REGISTRATION REPORT

Part A

Risk Management

Product code: MAN6Z

Product name(s): ZEOCOP WG

Chemical active substance(s):

Tribasic Copper Sulphate, 60 g/kg (as Cu metal)

Southern Zone & Interzonal

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: MANICA S.P.A.

Date: 15/07/2025

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PART A

RISK MANAGEMENT

1 Details of the application

The company MANICA S.P.A. has requested a marketing authorisation in France for the product ZEOCOP WG (product code: MAN6Z), containing 60 g/kg copper[1] (in the form of tribasic copper sulphate (CAS n° 12527-76-3)) as a fungicide and bactericide 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 MANICA S.P.A.'s application submitted on 25/07/2022 to market ZEOCOP WG (MAN6Z) 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 first authorisation of this product in France and in other Member States (MSs) of the European Union.

The present application (2022-2984) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009[2], 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 ZEOCOP WG (MAN6Z) has been made using endpoints agreed in the EU peer review of copper compounds. It also includes assessment of data and information related to ZEOCOP WG (MAN6Z) 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-taget organisms for the representative uses on grapevine, cucurbits and tomatoes, as well as to workers for the grapevine use.

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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.

In the framework of MRL review for copper compounds under Article 12 of Regulation (CE) 396/2005, EFSA published a reasoned opinion (EFSA, 2018[6]). 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 546/2011[7], 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 ZEOCOP WG (MAN6Z).

1.2 Letters of Access

The applicant is the owner of data which support the renewal of approval of the active substance.

1.3 Justification for submission of tests and studies

According to the applicant: « The tests and studies submitted in this registration dossier are required according to Regulation 284/2013 in order to support the intended uses for this plant protection product. »

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 3.

2 Details of the authorisation decision

2.1 Product identity

Product code	MAN6Z
Product name in MS	ZEOCOP WG
Authorisation number	-
Kind of use	Professional use
Low risk product (article 47)	No
Function	Fungicide and bactericide

[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

Applicant	MANICA S.P.A.
Active substance(s) (incl. content)	copper, 60 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

2.2 Conclusion

The evaluation of the application for ZEOCOP WG (MAN6Z) 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

N/A : no marketing authorisation granted

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

N/A : no marketing authorisation granted

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 2017[8] 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.

Finally, the French Order of 12 April 2021[9] 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 extrapolation[10] is to supply "minor" crops with registered plant protection products.

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

Finally, the French Order of 20 November 2021[11] 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 crop[12] 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

N/A : no marketing authorisation granted

2.5.2 Specific restrictions linked to the intended uses

[8] 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/AGRG1632554A/jo/texte ; https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id

[9] https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456

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

[11] Arrêté du 20 novembre 2021 relatif à la protection des abeilles et des autres insectes pollinisateurs et à la préservation des services de pollinisation lors de l'utilisation des produits phytopharmaceutiques - Légifrance (legifrance.gouv.fr)

[12] https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456

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

None.

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 12 April 2021 (highlighted in green), evaluated and concluded as safe uses by France as zRMS (field usas) and izRMS (greenhouse uses). 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:15/07/2025

PPP (product name/code):	ZEOCOP WG / MAN6Z	Formulation type:	WG [a, b]
Active substance 1:	Copper (tribasic copper sulphate)	Conc. of a.s. 1:	60 g/kg [c]
Safener:	-	Conc. of safener:	- [c]
Synergist:	-	Conc. of synergist:	- [c]
Applicant:	MANICA S.P.A.	Professional use:	☒
Zone(s):	Southern Zone & Interzonal [d]	Non-professional use:	☐
Verified by MS:	Yes		
Field of use:	Fungicide & bactericide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method/Kind	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	kg 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	Stone fruits (Peach, nectarine, apricot, cherry, plum)	F	Bacteria: *Xanthomonas arboricola pv. pruni* (XANTPR)	Foliar spray	Post-flowering BBCH 69-85	a) 6 b) 6	7	a) 3 b) 18	a) 0.18 b) 1.08	1000	21	**Not acceptable** (MRL)
2	FR	Grapes	F	*Plasmopara viticola*	Foliar spray	BBCH 11-89	a) 10 b) 10	7	a) 5 b) 50	a) 0.3 b) 3	500-1000	7	**Not acceptable** (MRL, workers)
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)													
3	FR	Tomato Eggplant	G	*Phytophthora infestans*	Foliar spray	BBCH 10-89	a) 10 b) 10	7	a) 5 b) 50	a) 0.3 b) 3	500-800	3	**Not acceptable** (MRL)

