REGISTRATION REPORT

Part A

Risk Management

Product name(s): XEDATHANE-HN

Active Substance(s):

Pyrimethanil, 156 g/L

COUNTRY: FRANCE

Interzonal

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: XEDA International S.A.

Date: 01/06/2016

Table of Contents

PART A – Risk Management

The company XEDA International S.A. has requested marketing authorisation in France for the product XEDATHANE-HN (identical to XEDATHANE-A), containing 156 g/L pyrimethanil for use as a post-harvest fungicide.

The applicant first applied for a mutual recognition in France based on the assessment prepared by Belgium for the preparation XEDATHANE-A (application n°2011-6050). Regarding the magnitude of residues in apple after a post-harvest treatment indoor, the number of residue trials available to support the intended GAP in France was not sufficient. An exceedance of the MRL in apple cannot be excluded. The lack of data does not allow taking into account the contribution of the requested use to the dietary burden and to the consumer exposure. As a consequence, an authorisation could not be granted in France.

A new application n°2014-1628 was provided by XEDA International S.A. with additional data to address the concerns highlighted previously.

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 XEDATHANE-HN where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of XEDATHANE-HN have been made using endpoints agreed in the EU peer review of pyrimethanil.

This document describes the specific conditions of use and labelling required for France for the registration of XEDATHANE-HN.

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 XEDA International S.A.'s application to market XEDATHANE-HN in France as a fungicide (product uses described under point 2.3). France acted as an interzonal Rapporteur Member State (izRMS) 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

Pyrimethanil

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

Commission Implementing Regulation (EU) No 678/2014 of 19 June 2014 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances clopyralid, cyprodinil, fosetyl, pyrimethanil and trinexapac

Specific provisions of regulation were as follows :

PART A

Only uses as fungicide may be authorised.

PART B

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on pyrimethanil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 May 2006 shall be taken into account.

In this overall assessment Member States:

— must pay particular attention to the protection of aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate, such as buffer zones,

— must pay particular attention to the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment.

The Member States concerned shall request the submission of further studies to confirm the risk assessment to fish. They shall ensure that the notifiers at whose request pyrimethanil has been included in this Annex provide such studies to the Commission within two years from the entry into force of this Directive.

An EFSA conclusion is available (EFSA Scientific Report (2005) 57, 1– 70).

A Review Report is available (SANCO/10019/2006 final, 23 November 2010).

1.3 Regulatory approach

The present application (2014-1628) 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 12 September 2006[3] provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres;
- unless formally 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, 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.

[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] http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000425570
[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 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 XEDATHANE-HN, 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 the supporting data in Document K; the ownership of the data is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7. A copy of the letter(s) of access is reproduced in Part A, Appendix 3.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	XEDATHANE-HN
Authorisation number	2160230
Function	post-harvest fungicide
Applicant	XEDA International S.A.
Composition	156 g/L pyrimethanil
Formulation type (code)	Hot fogging concentrate (HN)
Packaging	Metal canisters (5 L)

[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

2.2 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	Flammable liquids, Hazard Category 3 Skin sensitisation, Hazard Category 1 Eye irritation, Hazard Category 2 Specific target organ toxicity — Single exposure, Hazard Category 3, Narcosis	
Environmental hazards	Hazardous to the aquatic environment — Chronic Hazard, Category 3	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H226	Flammable liquid and vapour.
	H317	May cause an allergic skin reaction.
	H319	Causes serious eye irritation.
	H336	May cause drowsiness or dizziness.
	H412	Harmful to aquatic life with long lasting effects.
Precautionary statements –	***For the P phrases, refer to the extant legislation***	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	EUH 066	Repeated exposure may cause skin dryness or cracking.

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

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

The authorisation of the preparation is linked for professional uses only to the following conditions:

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via water discharge pipes).

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment[8]: refer to the Decision in Appendix 1 for the details
Re-entry period[9]: Not applicable
Pre-harvest interval[10]: Not applicable
Other mitigation measures: - The product must be stored protected from frost. - The re-entry in the storage room should be forbidden before the product is completely deposed and dried on the fruits.
The label should include the following recommendations: - Do not apply on fruits intended to fermentation (cider production…). - When the use of XEDATHANE-HN is considered during storage, avoid the use of the same mode of action (pyrimethanil or cyprodinil, actives substances of the anilo pyrimidin group FRAC D1) for the last(s) fungicide application(s) before harvest. The label must reflect the conditions of authorisation.

