

REGISTRATION REPORT

Part A

Risk Management

Product code: S1688

Product name: RAPIDINSECT SPRAY

Active substances:

pyrethrins, 0.1 g/L

rapeseed oil, 10 g/L

COUNTRY: FRANCE

Southern Zone for field uses

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Amateur uses

Applicant: Evergreen Garden Care France SAS

Date: 09/12/2019 (Decision)

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PART A – Risk Management

The company Evergreen Garden Care France SAS has requested marketing authorisation in France for the product RAPIDINSECT SPRAY (product code: S1688), containing 0.1 g/L pyrethrins and 10 g/L rapeseed oil, for use as an insecticide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to RAPIDINSECT SPRAY where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of RAPIDINSECT SPRAY have been made using endpoints agreed in the EU peer reviews of both pyrethrins and rapeseed oil.

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

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 Evergreen Garden Care France SAS's application to market RAPIDINSECT SPRAY 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 for open field uses. The evaluation is based on the UK Registration Report for the protected uses.

1.2 Active substance approval

Pyrethrins

Commission Implementing Regulation (EU) 2017/195 of 3 February 2017 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of several active substances listed in Part B of the Annex to Implementing Regulation (EU) No 686/2012 (AIR IV renewal programme).

and

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

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

PART A

Only uses as insecticide may be authorised.

PART B

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pyrethrins (SANCO/2627/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.

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

- (a) the risk to operators and workers;
- (b) the risk to non-target organisms.

Conditions of use shall, where appropriate, include the application of adequate personal protective equipment and other risk mitigation measures.

Further studies were identified which were at this stage considered necessary in relation to the approval of pyrethrins under the current approval conditions.

The applicant shall submit confirmatory information as regards:

- (1) the specification of the technical material, as commercially manufactured including information on any relevant impurities and its equivalence with the specifications of the test material used in the toxicity studies;
- (2) the risk from inhalation;
- (3) the residue definition;
- (4) the representativeness of the major component “pyrethrin 1”¹ as regards the fate and behaviour in soil and water.

The applicant shall submit to the Commission, the Member States and the Authority the information set out in points (1) by 31 March 2014 and the information set out in points (2), (3) and (4) by 31 December 2015.

EFSA conclusions are available (EFSA Journal 2013;11(1):3032 [approval] and Efsa Technical Report (13 May 2015) [confirmatory data]).

Review Reports are available (SANCO/2627/08 – rev. 1 8 July 2008 [original approval] and SANCO/2627/08 – final 16 July 2013 [conditions of approval]).

Rapeseed oil

Commission Implementing Regulation (EU) 2017/195 of 3 February 2017 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of several active substances listed in Part B of the Annex to Implementing Regulation (EU) No 686/2012 (AIR IV renewal programme).
and

Commission Implementing Regulation (EU) No 1150/2013 of 14 November 2013 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance rape seed oil.

Specific provisions of Regulation (EU) No 1150/2013 were as follows:

PART A

Only uses as insecticide and acaricide may be authorised.

PART B

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on rape seed oil (SANCO/2623/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account.

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

An EFSA conclusion is available (EFSA Journal 2013;11(1):3058).

Review Reports are available (SANCO/2623/08 – rev. 1 25 July 2008 [original approval] and SANCO/2623/08 – final 3 October 2013 [conditions of approval]).

1.3 Regulatory approach

The present applications (2016-0053, 2016-0062 and 2016-1468) for marketing authorisation for uses in open field and under protection [based on a UK evaluation]) were 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

¹ Remark by zRMS: (*sic*) – according to ISO 765, this moiety is written as “pyrethrin I”, with a Roman numeral rather than a Western Arabic/European numeral.

States of the Southern zone, taking into account the worst-case uses (“risk envelope approach”)² – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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

The French Order of 4 May 2017³ 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 1107/2009⁴, 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 546/2011⁵, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014⁶ 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 extrapolation⁷ 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.

