

## **REGISTRATION REPORT**

### **Part A**

### **Risk Management**

**Product code: NLS 484A**

**Product name: RAPIDINSECT**

**Active substances:**

**rape seed oil, 700 g/L**

**pyrethrins, 7 g/L**

**COUNTRY: FRANCE**

**Southern Zone**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(marketing authorisation)**

**Applicant: SCOTTS France SAS**

**Date: 23/04/2018**

## Table of Contents

<b>1</b>	<b>DETAILS OF THE APPLICATION.....</b>	<b>3</b>
1.1	APPLICATION BACKGROUND.....	3
1.2	ACTIVE SUBSTANCE APPROVAL.....	3
1.3	REGULATORY APPROACH.....	5
1.4	DATA PROTECTION CLAIMS.....	6
1.5	LETTER(S) OF ACCESS.....	6
<b>2</b>	<b>DETAILS OF THE AUTHORISATION.....</b>	<b>6</b>
2.1	PRODUCT IDENTITY.....	6
2.2	CLASSIFICATION AND LABELLING.....	6
2.2.1	<i>Classification and labelling under Directive 99/45/EC.....</i>	<i>6</i>
2.2.2	<i>Classification and labelling in accordance with Regulation (EC) No1272/2008.....</i>	<i>6</i>
2.2.3	<i>Other phrases in compliance with Regulation (EU) No 547/2011.....</i>	<i>7</i>
2.2.4	<i>Other phrases linked to the preparation.....</i>	<i>7</i>
2.3	PRODUCT USES.....	8
<b>3</b>	<b>RISK MANAGEMENT.....</b>	<b>13</b>
3.1	REASONED STATEMENT OF THE OVERALL CONCLUSIONS TAKEN IN ACCORDANCE WITH THE UNIFORM PRINCIPLES.....	13
3.1.1	<i>Physical and chemical properties.....</i>	<i>13</i>
3.1.2	<i>Methods of analysis.....</i>	<i>13</i>
3.1.3	<i>Mammalian Toxicology.....</i>	<i>13</i>
	RAPIDINSECT (NLS 484A) IS INTENDED TO BE USED BY NON-PROFESSIONAL USERS DURING HOME GARDEN APPLICATION.....	15
3.1.4	<i>Residues and Consumer Exposure.....</i>	<i>15</i>
3.1.5	<i>Environmental fate and behaviour.....</i>	<i>15</i>
3.1.6	<i>Ecotoxicology.....</i>	<i>16</i>
3.1.7	<i>Efficacy.....</i>	<i>16</i>
3.2	CONCLUSIONS ARISING FROM FRENCH ASSESSMENT.....	16
3.3	SUBSTANCES OF CONCERN FOR NATIONAL MONITORING.....	16
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.....	16
3.4.1	<i>Post-authorisation monitoring.....</i>	<i>16</i>
3.4.2	<i>Label amendments.....</i>	<i>16</i>
	<b>APPENDIX 1 – COPY OF THE FRENCH DECISION.....</b>	<b>17</b>
	<b>APPENDIX 2 – COPY OF THE DRAFT PRODUCT LABEL AS PROPOSED BY THE APPLICANT.....</b>	<b>26</b>
	<b>APPENDIX 3 – LETTER(S) OF ACCESS.....</b>	<b>31</b>

## PART A – Risk Management

The company SCOTTS France SAS has requested marketing authorisation in France for the product RAPIDINSECT (formulation code: NLS 484A), containing 700 g/L rapeseed oil and 7 g/L pyrethrins 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 (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 rape seed oil and pyrethrins.

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 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 SCOTTS 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 first authorisation of this product in France and in other MSs of the Southern zone. The application also encompassed a specific request for home garden (non-professional) use.

### 1.2 Active substance approval

#### Rape seed oil

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]).

### **Pyrethrins**

Commission Implementing Regulation (EU) No 798/2013 of 21 August 2013 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance pyrethrins.

#### **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.

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 I”<sup>1</sup> 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]).

<sup>1</sup> 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.

### 1.3 Regulatory approach

The present application (2014-1780) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)<sup>2</sup> in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses (“risk envelope approach”)<sup>3</sup> – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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

- The French Order of 4 May 2017<sup>4</sup> provides that:
- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight hours for indoor uses.

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

The current document (RR) based on Anses’s assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009<sup>5</sup>, implementing regulations and French regulations.

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

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011<sup>6</sup>, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014<sup>7</sup> provides that:

- an authorisation granted for a “reference” crop applies also for “linked” crops, unless formally stated in the Decision
- the “reference” and “linked” crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “linked” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those “linked” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation<sup>8</sup> is to supply “minor” crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

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

<sup>2</sup> French Food Safety Agency, Afssa, before 1 July 2010

<sup>3</sup> SANCO document “risk envelope approach”, European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the “risk envelope approach”; SANCO/11244/2011 rev. 5

<sup>4</sup> <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRGI632554A/jo/texte>

<sup>5</sup> REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

<sup>6</sup> COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

<sup>7</sup> <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRGI407093A/jo>

<sup>8</sup> SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

## 1.4 Data protection claims

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

## 1.5 Letter(s) of Access

The applicant has provided the supporting data in Document K; the ownership of the data is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7. A copy of the letter(s) of access is reproduced in Part A, Appendix 3.

## 2 DETAILS OF THE AUTHORISATION

### 2.1 Product identity


<b>Product name (code)</b>	RAPIDINSECT (NLS 484A)
<b>Authorisation number</b>	2171312
<b>Function</b>	Insecticide (Home and Garden).
<b>Applicant</b>	SCOTT'S France SAS
<b>Composition</b>	700 g/L rape seed oil 7 g/L pyrethrins
<b>Formulation type (code)</b>	Emulsifiable concentrate (EC)
<b>Packaging</b>	Bottles polyethylene terephthalate (PET) 7 mL ; 14 mL

### 2.2 Classification and labelling

#### 2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

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

<b>Physical hazards</b>	-	
<b>Health hazards</b>	-	
<b>Environmental hazards</b>	Hazardous to the aquatic environment, Chronic Hazard, Category 1	
<b>Hazard pictograms</b>		
<b>Signal word</b>	Warning	
<b>Hazard statements</b>	H410	Very toxic to aquatic life with long-lasting effects.
<b>Precautionary statements –</b>	<i>For the P phrases, refer to the extant legislation</i>	

<b>Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)</b>	-	-
--	---	---

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

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

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

	Do not discharge into the sink, gutter or any other water hole the non-used container leftovers and the sprayer washing water.
	Do not apply when bees and beneficial organisms are present.
	Harmful for earthworms and other soil organisms.
	The formulation must be protected from freezing

### 2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment: refer to the Decision in Appendix 1 for the details
Re-entry period: wait for complete drying of treated area
Pre-harvest interval: Not applicable
Other mitigation measures: -
The label may include the following recommendations: -
The label must reflect the conditions of authorisation.