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 to be acceptable. The appearance of the product is that of brown solid, with mild odour. The product is not explosive and has no oxidising properties. It is not flammable. It has a self-ignition temperature of 173.4°C. In aqueous solution, it has a pH value around 6.1 at 20.4°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 changed. The stability data indicate a shelf-life of at least 2 years at ambient temperature when stored in paper bags multi-layer (3 layer in paper/inner plastic PE). The product's technical characteristics are acceptable for a WG formulation.

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

- The efficacy level of MAN 6Z (ZEOCOP WG) is considered still acceptable for the requested uses, although reduction of dose rates is likely to lead to less regular and/or less persistence of action of the treatments.
- The phytotoxicity level of MAN 6Z (ZEOCOP WG) is considered acceptable for the requested uses. Nevertheless, some phytotoxic symptoms can occur after applications of copper-based products, especially on stone fruits and table grape. Therefore, specific attention should be paid to conditions of application (caution on sensible growth stages, and/or on sensitive cultivars).
- The risk of negative impact on yield and quality are considered negligible on a majority of crops. Nevertheless, spotting can occur after applications of copper-based products, especially on table grape. Therefore, specific attention should be paid to conditions of application (avoid sensible growth stages…).
- There is a known risk of possible effects on the wine making process. However, this risk of negative impact is considered acceptable. A warning and specific recommendation should be included in the label.
- The risks of negative impact on propagation, succeeding crops and adjacent crops are considered negligible.
- There is a risk of resistance to copper for *Xanthomonas arboricola* in stone fruits requiring to set up a monitoring of resistance.

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, this method is not specific to the variant tribasic copper sulphate. A complementary method should be provided to confirm the identity of the variant in the product.

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

3.3.2 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, acidic), soil, water (surface and drinkng), air and body fluids.

According to EFSA conclusions, an interaboratory 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 and are required. 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

Product name and code	ZEOCOP® WG / MAN6Z
Formulation type	Wettable granules (WG)
Category	Fungicide / Bactericide
Active substance(s) (incl. content)	**Tribasic copper sulphate** 60 g Cu a.i./kg
AOEL systemic	0.08 mg/kg bw/d
AAOEL systemic	Not available
Inhalation absorption	100 %
Oral absorption	50 %
Dermal absorption	Concentrate: 1% Dilution: 9% (See Appendix 2, point A 2.10)

3.4.1 Acute toxicity

ZEOCOP WG (MAN6Z) has a low acute oral, inhalational and dermal toxicity. It is not irritating to skin or eye and is not a skin sensitizer.

3.4.2 Operator exposure

Considering proposed uses, operator systemic exposure was estimated using the EFSA model[13]:

Long term exposure for outdoor uses:

[13] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)

		Copper (under the form of tribasic copper sulphate)	
Model data	**Level of PPE**	**Total absorbed dose (long term) (mg/kg/day)**	**% of systemic AOEL**
Critical use: Grape Tractor mounted application outdoors, upward spraying			
Application rate		0.3 kg a.s./ha	
Spray application (AOEM**;** 75th percentile for long term exposure, 95th for acute exposure) Body weight: 60 kg	Work wear (arms, body and legs covered) and gloves during M/L and A	0,0087	10,93%
Critical use: Grape Handheld sprayer application outdoors, downward spraying			
Application rate		0.3 kg a.s./ha	
Spray application (AOEM**;** 75th percentile for long term exposure, 95th for acute exposure) Body weight: 60 kg	Work wear (arms, body and legs covered) and gloves during M/L and A	0,0145	18,10%
Critical use: Grape Knapsack sprayer application outdoors, downward spraying			
Application rate		0.3 kg a.s./ha	
Spray application (AOEM**;** 75th percentile for long term exposure, 95th for acute exposure) Body weight: 60 kg	Work wear (arms, body and legs covered) and gloves during M/L and A	0,0142	17,80%
Critical use: Stone fruit Handheld sprayer application outdoors, upward spraying on dense foliage			
Application rate		0.18 kg a.s./ha	
Spray application (AOEM**;** 75th percentile for long term exposure, 95th for acute exposure) Body weight: 60 kg	Work wear (arms, body and legs covered) and gloves during M/L and A	0,0700	87,53%
Critical use: Stone fruit Knapsack sprayer application outdoors, upward spraying on dense foliage			
Application rate		0.18 kg a.s./ha	
Spray application (AOEM**;** 75th percentile for long term exposure, 95th for acute exposure) Body weight: 60 kg	Work wear (arms, body and legs covered) and gloves during M/L and A	0,0701	87,59%

