REGISTRATION REPORT Part A

Risk Management

Product code: BM124SC

Product name(s): LIMPIC 124 SC

Chemical active substance:

Copper, 124 g/L

Southern Zone
Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE (Authorisation renewal according to Art.43)

Applicant: ASCENZA France

Submission date: 31 March 2019

MS Finalisation date: 15 July 2025

Table of Contents

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

BM124SC / LIMPIC 124 SC
Part A - National Assessment
FRANCE

FRANCE	
5.1.1	Post-authorisation monitoring
5.1.2	Post-authorisation data requirements
Appendix 1	Copy of the product authorisation 18
Appendix 2	Copy of the product label21

PART A

RISK MANAGEMENT

1 Details of the application

The company ASCENZA France has requested a marketing authorisation in France for the product LIMPIC 124 SC (product code: BM124SC), containing 124 g/L of copper¹ (in the form of Bordeaux mixture (CAS No 8011-63-0) as a fungicide for professional uses.

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

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

1.1 Application background

The present registration report concerns the evaluation of ASCENZA France's application submitted on 01/04/2019 to market LIMPIC 124 SC (BM124SC) in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the re-registration of authorisation after the renewal of approval of the active substance copper compounds of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2019-3603) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) No 1107/2009², the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")³. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of LIMPIC 124 SC (BM124SC) has been made using endpoints agreed in the EU peer review of copper compounds. It also includes assessment of data and information related to LIMPIC 124 SC (BM124SC) where those data have not been considered in the EU peer review process.

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

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

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

SANCO document "risk envelope approach", European Commission (14 March 2011). <u>Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5</u>

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

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) No 396/2005, EFSA published a reasoned opinion (EFSA, 2018⁶). Based on an evaluation of the available data MRL have been proposed and a consumer risk assessment has been conducted. Some information required by the regulation has not been transmitted and a chronic risk for the consumers was identified. Therefore the consumer risk assessment is only tentative and some of the proposed MRL still require a decision by risk managers. Exposure reduction measures could also be investigated.

This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail. The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

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

This document also describes the specific conditions of use and labelling required for France for the registration of LIMPIC 124 SC (BM124SC).

1.2 Letters of Access

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

1.3 Justification for submission of tests and studies

According to the applicant: « The study reports submitted within this application are in agreement with the data requirements of the Regulation 284/2013. No vertebrate studies are included within the present application.».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of LIMPIC 124 SC (BM124SC), 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	BM124SC
Product name in MS	LIMPIC 124 SC
Authorisation number	2180671
Kind of use	Professional use

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).

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

BM124SC / LIMPIC 124 SC Part A - National Assessment FRANCE

Low risk product (article 47)	No
Function	Fungicide
Applicant	ASCENZA France
Active substance (incl. content)	copper, 124 g/L
Formulation type	Suspension concentrate [SC]
Packaging	HDPE (1 L, 5 L, 20 L)
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 LIMPIC 124 SC (BM124SC) resulted in the decision **to refuse** the authorisation.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

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

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

Hazard class(es), categories:	Skin sensitisation, category 1B Hazardous to the aquatic environment - Acute Hazard, category 1 Hazardous to the aquatic environment - Chronic Hazard, category 1
Hazard pictograms:	GHS07 GHS09
Signal word:	Warning
Hazard statement(s):	H317: May cause an allergic skin reaction. H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long-lasting effects.
Precautionary statement(s):	For the P phrases, refer to the existing legislation
Additional labelling phrases:	Contains 1,2-benzisothiazol-3(2H)-one.

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

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

N/A: marketing authorisation withdrawn.

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

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017⁸ 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 2014⁹ 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 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 2021¹¹ 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 crop¹² 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.

Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte; https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id

⁹ http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

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

https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734

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.

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.

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.

