

REGISTRATION REPORT
Part A
Risk Management

Product code: FRS02091

Product name: RAPID'TOTAL

Chemical active substances:

**Potassium salts of fatty acids, 10g/L
sulphur, 4g/L**

Southern Zone/Interzonal

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE
(New application)

Applicant: Evergreen Garden Care France SAS
Date: 26/12/2019

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PART A

RISK MANAGEMENT

1 Details of the application

The company Evergreen Garden Care France SAS has requested a marketing authorisation in France for the product RAPID'TOTAL (product code: FRS02091), containing 10g/L potassium salts of fatty acids and 4g/Lsulphur¹ as a fungicide/insecticide/acaricide for non-professional uses.

The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in the Registration Report, Part B include assessment of further data or information as required at national registration by EU regulations. It also includes assessment of data and information related to RAPID'TOTAL (FRS02091) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of RAPID'TOTAL (FRS02091) have been made using endpoints agreed in the EU peer reviews of potassium salts of fatty acids and sulphur.

This document describes the specific conditions of use and labelling required for France for the registration of RAPID'TOTAL (FRS02091).

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

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

Appendix 3 of this document contains a copy of the letter(s) of access.

1.1 Application background

The present registration report concerns the evaluation of Evergreen Garden Care France SAS's application to market RAPID'TOTAL (FRS02091) in France as a fungicide/insecticide/acaricide (product uses described under point 2.3). France acted as a zonal and interzonal Rapporteur Member State (zRMS and izRMS) 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 and European Union.

The present application (2018-0377) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) in the context of the zonal procedure for all Member States of the Southern zone for field uses and for all Member States of the European Union for uses under protection, taking into account the worst-case uses ("risk envelope approach")² – the highest application rates applied for in the Southern zone for field uses and for all Member States of the European Union for uses under protection. When risk mitigation measures were necessary, they are adapted to the situation in France.

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009³, implementing regulations, and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national

¹ To reflect ISO 765-1976, the spelling "sulphur" is used in this Registration Report Part A instead of "sulphur". The traditional spelling is retained only when used as a part of a commercial name or in a citation.

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

level. This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011⁴, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

1.2 Letters of Access

The applicant has provided letters of access for the active substance.

1.3 Justification for submission of tests and studies

According to the applicant: “*All tests and studies were prepared and submitted in support of the assessment as required according to 284/2013 EU.*”

2 Details of the authorisation decision

2.1 Product identity

Product code	FRS02091
Product name in MS	RAPID'TOTAL
Authorisation number	2190811
Low risk (article 47)	No
Function	Fungicide/insecticide/acaricide
Applicant	Evergreen Garden Care France SAS
Active substance(s) (incl. content)	Potassium salts of fatty acids, 10g/L Sulphur, 4g/L
Formulation type	Other liquids to be applied undiluted (AL)
Packaging	HDPE Mars 800 mL RTU with trigger. HDPE Vanguard 1000 mL RTU with trigger. HDPE Vanguard 3 L RTU with nested trigger. HDPE Vanguard 5 L RTU with nested trigger. Non-professional user.
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None.
Recommended tank mixtures	None.

2.2 Conclusion

The evaluation of the application for RAPID'TOTAL (FRS02091) resulted in the decision **to grant the authorisation, except for use against rust diseases and certain diseases of trees and shrubs (insufficient efficacy data).**

⁴ COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

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

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

Hazard class(es), categories:	-
Hazard pictograms:	-
Signal word:	-
Hazard statement(s):	-
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation</i>
	Given the diversity of species and varieties of ornamental crops, it is advisable to test the phytotoxicity of RAPID'TOTAL (FRS02091) on some plants of the same variety, and at the same stage of development, before using the product on a larger scale.
	Contains 1,2-benzisothiazol-3(2H)-one. May cause an allergic reaction [EUH208].

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

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

	refer to 2.5.
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2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

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

The French Order of 4 May 2017⁵ provides that:

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

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process

⁵ Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte>.

in France. However, non-spraying buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

Finally, the French Order of 26 March 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 “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data 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.

2.5.1 Restrictions linked to the PPP

The authorisation of the PPP is linked to the following conditions:

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
	Do not dispose of unused spray in the sink, gutter or any other water point.
	Do not treat when bees and beneficial organisms are visiting the area.
Other specific restrictions	
Storage	Protect from frost.
Re-entry period	Wait for complete drying of the treated area.

