REGISTRATION REPORT
Part A
Risk Management

Product code: SPU-00760-F
Product name(s): CUPROZIN 35 WP
Chemical active substances:
copper (in the form of copper oxychloride), 350 g/kg

Southern Zone
Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE
(authorisation renewal according to Article 43)

Applicant: COSACO GmbH
Date: 15/07/2025

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PART A

RISK MANAGEMENT

1 Details of the application

The company COSACO GMBH has requested a marketing authorisation in France for the product CUPROZIN 35 WP (product code: SPU-00760-F), containing 350 g/kg copper (in the form of copper oxychloride), for use as a fungicide.

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 COSACO GMBH's application submitted on 01/04/2019 to market CUPROZIN 35 WP (SPU-00760-F) 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 substances copper compounds of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2019-3716) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009[1], 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")[2]. 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 CUPROZIN 35 WP (SPU-00760-F) has been made using endpoints agreed in the EU peer reviews of copper compounds. It also includes assessment of data and information related to CUPROZIN 35 WP (SPU-00760-F) where those data have not been considered in the EU peer review process.

The conclusions of the assessment published by EFSA 2018[3,4], as part of the procedure for the renewal of the approval of copper compounds, based on the available information, identify riskfot 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 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

2 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

3 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

4 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[5]). 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[6], 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 CUPROZIN 35 WP (SPU-00760-F).

1.2 Letters of Access

The applicant is the owner of data which support the renewal of approval of the active substance. The applicant has provided letter of access for active substance data. This letter of access is available upon request.

1.3 Justification for submission of tests and studies

According to the applicant: " *All other information was already submitted for the first authorization of the product.*"

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of CUPROZIN 35 WP (SPU-00760-F), 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	COC 35 WP
Product name in MS	CUPROZIN 35 WP
Authorisation number	2180889

[5] 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).

[6] 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

Kind of use	Professional use
Low risk product (article 47)	No
Function	Fungicide
Applicant	COSACO GMBH
Active substance(s) (incl. content)	350 g/kg copper (in the form of copper oxychloride)
Formulation type	Wettable powder [WP]
Packaging	- Sachet in PE/Al (0.01kg, 0.1 kg) - Bag in PET/PE/Al foil (0.1kg, 1 kg) - Sack in PE lined multi-layer paper (1kg, 1.7 kg, 2 kg, 2.5 kg) - Sack in PE lined multi-layer paper (10 kg,20 kg,25 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 CUPROZIN 35 WP (SPU-00760-F) resulted in the decision to **withdraw** 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:	Hazardous to the aquatic environment - Acute Hazard, category 1 Hazardous to the aquatic environment - Chronic Hazard, category 1
Hazard pictograms:	 GHS09
Signal word:	Warning
Hazard statement(s):	H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long-lasting effects.
Precautionary statement(s):	***For the P phrases, refer to the existing legislation***

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
	For other restrictions refer to 2.5

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[7] 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 2014[8] 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[9] 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.

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7 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, modifié par l’arrêté du 27 décembre 2019 https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte ; https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id

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

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

Finally, the French Order of 20 November 2021[10] 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[11] 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.

[10] https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734

[11] 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.

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. 2, date: 15 July 2025

PPP (product name/code):	Cuprozin 35 WP	Formulation type:	WP
Active substance 1:	Copper oxychloride	Conc. of as 1:	350 g/kg
Applicant:	COSACO GmbH	Professional use:	☒
Zone(s):	southern	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.	**Member state(s)**	**Crop and/or situation (crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application** Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	**Application rate** kg product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
Field uses – Southern EU													
1	FR	Peach	F	Peach leaf curl *(Taphrina deformans)* TAPHDE	Spraying	BBCH 00 - 03	a) 1 b) 1	N/A	a) Up to 3.57 kg/ha	a) Up to 1.25	-	BBCH 03	**Not acceptable** (worker, PPE*)
2	Southern zone	Grapevine *(Vitis vinifera)*	F	Downy mildew	Spraying	At infection risk from	a) 5 b) 5	7	a) 3 - 2.2 b) 11.43	a) 1.05 - 0.77 b) 4.0	1000	21	**Not acceptable** (worker, PPE*)