## 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/(NLS484A)**  
active substance 1 **rape seed oil**  
active substance 2 **pyrethrins**

GAP rev, date : 2018-04-23  
Formulation type: **emulsifiable concentrate (EC)**  
Conc. of a.s. 1: **700 g/L**  
Conc. of a.s. 2: **7 g/L**

Applicant: **SCOTTS France SAS**  
Zone(s): **southern EU**  
Verified by MS: **yes**

professional use ☐  
non-professional use ☒

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
1	France	All Ornamental flowers and shrubs	G <sub>n</sub>	Aphids (examples: Macrosiphum rosae 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) 7 L product/ ha b) 14 L product / ha	a) Pyrethrins 0.049 kg/ha Rape seed oil 4.9 kg/ha b) Pyrethrins 0.098 kg/ha Rape seed oil 9.8 kg/ha	Min 600 L/ha (low height crops)  Max 1000 L/ha (roses and other crops)	n.a.	Home and garden use  <b>acceptable</b>
2	France	All Ornamental flowers and shrubs	G <sub>n</sub>	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) 7 L product/ ha b) 14 L product / ha	a) Pyrethrins 0.049 kg/ha Rape seed oil 4.9 kg/ha b) Pyrethrins 0.098 kg/ha Rape seed oil 9.8 kg/ha	Min 600 L/ha (low height crops)  Max 1000 L/ha (roses and other crops)	n.a.	Home and garden use  <b>acceptable</b>



1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
3	France	All Ornamental flowers and shrubs	G <sub>n</sub>	Caterpillars (example: <i>Pieris sp.</i> 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) Pyrethrins 0.049 kg/ha Rape seed oil 4.9 kg/ha b) Pyrethrins 0.098 kg/ha Rape seed oil 9.8 kg/ha	Min 600 L/ha (low height crops) Max 1000 L/ha (roses and other crops)	n.a.	Home and garden use  <b>acceptable</b>
4	France	All Ornamental flowers and shrubs	G <sub>n</sub>	Leaf beetles (example: <i>Lilioceris lili</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) 7 L product/ ha b) 14 L product / ha	a) Pyrethrins 0.049 kg/ha Rape seed oil 4.9 kg/ha b) Pyrethrins 0.098 kg/ha Rape seed oil 9.8 kg/ha	Min 600 L/ha (low height crops) Max 1000 L/ha (roses and other crops)	n.a.	Home and garden use  <b>acceptable</b>
5	France	All Ornamental flowers and shrubs	G <sub>n</sub>	Scale insects (example <i>Coccus hesperidum</i> COCCHÉ)  Mealybugs (example <i>Pseudococcus sp.</i> 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) Pyrethrins 0.049 kg/ha Rape seed oil 4.9 kg/ha b) Pyrethrins 0.098 kg/ha Rape seed oil 9.8 kg/ha	Min 600 L/ha (low height crops) Max 1000 L/ha (roses and other crops)	n.a.	Home and garden use  <b>acceptable</b>

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
6	France	All Ornamental flowers and shrubs	G <sub>n</sub>	Leaf miners (example <i>Plutella xylostella</i> 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) Pyrethrins 0.049 kg/ha Rape seed oil 4.9 kg/ha b) Pyrethrins 0.098 kg/ha Rape seed oil 9.8 kg/ha	Min 600 L/ha (low height crops) Max 1000 L/ha (roses and other crops)	n.a.	Home and garden use <b>acceptable</b>
7	France	All Ornamental flowers and shrubs	G <sub>n</sub>	Stink bugs (example <i>Eurydema sp.</i> 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) Pyrethrins 0.049 kg/ha Rape seed oil 4.9 kg/ha b) Pyrethrins 0.098 kg/ha Rape seed oil 9.8 kg/ha	Min 600 L/ha (low height crops) Max 1000 L/ha (roses and other crops)	n.a.	Home and garden use <b>acceptable</b>
8	France	All Ornamental flowers and shrubs	G <sub>n</sub>	Flea beetles (example <i>Epitrix intermedia</i> 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) Pyrethrins 0.049 kg/ha Rape seed oil 4.9 kg/ha b) Pyrethrins 0.098 kg/ha Rape seed oil 9.8 kg/ha	Min 600 L/ha (low height crops) Max 1000 L/ha (roses and other crops)	n.a.	Home and garden use <b>acceptable</b>

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
9	France	All Ornamental flowers and shrubs	G <sub>n</sub>	Leafhopper (example <i>Typhlocyba pomaria</i> 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) Pyrethrins 0.049 kg/ha Rape seed oil 4.9 kg/ha b) Pyrethrins 0.098 kg/ha Rape seed oil 9.8 kg/ha	Min 600 L/ha (low height crops) Max 1000 L/ha (roses and other crops)	n.a.	Home and garden use <b>acceptable</b>
10	France	All Ornamental flowers and shrubs	G <sub>n</sub>	Whitefly (example. <i>Trialeurodes</i> <i>vaporariorum</i> 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) 14 L product/ ha b) 28 L product / ha	a) Pyrethrins 0.098 kg/ha Rape seed oil 9.8 kg/ha b) Pyrethrins 0.196 kg/ha Rape seed oil 19.6 kg/ha	Min 600 L/ha (low height crops) Max 1000 L/ha (roses and other crops)	n.a.	Home and garden use <b>acceptable</b>

**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 authorization possible for uses where the line is highlighted in grey, Use should be crossed  
 out when the notifier no longer supports this use.

<b>Remarks columns:</b>	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m <sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	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 (NLS 484A) is an emulsifiable concentrate formulation (EC). 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 a clear, yellow liquid, with a resinous odour. It is not explosive and has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 405 °C. In aqueous solution (1 % dilution), it has a pH value of 6.23 at room temperature. There is an effect of low temperature on the stability of the formulation, since after seven days at 0°C, the technical properties were changed. There is no effect of high temperature 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 shelf life of at least two years at ambient temperature when stored in PET packaging. The technical characteristics are acceptable for an EC formulation.

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

The formulation must be protected from freezing.

##### 3.1.2 Methods of analysis

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

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

###### 3.1.2.2 Analytical methods for residues

Analytical methods for the determination of residues of pyrethrins and rape seed 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.

Other data gaps in EFSA conclusion:

According to EFSA conclusions, methods of analysis for soil, water and air are missing for the active substance pyrethrins.

##### 3.1.3 Mammalian Toxicology

###### Endpoints used in risk assessment

Active substance: <b>pyrethrins</b>			
ADI	0.04 mg kg bw/d		Efsa (2013)
ARfD	0.2 mg/kg bw		
AOEL	0.07 mg/kg bw/d		
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (used in formulation) 7 g/L	Spray dilution (used in formulation) 0.05 - 0.17 g/L
	<b>Dermal absorption endpoints %</b>	<b>75%</b>	<b>75%</b>
Active substance: <b>rape seed oil</b>			
ADI	Not applicable		Efsa (2012)
ARfD	Not applicable		
AOEL	Not applicable		
Dermal absorption	Not needed		

### 3.1.3.1 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.

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	none
Hazard pictograms:	none
Signal word:	none
Hazard statement(s):	none
Precautionary statement(s):	<b><i>For the P phrases, refer to the extant legislation</i></b>

Special rule for labelling of plant protection product (PPP):

Re-entry period: wait for complete drying of the treated area

The proposed packaging has been described in sufficient detail.