1.4 Data protection claims

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

² 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

³ 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>

⁴ 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

⁵ 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

⁶ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRGI407093A/jo>

⁷ SANCO document “guidance document: Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

1.5 Letter(s) of Access

Letters of access have been supplied.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	RAPIDINSECT SPRAY (product code: S1688).
Authorisation number	2190808
Function	Insecticide, acaricide
Applicant	Evergreen Garden Care France SAS.
Composition	0.1 g/L pyrethrins. 10 g/L rapeseed oil.
Formulation type (code)	Other liquids to be applied undiluted (AL).
Packaging	HDPE (600 mL, 650 mL, 700 mL, 750 mL, 800 mL, 850 mL, 900 mL, 950 mL, 1 L) bottles with trigger sprayer. PET (600 mL, 650 mL, 700 mL, 750 mL, 800 mL, 850 mL, 900 mL, 950 mL, 1 L) bottles with trigger sprayer Refill containers are not acceptable for non-professional users.

2.2 Classification and labelling

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

Physical hazards	-	
Health hazards	-	
Environmental hazards	Hazardous to the aquatic environment, Chronic Hazard, Category 3.	
Hazard pictograms	-	
Signal word	-	
Hazard statements	H412	Harmful to aquatic life with long-lasting effects.
Precautionary statements	<i>For the P phrases, refer to the existent legislation</i>	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	EUH208	Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.

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

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

The authorisation of the product is linked for non-professional uses only to the following conditions:

	Do not dispose of unused spray and sprayer washings in the sink, gutter or any other water point.
	Do not apply when beneficial organisms are present.
	Do not apply when pollinating insects (bees, bumblebees, ...) or beneficial organisms (ladybug) are present.
	The product must be stored at a temperature below 40 °C.

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2.3 Product uses

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

When the conclusion is “not acceptable”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.

When a use is “acceptable” with GAP restrictions, the modifications of the GAP are in bold.

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

PPP (product name/code): RAPIDINSECT SPRAY / S16881
Active substance 1: rapeseed oil
Active substance 2: pyrethrins
Applicant: Evergreen Garden Care France SAS
Zone(s): southern ^(d)
Verified by MS: yes
Field of use: insecticide

GAP rev. 2019-12-09
Formulation type: Any other liquid (AL) ^(a, b)
Conc. of a.s. 1: 10 g/L ^(c)
Conc. of a.s. 2: 0.1 g/L ^(c)
Professional use: ☐
Non-professional use: ☒

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: zRMS conclusion (f) (g)
					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	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	FR	All Ornamentals (Roses and Flowers)	F	Aphids (examples: <i>Macrosiphum rosae</i> MACSRO - <i>Aphis pomi</i> APHIPO – <i>Aphis fabae</i> APHIFA – <i>Myzus persicae</i> 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) 1000 L product/ ha (equivalent to 1 L product/10 m ²) b) 2000 L product / ha (equivalent to 2 L product/10 m ²)	a) Pyrethrins 0.1 kg/ha Rapeseed oil 10 kg/ha b) Pyrethrins 0.2 kg/ha Rapeseed oil 20 kg/ha	Ready-to- use product, no dilution required	n.a.	Home and garden use Plant height < 50 cm Acceptable

