REGISTRATION REPORT Part A Risk Management

Product code: PYRETHRINS 2% W/V EC Product name: PIRECRIS Chemical active substance(s):

pyrethrins, 20 g/L

Interzonal Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE (label extension)

Applicant: SEIPASA S.A. Date: 14/03/2024

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PART A RISK MANAGEMENT

1 Details of the application

The company SEIPASA S.A. has requested a marketing authorisation in France for the product PIRECRIS (product code : PYRETHRINS 2% W/V EC, market authorisation n° 2161106), containing 20 g/L pyrethrins as an insecticide for professional uses.

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

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

1.1 Application background

The present registration report concerns the evaluation of SEIPASA S.A's application submitted on 30/05/2022 to market PIRECRIS (PYRETHRINS 2% W/V EC) in France (product uses described under point 2.3). France acted as a zonal (zRMS open field uses) and interzonal Rapporteur Member State (izRMS, greenhouse uses) for this request and assessed the application submitted for the label extension of this product in France and in other Member States (MSs) of the European Union.

The present application (2022-2688) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009¹, the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone for field uses and for all MSs of the European Union for uses under protection, taking into account the worst-case uses ("risk envelope approach")². When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of PIRECRIS (PYRETHRINS 2% W/V EC) has been made using endpoints agreed in the EU peer review of pyrethrins . It also includes assessment of data and information related to PIRECRIS (PYRETHRINS 2% W/V EC) where those data have not been considered in the EU peer review process.

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 risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011³, and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

This document also describes the specific conditions of use and labelling required for France for the extension of use of PIRECRIS (PYRETHRINS 2% W/V EC).

¹ 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

² SANCO document "risk envelope approach", European Commission (14 March 2011). <u>Guidance document on the preparation and submission</u> of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. <u>5</u>

³ COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

1.2 Letters of Access

The applicant has provided a letter of access for active substance (and/or PPP data). This letter of access is available upon request.

1.3 Justification for submission of tests and studies

According to the applicant: « All conducted studies are necessary for evaluation and authorisation of extension of use of major crops (grapes) of this product.

For the extension of use to greenhouse crops (strawberries, cane fruits, other small fruits and berries and cucurbits with edible peel) against *Drosophila suzukii* and Whitefly, new studies are submitted, which demonstrate the efficacy of the PPP against this pest».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of PIRECRIS (PYRETHRINS 2% W/C EC), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

[
Product code	PYRETHRINS 2% W/V EC
Product name in MS	PIRECRIS
Authorisation number	2161106
Kind of use	Professional use
Function	Insecticide
Applicant	SEIPASA S.A
Active substance(s) (incl. content)	Pyrethrins (20 g/L).
Formulation type	Emulsifiable concentrate [Code: EC].
Packaging	Packaging not changed (see first Market authorisation)
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.1 **Product identity**

2.2 Conclusion

The evaluation of the application for PIRECRIS (PYRETHRINS 2% W/V EC) resulted in the decision **to refuse** the authorisation.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

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

Refers to marketing authorisation: no label extension of marketing authorisation granted

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
	For other restrictions refer to 2.5

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017⁴ provides that:

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

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

Moreover, the French Order of 12 April 2021⁵ provides that:

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

⁵ <u>https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456</u>

- an authorisation granted for a "reference" crop applies also for "related" crops, unless formally stated in the Decision
- the "reference" and "related" crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "related" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those "related" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁶ 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.

Finally, the French Order of 20 November 2021⁷ on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless otherwise stated in the product authorisation, use on attractive crop⁸ when in flower and on foraging area is forbidden. Specific conditions of application on flowering crops should be respected. As consequences specific SPe 8 may include reference to this order.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

2.5.1 Restrictions linked to the PPP

Refers to marketing authorisation: no label extension of marketing authorisation granted.

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

⁶ SANCO document "guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs": SANCO/ 7525/VI/95 - rev.9

⁷ <u>https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734</u>

⁸ List of culture considered as unattractive to bees and other pollinators insects defined by French Agricultural ministry and published in Bulletin Officiel du ministère chargé de l'agriculture.

