REGISTRATION REPORT

Part A

Risk Management

Product code: NLS 484A

Product name: RAPIDINSECT

Chemical active substances:

pyrethrins, 7 g/L
rape seed oil, 700 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(label extension, label extension according to Art. 51)

Applicant: Evergreen Garden Care France SAS

Date: 2020/08/28

Table of Contents

PART A
RISK MANAGEMENT

1 Details of the application

The company Evergreen Garden Care France SAS has requested an extension of uses in France for the product RAPIDINSECT (product code: NLS 484A; authorisation nº 2171312), containing 700 g/L rape seed oil and 7 g/L pyrethrins, as an insecticide for non-professional uses.

The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France. The information, data and assessments provided in the Registration Report, Part B include assessment of further data or information as required at national registration by EU regulations. It also includes assessment of data and information related to RAPIDINSECT (NLS 484A) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of RAPIDINSECT (NLS 484A) have been made using endpoints agreed in the EU peer reviews of both active substances.

For label extension according to Art.51, the conclusions of the risk assessment are based on the present label extension registration of the product. Therefore, the evaluation of the current application is limited to the points not covered by the existing registration.

This document describes the specific conditions of use and labelling required for France for the registration of RAPIDINSECT (NLS 484A).

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

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

Appendix 3 of this document contains a copy of the Letter(s) of Access.

1.1 Application background

The present registration report concerns the evaluation of Evergreen Garden Care France SAS's application to market RAPIDINSECT (NLS 484A) 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 label extension of this product in France and in other MSs of the Southern zone.

The present application (2019-2437, 2019-1627) 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, taking into account the worst-case uses ("risk envelope approach")[1] – the highest application rates applied for in the Southern zone for field uses. When risk mitigation measures were necessary, they are adapted to the situation in France.

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[2], 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

[1] 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

[2] 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

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 on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011[3], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

1.2 Letters of Access

The applicant has provided a letter of access for active substance pyrethrins.

1.3 Justification for submission of tests and studies

According to the applicant: "*This application follows the data requirements for the active substances laid down in Regulation (EC) No. 544/2011 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.*"

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of RAPIDINSECT (NLS 484A)., it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

Product code	NLS 484A.
Product name in MS	RAPIDINSECT.
Authorisation number	2171312.
Low risk (article 47)	No (not applicable)
Function	Insecticide
Applicant	Evergreen Garden Care France SAS.
Active substance(s) (incl. content)	Rape seed oil, 700 g/L. Pyrethrins, 7 g/L.
Formulation type	Emulsifiable concentrate [EC].
Packaging	PET 7 & 14 mL bottles. Non-professional user.
Coformulants of concern for national authorisations	None.
Mandatory tank mixtures	None.
Recommended tank mixtures	None.

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

2.2 Conclusion

The evaluation of the application for RAPIDINSECT (NLS 484A) resulted in the decision **to refuse** the label extension of the authorisation.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

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

Classification not changed. Refer to the decision of product authorization.

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

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

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

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

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017[4] provides that:

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

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

Finally, the French Order of 26 March 2014[5] provides that:

- an authorisation granted for a “reference” crop applies also for “linked” crops, unless formally stated in the Decision

[4] Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, modifié par l’arrêté du 27 décembre 2019 https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte ; https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id

[5] https://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

- 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 “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[6] 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.

2.5.1 Restrictions linked to the PPP

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

2.5.2 Specific restrictions linked to the intended uses

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

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

2.6 Intended uses (only NATIONAL GAP)

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

Overall comment: during the commenting phase, the applicant has asked to France to drop the following uses, as they are not sufficiently supported in France: apricot, plums, peaches, cherry, carrot, melon, raspberry, fresh beans with pods, fresh peas with pods, pulses, leafy cabbage, flowering brassica and lettuce (only in France), chicory (in France) *(see residues section in reporting table part B).*

However, as this request was made only at the commenting phase after evaluation, France as zRMS maintains the whole assessment in the current dRR and modifies only the part A for uses in France.

			GAP rev. 1, date: 2020/08/28
PPP (product name/code):	RAPIDINSECT/ NLS 484A	Formulation type:	Emulsifiable concentrate (EC)[a, b]
Active substance 1:	Pyrethrins	Conc. of a.s. 1:	7 g/L[c]
Active substance 2:	Rape seed oil	Conc. of a.s. 2:	700 g/L[c]
Applicant:	Evergreen Garden Care France SAS	Professional use:	☐
Zone(s):	Southern Zone[d]	Non-professional use:	☒
Verified by MS:	Yes		
Field of use:	insecticide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f] zRMS conclusion
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
Label extension													
6	FR	Pear including but not limited to *Pyrus communis* [PYUCO]	Fn	Aphids including but not limited to examples: Macrosiphum rosae [MACSRO] - *Aphis pomi* [APHIPO] – *Aphis fabae* [APHIFA] – *Myzus persicae* [MYZUP]	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 b) 14	a) Pyre-thrum 49 Rape seed oil 4900 b) Pyrethrum 98 Rape seed oil 9800	Min 600 L/ha (low-height crops) Max 1000 L/ha	3	**Not acceptable** (consumer exposure, groundwater, aquatic organisms, soil macro-organisms)
7	FR	Apple including but not limited to *Malus domestica* [MABSD]	Fn	Aphids including but not limited to examples: Macrosiphum rosae [MACSRO] - *Aphis pomi* [APHIPO] – *Aphis fabae* [APHIFA] – *Myzus persicae* [MYZUP]	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 b) 14	a) Pyre-thrum 49 Rape seed oil 4900 b) Pyrethrum 98 Rape seed oil 9800	Min 600 L/ha (low-height crops) Max 1000 L/ha	3	**Not acceptable** (consumer exposure, groundwater, aquatic organisms, soil macro-organisms)
8	FR	Apple including but not limited to *Malus domestica* [MABSD]	Fn	Mites including but not limited to examples: *Tetranychus urticae* TETRUR	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 b) 14	a) Pyre-thrum 49 Rape seed oil 4900 b) Pyrethrum 98 Rape seed oil 9800	Min 600 L/ha (low-height crops) Max 1000 L/ha	3	**Not acceptable** (consumer exposure, groundwater, aquatic organisms, soil macro-organisms)

