

REGISTRATION REPORT

Part A

Risk Management

Product code: COH 220 WG

Product name: BLUE SHIELD HI BIO WG

Chemical active substance:

Copper hydroxide, 220 g/kg

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(authorisation renewal)

Applicant: Albaugh TKI d.o.o.

Date: 15/07/2025

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PART A

RISK MANAGEMENT

1 Details of the application

The company Albaugh TKI d.o.o. has requested a marketing authorisation in France for the product BLUE SHIELD HI BIO WG (formulation code: COH 220 WG), containing 220 g/kg copper¹ (in the form of copper hydroxide (CAS n° 20427-59-2)) for professional uses.

Appendix 1 of this document provides a copy of the product authorisation.

Appendix 2 of this document contains a copy of the product label (draft as proposed by the applicant).

1.1 Application background

The present registration report concerns the evaluation of Albaugh TKI d.o.o.'s application submitted on 29/03/2019 to market COPENICO HI BIO WG in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for field uses and interzonal Rapporteur Member State (izRMS) for greenhouse uses for this request and assessed the application submitted for the re-registration of authorisation after the renewal of approval of the active substances copper compounds of this product in France and in other Member States (MSs) of the European Union.

The present application (2019-2532 and 2019-5244) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009², the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone for field uses and for all MSs of the European Union for greenhouse uses, taking into account the worst-case uses ("risk envelope approach")³. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of COPENICO HI BIO WG has been made using endpoints agreed in the EU peer review of copper compounds. It also includes assessment of data and information related to COPENICO HI BIO WG where those data have not been considered in the EU peer review process.

The conclusions of the assessment published by EFSA 2018^{4,5}, as part of the procedure for the renewal of the approval of copper compounds, based on the available information, identify risk for non-target organisms for the representative uses on grapevine, cucurbits and tomatoes, as well as to workers for the grapevine use.

¹ COMMISSION IMPLEMENTING REGULATION (EU) 2018/1981 of 13 December 2018 renewing the approval of the active substances copper compounds, as candidates for substitution, 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

² 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

³ 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](#)

⁴ Peer review of the pesticide risk assessment of the active substance copper compounds Copper(I), copper(II) variants namely copper hydroxide, copper oxychloride, tribasic copper sulfate, copper(I) oxide, Bordeaux mixture, EFSA Journal 2018;16(1):515

⁵ Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for copper compounds copper(I), copper(II) variants namely copper hydroxide, copper oxychloride, tribasic copper sulfate, copper(I) oxide, Bordeaux mixture in light of confirmatory data. EFSA supporting publication 2018:EN-1486.

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In the framework of MRL review for copper compounds under Article 12 of Regulation (CE) 396/2005, EFSA published a reasoned opinion (EFSA, 2018⁶). Based on an evaluation of the available data MRL have been proposed and a consumer risk assessment has been conducted. Some information required by the regulation has not been transmitted and a chronic risk for the consumers was identified. Therefore the consumer risk assessment is only tentative and some of the proposed MRL still require a decision by risk managers. Exposure reduction measures could also be investigated.

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 risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011⁷, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

This document also describes the specific conditions of use and labelling required for France for the registration of COPERNICO HI BIO WG.

1.2 Letters of Access

The applicant has provided letters of access for active substance and PPP data. These letters of access are available upon request.

1.3 Justification for submission of tests and studies

According to the applicant: « New studies are provided with this dossier following the requirements of Regulation (EC) 284/2013 as well as new information found to be necessary following the renewal of copper. This information is highlighted in accordance with section 1.1. All other information was already submitted for the first authorization of the product. ».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of BLUE SHIELD HI BIO WG (COH 220 WG), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7. » or « There is no new data submitted with this applicationDetails of the authorisation decision

1.5 Product identity

Product code	COH 220 WG
Product name in MS	BLUE SHIELD HI BIO WG
Authorisation number	2090133
Kind of use	Professional use
Low risk product (article 47)	No

⁶ REASONED OPINION ADOPTED: 1 March 2018. Review of the existing maximum residue levels for copper compounds according to Article 12 of Regulation (EC) No 396/2005 European Food Safety Authority (EFSA).