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (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: 14/03/2024
PPP (product name/code):	Pyrethrins 2% w/v EC/PERICRIS	Formulation type:	EC ^(a, b)
Active substance 1:	Pyrethrins	Conc. of a.s. 1:	20 g/L ^(c)
Applicant:	SEIPASA S.A	Professional use:	\boxtimes
Zone(s):	Interzonal ^(d)	Non-professional use:	
Verified by MS:	Yes		
Field of use:	Insecticide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-	Member		F, En		Application	Application			11			PHI (dava)	Remarks:
No. ^(e)	state(s)	or situation (crop destination/purpose of crop)	Fn, Fpn G, Gn, Gpn or I	controlled (additionally: developmental stages of the pest or pest group)	Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	product/ha a) max. rate per appl. b) max. total rate	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	L/ha min/ma		e.g. g safener/synergist per ha (f)
Zonal	uses (field	or outdoor uses, ce	ertain t	types of protected crops)									
1	France	Grapes	F	Cicadellidae	Foliar spray	At pest presence. BBCH 50: inflorescence emerge BBCH 80: ripening-harvest	a) 1 b) 3	7	a) 1.5 b) 4.5	a) 30 b)90	200- 800	3	Not acceptable (consumer exposure, groundwater, aquatic organisms, birds/mam- mals, and soil organ- isms).
Interz	terzonal 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)												

Part A - National Assessment

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member	Crop and/		Pests or Group of pests	Application				Max Application rate			PHI (days)	Remarks:
INO. (*	state(s)	Fon	Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	product/ha a) max. rate per appl.	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	min/ma		e.g. g safener/synergist per ha (f)		
1	FR	Strawberry	G	Drosophila suzukii	Foliar spray	BBCH 40-89	a) 3 b) 3	7	a) 1.5 b) 4.5	a) 30 b) 90	300- 1000	1	Not acceptable (MRL) AND For permanent green- house with soil-bound- Not acceptable (consumer exposure, groundwater ,aquatic organisms, birds/mam- mals). For walk-in tunnel Not, acceptable (consumer exposure, groundwater, aquatic organisms, birds/mam- mals, soil organisms).

Part A - National Assessment

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-	Member	Crop and/		Pests or Group of pests	Application			Max Application rate			PHI	Remarks:	
No. (*	state(s)	or situation (crop destination/purpose of crop)	Fn, Fpn G, Gn, Gpn or I	controlled (additionally: developmental stages of the pest or pest group)	Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	product/ha a) max. rate per appl.	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	L/ha min/ma	(days)	e.g. g safener/synergist per ha (f)
2	FR	Cane fruits (blackberries, dewberries, raspberries (red and yellow) and others)	G	Drosophila suzukii	Foliar spray	BBCH 40-89	a) 3 b) 3	7	a) 1.5 b) 4.5	а) 30 b) 90	300- 1000	1	Not acceptable (MRL) AND for permanent green- house with soil less Not acceptable (consumer exposure) For permanent green- house with soil-bound Notacceptable (consumer exposure, groundwater , aquatic organisms, birds/mam- mals). For walk-in tunnel Not acceptable (consumer exposure, groundwater, aquatic organisms, birds/mam- mals, soil organisms).

Part A - National Assessment

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-		Crop and/		Pests or Group of pests	Application	1			Max Application	rate		PHI	Remarks:
No.	e) state(s)	or situation (crop destination/purpose of crop)	Fpn G,	controlled (additionally: developmental stages of the pest or pest group)	Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	product/ha a) max. rate per appl.	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	L/ha min/ma	(days)	e.g. g safener/synergist per ha
3	FR	Other small fruits and berries (Blueberries, Cranberries, Currants (black, red and white), Gooseberries (green, red and yellow), Rose hips, Mulberries (black and white), Azaroles /Mediterranean medlars, Elderberries and others)	G	Drosophila suzukii	Foliar spray	BBCH 40-89	a) 3 b) 3	7	a) 1.5 b) 4.5	a) 30 b) 90	300- 1000	1	Not acceptable (MRL) AND For permanent green- house with soil less Not acceptable (consumer exposure) For permanent green- house with soil-bound Not acceptable (consumer exposure, groundwater, aquatic organisms, birds/mam- mals). For walk-in tunnel Not acceptable (consumer exposure, groundwater aquatic or- ganisms, birds/mam- mals, soil organisms).

Part A - National Assessment

FRANCE

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-	Member		F,	Pests or Group of pests	Application	Application			Max Application rate			PHI	Remarks:
No. ^(e)	state(s)	or situation (crop destination/purpose of crop)	Fn, Fpn G, Gn, Gpn or I	pn (additionally: a, (additionally: b, developmental stages of cpn the pest or pest group)	Method/Ki nd		Max. number a) per use b) per crop/ season	Min. interval between applications (days)	product/ha a) max. rate per appl.	a) max. rate per	L/ha min/ma	(days)	e.g. g safener/synergist per ha
4	FR	Cucurbits with edible peel (Cucumber, Courgette, Gherkins, and others)	G	Whitefly	Foliar spray	BBCH 12-89	a) 3 b) 3	7	a) 1.5 b) 4.5	a) 30 b) 90	300- 1000	1	Not acceptable (MRL) AND for permanent green- house with soil less Not acceptable (consumer exposure) For permanent green- house with soil-bound Not acceptable (consumer exposure, groundwater, aquatic organisms, birds/mam- mals). For walk-in tunnel Notacceptable (consumer exposure, groundwater, aquatic organisms, birds/mam- mals, soil organisms).

