REGISTRATION REPORT

Part A

Risk Management

Product code: LBG-51FCm

Product name(s): VAHINE

Active Substance(s):

captan, 360 g/L

potassium phosphonates, 660 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: **ADAMA France S.A.S.**

Date: **21/12/2018**

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PART A – Risk Management

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

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

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 ADAMA France S.A.S.'s application to market VAHINE (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.

1.2 Active substance approval

Captan

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 captan for uses other than tomatoes 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 captan, 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: - the operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure; - the dietary exposure of consumers in view of future revisions of Maximum Residue Levels; - the protection of groundwater under vulnerable conditions. Conditions of authorisation should include risk

mitigation measures and monitoring programmes should be initiated in vulnerable zones, where appropriate; - the protection of birds, mammals and aquatic organisms. Conditions of authorisation should include risk mitigation measures. - The Member States concerned shall request the submission of further studies to confirm the long term risk assessment for birds and mammals, as well as the toxicological assessment on metabolites potentially present in groundwater under vulnerable conditions. They shall ensure that the notifiers at whose request captan has been included in this Annex provide such studies to the Commission within two years from the approval.
An EFSA conclusion is available (EFSA Journal 2014;12(4):3663). A Review Report is available (SANCO/10030/2006 – rev. 4, 11 July 2008).

Potassium phosphonates

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.
Specific provisions of Regulation (EU) No 540/2011 were as follows : 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 potassium phosphonates, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013, shall be taken into account. In this overall assessment Member States shall pay particular attention to: - the risk to birds and mammals, - the risk of eutrophication of surface water, if the substance is applied in regions or under conditions favouring a quick oxidation of the active substance in surface water. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards the long-term risk to insectivorous birds. The applicant shall submit to the Commission, the Member States and the Authority that information by 30 September 2015.
An EFSA conclusion is available (EFSA Journal 2012;10(12):2963). A Review Report is available (SANCO/10416/2013 rev 2, 15 March 2013).

1.3 Regulatory approach

The present application (2016-0093) 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 Southern zone, taking into account the worst-case uses ("risk envelope approach")[2] – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

According to the French law and procedures, specific conditions of use are set out in the Decision letter.

[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.

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.
- 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 VAHINE (LBG-51FCm), 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

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

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[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.

[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)	VAHINE (LBG-51FCm)
Authorisation number	N/A: No marketing authorisation granted
Function	fungicide
Applicant	ADAMA France S.A.S.
Composition	360 g/L captan 660 g/L potassium phosphonates
Formulation type (code)	Suspension concentrate (SC)
Packaging	-

2.2 Classification and labelling

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

Physical hazards	-	
Health hazards	Skin sensitization - Category 1B Eye irritation - Category 2 Acute inhalation toxicity - Category 4 Carcinogenicity - Category 2	
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.
	H332	Harmful if inhaled.
	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.

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

N/A: Not registered in France.

2.2.3 Other phrases linked to the preparation

N/A: Not registered in France.

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant evaluated and concluded as safe uses by France as zRMS. When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.

PPP (product name/code):	**VAHINE (LBG-51FCm)**	Formulation type:	**SC** [a, b]
Active substance 1:	captan	Conc. of as 1:	**360 g/L** [c]
Active substance 2:	potassium phosphonates	Conc. of as 2:	**660 g/L** [c]
Safener:	none	Conc. of safener:	conc. [c]
Synergist:	none	Conc. of synergist:	conc. [c]
Applicant:	**ADAMA France S.A.S.**	Professional use:	☒
Zone(s):	southern [d]	Non professional use:	☐
Verified by MS:	yes		
Field of use:	fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
					Application				**Application rate**				
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)	Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/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)													
New 1A	France	Apple, pear, quince	F	Scab (*Venturia inaequalis / Venturia pirina),* Brown spot *(Stemphylium vesicarium)*	Foliar spray	BBCH 09 (leaf emergence) – 81 March – mid of June*	a) 6 b) 6	(7 days)	a) 3 L/ha b) 18 L /ha	a) 1.080+1.320 b) 6.48+7.92	500-1500	28*	**Not acceptable (aquatic organisms risk)** **Not acceptable** (risk for workers and resident (children and adults)) ***** for early pome fruit varieties, 28 d PHI; for late pome fruit varieties, last application by mid of June
New 1B	France	Apple, pear, quince	F	Scab (*Venturia inaequalis / Venturia pirina),* Brown spot *(Stemphylium vesicarium)*	Foliar spray	BBCH 09 (leaf emergence) – 81 March – mid of July*	a) 4 b) 4	(7 days)	a) 3 L/ha b) 12 L /ha	a) 1.080+1.320 b) 4.32+5.28	500-1500	28*	**Not acceptable** (risk for workers and resident (children and adults)) ***** for early pome fruit varieties, 28d PHI; for late pome fruit varieties, last application by mid of July