	FR	VITVI		*(Plasmopara viticola)* PLASVI		BBCH 71 to 85							
3	Southern zone FR	Pome fruit (apple, pear) *(Malus domestica)* MABSD, *(Pyrus communis)* PYUCO	F	Scab *(Venturia inaequalis)* VENTIN + VENTPI	Spraying	At infection risk until BBCH 59	a) 5[1] b) 10 a)1 b)1	5	a) 2.2-2.0 to 1.6-1.4 b) 11.43	a) 0.77 - 0.70 to 0.56 - 0.49 b) 4.0	850-1000	N/A	**Not acceptable** (worker, PPE*)
4	Southern zone FR	Tomato *(Solanum lycopersicum)* LYPES	F	Late blight *(Phytophthora infestans)* PHYTIN	Spraying	At infection risk from BBCH 21 to 89	a) 5 b) 5	5	a) 2.0 to 1.7 b) 10.0	a) 0.70 - 0.595 b) 3.5	800	3	**Not acceptable** (PPE*)

* **PPE: Personal protective equipment. The information is insufficient to ensure the performance of the clothing PPE** (in accordance with standard NF EN ISO 27065/A1) for this type of formulation (WP). A. Shaw *and al.* (2018).

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)

CUPROZIN 35 WP (SPU-00760-F) is a wettable powder (WP). 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 a light green with a slightly sulphurous and mineral odour. It is not explosive and has no oxidising properties. The product is not flammable. It has a self-ignition temperature of >400°C. In aqueous solution (1% dilution), it has a pH value of 7.77 at 21°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 multilayer paper bag, which can be extrapolated to other claimed packaging. Its technical characteristics are acceptable for a wettable powder (WP) formulation.

The formulation is not classified for the physico-chemical aspect.

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

- The efficacy level of CUPROZIN 35 WP (SPU-00760-F) is considered acceptable for all the requested uses.

- The phytotoxicity level of CUPROZIN 35 WP (SPU-00760-F) is considered acceptable for all the requested uses.

- The risks of negative impact on yield, cider-making process, 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 acceptable.

- The risk of resistance developing or appearing to copper does not require a monitoring for all claimed 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, this method is not specific to the variant copper oxychloride. A complementary method shall be provided to confirm the identity of the variant in the formulation.

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

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, oily, acidic and dry content commodities), soil, water (surface and drinking), air and body fluids.

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

Analytical methods for the determination of residues of copper in food of animal origin are missing and are required. Moreover, the LOQ of the available methods for the determination of residues of copper in water is not in accordance with the European Directive 98/83/EC.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Active substance(s) (incl. content)	**Copper (copper oxychloride)** 350 g/kg
AOEL systemic	0.08 mg/kg bw/d
AAOEL	Not necssary
Inhalation absorption	100%
Oral absorption	50%
Vapour pressure	Not necessary
Dermal absorption	Concentrate: 1% Dilution: 9% (Based on *in vitro* human skin studies)

3.4.1 Acute toxicity

CUPROZIN 35 WP (SPU-00760-F) containing 350 g/kg Copper (copper oxychloride) has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is not a skin sensitiser.

3.4.2 Operator exposure

Considering the proposed uses, operator systemic exposure was estimated using the EFSA model[12]:

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

		Copper under the form of copper oxychloride	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Critical use: Stone fruits (peach)			
Tractor mounted outdoor, upward applications [1]			
Application rate		1.25 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) and gloves during M/L and A + FP1, P1 RPE M/L	0.0508	63%
Critical uses : grape			
Manual knapsack outdoor, upward applications			
Application rate		1.05 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) and gloves during M/L and A	0,0036	4.6%
Critical use: Fruting vegetables (tomato)			
Tractor mounted outdoor, downward applications			
Application rate		0.77 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) and gloves during M/L and A + FP1, P1 RPE M/L	0.0332	42%

[1] covers pome fruits (apple) and grapes.