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

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

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

GAP rev. 1, date: 2025/07

PPP (product name/code): LIMPIC 124 SC / BM124SC Formulation type: SC ^(a, b)
Active substance 1: copper (Bordeaux mixture) Conc. of as 1: 124 ^(c)
Applicant: ASCENZA France Professional use:

Zone(s): Southern Zone ^(d) Non professional use: □

Verified by MS: Yes

Field of use: Fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-	Member	Crop and/			Application	n			Application rate			PHI	Remarks:
No. (e)	state(s)	or situation (crop destination/purpose of crop)	Fn, Fpn G, Gn, Gpn or I	controlled (additionally: developmental stages of the pest or pest group)	Method/Ki nd	stage of crop &	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x	(days)	e.g. g safener/synergist per ha (f)
Consid	dering the	restriction of the u	se of P	PP containing copper co	mpounds t	o a maximum app	lication rate	of 28 kg/ha of	f copper over a j	period of 7 years	(i.e. on	average	e 4kg/ha/year).
Zonal	uses (field	or outdoor uses, co	ertain t	ypes of protected crops)									
1	FR, IT, PT, ES	Grapes	F	Plasmopara viticola	Foliar spray		a) 4 b) 4	7 days	a) 6 b) 24	,	100- 1000	21 days	Not acceptable (composition, worker,)
Intera	nterzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)								rvest treatme	nt or for treatn	empty	storage rooms)	

BM124SC / LIMPIC 124 SC

Part A - National Assessment

FRANCE

1	2	3	4	5	6	7	8	9	10	11	12	13	14
		Crop and/		• •	Application	ı			Application rate				Remarks:
No. (e)	state(s)	or situation (crop destination/purpose of crop)	Fn, Fpn G, Gn, Gpn or I	controlled (additionally: developmental stages of the pest or pest group)	Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x	(days)	e.g. g safener/synergist per ha (f)
-													
Mino	r uses acc	cording to Article	51 (zc	onal uses)									
-													
Mino	r uses acc	cording to Article	51 (in	terzonal uses)									
-													

Remarks

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

table heading:

- c) 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

Remarks columns:

- 1 Numeration necessary to allow references
- 2 Use official codes/nomenclatures of EU Member States
- 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)
- 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
- 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.
- 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.

- (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.
- Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- 8 The maximum number of application possible under practical conditions of use must be provided.
- 9 Minimum interval (in days) between applications of the same product
- 10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
- 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
- 12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
- 13 PHI minimum pre-harvest interval
- 14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorisation decision and risk management

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

All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is that of a blue liquid, with an uncharac-teristic odour. It is not explosive, has no oxidising properties. No self-ignition is observed up to 380 °C. It has a pH value around 8.0 at 25 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active in-gredient 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 HDPE/COEX packaging. Its technical characteristics are acceptable for a suspension concentrate formulation.

The information provided does not ensure compliance with Regulation (EU) No 2021/383. Hence, the evaluation of the product LIMPIC 124 SC (BM124SC) cannot be finalised.

No classification required for physical chemical properties.

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

- The efficacy level of LIMPIC 124 SC (BM124SC) is considered to be acceptable for the requested use.
- The phytotoxicity level of LIMPIC 124 SC (BM124SC) is considered to be acceptable for the requested use.
- The risks of negative impact on yield, propagation and adjacent crops are considered to be negligible. Risks with copper such as spotting of table grape berries or on the wine-making process are known. However, these risks of negative impact are considered to be acceptable.
- The risk of resistance developing or appearing to copper does not require a monitoring for the requested use.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

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

3.3.2 Analytical methods for residues

Analytical methods are available in the Renewal Assessment Report and in this dossier and validated for the determination of residues of copper soil, water (surface), air and body fluids. According to EFSA conclusions, an inter-laboratory validation (ILV) of the analytical methods for the determination of residues of copper in plants is required.

Analytical methods for the determination of residues of copper in food of animal origin are missing, but considering the intended use, no method is considered necessary.

