REGISTRATION REPORT

Part A

Risk Management

Product name(s): FOLPEC LIQUIDE 50 SC

Active Substance:

Folpet, 500 g/L

COUNTRY: FRANCE

Interzonal

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: Sapec Agro S.A.

Date: 2018-09-17

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PART A – Risk Management

The company Sapec Agro S.A. has requested a new application in France for the product FOLPEC LIQUIDE 50 SC, containing 500 g/L folpet 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 FOLPEC LIQUIDE 50 SC where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of FOLPEC LIQUIDE 50 SC have been made using endpoints agreed in the EU peer review of folpet.

This document describes the specific conditions of use and labelling required for France for the registration of FOLPEC LIQUIDE 50 SC.

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 Sapec Agro S.A.'s application to market FOLPEC LIQUIDE 50 SC in France as a fungicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for outdoor uses 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. France acted as an interzonal Rapporteur Member State (izRMS) for indoor uses for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the European Union.

1.2 Active substance approval

Folpet

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 can be authorised. PART B In assessing applications to authorise plant protection products containing folpet for uses other than winter wheat 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 folpet, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 29 September 2006 shall be taken into account. In this overall assessment Member States must pay particular attention to: - operators and workers safety. Authorised conditions of use must prescribe the application of adequate

personal protective equipment; - the dietary exposure of consumers in view of future revisions of Maximum Residue Levels; - the protection of birds, mammals, aquatic and soil organisms. Conditions of authorisation should include risk mitigation measures. The Member States concerned shall request the submission of further studies to confirm the risk assessment for birds, mammals and earthworms. They shall ensure that the notifiers at whose request folpet has been included in this Annex provide such studies to the Commission within two years from the approval.
An EFSA conclusion is available (EFSA Scientific Report (2009) 297, 1-80). A Review Report is available (SANCO/10032/2006 rev. 5, 11 July 2008).

1.3 Regulatory approach

The present application (2013-1240) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)[1] in the context of the zonal procedure for all Member States of the European Union, taking into account the worst-case uses ("risk envelope approach")[2] – the highest application rates over the European Union. 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 4th May 2017[3] 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[4], 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[5], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[6] provides that:
- an authorisation granted for a "reference" crop applies also for "linked" crops, unless formally stated in the Decision

[1] French Food Safety Agency, Afssa, before 1 July 2010

[2] 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

[3] 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

[4] 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

[5] 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

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

- 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[7] 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 FOLPEC LIQUIDE 50 SC, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

Not necessary: the applicant has provided equivalent studies to the original applicant’s Annex II dossier.

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

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	FOLPEC LIQUIDE 50 SC
Authorisation number	Not applicable
Function	fungicide
Applicant	Sapec Agro S.A.
Composition	500 g/L folpet
Formulation type (code)	suspension concentrate (SC)
Packaging	N/A: not registered in France.

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

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

Physical hazards	-	
Health hazards	Carcinogenicity, Hazard Category 2 Eye irritation, Hazard Category 2 Skin sensitisation, Hazard Category 1A	
Environmental hazards	Hazardous to the aquatic environment, Acute, Hazard Category 1	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H317	May cause an allergic skin reaction
	H319	Causes serious eye irritation
	H351	Suspected of causing cancer
	H400	Very toxic to aquatic life
Precautionary statements –	***For the P phrases, refer to the extant legislation***	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	-	- Contains 1,2-benzisothiazol-3(2H)-one

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

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

N/A: not registered in France.

2.2.4 Other phrases linked to the preparation

N/A: not registered in France.