[8] If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

[9] The legal basis for this is **Titre I Article 3** of the French Order of 12 September 2006 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

[10] According to the French Order of 12 September 2006, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 march 2014 (highlighted in green), evaluated and concluded as safe uses by France as izRMS. Those uses are then granted in France.
When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.
When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.
Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 2016-06-01

PPP (product name/code):	**XEDATHANE-HN**	Formulation type:	**HN** [a, b]
Active substance 1:	Pyrimethanil	Conc. of as 1:	**156 g/L** [c]
Applicant:	**XEDA INTERNATIONAL**	Professional use:	☒
Zone(s):	interzonal [d]	Non professional use:	☐
Verified by MS:	Yes=		
Field of use:	fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation (crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg 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		
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
1	All	Pome fruits	I	*Botrytis spp* *Gloeosporium*	Thermone-bulization (HN)	Harvested fruits & post-harvest	a) 1 b) 1 post-harvest treatment	-	a) 50 g/ton of fruit b) 50 g/ton of fruit	a) 8 g a.s/ton fruit b) 8 g a.s./ton fruit	N/A (thermone-bulization)	-	Post-harvest treatment Acceptable Efficacy demonstrated on Gloeosporium only. except on fruits intended to fermentation (cider production…)

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 authorization 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 formulation XEDATHANE HN is a liquid for hot nebulization. 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 that of pale yellow translucent with a fruit odour liquid. It is not explosive and has no oxidizing properties.

The product has a flash point of 56.5°C and is classified H226 Cat 3 GHS02 Warning.

It has a self-ignition temperature of 364°C. In aqueous solution (1%), it has a pH value 6.0 at ambient temperature. There is no effect high temperature on the stability of the formulation, since after 14 days at 54°C, neither the active ingredient content nor the technical properties were changed.

The preparation is not stable at 0°C and must be protected from frost.

The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in tin plate container.

Its technical characteristics are acceptable for a HN formulation.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical method for the determination of active substance in the formulation is available but not fully validated. Chromatogram of blank formulation is required in post authorization to check if specificity is acceptable.

As relevant impurities (cyanamide) are by-products of the manufacturing process for pyrimethanil and as such cannot be formed by storage of the formulation, an analytical method for the determination of relevant impurities in the formulation is not necessary.

3.1.2.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report and validated for the determination of residues of pyrimethanil in plants (high water content), soil, water (surface and drinking) and air. Analytical method for the determination of pyrimethanil residues in foodstuffs of animal origin is required for the renewal of the active substance.

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

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

XEDATHANE-HN containing 156 g/L of pyrimethanil has a low toxicity in respect to acute oral, dermal and inhalational toxicity and is not irritating to the rabbit skin. It has been found to be classified for irritancy to rabbit eyes and is a skin sensitiser according to M&K test.

3.1.3.2 Operator Exposure

XEDATHANE-HN is a liquid for hot nebulization (HN). It is used as a fungicide for post-harvest application on fruits. Treatment is realised by thermonebulization, directly in the conservation rooms or cells, in cold classical treatment, controlled atmosphere or Ultra-low Oxygen (ULO).

Crop	**Formulation**			**Application rate per treatment**		**Equipment type**
	Type	Conc. of a.s.	container size & type	dose product (g/t)	Maximum application rate (g a.s./t)	
Pome Fruits - Post-harvest application	HN (hot nebulization)	160 g/L	Ready to use/ 5 L packaging	50 g/t	8 g/t	Thermo-nebulization

An estimate of the operator exposure was made by the applicant, based on specific exposure data from Model 3/Fogging of the TNsG (data source HSE survey 2000; reference: HSL report in press), and show acceptable risk wearing gloves and safety shoes. However the uncertainty of these values is significant, as they are only based on four data. Furthermore, the HSE raw data remain difficult to obtain, to know more precisely the conditions of the studies that led to the available data.

