

# **REGISTRATION REPORT**

## **Part A**

### **Risk Management**

**Product code: A16971B**

**Product name(s): MINECTO ONE**

**Active Substance(s):**

**Cyantraniliprole, 400 g/kg**

**COUNTRY: FRANCE**

**Southern Zone**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(New application)**

**Applicant: SYNGENTA France SAS**

**Date: 12/08/2021**

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## **PART A – Risk Management**

The company SYNGENTA France S.A.S. has requested marketing authorisation in France for the product MINECTO ONE (product code: A16971B), containing 400 g/kg cyantraniliprole 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 MINECTO ONE (A16971B) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of MINECTO ONE (A16971B) have been made using endpoints agreed in the EU peer review of cyantraniliprole.

This document describes the specific conditions of use and labelling required for France for the registration of MINECTO ONE (A16971B).

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

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

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

## **1 DETAILS OF THE APPLICATION**

### **1.1 Application background**

The present registration report concerns the evaluation of SYNGENTA France S.A.S.'s application to market MINECTO ONE (A16971B) 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**

#### **Cyantraniliprole**

Commission Implementing Regulation (EU) 2016/1414 of 24 August 2016 approving the active substance cyantraniliprole, 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) 2016/1414 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 cyantraniliprole, and in particular Appendices I and II thereto, shall be taken into account.

In this overall assessment Member States shall pay particular attention to:

- (a) the risk to operators;
- (b) the risk to aquatic organisms, bees and other non-target arthropods;
- (c) the risk to bees and bumble bees released for pollination, when the substance is applied in glasshouses;
- (d) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions.

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

The applicant shall submit to the Commission, Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water within 2 years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface

and groundwater.

An EFSA conclusion is available (EFSA Journal 2014;12(9):3814).

A Review Report is available (SANTE/00111/2015 rev 1, 12 July 2016).

### 1.3 Regulatory approach

The present application (2016-2602; 2016-2624, 2019-6156 et 2020-3860) 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 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.

Moreover, the French Order of 12 April 2021<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

<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/AGRGI632554A/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 <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

<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

applicant.

Finally, the French Order of 20 November 2021<sup>7</sup> on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless otherwise stated in the product authorisation, use on attractive culture<sup>8</sup> when in flower and on foraging area is forbidden. Specific conditions of application on flowering crops should be respected. As consequences specific SPe 8 may include reference to this order.

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

#### **1.4 Data protection claims**

Where protection for data is being claimed for information supporting registration of MINECTO ONE (A16971B), 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: the applicant is the owner of the active substance data.

The applicant has provided a letter of access for DuPont cyantraniliprole-containing formulation's data.

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

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


## 2 DETAILS OF THE AUTHORISATION

### 2.1 Product identity

<b>Product name (code)</b>	MINECTO ONE (A16971B)
<b>Authorisation number</b>	N/A : no marketing authorisation granted
<b>Function</b>	Insecticide
<b>Applicant</b>	SYNGENTA France SAS
<b>Composition</b>	400 g/kg cyantraniliprole
<b>Formulation type (code)</b>	Water-dispersible granule (WG)
<b>Packaging</b>	N/A : no marketing authorisation granted

### 2.2 Classification and labelling

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

<b>Physical hazards</b>		
<b>Health hazards</b>	-	
<b>Environmental hazards</b>	Hazardous to the aquatic environment, Acute Hazard, Category 1 Hazardous to the aquatic environment, Chronic Hazard, Category 1	
<b>Hazard pictograms</b>		
<b>Signal word</b>		
<b>Hazard statements</b>	H400	Very toxic to aquatic life
	H410	Very 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>		

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

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

N/A : 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 12 April 2021 (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.

Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 12/08/2022

PPP (product name/code): MINECTO ONE (A16971B)  
 Active substance: cyantraniliprole  
 Safener: -  
 Synergist: -  
 Applicant: SYNGENTA France S.A.S.  
 Zone(s): Southern <sup>(d)</sup>  
 Verified by MS: yes  
 Field of use: insecticide

Formulation type: WG <sup>(a, b)</sup>  
 Conc. of as: 400 g/kg <sup>(c)</sup>  
 Conc. of safener: -  
 Conc. of synergist: -  
 Professional use: ☒  
 Non professional use: ☐

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G 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
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
1	<u>S-EU</u> : FR	Pome fruit (apple, pear, quince, medlar, loquat, carb apple)	F	Codling moth ( <i>Cydia pomonella</i> ); oriental fruit moth ( <i>Cydia molesta</i> ); leafrollers ( <i>Archips spp</i> ; <i>Adoxophyes spp</i> ; <i>Argyrotenia spp</i> ; <i>Pandemis spp</i> ; <i>Cheimatobia spp</i> ; <i>Spilonota sp.</i> ) Leafminers ( <i>Phyllonorictor spp</i> ; <i>Leucoptera spp</i> ; <i>Lithocolletis spp.</i> )	Foliar spray	BBCH 60-87	a) 2 (10) b) 2	a) 0.1875 b) 0.375	a) 75 b) 150	Min: 300 Max: 1500	7	Not acceptable (risk for ground water and aquatic organisms)
2	<u>S-EU</u> : FR	Apricot	F	Oriental fruit moth ( <i>Cydia molesta</i> ); peach twig borer ( <i>Anarsia lineatella</i> )	Foliar spray	BBCH 69-87	a) 1 (-) b) 1	a) 0.3125 b) 0.3125	a) 125 b) 125	Min: 600 Max: 1500	3	Not acceptable (risk for ground water and aquatic organisms and for MRL)

