

REGISTRATION REPORT

Part A

Risk Management

Product code: DPX-GFJ52-46.1 WG

Product name(s): KOCIDE OPTI

Chemical active substance(s):

copper, 300 g/kg

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(Authorisation renewal according to Article 43)

Applicant: COSACO GmbH

Date: 15 July 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 KOCIDE OPTI (DPX-GFJ52-46.1 WG) (formulation code: WG), containing 300 g/kg copper¹ (in the form of 460.7 g/kg copper hydroxide (CAS n° 20427-59-2)) as a fungicide for professional uses.

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

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

1.1 Application background

The present registration report concerns the evaluation of COSACO GmbH's application submitted on 01/04/2019 to market KOCIDE OPTI (DPX-GFJ52-46.1 WG) in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for field uses and interzonal Rapporteur Member State (izRMS) for greenhouse uses for this request and assessed the application submitted for the re-registration of authorisation after the renewal of approval of the active substances copper compounds of this product in France and in other Member States (MSs) of the European Union.

The present application (2019-2563) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009², the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone for field uses and for all MSs of the European Union for greenhouse uses, taking into account the worst-case uses ("risk envelope approach")³. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of KOCIDE OPTI (DPX-GFJ52-46.1 WG) has been made using endpoints agreed in the EU peer review(s) of copper compounds. It also includes assessment of data and information related to KOCIDE OPTI (DPX-GFJ52-46.1 WG) where those data have not been considered in the EU peer review process.

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.

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](#)

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The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011⁴, 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 KOCIDE OPTI (DPX-GFJ52-46.1 WG).

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 tests and study reports submitted are considered necessary for the renewal of the product ».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of KOCIDE OPTI (DPX-GFJ52-46.1 WG), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

Product code	DPX-GFJ52-46.1 WG
Product name in MS	KOCIDE OPTI
Authorisation number	2090170
Kind of use	Professional use
Low risk product (article 47)	No
Function	Fungicide
Applicant	COSACO GmbH
Active substance(s) (incl. content)	Copper 300 g/kg (460.7 g/kg in the form of copper hydroxide)
Formulation type	Water dispersible granule [WG]
Packaging	Bag in PET/Al/OPA/LDPE (2 kg, 3 kg, 5 kg, 6 kg, 10 kg, 20 kg , 25 kg) Bag in PET/Al/LDPE (0,04 kg, 0,1 kg, 0,25 kg, 0,5 kg, 1 kg)
Coformulants of concern for national authorisations	-

⁴ COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

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Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for KOCIDE OPTI (DPX-GFJ52-46.1 WG) resulted in the decision **to grant** the authorisation.



2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

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

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

Hazard class(es), categories:	Acute toxicity (oral), category 4 Eye irritation, category 2 Acute toxicity (inhalation), category 4 Hazardous to the aquatic environment - Acute Hazard, category 1 Hazardous to the aquatic environment - Chronic Hazard, category 1
Hazard pictograms:	  GHS07 GHS09
Signal word:	Warning
Hazard statement(s):	H302: Harmful if swallowed. H319: Causes serious eye irritation. H332: Harmful if inhaled. H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long-lasting effects.
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation</i>
Additional labelling phrases:	EUH 208 : Contains 2,4,7,9-Tetramethyldec-5-yne-4,7-diol. May produce an allergic reaction.

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.
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	For other restrictions refer to 2.5
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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 2017⁵ 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 2014⁶ 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 extrapolation⁷ 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 2021⁸ 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 crop⁹ 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.

⁵ 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/AGRGI632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorie-Lien=id>

⁶ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRGI407093A/jo>

⁷ SANCO document “guidance document: Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

⁸ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734>

⁹ 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.