Since :
- XEDATHANE-HN is a ready-to use formulation,
- the treatment is done in closed environment,
- the application is made by a licensed applicator,
- when loading the preparation in the specific equipment dedicated, the applicator only needs to place a suction hose pipe directly into the drum,
- during treatment, the operator is always outside the treated area,
- during the treatment, thermofoggers are well equipped with suitable protective clothing and gas mask (with organic vapour filters) which leads to minimize inhalation and dermal exposure, in the case of possible leaks,

in conclusion (in accordance with Belgium conclusions), the product XEDATHANE-HN can be handled safely under the recommended conditions of use.

Thermofoggers will have to be equipped with suitable PPE/RPE when handling the preparation (e.g.: when placing the suction hose pipe into the drum, when uninstalling the device, when recovering the residual effluent felt during the fogging,….), during application and cleaning of sprayer.

On the basis of estimation of operator exposure and according to measures of risk prevention, the operator should wear personal protective equipment:

- **During application:**
  - Use of certified gloves for chemical protection (standard EN 374-3) made of nitrile or neoprene,
  - Use of full face mask of type A2P3 (standards EN 12941 and EN 12942),
  - Use of coverall in fibre made of cotton or synthetic (category III, type 6 EN 13034),
  - Use of respirator for assisted ventilation with filter type P3 (category III, EN 12941 and EN 12942, marking A2P3,
- **During cleaning of sprayer:**
  - Use of certified gloves for chemical protection (standard EN 374-3) made of nitrile or neoprene,
  - Use of full face mask of type A2P3 (standards EN 12941 and EN 12942),
  - Use of coverall in fibre made of cotton or synthetic (category III, type 6 EN 13034).

Furthermore, the operator should wear partial personal protective equipment (apron or overall) of category III and type PB (3) above the aforementioned coverall.

The re-entry in the storage room should be forbidden before the product is completely deposed on the fruits and has completely dried.

3.1.3.3 Bystander Exposure

The bystander exposure is not considered relevant since the application of the product is intended in enclosed spaces, with limited access to non-professionals.

Anyway, if a person should be present during the treatment, he will have to wear suitable PPE/RPE to minimise inhalation and dermal exposure (please refer to PPE/RPE recommendations of the applicant for operators.

3.1.3.4 Worker Exposure

The models usually use to achieve the risk assessments of the plant protection products (EUROPOEM II) are not applicable to the application method of XEDATHANE-HN.

When fruits have been treated by the XEDATHANE-HN, there is no need for workers to have contact with the treated food (usually stored in controlled atmosphere) before complete elimination of the XEDATHANE-HN. Workers will theoretically re-enter the treated area after 3 to 9 months after treatment.

It is considered that there is the risk for workers under the recommended conditions of use.

3.1.4 Residues and Consumer Exposure

Primary crop metabolisms were sufficiently investigated to define residue of pyrimethanil for enforcement and risk assessment in crops under consideration.

Regarding the magnitude of residues in pome-fruits, a sufficient number of residue trials are available to support the intended GAPs in France. These data allowed confirming that no MRL exceedance will result from intended uses.

Magnitude of pyrimethanil residues in processed commodities was sufficiently documented to support the intended uses of the preparation XEDATHANE-HN.

For pyrimethanil, the residue data on apple pomace do not modify the dietary burden and no MRL exceedence is awaited in foods of animal origin.

3.1.4.2 Consumer exposure

The toxicological profile of pyrimethanil was evaluated at EU level, which resulted in the proposal of an ADI (0.17 mg/kg) that was considered in the frame of this evaluation. Setting of an ArfD was not deemed necessary.

Chronic consumer exposure resulting from the uses proposed in the framework of this application was calculated for pyrimethanil. Based on EFSA PRIMo (rev2), chronic exposure was considered as acceptable for all groups of consumers.

3.1.4.3 Mitigation measures

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

3.1.5 Environmental fate and behaviour and Ecotoxicology

Considering that only storage and indoor uses are intended for France, no assessments based on outdoor uses would be performed in the current registration report. For the storage and indoor uses, no significant exposure of the environment is expected. This is in accordance with the European conclusions for the active substance. Therefore, the ecotoxicological risk for environment is considered as negligible.