According to the model calculations, it can be concluded that the risk for the operator using CUPROZIN 35 WP (SPU-00760-F) is acceptable with a working coverall and gloves during mixing/loading and application, and respiratory protective equipement FP1, P1 RPE during mixing/loading.

3.4.3 Worker exposure

Workers may have to enter treated areas after treatment for different activities on crop. Therefore, estimation of worker exposure was calculated according to AOEM model. Exposure is summarised in the table below:

		Copper under the form of copper oxychloride	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Critical use: Grapes			
Hand harvesting Outdoor Work rate: 8 hours/day DT_{50}: 30 days DFR: 3µg/cm²/kg a.s./ha Interval between applications: 7 days			
Application rate		4 x 1 kg.as/ha	

		(3 x 1.05 kg.as/ha ; 5 x 0.8 kg.as/ha)	
EFSA model 2014 (AOEM Excel calculator) Body weight: 60 kg	Work wear (arms, body and legs covered) and gloves TC:10100 cm²/person/h	1.1598 (0.9828 ; 1.0802)	1450% (1229% ; 1350%)
Critical use: pome fruits (apple) Covering: stone fruits (peach)			
Searching, reaching, picking Outdoor Work rate: 8 hours/day, DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 5 days			
Number of applications and application rate		5 x 0.77 kg.as/ha	
EFSA model 2014 (AOEM Excel calculator) Body weight: 60 kg	Work wear (arms, body and legs covered) and gloves TC: 2250 cm^2/person/h	0,2508	314%
Critical use: fruting vegetables (tomato)			
Reaching, picking Outdoor Work rate: 8 hours/day, DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 5 days			
Number of applications and application rate		5 x 0.7 kg.as/ha	
EFSA model 2014 (AOEM Excel calculator) Body weight: 60 kg	Work wear (arms, body and legs covered) and gloves TC: 580 cm^2/person/h	0.0588	73%

It is concluded that there is no unacceptable risk anticipated for the worker re-entering into tomato crops. **However, an unacceptable risk was anticipated for the worker re-entering into stone fruits, pome fruits and grapes.**

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[13].
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*."

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

3.4.5 Resident exposure

Residential exposure was assessed according to EFSA model. An acceptable risk was determined for residents (adult and child) whithout drift reduction technology and considering a buffer zone of 10 meters for high crops.

		Copper under the form of copper oxychloride	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Critical use: pome fruits **(**apple) Covering: stone fruits (peach)			
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: 5 days Volume min: 850 L/ha			
Number of applications and application rate		5 x 0.77 kg as./ha	
Resident child Body weight: 10 kg	**Sum (mean)**	0.0519	65
Resident adult Body weight: 60 kg	**Sum (mean**)	0.0272	34

3.4.6 Combined exposure

Not relevant. The product contains only one active substance.

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

For France, an exceedance of the current MRL for copper as laid down in Reg. (EC) 396/2005 of 50 mg/kg in grapes, 5 mg/kg in pome fruits for pre-flowering uses, 5 mg/kg in stone fruits (peach) for pre-flowering uses, 5.0 mg/kg in outdoor tomato and aubergine **is not expected**.

The acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for copper.

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

zRMS considers no firm conclusion can be reached for any of the intended uses of the product CUPROZIN 35 WP.

Information on CUPROZIN 35 WP (KCA 8.8)

Crop	PHI for product code proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for SPU-00760-F Blue proposed by zRMS	zRMS Comments (if different PHI proposed)
Grape	21 days	Yes	21 days	
Stone fruits	F (BBCH 03)	Yes	F (BBCH 03)	
Pome fruits	F (BBCH 59)	Yes	F (BBCH 59)	
Tomato, aubergine	3 days	Yes	3 days	

* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

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 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.

In the absence of reliable $PEC_{soil,\ accumulation}$ for the active substance, the risk assessment for the non-target terrestrial organisms cannot be finalised for all intended uses.

