REGISTRATION REPORT

Part A

Risk Management

Product code: LBG-51FCm

Product name: VAHINE

Chemical active substances:

captan, 360 g/L
potassium phosphonates, 660 g/L
(phosphonic acid equivalent, 440 g/L)

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: ADAMA France S.A.S.

MS Finalisation Date: 2020/07/02

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PART A
RISK MANAGEMENT

1 Details of the application

The company ADAMA France S.A.S. has requested a marketing authorisation in France for the product VAHINE (product code: LBG-51FCm), containing 360 g/L captan[1] and 660 g/L potassium phosphonates[2], 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 addendum 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 VAHINE (product code: LBG-51FCm) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of VAHINE (product code: LBG-51FCm) have been made using endpoints agreed in the EU peer reviews of captan and potassium phosphonates.

This document describes the specific conditions of use and labelling required for France for the registration of VAHINE (product code: LBG-51FCm).

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

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

Appendix 3 of this document contains a copy of the Letter(s) of Access.

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1.1 Application background

The present registration report concerns the evaluation of ADAMA France S.A.S.'s application to market VAHINE (product code: LBG-51FCm) in France as a fungicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

The present application (2019-0301) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[3] – the highest application rates 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[4], implementing regulations, and French regulations.

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

2 Commission Implementing Regulation (EU) No 369/2013 of 22 April 2013 approving the active substance potassium phosphonates, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

3 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 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 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 on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011[5], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

1.2 Letters of Access

Not necessary for the active substance captan: the applicant is the owner of the active substance.

The applicant has provided a letter of access for the active substance potassium phosphonates.

1.3 Justification for submission of tests and studies

According to the applicant:

"*All tests and studies were prepared and submitted in support of the assessment as required according to 284/2013 EU*."

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of VAHINE (product code: LBG-51FCm), 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	LBG-51FCm.
Product name in MS	VAHINE
Authorisation number	-
Low risk (article 47)	No.
Function	Fungicide.
Applicant	ADAMA France S.A.S.
Active substances (incl. content)	Captan, 360 g/L. Potassium phosphonates, 660 g/L.
Formulation type	Suspension concentrate [SC].
Packaging	N/A : no marketing authorisation granted
Coformulants of concern for national authorisations	-
Restrictions related to identity	-

[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

Mandatory tank mixtures	None.
Recommended tank mixtures	None.

2.2 Conclusion

The evaluation of the application for VAHINE (product code: LBG-51FCm) resulted in **the decision to refuse the authorisation**.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Acute toxicity (inhalation), category 4. Eye irritation, category 2. Skin sensitisation, category 1. Carcinogenicity, category 2. Hazardous to the aquatic environment - Acute Hazard, category 1.
Hazard pictograms:	
Signal word:	Warning.
Hazard statement(s):	H317: May cause an allergic skin reaction. H319: Causes serious eye irritation. H332: Harmful if inhaled. H351: Suspected of causing cancer. H400: Very toxic to aquatic life.
Precautionary statement(s):	***For the P phrases, refer to the extant legislation.***
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use [EUH401]. Contains 1,2-benzisothiazol-3(2*H*)-one and poly(oxy-1,2-ethanediyl), α-[2-(tert-dodecylthio)ethyl]-ω-hydroxy-.

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

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

N/A : no marketing authorisation granted

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

1107/2009)

N/A : no marketing authorisation granted.

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[6] 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[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 "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[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.

2.5.1 Restrictions linked to the PPP

N/A : no marketing authorisation granted

2.5.2 Specific restrictions linked to the intended uses

N/A : no marketing authorisation granted

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

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

2.6 Intended uses (only NATIONAL GAP)

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

GAP rev. 1, date: 2020-07-02

PPP (product name/code):	LBG-51FCm / VAHINE	Formulation type:	SC [a, b]
Active substance 1:	Captan (c)	Conc. of a.s. 1:	360 g/L [c]
Active substance 2:	Potassium phosphonates (pp)	Conc. of a.s. 2:	660 g/L [c]
Safener:	-	Conc. of safener:	-
Synergist:	-	Conc. of synergist:	-
Applicant:	ADAMA France S.A.S.	Professional use:	☒
Zone(s):	Southern [d]	Non-professional use:	☐
Verified by MS:	Yes		