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G 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
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
3	<u>S-EU</u> : FR	Peach, nectarine	F	Oriental fruit moth ( <i>Cydia molesta</i> ); peach twig borer ( <i>Anarsia lineatella</i> ) thrips ( <i>Frankliniella occidentalis</i> ; <i>Taeniothrips meridionalis</i> )	Foliar spray	BBCH 69-87	a) 1 (-) b) 1	a) 0.3125 b) 0.3125	a) 125 b) 125	Min: 600 Max: 1500	7	Not acceptable (risk for ground water and aquatic organisms)
4	<u>S-EU</u> : FR	Plum	F	Plum fruit moth ( <i>Cydia funebrana</i> )	Foliar spray	BBCH 69-87	a) 1 (-) b) 1	a) 0.3125 b) 0.3125	a) 125 b) 125	Min: 300 Max: 1500	7	Not acceptable (risk for ground water and aquatic organisms and for MRL)
5	<u>S-EU</u> : FR	Leek	F	Onion thrips ( <i>Thrips tabaci</i> )	Foliar spray	BBCH 12-49	a) 1 (-) b) 1	a) 0.3125 b) 0.3125	a) 125 b) 125	Min: 200 Max: 1000	14	Not acceptable (risk for ground water and aquatic organisms and for MRL)
6	<u>S-EU</u> : FR	Onion, garlic, shallots	F	Onion thrips ( <i>Thrips tabaci</i> )	Foliar spray	BBCH 12-49	a) 1 (-) b) 1	a) 0.3125 b) 0.3125	a) 125 b) 125	Min: 200 Max: 1000	14	Not acceptable (risk for ground water and aquatic organisms)
7	<u>S-EU</u> : FR	Broccoli (calabrese and Chinese kale (Chinese broccoli))*	F	<i>Mamestra brassicae</i> spp; large white ( <i>Pieris brassicae</i> ); small white ( <i>Pieris rapae</i> ); diamondback moth ( <i>Plutella xylostella</i> ); <i>Autographa gamma</i> ; cabbage root fly ( <i>Delia radicum</i> )	Foliar spray	BBCH 12 -55	a) 2 (7) b) 2	a) 0.1875 b) 0.375	a) 75 b) 150	Min: 200 Max: 1000	3	Not acceptable (risk for ground water and aquatic organisms)  Efficacy against <i>Delia radicum</i>
8	<u>S-EU</u> : FR	Cauliflower	F	<i>Mamestra brassicae</i> spp; large white ( <i>Pieris brassicae</i> ); small white ( <i>Pieris rapae</i> ); diamondback moth ( <i>Plutella xylostella</i> ); <i>Autographa gamma</i> ; cabbage root fly ( <i>Delia radicum</i> )	Foliar spray	BBCH 12 -55	a) 2 (7) b) 2	a) 0.1875 b) 0.375	a) 75 b) 150	Min: 200 Max: 1000	3	Not acceptable (risk for ground water and aquatic organisms)  Efficacy against <i>Delia radicum</i>



1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G 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
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
9	<u>S-EU</u> : FR	Brussels sprouts	F	<i>Mamestra brassicae</i> spp; large white ( <i>Pieris brassicae</i> ); small white ( <i>Pieris rapae</i> ); diamondback moth ( <i>Plutella xylostella</i> ); <i>Autographa gamma</i> ; cabbage root fly ( <i>Delia radicum</i> )	Foliar spray	BBCH 12-55	a) 2 (7) b) 2	a) 0.1875 b) 0.375	a) 75 b) 150	Min: 200 Max: 1000	3	<b>Not acceptable (risk for ground water and aquatic organisms)</b> Efficacy against <i>Delia radicum</i>
10	<u>S-EU</u> : FR	Cabbage (red cabbage, white cabbage and Savoy cabbage)	F	<i>Mamestra brassicae</i> spp; large white ( <i>Pieris brassicae</i> ); small white ( <i>Pieris rapae</i> ); diamondback moth ( <i>Plutella xylostella</i> ); <i>Autographa gamma</i> ; cabbage root fly ( <i>Delia radicum</i> )	Foliar spray	BBCH 12-55	a) 2 (7) b) 2	a) 0.1875 b) 0.375	a) 75 b) 150	Min: 200 Max: 1000	3	<b>Not acceptable (risk for ground water and aquatic organisms and for MRL)</b> Efficacy against <i>Delia radicum</i>
11	<u>S-EU</u> : FR	Kale (collards, curly kale, Peking cabbage, Chinese cabbage, Mitzuna, Komatsuna, mustard)*	F	<i>Mamestra brassicae</i> spp; large white ( <i>Pieris brassicae</i> ); small white ( <i>Pieris rapae</i> ); diamondback moth ( <i>Plutella xylostella</i> ); <i>Autographa gamma</i> ; cabbage root fly ( <i>Delia radicum</i> )	Foliar spray	BBCH 12-20	a) 2 (7) b) 2	a) 0.1875 b) 0.375	a) 75 b) 150	Min: 200 Max: 1000	3	<b>Not acceptable (risk for ground water and aquatic organisms and for MRL)</b> Efficacy against <i>Delia radicum</i>
12	<u>S-EU</u> : FR	Lettuce	F	<i>Autographa sp.</i> , <i>Heliothis armigera</i> , <i>Mamestra brassicae</i>	Foliar spray	BBCH 12-49	a) 2 (7) b) 2	a) 0.1875 b) 0.375	a) 75 b) 150	Min: 200 Max: 1000	7	<b>Not acceptable (risk for ground water and aquatic organisms and for MRL)</b>
13	<u>S-EU</u> : FR	Lettuce	G	<i>Autographa sp.</i> , <i>Heliothis armigera</i> , <i>Mamestra brassicae</i>	Foliar spray	BBCH 12-49	a) 2 (7) b) 2	a) 0.1875 b) 0.375	a) 75 b) 150	Min: 200 Max: 1000	7	<b>Not acceptable (risk for ground water and aquatic organisms and for MRL)</b>

