

## **REGISTRATION REPORT**

### **Part A**

### **Risk Management**

**Product codes: ESAR 110-I**

**ESAR 110-I (Pyriproxyfen 10% EC)**

**ESAR 110-I (Pyriproxyfen 100g/L EC)**

**Pyriproxyfen 10% EC**

**Pyriproxyfen 100g/L EC**

**Product name: PYRIPROX**

**Active substance:**

**pyriproxyfen, 100g/L**

**COUNTRY: FRANCE**

**Southern Zone**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(New application)**

**Applicant: EXCLUSIVAS SARABIA S.A.**

**Date: 30/07/2020**

## Table of Contents

<b>1</b>	<b>DETAILS OF THE APPLICATION.....</b>	<b>7</b>
1.1	APPLICATION BACKGROUND.....	7
1.2	ACTIVE SUBSTANCE APPROVAL.....	7
1.3	REGULATORY APPROACH .....	8
1.4	DATA PROTECTION CLAIMS .....	9
1.5	LETTER(S) OF ACCESS .....	9
<b>2</b>	<b>DETAILS OF THE AUTHORISATION .....</b>	<b>9</b>
2.1	PRODUCT IDENTITY .....	9
2.2	CLASSIFICATION AND LABELLING.....	9
2.2.1	<i>Classification and labelling in accordance with Regulation (EC) No1272/2008 .....</i>	<i>9</i>
2.2.2	<i>Other phrases in compliance with Regulation (EU) No 547/2011 .....</i>	<i>9</i>
2.2.3	<i>Other phrases linked to the preparation .....</i>	<i>9</i>
2.3	PRODUCT USES.....	10
<b>3</b>	<b>RISK MANAGEMENT.....</b>	<b>13</b>
3.1	REASONED STATEMENT OF THE OVERALL CONCLUSIONS TAKEN IN ACCORDANCE WITH THE UNIFORM PRINCIPLES.....	13
3.1.1	<i>Physical and chemical properties .....</i>	<i>13</i>
3.1.2	<i>Methods of analysis .....</i>	<i>13</i>
3.1.3	<i>Mammalian Toxicology .....</i>	<i>13</i>
3.1.4	<i>Residues and Consumer Exposure .....</i>	<i>15</i>
3.1.5	<i>Environmental fate and behaviour.....</i>	<i>16</i>
3.1.6	<i>Ecotoxicology.....</i>	<i>17</i>
3.1.7	<i>Efficacy .....</i>	<i>17</i>
3.2	CONCLUSIONS ARISING FROM FRENCH ASSESSMENT .....	18
3.3	SUBSTANCES OF CONCERN FOR NATIONAL MONITORING .....	18
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 .....	18
3.4.1	<i>Post-authorisation monitoring.....</i>	<i>18</i>
3.4.2	<i>Post-authorisation data requirements .....</i>	<i>18</i>
3.4.3	<i>Label amendments .....</i>	<i>18</i>
	<b>APPENDIX 1 – COPY OF THE FRENCH DECISION .....</b>	<b>19</b>
	<b>APPENDIX 2 – COPY OF THE DRAFT PRODUCT LABEL AS PROPOSED BY THE APPLICANT .....</b>	<b>24</b>

**(right)**

**Directions for use:**


PYRIPROX is an Emulsifiable Concentrate (EC) formulation containing 100 g/L of pyriproxyfen used as a stomach and contact insecticide against scales, whiteflies and aphids in a range of crops.

Harvest interval: follow harvest intervals where recommended.

Use the rates recommended to ensure good spray coverage.

Recommendations	Rate of use	PHI
<b>Table and wine grapes</b> Pests: scales: mealybug ( <i>Planococcus citri</i> ) Applications in pre-flowering (winter treatments) (BBCH 92 to 60)  Maximum number of applications: 1 per season	0.05-0.075% (50-75 ml PYRIPROX /100 L water) Spray volume: 600-800 L/ha Equivalent to 600 ml PYRIPROX/Ha	n.a.
<b>Citrus (oranges, lemon and tangerines)</b> Pest: Black scale ( <i>Saissetia oleae</i> ), Citrus mussel scale ( <i>Lepidosaphes Beckii</i> ), Chaff scale ( <i>Parlatoria pergandei</i> ), Red scale ( <i>Aonidiella aurantii</i> ) and Oelander scale ( <i>Aspidiotus nerii</i> ) and others.  Application when larvae were detected.  Maximum number of applications: 1 per season	0.025-0.10% (25-100 ml PYRIPROX/100 L water) Spray volume: 1000-1500 L/ha Equivalent to 250-1200 ml PYRIPROX/Ha	30 days
<b>Pome fruit trees (apples and pears)</b> Pests: San Jose Scale ( <i>Quadraspidiotus perniciosus</i> ) Applications in pre-flowering (winter treatments) (BBCH 92 to 60)  Maximum number of applications: 1 per season	0.0375-0.05% (37.5-50 ml PYRIPROX /100 L water) Spray volume: 1000 L/ha Equivalent to 375-500 ml PYRIPROX/Ha	n.a.
<b>Stone fruit trees (peach, nectarine, apricot, cherries and plums)</b> Pests: San Jose Scale ( <i>Quadraspidiotus perniciosus</i> ) Applications in pre-flowering (winter treatments) (BBCH 92 to 60)  Maximum number of applications: 1 per season	0.0375-0.05% (37.5-50 ml PYRIPROX /100 L water) Spray volume: 1000 L/ha Equivalent to 375-500 ml PYRIPROX/Ha	n.a.
<b>Tomato and aubergines</b> Pests: whiteflies and aphids Application when larvae were detected.  Maximum number of applications: Up to 2 applns per season with an interval of 15 days	0.05-0.075% (50-75 ml PYRIPROX/100 L water) Spray volume: 1000-1500 L/ha Equivalent to 0.50-1.125 ml PYRIPROX/Ha.	3 days
<b>Cotton</b> Pests: whiteflies. Application when larvae were detected.  Maximum number of applications: Up to 2 applns per season with an interval of 15 days	0.1% (100 ml PYRIPROX/100 L water) Spray volume: 750 L/ha Equivalent to 0.75 ml PYRIPROX/Ha.	n.a.
<b>Nursery of vegetables</b> Pests: whiteflies and aphids	0.05-0.075% (50-75 ml PYRIPROX /100 L water)	n.a.