2.3 Product uses

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: 2018-09-17

PPP (product name/code) **FOLPEC LIQUIDE 50 SC**
active substance 1 **folpet**
Applicant: **Sapec Agro S.A.**
Zone(s): **interzonal**
Verified by MS: **yes**

Formulation type: **SC**
Conc. of as 1: **500 g/L**
professional use ☒
non-professional use ☐

Crop and/ or situation (a)	Zone	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
				Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Wine grapes	SEU	F	*Plasmopara viticola, Phomopsis* spp.	SC	500 g/L	Foliar spray (Handheld and tractor application)	BBCH 07- 85	10	7-28 days	0.15-15	100-1000	1.5	28	**Not acceptable (risk for aquatic organisms and non-target arthropods)**
Tomato and Eggplant	SEU	F	*Alternaria, Cladosporium, Colletotrichum, Septoria, Botrytis, Phythophthora infestans*	SC	500 g/L	Foliar spray (Handheld and tractor application)	BBCH 13-89	4	7-28 days	0.125-0.250	500-1000	1.25	7	**Not acceptable for tomato (missing efficacy data, risk for aquatic organisms and non-target arthropods)** **Not acceptable for eggplant (MRL non-compliance)**

Crop and/ or situation (a)	Zone	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
				Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Tomato and Eggplant	SEU	G	*Alternaria, Cladosporium, Colletotrichum, Septoria, Botrytis, Phythophthora infestans*	SC	500 g/L	Foliar spray (Handheld application)	BBCH 13-89	3	7-28 days	0.096-0.125	1000 - 1300	1.25	7	**Not acceptable for tomato (missing efficacy data)** **Not acceptable for eggplant (MRL non-compliance)**

Remarks:
(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at 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
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) 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

FOLPEC LIQUIDE 50 SC is a suspension concentrate (SC). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is a cream liquid, with a characteristic odour. It is not explosive and has no oxidizing properties. The product is not flammable and has no flash point. It has no self-ignition temperature up to 400°C. In aqueous solution (1%), it has a pH value of 7.6 at 25.4°C. There is no effect of low and high temperature on the stability of the formulation, after 7 days at 0°C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE commercial packaging. Persistent foaming test and suspensibility test are required in post registration at the maximum use concentration.

Its technical characteristics are acceptable for a SC formulation.

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

3.1.2 Methods of analysis

Analytical methods for the determination of the active substance and the relevant impurities (carbon tetrachloride and perchloromethylmercaptan) in the formulation are available and validated. Nevertheless, the specificity of the method for the determination of the relevant impurities in the formulation should be demonstrated and is required in post-registration.

Analytical methods are available in the DAR/this dossier and validated for the determination of residues of folpet in plants (grapes and tomatoes), soil, water (surface and drinking) and air.

Analytical methods for the determination of residues of folpet in foodstuffs of animal origin are not necessary.

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

3.1.3 Mammalian Toxicology

The following endpoints were used in risk assessment.

Active Substance: **folpet**			
ADI	0.1 mg kg bw/d		EU2007
ARfD	0.2 mg/kg bw		
AOEL	0.1 mg/kg bw/d		
Dermal absorption	Based on an *in vitro*/human study performed on formulation, according to the guidance on dermal absorption (EFSA 2012):		
		Concentrate (tested) 500 g/L	Diluted formulation (tested) 1.5 g/L
	In vitro (human) %	0.5	6.5
		Concentrate (used in formulation) 500 g/L	Spray dilution (used in formulation) 0.96 g/L
	Dermal absorption endpoints %	**0.5 %**	**10%**

3.1.3.1 Acute Toxicity

FOLPEC LIQUIDE 50 SC containing 500 g/L folpet has a low toxicity in respect to acute oral, dermal and inhalation toxicity and is no irritating to the rabbit skin. However, the formulation is harmful by inhalation, irritating to eyes and it is a skin sensitizer.

3.1.3.2 Operator Exposure

The critical use patterns (worst cases) are summarized hereafter.

Crop	F/G[8]	Equipment	Application rate L product/ha	Spray dilution (L/ha)	Model
Vine	F	Tractor mounted/trailed broadcast air-assisted	3 L/ha (1562 g as/L)	100	BBA
		Hand-held/hydraulic nozzles: high level target			
Tomato and eggplant	F	Tractor mounted/trailed boom sprayer: hydraulic nozzles	2.5 L/ha (1302 g as/L)	500	BBA
	G	Lance		1000	BBA

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

Crop	Equipment	PPE and/or working coverall	% AOEL folpet
Vine	Tractor mounted/trailed broadcast air-assisted	Working coverall and gloves during mixing/loading and application	43
	Hand-held/hydraulic nozzles: high level target		29
Tomato and eggplant	Tractor mounted/trailed boom sprayer: hydraulic nozzles		11
	Lance (mixing and loading: Tractor mounted/trailed boom sprayer: hydraulic nozzles Application: Hand-held/hydraulic nozzles: high level target)		21

According to the model calculations, it can be concluded that the risk for the operator using FOLPEC LIQUIDE 50 SC is acceptable with a working coverall (90% protection factor) and gloves during mixing/loading and application.