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G 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
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
14	<u>S-EU</u> : FR	Lettuce similar (broad leaved endive, rocket, chard, Italian corn salad, lamb's lettuce and Eruca (rucola))	F	<i>Autographa sp.</i> , <i>Heliothis armigera</i> , <i>Mamestra brassicae</i>	Foliar spray	BBCH 12-49	a) 2 (7) b) 2	a) 0.1875 b) 0.375	a) 75 b) 150	Min: 200 Max: 1000	7	Not acceptable (risk for ground water and aquatic organisms and for MRL)
15	<u>S-EU</u> : FR	Lettuce similar (broad leaved endive, rocket, chard, Italian corn salad, lamb's lettuce and Eruca (rucola))	G	<i>Autographa sp.</i> , <i>Heliothis armigera</i> , <i>Mamestra brassicae</i>	Foliar spray	BBCH 12-49	a) 2 (7) b) 2	a) 0.1875 b) 0.375	a) 75 b) 150	Min: 200 Max: 1000	7	Not acceptable (MRL)
16	<u>S-EU</u> : FR	Beans with pods	F	Tomato fruitworm ( <i>Heliothis armigera</i> ), European corn borer ( <i>Ostrinia nubilalis</i> )	Foliar spray	BBCH 20-89	a) 2 (7) b) 2	a) 0.1875 b) 0.375	a) 75 b) 150	Min: 200 Max: 1000	3	Not acceptable (risk for ground water and aquatic organisms)
17	<u>S-EU</u> : FR	Beans without pods	F	Tomato fruitworm ( <i>Heliothis armigera</i> ), European corn borer ( <i>Ostrinia nubilalis</i> )	Foliar spray	BBCH 20-89	a) 2 (7) b) 2	a) 0.1875 b) 0.375	a) 75 b) 150	Min: 200 Max: 1000	3	Not acceptable (risk for ground water and aquatic organisms)
18	<u>S-EU</u> : FR	Peas without pods	F	Pea moth ( <i>Cydia nigricana</i> ) Tomato fruitworm ( <i>Heliothis armigera</i> )	Foliar spray	BBCH 60-79	a) 2 (7) b) 2	a) 0.1875 b) 0.375	a) 75 b) 150	Min: 200 Max: 1000	3	Not acceptable (risk for ground water and aquatic organisms)
19	<u>S-EU</u> : FR	Peas without pods (fresh lentils)	F	Pea moth ( <i>Cydia nigricana</i> ) Tomato fruitworm ( <i>Heliothis armigera</i> )	Foliar spray	BBCH 60-79	a) 2 (7) b) 2	a) 0.1875 b) 0.375	a) 75 b) 150	Min: 200 Max: 1000	3	Not acceptable (risk for ground water and aquatic organisms and for MRL)

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G 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
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
20	<u>S-EU : FR</u>	Carrot	F	Carrot fly ( <i>Psila rosae</i> )	Foliar spray	BBCH 20-49	a) 2 (7) b) 2	a) 0.1875 b) 0.375	a) 75 b) 150	Min: 200 Max: 1000	7	<b>Not acceptable</b> (risk for ground water and aquatic organisms)  Efficacy against <i>Psila rosae</i>

**Remarks table heading:**

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

(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008

(c) g/kg or g/L

(d) Select relevant

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

(f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

**Remarks columns:**

1 Numeration necessary to allow references

2 Use official codes/nomenclatures of EU Member States

3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)

4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.

6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench  
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

8 The maximum number of application possible under practical conditions of use must be provided.

9 Minimum interval (in days) between applications of the same product

10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.

11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).

12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.

13 PHI - minimum pre-harvest interval

14 Remarks may include: Extent of use/economic importance/restrictions

### 3 RISK MANAGEMENT

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

##### 3.1.1 Physical and chemical properties

MINECTO ONE (A16971B) is a water dispersible granule formulation (WG). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is a brown beige solid, with a weak loamy odour. It is not explosive and has no oxidizing properties. The product is not flammable. It has a self-ignition temperature of  $238 \pm 5$  °C. In aqueous solution (1% w/v), it has a pH value of 9.8 at 25°C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE, LDPE, or laminated paper/PET metallized/LDPE. Its technical characteristics are acceptable for a water dispersible granule formulation.

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 methods for the determination of the active substance and the relevant impurities in the formulation are available and validated.

###### 3.1.2.2 Analytical methods for residues

Analytical methods are available in the monograph and validated for the determination of residues of cyantraniliprole in plants, food of animal origin, soil, water (surface and drinking) and air.

