

# **REGISTRATION REPORT**

## **Part A**

### **Risk Management**

**Product name: OROCIDÉ**

**Active substance:  
orange oil, 60 g/L**

**COUNTRY: FRANCE**

**Interzonal**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(new application)**

**Applicant: Oro Agri International Ltd**

**Date: 2018-10-25 (Decision)**

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## **PART A – Risk Management**

The company Oro Agri International Ltd has requested new application in France for the product OROCIDÉ, containing 60 g/L orange oil 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 OROCIDÉ where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of OROCIDÉ have been made using endpoints agreed in the EU peer review of orange oil.

This document describes the specific conditions of use and labelling required for France for the registration of OROCIDÉ.

Appendix 1 of this document provides a copy of the French Decision.

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

Appendix 3 of this document is a copy of the letter of Access.

### **1 DETAILS OF THE APPLICATION**

#### **1.1 Application background**

The present registration report concerns the evaluation of Oro Agri International Ltd's application to market OROCIDÉ in France as an insecticide (product uses described under point 2.3). France acted as both a zonal Rapporteur Member State (zRMS) for field uses and an interzonal Rapporteur Member State (izRMS) for greenhouse uses. France assessed the application submitted for the first authorisation of this product in France and in other MSs of the European Union.

#### **1.2 Active substance approval**

##### **Orange oil**

Commission Implementing Regulation (EU) No 1165/2013 of 18 November 2013 approving the active substance orange oil, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

Specific provisions of Regulation (EU) No 1165/2013 were as follows :

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on orange oil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account.

In this overall assessment Member States shall pay particular attention to: (a) the protection of operators and workers; (b) the risk to birds and mammals.

Conditions of use shall include risk mitigation measures, where appropriate.

The applicant shall submit confirmatory information as regards (1) the metabolite fate of orange oil and the route and rate of degradation in soil; (2) the validation of endpoints used in the ecotoxicological risk assessment.

The applicant shall submit that information to the Commission, Member States and the Authority by 30 April 2016.

An EFSA conclusion is available (EFSA Journal 2013;11(2):3090).

A Review Report is available (SANCO/12083/2013 rev 3, 3 October 2013).

### 1.3 Regulatory approach

The present application (2015-1147) 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 for field uses, and for all Member States of the European Union for glasshouse uses, taking into account the worst-case uses (“risk envelope approach”)<sup>1</sup> – the highest application rates over the European Union. When risk mitigation measures were necessary, they are adapted to the situation in France.

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

The French Order of 4th 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.

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

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<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 <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte>

<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/AGRG1407093A/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

## 1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of OROCIDÉ, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

## 1.5 Letter of Access

The applicant has provided a letter of access.

Provided upon request

## 2 DETAILS OF THE AUTHORISATION

### 2.1 Product identity

<b>Product name</b>	OROCIDE
<b>Authorisation number</b>	2180631
<b>Function</b>	Insecticide
<b>Applicant</b>	Oro Agri International Ltd
<b>Composition</b>	60 g/L orange oil
<b>Formulation type (code)</b>	Micro-emulsion (ME)
<b>Packaging</b>	Bottle HDPE (5 L)

### 2.2 Classification and labelling

#### 2.2.1 Classification and labelling in accordance with Regulation (EC) No 1272/2008

<b>Physical hazards</b>	-	
<b>Health hazards</b>	Skin corrosion cat. 1 Acute toxicity (inhalation) cat. 4	
<b>Environmental hazards</b>	Hazardous to the aquatic environment - Chronic Hazard, cat. 2	
<b>Hazard pictograms</b>		
<b>Signal word</b>	Warning	
<b>Hazard statements</b>	H314	Causes severe skin burns and eye damage
	H332	Harmful if inhaled
	H411	Toxic to aquatic life with long lasting effects
<b>Precautionary statements –</b>	<i>For the P phrases, refer to the extant legislation</i>	

<b>Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)</b>	EUH208	Contains 1,2-benzisothiazol-3(2H)-one. May cause an allergic reaction.
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*See Part C for justifications of the classification and labelling proposals.*

