REGISTRATION REPORT

Part A

Risk Management

Product code: Sulphur + Copper Oxychloride DP

Product name: SULCOP DP

Active substances:

sulphur 600 g/kg

copper (in the form of copper oxychloride) 40 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: **Sulphur Mills Limited**

Date: **28/12/2018**

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PART A – Risk Management

The company SULPHUR MILLS LIMITED has requested marketing authorisation in France for the product SULCOP DP (product code: SULPHUR + COPPER OXYCHLORIDE DP), containing 600 g/kg sulphur[1] and 40 g/kg copper (73 g/kg in the form of copper oxychloride), for use as a fungicide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 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 SULCOP DP (SULPHUR + COPPER OXYCHLORIDE DP) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of SULCOP DP (SULPHUR + COPPER OXYCHLORIDE DP) have been made using endpoints agreed in the EU peer reviews of copper compounds and sulphur.

This document describes the specific conditions of use and labelling required for France for the registration of SULCOP DP (SULPHUR + COPPER OXYCHLORIDE DP).

Appendix 1 of this document provides a copy of the French Decision.

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

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

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of SULPHUR MILLS LIMITED's application to market SULCOP DP (SULPHUR + COPPER OXYCHLORIDE DP) 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.

1.2 Active substance approval

Sulphur

Regulations 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.
Specific provisions of Regulation (EU) No 540/2011 were as follows: PART A Only uses as fungicide and acaricide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sulphur, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 12 March 2009 shall be taken into account. In this overall assessment Member States shall pay particular attention to: - the protection of birds, mammals, aquatic organisms and non-target arthropods. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall ensure that the notifier submit to the Commission further information to confirm the risk assessment for birds, mammals, sediment dwelling organisms and non-target arthropods. They

[1] Comment: To reflect ISO 765-1976, the spelling "sulphur" is used in this Registration Report Part A instead of "sulphur". The traditional spelling is retained only when used as a part of a commercial name or in a citation.

shall ensure that the notifier at whose request sulphur has been included in this Annex provide such data to the Commission at latest by 30 June 2011.
An EFSA conclusion is available (EFSA Scientific Report (2008) 221, 1-70). A Review Report is available (SANCO/2676/08 – final 13 July 2012).

Copper compounds

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. Commission Implementing Regulation (EU) No 2015/232 of 13 February 2015 amending and correcting Implementing Regulation (EC) No 540/2011 as regards the conditions of approval of the active substance copper compounds.
Specific provisions of Regulation (EU) No 540/2011 were as follows: PART A Only uses as bactericide and fungicide may be authorised. PART B In assessing applications to authorise plant protection products containing copper for uses other than on tomatoes in greenhouses, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on copper compounds, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 January 2009 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the specification of the technical material as commercially manufactured which must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material, — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate, — the protection of water and non-target organisms. In relation to these identified risks risk mitigation measures, such as buffer zones, should be applied where appropriate, — the amount of active substance applied and ensure that the authorised amounts, in terms of rates and number of applications, are the minimum necessary to achieve the desired effects. The concerned Member States shall request the submission of information to further address: — the risk from inhalation, — the risk assessment for non-target organisms and for soil and water. They shall ensure that the notifier at whose request copper compounds have been included in this Annex provides such information to the Commission by 30 November 2011 at the latest. Member States shall initiate monitoring programmes in vulnerable areas where the contamination of the soil compartment by copper is of concern, in order to set, where appropriate, limitations such as maximum application rates.

Specific provisions of Regulation (EU) No 2015/232 were as follows:

PART A

Only uses as bactericide and fungicide may be authorised.

PART B

In assessing applications to authorise plant protection products containing copper for uses other than on tomatoes in greenhouses, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on copper compounds, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 January 2009 shall be taken into account.

In this overall assessment Member States must pay particular attention to:

— the specification of the technical material as commercially manufactured which must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material,

— the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate,

— the protection of water and non-target organisms. In relation to these identified risks risk mitigation measures, such as buffer zones, should be applied where appropriate,

— the amount of active substance applied and ensure that the authorised amounts, in terms of rates and number of applications, are the minimum necessary to achieve the desired effects and do not cause any unacceptable effect on the environment taking into account background levels of copper at the application site.

The notifiers shall present to the Commission, the Authority and the Member States a monitoring programme for vulnerable areas where the contamination of the soil and water (including sediments) by copper is a concern or may become one.