⁷ 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

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Function	Fungicide
Applicant	Albaugh TKI d.o.o.
Active substance (incl. content)	copper, 220 g/kg
Formulation type	Water-dispersible granule [WG]
Packaging	N/A : no marketing authorisation granted
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

1.6 Conclusion

The evaluation of the application for BLUE SHIELD HI BIO WG (COH 220 WG) resulted in the **decision to refuse the authorisation**.

1.7 Substances of concern for national monitoring

Refer to 5.1.1.

1.8 Classification and labelling

1.8.1 Classification and labelling under Regulation (EC) No 1272/2008

N/A : no marketing authorisation granted

1.8.2 Standard phrases under Regulation (EU) No 547/2011

N/A : no marketing authorisation granted

1.8.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

1.9 Risk management

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1.10 Intended uses (only NATIONAL GAP)

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 izRMS. Those uses are then granted in France.

When the conclusion is “not acceptable” or “not finalised”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.

When a use is “acceptable” with GAP restrictions, the modifications of the GAP are in bold.

Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, 15/07/2025

PPP (product name/code): BLUE SHIELD HI BIO WG / COH 220 WG

Formulation type: WG ^(a, b)

Active substance 1: copper (hydroxide)

Conc. of a.s. 1: 220 g/kg ^(c)

Safener: N/A

Conc. of safener: N/A

Synergist: N/A

Conc. of synergist: N/A

Applicant: Albaugh TKI d.o.o.

Professional use: ☒

Zone(s): Southern Zone

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 or situation (crop destination/purpose of crop)	F, F _n , F _{pn} G, G _n , G _{pn} 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)
					Method/Ki nd	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 a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	Grape vine	F	<i>Plasmopara viticola</i>	Overall spraying	BBCH 15-91 Spring Summer	5	7 days	a) 3,4 b) 18	a) 0,75 b) 4	1000	21	Not acceptable (worker)

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Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(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	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
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	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)	9	Minimum interval (in days) between applications of the same product
	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	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.
	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.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

2 Background of authorisation decision and risk management

2.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a dark green granular solid with a characteristic odour. It is not explosive or oxidising. The product is not flammable. It has a self-ignition temperature of 170°C. In aqueous solution of 1%, it has a pH value around 7.8 at 20 °C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active ingredient content nor the technical properties were significantly different. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in a multilayer paper/plastic sack. Its technical characteristics are acceptable for a WG formulation.

No additional classification is required as a consequence of the physical chemical properties.

2.2 Efficacy (Part B, Section 3)

Considering the data submitted:

- The efficacy level of BLUE SHIELD HI BIO WG (COH 220 WG) is considered acceptable for the requested use.
- The phytotoxicity level of BLUE SHIELD HI BIO WG (COH 220 WG) is considered acceptable for the requested use.
- The risks of negative impact on yield, propagation and adjacent crops are considered negligible. Risks with copper such as spotting of table grape berries or on the wine-making process are known. However, these risks of negative impact are considered acceptable.
- The risk of resistance developing or appearing to copper does not require a monitoring for the claimed use.

2.3 Methods of analysis (Part B, Section 5)

2.3.1 Analytical method for the formulation

Analytical methods for the determination of copper in the formulation are available and validated. However, this method is not specific to the variant copper hydroxide. A complementary method shall be provided to confirm the identity of the variant in the formulation.

Analytical methods for the determination of the relevant impurities are available and validated.

2.3.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report/this dossier and validated for the determination of residues of copper in plants (high water, oily, acidic and dry content commodities), soil, water (surface and drinking), air and body fluids.

According to EFSA conclusions, an ILV of the analytical methods for the determination of residues of copper in plants is required.

Analytical methods for the determination of residues of copper in food of animal origin are missing but this is considered acceptable considering the intended uses in France.

Moreover, the LOQ of the available methods for the determination of residues of copper in water is not in accordance with the European Directive 98/83/EC.