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

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe 2	To protect aquatic organisms, do not discharge waste water from soil-less glasshouses directly into surface water.
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres <sup>7</sup> to surface water bodies for uses on tomato and pepper in open, non-permanent and permeable structures, and under tunnel.
SPe 8	For open, non-permanent and permeable structures, and under tunnel: <ul style="list-style-type: none"> <li>- 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.</li> </ul> For permanent structures: <ul style="list-style-type: none"> <li>- May affect beneficial insects.</li> <li>- Precaution should be taken when introducing pollinators.</li> </ul>

### 2.2.3 Other phrases linked to the preparation

Wear suitable personal protective equipment <sup>8</sup> : refer to the Decision in Appendix 1 for the details
Re-entry period <sup>9</sup> : 8 hours for indoor applications
Pre-harvest interval <sup>10</sup> : 1 day
Other mitigation measures: <ul style="list-style-type: none"> <li>- Shake before use.</li> <li>- The efficacy level of the product is considered as variable and partial, specify the optimal conditions of use</li> </ul>
The label may include the following recommendations: <ul style="list-style-type: none"> <li>- EUH208: Contains 1,2-benzisothiazol-3(2H)-one. May cause an allergic reaction.</li> </ul> The label must reflect the conditions of authorisation.

<sup>7</sup> The legal basis for this is **Titre III Article 12** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

<sup>8</sup> If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

<sup>9</sup> The legal basis for this is **Titre I Article 3** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

<sup>10</sup> According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

## 2.3 Product uses

**Please note:** The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as izRMS. Those uses are then granted in France.

GAP rev. 1, date: 2018-10-25

PPP (product name/code): **OROCIDE**  
Active substance 1: Orange oil  
Applicant: **Oro Agri International Ltd**  
Zone(s): interzonal <sup>(d)</sup>  
Verified by MS: yes  
Field of use: insecticide, fungicide

Formulation type: **ME** <sup>(a, b)</sup>  
Conc. of as 1: **60 g/L** <sup>(c)</sup>  
Professional use:   
Non professional use:

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	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
<b>Interzonal uses (in greenhouses (or other closed places of plant production))</b>													
1	FR	Tomato Eggplant	G	Whitefly	Spray	BBCH 12-89	5	7	a) 2 b) 10	a) 120 b) 600	100- 500	1	Acceptable
2	FR	Pepper Chili	G	Whitefly	Spray	BBCH 12-89	5	7	a) 2 b) 10	a) 120 b) 600	100- 500	1	Acceptable

**Remarks table heading:**  
(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)  
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008  
(c) g/kg or g/L

(d) Select relevant  
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1  
(f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

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

OROCIDE is a micro-emulsion (ME). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a green homogenous liquid, with a citrus odour. It is not explosive, has no oxidizing properties and is not flammable (no flash point up to 110 °C). It has a self-ignition temperature of 431 °C. In aqueous solution (1 % w/v), it has a pH value 8.0 at ambient temperature. There is no effect of low and high temperatures on the stability of the formulation, since after 7 days at 0 °C and after 14 days at 54 °C in sealed flask, neither the active substance' content nor the technical properties were changed.

Nevertheless, as a soluble precipitate was formed, the mention “shake before use” must be reported on the label. The results of the persistent foaming are within the acceptable range at 0.8 % (v/v) after adding antifoam at 0.001 % (w/v), so the addition of antifoam is recommended on the label with an indication of the antifoam type and concentration.

The stability data indicate a shelf life of at least two years at ambient temperature when stored in PE. Its technical characteristics are acceptable for a ME formulation.

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

##### 3.1.2 Methods of analysis

Analytical method for the determination of the active substance in the formulation is available and validated. As orange oil does not contain relevant impurity, no analytical method is required.

According to Regulation (EU) No 588/2014, no residue definition and no MRL were set for plants and foodstuffs of animal origin. Thus, analytical methods for the determination of orange oil residues in plants and foodstuffs of animal origin are not necessary.