Long term exposure for indoor uses:

		Copper (under the form of tribasic copper sulphate)	
Model data	**Level of PPE**	**Total absorbed dose (long term) (mg/kg/day)**	**% of systemic AOEL**
Critical use: Fruiting vegetables (tomato, covering eggplant) Handheld sprayer application indoors, downward spraying			
Application rate		0.3 kg a.s./ha	
Spray application (AOEM**;** 75th percentile for long term exposure, 95th for acute exposure) Body weight: 60 kg	Work wear (arms, body and legs covered) and gloves during M/L and A	0,0145	18,10%
Critical use: Fruiting vegetables (tomato, covering eggplant) Knapsack sprayer application indoors, downward spraying			
Application rate		0.3 kg a.s./ha	
Spray application (AOEM**;** 75th percentile for long term exposure, 95th for acute exposure) Body weight: 60 kg	Work wear (arms, body and legs covered) and gloves during M/L and A	0,0142	17,80%

According to the exposure assessment using EFSA model, operator exposure to ZEOCOP WG (MAN6Z) is below the AOEL value of copper, with a working coverall and gloves during mixing/loading and application.

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

3.4.3 Worker exposure

Workers may have to enter into treated areas after treatment for crop hand harvesting or reaching, picking or searching, reaching, picking activities. Therefore, estimation of worker exposure was calculated according to AOEM model.

Worker exposure for outdoor uses:

Tier 1 assessment:

		Copper (under the form of tribasic copper sulphate)	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Critical use: Grape (hand harvesting outdoors) Work rate: 8 hours/day, DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		10 x 0.3 kg a.s./ha	
Body weight: 60 kg	Work wear (arms, body and legs covered) TC: 10100 cm^2/person/h	**0,5855**	**731,89%**
	Work wear (arms, body and legs covered) and gloves TC: Not available for this assessment	-	-
Critical use: Stone fruit (searching, reaching and picking outdoors) Work rate: 8 hours/day, DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		6 x 0.18 kg a.s./ha	
Body weight: 60 kg	Work wear (arms, body and legs covered) and gloves TC: 2250 cm^2/person/h	0,0606	75,80%

It should be noted that the AOEL is exceeded already at the 1st application: just after 1st application (t = 0 day) systemic exposure = 0.011 mg/kg bw/d = 137.5% AOEL and just before the 2nd application (t = 7 days before the 2nd application) the systemic exposure = 0.093 mg/kg bw/d = 116.3%.

A refined DT_{50} of 7 days based on 'Peer review of the pesticide risk assessment of the active substance copper compounds, EFSA Journal 2018;16(1):5152' is also proposed by the applicant. As a Tier 2 assessment, calculations has been performed below using EFSA model (2014):

Tier 2 assessment:

		Copper (under the form of tribasic copper sulphate)	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Critical use: Grape (hand harvesting outdoors) Work rate: 8 hours/day, DT_{50}: 7 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		10 x 0.3 kg a.s./ha	
Body weight: 60 kg	Work wear (arms, body and legs covered) TC: 10100 cm^2/person/h	**0,2179**	**272,43%**
	Work wear (arms, body and legs covered) and gloves TC: Not available for this assessment	-	-
Critical use: Stone fruit (searching, reaching and picking outdoors) Work rate: 8 hours/day, DT_{50}: 7 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		6 x 0.18 kg a.s./ha	
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm^2/person/h	0,0287	35,88%

Worker exposure for indoor uses:

		Copper (under the form of tribasic copper sulphate)	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Critical use: Fruiting vegetables (reaching and picking indoors) Work rate: 8 hours/day, DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		10 x 0.3 kg a.s./ha	
Body weight: 60 kg	Work wear (arms, body and legs covered) and gloves TC: 580 cm^2/person/h	0,0336	42,03%

Further refinement for worker exposure is not necessary for indoor uses.