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, 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: zRMS conclusion (f) (g)
					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	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
2	FR	All Ornamentals and ornamental shrubs (Roses and Flowers)	F	Aphids (examples: <i>Macrosiphum rosae</i> MACSRO - <i>Aphis pomi</i> APHIPO – <i>Aphis fabae</i> APHIFA – <i>Myzus persicae</i> 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) 1000 L product/ ha (equivalent to 1 L product/10 m ²) b) 2000 L product / ha (equivalent to 2 L product/10 m ²)	a) Pyrethrins 0.1 kg/ha Rapeseed oil 10 kg/ha b) Pyrethrins 0.2 kg/ha Rapeseed oil 20 kg/ha	Ready-to- use product, no dilution required	n.a.	Acceptable
3	FR	All Ornamental trees	F	Aphids (examples: <i>Macrosiphum rosae</i> MACSRO - <i>Aphis pomi</i> APHIPO – <i>Aphis fabae</i> APHIFA – <i>Myzus persicae</i> 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) 1000 L product/ha (equivalent to 1 L product/10 m ²) b) 2000 L product / ha (equivalent to 2 L product/10 m ²)	a) Pyrethrins 0.1 kg/ha Rapeseed oil 10 kg/ha b) Pyrethrins 0.2 kg/ha Rapeseed oil 20 kg/ha	Ready-to- use product, no dilution required	n.a.	Acceptable
4	FR	All Ornamentals (Roses and Flowers)	F	Mites (example: <i>Tetranychus urticae</i> 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) 1000 L product/ha (equivalent to 1 L product/10 m ²) b) 2000 L product / ha (equivalent to 2 L product/10 m ²)	a) Pyrethrins 0.1 kg/ha Rapeseed oil 10 kg/ha b) Pyrethrins 0.2 kg/ha Rapeseed oil 20 kg/ha	Ready-to- use product, no dilution required	n.a.	Acceptable
5	FR	All Ornamentals and ornamental shrubs (Roses and Flowers)	F	Mites (example: <i>Tetranychus urticae</i> 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) 1000 L product/ha (equivalent to 1 L product/10 m ²) b) 2000 L product / ha (equivalent to 2 L product/10 m ²)	a) Pyrethrins 0.1 kg/ha Rapeseed oil 10 kg/ha b) Pyrethrins 0.2 kg/ha Rapeseed oil 20 kg/ha	Ready to use product, no dilution required	n.a.	Acceptable

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, 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: zRMS conclusion (f) (g)
					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	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
6	FR	All Ornamental trees	F	Mites (example: <i>Tetranychus urticae</i> 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) 1000 L product/ha (equivalent to 1 L product/10 m ²) b) 2000 L product / ha (equivalent to 2 L product/10 m ²)	a) Pyrethrins 0.1 kg/ha Rapeseed oil 10 kg/ha b) Pyrethrins 0.2 kg/ha Rapeseed oil 20 kg/ha	Ready-to- use product, no dilution required	n.a.	Acceptable
7	FR	All Ornamentals (Roses and Flowers)	F	Caterpillars (example: <i>Pieris</i> 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) 1000 L product/ha (equivalent to 1 L product/10 m ²) b) 2000 L product / ha (equivalent to 2 L product/10 m ²)	a) Pyrethrins 0.1 kg/ha Rapeseed oil 10 kg/ha b) Pyrethrins 0.2 kg/ha Rapeseed oil 20 kg/ha	Ready-to- use product, no dilution required	n.a.	Acceptable
8	FR	All Ornamentals and ornamental shrubs (Roses and Flowers)	F	Caterpillars (example: <i>Pieris</i> 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) 1000 L product/ha (equivalent to 1 L product/10 m ²) b) 2000 L product / ha (equivalent to 2 L product/10 m ²)	a) Pyrethrins 0.1 kg/ha Rapeseed oil 10 kg/ha b) Pyrethrins 0.2 kg/ha Rapeseed oil 20 kg/ha	Ready-to- use product, no dilution required	n.a.	Acceptable
9	FR	All Ornamentals (Roses and Flowers)	F	Leaf beetles (example: <i>Lilioceris lilii</i> 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) 1000 L product/ha (equivalent to 1 L product/10 m ²) b) 2000 L product / ha	a) Pyrethrins 0.1 kg/ha Rapeseed oil 10 kg/ha b) Pyrethrins 0.2 kg/ha Rapeseed oil 20 kg/ha	Ready-to- use product, no dilution required	n.a.	Acceptable

