REGISTRATION REPORT

Part A

Risk Management

Product code: DSPF022

Product name(s): PESCARA, MOGADOR

Chemical active substance(s):

copper hydroxide, 150 g/L
potassium phosphonates, 450 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: DE SANGOSSE

Date: 2018/12/28

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PART A
RISK MANAGEMENT

1 Details of the application

The company DE SANGOSSE has requested marketing authorisation in France for the product PESCARA (formulation code: DSPF022), containing 150 g/L copper hydroxide and 450 g/L potassium phosphonates[1] (equivalent to 300 g/L phosphonic acid[2]), for use as a fungicide for professional uses.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to PESCARA (DSPF022) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of PESCARA (DSPF022) have been made using endpoints agreed in the EU peer reviews of copper and potassium phosphonates.

This document describes the specific conditions of use and labelling required for France for the registration of PESCARA (DSPF022).

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

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

Appendix 3 of this document is a copy of the letter(s) of Access.

Appendix 4 of this document is the list of data considered for national authorisation.

1.1 Application background

The present registration report concerns the evaluation of DE SANGOSSE's application to market PESCARA (DSPF022) in France as a fungicide (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 first authorisation of this product in France and in other MSs of the Southern zone.

The present application (2016-4429) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[3] – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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1 Formerly potassium phosphite

2 Phosphorous acid, $P(OH)_3$, is an oxy-acid in equilibrium with its tautomeric form $HPO(OH)_2$, phosphonic acid. This equilibrium is in favour of the phosphonic form due to the strong P=O bond present in the form $HPO(OH)_2$ [JP Guthrie (1978) ; Troev KD (2006)]. In the literature, the term "phosphorous acid" is frequently used for the tautomeric mixture of phosphorous and phosphonic acids, despite the predominance of the phosphonic form. Esters and salts of phosphonic and phosphorous acids are called respectively phosphites, $P(OR)_3$, and phosphonates, $HPO(OR)_2$.

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

1.2 Letters of Access

The applicant has provided letter(s) of access for copper hydroxide and potassium phosphonates data.

1.3 Justification for submission of tests and studies

According to the applicant : “This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013”.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of PESCARA (DSPF022), 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	DSPF022
Product name in MS	PESCARA, MOGADOR
Authorisation number	N/A : not registered in France
Low risk (article 47)	No
Function	Fungicide
Applicant	DE SANGOSSE SAS
Active substance(s) (incl. content)	Copper hydroxide, 150 g/L Potassium phosphonates, 450 g/L
Formulation type	Suspension concentrate [SC]
Packaging	N/A : not registered in France
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 PESCARA (DSPF022) 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:	Eye irritation, Hazard Category 2 Acute toxicity (inhalation), Hazard Category 4 Hazardous to the aquatic environment — Acute Hazard, Category 1 Hazardous to the aquatic environment — Chronic Hazard, Category 1
Hazard pictograms:	 SGH07 SGH09
Signal word:	Warning
Hazard statement(s):	H319 : Causes serious eye irritation. H332 : Harmful if inhaled. H400 : Very toxic to aquatic life. H410 : Very toxic to aquatic life with long-lasting effects.
Precautionary statement(s):	***For the P phrases, refer to the extant legislation***
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

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

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

N/A : not registered in France

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

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017 [4] provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres;
- unless formally 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, drift buffer zones may be reduced under some circumstances as explained in

[4] 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 https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte

appendix 3 of the above-mentioned French Order.

Finally, the French Order of 26 March 2014[5] provides that:

- an authorisation granted for a "reference" crop applies also for "linked" crops, unless formally stated in the Decision
- the "reference" and "linked" 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 "linked" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those "linked" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[6] 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.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

2.5.1 Restrictions linked to the PPP

The authorisation of the PPP is linked to the following conditions:

Operator protection:	
-	refer to the Decision in Appendix 1 for the details
Worker protection:	
-	refer to the Decision in Appendix 1 for the details
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
Other specific restrictions	
Re-entry period	N/A : not registered in France
Storage	N/A : not registered in France
Risk mitigation measure	N/A : not registered in France
Agricultural recommendations	It N/A : not registered in France

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.