Conclusion for worker exposure (outdoor and indoor):
According to the exposure assessment using EFSA model, worker exposure to ZEOCOP WG (MAN6Z) is above the AOEL value of copper for the use on grapes outdoor, with a working coverall and gloves.

Based on the exposure assessment using EFSA model, worker exposure to ZEOCOP WG (MAN6Z) is **above the AOEL** value of 0.08 mg/kg b.w/day for use on grapes taking into account that work wear (arms, body and legs covered) is worn. It should be noted that the AOEL is exceeded already at the 1st application: just after 1st application (t = 0 day) systemic exposure = 0.011 mg/kg bw/d = 137.5% AOEL and just before the 2nd application (t = 7 days before the 2nd application) the systemic exposure = 0.093 mg/kg bw/d = 116.3%.

According to the exposure assessment using EFSA model, worker exposure to ZEOCOP WG (MAN6Z) is below the AOEL value of copper for all the other uses, with a working coverall and gloves.

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

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 set[14].
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

Resident exposure was assessed according to EFSA model incorporating a distance of 10 metres from the spray boom, without drift reduction technology.

Resident exposure for outdoor uses:

		Copper (under the form of tribasic copper sulphate)	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Critical use: Grape Tractor mounted application outdoors, upward spraying Buffer zone: 10 m Drift reduction technology: No DT50: 30 days DFR: 3 µg/cm²/kg a.s./ha			
Number of applications and application rate		10 x 0.3 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (95th percentile)	0,0076	9,47%
	Vapour (95th percentile)	0,0011	1,34%
	Deposits (95th percentile)	0,0005	0,63%

[14] 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)

	Re-entry (95th percentile)	0,0245	30,57%
	All pathways (mean)	0,0259	32,43%
Resident adult Body weight: 60 kg	Drift (95th percentile)	0,0042	5,22%
	Vapour (95th percentile)	0,0002	0,29%
	Deposits (95th percentile)	0,0002	0,22%
	Re-entry (95th percentile)	0,0136	16,98%
	All pathways (mean)	0,0139	17,41%

Further refinement of the resident exposure is not necessary for outdoor uses.

Resident exposure for indoor uses:

In the context of indoor uses, resident exposure is not relevant.

According to the exposure assessment performed by EFSA model, resident exposure to ZEOCOP WG (MAN6Z) is below the AOEL value of copper, without mitigation measures.

3.4.6 Combined exposure

Not relevant. The product contains only one active substance.

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

Due to insufficient data on the magnitude of residue in plants, the uses on stone fruit, grapes and tomato (indoor) cannot be recommended.
The acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for copper.
Due to insufficient data on the on the magnitude of copper residue in plants, the chronic intakes of copper residues cannot be performed.
As far as consumer health protection is concerned, France disagrees with the authorization of the intended use.

Summary for MAN6Z/ZEOCOP® WG

Crop	**PHI for MAN6Z/ZEOCOP® WG proposed by applicant**	**PHI/ Withholding period* sufficiently supported for**	**PHI for MAN6Z/ZEOCOP® WG proposed by zRMS**	**zRMS Comments (if different PHI proposed)**
		Copper compounds		
Stone fruits	21	**No**	-	**Not recommended use**
Grapes	7	**No**	-	**Not recommended use**
Tomato and aubergine	3	**No**	-	**Not recommended use**

NR: not relevant
* Purpose of withholding period to be specified

Waiting periods before planting succeeding crops: Not relevant.

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.

