REGISTRATION REPORT

Part A

Risk Management

Product code: SHA 0400 C

Product name: SHIP 10 WG

Chemical active substance:

cyproconazole, 100 g/kg

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: SHARDA CROPCHEM ESPAÑA S.L.

Date: 31/12/2019

Table of Contents

PART A

RISK MANAGEMENT

1 Details of the application

The company SHARDA CROPCHEM ESPAÑA S.L. has requested a marketing authorisation in France for the product SHIP 10 WG (formulation code: SHA 0400 C), containing 100 g/kg cyproconazole, as a fungicide for professional uses.

The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in the Registration Report, Part B include assessment of further data or information as required at national registration by EU regulations. It also includes assessment of data and information related to SHIP 10 WG (SHA 0400 C) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of SHIP 10 WG (SHA 0400 C) have been made using endpoints agreed in the EU peer review of cyproconazole.

This document describes the specific conditions of use and labelling required for France for the registration of SHIP 10 WG (SHA 0400 C).

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

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

1.1 Application background

The present registration report concerns the evaluation of SHARDA CROPCHEM ESPAÑA S.L.'s application to market SHIP 10 WG (SHA 0400 C) in France as a fungicide (product uses described under point 2.6). 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 (2016-2513) 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")[1] – the highest application rates applied for in the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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[2], 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.

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1 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.

2 REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011[3], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

1.2 Letters of Access

The applicant has provided a letters of access.

1.3 Justification for submission of tests and studies

According to the applicant: "*This dossier relies on new test and studies providing data and information specific to the formulation SHIP 10 WG (SHA 0400 C) as required by the EU regulations*."

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of SHIP 10 WG (SHA 0400 C), 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	SHA 0400 C.
Product name in MS	SHIP 10 WG (SHA 0400 C).
Authorisation number	N/A : no marketing authorisation granted
Low risk (article 47)	No.
Function	Fungicide.
Applicant	Sharda Cropchem España S.L.
Active substance(s) (incl. content)	Cyproconazole 100 g/kg.
Formulation type	Water-dispersible granules [WG].
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.

[3] 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

2.2 Conclusion

The evaluation of the application for SHIP 10 WG (SHA 0400 C) resulted in **the decision to refuse the authorisation**. **This product present an unacceptable risk for the worker. It is possible to exceed MRLs**

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

N/A: No marketing autorisation granted.

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

N/A: No marketing autorisation granted.

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

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

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

- an authorisation granted for a “reference” crop applies also for “linked” crops, unless formally stated 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

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

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 “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[6] is to supply “minor” crops with registered plant protection products.

Therefore the GAP table (Section 2.6) 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:	
-	N/A : No marketing autorisation granted.
Worker protection:	
-	N/A : No marketing autorisation granted.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
SP 1	No marketing autorisation granted.
SPe 3	No marketing autorisation granted.
Other specific restrictions	
Re-entry period	48 hours.
SPa 1	No marketing autorisation granted.

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.

[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: The GAP Table below reports the intended uses proposed by the applicant.
When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.

GAP rev. 2, date: 31/12/2019

PPP (product name/code):	SHIP 10 WG / SHA 0400 C	Formulation type:	WG (a, b)
Active substance 1:	Cyproconazole	Conc. of a.s. 1:	100 g/kg (c)
Applicant:	SHARDA CROPCHEM ESPAÑA S.L	Professional use:	☒
Zone(s):	Southern Zone (d)	Non-professional use:	☐
Verified by MS:	**Yes**		
Field of use:	Fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	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
					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		
1	SEU	Grape	F	Powdery mildew *(Uncinula necator)*	Foliar spray	BBCH 14-79	a) 7 b) 7	14	a) 0.1 b) 0.7	a) 10 b) 70	800 - 1000	14	Not acceptable (risk for worker, exceedence MRL)

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.

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)

SHIP 10 WG (SHA 0400 C) is a water-dispersible granule formulation. All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is that of light brown, free–flowing granules, with a faint odour. It is not explosive, has no oxidising properties and is not highly flammable. It has a self-ignition temperature of 253 °C. In aqueous solution of 1 %, it has a pH value around 9.905 at 20 °C. There is no effect of low and high temperatures 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 PE bags. The technical characteristics are acceptable for a water-dispersible granules formulation.