(Left)

 <b>WARNING</b>	<p>H410: Very toxic to aquatic life with long lasting effects.  P261: Avoid breathing vapours/spray  P281: Use personal protective equipment as required  P302+P352: IF ON THE SKIN: wash with plenty of water and soap.  P333+P313: If skin irritation or a rash occurs: Get medical advice/attention.  P305+P351+P338+P310: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do-continue rinsing. Immediately call a Poison center.  P308+P313: If eye irritation persists get medical advice/attention.  P501: Dispose of contents/container in accordance with local/regional/national/international regulation.</p>
---	---

#### SAFETY PRECAUTIONS

##### Operator Protection

WHEN USING DO NOT EAT, DRINK OR SMOKE.  
AFTER CONTACT WITH SKIN OR EYES, WASH IMMEDIATELY with plenty of water.  
DO NOT BREATHE SPRAY.  
WASH HANDS AND EXPOSED SKIN before meals and after work.

##### Environmental Protection

**Sp1:** 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].

**Sp3:** To protect aquatic organisms respect an unsprayed buffer zone of 8 m in grapes or 5 meters with 50% reducing drift nozzles, for citrus 20 m with normal nozzles, or 15 meters with 50% reducing drift nozzles, or 10 meters with 75% reducing drift nozzles, for pome and stone fruit trees (including plums and cherries) 25 m with normal nozzles, or 20 meters with 50% reducing drift nozzles, or 15 meters with 75% reducing drift nozzles, for tomato and aubergines, 2.5 m for normal nozzles and for ornamentals 2.0 m with normal nozzles to non-agricultural land/surface water bodies. No buffer zone is required for cotton.

##### Storage and Disposal

KEEP AWAY FROM FOOD, DRINK AND ANIMAL FEEDING STUFFS.  
KEEP OUT OF REACH OF CHILDREN.  
KEEP IN ORIGINAL CONTAINER, tightly closed, in a safe place.  
WASH OUT CONTAINER THOROUGHLY, empty washings into spray tank and dispose of safely.

.....25

**(right)**

**Directions for use:**

PYRIPROX is an Emulsifiable Concentrate (EC) formulation containing 100 g/L of pyriproxyfen used as a stomach and contact insecticide against scales, whiteflies and aphids in a range of crops.

Harvest interval: follow harvest intervals where recommended.

Use the rates recommended to ensure good spray coverage.

Recommendations	Rate of use	PHI
<b>Table and wine grapes</b> Pests: scales: mealybug ( <i>Planococcus citri</i> ) Applications in pre-flowering (winter treatments) (BBCH 92 to 60)  Maximum number of applications: 1 per season	0.05-0.075% (50-75 ml PYRIPROX /100 L water) Spray volume: 600-800 L/ha Equivalent to 600 ml PYRIPROX/Ha	n.a.
<b>Citrus (oranges, lemon and tangerines)</b> Pest: Black scale ( <i>Saissetia oleae</i> ), Citrus mussel scale ( <i>Lepidosaphes Beckii</i> ), Chaff scale ( <i>Parlatoria pergandei</i> ), Red scale ( <i>Aonidiella aurantii</i> ) and Oelander scale ( <i>Aspidiotus nerii</i> ) and others.  Application when larvae were detected.  Maximum number of applications: 1 per season	0.025-0.10% (25-100 ml PYRIPROX/100 L water) Spray volume: 1000-1500 L/ha Equivalent to 250-1200 ml PYRIPROX/Ha	30 days
<b>Pome fruit trees (apples and pears)</b> Pests: San Jose Scale ( <i>Quadraspidiotus perniciosus</i> ) Applications in pre-flowering (winter treatments) (BBCH 92 to 60)  Maximum number of applications: 1 per season	0.0375-0.05% (37.5-50 ml PYRIPROX /100 L water) Spray volume: 1000 L/ha Equivalent to 375-500 ml PYRIPROX/Ha	n.a.
<b>Stone fruit trees (peach, nectarine, apricot, cherries and plums)</b> Pests: San Jose Scale ( <i>Quadraspidiotus perniciosus</i> ) Applications in pre-flowering (winter treatments) (BBCH 92 to 60)  Maximum number of applications: 1 per season	0.0375-0.05% (37.5-50 ml PYRIPROX /100 L water) Spray volume: 1000 L/ha Equivalent to 375-500 ml PYRIPROX/Ha	n.a.
<b>Tomato and aubergines</b> Pests: whiteflies and aphids Application when larvae were detected.  Maximum number of applications: Up to 2 applns per season with an interval of 15 days	0.05-0.075% (50-75 ml PYRIPROX/100 L water) Spray volume: 1000-1500 L/ha Equivalent to 0.50-1.125 ml PYRIPROX/Ha.	3 days
<b>Cotton</b> Pests: whiteflies. Application when larvae were detected.  Maximum number of applications: Up to 2 applns per season with an interval of 15 days	0.1% (100 ml PYRIPROX/100 L water) Spray volume: 750 L/ha Equivalent to 0.75 ml PYRIPROX/Ha.	n.a.
<b>Nursery of vegetables</b> Pests: whiteflies and aphids	0.05-0.075% (50-75 ml PYRIPROX /100 L water)	n.a.

..27

Recommendations	Rate of use	PHI
Application when larvae were detected.  Maximum number of applications: 1 per season	Spray volume: 800 L/ha Equivalent to 400-600 ml PYRIPROX/Ha	
<b>Ornamentals</b> Pests: whiteflies and aphids Application when larvae were detected.  Maximum number of applications: 1 per season	0.05-0.075% (50-75 ml PYRIPROX /100 L water) Spray volume: 1000 L/ha Equivalent to 500-750 ml PYRIPROX/Ha	n.a.

## APPLICATION

### Mixing

Ensure the sprayer is clean and calibrated before use.

Half fill the spray tank with clean water and begin agitation. Add the required amount of PYRIPROX and the remaining water. Continue agitation until spraying is complete.

### Water Volume

Ensure sufficient water volumes are used to give good crop coverage. For conventional treatment the water volumes recommended are the minimum. For glasshouse crops apply high volume using sufficient water to ensure thorough crop coverage.

### Caution

Always avoid spraying crops that are under stress at time of application.

### Compatibility

PYRIPROX is compatible with many plant protection products.

Always consult the mixture product label first and apply under the approved conditions.

Follow the country regulation before any tank mixing with any other approved plant protection products.

## CONDITIONS OF SALE

All goods supplied by us are of high grade and we believe them to be suitable but, as we cannot exercise control over their storage, handling mixing or use or the weather conditions before, during and after application which may affect the performance of the goods, all conditions and warranties, statutory or otherwise, as to the quality or fitness for any purpose of our goods are excluded, and no responsibility will be accepted by us or re-sellers for any failure in performance, damage or injury whatsoever arising from their storage, handling, application or use. These conditions cannot be varied by our staff or agents whether or not they supervise or assist in the use of such goods.