That monitoring programme shall be submitted by 31 July 2015. The interim results of such monitoring programme shall be submitted as interim report to the Rapporteur Member State, the Commission and the Authority by 31 December 2016. Final results shall be submitted by 31 December 2017.

Commission Implementing Regulation (EU) 2018/84 of 19 January 2018 extended the approval's expiration date to 31 January 2019.

There is an EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance (EFSA Scientific Report (2008) 187, 1-101), as amended (EFSA Journal 2013;11(6):3235).

There is also an EFSA conclusion on the 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):5152 where risks were identified for environmental organisms on the representative uses in vineyard, cucurbits and tomato as well as for workers in vineyard.

A Review Report is available (SANCO/150/08 final, 10 October 2014) and a list of studies relied on (2018).

1.3 Regulatory approach

The present application (2014-3638) was evaluated in France by the French Agency for Food, Environmental and

Occupational Health & Safety (Anses)[2] 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.

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 three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight 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 Appendix 3 of the above-mentioned French Order.

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009[5], implementing regulations, and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. 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 conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011[6], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[7] 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[8] 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.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of SULCOP DP (SULPHUR + COPPER OXYCHLORIDE DP), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

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2 French Food Safety Agency, Afssa, before 1 July 2010.

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.

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.

5 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.

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

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

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

1.5 Letter(s) of Access

The applicant has provided letter(s) of access valid only in France.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	SULCOP DP (Sulphur + Copper Oxychloride DP).
Authorisation number	N/A : no marketing authorisation granted
Function	Fungicide.
Applicant	SULPHUR MILLS LIMITED
Composition	600 g/kg sulphur; 40 g/kg copper (as copper oxychloride).
Formulation type (code)	Dustable powder (DP).
Packaging	-

2.2 Classification and labelling

2.2.1 Classification and labelling in accordance with Regulation (EC) No1272/2008

Physical hazards	-	
Health hazards	Eye irritation category 2	
Environmental hazards	Hazardous to the aquatic environment — Acute, Hazard Category 1 Hazardous to the aquatic environment — Chronic, Hazard Category 1	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H319 H400 H410	Causes serious eye irritation. Very toxic to aquatic life. Very toxic to aquatic life with long-lasting effects.
Precautionary statements –	***For the P phrases, refer to the extant legislation***	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)		

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

2.2.2 Other phrases in compliance with Regulation (EU) No 547/2011

N/A: Not registered in France.

2.2.3 Other phrases linked to the preparation

N/A: Not registered in France.

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant 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.

GAP rev. 01, date: 2018-12-28

PPP (product name/code):	**SULCOP DP (Sulphur + Copper Oxychloride DP)**	Formulation type:	**WG** [a, b]
Active substance 1:	Copper	Conc. of a.s. 1:	**40 g/kg** [c]
Active substance 2:	Sulphur	Conc. of a.s. 1:	**600 g/kg** [c]
Applicant:	**SULPHUR MILLS LIMITED**	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)	kg 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	Grapevine (VITVI)	F	Powdery mildew of grapevine (UNCINE) & downy mildew of grapevine (PLASVI)	dusting / row	**Until BBCH 19**	**1**	-	a) 26 kg/ha b) 26 kg/ha	a) 15 600 g S/ha + 1040 g Cu/ha b) 15 600 g S/ha + 1040 g Cu/ha	No water needed	21	**Not acceptable** (MRL exceedance) **Not acceptable** (bees; soil macro-organisms; operators, bystanders) **Not acceptable for downy mildew** (efficacy) ***Ecotoxicology data support only one application, with a timing of growth stage BBCH 19 at the latest.***

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 RISK MANAGEMENT

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties

SULCOP DP (SULPHUR + COPPER OXYCHLORIDE DP) is a dustable powder. All studies were performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a light green dust powder, with characteristic odour. It is not explosive and has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 257°C. In 1% aqueous solution, it has a pH value of 9.7 at 22°C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54°C, neither the active substance content nor the technical properties were changed. The stability data indicate a shelf life of at least two years at ambient temperature when stored in aluminium packaging. As the formulation is dustable powder, the paper packaging may be considered acceptable. The technical characteristics are acceptable for a dustable powder formulation.

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

Data required at the renewal of copper's approval:

No analytical method for the determination of the relevant impurities (lead, arsenic, cadmium) of the active substance copper oxychloride was submitted.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methods for the determination of the active substances (sulphur and copper) in the formulation are available and validated.

As the active substance sulphur does not contain any relevant impurity, no analytical method is required.

3.1.2.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report (DAR) and in the dossier and validated for the determination of residues of copper in plants (grapes), water and soil.