NLS 484A/RAPIDINSECT
Part A - National Assessment
FRANCE DEPR version

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f] zRMS conclusion
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
9	FR	Aubergine including but not limited to *Solanum melongena* [SOLME]	Fn	Aphids including but not limited to examples: Macrosiphum rosae [MACSRO] - *Aphis pomi* [APHIPO] – *Aphis fabae* [APHIFA] – *Myzus persicae* [MYZUP]	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 b) 14	a) Pyre-thrum 49 Rape seed oil 4900 b) Pyrethrum 98 Rape seed oil 9800	Min 600 L/ha (low-height crops) Max 1000 L/ha	3	**Not acceptable** (consumer exposure, groundwater, aquatic organisms, soil macro-organisms)
11	FR	Cabbage including but not limited to *Brassica sylvestris* [BRSOX]	Fn	Aphids including but not limited to examples: Macrosiphum rosae [MACSRO] - *Aphis pomi* [APHIPO] – *Aphis fabae* [APHIFA] – *Myzus persicae* [MYZUP]	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 b) 14	a) Pyre-thrum 49 Rape seed oil 4900 b) Pyrethrum 98 Rape seed oil 9800	Min 600 L/ha (low-height crops) Max 1000 L/ha	3	**Not acceptable** (consumer exposure, groundwater, aquatic organisms, soil macro-organisms)
12	FR	Cabbage including but not limited to *Brassica sylvestris* [BRSOX]	Fn	Caterpillars including but not limited to examples: *Pieris sp*. PIERSP	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 b) 14	a) Pyre-thrum 49 Rape seed oil 4900 b) Pyrethrum 98 Rape seed oil 9800	Min 600 L/ha (low-height crops) Max 1000 L/ha	3	**Not acceptable** (consumer exposure, groundwater, aquatic organisms, soil macro-organisms)

NLS 484A/RAPIDINSECT
Part A - National Assessment
FRANCE DEPR version

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f] zRMS conclusion
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
13	FR	Cucumbers including but not limited to *Cucumis sativus* [CUMSA]	Fn	Aphids including but not limited to examples: Macrosiphum rosae [MACSRO] - *Aphis pomi* [APHIPO] – *Aphis fabae* [APHIFA] – *Myzus persicae* [MYZUP]	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 b) 14	a) Pyre-thrum 49 Rape seed oil 4900 b) Pyrethrum 98 Rape seed oil 9800	Min 600 L/ha (low-height crops) Max 1000 L/ha	3	**Not acceptable** (consumer exposure, groundwater, aquatic organisms, soil macro-organisms)
14	FR	Cucumbers including but not limited to *Cucumis sativus* [CUMSA]	Fn	Whitefly including but not limited to examples: *Trialeurodes vaporariorum* TRIAVA	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 b) 14	a) Pyre-thrum 49 Rape seed oil 4900 b) Pyrethrum 98 Rape seed oil 9800	Min 600 L/ha (low-height crops) Max 1000 L/ha	3	**Not acceptable** (consumer exposure, groundwater, aquatic organisms, soil macro-organisms)
15	FR	Courgette including but not limited to *Cucurbita pepo* var. *giromontiina* [CUUPG]	Fn	Aphids including but not limited to examples: Macrosiphum rosae [MACSRO] - *Aphis pomi* [APHIPO] – *Aphis fabae* [APHIFA] – *Myzus persicae* [MYZUP]	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 b) 14	a) Pyre-thrum 49 Rape seed oil 4900 b) Pyrethrum 98 Rape seed oil 9800	Min 600 L/ha (low-height crops) Max 1000 L/ha	3	**Not acceptable** (consumer exposure, groundwater, aquatic organisms, soil macro-organisms)

NLS 484A/RAPIDINSECT
Part A - National Assessment
FRANCE DEPR version

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f] zRMS conclusion
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
17	FR	Strawberry including but not limited to *Fragaria x ananassa* [FRAAN]	Fn	Aphids including but not limited to examples: Macrosiphum rosae [MACSRO] - *Aphis pomi* [APHIPO] – *Aphis fabae* [APHIFA] – *Myzus persicae* [MYZUP]	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 b) 14	a) Pyre-thrum 49 Rape seed oil 4900 b) Pyrethrum 98 Rape seed oil 9800	Min 600 L/ha (low-height crops) Max 1000 L/ha	3	**Not aceptable** (consumer exposure, groundwater, aquatic organisms, soil macro-organisms)
21	FR	Peas including but not limited to *Pisum sativum* [PIBSX]	Fn	Aphids including but not limited to examples: Macrosiphum rosae [MACSRO] - *Aphis pomi* [APHIPO] – *Aphis fabae* [APHIFA] – *Myzus persicae* [MYZUP]	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 b) 14	a) Pyre-thrum 49 Rape seed oil 4900 b) Pyrethrum 98 Rape seed oil 9800	Min 600 L/ha (low-height crops) Max 1000 L/ha	3	**Not acceptable** (MRL, consumer exposure, groundwater, aquatic organisms, soil macro-organisms)
22	FR	Pepper including but not limited to *Capsicum annuum* [CPSAN]	Fn	Aphids including but not limited to examples: Macrosiphum rosae [MACSRO] - *Aphis pomi* [APHIPO] – *Aphis fabae* [APHIFA] – *Myzus persicae* [MYZUP]	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 b) 14	a) Pyre-thrum 49 Rape seed oil 4900 b) Pyrethrum 98 Rape seed oil 9800	Min 600 L/ha (low-height crops) Max 1000 L/ha	3	**Not acceptable** (consumer exposure, groundwater, aquatic organisms, soil macro-organisms)

