

REGISTRATION REPORT

Part A

Risk Management

Product code: Copper hydroxide 20 WG

Product name(s): CUIVRISTAL

Chemical active substance:

Copper, 200 g/kg

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(Authorisation renewal according to Art. 43)

Applicant: ASCENZA France

Submission date : April 2019

MS Finalisation Date : 15 July 2025

Table of Contents

1	Details of the application	4
1.1	Application background	4
1.2	Letters of Access	5
1.3	Justification for submission of tests and studies	5
1.4	Data protection claims	5
2	Details of the authorisation decision	5
2.1	Product identity	5
2.2	Conclusion	6
2.3	Substances of concern for national monitoring	6
2.4	Classification and labelling	6
2.4.1	Classification and labelling under Regulation (EC) No 1272/2008	6
2.4.2	Standard phrases under Regulation (EU) No 547/2011	7
2.4.3	Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)	7
2.5	Risk management	7
2.5.1	Restrictions linked to the PPP	8
2.5.2	Specific restrictions linked to the intended uses	8
2.6	Intended uses (only NATIONAL GAP)	9
3	Background of authorisation decision and risk management	11
3.1	Physical and chemical properties (Part B, Section 2)	11
3.2	Efficacy (Part B, Section 3)	11
3.3	Methods of analysis (Part B, Section 5)	11
3.3.1	Analytical method for the formulation	11
3.3.2	Analytical methods for residues	12
3.4	Mammalian toxicology (Part B, Section 6)	12
3.4.1	Acute toxicity	12
3.4.2	Operator exposure	12
3.4.3	Worker exposure	13
3.4.4	Bystander exposure	14
3.4.5	Resident exposure	14
3.5	Residues and consumer exposure (Part B, Section 7)	15
3.6	Environmental fate and behaviour (Part B, Section 8)	15
3.7	Ecotoxicology (Part B, Section 9)	16
3.8	Relevance of metabolites (Part B, Section 10)	17
4	Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)	17
5	Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation	18

Copper hydroxide 20 WG / CUIVRISTAL
Part A - National Assessment
FRANCE

5.1.1	Post-authorisation monitoring.....	18
5.1.2	Post-authorisation data requirements	18
Appendix 1	Copy of the product authorisation	19
Appendix 2	Copy of the product label	22

PART A

RISK MANAGEMENT

1 Details of the application

The company ASCENZA France has requested a marketing authorisation in France for the product CUIVRISTAL (product code: Copper hydroxide 20 WG), containing 200 g/kg of copper¹ (in the form of copper hydroxide (CAS No 20427-59-2)) as a fungicide 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 ASCENZA France's application submitted on 01/04/2019 to market CUIVRISTAL (Copper hydroxide 20 WG) in France (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 re-registration of authorisation after the renewal of approval of the active substance copper compounds of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2019-2643) 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, 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 CUIVRISTAL (Copper hydroxide 20 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 CUIVRISTAL (Copper hydroxide 20 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.

Copper hydroxide 20 WG / CUIVRISTAL
Part A - National Assessment
FRANCE

In the framework of MRL review for copper compounds under Article 12 of Regulation (CE) No 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 CUIVRISTAL (Copper hydroxide 20 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: « *The study reports submitted within this application are in agreement with the data requirements of the Regulation 284/2013. No vertebrate studies are included within the present application* ».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of CUIVRISTAL (Copper hydroxide 20 WG), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

Product code	Copper hydroxyde 20 WG
Product name in MS	CUIVRISTAL
Authorisation number	2180657

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

Copper hydroxide 20 WG / CUIVRISTAL
Part A - National Assessment
FRANCE

Kind of use	Professional use
Low risk product (article 47)	No
Function	Fungicide
Applicant	ASCENZA France
Active substance(s) (incl. content)	copper, 200 g/kg
Formulation type	Water-dispersible granule [WG]
Packaging	HDPE ⁸ (300 g) LDPE ⁹ (9 kg)
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for CUIVRISTAL (Copper hydroxide 20 WG) resulted in the decision **to refuse** the authorisation.



