data and information requirements for a possible approval of *T. atroviride* SC1 were published on the 13th of March 2013. The Draft Assessment Report (DAR) for *T. atroviride* SC1 published in May 2014 and the final addendum thereof, published in February 2015, are considered to provide the relevant review information or a reference to where such information can be found. The conclusion of EFSA[1] on the peer review of the pesticide risk assessment of the active substance was published in April 2015.

The review report (SANTE/10389/2016 rev. 1; 22 March 2016) mentions particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing *Trichoderma atroviride* strain SC1.

[1] EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance Trichoderma atroviride strain SC1. EFSA Journal 2015;13(4):4092, 33 pp. doi:10.2903/j.efsa.2015.4092

On the basis of the proposed and supported uses, the following issue has been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

Member States shall pay particular attention to the protection of operators and workers, taking into account that microorganisms are considered as potential sensitisers.

Conditions of use shall include risk mitigation measures where appropriate.

Also, EFSA conclusions on *Trichoderma atroviride* strain SC1raised several data gaps and concerns.

These concerns have been addressed within the current submission.

1.3 Regulatory approach

The dossier was submitted to France in June 2015 for first registration of the product following Regulation (EC) No 1107/2009 according to national requirements.

To obtain approval, the product VINTEC was supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment according to Uniform Principles, using available endpoints from the DAR of the active substance *T. atroviride* SC1.

VINTEC was approved for indoor and field uses in vineyards in France in February 2017, the original registration followed an inter-zonal registration with France as inter-zonal RMS for indoor uses and a zonal registration with France as zonal RMS for the Southern Zone.

1.4 Data protection claims

Please refer to the reference list included in the RR documents, Part B section 1-7. The applicant, Bi-PA nv, Technologielaan 7, 1840 Londerzeel, Belgium, is holder of most proprietary data used in the dossier, some of the efficacy data are owned by Belchim but a LoA is available. Data protection is claimed for all efficacy data including that are owned by third parties.

1.5 Letters of Access

Bi-PA NV is the owner of the data that supported the EU review of the active ingredient *Trichoderma atroviride* strain SC1. Some efficacy studies are owned by BELCHIM Corp Protection. A copy of the letter of access is provided.

2 Details of the authorisation

2.1 Product identity

Product Name	VINTEC
Authorisation Number (for re-registration)	France: no. 2169998
Function	Biological fungicide
Applicant	Bi-PA nv
Composition	*T. atroviride* SC1: 1×10^{13} CFU/kg, 150 g/kg
Formulation type	Water dispersible granules [Code: WG]
Packaging	25 g; 50 g; 100 g; 200 g; 400 g; 1 kg Bags made of LDPE/Aluminium/LDPE

2.2 Classification and labelling under Regulation (EC) 1272/2008

The identity of all substances in the mixture that contribute to the classification of the mixture *:			
-			
Pictogram:	-	Signal word:	-
H-statements:	-		
P-statements:	P261	Do not breathe dust/fume/gas/mist/vapours/spray.	
	P262	Do not get in eyes, on skin, or on clothing.	
	P280c	Wear protective gloves and protective clothing.	
	P302+P352	IF ON SKIN: Wash with plenty of water/...	
	P305+P351+P338+P310	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor/....	
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.	
	P342+P311	If experiencing respiratory symptoms: Call a POISON CENTER/doctor/...	
Supplemental Hazard information:	EUH401	To avoid risks to human health and the environment, comply with the instructions for use.	
	SP1	Do not contaminate water with the product or its container.	
Child-resistant fastening obligatory?			not applicable
Tactile warning of danger obligatory?			not applicable

Explanation:	
Pictogram:	-
H-statements:	-
P-statements:	P305+P351+P338+P313 as proposed by the applicant has been corrected to P305+P351+P338+P310. P261 and P284 were proposed by the applicant but not assigned as considering the intended use significant inhalation exposure to the product is not expected.
Other:	SP1 based on guideline 547/2011. EUH401 for all PPPs.