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

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

- the efficacy level of SHIP 10 WG (SHA 0400 C) is considered satisfactory for the requested use.
- the phytotoxicity level of SHIP 10 WG (SHA 0400 C) is considered negligible for the requested use.
- the risks of negative impact on yield, quality, transformation processes (wine-making), propagation and adjacent crops are considered negligible.

There is a risk of resistance developing or appearing to cyproconazole for powdery mildew in grape. This requires monitoring and the setting-up of efficacy trials in situations of characterised resistance. To avoid the development of resistance of powdery mildew in grape to cyproconazole, the number of applications is limited to two per crop cycle on grape.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical methodology for the determination of the active substance in the formulation is available and validated. As the active substance cyproconazole does not contain any relevant impurity, no pertinent analytical method is required.

3.3.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report (DAR)/this dossier and validated for the determination of residues of cyproconazole in plants (acidic commodities), foodstuffs of animal origin, soil, water (surface and drinking) and air.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

<table>
<tr><td colspan="4">Active substance: cyproconazole</td></tr>
<tr><td>ADI</td><td colspan="2">0.02 mg/kg bw/d</td><td rowspan="4">EU (2011)</td></tr>
<tr><td>ARfD</td><td colspan="2">0.02 mg/kg bw</td></tr>
<tr><td>AOEL</td><td colspan="2">0.02 mg/kg bw/d</td></tr>
<tr><td>AAOEL</td><td colspan="2">not determined</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)
100 g/kg</td><td>Spray dilution
(used in formulation)
0.01 g/L</td></tr>
<tr><td>Dermal absorption endpoints %</td><td>25</td><td>75</td></tr>
<tr><td>Oral absorption</td><td colspan="2"></td><td>100</td></tr>
</table>

3.4.1 Acute toxicity

SHIP 10 WG (SHA 0400 C), containing 100 g/kg cyproconazole, has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitiser.

3.4.2 Operator exposure

Summary of critical use patterns (worst cases):

Crop type	F/G[7]	Equipment *Application method*	Maximum application rate (product) [g a.s./ha]	Minimum volume water (L/ha)	Max. number (min. interval between applications in days)
Grape	F	Vehicle-mounted *Upward spraying*	0.1 kg/ha [10 g cyproconazole/ha]	800	7 (14)

[7] Open field or glasshouse

Considering the proposed use, operator systemic exposure was estimated using the EFSA model[8]:

Crop	Equipment	PPE and/or working coverall	% AOEL cyproconazole
Grape	Vehicle-mounted *Upward spraying*	Working coverall and gloves during mixing/loading and application	11

According to the model calculations, it may be concluded that the risk for the operator using SHIP 10 WG (SHA 0400 C) is acceptable with a working coverall and gloves during mixing/loading and application.

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

3.4.3 Worker exposure

EFSA model: Workers may have to enter treated areas after treatment for crop hand-harvesting. Therefore estimation of worker exposure was calculated according to the AOE model. **Exposure is estimated to be 491 % of the AOEL of cyproconazole with PPE. It may therefore be concluded that there is an unacceptable risk anticipated for the worker.**

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

3.4.4 Bystander and resident exposure

EFSA model (w/o AAOEL): Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e., no acute operator or bystander exposure assessments can be performed with the AOE model where no AAOEL has been set[9].

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. An acceptable risk was determined for residents (adult and/or child) when mitigation measures such as a buffer zone of 10 metres are taken:

[8] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)
[9] Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

Model (AOEM) - All pathways (mean)	% AOEL cyproconazole
Resident (children)	26
Resident (adults)	13

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

Critical GAP(s) and overall conclusion

Overall conclusion

The data available are considered insufficient for risk assessment.

Due to a lack of data, the chronic and short-term intakes of cyproconazole residues resulting from the use proposed in the framework of this application cannot be assessed. As far as consumer health protection is concerned, France as zRMS does not agree with the authorisation of the intended use.

Data gaps

Noticed data gaps are:

- Additional residue trials on grapes for the Northern zone according to the intended GAP.
- Residue trials on grapes for the Southern zone according to the intended GAP.
- Residue definition covering fruits and fruiting vegetables.

Summary of the evaluation

SHIP 10 WG (SHA 0400 C) contains cyproconazole.

Summary for cyproconazole

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	Grape	No	No	N.A	Yes	Not assessed		

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

As insufficient data on the nature and magnitude of residues on grapes are available, it could not be determined whether an MRL exceedence may occur for the intended GAP.