The active substance(s) are/is neither toxic nor very toxic hence no analytical method is required for the determination of residues in biological fluids and tissues.

##### 3.1.3 Mammalian Toxicology

###### 3.1.3.1 Acute Toxicity

MINECTO ONE (A16971B) containing 400 g/L cyantraniliprole has a low toxicity in respect to acute oral, inhalation and dermal toxicity, is not irritating to the rabbit eye or skin 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

###### FIELD USES:

**Table: Estimated operator exposure to cyantraniliprole**

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of AOEL
<b>Broadcast air assisted sprayer</b> <i>Risk envelope : 125g as/ha on plum, peach, apricot</i>			
<b>UK POEM</b>	no PPE	0.0349	499
	gloves mixing/loading	0.0349	499

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of AOEL
<ul style="list-style-type: none"> <li>15 ha/day, 6 h/day</li> <li>200 L/ha</li> <li>60 kg operator</li> </ul>	Gloves mixing/loading and application	0.0274	391
<b>German Model</b> <ul style="list-style-type: none"> <li>8 ha/day</li> <li>70 kg operator</li> </ul>	no PPE	0.0053	76
<b>Broadcast air assisted sprayer</b> <i>75g as/ha on pome fruits</i>			
<b>UK POEM</b> <ul style="list-style-type: none"> <li>15 ha/day, 6 h/day</li> <li>200 L/ha</li> <li>60 kg operator</li> </ul>	no PPE	0.0209	299
	gloves mixing/loading	0.0209	299
	Gloves mixing/loading and application	0.0164	235
<b>Tractor-mounted boom sprayer, hydraulic nozzles</b> <i>Risk envelope : 125 g as/ha on leek and onion</i>			
<b>UK POEM</b> <ul style="list-style-type: none"> <li>50 ha/day, 6 h/day</li> <li>60 kg operator</li> </ul>	no PPE	0.0389	556
	gloves mixing/loading	0.0388	555
	Gloves mixing/loading and application	0.0279	398
<b>German Model</b> <ul style="list-style-type: none"> <li>8 ha/day</li> <li>70 kg operator</li> </ul>	no PPE	0.0025	36
<b>Tractor-mounted boom sprayer, hydraulic nozzles</b> <i>Risk envelope : 75 g as/ha on cabbage, lettuce, beans, carrot</i>			
<b>UK POEM</b> <ul style="list-style-type: none"> <li>50 ha/day, 6 h/day</li> <li>60 kg operator</li> </ul>	no PPE	0.0234	334
	gloves mixing/loading	0.0343	323
	Gloves mixing/loading and application	0.0167	239

According to the model calculations, it can be concluded that the risk for the operator using MINECTO ONE (A16971B) on pome fruits, plum, apricots and peach with a broadcast air assisted sprayer is acceptable at the highest dose and without the use of personal protective equipment using the German model but is not acceptable using the UK model even at the lowest dose.

The risk for the operator using MINECTO ONE (A16971B) on pome fruits, plum, apricots and peach with a broadcast air assisted sprayer is acceptable at the highest dose and without the use of personal protective equipment using the German model but is not acceptable using the UK model.

The risk is acceptable with a hand-held sprayer at the highest dose without the use of PPE using the German model.

## GREENHOUSE USE:

The greenhouse use has been evaluated by UK in a dedicated RR. The evaluation of RMS FR has been included in this document.

**Table: Estimated operator exposure to cyantraniliprole**

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of AOEL
<b>Hand-held sprayer</b> <i>Risk envelope : 75g as/ha on lettuce</i>			
<b>UK POEM</b> <ul style="list-style-type: none"> <li>1 ha/day, 6 h/day</li> <li>200 L/ha</li> <li>60 kg operator</li> </ul>	no PPE	0.0200	286
	gloves mixing/loading	0.0200	286
	Gloves mixing/loading and application	0.0101	144
<b>German Model</b> <ul style="list-style-type: none"> <li>1 ha/day</li> </ul> 70 kg operator	no PPE	0.0027	39

According to the model calculations, it can be concluded that the risk for the operator using MINECTO ONE (A16971B) on lettuce with a hand-held sprayer is not acceptable even with the use of personal protective equipment using the UK model. However, the risk is acceptable using the German model even without the use of PPEs.

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

### 3.1.3.3 Bystander Exposure

Bystander exposure assessment was conducted according to EUROPOEM II model, assuming an incidental bystander is located at the border of a crop treated with a tractor-mounted air assisted sprayer.

**Table: Estimated bystander exposure**

HIGH CROPS (1.125 l/ha)	
Parameters	Cyantraniliprole
Potential dermal exposure (mg/person/day) = AR x D x BSE	2.4863
Dermal absorbed dose (mg/kg bw/day) = dermal exposure x DA	0.0012
Potential inhalation exposure (mg/person/day) = IE x T x C	0.0031
Inhalation absorbed dose (mg/kg bw/day)	0.0001
<b>Total systemic exposure (mg/kg bw/day) = total systemic exposure/BW</b>	0.0013
<b>% of AOEL</b>	18.5

No bystander exposure is expected for indoor uses.

### 3.1.3.4 Worker Exposure

Estimations of worker exposure have been undertaken for MINECTO ONE (A16971B) using the critical uses and the EUROPOEM model.