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

⁶ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGR1407093A/jo>.

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

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, evaluated and concluded as safe uses by France as zRMS and izRMS. 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.

PPP (product name/code):	RAPID'TOTAL (FRS02091)		GAP rev. 1, date: 2019-12-26									
Active substance 1:	Potassium salt of fatty acids		Formulation type: Other liquids to be applied undiluted [Code: AL]									
Active substance 2:	Sulphur		Conc. of a.s. 1: 10g/L									
Safener:	--		Conc. of a.s. 2: 4g/L									
Synergist:	--		Conc. of safener: --									
Applicant:	Evergreen		Conc. of synergist: --									
Zone(s):	Zonal/Interzonal		Professional use: <input type="checkbox"/>									
Verified by MS:	yes		Non-professional use: <input checked="" type="checkbox"/>									
Field of use:	Fungicide/insecticide /acaricide											

1	2	3	4	5	6	7	8	9	10	11	12	13	14	
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate				PHI (days)	Remarks: e.g. g safener/ synergist per ha

Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)

1	FR	All non-woody ornamentals, for examples: NNNZD; NNNZA; NNNGB; NNNZI; NNNZT	G	Aphids including but not limited to 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	During vegetation growth (April to September) BBCH 14-69	a) 1 b) 2	7	a) 1000 (1 L/10 m ²) b) 2000	a) Potassium salt of fatty acids: 10 Sulphur: 4 b) Potassium salts of fatty acids: 20 Sulphur: 8	Ready-to-use product, no dilution required	n.a.	Acceptable
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2	FR	All woody ornamentals and ornamental shrubs (roses and flowers), for examples: NNNZG; NNNZA; NNNGB; NNNZT; ROSXM; ROSSS	G	Aphids including but not limited to 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	During vegetation growth (April to September) BBCH 15-93	a) 1 b) 2	7	a) 1000 b) 2000	a) Potassium salt of fatty acids: 10 Sulphur: 4 b) Potassium salts of fatty acids: 20 Sulphur: 8	Ready-to-use product, no dilution required	n.a.	Acceptable
3	FR	All non-woody ornamentals, for examples: NNNZD; NNNZA; NNNGB; NNNZI; NNNZT	G	Mites including but not limited to example: <i>Tetranychus urticae</i> TETRUR]	Foliar sprayer: Covering both sides of leaves of infested plants	During vegetation growth (April to September) BBCH 14-69	a) 1 b) 2	7	a) 1000 b) 2000	a) Potassium salt of fatty acids: 10 Sulphur: 4 b) Potassium salts of fatty acids: 20 Sulphur: 8	Ready-to-use product, no dilution required	n.a.	Acceptable
4	FR	All woody ornamentals and ornamental shrubs (roses and flowers), for examples: NNNZG; NNNZA; NNNGB; NNNZT; ROSXM; ROSSS	G	Mites including but not limited to example: <i>Tetranychus urticae</i> TETRUR]	Foliar sprayer: Covering both sides of leaves of infested plants	During vegetation growth (April to September) BBCH 15-93	a) 1 b) 2	7	a) 1000 b) 2000	a) Potassium salt of fatty acids: 10 Sulphur: 4 b) Potassium salts of fatty acids: 20 Sulphur: 8	Ready-to-use product, no dilution required	n.a.	Acceptable
5	FR	All non-woody ornamentals, for examples: NNNZD; NNNZA; NNNGB; NNNZI; NNNZT	G	Whitefly including but not limited to: <i>Trialeurodes vaporariorum</i> [TRIAVA] - <i>Bemisia tabaci</i> [BEMITA]	Foliar sprayer: Covering both sides of leaves of infested plants	During vegetation growth (April to September) BBCH 14-69	a) 1 b) 2	7	a) 1000 b) 2000	a) Potassium salt of fatty acids: 10 Sulphur: 4 b) Potassium salts of fatty acids: 20 Sulphur: 8	Ready-to-use product, no dilution required	n.a.	Acceptable