As insufficient residue data are available, it is not possible to conclude whether residues of cyproconazole

would exceed the trigger values defined in Reg. (EU) No 283/2013. The need to investigate the effect of industrial and/or household processing could not be assessed.

As grapes are not expected to be grown in rotation, further investigation of residues in rotational crops is not required.

Since the use under consideration is not a crop that is fed to animals, considerations about livestock are not required in the framework of this evaluation. Consequently, no dietary burden calculation has been performed.

Moreover, considering the insufficient residue data provided in this submission for the intended use, chronic and short-term intakes of cyproconazole residues could not be assessed.

The intended use is not sufficiently supported by available data.

3.5.1.1 Summary for SHIP 10 WG (SHA 0400C)

Table 1 Information on SHIP 10 WG (SHA 0400C) (KCA 6.8)

Crop	PHI for SHIP 10 WG (SHA 0400C) requested by applicant	PHI/withholding period* sufficiently supported for cyproconazole	PHI for SHIP 10 WG (SHA 0400C) proposed by zRMS	zRMS Comments (if different PHI proposed)
Grapes	14 days	Use is considered to be not supported		

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

Table 2 Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for SHIP 10 WG (SHA 0400C)
Crop group	Led by cyproconazole	
Not relevant		

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

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

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

PECsoil and PECsw values derived for the active substance and its metabolites are used for the ecotoxicological risk assessment.

PECgw values for cyproconazole and its metabolites do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009 and guidance document SANCO 221/2000. Therefore no unacceptable risk of groundwater contamination is expected for the intended use.

Based on vapour pressure, information on volatilisation from plants and soil, and DT_{50} calculation, no significant contamination of the air compartment is expected for the intended use.

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance and its metabolites 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, aquatic organisms, mammals, other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants are acceptable for the intended uses when there is an unsprayed buffer zone of 5 metres to surface water bodies.

According to new requirements of Reg. No. 284/2013, information on chronic effects on adult bees and on development of bees should have been submitted, as exposure of bees to the formulation cannot be excluded. In the absence of these data, the risk for bees cannot be finalised.

3.8 Relevance of metabolites (Part B, Section 10)

Triazole Acetic Acid (TAA) : PECgw = 178 µg/L
The metabolite is not relevant.
For further details, please refer to Part B section 10.

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

SHIP 10 WG (SHA 0400 C) contains cyproconazole, which is approved as a candidate for substitution because it fulfils two PBT (Persistent, Bio-accumulable, Toxic) criteria.

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, if the candidate a.s. for substitution is an important part of the resistance management strategy, **substitution will not be considered for the use in question.**

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

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

5.1.1 Post-authorisation monitoring

N/A : not registered in France ».

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 du produit phytopharmaceutique ***SHIP 10 WG***

de la société	*SHARDA CROPCHEM ESPAÑA S.L.*
enregistrée sous le	*n°2016-2513*

Vu les conclusions de l'évaluation de l'Anses du 15 octobre 2019,

Considérant que le produit peut présenter un effet nocif pour les travailleurs,

Considérant que l'estimation de l'exposition chronique et aiguë pour le consommateur ne peut pas être conduite en raison d'un manque d'essais résidus,

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.

SHIP 10 WG
AMM n°-

Page 1 sur 3

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Informations générales sur le produit	
Nom du produit	SHIP 10 WG
Type de produit	Produit de référence
Titulaire	SHARDA CROPCHEM ESPAÑA S.L. Carril Condomina n°3 30006 Murcia Espagne
Formulation	Granulé dispersable (WG)
Contenant	100 g/kg - cyproconazole
Numéro d'intrant	714-2016.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usage	Professionnel

A Maisons-Alfort le, 31 DEC. 2019

Caroline SEMAILLE
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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Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12703204 Vigne*Trt Part.Aer.*Oïdium(s)	0,1 kg/ha	7/an	14
	Motivation du refus : L'usage est refusé en raison de risques d'effet nocif pour les travailleurs et au motif que le respect des limites maximales de résidus n'a pas pu être vérifié par manque d'essais résidus.		

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.

NOTICE D'EMPLOI

IMPORTANT : Ces informations font parties de l'étiquette du produit SHIP 10 WG. Toutes les instructions de cette étiquette doivent être lues attentivement avant l'emploi.