3.1.6 Efficacy

This is a demand for the new preparation, XEDATHANE-HN, based on 160 g/L of pyrimethanil (HN, hot fogging concentrate- hot nebulization), submitted by XEDA International. It is intended for post-harvest treatment of pome

fruits to control storage diseases: *Gloeosporium album* and *Botrytis cinerea*. This product is already registered in Belgium and in Italy.

The efficacy of the product at the intended rate was demonstrated on *Gloesporium* diseases on pome fruits.

The provided efficacy data is not sufficient to conclude on the efficacy of the test product on other storage diseases (insufficient number of trials with sufficient infestation levels). However, it can be stated that the treatment targeting *Gloesporium* will have a secondary effect on other storage disease such as *Botrytis cinerea* and *Penicillium expansum*, without being able to quantify this effect.

No adverse effect is expected on fruits. The risk of negative taint effect is judged low, based on taint studies provided. In the absence of study of the impact of the product on fermentation process, a possible impact on these processes cannot be excluded. A warning should be put on the label, for fruits intended to fermentation process (cider production…).

The resistance risk is high. A monitoring should be performed on the 2 targeted diseases; their results should be provided to authorities in case of evolution of the resistance situation. As preventive management measure to delay resistance issues, it is advised to avoid the use of the same mode of action in pre-harvest (the 1 or 2 last fungicides treatments) and in post-harvest (as well, if more than 1 treatment is applied in post-harvest, alternation is highly recommended).

Crop	Target diseases	Application rate	Nber of applic.	Method of application & Application stage	Conclusion for section 7 - France	Comment
Pome fruits (storage diseases)	*Gloeo-sporium*	0,05 L/ton of fruits (8 g a.s./ton)	1	Post-harvest treatment of fruits (untill 15 days after harvest), directly in the storage room, by thermonebulization.	**Acceptable**	Label warning on fruits intended to fermentation (cider production…). To prevent resistance, avoid the use of the same mode of action just before harvest and in post-harvest.
	Botrytis cinerea				**Acceptable as a secondary effect of treatment targeting *Gloesporium***	

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation can be granted as proposed in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

No information stated.

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

A monitoring should be performed on the 2 targeted diseases (*Botrytis cinerea* and *Gloeosporium album)*. The applicant should provide a baseline sensitivity of these diseases to pyrimethanil. The results should be provided to authorities in case of evolution of the resistance situation.

3.4.2 Post-authorisation data requirements

The French Decision requests the submission of post-authorisation confirmatory pieces of information within 6 months regarding:

- Chromatogram of blank formulation to check if specificity of active substance's analytical method is acceptable.

3.4.3 Label amendments (see label in Appendix 2):

The draft label proposed by the applicant in appendix 2 may be corrected with consideration of any new element under points 2.2.1 (or 2.2.2), 2.2.3 and 2.2.4.

The label shall reflect the detailed conditions stipulated in the Decision.

Appendix 1 – Copy of the French Decision

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

anses
agence nationale de sécurité sanitaire alimentation, environnement, travail

Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) N° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et règlementaire,

Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique ***XEDATHANE-HN***

de la société *XEDA INTERNATIONAL S.A.*

enregistrée sous le *n°2014-1628*

Vu les conclusions de l'évaluation du 1er mars 2016,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France pour les usages et dans les conditions précisés dans la présente décision et ses annexes.

La présente décision s'applique sans préjudice des autres dispositions applicables.

Avertissement :

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.

XEDATHANE-HN
AMM n°2160230

Page 1 sur 6

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

anses
agence nationale de sécurité sanitaire alimentation, environnement, travail

Informations générales sur le produit	
Nom du produit	XEDATHANE-HN
Type de produit	Produit de référence
Titulaire	XEDA INTERNATIONAL S.A. Z.A. n° 2, 1397 Route Nationale 7, Z.A.C. LA CRAU, 13670 SAINT ANDIOL FRANCE
Formulation	Produit pour nébulisation à chaud (HN)
Contenant	156 g/L – pyriméthanil
Numéro d'intrant	778-2014.01
Numéro d'AMM	2160230
Fonction	Fongicide
Gamme d'usages	Professionnel

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 30 avril 2019.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) 1107/2009, dans les trois mois suivant le renouvellement de l'approbation de la substance active, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance de la durée nécessaire pour mener à bien l'examen et adopter une décision sur le renouvellement.