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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:

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
SPe 1	To protect earthworms and other soil macro-organisms, limit copper inputs to 4 kg/ha/year from all sources.
SPe 2	To protect aquatic organisms, do not discharge waste water from soil-less greenhouses directly into surface water.
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 20 metres and a planted buffer strip of 20 metres to adjacent surface water bodies.
SPe 8	To protect bees and other pollinating insects, do not use in the presence of bees and other pollinators, and do not apply during the flowering period of attractive crops.
Precautionary statement for permanent greenhouse	For applications under permanent greenhouse: “May affect pollinators. Avoid unnecessary exposure”.
Other specific restrictions	
Re-entry period	24 hours.
Storage	None
SPa 1	None
Risk mitigation measures	None
Bystander and resident protection	Maintain a distance of at least 3 meters between the spray boom and: <ul style="list-style-type: none"> - areas frequented by people present at the time of spraying; - areas likely to be frequented by residents.

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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.

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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 izRMS. 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.

PPP (product name/code): DPX-GFJ52-46.1 WG

Formulation type: WG ^(a, b)

Active substance 1: copper hydroxide

Conc. of as 1: 300 g/kg ^(c)

Applicant: COSACO GmbH

Professional use: X

Zone(s): southern/ ^(d)

Non professional use: ☐

Verified by MS: yes

Field of use: fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destina- tion / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & sea- son	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	g as/hL	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Field uses													
1	FR	Grapes		Downy Mildew (<i>Plasmopara viti- cola</i>) PLASVI	Hydraulic sprayer or air-blast atom- iser, low volume, overall.	From 5-6 leaves to harvest (BBCH 15-85)	5	7	300	450	150 – 500	21	Non acceptable (risk for worker)

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2	FR	Apple	F	<i>Venturia inaequalis</i> VENTIN	Hydraulic sprayer or air-blast atom- iser, high volume, overall.	BBCH (00- 69)	3	7	75	225-750	500- 1000	F	Non acceptable (risk for worker)
3	FR	Olive	F		Hydraulic sprayer or air-blast atom- iser, high volume, overall.	BBCH 00-99	3	14	75	600-900	1000- 1200	14	Non acceptable (risk for worker)
4	FR	Peach, Apricot, Nectarine	F	<i>Taphrina deformans</i> TAPHDE	Hydraulic sprayer or air-blast atom- iser, high volume, overall.	BBCH (00- 69)	3	7	75	225-750	500- 1000	F	Non acceptable (risk for worker)
5	FR	Cucum- ber/Courgette	F	<i>Pseudoperonospora</i> <i>cubensis</i> PSPECU	Hydraulic boom sprayer, low-high volume	BBCH (15- 89)	4	7	75	225-900	500- 1200	3	Acceptable
6	FR	Melon	F	<i>Pseudoperonospora</i> <i>cubensis</i> PSPECU	Hydraulic boom sprayer, low-high volume	BBCH (15- 89)	4	7	75	225-900	500- 1200	7	Not acceptable (MRL) bees and bumblebees, soil macro-organisms)
7	FR	Tomato	F	<i>Phytophthora infes- tans</i> PSPECU	Hydraulic boom sprayer, low-high volume	BBCH (19- 89)	5	7	300	525-600	200- 1000	7	Acceptable
EU-wide uses (use on sowing seed, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
1	FR	Cucum- ber/Courgette	G	<i>Pseudoperonospora</i> <i>cubensis</i> PSPECU	Hydraulic boom sprayer, low-high volume	BBCH (15- 89)	4	7	75	225-900	500- 1200	3	Acceptable
2	FR	Melon	G	<i>Pseudoperonospora</i> <i>cubensis</i> PSPECU	Hydraulic boom sprayer, low-high volume	BBCH (15- 89)	4	7	75	225-900	500- 1200	7	Not acceptable (MRL)
3	FR	Tomato	G	<i>Phytophthora infes- tans</i> PSPECU	Hydraulic boom sprayer, low-high volume	BBCH (19- 89)	5	7	300	525-600	200- 1000	3	Acceptable

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Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	International Technical Monograph n°2, 6th Edition Revised May 2008 g/kg or g/l	(f)	No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
Remarks columns:	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	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)

KOCIDE OPTI (DPX-GFJ52-46.1 WG) is a water dispersible granule (WG). 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 medium blue granule, with a mild odour. It is not explosive and has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 209-216°C. In aqueous solution (1% dilution), it has a pH value of 9.81 at 20 °C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in multilayer paper bag and multilayer plastic bag. Its technical characteristics are acceptable for a water dispersible granule (WG) formulation. The formulation is not classified for the physico-chemical aspect.