..28

## PART A – Risk Management

The company EXCLUSIVAS SARABIA S.A. has requested marketing authorisation in France for the product PYRIPROX (ESAR 110-I, ESAR 110-I (Pyriproxyfen 10% EC), ESAR 110-I (Pyriproxyfen 100g/L EC), Pyriproxyfen 10% EC, Pyriproxyfen 100g/L EC), containing 100g/L pyriproxyfen, for use as an insecticide.

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 PYRIPROX (ESAR 110-I, ESAR 110-I (Pyriproxyfen 10% EC), ESAR 110-I (Pyriproxyfen 100g/L EC), Pyriproxyfen 10% EC, Pyriproxyfen 100g/L EC) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of PYRIPROX (ESAR 110-I, ESAR 110-I (Pyriproxyfen 10% EC), ESAR 110-I (Pyriproxyfen 100g/L EC), Pyriproxyfen 10% EC, Pyriproxyfen 100g/L EC) have been made using endpoints agreed in the EU peer review of pyriproxyfen.

This document describes the specific conditions of use and labelling required for France for the registration of PYRIPROX (ESAR 110-I, ESAR 110-I (Pyriproxyfen 10% EC), ESAR 110-I (Pyriproxyfen 100g/L EC), Pyriproxyfen 10% EC, Pyriproxyfen 100g/L EC).

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.

## 1 DETAILS OF THE APPLICATION

### 1.1 Application background

The present registration report concerns the evaluation of EXCLUSIVAS SARABIA S.A.'s application to market PYRIPROX (ESAR 110-I, ESAR 110-I (Pyriproxyfen 10% EC), ESAR 110-I (Pyriproxyfen 100g/L EC), Pyriproxyfen 10% EC, Pyriproxyfen 100g/L EC) in France as an insecticide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

### 1.2 Active substance approval

#### Pyriproxyfen

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

Specific provisions of Regulation (EU) No 540/2011 were as follows:

#### PART A

Only uses as insecticide may be authorised.

#### PART B

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pyriproxyfen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 May 2010 shall be taken into account.

In the overall assessment Member States must pay particular attention to:

—the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, where appropriate;

—the risk to aquatic organisms. Conditions of use shall include adequate risk mitigation measures, where appropriate.

The Member States concerned shall ensure that the notifier submits to the Commission further information confirming the risk assessment in respect of two points, namely the risk posed to aquatic insects by pyriproxyfen and the metabolite DPH-pyr and the risk posed by pyriproxyfen to pollinators. They shall ensure that the notifier provides such information to the Commission by 30 June 2012.

EFSA conclusions are available (EFSA Journal 2014;12(5):3677) and EFSA Journal 2019;17(7):5732.

### 1.3 Regulatory approach

The present application (2015-2627) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses (“risk envelope approach”)<sup>1</sup> – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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

The French Order of 4 May 2017<sup>2</sup> provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight hours for indoor uses.

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

The current document (RR) based on Anses’s assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009<sup>3</sup>, implementing regulations, and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail.

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011<sup>4</sup>, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014<sup>5</sup> 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<sup>6</sup> 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.

<sup>1</sup> 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.

<sup>2</sup> *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*,  
<https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRGI632554A/jo/texte> ;  
<https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>.

<sup>3</sup> 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.

<sup>4</sup> 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.

<sup>5</sup> <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRGI407093A/jo>.

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



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 PYRIPROX (ESAR 110-I, ESAR 110-I (Pyriproxyfen 10% EC), ESAR 110-I (Pyriproxyfen 100g/L EC), Pyriproxyfen 10% EC, Pyriproxyfen 100g/L EC), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

#### 1.5 Letter(s) of Access

Not necessary: active substance data are not protected any more.

The technical material (pyriproxyfen) used for the preparation of product PYRIPROX (ESAR 110-I, ESAR 110-I (Pyriproxyfen 10% EC), ESAR 110-I (Pyriproxyfen 100g/L EC), Pyriproxyfen 10% EC, Pyriproxyfen 100g/L EC) has been submitted for the chemical equivalence in FRANCE from the company EXCLUSIVAS SARABIA S.A. The equivalence report is accepted.

## 2 DETAILS OF THE AUTHORISATION

### 2.1 Product identity

<b>Product name (code)</b>	PYRIPROX. (ESAR 110-I ESAR 110-I (Pyriproxyfen 10% EC) ESAR 110-I (Pyriproxyfen 100 g/L EC) Pyriproxyfen 10% EC Pyriproxyfen 100 g/L EC)
<b>Authorisation number</b>	N/A : no marketing authorisation granted
<b>Function</b>	Insecticide.
<b>Applicant</b>	EXCLUSIVAS SARABIA S.A.
<b>Composition</b>	100g/L pyriproxyfen.
<b>Formulation type (code)</b>	Emulsifiable concentrate (EC).
<b>Packaging</b>	HDPE/EVOH (15 mL, 100 mL, 250 mL, 1 L, 5 L).

### 2.2 Classification and labelling

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

N/A : no marketing authorisation granted.

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

N/A : no marketing authorisation granted.

#### 2.2.3 Other phrases linked to the preparation

N/A : no marketing authorisation granted.

## 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 zRMS. 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.

GAP rev. 1, date:2020-07-30

PPP (product name/code) **PYRIPROX (ESAR 110-I, ESAR 110-I (Pyriproxyfen 10% EC), ESAR 110-I (Pyriproxyfen 100g/L EC), Pyriproxyfen 10% EC, Pyriproxyfen 100g/L EC)** Formulation type: **EC**  
Conc. of a.s. 1: **100g/L**

active substance 1 **pyriproxyfen**  
Applicant: **EXCLUSIVAS SABARIA S.A** professional use ☒  
Zone(s): **southern** 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- No. <sup>(e)</sup>	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 ( <sup>(f)</sup> )
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/season [year]	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1 and 2	FR	Wine grapes Table grapes	F	Scales	Overall, high- volume spraying	Pre-flowering BBCH 92-60	1	-	a) 0.30 – 0.60  b) 0.30-0.60	a) 30.0-60.0  b) 30.0-60.0	600- 800	F (BBC H 60)	<b>Not acceptable</b> (risk for groundwater, aquatic organisms, non-target arthropods, soil macro-organisms, efficacy: highest rate not justified)
1 and 2	FR	Wine grapes Table grapes	F	Scales	Overall, high- volume spraying	Pre-flowering BBCH 92-60	1	-	<b>a) 0.30</b>  <b>b) 0.30</b>	<b>a) 30.0</b>  <b>b) 30.0</b>	600- 800	F (BBC H 60)	<b>Not acceptable</b> (Risk for groundwater, aquatic organisms, non-target arthropods, soil macro-organisms)
3	FR	Citrus (oranges, tangerines, lemon, lime and grapefruit)	F	Scales ( <i>Chrysomphalus dictyospermi</i> , <i>Parlatoria pergandei</i> , <i>Lepidosaphes sp.</i> , <i>Saissetia</i> )	Overall, high - volume spraying	All stages	1	-	a) 0.25-1.200  b) 0.25-1.200	a) 25.0-120.0  b) 25.0 – 120.0	1000- 1500	30	<b>Not acceptable</b> (Risk for groundwater, aquatic organisms, non-target arthropods, soil macro-organisms)

Applicant: EXCLUSIVAS SARABIA S.A.