2.4 Mammalian toxicology (Part B, Section 6)

	Copper (II) hydroxide
Common Name	Copper hydroxide
CAS-No.	20427-59-2
Agreed EU endpoints	
AOEL systemic	0.08 mg/kg bw/d (based on human data)
AAOEL	Not applicable
Oral absorption	50%
Vapour pressure	Not applicable as expected to be negligible (all copper variants)
Reference	EFSA Journal 2018;16(1):5152 Review Report : SANTE/10506/2018 Rev. 5 27 November 2018
Dermal absorption	Concentrate: 1% Dilution: 9%

2.4.1 Acute toxicity

COH 220 WG (BLUE SHIELD HI BIO WG) containing 220 g/kg copper hydroxide has a low toxicity in respect to acute oral and dermal toxicity, is harmful if inhaled, is irritating to the rabbit eye and is not a skin sensitiser.

2.4.2 Operator exposure

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		Copper hydroxide	
Model data [#]	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL ^{##}
Tractor-mounted boom spray application outdoors to high crops (grapes, use no. 2) Application rate: 0.75 kg a.s./ha			
EFSA model (75 th percentile) Body weight: 60 kg	Working coverall	0.0424	53
	Working coverall and gloves during mix/loading and application	0.0192	24
Manual knapsack spray application outdoors to high crops (grapes, use no. 2) Application rate: 0.75 kg a.s./ha			
EFSA model (75 th percentile) Body weight: 60 kg	Working coverall	0.0080	10
	Working coverall and gloves during mix/loading and application	0.0033	4
Manual hand-held spray application outdoors to high crops (grapes, use no. 2) Application rate: 0.75 kg a.s./ha			
EFSA model (75 th percentile) Body weight: 60 kg	Working coverall	0.0168	21
	Working coverall and gloves during mix/loading and application	0.0062	8

According to the model calculations, it can be concluded that the risk for the operator using COH 220 WG (BLUE SHIELD HI BIO WG) is acceptable with a working coverall and gloves during mixing/loading and application.

2.4.3 Worker exposure

		Copper hydroxide	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL ⁽¹⁾
Hand-harvesting grapes (use no. 2)			
Number of applications and application rate:		5 x 0.75 kg a.s./ha (interval 7 days, PHI 21 days)	

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Model data	Level of PPE	Copper hydroxide	
		Total absorbed dose (mg/kg/day)	% of systemic AOEL ⁽¹⁾
EFSA model 2014 (AOEM Excel calculator) Work rate: 8 hours/day TC work wear: 10100 cm ² /person/h TC work wear + gloves : No TC available ⁽²⁾ Initial DFR: 3 µg a.s. /cm ² / kg a.s. /ha DT ₅₀ : 30 days Body weight: 60 kg	Work wear (arms, body and legs covered)	1.0127	1266
	Work wear (arms, body and legs covered) and gloves	-	-

⁽¹⁾ Reference Value Non Acutely Toxic Active Substance (RVNAS)

⁽²⁾ For grapes, the applicant proposed a specific refined TC value considering gloves. This TC value cannot be accepted since the setting of a new TC value at European level requires a comprehensive analysis based on all data available.

It is concluded that there is unacceptable risk anticipated for the worker for grapes.

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

2.4.4 Bystander exposure

EFSA model (w/o AAOEL): Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set¹³.

Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): “No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.”

2.4.5 Resident exposure

Residential exposure was assessed according to EFSA model. An acceptable risk was determined for residents (adult and child) when mitigation measures such as a buffer zone of 10 meters are taken:

Model (AOEM) - All pathways (mean)	% AOEL Copper hydroxide
Resident (children)	52
Resident (adults)	28

¹³ Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

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In conclusion, according to the EFSA model, there is no unacceptable risk anticipated for resident (adult and child) after incidental exposure to copper.

2.4.6 Combined exposure

Not relevant. The product contains only one active substance.

2.5 Residues and consumer exposure (Part B, Section 7)

An exceedance of the current MRL for copper as laid down in Reg. (EC) 396/2005 of 50 mg/kg in grapes is not expected. The acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for copper.