* according to Reg. (EC) 1272/2008, Title III, article 18, 3 (b)

2.3 Product uses

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G 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
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha and CFU/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	Netherlands	Grapes, nursery (VITVI)	I	*Phaeomoniella chlamydospora* (PHMOCH) *Phaeoacremonium aleophilum* (TOGNMI)	Dipping of root stocks and scions	Grafting period (BBCH 00)	4*	a) 0,2 kg/hl[1] b) 0,8 kg/hl	a) 2 x 1012 CFU/hL b) 8 x 1012 CFU/hL		-	Dose rate for nursery application is expressed per hL, since this concerns a dipping treatment: Product: 0.2 kg product per hL A.s.: 2 x 10^{12} CFU/hL *Maximum four applications during the process: - Watering of scions and rootstocks before storage - Re-watering of scions and rootstocks before grafting - Stratification - Acclimatization

[1] 100 L water for 3 x 1000 plants (the liquid in the container can be used three times). If the volume is unknown : 2 g per 100 grafts or 35 rootstocks. After planting in the nursery, there can be 200.000 to 300.000 plants per ha

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

VINTEC constitutes the representative formulation that has been evaluated in the DAR. The endpoints have not been evaluated by zRMS FR. All studies have been performed in accordance with the current requirements, the critical GAP and the results are deemed to be acceptable. VINTEC (*Trichoderma* granule) is a pale green water dispersible granule (WG-)formulation with a characteristic odour. It is neither explosive, nor oxidizing. The formulation is not flammable, as it could not be ignited by a 2-minute long exposure to an ignition source. VINTEC is not considered self-heating, as its auto-ignition temperature was measured to be > 140°C. The pH of the 1% diluted formulation is 7.64. No loss of viable spores / g was observed (concentration remained above the minimum of 1×10^{10} CFU / g specified in the Implementing Regulation at all times), contaminating micro-organisms remained below SANCO/12116/2012 – rev. 0 – defined thresholds, and no significant changes in the product characteristics were noted upon 24 months-storage of VINTEC (*Trichoderma* granule) in commercial packaging (LDPE/Aluminium/LDPE) at 4°C, *except* for the retention in the wet sieve test, which exceeded the 2% limit value. ZRMS FR already requested additional data, addressing the possibility of blockage of nozzles or filtres in the application machine when the product is applied by spraying. According to the applicant, the data are to be provided within 2 years after authorization. A restriction sentence is proposed to avoid problems relating to sedimentation during application (see below). A two year shelf-life in the proposed commercial packaging (LDPE/Aluminium/LDPE-bags) at a storage temperature of 4°C is granted.

The in-use concentration according to the NL-GAP is 0.2% (0.2 kg in 100 L). The technical properties for which the in-use concentration applies regarding testing (i.e., suspensibility and persistent foam formation) have been tested at 0.2%. Suspensibility was measured to be 71.4% and persistent foam formation was 1.15 mL after 1 min; both properties are therefore within acceptable limits. Despite being acceptable, the suspensibility tends to be on the low side. Also, the wet sieve results suggest that the product, upon dissolution, is prone to sedimentation. As a result, a restriction sentence is proposed addressing potential sedimentation during use. The remaining required technical properties (wettability, dispersibility, dustiness, flowability, and attrition resistance) were deemed to be acceptable. Regarding the wet sieve test; see above comment.

Implications for labelling: A two year shelf-life has been demonstrated at 4°C. As a result, the following storage recommendation is proposed: “Store at ≤4°C”.

Considering the low suspensibility of the product, the following restriction sentence is proposed: “Stir during use”.

Compliance with FAO specifications: The product VINTEC complies with the FAO specification of water dispersible granules. Currently a FAO specification does not exist for microbial plant protection products.

Compatibility of mixtures: VINTEC is not intended to be used together with adjuvants in tank mixes.

Nature and characteristics of the packaging: Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable of Vintec.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Methods are available to quantify the content of the active ingredient in the formulation, and to determine potential microbial contaminants.

The number of viable spores in the formulation is determined by Thoma chamber counting under a microscope. The viability of the spores is tested by spreading a product suspension potato dextrose agar followed by a 24 h incubation at 20°C and counting of germinated and non-germinated spores. These methods were considered acceptable in the EU evaluation. According to the DAR, for the determination of impurities ‘methods used for the

determination of microbial contaminants in the formulated product VINTEC are international standard methods, so validation data are not necessary.

3.1.2.2 Analytical methods for residues

No methods for residue quantification of the active micro-organism, relevant metabolites, or viable/non-viable residues have been reviewed on EU level. No residue definitions are applicable for *T. atroviride* SC1 or its metabolites.