[5] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

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

2.6 Intended uses (only NATIONAL GAP)

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

GAP rev. 1, date: -2018-12-28

PPP (product name/code):	PESCARA, MOGADOR / DSPF022	Formulation type:	SC [a, b]
Active substance 1:	copper hydroxide	Conc. of a.s. 1:	150 g/L [c]
Active substance 2:	potassium phosphonates	Conc. of a.s. 2:	450 g/L [c]
Safener:	-	Conc. of safener:	- [c]
Synergist:	-	Conc. of synergist:	- [c]
Applicant:	DE SANGOSSE SAS	Professional use:	☒
Zone(s):	southern [d]	Non-professional use:	☐
Verified by MS:	**Yes**		

Field of use: fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	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 / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	Grapes *Vitis vinifera* (VITVI) (wine & table)	F	Downy mildew *(Plasmopara viticola)* *(PLASVI)*	Foliar spray	From BBCH 15	a) 5 b) 5	8	a) 4 L/ha b) 20 L/ha	a) 1200 g/ha of phosphonic acid 600 g/ha of copper b) 6000 g/ha of phosphonic acid 3000 g/ha of copper	100 / 1000	21	**Not acceptable** (worker exposure - non-target arthropods and soil macro-organisms not finalised)

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorisation decision and risk management

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

PESCARA (DSPF022) is a blue-green water-based liquid formulation. All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The formulation is not explosive and has no oxidising properties. It is not flammable and has a self-ignition temperature above 652 °C. In aqueous solution (1 %), it has a pH value of 10.0 at ambient temperature and its alkalinity is 2.6 % as NaOH.

There is no effect of low and high temperatures on the stability of the formulation, since after seven days at 0 °C and 14 days at 54 °C, neither the active substances' content nor the technical properties were changed. The stability data indicate a shelf life of at least one year at ambient temperature when stored in HDPE packaging. Results of the final two-year shelf life study (including suspensibility and dispersion with chemical assays) are required post-authorisation. The technical characteristics are acceptable for a SC formulation.

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

The packaging must be rinsed three times before disposal.

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

- The efficacy level of PESCARA (DSPF022) is considered acceptable for the requested uses;
- The phytotoxicity level of PESCARA (DSPF022) is considered acceptable for the requested uses;
- The risks of negative impact on yield, quality, transformation processes and propagation are considered acceptable. Some risks are known with copper, such as marks on table grapes and impact on the wine-making processes. However, these risks of negative impact are considered acceptable;
- The risk of negative impact on adjacent crops is considered negligible;
- The risk of resistance developing or appearing to hydroxide of copper and potassium phosphonates does not require 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 substances in the formulation are available and validated. Relevant impurities (lead, cadmium, arsenic) are by-products of the manufacturing process for copper hydroxide and as such cannot be formed by storage of the formulation. However, analytical methods (CIPAC) for the determination of relevant impurities in the preparation can be used.

3.3.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report (DAR) and in this dossier and are validated for the determination of residues of potassium phosphonates and copper hydroxide in plants (acidic crops), soil, water (surface and drinking) and air.

Analytical methods for the determination of residues of potassium phosphonates and copper hydroxide in foodstuffs of animal origin are not necessary.

The active substance potassium phosphonates is neither toxic nor very toxic. Hence, no analytical method is required for the determination of residues in biological fluids and tissues.