2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

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

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Acute toxicity (oral), category 4 Skin sensitisation, category, 1B Hazardous to the aquatic environment - Acute Hazard, category 1 Hazardous to the aquatic environment - Chronic Hazard, category 1
Hazard pictograms:	  GHS07 GHS09
Signal word:	Warning

⁸ HDPE : High density polyethylene

⁹ LDPE : Lowdensity polyethylene

Copper hydroxide 20 WG / CUIVRISTAL
Part A - National Assessment
FRANCE

Hazard statement(s):	H302: Harmful if swallowed. H317: May cause an allergic skin reaction. H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long-lasting effects.
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation</i>
Additional labelling phrases:	-

See Part C for justifications of the classification and labelling proposals.

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

N/A : marketing authorisation withdrawn.

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

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017¹⁰ provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres for products applied through spraying or dusting;
- unless otherwise stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

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

Moreover, the French Order of 26 March 2014¹¹ provides that:

- an authorisation granted for a “reference” crop applies also for “related” crops, unless formally stated in the Decision
- the “reference” and “related” 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 “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation¹² is to supply “minor” crops with registered plant protection products.

¹⁰ 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, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRGI632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

¹¹ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRGI407093A/jo>

¹² SANCO document “guidance document: Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

Copper hydroxide 20 WG / CUIVRISTAL
Part A - National Assessment
FRANCE

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

Finally, the French Order of 20 November 2021¹³ on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless otherwise stated in the product authorisation, use on attractive crop¹⁴ when in flower and on foraging area is forbidden. Specific conditions of application on flowering crops should be respected. As consequences specific SPe 8 may include reference to this order.

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

2.5.1 Restrictions linked to the PPP

The authorisation of the PPP is linked to the following conditions:

N/A : marketing authorisation withdrawn

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

¹³ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734>

¹⁴ List of culture considered as unattractive to bees and other pollinators insects defined by French Agricultural ministry and published in Bulletin Officiel du ministère chargé de l'agriculture.

Copper hydroxide 20 WG / CUIVRISTAL

Part A - National Assessment

FRANCE

2.6 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 zRMS. Those uses are then granted in France.

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

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

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

GAP rev. 1, date: July 2025

PPP (product name/code): CUIVRISTAL / copper hydroxyde 20 WG

Formulation type: WG ^(a, b)

Active substance : copper (hydroxide)

Conc. of a.s. 1: 200 g/kg ^(c)

Applicant: ASCENZA France

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 or (crop destination/purpose of crop)	and/ situation 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/synergis 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 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		
Considering the restriction of the use of PPP containing copper compounds to a maximum application rate of 28 kg/ha of copper over a period of 7 years (i.e. on average 4kg/ha/year) .													
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR, ES, PT, IT	Grapes	F	<i>Plasmopara viticola</i>	Foliar spray	BBCH 13-60 and BBCH 69-81 (Avoid flowering period)	a) 4 b) 4	7 days	a) 3.75 b) 15	a) 750 b) 3000	100 / 1000	21 days	Not acceptable (risk for worker)
2	FR, ES, PT, IT	Olive	F	<i>Spilocaea oleagina</i> <i>Colletotrichum</i> <i>gloeosporioides</i>	Foliar spray	BBCH 13-60 and BBCH 69-89 (Avoid flowering period)	a) 2 b) 2	90 days	a) 6 b) 12	a) 1200 b) 2400	500 / 1000	15 days	Not acceptable (risk for worker)

Copper hydroxide 20 WG / CUIVRISTAL

Part A - National Assessment

FRANCE

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop or and/ situation (crop destination/purpose of crop)	F, Fn, 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)
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg 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/ma x		
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
-													
Minor uses according to Article 51 (zonal uses)													
-													
Minor uses according to Article 51 (interzonal uses)													
-													

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/m³ 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 Background of authorisation decision and risk management

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

All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is that of a green granule, with an uncharacteristic odour. It is not explosive, has no oxidising properties. The product has a self-ignition temperature of 230 °C. It has a pH value around 9.7 in a 1 % aqueous solution. 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 changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in polyethylene bottles or low density polyethylene bags. Its technical characteristics are acceptable for a wettable granule formulation.