The measuring spoon is too small to ensure a minimal exposure of amateur gardener: risk of spill when one operation is needed for the lowest dose. Moreover, many operations are needed for the highest dose.

In summary, lack of compliance with the provisions of French Decree No. 2010-1755 of 30 December 2010<sup>9</sup> and Orders of 30 December 2010 relating to the use of certain plant protection products by non-professional users<sup>10</sup> is considered as non-compliant.

### 3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G <sup>11</sup>	Equipment	Application rate ml product/10 m <sup>2</sup> (g a.s./10 m <sup>2</sup> )	Spray dilution (L/m <sup>2</sup> )	Model
Ornamentals (roses, flowers, trees, shrubs)	F and G	Pre-pressurised sprayer	14 mL/10 m <sup>2</sup> (98 g pyrethrins/10m <sup>2</sup> )	0.6-1	French garden studies (UPJ, 2005 <sup>12</sup> )

Considering proposed uses, operator systemic exposure was estimated using the French 2005 study dedicated to non-professional use:

Crop	Equipment	PPE and/or working coverall	% AOEL pyrethrins (0.07 mg/kg bw/d)
Rosebush-like plants	Pre-pressurised sprayer	no PPE	38
Flower beds, vegetable crop (< 60 cm)			38
Hedges and tall crops (> 60 cm)			38

<sup>9</sup> Décret n° 2010-1755 du 30 décembre 2010 relatif à la cession des produits phytopharmaceutiques aux utilisateurs non professionnels et aux conditions de vente et d'emploi de ces produits

<sup>10</sup> Arrêté du 30 décembre 2010 relatif aux conditions d'emballage des produits phytopharmaceutiques pouvant être employés par des utilisateurs non professionnels and Arrêté du 30 décembre 2010 interdisant l'emploi de certains produits phytopharmaceutiques par des utilisateurs non professionnels

<sup>11</sup> Open air or glasshouse

<sup>12</sup> Studies submitted by the Union des entreprises pour la Protection des Jardins et des espaces verts (UPJ, the French trade association for garden/amenity pesticide manufacturers) in 2005, to allow assessment of the exposure of home gardeners

According to the model calculations, it may be concluded that the risk for the operator using RAPIDINSECT (NLS 484A) is acceptable without PPE.

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

### **3.1.3.3 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 (user).

### **Resident Exposure**

Residential exposure was assessed according to BREAM model. Exposure is estimated to be 39 % of the AOEL of pyrethrins (based on modelled calculations for children playing on a freshly treated lawn).

It may be concluded that there is no unacceptable risk to the resident exposed to RAPIDINSECT (NLS 484A).

### **3.1.3.4 Worker Exposure**

RAPIDINSECT (NLS 484A) is intended to be used by non-professional users during home garden application.

In this case of non-professional users, 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.

### **3.1.4 Residues and Consumer Exposure**

As the product is for use on non-edible ornamental plants, no consumer exposure is anticipated.

### **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.

The evaluation performed takes into account the specificity of the intended uses (non-professional use, home and garden).

For uses under protection (greenhouses), only exposure of the surface water compartment was taken into account. For open air uses, exposure of the groundwater and surface water compartments were taken into account. The PEC values of rape seed oil, pyrethrin I 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 considering scenarios specific to home and garden uses. PEC<sub>sw</sub> values derived for the active substances and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed. PEC<sub>gw</sub> values for rape seed oil and its metabolites and for pyrethrin I do not occur at levels exceeding those mentioned in Regulation EC 1107/2009 and guidance document SANCO 221/2000 on the relevance of metabolites in groundwater.

However, in the absence of estimated exposure to the other pyrethrin compounds (cinerin I, jasmolin I, pyrethrin II, cinerin II and jasmolin II) and given that a complete elucidation of pyrethrins' fate in soil is unavailable, the evaluation of the risk of groundwater contamination cannot be finalised.

According to RMS Italy, confirmatory data assessed in the DAR Addendum of July 2016 demonstrate that pyrethrin I is representative with respect to the environmental assessment of all the pyrethrin components. However, for pyrethrin I, studies are available with material labelled in 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 the first degradation step). Despite the RMS's request, this data gap has not been addressed in the current submission.

**Therefore in agreement with EFSA conclusions, the zRMS (France) considers that the environmental risk assessment cannot be finalised based on the available data, except for indoor and balcony plants (negligible exposure of the environmental compartments).**

### 3.1.6 Ecotoxicology

For home and garden uses, only bird and aquatic assessment is considered relevant for the ecotoxicological evaluation. The risk to birds is considered acceptable for the intended uses. For aquatic organisms, since the surface water exposure assessment has not been finalised (as above), it is not possible to finalise the risk assessment for aquatic organisms from pyrethrins and their metabolites and for the preparation RAPIDINSECT (NLS 484A).

Since no further data are available for pyrethrins and rape seed oil to refine the risk to aquatic organisms, it is considered that the assessment cannot be finalised.

For applications on indoor and balcony plants (negligible exposure of the environmental compartments), no risk assessment is needed, therefore, the risk is considered acceptable.

### 3.1.7 Efficacy

Considering the data submitted:

- ✓ The efficacy of RAPIDINSECT (NLS 484A) is considered satisfactory for the requested uses.
- ✓ The level of phytotoxicity of RAPIDINSECT (NLS 484A) is considered acceptable.
- ✓ The risk of negative impact on succeeding and adjacent crops is considered acceptable.
- ✓ The risk of pathogens developing resistance to rape seed oil and pyrethrins is considered to be low for the requested uses.

## 3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation can be granted. A copy of the decision issued can be found in Appendix 1 – Copy of the product Decision.

## 3.3 Substances of concern for national monitoring

No information stated.

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

### 3.4.1 Post-authorisation monitoring

No further information is required.

### 3.4.2 Label amendments

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

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



## Appendix 1 – Copy of the French Decision



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

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

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

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

*de la société SCOTTS FRANCE SAS*

*enregistrée sous le n°2014-1780*

*Vu les conclusions de l'évaluation de l'Anses du 13 décembre 2017,*

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

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

#### Avertissement :

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



Informations générales sur le produit	
Nom du produit	RAPIDINSECT
Type de produit	Produit de référence
Titulaire	SCOTTS FRANCE SAS 21, chemin de la Sauvegarde 69134 ECULLY CEDEX France
Formulation	Concentré émulsionnable (EC)
Contenant	7 g/L - pyréthrinés 700 g/L - huile de colza
Numéro d'intrant	731-2014.01
Numéro d'AMM	2171312
Fonction	Insecticide
Gamme d'usages	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.