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

3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to EUROPOEM. Exposure is estimated to 11 % of the AOEL of folpet.

It is concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to FOLPEC LIQUIDE 50 SC.

3.1.3.4 Resident Exposure

Residential exposure was assessed according to EUROPOEM II. Exposure was estimated to be 1.1 % and 4 % of the AOEL of folpet, respectively for adults and children. It may be concluded that there is no unacceptable risk to the resident exposed to FOLPEC LIQUIDE 50 SC.

Based on the currently available data (2001-2006) in the report of the ORP (French pesticides residues observatory), the respiratory exposure of people living near sprayed areas was estimated, as follows:

Folpet

[8] Open field or glasshouse

		% ADI	% ADI
Maximum daily measurement (3950 ng/m³)	Adult	1.6	1.6
	Child	2.2	2.2
Maximum weekly measurement (82 ng/m³)	Adult	< 0.1	< 0.1
	Child	< 0.1	< 0.1

3.1.3.5 Worker Exposure

Workers may have to enter treated areas after treatment for crop harvesting activities. Therefore, estimation of worker exposure was calculated according to EUROPOEM II. Exposure is estimated to 94 % of the AOEL of folpet.

It is 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 FOLPEC LIQUIDE 50 SC.

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

3.1.4 Residues and Consumer Exposure

Overall conclusion for outdoor uses
The data available are considered sufficient for risk assessment. An exceedance of the current MRL for folpet as laid down in the Regulation (EU) No 396/2005 is not expected except for eggplant.

The chronic and the short-term intakes of folpet residues resulting from the uses proposed in the framework of this application are unlikely to present a public health concern.

As far as consumer health protection is concerned, zRMS agrees with the authorization of the proposed uses.

According to available data, no specific mitigation measures should apply.

Data gaps: none.

Data required post-authorisation: none

Table -1: Summary for folpet

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg EU 2016/156	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
/	Wine grapes	Yes	Yes (12 NEU and 17 SEU)	Yes	Yes	Yes	No	No	-
/	Tomato	Yes	Yes (8 SEU)	Yes	Yes	Yes		No	-
/	Eggplant	Yes	Yes (8 SEU on tomatoes) (extrapolation from tomatoes)	Yes	Yes	No		No	Use not supported because of MRL exceedance

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

For eggplant, in force MRL of 0.03 * mg/kg (Reg EU N°2016/156) is exceeded. Use on eggplant is not supported.

The effects of processing on the nature of folpet residues have been investigated. Data on effects of processing on the amount of residue have been submitted.
These data were considered for risk assessment.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Table-2: Information on FOLPEC LIQUIDE 50 SC

Crop	PHI for FOLPEC LIQUIDE 50 SC proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for FOLPEC LIQUIDE 50 SC proposed by zRMS	zRMS Comments (if different PHI proposed)
		Folpet		
Wine grapes	28 days	Yes	28 days	
Tomato	7 days	Yes	7 days	

NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Overall conclusion for indoor uses

The data available are considered sufficient for risk assessment. An exceedance of the current MRL for folpet as laid down in the Regulation (EU) No 396/2005 is not expected except for eggplant.

The chronic and the short-term intakes of folpet residues resulting from the uses proposed in the framework of this application are unlikely to present a public health concern.

As far as consumer health protection is concerned, France agrees with the authorization of the proposed uses.

According to available data, no specific mitigation measures should apply.

Data gaps: none.

Data required in post-authorisation: none.