**Table: Usage scenarios for which worker exposure has been considered**

Crop (field use)	Application rate (kg a.s./ha)	Minimum water volume (L/ha)	Re-entry activities
Orchards	Cyantraniliprole	200	Searching, reaching, picking
Lettuce (Indoor)			

**Table: Parameters used for calculation**

Parameters and units		Cyantraniliprole
<b>DFR</b>	Dislodgeable foliar residues ( $\mu\text{g}/\text{cm}^2/\text{kg}$ a.s./ha) (default value)	3
<b>AR</b>	Application rate (kg a.s./ha)	0.125
<b>TC</b>	Transfer coefficient ( $\text{cm}^2/\text{person}/\text{h}$ )	10 000 (field uses) 5000 (indoor use)
<b>T</b>	Task duration (h)	8
<b>BW</b>	Body weight (kg)	60
<b>DA</b>	Dermal absorption; worst case (%)	3
<b>P</b>	Penetration factor (1: without PPE; 0.1: coverall and gloves)	0.1
<b>TSF</b>	Task Specific Factor (indoor use)	0.03

The potential inhalation exposure is considered to be negligible for outdoor application; the worker total systemic exposure is calculated as follows:

**Table: Estimated worker exposure (field uses)**

Parameters	Cyantraniliprole	
	No PPE	Working coverall + gloves
$\text{DE}_{\text{systemic}}$ (mg/kg bw/day)	0.0150	0.00150
% of AOEL	214	21

**Table: Estimated worker exposure (indoor use)**

Parameters	Cyantraniliprole	
	No PPE	Working coverall + gloves
$\text{DE}_{\text{systemic}}$ (mg/kg bw/day)	0.0093	0.0012
% of AOEL	133	17

It is concluded that there is no unacceptable risk anticipated for the worker wearing PPEs (work wear and gloves), when re-entering crops treated with MINECTO ONE (A16971B).

As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

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

### 3.1.3.6 Relevance of metabolites

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to 3.1.5 for conclusion on the risk of groundwater contamination.

### 3.1.4 Residues and Consumer Exposure

The data available are considered sufficient for risk assessment. An exceedance of the current MRL for cyantraniliprole as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of cyantraniliprole residues resulting from the uses proposed in the framework of this application are unlikely to present a public health concern.

As far as consumer health protection is concerned, France, zRMS agrees with the authorization of the intended uses, **except for apricots, plums, other salads, leeks, lentils, leafy brassica and lettuce (indoor). Concerning the uses on plums and lentils insufficient residues trials were submitted to support the intended uses. Concerning the uses on apricots, other salads (outdoor), lettuce (indoor), leeks, lentils and leafy brassica an exceedance of the MRL cannot be excluded.**

### Summary for MINECTO ONE (A16971B)

Crop	PHI for Cyantraniliprole MINECTO ONE (A16971B) proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for MINECTO ONE (A16971B) proposed by zRMS	zRMS Comments
		Cyantraniliprole		
Pome fruits	7 d	Yes	7 d	
Peach	7 d	Yes	7 d	
Carrots and other root and tuber vegetables except sugar beet	7 d	Yes	7 d	
Bulb vegetables (Onion, Shallots, Garlic)	14 d	Yes	14 d	
Spring onions/green onions and Welsh onions	14 d	Yes	14 d	
Lettuce	7 d	Yes	7 d	
Fresh beans and peas with pods	3 d	Yes	3 d	
Fresh beans and peas without pods	3 d	Yes	3 d	
Cauliflower, Broccoli	3 d	Yes	3 d	
Head Cabbage, Brussels sprout	3 d	Yes	3 d	

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).



## Waiting periods before planting succeeding crops

Not relevant.

### 3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate PEC values for the active 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 of cyantraniliprole 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.

PEC soil derived for the active substance and its metabolites are used for the ecotoxicological risk assessment

As this dossier was submitted before the enforcement of the European guidance on protected crops<sup>9</sup>, no risk assessment of groundwater contamination is needed for greenhouse uses.

**Regarding field uses, groundwater exposure calculations (first tier approach) and surface water exposure calculations could not be scrutinised because input/output files were not made available.**

In addition, according to information made available to zRMS, groundwater and surface water exposure calculations do not take into account the recommendations of EFSA guidance (2014)<sup>10</sup> regarding the use of geometric mean of adsorption coefficients. Moreover, for some uses, the application dates considered in modelling do not cover the whole intended application periods. **Consequently, the risk assessment of groundwater contamination and the exposure assessment for surface water compartment cannot be finalised for all field uses.**

Additional groundwater exposure calculations are provided by the applicant. However, they could not be used for risk assessment since they are not in agreement with the approach defined during the European assessment of the active substance and are not relevant given the available data.

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 and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants are acceptable for the intended uses. Risk mitigations are required for non-target arthropods and bees.

**Risk is not finalised for aquatic organisms for all intended uses.**

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<sup>9</sup> EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments; EFSA Journal 2014;12(3):3615

<sup>10</sup> EFSA (2014) European Food Safety Authority, 2014. EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662, 37 pp., doi:10.2903/j.efsa.2014.3662

### **3.1.7 Efficacy**

Considering the data submitted:

- The efficacy level of MINECTO ONE (A16971B) is considered satisfactory for all the requested uses.
- The phytotoxicity level of MINECTO ONE (A16971B) is considered negligible for all the requested uses.
- The risks of negative impact on yield, quality, cider-making, propagation, succeeding and adjacent crops are considered negligible.
- Considering the data submitted, particular attention should be paid to the conditions of use of the product as part of the implementation of an IPM program, in terms of biological compatibility with biological control agents.
- There is a risk of resistance developing or appearing to cyantraniliprole for *Cydia pomonella* on apple, *Frankliniella occidentalis* on peach and *Helicoverpa armigera* on lettuce, this requires monitoring.