No additional methods for the determination of residues have been submitted here for the following reasons: according to the Review Report, the product as well as the active ingredient *T. atroviride* SC1 is regarded to be non-hazardous. No risks to humans, non-target species, or the environment are anticipated. Furthermore, the strain does not produce metabolites of toxicological concern. *T. atroviride* SC1 was demonstrated not to persist in their natural environment at levels higher than naturally occurring in soil. The risk that toxins or other metabolites might be secreted at levels higher than the natural background or dangerous for human and animal health, groundwater or the environment is deemed to be very low.

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

All submitted toxicological studies and supplemental information on *Trichoderma atroviride* SC1 including VINTEC prove that these are non-toxic and non-infectious to mammals and impose no health risk for operators, bystanders or workers. Since no hazard identification can be made for any clearly adverse effect of *Trichoderma harzianum*, a formal dose-response assessment is not necessary.

For details of the formulation VINTEC, please refer to RR Part C. The results of toxicological studies conducted with the plant protection product VINTEC are summarised in **Table 3.1.3.1-1.**

Table 3.1.3-1 Summary of acute toxicity studies on VINTEC containing *Trichoderma atroviride* SC1

Study type	Test item	Dose level	Findings	Report
Acute oral toxicity Rat	VINTEC	4.1×10^8 CFU/animal	No toxicity no infectivity	2012
Acute inhalation rat (**)	VINTEC	4.7×10^8 CFU/animal	No toxicity no infectivity	2012
Skin irritation Rabbit	VINTEC	100 mg/animal (1.1×10^9 CFU)	Not irritating	2012
Eye irritation Rabbit	VINTEC	500 mg/animal (5.5×10^9 CFU)	Not irritating	2012

(**) Intratracheal study available as worst case

Based on the above studies and data on co-formulants, the formulation VINTEC does not require classification according to its toxicological properties. However, in accordance with the PRAPeR Expert Meeting on micro-organisms in June 2009 the following labelling is proposed:

"*Trichoderma atroviride* SC1 may have the potential to provoke sensitizing reactions."

3.1.3.2 Operator Exposure

Trichoderma atroviride SC1 acts highly specific and is not pathogenic to mammals. This has been shown in tests on toxicity, pathogenicity and infectiveness to vertebrates, all without adverse effects.

No harmful effects have been observed on personnel in research or industrial mass production, over a production period of more than 10 years. Additionally, as all inert co-formulants used in the formulation are of negligible toxicity as well, a toxic effect of VINTEC on the operator, worker, or bystander can be excluded.

Estimation of operator exposure

Since no adverse effects were obtained in any study on toxicity, pathogenicity or infectiveness, calculations on the health risk for operators become meaningless: no target organ exists and no dose-effect response (LOAEL) can be determined.

Trichoderma atroviride SC1 preparations including the formulation VINTEC, are, therefore, considered safe for operators when the potential sensitising properties are considered and appropriate personal protection equipment is worn (gloves andcoverall). As VINTEC is a wettable granule and nearly dust free respiratory protection equipment is not necessary.

3.1.3.3 Bystander Exposure

Following the above given reasons for abstaining from an estimation of operator risk assessment, this also applies with regard to bystanders. *Trichoderma atroviride* SC1 preparations including the formulation VINTEC are considered safe for bystanders and resident as well. Furthermore, since the application concern a dipping application indoors no significant bystander or resident exposure is expected.

3.1.3.4 Worker Exposure

Following a similar argument to above, this also applies with regard to workers. *Trichoderma atroviride* SC1 preparations including the formulation VINTEC are considered safe for workers as well.

3.1.4 Residues and Consumer Exposure

3.1.4.1 Residues

Contamination of grapes with *Trichoderma atroviride* strain SC1 is expected to be comparable to those of naturally occurring Trichoderma populations (1×10^1 to 3.9×10^2 CFU/g of dry soil) and therefore regarded negligible. Moreover, according to the intended use in grape production the MPCP is applied either in winter just after pruning or at least two years before harvest (nursery application). At this time there are no leaves or grapes present and accordingly deposit of MPCP on the grapes can be excluded. *Trichoderma atroviride* strain SC1 is proposed to be included in Annex IV of Regulation (EC) No 396/2005.

As the first harvest of grapes usually takes place several years after application the deposit of residues higher than the indigenous occurrence of the MPCA on grapes or in berries at harvest is unlikely.