* As some standards may have undergone changes, it is the responsibility of the applicant to update the references.

Remarks (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

- table(b)Catalogue of pesticide formulation types and international coding system CropLifeheading: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.

Part A - National Assessment

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

3 Background of authorisation decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

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 a translucent yellow liquid, with chemical odour. It is not explosive, has no oxidising properties. It is not flammable, and it has a self ignition temperature of 418°C. It does not contain >10% of hydrocarbons or other components classified as H304. The product showed a Newtonian behaviour and it should be considered as surface-active material. In aqueous emulsion, it has a pH value around 5.27.

The stability data at 54°C for 2 weeks and at 0°C for 7 days indicated that the product shows no degradation of active substances neither significant change of its physical-chemical properties. Based on two-year storage stability data, it has been demonstrated that the product is stable in HDPE packaging at ambient temperature. A shelf life of at least two years can be assigned.

3.2 Efficacy (Part B, Section 3)

Considering the data provided :

-PIRECRIS (PYRETHRINS 2% W/V EC) efficacy level is considered acceptable for all claimed uses.

-PIRECRIS (PYRETHRINS 2% W/V EC) phytotoxicity level is considered negligible for all claimed uses. -The risks of adverse effects on yield, quality, wine making process and propagation are considered negligible.

-The risks of adverse effects on succeeding and adjacent crops are considered negligible.

-Considering the data provided, a particular care should be given to the conditions of application of PIRECRIS (PYRETHRINS 2% W/V EC) in the frame of IPM.

- The risk of resistance apparition and development to pyrethrins does not require any monitoring data for the claimed uses

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Validated methods for the determination of the active substance in the product are available. As no relevant impurity has been defined, no analytical method is required for their determination in the product.

3.3.2 Analytical methods for residues

Analytical methods for the determination of pyrethrins residues in plant matrices are available in the DAR of pyrethrins. New methods were provided for the determination of pyrethrins residues in matrices with high water or high acid content, however as the extraction efficiency of these methods is not demonstrated, they are not considered validated.

Analytical methods for the determination of pyrethrins residues in water, soil, air and body fluids are not available, and shall be provided at the renewal of the active substance (currently ongoing).

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Agreed EU endpoints	
Active substance	Pyrethrins
AOEL systemic	0.07 mg/kg bw/day
AAOEL	-
Oral absorption	55%
Vapour pressure	pyrethrin 1: 6.9×10^{-5} Pa (25°C) pyrethrin 2: 2.7×10^{-5} Pa (25°C)
Reference	EFSA Supporting publication 2017 (EFSA Supporting publication 2017:EN-1212)
Dermal absorption	Concentrate : 10% Dilution : 10% Default values (<i>EFSA Journal 2013;11(1):3032</i>)

3.4.1 Acute toxicity

PIRECRIS (PYRETHRINS 2% W/V EC) containing 20 g/L pyrethrins has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is a skin sensitiser.

3.4.2 Operator exposure

Considering the proposed uses, the operator systemic exposure was estimated using the EFSA model 2014 :

		Pyrethrins				
Model data	Level of PPE	% AOEL				
Application : Tra outdoor Grapes						
Application rate:	1.5 L/PIRECRIS (PYRETHRINS 2% W/V EC) /ha	3 x 0.03 kg pyrethrins / ha				
Spray ap-plica- tion (AOEM; 75th percentile) Body weight: 60 kg	Working coverall and gloves during mix/loading and application	1.86%				

		Pyrethrins
Model data	Level of PPE	% AOEL
Indoor	nual / <i>upward spraying</i> other small fruits and fruiting vegetables.	1
Application rate:	1.5 L/PIRECRIS (PYRETHRINS 2% W/V EC) /ha	3 x 0.03 kg pyrethrins / ha
Spray ap-plica- tion (AOEM; 75th percentile) Body weight: 60 kg	Working coverall and gloves during mix/loading and application	3.39%

According to the model calculations, it can be concluded that the risk for the operator using PIRECRIS (PYRETHRINS 2% W/V EC) is acceptable with a working coverall and gloves during mixing/loading and application.