For chronic intake of copper residues, the calculation includes uncertainties linked to the methodology. Therefore, zRMS considers that the risk assessment for consumers cannot be finalized.

zRMS considers no firm conclusion can be reached for any of the intended uses of the product BLUE SHIELD HI BIO (COH 220 WG).

Information on BLUE SHIELD HI BIO (COH 220 WG)

Crop	PHI for BLUE SHIELD HI BIO (COH 220 WG) proposed by applicant	PHI/ Withholding period* sufficiently supported for Copper	PHI for BLUE SHIELD HI BIO (COH 220 WG) Blue proposed by zRMS	zRMS Comments (if different PHI proposed)
Grape	21 days	Yes	21 days	

2.6 Environmental fate and behaviour (Part B, Section 8)

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 copper in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

No reliable PEC soil were available for the active substance mainly due to a too short period for estimating the accumulation in soil. Therefore, the risk assessment for the non-target terrestrial organisms cannot be finalised for all intended uses.

Given the uncertainties identified by zRMS in the notifier's exposure calculation (FOCUS STEP 1-2 for all entries to water bodies and FOCUS STEP 1-2 PEC_{sw} including mitigation measures) and the absence of results for all FOCUS scenarios, PEC_{sw} derived for the active substance cannot be used for the ecotoxicological risk assessment. As a consequence, the risk assessment cannot be finalised for the non-

target aquatic organisms.

PEC_{gw} for copper do not occur at levels exceeding those mentioned in Directive 98/83/CE. Therefore, no unacceptable risk of groundwater contamination is expected for all intended uses.

Based on vapour pressure, no significant contamination of the air compartment is expected for the intended uses.

2.7 Ecotoxicology (Part B, Section 9)

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.

An EFSA' Statement of the PPR panel on a framework for conducting the environmental exposure and risk assessment for transition metals when used as active substances in plant protection products was recently published (2021). This document provides useful recommendations upon applicability of new methodologies in the context of transition metals and possible areas of development for assessing the risk from transition metals used in PPPs. However, it does not provide valid tools for exposure assessment in the environment and toxicity estimation upon non-target organisms. Furthermore, no clear specific risk assessment schemes for transition metals used as active substances in PPPs is provided. Therefore, the risk assessment and conclusion are based on the methodology agreed by the experts during the renewal approval of the active substance. The EU-agreed endpoints recommended in the EFSA journal (EFSA Journal 2018;16(1):5152) were considered for the Art. 43 dossiers for copper compounds.

Based on the guidance documents, the risks for **non-target arthropods other than bee** and non-target **terrestrial plants** are acceptable for the intended uses.

For aquatic organisms, as the toxicity reference value for copper proposed by the applicant was based on an approach rejected at European level, it could not be used. In addition, no reliable PEC_{sw} were provided by the applicant for all uses. Therefore, the risk assessment for aquatic non-target species could not be finalised for all intended uses.

For birds and mammals, the risk is not acceptable at Tier 1 for all intended uses. The arguments provided by the applicant to refine the risk assessment are identical to those that were considered insufficient at the European level. Therefore, without further data, the risk assessment for birds and mammals cannot be finalised.

For bees, the risk assessment provided by the applicant is based on the EFSA Guidance Document¹⁴. For adult honey bees, the risk is not acceptable at Tier 1 for all intended uses. Higher-tier studies (cage and tunnel tests) are available and demonstrate that no adverse effects on adult honey bees are expected for all intended uses. For honey bee larvae, the risks are not acceptable at Tier 1 for all intended uses. The higher-tier studies are not sufficient to demonstrate the absence of adverse effects of the product BLUE SHIELD HI BIO (COH 220 WG) on honey bee larvae. Therefore, the risk assessment for honey bee larvae cannot be finalised for all intended uses.

¹⁴ EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) EFSA Journal 2013;11(7):3295

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For bumble bees, no acute risk assessment was provided by the applicant, although standard study protocols are available. Therefore, the risk assessment for bumble bees cannot be finalised for all intended uses. Overall, the risk for bees cannot be finalised for all requested uses.

