

REGISTRATION REPORT

Part A

Risk Management

Product code: SFPCC6208

Product name: SELVA

Chemical active substances:

cymoxanil, 30 g/L

copper, 300 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT

(authorisation renewal)

Applicant: Société Financière de Pontarlier

Date: 15/07/2025

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PART A

RISK MANAGEMENT

1 Details of the application

The company Société Financière de Pontarlier has requested a marketing authorisation in France for the product SELVA (formulation code: SFPCC6208), containing 30 g/L cymoxanil¹ and 300 g/L copper² (in the form of copper oxychloride (CAS n° 1332-65-6)) 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).

Appendix 3 of this document is the list of data considered for national authorisation.

1.1 Application background

The present registration report concerns the evaluation of Société Financière de Pontarlier's application submitted on 01/04/2019 to market SELVA (SFPCC6208) in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the re-registration of authorisation after the renewal of approval of the active substances copper compounds of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2019-2913) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009³, 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")⁴. 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 SELVA (SFPCC6208) has been made using endpoints agreed in the EU peer reviews of copper compounds and cymoxanil. It also includes assessment of data and information related to SELVA (SFPCC6208) where those data have not been considered in the EU peer review process.

The conclusions of the assessment published by EFSA 2018^{5,6}, as part of the procedure for the renewal of the approval of copper compounds, based on the available information, identify risk for non-target organisms

¹ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances Text with EEA relevance

² 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

³ 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

⁴ 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](#)

⁵ 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

⁶ 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.

for the representative uses on grapevine, cucurbits and tomatoes, as well as to workers for the grapevine use.

In the framework of MRL review for copper compounds under Article 12 of Regulation (CE) 396/2005, EFSA published a reasoned opinion (EFSA, 2018⁷). 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.

In order to comply with the provisions of Regulation (EC) No 1107/2009 (Commission Implementing Regulation (EU) 2015/2033) and according to Art. 43 of Regulation (EC) No 1107/2009, and in accordance with the guidance document SANCO/2010/13170, the outcome of the risk assessment for the re-registration of plant protection product only applies to copper following its renewal of approval. For cymoxanil, provisions of the initial authorisation remain.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011⁸, 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 SELVA (SFPCC6208).

1.2 Letters of Access

Not necessary for cymoxanil: data protection on the current Annex I dossier for a.s. cymoxanil has expired.

SFP has provided letter of Access to the Annex I inclusion of copper from members of the EU Cu Task Force. This letter of access is available upon request.

1.3 Justification for submission of tests and studies

According to the applicant: *« Tests with cymoxanil and SELVA (SFPCC6208) were done for the equivalence evaluations of SFP's cymoxanil source and for the previous authorizations of SELVA (SFPCC6208) in France. No additional studies were done for this Article 43 renewal. ».*

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of SELVA (SFPCC6208), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7. »

⁷ 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).

⁸ 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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2 Details of the authorisation decision

2.1 Product identity

Product code	SFPCC6208
Product name in MS	SELVA
Authorisation number	9200436
Kind of use	Professional use
Low risk product (article 47)	No
Function	Fungicide
Applicant	Société Financière de Pontarlier
Active substances (incl. content)	cymoxanil, 30 g/L copper, 300 g/L
Formulation type	Suspension concentrate [SC]
Packaging	Can in HDPE (10 L)
Coformulants of concern for national authorisations	None
Restrictions related to identity	None
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for SELVA (SFPCC6208) 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:	Hazardous to the aquatic environment - Acute Hazard, category 1 Hazardous to the aquatic environment - Chronic Hazard, category 1
Hazard pictograms:	 GHS09

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Signal word:	Warning
Hazard statement(s):	H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long-lasting effects.
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation</i>
Additional labelling phrases:	EUH 208 : Contains Cymoxanil (ISO)(57966-95-7), 1,2-benzisothiazol-3(2H)-one(2634-33-5). 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

	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 2017⁹ provides that:

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

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

Finally, the French Order of 26 March 2014¹⁰ 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 extrapolation¹¹ is to supply “minor” crops with registered plant protection products.

⁹ Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, modifié par l'arrêté du 27 décembre 2019 <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

¹⁰ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo>

¹¹ SANCO document “guidance document: Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

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

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:

The applicant is required to comply with the current applicable standard for clothing type PPE (ISO EN 27065)¹².