NLS 484A/RAPIDINSECT
Part A - National Assessment
FRANCE DEPR version

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f] zRMS conclusion
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
23	FR	Potato including but not limited to *Solanum tuberosum* [SOLTU]	Fn	Aphids including but not limited to examples: Macrosiphum rosae [MACSRO] - *Aphis pomi* [APHIPO] – *Aphis fabae* [APHIFA] – *Myzus persicae* [MYZUP]	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 b) 14	a) Pyre-thrum 49 Rape seed oil 4900 b) Pyrethrum 98 Rape seed oil 9800	Min 600 L/ha (low-height crops) Max 1000 L/ha	3	**Not acceptable** (consumer exposure, groundwater, aquatic organisms, soil macro-organisms)
24	FR	Potato including but not limited to *Solanum tuberosum* [SOLTU]	Fn	Colorado beetle [LPTNDE] - *Leptinotarsa decemlineata*	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 b) 14	a) Pyre-thrum 49 Rape seed oil 4900 b) Pyrethrum 98 Rape seed oil 9800	Min 600 L/ha (low-height crops) Max 1000 L/ha	3	**Not acceptable** (consumer exposure, groundwater, aquatic organisms, soil macro-organisms)
27	FR	Tomato including but not limited to *Solanum lycopersicum* [LYPES]	Fn	Aphids including but not limited to examples: Macrosiphum rosae [MACSRO] - *Aphis pomi* [APHIPO] – *Aphis fabae* [APHIFA] – *Myzus persicae* [MYZUP]	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 b) 14	a) Pyre-thrum 49 Rape seed oil 4900 b) Pyrethrum 98 Rape seed oil 9800	Min 600 L/ha (low-height crops) Max 1000 L/ha	3	**Not acceptable** (consumer exposure, groundwater aquatic organisms, soil macro-organisms)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f] zRMS conclusion
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
28	FR	Tomato including but not limited to *Solanum lycopersicum* [LYPES]	Fn	Whitefly including but not limited to examples: *Trialeurodes vaporariorum* TRIAVA	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 b) 14	a) Pyre-thrum 49 Rape seed oil 4900 b) Pyrethrum 98 Rape seed oil 9800	Min 600 L/ha (low-height crops) Max 1000 L/ha	3	**Not acceptable** (consumer exposure, groundwater, aquatic organisms, soil macro-organisms)
29	FR	Tomato including but not limited to *Solanum lycopersicum* [LYPES]	Fn	Mites including but not limited to examples: *Tetranychus urticae* TETRUR	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 b) 14	a) Pyre-thrum 49 Rape seed oil 4900 b) Pyrethrum 98 Rape seed oil 9800	Min 600 L/ha (low-height crops) Max 1000 L/ha	3	**Not acceptable** (consumer exposure, groundwater aquatic organisms, soil macro-organisms)
31	FR	Strawberry including but not limited to *Fragaria x ananassa* [FRAAN]	Fn	Mites including but not limited to examples: *Tetranychus urticae* TETRUR	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 b) 14	a) Pyre-thrum 49 Rape seed oil 4900 b) Pyrethrum 98 Rape seed oil 9800	Min 600 L/ha (low-height crops) Max 1000 L/ha	3	**Not acceptable** (consumer exposure, groundwater, , aquatic organisms, soil macro-organisms)

NLS 484A/RAPIDINSECT
Part A - National Assessment
FRANCE DEPR version

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f] zRMS conclusion
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
Label extension accordieng to Art. 51													
1	FR	All Ornamentals (Roses and Flowers)	Fn	Aphids (examples: Macrosiphum rosae MACSRO - *Aphis pomi* APHIPO – *Aphis fabae* APHIFA – *Myzus persicae* MYZUP)	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 L product/ ha b) 14 L product / ha	a) Pyrethrum 0.049 kg/ha Rapeseed oil 4.9 kg/ha b) Pyrethrum 0.098 kg/ha Rapeseed oil 9.8 kg/ha	Min 600 L/ha (low height crops) Max 1000 L/ha (roses and other crops)	n.a.	**Not acceptable** (aquatic organisms, non-target soil organisms)
2	FR	All Ornamentals and ornamental shrubs (Roses and Flowers)	Fn	Aphids (examples: Macrosiphum rosae MACSRO - *Aphis pomi* APHIPO – *Aphis fabae* APHIFA – *Myzus persicae* MYZUP)	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 L product/ ha b) 14 L product / ha	a) Pyrethrum 0.049 kg/ha Rapeseed oil 4.9 kg/ha b) Pyrethrum 0.098 kg/ha Rapeseed oil 9.8 kg/ha	Min 600 L/ha (low height crops) Max 1000 L/ha (roses and other crops)	n.a.	**Not acceptable** (aquatic organisms, non-target soil organisms)
3	FR	All Ornamental trees	Fn	Aphids (examples: Macrosiphum rosae MACSRO - *Aphis pomi* APHIPO – *Aphis fabae* APHIFA – *Myzus persicae* MYZUP)	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 L product/ ha b) 14 L product / ha	a) Pyrethrum 0.049 kg/ha Rapeseed oil 4.9 kg/ha b) Pyrethrum 0.098 kg/ha Rapeseed oil 9.8 kg/ha	Min 600 L/ha (low height crops) Max 1000 L/ha (roses and other crops)	n.a.	**Not acceptable** (aquatic organisms, non-target soil organisms)

NLS 484A/RAPIDINSECT
Part A - National Assessment
FRANCE DEPR version

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f] zRMS conclusion
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
4	FR	All Ornamentals (Roses and Flowers)	Fn	Mites (example: *Tetranychus urticae* TETRUR)	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 L product/ ha b) 14 L product / ha	a) Pyrethrum 0.049 kg/ha Rapeseed oil 4.9 kg/ha b) Pyrethrum 0.098 kg/ha Rapeseed oil 9.8 kg/ha	Min 600 L/ha (low height crops) Max 1000 L/ha (roses and other crops)	n.a.	**Not acceptable** (aquatic organisms, non-target soil organisms)
5	FR	All Ornamentals and ornamental shrubs (Roses and Flowers)	Fn	Mites (example: *Tetranychus urticae* TETRUR)	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 L product/ ha b) 14 L product / ha	a) Pyrethrum 0.049 kg/ha Rapeseed oil 4.9 kg/ha b) Pyrethrum 0.098 kg/ha Rapeseed oil 9.8 kg/ha	Min 600 L/ha (low height crops) Max 1000 L/ha (roses and other crops)	n.a.	**Not acceptable** (aquatic organisms, non-target soil organisms)
6	FR	All Ornamental trees	Fn	Mites (example: *Tetranychus urticae* TETRUR)	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 L product/ ha b) 14 L product / ha	a) Pyrethrum 0.049 kg/ha Rapeseed oil 4.9 kg/ha b) Pyrethrum 0.098 kg/ha Rapeseed oil 9.8 kg/ha	Min 600 L/ha (low height crops) Max 1000 L/ha (roses and other crops)	n.a.	**Not acceptable** (aquatic organisms, non-target soil organisms)

NLS 484A/RAPIDINSECT
Part A - National Assessment
FRANCE DEPR version

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f] zRMS conclusion
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
7	FR	All Ornamentals (Roses and Flowers)	Fn	Caterpillars (example: *Pieris sp*. PIERSP)	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 L product/ ha b) 14 L product / ha	a) Pyrethrum 0.049 kg/ha Rapeseed oil 4.9 kg/ha b) Pyrethrum 0.098 kg/ha Rapeseed oil 9.8 kg/ha	Min 600 L/ha (low height crops) Max 1000 L/ha (roses and other crops)	n.a.	**Not acceptable** (aquatic organisms, non-target soil organisms)
8	FR	All Ornamentals and ornamental shrubs (Roses and Flowers)	Fn	Caterpillars (example: *Pieris sp*. PIERSP)	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 L product/ ha b) 14 L product / ha	a) Pyrethrum 0.049 kg/ha Rapeseed oil 4.9 kg/ha b) Pyrethrum 0.098 kg/ha Rapeseed oil 9.8 kg/ha	Min 600 L/ha (low height crops) Max 1000 L/ha (roses and other crops)	n.a.	**Not acceptable** (aquatic organisms, non-target soil organisms)
9	FR	All Ornamentals (Roses and Flowers)	Fn	Leaf beetles (example: *Lilioceris lilii* CRIELI)	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 L product/ ha b) 14 L product / ha	a) Pyrethrum 0.049 kg/ha Rapeseed oil 4.9 kg/ha b) Pyrethrum 0.098 kg/ha Rapeseed oil 9.8 kg/ha	Min 600 L/ha (low height crops) Max 1000 L/ha (roses and other crops)	n.a.	**Not acceptable** (aquatic organisms, non-target soil organisms)