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

3.4.3 Worker exposure

Workers may have to enter into treated areas after treatment for crop hand harvesting or reaching, picking activities. Therefore, the estimation of worker exposure was calculated according to AOEM model 2014.

		Pyrethrins	
Model data	Level of PPE	%AOEL	
Activity: Hand harvesting Outdoor Work rate: 8 hours/day Number of applications : 3 Interval between treatments: 7 days			
DT50:		30 days	
DFR:		3 μg/cm ² /kg a.s./ha	
Application rate (kg	as/ha)	3 x 0.03 kg pyrethrins/ha	
Body weight: 60 kg	Work wear (arms, body and legs covered) TC: 10100 cm2/person/h	44.57%	

Outdoor uses : There is no unacceptable risk anticipated for the worker reentering into treated crops.

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

Model data Level of PPE		Pyrethrins	
		%AOEL	
Activity: Reaching, p Indoor Work rate: 8 hours/d Number of applicatio Interval between trea	ay ons : 3		
DT50:		30 days	
DFR:		3 μg/cm ² /kg a.s./ha	
Application rate (kg	as/ha)	3 x 0.03 kg Pyrethrins /ha	
Body weight: 60 kg	Work wear (arms, body and legs covered) + gloves TC: 750 cm2/person/h	3.31%	

Indoor uses: There is no unacceptable risk anticipated for the worker reentering into treated crops.

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

3.4.4 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 .

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."

3.4.5 Resident exposure

Outdoor uses :

Resident exposure was assessed according to EFSA model without mitigation measures, a distance of 10 metres from the spray boom and no drift reduction technology was considered.

		Pyrethrins		
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	
Tractor mounted boon Buffer zone: 10 (m) Drift reduction techno DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s Interval between treat	./ha	s to high crops		
Number of application	ns and application rate	3 x 0.03 kg a.s./ha		
Resident child	Drift (75 th perc.)	0.0021	3.00	
Body weight: 10 kg	Vapour (75 th perc.)	0.0011	1.53%	
	Deposits (75 th perc.)	0.0000	0.04%	
	Re-entry (75 th perc.)	0.0013	1.86%	
	Sum (mean)	0.0013	5.02%	
Resident adult	Drift (75 th perc.)	0.0035	1.66%	
Body weight: 60 kg	Vapour (75 th perc.)	0.0002	0.33%	
	Deposits (75 th perc.)	0.0000	0.01%	
	Re-entry (75 th perc.)	0.0007	1.03%	
	Sum (mean)	0.0016	2.25%	

An acceptable risk was determined for resident (adult and child).

Indoor uses :

Not applicable for the proposed uses. Since the application will take place in greenhouses, no bystander or resident exposure is expected for the intended uses.

3.4.6 Combined exposure

Not relevant. The product contains only one active substance.

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

An exceedance of the current MRL of 1 mg/kg for pyrethrins in grapes, cucurbits with edible peel and blueberries as laid down in Reg. (EU) 396/2005 is not expected according to the uses intended in France.

The number of residue trials is not considered sufficient to support the intended uses on strawberries, cane fruits, cranberries, currants, gooseberries, rose hips, mulberries, azaroles and elderberries in France.

The chronic and the short-term intakes of pyrethrins residues are unlikely to present a public health concern regarding the provisional residue definition for risk assessment set as "pyrethrins, sum of pyrethrin 1&2, cinerin 1&2 and jasmolin 1&2" considering the uncertainties related to the pyrethrolone metabolites and the toxicological relevance of hydroxy-chrysanthemic acid metabolites..

Confirmatory data regarding these uncertainties were further submitted.

Nevertheless as:

- Confirmatory data were not considered sufficient by EFSA to address in general the fate of the pyrethrolone moiety or of the hydroxy-chrysanthemic acid metabolites in treated crops and to demonstrate that residues of metabolites will be regularly below LOQ or not even formed.
- Information on the toxicity (including genotoxicity) of the metabolites were not considered sufficient by EFSA to conclude on their toxicological profile

EFSA considered that a firm conclusion on the consumer risk assessment is still not possible and further evidence is necessary to ascertain the actual exposure and risk potential for the consumer related to the use of pyrethrins (EFSA, 2017).

Consequently a firm conclusion cannot be reached for the intended uses in the framework of this dossier.