A Maisons-Alfort, le 23 AVR. 2018

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



## ANNEXE I : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	Contenance
Bouteilles unidoses en polyéthylène téréphtalate	7 mL ; 14 mL

Les emballages bouteilles en polyéthylène téréphtalate de 100 mL, 200 mL et 500 mL proposées sont refusés car ils ne permettent pas de garantir des conditions d'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 1	H410 : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme
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 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 arthropodes non cibles (mètres)	Zone Non Traitee plantes non cibles (mètres)	Mention abeilles	
14053107 Arbres et arbustes*Trt Part.Aer.*Acaréens	7 mL/L	2/an	-	Non applicable	-	-	-	
	Intervalle minimum entre les applications : 7 jours. Uniquement sous abri. Non autorisé en plein champ car des risques inacceptables, de contamination des eaux souterraines et pour les organismes aquatiques ne peuvent être exclus.							
01002019 Arbres et arbustes*Trt Part.Aer.*Aleurodes	14 mL/L	2/an	-	Non applicable	-	-	-	
	Intervalle minimum entre les applications : 7 jours. Uniquement sous abri.							
14053102 Arbres et arbustes*Trt Part.Aer.*Chenilles phytophages	7 mL/L	2/an	-	Non applicable	-	-	-	
	Intervalle minimum entre les applications : 7 jours. Uniquement sous abri. Non autorisé en plein champ car des risques inacceptables, de contamination des eaux souterraines et pour les organismes aquatiques ne peuvent être exclus.							
00502025 Arbres et arbustes*Trt Part.Aer.*Cicadelles et cercopides	7 mL/L	2/an	-	Non applicable	-	-	-	
	Intervalle minimum entre les applications : 7 jours. Uniquement sous abri. Non autorisé en plein champ car des risques inacceptables, de contamination des eaux souterraines et pour les organismes aquatiques ne peuvent être exclus.							
14053101 Arbres et arbustes*Trt Part.Aer.*Cochenilles	7 mL/L	2/an	-	Non applicable	-	-	-	
	Intervalle minimum entre les applications : 7 jours. Uniquement sous abri. Non autorisé en plein champ car des risques inacceptables, de contamination des eaux souterraines et pour les organismes aquatiques ne peuvent être exclus.							

RAPIDINSECT  
AMM n°2171312

Page 4 sur 9





### Liste des usages autorisés

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
<b>00502027</b> Arbres et arbustes*Trt Part.Aer.*Coléoptères phytophages	7 mL/L	2/an	-	Non applicable	-	-	-	-
	Intervalle minimum entre les applications : 7 jours. Uniquement sous abri. Non autorisé en plein champ car des risques inacceptables, de contamination des eaux souterraines et pour les organismes aquatiques ne peuvent être exclus.							
<b>14053105</b> Arbres et arbustes*Trt Part.Aer.*Pucerons	7 mL/L	2/an	-	Non applicable	-	-	-	-
	Intervalle minimum entre les applications : 7 jours. Uniquement sous abri. Non autorisé en plein champ car des risques inacceptables, de contamination des eaux souterraines et pour les organismes aquatiques ne peuvent être exclus.							
<b>14053100</b> Arbres et arbustes*Trt Part.Aer.*Ravageurs divers (1)	7 mL/L	2/an	-	Non applicable	-	-	-	-
	Intervalle minimum entre les applications : 7 jours. Uniquement sous abri. Non autorisé en plein champ car des risques inacceptables, de contamination des eaux souterraines et pour les organismes aquatiques ne peuvent être exclus.							
<b>17403101</b> Cultures florales et plantes vertes*Trt Part.Aer.*Acariens	7 mL/L	2/an	-	Non applicable	-	-	-	-
	Intervalle minimum entre les applications : 7 jours. Uniquement sous abri. Non autorisé en plein champ car des risques inacceptables, de contamination des eaux souterraines et pour les organismes aquatiques ne peuvent être exclus.							
<b>17403102</b> Cultures florales et plantes vertes*Trt Part.Aer.*Aleurodes	14 mL/L	2/an	-	Non applicable	-	-	-	-
	Intervalle minimum entre les applications : 7 jours. Uniquement sous abri.							

RAPIDINSECT  
AMM n°2171312

Page 5 sur 9



### Liste des usages autorisés

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
<b>17403108</b> Cultures florales et plantes vertes*Trt Part.Aer.*Chenilles phytophages	7 mL/L Intervalle minimum entre les applications : 7 jours. Uniquement sous abri. Non autorisé en plein champ car des risques inacceptables, de contamination des eaux souterraines et pour les organismes aquatiques ne peuvent être exclus.	2/an	-	Non applicable	-	-	-	-
<b>17403109</b> Cultures florales et plantes vertes*Trt Part.Aer.*Cicadelles	7 mL/L Intervalle minimum entre les applications : 7 jours. Uniquement sous abri. Non autorisé en plein champ car des risques inacceptables, de contamination des eaux souterraines et pour les organismes aquatiques ne peuvent être exclus.	2/an	-	Non applicable	-	-	-	-
<b>17403103</b> Cultures florales et plantes vertes*Trt Part.Aer.*Cochenilles	7 mL/L Intervalle minimum entre les applications : 7 jours. Uniquement sous abri. Non autorisé en plein champ car des risques inacceptables, de contamination des eaux souterraines et pour les organismes aquatiques ne peuvent être exclus.	2/an	-	Non applicable	-	-	-	-
<b>00504036</b> Cultures florales et plantes vertes*Trt Part.Aer.*Coléoptères phytophages	7 mL/L Intervalle minimum entre les applications : 7 jours. Uniquement sous abri. Non autorisé en plein champ car des risques inacceptables, de contamination des eaux souterraines et pour les organismes aquatiques ne peuvent être exclus.	2/an	-	Non applicable	-	-	-	-
<b>17403104</b> Cultures florales et plantes vertes*Trt Part.Aer.*Pucerons	7 mL/L Intervalle minimum entre les applications : 7 jours. Uniquement sous abri. Non autorisé en plein champ car des risques inacceptables, de contamination des eaux souterraines et pour les organismes aquatiques ne peuvent être exclus.	2/an	-	Non applicable	-	-	-	-