An analytical method is available in the DAR and validated for the determination of residues of copper in tissues and body fluids.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment:

Active substance: **copper hydroxide**			
ADI	0.15 mg/kg bw/d		EU (2009)
ARfD	Not applicable		
AOEL	0.072 mg/kg bw/d		
Dermal absorption	Based on an *in vitro* human study performed on several formulations containing copper in different forms *:		
		Concentrate (tested)	Diluted formulation (tested)
	Dermal absorption endpoints %	**1**	**9**

* The dermal absorption values are those accepted after the peer review of copper compounds (EFSA Journal 2018;16(1):5152, 119 pp. doi:10.2903/j.efsa.2018.5152)

Active substance: **potassium phosphonates**			
ADI	2.25 mg/kg bw/d		EU (2013)
ARfD	Not applicable		
AOEL	5 mg/kg bw/d		
Dermal absorption	Based on default values according to guidance on dermal absorption (EFSA 2012) :		
		Concentrate (used in formulation)	Spray dilution (used in formulation)
	Dermal absorption endpoints %	**25**	**75**

3.4.1 Acute toxicity

PESCARA (DSPF022), containing 450 g/L potassium phosphonates and 250 g/L copper hydroxide, has a low acute oral and dermal toxicity. The formulation is not irritating to the rabbit skin and is not a skin sensitiser but is irritating to the rabbit eye and has acute inhalational toxicity.

The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.4.1.

3.4.2 Operator exposure

Summary of critical use patterns (worst cases):

Crop	F/G[7]	Equipment	Application rate L product/ha (g a.s./ha)	Spray dilution (L/ha)	Model
Grapes	F	Vehicle-mounted sprayer *Upward spray-ing*	4 L/ha (1800 g/ha of potassium phosphonates and 600 g/ha of copper)	100-1000	EFSA

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

Crop	Equipment	PPE and/or working coverall	% AOEL potassium phosphonates	% AOEL copper hydroxide
Tractor mounted boom spray application outdoors to high crops Buffer zone: 5 m Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 8 days				
Grapes	Vehicle-mounted spray-er	Working coverall and gloves during mix-ing/loading and application	6.1	21
Tractor mounted boom spray application outdoors to high crops Buffer zone: 10 m Drift reduction technology: yes DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 8 days				
Grapes	Vehicle-mounted spray-er	Working coverall and gloves during mix-ing/loading and application	5.9	20

According to the model calculations using the EFSA model for PESCARA (DPSF022), exposure of the operator using the product on grapes attains up to 6 % of the potassium phosphonates' AOEL and 21 % of the copper AOEL with the AOEM model, based on a vehicle-mounted sprayer without mitigation measures and with PPE.

When drift-reduction technology and mitigation measures such as a buffer zone of 10 metres are taken into account, exposure of the operator using product on grapes attains up to 6 % of the potassium phosphonates' AOEL and 20 % of the copper AOEL with the AOEM model, based on a vehicle-mounted sprayer and with PPE.

According to the model calculations, it may be concluded that the risk for the operator using PESCARA (DSPF022) is acceptable with a working coverall (90 % protection factor) and gloves during mixing/loading and application.

[7] Open field or glasshouse

3.4.3 Worker exposure

Workers may have to enter treated areas after treatment for crop harvesting activities. Therefore estimation of worker exposure was calculated according to the EFSA model. Exposure is estimated to be 390 % of the AOEL of potassium phosphonates and 1083 % of the AOEL of copper hydroxide with a working coverall (without gloves).

It may be concluded that without taking into account a re-entry period, there is unacceptable risk anticipated for workers wearing a working coverall and gloves, when re-entering crops treated with PESCARA (DSPF022).

3.4.4 Bystander and resident exposure

In the absence of AAOEL determined for copper hydroxide and potassium phosphonates, it may be considered that the risk assessment for the bystander is covered by the resident risk assessment.

Indeed, 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*."

Residential exposure was assessed according to the EFSA model. Exposure is presented below:

	% AOEL phosphonate potassium		% AOEL copper	
Uses/crops	**Adult** Body weight: 60 kg	**Child** Body weight: 10 kg	**Adult** Body weight: 60 kg	**Child** Body weight: 10 kg
Tractor mounted boom spray application outdoors to high crops Buffer zone: 5 m Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 8 days				
Grapes	**21**	**38**	**59**	**109**
Tractor mounted boom spray application outdoors to high crops Buffer zone: 10 m Drift reduction technology: yes DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 8 days				
Grapes	**14**	**25**	**39**	**73**

When drift reduction technology and mitigation measures such as a buffer zone of 10 metres are taken into account, it may be concluded that there is no undue risk to any adult or child bystander and resident after accidental exposure to potassium phosphonates and copper from application of PESCARA (DSPF022) to grapes.