NLS 484A/RAPIDINSECT
Part A - National Assessment
FRANCE DEPR version

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f] zRMS conclusion
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
10	FR	All Ornamentals (Roses and Flowers)	Fn	Scale insects (example *Coccus hesperidum* COCCHE) Mealybugs (example *Peudococcus sp.* PSECSP)	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 L product/ ha b) 14 L product / ha	a) Pyrethrum 0.049 kg/ha Rapeseed oil 4.9 kg/ha b) Pyrethrum 0.098 kg/ha Rapeseed oil 9.8 kg/ha	Min 600 L/ha (low height crops) Max 1000 L/ha (roses and other crops)	n.a.	**Not acceptable** (aquatic organisms, non-target soil organisms)
11	FR	All Ornamentals and ornamental shrubs (Roses and Flowers)	Fn	Scale insects (example *Coccus hesperidum* COCCHE) Mealybugs (example *Peudococcus sp.* PSECSP)	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 L product/ ha b) 14 L product / ha	a) Pyrethrum 0.049 kg/ha Rapeseed oil 4.9 kg/ha b) Pyrethrum 0.098 kg/ha Rapeseed oil 9.8 kg/ha	Min 600 L/ha (low height crops) Max 1000 L/ha (roses and other crops)	n.a.	**Not acceptable** (aquatic organisms, non-target soil organisms)
12	FR	All Ornamental trees	Fn	Scale insects (example *Coccus hesperidum* COCCHE) Mealybugs (example *Peudococcus sp.* PSECSP)	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 L product/ ha b) 14 L product / ha	a) Pyrethrum 0.049 kg/ha Rapeseed oil 4.9 kg/ha b) Pyrethrum 0.098 kg/ha Rapeseed oil 9.8 kg/ha	Min 600 L/ha (low height crops) Max 1000 L/ha (roses and other crops)	n.a.	**Not acceptable** (aquatic organisms, non-target soil organisms)

NLS 484A/RAPIDINSECT
Part A - National Assessment
FRANCE DEPR version

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f] zRMS conclusion
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
13	FR	All Ornamentals (Roses and Flowers)	Fn	Leaf miners (example *Plutella xylostella* PLUTMA)	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 L product/ ha b) 14 L product / ha	a) Pyrethrum 0.049 kg/ha Rapeseed oil 4.9 kg/ha b) Pyrethrum 0.098 kg/ha Rapeseed oil 9.8 kg/ha	Min 600 L/ha (low height crops) Max 1000 L/ha (roses and other crops)	n.a.	**Not acceptable** (aquatic organisms, non-target soil organisms)
14	FR	All Ornamentals and ornamental shrubs (Roses and Flowers)	Fn	Leaf miners (example *Plutella xylostella* PLUTMA)	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 L product/ ha b) 14 L product / ha	a) Pyrethrum 0.049 kg/ha Rapeseed oil 4.9 kg/ha b) Pyrethrum 0.098 kg/ha Rapeseed oil 9.8 kg/ha	Min 600 L/ha (low height crops) Max 1000 L/ha (roses and other crops)	n.a.	**Not acceptable** (aquatic organisms, non-target soil organisms)
15	FR	All Ornamentals (Roses and Flowers)	Fn	Stink bugs (example *Eurydema sp* EURDSP)	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 L product/ ha b) 14 L product / ha	a) Pyrethrum 0.049 kg/ha Rapeseed oil 4.9 kg/ha b) Pyrethrum 0.098 kg/ha Rapeseed oil 9.8 kg/ha	Min 600 L/ha (low height crops) Max 1000 L/ha (roses and other crops)	n.a.	**Not acceptable** (aquatic organisms, non-target soil organisms)

NLS 484A/RAPIDINSECT
Part A - National Assessment
FRANCE DEPR version

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f] zRMS conclusion
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
16	FR	All Ornamentals (Roses and Flowers)	Fn	Flea beetles (example *Epitrix intermedia* EPIXIN)	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 L product/ ha b) 14 L product / ha	a) Pyrethrum 0.049 kg/ha Rapeseed oil 4.9 kg/ha b) Pyrethrum 0.098 kg/ha Rapeseed oil 9.8 kg/ha	Min 600 L/ha (low height crops) Max 1000 L/ha (roses and other crops)	n.a.	**Not acceptable** (aquatic organisms, non-target soil organisms)
17	FR	All Ornamentals (Roses and Flowers)	Fn	Leafhopper (example Typhlocyba pomaria TYCYPO)	Foliar sprayer: Covering both sides of leaves of infested plants after dilution in water	During vegetation growth (April to September)	Max 2	Interval min 7 days	a) 7 L product/ ha b) 14 L product / ha	a) Pyrethrum 0.049 kg/ha Rapeseed oil 4.9 kg/ha b) Pyrethrum 0.098 kg/ha Rapeseed oil 9.8 kg/ha	Min 600 L/ha (low height crops) Max 1000 L/ha (roses and other crops)	n.a.	**Not acceptable** (aquatic organisms, non-target soil organisms)

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(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	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		
	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)	8	The maximum number of application possible under practical conditions of use must be provided.
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	9	Minimum interval (in days) between applications of the same product
			10	For specific uses other specifications might be possible, e.g.: g/m^3 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).
			12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
	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.	13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorisation decision and risk management

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

The physico-chemical properties of the formulation were evaluated and considered acceptable during the initial evaluation of this formulation. The intended concentrations requested for the extension of use(s) (concentrations of 0.7 % v/v) are covered by the in-use concentrations already authorised.

Apropos the specifications of pyrethrins, EFSA's conclusions indicate that with regard to the impact on human and animal health, including non-target organisms, it cannot be concluded that the test material used in the toxicity studies is representative of the proposed technical product. Similarly, a conclusion cannot be reached on the toxicological relevance of the impurity consisting of a complex range of natural plant products co-extracted with pyrethrins. Finally, none of the proposed specifications for pyrethrins were considered acceptable.