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, 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: zRMS conclusion (f) (g)
					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	kg 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)	F	Scale insects (example <i>Coccus hesperidum</i> COCHE) Mealybugs (example <i>Pseudococcus</i> 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) 1000 L product/ ha (equivalent to 1 L product/10 m ²) b) 2000 L product / ha (equivalent to 2 L product/10 m ²)	a) Pyrethrins 0.1 kg/ha Rapeseed oil 10 kg/ha b) Pyrethrins 0.2 kg/ha Rapeseed oil 20 kg/ha	Ready-to- use product, no dilution required	n.a.	Acceptable
11	FR	All Ornamentals and ornamental shrubs (Roses and Flowers)	F	Scale insects (example <i>Coccus hesperidum</i> COCHE) Mealybugs (example <i>Pseudococcus</i> 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) 1000 L product/ha (equivalent to 1 L product/10 m ²) b) 2000 L product / ha (equivalent to 2 L product/10 m ²)	a) Pyrethrins 0.1 kg/ha Rapeseed oil 10 kg/ha b) Pyrethrins 0.2 kg/ha Rapeseed oil 20 kg/ha	Ready-to- use product, no dilution required	n.a.	Acceptable

Remarks table heading:

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

(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
 (f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
 (g) **For all uses other than indoor plants and balconies, the risk assessment for aquatic organisms is not finalised when the preparation is applied with a pre-pressure spray device.**

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	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m 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).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
		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 RISK MANAGEMENT

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

3.1.1 Physical and chemical properties

RAPIDINSECT SPRAY is an “other liquid to be applied undiluted” formulation (AL). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is that of an opaque white liquid, with oily type odour. It is not explosive and has no oxidising properties. Data for flammability and self-ignition temperature were not provided. The neat formulation has a pH value of 5.12 at 22 °C. There is no effect of low and high temperatures on the stability of the formulation, since after seven days at 0 °C and eight weeks at 40 °C, neither the active substances’ content nor the technical properties were changed. The stability data indicate a provisional shelf life of two years at ambient temperature when stored in HDPE or in PET. The technical characteristics are acceptable for an AL formulation.

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

The formulation must be stored at a temperature below 40 °C.

3.1.2 Methods of analysis

Analytical methods for the determination of active substances (pyrethrins and rapeseed oil) and relevant impurity (erucic acid) in the formulation are available and validated.

Analytical methods for the determination of residues of pyrethrins and rapeseed oil in plants and foodstuffs of animal origin are not necessary.

The active substances are neither toxic nor very toxic, hence no analytical method is required for the determination of residues in biological fluids and tissues.

According to EFSA conclusions, methods of analysis for soil, water and air are missing for the active substance pyrethrins. According to the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for pyrethrins in the light of confirmatory data, the specification is not acceptable.

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

Active substance: pyrethrins			
ADI	0.04 mg/kg bw/d		Efsa (2013)
ARfD	0.2 mg/kg bw		
AOEL	0.07 mg/kg bw/day		
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (used in formulation) 0.1 g/L	Spray dilution (used in formulation) 0.1 g/L
	Dermal absorption endpoints %	75	75

Active Substance: Rapeseed oil		
ADI	Not relevant	Efsa (2013)

ARfD	Not relevant	
AOEL	Not relevant	
Dermal absorption	Not relevant	

3.1.3.1 Acute Toxicity

RAPIDINSECT SPRAY, containing 0.1 g/L pyrethrins and 10 g/L rapeseed 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.

The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.2.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G ⁸	Equipment	Application rate L product/ha (g a.s./ha)	Spray dilution (L/ha)	Model
Ornamentals	F	Pre-pressure sprayer	1000 L/ha (100 g pyrethrins/ha)	-	UPJ
		Home garden sprayer (5 litre tank) separate measure	Equivalent to: 1 L product/10 m² and 0.1 g pyrethrins/10 m²		UK POEM

Considering the proposed uses, operator systemic exposure was estimated using the UK-POEM model and French study (2005) dedicated to amateur use:

Crop	Model	Equipment	PPE and/or working coverall	% AOEL Pyrethrins
Ornamentals	UPJ	Pre-pressure sprayer	-	3.3
Ornamentals	UK POEM	Home garden sprayer (5 litre tank), separate measure	-	29

According to the model calculations, it may be concluded that the risk for the operator using RAPIDINSECT SPRAY is acceptable without PPE.

The proposed packaging has been described in sufficient details, and its compliance can therefore be finalised.