The PEC (predicted environmental concentration) of copper in soil, surface water and groundwater have been assessed according to 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 uses under permanent greenhouse with soil-less culture, no exposure assessment for all environmental compartments is needed.
For all other uses, PEC_{soil} and $PEC_{soil,\ accumulation}$ (derived for 10 years) can be used for the risk assessment for the non-target terrestrial organisms.
For uses under permanent greenhouse with soil-bound culture, the PEC_{sw}, $PEC_{sediment}$ and $PEC_{sediment,\ accumulation}$ can be used for the risk assessment for the non-target aquatic organisms.
For all uses except uses under permanent greenhouse, the PEC_{sw} can be used for the risk assessment for the non-target aquatic organisms and mitigation measures are proposed. Given the uncertainties identified by zRMS in the notifier's exposure calculation (FOCUS STEP 1-2 for all entries to water bodies), $PEC_{sediment}$ and $PEC_{sediment,\ accumulation}$ 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 these uses.

For all intended uses except for uses under permanent greenhouse with soil-less culture, PEC_{gw} for the active substance do not occur at levels exceeding those mentioned in Regulation (EC) n°546/2011. Therefore, no unacceptable risk of groundwater contamination is expected for these intended uses.

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

For uses under permanent greenhouse with soil-less cultivation, exposure of non-target organisms is negligible in the conditions of uses described under 2.5.

For aquatic organisms, no reliable PECsed were provided by the applicant for uses in open-fields and tunnels. Therefore, the risk assessment for aquatic organisms could not be finalised for uses in open-fields and tunnels.
For uses in permanent greenhouses with soil-bound cultivation, no acceptable risk to aquatic organsims could be demonstrated with the available data. As the toxicity reference value for copper proposed by the applicant to refine the risk assessment for sediment delling organisms was based on an approach rejected

at European level, it could not be used. Therefore, the risk assessment for aquatic organisms could not be finalised for the uses under permanent greenhouse with soil-bound cultivation.

Based on the guidance documents, the risks for **non-target terrestrial plants** are acceptable 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 except for applications under permanent greenhouse.

For bees, the risk assessment provided by the applicant is based on the EFSA Guidance Document[15].
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 risk is acceptable at Tier 1 for all intended uses.
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 except for uses under permanent greenhouses with a precautionary statement.
Overall, the risk for bees cannot be finalised for all requested uses except for applications under permanent greenhouse. For these structures, the following precautionary statement should be applied: "May affect pollinators. Avoid unnecessary exposure".

For non-target arthropods, an acceptable risk could not be demonstrated via in-field exposure. No data are provided by the applicant to refine the risk assessment. Therefore the risk to non-target arthropods could not be finalised for all intended uses except for application under permanent greenhouse. For these structures, the following precautionary statement should be applied: "May affect beneficial insects. Avoid unnecessary exposure".

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 4 kg Cu/ha/year. Therefore, an acceptable risk for earthworms is demonstrated for all intended uses of ZEOCOP WG (MAN6Z).
For other soil meso- and macro-organisms, the risk is not acceptable at Tier 1 for all intended uses for applications in open-field, in walk-in tunnels, or in permanent greenhouse with soil-bound cultivation. 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 except for uses under permanent greenhouse with soil-less cultivation.
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.

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.

[15] 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

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

ZEOPCOP (MAN6Z) contains copper compounds, which are approved as a candidate for substitution because two PBT criteria are met (Persistent and Toxic).

Steps 1 and 2 (French guidance document 27 July 2015):
In accordance with Article 50, paragraphs 1.b) 1.c) and 1.d) of Regulation (EC) N°1107/2009, taking into account minor uses, management of resistance and the agronomic interest of the active substance especially in the context of organic agriculture**, substitution 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

The monitoring of resistance to copper should be implemented on *Xanthomonas arboricola* on stone fruits. A report on the results of the monitoring put in place should be provided at the time of the next renewal of the product.

5.1.2 Post-authorisation data requirements

None.

Appendix 1 Copy of the product authorisation

ZEOCOPWG_PAMM
_2022-2984_D.pdf

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.