Evaluator: FRANCE  
Date: 30/07/2020

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	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 <sup>(f)</sup>
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/season [year]	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
4	FR	Pome fruits (apples, pears)	F	San Jose scale ( <i>Quadraspidiotus perniciosus</i> )	Overall, high- volume spraying	Winter treatments. From harvest to pre-flowering (BBCH 92-60)	1	-	a) 0.375-0.50  b) 0.375-0.50	a) 37.5 – 50.0  b) 37.5 – 50.0	1000	F (BBC H 60)	<b>Not acceptable</b> (risk for groundwater, aquatic organisms, non-target arthropods, soil macro-organisms, efficacy: highest rate not justified)
4	FR	Pome fruits (apples, pears)	F	San Jose scale ( <i>Quadraspidiotus perniciosus</i> )	Overall, high- volume spraying	Winter treatments. From harvest to pre-flowering (BBCH 92-60)	1	-	<b>a) 0.375</b>  <b>b) 0.375</b>	<b>a) 37.5</b>  <b>b) 37.5</b>	1000	F (BBC H 60)	<b>Not acceptable</b> (Risk for groundwater, aquatic organisms, non-target arthropods, soil macro-organisms)
5	FR	Stone fruits (peaches, apricots)	F	San Jose scale ( <i>Q. perniciosus</i> )	Overall, high- volume spraying	Winter treatments. From harvest to pre-flowering (BBCH 92-60)	1	-	a) 0.375-0.50  b) 0.375-0.50	a) 37.5 – 50.0  b) 37.5 – 50.0	1000	F (BBC H 60)	<b>Not acceptable</b> (Risk for groundwater, aquatic organisms, non-target arthropods, soil macro-organisms, efficacy: highest rate not justified)
5	FR	Stone fruits (peaches, apricots)	F	San Jose scale ( <i>Q. perniciosus</i> )	Overall, high- volume spraying	Winter treatments. From harvest to pre-flowering (BBCH 92-60)	1	-	<b>a) 0.375</b>  <b>b) 0.375</b>	<b>a) 37.5</b>  <b>b) 37.5</b>	1000	F (BBC H 60)	<b>Not acceptable</b> (Risk for groundwater, aquatic organisms, non-target arthropods, soil macro-organisms)
6	FR	Tomato, aubergines	F	Whiteflies	Overall, high- volume spraying	All stages	1-2 (15-30)	-	a) 0.50-0.75  b) 1.0-1.50	a) 50.0-75  b) 100.0 – 150.0	1000- 1500	3	<b>Not acceptable</b> (Risk of MRL exceedance; efficacy: highest rate not justified, risk for groundwater, aquatic organisms, non-target arthropods, soil macro-organisms)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	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:
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/season [year]	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
6	FR	Tomato, aubergines	F	Whiteflies	Overall, high- volume spraying	All stages	2 (15-30)	-	a) 0.50  b) 1.0	a) 50.0  b) 100.0	1000- 1500	3	<b>Not acceptable</b> (Risk of MRL exceedance, risk for groundwater, aquatic organisms, non-target arthropods, soil macro-organisms)
8	FR	Ornamentals	F	Whiteflies, scales	Overall, high- volume spraying	All stages	1	-	a) 0.50-0.75  b) 0.50-0.75	a) 50.0-75.0  b) 50.0 -75.0	1000	n.a.	<b>Not acceptable</b> (Risk for groundwater, aquatic organisms, non-target arthropods, soil macro-organisms)

**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.

**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.

(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.

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

PYRIPROX (ESAR 110-I, ESAR 110-I (Pyriproxyfen 10% EC), ESAR 110-I (Pyriproxyfen 100g/L EC), Pyriproxyfen 10% EC, Pyriproxyfen 100g/L EC) is an emulsifiable concentrate (EC) formulation. All studies were performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a transparent amber liquid with a mild odour. It is not explosive and has no oxidising properties. The product has a flash point of 89.5°C. It has a self-ignition temperature of 275°C. In aqueous solution (1%), it has a pH value of 5.8 at 20.4°C. There is no effect of low and high temperatures on the stability of the formulation, since after seven days at 0°C and 14 days at 54°C, neither the active substance content nor the technical properties were changed. The stability data indicate a shelf life of at least two years at ambient temperature when stored in HDPE/EVOH packaging. The technical characteristics are acceptable for an EC formulation.

HDPE packaging (15 mL, 100mL, 250mL, 1L, 5L) are not granted because stability data was not submitted with this type of packaging."

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

##### 3.1.2 Methods of analysis

###### 3.1.2.1 Analytical method for the formulation

Analytical methodology for the determination of the active substance is available and validated. No analytical method for the determination of the relevant impurity (toluene [methylbenzene]) of the active substance pyriproxyfen has been submitted.

###### 3.1.2.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report (DAR)/this dossier and validated for the determination of residues of pyriproxyfen in plants (matrices rich in water, acid and oil), soil, water (surface and drinking) and air.

##### 3.1.3 Mammalian Toxicology

###### Endpoints used in risk assessment

Active substance: <b>pyriproxyfen</b>			
ADI	0.1 mg/kg body weight/day		EU (2009)
ARfD	Not applicable		
AOEL	0.04 mg/kg body weight/day		
Dermal absorption	Based on an <i>in vitro/vivo</i> rat/human study performed on a similar formulation: the dermal absorption value for concentrate is 3 % and for spray dilution 4 %. These values are calculated in the “ <a href="#">Pyriproxyfen RAR 17 Volume 3 CP B.6 Pyriproxyfen 100 g/L EC March 2019</a> ” with a triple-pack approach.		
		Concentrate (tested) 100g/L	Diluted formulation (tested) 0.015g/L
	<i>In vivo</i> (rat) %	13.93	22.68
	<i>In vitro</i> (rat) %	20.52	61.87
	<i>In vitro</i> (human) %	4.62	11

		Concentrate (used in formulation) 100g/L	Spray dilution (used in formulation) 0.016g/L
	<b>Dermal absorption endpoints %</b>	<b>3</b>	<b>4</b>

### 3.1.3.1 Acute Toxicity

PYRIPROX (ESAR 110-I, ESAR 110-I (Pyriproxyfen 10% EC), ESAR 110-I (Pyriproxyfen 100g/L EC), Pyriproxyfen 10% EC, Pyriproxyfen 100g/L EC), containing 100g/L pyriproxyfen, has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin and eye, and is not a skin sensitiser. The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.2.