PRECAUTIONS:

Pour l'utilisateur: Eviter le contact du produit avec les yeux, la peau et les voies respiratoires. En cas d'incident en cours d'application, arrêter le pulvérisateur en zone non contaminée autant que possible, ne pas porter les mains ou les gants souillés à la bouche, ne pas déboucher une buse en soufflant. Après l'application, rincer les équipements de protection, se laver les gants puis les mains, prendre une douche. Ne pas réutiliser l'emballage du produit.

Stockage: Conserver le produit dans son emballage d'origine fermé de manière étanche, dans un endroit bien ventilé et sous clef, hors de portée des enfants. Conserver à l'écart des aliments et boissons, y compris ceux pour animaux.

Après utilisation: Eliminer les emballages *via* les collectes organisées par les distributeurs partenaires de la filière ADIVALOR (08 10 12 18 85, numéro Azur prix d'un appel local), en accord avec la réglementation en vigueur.

PREPARATION DE LA BOUILLIE:

Bien agiter l'emballage avant utilisation. Remplir la cuve à moitié d'eau. Mettre l'agitateur en marche. Ajouter SHIP 10 WG, compléter en eau pour remplir la cuve. Maintenir l'agitation.

MELANGE:

Respecter la réglementation en vigueur et les recommandations des guides de bonnes pratiques officiels disponibles sur le site : http://e-phy.agriculture.gouv.fr

NOTES GÉNÉRALES:

Consulter les procédures de nettoyage des appareils sur les étiquettes de tous produits associés et être sûr d'utiliser le procédé le plus rigoureux et recommandé. Respecter les bonnes pratiques agricoles.

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.

USAGES ET DOSES AUTORISES:

SHIP 10 WG est un fongicide pouvant être utilisé sur les cultures et aux doses d'application suivantes :

Cultures	Cibles	Dose d'emploi (kg/ha)	Volume de dilution	nombre maximal d'applications	Stade d'application	Délai avant récolte
Vigne	oïdium de la vigne (*Uncinula necator*)	0.1	800-1000	7	BBCH 14-79	14

SHIP 10 WG

Granulés dispersibles dans l'eau (WG) contenant 100 g/kg de cyproconazole

AMM n° XXXXXXXXX délivrée le XX/XX/XXXX par le Ministère de l'agriculture, de l'agro-alimentaire et de la forêt

FONGICIDE / VIGNE

SHIP 10 WG est un fongicide à usage agricole et professionnel uniquement, pouvant être utilisé sur la vigne

SHIP 10 WG se présente sous de granulés dispersibles dans l'eau (WG) contenant 100g/kg de cyproconazole.

Poids net: XXXXX **Date de fabrication : XX/XX/XXXX**

Lot N°: XXXXX **Date d'expiration: XX/XX/XXXX**

Détenteur d'homologation:
SHARDA EUROPE b.v.b.a.
Jozef Mertensstraat, 142
1702 Dilbeek
Belgique

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).

SGH08 SGH09

ATTENTION

Mentions de danger:
H361d : Susceptible de nuire au fœtus.
H411 : Toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme

Conseils de prudence:
P201 : Se procurer les instructions avant utilisation
P281 : Utiliser l'équipement de protection individuel requis
P308+P313 : EN CAS d'exposition prouvée ou suspectée: consulter un médecin
P273 : Éviter le rejet dans l'environnement
P391 : Recueillir le produit répandu.
P501 : Éliminer le contenu/récipient à une installation approuvée d'élimination des déchets.
EUH401 Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.

Sp1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Eviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

ÉQUIPEMENT DE PROTECTION:

Pendant la phase de mélange/chargement Combinaison de travail tissée en coton/polyester (35%/65%) avec un grammage d'au moins 230 g/m² avec traitement déperlant, Gants en nitrile certifiés EN 374-3

Pendant la phase d'application: Combinaison de travail tissée en coton/polyester (35%/65%) avec un grammage d'au moins 230 g/m² avec traitement déperlant. Si application avec tracteur sans cabine: Gants en nitrile certifiés EN 374-3, . Si application avec tracteur avec cabine : Gants en nitrile certifiés EN 374-3 à usage unique lors d'interventions sur le matériel de pulvérisation. Dans ce cas les gants doivent être stockés à l'extérieur de la cabine,

Pendant phase de nettoyage du matériel: Combinaison de travail tissée en coton/polyester (35%/65%) avec un grammage d'au moins 230 g/m² avec traitement déperlant. Gants en nitrile certifiés EN 374-3.