6	FR	All woody ornamentals and ornamental shrubs (roses and flowers), for examples: NNNZG; NNNZA; NNNGB; NNNZT; ROSXM; ROSSS	G	Whitefly including but not limited to: <i>Trialeurodes vaporariorum</i> [TRIAVA] – <i>Bemisia tabaci</i> [BEMITA]	Foliar sprayer: Covering both sides of leaves of infested plants	During vegetation growth (April to September) BBCH 15-93	a) 1 b) 2	7	a) 1000 b) 2000	a) Potassium salt of fatty acids: 10 Sulphur: 4 b) Potassium salts of fatty acids: 20 Sulphur: 8	Ready-to-use product, no dilution required	n.a.	Acceptable
7	FR	All woody ornamentals and ornamental shrubs (roses and flowers), for examples: NNNZG; NNNZA; NNNGB; NNNZT; ROSXM; ROSSS	G	Rose black spot (<i>Diplocarpon rosae</i> DIPCRO)	Foliar sprayer: Covering both sides of leaves of infested plants	During vegetation growth (April to September) BBCH 15-93	a) 1 b) 6	7	a) 1000 b) 6000	a) Potassium salt of fatty acids: 10 Sulphur: 4 b) Potassium salts of fatty acids: 60 Sulphur: 24	Ready-to-use product, no dilution required	n.a.	Not Acceptable (Lack of efficacy data)
8	FR	All woody ornamentals and ornamental shrubs (roses and flowers), for examples: NNNZG; NNNZA; NNNGB; NNNZT; ROSXM; ROSSS	G	Rusts including but not limited to examples: <i>Phragmidium mucronatum</i> [PHRAMU], <i>Phragmidium tuberculatum</i> [PHRATU]	Foliar sprayer: Covering both sides of leaves of infested plants	During vegetation growth (April to September) BBCH 15-93	a) 1 b) 6	7	a) 1000 b) 6000	a) Potassium salt of fatty acids: 10 Sulphur: 4 b) Potassium salts of fatty acids: 60 Sulphur: 24	Ready-to-use product, no dilution required	n.a.	Not Acceptable (Lack of efficacy data)
9	FR	All non-woody ornamentals, for examples: NNNZD; NNNZA; NNNGB; NNNZI; NNNZT	G	Rusts including but not limited to examples: <i>Phragmidium mucronatum</i> [PHRAMU], <i>Phragmidium tuberculatum</i> [PHRATU]	Foliar sprayer: Covering both sides of leaves of infested plants	During vegetation growth (April to September) BBCH 14-69	a) 1 b) 6	7	a) 1000 b) 6000	a) Potassium salt of fatty acids: 10 Sulphur: 4 b) Potassium salts of fatty acids: 60 Sulphur: 24	Ready-to-use product, no dilution required	n.a.	Not Acceptable (Lack of efficacy data)

10	FR	All woody ornamentals and ornamental shrubs (roses and flowers), for examples: NNNZG; NNNZA; NNNGB; NNNZT; ROSXM; ROSSS	G	Powdery mildews including but not limited to examples: <i>Sphaerotheca pannosa</i> [SPHRPA], <i>Erysiphe</i> sp. [ERYSSP]	Foliar sprayer: Covering both sides of leaves of infested plants	During vegetation growth (April to September) BBCH 15-93	a) 1 b) 6	7	a) 1000 b) 6000	a) Potassium salt of fatty acids: 10 Sulphur: 4 b) Potassium salts of fatty acids: 60 Sulphur: 24	Ready-to-use product, no dilution required	n.a.	Acceptable
11	FR	All non-woody ornamentals, for examples: NNNZD; NNNZA; NNNGB; NNNZI; NNNZT	G	Powdery mildews including but not limited to examples: <i>Sphaerotheca pannosa</i> [SPHRPA], <i>Erysiphe</i> sp. [ERYSSP]	Foliar sprayer: Covering both sides of leaves of infested plants	During vegetation growth (April to September) BBCH 14-69	a) 1 b) 6	7	a) 1000 b) 6000	a) Potassium salt of fatty acids: 10 Sulphur: 4 b) Potassium salts of fatty acids: 60 Sulphur: 24	Ready-to-use product, no dilution required	n.a.	Acceptable

Zonal uses (field or outdoor uses, certain types of protected crops)