### 3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G <sup>7</sup>	Equipment	Application rate L product/ha (g a.s./ha)	Spray dilution (L/ha)	Model
<i>Citrus</i>	F	Tractor-mounted/trailed broadcast air-assisted sprayer	0.25-1.2 (25-120)	1000-1500	BBA
Tomatoes	F	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	0.50-1.125 (50-112.5)	1000-1500	BBA
Ornamentals	F	Hand-held sprayer	0.50-0.75 (50-75)	1000	BBA

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

Crop	Equipment	PPE and/or working coverall	% AOEL pyriproxyfen
<i>Citrus</i>	Tractor-mounted/trailed broadcast air-assisted sprayer	Working coverall and gloves during mixing/loading and application	3.9
Tomatoes	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	Working coverall and gloves during mixing/loading and application	1.5
Ornamentals	Hand-held sprayer	Working coverall and gloves during mixing/loading and application	M&L: 0.02 A: 1.70

According to the model calculations, it may be concluded that the risk for the operator using PYRIPROX (ESAR 110-I, ESAR 110-I (Pyriproxyfen 10% EC), ESAR 110-I (Pyriproxyfen 100g/L EC), Pyriproxyfen 10% EC, Pyriproxyfen 100g/L EC) is acceptable with a working coverall (90 % protection factor) and gloves during mixing/loading and application.

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

### 3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to be 4 % of the AOEL of pyriproxyfen in the worst-case, corresponding to *Citrus*. It may be concluded that there is no unacceptable risk to the

<sup>7</sup> Open field or glasshouse

bystander after incidental short-term exposure to PYRIPROX (ESAR 110-I, ESAR 110-I (Pyriproxyfen 10% EC), ESAR 110-I (Pyriproxyfen 100g/L EC), Pyriproxyfen 10% EC, Pyriproxyfen 100g/L EC).

### 3.1.3.4 Worker Exposure

Workers may have to enter treated areas after treatment for crop inspection/harvesting, searching, reaching and picking activities. Therefore, estimation of worker exposure was calculated according to EUROPOEM II. Exposure is estimated to be 3.6 % of the AOEL of pyriproxyfen.

It may be concluded that without taking into account a re-entry period, there is no unacceptable risk anticipated for workers wearing a working coverall and gloves, when re-entering crops treated with PYRIPROX (ESAR 110-I, ESAR 110-I (Pyriproxyfen 10% EC), ESAR 110-I (Pyriproxyfen 100g/L EC), Pyriproxyfen 10% EC, Pyriproxyfen 100g/L EC).

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

### 3.1.4 Residues and Consumer Exposure

The data available are considered sufficient for risk assessment, **except for the uses on tomato and aubergine.**

No exceedance of the current MRLs for pyriproxyfen as laid down in Reg. (EU) 396/2005 is expected.

The chronic and short-term intakes of pyriproxyfen residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, France agrees with the authorisation of the intended uses, except for the uses on tomato and aubergine.

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

#### 3.1.4.1 Residues

**Table 3.1.4-1: Summary for pyriproxyfen**

Use- No. *	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported ?	Sample storage covered by stability data?	MRL compliance Reg. 2016/1902 ?	Chronic risk for consumer s identified ?	Acute risk for consumer s identified ?	Comments
1	Wine Grapes	Yes	Yes	Yes	Yes	Yes	No	No	
2	Table grapes	Yes	Yes	Yes	Yes	Yes			
3	Citrus	Yes	Yes	Yes	Yes	Yes			
4	Pome fruits (apples, pears)	Yes	Yes	Yes	Yes	Yes			
5	Stone fruits (peaches, apricots)	Yes	Yes	Yes	Yes	Yes			
6	Tomato, aubergines	Yes	No	No	/	No	/	/	
8	Ornamentals	Not assessed for consumer safety							

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

The effects of processing on the nature of pyriproxyfen residues have been investigated. Data on effects of

processing on the amount of residue have been submitted. These data were not considered for risk assessment.

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

Considering dietary burden and based on the intended uses, a significant modification of the intake was calculated for livestock compared with the representative uses of the active substance, but this higher exposure was compliant with the extant MRL in animal commodities. Further investigation of residues as well as the modification of MRLs in commodities of animal origin are therefore not necessary.

### 3.1.4.2 Consumer exposure

**Information on PYRIPROX (ESAR 110-I, ESAR 110-I (Pyriproxyfen 10% EC), ESAR 110-I (Pyriproxyfen 100g/L EC), Pyriproxyfen 10% EC, Pyriproxyfen 100g/L EC) (KCA 6.8)**

Crop	PHI for PYRIPROX (ESAR 110-I, ESAR 110-I (Pyriproxyfen 10% EC), ESAR 110-I (Pyriproxyfen 100g/L EC), Pyriproxyfen 10% EC, Pyriproxyfen 100g/L EC) requested by applicant	PHI/withholding period* sufficiently supported for pyriproxyfen	PHI for PYRIPROX (ESAR 110-I, ESAR 110-I (Pyriproxyfen 10% EC), ESAR 110-I (Pyriproxyfen 100g/L EC), Pyriproxyfen 10% EC, Pyriproxyfen 100g/L EC) proposed by zRMS	zRMS Comments (if different PHI proposed)
Wine grapes	F (BBCH 60)	F (BBCH 60)	F (BBCH 60)	/
Table grapes	F (BBCH 60)	F (BBCH 60)	F (BBCH 60)	/
Citrus	30	30	30	/
Pome fruits (apples, pears)	F (BBCH 60)	F (BBCH 60)	F (BBCH 60)	/
Stone fruits (peaches, apricots)	F (BBCH 60)	F (BBCH 60)	F (BBCH 60)	/

NR: not relevant

\* Purpose of withholding period to be specified

\*\* F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

### 3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of 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 pyriproxyfen 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.

PECsoil and PECsw values (up to FOCUS Step 3) derived for the active substance and its metabolites are used for the ecotoxicological risk assessment. PECsw and PECsed values including mitigation measures (FOCUS Step 4) could not be validated, since the model used by the applicant took into account run-off mitigation factors not in agreement with the extant guidance document.