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	
-	-
Other specific restrictions	

The conditions of use of the active substance cymoxanil specified in the previous evaluations are not changed.

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.

¹² Protective clothing – Performance requirements for protective clothing worn by operators applying pesticides and for re-entry workers. EN ISO 27065:2017

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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 zRMS. Those uses are then granted in France.

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

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

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

GAP rev. 1, date:15/07/2025

PPP (product name/code): SELVA / SFPCC6208
Active substance 1: Cymoxanil
Active substance 2: Copper oxychloride
Safener: NA
Synergist: NA
Applicant: Société Financière de Pontarlier
Zone(s): Southern Zone ^(d)
Verified by MS: Yes
Field of use: Fungicide

Formulation type: SC ^(a, b)
Conc. of a.s. 1: 30 g/L ^(c)
Conc. of a.s. 2: 300 g/L ^(c) (as copper)
Conc. of safener: -
Conc. of synergist: -
Professional use: ☒
Non-professional use: ☐

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop or situation (crop destination/purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergis per ha (f)
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or 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		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	Southern zone (FR, PT)	Grapes	F	Downy mildew	Spraying	Post-flowering (BBCH 71) to harvest (BBCH 89)	2	7	a) 4 L b) 8 L	a) 120 g/ha cymoxanil; 1200 g/ha copper b) 240 g/ha cy- moxanil; 2400 g/ha copper	200- 1000	21	Not acceptable (workers)

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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 International Technical Monograph n°2, 6th Edition Revised May 2008	(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)	g/kg or g/l	(f)	No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
Remarks columns:	1	Numeration necessary to allow references	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)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a blue / green opaque liquid with no odour. It is not explosive, and has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 424 ± 4 °C. In aqueous solution, it has a pH value around 5.4 at 21 °C. There is no effect of low temperature on the stability of the formulation after 7 days at 0 °C, neither the active ingredient content nor the technical properties were changed. The content of active substance is not stable after 18 weeks storage at 30 °C, therefore, the product must be stored under a temperature of 30 °C. The stability data indicate a shelf life of 17 months at ambient temperature when stored in HDPE. Its technical characteristics are acceptable for an SC formulation.

Nevertheless, suspensibility at lower and higher concentration of use after storage (low temperature, accelerated and long term) has not been provided and is required in post-authorization.

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

- The efficacy level of the product SELVA (SFPCC6208) is considered satisfactory for the claimed use.
- The phytotoxicity level of SELVA (SFPCC6208) is considered acceptable for the claimed use.
- The risks of negative impact on yield, propagation, adjacent crops are considered negligible. Risks with copper such as spotting of table grape berries or on the wine-making process are known. However, these risks of negative impact are considered acceptable.
- The risk of resistance development or appearance to copper does not require a monitoring for the claimed use.
- There is a risk of resistance development or appearance to cymoxanil for *Plasmopara viticola* on grapevine requiring a monitoring.
- To avoid the development of resistance of *Plasmopara viticola* to cymoxanil, the number of applications is limited to 2 applications per crop cycle on grapevine.
- To manage the risk of resistance with cymoxanil it is recommended to follow the limitations of use by chemical group recommended by the note on resistance management on grapevine diseases.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical method for the determination of copper in the formulation is provided and validated. However,

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this method is not specific to the variant copper oxychloride. A complementary method shall be provided to confirm the identity of the variant.

Analytical methods for the determination of relevant impurities of copper (arsenic, cadmium and lead) in the formulation were not provided and are required in post-authorization.

3.3.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report and in this dossier and validated for the determination of residues of copper compounds in plants (high wet / acidic 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, but considering the intended use, no method is considered necessary.

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)

	Active substance 1	Active substance 2
Common Name	Cymoxanil	Copper oxychloride
CAS-No.	57966-95-7	1332-65-6 or 1332-40-7
Classification and proposed labelling		
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: Acute Tox 4, Skin Sens. 1, STOT RE 2, Repr. 2 Code(s) for hazard pictogram(s): GHS08, GHS07 Signal word: Warning Hazard statement(s): H302, H317, H373, H361fd Precautionary statement(s):	Hazard classes (s), categories: Acute oral Cat. 3 Acute inhalation Cat. 4 Code(s) for hazard pictogram(s): GHS06 Signal word: Danger Hazard statement(s): H301, H332 Precautionary statement(s):
Additional C&L proposal	-	
Agreed EU endpoints		
AOEL systemic	0.01 mg/kg bw/d (corrected for 75% oral absorption)	0.08 mg Cu/kg bw/d (Including correction for limited oral absorption/bioavailability (50%)).
Reference	EFSA Scientific Report (2008) 167, 1-116	EFSA Journal 2018;16(1):5152
Conditions to take into account/critical areas of concern with regard to toxicology		
According to Review Report/EFSA Conclusion for active substance	None	None