1	FR	All non-woody ornamentals, for examples: NNNZD; NNNZA; NNNGB; NNNZI; NNNZT	F	Aphids including but not limited to 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	During vegetation growth (April to September) BBCH 14-69	a) 1 b) 2	7	a) 1000 b) 2000	a) Potassium salt of fatty acids: 10 Sulphur: 4 b) Potassium salts of fatty acids: 20 Sulphur: 8	Ready-to-use product, no dilution required	n.a.	Acceptable
2	FR	All woody ornamentals and ornamental shrubs (roses and flowers), for examples: NNNZG; NNNZA; NNNGB; NNNZT; ROSXM; ROSSS	F	Aphids including but not limited to 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	During vegetation growth (April to September) BBCH 15-93	a) 1 b) 2	7	a) 1000 b) 2000	a) Potassium salt of fatty acids: 10 Sulphur: 4 b) Potassium salts of fatty acids: 20 Sulphur: 8	Ready-to-use product, no dilution required	n.a.	Acceptable

3	FR	All non-woody ornamentals, for examples: NNNZD; NNNZA; NNNGB; NNNZI; NNNZT	F	Mites including but not limited to example: <i>Tetranychus urticae</i> [TETRUR]	Foliar sprayer: Covering both sides of leaves of infested plants	During vegetation growth (April to September) BBCH 14-69	a) 1 b) 2	7	a) 1000 b) 2000	a) Potassium salt of fatty acids: 10 Sulphur: 4 b) Potassium salts of fatty acids: 20 Sulphur: 8	Ready-to-use product, no dilution required	n.a.	Acceptable
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6	FR	All woody ornamentals and ornamental shrubs (roses and flowers), for examples: NNNZG; NNNZA; NNNGB; NNNZT; ROSSM; ROSSS	F	Whitefly including but not limited to: <i>Trialeurodes vaporariorum</i> [TRIAVA] – <i>Bemisia tabaci</i> [BEMITA]	Foliar sprayer: Covering both sides of leaves of infested plants	During vegetation growth (April to September) BBCH 15-93	a) 1 b) 2	7	a) 1000 b) 2000	a) Potassium salt of fatty acids: 10 Sulphur: 4 b) Potassium salts of fatty acids: 20 Sulphur: 8	Ready-to-use product, no dilution required	n.a.	Acceptable

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9	FR	All non-woody ornamentals, for examples: NNNZD; NNNZA; NNNGB; NNNZI; NNNZT	F	Rusts including but not limited to examples: <i>Phragmidium mucronatum</i> [PHRAMU], <i>Phragmidium tuberculatum</i> [PHRATU]	Foliar sprayer: Covering both sides of leaves of infested plants	During vegetation growth (April to September) BBCH 14-69	a) 1 b) 6	7	a) 1000 b) 6000	a) Potassium salt of fatty acids: 10 Sulphur: 4 b) Potassium salts of fatty acids: 60 Sulphur: 24	Ready-to-use product, no dilution required	n.a.	Not Acceptable (Lack of efficacy data)
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11	FR	All non-woody ornamentals, for examples: NNNZD; NNNZA; NNNGB; NNNZI; NNNZT	F	Powdery mildews including but not limited to examples: <i>Sphaerotheca pannosa</i> [SPHRPA], <i>Erysiphe</i> sp. [ERYSSP]	Foliar sprayer: Covering both sides of leaves of infested plants	During vegetation growth (April to September) BBCH 14-69	a) 1 b) 6	7	a) 1000 b) 6000	a) Potassium salt of fatty acids: 10 Sulphur: 4 b) Potassium salts of fatty acids: 60 Sulphur: 24	Ready-to-use product, no dilution required	n.a.	Acceptable
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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.

Remarks columns: 1 Numeration necessary to allow references.
 2 Use official codes/nomenclatures of EU Member States.
 3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure).
 4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application.
 5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
 6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

(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.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application.
 8 The maximum number of application possible under practical conditions of use must be provided.
 9 Minimum interval (in days) between applications of the same product.
 10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
 12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
 13 PHI - minimum pre-harvest interval.
 14 Remarks may include: Extent of use/economic importance/restrictions.

3 Background of authorisation decision and risk management

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

Commercial packaging:

Bottle made of HDPE: 800 mL or 1 L, with a trigger spray.

Container made of HDPE: 3 L or 5 L, with a trigger spray.