La présente décision peut être retirée ou modifiée avant cette échéance si des éléments le justifient.

A Maisons-Alfort, le - 1 JUIN 2016

Françoise WEBER
Directrice générale adjointe des produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

XEDATHANE-HN
AMM n°2160230

Page 2 sur 6

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

anses
agence nationale de sécurité sanitaire alimentation, environnement, travail

ANNEXE I : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	**Contenance**
Bidons en métal sans vernis intérieur	5 L

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	**Mention de danger**
Liquides inflammables, catégorie 3	H226 : Liquides et vapeurs inflammables
Sensibilisation cutanée, catégorie 1	H317 : Peut provoquer une allergie cutanée
Lésions oculaires graves/irritation oculaire, catégorie 2	H319 : Provoque une sévère irritation des yeux
Toxicité spécifique pour certains organes cibles - Exposition unique, catégorie 3 : Effets narcotiques	H336 : Peut provoquer somnolence ou des vertiges
Dangers pour le milieu aquatique - Danger chronique, catégorie 3	H412 : Nocif pour les organismes aquatiques, entraine des effets néfastes à long terme
EUH066 : L'exposition répétée peut provoquer dessèchement ou gerçures de la peau. Pour les phrases P se référer à la règlementation en vigueur. **Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.**	

XEDATHANE-HN
AMM n°2160230

Page 3 sur 6

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

anses
agence nationale de sécurité sanitaire alimentation, environnement, travail

Liste des usages autorisés

En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
12604201 Pommier*Trt Prod. Réc.*Maladies de conservation	**50 mL/t**	**1/an**	-	-	-	-	-	-
	Non autorisé sur les fruits destinés à la fermentation. Efficacité montrée sur *Gloeosporium*. Application par thermo-nébulisation dans la chambre de stockage des fruits.							

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

anses
agence nationale de sécurité sanitaire alimentation, environnement, travail

Conditions d'emploi du produit

Stockage et utilisation du produit

Protéger la préparation du gel.

Protection de l'opérateur et du travailleur

Il convient de rappeler que l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections complémentaires comme les protections individuelles.

En tout état de cause, le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage). Les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

Pour l'opérateur, porter

Dans le cadre d'une application effectuée par thermo-nébulisation dans la chambre de stockage à l'aide des appareils électrofogs Xéda :

- **pendant le traitement ou en cas d'intervention d'urgence dans l'enceinte de stockage**

- Gants de protection en nitrile ou néoprène certifiés EN-374-3, pour les produits chimiques (catégorie III) ;
- Masque facial intégral de type A2P3 à ventilation assistée (catégorie III. normes EN 12941 et EN 12942) ;
- Combinaison (catégorie III, type 6 EN 13034).

- **pendant le nettoyage du matériel de nébulisation**

- Gants de protection en nitrile ou néoprène certifiés EN-374-3, pour les produits chimiques (catégorie III) ;
- Masque intégral de type A2P3 selon les normes EN 12941 et EN 12942 ;
- Combinaison (catégorie III, type 6 EN 13034) ;
- EPI partiel (blouse) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée.

Autres mesures de protection

La rentrée dans la cellule de conservation ne devra pas se produire avant le dépôt complet puis le séchage du produit sur les fruits.

Respect des limites maximales de résidus (LMR)

Les conditions d'utilisation de la préparation, compte tenu des bonnes pratiques agricoles critiques proposées pour chaque usage figurant dans la liste des usages autorisés, permettent de respecter les limites maximales de résidus.

Protection de l'environnement (milieux, faune et flore)

Protection de l'eau

- SP 1 : 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].

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

anses
agence nationale de sécurité sanitaire alimentation, environnement, travail

Exigences complémentaires post-autorisation

A défaut de transmission de ces données dans les délais impartis à compter de la date de la présente décision, la présente décision pourra être retirée ou modifiée.

Détail de la demande post autorisation	Délai (mois)	Récurrence (mois)
Fournir le chromatogramme du blanc de la formulation XEDATHANE-HN pour vérifier la spécificité de la méthode d'analyse de la substance active dans la préparation.	6	-
Mettre en place un programme de suivi de la résistance sur *Botrytis cinerea* et *Gloeosporium album*.	-	-
Fournir toute nouvelle information aux autorités compétentes dans le cadre du suivi de la résistance sur *Botrytis cinerea* et *Gloeosporium album*.	-	-

Recommandations relatives à l'étiquette du produit

Il est recommandé de faire figurer les informations suivantes sur l'étiquette :

- Le produit ne doit pas être appliqué sur les fruits destinés à la fermentation (production de cidre, de poiré...).