1	2	3	4	5	6	7	8	9	10	11	12	13	14
					Application				**Application rate**				
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)	Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
New 2	France	Apple, pear, quince	F	Foliar diseases: ashy leaf spot *(Mycosphaerella pyri)* rust *(Gymnosporangium fuscum)* and *Entomosporium maculatum.* Early diseases on fruits: *Sooty blotch (Gloeodes pomigena),* flyspeck (*Schyzothyrium pomi)* *Botrytis cinerea, Botryosphaeria obtuse.*	Foliar spray	BBCH 71 – 81 April – mid of July*	a) 4 b) 4	(7 days)	a) 3 L/ha b) 12 L /ha	a) 1.080+1.320 b) 4.32 + 5.28	500-1500	28*	**Not acceptable** (risk for workers and resident (children and adults)) ***** for early pome fruit varieties, 28d PHI; for late pome fruit varieties, last application by mid of July Efficacy shown on *Mycosphaerella pyri, Gymnosporangium fuscum, Entomosporium maculatum., Gloeodes pomigena* and *Schyzothyrium pomi*

Remarks table heading:

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

Remarks columns:

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

3 RISK MANAGEMENT

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

3.1.1 Physical and chemical properties

The preparation VAHINE (LBG-51FCm) is a green (olive like), viscous suspension, with specific organic odour (suspension concentrate), containing 360 g/L of captan and 660 g/L of potassium phosphonates. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. It is not explosive and has no oxidising properties. The product 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 temperature on the stability of the formulation, since after 7 days at 0°C and 8 weeks at 40°C, neither the active ingredient 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 1 year at ambient temperature when stored in HDPE packaging. Results of the 2 year shelf life study are required in post authorisation. Its technical characteristics are acceptable for an SC formulation. The formulation must be stored at a temperature below 40°C. The formulation must be stirred before use.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

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

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

3.1.2.2 Analytical methods for residues

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

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

VAHINE (LBG-51FCm) containing 360 g/L of captan and 660 g/L of potassium phosphonate has a low toxicity in respect to acute oral and dermal toxicity and is not irritating to the rabbit skin. It is irritating to the rabbit eye and is a skin sensitiser.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G[8]	Equipment	Application rate kg/L product/ha (g as/ha)	Spray dilution (L/ha)	Model
Apple	F	Tractor-mounted sprayer	3 L product/ ha (1.08 kg captan/ ha and 1.98 kg potassium phosphonate/ ha)	500-1500	AOEM

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

[8] Open field or glasshouse.

Crop	Equipment	PPE and/or working coverall	% AOEL captan	% AOEL potassium phosphonate
Apple	Tractor-mounted sprayer	Working coverall and gloves during mixing/loading and application	58	0.5

According to the model calculations, it can be concluded that the risk for the operator using VAHINE (LBG-51FCm) 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

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 AOEM 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."

3.1.3.4 Worker Exposure

Workers may have to enter treated areas after treatment for crop searching, reaching and picking activities. Therefore, estimation of worker exposure was calculated according to AOEM model. Exposure is estimated to 930 % of the AOEL of captan and 5.9% of the AOEL of potassium phosphonate.

It is concluded that without taking into account a re-entry period, there is an unacceptable risk anticipated for workers wearing a working coverall and gloves, when re-entering crops treated with VAHINE (LBG-51FCm).

A field study had been provided by the applicant. Nevertheless, it has not been considered acceptable.

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

3.1.4 Residues and Consumer Exposure

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs of 10 mg/kg for captan and 150 mg/kg for fosetyl as laid down in Reg. (EU) 396/2005 is not expected.

As far as consumer health protection is concerned, Anses, France agrees with the authorization of the intended use(s).
The preparation VAHINE (LGB-51FCm) is composed of captan and potassium phosphonates.

[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).

3.1.4.1 Summary for potassium phosphonates

Use-No.*	**Crop**	**Plant metabolism covered?**	**Sufficient residue trials?**	**PHI sufficiently supported?**	**Sample storage covered by stability data?**	**MRL compliance Reg 2018/832**	**Chronic risk for consumers identified?**	**Acute risk for consumers identified?**	**Comments**
1	Pome fruits	Yes	Yes (8 NEU and 8 SEU)	Yes	Yes	Yes	No	No	-

The effects of processing on the nature of potassium phosphonates residues have been investigated. Data on effects of processing on the amount of residue have been submitted.

These data were not considered for risk assessment.

Since pome fruits are perennial crops, there is no need to investigate residues 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.

3.1.4.2 Summary for captan

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg 2016/452	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	Pome fruits	Yes	Yes	Yes	Yes	Yes	No	No	-

The effects of processing on the nature of captan residues have been investigated. Data on effects of processing on the amount of residue have been submitted.
These data were considered for risk assessment, especially for apple juice.