**PEC<sub>gw</sub> values for pyriproxyfen and its metabolites presented by the applicant could not be used, since some input parameters are not justified (formation fractions of metabolites) or are not in agreement with the recommendations of the extant guidance documents (adsorption). Therefore, the risk assessment for groundwater contamination is not finalised for the intended uses.**

Based on vapour pressure, information on volatilisation from plants and soil, and DT<sub>50</sub> calculation, no significant contamination of the air compartment is expected for the intended uses.

### 3.1.6 Ecotoxicology

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance 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, mammals, bees, micro-organisms and terrestrial plants are acceptable for the intended uses.

**For the risk assessment for aquatic organisms, PEC<sub>sw</sub> and PEC<sub>sed</sub> values including mitigation measures (FOCUS Step 4) could not be validated, since the model used by the applicant took into account run-off mitigation factors which are not in agreement with the extant guidance document. Consequently the risk assessment is based on PEC<sub>sw</sub> calculated on Step 3. The TER values using FOCUS STEP 3 PEC<sub>sw</sub> values for pyriproxyfen are below the relevant triggers, indicating that the risk to aquatic organisms is not finalised for all intended use of PYRIPROX (ESAR 110-I, ESAR 110-I (Pyriproxyfen 10% EC), ESAR 110-I (Pyriproxyfen 100g/L EC), Pyriproxyfen 10% EC, Pyriproxyfen 100g/L EC).**

**For non-target arthropods, considering that pyriproxyfen is an insect growth regulator (IGR), and in the absence of additional tests involving sensitive life stages (larval stage), it is the zRMS's opinion that the pertinent risk assessment cannot be finalised.**

**For the risk assessment to soil macro-organisms, the applicant did not provide a toxicity study of the formulation to the soil invertebrate indicator species *Hypoaspis aculeifer*. Therefore, the risk assessment to soil macro organisms is likewise not considered finalised by France as zRMS.**

Risk mitigations measures are required in order to protect bees:

*“Dangerous to bees. To protect bees and pollinating insects do not apply to crop plants when in flower or during the honeydew production period. Do not use where bees are actively foraging. Do not apply when flowering weeds are present.”*

### 3.1.7 Efficacy

Considering the data submitted:

- The efficacy level of PYRIPROX (ESAR 110-I, ESAR 110-I (Pyriproxyfen 10% EC), ESAR 110-I (Pyriproxyfen 100g/L EC), Pyriproxyfen 10% EC, Pyriproxyfen 100g/L EC) is considered satisfactory for all the requested uses. **On grape, the dose of 0.3 L/ha is considered efficacious and sufficient. On stone and pome fruits, the dose of 0.375 L/ha is considered efficacious and sufficient. On tomato and aubergine, the dose of 0.5 L/ha is considered efficacious and sufficient.**
- The phytotoxicity level of PYRIPROX (ESAR 110-I, ESAR 110-I (Pyriproxyfen 10% EC), ESAR 110-I (Pyriproxyfen 100g/L EC), Pyriproxyfen 10% EC, Pyriproxyfen 100g/L EC) is considered negligible for all the requested uses.
- The risks of negative impact on yield, quality, transformation processes (wine- and cider-making), propagation, succeeding and adjacent crops are considered negligible.

- There is a risk of resistance developing or appearing to pyriproxyfen for whiteflies on tomato: this requires monitoring.

Restrictions: None.

### **3.2 Conclusions arising from French assessment**

Taking into account the above assessment, an authorisation **cannot be granted**. A copy of the Decision issued can be found in Appendix 1 – Copy of the product Decision.

### **3.3 Substances of concern for national monitoring**

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**

N/A : no marketing authorisation granted.

#### **3.4.2 Post-authorisation data requirements**

N/A : no marketing authorisation granted.

#### **3.4.3 Label amendments**

The draft label proposed by the applicant is presented in Appendix 2.

## Appendix 1 – Copy of the French Decision



### 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 réglementaire,*

*Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique **PYRIPROX***

*de la société **EXCLUSIVAS SARABIA, S.A.***

*enregistrée sous le **n°2015-2627***

*Vu les conclusions de l'évaluation de l'Anses du 23 juillet 2020,*

*Considérant qu'un risque d'effet inacceptable pour les organismes aquatiques, les macroorganismes du sol et les arthropodes non cibles ainsi qu'un risque inacceptable de contamination des eaux souterraines, liés à l'utilisation du produit, ne peuvent être exclus,*

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

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



Informations générales sur le produit	
Nom du produit	PYRIPROX
Type de produit	Produit de référence
Titulaire	EXCLUSIVAS SARABIA, S.A. Cami de l'Albi rec nou s/n 25110 ALPICAT, LERIDA Espagne
Formulation	Concentré émulsionnable (EC)
Contenant	100 g/L - pyriproxifène
Numéro d'intrant	509-2015.01
Numéro d'AMM	-
Fonction	Insecticide
Gamme d'usage	Professionnel

A Maisons-Alfort, le 30 JUL. 2020

Pour le Directeur général  
de l'Agence nationale de sécurité sanitaire de  
l'alimentation, de l'environnement et du travail  
et par délégation  
Le Directeur général délégué  
en charge du Pôle Sciences pour l'expertise

Pr Gérard LASFARGUES

PYRIPROX  
AMM n°-

Page 2 sur 5



## ANNEXE I : Conditions de mise sur le marché demandées

Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12053101 Agrumes*Trt Part.Aer.*Cochenilles	1,2 L/ha	1/an	30
	<b>Motivation du refus :</b> L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques, les macroorganismes du sol, les arthropodes non cibles ainsi qu'un risque inacceptable de contamination des eaux souterraines.		
01002019 Arbres et arbustes*Trt Part.Aer.*Aleurodes	0,75 L/ha	1/an	Non applicable
	<b>Motivation du refus :</b> L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques, les macroorganismes du sol, les arthropodes non cibles ainsi qu'un risque inacceptable de contamination des eaux souterraines.		
14053101 Arbres et arbustes*Trt Part.Aer.*Cochenilles	0,75 L/ha	1/an	Non applicable
	<b>Motivation du refus :</b> L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques, les macroorganismes du sol, les arthropodes non cibles ainsi qu'un risque inacceptable de contamination des eaux souterraines.		
17403102 Cultures florales et plantes vertes*Trt Part.Aer.*Aleurodes	0,75 L/ha	1/an	Non applicable
	<b>Motivation du refus :</b> L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques, les macroorganismes du sol, les arthropodes non cibles ainsi qu'un risque inacceptable de contamination des eaux souterraines.		