Field of use:	Fungicide

LBG-51FCm/ VAHINE
Part A - National Assessment
FRANCE

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	Apple, pear, quince	F	Scab (*Venturia inaequalis / Venturia pyrina),* Brown spot *(Stemphylium vesicarium*) Foliar diseases: ashy leaf spot *(Myco-sphaerella pyri)* rust *(Gymnosporangium fuscum)* and *Entomosporium macula-tum.* Early diseases on fruits: Sooty blotch (*Gloeodes pomigena*), Flyspeck (*Schizothyrium pomi*) *Botrytis cinerea, Botr-yosphaeria obtusa*	Foliar spray	BBCH 09-81 March- July	a) 1 b) 3	10	a) 3 b) 9	a) 1080 (c) + 1980 (pp) b) 3240 (c) + 5940 (pp)	500-1000	28	**Not acceptable** (worker, bystander and resident (child))

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.

LBG-51FCm/ VAHINE
Part A - National Assessment
FRANCE

Remarks columns:	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States		
	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)	8	The maximum number of application possible under practical conditions of use must be provided.
	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	9	Minimum interval (in days) between applications of the same product
			10	For specific uses other specifications might be possible, e.g.: g/m^3 in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
			12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
	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.	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)

The product VAHINE (product code: LBG-51FCm) is a green (olive-like), viscous suspension, with specific organic odour. It is a suspension concentrate, containing 360 g/L captan and 660 g/L potassium phosphonates (TC). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. It is not explosive, has no oxidising properties and is not flammable. It has a self-ignition temperature of 325 °C. In aqueous solution (1 %), it has a pH value of 4.59 at 21.2 °C. There is no effect of low and high temperatures on the stability of the formulation, since after seven days at 0 °C and eight weeks at 40 °C, neither the active substances' content nor the technical properties were changed. However, phase separation was noticed after low-temperature storage. The stability data (interim report) indicate a shelf life of two years at ambient temperature when stored in HDPE packaging. The technical characteristics are acceptable for an SC formulation. The formulation must be stored at a temperature below 40 °C. The formulation must be shaken before use.

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

3.3 Efficacy data

The efficacy level of VAHINE (product code: LBG-51FCm) is considered satisfactory for all the requested uses. Efficacy is proved on *Gloeodes pomigena* and *Schizothyrium pomi*

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

The risk of resistance developing or appearing to captan and potassium phosphonates does not require monitoring for the requested uses.

3.3.2 Adverse effects on treated crops

The phytotoxicity level of VAHINE (product code: LBG-51FCm) is considered acceptable for all the requested uses.

3.3.3 Observations on other undesirable or unintended side-effects

The risks of negative impact on yield, quality, cider-making, propagation and adjacent crops are considered negligible.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

Analytical methods for the determination of the active substances and the relevant impurities (folpet, carbon tetrachloride, perchloro-methyl-mercaptan from captan) in the formulation are available and validated.

3.4.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Reports (DARs) and this dossier and validated for the determination of residues of potassium phosphonates and captan in plants (high-water-content crops), foodstuffs of animal origin, soil, water (surface and drinking) and air.

An analytical method is available in this dossier and validated for the determination of residues of captan in tissues and body fluids.

3.5 Mammalian toxicology (Part B, Section 6)

Active substance	**Potassium phosphonates**		**Captan**	
ADI	2.25 mg/kg bw/d	EU (01/10/2013)	0.1 mg/kg bw/d	EU (01/10/2007)
ARfD	NA		0.3 mg/kg bw	
AOEL	5 mg/kg bw/d		0.1 mg/kg bw/d	
AAOEL	-		-	
Dermal absorption (%)	Based on an *in vitro* human study performed on the formulation according to revised guidance on dermal absorption (Efsa 2017)			
	Concentrate (tested) 422 g/L	Dilution (tested) 0.70 g/L	Concentrate (tested) 360 g/L	Dilution (tested) 0.60 g/L
	0.15	4	0.67	22
Oral absorption (%)	100			

3.5.1 Acute toxicity

VAHINE (product code: LBG-51FCm), containing 660 g/L potassium phosphonates (440 g/L phosphonic acid equivalent) and 360 g/L captan, has a low acute oral and dermal toxicity. It is harmful if inhaled, a serious eye irritant and a skin sensitiser. It is also a carcinogen (cat. 2).