⁸ Open field or glasshouse

In summary, compliance with the provisions of French Decree No. 2010-1755 of 30 December 2010 and Orders of 30 December 2010 relating to the use of certain plant protection products by non-professional users, is considered to be finalised for all packaging with trigger sprayer. However, refill containers are not acceptable for non-professional users.

3.1.3.3 Bystander Exposure

In the context of use by non-professionals, it may be considered that the assessment for bystanders is covered by that for the operator (user).

3.1.3.4 Worker Exposure

RAPIDINSECT SPRAY is intended to be used by amateurs during home garden application. In this case of the non-professional user, 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.

3.1.3.5 Resident Exposure

Residential exposure was assessed according to BREAM model. Exposure is estimated to be 40 % of the AOEL of pyrethrins. It may be concluded that there is no unacceptable risk to the resident exposed to RAPIDINSECT SPRAY.

3.1.4 Residues and Consumer Exposure

Considering the use under consideration, ornamental crops, and residue data available, consumer risk assessment is not deemed necessary.

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

According to the available data, no specific mitigation measures are recommended.

3.1.5 Environmental fate and behaviour

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

Exposure calculations are not deemed necessary when the product is applied on indoor and balcony plants or when it is applied with a hand-held trigger sprayer.

When the product is not applied with a hand-held trigger sprayer, the PEC values of rapeseed oil, pyrethrins and their metabolites in surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios or specific approaches for home and garden uses, to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided. No PEC_{soil} values are required for home garden products.

PEC_{sw} 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. Therefore in agreement with EFSA conclusions, France as zRMS considers that the surface water exposure calculations cannot be finalised based on the available data.

PECgw values for rapeseed oil, pyrethrins and their metabolites do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

Based on vapour pressure, information on volatilisation from plants and soil, and DT₅₀ calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.6 Ecotoxicology

For scenarios here the product is applied with a hand-held trigger sprayer, no risk assessment for non-target organisms is deemed necessary, except for bees, where an exposure cannot be excluded. The field study cannot be used to cover the risk for bees, therefore the risk for bees is not considered finalised with the available information.

When the product is not applied with a hand-held trigger sprayer, the risk assessment for birds, aquatic organisms and bees was performed, due to a potential increase of the treated areas and spray drift. For birds, the risk is considered acceptable for the intended uses.

For aquatic organisms and bees, the risk assessment is considered not finalised for the intended uses.

In addition, some safety phrases should be included on the label of this product.

For indoor and balcony plants, risk assessment for non-target organisms is not considered relevant.

3.1.7 Efficacy

The efficacy of RAPIDINSECT SPRAY is considered satisfactory on the requested uses.

The level of phytotoxicity of RAPIDINSECT SPRAY is considered acceptable.

The risk of negative impact of RAPIDINSECT SPRAY on succeeding crops is considered negligible.

The risk of negative impact of the product on adjacent crops is judged acceptable. Nevertheless, specific attention should be paid to the conditions of application of RAPIDINSECT SPRAY next to ornamental crops.

In the absence of specific data, particular attention should be paid to the conditions of use of the product in the context of joint use with beneficial insects.

The risk of occurrence or development of resistance to pyrethrins and rapeseed oil is considered very low for the requested uses. The risk of occurrence or development of resistance to pyrethrins applied in amateur gardens should not be increased compared with professional use.

Agronomic recommendations:

Given the diversity of species and varieties in ornamental crops, before using RAPIDINSECT SPRAY on a wide area, it is recommended to test the crop safety of the product on a few plants of the same variety and at the same growth stage.

3.2 Conclusions arising from French assessment

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

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

No further information is required.

3.4.2 Post-authorisation data requirements

No further information is required.

3.4.3 Label amendments

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

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

Appendix 1 – Copy of the French Decision



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

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

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

*Vu la demande d'autorisation de mise sur le marché et la demande associée du produit phytopharmaceutique
RAPIDINSECT SPRAY*

de la société Evergreen Garden Care France SAS

enregistrées sous les n°2016-0053, 2016-1468 et 2016-0062

Vu les conclusions de l'évaluation de l'Anses du 28 octobre 2019,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France, sous réserve du respect de la composition du produit autorisée dans les conclusions de l'évaluation, pour les usages et dans les conditions précisés dans la présente décision et ses annexes.