3.2 Efficacy (Part B, Section 3)

3.2.1 Efficacy data

The efficacy level of the RAPIDINSECT (NLS 484A) product is considered acceptable on aphids on all requested crops grown in the open air. Against mites, the efficacy is considered acceptable on apple trees only. Against caterpillars of cabbage, the efficacy is considered acceptable. **On the other crops, in the absence of data, it is not possible to finalise the evaluation for mites, flies, phytophagous beetles and whitefly.**

3.2.2 Information on the occurrence or possible occurrence of the development of resistance

The risk of the occurrence or development of resistance to rape seed oil and pyrethrins does not require monitoring for the requested uses.

3.2.3 Adverse effects on treated crops

The level of selectivity of the RAPIDINSECT (NLS 484A) product is considered satisfactory for the requested uses.

3.2.4 Observations on other undesirable or unintended side-effects

The risk of negative impact on succeeding and adjacent crops is considered negligible.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical methods for the determination of the active substances and the relevant impurity in the formulation are available and validated.

3.3.2 Analytical methods for residues

The analytical methods for the determination of pyrethrins residues in plants submitted at European level and in this dossier are considered to be validated. As no MRL/residue definition in plants and foodstuffs of animal origin is fixed for rape seed oil, no analytical method is necessary for the determination of its residues in these matrices.

To update the dossier, an ILV of the method of determination of residues of pyrethrins in crop matrices with a high water content or acidic matrices is required.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Agreed EU endpoints		
Active substance	**Pyrethrins**	**Rape seed oil**
AOEL systemic	0.07 mg/kg bw/day	No AOEL defined – food-grade quality of the active substance.
AAOEL	none	None: – food-grade quality of the active substance.
Oral absorption (%)	55	Not applicable.
Vapour pressure	pyrethrin I: 6.9×10^{-5} Pa (25 °C) pyrethrin II: 2.7×10^{-5} Pa (25 °C)	1.33×10^{-18} Pa (obtained by calculation) RMS proposal: < 10^{-5} Pa
Reference	EFSA Supporting publication 2017[7] FINAL Review report for the active substance pyrethrins, 16 July 2013, SANCO/2627/08. (no AOEL estblished by EFSA)	EFSA Journal 2013; 11(1): 3068 UE 2013 : SANCO/2623/08 – final (3 October 2013)
Dermal absorption (%)	Undiluted: 70 Diluted: 70 Default values (EFSA 2017)	None (no exposure assessment was deemed necessary)

3.4.1 Acute toxicity

RAPIDINSECT (NLS 484A), containing 7 g/L pyrethrins and 700 g/L rape seed oil, has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitiser.

[7] EFSA (European Food Safety Authority), 2017. Technical report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for pyrethrins in light of confirmatory data. EFSA supporting publication 2017:EN-1212. 33 pp. doi:10.2903/sp.efsa.2017.EN-1212

3.4.2 Operator exposure

Considering the proposed uses, systemic exposure of non-professional users was estimated using the French study dedicated to amateur use (2005):

		Pyrethrins	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Pre-pressure sprayer to high crops (orchards (including raspberry) and vegetables > 60 cm: eggplant, cucumber, courgette, strawberries, bean, pepper, tomato) and to low crops (vegetables < 60 cm): carrot, cabbage, melon, lettuce, peas, potato, chicory). Application rate: 7 mL product/10 m² (0.049 g a.s./10 m²)			
UPJ Application volume: 0.1 L/m² 0.049 g a.s./10 m² Body weight: 60 kg	Without gloves	0.0216	32

According to the UPJ model, the risk for the non-professional user applying RAPIDINSECT (NLS 484A) is acceptable without the use of personal protective equipment.

3.4.3 Worker exposure

RAPIDINSECT (NLS 484A) is intended to be used by non-professional users for home garden application. In this case, the worker is also the user of the product. It will be necessary to ensure complete drying of the treated area or of treated plants before handling them.

3.4.4 Bystander and resident exposure

Bystander exposure:
In the context of use by non-professionals, it is considered that the assessment for bystanders is covered by that for the operator.

Residential exposure:
As a worst-case approach, France as zRMS has estimated recreational exposure for residents. Results are presented in table below:

EFSA model – Recreational exposure Application rate: 2 x 49 g a.s./ha		
	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Child	0.0172	25
Adult	0.0077	11

It may be concluded that there is no unacceptable risk anticipated for the resident (adult and child) when RAPIDINSECT (NLS 484A) is applied for the intended uses.

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

Overall conclusion

According to Regulation (EC) No 839/2008 of 31 July 2008 as regards rape seed oil, EFSA concluded that the inclusion of that substance in Annex IV to Regulation (EC) No 396/2005 was appropriate. Rape seed oil is listed in Annex IV to Regulation (EC) No 396/2005 and therefore has an MRL exemption. No further assessment is required on metabolism and residues and no safety concern was identified for rape seed oil regarding the use of RAPIDINSECT (NLS 484A).

No exceedence of the current MRL for pear, apple, aubergine, cucumber, courgette, strawberry, fresh peas without pods, pepper, potato and tomato of 1 mg/kg for pyrethrins as laid down in Reg. (EU) 396/2005 is expected. **For dry peas, compliance with the extant MRL cannot be verified, due to a lack of residues data.**

According to the provisional residue definition for risk assessment set as "*pyrethrins, sum of pyrethrin 1&2, cinerin 1&2 and jasmolin 1&2*" (*sic*), the chronic and short-term intakes of pyrethrins residues are unlikely to present a public health concern. However, this conclusion was not complete, as uncertainties were identified related to the pyrethrolone metabolites and the toxicological relevance of hydroxyl-chrysanthemic acid metabolites.

Confirmatory data regarding these uncertainties were submitted. Nevertheless, as:

- confirmatory data were not considered sufficient by EFSA to address in general the fate of the pyrethrolone moiety or of the hydroxyl-chrysanthemic acid metabolites in treated crops and to demonstrate that residues of metabolites will regularly be below the LOQ or not even formed;
- information on the toxicity (including genotoxicity) of metabolites was not considered sufficient by EFSA to conclude on their toxicological profile. EFSA considered that a firm conclusion on the consumer risk assessment is still not possible and further evidence is necessary to ascertain the actual exposure and risk potential for the consumer related to the use of pyrethrins (EFSA, 2017).

Consequently, no firm conclusion can be reached for any of the intended uses of the product RAPIDINSECT (NLS 484A).

Data gaps

Residue trials on several crops.

Others: see European assessment.

Summary for RAPIDINSECT (NLS 484A)

Information on RAPIDINSECT (NLS 484A)

Crop	PHI for RAPIDINSECT (NLS 484A) requested by applicant	PHI/withholding period* sufficiently supported for		PHI for RAPIDINSECT (NLS 484A) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Pyrethrins	Rape seed oil		
Pear	3 days	Yes	Yes	NA	Not possible to conclude on risk assessment.