However, without mitigation measures, it may be concluded that there is undue risk to child residents after accidental exposure to copper from application of PESCARA (DSPF022) to grapes.

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

The data available are considered sufficient for risk assessment. Any exceedence of the current MRL of 100 mg/kg for potassium phosphonates (fosetyl) and 50 mg/kg for copper as laid down in Regulation (EU) n° 396/2005 is not expected.

The chronic and short-term intakes of phosphonic acid and copper residues are unlikely to present a public health concern. As far as consumer health protection is concerned, France agrees with the authorisation of the intended uses.

According to available data, the following specific mitigation measure is recommended:

- Other fungicide active substances than potassium phosphonates, authorised on grapes (fosetyl-aluminium or disodium phosphonate) can lead to the presence of phosphonic acid in harvested products. The accumulated use of these active substances on the same plots could lead to an exceedence of the extant MRLs. In consequence, it is recommended to limit the use of products containing these substances to a total of 10 kg equivalent of phosphonic acid per hectare per year on grapes.

Toxicological reference values for the dietary risk assessment of copper hydroxide and potassium phosphonates:

Reference value	Source	Year	Value	Study relied upon	Safety factor
Copper hydroxide – Copper compounds (copper)					
ADI[(a)(b)]	EFSA	2008	0.15 mg/kg bw/day	WHO value of 0.15 mg Cu/kg bw/day for children (based on human data) Supported by 1-year dog study	No safety factor 100
ARfD	EFSA	2008	Not applicable		
Fosetyl-Al					
ADI	EFSA	2005	3 mg/kg bw/d	2-year rat and dog	100
ARfD	EFSA	2005	Not necessary		
Fosetyl[(c)]					
ADI	EFSA	2012b	2.8 mg/kg bw/d	Calculated, from the fosetyl-Al ADI using an appropriate molecular weight conversion	
ARfD	EFSA	2012b	Not necessary		
Potassium phosphonates (formerly potassium phosphite) [(c)]					
ADI	EFSA	2013	2.25 mg Cu/kg bw/day		
ARfD	EFSA	2013	Not applicable		

(a) It was felt by the meeting of experts that the term "ADI" was not adequate to copper as an essential micronutrient essential for life; the term "upper limit" was considered as more appropriate. (EFSA Scientific Report (2008) 187, 1-101 - Conclusion on the peer review of copper compounds)

(b) Initially in the draft assessment report, the rapporteur Member State proposed to base the ADI on the 1-year dog study. The experts agreed that it should be mentioned that copper (I) and (II) variants are a specific situation, in which it is justified to set reference values based on human data, as they are more relevant than the animal data. (EFSA Scientific Report (2008) 187, 1-101 - Conclusion on the peer review of copper compounds).

(c) To be noted that during the fosetyl renewal peer review, new ADI and ARfD have been proposed for fosetyl and phosphonic acid. However, these values have not been adopted at EU level.

Summary for copper hydroxide:

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1 (FR)	Table grape	Yes	Yes (26 SEU)	Yes	Yes	Yes	No	Not relevant
1 (FR)	Wine grape	Yes	Yes** (13 NEU, 13 SEU)	Yes	Yes	Yes		
2 (SEU)	Table grape	Yes	Yes (26 SEU)	Yes	Yes	Yes		
2 (SEU)	Wine grape	Yes	Yes (26 SEU)	Yes	Yes	Yes		

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** No sufficient trials for proposed GAP (2 NEU, 26 SEU). But sufficient trials for the GAP proposed by zRMS (cGAP EU TF).

For table grapes, a sufficient number of residue trials is available to support the intended GAPs in France and Southern Europe.