3.2 Efficacy (Part B, Section 3)

The efficacy of the product KOCIDE OPTI (DPX-GFJ52-46.1 WG) is considered acceptable for all the intended uses.

The phytotoxicity level of KOCIDE OPTI (DPX-GFJ52-46.1 WG) is considered acceptable for all the requested uses. Nevertheless, some phytotoxic symptoms can occur after applications of copper-based products, especially on pome fruits, table grape. Therefore, specific attention should be paid to conditions of application (avoid sensible growth stages, or apply a reduced dose rate...).

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, or apply a reduced dose rate...).

The risk of negative impact on the wine making process is considered acceptable. However, there is a known risk of possible effects on the wine making process. The same reasoning is applied to cider-making process.

The risks of negative impact on propagation, succeeding crops and adjacent crops are considered negligible.

There is a risk of resistance development or appearance to copper for *Xanthomonas* bacteria requiring 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 copper hydroxide. A complementary method shall be provided to confirm the identity of the variant in the formulation.

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

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)

3.4.1 Acute toxicity

DPX-GFJ52-46.1 WG containing 300 g/kg copper (under the form of copper hydroxide) is harmful if swallowed and if inhaled, has a low toxicity in respect to dermal toxicity, is irritating to the rabbit eye but not irritating to rabbit skin and is not a skin sensitiser.

3.4.2 Operator exposure

Considering the proposed uses, operator systemic exposure was estimated using the EFSA model¹⁰:

		Copper	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Critical use : Olive ¹			
Vehicle-mounted – Upward application – Outdoor (late season)			
Application rate		0.9 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A and gloves	0,0226	28%
Manual-hand held – Upward application – Outdoor (late season)			
Application rate		0.9 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L andA and gloves	0,0732	92%

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

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Copper			
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Manual-knapsack – Upward application – Outdoor (late season)			
Application rate		0.9 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A and gloves	0,0730	92%
Critical use : Fruiting vegetables (melon) ²			
Vehicle-mounted – Downward application - Outdoor			
Application rate		0.9 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A and gloves	0,0031	3.9%
Manual-hand held – Upward application - Indoor			
Application rate		0.9 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0,0069	8.6%

¹ covers apple, stone fruit, grape

² covers cucumber, tomato, melon

According to the model calculations, it can be concluded that the risk for the operator using DPX-GFJ52-46.1 WG is acceptable with a working coverall and gloves during mixing/loading and application.

3.4.3 Worker exposure

Workers may have to enter into treated areas after treatment for different task on crops. Therefore, estimation of worker exposure was calculated according to the EFSA model.

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 : 7 days DFR: 3µg/cm ² /kg a.s./ha Interval between applications: 7 days			
Application rate		5 x 0.45 kg.as/ha	

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EFSA model 2014 Body weight: 60 kg	Work wear (arms, body and legs covered) TC: 10100 cm ² /person/h	0.6076	760
Critical use: olive Covering: stone fruits (apricot, peach, nectarine), pome fruits (apple)			
Searching, reaching, picking Outdoor Work rate: 8 hours/day, DT ₅₀ : 7 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 14 days			
Number of applications and application rate		3 x 0.9 kg.as/ha	
EFSA model 2014 Body weight: 60 kg	Work wear (arms, body and legs covered) and gloves TC: 2250 cm ² /person/h	0.1638	205
Critical use: fruting vegetables (melon, cucumber, tomato)			
Reaching, picking Outdoor 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		4 x 0.9 kg.as/ha	
EFSA model 2014 Body weight: 60 kg	Work wear (arms, body and legs covered) and gloves TC: 580 cm ² /person/h	0.0599	75
Critical use: fruting vegetables (melon, cucumber, tomato)			
Reaching, picking Indoor 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		4 x 0.9 kg.as/ha	
EFSA model 2014 Body weight: 60 kg	Work wear (arms, body and legs covered) and gloves TC: 580 cm ² /person/h	0.0599	75

It is concluded that there is no unacceptable risk anticipated for the worker **except when re-entering into orchards and vineyards for which the AOEL is exceeded.**

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 set¹¹.