For soil organisms, since no reliable PEC soil are available, a Tier 1 risk assessment cannot be conducted. For earthworms, the higher tier earthworm field trial data from a study conducted over 10 years with copper application every year demonstrates that there is an acceptable risk to earthworms for applications up to 4kg cu/ha/yr. Therefore, an acceptable risk for earthworms is demonstrated for all intended uses of BLUE SHIELD HI BIO (COH 220 WG).

For other soil meso- and macro-organisms, no higher-tier studies are available and extrapolating the results of the multiyear field study with earthworms to other soil meso- and macro-organisms was not supported by the experts at the Peer Review experts' meeting 169. Therefore, the risk for soil meso- and macro-organisms other than earthworms could not be finalised for all intended uses.

For soil micro-organisms, based on a lack of effect at field level, the risks to soil micro-organisms are acceptable for the intended uses.

2.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to environmental fate and behaviour above for conclusion on the risk of groundwater contamination.

3 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

BLUE SHIELD HI BIO (COH 220 WG). contains copper compounds, which is approved as a candidate to substitution because it fulfills PBT criteria (Persistent and Toxic);

Steps 1 and 2 (French guidance document 27 July 2015):

- **Taking into account the agronomic interest, especially in the context of organic farming**

In accordance with Article 50, paragraphs 1.b) 1.c) and 1.d) of Regulation (EC) N°1107/2009,

- considering the absence of plant protection products or non-chemical methods of prevention or control allowing to consider a substitution of the product without major practical or economic disadvantage, and specially in the frame of organic farming,
- considering also the need to guarantee a diversity of modes of action to reduce the emergence of resistance in target microorganisms,
- considering the need to take into account the minor uses of the product,

the substitution of the product will not be considered for all intended uses.

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

When the conclusions of the assessment is “Not acceptable”, please refer to relevant summary under point 3, “Background of authorisation decision and risk management”.

4.1.1 Post-authorisation monitoring

None.

4.1.2 Post-authorisation data requirements

The following data would have been required to update the dossier:

- An analytical method for the confirmation of the identity of the Copper variant in the product.

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Appendix 1 Copy of the product authorisation



BLUESHIELD_PREX_2
019-2532_D.pdf

Appendix 2 Copy of the product label

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.

Blue shield® HiBIO® WG

FONGICIDE CONTRE LE MILDIOU DE LA VIGNE*

*Consulter les usages autorisés sur le sac

FONGICIDE

220 g/kg d'hydroxyde de cuivre (II)

Granulés à disperser dans l'eau (WG) Autorisation de Mise sur le Marché n° 2090133

Produit utilisable en Agriculture Biologique en application du RCE n° 834/2007

Détenteur de l'Autorisation de Mise sur le Marché :

ALBAUGH UK Ltd

1 Northumberland Avenue - Trafalgar Square LONDON WC2N 5BW · ROYAUME-UNI

EMB: Albaugh TKI d.o.o, Slovenie

Blue Shield® et Hi Bio® sont des marques déposées d'Albaugh, LLC ou une de ses filiales

Interdiction de réutiliser l'emballage

RÉSERVÉ À UN USAGE EXCLUSIVEMENT PROFESSIONNEL



DANGER

BLUE SHIELD® HIBIO® WG - A.M.M. n° 2090133

220 g/kg d'hydroxyde de cuivre (II) (22 % p/p) - Granulés à disperser dans l'eau (WG)

H318 Provoque de graves lésions des yeux.

H332 Nocif par inhalation

H410 Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.

EUH401 Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.

P261 Eviter de respirer les poussières/brouillards

P280 Porter des gants de protection, des vêtements de protection, un équipement de protection des yeux/du visage.

P304+P340 EN CAS D'INHALATION : Transporter la personne à l'extérieur et la maintenir dans une position où elle peut confortablement respirer

P305+P351 +P338 EN CAS DE CONTACT AVEC LES YEUX : rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer.