Table -3: Summary for folpet

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg EU 2016/156	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
/	Tomato	Yes	Yes (14 indoor)	Yes	Yes	Yes	No	No	
/	Eggplant	Yes	Yes (14 indoor on tomatoes) (extrapolation from tomatoes)	Yes	Yes	No		No	Use not supported because of MRL exceedance

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

For eggplant, in force MRL of 0.03 * mg/kg (Reg EU 2016/156) is exceeded. Use on eggplant is not supported.

The effects of processing on the nature of folpet residues have been investigated. Data on effects of processing on the amount of residue have been submitted.
These data were considered for risk assessment.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Table-4: Information on FOLPEC LIQUIDE 50 SC

Crop	PHI for FOLPEC LIQUIDE 50 SC proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for FOLPEC LIQUIDE 50 SC proposed by zRMS	zRMS Comments (if different PHI proposed)
		Folpet		
Tomato	7 days	Yes	7 days	

NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of the Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate 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 of folpet and its metabolites in soil, 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.

For all field uses, the PEC of folpet in surface water have not been calculated adequately and thus risk assessment for aquatic organisms could not be finalized for field uses.

For tomato use under glasshouse, the PEC in surface water has been calculated considering a loss of 0.1% of the active substance to the standard surface water body and is used for the ecotoxicological risk assessment.

PECgw for folpet and its metabolite do not occur at levels exceeding those mentioned in the Regulation (EC) No 1107/2009 and the guidance document SANCO 221/2000 for field uses. For tomato use under glasshouse, groundwater contamination is considered negligible.

Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses in open field and under glasshouse.

Based on vapour pressure, information on volatilisation from plants and soil, and DT50 calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.6 Ecotoxicology

The ecotoxicological risk assessment of the formulation was performed according to the requirements of the Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review 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 bees, earthworms and other soil macro-organisms, micro-organisms and non-target plants are acceptable for the intended uses.

For birds and mammals, the risks are acceptable when the interval between applications are minimum 10 days for tomato and 14 days for vine but was not finalized for secondary poisoning for fish-eating birds and mammals.

For aquatic organisms, the exposure calculation was not validated by zRMS so the risk to aquatic organisms was not finalized.

For non-target arthropods, as no sufficient data was submitted with FOLPEC LIQUIDE 50 SC, the risk was not considered acceptable for these organisms.

For uses in greenhouse, the risks for bees, non-target arthropods, earthworms and other soil macro-organisms, micro-organisms and non-target plants are acceptable for the intended uses.

3.1.7 Efficacy

FOLPEC LIQUIDE 50 SC efficacy is considered as satisfying for its uses on grapevine. **However, as a very low data package was provided, the evaluation of the efficacy of FOLPEC LIQUIDE 50 SC is considered as unfinalisable for the use on tomato *Phytophthora infestans*. Furthermore, no data was provided on the other claimed tomato pathogens. Therefore, zRMS expresses an unfavourable opinion on those targets.**

FOLPEC LIQUIDE 50 SC risk of phytotoxicity to the host crop is considered as negligible for its uses on grapevine. However, as a very low data package was provided, the evaluation of FOLPEC LIQUIDE 50 SC risk of phytotoxicity is considered as unfinalisable for its use on tomato.

The risks of negative impact on yield, quality, wine making, multiplication, succeeding and adjacent crops are considered as negligible.

The risk of resistance appearance or development is considered as low.

Crop and/ or situation	Pests or Group of pests controlled	Application rate per treatment	Max number of appli.	Opinion	Comments
Wine grapes	*Plasmopara viticola, Phomopsis* spp.	3 L/ha	10	Favourable	-
Tomato (field)	*Phytophthora infestans* ~~***Alternaria, Cladosporium, Colletotrichum, Septoria, Botrytis***~~*****	2.5 L/ha	4	Impossible to conclude with the low data package provided	This use has to be decided at a national level, regarding wether or not preparations delivering 1500 g/ha of folpet are registered to control this target.

*** No data provided**

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation cannot be granted.

Some uses are not supported because of an exceeding of the MLR of the active substance,

In field, risk for aquatic organisms cannot be excluded considering that the estimated exposure levels for these organisms do not take in account some parameters,

In field, risk to non-target arthropods cannot be excluded in the absence of sufficient toxicity data with the product,

The efficacy cannot be demonstrated on some uses in absence of sufficient data.