¹¹ Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

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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

Outdoor: Residential exposure was assessed according to EFSA model incorporating a distance of 10 meters for high crops and 2-3 meters for low crops. An acceptable risk was determined for residents (adult and child) without drift reduction technology.

Copper			
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Critical use : Grape			
Tractor mounted upward application (covers manual application) Buffer zone: 10 m Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days Volume min : 150 L/ha			
Number of applications and application rate		5 x 0.45 kg a.s./ha	
Resident child Body weight: 10 kg	Sum (mean)	0,0464	58
Resident adult Body weight: 60 kg	Sum (mean)	0,0253	32
Critical use : Olive (early season) Covering Pome fruits (apple), stone fruits (apricot, peach, nectarine), fruiting vegetables (melon, cucumber, tomato)			
Tractor mounted upward application (covers manual 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: 14 days Volume min : 1000 L/ha			
Number of applications and application rate		3 x 0.9 kg a.s./ha	
Resident child Body weight: 10 kg	Sum (mean)	0.0368	46
Resident adult Body weight: 60 kg	Sum (mean)	0.0193	24

There is no unacceptable risk to bystander and resident.

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

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 (apple, pear, quince, medlar) for pre-flowering uses, 5 mg/kg in stone fruits (apricot, peach, nectarine) for pre-flowering uses, 30 mg/kg in olive, 20 mg/kg in citrus trees (orange, lemon, mandarin, grapefruit), 5.0 mg/kg in outdoor and indoor tomato and aubergine, 5.0 mg/kg in outdoor and indoor edible peel cucurbits (cucumber, courgette and gherkin) is not expected.

Due to MRL exceedance, the uses on inedible peel cucurbits (outdoor and indoor), cannot be recommended.

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 DPX-GFJ-46.1 WG.

Crop	PHI for DPX-GFJ52-46.1 WG proposed by applicant	PHI/ Withholding period* sufficiently supported for Copper	PHI for DPX-GFJ52-46.1 WG proposed by zRMS	zRMS Comments (if different PHI proposed)
<i>Outdoor uses</i>				
Citrus trees	14 days	Yes	14 days	
Peach, apricot, nectarine	90 days	Yes	F	
Pome fruits	F	Yes	F	
Olive	14 days	Yes	14 days	
Grape	21 days	Yes	21 days	
Tomato, aubergine	7 days	Yes	7 days	
Cucurbits edible peel	3 days	Yes	3 days	
Cucurbits inedible peel	7 days	n.a. (MRL exceedance)	-	Not recommended use
<i>Indoor uses</i>				
Tomato, aubergine	3 days	Yes	3 days	
Cucurbits edible peel	3 days	Yes	3 days	
Cucurbits inedible peel	7 days	n.a. (MRL exceedance)	-	Not recommended use

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.

PEC soil and PECsoil, acucmuation (derived from 10 years) can be used for the risk assessment for the non-target terrestrial organisms for all intended uses.

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

For the uses on vineyards, tomatoes, cucumbers (field and greenhouse uses), PEC_{gw} for copper do not occur at levels exceeding those mentioned in Directive 98/83/CE¹². Therefore, no unacceptable risk of groundwater contamination is expected for these intended uses.

For the uses on apple, olive, Orange, citron, mandarin, Peach, Apricot, Nectarine, and lettuce, the risk to groundwater contamination cannot be finalised due to the absence of reliable FOCUS groundwater modelling.