Since there is no MRL set for sulphur residues, analytical methods are not required for their determination in plants, foodstuffs of animal origin, water (drinking or surface), soil and air.

3.1.3 Mammalian Toxicology

<table>
<tr><td colspan="4">Active substance: sulphur</td></tr>
<tr><td>ADI</td><td colspan="2">Not applicable</td><td rowspan="3">EU (2010)</td></tr>
<tr><td>ARfD</td><td colspan="2">Not applicable</td></tr>
<tr><td>AOEL</td><td colspan="2">Not applicable*</td></tr>
<tr><td rowspan="3">Dermal absorption</td><td colspan="3">Based on default values according to guidance on dermal absorption (Efsa 2012):</td></tr>
<tr><td></td><td>Concentrate
(used in formulation)
600 g/kg</td><td>Spray dilution</td></tr>
<tr><td>Dermal absorption endpoints %</td><td>10</td><td>Not relevant</td></tr>
</table>

*Average sulphur background intake value was 26 mg/kg bw/day [overall intake: 1.6 g/person/day, US National Academy of Medicine].

Active substance: **copper**			
ADI	0.15 mg/kg body weight/day		EU (2009)
ARfD	Not applicable		
AOEL	0.072 mg/kg body weight/day		
Dermal absorption*	Based on default values (applicant does not belong to the copper Task Force)		
		Concentrate 72.7g/kg (eq. to 40 g/kg)	Spray dilution
	Dermal absorption endpoints	**10**	**Not relevant**

* 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).

3.1.3.1 Acute Toxicity

SULCOP DP (SULPHUR + COPPER OXYCHLORIDE DP), containing 40g/kg copper (in the form of copper oxychloride) and 600g/kg sulphur, has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin and is not a skin sensitiser. It is irritating to the rabbit eye.

The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.2.

3.1.3.2 Operator Exposure

Summary of critical use patterns:

Crop	F/G[9]	Equipment	Application rate kg/L product/ha (g a.s./ha)	Spray dilution (L/ha)	Model
Grapes	F	Tractor-mounted or trailed dust applicator	26 kg product/ha (1040 g copper/ha) (1560 g sulphur/ha)	-	Field study (Garofani, 2010)

Considering the proposed use, operator systemic exposure was estimated using a field study.

Estimation of the potential operator exposure to a powder plant protection product applied with a tractor-mounted dust applicator is considered inappropriate using the currently valid models (UK POE and German models). An operator exposure study was submitted by the applicant. This study is considered acceptable for estimating the exposure to sulphur. However, the extrapolation for copper as proposed by the applicant (*pro rata* calculation) is considered unacceptable.

The exposure risk assessment cannot be finalised, due to the lack of information concerning exposure to copper.

For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

3.1.3.3 Bystander Exposure

The exposure of bystanders present at the time of powder application was determined during the above-mentioned study. **Considering the lack of data for the active substance copper, the risk cannot be assessed for the bystander exposure.**

3.1.3.4 Worker Exposure

[9] Open field or glasshouse.

Workers may have to enter treated areas after treatment. Therefore, estimation of worker exposure was calculated according to EUROPOEM II. Exposure is estimated to be 87 % of the AOEL of copper and 3.6 % of the AOEL of sulphur.

It may be concluded that without taking into account a re-entry period, there is no unacceptable risk anticipated for workers wearing a working coverall and gloves, when re-entering crops treated with SULCOP DP (SULPHUR + COPPER OXYCHLORIDE DP).

For details of personal protective equipment for workers, refer to the Decision in Appendix 1.

3.1.3.5 Resident Exposure

Due to the lack of information considering resident exposure, the risk cannot be assessed.

3.1.4 Residues and Consumer Exposure

Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation Sulphur + Copper Oxychloride DP are presented in Part B, paragraph IIIA 8.3 and paragraph IIIA 8.12 Residue trials. They have been selected from the individual GAPs in the SEU for grapes. A list of all intended uses within the SEU is given in Part B.

Overall conclusion

As sulphur is included in Annex IV of Regulation (EC) No 396/2005, no MRLs are required for this a.s. Any exceedance of the current MRL of 50 mg/kg on grapes for copper as laid down in Reg. (EU) 396/2005 is not expected.

The data available are considered sufficient for risk assessment.

No dietary risk assessment needed to be carried out for sulphur, since toxicological reference values are not set.

The chronic intake of copper residues resulting from the use intended use in the framework of this application could not be finalised as no residue data in accordance with the formulation (DP) is available in the dossier/data package.