- Lorsque le traitement à base de XEDATHANE-HN est envisagé durant la phase de stockage, éviter l'emploi au champ de pyriméthanil et de cyprodinil (appartenant au groupe des anilino pyrimides - groupe FRAC D1) pour le ou les derniers traitements fongicides avant récolte.

XEDATHANE-HN
AMM n°2160230

Page 6 sur 6

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

Projet d'étiquette XEDATHANE-HN

XEDA INTERNATIONAL, 1397 route nationale 7, Z.A.C. la Crau, 13670 St Andiol/ France, Tél : + 33 4 90 90 23 23, Fax : + 33 4 90 90 23 20 Agrément distribution et application de produits phytopharmaceutiques N°PA01355 Autorisation de mise sur le marché n°******** du ******** **PRODUIT DESTINE A UN USAGE PROFESSIONNEL**
CONTIENT : 15,2% poids/poids soit 153,6g/litre de pyriméthanil
EMBALLAGE : Quantité nette par emballage 5 litres
Fabriqué le /Lot n°
USAGE : HN (produit pour nébulisation à chaud) Pommier, Poirier, Cognassier, Nèfle, Nashi, Pommette * Traitement des produits récoltés * maladies de conservation (*Gloeosporium* spp., *Botrytis*).
CONDITIONS ET DOSE D'EMPLOI : XEDATHANE-HN doit être utilisé exclusivement par thermonébulisation avec les « électrofogs » XEDA et en se conformant à la fiche technique du produit. Température de traitement 180 ± 5°C. De 50 g de XEDATHANE-HN par tonne de fruits à traiter en une application. Dans le cas d'une chambre partiellement remplie, évaluer le dosage du produit en ajoutant au tonnage réel le tonnage correspondant à 20% du volume vide. Ex. : chambre de 400T remplie à 300T=300T+100T à 20%=320T La dose agréée est la plus petite dose qui garantit la meilleure efficacité dans la plupart des situations. Elle peut être réduite, sous la responsabilité de l'utilisateur. La diminution de la dose appliquée n'autorise pas l'augmentation du nombre maximal d'applications. Une réduction inappropriée de la dose peut cependant augmenter le risque d'une moins bonne efficacité et de la qualité, ainsi qu'augmenter le risque d'apparition de résistance. **DATE DE TRAITEMENT :** Le plus tôt possible après la récolte sans excéder les 15 jours. **PRECAUTIONS ET CONDITIONS D'APPLICATION :** Avant de commencer le traitement, s'assurer que les fruits dans la chambre à traiter sont secs et correctement protégés conformément à la fiche technique correspondante. Les palox du haut de chaque pile doivent être individuellement couverts. L'Electrofog est placé à l'extérieur de la cellule à traiter, seul le tube de nébulisation est introduit dans la chambre de stockage (40cm). Un seau métallique est positionné sous le déflecteur situé en bout de tube de manière à recueillir les éventuels écoulements de produit. **COMPATIBILITE :** XEDATHANE-HN est compatible avec la gamme des aérosols XEDA. L'utilisateur est responsable et il doit s'informer auprès des distributeurs de la miscibilité avec d'autres produits.
Délai de rentrée : la rentrée dans la zone traitée ne devra pas se produire avant le dépôt complet puis le séchage du produit sur les fruits. Attendre un minimum de 6 heures avant de pénétrer dans la chambre pour enlever les protections et remettre la chambre en régime.

STOCKAGE :
Les bidons doivent être stockés à une température comprise entre +10°C et +30°C. Le produit est utilisable jusqu'à 3 ans après l'année de fabrication si les bidons sont gardés, scellés à la température indiquée. Ne pas conserver de bidons entamés.

ELIMINATION :
Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux. Traitement obligatoire des eaux de rinçage rejetées.
Eliminer les emballages vides via une collecte organisée par les distributeurs de la filière ADIVALOR.
Il est strictement interdit de réutiliser l'emballage vide du produit.