For wine grapes, a sufficient number of residue trials is available to support all the intended GAPs in Southern Europe except in France. However, a sufficient number of residue trials is available to support the EU CTF cGAP (as fall-back GAP) in France. Therefore this GAP was proposed.

Since copper is a mineral compound, there is no need to investigate the effects of industrial and/or household processing on the nature of the residue. Data on effects of processing on the amount of residue have been submitted, and processing factors have been defined and considered to refine consumer risk assessment.

Residues in succeeding crops have not been investigated. However, copper occurs naturally in soils. Copper can be used applied as fertiliser, and is also added to soil when spreading sewage sludge, animal manure and urban compost as part of normal agricultural practice. Finally, copper is a contact fungicide/bactericide. As a result, studies for residues in succeeding crops are not relevant.

As grapes are not fed to livestock, there is no need to investigate residue levels in succeeding crops and in livestock.

Chronic consumer exposure resulting from copper background in all food commodities and from water was calculated according to EFSA PRIMo (rev2) model. Considering uses of copper as plant protection products, chronic exposure remains acceptable for all groups of consumers (maximum 77.54 % ADI for WHO cluster B).

Summary for potassium phosphonates:

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1 (FR)	Table grape	Yes	Yes (8 SEU)	Yes	Yes	Yes	No	No

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1 (FR)	Wine grape	Yes	Yes (8 NEU, 8 SEU)	Yes	Yes	Yes		No
2 (SEU)	Table grape	Yes	Yes (8 SEU)	Yes	Yes	Yes		No
2 (SEU)	Wine grape	Yes	Yes (8 SEU)	Yes	Yes	Yes		No

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

The effects of processing on the nature of potassium phosphonates residues have been investigated. Data on effects of processing on the amount of residue have been submitted. These data were not considered for risk assessment.

Since grapes are perennial crops and are not fed to livestock, there is no need to investigate residue levels in succeeding crops and in livestock.

Summary for PESCARA (DSPF022):

Crop	PHI for PESCARA (DSPF022) requested by applicant	PHI/withholding period* sufficiently supported for		PHI for PESCARA (DSPF022) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Copper hydroxide	Potassium phosphonates		
Table grape	21 days	Yes	Yes	21 days	-
Wine grape	21 days	Yes	Yes	21 days	-

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

Waiting periods before planting succeeding crops is not relevant.

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

The fate and behaviour in the environment of the formulation has been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review were used to calculate predicted environmental concentration (PEC) values for the active substances 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.

PEC_{SOIL} and PEC_{SW} values derived for the active substances and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed. For the active substance potassium phopshonates, the maximum PECsw values were higher than 35 µg of phosphorous equivalent/L (OECD, 1982[8]). Therefore there is a potential risk of eutrophication for surface water. This

[8] O.E.C.D. 1982. Eutrophication of Waters. Monitoring, Assessment and Control. O.E.C.D. Paris. 154 pp.

risk would be addressed by the requirement for an unsprayed buffer zone of 50 metres with a 20 metres planted buffer strip, see Section 2.5.1

PEC_{GW} values for the active substances and their metabolites do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009, and in Directive 98/83/EC[9]. Therefore, no unacceptable risk of groundwater contamination is expected from the intended uses.

3.7 Ecotoxicology (Part B, Section 9)

The risk assessment of the formulation PESCARA (DSPF022) was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review for 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.

Based on the guidance documents, the risks for birds, mammals, bees and other non-target arthropods, and micro-organisms are acceptable for all the intended uses.

For aquatic organisms, mitigation measures are needed to reduce entry via spray drift and runoff. Indeed, for those organisms, the risks are acceptable when a 50 metres no-spray buffer zone including a planted buffer strip of 20 metres is applied for five applications per year at 600 g Cu/ha in vineyards.

Concerning **non-target arthropods other than bees, it is not possible to finalise the risk assessment for the intended use of PESCARA (DSPF022) in vineyards with the data that are available**.

In addition, according to the new requirement, chronic studies on soil organisms other than earthworms are required for *Folsomia candida* and *Hypoaspis aculeifer*. Considering the available data, **such studies are required for PESCARA (DSPF022) and without these studies it is not possible to finalise the risk assessment for soil organisms**.