RAPID'TOTAL (FRS02091) is a water-based liquid ready-to-use preparation (AL). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is an off-white liquid with no particular odour. It is not explosive and has no oxidising properties. The product is not flammable and no self-ignition temperature could be determined. Undiluted, it has a pH value of 9.75 at room temperature. There is no effect high temperature on the stability of the formulation, since after 14 days at 54°C and 24 months at room temperature, 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 HDPE. Its technical characteristics are acceptable for an AL formulation.

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

The formulation should be protected from frost.

3.2 Efficacy (Part B, Section 3)

3.3 Efficacy data

Considering the data submitted:

- o **Given the lack of data or possible extrapolation for uses on rusts (of woody and non-woody ornamentals), the evaluation of the efficacy of RAPID'TOTAL (FRS02091) for these uses cannot be considered finalised.**
- o The level of efficacy of RAPID'TOTAL (FRS02091) is considered acceptable for the other uses.

Restrictions: none.

Post-authorisation data: none.

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

Considering the data submitted:

- o The risk of resistance developing or appearing to potassium salts of fatty acids and sulphur does not require monitoring for the requested uses.

Resistance monitoring data: none.

Post-authorisation data: none.

3.3.2 Adverse effects on treated crops

Considering the data submitted:

- o The phytotoxicity level of RAPID'TOTAL (FRS02091) is considered acceptable for all the requested uses.

Restrictions: none.

Post-authorisation data: none.

Precautions for use: given the diversity of species and varieties of ornamental crops, it is advised to test the selectivity of the preparation RAPID'TOTAL (FRS02091) on some plants of the same variety, and at the same stage of development, before using the preparation on larger areas.

3.3.3 Observations on other undesirable or unintended side-effects

Considering the data submitted:

- o The risk of adverse effect on succeeding crops is considered negligible.
- o The risk of adverse effect on adjacent crops is considered negligible.

Restrictions: none.

Post-authorisation data: none.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

Analytical methods for the determination of the active substances in the formulation are available and validated. As neither active substance contains any relevant impurity, no pertinent analytical method is required.

Considering the intended uses (turf, ornamental plants, ...) analytical methods for the determination of residues of fatty acid potassium salts and sulphur in plants and in foodstuffs of animal origin are not necessary.

3.4.2 Analytical methods for residues

According to the EFSA conclusions, analytical methods for the determination of residues of fatty acid potassium salts in soil, water and air will be required at the time of the renewal of this substance's approval. To update the dossier, an analytical method for the determination of residues of fatty acid potassium salts in tissues and body fluids will also be required during the renewal (re-registration) process.

3.5 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Active substance: sulphur		
ADI	Not applicable	Efsa (2008)

ARfD	Not applicable	
AOEL*	Replaced by average sulphur background intake value (ASBIV): 26 mg/kg body weight/day*	
AAOEL	Not applicable	
Dermal absorption	Based on the peer review of the pesticide assessment of the active substance sulphur (EFSA Scientific Report (2008) 221, 1-70):	
		Concentrate (used in formulation) 4g/L
	Dermal absorption endpoints %	10

* Average sulphur background intake value was 26 mg/kg body weight/day [overall intake: 1.6 g/person/day, US National Academy of Medicine

Active substance: Fatty acids, potassium salts		
ADI	Not applicable.	Efsa (2013)
ARfD	Not applicable.	
AOEL	Normal dietary intakes of fatty acids of 821 mg/kg body weight/day (data derived from the UK National Diet & Nutrition Survey series)	
AAOEL	Not applicable.	
Dermal absorption	Based default values according to guidance on dermal absorption (Efsa 2012):	
		Concentrate (used in formulation) 10 g/L
	Dermal absorption endpoints %	75

3.5.1 Acute toxicity

RAPID'TOTAL (FRS02091), containing 4g/L sulphur and 10g/L fatty acids C7-C18 potassium salts, has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitisier.