A copy of the decision issued can be found in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

N/A: not registered in France.

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 France.

3.4.2 Post-authorisation data requirements

N/A: not registered in France.

3.4.3 Label amendments

N/A: not registered in France.

Appendix 1 – Copy of the French Decision

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RÉPUBLIQUE FRANÇAISE

anses

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 ***FOLPEC LIQUIDE 50 SC***

de la société *SAPEC AGRO S.A.*

enregistrée sous le *n°2013-1240*

Vu les conclusions de l'évaluation de l'Anses du 21 août 2017,

Considérant qu'aux bonnes pratiques revendiquées, certains usages sont susceptibles d'entraîner un dépassement des limites maximales de résidus de la substance active,

Considérant que les niveaux d'exposition estimés pour les organismes aquatiques ne prennent pas en compte certains paramètres et que le risque pour ces organismes ne peut être exclu en plein champ,

Considérant qu'en l'absence de données de toxicité suffisantes réalisées avec le produit sur les arthropodes non cibles, le risque pour ces organismes ne peut être exclu en plein champ,

Considérant qu'en l'absence de données suffisantes l'efficacité ne peut être démontrée sur certains usages en plein champ et sous abri,

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.

FOLPEC LIQUIDE 50 SC
AMM n°-

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Informations générales sur le produit	
Nom du produit	FOLPEC LIQUIDE 50 SC
Type de produit	Produit de référence
Titulaire	SAPEC AGRO S.A. 3°A, Parque das Nacoes Alameda dos Oceanos Lote 1.06.1.1 1990-207 Lisboa PORTUGAL
Formulation	Suspension concentrée (SC)
Contenant	500 g/L - folpel
Numéro d'intrant	907-2013.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usages	Professionnel

A Maisons-Alfort, le 17 SEP. 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)
16953207 Tomate*Trt Part.Aer.*Maladies des taches brunes	2,5 L/ha	3/an	7
	Motivation du refus : L'usage sur aubergine est refusé à 3 et 4 applications par an en raison d'un risque de dépassement des limites maximales de résidus de la substance active en vigueur. L'usage sur tomate est refusé en raison de l'absence de données efficacité et, en plein champ, l'usage est refusé également à 4 applications par an en raison de l'absence d'éléments permettant d'exclure un risque d'effets nocifs pour les organismes aquatiques et les arthropodes non cibles.		
16953201 Tomate*Trt Part.Aer.*Mildiou(s)	2,5 L/ha	3/an	7
	Motivation du refus : L'usage sur aubergine est refusé à 3 et 4 applications par an en raison d'un risque de dépassement des limites maximales de résidus de la substance active en vigueur. L'usage sur tomate est refusé en raison d'un nombre insuffisant de données efficacité fournis et, en plein champ, l'usage est refusé également à 4 applications par an en raison de l'absence d'éléments permettant d'exclure un risque d'effets nocifs pour les organismes aquatiques et les arthropodes non cibles.		
16953203 Tomate*Trt Part.Aer.*Pourriture grise et sclérotinioses	2,5 L/ha	3/an	7
	Motivation du refus : L'usage sur aubergine est refusé à 3 et 4 applications par an en raison d'un risque de dépassement des limites maximales de résidus de la substance active en vigueur. L'usage sur tomate est refusé en raison de l'absence de données efficacité et, en plein champ, l'usage est refusé également à 4 applications par an en raison de l'absence d'éléments permettant d'exclure un risque d'effets nocifs pour les organismes aquatiques et les arthropodes non cibles.		

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Liste des usages refusés			
Usages	**Dose d'emploi**	**Nombre maximum d'applications**	**Délai avant récolte (jours)**
12703202 Vigne*Trt Part.Aer.*Excoriose	3 L/ha	10/an	28
	Motivation du refus : L'usage est refusé en raison de l'absence d'éléments permettant d'exclure un risque d'effets nocifs pour les organismes aquatiques et les arthropodes non cibles.		
12703203 Vigne*Trt Part.Aer.*Mildiou(s)	3 L/ha	10/an	28
	Motivation du refus : L'usage est refusé en raison de l'absence d'éléments permettant d'exclure un risque d'effets nocifs pour les organismes aquatiques et les arthropodes non cibles.		