ZEOCOP® WG

Composition :	Cuivre 60 g/kg, soit 6% (m/m) sous forme de sulfate de cuivre tribasique
Formulation :	Granulé dispersable [WG]
Type de produit :	FONGICIDE utilisé en traitement préventif contre la bactériose des fruits à noyau et le mildiou de la vigne, de la tomate et de l'aubergine (sous abri).
Mode d'action :	GROUPE **M01** FONGICIDE
Détenteur de l'A.M.M :	MANICA S.p.A., Via all'Adige 4, 38068 ROVERETO (Trento), ITALIE Tel. +39 0464 433705 www.manica.com
Distributeur :	Nom, adresse www.internet.com

N° de lot et date de fabrication : voir emballage
X L/kg e

RESERVE A UN USAGE EXCLUSIVEMENT PROFESSIONNEL

UTILISEZ LES PRODUITS PHYTOPHARMACEUTIQUES AVEC PRÉCAUTION.
AVANT TOUTE UTILISATION, LISEZ L'ÉTIQUETTE ET LES INFORMATIONS CONCERNANT LE PRODUIT.
RÉEMPLOI DE L'EMBALLAGE INTERDIT.

Lire les instructions ci-jointes avant l'emploi.

Attention

ZEOCOP® WG– AMM N° 0000000 – UFI : xxxxx

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.
P273	Éviter le rejet dans l'environnement.
P280	Porter des gants de protection/ des vêtements de protection/ un équipement de protection des yeux/ du visage
P391	Recueillir le produit répandu.
P501	Eliminer le contenu/récipient conformément à la réglementation en vigueur.

Délai de rentrée des travailleurs dans la zone traitée :
6 heures après traitement pour les usages en plein champ et pour l'usage « tomate-aubergine » sous abri ouvert.
8 heures après traitement pour l'usage « tomate-aubergine » en milieu fermé

SP 1	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.
SPe 3	Pour protéger les organismes aquatiques, respecter une zone non traitée de 50 mètres par rapport aux points d'eau comportant un dispositif végétalisé permanent non traité d'une largeur de 20 mètres pour l'usage « fruits à noyau ».

	SPe 3	Pour protéger les organismes aquatiques, respecter une zone non traitée de 20 mètres par rapport aux points d'eau comportant un dispositif végétalisé permanent non traité d'une largeur de 20 mètres pour les usages « vigne » et « tomate-aubergine » sous abri ouvert au moment du traitement.
	SPe 3	Pour protéger les arthropodes non cibles/les insectes, respecter une zone non traitée de 10 mètres par rapport à la zone non cultivée adjacente pour l'usage « fruits à noyau ».
	SPe 3	Pour protéger les arthropodes non cibles/les insectes, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente pour l'usage « vigne ». Seules les utilisations entraînant une application totale maximale de 28 kg de cuivre par hectare sur une période de sept ans sont autorisées.

Premiers secours

En cas d'urgence, appelez le 15 ou le 112 ou contactez le centre antipoison le plus proche puis signalez vos symptômes au réseau "Phyt'attitude". N° vert 0 800 887 887 (appel gratuit depuis un poste fixe).

Conseils généraux
S'éloigner de la zone dangereuse.
En cas d'exposition ou de symptômes, appeler un CENTRE ANTIPOISON ou un médecin.

Inhalation
Transporter la victime à l'extérieur et la maintenir au repos dans une position où elle peut confortablement respirer. En cas de trouble respiratoire, contacter sans délai les secours : le 15, le 112 ou un centre anti-poison.

Contact avec la peau
Enlever immédiatement tous les vêtements contaminés. Rincer immédiatement et abondamment la peau à l'eau ou se doucher. En cas d'irritation ou éruption cutanée, consulter un spécialiste.

Contact avec les yeux
Rincer immédiatement pendant 15 à 20 minutes sous un filet d'eau paupières ouvertes. Consulter un spécialiste.

Ingestion
Rincer immédiatement la bouche avec de l'eau. Ne PAS faire vomir sans avis médical. Contacter sans délai les secours : le 15, le 112 ou un centre anti-poison. 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.

Intoxication animale
Contacter votre vétérinaire.

Fiche de données de sécurité disponible sur simple demande.

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.