3.5.2 Operator exposure

Considering the proposed uses, operator systemic exposure was estimated using the French study from the EFSA model[9]:

[9] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)

		Captan		Potassium phosphonates	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Outdoor upward spraying, vehicle-mounted, pome fruit					
Application rate:		1080 g a.s./ha		1980 g a.s./ha	
EFSA Model Spray application HCTM Body weight: 60 kg	No PPE*	0.4809	**480.90**	0.1105	2.21
	Gloves mixing/loading and application	0.0561	56.11	0.0162	0.32

* No PPE: Operator wearing long sleeved shirt, long trousers

According to the model calculations, it may be concluded that the risk for the operator using VAHINE (product code: LBG-51FCm) 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.

3.5.3 Worker exposure

EFSA model: Workers may have to enter treated areas after treatment for crop inspection/irrigation or cutting, sorting, bundling, carrying, hand-harvesting, maintenance, or searching/reaching/picking activities. Therefore, estimation of worker exposure was calculated according to the AOE model. Exposure is summarised in the table below:

		Captan		Potassium phosphonates	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Searching, reaching, picking Outdoor, upward application, vehicle-mounted					
Number of applications and application rate:		3×1080 g a.s./ha		3×1320 g a.s./ha	
8 hours/day, DT_{50}: 30 days DFR = 3 µg/cm²/kg a.s./ha Body weight: 60 kg	Work-wear – arms, body and legs covered TC = 4500 cm²/person/h	1.0366	**1036.55**	0.2303	4.61
	Work-wear and gloves TC = 2250 cm²/person/h	0.5183	**518.28**	0.1152	2.30

It may be concluded that there is an unacceptable risk anticipated for the worker.

3.5.4 Bystander and resident exposure

Residential exposure was assessed according to the EFSA model[10] incorporing a distance of 10 metres from the spray boom and a drift reduction technology. **An unacceptable risk was determined for residents (child), even when mitigation measures such as a buffer zone of 10 metres are taken**:

Model (AOEM) - All pathways (mean)	% AOEL captan	% AOEL potassium phosphonates
Resident (children)	**106.0**	0.66
Resident (adults)	71.49	0.32

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[11].

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*."

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

Overall conclusion

The data available are considered sufficient for risk assessment. No exceedence of the current MRL for captan and potassium phosphonates (MRL set for fosetyl including potassium phosphonates) as laid down in Reg. (EU) 396/2005 is expected.

The chronic and short-term intakes of captan, potassium phosphonates and fosetyl residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, France as zRMS agrees with the authorisation of the intended uses on apple, pear and quince.

According to the available data, the following specific mitigation measures are recommended:

Other fungicide active substances than potassium phosphonates authorised on pome fruit (fosetyl-aluminium or disodium phosphonate) can lead to the presence of phosphonic acid in harvested products. The accumulated use of these active substances on the same plots could lead to an exceedence of the extant MRLs. As a consequence, it is recommended to limit the use of products containing these substances on pome fruit to a total of 13.2 kg equivalent of phosphonic acid per hectare per year.

[10] EFSA Journal 2014;12(10):3874.

[11] 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)

Table: Information on VAHINE (product code: LBG-51FCm) (KCA 6.8)

Crop	**PHI for VAHINE (product code: LBG-51FCm) requested by applicant**	**PHI/withholding period* sufficiently supported for**		PHI for VAHINE (product code: LBG-51FCm) **proposed by zRMS**	**zRMS Comments (if different PHI proposed)**
		Captan	Potassium **phosphonates**		
Apple, pear and quince	28 days	Yes	Yes	28 days	

Waiting periods before planting succeeding crops: Not relevant.

3.7 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 substances and their 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 captan and potassium phosphonates and their 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 substances and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed. According to the classification proposed in the relevant OECD document12, the PECsw values obtained for the intended field uses meet the classification “hypereutrophic” (concentration in water: > 100 µg/L). To protect aquatic ecosystems and to limit the risk of eutrophication, an unsprayed buffer zone of 5 metres to surface water bodies and a permanent planted buffer strip of 5 metres width to the edge of surface water bodies should be respected.