3.4.1 Acute toxicity

SFPCC6208 (SELVA) containing 300 g/L copper oxychloride and 30 g/L cymoxanil has a low toxicity in respect to acute oral, inhalation and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitizer.

3.4.2 Operator exposure

		Copper under the form of copper oxychloride	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Critical use: Grapes			
Tractor mounted outdoor, upward applications ¹			
Application rate		1.2 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Potential exposure	0.3139	414.89
	Work wear (arms, body and legs covered) M/L and A + gloves during M/L and A	0.0323	40.39
Manual knapsack outdoor, upward applications			
Application rate		1.2 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Potential exposure	0.1301	162.63
	Work wear (arms, body and legs covered) M/L and A + gloves during M/L and A	0.0041	5.12
Manual Hand-Held outdoor, upward applications			
Application rate		1.2 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Potential exposure	0.1987	248.31
	Work wear (arms, body and legs covered) M/L and A + gloves during M/L and A	0.0081	10.14

The operator exposure estimates performed indicate acceptable levels of exposure for all requested uses with the use of work wear and gloves during mixing/loading and application phases.

3.4.3 Worker exposure

The estimation of the worker exposure is estimated with the EFSA model.

zRMS has assessed the worker exposure for professional use using a dermal absorption value of 10% for the dilution formulation.

The estimated worker exposure for professional use is presented in the table below :

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		Copper under the form of copper oxychloride	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Critical Use: Grapes			
Hand harvesting Outdoor Work rate: 8 hours/day DT ₅₀ : 30 days DFR: 3µg/cm ² /kg a.s./ha Interval between applications: 10 days			
Application rate		2 x 1.2 kg.as/ha	
EFSA model 2014 (AOEM Excel calculator) Body weight: 60 kg	Potential TC: 30000 cm ² /person/h	2.6650	3331.20
	Work wear (arms, body and legs covered) TC: 10100 cm ² /person/h	0.8972	1121.50
	Work wear (arms, body and legs covered) + gloves TC: 3000 cm ² /person/h	0.2665	333.12

The worker exposure is higher than the AOEL for Grapes at the dose of 2*1.2 kg as/ha. Grape application is therefore unacceptable for the worker.

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.

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.”

No AAOEL has been set for copper. Thus, for this active substance, residents exposure assessment covers bystanders exposure.

3.4.5 Resident exposure

		Copper under the form of copper oxychloride	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Grapes			
AOEM calculator (EFSA Model) Tractor mounted, upward application** Buffer zone: 10 m Drift reduction technology: Yes			

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DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days Volume min: 200 L/ha			
Number of applications and application rate		2*1.5 kg as/ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0420	52.55
	Vapour (75 th perc.)	0.0011	1.34
	Deposits (75 th perc.)	0.0004	0.47
	Re-entry (75 th perc.)	0.0375	46.85
	Sum (mean)	0.0589	73.68
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0232	28.99
	Vapour (75 th perc.)	0.0002	0.29
	Deposits (75 th perc.)	0.0001	0.17
	Re-entry (75 th perc.)	0.0208	26.03
	Sum (mean)	0.0321	40.13
Grapes			
AOEM calculator (EFSA Model) Tractor mounted / Hand-Held / Manual Knapsack, upward application** Buffer zone: 10 m Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days Volume min: 200 L/ha			
Number of applications and application rate		2*1.5 kg as/ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0841	105.11
	Vapour (75 th perc.)	0.0011	1.34
	Deposits (75 th perc.)	0.0008	0.94
	Re-entry (75 th perc.)	0.0375	46.85
	Sum (mean)	0.0869	108.66
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0464	57.97
	Vapour (75 th perc.)	0.0002	0.29
	Deposits (75 th perc.)	0.0003	0.34
	Re-entry (75 th perc.)	0.0208	26.03
	Sum (mean)	0.0474	59.23

Exposure of residents to copper hydroxide is lower than the AOEL for grape use with vehicle mounted-drift reduction application, but higher than the AOEL for vehicle mounted without drift reduction nozzles, manual Knapsack and Manual Hand held applications.