RAPIDINSECT  
AMM n°2171312

Page 6 sur 9



### Liste des usages autorisés

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitee arthropodes non cibles (mètres)	Zone Non Traitee plantes non cibles (mètres)	Mention abeilles
<b>17403100</b> Cultures florales et plantes vertes*Trt Part.Aer.*Ravageurs divers (1)	7 mL/L Intervalle minimum entre les applications : 7 jours. Uniquement sous abri. Non autorisé en plein champ car des risques inacceptables, de contamination des eaux souterraines et pour les organismes aquatiques ne peuvent être exclus.	2/an	-	Non applicable	-	-	-
<b>00701022</b> Plantes d'intérieur et balcons*Trt Part.Aer.*Chenilles phytophages	7 mL/L Intervalle minimum entre les applications : 7 jours.	2/an	-	Non applicable	-	-	-
<b>00701018</b> Plantes d'intérieur et balcons*Trt Part.Aer.*Cochenilles	7 mL/L Intervalle minimum entre les applications : 7 jours.	2/an	-	Non applicable	-	-	-
<b>00701020</b> Plantes d'intérieur et balcons*Trt Part.Aer.*Pucerons	7 mL/L Intervalle minimum entre les applications : 7 jours.	2/an	-	Non applicable	-	-	-
<b>17453100</b> Plantes d'intérieur et balcons*Trt Part.Aer.*Ravageurs divers (1)	7 mL/L Intervalle minimum entre les applications : 7 jours.	2/an	-	Non applicable	-	-	-
<b>17303101</b> Rosier*Trt Part.Aer.*Acariens	7 mL/L Intervalle minimum entre les applications : 7 jours. Uniquement sous abri. Non autorisé en plein champ car des risques inacceptables, de contamination des eaux souterraines et pour les organismes aquatiques ne peuvent être exclus.	2/an	-	Non applicable	-	-	-

RAPIDINSECT  
AMM n°2171312





Liste des usages autorisés									
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.									
Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitee aquatique (mètres)	Zone Non Traitee arthropodes non cibles (mètres)	Zone Non Traitee plantes non cibles (mètres)	Mention abeilles	
17303117 Rosier*Trt Part.Aer.*Aleurodes	14 mL/L	2/an	-	Non applicable	-	-	-	-	
	Intervalle minimum entre les applications : 7 jours. Uniquement sous abri.								
17303105 Rosier*Trt Part.Aer.*Chenilles phytophages	7 mL/L	2/an	-	Non applicable	-	-	-	-	
	Intervalle minimum entre les applications : 7 jours. Uniquement sous abri. Non autorisé en plein champ car des risques inacceptables, de contamination des eaux souterraines et pour les organismes aquatiques ne peuvent être exclus.								
17303118 Rosier*Trt Part.Aer.*Cochenilles	7 mL/L	2/an	-	Non applicable	-	-	-	-	
	Intervalle minimum entre les applications : 7 jours. Uniquement sous abri. Non autorisé en plein champ car des risques inacceptables, de contamination des eaux souterraines et pour les organismes aquatiques ne peuvent être exclus.								
17303108 Rosier*Trt Part.Aer.*Pucerons	7 mL/L	2/an	-	Non applicable	-	-	-	-	
	Intervalle minimum entre les applications : 7 jours. Uniquement sous abri. Non autorisé en plein champ car des risques inacceptables, de contamination des eaux souterraines et pour les organismes aquatiques ne peuvent être exclus.								

RAPIDINSECT  
AMM n°2171312

Page 8 sur 9





## Conditions d'emploi du produit

### Stockage et manipulation du produit

- Ne pas stocker dans un local où la température peut descendre en dessous de 0°C.

### **Délai de rentrée:**

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 et les eaux de lavage du pulvérisateur.

#### **Protection de la faune**

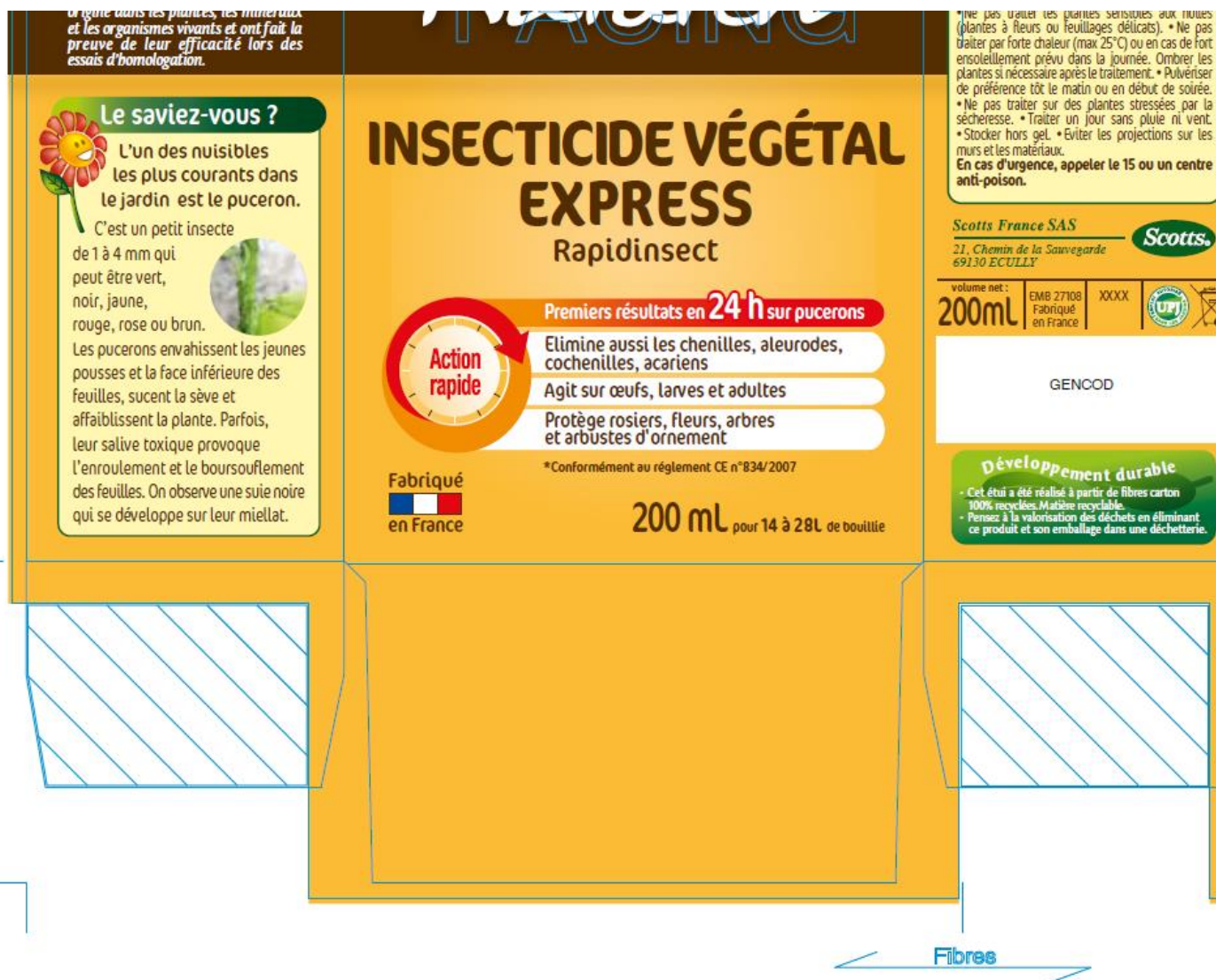
- Dangereux pour les vers de terre et les autres macro-organismes du sol.
- Ne pas appliquer en présence d'insectes pollinisateurs et/ou auxiliaires (abeilles, bourdons, coccinelles, ...).