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

Avertissement :

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

RAPIDINSECT SPRAY
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Informations générales sur le produit	
Noms du produit	RAPIDINSECT SPRAY POLYSECT PLUS SPRAY
Type de produit	Produit de référence
Titulaire	Evergreen Garden Care France SAS 21 chemin de la Sauvegarde 69130 ECULLY FRANCE
Formulation	Autre liquide (AL)
Contenant	0,1 g/L - pyrèthrine 10 g/L - huile de colza
Numéro d'intrant	013-2016.01
Numéro d'AMM	2190808
Fonction	Insecticide et acaricide
Gamme d'usage	Amateur / emploi autorisé dans les jardins

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active qui arrivera à échéance le plus tôt. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 août 2021.

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

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

Attention : à compter du 01/01/2019, la mise sur marché, la délivrance, l'utilisation et la détention des produits de la gamme d'usages « amateur » sont exclusivement réservées aux utilisateurs professionnels, en application de l'article L. 253-7-III du Code rural et de la pêche maritime, à l'exception des produits de la gamme amateurs inscrits sur la liste des produits de biocontrôle, des produits utilisables en agriculture biologique ou des produits à faible risque. Cette interdiction ne s'applique pas aux traitements et mesures nécessaires à la destruction et à la prévention de la propagation des organismes nuisibles mentionnés à l'article L. 251-3, en application de l'article L. 251-8 du même Code.

A Maisons-Alfort le,

09 DEC. 2019

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)

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ANNEXE I : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	Contenance
Bouteilles en polyéthylène haute densité avec gâchette de pulvérisation.	600 mL ; 650 mL ; 700 mL ; 750 mL ; 800 mL ; 850 mL ; 900 mL ; 950 mL ; 1 L
Bouteilles en polyéthylène téréphthalate avec gâchette de pulvérisation.	600 mL ; 650 mL ; 700 mL ; 750 mL ; 800 mL ; 850 mL ; 900 mL ; 950 mL ; 1 L

Les bidons de 2,1 L à 5 L en polyéthylène haute densité sont refusés car ils ne permettent pas de garantir une exposition minimale de l'utilisateur non professionnel.

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	Mention de danger
- Dangers pour le milieu aquatique - Danger chronique, catégorie 3	H412 : Nocif pour les organismes aquatiques, entraîne des effets néfastes à long terme
EUH208 : Contient de la 1,2-benzisothiazol-3(2H)-one. Peut produire une réaction allergique	
Pour les phrases P se référer à la réglementation en vigueur.	
Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.	



Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
14053107 Arbres et arbustes*Trt Part.Aer.* Acaréens	1 L/10 m ²	2/an	entre avril et septembre	Non applicable	-	-	-	-
Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.								
01002019 Arbres et arbustes*Trt Part.Aer.* Aleurodes	1 L/10 m ²	2/an	entre avril et septembre	Non applicable	-	-	-	-
Uniquement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.								
14053102 Arbres et arbustes*Trt Part.Aer.* Chenilles phytophages	1 L/10 m ²	2/an	entre avril et septembre	Non applicable	-	-	-	-
Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.								
14053101 Arbres et arbustes*Trt Part.Aer.* Cochenilles	1 L/10 m ²	2/an	entre avril et septembre	Non applicable	-	-	-	-
Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.								
00502027 Arbres et arbustes*Trt Part.Aer.* Coléoptères phytophages	1 L/10 m ²	2/an	entre avril et septembre	Non applicable	-	-	-	-
Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.								