3.8 Relevance of metabolites (Part B, Section 10)

Not relevant.

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

PESCARA (DSPF022) contains copper compounds (copper hydroxide) which is approved as a candidate for substitution because it fulfils two PBT criteria (Persistent and Toxic);

As a conclusion of the comparative assessment:

The use on grapes (wine & table) against downy mildew (*Plasmopara viticola*/PLASVI) is not suitable for substitution because:

Step 1 (French guidance document 27 July 2015):

- Taking into account the management of resistance:

In accordance with Articles 50(1)(c) of Regulation (EC) No 1107/2009, in the framework of taking the prevention of the appearance of resistance into account, the product has a noticeable usefulness in the resistance management strategy; **therefore substitution will not be considered for the use in question.**

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

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 the 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 : not registered in France.

Appendix 1 Copy of the product authorisation

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Décision relative à une demande d'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 d'autorisation de mise sur le marché et les demandes associées du produit phytopharmaceutique **PESCARA***

de la société *DE SANGOSSE*

enregistrées sous les n° *2016-4429, 2018-2301 et 2018-2304*

Vu les conclusions de l'évaluation de l'Anses du 17 décembre 2018,

Considérant que l'utilisation du produit ne permet pas de garantir l'absence d'effet nocif pour le travailleur et le consommateur,

Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 sont respectées,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas autorisée** en France.

PESCARA
AMM n°-

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Informations générales sur le produit	
Noms du produit	PESCARA MOGADOR
Type de produit	Produit de référence
Titulaire	DE SANGOSSE Bonnel CS 10005 47480 Pont du Casse France
Formulation	Suspension concentrée (SC)
Contenant	450 g/L - phosphonates de potassium 250 g/L - hydroxyde de cuivre (équivalent à 150 g/kg de cuivre)
Numéro d'intrant	1023-2016.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usage	Professionnel

A Maisons-Alfort le,

2 8 DEC. 2018

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

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ANNEXE I : Conditions de mise sur le marché demandées

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12703203 Vigne*Trt Part.Aer.* Mildiou(s)	4 L/ha	5/an	21
	Motivation du refus : L'usage est refusé en raison d'un risque inacceptable pour les travailleurs et en raison d'un manque de données ne permettant pas d'exclure un risque inacceptable pour les arthropodes non cibles (autres que les abeilles) et les macro-organismes du sol. L'usage est également refusé à 5 applications sur raisin de cuve en raison d'un risque de dépassement des limites maximales de résidus en vigueur pour le cuivre.		

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 LABEL of DSPF022
November 2016

DSPF022
Fongicide pour le traitement du mildiou de la vigne

Formulation liquide : Suspension concentrée (SC)
Produit réservé aux professionnels

Substances actives : 150 g/L de cuivre (8.9%) sous forme hydroxyde + 450 g/L de phosphonates de potassium (26.8%)
Autorisation de mise sur le marché n°xxxxxx

Mis sur le marché et distribué par :
DE SANGOSSE S.A.S
BONNEL CS 10005
47480 PONT DU CASSE
France
Tel : +33(0)5 53 69 36 30
Fax : +33(0)5 53 66 30 65

Volume :
Numéro de lot :
Date de fabrication de la préparation :

ATTENTION

H319 Provoque une sévère irritation des yeux
H332 Nocif par inhalation
H400 Très toxique pour les organismes aquatiques
H410 Très toxique pour les organismes aquatiques, entraine des effets néfastes à long terme

P261 Éviter de respirer les brouillards/vapeurs
P264 Se laver les mains soigneusement après manipulation
P273 Eviter le rejet dans l'environnement
P280 Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage
P304+P340 EN CAS D'INHALATION : transporter la victime à l'extérieur et la maintenir au repos dans une position où elle peut confortablement respirer.
P305+P351+P338 EN CAS DE CONTACT AVEC LES YEUX : rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer
P337+P313 : Si l'irritation oculaire persiste : consulter un médecin

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

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DRAFT LABEL of DSPF022
November 2016

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.]
SPe3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau / Pour protéger les plantes non ciblées, respecter une zone-tampon non traitée de 5 mètres par rapport aux terres non agricoles, lors d'applications tardives (juin – septembre).