---

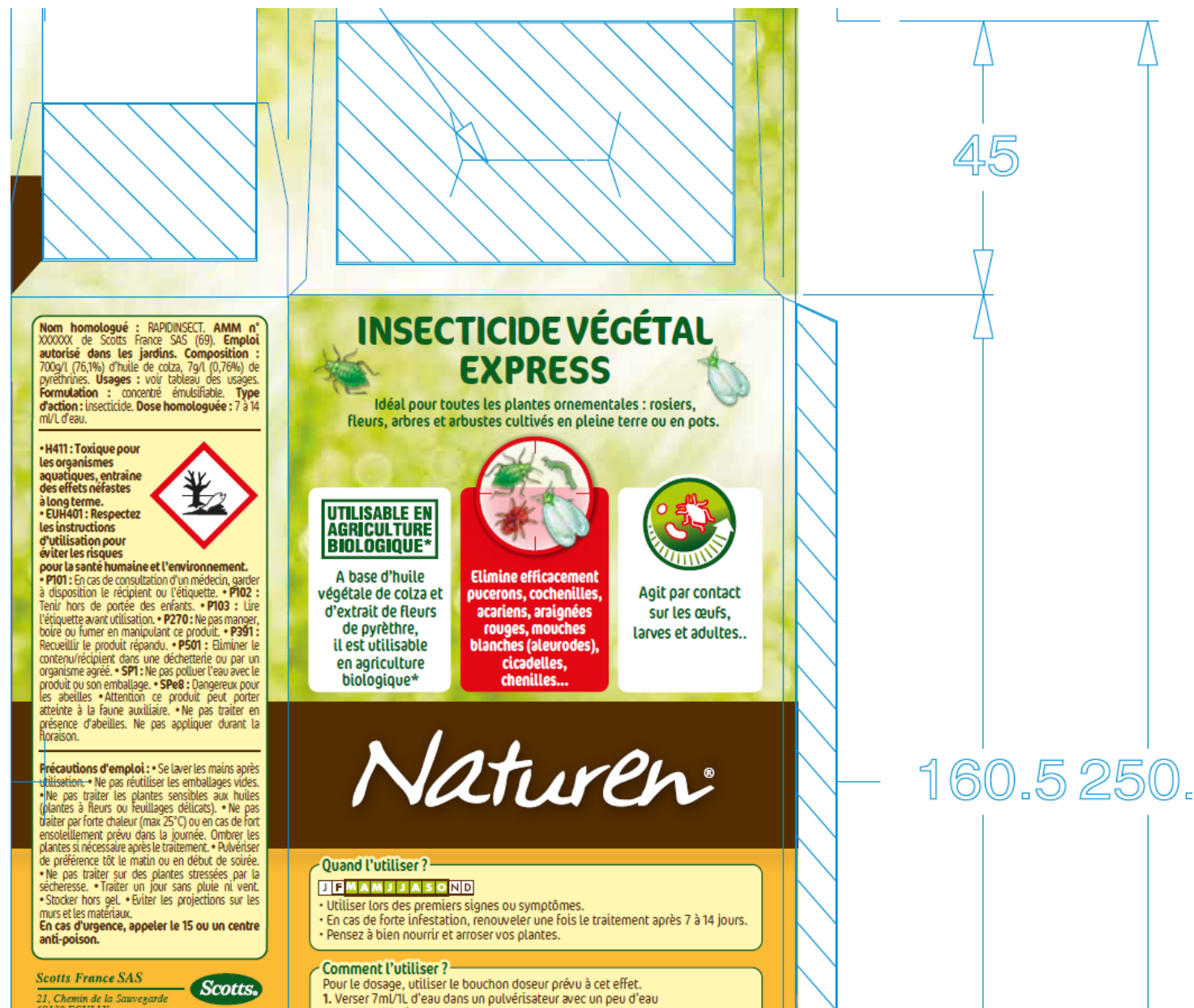
**Appendix 2 – Copy of the draft product label as proposed by the applicant**

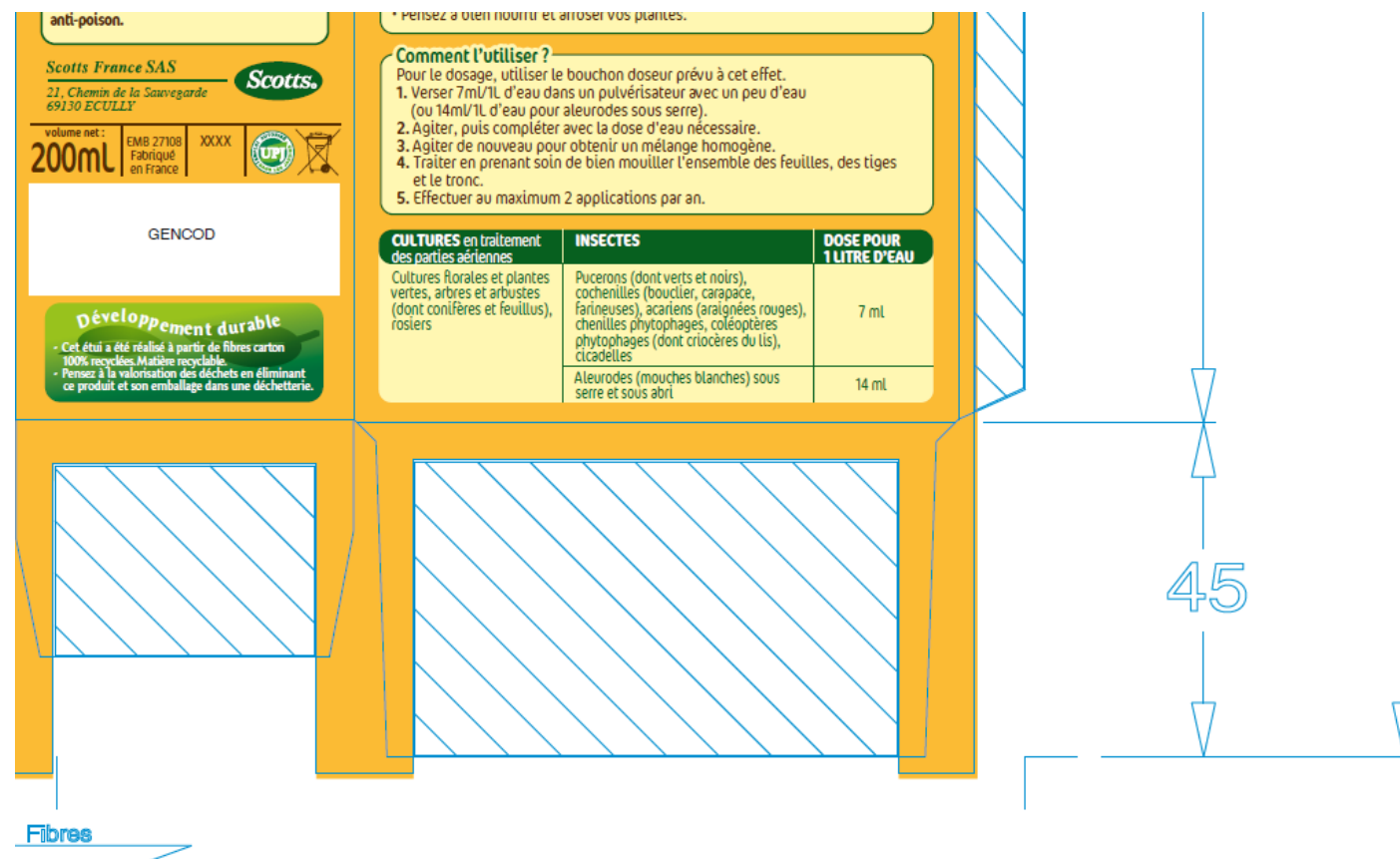
Réf. document « Projet d'étiquette », 20/06/2014