P310 Appeler immédiatement un CENTRE ANTIPOISON ou un médecin.

P391 Recueillir le produit répandu.

P501 Éliminer le contenu/récipient en accord avec la réglementation locale.

Délai de rentrée : 24 heures.

SPe3 Pour protéger les organismes aquatiques, respecter une zone végétalisée de 20 m par rapport aux masses d'eau de surface.

SP1 Ne pas polluer l'eau avec le produit ou son emballage. (Ne pas nettoyer le matériel d'application près des eaux de surface. /Eviter la contamination via les systèmes des eaux à partir des cours de ferme ou des

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routes).

SPo2 Laver tous les vêtements de protection après utilisation

Fiche de Données de Sécurité disponible sur simple appel au 04 78 64 3218 ou sur internet :

www.quickfds.com

EN CAS D'URGENCE: Composer le 0 800 21 01 55, le 15 ou le 112 ou contacter le centre anti-poison le plus proche.

PREMIERS SECOURS

S'éloigner de la zone dangereuse. En cas de contact/d'exposition/d'ingestion, si les symptômes persistent ou en cas de malaise, obtenir un avis médical sans délai (médecin, SAMU (15) ou centre antipoison) et présenter l'étiquette et/ou la Fiche de Données de Sécurité.

En cas de contact cutané : enlever tout vêtement souillé, laver avant de le réenfiler. Rincer immédiatement et abondamment la peau sous l'eau du robinet.

En cas de projection dans les yeux : rincer immédiatement pendant 15 à 20 minutes sous un filet d'eau paupières ouvertes et écartées du globe oculaire. Ne pas faire couler vers l'œil non atteint.

En cas d'inhalation : mettre la personne à l'air frais et au repos.

En cas d'ingestion : rincer immédiatement la bouche avec de l'eau. Ne pas faire vomir sans avis médical.

En cas d'intoxication animale : contactez votre vétérinaire.

Bien lire cette étiquette avant l'utilisation de ce produit, respecter les précautions d'emploi.

Produit utilisable en Agriculture Biologique en application du RCE N° 834/2007.

DESCRIPTIF DU PRODUIT

Mode d'action

BLUE SHIELD® HIBIO® WG est un fongicide anti-mildiou de contact multi-sites strictement préventif (code FRAC M1). Il contient du cuivre métal de la forme hydroxyde de cuivre.

Tableau des usages autorisés

Traitement des parties aériennes

Culture	Cibles	Dose*	DAR	Nombre Maximum d'applications	ZNT Aqua ZNT Terre-stre
Vigne	Mildiou	3,75 kg/ha	21 jours	5 /an	20 m 5m

** Seules les utilisations entraînant une application totale maximale de 28 kg de cuivre par hectare sur une période de 7 ans sont autorisées.*

Raisin de table : BLUE SHIELD® HIBIO® WG s'utilise également sur raisin de table jusqu'au stade nouaison (risque de « marquages »). Albaugh ne préconise l'utilisation de ce produit que sur les cultures et cibles mentionnées ci-dessus et, à ce titre, décline toute responsabilité concernant son utilisation aux autres usages prévus par le catalogue des usages en vigueur. Limites maximales de résidus : se reporter aux LMR définies au niveau de l'Union Européenne, consultables à l'adresse : <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database>

RECOMMANDATIONS D'EMPLOI

Conditions d'application

En viticulture conventionnelle comme en viticulture respectant le cahier des charges de l'Agriculture Biologique, **BLUE SHIELD® HIBIO® WG** peut s'utiliser pendant toute la période de risque du mildiou dès les premiers stades de végétation de la vigne jusqu'en fin de saison. Le traitement doit couvrir toute la végétation. Renouveler BLUE SHIELD® HIBIO® WG en tenant compte de la croissance de la végétation, des conditions climatiques, des lessivages éventuels et de la virulence de l'infestation. Appliqué selon les Bonnes Pratiques Agricoles, BLUE SHIELD® HIBIO® WG est sélectif des cépages actuels de vigne, en bon état végétatif.