According to the EFSA conclusions<sup>11</sup>, no residue definition was set for soil (not relevant), so an analytical method for the determination of orange oil residues in soil is not necessary.

According to the environment experts, there is no residue definition for water and air, analytical methods fully validated for the determination of orange oil residues in water and air are not necessary.

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

##### 3.1.3 Mammalian Toxicology

The endpoints used in risk assessment are shown below:

Active substance: <b>orange oil</b>			
ADI	not necessary		EU (October 2013)
ARfD	not necessary		
AOEL	1 mg/kg bw/day		
Dermal absorption	Based on default values according to guidance on dermal absorption (EFSA 2012):		
		Concentrate (used in formulation) 60 g/L	Spray dilution (used in formulation) 0.48 g/L

<sup>11</sup> EFSA Journal 2013;11(2):3090

	<b>Dermal absorption endpoints %</b>	<b>25 %</b>	<b>75 %</b>
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### 3.1.3.1 Acute Toxicity

OROCIDE has a low acute oral, inhalational and dermal toxicity, is irritating to the rabbit skin, but is an eye irritant and 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

Critical use patterns (worst cases) for glasshouse uses are summarised in the table below.

Crop	F/G <sup>12</sup>	Equipment	Application rate L product/ha (g a.s./ha)	Spray dilution (L/ha)	Model
Tomato, pepper and chili	G	Lance	2 L/ha (120 g/ha)	100-500	BBA model

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

Crop	Equipment	PPE and/or working coverall	% AOEL orange oil
Tomato, pepper and chili	Lance (high target) (BBA model)	Working coverall and gloves during mixing/loading and application	1.2 %

According to the model calculations, it may be concluded that the risk for the operator using OROCIDÉ 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

Bystanders are not expected to be present in greenhouse during application. Evaluation is not deemed necessary.

### 3.1.3.4 Worker Exposure

Workers may have to enter treated areas after treatment for crop harvesting activities. Therefore, estimation of worker exposure was calculated according to EUROPOEM II. Exposure is estimated to be 3.8% of the AOEL of orange oil.

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 OROCIDÉ.

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 purposes. Orange oil was temporarily included in Annex IV of Regulation (EC) No 396/2005. Therefore estimation of exposure through diet and other means is not considered relevant and it is considered that the use of orange oil do not represent unacceptable acute and chronic risks for the consumer.

As far as consumer health protection is concerned, France agrees with the authorization of the intended uses.

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

<sup>12</sup> Open field or glasshouse

### 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 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 D-limonene, lead component of orange oil in soil and surface water, have been assessed according to FOCUS guidance documents and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PEC<sub>soil</sub> and PEC<sub>sw</sub> values derived for the active substance are used for the ecotoxicological risk assessment.

PEC<sub>gw</sub> calculations for orange oil are not considered relevant considering its very high vapour pressure and thus its quick dissipation.

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

Based on the guidance documents, the risks for birds, aquatic organisms, mammals, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants are acceptable for the intended uses when the following risk mitigation measures are considered in open, non-permanent and permeable structures, and under tunnel:

- To protect aquatic organisms, respect an unsprayed buffer zone of 5 meters to surface water bodies for uses on tomato and pepper.
- 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.

For uses in permanent structures, the following precaution measure is applied:

- May affect beneficial insects.
- Precaution should be taken when introducing pollinators.

### 3.1.7 Efficacy

Considering the data submitted:

- The efficacy level of OROCIDÉ is considered partial and variable for all the claimed uses. However it is considered acceptable for this type of product based on plant extracts.
- The phytotoxicity level of OROCIDÉ is considered acceptable for all the claimed uses.
- The risks of negative impact on yield, quality, propagation, succeeding crops and adjacent crops are considered acceptable.
- The risk of resistance development or appearance to orange oil does not require a monitoring for the claimed uses.

## 3.2 Conclusions arising from French assessment

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

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

No information stated.

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

#### **3.4.1 Post-authorisation monitoring**

No further information is required.