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

¹² Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption

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assessment and conclusion are based on the methodology agreed by the experts during the renewal approval of the active substance. The EU-agreed endpoints recommended in the EFSA journal (EFSA Journal 2018;16(1):5152) were considered for the Art. 43 dossiers for copper compounds.

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

For 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 aquatic organisms, as the toxicity reference value for copper proposed by the applicant was based on an approach rejected at European level, it could not be used. In addition, no reliable PEC_{sw} and PEC_{sed} were provided by the applicant for all uses. Therefore, the risk assessment for non-target aquatic species could not be finalised for uses in open field, in tunnels or in permanent greenhouses with soil-bound cultivation. For uses in permanent greenhouses with soil-less cultivation, the exposure of aquatic organisms to the active substance from the use of the product KOCIDE OPTI (DPX-GFJ52-46.1 WG) is considered negligible.

For bees, the risk assessment provided by the applicant is based on the EFSA Guidance Document¹³.

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 KOCIDE OPTI (DPX-GFJ52-46.1 WG) on honey bee larvae. Therefore, the risk assessment for honey bee larvae cannot be finalised for applications in open-field or in walk-in tunnels.

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 applications in open-field or in walk-in tunnels.

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 earthworms, the higher tier earthworm field trial data from a study conducted over 10 years with copper application every year demonstrates that there is an acceptable risk to earthworms for applications up to 4kg cu/ha/yr. Therefore, an acceptable risk for earthworms is demonstrated for all intended uses of KOCIDE OPTI (DPX-GFJ52-46.1 WG).

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, except for tomatoes, melons and cucumbers. 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, except for tomatoes, melons and cucumbers.

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.

¹³ 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

3.8 Relevance of metabolites (Part B, Section 10)

No metabolites are highlighted in the EFSA Journal 2018;16(1):5152. Therefore, assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore not required.

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

KOCIDE OPTI contains copper compounds, which is approved as a candidate to substitution because it fulfills PBT criteria (Persistent and Toxic);

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

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

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

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

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

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

- Set up field monitoring of impacts on birds and mammals, applying the recommendations of the EFSA 2023 guidance document. Provide the competent authorities with any new information likely to refine the risk assessment.
- Set up a copper resistance monitoring system.
Provide the competent authorities with any new information likely to modify the analysis of the risk of resistance.

5.1.2 Post-authorisation data requirements

The French Decision requests the submission of post-authorisation confirmatory pieces of information regarding:

- Provide chronic toxicity studies to refine the assessment of chronic risks to birds and mammals.
- Provide laboratory and field toxicity tests on soil organisms other than earthworms.

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Appendix 1 Copy of the product authorisation



KOCIDEOPTI_PREX_2
019-2563_D.pdf

Appendix 2 Copy of the product label

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

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KOCIDE® OPTI

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 : XXXXX

KOCIDE® OPTI - A.M.M n° 2090170

Granulés dispersables (WG) contenant 300 g/kg de cuivre de l'hydroxyde de cuivre

Détenteur d'AMM : Spiess-Urania Chemicals GmbH, Frankenstrasse 18 b, 20097 Hambourg, Allemagne



DANGER

H302 : Nocif en cas d'ingestion

H332 : Nocif par inhalation

H319 : Provoque une sévère irritation des yeux

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

P261 : Eviter de respirer les poussières

P264 : Se laver les mains soigneusement après manipulation

P270 : Ne pas manger, boire ou fumer en manipulant ce produit

P271 : Utiliser seulement en plein air ou dans un endroit bien ventilé.

P280 : Porter des gants de protection/des vêtements de protection/un équipement de protection respiratoire.

P304+P340 : EN CAS D'INHALATION: transporter la victime à l'extérieur et la maintenir au repos dans une position où elle peut confortablement respirer

P330 : Rincer la bouche

P391 : Recueillir le produit répandu

P501 : Eliminer 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. Eviter 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 93 kg/ha de KOCIDE® OPTI 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 vigne, 10 m sur agrumes, 15 m sur olivier et 20 m sur fruits à noyaux et fruits à pépins.