NLS 484A/RAPIDINSECT
Part A - National Assessment
FRANCE DEPR version

Crop	PHI for RAPIDINSECT (NLS 484A) requested by applicant	PHI/withholding period* sufficiently supported for		PHI for RAPIDINSECT (NLS 484A) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Pyrethrins	Rape seed oil		
Apple	3 days	Yes	Yes	NA	Not possible to conclude on the risk assessment.
Aubergine	3 days	Yes	Yes	NA	Not possible to conclude on the risk assessment.
Cabbage head	3 days	Yes for head cabbage.	Yes	NA	Furthermore, not possible to conclude on the risk assessment.
Cucumbers	3 days	Yes	Yes	NA	Not possible to conclude on the risk assessment.
Courgette	3 days	Yes	Yes	NA	Not possible to conclude on the risk assessment.
Strawberry	3 days	Yes	Yes	NA	Not possible to conclude on the risk assessment.
Peas without pods	3 days	Yes for fresh pea without pods	Yes	NA	Furthermore, not possible to conclude on the risk assessment.
Pepper	3 days	Yes	Yes	NA	Not possible to conclude on the risk assessment.
Potato	3 days	Yes	Yes	NA	Not possible to conclude on the risk assessment.
Tomato	3 days	Yes	Yes	NA	Not possible to conclude on the risk assessment.

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.

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

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

The PEC values of pyrethrins, rape seed oil and their metabolites in surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models or specific approaches for home and garden uses, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

Considering the home and garden intended uses for the formulated product, no PECsoil calculation is required.

PECsw values derived for the active substances and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

However, for pyrethrin I, studies are available with material labelled at the cyclopropane ring only. Therefore, a data gap has been identified to address the fate and behaviour of the cyclopentelone moiety after the rupture of the ester bridge in the pyrethrins (normally first degradation step). This data gap has not been addressed in the current submission regarding the fate in water. **Therefore, in agreement with EFSA conclusions, France as zRMS considers that the environmental risk assessment for the surface water compartment cannot be finalised based on the available data.**

For all uses, PECgw values for pyrethrins and rape seed oil do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009.

For uses on apricots, cherries, peaches, plums, pears, apples, cabbage, lettuce and chicory, PECgw values for fatty acids do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009. Therefore, no unacceptable risk of groundwater contamination is expected for these uses.

For all other uses, PECgw calculations were not used, since they rely on Freundlich exponent and vapour pressure parameters that underestimate PECgw values. Consequently, the risk assessment for groundwater contamination by fatty acids cannot be finalised for these uses.

Based on vapour pressure, information on volatilisation from plants and soil, and DT_{50} calculation, no significant contamination of the air compartment is expected for the intended uses.

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substances and their 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.

Considering the home and garden uses, since the product is used as a foliar spray, only the risk assessment for birds, aquatic organisms and bees was performed.

For birds, the risk is considered acceptable for the intended uses.

For aquatic organisms, the available data in the environmental fate section are not sufficient to determine a complete degradation scheme in water for pyrethrins. Therefore, the risk assessment of pyrethrins for aquatic organisms cannot be finalised, as it is not possible to determine if all the metabolites of pyrethrins have been identified.

For bees, according to new requirements of Reg. No. 284/2013, information on development of bees should have been submitted as exposure of bees to the formulation cannot be excluded. In the absence of these data, the risk for bees cannot be finalised.

For non-target soil organisms, according to new requirements of Reg. No. 284/2013, chronic toxicity studies on *Eisenia fetida* and *Folsomia candida* should have been submitted. Moreover, without these data, the toxicity of the formulation on soil organisms could not be assessed. Thus, the risk is not finalised for these organisms.

3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the Steps described in SANCO/221/2000 guidance document. Please refer to 3.7 for conclusion on the risk of groundwater contamination.

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

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

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

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

5.1.1 Post-authorisation monitoring

N/A.

5.1.2 Post-authorisation data requirements

N/A.

Appendix 1 Copy of the product authorisation

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

anses

Décision relative à une demande d'extension d'usages d'un produit phytopharmaceutique

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

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

Vu les demandes d'extensions d'usages majeurs et mineurs du produit phytopharmaceutique ***RAPIDINSECT***

de la société	*EVERGREEN GARDEN CARE France SAS*
enregistrées sous les	*n°2019-2437 et 2019-1627*

Vu les conclusions de l'évaluation de l'Anses du 12 juin 2020, relatives à une demande d'extension d'usages majeurs,

Vu les conclusions de l'évaluation de l'Anses du 12 juin 2020 relatives à une demande d'extension d'usages mineurs,

Considérant que les données fournies ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol,

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

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

RAPIDINSECT

AMM n°2171312

Page 1 sur 8

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

Informations générales sur le produit	
Nom du produit	RAPIDINSECT
Type de produit	Produit de référence
Titulaire	EVERGREEN GARDEN CARE France SAS 4 allée des Séquoias 69760 LIMONEST France
Formulation	Concentré émulsionnable (EC)
Contenant	7 g/L - pyréthrines 700 g/L - huile de colza
Numéro d'intrant	731-2014.01
Numéro d'AMM	2171312
Fonction	Insecticide
Gamme d'usage	Amateur / emploi autorisé dans les jardins

A Maisons-Alfort, le 28 AOUT 2020

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

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

anses

ANNEXE I : Conditions de mise sur le marché demandées

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
14053107 Arbres et arbustes* Trt Part.Aer.*Acariens	7 mL/L	2/an	Non applicable
	Motivation du refus : L'usage est refusé en plein champ au motif qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peut être exclu.		
14053102 Arbres et arbustes* Trt Part.Aer.*Chenilles phytophages	7 mL/L	2/an	Non applicable
	Motivation du refus : L'usage est refusé en plein champ au motif qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peut être exclu.		
00502025 Arbres et arbustes* Trt Part.Aer.*Cicadelles et cercopides	7 mL/L	2/an	Non applicable
	Motivation du refus : L'usage est refusé en plein champ au motif qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peut être exclu.		
14053101 Arbres et arbustes* Trt Part.Aer.*Cochenilles	7 mL/L	2/an	Non applicable
	Motivation du refus : L'usage est refusé en plein champ au motif qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peut être exclu.		
00502027 Arbres et arbustes* Trt Part.Aer.*Coléoptères phytophages	7 mL/L	2/an	Non applicable
	Motivation du refus : L'usage est refusé en plein champ au motif qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peut être exclu.		
14053105 Arbres et arbustes* Trt Part.Aer.*Pucerons	7 mL/L	2/an	Non applicable
	Motivation du refus : L'usage est refusé en plein champ au motif qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peut être exclu.		
14053100 Arbres et arbustes* Trt Part.Aer.*Ravageurs divers	7 mL/L	2/an	Non applicable
	Motivation du refus : L'usage est refusé en plein champ au motif qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peut être exclu.		