3.1.5 Environmental fate and behaviour

Based on available information derived from published literature on *T. atroviride* and other *Trichoderma* species, the environmental fate and population dynamics of *T. atroviride* SC1 in the environment can be summarized as follows:

Soil and groundwater

T. atroviride SC1 will colonize cutting wounds following application of the product in nurseries. No dispersal to the environment is expected when young plants are planted in vineyards.

In this case, the environmental behaviour of *T. atroviride* SC1 upon treatment of grapevine can be assessed based on published information on *Trichoderma* spp. as follows:

After reaching the soil environment, the fungus may establish stable populations in the surface soil and the rhizosphere. Due to competition and other abiotic factors population densities decline by time. Long time persistence may occur in the form of dormant conidia at levels not exceeding those of natural *Trichoderma* populations. Although vertical movement of the fungus appears possible, survival in deeper sediment layers is strongly restricted. Horizontal spread in the soil as well as to above ground plant parts might occur to a limited

extend. The impact of *T. atroviride* SC1 onto soil microbial communities is short and no adverse effects are to be expected as the fungus appears to become part of the soil community at the treatment site. *T. atroviride* SC1 populations probably reaching the soil environment upon treatment of grapes after pruning are therefore not considered to accumulate or grow to an unlimited extent in soil. Due to the general absence of pathogenicity or toxicity to any non-target organism, *T. atroviride* SC1 does not present any health or environmental concern.

The overall view of available information on *Trichoderma* species in general and *T. atroviride* in particular reveals that movement beyond the rhizosphere is restricted. As an ubiquitous saprophytic fungus, *T. atroviride* is living in the upper layer of soils, rich in organic matter. As for other soil-inhabiting fungi, there is little horizontal movement of *T. atroviride* in soil. Colonization of the plant rhizosphere may result in wider spreading. Vertical movement is limited and may only occur after heavy water supply, though some leakage of the spores through the soil to groundwater habitats may occur. However, as *T. atroviride* is ubiquitously distributed in soils, it is likely that spores occur naturally in groundwater. Spores do not germinate and grow in groundwater due to insufficient nutrient availability. Dilution as a result of continuous water flow and predation by groundwater inhabiting organisms will cause a continuous decline of the spores. *T. atroviride* SC1 is intended to be used as an indoor-application during nursery process (dip or drench). Therefore, accumulation of the spores in groundwater is very unlikely.

T. atroviride does not produce any toxins or secondary metabolites of toxicological concern at substantial quantities and therefore leaching to groundwater is not relevant to this fungus.

Surface water

According to information from the published literature, it can be assumed that *Trichoderma* spp. including *T. atroviride* might be able to survive in aquatic environments under certain favourable conditions. However, germination and population growth is likely to be prevented in most cases due to nutrient depletion. Spores eventually reaching surface waters upon field application of *T. atroviride* SC1 are likely to settle down and survive in the sediments. According to the Guidance Document[2] on protected crops, for micro-organisms no specific exposure models for mBCAs are available so far and the models used in the environmental risk assessment proposed for use in this Guidance are not always capable of, or meant for, predicting fate and behaviour of such products in the environment. For permanent structures OECD (2012) document 67 (ENV/JM/MONO(2012)1) indicates that discharge to surface water should be considered.

Making use of the common approach to assume a deposition value of 0.1 % of the dose rate as emission input to surface water (Linders and Jager, 1997), a PEC calculation is presented below.

PEC_{SW} for *T. atroviride* SC1 in the edge-of-field ditch following application in greenhouses

PEC_{SW} (30 cm)	**Single application** **Actual**
Vintec [µg/L] *T. atroviride* SC1 [CFU/L]	6.25 6.25×10^4

Spores of *T. atroviride* SC1 will not affect sewage treatment plants. Their population will not be higher than those of indigenous *Trichoderma* strains that are present in surface waters through natural processes. Effects on analytical methods for drinking water analysis can be excluded because methods used for this purpose are highly specific for the target organism and will not allow growth of *Trichoderma spp*.

Air

Trichoderma spp. occasionally has been isolated from the air. Hence, members of the genus appear to occur in the air naturally, however at low frequency and low concentrations. Dispersal of spores via spray drift following an application of *T. atroviride* SC1 is negligible, as the application is performed by a dip or drench application under indoor-conditions in closed buildings. Nevertheless, if there would be any dispersal leading to temporary populations in the atmosphere, long-term persistence is not expected. It was shown for *Trichoderma harzianum* that even under protected conditions in the greenhouse fungal spores disappeared within one day from the air. Further information on the persistence in air is not required, since the toxicological studies and the temperature growth

[2] EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments. EFSA Journal 2014;12(3):3615, 43 pp., doi:10.2903/j.efsa.2014.3615

profile of this strain prove that it is not able to infect humans, and imposes no risk for workers, operators or bystanders via inhalation or any other exposure route. Likewise, long-distance transport of spores is not likely to occur.