PYRIPROX  
AMM n°.

Page 3 sur 5



Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
<b>17403103</b> Cultures florales et plantes vertes*Trt Part.Aer.*Cochenilles	0,75 L/ha	1/an	Non applicable
<b>Motivation du refus :</b> L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques, les macroorganismes du sol, les arthropodes non cibles ainsi qu'un risque inacceptable de contamination des eaux souterraines.			
<b>12553108</b> Pêcher*Trt Part.Aer.*Cochenilles	0,375 L/ha	1/an	F (BBCH 60)
<b>Motivation du refus :</b> L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques, les macroorganismes du sol, les arthropodes non cibles ainsi qu'un risque inacceptable de contamination des eaux souterraines. L'usage est refusé aux mêmes motifs pour la dose de 0,5 L/ha ainsi que du fait que l'intérêt de cette dose supérieure n'est pas démontré.			
<b>12603149</b> Pommier*Trt Part.Aer.*Cochenilles	0,375 L/ha	1/an	F (BBCH 60)
<b>Motivation du refus :</b> L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques, les macroorganismes du sol, les arthropodes non cibles ainsi qu'un risque inacceptable de contamination des eaux souterraines. L'usage est refusé aux mêmes motifs pour la dose de 0,5 L/ha ainsi que du fait que l'intérêt de cette dose supérieure n'est pas démontré.			

PYRIPROX  
AMM n°:

Page 4 sur 5





Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
<b>16953101</b> Tomate*Trt Part.Aer.*Aleurodes	0,5 L/ha	2/an	3
	<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque de dépassement des limites maximale de résidus. L'usage est également refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques, les macroorganismes du sol, les arthropodes non cibles ainsi qu'un risque inacceptable de contamination des eaux souterraines. L'usage est refusé aux mêmes motifs pour la dose de 0,75 L/ha ainsi que du fait que l'intérêt de cette dose supérieure n'est pas démontré.		
<b>12703136</b> Vigne*Trt Part.Aer.*Cochenilles	0,3 L/ha	1/an	F (BBCH 60)
	<b>Motivation du refus :</b> L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques, les macroorganismes du sol, les arthropodes non cibles ainsi qu'un risque inacceptable de contamination des eaux souterraines. L'usage est refusé aux mêmes motifs pour la dose de 0,75 L/ha ainsi que du fait que l'intérêt de cette dose supérieure n'est pas démontré.		

PYRIPROX  
AMM n°:

Page 5 sur 5

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

# PYRIPROX

INSECTICIDE  
EMULSIFIABLE CONCENTRATE (EC)

Composition :

Pyriproxyfen ..... 100 g/L

Reg. No.- xxxxxx

Content: xx L

Batch Nr :

Manufacturing date :

Manufacturer: EXCLUSIVAS SARABIA S.A.  
Cami de l'Albi-Rec Nou s/n  
25110-ALPICAT (LERIDA)  
SPAIN

**READ THE LABEL BEFORE USE. USING THIS PRODUCT IN A MANNER  
THAT IS INCONSISTANT WITH THE LABEL MAY BE AN OFFENCE.**

**FOLLOW THE CODE OF PRACTICE FOR USING PLANT PROTECTION  
PRODUCTS.**



**(right)**

**Directions for use:**


PYRIPROX is an Emulsifiable Concentrate (EC) formulation containing 100 g/L of pyriproxyfen used as a stomach and contact insecticide against scales, whiteflies and aphids in a range of crops.

Harvest interval: follow harvest intervals where recommended.

Use the rates recommended to ensure good spray coverage.

Recommendations	Rate of use	PHI
<b>Table and wine grapes</b> Pests: scales: mealybug ( <i>Planococcus citri</i> ) Applications in pre-flowering (winter treatments) (BBCH 92 to 60)  Maximum number of applications: 1 per season	0.05-0.075% (50-75 ml PYRIPROX /100 L water) Spray volume: 600-800 L/ha Equivalent to 600 ml PYRIPROX/Ha	n.a.
<b>Citrus (oranges, lemon and tangerines)</b> Pest: Black scale ( <i>Saissetia oleae</i> ), Citrus mussel scale ( <i>Lepidosaphes Beckii</i> ), Chaff scale ( <i>Parlatoria pergandei</i> ), Red scale ( <i>Aonidiella aurantii</i> ) and Oelander scale ( <i>Aspidiotus nerii</i> ) and others.  Application when larvae were detected.  Maximum number of applications: 1 per season	0.025-0.10% (25-100 ml PYRIPROX/100 L water) Spray volume: 1000-1500 L/ha Equivalent to 250-1200 ml PYRIPROX/Ha	30 days
<b>Pome fruit trees (apples and pears)</b> Pests: San Jose Scale ( <i>Quadraspidiotus perniciosus</i> ) Applications in pre-flowering (winter treatments) (BBCH 92 to 60)  Maximum number of applications: 1 per season	0.0375-0.05% (37.5-50 ml PYRIPROX /100 L water) Spray volume: 1000 L/ha Equivalent to 375-500 ml PYRIPROX/Ha	n.a.
<b>Stone fruit trees (peach, nectarine, apricot, cherries and plums)</b> Pests: San Jose Scale ( <i>Quadraspidiotus perniciosus</i> ) Applications in pre-flowering (winter treatments) (BBCH 92 to 60)  Maximum number of applications: 1 per season	0.0375-0.05% (37.5-50 ml PYRIPROX /100 L water) Spray volume: 1000 L/ha Equivalent to 375-500 ml PYRIPROX/Ha	n.a.
<b>Tomato and aubergines</b> Pests: whiteflies and aphids Application when larvae were detected.  Maximum number of applications: Up to 2 applns per season with an interval of 15 days	0.05-0.075% (50-75 ml PYRIPROX/100 L water) Spray volume: 1000-1500 L/ha Equivalent to 0.50-1.125 ml PYRIPROX/Ha.	3 days
<b>Cotton</b> Pests: whiteflies. Application when larvae were detected.  Maximum number of applications: Up to 2 applns per season with an interval of 15 days	0.1% (100 ml PYRIPROX/100 L water) Spray volume: 750 L/ha Equivalent to 0.75 ml PYRIPROX/Ha.	n.a.
<b>Nursery of vegetables</b> Pests: whiteflies and aphids	0.05-0.075% (50-75 ml PYRIPROX /100 L water)	n.a.