3.5.2 Operator exposure

Summary of critical use patterns (worst cases):

Crop type	F/G ⁸	Equipment <i>Application method</i>	Maximum application rate g a.s./ha	Minimum volume water (L/ha)
Ornamentals	F	Foliar sprayer	Sulphur 24 g a.s./ha Fatty acids C7-C18 and C18 unsaturated, potassium salts 60 g a.s./ha	Ready-to-use
Ornamentals	G	Foliar sprayer	Sulphur 24 g a.s./ha Fatty acids C7-C18 and C18 unsaturated, potassium salts 60 g a.s./ha	Ready-to-use

⁸ Open field or glasshouse

Considering proposed field (garden) and greenhouse uses, operator systemic exposure was estimated using the study from the French trade association for garden/amenity pesticide manufacturers (UPJ), 2009-2010⁹ and EFSA models:

Crop	Equipment	PPE and/or working coverall	% AOEL sulphur	% AOEL fatty acids
Operator exposure model EFSA				
Ornamentals	Foliar sprayer	-	0.65	0.15
Operator exposure UPJ model				
Rosebush-like plants	Foliar sprayer	-	0.02	0.03
Flower bed, vegetable crop (< 60 cm)	Foliar sprayer	-	0.03	0.05
Hedges and high crops (> 60 cm)	Foliar sprayer	-	0.03	0.05

According to the model calculations, it may be concluded that the risk for the non-professional using RAPID'TOTAL (FRS02091) is acceptable without personal protective equipment.

The proposed packaging has been described in sufficient details, and its compliance can therefore be finalised for home-garden use.

Refill container (3L ; 5L) were not acceptable for non-professional user

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 Mars and Vanguard bottles and a drum with sprayer.

However, a drum without sprayer is not considered compliant.

3.5.3 Worker exposure

RAPID'TOTAL (FRS02091) is intended to be used by amateurs for 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.

3.5.4 Bystander and resident 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.

EFSA model (Golf course, turf or other sports lawns): Recreational exposure was assessed according to the EFSA model. Exposure is estimated to be 0.0% and 0.0% of the AOEL of sulphur and fatty acids for

⁹ AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874).

children and adults, respectively. It may be concluded that there is no unacceptable risk anticipated for recreational exposure.

Combined exposure:

Currently no EU-harmonised guidance is available on the risk assessment of combined exposure to multiple active substances. Most assessment approaches employed up to now make use of the Hazard Index (HI) concept. It is therefore suggested that this be used as a first-tier assessment.

A cumulative assessment for operators (users) has been performed. At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity.

Hazard quotients (HQ) for each active substance and the HI (sum of hazard quotients) are:

Application scenario	Active substance	Estimated exposure/AOEL (HQ)			
		Model EFSA	Model (UPJ)		
			Rosebush-like plants	Flower bed, vegetable crop (< 60 cm)	Hedges and high crops (> 60 cm)
Operators	Potassium salts of fatty acids	0.0015	0.0002	0.0003	0.0003
	Sulphur	0.0065	0.0003	0.0005	0.0005
	Cumulative risk for operators (HI)	0.008	0.0005	0.0008	0.0008
Workers	Potassium salts of fatty acids			not relevant	
	Sulphur			not relevant	
	Cumulative risk workers (HI)			not relevant	
Bystander/Resident-child	Potassium salts of fatty acids			not relevant	
	Sulphur			not relevant	
	Cumulative risk bystander – child (HI)			not relevant	
Bystander/Resident - adult	Potassium salts of fatty acids			not relevant	
	Sulphur			not relevant	
	Cumulative risk bystander – adult (HI)			not relevant	

The Hazard Index is < 1. Thus combined exposure to all active substances in RAPID'TOTAL (FRS02091) is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.

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

Not relevant – non-edible crops only.

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

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

The PEC values of potassium salts of fatty acids and sulphur in surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

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

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

PECgw calculations are not deemed necessary when the product is applied with a handheld trigger sprayer.

When the product is not applied with a handheld trigger sprayer, PECgw for potassium salts of fatty acids and sulphates do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and directive 98/83/EC respectively provided the product is applied between April and August only. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses between April and August.

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.

3.8 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substances were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Different types of packaging are requested for this product for home-garden uses.

When the product is applied with a handheld trigger sprayer, considering the packaging and the application method of the preparation (ready-to-use product), exposure of soil and surface water compartments to active substance is considered negligible. **Consequently, no risk assessment for non-target organisms is deemed necessary, except for pollinating insects, where an exposure cannot be excluded.**

No sufficient data on the effects of RAPID'TOTAL (FRS02091) on honeybee development including emergence of honeybee larvae are available. Thus the chronic risk for honeybee larvae cannot be finalized.