PECgw values for captan, its metabolites and potassium phosphonates (phosphonic acid equivalent) 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 uses.

[12] OECD (1982) Eutrophication of Waters. Monitoring, Assessment and Control.

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 uses.

3.8 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 substances and their 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, bees and other non-target arthropods, earthworms, other soil macro- and micro-organisms and terrestrial plants are acceptable for the intended uses. Risk mitigation measures are required for aquatic organisms.

3.9 Relevance of metabolites (Part B, Section 10)

The metabolites THPI and THPAM are predicted to occur in groundwater at concentrations above 0.75 µg/L. From a toxicological point of view, based on the data available, neither are considered to be relevant metabolites in groundwater according to guidance document SANCO 221/2000.

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

The active substances captan and potassium phosphonates are not approved as candidates of substitution, therefore a comparative assessment is not foreseen.

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 : no marketing authorisation granted.

5.1.2 Post-authorisation data requirements

N/A : no marketing authorisation granted.

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 ***VAHINE***

de la société	*ADAMA FRANCE SAS*
enregistrée sous le	*n°2019-0301*

Vu les conclusions de l'évaluation de l'Anses du 15 mai 2020,

Considérant que l'estimation de l'exposition, liée à l'utilisation du produit, est supérieure au niveau acceptable d'exposition au captane pour le travailleur, le résident enfant et les personnes présentes ;

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.

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Informations générales sur le produit	
Nom du produit	VAHINE
Type de produit	Produit de référence
Titulaire	ADAMA FRANCE SAS 33 rue de Verdun 92156 SURESNES France
Formulation	Suspension concentrée (SC)
Contenant	660 g/L - phosphonates de potassium 360 g/L - captane
Numéro d'intrant	020-2019.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usage	Professionnel

A Maisons-Alfort, le 02 JUIL. 2020

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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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)**
12613203 Pommier*Trt Part.Aer.* Maladies du feuillage	3 L/ha	3/an	28
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour le travailleur, le résident enfant et les personnes présentes.		
12603211 Pommier*Trt Part.Aer.* Maladies précoces des fruits	3 L/ha	3/an	28
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour le travailleur, le résident enfant et les personnes présentes.		
12613208 Pommier*Trt Part.Aer.* Stemphyliose	3 L/ha	3/an	28
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour le travailleur, le résident enfant et les personnes présentes.		
12603203 Pommier*Trt Part.Aer.* Tavelure(s)	3 L/ha	3/an	28
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour le travailleur, le résident enfant et les personnes présentes.		

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.

MODE D'EMPLOI :

Usages et doses homologués :

Libellé de l'usage	Cultures associées pour le produit	Cibles associées pour le produit	Dose homologuée	Nombre maximum d'applications/an/ culture associée	DAR (délai avant récolte)
Pommier*Trt. Part. Aer.*Tavelure(s)	Pommier, Poirier, Cognassier, Nashi, Nèfles, Pommette	Tavelure du pommier, Tavelure du poirier	3L/ha	3	28 jours et dernière application fin juillet
Pommier*Trt. Part. Aer.*Stemphyliose	Pommier, Poirier, Cognassier, Nashi, Nèfles, Pommette	Stemphyliose	3L/ha	3	28 jours et dernière application fin juillet
Pommier*Trt. Part. Aer.*Maladies du feuillage	Pommier, Poirier, Cognassier, Nashi, Nèfles, Pommette	Maladies du feuillage	3L/ha	3	28 jours et dernière application fin juillet
Pommier*Trt. Part. Aer.*Maladies précoces des fruits	Pommier, Poirier, Cognassier, Nashi, Nèfles, Pommette	Maladies précoces des fruits	3L/ha	3	28 jours et dernière application fin juillet

ADAMA France ne préconise l'utilisation de ce produit que sur les cultures et cibles mentionnées dans le tableau ci-dessus et, à ce titre, décline toute responsabilité concernant l'élargissement de son utilisation à d'autres cultures et cibles telles que prévues par le catalogue des usages fixé par l'arrêté du 26 mars 2014.

Ainsi, l'attention de l'utilisateur est attirée sur les risques éventuels de non-conformité de cet élargissement permis par ce catalogue.