Précautions d'emploi

Pendant l'application

- Eviter tout contact avec la peau et les yeux.
- Ne pas traiter en présence de vent.
- Ne pas respirer les vapeurs, ni le brouillard de pulvérisation.

- Ne pas pulvériser à proximité des points d'eau (mares, cours d'eau, fossés ...).
- Ne pas souffler dans les buses pour tenter de les déboucher.

Après l'application

Immédiatement après l'application, nettoyer les équipements de protection, se laver les mains à l'eau savonneuse, prendre une douche et changer de vêtements

Mélanges extemporanés et compatibilités

Seuls les mélanges extemporanés autorisés peuvent être utilisés. Tout mélange doit être préalablement testé.

Nettoyage du pulvérisateur et gestion des fonds de cuve

Avant le traitement, vérifier que le matériel d'application et de préparation de la bouillie est propre, exempt de tout résidu d'application précédente. Certains produits nécessitent un nettoyage selon une procédure particulière (se référer aux consignes du fabricant). Après l'application du produit, l'intégralité de l'appareil (cuve, rampe, circuit, buses ...) doit être rincée à l'eau claire. Le rinçage du pulvérisateur, l'épandage ou la vidange du fond de cuve et l'élimination des effluents doivent être réalisés conformément à la réglementation en vigueur.

Élimination du produit, de l'emballage

Le réemploi de l'emballage est interdit. Apporter les emballages vidés et pliés à votre distributeur partenaire d'A.D.I.VALOR ou à un autre service de collecte spécifique. Pour l'élimination des produits non utilisables, conserver le produit dans son emballage d'origine. Apporter à votre distributeur partenaire d'A.D.I.VALOR ou faites appel à une entreprise habilitée pour la collecte et l'élimination des déchets dangereux.

En cas de déversement accidentel

Se protéger (équipements de protections individuels) et sécuriser la zone. Prévenir les pompiers (18 ou 112) en cas de danger immédiat pour l'environnement que vous ne pouvez gérer avec vos propres moyens. Collecter tout ce qui a pu être en contact avec le produit, terre souillée incluse. Nettoyer le site et le matériel utilisé, en prenant soin de confiner les effluents générés par l'opération de nettoyage. Les éliminer selon la réglementation en vigueur. Pour plus de détails, se reporter à la Fiche de Données de Sécurité. En cas de mélange, incorporer d'abord **BLUE SHIELD® HIBIO® WG**. Ne pas mélanger **BLUE SHIELD® HIBIO® WG** avec un produit à base de fosétyl. Les mélanges avec les engrais foliaires sont déconseillés et sont sous la responsabilité de l'utilisateur. Réaliser un test préalable.

Préparation de la bouillie

- 1) Vérifier le bon état du matériel de pulvérisation.
- 2) Remplir d'eau propre la cuve du pulvérisateur aux deux tiers de la quantité souhaitée.
- 3) Mettre en route l'agitation et la maintenir pendant toute la durée de la mise en œuvre du traitement.
- 4) Introduire la quantité nécessaire de produit dans le pulvérisateur.
- 5) Compléter le niveau d'eau.
- 6) Rincer l'emballage (3 fois) et le rendre inutilisable.
- 7) En cas d'emballage incomplètement utilisé, le refermer et le stocker en lieu sûr.

Cultures de remplacement

L'agriculteur doit conduire la culture de remplacement selon les bonnes pratiques agricoles en tenant compte, sous sa responsabilité, de tous les facteurs particuliers concernant l'exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales ; il doit utiliser les techniques permettant à la culture de remplacement de bénéficier des meilleures conditions de croissance.

Nos recommandations tiennent compte des informations disponibles à la date de fabrication du produit.