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

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FONGICIDE

FOLPEC LIQUIDE 50 SC®

Suspension Concentrée (SC)

contenant 500 g/l de folpel

Fongicide Liquide Vigne et Tomate

Autorisation de Mise sur le Marché n° XXXXXX

« RÉSERVÉ À UN USAGE EXCLUSIVEMENT PROFESSIONNEL »

Homologué par:

SAPEC AGRO S.A.

Avenida do Rio Tejo - Herdade das Praias

2910-440 SETÚBAL - PORTUGAL

Tel: +351 265710100

Lot N°.....

Date de fabrication :

Prepared by Sapec Agro SA

FOLPEC LIQUIDE 50 SC®
Suspension Concentrée contenant 500 g/l de folpel
AMM n° XXXXXX

SGH07

SGH08

DANGER

SGH09

H332	**Nocif par inhalation.**
H319	**Provoque une sévère irritation des yeux.**
H351	**Susceptible de provoquer le cancer.**
H317	**Peut provoquer une allergie cutanée.**
H400	**Très toxique pour les organismes aquatiques.**

P102	Tenir hors de portée des enfants.
P201	Se procurer les instructions avant l'utilisation.
P260	Ne pas respirer les aérosols.
P262	Éviter tout contact avec les yeux, la peau ou les vêtements.
P270	Ne pas manger, boire ou fumer en manipulant le produit.
P273+391	Éviter le rejet dans l'environnement.
P280	Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage.
P301+310	EN CAS D'INGESTION: appeler immédiatement un CENTRE ANTIPOISON ou un médecin.

S36/37	Porter un vêtement de protection et des gants appropriés.
S42	Pendant les pulvérisations, porter un appareil respiratoire approprié.
S46	En cas d'ingestion, consulter immédiatement un médecin et lui montrer l'emballage ou l'étiquette.
S61	Éviter le rejet dans l'environnement. Consulter les instructions spéciales/la fiche de données de sécurité.

Conditions d'emploi
Respectez les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement.
- Délai de rentrée des travailleurs sur la parcelle: 48 heures après traitement
-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 20 mètres, incluant une bande tampon végétalisée, par rapport aux points d'eau

Distributeur :

La fiche de données de sécurité est disponible sur demande chez votre fournisseur de produits phytopharmaceutiques et elle est également téléchargeable et imprimable à partir des sites www.sapecagro.fr et www.quickfds.com.

En cas d'urgence **appelez le n° 15 ou le Centre Anti-poison** (Paris : 01 40 05 48 48), puis signalez vos symptômes au réseau Phyt'attitude, n° vert 0 800 887 887 (appel gratuit depuis un poste fixe).

Fabriqué au PORTUGAL **Contenu : XX L e**

FOLPEC LIQUIDE® -Marque déposée par SAPEC AGRO
SAPEC AGRO, S.A. Avenida do Rio Tejo - Herdade das Praias, 2910-440 Setúbal – Portugal

FOLPEC LIQUIDE 50 SC
500 g/l de folpel

PRESENTATION ET MODE D'ACTION
Le folpel est actif sur un grand nombre de champignons parasites en inhibant la germination des spores.
FOLPEC LIQUIDE® 50 SC est un fongicide multisite qui agit préventivement et par contact sur les maladies de la vigne et de la tomate. Il est doté d'une bonne persistance et d'une action stimulante sur la végétation.

USAGES, DOSES, SPECIFICATIONS D'USAGE, DELAI AVANT RECOLTE (DAR), ZONE NON TRAITEE (ZNT) ET MENTIONS ABEILLES.