Délai de rentrée des travailleurs sur la parcelle : 48h après traitement conformément à l'arrêté du 4 mai 2017.

Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur selon l'arrêté du 7 avril 2010 modifié par l'arrêté du 12 juin 2015.

Limites maximales de résidus : se reporter aux LMR définies au niveau de l'Union Européenne, consultables à l'adresse :

http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database

Période d'emploi :
Suivre les avis des Stations d'Avertissements Agricoles.

Conditions d'emploi :
Volume d'eau : adapter au volume de végétation. Les doses sont données sur la base d'un volume de traitement de 1000 L/ha. Ainsi, jusqu'à 1000 L/ha, il faut utiliser la dose en L/ha (ex : 3 L/ha sur tavelure) et au-dessus de 1000 L/ha, il faut utiliser la dose en L/hL, (ex : 0,3 L/hL sur tavelure).

Préparation de la bouillie :
Agiter énergiquement le bidon avant usage. Verser directement la quatité requise de **Vahiné®** dans le réservoir en cours de remplissage, l'agitation étant en mouvement.
Vahiné® est incompatible avec les huiles blanches, les produits alcalins ou la bouillie bordelaise. Il faut un délai d'au moins une semaine et si possible 10 jours entre l'application de captane et celle de l'huile. Sur les variétés de pommes Rouges américaines et Braeburn, il est déconseillé d'associer du captane au soufre (pour pulvérisation). Pour toute information complémentaire, nous consulter.

Mélanges :
Les produits à base d'engrais foliaires et/ou d'oligoéléments pouvant avoir des propriétés physico-chimiques et biologiques très variables selon le type de produit, les mélanges de ces engrais foliaires et de ces oligoéléments avec **Vahiné®** peuvent parfois poser des problèmes de compatibilité (mauvaise mise en suspension de la bouillie, phytotoxicité sur les arbres). Ainsi il convient de bien lire les recommandations mentionnées sur l'étiquette de l'engrais foliaire ou de l'oligoélément et de faire un test préalable dans un petit récipient à part avant toute utilisation.
Nous déconseillons l'utilisation du Vahiné® dans un itinéraire technique contenant du Movento® (Marque déposée Bayer S.A.S. – Bayer Cropscience - 100 g/L spirotetramat, SC ; AMM N°2110086 ; Attention, H317, H361fd, H411, EUH401).

PRÉCAUTIONS GÉNÉRALES

Équipements de protection individuelle (EPI) :
Mélange/chargement :

- Gants en nitrile certifiés EN 374-3.
- Combinaison de travail tissée en polyester 65%/ coton 35% avec un grammage de 230 g/m² ou plus avec traitement déperlant.
- EPI partiel (blouse) à manches longues de catégorie III et de type PB (3) à porter par-dessus la combinaison pré-citée.
- Bottes hautes EN 13832-3.

Application :

- Combinaison de travail tissée en polyester 65%/ coton 35% avec un grammage de 230 g/m² ou plus avec traitement déperlant.
- Catégorie III/ tablier de Type PB (3) manches longues, porté par-dessus la combinaison proposée ci-dessus.
- Bottes hautes EN 13832-3.
- Gants en nitrile certifiés EN 374-3. Gants à usage unique dans le cas d'utilisation d'un tracteur à cabine ou sans cabine.

Le port de gants pendant l'application avec un tracteur à cabine n'est nécessaire que lors d'interventions sur le matériel de pulvérisation et les gants doivent être stockés à l'extérieur de la cabine.

Nettoyage :

- Gants en nitrile certifiés EN 374-3.
- Combinaison de travail tissée en polyester 65%/ coton 35% avec un grammage de 230 g/m² ou plus avec traitement déperlant.
- EPI partiel (blouse) à manches longues de catégorie III et de type PB (3) à porter par-dessus la combinaison pré-citée.
- Bottes hautes EN 13832-3.

Gestion du risque d'apparition de résistance :

L'utilisation répétée, sur une même parcelle, de préparations à base de substances actives de la même famille chimique ou ayant le même mode d'action, peut conduire à l'apparition d'organismes résistants. Pour réduire ce risque, il est conseillé d'alterner ou d'associer, sur une même parcelle, des préparations à base de substances actives de familles chimiques différentes ou à modes d'action différents, tant au cours d'une saison culturale que dans la rotation.