In conclusion, *T. atroviride* may survive in soil for several months as a saprophyte, but there is no risk for uncontrolled growth, since this widespread and naturally occurring soil fungus is subject to competition and antagonism in its natural habitat. As parasitism of *T. atroviride* is limited to other micro-organisms and since the fungus is unable to grow at 37°C, any potential dispersal of this fungus is negligible and does not impose any health or environmental risk.

3.1.5.1 Predicted Environmental Concentration in Soil (PEC_{Soil})

Considering the mode of application (Dipping and drenching of root stocks and scions) for the preparation VINTEC, exposure of environmental compartments to the active substance is considered negligible. Consequently, no risk assessment for environment and non-target organisms is deemed necessary. Therefore, PECsoil calculations performed by the notifier are not presented by zRMS in the Core dossier.

3.1.5.2 Predicted Environmental Concentration in Surface Water (PEC_{SW})

Please refer to 3.1.5.

3.1.5.3 Predicted Environmental Concentration in Air (PEC_{Air})

Not applicable.

3.1.6 Ecotoxicology

3.1.6.1 Effects on Terrestrial Vertebrates

Birds

Nursery application is considered not relevant for exposure to birds. As a result, the risk to birds is considered negligible and need not be evaluated.

Mammals

Nursery application is considered not relevant for exposure to mammals. As a result, the risk to mammals is considered negligible and need not be evaluated.

3.1.6.2 Effects on Aquatic Species

The predicted environmental concentration (PEC_{SW}) is calculated as 6.25×10^4 CFU/L (TOXSWA, 0.1% drift). According to the part B of the Uniform Principles, no assessment factors and trigger values are used for the risk assessment of micro-organisms. For micro-organism an authorization should be granted if the micro-organism is not pathogenic to non-target species. The chemical risk assessment and triggers can be applied if a metabolite is present in the product and responsible for the mode of action and toxic effects. As a surrogate risk assessment for a micro-organism the cMS will use the margin of safety concept.

Table 3.1.6.2-1 Aquatic organisms: acceptability of risk for *T. atroviride* SC1 for each organism group for the use of VINTEC in grapes, nursery (0.2 kg product/hL)

Species	Test substance	LC_{50}/EC_{50} [CFU/L]	PEC_{SW}[1] [CFU/L]	MoS
Fish	VINTEC	$> 1 \times 10^9$	6.25×10^4	$> 1.6 \times 10^4$
Daphnia	VINTEC	$> 1 \times 10^9$	6.25×10^4	$> 1.6 \times 10^4$
Algae	VINTEC	$> 1 \times 10^9$	6.25×10^4	$> 1.6 \times 10^4$

PEC: Predicted environmental concentration;

[1] TOXSWA (0.1% drift)

Based on the high margin of safety no risk to aquatic organisms is expected due to field application of *T. atroviride* SC1 according to the intended GAP.

3.1.6.3 Effects on Bees and Other Arthropod Species

The effects on bees and other arthropod species was addressed by zRMS in the Core dossier. According to zRMS: "*Considering the mode of application for the product as an indoor use during nursery process (dip or drench), the exposure for bees [and other arthropod species] is considered negligible. Consequently, no risk assessment for bees [and other arthropods species] is deemed necessary. Therefore, hazard quotients performed by the notifier are not presented by zRMS in this document*". The CMS agrees with this statement.

T. atroviride SC1 is intended for indoor-application during nursery process on young grapevine plants. Exposure of soil- and leaf dwelling non-target arthropods is very unlikely as spray drift will not occur. Risk assessment calculations with national specific drift rates are considered not necessary.

3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms

Indoor-application during nursery process on young grapevine plants is considered not relevant for exposure to soil macro-organisms. For the soil compartment in permanent structures the relevance of a risk assessment for soil may be doubted, as in permanent systems the soils can hardly be considered similar to field soils[3]. As a result, the risk to earthworms and other soil macro-organisms is considered negligible and need not be evaluated.