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Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
14053105 Arbres et arbustes*Trt Part.Aer.* Pucerons	1 L/10 m ²	2/an	entre avril et septembre	Non applicable	-	-	-
Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.							
14053100 Arbres et arbustes*Trt Part.Aer.* Ravageurs divers	1 L/10 m ²	2/an	entre avril et septembre	Non applicable	-	-	-
Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.							
17403101 Cultures florales et plantes vertes* Trt Part.Aer.* Acaréens, phytoptés et tarsonèmes	1 L/10 m ²	2/an	entre avril et septembre	Non applicable	-	-	-
Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.							
17403102 Cultures florales et plantes vertes* Trt Part.Aer.* Aleurodes	1 L/10 m ²	2/an	entre avril et septembre	Non applicable	-	-	-
Uniquement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.							
17403108 Cultures florales et plantes vertes* Trt Part.Aer.* Chenilles phytophages	1 L/10 m ²	2/an	entre avril et septembre	Non applicable	-	-	-
Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.							

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Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
17403109 Cultures florales et plantes vertes* Trt Part.Aer.* Cicadelles	1 L/10 m ²	2/an	entre avril et septembre	Non applicable	-	-	-
Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.							
17403103 Cultures florales et plantes vertes* Trt Part.Aer.* Cochenilles	1 L/10 m ²	2/an	entre avril et septembre	Non applicable	-	-	-
Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.							
00504036 Cultures florales et plantes vertes* Trt Part.Aer.* Coléoptères phytophages	1 L/10 m ²	2/an	entre avril et septembre	Non applicable	-	-	-
Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.							
17403104 Cultures florales et plantes vertes* Trt Part.Aer.* Pucerons	1 L/10 m ²	2/an	entre avril et septembre	Non applicable	-	-	-
Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.							
17403100 Cultures florales et plantes vertes* Trt Part.Aer.* Ravageurs divers	1 L/10 m ²	2/an	entre avril et septembre	Non applicable	-	-	-
Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.							

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Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitee aquatique (mètres)	Zone Non Traitee arthropodes non cibles (mètres)	Zone Non Traitee plantes non cibles (mètres)	Mention abeilles
00701022 Plantes d'intérieur et balcons* Trt Part.Aer.* Chenilles phytophages	1 L/10 m ²	2/an	entre avril et septembre	Non applicable	-	-	-	-
Intervalle minimum entre les applications : 7 jours.								
00701018 Plantes d'intérieur et balcons* Trt Part.Aer.* Cochenilles	1 L/10 m ²	2/an	entre avril et septembre	Non applicable	-	-	-	-
Intervalle minimum entre les applications : 7 jours.								
00701020 Plantes d'intérieur et balcons* Trt Part.Aer.* Pucerons	1 L/10 m ²	2/an	entre avril et septembre	Non applicable	-	-	-	-
Intervalle minimum entre les applications : 7 jours.								
17453100 Plantes d'intérieur et balcons* Trt Part.Aer.* Ravageurs divers	1 L/10 m ²	2/an	entre avril et septembre	Non applicable	-	-	-	-
Intervalle minimum entre les applications : 7 jours.								
17303101 Rosier*Trt Part.Aer.* Acaricidés	1 L/10 m ²	2/an	entre avril et septembre	Non applicable	-	-	-	-
Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.								

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Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
17303105 Rosier*Trt Part.Aer.* Chenilles phytophages	1 L/10 m ²	2/an	entre avril et septembre	Non applicable	-	-	-	-
Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.								
17303118 Rosier*Trt Part.Aer.* Cochenilles	1 L/10 m ²	2/an	entre avril et septembre	Non applicable	-	-	-	-
Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.								
17303108 Rosier*Trt Part.Aer.* Pucerons	1 L/10 m ²	2/an	entre avril et septembre	Non applicable	-	-	-	-
Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.								

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Conditions d'emploi du produit

Stockage et manipulation du produit

- Ne pas stocker le produit dans un local où la température peut dépasser 40°C.

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

- Attendre le séchage complet de la zone traitée.