Culture	Cibles & Usages	Dose (L/ha)	Nombre d'applications	Intervalle minimum entre applications	DAR (jours)	ZNT (en m)	Délai réentrée (heures)
Vigne	Excoriose	3	10	7 jours	28		48
	Mildiou	3	10	7 jours	28		
Tomate (plein champ)	Alternariose	2.5	4	7 jours	7		
	Cladosporiose	2.5	4	7 jours	7		
	Septoriose	2.5	4	7 jours	7		
	Pourriture grise	2.5	4	7 jours	7		
Tomate (sous serre)	Alternariose	3.2	3	7 jours	7		
	Cladosporiose	3.2	3	7 jours	7		
	Septoriose	3.2	3	7 jours	7		
	Pourriture grise	3.2	3	7 jours	7		

Les limites maximales de résidus sont disponibles sur le site : http://ec.europa.eu/sanco_pesticides/public/index.cfm

RECOMMANDATION D'UTILISATION

PREPARATION DE LA BOUILLIE
FOLPEC LIQUIDE 50 SC® s'utilise en pulvérisation après dilution dans l'eau. Remplir la cuve à 3/4 d'eau, mettre sous agitation, agiter le bidon et verser la quantité de FOLPEC LIQUIDE 50 SC® nécessaire puis compléter le remplissage avec la quantité d'eau nécessaire. Maintenir l'agitation jusqu'à la fin de l'application.
Utiliser un volume d'eau de 100 à 1300 l/ha selon la culture, son stade et le matériel de traitement utilisé.

APPLICATION

Sur Vigne

*Excoriose : Le premier traitement peut s'effectuer dès la sortie des premières feuilles (jeune pousse juste visible) dans la limite de 10 applications/an

*Mildiou : Se référer au bulletin de santé du végétal et en cas de lessivage procéder au renouvellement du traitement dans la limite de 10 applications/an

Respecter le délai d'emploi avant récolte de 28 jours.

Dernière application BBCH 85.

Sur Tomate :

Tomate, en champ: Effectuer un maximum de 4 traitements du stade de 3-4 feuilles jusqu'à 7 jours avant la récolte avec un maximum de 2.5L/ha par traitement.

Tomate, en serre: Effectuer un maximum de 3 traitements du stade de 3-4 feuilles jusqu'à 7 jours avant la récolte avec un maximum de 3.2L/ha par traitement.

Dernière application BBCH 89.

CONDITIONS D'EMPLOI

COMPATIBILITÉ' - Le produit n'est pas miscible avec la bouillie bordelaise et Huile blanche ou autre produit Huileux.

Egalement pour tout mélange autorisé il est préférable de tester la compatibilité physique des produits.

PHYTOTOXICITE - Un délai de 20 jours est nécessaire après une application avec des huiles minérales et produits à la base de soufre.

MELANGES
Les mélanges doivent être mis en œuvre conformément à la législation en vigueur et aux recommandations des guides de bonnes pratiques des officiels.
Consulter le site : http://e-phy.agriculture.gouv.fr

PRECAUTIONS D'EMPLOI
- Conserver FOLPEC LIQUIDE 50 SC® dans son emballage d'origine et le stocker dans un local phytosanitaire conforme et fermé à clé. Conserver hors de porte des enfants, à l'écart des aliments et boissons y compris ceux pour animaux.

- Pendant la préparation de la bouillie et au cours de l'application :
    - Porter un vêtement de protection et des gants appropriés.
    - Ne pas traiter les cours d'eau et fossés en eau. Appliquer la bouillie dans les cultures par temps calme, sans vent fort pour éviter toute dérive de pulvérisation vers les fossés, cours d'eau, chemins, abords de ferme ou bâtiments.
    - Appliquer, après dilution, les fonds de cuve conformément à la législation en vigueur.

- Emballage :
    - Réemploi de l'emballage interdit ; rincer soigneusement le bidon en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur, ou dans la cuve de rinçage pour l'injection directe.
    - Éliminer les emballages vides *via* une collecte organisée par un service de collecte spécifique.
    - Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.

Important
Respecter les usages, doses, conditions et précautions d'emploi mentionnées sur l'emballage. Elles ont été déterminées 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…

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 issues des cultures protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur.

Appendix 3 – Letter(s) of Access

Not applicable.