As far as consumer health protection is concerned, France as zRMS disagrees with the authorisation of the intended use.

Summary of the evaluation

The preparation SULCOP DP (SULPHUR + COPPER OXYCHLORIDE DP) contains sulphur and copper.

Summary for sulphur

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EC) No 459/2010	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	Grapes	Yes	NR	NR	NR	No MRL required	No	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 data presented below, available in the DAR of sulphur (2007), have been evaluated as sufficient to support the authorisation of sulphur as an active substance. It is important to note that sulphur fulfils criteria of Annex VI of Regulation 2229/2004. Furthermore, sulphur is included in Annex IV of Regulation 396/2005. This Annex includes substances for which no MRL is required to be set.

Summary for copper

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EC) No 149/2008	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	Grapes	Yes	No	No	Yes	Not demonstrated	Not finalised	Not finalised	No residue trials with DP formulation

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

For grapes, specific residue trials in accordance with the critical intended GAP should have been submitted to support the use of the DP formulation. In the absence of such specific data, it was not possible to conclude that the extant MRL on grapes for copper will not be exceeded.

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 effect of processing on the amount of residue have been submitted, and processing factors have been defined but not considered to refine consumer risk assessment.

Considering that grapevine is a permanent crop, residues in succeeding crops have not been investigated.

As grapes are not fed to livestock, no impact on MRLs for animal commodities are expected.

In the absence of specific residue trials carried out with a DP formulation on grapes, the chronic consumer exposure resulting from copper could not be finalised.

Information on SULCOP DP (SULPHUR + COPPER OXYCHLORIDE DP)

Crop	PHI for SULCOP DP (Sulphur + Copper Oxychloride DP) requested by applicant	PHI/withholding period* sufficiently supported for		PHI for SULCOP DP (Sulphur + Copper Oxychloride DP) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Sulphur	Copper		
Grapes	21 days	Yes	No	-	

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).

Waiting periods before planting succeeding crops

Not relevant.

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment of the formulation have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review were used to calculate predicted environmental concentrations (PECs) 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.

The PEC values for copper and sulphur in soil and surface water have been assessed using the endpoints established in the EU review. PECsoil and PECsw values derived for the active substance are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

Compared with natural background occurrence of copper in soil, no unacceptable risk of groundwater contamination is expected for the intended uses. PECgw values for sulphur do not exceed the trigger of 250 mg/L (Directive 98/83/CE). Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses when the formulated product is applied at a maximum annual dose of 4 kg Cu/ha/year.

3.1.6 Ecotoxicology

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 substances 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 terrestrial vertebrates, non-target arthropods, micro-organisms and non-target plants can be considered acceptable for the intended uses.

Considering bees, according to new requirements of Reg. (EU) No. 284/2013, a chronic toxicity study of the formulation SULCOP DP (Sulphur + Copper Oxychloride DP) for adult bees and data on effects on development of bees should have been submitted by the applicant, as exposure of bees to the formulation during the flowering period cannot be excluded. Therefore, the risk to bees cannot be completely finalised and mitigation measures such as “to protect bees and other pollinating insects, do not apply during flowering” should be set at Member State level.

The risk to aquatic organisms following the intended use of SULCOP DP (Sulphur + Copper Oxychloride DP) can be considered acceptable with the following mitigation measures:

A 50 m unsprayed buffer zone for early application (until BBCH 19) on vineyard and a 20 m planted buffer zone.

For application after BBCH 19, the risk to aquatic organisms is considered unacceptable following the intended use of SULCOP DP (Sulphur + Copper Oxychloride DP).

In addition, according to the new requirement of the Regulation (EU) 284/2011, chronic studies on soil organisms *i.e.* earthworms and other than earthworms (*Folsomia candida* and *Hypoaspis aculeifer)* are required. **Considering the available data, such studies are required for SULCOP DP (Sulphur + Copper Oxychloride DP) and without these studies it is not possible to finalise the risk assessment for soil organisms.**

3.1.7 Efficacy

Considering the data submitted:

- The efficacy level of SULCOP DP (SULPHUR + COPPER OXYCHLORIDE DP) is considered acceptable for the use on powdery mildew. **Considering the lack of data or possible extrapolation on downy mildew, the evaluation of the efficacy of SULCOP DP (SULPHUR + COPPER OXYCHLORIDE DP) on this use cannot be finalised.**
- The phytotoxicity level of SULCOP DP (SULPHUR + COPPER OXYCHLORIDE DP) is considered acceptable for all the requested uses.
- The risk of negative impact on yield, quality, propagation and transformation process (wine-making) is considered acceptable. Risks with copper such as spotting of table grapes (for applications after BBCH 71) and impact on the wine-making process are known. 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 copper and sulphur does not require monitoring for the intended uses.