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

The French Decision requests the submission of post-authorisation confirmatory pieces of information within 24 months regarding:

- The results of the test of persistent foaming at the maximum use concentration with antifoam.
- The surface tension,
- The results of the emulsification and re-emulsification properties at the maximum use concentration.

#### **3.4.3 Label amendments**

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

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

## Appendix 1 – Copy of the French Decision



### 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 **OROCIDE***

*de la société Oro Agri International Ltd*

*enregistrée sous le n°2015-1147*

*Vu les conclusions de l'évaluation de l'Anses du 2 octobre 2018,*

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

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

#### **Avertissement :**

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



Informations générales sur le produit	
Nom du produit	OROCIDE
Type de produit	Produit de référence
Titulaire	Oro Agri International Ltd Bankastraat 75 9715CJ GRONINGEN Pays-Bas
Formulation	Micro-émulsion (ME)
Contenant	60 g/L - huile essentielle d'orange
Numéro d'intrant	9874-2015.01
Numéro d'AMM	2180631
Fonction	Insecticide
Gamme d'usage	Professionnel

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active qui arrivera à échéance le plus tôt. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 30 avril 2025.

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

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

A Maisons-Alfort le,

25 OCT. 2018

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



## ANNEXE I : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	Contenance
Bidons en polyéthylène haute densité	5 L

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	Mention de danger
Corrosion cutanée/irritation cutanée - Catégories 1	H314 : Provoque des brûlures de la peau et des lésions oculaires graves
Toxicité aiguë par inhalation - Catégorie 4	H332 : Nocif par inhalation
Dangers pour le milieu aquatique - Danger chronique, catégorie 2	H411 : Toxique pour les organismes aquatiques, entraîne des effets à long terme
EUH208 : Contient de la 1,2-benzisothiazol-3(2H)-one. Peut produire une réaction allergique.	
Pour les phrases P se référer à la réglementation en vigueur.	
<b>Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.</b>	



**Liste des usages autorisés**

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
<b>16863103</b> Poivron*Trt Part.Aer.* Aleurodes	2 L/ha	5/an	Entre les stades BBCH 12 et BBCH 89	1	-	-	
	Uniquement sous abri. Intervalle minimum entre les applications : 7 jours						
<b>16953101</b> Tomate*Trt Part.Aer.* Aleurodes	2 L/ha	5/an	Entre les stades BBCH 12 et BBCH 89	1	-	-	
	Uniquement sous abri. Intervalle minimum entre les applications : 7 jours						

OROCIDE  
AMM n°2180631



## Conditions d'emploi du produit

### Stockage et manipulation du produit

- Agiter avant utilisation.

### Protection de l'opérateur et du travailleur

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- 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 individuelles
- 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,

##### **• 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) ;
- Protections respiratoires certifiées : demi-masque certifié (EN 140) équipé d'un filtre P3 (EN143) ou A2P3 (EN 14387) ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3)

OU

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m<sup>2</sup> 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 ;
- Protections respiratoires certifiées : demi-masque certifié (EN 140) équipé d'un filtre P3 (EN143) ou A2P3 (EN 14387) ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3)

##### **• pendant l'application : sans contact intense avec la végétation - Culture haute (> 50 cm)**

- 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 ;
- Protections respiratoires certifiées : demi-masque certifié (EN 140) équipé d'un filtre P3 (EN143) ou A2P3 (EN 14387) ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3)

##### **• 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)
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3)

OU

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m<sup>2</sup> ou plus avec traitement déperlant ;
- EPI partiel (blouse) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;



- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3).

**Pour le travailleur, porter**

- Une combinaison de travail (cotte en coton/polyester 35 %/65 % - grammage d'au moins 230 g/m<sup>2</sup>) avec traitement déperlant et, en cas de contact avec la culture traitée, des gants en nitrile certifiés EN 374-3.

**Délai de rentrée en application de l'arrêté du 4 mai 2017 :**

- 8 heures sous abri

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

**Protection de l'eau**

- SP 1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

**Protection de la faune**

SPe 2 : Pour protéger les organismes aquatiques, ne pas rejeter les eaux usées des serres hors sol directement dans les eaux de surface.

SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau dans le cas de structures ouvertes, non permanentes ou perméables, et tunnels.

**SPe 8 :**

Dans le cas de structures ouvertes, non permanentes ou perméables et tunnels:

- Dangereux pour les abeilles/ Pour protéger les abeilles et autres insectes pollinisateurs, ne pas appliquer durant la floraison et les périodes de production d'exsudats / Ne pas utiliser en présence d'abeilles/Ne pas appliquer lorsque des adventices en fleur sont présentes.

Dans le cas de structures permanentes

- Peut porter atteinte aux insectes pollinisateurs. Eviter toute exposition inutile.
- Peut porter atteinte à la faune auxiliaire

**Exigences complémentaires post-autorisation**

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

Détail de la demande post autorisation	Délai (mois)	Récurrance (mois)
Fournir le résultat du test de la persistante de la mousse avec un agent anti-moussant à la concentration maximale d'utilisation.	24	-
Fournir la tension de surface.	24	-
Fournir le résultat du test d'émulsification et de ré-émulsification à la concentration maximale d'utilisation.	24	-

**Recommandations relatives à l'étiquette du produit**

- L'efficacité du produit étant variable et partielle, préciser les conditions optimales d'utilisation.

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

**OROCIDE**

**INSECTICIDE POLYVALENT  
MULTI-CULTURES - FORMULATION (SL)**

MATIÈRE ACTIVE	AMMP N°
HUILE ESSENTIELLE D'ORANGES DOUCES 60 g/l	AUTORISATION DE MISE SUR LE MARCHÉ N° ...

**MENTIONS DE DANGER:** H319 Provoque une sévère irritation des yeux. H332 Nocif par inhalation. H411 Toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.

**CONSEILS DE PRUDENCE:** P102 Tenir hors de portée des enfants. P103 Lire l'étiquette avant utilisation. P261 A Éviter de respirer les vapeurs. P264 Se laver les mains soigneusement après manipulation. P280 Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage. P304 + P340 EN CAS D'INHALATION: transporter la victime à l'extérieur et la maintenir au repos dans une position où elle peut confortablement respirer. P305 + P351+ P338 EN CAS DE CONTACT AVEC LES YEUX: rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer. P312 Appeler un CENTRE ANTIPOISON ou un médecin en cas de malaise. P337 + P313 Si l'irritation oculaire persiste: consulter un médecin. P391 Recueillir le produit répandu.

P502 Se reporter au fabricant/fournisseur pour des informations concernant la récupération/le recyclage.

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

**SF245-01** Ne pas ré-entrer dans la parcelle avant séchage complet des parties traitées.

**FABRICANT ET DISTRIBUTEUR**

**ORO AGRI**  
ORO AGRI INTERNATIONAL LTD

BANKASTRAAT 75  
9715CJ GRONINGEN • THE NETHERLANDS  
TEL.: +31 50 820 04 11  
[WWW.OROAGRI.COM](http://WWW.OROAGRI.COM)

**VOLUME NET**

**5L**

PLB038FR0005L-FR00ALP

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#### MODE D'ACTION

**OROCIDE**® est une solution curative, à appliquer en pulvérisation foliaire seulement en présence des ravageurs ciblés. **OROCIDE** a un mode d'action physique, agissant par contact sur les insectes à corps mous tels que la mouche blanche. La substance active, l'essence d'orange, a un pouvoir de dessiccation, qui permet un effet de choc pour contrôler les pressions parasitaires.

#### RÉGLEMENTATION

**OROCIDE** est un insecticide à utiliser sous serres. Délai de rentrée : 48 h. **Aucun Délai Avant Récolte**, aucune **Limite Maximale de Résidus** ne sont applicables avec **OROCIDE**.