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

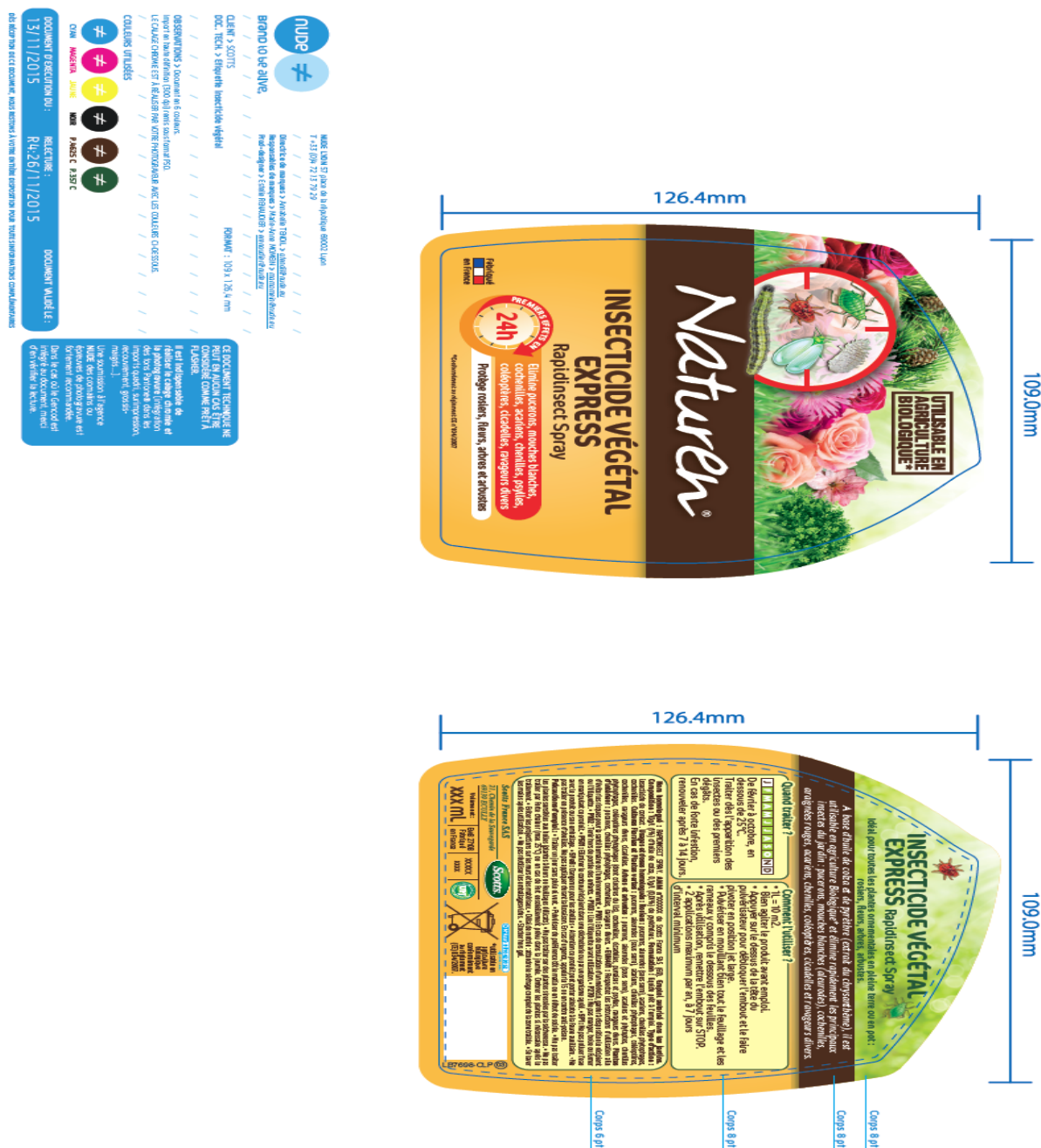
Protection de l'eau

- Ne pas rejeter dans l'évier, le caniveau ou tout autre point d'eau les fonds de bidon non utilisés.

Protection de la faune

- Ne pas appliquer en présence d'insectes pollinisateurs (abeilles, bourdons ...) ou d'auxiliaires (coccinelles).

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



Appendix 3 – Letter(s) of Access

Provided upon request.