Since pome fruits are perennial crops, there is no need to investigate residues 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.

3.1.4.3 Summary for VAHINE (LBG-51FCm)

Crop	PHI for LBG-51FCm proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for LBG-51FCm proposed by zRMS	zRMS Comments (if different PHI proposed)
		Potassium phosphonates	Captan		
Pome fruits	28 days	Yes	Yes	28 days	/

Waiting periods before planting succeeding crops.
Not relevant.

3.1.5 Environmental fate and behaviour

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 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 of captane, phosphonic acid equivalents 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.

PEC soil and PECsw derived for the active substances and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PECgw for active substances and their metabolites do not occur at levels exceeding those mentioned in regulation EC 1107/2009, guidance document SANCO 221/2000[10] and in Directive 98/83/CE[11].

Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

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 Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance(s) and its/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-organisms and micro-organisms and terrestrial plants are acceptable for the intended uses.

For aquatic organisms, mitigation measures (20 m unsprayed buffer zone included a 5 m vegetated filter strip, to not apply on drained soil, to not apply more than 4 times per season, to not apply before BBCH stage 69) are required to conclude to an acceptable risk.

[10] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev10-final, 25 February 2003.
[11] Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.

According to the regulation (EU) 284/2013, information on the chronic toxicity for adult bees and on brood development of the formulated product should have been provided. As such data are not available the following restriction has to be applied: do not apply this formulation during flowering period.

3.1.7 Efficacy

Considering the data submitted:

- the efficacy level of VAHINE (LBG-51FCm) is considered as satisfactory for all the claimed uses.
- the phytotoxicity level of VAHINE (LBG-51FCm) is considered as acceptable for all the claimed uses.
- the risks of negative impact on yield, quality, cider-making, propagation and adjacent crops are considered as negligible.
- the risk of resistance development or appearance to captan and potassium phosphonate does not require a monitoring for the claimed uses.

Restrictions: None

Resistance monitoring data: None

Post-authorization data: None

3.2 Conclusions arising from French assessment

Taking into account the above assessment, considering that unacceptable risks are expected for workers, and resident (children and adults) an authorisation **cannot be granted** in France – see Copy of the product Decision.

3.3 Substances of concern for national monitoring

N/A : Not registered in Fance.

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

3.4.1 Post-authorisation monitoring

N/A : Not registered in Fance.

3.4.2 Label amendments

N/A : Not registered in Fance.

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 et les demandes associées du produit phytopharmaceutique ***VAHINE***

de la société *ADAMA FRANCE SAS*

enregistrées sous les *n°2016-0093, 2016-0094 et 2017-0901*

Vu les conclusions de l'évaluation de l'Anses du 25 juin 2018,

Vu les éléments complémentaires fournis par la direction de l'évaluation des produits réglementés le 14 décembre 2018,

Considérant que l'estimation de l'exposition, liée à l'utilisation du produit VAHINE, pour les usages revendiqués, est supérieure au niveau acceptable d'exposition à la substance active captane pour le travailleur et le résident,

Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 relatives à l'absence d'effet nocif pour la santé humaine sont respectées,

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

VAHINE
AMM n°-

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anses

Informations générales sur le produit	
Noms du produit	VAHINE MOOREA MERPAN PLUS
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	061-2016.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usage	Professionnel

A Maisons-Alfort le, 21 DEC. 2018

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

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anses
agence nationale de sécurité sanitaire alimentation, environnement, travail

ANNEXE I : Conditions de mise sur le marché demandées

Classification du produit	
Catégorie de danger	**Mention de danger**
Sensibilisants cutanés - Catégorie 1B	H317 : Peut provoquer une allergie cutanée
Lésions oculaires graves et irritation oculaire - Catégorie 2	H319 : Provoque une sévère irritation des yeux
Toxicité aiguë par inhalation - Catégorie 4	H332 : Nocif par inhalation
Cancérogénicité - Catégorie 2	H351 : Susceptible de provoquer le cancer
Dangers pour le milieu aquatique - Danger aigu, Catégorie 1	H400 : Très toxique pour les organismes aquatiques
Pour les phrases P se référer à la règlementation en vigueur.	