Tank mixtures are not recommended with this product.

No classification required for physical chemical properties.

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

- The efficacy level of CUIVRISTAL (Copper hydroxide 20 WG) is considered to be acceptable for all the requested uses.
- The phytotoxicity level of CUIVRISTAL (Copper hydroxide 20 WG) is considered to be acceptable for all the requested uses.
- The risks of negative impact on yield, propagation, succeeding 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 to be acceptable.
- The risk of resistance developing or appearing to copper does not require monitoring for the requested uses.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

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

3.3.2 Analytical methods for residues

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

According to EFSA conclusions, an inter-laboratory validation (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 considering the intended use, no method is considered necessary.

Moreover, the limit of quantification (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.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Agreed EU endpoints	
Active substance	Copper hydroxide 200 g/kg
AOEL systemic (mg/kg bw/d)	0.08
AAOEL	Not necessary
Inhalation absorption	100 %
Oral absorption	50 %
Vapour pressure	Not necessary
Dermal absorption	Concentrate: 1 % Dilution: 9 % (Based on <i>in vitro</i> through human skin studies; see point 6.5 Part B6)

3.4.1 Acute toxicity

CUIVRISTAL (Copper hydroxide 20 WG) containing 200 g of copper/kg (in the form of copper hydroxide) has a low acute, inhalational and dermal toxicity, is harmful if swallowed, is not irritating to the rabbit skin or eye and is a skin sensitiser.

3.4.2 Operator exposure

Considering proposed uses, operator systemic exposure was estimated using the EFSA model¹⁵ (worst case):

Model data	Level of PPE	Copper in the form of copper hydroxide	
		Total absorbed dose	% systemic AOEL

¹⁵ AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014;12 (10):3874)

Copper hydroxide 20 WG / CUIVRISTAL
Part A - National Assessment
FRANCE

		(mg/kg b.w./day)	
Olives (covering grape)			
Vehicle mounted, outdoor, upward spraying			
Application rate		1.2 kg. as/ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Gloves and work wear during M/L and application	0.0292	36.5 %
manual knapsack, outdoor, upward spraying)			
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Gloves and work wear during M/L and application	0.0038	4.8 %
manual knapsack, outdoor, upward spraying, late foliar			
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Potential exposure	1,9028	2378 %
	Work wear during M/L and ap- plication	0,1059	132 %
	Gloves and work wear during M/L and application	0,074	92.78 %

According to the model calculations, it can be concluded that there is no unacceptable risk for the operator using CUIVRISTAL (Copper hydroxide 20 WG) with a working coverall and gloves during mixing/loading and application.

3.4.3 Worker exposure

Workers may have to enter in treated areas after treatment for hand harvesting and/or reaching, picking and searching activities. Therefore, estimation of worker exposure was calculated according to the EFSA model.

		Copper in the form of copper hydroxide	
Model data	Level of PPE	Total absorbed dose (mg/kg b.w./day)	% systemic AOEL
Critical use: Grapes			
Hand harvesting Outdoor Work rate: 8 hours/day DT ₅₀ : 30 days DFR: 3µg/cm ² /kg a.s./ha Interval between applications: 7 days			
Application rate		4 x 0.75 kg. a.s./ha	
EFSA model 2014 Body weight: 60 kg	Work wear (arms, body and legs covered) TC: 10100 cm ² /person/h	0.8699	1087 %
Critical use: Olives			
Searching, reaching, picking Outdoor Work rate: 8 hours/day DT ₅₀ : 30 days Initial DFR: 3 cm ² /kg a.s./ha Interval between applications: 90 day			
Application rate		2 x 1.2 kg. a.s./ha	
EFSA model 2014 Body weight: 60 kg	Work wear (arms, body, and legs covered) and gloves TC: 2250	0.1094	136.69 %

There is an **unacceptable** risk anticipated for the worker, even with the wear of PPE (work wear and

gloves).

No realistic re-entry period into treated crop for worker can be envisaged (calculated re-entry would be *ca.* 14 days, which unrealistic given usual agricultural practices)

3.4.4 Bystander exposure

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 set¹⁶.