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

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Agreed EU endpoints	
Active substance	Copper hydroxide 124 g/L
AOEL systemic	0.08 mg/kg bw/d
AAOEL	Not necessary
Inhalation absorption	100 %
Oral absorption	50 %
Vapour pressure	Not necessary
Dermal absorption	Concentrate: 1 % Dilution: 9 % (Based on <i>in vitro</i> through human skin studies; see point 6.5 Part B6)

3.4.1 Acute toxicity

LIMPIC 124 SC (BM124SC) containing 124 g of copper/L (in the form of Bordeaux mixture) has a low acute, inhalational and dermal toxicity, is harmful if swallowed, is not irritating to the rabbit skin or eye and is a skin sensitiser.

3.4.2 Operator exposure

Considering proposed uses, operator systemic exposure was estimated using the EFSA model¹³ (worst case):

		Active:	copper
Model data	Level of PPE	Total absorbed dose (mg/kg b.w./day)	% systemic AOEL
Grapes (application equipm	ent: vehicle mounted, upward spraying)		
Spray application (AOEM; 75 th percentile)	Potential exposure	0.1434	179.27 %
Body weight: 60 kg	Gloves and workwear during M/L and application	0.0176	22.00 %
Grapes (application equipm	ent: hand-held, upward spraying)		

12

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

BM124SC / LIMPIC 124 SC Part A - National Assessment FRANCE

Spray application (AOEM; 75 th percentile)	Potential exposure	0.1264	158.04 %
Body weight: 60 kg	Gloves and workwear during M/L and application	0.0054	6.80 %
Grapes (application equipme	ent: knap-sack, upward spraying)		
Spray application (AOEM; 75 th percentile)	Potential exposure	0.0946	118.25 %
Body weight: 60 kg	Gloves and workwear during M/L and application	0.0033	4.08 %

According to the model calculations, it can be concluded that there is no unacceptable risk for the operator using LIMPIC 124 SC (BM124SC) with a working coverall and gloves during mixing/loading and application with vehicle mounted, hand held ad knap-sack applications.

3.4.3 Worker exposure

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

		Active: copper			
Model data	Level of PPE	Total absorbed dose (mg/kg b.w./day)	% systemic AOEL		
Grapes (application equipment Task: hand harvesting	t: vehicle mounted , upward spraying)			
	Potential TC: 30000 cm ² /person/h	2.5631	3203.91 %		
Body weight: 60 kg	Work wear (arms, body, and legs covered) TC: 10100 cm²/person/h	0.8629	1078.65 %		

There is an **unacceptable** risk anticipated for the worker, even with the wear of PPE (work wear). No realistic re-entry period into treated crop for worker can be envisaged (calculated re-entry would be *ca.* 103 days, which unrealistic given usual agricultural practices)

3.4.4 Bystander exposure

Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set¹⁴.

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

3.4.5 Resident exposure

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

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

		Copper				
Model data	AOEM model	Total absorbed dose (mg/kg b.w./day)	% of systemic AOEL			
Number of application	ns and application rate	4 x 0.744 kg Cu/ha				
Vehicle mounted Buffer zone 10m Drift reduction						
Resident child	Drift (75 th perc.)	0,0470	58,73			
Body weight: 10 kg	Vapour (75 th perc.)	0,0011	1,34			
	Deposits (75 th perc.)	0,0004	0,46			
	Re-entry (75 th perc.)	0,0360	45,05			
	Sum (mean)	0,0611	76,32			
Resident adult	Drift (75 th perc.)	0,0259	32,36			
Body weight: 60 kg	Vapour (75 th perc.)	0,0002	0,29			
	Deposits (75 th perc.)	0,0001	0,17			
	Re-entry (75 th perc.)	0,0200	25,03			
	Sum (mean)	0,0332	41,55			
Manual handheld an Buffer zone 10m	nd manual knapsack					
Resident child Body weight: 10 kg	Drift (75 th perc.)	0,0940	117,45			
	Vapour (75 th perc.)	0,0011	1,34			
	Deposits (75 th perc.)	0,0007	0,93			
	Re-entry (75 th perc.)	0,0360	45,05			
	Sum (mean)	0,0923	115,38			
Resident adult	Drift (75 th perc.)	0,0518	64,73			
Body weight: 60 kg	Vapour (75 th perc.)	0,0002	0,29			
	Deposits (75 th perc.)	0,0003	0,33			
	Re-entry (75 th perc.)	0,0200	25,03			
	Sum (mean)	0,0503	62,85			

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

However, according to the model calculations, there is an **unacceptable** risk for the resident (child) using manual applications.