VAHINE
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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	4/an	28
	Motivation du refus : L'usage est refusé en raison d'un risque inacceptable pour les travailleurs et pour les résidents. L'usage revendiqué avec un délai avant récolte correspondant à une dernière application mi-juillet pour les variétés tardives est également refusé pour les mêmes raisons.		
12603211 Pommier*Trt Part.Aer.* Maladies précoces des fruits	3 L/ha	4/an	28
	Motivation du refus : L'usage est refusé en raison d'un risque inacceptable pour les travailleurs et pour les résidents. L'usage revendiqué avec un délai avant récolte correspondant à une dernière application mi-juillet pour les variétés tardives est également refusé pour les mêmes raisons.		
12613208 Pommier*Trt Part.Aer.* Stemphyliose	3 L/ha	4/an	28
	Motivation du refus : L'usage est refusé en raison d'un risque inacceptable pour les travailleurs et pour les résidents. Les usages revendiqués à 6 applications/an et avec un délai avant récolte correspondant à une dernière application mi-juin ou mi-juillet pour les variétés tardives sont également refusés pour les mêmes raisons.		
12603203 Pommier*Trt Part.Aer.* Tavelure(s)	3 L/ha	4/an	28
	Motivation du refus : L'usage est refusé en raison d'un risque inacceptable pour les travailleurs et pour les résidents. Les usages revendiqués à 6 applications par an et avec un délai avant récolte correspondant à une dernière application mi-juin ou mi-juillet sont également refusés pour les mêmes raisons.		

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

Nettoyage de l'équipement : Ne pas laisser de bouillie prête à l'emploi dans le pulvérisateur. Eliminer les fonds de cuve et les eaux de rinçage conformément à la réglementation en vigueur. Eviter 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).

IMPORTANT : Respecter les usages, doses, conditions et précautions d'emploi mentionnes sur l'emballage qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est prescrite. Conduisez sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces, la pression parasitaire... Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de mise sur le marché. Compte tenu de la diversité des législations existantes, il est recommandé, dans le cas où les données physiques ou issues de cultures protegees avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur. ADAMA France s.a.s ne saurait être tenu en aucun cas responsable des conséquences éventuelles à toute copie (totale ou partielle) de cette étiquette, à sa diffusion ou son utilisation non autorisée.

VAHINÉ®

AMM N°XX.XX.XX
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 : Eviter 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 : Eliminer le contenu / récipient dans un centre de collecte des déchets dangereux ou spéciaux.
SPI : Ne pas polluer l'eau avec le produit ou son emballage.
SPe3 : pour protéger les organismes aquatiques, respecter une zone non traitée comportant un dispositif végétalisé permanent de 20 metres par rapport aux points d'eau.

PRODUIT POUR LES PROFESSIONNELS : RESPECTER LES CONDITIONS D'EMPLOI.
Lire les instructions ci-jointes avant emploi.

Titulaire de l'AMM : ADAMA France s.a.s - 6/8, avenue de la Cristallerie 92236 Sèvres Cedex - Tel. : 01 41 90 16 96 - Fax : 01 46 42 71 17

Produit fabriqué en Israël

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

VAHINÉ®

Culture
Arboriculture.

La fiche de données de sécurité peut être obtenue gratuitement sur Internet www.quickfds.com ou en écrivant à fds@adama.com ou par courrier à l'adresse postale d'ADAMA. s.a.s ou en scannant le flashcode avec votre téléphone mobile.

Matières actives : Captane 360 g/L + 660 g/L phosphonates de potassium.
Formulation : SC - Suspension concentrée
AMM N°XXXXXX

Titulaire de l'AMM :
ADAMA France s.a.s
6/8, avenue de la Cristallerie
92236 Sèvres Cedex
Tél. : 01 41 90 16 96
Fax : 01 46 42 71 17
® Marque enregistrée par une société du groupe ADAMA

STOCKER ENTRE 40° 0°

FONGICIDE
Polyvalent

ADAMA

10 Litres

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 (Délais avant récolte)
Pommier*Tr. Part. Aer.*Tavelure(s)	Pommier, Poirier, Cognassier, Nashi, Nefles, Pommette	Tavelure du pommier, Tavelure du poirier	3 L/ha	10	28 jours
Pommier*Tr. Part. Aer.*Stemphyliose	Pommier, Poirier, Cognassier, Nashi, Nefles, Pommette	Stemphyliose	3 L/ha	10	28 jours
Pommier*Tr. Part. Aer.*Maladies du feuillage	Pommier, Poirier, Cognassier, Nashi, Nefles, Pommette	Maladies du feuillage	3 L/ha	4	28 jours
Pommier*Tr. Part. Aer.*Maladies precoces des fruits	Pommier, Poirier, Cognassier, Nashi, Nefles, Pommette	Maladies precoces des fruits	3 L/ha	4	28 jours

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 12 juin 2015 relatif à la mise sur le marché et à l'utilisation des produits visés à l'article L. 253-1 du code rural.

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.

Les Limites Maximales de Résidus sont consultables à l'adresse suivante :
http://ec.europa.eu/sanco_pesticides/public/index.cfm

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

Equipements 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. Eliminer 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.

Appendix 3 – Letter(s) of Access

Provided upon request.