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.”

3.4.5 Resident exposure

Residential exposure was assessed according to EFSA model, without drift reduction technology and considering a buffer zone of 10 metres for high crops.

		Copper	
Model data	AOEM model	Total absorbed dose (mg/kg b.w./day)	% of systemic AOEL
Critical use: Grapes			
AOEM calculator (EFSA Model) Tractor mounted, upward application Buffer zone: 10 m Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days Volume min: 500 L/ha			
Number of applications and application rate		4 x 0.75 kg Cu/ha	
Resident child Body weight: 10 kg	Sum (mean)	0.0431	54 %
Resident adult Body weight: 60 kg	Sum (mean)	0.0234	29 %
Critical use Olives			
AOEM calculator (EFSA Model) Tractor mounted, upward application Buffer zone: 10 m Drift reduction technology: no DT ₅₀ : 30 days Initial DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 90 days Volume min: 500 L/ha			

¹⁶ 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)

Copper hydroxide 20 WG / CUIVRISTAL
Part A - National Assessment
FRANCE

Number of applications and application rate		2 x 1.2 kg Cu/ha	
Resident child Body weight: 10 kg	Sum (mean)	0.0399	49.89 %
Resident adult Body weight: 60 kg	Sum (mean)	0.0211	26.43 %

According to the model calculations, it can be concluded that there is no unacceptable risk for the resident (adult and/or child).

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

An exceedance of the current MRL for copper as laid down in Regulation (EC) No 396/2005 is not expected for table and wine grapes, table olive and olive for oil production.

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 finalised.

zRMS considers no firm conclusion can be reached for any of the requested uses of the product CUIVRISTAL (Copper hydroxide 20 WG).

Summary for CUIVRISTAL

Information on CUIVRISTAL (KCA 6.8)

Crop	PHI for CUIVRISTAL proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for CUIVRISTAL proposed by zRMS	zRMS Comments (if different PHI proposed)
Grapes (table and wine)	21 days	Yes	21 days	-
Olive (table and oil production)	15 days	Yes	15 days	-

NR: not relevant

* Purpose of withholding period to be specified

3.6 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 values 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.

Copper hydroxide 20 WG / CUIVRISTAL
Part A - National Assessment
FRANCE

No reliable PEC soil were available for the active substance mainly due to a shorter period for estimating the accumulation in soil. Therefore, the risk assessment for the non-target terrestrial organisms cannot be finalised for all requested 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} values including mitigation measures) and the absence of results for all FOCUS scenarios, PEC_{sw} values 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.

For the uses on grapes, PEC_{gw} values for copper do not occur at levels exceeding those mentioned in Directive 98/83/CE10. Therefore, no unacceptable risk of groundwater contamination is expected for these requested uses.

For the uses on olive, the risk to groundwater contamination cannot be finalised due to the absence of reliable FOCUS groundwater modelling.

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

3.7 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 terrestrial plants** are acceptable for the requested 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} and PEC_{sed} were provided by the applicant for all uses. Therefore, the risk assessment for aquatic non-target species could not be finalised for all requested 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 acute risk is not acceptable at Tier 1 for all requested uses. Higher-tier studies (cage and tunnel tests) are available and demonstrate that no adverse effects on adult honey bees are expected for all requested uses.

For honey bee larvae, according to new requirements of Regulation No 284/2013, data on development of bees should have been submitted by notifier as exposure of bees to the formulation cannot be excluded. Therefore, the risk assessment to bees cannot be completely fulfilled and the risk assessment for bees cannot be finalised.

For non-target arthropods, the applicant used toxicity data of another product than CUIVRISTAL (Copper hydroxide 20 WG). However, the available data are not sufficient to determine whether these toxicity data are representative of the toxicity of the product CUIVRISTAL (Copper hydroxide 20 WG), due to the increase in acute oral toxicity of the product CUIVRISTAL for bees. Therefore, the risk assessment for non-target arthropods cannot be finalised.

For soil organisms, since no reliable PEC soil values 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 requested uses of CUIVRISTAL (Copper hydroxide 20 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 macro-organisms other than earthworms could not be finalised for all requested uses.