When the product is not applied with a handheld 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.

The risk to birds is considered acceptable for the intended uses. For aquatic organisms, the risk may be considered acceptable, with the following mitigation:

To protect aquatic organisms, apply at least 5 metres away from any surface water bodies (well, pond, stream, river,...).

For other non-target organisms, the following safety phrases might be added on the label:

Do not apply when beneficial organisms are present (adybirds, lacewings, hoverflies, ground beetles...).

3.9 Relevance of metabolites (Part B, Section 10)

Not relevant.

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

Neither active substance is approved as a candidate for substitution, therefore a comparative assessment is not foreseen.

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

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

5.1.1 Post-authorisation monitoring

None.

5.1.2 Post-authorisation data requirements

None.

Appendix 1 Copy of the product authorisation



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 RAPID'TOTAL

*de la société EVERGREEN GARDEN CARE FRANCE SAS
enregistrée sous le n°2018-0377*

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.



Informations générales sur le produit	
Nom du produit	RAPID'TOTAL
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	4 g/L - soufre 10 g/L - acides gras C ₇ à C ₁₈ et C ₁₈ insaturé (sels de potassium)
Numéro d'intrant	082-2018.01
Numéro d'AMM	2190811
Fonction	Acaricide, fongicide, insecticide
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,

26 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)



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	800 mL ; 1L
Bidons en polyéthylène haute densité	3 L ; 5 L

Les bidons « recharge » de 3 L et 5 L en polyéthylène haute densité sont refusés car ils ne permettent pas de garantir une exposition minimale de l'utilisateur.

Classification du produit

La classification retenue est la suivante :

Sans classement.

Pour les phrases P se référer à la réglementation en vigueur.

EUH208 : Contient de la 1,2-benzisothiazol-3(2H)-one. Peut produire une réaction allergique.

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 aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
14053107 Arbres et arbustes*Ttr Part.Aer.* Acariens	100 mL/m ²	2/an	entre les stades BBCH 15 et BBCH 93	Non applicable	-	-	-	-
				Également autorisé sous abri. Intervalle minimum entre les applications : 7 jours.				
01002019 Arbres et arbustes*Ttr Part.Aer.* Aileurodes	100 mL/m ²	2/an	entre les stades BBCH 15 et BBCH 93	Non applicable	-	-	-	-
				Également autorisé sous abri. Intervalle minimum entre les applications : 7 jours.				
14053204 Arbres et arbustes*Ttr Part.Aer.* Oïdium(s)	100 mL/m ²	6/an	entre les stades BBCH 15 et BBCH 93	Non applicable	-	-	-	-
				Également autorisé sous abri. Intervalle minimum entre les applications : 7 jours.				
14053105 Arbres et arbustes*Ttr Part.Aer.* Pucerons	100 mL/m ²	2/an	entre les stades BBCH 15 et BBCH 93	Non applicable	-	-	-	-
				Également autorisé sous abri. Intervalle minimum entre les applications : 7 jours.				



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 aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
17403101 Cultures florales et plantes vertes*Ttr Part.Aer.*Acariens, phytopotes et tarsonèmes	100 mL/m ²	2/an	BBCH 14 et BBCH 69	entre les stades	Non applicable	-	-	-
				Également autorisé sous abri. Intervalle minimum entre les applications : 7 jours.				
17403102 Cultures florales et plantes vertes*Ttr Part.Aer.*Aleurodes	100 mL/m ²	2/an	BBCH 14 et BBCH 69	entre les stades	Non applicable	-	-	-
				Également autorisé sous abri. Intervalle minimum entre les applications : 7 jours.				
17403202 Cultures florales et plantes vertes*Ttr Part.Aer.*Oïdium(s)	100 mL/m ²	6/an	BBCH 14 et BBCH 69	entre les stades	Non applicable	-	-	-
				Également autorisé sous abri. Intervalle minimum entre les applications : 7 jours.				
17403104 Cultures florales et plantes vertes*Ttr Part.Aer.*Pucerons	100 mL/m ²	2/an	BBCH 14 et BBCH 69	entre les stades	Non applicable	-	-	-
				Également autorisé sous abri. Intervalle minimum entre les applications : 7 jours.				