Given the uncertainties identified by zRMS in the notifier's exposure calculation (FOCUS STEP 1-2 for all entries to water bodies and FOCUS STEP 1-2 PECsw including mitigation measures) and the absence of results for all FOCUS scenarios, PECsw derived for the active substance cannot be used for the ecotoxicological risk assessment. No reliable PECsed are available for all intended uses. As a consequence, the risk assessment cannot be finalised for the non-target aquatic organisms.

For the uses on vineyards, tomato (field and greenhouse uses), PECgw for copper do not occur at levels exceeding those mentioned in Directive 98/83/CE[14]. Therefore, no unacceptable risk of groundwater contamination is expected for these intended uses.
For the uses on peach, potato,olive, pome fruit, and citrus, the risk to groundwater contamination cannot be finalised due to the absence of reliable FOCUS groundwater modelling.

[14] Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption

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.

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** and **non-target arthropods other than bees** are acceptable for the intended uses.

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

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

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 risks are not acceptable at Tier 1 for all intended uses and the higher-tier studies are not sufficient to demonstrate the absence of adverse effects of the product CUPROZIN 35 WP (SPU-00760-F) on honey bee larvae. Therefore, the risk assessment for honey bee larvae cannot be finalised 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 for all intended uses.
Overall, the risk assessment to bees cannot be completely fulfilled and the risk assessment for bees cannot be finalised.

[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

For soil organisms, since PECsoil accumulation are not reliable, 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 4 kg cu/ha/yr. Therefore, an acceptable risk for earthworms is demonstrated for all intended uses of CUPROZIN 35 WP (SPU-00760-F).

For other soil macro-organisms, no higher-tier studies are available and extrapolating the results of the multiyear field study with earthworms to other soil macro-organisms was not supported by the experts at the Peer Review experts' meeting 169.
Further data are *considered required to for conclude to an acceptable risk for Folsomia candida and Hypoaspis* aculeifer. Thus, it is not possible to finalise the risk assessment for these species.
Therefore, the risk for soil meso and macro-organisms other than earthworms could not be finalised for all intended uses of CUPROZIN 35 WP (SPU-00760-F).

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.

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

CUPROZIN 35 WP (SPU-00760-F) contains copper compounds, which is approved as a candidate to substitution because it fulfills PBT criteria (Persistant and Toxic);

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

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

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

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

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

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

N/A : marketing authorisation withdrawn

5.1.2 Post-authorisation data requirements

N/A : marketing authorisation withdrawn

Appendix 1 Copy of the product authorisation

RÉPUBLIQUE FRANÇAISE
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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 règlementaire,

*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 **CUPROZIN 35 WP***

de la société	*COSACO GmbH*
enregistrée sous le	*n° 2019-3716*

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

Considérant que les informations disponibles ne permettent pas de s'assurer de la performance des équipements de protection individuelle pour cette formulation de type poudre mouillable,

Considérant en conséquence qu'un risque d'effet nocif pour les opérateurs et les travailleurs lié à l'utilisation du produit ne peut être exclu ;

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

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Informations générales sur le produit	
Nom du produit	CUPROZIN 35 WP
Type de produit	Produit de référence
Titulaire	COSACO GmbH Singapurstrasse 1 D-20457 HAMBOURG Allemagne
Formulation	Poudre mouillable (WP)
Contenant	588.8 g/kg - oxychlorure de cuivre (équivalent 350 g/kg de cuivre)
Numéro d'intrant	992-2015.01
Numéro d'AMM	2180889
Fonction	Fongicide
Gamme d'usage	Professionnel

A Maisons-Alfort, le 15/07/2025

DocuSigned by:
Charlotte Grastilleur
AE281A955A42454

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

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ANNEXE : 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**
12603203 Fruits à pépins*Trt Part.Aer.*Tavelure(s)	2,2 kg/ha	1/an	F (BBCH 59)	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 opérateurs et les travailleurs, aux conditions d'emploi revendiquées.				
12553203 Pêcher - Abricotier*Trt Part.Aer.*Cloque(s)	3,57 kg/ha	1/an	F (BBCH 03)	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 opérateurs et les travailleurs.				
16953201 Tomate - Aubergine*Trt Part.Aer.*Mildiou(s)	2 kg/ha	5/an	3	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 opérateurs et les travailleurs.				
12703203 Vigne*Trt Part.Aer.*Mildiou(s)	3 kg/ha	5/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 opérateurs et les travailleurs.				