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

3.8 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.

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

CUIVRISTAL (Copper hydroxide 20 WG) contains copper compounds, which is approved as a candidate for 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) No 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,

Copper hydroxide 20 WG / CUIVRISTAL
Part A - National Assessment
FRANCE

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

5 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”.

5.1.1 Post-authorisation monitoring

None.

5.1.2 Post-authorisation data requirements

N/A : marketing authorisation withdrawn

Copper hydroxide 20 WG / CUIVRISTAL
Part A - National Assessment
FRANCE

Appendix 1 Copy of the product authorisation

DocuSign Envelope ID: 37BDD854-DA94-40F9-A221-F13D308BFEA3



Décision relative à une demande de renouvellement de l'autorisation de mise sur le marché d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) n° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et réglementaire,

Vu la demande de renouvellement de l'autorisation de mise sur le marché, suite au renouvellement de l'approbation de la substance active composés du cuivre, du produit phytopharmaceutique CUIVRISTAL

de la société ASCENZA France

enregistrée sous le n° 2019-2643

Vu les conclusions de l'évaluation de l'Anses du 24 juin 2022,

Considérant qu'un risque d'effet nocif pour les travailleurs, lié à l'utilisation du produit, ne peut être exclu,

Considérant qu'en conséquence, les exigences mentionnées à l'article 29 du règlement (CE) n° 1107/2009 ne sont plus remplies,

L'autorisation de mise sur le marché du produit phytopharmaceutique désigné ci-après n'est pas renouvelée en France.

Copper hydroxide 20 WG / CUIVRISTAL
Part A - National Assessment
FRANCE

DocuSign Envelope ID: 37BDD854-DA94-40F9-A221-F13D3088FEA3



Informations générales sur le produit	
Nom du produit	CUIVRISTAL
Type de produit	Produit de référence
Titulaire	ASCENZA France 27 avenue Carnot 91300 MASSY France
Formulation	Granulé dispersable (WG)
Contenant	307,2 g/kg - hydroxyde de cuivre (équivalent à 200 g/kg de cuivre)
Numéro d'intrant	9882-2013.01
Numéro d'AMM	2180657
Fonction	Fongicide
Gamme d'usage	Professionnel

A Maisons-Alfort, le 15/07/2025

DocuSigned by:
Charlotte Grastilleur
AJ287A9055A42E54

Directrice générale déléguée
en charge du pôle produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

Copper hydroxide 20 WG / CUIVRISTAL
Part A - National Assessment
FRANCE

DocuSign Envelope ID: 37BDD854-DA94-40F9-A221-F13D308BFEA3



ANNEXE : Conditions de mise sur le marché

Liste des usages retirés					
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)	Délai accordé pour la vente et la distribution	Délai accordé pour le stockage et l'utilisation des stocks
12503201 Olivier*Trt Part.Aer.*Maladies des fruits	6 kg/ha	1/an	15	6 mois à compter de la présente décision	18 mois à compter de la présente décision
	Motivation du retrait : L'usage est retiré car les données disponibles ne permettent pas d'exclure un risque d'effet nocif pour les travailleurs, aux conditions d'emploi revendiquées.				
12503203 Olivier*Trt Part.Aer.*Maladies du feuillage	6 kg/ha	1/an	15	6 mois à compter de la présente décision	18 mois à compter de la présente décision
	Motivation du retrait : L'usage est retiré car les données disponibles ne permettent pas d'exclure un risque d'effet nocif pour les travailleurs, aux conditions d'emploi revendiquées.				
12703203 Vigne*Trt Part.Aer.*Mildiou(s)	3,75 kg/ha	4/an	21	6 mois à compter de la présente décision	18 mois à compter de la présente décision
	Motivation du retrait : L'usage est retiré car les données disponibles ne permettent pas d'exclure un risque d'effet nocif pour les travailleurs, aux conditions d'emploi revendiquées.				

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.