SPe3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 10 m comportant un dispositif végétalisé d'une largeur de 10 m en bordure des points d'eau pour les usages sur cultures maraîchères.

Délai de rentrée des travailleurs sur la parcelle : 24 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 :

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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 :

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

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

Usages et doses homologués

KOCIDE® OPTI 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	2,5 kg/ha	3	BBCH 00 à 69	90
Agrumes	Pourriture du fruit (Phytophthora)	3 kg/ha	3	BBCH 71 à 89	21
Pommier, Poirier, fruits à pépins	tavelure	2,5 kg/ha	3	BBCH 00 à 69	F
Vigne	Mildiou	1,5 kg/ha	5	BBCH 15 à 85	21
Tomate	Mildiou	2 kg/ha	5	BBCH 19 à 89	3
Olivier	Maladie de l'œil de paon	3 kg/ha	3	Toute l'année	14
Melon	Mildiou			BBCH 15 à 89	7
Concombre, courgette	Mildiou	3 kg/ha	4	BBCH 15 à 89	3
Laitue (plein champ)	Mildiou	2 kg/ha	4	BBCH 15 à 49	15

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 (tavelure/bactériose):

Réaliser 1 à 3 applications 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 » (tavelure):

À l'automne, intervenir pendant la période de chute des feuilles. Au printemps, intervenir dès la reprise de végétation (stade B) jusqu'au stade gonflement des boutons floraux (stade D1). Avant toute utilisation, vérifier la sensibilité variétale.

Olivier :

À l'automne, traiter après la récolte. Renouveler l'application en cas de précipitations importantes (>30 mm). Contre l'antracnose, traiter après le stade BBCH 71.

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Vigne:

Réaliser jusqu'à 5 applications en préventif à une cadence de 8 à 10 jours au maximum dans un volume de bouillie de 1000 L/ha entre la nouaison (début du développement des baies) et la véraison (stades BBCH 71 à 85). Adapter la dose entre 1,2 et 1,5 kg/ha selon la pression de maladie.

Quel que soit le programme, respecter une dose totale maximum de 7,5 kg/ha par saison sur la culture.

L'application devra être renouvelée si un épisode pluvieux significatif (>60 mm) intervient juste après traitement.

Tomate :

Afin de limiter les contaminations par le champignon, appliquer préventivement à la cadence moyenne de 7 à 12 jours, afin de protéger les feuilles en développement à partir des premiers risques de contaminations mentionnés par les Bulletins de Santé du Végétal ou les bulletins techniques des organisations professionnelles.

Adapter la dose entre 1,75 et 2 kg/ha selon la pression de maladie.

Melon, Concombre/courgette :

Appliquer jusqu'à 3 applications dans un volume de bouillie minimum de 500 L/ha et maximum 1200 L/ha. Adapter la dose selon la pression de maladie. Intervalle minimum de 7 jours entre 2 applications. Adapter la dose entre 0,75 et 3 kg/ha selon la pression de maladie.

Laitue (plein champ):

Appliquer jusqu'à 3 applications dans un volume de bouillie minimum de 300 L/ha et maximum 1000 L/ha. Adapter la dose entre 0,45 et 3 kg/ha selon la pression de maladie. Intervalle minimum de 7 jours entre 2 applications.

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:

Remplir la cuve du pulvérisateur au 2/3. Ajouter le produit puis compléter le volume d'eau requis en maintenant l'agitation. Appliquer immédiatement après la préparation.

- 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.

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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

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 ramppe)	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/m ² 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	
Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3)	X				X
Bottes de protection certifiées EN 13 832- 3	X		X	X	X

1) Dans ce cas les gants 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		X	

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EN 13 832-3			
Combinaison de protection de cat. III type 4 avec capuche	X	X	
Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3)			
Protections respiratoires certifiées : demi-masque certifié (EN 140) équipé d'un filtre P3 (EN143) ou A2P3 (EN 14387)	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 : 24 heures après le traitement