Post-authorisation data: none.

Missing data: none.

Warning on the label: warn users on the label about the risk of spotting on berries of table grape (for applications after fruit set, BBCH 71), and the risk of impact on the wine-making process.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation **cannot be granted** on table and wine grape, as proposed in Appendix 1 – Copy of the product Decision, as the risk assessment for operators, bystanders, residents, consumers, soil organisms and for use against downy mildew cannot be finalised.

3.3 Substances of concern for national monitoring

N/A: Not registered in Fance.

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

3.4.1 Post-authorisation monitoring

N/A: Not registered in Fance.

3.4.2 Post-authorisation data requirements

N/A: Not registered in Fance.

3.4.3 Label amendments

N/A: Not registered in Fance.

Appendix 1 – Copy of the French Decision

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anses
agence nationale de sécurité sanitaire alimentation, environnement, travail

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 du produit phytopharmaceutique ***SULCOP DP***

de la société	*SULPHUR MILLS LIMITED*
enregistrée sous le	*n°2014-3638*

Considérant que les données fournies pour des applications tardives ne permettent pas d'exclure un risque de dépassement des limites maximales de résidus pour le cuivre et un risque d'effet inacceptable pour les espèces aquatiques non cibles,

Considérant que les données fournies ne permettent pas d'exclure, pour des applications précoces, l'absence d'effet nocif pour les opérateurs et les personnes présentes,

Considérant qu'en l'absence de données de toxicité sur les vers de terre Folsomia candida et Hypoaspis aculeifer, un risque d'effet inacceptable pour les macroorganismes du sol ne peut être exclu,

Considérant en conséquence 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.

SULCOP DP
AMM n°-

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Informations générales sur le produit	
Nom du produit	SULCOP DP
Type de produit	Produit de référence
Titulaire	SULPHUR MILLS LIMITED Unity House Fletcher Street BOLTON BL3 6NE Royaume-Uni
Formulation	Poudre pour poudrage (DP)
Contenant	40 g/kg - cuivre (sous forme d'oxychlorure de cuivre) 600 g/kg - soufre
Numéro d'intrant	9622-2014.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usage	Professionnel

A Maisons-Alfort le, 28 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)

SULCOP DP
AMM n°-

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Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12703203 Vigne*Trt Part.Aer.*Mildiou(s)	26 kg/ha	8/an	21
	Motivation du refus : L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus en vigueur pour le cuivre. L'usage est également refusé en raison de l'absence de données concernant l'efficacité du cuivre par poudrage, en l'absence de données permettant d'exclure un effet nocif pour les opérateurs et les personnes présentes, et en l'absence de données permettant d'exclure un risque inacceptable pour les macroorganismes du sol.		
12703204 Vigne*Trt Part.Aer.*Oïdium(s)	26 kg/ha	8/an	21
	Motivation du refus : L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus en vigueur pour le cuivre. L'usage est également refusé en raison de l'absence de données permettant d'exclure un effet nocif pour les opérateurs et les personnes présentes, et en l'absence de données permettant d'exclure un risque inacceptable pour les macroorganismes du sol.		

SULCOP DP

AMM n°-

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Appendix 2 – Copy of the draft product label as proposed by the applicant

NOTICE D'EMPLOI

IMPORTANT: Ces informations font parties de l'étiquette du produit SULCOP DP. Toutes les instructions de cette section doivent être lues attentivement.

MODE D'EMPLOI:

SULCOP DP s'utilise en poudrage à la dose préconisée en utilisant une poudreuse ou tout autre appareil adapté à ce type d'application. Dans le cas de foyers d'oïdium ou de mildiou distincts, appliquer en localisé.

PRECAUTIONS:

Stockage:
Conserver le produit dans son emballage d'origine, dans des locaux fermés à clé, hors de portée des enfants. Conserver à l'écart des aliments et boissons, y compris ceux pour animaux.