PRECONISATIONS D'EMPLOI

Usages et doses autorisés en traitement des parties aériennes

Usages plein champ

Culture	Cibles / Usages	Dose maximum d'emploi	Nombre maximum d'applications par an et intervalle entre applications	Stades d'application	Délai avant récolte (en jours)	ZNT organismes aquatique *	ZNT arthropodes non cibles **
Fruits à noyau (pêcher, nectarinier, abricotier, cerisier, prunier)	Bactériose	3 kg/ha	6 applications à 7 jours d'intervalle	BBCH 69-85 (à partir de la fin de la floraison jusqu'au stade « coloration avancée » des fruits)	21 jours	50 m (dont DVP 20 m)	10 m
Vigne	Mildiou	5 kg/ha	10 applications à 7 jours d'intervalle	BBCH 11-89 (du stade 1ère feuille étalée à la maturité des baies)	7 jours	20 m (dont DVP 20 m)	5 m

* Pour protéger les organismes aquatiques, respecter une zone non traitée de 50 mètres par rapport aux points d'eau comportant un dispositif végétalisé permanent non traité d'une largeur de 20 mètres pour l'usages « fruits à noyau », et respecter une zone non traitée de 20 mètres par rapport aux points d'eau comportant un dispositif végétalisé permanent non traité d'une largeur de 20 mètres pour l'usage « vigne ».
** Pour protéger les arthropodes non cibles/les insectes, respecter une zone non traitée de 10 mètres par rapport à la zone non cultivée adjacente pour l'usage « fruits à noyau » et de 5 mètres pour l'usage « vigne ».

Usages sous abri

Culture	Cibles / Usages	Dose maximum d'emploi	Nombre maximum d'applications par an et intervalle entre applications	Stades d'application	Délai avant récolte (en jours)	ZNT organismes aquatique *	ZNT arthropodes non cibles
Tomate, Aubergine	Mildiou	5 kg/ha	10 applications à 7 jours d'intervalle	BBCH 10-89 (du stade cotylédons étalés à la maturation complète des fruits)	3 jours	20 m (dont DVP 20 m)	-

* Pour protéger les organismes aquatiques, respecter une zone non traitée de 20 mètres par rapport aux points d'eau comportant un dispositif végétalisé permanent non traité d'une largeur de 20 mètres pour l'usage « tomate-aubergine » sous abri ouvert au moment du traitement.

Respect des limites maximales de résidus (LMR)
Pour chaque usage figurant dans la liste des usages autorisés, les conditions d'utilisation du produit permettent de respecter les limites maximales de résidus.

Nouveau catalogue des usages et usages mineurs
MANICA ne préconise l'utilisation de ce produit que sur les cultures et usages mentionnés dans le tableau ci-dessus et décline toute responsabilité concernant son utilisation pour d'autres usages tels que prévus par le catalogue des usages en vigueur.

INFORMATIONS RELATIVES A L'EMPLOI
ZEOCOP® WG est un fongicide de contact à utiliser en traitement des parties aériennes, de façon préventive en fonction des risques de maladies. Suivre les préconisations des Bulletins de Santé du Végétal. Les traitements doivent être renouvelés, selon la climatologie, afin de protéger toute la végétation.

Précautions d'emploi
Traiter uniquement par temps calme. Ne traiter que les cultures saines et non endommagées.
Ne pas traiter en cas d'hygrométrie inférieure à 60% et par des températures supérieures à 30°C.
En cas de stress hydrique marqué et de fortes amplitudes thermiques, éviter de traiter les cultures.
Eviter la dérive sur les cultures voisines.

Mélanges extemporanés et Compatibilités
Les mélanges extemporanés doivent être mis en œuvre conformément à la réglementation en vigueur. Pour les produits en association, consulter leur fiche technique. En cas de mélange de ces produits, la plus forte valeur pour chacun des critères (DAR, ZNT, délai de rentrée) s'applique.

Préparation et application de la bouillie
Utiliser ZEOCOP® WG avec des volumes d'eau compris entre 500 et 1000 L/ha.
Verser directement ZEOCOP® WG, présenté sous forme de granulés dispersables, dans la cuve remplie à moitié d'eau, le système d'agitation en fonctionnement. Compléter la cuve avec le volume d'eau nécessaire.

MODE D'ACTION
Le cuivre, composé inorganique (électrophile), a une action de contact multisite.
Code FRAC : M 01

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, MANICA décline toute responsabilité quant à d'éventuelles conséquences qui pourraient être dues à de telles résistances.