Summary for PIRECRIS (PYRETHRINS 2% W/V EC)

Table 3.5-1:Information on PIRECRIS (PYRETHRINS 2% W/V EC) (KCA 6.8)

	PHI for PIRECRIS (PYRETHRINS 2%	PHI/ Withholding period* sufficiently supported for	PHI for PIRE- CRIS	zRMS Com- ments (if differ- ent PHI proposed)
Сгор	W/V EC) proposed by appli- cant	Pyrethrins	(PYRETHRINS 2% W/V EC) proposed by zRMS	
Grapes	3 days	Yes	NA	Not possible to conclude on the consumer risk assessment
Strawberry	1 day	No	NA	Not possible to conclude on the consumer risk assessment
Cane fruits	1 day	No	NA	Not possible to conclude on the consumer risk assessment
Cranberries, Currants (black, red and white), Gooseberries (green, red and yellow),	1 day	No	NA	Not possible to conclude on the consumer risk assessment

Сгор	PHI for PIRECRIS (PYRETHRINS 2% W/V EC) proposed by appli- cant	PHI/ Withholding period* sufficiently supported for Pyrethrins	PHI for PIRE- CRIS (PYRETHRINS 2% W/V EC) proposed by zRMS	zRMS Com- ments (if differ- ent PHI proposed)
Rose hips, Mulberries (black and white), Azaroles / Mediterranean medlars, Elderberries and others)				
Blueberries	1 day	Yes	NA	Not possible to conclude on the consumer risk assessment
Cucurbits with edible peel	1 day	Yes	NA	Not possible to conclude on the consumer risk assessment

NR: not relevant

Purpose of withholding period to be specified

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

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

The PEC values of pyrethrin 1 and its metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

No exposure of the environmental compartment is expected from soil-less uses under permanent greenhouses.

For field uses and walk-in tunnels, PECsoil values derived for the active substance are used for the ecotoxicological risk assessment. For soil bound uses under permanent greenhouses no PECsoil are required.

For field uses, walk-in tunnels and soil bound uses under permanent greenhouses, surface water exposure calculations could not be validated, due to several major deviations. As a consequence, the exposure assessment for the surface water compartment cannot be finalised.

For field uses, walk-in tunnels and soil bound uses under permanent greenhouses, PECgw values for pyrethrin 1 do not occur at levels exceeding those mentioned in Regulation (EC) no 1107/2009. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

According to the RMS, Italy, confirmatory data assessed in the addendum of July 2016 demonstrate that pyrethrin 1 is representative with respect to the environmental assessment of all the pyrethrin components. However, for pyrethrin 1, studies are available with material labelled in the cyclopropane ring only. Therefore, a data gap has been identified to address the fate and behaviour of the cyclopentelone moiety after the rupture of the ester bridge in the pyrethrins (normally the first degradation step). This data gap has not been addressed in the current submission. Therefore, in agreement with the EFSA conclusions, based on the available data, France as zRMS considers that the environmental risk assessment cannot be finalised, except for soil-less uses under permanent greenhouses.

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance and its metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Based on the guidance documents, the risks for birds, aquatic organisms, mammals, bees and other nontarget arthropods, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants are acceptable for the intended uses in soil-less greenhouses in the conditions of uses described under 2.5.

For field uses, walk-in tunnels and soil bound uses under permanent greenhouses, surface water exposure calculations could not be validated. Moreover a complete fate and behavior of pyrethrins in water system is not available. Thus, based on the guidance documents, the risk for the aquatic organisms, mammals and birds is not finalized.

For field uses, walk-in tunnels and soil bound uses under permanent greenhouses, a complete fate and behavior of pyrethrins in soil is not available. Thus, the risk for the soil organisms is not finalized.

For field uses and walk-in tunnels, more information on effects on brood is required. Thus, based on the available data, the risk for the bees is not finalized.

Based on the guidance documents, the risks for other non-target arthropods and terrestrial plants are acceptable for the intended uses in the conditions of uses described under 2.5.

3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to environmental fate and behaviour above for conclusion on the risk of groundwater contamination.

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

The active substance pyrethrins is not approved as a candidate for substitution, therefore a comparative assessment is not foreseen.

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

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

5.1.1 **Post-authorisation monitoring**

None.

5.1.2 Post-authorisation data requirements

None.