Les indications d'emploi inscrites sur nos notices et étiquettes sont établies d'après des résultats d'essais officiels et privés qui se sont montrés les plus constants dans la pratique. Elles ne constituent pas des règles absolues mais des recommandations générales qui doivent être adaptées au cas particulier de tout traitement, en raison des nombreux facteurs qui échappent à notre contrôle, tels que variétés végétales, état de la culture, conditions atmosphériques particulières, matériel et conditions d'application.
Nous déclinons en conséquence toute responsabilité découlant de toute adaptation ou mélange à d'autres substances en dehors de notre contrôle ou de nos recommandations. Notre responsabilité est expressément limitée à la fourniture de spécialités contrôlées légalement autorisées à la vente et conformes à la formule indiquée sur l'emballage

ADIVALOR

Photo ?

règlement (CE) n°1272/2008 = CLP, classification, emballages, étiquetage des substances et des mélanges

taille de chaque pictogramme = un quinzième de la surface de l'étiquette

ATTENTION
Liquide et vapeurs inflammables
Peut provoquer une allergie cutanée. Provoque une sévère irritation des yeux. Peut provoquer somnolence ou vertiges. Nocif pour les organismes aquatiques, entraîne des effets néfastes à long terme.
Prévention : Tenir à l'écart de la chaleur/des étincelles/des flammes nues/des surfaces chaudes. – Ne pas fumer. Éviter de respirer les fumées/brouillards/ aérosols. Eviter le rejet dans l'environnement. Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage
Intervention : Si l'irritation oculaire persiste: consulter un médecin. En cas d'irritation ou d'éruption cutanée : consulter un médecin.
Elimination : Éliminer le contenu/récipient conformément à la réglementation nationale.
L'exposition répétée peut provoquer dessèchement ou gerçures de la peau.
Respectez les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement.
Ne pas polluer l'eau avec le produit ou son emballage. [Ne pas nettoyer le matériel d'application près des eaux de surface. /Eviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes]

CONSULTER LA FICHE TECHNIQUE ET LES DONNEES DE SECURITE disponibles sur demande : fds@xeda.com ou accessibles sur www.quickfds.fr

Appendix 3 – Letter(s) of Access

ANSES – DPR – UGAmm
253 avenue du Général Leclerc
94700 Maisons-Alfort
Cédex
France

LETTER OF ACCESS

We, Agriphar S.A., rue de Renory 26/1, B-4102 Ougrée, Belgium, hereby authorize you to use our data package on pyrimethanil technical (AFSSA Dossier Reference : 2007-3819) in support of the registration requested by the company XEDA International SA, located at Z.A. La Crau, 13670 Saint-Andiol, France, for the following product:

"XEDATHANE-HN" (pyrimethanil 153 g/L HN)

This letter of access is only applicable to the above mentioned product, any subsequent products notified for registration and containing the active ingredient Pyrimethanil or any amendment made to the registration of XEDATHANE-HN must be supported with a new letter of access.

This letter of access is valid exclusively for Pyrimethanil from Agriphar origin as the sole source of active ingredient and is not a general letter of access. The right of referral is solely granted to XEDA International SA and is not transferable to any further companies or other legal or natural entities.

XEDA International SA is not authorised to receive any copies of the dossier nor is it authorized to inspect or view the dossier or any specific document in whole or in part. All data remains the confidential property of Agriphar.

Made in Ougrée, 10/03/2014

Isabelle Cornille
Regulatory Affairs Project Manager
Agriphar S.A.

Dr Georges Neumann
Executive vice-president
Agriphar S.A.

Your partner in plant protection
AGRIPHAR s.a. Rue Renory, 26/1 | BE-4102 Ougrée
T + 32 (0)4 385 97 11 | F + 32 (0)4 385 97 97 | info@agriphar.com | www.agriphar.com
NE BE 0877.444.281 | TVA BE 0877.444.281 | BNP PARIBAS IBAN BE98 0014 6215 8293 BIC GEBABEBB
BYBLOS BANK EUROPE SA IBAN BE12 6752 0922 0192 BIC BYBOBEBB | ING IBAN BE26 3401 5510 2129 BIC BBRUBEBB