FONGICIDE

CUIVRISTAL®

Fongicide anti-mildiou de la vigne*

(* CF. tableau des usages dans le livret)

**Hydroxyde de cuivre 339g/kg (33.9% p/p) (Equivalent à 200g/kg (20 % p/p) de Cuivre) – Granulés
 dispersables (WG)**


Quantité nette ou volume net : Kg ou litres avec 

RÉSERVÉ À UN USAGE EXCLUSIVEMENT PROFESSIONNEL

**«Lire les instructions ci-jointes avant l'emploi» et «Consulter ce livret avant toute utilisation »
 Ou « Consulter les informations mentionnées sur ce sac avant toute utilisation »**

Code EAN / ~~Emballages~~

AMM N° 2180657

N° LOT : voir sur le bidon / sac
 Date de fabrication : voir sur le bidon / sac
 ® : marque déposée par ASCENZA AGRO S.A

Distribué par :
~~Ascenza France S.A.S~~
 Immeuble Odysée – A3
 2-12 rue du chemin des Femmes
 91300 MASSY
 www.sapecaagro.fr
 Tél. : 01 69 53 98 89

Copper hydroxide 20 WG / CUIVRISTAL
Part A - National Assessment
FRANCE

CUIVRISTAL®

339g/kg (33.9% p/p) d'Hydroxyde de cuivre (équivalent à 200 g/kg (20% p/p) de cuivre)

PREMIERS SECOURS :

• **Premiers soins :**

S'éloigner de la zone dangereuse.

- **En cas de contact cutané** : enlever tout vêtement souillé, rincer immédiatement et abondamment la peau sous l'eau du robinet avec du savon neutre durant 15-20 minutes. En cas d'irritation ou éruption cutanée, consulter un spécialiste.
- **En cas de projection dans les yeux** : rincer immédiatement pendant 15 à 20 minutes sous un filet d'eau paupières ouvertes. Pensez à enlever les lentilles de contact si elles peuvent être facilement enlevées. Consulter immédiatement un spécialiste.
- **En cas d'inhalation** : en cas de trouble respiratoire, contacter sans délai les secours : le 15, le 112 ou un centre antipoison.
- **En cas d'ingestion** : rincer immédiatement la bouche avec de l'eau si la personne est consciente. Ne pas faire vomir sans avis médical. Ne rien faire avaler à une personne inconsciente. Contacter sans délai les secours : le 15, le 112 ou un centre antipoison.

Dans tous les cas, si les symptômes persistent ou en cas de malaise, consulter un médecin et lui présenter l'étiquette et/ou la fiche de données de sécurité. Antidotes : EDTA, BAL ou ~~penicillamine~~.
En cas d'intoxication animale, contactez votre vétérinaire.

DESCRIPTIF DU PRODUIT ET MODE D'ACTION

CUIVRISTAL® est un fongicide de contact contenant 200 g/kg de cuivre (sous forme hydroxyde) agissant préventivement.

• **Tableau des usages autorisés**

Culture	Cibles	Dose maximum d'emploi	Nombre maximum d'applications	Intervalle minimum entre les applications	Stade d'application/ conditions d'emploi	Délai avant récolte (DAR)	ZNT* aquatique
Vigne (raisin de cuve et raisin de table)	Mildiou	3,75 kg/ha	4/an**	7 jours	Entre les stades : BBCH 13-57 Entre les stades : BBCH 69-81	21 jours	50m (dont DVP 20m)
Olivier	Maladie oeil de paon et maladies des fruits	6kg/ha	2/an	Na	13-89	15 jours	50m (dont DVP 20m)

* Zone non traitée (voir phrase SPe 3)

** Ne pas dépasser 4 applications par an et par culture

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>

ASCENZA AGRO 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.

RECOMMANDATIONS D'EMPLOI

• **Conditions d'application**

Vigne

L'application de CUIVRISTAL® s'effectue préventivement dès l'identification des risques (Observations, bulletins de santé du végétal). Il s'utilise du stade 13 (3 feuilles étalées) au stade 57 (inflorescences complètement développées,

Copper hydroxide 20 WG / CUIVRISTAL
Part A - National Assessment
FRANCE

fleurs séparées), et du stade 69 (fin de la floraison) au stade 81 (début véraison). L'Application durant la floraison est proscrite.