Appendix 1 Copy of the product authorisation

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Décision relative à une demande d'extension d'usages 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'extension d'usages majeurs du produit phytopharmaceutique PIRECRIS

de la société	SEIPASA SA
enregistrée sous le	n° 2022-2688

Vu les conclusions de l'évaluation de l'Anses du 19 octobre 2023,

Considérant que les données disponibles ne permettent pas d'exclure un risque inacceptable pour les organismes aquatiques, les oiseaux et les mammifères pour les utilisations en pleine terre,

Considérant également que les données disponibles ne permettent pas d'exclure un risque inacceptable pour les organismes du sol pour les utilisations sous tunnel et en plein champ,

Considérant par ailleurs, que les données disponibles ne permettent pas d'exclure pour les utilisations en pleine terre, un risque de contamination des eaux souterraines,

Considérant enfin, qu'il existe un risque de dépassement des limites maximales de résidus sur fraisiers, framboisiers, cassissier, groseilliers, sureau noir, mûrier, airelle, églantier-cynorhodon et azerolier et que les données disponibles ne permettent pas d'exclure un risque d'effet nocif pour les consommateurs pour les autres usages,

Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 sont respectées,

L'autorisation de mise sur le marché du produit référencé ci-après n'est pas étendue aux usages décrits dans la présente décision.

THIOVIT JET MICROBILLES AMM n°2000018

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Informations générales sur	r le produit	
Nom du produit	PIRECRIS	
Type de produit	Produit de référence	
Titulaire	SEIPASA SA C/ Almudévar 2 22240 Tardienta (Huesca) Espagne	
Formulation	Concentré émulsionnable (EC)	
Contenant	20 g/L - pyréthrines	
Numéro d'intrant	738-2014.01	
Numéro d'AMM	2161106	
Fonction	Insecticide	
Gamme d'usage Professionnel		

A Maisons-Alfort, le 14/03/2024

Uccusigned by: Ucarlotte Grastilleur AE281A955A42454

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

PIRECRIS AMM nº 2161106

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Liberté Égalité Fraternité



ANNEXE : Conditions de mise sur le marché demandées

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)	
	1,5 L/ha	3/an	1	
12153115 Cassissier*Trt Part.Aer.*Mouches des fruits	Motivation du refus : L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus sur cassissier, groseilliers, sureau noir, mûrier, airelle, églantier-cynorhodon, et azerolier, et car les données disponibles ne permettent pas d'exclure un risque d'effet nocif pour le consommateur pour une utilisation sur myrtillier. L'usage est également refusé car pour les cultures en pleine terre, les données disponibles ne permettent pas d'exclure un risque d'effets inacceptables pour les organismes aquatiques, les oiseaux, et les mammifères ni un risque de contamination des eaux souterraines, ni un risque d'effets inacceptables pour les organismes du sol pour les cultures sous tunnel.			
	1,5 L/ha	3/an	1	
16323103 Cucurbitacées à peau comestible*Trt Part.Aer.*Aleurodes	pour les cultures en pleine terre, le organismes aquatiques, les oisea	s disponibles ne permettent pas d'exclure un risque o es données disponibles ne permettent pas d'exclure nux, et les mammifères ni un risque de contaminati anismes du sol pour les cultures sous tunnel.	un risque d'effets inacceptables pour les	
	1,5 L/ha	3/an	1	
01125024 Fraisier*Trt Part.Aer.*Mouches	Motivation du refus : L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus et car pour les cultures en pleine terre, les données disponibles ne permettent pas d'exclure un risque d'effets inacceptables pour les organismes aquatiques, les oiseaux, et les mammifères ni un risque de contamination des eaux souterraines, ni un risque d'effets inacceptables pour les organismes du sol pour les cultures sous tunnel.			

PIRECRIS

AMM nº 2161106

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			anses
Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
	1,5 L/ha	3/an	1
12353115 Framboisier*Trt Part.Aer.*Mouches des fruits	terre, les données disponibles ne p	risque de dépassement des limites maximales de re permettent pas d'exclure un risque d'effets inacceptal risque de contamination des eaux souterraines, ni u s sous tunnel.	bles pour les organismes aquatiques, les
	1,5 L/ha	3/an	3
12703121 Vigne*Trt Part.Aer.*Autres cicadelles		e les données disponibles ne permettent pas d'e ts inacceptables pour les organismes aquatiques, le mination des eaux souterraines.	
	1,5 L/ha	3/an	3
12703122 Vigne*Trt Part.Aer.*Cicadelles de la flavescence dorée		e les données disponibles ne permettent pas d'e ts inacceptables pour les organismes aquatiques, le mination des eaux souterraines.	

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Appendix 2 Copy of the product label

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.

<u>Zone principale</u> (Disponibilité d'information dans la zone centrale de l'étiquette)

PIRECRIS

INSECTICIDE – concentré émulsionnable (EC)

Contenu net: 5 litres

Teneur en substance active: Pyréthrines 20 g/l (2,14 % w/w) N° AMM : 2161106

Détenteur de l'Autorisation de Mise sur le Marché (AMM) SEIPASA, S.A C/Almudévar, 2 22240 Tardienta (Huesca) Tel:00 34 974 253 433 Fax: 00 34 974 253 498 Email: consulta@seipasa.com.