PREVENTION ET GESTION DE LA RESISTANCE

L'utilisation répétée, sur une même parcelle, de préparations à base de substances actives de la même famille chimique ou ayant le même mode d'action, peut conduire à l'apparition d'organismes résistants. Pour réduire ce risque, l'utilisateur doit raisonner en premier lieu les pratiques agronomiques et respecter les conditions d'emploi du produit. Il est conseillé d'alterner ou d'associer, sur une même parcelle, des préparations à base de substances actives de familles chimiques différentes ou à modes d'action différents, tant au cours d'une saison culturale que dans la rotation. En dépit du respect de ces règles, on ne peut pas exclure une altération de l'efficacité de cette préparation liée à ces phénomènes de résistance. De ce fait, PHILAGRO France décline toute responsabilité quant à d'éventuelles conséquences qui pourraient être dues à de telles résistances.

MISE EN OEUVRE REGLEMENTAIRE ET BONNES PRATIQUES

Stockage du produit

Conserver le produit uniquement dans son emballage d'origine, dans un local phytopharmaceutique conforme à la réglementation en vigueur et fermé à clé, à l'abri de l'humidité, du gel, dans un endroit frais, aéré et ventilé, à l'écart des aliments et boissons, y compris ceux pour animaux. Conserver hors de la portée des enfants et des personnes non autorisées.

Protection de l'opérateur et du travailleur

Se laver les mains après toute manipulation/utilisation/intervention dans une parcelle préalablement traitée. Ne pas manger, boire, téléphoner ou fumer lors de l'utilisation du produit.

AVERTISSEMENT

Toute reproduction totale ou partielle de cette étiquette est interdite. Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage. Ils ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduire sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous la responsabilité de l'utilisateur, de tous les facteurs particuliers concernant l'exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces ... Le fabricant garantit la qualité du produit vendu dans son emballage d'origine et stocké selon les conditions préconisées, ainsi que sa conformité à l'Autorisation de Mise sur le Marché délivrée par les Autorités Compétentes françaises. Pour les denrées issues de cultures protégées avec ce produit et destinées à l'exportation, il est de la responsabilité de l'exportateur de s'assurer de la conformité avec la réglementation en vigueur dans le pays importateur. Avant toute utilisation, assurez-vous que celle-ci est indispensable. Privilégiez chaque fois que possible les méthodes alternatives et les produits présentant le risque le plus faible pour la santé humaine et animale et pour l'environnement, conformément aux principes de la protection intégrée, consultez <http://agriculture.gouv.fr/ecophyto>. Pour les usages autorisés, doses, conditions et restrictions d'emploi : se référer à l'étiquette du produit.

Caractéristiques des EPI	PROTECTION DE L'UTILISATEUR PENDANT LES PHASES DE :			PROJECTION DU TRAVAILLEUR
	MÉLANGE/CHARGEMENT	APPLICATION AVEC : PULVÉRISATEUR	NETTOYAGE	
GANTS EN NITRILE réutilisables (certifiés EN 374-3) ou à usage unique (certifiés EN 374-2)	Réutilisables	A usage unique (portés et stockés à l'extérieur de la cabine)	Réutilisables	
EPI VESTIMENTAIRE conforme à la norme NF EN ISO 27065	EPI vestimentaire ET EPI partiel	✓	EPI vestimentaire ET EPI partiel	✓
EPI PARTIEL tablier ou blouse à manches longues catégorie III type PB3 certifié EN14605+A1		✓		
LUNETTES OU ÉCRAN FACIAL certifiés EN 166:2002 (CE, sigle 3)	✓	✓	✓	
PROTECTION RESPIRATOIRE masque ou demi-masque		Si exposition à des particules		

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filtrant anti-aérosol (EN149) ou (EN 140:1998) équipé d'un filtre P3 (EN 143:2006) ou A2P3 (EN 14387:2008)		(stocké à l'exté- rieur de la ca- bine)		
BOTTES certifiées EN 13 832- 3:2006	✓	✓	✓	

Rapporter les équipements de protection individuelle (EPI) usagés dans un sac translucide à votre distributeur partenaire ECO EPI ou faire appel à une entreprise habilitée pour la collecte et l'élimination de produits dangereux

LEB BONS GESTES POUR TRAITER EN TOUTE SÉCURITÉ

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