### Appendix 3 – Letter(s) of Access

(a) Rape seed oil

NB. The following is a letter of supply rather than a letter of access.

<b>O. &amp; L. SELS · NEUSS</b> GMBH & CO. KOMMANDITGESELLSCHAFT		
Düsseldorfer Str. 99 · 41460 Neuss · Telefon 02131/2799-0		<b>SPEISEÖLE FUTTERMITTEL</b>
<small>O. &amp; L. Sels GmbH &amp; Co. KG, Postfach 101348, 41413 Neuss</small>		<b>Fax</b> 02131-
Scotts France SAS 21 chemin de la Sauvegarde 69134 Ecully cedex France		Zentrale/Versand/Raps 27 54 32 GF/Vertrieb 27 99 66 QM 27 99 50 Einkauf Technik 27 34 79 Buchhaltung 56 11 30
Neuss, 24.04.2012		
<b>Rapindinsect (product code: NLS484A)</b> for using in France		
Dear Sir or Madam,		
Ölmühle O. & L. SELS GmbH & CO. KG, Düsseldorfer Straße 99-101, D-41460 Neuss, Germany, hereby certifies, that we supply the company Scotts France SAS, 21 chemin de la Sauvegarde, 69134 Ecully cedex, France, with rapeseed oil for the preparation of the product Rapindinsect (product code: NLS484A).		
Kind regards,		
 O. & L. SELS GmbH & Co. Kommanditgesellschaft Düsseldorfer Str. 99-101 41460 Neuss		
Sparkasse Neuss 150 126 BLZ 305 500 00 HVB 363 747 175 BLZ 300 201 86	Bankhaus Lampe 1 541 560 BLZ 480 201 51 Commerzbank 7 802 531 BLZ 300 400 00	Deutsche Bank 9 105 750 BLZ 300 700 10 HSBC Trinkaus & Burkhardt 10 348 005 BLZ 300 308 80
<small>USt.-IdNr.: DE 196695577 - HRB 2480 Neuss - Geschäftsführer: Jürgen Sels, Dr. G. H. Sels</small>		

*Confirmation of equivalence of the O. & L. SELS Oil Mill's source with the source of rape seed oil recognised at EU level.*

  
*Liberté • Égalité • Fraternité*  
**RÉPUBLIQUE FRANÇAISE**

MINISTÈRE DE L'ALIMENTATION, DE L'AGRICULTURE ET DE LA PÊCHE

**Direction Générale de l'Alimentation**

**Sous-Direction de la Qualité et de la Protection des Végétaux**

**Bureau de la Réglementation et de la Mise sur le Marché des Intrants**

Adresse : 251, rue de Vaugirard  
75 732 PARIS CEDEX 15  
Dossier suivi par : Sophie Simon  
sophie.simon@agriculture.gouv.fr  
Tél. : 01 49 55 45 94 Fax : 01 49 55 59 49

**SCOTTS FRANCE SAS**  
**21 CHEMIN DE LA SAUVEGARDE**  
**69134 ECULLY CEDEX**  
**FRANCE**

Réf : Paris, le **14 JUIN 2010**

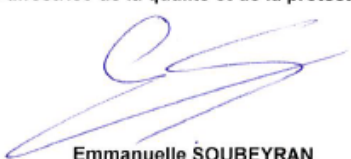
**Objet : reconnaissance d'équivalence pour une nouvelle origine**

Vu la demande de reconnaissance d'équivalence portant la référence 2009-1717 spe,  
Vu l'avis de l'AFSSA du 11 mai 2010,

Les spécifications techniques de la substance active HUILE DE COLZA décrites dans le dossier déposé par SCOTTS sous la référence n° 2009-1717 spe par rapport à celles de la source déposée par W. Neurdorff GmbH KG reconnue au niveau européen et selon le document guide Sanco/10597/2003 rev.7 sont considérées comme équivalentes.

La nouvelle origine de la substance active HUILE DE COLZA, décrite dans le dossier déposé par SCOTTS sous la référence n° 2009-1717 spe est officiellement reconnue équivalente.

**Pour le Ministre et par délégation du Directeur général de l'alimentation,  
l'ICSPV, Sous-directrice de la qualité et de la protection des végétaux,**

  
**Emmanuelle SOUBEYRAN**



(b) Letters of access for pyrethrins



ANSES-DPR-UGamm  
14 rue Pierre et Marie Curie  
94701 Maisons Alfort Cedex  
France

*14 April 2016*

*To Whom It may Concern;*

By this letter, we, **McLaughlin Gormley King Company**, based at **8810 Tenth Avenue North, Minneapolis, Minnesota 55427, USA**, would like to supply the following information regarding the submission of the Pyrethrins + Rapeseed oil dossier (formula code NLS484A) by **Scotts France SAS, located in 21 Chemin de la Sauvegarde, F-69134 Ecully, France**

In relation to the identified data gaps in the EFSA conclusion data to address the following points has been supplied to meet the confirmatory data requirements set as part of the approval of pyrethrins:

- the representativeness of the major component 'pyrethrin 1' as regards the fate and behaviour in soil and water.

Data were supplied to the RMS Italy by the due date, 31 December 2015, and in accordance with Commission Guidance document SANCO/5634/2009 rev 6.1, December 2013 these data should be considered by the RMS and assessments of product authorisations should be undertaken without referral pending confirmatory information.