Avant d'utiliser un produit phytosanitaire, veuillez lire attentivement l'étiquette. RESERVÉ À UN USAGE EXCLUSIVEMENT PROFESSIONNEL Date de fabrication: Numéro de lot: Date d'expiration: 2 ans après la date de fabrication.

ZONE DE SÉCURITÉ (Disponibilité d'information sur la partie gauche de l'étiquette)

PIRECRIS AMM : 2161106 Mention d'avertissement: ATTENTION Symboles et pictogrammes:



Mentions de danger :

H317 Peut provoquer une allergie cutanée.

H410 Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.

Conseils de prudence :

P102 Tenir hors de portée des enfants.

P261 Éviter de respirer les poussières/fumées/gaz/brouillards/vapeurs/ aérosols.

P272 Les vêtements de travail contaminés ne devraient pas sortir du lieu de travail.

P273 Éviter le rejet dans l'environnement.

P280 Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/ du visage.

P302+P352: En cas de contact avec la peau: Laver abondamment à l'eau et au savon.

P333+P313: En cas d'irritation ou d'éruption cutanée: consulter un médecin.

P363 Laver les vêtements contaminés avant réutilisation.

P391 Recueillir le produit répandu.

P501 Éliminer le contenu/récipient conformément à la réglementation.

Autres phrases et mentions obligatoires

EUH401 Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.

SP1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

SPe8 : Dangereux pour les abeilles. Pour protéger les abeilles et autres insectes pollinisateurs, ne pas appliquer durant la floraison et en période de production d'exsudat. Peut porter atteinte à la faune auxiliaire, éviter toute exposition inutile.

Délai de rentrée : 48 heures.

Recommandations en cas d'intoxication ou accident:

Premiers secours:

Retirer la personne de la zone contaminée.

Retirer immédiatement les vêtements souillés.

Rincer immédiatement et abondamment les yeux avec de l'eau pendant au moins 15 minutes. Laver abondamment la peau avec de l'eau et du savon.

Ne rien donner par la bouche.

En cas d'ingestion, ne pas faire vomir. Attention: Peut causer une pneumonie lipidique.

Garder le patient au repos.

Contrôler la respiration. Si nécessaire, pratiquer la respiration artificielle. Peut provoquer une paresthésie orale. Le risque de réactions d'hypersensibilité avec bronchospasme.

Si la personne est inconsciente, allongez-le sur le côté, la tête plus basse que le reste du corps et les genoux légèrement pliés.

Amener le patient à l'hôpital et, si possible, prendre l'emballage ou l'étiquette. Réaliser un traitement symptomatique.

NE LAISSER EN AUCUN CAS LE PATIENT TOUT SEUL. EN CAS D'URGENCE APPELER LE 15 OU LE CENTRE ANTI-POISON PUIS SIGNALEZ VOS SYMPTOMES AU RESEAU PHYT'ATTITUDE N° VERT 0 800 887 887 (APPEL GRATUIT DEPUIS UN POSTE FIXE).

Pour éviter les risques pour les hommes et l'environnement suivez les instructions d'utilisation.

Une fois cet emballage est vide suite à l'utilisation de son contenu, c'est un déchet dangereux par conséquent l'utilisateur est obligé de le remettre à un service de collecte spécifique aux produits professionnels comme la filière ADIVALOR, ou à un autre service de collecte spécifique comme Eco-Emballages (Point Vert) pour les produits grand public.

RÉEMPLOI DE L'EMBALLAGE INTERDIT. 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.)

Fiche de Données de Sécurité disponible sur : www.seipasa.com/fr/

Zone d'utilisation (Disponibilité d'information sur la zone droite de l'étiquette)

CARACTÉRISTIQUES :

PIRECRIS est un insecticide naturel à large spectre à base de pyréthrines naturelles pour lutter contre les ravageurs des différentes cultures. Sa formulation liquide 100% d'origine végétale a une action par contact mais également par ingestion en affectant le système nerveux des insectes (GROUP 3A INSECTICIDE). Son effet est rapide (forte puissance d'abattement ou « knock down ») et d'une basse persistance.