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.

Cuprozin 35 WP – projet d'étiquette art. 43 (mars 2019)

CUPROZIN® 35 WP

FONGICIDE
Vigne – Arboriculture – Cultures légumières
Utilisable en Agriculture Biologique en application du Règlement (CE) n°834/2007.

Poids net de produit : XXXXX kg
Date de fabrication : JJ/MM/AAAA

Numéro de lot : XXXX

CUPROZIN 35 WP® - A.M.M n° 2180889
Poudre mouillable (WP) contenant 350 g/kg de cuivre de l'oxychlorure de cuivre
Détenteur d'AMM : Spiess-Urania Chemicals GmbH, Frankenstrasse 18 b, 20097 Hambourg, Allemagne

ATTENTION

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

P391 : Recueillir le produit répandu
P501 : Éliminer le contenu et son récipient conformément à la réglementation.
EUH401 – Respecter les instructions d'utilisation pour 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.]
SPe1 : Pour protéger les organismes du sol, la dose totale de cuivre ne doit pas dépasser 28 kg/ha sur une période de 7 ans, soit l'équivalent d'une dose totale de 80 kg/ha de Cuprozin® 35 WP maximum sur une période de 7 ans
SPe3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 m par rapport aux points d'eau pour les usages sur tomate et pomme de terre, 10 m sur vigne, agrumes et pour les stades tardifs sur fruits à pépin et 15 m sur olivier.
SPe3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 20 m comportant un dispositif végétalisé d'une largeur de 20 m en bordure des points d'eau pour les usages sur pêcher et les stades précoces des fruits à pépins.

Délai de rentrée des travailleurs sur la parcelle : 6 heures après traitement

LIRE ATTENTIVEMENT L'ETIQUETTE AVANT EMPLOI
RÉSERVÉ À UN USAGE EXCLUSIVEMENT PROFESSIONNEL

Les limites maximales de résidus sont disponibles sur le site : http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=FR

PREMIERS SECOURS : consulter la Fiche de Données de Sécurité
Commentaire général : Des symptômes peuvent apparaître plusieurs heures après l'exposition, aussi un avis médical peut être nécessaires jusqu'à 48h après utilisation du produit. Retirer les vêtements et chaussures contaminés et les nettoyer avant réutilisation.
En cas d'inhalation :
Déplacer la personne hors de la zone de danger. Assurer une bonne ventilation à l'air frais. En cas d'évanouissement, mettre la victime en position latérale de sécurité et consulter un médecin.
En cas de contact avec la peau :
Rincer immédiatement à l'eau et au savon.
En cas de contact avec les yeux :

Cuprozin 35 WP – projet d'étiquette art. 43 (mars 2019)

Enlever les lentilles de contact. Rincer pendant 10-15 minutes à l'eau courante en soulevant les paupières et en protégeant l'œil affecté. Suivre un traitement ophtalmologique.
En cas d'ingestion :
Consulter un médecin immédiatement. Ne pas faire vomir. Rincer la bouche abondamment à l'eau. Ne pas essayer de faire avaler quelque chose à une personne inconsciente.
Commentaire pour les médecins : traitement symptomatique

Fiche de données de sécurité disponible sur Internet (www.quickfds.com) et sur demande à CERTIS au 01.34.91.90.00. En cas d'urgence, appeler le 15 ou un centre anti-poison (coordonnées au 01 45 42 59 59) puis signalez vos symptômes au réseau Phyt'attitude (N°0 800 887 887 – appel gratuit depuis un poste fixe). En cas d'incident ou d'accident appeler le 01.72.11.00.03 (Certis Carechem, numéro d'urgence 24h/24h).