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 aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
17303101 Rosier*Ttr Part.Aer.*Acariens	100 mL/m ²	2/an	entre les stades BBCH 15 et BBCH 93	Non applicable	-	-	-	-
Également autorisé sous abri. Intervalle minimum entre les applications : 7 jours.								
17303117 Rosier*Ttr Part.Aer.*Aleurodes	100 mL/m ²	2/an	entre les stades BBCH 15 et BBCH 93	Non applicable	-	-	-	-
Également autorisé sous abri. Intervalle minimum entre les applications : 7 jours.								
17303201 Rosier*Ttr Part.Aer.*Maladies des taches noires	100 mL/m ²	6/an	entre les stades BBCH 15 et BBCH 93	Non applicable	-	-	-	-
Également autorisé sous abri. Intervalle minimum entre les applications : 7 jours.								
17303203 Rosier*Ttr Part.Aer.*Oïdium(s)	100 mL/m ²	6/an	entre les stades BBCH 15 et BBCH 93	Non applicable	-	-	-	-
Également autorisé sous abri. Intervalle minimum entre les applications : 7 jours.								



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	Décalage avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
17303108 Rosier*Ttr Part.Aer.*Pucerons	100 mL/m ²	2/an	entre les stades BBCH 15 et BBCH 93	Non applicable	-	-	-	-

Également autorisé sous abri.
Intervalle minimum entre les applications : 7 jours.

RAPID'TOTAL
AMM n°2190811



Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
14053200 Arbres et arbustes*Ttr Part.Aer.* Maladies diverses	100 mL/m ²	6/an	Non applicable
Motivation du refus : L'usage est refusé en raison d'un manque de données efficacité.			
14053203 Arbres et arbustes*Ttr Part.Aer.* Rouille(s)	100 mL/m ²	6/an	Non applicable
Motivation du refus : L'usage est refusé en raison d'un manque de données efficacité.			
17403203 Cultures florales et plantes vertes*Ttr Part.Aer.* Rouille(s)	100 mL/m ²	6/an	Non applicable
Motivation du refus : L'usage est refusé en raison d'un manque de données efficacité.			
17303210 Rosier*Ttr Part.Aer.* Rouille(s)	100 mL/m ²	6/an	Non applicable
Motivation du refus : L'usage est refusé en raison d'un manque de données efficacité.			



Conditions d'emploi du produit

Stockage et manipulation du produit

- Protéger du gel.

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.

Protection de la faune

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

Recommandations relatives à l'étiquette du produit

Il est recommandé de faire figurer l'information suivante sur l'étiquette :

- Préciser les conditions d'utilisation sur cultures ornementales afin de prévenir tout risque éventuel de phytotoxicité.

Appendix 2 Copy of the product label

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





FRONT LABEL
186,3 X 127,8 MM

AVEC trigger



FRONT LABEL
186,3 X 127,8 MM



FRONT LABEL
186,3 X 127,8 MM



Commentaires : **Visuels : Haupe déf.**

ATTENTION : Ce document est un document d'exécution et non un doc prêt à flasher.
Les recouvrements, surimpressions de couleurs et calage chrome sont à réaliser par le photograveur.

AVEC trigger

0 10 20 30 40 50 60 70 80 90 100

Client : SCOTTS Exé : Fertiligène Phyto NATUREL 3 L - avec trigger N° Dossier : SCO170082	Date : 26/01/2018 Infographiste : Relecture : 2 LG
Impression : 6 couleurs QUADRI PMS 214C PMS 381C	Livraison exé : Logiciels : ILLUSTRATOR CC - PHOTOSHOP CC
Bendays : Logo Fertiligène : Magenta 80% à 100% Cyan 0% à 100% Ocre jaune N. 50% Noir 0% à 100% C1 100% / M20% A réaliser par le photograveur : C. 100% + A20% en sur impression sur le PMS 381C.	Logo Fertiligène : Magenta 80% à 100% Cyan 0% à 100% Ocre jaune N. 50% Noir 0% à 100% C1 100% / M20% A réaliser par le photograveur : C. 100% + A20% en sur impression sur le PMS 381C.



FRONT LABEL
186,3 X 127,8 MM

Appendix 3 Letter of Access

Provided upon request.