(Left)

 <p>WARNING</p>	<p>H410: Very toxic to aquatic life with long lasting effects.  P261: Avoid breathing vapours/spray  P281: Use personal protective equipment as required  P302+P352: IF ON THE SKIN: wash with plenty of water and soap.  P333+P313: If skin irritation or a rash occurs: Get medical advice/attention.  P305+P351+P338+P310: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do-continue rinsing. Immediately call a Poison center.  P308+P313: If eye irritation persists get medical advice/attention.  P501: Dispose of contents/container in accordance with local/regional/national/international regulation.</p>
--	---

#### SAFETY PRECAUTIONS

##### Operator Protection

WHEN USING DO NOT EAT, DRINK OR SMOKE.  
AFTER CONTACT WITH SKIN OR EYES, WASH IMMEDIATELY with plenty of water.  
DO NOT BREATHE SPRAY.  
WASH HANDS AND EXPOSED SKIN before meals and after work.

##### Environmental Protection

**Sp1:** 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].

**Sp3:** To protect aquatic organisms respect an unsprayed buffer zone of 8 m in grapes or 5 meters with 50% reducing drift nozzles, for citrus 20 m with normal nozzles, or 15 meters with 50% reducing drift nozzles, or 10 meters with 75% reducing drift nozzles, for pome and stone fruit trees (including plums and cherries) 25 m with normal nozzles, or 20 meters with 50% reducing drift nozzles, or 15 meters with 75% reducing drift nozzles, for tomato and aubergines, 2.5 m for normal nozzles and for ornamentals 2.0 m with normal nozzles to non-agricultural land/surface water bodies. No buffer zone is required for cotton.

##### Storage and Disposal

KEEP AWAY FROM FOOD, DRINK AND ANIMAL FEEDING STUFFS.  
KEEP OUT OF REACH OF CHILDREN.  
KEEP IN ORIGINAL CONTAINER, tightly closed, in a safe place.  
WASH OUT CONTAINER THOROUGHLY, empty washings into spray tank and dispose of safely.

**(right)**

**Directions for use:**

PYRIPROX is an Emulsifiable Concentrate (EC) formulation containing 100 g/L of pyriproxyfen used as a stomach and contact insecticide against scales, whiteflies and aphids in a range of crops.

Harvest interval: follow harvest intervals where recommended.

Use the rates recommended to ensure good spray coverage.

Recommendations	Rate of use	PHI
<b>Table and wine grapes</b> Pests: scales: mealybug ( <i>Planococcus citri</i> ) Applications in pre-flowering (winter treatments) (BBCH 92 to 60)  Maximum number of applications: 1 per season	0.05-0.075% (50-75 ml PYRIPROX /100 L water) Spray volume: 600-800 L/ha Equivalent to 600 ml PYRIPROX/Ha	n.a.
<b>Citrus (oranges, lemon and tangerines)</b> Pest: Black scale ( <i>Saissetia oleae</i> ), Citrus mussel scale ( <i>Lepidosaphes Beckii</i> ), Chaff scale ( <i>Parlatoria pergandei</i> ), Red scale ( <i>Aonidiella aurantii</i> ) and Oelander scale ( <i>Aspidiotus nerii</i> ) and others.  Application when larvae were detected.  Maximum number of applications: 1 per season	0.025-0.10% (25-100 ml PYRIPROX/100 L water) Spray volume: 1000-1500 L/ha Equivalent to 250-1200 ml PYRIPROX/Ha	30 days
<b>Pome fruit trees (apples and pears)</b> Pests: San Jose Scale ( <i>Quadraspidiotus perniciosus</i> ) Applications in pre-flowering (winter treatments) (BBCH 92 to 60)  Maximum number of applications: 1 per season	0.0375-0.05% (37.5-50 ml PYRIPROX /100 L water) Spray volume: 1000 L/ha Equivalent to 375-500 ml PYRIPROX/Ha	n.a.
<b>Stone fruit trees (peach, nectarine, apricot, cherries and plums)</b> Pests: San Jose Scale ( <i>Quadraspidiotus perniciosus</i> ) Applications in pre-flowering (winter treatments) (BBCH 92 to 60)  Maximum number of applications: 1 per season	0.0375-0.05% (37.5-50 ml PYRIPROX /100 L water) Spray volume: 1000 L/ha Equivalent to 375-500 ml PYRIPROX/Ha	n.a.
<b>Tomato and aubergines</b> Pests: whiteflies and aphids Application when larvae were detected.  Maximum number of applications: Up to 2 applns per season with an interval of 15 days	0.05-0.075% (50-75 ml PYRIPROX/100 L water) Spray volume: 1000-1500 L/ha Equivalent to 0.50-1.125 ml PYRIPROX/Ha.	3 days
<b>Cotton</b> Pests: whiteflies. Application when larvae were detected.  Maximum number of applications: Up to 2 applns per season with an interval of 15 days	0.1% (100 ml PYRIPROX/100 L water) Spray volume: 750 L/ha Equivalent to 0.75 ml PYRIPROX/Ha.	n.a.
<b>Nursery of vegetables</b> Pests: whiteflies and aphids	0.05-0.075% (50-75 ml PYRIPROX /100 L water)	n.a.

Recommendations	Rate of use	PHI
Application when larvae were detected.  Maximum number of applications: 1 per season	Spray volume: 800 L/ha Equivalent to 400-600 ml PYRIPROX/Ha	
<b>Ornamentals</b> Pests: whiteflies and aphids Application when larvae were detected.  Maximum number of applications: 1 per season	0.05-0.075% (50-75 ml PYRIPROX /100 L water) Spray volume: 1000 L/ha Equivalent to 500-750 ml PYRIPROX/Ha	n.a.

## APPLICATION

### Mixing

Ensure the sprayer is clean and calibrated before use.

Half fill the spray tank with clean water and begin agitation. Add the required amount of PYRIPROX and the remaining water. Continue agitation until spraying is complete.

### Water Volume

Ensure sufficient water volumes are used to give good crop coverage. For conventional treatment the water volumes recommended are the minimum. For glasshouse crops apply high volume using sufficient water to ensure thorough crop coverage.

### Caution

Always avoid spraying crops that are under stress at time of application.

### Compatibility

PYRIPROX is compatible with many plant protection products.

Always consult the mixture product label first and apply under the approved conditions.

Follow the country regulation before any tank mixing with any other approved plant protection products.

## CONDITIONS OF SALE

All goods supplied by us are of high grade and we believe them to be suitable but, as we cannot exercise control over their storage, handling mixing or use or the weather conditions before, during and after application which may affect the performance of the goods, all conditions and warranties, statutory or otherwise, as to the quality or fitness for any purpose of our goods are excluded, and no responsibility will be accepted by us or re-sellers for any failure in performance, damage or injury whatsoever arising from their storage, handling, application or use. These conditions cannot be varied by our staff or agents whether or not they supervise or assist in the use of such goods.