### **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**

None.

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

- None.

#### **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

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

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*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 et les demandes associées du produit phytopharmaceutique*  
**MINECTO ONE**

*de la société* SYNGENTA FRANCE SAS

*enregistrées sous les* n°2016-2602, 2016-2624, 2019-6156 et 2020-3860

*Vu les conclusions de l'évaluation de l'Anses du 15 juin 2022,*

*Considérant qu'un risque inacceptable de contamination des eaux souterraines lié à l'utilisation du produit ne peut être exclu,*

*Considérant également qu'un risque d'effet inacceptable pour les organismes aquatiques, lié à l'utilisation du produit, ne peut être exclu,*

*Considérant qu'il ne peut pas 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	MINECTO ONE
Type de produit	Produit de référence
Titulaire	SYNGENTA FRANCE SAS 1228 Chemin de l'Hobit 31790 SAINT SAUVEUR France
Formulation	Granulé dispersable (WG)
Contenant	400 g/kg - cyantraniliprole
Numéro d'intrant	062-2016.01
Numéro d'AMM	-
Fonction	Insecticide
Gamme d'usage	Professionnel

A Maisons-Alfort, le 12/08/2022

DocuSigned by:  
  
 AE281A955A42454...

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

**ANNEXE : Conditions de mise sur le marché demandées**

Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
<b>16203103</b> Carotte*Trt Part.Aer.*Mouches	187,5 g/ha	2/an	7
<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 ni un risque inacceptable de contamination des eaux souterraines.			
<b>00516024</b> Choux à inflorescence*Trt Part.Aer.*Chenilles phytophages	187,5 g/ha	2/an	3
<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 ni un risque inacceptable de contamination des eaux souterraines.			
<b>00516029</b> Choux à inflorescence*Trt Part.Aer.*Mouches	187,5 g/ha	2/an	3
<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 ni un risque inacceptable de contamination des eaux souterraines.			
<b>00516046</b> Choux feuillus*Trt Part.Aer.*Chenilles phytophages	187,5 g/ha	2/an	3
<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques ni un risque inacceptable de contamination des eaux souterraines.			
<b>00516050</b> Choux feuillus*Trt Part.Aer.*Mouches	187,5 g/ha	2/an	3
<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques ni un risque inacceptable de contamination des eaux souterraines.			

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Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
<b>00517023</b> Choux pommés*Trt Part.Aer.*Chenilles phytophages	187,5 g/ha	2/an	3
<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 ni un risque inacceptable de contamination des eaux souterraines.			
<b>00517027</b> Choux pommés*Trt Part.Aer.*Mouches	187,5 g/ha	2/an	3
<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 ni un risque inacceptable de contamination des eaux souterraines.			
<b>12603103</b> Fruits à pépins*Trt Part.Aer.*Chenilles foreuses des fruits	187,5 g/ha	2/an	7
<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 ni un risque inacceptable de contamination des eaux souterraines.			
<b>12603105</b> Fruits à pépins*Trt Part.Aer.*Chenilles phytophages	187,5 g/ha	2/an	7
<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 ni un risque inacceptable de contamination des eaux souterraines.			
<b>16573104</b> Haricots et Pois écosés frais*Trt Part.Aer.*Chenilles phytophages	187,5 g/ha	2/an	3
<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus sur lentilles fraîches et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques ni un risque inacceptable de contamination des eaux souterraines.			
<b>00516011</b> Haricots et pois non écosés frais*Trt Part.Aer.*Chenilles phytophages	187,5 g/ha	2/an	3
<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 ni un risque inacceptable de contamination des eaux souterraines.			
<b>16603105</b> Laitue*Trt Part.Aer.*Chenilles phytophages	187,5 g/ha	2/an	7
<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques ni un risque inacceptable de contamination des eaux souterraines.			

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Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
<b>16803102</b> Oignon*Trt Part.Aer.*Thrips	312,5 g/ha	1/an	14
<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 ni un risque inacceptable de contamination des eaux souterraines.			
<b>12553103</b> Pêcher - Abricotier*Trt Part.Aer.*Chenilles foreuses des fruits	312,5 g/ha	1/an	-
<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus sur abricotier et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques ni un risque inacceptable de contamination des eaux souterraines.			
<b>12553116</b> Pêcher - Abricotier*Trt Part.Aer.*Thrips	312,5 g/ha	1/an	7
<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 ni un risque inacceptable de contamination des eaux souterraines.			
<b>16843103</b> Poireau*Trt Part.Aer.*Thrips	312,5 g/ha	1/an	14
<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques ni un risque inacceptable de contamination des eaux souterraines.			
<b>12653102</b> Prunier*Trt Part.Aer.*Chenilles foreuses des fruits	312,5 g/ha	1/an	7
<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques ni un risque inacceptable de contamination des eaux souterraines.			