In relation to the identified data gaps in the EFSA conclusion data/ information to address the following points is being developed as part of the AIR 4 renewal dossier due to be submitted in 2017:

- Method of analysis of Pyrethrum residues present in soils;
- Method of analysis of Pyrethrum residues present in water;
- Method of analysis of Pyrethrum residues in air;
- The preferential metabolism/degradation/conversion of each isomer
- Studies to address the fate and behaviour of the cyclopentelone moieties after the rupture of the ester bridge in the pyrethrins
- Studies to address the degradation of pyrethrins in additional soils
- Information for the approval of the substance as it relates to the metabolite "chrysanthemic acid"

8810 Tenth Avenue North  
Minneapolis, MN 55427  
TOLL FREE 800.645.6466  
TEL 763.544.0341  
FAX 763.544.6437  
WWW.MGK.COM

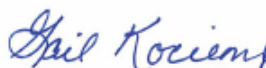
Insect Control Solutions

- Information on the presence or absence of metabolites in plants as it relates to herbivorous birds and if found, calculation of TER to be supplied
- Information from the Confirmatory data for the approval of the substance as it relates to the metabolite "chrysanthemic acid" TER calculations for aquatic organisms for this metabolite or TER calculations based on the toxicity values of the active substance divided by 10;
- PECgw calculations on pyrethrins and new metabolites of pyrethrins to be supplied;
- PECsw and TER calculations on pyrethrins and its metabolites for early applications (ornamentals > 50 cm, trees < 2 m and > 2 m) to be supplied.

In accordance with Commission Guidance document SANCO/10328/2004, rev 8, 24.01.12, active substance data listed in the EFSA conclusion, other than confirmatory data, should be considered in the next 'scheduled' peer reviewed EU procedure.

Therefore please note that this information is not currently available to ANSES as it was only either supplied as part of the confirmatory information submitted late in December 2015 to RMS Italy or is only being conducted now as a part of the AIR 4 Renewal of Pyrethrins. All of this information and data will eventually be submitted to RMS Italy for review as part of the renewal dossier.

Yours sincerely,



Gail Kociemba  
Global Regulatory Affairs Manager  
McLaughlin Gormley King Company





7 May 2012

ANSES - DPR – UGAmm  
253 avenue du Général Leclerc  
94701 Maisons Alfort Cedex  
France

**RE: LETTER OF ACCESS - Directive 91/414/EEC**

***To Whom It may Concern;***

By this letter, we, **McLaughlin Gormley King Company**, based at **8810 Tenth Avenue North, Minneapolis, Minnesota 55427, USA**, certify that **Scotts France SAS** based in **21 chemin de la Sauvegarde, 69134 Ecully cedex, France**, is authorised to cite, refer to, rely on and make use of the data listed herein below for the purpose of obtaining, maintaining or renewing **Scotts France SAS** for products containing Pyrethrins as active substance, whether alone or in combination with other active substances, in the Member State of ; **France** following the entry into force of the inclusion of Pyrethrins in Annex I to Directive 91/414/EEC (Repealed by 1107/2009/EC), by adoption of Commission Directive 2008/127/EC (Repealed by Regulation 540/2011/EU).

We certify that we are the owner, either outright or jointly, of the data listed on the attached Exhibit A as described therein and that the data are subject to protection pursuant to Article 13 of Directive 91/414/EEC as noted therein.

Accordingly, we authorise **Scotts France SAS** to make use, rely on and cite the data listed in Exhibit A for the purpose of supporting or granting **Scotts France SAS** registration for the Product **Rapindinsect**, with the product code **NLS484A**.

**IUPAC Name:**

**Pyrethrin I:** *Roth:* (Z)-(S) -2-methyl-4-oxo-3-(penta-2,4-dienyl)cyclopent-2-enyl (1R)-trans-2,2-dimethyl-3-(2-methylprop-1-enyl)-cyclopropanecarboxylate; or (Z)-(S) -2-methyl-4-oxo-3-(penta-2,4-dienyl)cyclopent-2-enyl (+) trans-chrysanthemate

**Cinerin I:** *Roth:* (Z)-(S) -3-(but-2-enyl)-2-methyl-4-oxocyclopenten-2-enyl (1R)-trans-2,2-dimethyl-3-(2-methylprop-1-enyl)-cyclopropanecarboxylate; or (Z)-(S) -3-(but-2-enyl)-2-methyl-4-oxocyclopenten-2-enyl (+) trans-chrysanthemate

**Jasmolin I:** *Roth:* (Z)-(S) -2-methyl-4-oxo-3-pent-(2-enyl)cyclopent-2-enyl (1R)-trans-2,2-dimethyl-3-(2-methylprop-1-enyl)-cyclopropanecarboxylate; or (Z)-(S) -2-methyl-4-oxo-3-(pent-2-enyl)cyclopent-2-enyl (+) trans-chrysanthemate

8810 Tenth Avenue North  
Minneapolis, MN 55427  
TOLL FREE 800.645.6466  
TEL 763.544.0341  
FAX 763.544.6437  
WWW.MGK.COM

Insect Control Solutions



**Pyrethrin II:** *Roth:* (Z)-(S) -2-methyl-4-oxo-3-(penta-2,4-dienyl)cyclopent-2-enyl (E)- (1R)-trans-3-(2-methoxycarbonylprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate; or (Z)-(S) -2-methyl-4-oxo-3-(penta-2,4-dienyl)cyclopent-2-enyl pyrethrate

**Cinerin II:** *Roth:* (Z)-(S) -3-(but-2-enyl)-2-methyl-4-oxocyclopent-2-enyl (E)- (1R)-trans-3-(2-methoxycarbonylprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate; or (Z)-(S) -3-(but-2-enyl)-2-methyl-4-oxocyclopent-2-enyl pyrethrate

**Jasmolin II:** *Roth:* (Z)-(S) -2-methyl-4-oxo-3-(pent-2-enyl)cyclopent-2-enyl (E)- (1R)-trans-3-(2-methoxycarbonylprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate; or (Z)-(S) -2-methyl-4-oxo-3-(pent-2-enyl)cyclopent-2-enyl pyrethrate

**CIPAC No:** 32

**CAS No:** Pyrethrins: 8003-34-7

Pyrethrin I: 121-21-1, Cinerin I: 25402-06-6, Jasmolin I: 4466-14-2, Pyrethrin II: 121-29-9,  
Cinerin II: 121-20-0, Jasmolin II: 1172-63-0.

This Letter of Access is granted in favour, and is valid only in respect, of **Scotts France SAS** and is not transferable or assignable to any other entity or person. This Letter of Access is not transferable to further products. This Letter of Access is only relevant to the above mentioned product when the Active Substance has been produced by MGK. This Letter of Access must not be used for alternative sources of the Active Substance.

We maintain the right to cancel the support of this letter of access in cases where there is a breach on behalf of **Scotts France SAS** against the agreement under which they were granted this letter of access or a breach of a regulatory requirement.

Further data or clarifications are available upon request from MGK.

Yours sincerely,

April Umahn  
International Regulatory Affairs Specialist  
McLaughlin Gormley King Company



8810 Tenth Avenue North  
Minneapolis, MN 55427

TOLL FREE 800.645.6466  
TEL 763.544.0341  
FAX 763.544.6437  
WWW.MGK.COM

Insect Control Solutions

**NB.** The 17-page list of data specified in Appendix A to the above letter is available from Anses on request.