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

An exceedance of the current MRL for copper as laid down in Reg. (EC) No 396/2005 of 50 mg/kg in grapes is not expected.

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

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

zRMS considers no firm conclusion can be reached for any of the requested uses of the product

LIMPIC 124 SC.

Information on LIMPIC 124 SC (KCA 6.8)

Crop PHI for LIMPIC 124 SC proposed by applicant		PHI/ Withholding pe- riod* sufficiently sup- ported for Copper	PHI for LIMPIC 124 SC proposed by zRMS	zRMS Comments (if different PHI pro- posed)
Outdoor uses				
Grape	rape 21 days		21 days	

NR: not relevant

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

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate PEC values for the active substance for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC values of copper in soil, surface water and groundwater have been assessed according to FOCUS guid-ance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the end-points established in the EU conclusions or agreed in the assessment based on new data provided.

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

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

PECgw values for copper do not occur at levels exceeding those mentioned in Directive 98/83/CE. Therefore, no unacceptable risk of groundwater contamination is expected for all requested uses.

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

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

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).

BM124SC / LIMPIC 124 SC Part A - National Assessment FRANCE

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

Based on the guidance documents, the risks for **non-target terrestrial plants** are acceptable for the requested uses.

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

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

For bees, the acute risk is not acceptable at Tier 1 for all requested uses. Higher-tier studies (cage and tunnel tests) are available and demonstrate that no adverse effects on adult honey bees are expected for all requested uses.

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

For non-target arthropods, the applicant used toxicity data of another product than LIMPIC 124 SC (BM124SC). However, the available data are not sufficient to determine whether these toxicity data are representative of the toxicity of the product LIMPIC 124 SC, due to the increase in acute oral toxicity of the product LIMPIC 124 SC (BM124SC) for bees. Therefore, the risk assessment for non-target arthropods cannot be finalised.

For soil organisms, since no reliable PEC soil values are available, a Tier 1 risk assessment cannot be conducted.

For earthworms, the higher tier earthworm field trial data from a study conducted over 10 years with copper application every year demonstrates that there is an acceptable risk to earthworms for applications up to 4kg cu/ha/yr. Therefore, an acceptable risk for earthworms is demonstrated for all requested uses of LIMPIC 124 SC (BM124SC).

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

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

3.8 Relevance of metabolites (Part B, Section 10)

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

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

LIMPIC 124 SC contains copper compounds, which is approved as a candidate for 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) No 1107/2009,

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

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

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

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

5.1.1 Post-authorisation monitoring

None.

5.1.2 Post-authorisation data requirements

N/A: marketing authorisation withdrawn.

Appendix 1 Copy of the product authorisation

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





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

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

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

Vu la demande de renouvellement de l'autorisation de mise sur le marché, suite au renouvellement de l'approbation de la substance active composé du cuivre, et les données fournies en réponse aux demandes en post-autorisation du produit phytopharmaceutique LIMPIC 124 SC

de la société ASCENZA France

enregistrées sous les n° 2019-3603 et 2020-3855

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

Considérant qu'en application de l'article 27 du règlement (CE) n° 1107/2009, les coformulants inscrits à l'annexe III de ce règlement ne peuvent pas entrer dans la composition d'un produit phytopharmaceutique,

Considérant que les éléments disponibles relatifs à la composition du produit ne permettent pas de s'assurer que le produit LIMPC 124 SC ne contient pas de coformulant figurant à l'annexe III du règlement (CE) n° 1107/2009,