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

## Minecto One

**Appel en cas d'urgence** : 15 ou centre anti-poison puis signalez vos symptômes au réseau Phyt'attitude N° Vert 0800 887 887 (appel gratuit depuis un poste fixe).

**Numéro d'urgence Syngenta** : N° Vert  
0 800 803 264

En cas d'accident de transport : 06 11 07 32 81

**Renseignements techniques** :  
Numéro Indigo 0 825 00 05 52  
**Fiches de données de sécurité** :  
[www.quickfds.com](http://www.quickfds.com)

**400 g/kg (40%) de cyantraniliprole\***  
Formulation : WG Granulés dispersables  
AMM N° XXXXXXX

Cultures autorisées	Cibles	Dose	DAR
Arboriculture fruitière et cultures légumières	Se référer à l'intérieur du livret		



### Attention

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

P273 Éviter le rejet dans l'environnement. P391 Recueillir le produit répandu. P501 Éliminer le contenu/récipient dans une installation d'élimination des déchets agréée.  
Délai de rentrée sur les parcelles traitées : 6 heures (8 heures sous abris).  
SPe 3 Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.  
SP 1 Ne pas polluer l'eau avec le produit ou son emballage.

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

*Autres conditions d'utilisation et précautions d'usage : lire attentivement le livret détachable*

**PRODUIT POUR LES PROFESSIONNELS**

® Marque enregistrée d'une société du groupe Syngenta.

\* Substance active d'une société du groupe Syngenta.

[www.syngenta.fr](http://www.syngenta.fr)



## PRECONISATIONS D'EMPLOI

### TABLEAU DES USAGES

**Avertissement nouveau catalogue des usages** (arrêté du 26 mars 2014) : nos produits n'ayant pas été testés systématiquement sur l'ensemble des cultures rattachées et pour tous les nouveaux usages, nous vous recommandons vivement de contacter notre service technique, en particulier pour la conformité aux LMR et au risque de moindre sélectivité.

Cultures autorisées	Cibles	Dose	Nombre max. d'application	DAR	ZNT
<b>Pommier</b> , Pommette, Néflier, Poirier, Cognassier, Nashi	Chenilles foreuses des fruits Chenilles phytophages	0,1875 kg/ha	2	7 jours	5 mètres
<b>Abricotier</b>	Chenilles foreuses des fruits	0,3125 kg/ha	1	3 jours	5 mètres
<b>Pêcher</b> , Nectarinier	Chenilles foreuses des fruits Thrips	0,3125 kg/ha	1	7 jours	5 mètres
<b>Prunier</b>	Chenilles foreuses des fruits	0,3125 kg/ha	1	7 jours	5 mètres
<b>Choux à inflorescence</b> Choux fleurs, brocoli et autres <b>Choux feuillus</b> Choux vert, choux chinois et autres <b>Choux pommés</b> Choux bruxelles et autres	Chenilles phytophages Mouches	0,1875 kg/ha	2	3 jours	5 mètres
<b>Laitue</b> Chicorées-scaroles, Chicorées-frisées, Mâche, Roquette et autres salades	Chenilles phytophages	0,1875 kg/ha	2	7 jours	5 mètres
<b>Oignon</b> , Ail, Echalote	Thrips	0,3125 kg/ha	1	14 jours	5 mètres
<b>Poireau</b> , Oignon de printemps, Ciboule et variétés similaires	Thrips	0,3125 kg/ha	1	14 jours	5 mètres
<b>Carotte</b> , Céleri rave, Panais, Raifort, Topinambour, Persil à grosse racine, Scorsonère	Mouches Uniquement mouche de la carotte	0,1875 kg/ha	2	7 jours	5 mètres
<b>Pois écosés frais</b> Lentilles fraîches	Chenilles phytophages	0,1875 kg/ha	2	3 jours	5 mètres
<b>Haricots écosés frais</b> Fèves, pois sabre, flageolet, lima, niébé	Chenilles phytophages	0,1875 kg/ha	2	3 jours	5 mètres
<b>Haricots et pois non écosés frais</b>	Chenilles phytophages	0,1875 kg/ha	2	3 jours	5 mètres
<b>Porte-graines PPAMC, florales et potagères</b>	Mouches	0,1875 kg/ha	3	-	5 mètres
<b>Plantes à Parfum, aromatiques et médicinales, non alimentaires</b>	Ravageurs divers	0,1875 kg/ha	2	-	5 mètres

\*ZNT par rapport à un point d'eau temporaire ou permanent

Les Limites Maximales de Résidus sont consultables à l'adresse suivante :  
[http://ec.europa.eu/sanco\\_pesticides/public/index.cfm](http://ec.europa.eu/sanco_pesticides/public/index.cfm)

Dangereux pour les abeilles - Ne pas utiliser en présence d'abeilles.  
Ne pas traiter durant toute la période de floraison et pendant les périodes de production d'exsudats.  
Avant le traitement, détruire dans le couvert végétal spontané de la zone cultivée toutes les parties aériennes en fleurs ou avec production d'exsudats.

#### MELANGES :

Respecter la réglementation en vigueur selon l'arrêté du 07/04/2010.

### RECOMMANDATIONS POUR DE BONNES PRATIQUES AGRICOLES

#### RECOMMANDATIONS D'UTILISATION

##### Avant-propos :

Notre spécialité ne pouvant être testée sur toutes les variétés existantes, nous vous recommandons vivement de réaliser un test de sélectivité sur un échantillon des espèces susceptibles de recevoir le traitement avant de le généraliser, ou de consulter notre service technique.