Pendant le chargement puis le poudrage, lors du nettoyage de la poudreuse, ainsi que lors des interventions sur les parcelles traitées:

Pour l'opérateur, porter, pendant le chargement et pendant l'application:
- Gants en nitrile certifiés EN 374-3;
- Combinaison de travail tissée en polyester 65 %/coton 35 % avec un grammage d'au moins 230 g/m²;
- Bottes de protection certifiées EN 13 832-3
- Lunettes de protection certifiées EN-166 (CE sigle 3);
- Demi-masque de protection respiratoire certifié A2P3;

Pour l'opérateur, porter, pendant le nettoyage de la poudreuse:
- Combinaison de travail cotte en polyester 65 %/coton 35 % avec un grammage d'au moins 230 g/m² avec traitement déperlant ;
- Bottes de protection certifiées EN 13 832-3
- Gants en nitrile certifiés EN 374-3 ;
- Lunettes de protection certifiées EN-166 (CE sigle 3);

Pour le travailleur, porter, lors des interventions sur les parcelles traitées:
- Gants en nitrile certifiés EN 374-3;
- Combinaison de travail tissée en polyester 65 %/coton 35 % avec un grammage d'au moins 230 g/m²;
- Bottes de protection certifiées EN 13 832-3

Après utilisation:
Nettoyer très soigneusement les poudreuses aussitôt après le traitement. Immédiatement après l'application, changer de vêtements et laver le visage et les mains à l'eau savonneuse. La réutilisation ou l'incinération des emballages vides est interdite. Éliminer les emballages vides et les produits non utilisables en respectant la réglementation en vigueur et via les collectes organisées par les distributeurs partenaires de la filière ADIVALOR (consultez le site www.adivalor.fr ou 08 10 12 18 85, numéro Azur prix d'un appel local). Ne pas déverser les reliquats de produits dans les fossés, mares, cours d'eau ou égouts.

SULCOP DP

Poudre pour poudrage (DP) contenant 600 g/kg de Soufre et 40 g/K d'Oxychlorure de cuivre

AMM n° XXXXXXXXX délivrée le XX/XX/XXXX par le Ministère de l'alimentation, de l'agriculture et de la pêche

SULCOP DP est un fongicide pour traiter la vigne et est destiné à un usage agricole et professionnel uniquement.

SULCOP DP se présente sous la forme d'une poudre pour poudrage (SL) contenant 600 g/kg de Soufre et 40 g/K d'Oxychlorure de cuivre.

5 KG

Lot No. XXXXX

Détenteur d'homologation:
SULPHUR MILLS LIMITED
Unity House, Fletcher Street,
Bolton, BL3 6NE
Royaume Uni

Distribué par:
XXXXX
XXXXX

En cas d'urgence, appeler le 15 ou le centre antipoison puis signalez vos symptômes au réseau "Phyt'attitude" n° vert 0 800 887 887 (appel gratuit depuis un poste fixe).

Mentions de danger:
H412: Nocif pour les organismes aquatiques, entraîne des effets néfastes à long terme

Conseils de prudence:
P102: Tenir hors de portée des enfants
P103: Lire l'étiquette avant utilisation
P273: Éviter le rejet dans l'environnement
P391: Recueillir le produit répandu
P501: Éliminer le contenu/récipient conformément à la réglementation locale/régionale/nationale/internationale

SP1: Ne pas polluer l'eau avec le produit ou son emballage.

USAGES ET DOSES AUTORISES:

SULCOP DP peut être utilisé pour les usages et doses d'application suivantes:

Code d'usage	Usage	Dose d'emploi	Nombre maximum d'applic. (intervalle)	Délai avant récolte (jours)
12703204	Vigne / Traitement des parties aériennes / Oïdium	26 kg/ha	8 (5 jours)	21
12703203	Vigne / Traitement des parties aériennes / Mildiou	26 kg/ha	8 (5 jours)	21

En cas de pression normale, l'oïdium et le mildiou peuvent être contrôlés efficacement avec un programme de 8 applications par poudrage du stade BBCH 15-18 à 21 jours avant la récolte. Dans le cas de foyers d'oïdium et ou de mildiou distincts, appliquer en localisé.

CONDITIONS DE VENTE:

Tous nos produits sont de haute qualité et sont appropriés aux usages recommandés. Toutefois nous ne pouvons contrôler les conditions dans lesquels ils seront stockés, manipulés, mélangés ou utilisés ni contrôler les conditions climatiques dans lesquels ils seront employés. Ces différents paramètres précités peuvent affecter la performance du produit. C'est pourquoi, notre société et nos revendeurs déclineront toute responsabilité quant à la qualité des produits qui serait altérée par de mauvaises conditions de stockage, de manipulation ou d'application par l'utilisateur.

Appendix 3 – Letter(s) of Access

Provided upon request.