Dans le cadre des Bonnes Pratiques Agricoles :

Conditions de stockage : Conserver le produit dans son emballage d'origine, stocker dans un local réservé à cet usage, dans un endroit frais sec et bien ventilé à l'abri de la chaleur (T<40°C) et de l'humidité.

Emballages vides : Réemploi de l'emballage interdit. Lors de l'utilisation du produit, bien vider et rincer le bidon en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur. Éliminer les emballages vides via les collectes organisées par les distributeurs partenaires de la filière ADIVALOR. Rincer l'emballage au moins 4 fois avant son élimination. Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'enlèvement des produits dangereux.

Nettoyage de l'équipement : Ne pas laisser de bouillie prête à l'emploi dans le pulvérisateur. Éliminer les fonds de cuve et les eaux de rinçage conformément à la réglementation en vigueur. Éviter toute contamination des mares, puisards, ruisseaux, eaux souterraines ou de distribution ou de tout autre point d'eau, par le produit, la bouillie de pulvérisation et les eaux de rinçage des emballages et équipements de traitement.

Premiers secours :

Inhalation : Transporter la victime à l'air frais. En cas de respiration irrégulière ou d'absence de respiration, pratiquer la respiration artificielle. Consulter un médecin.

Contact cutané : Rincer immédiatement au savon et à grande eau en retirant les chaussures et vêtements contaminés. Consulter un médecin si nécessaire.

Contact avec les yeux : Rincer immédiatement et abondamment avec de l'eau. Après le rinçage initial, retirer les éventuelles lentilles de contact et continuer à rincer pendant au moins 15 minutes. Maintenir l'œil grand ouvert pendant le rinçage. Si les symptômes persistent, consulter un médecin.

Ingestion : Rincer la bouche. Boire beaucoup d'eau. Si les symptômes persistent, consulter un médecin.

Mesures d'urgence :
En cas d'urgence, contacter le centre antipoison le plus proche de votre domicile ou appeler le 15.

Présentez aux secours la fiche de données de sécurité. Puis signalez vos symptômes au réseau Phyt'attitude : tél. 0 800 887 887 (numéro vert).

ADAMA

VAHINÉ®

AMM N°XXXXXX
SC - Suspension concentrée
Captane 360 g/L (38.4%) + 660 g/L phosphonates de potassium.

Attention

H317 : Peut provoquer une allergie cutanée.
H319 : Provoque une sévère irritation des yeux.
H332 : Nocif par inhalation.
H351 : Susceptible de provoquer le cancer.
H400 : Très toxique pour les organismes aquatiques.
EUH 401: Respecter les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.

Délai de rentrée des travailleurs sur la parcelle : 48 h après traitement
P102 : Tenir hors de portée des enfants.
P201 : Se procurer les instructions avant utilisation.
P261 : Éviter de respirer les poussières/fumées/gaz/brouillards/vapeurs/aérosols.
P280 : Porter des gants de protection, des vêtements de protection, et un équipement de protection des yeux et du visage.
P302 + P352 : EN CAS DE CONTACT AVEC LA PEAU: laver abondamment à l'eau et au savon.
P304 + P340 : EN CAS D'INHALATION : Transporter la victime à l'extérieur et la maintenir au repos dans une position où elle peut confortablement respirer.
P305 + P351 + P338 : EN CAS DE CONTACT AVEC LES YEUX : Rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer.
P501 : Éliminer le contenu / récipient dans un centre de collecte des déchets dangereux ou spéciaux.

SP1 : Ne pas polluer l'eau avec le produit ou son emballage.
SPe3 : Pour proteger les organismes aquatiques, respecter une zone non traitée de 20 mètres comportant un dispositif végétalisé permanent de 5 mètres par rapport aux points d'eau.

RÉSERVÉ À UN USAGE EXCLUSIVEMENT PROFESSIONNEL.
Consulter le livret avant toute utilisation.

Réemploi de l'emballage interdit.

Produit fabriqué en Israël

N° de lot	VOIR SUR L'EMBALLAGE
Date de fabrication	

[redacted]

10 Litres

Appendix 3 Letter of Access

Provided upon request.