Une cadence de 7 à 10 jours est recommandée (adapter la cadence suivant la pression mildiou, l'intensité de la pousse et les conditions météorologiques).

- **Mélanges extemporanés**

Ne pas mélanger à des composés alcalins.

Les mélanges extemporanés doivent être mis en œuvre conformément à la réglementation en vigueur.

Consulter le site : <https://ephy.anses.fr/>

- **Préparation de la bouillie**

Le volume de bouillie doit être adapté au volume de végétation à protéger. Il sera spécifique au type de pulvérisateur utilisé, consulter votre technicien.

Ne pas ajouter CUIVRISTAL® directement dans la cuve. Diluer CUIVRISTAL® dans une petite quantité d'eau afin d'obtenir une texture crémeuse. Verser cette préparation dans la cuve remplie à 1/2 d'eau. Mettre sous agitation puis compléter le remplissage.

Laisser l'agitateur en fonctionnement pendant le trajet et jusqu'à la fin de la pulvérisation

D'une manière générale, pour déclencher tout traitement, il est conseillé de consulter son technicien habituel, de se conformer aux avis issus des organismes de prescription officiels (BSV...) et de baser sa décision sur les observations localisées de la pression parasitaire sur les cultures à protéger.

PREVENTION ET GESTION DE LA RÉSISTANCE

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, respecter les conditions d'emploi du produit et vérifier que la parcelle à traiter ne présente pas de souches de parasites résistantes. Pour réduire les risques de baisse d'efficacité, 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

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, à l'écart des aliments et boissons, y compris ceux pour animaux.
- Conserver hors de la portée des enfants et des personnes non autorisées.
- Températures de stockage : voir le pictogramme indiqué en première page du livret ou face avant du sac.

- **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

Dans le cadre des bonnes pratiques, il convient de privilégier les mesures de protection collective, mais aussi d'envisager l'adaptation du poste de travail. Par ailleurs, l'utilisation d'un matériel adapté et entretenu est cruciale, avant la mise en place de protections complémentaires comme les protections individuelles.

Le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène, (comme par exemple se laver les mains après toute manipulation/utilisation/intervention dans une parcelle préalablement traitée, 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.

Copper hydroxide 20 WG / CUIVRISTAL
Part A - National Assessment
FRANCE

Caractéristiques des EPI ▼	MÉLANGE /CHARGEMENT	PROTECTION DE L'UTILISATEUR PENDANT LES PHASES DE :				PROTECTION DU TRAVAILLEUR	
		APPLICATION AVEC :		PULVÉRISATEUR à dos en plein champ	NETTOYAGE		
		PULVÉRISATEUR pneumatique					
		TRACTEUR AVEC CABINE	TRACTEUR SANS CABINE				
GANTS EN NITRILE réutilisables (certifiés EN 374-3) ou à usage unique (certifiés EN 374-2)		Réutilisables	A usage unique*	A usage unique	Réutilisables	Réutilisables	Réutilisables
EPI VESTIMENTAIRE*** 45 % polyester / 35 % coton ≥ 230 g/m² + traitement déperlant		EPI vestimentaire ET			EPI vestimentaire ET		
EPI PARTIEL blouse ou tablier à manches longues catégorie III type PB1 certifié EN14605+A1		EPI partiel (Pulvérisateur pneumatique)			EPI partiel (Pulvérisateur pneumatique)		
COMBINAISON DE PROTECTION CHIMIQUE catégorie III type 3 ou 4 certifiée EN 14605+A1:2005		Type 4 (pulvérisateur à dos)	Type 4 (avec capuche)	Type 4 (avec capuche)	Type 4 (pulvérisateur à dos)		
LUNETTES de sécurité certifiées EN 166:2002 (C, sigle 3)							
PROTECTION RESPIRATOIRE demi-masque ou masque [EN 140:1998] équipé d'un filtre P3 [EN143:2000] ou A2P3 [EN 54387:2008]				**			
BOTTES de protection certifiées EN 113 B2-3:2006							

* 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.