Délai de réentrée dans les cultures : 24 heures

PRODUIT POUR LES PROFESSIONNELS : UTILISEZ LES PRODUITS PHYTOPHARMACEUTIQUES AVEC PRECAUTION. AVANT TOUTE UTILISATION, LISEZ L'ETIQUETTE ET LES INFORMATIONS CONCERNANT LE PRODUIT.

Premiers Secours
En cas d'inhalation : retirer la personne de la zone contaminée. Donner de l'air frais. Consulter un médecin en cas de malaise.
En cas de contact avec les yeux : Rincer immédiatement avec de l'eau pendant 15 minutes. Oter les lentilles de contact si la victime en porte. Consulter un médecin si l'irritation persiste ou si des symptômes apparaissent.
En cas de contact avec la peau : Laver immédiatement avec de l'eau et du savon. Retirer les vêtements contaminés. Consulter un médecin si l'irritation persiste ou si des symptômes apparaissent.
En cas d'ingestion : Ne pas faire vomir. Consulter un médecin si des symptômes apparaissent.

En cas d'urgence, appeler le 15 ou le 112 ou contacter le centre anti poison le plus proche. Puis signaler vos symptômes au réseau Phyt'attitude, n° vert 0 800 887 887 (appel gratuit depuis un poste fixe).

Fiche de données de sécurité disponible en consultant le site : www.desangosse.fr ou www.quickfds.com ou en appelant DE SANGOSSE au 05 53 69 36 30

Mode d'action et résistances
DSPF022 est un fongicide alliant l'action préventive du cuivre à l'effet systémique des phosphonates de potassium contre le mildiou de la vigne (*Plasmopara viticola*). DSPF022 doit être utilisé de façon préventive.
Le phosphonate de potassium agit d'une part directement sur le mildiou en déstabilisant les voies métaboliques impliquant le phosphate, et d'autre part de façon indirecte en stimulant les défenses naturelles de la vigne, agissant comme éliciteur. Le phosphonate de potassium appartient au groupe FRAC 33 et est considéré comme à faible risque en termes d'apparition de résistances. Le cuivre a une action multisites et est particulièrement efficace sur les spores du pathogène ; il appartient au groupe FRAC M1.
De par ces modes d'action complémentaires et multisites, l'apparition de résistance est improbable pour le produit DSPF022.

Usages

Usages autorisés	Stades d'application	Dose/ ha	Nombre maximum d'applications par an	Intervalle d'application	DAR
Vigne*Trt Part.Aer.* Mildiou (*Plasmopara vitícola*)	A partir de BBCH 15	4 L/ha	5	8 à 12 jours	21j

Recommandations d'emploi
Appliquer DSPF022 en préventif de tout évènement contaminant, à partir du stade 5 feuilles (BBCH 15). La cadence doit être adaptée à la pression et au stade d'application : elle varie de 8 jours en forte pression mildiou à 12 jours maximum en situation de faible pression.

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DRAFT LABEL of DSPF022
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DSPF022 a une action à la fois systémique et de contact. Il est recommandé d'adapter le volume d'eau au stade de développement de la culture et de soigner l'application afin que le produit recouvre bien l'ensemble de la végétation.

Se laver soigneusement les mains après toute utilisation/manipulation.
Ne pas manger, ne pas boire, ne pas téléphoner et ne pas fumer lors de l'utilisation de ce produit.

Compatibilité
Pour tout mélange avec d'autres produits phytopharmaceutiques, contacter votre interlocuteur DE SANGOSSE.
Ne pas mélanger DSPF022 avec des engrais foliaires contenant de l'azote ou ses dérivés.
Respecter la législation en vigueur sur les mélanges et les recommandations des guides de bonnes pratiques officiels.