*Procéder à l'utilisation du produit en respectant les 10 gestes responsables et professionnels recommandés par la profession. (voir détails en fin de livret)*

##### ➤ Sécurité applicateur

Lors de l'application du produit sur les semences :

- Protection des mains : à toutes les étapes de manipulation des produits, des bouillies, porter des gants en nitrile à recouvrir par les manches de la combinaison. Laver soigneusement les mains gantées, puis les mains à la fin de chaque phase de contact.
- Protection respiratoire : pour les opérations exposées à la poussière (en particulier nettoyage du matériel, porter des équipements protégeant les yeux, la bouche et le nez et notamment un masque équipé d'un filtre anti-poussière certifié minimum P2.
- Protection du corps : pour la phase de nettoyage du matériel, il est recommandé de porter une combinaison à capuche de type 5-6; pour les autres phases de travail, porter un vêtement de travail spécifique.

##### ➤ Premiers soins en cas d'incident :

**En cas d'ingestion** : appeler immédiatement un centre antipoison ou un médecin, et lui montrer l'emballage ou l'étiquette. Ne pas faire vomir.

**En cas de contact cutané** : enlever tout vêtement souillé et rincer immédiatement et abondamment la peau sous l'eau du robinet.

**En cas de projection dans les yeux** : rincer immédiatement pendant 15 à 20 minutes sous un filet d'eau tiède, paupières ouvertes et consulter un spécialiste.

**En cas d'inhalation** : amener la personne à l'air libre.

Pour des informations complémentaires, se référer à la section 4 de la fiche de données de sécurité.

#### Préparation du traitement :

- 1) Utiliser un matériel de pulvérisation en bon état et vérifié régulièrement.
- 2) Ne préparer que la quantité de bouillie nécessaire à la superficie à traiter de façon à éviter les surplus difficiles à éliminer.
- 3) Remplir le pulvérisateur sur une aire étanche sur laquelle les écoulements accidentels peuvent être récupérés ; veiller à éviter tout retour de bouillie vers la source d'eau en utilisant une cuve intermédiaire, et/ou un clapet anti-retour et/ou une vanne programmable.
- 4) Rincer les emballages vides trois fois et vider l'eau de rinçage dans la cuve.

#### Réalisation du traitement :

- 1) Consulter les prévisions météorologiques et ne pas traiter en cas de conditions défavorables (vent supérieur à 3 sur l'échelle de Beaufort, précipitations prévues à court terme)

- 2) Eviter les dérives d'embruns de pulvérisation sur les cultures voisines et l'environnement. L'utilisation de buses à limitation de dérive est recommandée. La mise en place de haies pour protéger les zones vulnérables avoisinantes (point d'eau, bâtiments) est également très efficace pour limiter la dérive.
- 3) Lorsque des risques de ruissellement existent sur une parcelle (parcelle en pente, sol battant ...), mettre en place une bande enherbée ou une haie pour faire obstacle au ruissellement qui peut entraîner du produit vers les points d'eau.

**Après application :**

- 1) Diluer au moins 5 fois le fond de cuve et pulvériser le mélange sur la parcelle déjà traitée.
- 2) Le volume du fond de cuve restant, dilué mais non pulvérisable, peut être vidangé sur une parcelle ou réutilisé pour la préparation d'une autre bouillie sous conditions spécifiées dans l'arrêté du 12 septembre 2006.
- 3) Lorsque le pulvérisateur est nettoyé sur le siège de l'exploitation, il est recommandé de le faire sur une zone spécialement équipée pour recueillir et confiner les eaux de lavage.
- 4) Les effluents phytopharmaceutiques générés sur l'exploitation lors de ces manipulations et non épanchés (fonds de cuve non épanchés, eaux de lavage et de rinçage, écoulements accidentels, etc...), doivent être traités selon les conditions spécifiées dans l'arrêté du 12 septembre 2006 : utilisation d'un système de traitement des effluents reconnu par le ministère de l'écologie (exemple : HélioSec®).

**Stockage des produits :**

- 1) Toujours conserver les produits dans leur emballage d'origine.
- 2) Les stocker dans un local réservé à cet usage, frais, sec, bien ventilé et fermant à clé. A l'abri du gel et de la chaleur.

**Gestion des emballages**

Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.

Réemploi de l'emballage interdit. Bien le vider et l'éliminer via une collecte organisée par un service de collecte spécifique (exemple AIVALOR )

**IMPORTANT : PRODUIT POUR LES PROFESSIONNELS** - 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. Conduire sur ces bases la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous les facteurs particuliers concernant votre exploitation tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces, la pression parasitaire, ... Le fabricant garantit la conformité de ses produits vendus dans leur emballage d'origine à l'Autorisation de Mise sur le Marché du Ministère de l'Agriculture. Compte tenu de la diversité des législations existantes, il appartient à l'utilisateur, dans le cas où les denrées issues des cultures protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur. Syngenta France S.A.S. ne saurait être tenu en aucun cas responsable des conséquences inhérentes à toute copie de cette étiquette, totale ou partielle et à la diffusion ou à l'utilisation non autorisée de cette dernière.

### **Appendix 3 – Letter(s) of Access**

Provided upon request.