3.1.6.5 Effects on Soil Non-target Micro-organisms

Indoor-application during nursery process on young grapevine plants is considered not relevant for exposure to soil micro-organisms. For the soil compartment in permanent structures the relevance of a risk assessment for soil may be doubted, as in permanent systems the soils can hardly be considered similar to field soils[2] As a result the risk to soil micro-organisms is considered negligible and need not be evaluated.

3.1.7 Efficacy

IIIA1 6 Efficacy Data and Information (including Value Data) on the Plant Protection Product
Please refer to the Core assessment of France.
The product is authorised in France for the use in grapevine nursery crops. Climatological and environmental circumstances relevant for the aspect efficacy in the claimed uses (greenhouses) in The Netherlands can sometimes vary from those in France and the Southern climate zones where the trials have been performed. However since in those regions the viticulture is a more prevalent practice, and the disease complex of esca is therefore more prevalent, it can be considered that those environments are a worst case in which to test efficacy, furthermore it concerns a biopesticide for which there exists more room for extrapolations based on expert judgement.
Therefore, for the evaluation of the aspect 'Efficacy' we refer to the evaluation of the member state of the original authorisation from France.

BCP511B (other code for VINTEC) is a fungicide against Esca related pathogens *Phaeoacremonium aleophilum* (Pal) and *Phaeomoniella chlamydospora* (Pch) on grape.

Possible development of resistance or cross-resistance
Trichoderma atroviride is naturally present in the environment. Therefore, its application in pest control means only a temporary fluctuation of the microbial population in the agricultural biotope. The understanding that Trichoderma atroviride SC1 presents no risk for the environment has been confirmed by numerous studies. Moreover, T. atroviride SC1 does not pose any risk on humans, as it was described in Section 3. Trichoderma is already known as an important tool for resistance management. No development of risk is expected due to multiple modes of action towards the target pathogens.

[3] EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments. EFSA Journal 2014;12(3):3615, 43 pp., doi:10.2903/j.efsa.2014.3615

3.2 Conclusions

The assessment conducted for VINTEC was in accordance with the Uniform Principles and demonstrates an acceptable risk to human health and the environment. An authorisation can therefore be granted.

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

None.

Appendix 1 Copy of the proposed product label

Wettelijk Gebruiksvoorschrift
Het middel is uitsluitend toegelaten als schimmelbestrijdingsmiddel voor het professionele gebruik door middel van dompelbehandeling in de volgende toepassingsgebieden onder de hierna vermelde toepassingsvoorwaarden.

Toepassingsvoorwaarden:

Toepassingsgebied	Type toepassing	Werkzaamheid getoetst op	Dosering* middel per toepassing	Maximaal aantal toepassingen per 12 maanden
Druiven (bedekte teelt, boomkwekerij)	Dompelbehandeling	Esca[1]	0,2 kg/hL[2]	4 (zie tabel toepassingstijdstip)

* Verlaging van de dosering is toegestaan, maar van het maximaal aantal toepassingen en de andere toepassingsvoorwaarden mag niet worden afgeweken. Werkzaamheid is vastgesteld voor de genoemde dosering per toepassing en niet voor verlaagde doseringen;
[1] Esca (*Phaeomoniella chlamydospora, Phaeoacremonium aleophilum*);
[2] 100 L water voor 3x1000 planten (de dompelvloeistof in de container kan 3 keer gebruikt worden).

Overige toepassingsvoorwaarden
Roeren tijdens gebruik.

Bevat *Trichoderma atroviride* SC1. Micro-organismen kunnen sensibiliserende reacties veroorzaken.

In de teelt van druif kan de werking variabel zijn. Dit middel is gebaseerd op een micro-organisme en kan bijdragen aan de preventieve bestrijding van Esca in combinatie met preventieve maatregelen.

Toepassinsgstijdstip	**Methode**
Na het klaarmaken van de onderstammen en stekken, vóór de koude bewaring	Onderdompelen van de onderstammen en stekken
Tijdens de rehydratatie, vóór het enten	Onderdompelen van de onderstammen en stekken
Bij het begin van de stratificatie	Aangieten van de geënte planten
Vóór het planten	Onderdompelen van de uiteinden van de plant (callusweefsel, jonge wortels)

Appendix 2 Letter of Access

Copies of the letters of access to third party data (Annex II and Annex III) needed for the evaluation of the formulation are provided with the dossier.