#### PRÉCAUTIONS ET CONSEILS D'EMPLOI

- Agiter le bidon avant emploi.
- Stocker le produit dans son emballage d'origine à température ambiante. Les bidons entamés devront être rebouchés soigneusement et utilisés dans les 6 mois.
- En cas d'ingestion, consulter un médecin.
- Éliminer les fonds de cuve par épandage rapide sur la culture la plus proche.
- Emballage : réemploi interdit.
- Rincer le bidon plusieurs fois et mélanger les eaux de rinçage à la bouillie. Éliminer les emballages vides selon la réglementation en vigueur.

#### RECOMMANDATIONS

**OROCIDE** doit être appliqué sur un feuillage sec afin d'éviter la dilution de la bouillie sur le feuillage, qui réduirait l'efficacité du traitement. Une bonne qualité de pulvérisation est nécessaire afin d'optimiser l'action de contact de **OROCIDE**. Compte tenu du mode d'action d'**OROCIDE**, il est déconseillé d'appliquer ce produit sur des plantes souffrant de stress hydrique. **OROCIDE** s'applique tôt en saison sur des foyers faiblement déclarés en maintenant une cadence de traitement qui est fonction de la présence du parasite.

Le mode d'action physique de **OROCIDE** garantit l'absence d'apparition de résistance. **OROCIDE** représente une bonne solution dans une stratégie de lutte contre les phénomènes de résistance vis-à-vis de produits de synthèse.

#### PRATIQUE DES MÉLANGES

Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur et aux recommandations des guides de bonnes pratiques. Les mélanges suivants sont déconseillés avec des adjuvants extemporanés et des préparations à pleine dose de soufre. Il est recommandé d'utiliser un agent antimousse, contenant des Polydiméthylsiloxanes en émulsion aqueuse, à la dose de 0,001% w/v.

#### USAGES ET DOSES D'EMPLOI

La dose maximale d'utilisation est fixée sur la base d'un volume d'eau maximal indiqué dans les tableaux ci-dessous. Lors de l'utilisation d'un volume d'eau plus faible, la dose par hectare peut être réduite en respectant la concentration de **OROCIDE** comprise selon les cibles entre 0,4 l/ha et 0,8 l/ha.

#### CULTURES MARAÎCHÈRES (SOUS SERRES)

CULTURE	USAGE	DOSE MAXIMALE - ha (% v/v)	NOMBRE TRAITEMENTS	ZONE DE TRAITEMENT
LÉGUMES-FRUITS	Aleurodes*	2 L/ha (0,4 %*)	1 - 5	sous serres
TOMATE	Aleurodes*	2 L/ha (0,4 %*)	1 - 5	sous serres
POIVRON	Aleurodes*	2 L/ha (0,4 %*)	1 - 5	sous serres
PIMENT	Aleurodes*	2 L/ha (0,4 %*)	1 - 5	sous serres

\* Homologué sur *Bemisia tabaci* et *Trialeurodes vaporariorum*

\*\* Calculé sur la base de 500 l/ha (le volume d'eau maximal pratiqué)

Sur cultures maraîchères, **OROCIDE** bénéficie d'une autorisation sous serre.

Il s'utilise tôt en saison sur attaques précoces sur feuilles. Il est utilisé en alternance à 5 - 10 jours d'intervalle contre les parasites (mouche blanche).

**En cas d'attaques modérées à fortes** : **OROCIDE** est utilisé en association avec une logique de mélange à dose réduite avec un insecticide homologué contre la mouche blanche.

**En cas de faible pression**, **OROCIDE** peut être utilisé en alternance à 5 - 10 jours.

L'absence de LMR et de Délai Avant Récolte facilitera l'usage de **OROCIDE** sur les périodes proches de la récolte.