Therefore, exposure of bystanders is acceptable for vehicle-mounted with drift reduction nozzles application but unacceptable for vehicle mounted without drift reduction nozzles, manual hand held and manual knapsack application.

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

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs on grapes (50 mg/kg) for copper is not expected.

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

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

Information on Selva (KCA 6.8)

Crop	PHI for SELVA (SFPCC6208) proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for SELVA (SFPCC6208) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Cymoxanil	Copper		
Grapes	21 days	not assessed	Yes	21 days	

NR: not relevant

* Purpose of withholding period to be specified

** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

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

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

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

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

FOCUS STEP 1-2 PEC_{sw} including mitigation measures for the active substance can be used for the ecotoxicological risk assessment. In the absence of $PEC_{sediment}$ and $PEC_{sediment, accumulation}$, the risk assessment cannot be finalised for the sediment-dwelling organisms.

PEC_{gw} for copper do not occur at levels exceeding those mentioned in Directive 98/83/CE¹³. Therefore, no unacceptable risk of groundwater contamination is expected for these intended uses.

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

3.7 Ecotoxicology (Part B, Section 9)

¹³ Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption

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

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

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

For aquatic organisms, as the toxicity reference value for copper proposed by the applicant was based on an approach rejected at European level, it could not be used. In addition, no reliable 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 intended uses. Higher-tier studies with the formulation performed following the EPPO 170 (4) 2010 guideline is available and demonstrate that no adverse effects on adult honey bees are expected for all intended uses.

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

For soil organisms, since PECsoil accumulation are not reliable, a Tier 1 risk assessment cannot be conducted. For earthworms, the higher tier earthworm field trial data from a study conducted over 10 years with copper application every year demonstrates that there is an acceptable risk to earthworms for applications up to 4 kg cu/ha/yr. Therefore, an acceptable risk for earthworms is demonstrated for all intended uses of SFPCC6208.

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.

Further data are considered required to for conclude to an acceptable risk for *Folsomia candida* and *Hypoaspis aculeifer*. Thus, it is not possible to finalise the risk assessment for these species.

Therefore, the risk for soil meso- and macro-organisms other than earthworms could not be finalised for all intended uses of SFPCC6208.

Furthermore, no unacceptable effects are expected from the use of Selva/SFPCC6208 when used according to the supported GAP to soil microbial activity.

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)

SELVA (SFPCC6208) contains copper compounds, which is approved as a candidate for substitution because it fulfils two PBT criteria (Persistent and Toxic).

Step 1 (French guidance document 27 July 2015):

- Taking into account the management of resistance:

In accordance with Article 50(1)(c) of Regulation (EC) N 1107/2009, in the frame of resistance emergence or development prevention, copper compounds is considered as an important tool in strategies to prevent resistance toward the partner organic substance, **substitution will not be considered for uses on grapes.**

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”.

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Appendix 1 Copy of the product authorisation



SELVA_PREX_2019-2
913_D.pdf

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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.



ELC étiquettes
L'EXPERTISE SUR-MESURE

46 ROUTE DU VERDOYER
87430 VERNEUIL SUR VIENNE

Tél 05 55 30 56 20
Fax 05 55 30 56 53
elc.contact@orange.fr
www.elc-etiquette.com

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Seul contre-indication, les séries d'encres seront imprimées suivant le standard Pantone®



RESPECT DE LA NORME INCO TEXTE À 1,2mm SUR LES MENTIONS SUIVANTES :
INGRÉDIENTS, VALEURS NUTRITIONNELLES, MODE DE CONSERVATION

Date : 24/01/2018 - 15.05 par : CM

Client : PHYTORIUS

Code Article : 73_0098

Code Client : -

Numéro de commande : 21495

Votre commande : SFP

Désignation : ETIQ SELVA Ro

Format : Large : 150 mm x Avance : 150 mm

Cyan
Magenta
Yellow
Black
DECOUPE



BON A TIRER :
Date & signature :

Si corrections nouveau BAT : OUI ☐ NON ☐ (à joindre)

g mandrin : 76

g maxi bobine : 0

Étiquettes par bobine : 1000

Enroulement

E3



Le délai de retour de ce BAT validé conditionne le respect du délai d'impression