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

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

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

LIMPIC 124 SC AMM n° 2180671

Page 1 sur 3

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





Informations générales sur le produit				
Noms du produit	LIMPIC 124 SC SULFOPEC CUIVRE 124 S			
Type de produit	Produit de référence			
Titulaire	ASCENZA France 27 avenue Carnot 91300 MASSY France			
Formulation	Suspension concentrée (SC)			
Contenant	124 g/L – cuivre (sous forme de bouillie bordelaise)			
Numéro d'intrant	9881-2013.01			
Numéro d'AMM	2180671			
Fonction	Fongicide			
Gamme d'usage	Professionnel			

A Maisons-Alfort, le 15/07/2025

Uarlotte Grastilleur

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

LIMPIC 124 SC AMM n° 2180671

Page 2 sur 3

BM124SC / LIMPIC 124 SC Part A - National Assessment FRANCE

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





ANNEXE : Conditions de mise sur le marché

Liste des usages retirés								
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)	Délai accordé pour la vente et la distribution	Délai accordé pour le stockage et l'utilisation des stocks			
12703203 Vigne*Trt Part.Aer.*Mildiou(s)	6 L/ha	4/an	-	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 résidents et personnes présentes enfants en cas d'application à l'aide d'une lance ou d'un pulvérisateur à dos, ni d'exclure un risque d'effet nocif pour les travailleurs, aux conditions d'emplois revendiquées, ni de s'assurer que le produit ne contient pas de coformulant figurant à l'annexe III du règlement (CE) n° 1107/2009.							

LIMPIC 124 SC AMM n° 2180671

Page 3 sur 3

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.

Draft Reference Label - Template - version 29/01/18 HF

FONGICIDE

LIMPIC [®] 124SC

Fongicide anti-mildiou pour la vigne*

(* CF. tableau des usages dans le livret)

Cuivre (sous forme de bouillie bordelaise) 124g/L (9,5% p/p) - Suspension concentrée (SC)

Quantité nette ou volume net : Kg ou litres avec Θ



RÉSERVÉ À UN USAGE EXCLUSIVEMENT PROFESSIONNEL

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

Code EAN / Emballages

AMM N° 2180671

N° LOT : voir sur le bidon / sac Date de fabrication : voir sur le bidon / sac XXXXX. 8 : marque déposée par ASCENZA AGRO S.A. Distribué par : Ascenza AGRO France S.A.S. Immeuble Odyssée – A3 2-12 rue du chemin des Femmes 91300 MASSY www.sapecagro.fr Tél.: 01 69 53 98 89

acc 2 UT /

IMPORTANT: LIRE LES INSTRUCTIONS CI-JOINTES AVANT L'EMPLOI

LIMPIC®124SC

124g/L (9,5% p/p) Cuivre (sous forme de bouillie bordelaise)

PREMIERS SECOURS:

· Premiers soins :

S'éloigner de la zone dangereuse.

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

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

DESCRIPTIF DU PRODUIT ET MODE D'ACTION

LIMPIC® 124SC est un fongicide de contact contenant 124 g/L de cuivre (sous forme de bouillie bordelaise) agissant préventivement.

Tableau des usages autorisés

Culture	Cibles	Dose maximum d'emploi	Nombre maximum d'applications	Intervalle minimum entre applications	Stade d'application/ conditions d'emploi	Délai avant récolte (DAR)	ZNT* aquatique
Vigne (raisin de cuve et	Marie ()				Entre les stades BBCH 13-57	F (BBCH 57)	50m (dont DVP de
raisin de table)	Mildiou(s)	6 L/ha	4/an**	7 jours	Entre les stades BBCH 69-81	21 jours	20m)

^{*} Zone non traitée (voir phrase SPe 3)

Limites maximales de résidus : se reporter aux LMR définies au niveau de l'Union Européenne, consultables à l'adresse : http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database

ASCENZA AGRO ne préconise l'utilisation de ce produit que sur les cultures et cibles mentionnées ci-dessus et, à ce titre, décline toute responsabilité concernant son utilisation aux autres usages prévus par le catalogue des usages en vigueur.