**IMPORTANT** : RESPECTER LES USAGES, DOSES, CONDITIONS ET PRÉCAUTIONS D'EMPLOI MENTIONNÉS SUR L'EMBALLAGE QUI ONT ÉTÉ DÉTERMINÉS EN FONCTION DES CARACTÉRISTIQUES DU PRODUIT ET DES APPLICATIONS POUR LESQUELLES IL EST PRÉCONISÉ. CONDUISEZ SUR CES BASES, LA CULTURE ET LES TRAITEMENTS SELON LA BONNE PRATIQUE AGRICOLE EN TENANT COMPTE, SOUS VOTRE RESPONSABILITÉ, DE TOUTS FACTEURS PARTICULIERS CONCERNANT VOTRE EXPLOITATION, COMME LA NATURE DU SOL, LES CONDITIONS MÉTÉOROLOGIQUES, LES MÉTHODES CULTURALES, LES VARIÉTÉS VÉGÉTALES, LA RÉSISTANCE DES ESPÈCES. LE FABRICANT GARANTIT LA QUALITÉ DE SES PRODUITS VENDUS DANS LEUR EMBALLAGE D'ORIGINE AINSI QUE LEUR CONFORMITÉ À L'AGRÉATION DÉLIVRÉE PAR LE MINISTÈRE DE L'AGRICULTURE.

P.18.03.95A00015-FR01ALP

### Appendix 3 – Letter of Access

**Oro Agri International Ltd.**  
9 Franklinstraat  
9285 WT Buitenpost  
The Netherlands

**ANNEXE A**

July 18, 2013

#### **Oro Agri International Ltd - LETTER OF ACCESS**

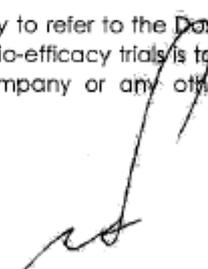
##### **Letter of Access for the use of PREV-AM<sup>®</sup> data to the benefit of Oro Agri International Ltd**

To whom it may concern,

**VIVAGRO**, located Espace France, Bat. C, 4 Voie Romaine, 31610 Canejan in France hereby authorizes Oro Agri International Ltd to refer to all files, all data, all studies, all summaries, all assessments and all relevant correspondence (hereinafter "Dossier"), owned and submitted by **VIVAGRO** for the support of the registration of the product **PREV-AM (60 g/l cold pressed orange oil)** at the European level, and in France (Registration number AMM n°2090127).

Therefore, **VIVAGRO** gives hereby the full access to:

- Entire Tier II, made under the regulation 91/414/EC, on the formulation **PREV-AM** (Annex III), which contains 7 sections.
  - The Biological assessment dossier, and all bio-efficacy trial final reports used to support the extension of the French label according to the AMM 2090127.
- 
- To any further data generated on **PREV-AM** development of use.

1. Permission to refer to the above mentioned Dossiers is granted to **Oro Agri International Ltd.** (hereinafter "Registering Company"), only and solely to support the registration of **PREV-AM** and **OROCIDE**, an insecticide and fungicide formulation containing the active substance, cold pressed orange oil for use in Southern Europe and more specifically in Italy, Spain and Portugal.
  2. This letter shall not be construed as authorization to use or consider the Dossier, directly or indirectly, in support of any other product application submitted by the Registering Company, for products not referenced in this letter.
  3. This letter is valid only in Southern Europe and more specifically in Italy, Spain and Portugal.
  4. This letter allows the Registering Company to refer to the Dossier provided to the authorities. None of final reports on bio-efficacy trials is to be released to or misreviewed by the Registering Company or any other company or person.
- 

5. **VIVAGRO** undertakes to supply directly the regulatory authorities with a copy of requested documents, in a professional and timely manner, and will co-operate fully taking into consideration the regulatory timeline.
6. **VIVAGRO** will keep **Oro Agri International Ltd** fully informed of all communication with regulatory authorities in relation to cold pressed orange oil and **PREV-AM**.
7. This letter is not transferable or assignable to any other company or other legal or natural entities without the express prior written authorization of **VIVAGRO** and may not be used in support of any other application for registration by the Registering Company or any third party.
8. The authorization granted by this letter has no time limit.
9. If you have any questions regarding this letter of access please contact the undersigned.

Yours sincerely,

Fabrice LEMARCHAND

  
**VIVAGRO SARL**  
Espace France - Bâtiment C  
4 yolo Roubaix - 59016 CANEJAN  
SIRET 404 268 288 00018 - APE 743 B