Mode d'action – Propriétés

Cuprozin® 35 WP est un fongicide cuprique de contact qui s'emploie de manière préventive pour lutter contre le mildiou et la cloque en viticulture, en arboriculture et en cultures maraîchères. Cuprozin® 35 WP contient du cuivre, sous la forme d'oxychlorure de cuivre (fongicide de contact multisite – code FRAC M1).

Usages et doses homologués

Cuprozin® 35 WP est homologué pour le traitement des parties aériennes.

Culture	Cible	Dose	Nombre d'application maximum	Stade d'application	Délai avant récolte
Pêcher, nectarinier, abricotier	cloque	3,57 kg/ha	1	BBCH 00 à 03	F
Pommier, Poirier, fruits à pépins	tavelure	2,2 kg/ha	1	Depuis le début du risque d'infection jusqu'à BBCH 59	F
Vigne	Mildiou	3 kg/ha	5	BBCH 71 à 85	21 jours
Tomate (plein champ uniquement)	mildiou	2 kg/ha	5	BBCH 21 à 89	3 jours
Agrumes	Pourriture du fruit (Phytophtora)	2,8 kg/ha	3	BBCH 81 à 85	14 jours
Olivier	Maladie de l'oeil de paon	3 kg/ha	4	Post-récolte	14 jours
Pomme de terre	mildiou	2,86 kg/ha	5	Dès la couverture du champ par la culture	14 jours

F: le délai avant récolte correspond au dernier stade d'application autorisé

Recommandations d'emploi
Si possible utiliser un pulvérisateur équipé de buses à jets portés et projetés quand le risque de contamination apparaît.

Pêcher/nectarinier, abricotier :
Réaliser 1 application avec un volume de bouillie de 1000 L/ha pendant la dormance de l'arbre en hiver ou jusqu'au gonflement des bourgeons foliaires (stades BBCH 00 à 03).

Pommier, poirier, fruits à « pépins » :
Réaliser 1 application avec un volume de bouillie de 850 à 1000 L/ha quand le risque de contamination apparaît et jusqu'à ce que la plupart des fleurs forment avec leurs pétales un ballon creux juste avant la floraison (stade BBCH 59). Avant toute utilisation, vérifier la sensibilité variétale.

Vigne:
Appliquer à la dose de 2,2 à 3 kg/ha selon la sévérité de la maladie dans un volume de bouillie de 1000 L/ha.
Réaliser jusqu'à 5 applications par an entre la nouaison (début du développement des baies) et la véraison (stades BBCH 71 à 85).

Tomates de plein champ:

Cuprozin 35 WP – projet d'étiquette art. 43 (mars 2019)

Réaliser jusqu'à 5 applications par saison avec un volume de bouillie de 800 L/ha quand les premières pousses latérales apparaissent (stade BBCH 21) et jusqu'à 3 jours avant la récolte.

Agrumes :
Appliquer entre le début de la coloration (changement de couleur) et jusqu'à l'intensification de la coloration spécifique à la variété dans un volume de bouillie de 1000 L/ha.

Olivier :
A l'automne, traiter après la récolte. Renouveler l'application en cas de précipitations importantes (>30 mm).

Pomme de terre :
Appliquer dès le début du risque d'infection, jusqu'à 5 traitements maximum. Varier la dose de 1,71 à 2,86 kg/ha selon la pression de la maladie. Ne pas dépasser 8,57 kg/ha au total sur la saison.

Risque de phytotoxicité: le produit est sélectif des variétés usuelles en bon état végétatif à la dose recommandée. En cas de conditions météorologiques défavorables (humidité, froid), certaines variétés de pommier sensibles au cuivre peuvent présenter certains symptômes (taches sur les feuilles, rougeur…).
Sur raisin de table, le marquage des baies peut apparaître dans le cas d'applications après le stade BBCH 71.
Sur raisin de cuve, le processus de vinification peut être impacté.