RECOMMANDATIONS D'EMPLOI

Conditions d'application

L'application de LIMPIC®124SC s'effectue préventivement dès l'identification des risques (Observations, bulletins de santé du végétal). Il s'utilise du stade 13 (3 feuilles étalées) au stade 57 (inflorescences complètement développées,

Prepared by Sapec Agro France

^{**} Ne pas dépasser 4 applications par an et par culture

SAPEC

Page 3 of 7

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

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

Traitez rang par rang et face par face pour assurer une couverture totale des organes à protéger.

Risque de marquage du raisin de table pour des applications après BBCH 71.

Mélanges extemporanés

Ne pas mélanger à des composés alcalins.

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

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

Préparation de la bouillie

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

Remplir la cuve à 1/2 d'eau, mettre sous agitation. Verser la quantité de LIMPIC®124SC nécessaire puis compléter le remplissage.

Veiller à une répartition homogène de la bouillie sur l'ensemble de la végétation à traiter.

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

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

PREVENTION ET GESTION DE LA RÉSISTANCE

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

MISE EN OEUVRE REGLEMENTAIRE ET BONNES PRATIQUES

Stockage du produit :

- Conserver le produit uniquement dans son emballage d'origine, dans un local phytopharmaceutique conforme à la règlementation en vigueur, à l'écart des aliments et boissons, y compris ceux pour animaux.
- Conserver hors de la portée des enfants et des personnes non autorisées.
- Températures de stockage : voir le pictogramme indiqué en première page du livret ou face avant du sac.

Protection de l'opérateur et du travailleur

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

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

Dennared by Canne Agen Eranen

SAPEC

Page 4 of 7

Le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène, (comme par exemple se laver les mains après toute manipulation/utilisation/intervention dans une parcelle préalablement traitée, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage). Les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

		MÉLANGE /CHARGEMENT	PROTECTION DE L'UTILISATEUR PENDANT LES PHASES DE :			
			APPLICATION AVEC:		NETTOYAGE	PROTECTION DU TRAVAILLEUR
Caractéristiques des EPI			PULVÉRISATEUR pneumatique			
			TRACTEUR AVEC CABINE	TRACTEUR SANS CABINE		
GANTS EN NITRILE réutilisables (certifiés EN 374-3) ou à usage unique (certifiés EN 374-2)		Réutilisables	A usage unique*	A usage unique	Réutilisables	Réutilisables
EPI VESTIMENTAIRE** 65 % polyester / 35 % coton >= 230 g/m² + traitement déperlant		EPI vestimentaire	4		EPI vestimentaire	4
EPI PARTIEL blouse ou tablier à manches longues catégorie III type PB3 certifié EN14605+A1		EPI partiel			ET EPI partiel	
COMBINAISON DE PROTECTION CHIMIQUE catégorie III type 3 ou 4 certifiée EN 14605+A1:2009				Type 4 (avec capuche)		
*Dans le cas d'une intervention sur le matériel pendar utilisation à l'extérieur de la cabine. **Ce vétement préconisé peut être remplacé par tout a sécurité de la directive 89/686/CEE.						

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

· Nettoyage du pulvérisateur et gestion des fonds de cuve :

- Ne pas traiter les cours d'eau et fossés en eau. Appliquer la bouillie dans les cultures par temps calme, sans vent fort, pour éviter toute dérive de pulvérisation vers les fossés, cours d'eau, chemins, abords de ferme ou bâtiments.
- A la fin de la période d'application du produit, l'intégralité de l'appareil (cuve, rampe, circuit, buses...)
 doit être rincée à l'eau claire. Le rinçage du pulvérisateur, l'épandage ou la vidange du fond de cuve et l'élimination des effluents doivent être réalisés conformément à la réglementation en vigueur.
- S'assurer d'un rinçage complet et soigné du pulvérisateur.