Usages autorisés et doses d'application

Traitements insecticides dans les cultures suivantes :

CULTURE	RAVAGEUR	NOMBRE MAXIMUM D'APPLICATION/ CAMPAGNE (INTERVALLE MINIMUM)	DOSES D'EMPLOI
Tomate Aubergine (Sous abri)	Aleurodes/Mouche Blanche	3 (7 jours)	1.5 l/ha (150 – 225 ml/hl)
Poivron (Sous abri)	Pucerons	3 (7 jours)	1.2 l/ha (120 – 180 ml/hl)
Vigne (Plein champ)	Cicadelles	3 (7 jours)	1.5 l/ha
Fraisier (Sous abri)	Mouches (Drosophila suzukii)	3 (7 jours)	1.5 l/ha
Petits fruits* (Sous abri)	Mouches (Drosophila suzukii)	3 (7 jours)	1.5 l/ha
Cucurbitacées à peau comestible (Sous abri)	Aleurodes/Mouche Blanche	3 (7 jours)	1.5 l/ha

*Framboisier, Mûres, Mûrier des haies, Cassissier, Myrtillier, Groseillier, Sureau noir, Mûrier, Airelle, Eglantier-Cynhorodon, Azerolier

Mode d'emploi :

Pirecris est idéal à inclure dans les programmes de lutte intégrée (et biologique), ainsi qu'en agriculture conventionnelle, en alternance avec des produits chimiques pour la gestion de la résistance.

Les traitements doivent commencer dès l'apparition des premiers individus. Effectuer les applications de préférence le soir ou aux premières heures du matin. Il est recommandé d'utiliser des volumes de bouillie et des pressions d'application adéquats pour assurer une bonne couverture foliaire, avec une attention particulière lors de l'application, à la partie inférieure des feuilles où la plupart des ravageurs se réfugient. Il est conseillé d'ajuster le pH de l'eau à des valeurs neutres ou légèrement acides entre 5-7 avant l'ajout de PIRECRIS.

Délais avant la récolte "DAR":

Pour toutes les cultures autorisées : 1 jour, sauf pour la vigne : 3 jours

CONDITIONS D'EMPLOI DU PRODUIT

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 à l'aide d'une lance (usage sous abri) pendant le mélange/chargement :

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de protection de catégorie III type 4 ou 3 (selon le niveau de protection recommandé pendant la phase d'application);
- OU
 - Gants en nitrile certifiés EN 374-3 ;
 - Combinaison de travail en polyester 65 / coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
 - EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;

Dans le cadre d'une application effectuée à l'aide d'une lance (usage sous abri) pendant l'application, sans contact intense avec la végétation, cultures hautes :

- Gants en nitrile certifiés EN 374-3 ,
- Combinaison de protection de catégorie III type 4 avec capuche ;
- Bottes de protection certifiées EN 13 832-3 ;

Dans le cadre d'une application effectuée à l'aide d'une lance (usage sous abri) pendant l'application avec contact intense avec la végétation, cultures hautes et basses :

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de protection de catégorie III type 3 avec capuche,
- Bottes de protection certifiées EN 13 832-3;

Dans le cadre d'une application effectuée à l'aide d'une lance (usage sous abri) pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés EN 374-3;
- Combinaison de protection de catégorie III type 4 ou 3 (selon le niveau de protection recommandé pendant la phase d'application);

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

Pour le travailleur, porter :

 une combinaison de travail (cotte en coton/polyester 35 % / 65 % - grammage d'au moins 230 g/m²) avec traitement déperlant et, en cas de contact avec la culture traitée, des gants en nitrile certifiés EN 374-3.

PRÉCAUTIONS:

Il est recommandé d'utiliser des buses antidérive.

Avertissements à l'utilisateur:

Les recommandations et les informations relatives aux produits et leur utilisation, sont le fruit d'études et de tests rigoureux. Toutefois, pendant l'utilisation peuvent apparaître de nombreux facteurs échappant à notre contrôle (différentes espèces et variétés de cultures, la préparation de mélanges, de l'application, les conditions météorologiques, le stade de croissance des cultures, etc...), nous vous conseillons toujours d'effectuer un test sur la culture. La société garantit la composition, la formulation et le contenu. L'utilisateur est responsable des dommages causés (manque d'efficacité, la toxicité, les déchets, etc....) pour inexécution totale ou partielle de l'étiquette. En cas de plainte ou réclamation concernant le produit ou le service, merci d'appeler le +34 962 541 163 et en donnant le numéro de lot du bon d'achat.

Instructions de stockage :

Gardez le produit dans son récipient d'origine, bien fermé, dans un endroit frais et sec. Ne pas stocker au-dessus de 50 °C. Ne pas exposer à la lumière et à toute source de chaleur. À n'utiliser qu'en cas de besoin reconnu. Ne pas dépasser les doses appropriées. Ne pas mélanger avec des matériaux oxydants, des produits excessivement alcalins ou acides.