MISE EN OEUVRE RÉGLEMENTAIRE ET BONNES PRATIQUES

Stockage

- Conserver le produit uniquement dans son emballage d'origine, dans un local phytopharmaceutique conforme à la réglementation en vigueur, à l'écart de tout aliment et boisson y compris ceux pour les animaux. Conserver hors de la portée des enfants et des personnes non autorisées.

Protection de l'opérateur et du travailleur

L'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections complémentaires comme les protections individuelles.
Le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage). Les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

Dans le cadre d'une application avec un pulvérisateur pneumatique ou atomiseur

Pour l'opérateur, porter :
• ***pendant la préparation/mélange/chargement et le nettoyage du matériel de pulvérisation***
- Gants en nitrile réutilisables (certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A));
- EPI vestimentaire (conforme à la norme NF EN ISO 27065/A1) et EPI partiel (blouse ou tablier à manches longues) catégorie III type PB3 (certifié NF EN 14605+A1) à porter par-dessus la combinaison précitée
OU combinaison de protection chimique catégorie III type 3 ou 4 (certifiée NF EN 14605+A1);

• ***pendant l'application*** **- Pulvérisation vers le haut (ex. : arboriculture-vigne lors du traitement des parties aériennes)**
Si application avec tracteur avec cabine fermée :
- Gants en nitrile à usage unique (certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C)) 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;
- EPI vestimentaire (conforme à la norme NF EN ISO 27065/A1).
Si application avec tracteur sans cabine :
- Gants en nitrile à usage unique (certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C));
- Combinaison de protection chimique catégorie III type 4, avec capuche (certifiée NF EN 14605+A1);
- En cas d'exposition aux gouttelettes pulvérisées, porter une protection respiratoire : demi-masque filtrant anti-aérosol (certifié NF EN 149) de classe FFP3 ou demi-masque (certifié NF EN 140) avec filtre anti-aérosol (certifié NF EN 143) de classe P3.

Dans le cadre d'une pulvérisation manuelle avec une lance sous serre

Pour l'opérateur, porter :
• ***pendant la préparation/mélange/chargement et le nettoyage du matériel de pulvérisation***
- Gants en nitrile réutilisables (certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A));
- EPI vestimentaire (conforme à la norme NF EN ISO 27065/A1) et EPI partiel (blouse ou tablier à manches longues) catégorie III type PB3 (certifié NF EN 14605+A1) à porter par-dessus la combinaison précitée
OU combinaison de protection chimique catégorie III type 3 ou 4 (certifiée NF EN 14605+A1);

• ***pendant l'application - sans contact intense avec la végétation ; Culture haute (> 50 cm) (ex : cultures tomates) :***
- Gants en nitrile réutilisables (certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A));
- Combinaison de protection chimique catégorie III type 4, avec capuche (certifiée NF EN 14605+A1);
- Bottes (certifiées NF EN 13832-3).

Dans le cadre d'une application manuelle avec un pulvérisateur à dos sous serre

Pour l'opérateur, porter :
• ***pendant la préparation/mélange/chargement et le nettoyage du matériel de pulvérisation***
- Gants en nitrile réutilisables (certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A));

- EPI vestimentaire (conforme à la norme NF EN ISO 27065/A1) et EPI partiel (blouse ou tablier à manches longues) catégorie III type PB3 (certifié NF EN 14605+A1) à porter par-dessus la combinaison précitée
OU combinaison de protection chimique catégorie III type 3 ou 4 (certifiée NF EN 14605+A1);

• ***pendant l'application - sans contact intense avec la végétation :***
- Gants en nitrile réutilisables (certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A));
- Combinaison de protection chimique catégorie III type 4, avec capuche (certifiée NF EN 14605+A1);
- Bottes (certifiées NF EN 13832-3).

Travailleur
Dans les cas où le travailleur serait amené à intervenir sur les parcelles traitées, porter un EPI vestimentaire (conforme à la norme NF EN ISO 27065/A1) et, en cas de contact avec la culture traitée, porter des gants en nitrile réutilisables (certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A)).

Elimination des équipements de protection individuelle (EPI)
Rapporter les 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
À 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.

Elimination du produit et de l'emballage
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 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.

AVERTISSEMENT
Toute reproduction totale ou partielle de cette étiquette est interdite.
Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage qui 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.