• Elimination du produit, de l'emballage :

- Réemploi de l'emballage interdit.
- Pour les bidons jusqu'à 25L: Lors de l'utilisation du produit, bien vider et rincer le bidon à l'eau claire (rinçage manuel à 3 reprises en agitant le bidon rempli au 1/3 ou rinçage mécanique d'une durée minimale¹ de 30 secondes) en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur. Apporter les emballages ouverts, rincés et égouttés à votre distributeur partenaire d'A.D.I.VALOR ou à un autre service de collecte spécifique.
- Pour les cartons et sacs: Apporter les emballages vidés et pliés à votre distributeur partenaire d'A.D.I.VALOR ou à un autre service de collecte spécifique
- <u>Pour les fûts plastiques et métalliques au-delà de 25L et ce jusqu'à 300L</u>: Apporter les emballages vidés et fermés à votre distributeur partenaire d'A.D.I.VALOR ou à un autre service de collecte spécifique
- Pour l'élimination des produits non utilisables, conserver le produit dans son emballage d'origine. Interroger votre distributeur partenaire d'A.D.I.VALOR ou faites appel à une entreprise habilitée pour la collecte et l'élimination des déchets dangereux.

En cas de déversement accidentel

¹ Le temps de rinçage recommandé pourra être allongé pour des produits moins aisés à rincer

SAPEC

Page 5 of 7

- Se protéger (EPI) et sécuriser la zone.
- Prévenir les pompiers (18 ou 112) en cas de danger immédiat pour l'environnement que vous ne pouvez gérer avec vos propres moyens.
- Collecter tout ce qui a pu être en contact avec le produit, terre souillée incluse.
- Nettoyer le site et le matériel utilisé, en prenant soin de confiner les effluents générés par l'opération de nettoyage. Les éliminer selon la réglementation en vigueur.



AVERTISSEMENT

Toute reproduction totale ou partielle de cette étiquette est interdite.

Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage. Ils ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduire sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous la responsabilité de l'utilisateur, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces... Le fabricant garantit la qualité du produit vendu dans son emballage d'origine et stocké selon les conditions préconisées, ainsi que sa conformité à l'Autorisation de Mise sur le Marché délivrée par les autorités compétentes françaises.

Pour les denrées issues de cultures protégées avec cette spécialité et destinées à l'exportation, il est de la responsabilité de l'exportateur de s'assurer de la conformité avec la réglementation en vigueur dans le pays importateur.

LIMPIC® 124SC

124g/L (9,5% p/p) de cuivre (sous forme de bouillie bordelaise) – Suspension concentrée (SC) Contient de la 1,2-benzisothiazol-3(2H)-one AMM n° 2180671



ATTENTION

H317 Peut provoquer une allergie cutanée

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

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

P280 Porter des gants de protection/des vêtements de protection/ un équipement de protection des yeux/du visage P302 + P352 EN CAS DE CONTACT AVEC LA PEAU : laver abondamment à l'eau et au savon.

SAPEC

Page 6 of 7

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

P391 Recueillir le produit répandu.

P501 Éliminer le contenu/récipient conformément à la réglementation nationale

Conditions d'emploi

Tenir hors de la portée des enfants

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

- SP1: Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.
- Délai de rentrée : 48 heures
- SPe1 : Pour protéger les organismes du sol, ne pas appliquer ce produit ou tout autre produit contenant du cuivre à une dose annuelle totale supérieure à 4 kg Cu/ha
- SPe3: Pour protéger les organismes aquatiques, respecter une zone non traitée de 50 mètres comportant un dispositif végétalisé permanent non traité d'une largeur de 20 mètres en bordure des points d'eau, pour 4 applications par an à la dose de 744 g Cu/ha.

EN CAS D'URGENCE

Composer le 15 ou le 112 ou contacter le centre anti poison le plus proche

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

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

RÉSERVÉ A UN USAGE EXCLUSIVEMENT PROFESSIONNEL

Fabriqué et conditionné au PORTUGAL

Contenu: XXXXXXX I ou Kg

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

XXXXXXXXXXXXXXX - Marque déposée par ASCENZA AGRO S.A

Draft Reference Label - Template - version 29/01/18 HF

SAPEC

Page 7 of 7

CONTENU DES ÉTIQUETTES APPOSÉES SUR LES EMBALLAGES

COMBINÉS (CARTONS DE REGROUPEMENT OU DES PACKS)