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

anses

Liste des usages refusés			
Usages	**Dose d'emploi**	**Nombre maximum d'applications**	**Délai avant récolte (jours)**
17403101 Cultures florales et plantes vertes* Trt Part.Aer.* Acariens, phytoptes et tarsonèmes	7 mL/L	2/an	Non applicable
	Motivation du refus : L'usage est refusé en plein champ au motif qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peut être exclu.		
17403108 Cultures florales et plantes vertes* Trt Part.Aer.*Chenilles phytophages	7 mL/L	2/an	Non applicable
	Motivation du refus : L'usage est refusé en plein champ au motif qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peut être exclu.		
17403109 Cultures florales et plantes vertes* Trt Part.Aer.*Cicadelles	7 mL/L	2/an	Non applicable
	Motivation du refus : L'usage est refusé en plein champ au motif qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peut être exclu.		
17403103 Cultures florales et plantes vertes* Trt Part.Aer.*Cochenilles	7 mL/L	2/an	Non applicable
	Motivation du refus : L'usage est refusé en plein champ au motif qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peut être exclu.		
00504036 Cultures florales et plantes vertes* Trt Part.Aer.*Coléoptères phytophages	7 mL/L	2/an	Non applicable
	Motivation du refus : L'usage est refusé en plein champ au motif qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peut être exclu.		
17403104 Cultures florales et plantes vertes* Trt Part.Aer.*Pucerons	***7 mL/L***	***2/an***	Non applicable
	Motivation du refus : L'usage est refusé en plein champ au motif qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peut être exclu.		
17403100 Cultures florales et plantes vertes* Trt Part.Aer.*Ravageurs divers	7 mL/L	2/an	Non applicable
	Motivation du refus : L'usage est refusé en plein champ au motif qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peut être exclu.		
00701022 Plantes d'intérieur et balcons* Trt Part.Aer.*Chenilles phytophages	7 mL/L	2/an	Non applicable
	Motivation du refus : L'usage est refusé car la revendication « plein champ » n'est pas adaptée au libellé de l'usage.		

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

anses

Liste des usages refusés			
Usages	**Dose d'emploi**	**Nombre maximum d'applications**	**Délai avant récolte (jours)**
00701018 Plantes d'intérieur et balcons* Trt Part.Aer.*Cochenilles	7 mL/L	2/an	Non applicable
	Motivation du refus : L'usage est refusé car la revendication « plein champ » n'est pas adaptée au libellé de l'usage.		
00701020 Plantes d'intérieur et balcons* Trt Part.Aer.*Pucerons	7 mL/L	2/an	Non applicable
	Motivation du refus : L'usage est refusé car la revendication « plein champ » n'est pas adaptée au libellé de l'usage.		
17453100 Plantes d'intérieur et balcons* Trt Part.Aer.*Ravageurs divers	7 mL/L	2/an	Non applicable
	Motivation du refus : L'usage est refusé car la revendication « plein champ » n'est pas adaptée au libellé de l'usage.		
17303101 Rosier*Trt Part.Aer.* Acariens	7 mL/L	2/an	Non applicable
	Motivation du refus : L'usage est refusé en plein champ au motif qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peut être exclu.		
17303105 Rosier*Trt Part.Aer.* Chenilles phytophages	7 mL/L	2/an	Non applicable
	Motivation du refus : L'usage est refusé en plein champ au motif qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peut être exclu.		
17303118 Rosier*Trt Part.Aer.* Cochenilles	7 mL/L	2/an	Non applicable
	Motivation du refus : L'usage est refusé en plein champ au motif qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peut être exclu.		
16403110 Choux*Trt Part.Aer.* Chenilles phytophages	7 mL/L	2/an	3
	Motivation du refus : L'usage est refusé au motif qu'un risque d'effet nocif pour le consommateur ne peut être exclu. L'usage est également refusé au motif qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peut être exclu.		
16403101 Choux*Trt Part.Aer.* Pucerons	7 mL/L	2/an	3
	Motivation du refus : L'usage est refusé au motif qu'un risque d'effet nocif pour le consommateur ne peut être exclu. L'usage est également refusé au motif qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peut être exclu.		

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

anses

Liste des usages refusés			
Usages	**Dose d'emploi**	**Nombre maximum d'applications**	**Délai avant récolte (jours)**
16323103 Concombre*Trt Part.Aer.* Aleurodes	7 mL/L	2/an	3
	Motivation du refus : L'usage est refusé au motif qu'un risque d'effet nocif pour le consommateur ne peut être exclu. L'usage est également refusé aux motifs qu'un risque inacceptable de contamination des eaux souterraines, ainsi qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peuvent être exclus.		
16323106 Concombre*Trt Part.Aer.*Pucerons	7 mL/L	2/an	3
	Motivation du refus : L'usage est refusé au motif qu'un risque d'effet nocif pour le consommateur ne peut être exclu. L'usage est également refusé aux motifs qu'un risque inacceptable de contamination des eaux souterraines, ainsi qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peuvent être exclus.		
16553104 Fraisier*Trt Part.Aer.*Acariens	7 mL/L	2/an	3
	Motivation du refus : L'usage est refusé au motif qu'un risque d'effet nocif pour le consommateur ne peut être exclu. L'usage est également refusé aux motifs qu'un risque inacceptable de contamination des eaux souterraines, ainsi qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peuvent être exclus.		
16553105 Fraisier* Trt Part.Aer.*Pucerons	7 mL/L	2/an	3
	Motivation du refus : L'usage est refusé au motif qu'un risque d'effet nocif pour le consommateur ne peut être exclu. L'usage est également refusé aux motifs qu'un risque inacceptable de contamination des eaux souterraines, ainsi qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peuvent être exclus.		
00517101 Pois écossés frais* Trt Part.Aer.*Pucerons	7 mL/L	2/an	3
	Motivation du refus : L'usage est refusé au motif qu'un risque d'effet nocif pour le consommateur ne peut être exclu. L'usage est également refusé aux motifs qu'un risque inacceptable de contamination des eaux souterraines, ainsi qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peuvent être exclus.		
16853102 Pois* Trt Part.Aer.*Pucerons	7 mL/L	2/an	3
	Motivation du refus : L'usage est refusé au motif que le respect des limites maximales de résidus des pyréthrines n'a pas pu être vérifié en l'absence de données résidus. L'usage est également refusé aux motifs qu'un risque d'effet nocif pour le consommateur, qu'un risque inacceptable de contamination des eaux souterraines, ainsi qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peuvent être exclus.		