Préparation de la bouillie
Après avoir rempli à moitié d'eau la cuve du pulvérisateur, verser DSPF022, puis terminer le remplissage en maintenant une agitation suffisante de la bouillie. Utiliser cette bouillie dans la journée.

La pulvérisation
Prendre conseil auprès de notre service technique si nécessaire. Éviter d'atteindre le point de ruissellement, ajuster pression et vitesse d'avancement afin d'obtenir une couverture (en gouttelettes) suffisante de la végétation.

Nettoyage du pulvérisateur et gestion des fonds de cuve :
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.

Autres informations
Nos préconisations sont issues d'essais réalisés sur plusieurs années. Cependant, plusieurs facteurs tels que les conditions climatologiques, techniques de traitement, mélanges non préconisés peuvent présenter des conséquences sur l'efficacité ou la sélectivité du traitement.

Recommandations de stockage
Stocker le produit dans l'emballage d'origine. Stocker le produit dans un local réservé à cet usage, frais, sec et bien ventilé et fermant à clé.
Conserver hors de la portée des enfants et des animaux domestiques. Conserver à l'écart des aliments et boissons, y compris ceux pour animaux.

Instructions pour l'élimination
Lors de l'utilisation du produit, bien vider et rincer le bidon (rinçage manuel à 3 reprises en agitant pendant 30s le bidon rempli au 1/3 ou rinçage mécanique pendant 30s minimum), 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'ADIVALOR ou à une autre collecte organisée. Réemploi de l'emballage interdit.
Pour l'élimination des produits non utilisables, rapporter le produit dans son emballage d'origine à votre distributeur partenaire d'ADIVALOR ou faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.
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 des produits dangereux. De Sangosse est partenaire de la filière ADIVALOR.

Equipements de protection individuelle
Pour protéger l'opérateur porter :
• Pendant le mélange/chargement :
- Gants en nitrile certifiés EN 374-3,
- Combinaison de travail tissée en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant,

DRAFT LABEL of DSPF022
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- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée,
- Protections respiratoires certifiées : demi-masque certifié (EN 140) équipé d'un filtre P3 (EN143) ou A2P3 (EN 14387),
- Lunettes de sécurité conforme à la réglementation et selon la norme EN 166.

• Pendant l'application :
Si application avec tracteur avec cabine :
- Combinaison de travail cotte en polyester 65 %/coton 35 % avec un grammage d'au moins 230 g/m² avec traitement déperlant,
- Gants en nitrile certifiés EN 374-3 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;

Si application avec tracteur sans cabine (application haute) :
- Gants en nitrile certifiés EN 374-3 à usage unique pendant l'application et dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation,
- Combinaison coton 35% polyester 65%, avec un grammage d'au moins 230 g/m² (avec traitement déperlant),
- Combinaison de protection de catégorie III type 4 avec capuche ;
- Lunettes de sécurité conforme à la réglementation et selon la norme EN 166,

• Pendant le nettoyage du matériel de pulvérisation :
- Gants en nitrile certifiés EN 374-3,
- Combinaison de travail tissée en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant,
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée,
- Lunettes de sécurité conforme à la réglementation et selon la norme EN 166,

Pour protéger le travailleur s'il doit intervenir sur une parcelle traitée :
Porter des gants en nitrile certifiés EN 374-3 et une combinaison de travail tissé en polyester 65 %/coton

Important
Respectez les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage, qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduisez sur ces bases la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous facteurs particuliers concernant votre exploitation tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces, la pression parasitaire... Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de vente du Ministère de l'Agriculture. Compte-tenu de la diversité des législations existantes, il est recommandé, dans le cas où les denrées protégées ou issues des cultures protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur. DE SANGOSSE ne saurait être tenu en aucun cas responsable des conséquences inhérentes à toute copie de cette étiquette, totale ou partielle et la diffusion ou à l'utilisation non autorisée de cette dernière.

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Appendix 3 Letter of Access

Provided upon request.