** En cas d'exposition aux gouttelettes pulvérisées, porter un demi-masque filtrant à particules [EN 149] ou un demi-masque [EN 140] équipé d'un filtre à particules P3 [EN 143].

*** Ce vêtement pronicol peut être remplacé par tout autre EPI vestimentaire, spécifique aux produits phytopharmaceutiques, conforme aux exigences essentielles de santé et de sécurité de la directive 89/686/CEE.

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.

• **Nettoyage du pulvérisateur et gestion des fonds de cuve :**

- Ne pas traiter les cours d'eau et fossés en eau. Appliquer la bouillie dans les cultures par temps calme, sans vent fort, pour éviter toute dérive de pulvérisation vers les fossés, cours d'eau, chemins, abords de ferme ou bâtiments.
- A la fin de la période d'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.
- S'assurer d'un rinçage complet et soigné du pulvérisateur.

• **Elimination du produit, de l'emballage :**

- Réemploi de l'emballage interdit.
- Pour les bidons jusqu'à 25L : Lors de l'utilisation du produit, bien vider et rincer le bidon à l'eau claire (rinçage manuel à 3 reprises en agitant le bidon rempli au 1/3 ou rinçage mécanique d'une durée minimale² de 30 secondes) en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur. Apporter les emballages ouverts, rincés et égouttés à votre distributeur partenaire d'A.D.I. VALOR ou à un autre service de collecte spécifique.
- Pour les cartons et sacs : Apporter les emballages vidés et pliés à votre distributeur partenaire d'A.D.I. VALOR ou à un autre service de collecte spécifique.
- Pour les fûts plastiques et métalliques au-delà de 25L et ce jusqu'à 300L : Apporter les emballages vidés et fermés 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. Interroger 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 (EPI) 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.

² Le temps de rinçage recommandé pourra être allongé pour des produits moins aisés à rincer



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 facteurs particuliers concernant votre 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 cette spécialité 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.

CUIVRISTAL®

Hydroxyde de cuivre 339g/kg (33.9% p/p) (Equivalent à 200g/kg (20 % p/p) de Cuivre) – Granulés dispersables (WG)
AMM n° 2180657



ATTENTION

H302 Nocif en cas d'ingestion

H317 Peut provoquer une allergie cutanée

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

P261 Éviter de respirer les poussières/fumées/ gaz/brouillards/ vapeurs/aérosols.

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

P301 + P312 EN CAS D'INGESTION: appeler un CENTRE ANTIPOISON ou un médecin en cas de malaise.

P302 + P352 EN CAS DE CONTACT AVEC LA PEAU: laver abondamment à l'eau et au savon.

P333 + P313 En cas d'irritation ou d'éruption cutanée : Consulter un médecin.

P501 Éliminer le contenu/récipient conformément à la réglementation nationale

Conditions d'emploi

Tenir hors de la portée des enfants

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

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

- Délai de rentrée : 48 heures

- SPe1 : Pour protéger les organismes du sol, ne pas appliquer ce produit ou tout autre produit contenant du cuivre à une dose annuelle totale supérieure à 4kg Cu/ha.

- SPe3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 50 mètres par rapport aux points d'eau comportant un dispositif végétalisé permanent d'une largeur de 20 mètres.

Copper hydroxide 20 WG / CUIVRISTAL
Part A - National Assessment
FRANCE

EN CAS D'URGENCE
Composer le 15 ou le 112 ou contacter le centre
anti poison le plus proche

Puis signalez vos symptômes au réseau Phyt'attitude, n° vert 0 800 887 887 (appel gratuit depuis un poste fixe).

Fiche de Données de Sécurité disponible sur : www.quickfds.com et www.sapecagro.fr

RÉSERVÉ A UN USAGE EXCLUSIVEMENT PROFESSIONNEL

Fabriqué et conditionné au PORTUGAL

Contenu : XXXXXX l ou Kg

ASCENZA AGRO, S.A. Avenida do Rio Tejo - Herdade das Praias, 2910-440 Setúbal – Portugal

XXXXXXXXXXXXXXXXX - Marque déposée par ASCENZA AGRO S.A