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

anses

Liste des usages refusés			
Usages	**Dose d'emploi**	**Nombre maximum d'applications**	**Délai avant récolte (jours)**
16863104 Poivron* Trt Part.Aer.*Pucerons	7 mL/L	2/an	3
	Motivation du refus : L'usage est refusé au motif qu'un risque d'effet nocif pour le consommateur ne peut être exclu. L'usage est également refusé aux motifs qu'un risque inacceptable de contamination des eaux souterraines, ainsi qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peuvent être exclus.		
15653101 Pomme de terre* Trt Part.Aer.*Coléoptères phytophages	7 mL/L	2/an	3
	Motivation du refus : L'usage est refusé au motif qu'un risque d'effet nocif pour le consommateur ne peut être exclu. L'usage est également refusé aux motifs qu'un risque inacceptable de contamination des eaux souterraines, ainsi qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peuvent être exclus.		
15653108 Pomme de terre* Trt Part.Aer.*Pucerons	7 mL/L	2/an	3
	Motivation du refus : L'usage est refusé au motif qu'un risque d'effet nocif pour le consommateur ne peut être exclu. L'usage est également refusé aux motifs qu'un risque inacceptable de contamination des eaux souterraines, ainsi qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peuvent être exclus.		
12603134 Pommier* Trt Part.Aer.*Acariens et phytoptes	7 mL/L	2/an	3
	Motivation du refus : L'usage est refusé au motif qu'un risque d'effet nocif pour le consommateur ne peut être exclu. L'usage est également refusé en plein champ au motif qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peut être exclu.		
12603150 Pommier* Trt Part.Aer.*Pucerons	7 mL/L	2/an	3
	Motivation du refus : L'usage est refusé au motif qu'un risque d'effet nocif pour le consommateur ne peut être exclu. L'usage est également refusé en plein champ au motif qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peut être exclu.		
16953109 Tomate* Trt Part.Aer.*Acariens	7 mL/L	2/an	3
	Motivation du refus : L'usage est refusé au motif qu'un risque d'effet nocif pour le consommateur ne peut être exclu. L'usage est également refusé aux motifs qu'un risque inacceptable de contamination des eaux souterraines, ainsi qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peuvent être exclus.		

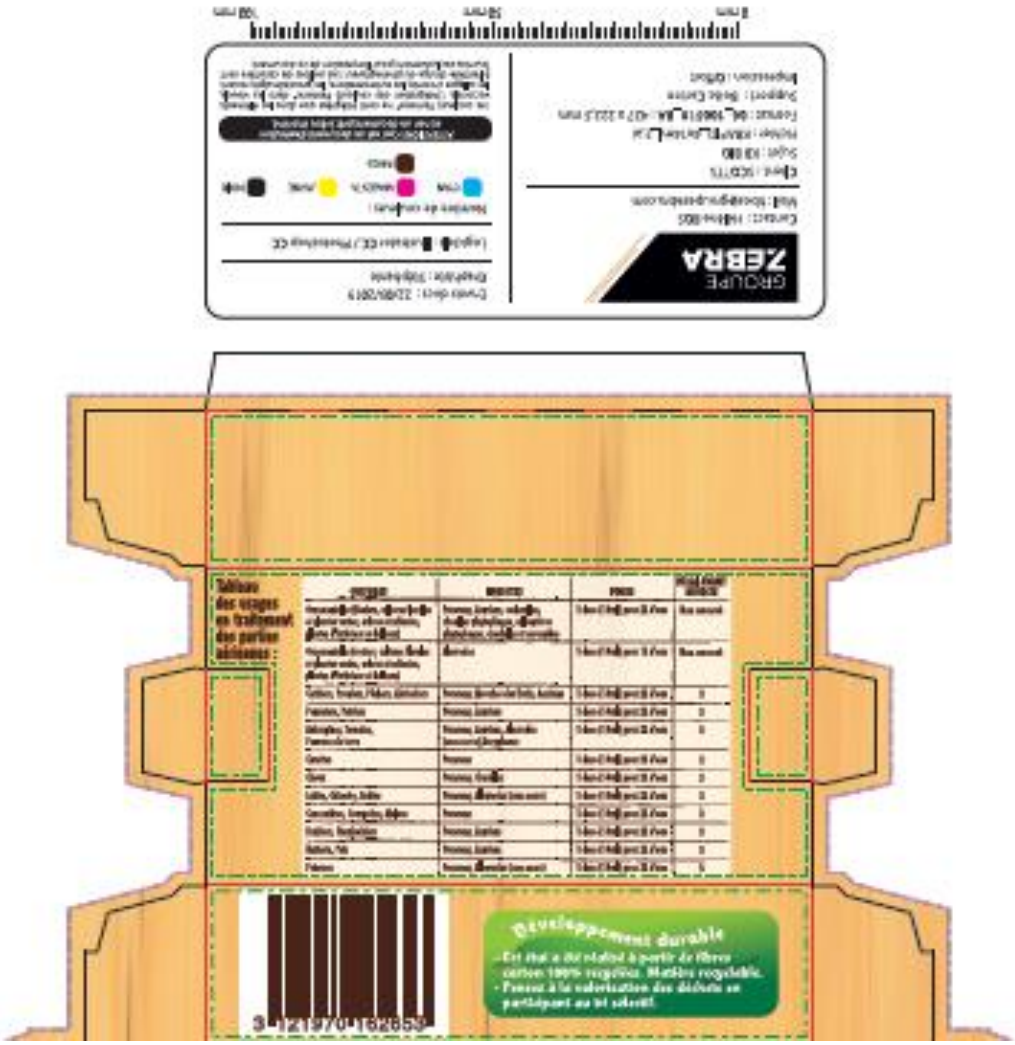
Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

anses

Liste des usages refusés			
Usages	**Dose d'emploi**	**Nombre maximum d'applications**	**Délai avant récolte (jours)**
16953101 Tomate* Trt Part.Aer.*Aleurodes	7 mL/L	2/an	3
	Motivation du refus : L'usage est refusé au motif qu'un risque d'effet nocif pour le consommateur ne peut être exclu. L'usage est également refusé aux motifs qu'un risque inacceptable de contamination des eaux souterraines, ainsi qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peuvent être exclus.		
16953104 Tomate*Trt Part.Aer.*Pucerons	7 mL/L	2/an	3
	Motivation du refus : L'usage est refusé au motif qu'un risque d'effet nocif pour le consommateur ne peut être exclu. L'usage est également refusé aux motifs qu'un risque inacceptable de contamination des eaux souterraines, ainsi qu'un risque d'effet inacceptable pour les organismes aquatiques et les macro-organismes du sol ne peuvent être exclus.		

Appendix 2 Copy of the product label

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



Appendix 3 Letter of Access

Provided upon request.