Mode d'emploi

- Préparation de la bouillie:

Préparer une pâte homogène avec le produit et un peu d'eau. Ajouter ensuite le volume d'eau requis en mélangeant. Ne pas utiliser le surplus de bouillie, ne jamais préparer plus de bouillie que nécessaire pour une surface donnée.

- Technique d'application

Une bonne couverture de la culture est essentielle afin de garantir l'efficacité du produit. Utiliser un volume de bouillie suffisant et un pulvérisateur approprié afin que toutes les parties de la plante soient traitées.

Remarque sur les doses d'applications:
Le nombre maximum d'application est limité à cause des propriétés de la substance active (cuivre). Une efficacité suffisante ne peut être garantie dans toutes les situations. Si besoin, le produit doit être utilisé en programme avec d'autres produits contenant d'autres substances actives que le cuivre.

- Nettoyage du pulvérisateur:

Le pulvérisateur (cuve, filtre, circuit et buses) doit être soigneusement nettoyé à l'eau après chaque utilisation pour éviter l'obstruction des injecteurs. Utiliser un détergent approprié. Répandre l'eau de rinçage sur la parcelle déjà traitée.

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

Important :
Respecter les usages, doses, conditions et précautions d'emploi mentionnées sur l'emballage. Elles ont été déterminées en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé.
Conduisez sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, 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 de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de vente du Ministère de l'Agriculture.
Compte tenu de la diversité des législations existantes, il est recommandé, dans le cas où les denrées issues des cultures protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur.

Conditions d'emploi du produit :

- **Protection de l'opérateur et du travailleur :**

Eviter tout contact non nécessaire avec le produit. Le non-respect des précautions d'emploi peut être nocif pour la santé. Stocker à l'écart des boissons et nourriture pour les hommes et les animaux, hors de portée des enfants, dans son emballage d'origine fermé. Ne pas boire, manger, fumer pendant l'utilisation

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Il convient de rappeler que 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.
En tout état de cause, le port de combinaison de travail dédiée ou d'équipements de protection individuels doit être associé à des réflexes d'hygiène (exemples : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (exemples : procédure d'habillage/déshabillage). Les modalités de nettoyage et de stockage des combinaisons de travail et des équipements de protection individuels réutilisables doivent être conformes à leur notice d'utilisation.

Pour l'opérateur, les équipements de protection individuels (EPI) suivants sont préconisés selon l'autorisation de mise sur le marché:

PULVERISATEUR TRACTE

EPI	Mélange/ chargement	Application (tracteur avec cabine)	Application (tracteur sans cabine, pulvérisateur à rampe)	Application (tracteur sans cabine, pulvérisateur pneumatique ou atomiseur)	Nettoyage
Gants certifiés EN 374-3	X	X (à usage unique, en cas d'intervention sur le matériel pendant la pulvérisation) 1)	X (à usage unique, en cas d'intervention sur le matériel pendant la pulvérisation)	X (à usage unique, en cas d'intervention sur le matériel pendant la pulvérisation)	X
Combinaison de travail polyester/coton 65%/35% (230 g/m² min.) avec traitement déperlant	X	X	X		X
Blouse ou tablier à manches longues (cat. 3, type PB (3)) à porter par-dessus la combinaison	X				X
Combinaison de protection de cat. III type 4 avec capuche				X	

1) Dans ce cas les gantes ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés à l'extérieur de la cabine.

PULVERISATEUR A DOS

EPI	Mélange/chargement	application	nettoyage
Gants certifiés EN 374-3	X	X	X
Combinaison de protection non tissée de cat. III type 4			X
Bottes de protection certifiées EN 13 832-3		X	
Combinaison de protection de cat. III type 4 avec capuche	X	X	

Pour le travailleur :
Porter une combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant et, en cas de contact avec la culture traitée, des gants de nitrile certifiés EN 374-3.
Délai de rentrée dans la parcelle : 6 heures