

REGISTRATION REPORT

Part A

Risk Management

Product code: ALD1901

Product name: ROMEO GARDEN

Active substance:

Cerevisane 941 g/kg

(cell walls of *Saccharomyces cerevisiae* strain LAS 117)

Low risk active substance

Southern Zone/Interzonal

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: AGRO-LEVURES ET DERIVES

Date: 2018/07/13

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PART A

RISK MANAGEMENT

1 Details of the application

The company AGRO-LEVURES ET DERIVES has requested marketing authorisation in France for the product ROMEO GARDEN (formulation code: ALD1901), containing 941 g/kg (924 g/kg min concentration) Cerevisane (cell walls of *Saccharomyces cerevisiae* strain LAS 117), for use as a systemic resistance inducer and as a fungicide for non-professional uses. Cerevisane is a low risk active substance, therefore ROMEO GARDEN (ALD1901) shall be authorized as a low risk plant protection product if compliant with article 47.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-10 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 ROMEO GARDEN (ALD1901) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of ROMEO GARDEN (ALD1901) have been made using endpoints agreed in the EU peer review of Cerevisane.

This document describes the specific conditions of use and labelling required for France for the registration of ROMEO GARDEN (ALD1901).

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

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

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

1.1 Application background

The present registration report concerns the evaluation of AGRO-LEVURES ET DERIVES's application to market ROMEO GARDEN (ALD1901) in France as a systemic resistance inducer (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 European Union.

The present application (2017-0114) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)¹ in the context of the zonal procedure for all Member States of the European Union, taking into account the worst-case uses ("risk envelope approach")² – the highest application rates over the European Union. 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.

¹ French Food Safety Agency, Afssa, before 1 July 2010

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

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 546/2011⁴, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

1.2 Letters 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.

1.3 Justification for submission of tests and studies

Not applicable.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

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 Details of the authorisation decision

2.1 Product identity

Product code	ALD1901
Product name in MS	ROMEO GARDEN
Low risk product (article 47)	Yes
Authorisation number	2180275
Function	Systemic resistance inducer
Applicant	AGRO-LEVURES ET DERIVES
Active substance(s) (incl. content)	Cerevisane (cell walls of <i>Saccharomyces cerevisiae</i> strain LAS 117), 941 g/kg (924 g/kg minimal concentration)
Formulation type	Wettable powder (WP)
Packaging	PET/aluminium/LDPE bags (1.25 g ; 2.5 g ; 5 g ; 10 g ; 12.5 g ; 20 g ; 25 g) Non-professional user.
Coformulants of concern for national authorisations	N/A
Restrictions related to identity	N/A
Mandatory tank mixtures	N/A
Recommended tank mixtures	N/A

2.2 Conclusion

The evaluation of the application for ROMEO GARDEN (ALD1901) resulted in the decision to grant the authorisation.

Only the uses of systemic resistance inducer plants were kept for all plant applied.

2.3 Substances of concern for national monitoring

Not applicable.

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:

No classification

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

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

For other restrictions refer to 2.5.

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

Not applicable.

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 4th May 2017⁵ provides that:

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

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, drift 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 “linked” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those “linked” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁷ is to supply “minor” crops with registered plant protection products.

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

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

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/AGRGI632554A/jo/texte>

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

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

2.5.1 Restrictions linked to the PPP

The authorisation of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
	refer to the Decision in Appendix 1
Worker protection:	
	refer to the Decision in Appendix 1
Integrated pest management (IPM)/sustainable use: N/A	
Environmental protection	
	Do not discharge into the sink, gutter or any other surface water body the unused dregs from containers or water used to wash the sprayer.
	To protect aquatic organisms, do not apply within 5 metres of a surface water body (such as a well, pond, pool, stream or river) for the outdoor uses.
Other specific restrictions	
	Re-entry period ⁸ : Wait until the treated zone or plants have dried

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):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
	The efficacy level of the product is considered as variable and partial. Precise optimal conditions of use.	
Environmental protection:		Relevant for use no.
	N/A	

⁸ The legal basis for this is Article 3 II of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

2.6 Uses (only NATIONAL GAP)

PPP (product name/code): ROMEO GARDEN (ALD1901)
Active substance 1: Cerevisane of *Saccharomyces cerevisiae* strain LAS 117
Safener: none
Synergist: none
Applicant: AGRO-LEVURES ET DERIVES
Zone(s): Southern/ interzonal ^(d)
Verified by MS: yes

Formulation type:
Conc. of as 1:
Conc. of safener:
Conc. of synergist:
Professional use:
Non professional use:

GAP, date: 2018-07-13

WP ^(a, b)
941 g/kg ^(c)

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Field of use: Systemic Resistance Inducer

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.*	Member state(s)	Crop and/or situation (crop destina- tion / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests con- trolled (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 a) per use b) per crop/ season	Min. interval between appli- cations (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
3	FR	Cucurbits with inedible peel	Fn	Powdery mildew ERYSCI PODOXA	Foliar spray	BBCH12 to BBCH89	a) 8 b) 8	7	a) 0.5 kg/ha b) 4 kg/ha	a) 0.47 kg/ha b) 3.8 kg/ha	100 / 1000	1	Not acceptable Only uses of Sys- temic Resistance Inducer acceptable in France
5	FR	Cucurbits with inedible peel	Gn, Fn	Systemic Resistance Inducer (demonstrated on powdery mildew ERYSCI, PODOXA)	Foliar spray	BBCH12 to BBCH89	a) 8 b) 8	7	a) 0.5 kg/ha b) 4 kg/ha	a) 0.47 kg/ha b) 3.8 kg/ha	100 / 1000	1	Acceptable
12	FR	Grapevine and Table grape VITVI	Fn	Powdery mildew UNCINE	Foliar spray	BBCH12 to BBCH89.	a) 10 b) 10	7	a) 0.25 kg/ha b) 2.5 kg/ha	a) 0.24 kg/ha b) 2.35 kg/ha	100 / 1000	1	Not acceptable Only uses of Sys- temic Resistance

													Inducer acceptable in France
13	FR	Grapevine and Table grape VITVI	Fn	Downy mildew PLASVI	Foliar spray	BBCH12 to BBCH89.	a) 10 b) 10	7	a) 0.25 kg/ha b) 2.5 kg/ha	a) 0.24 kg/ha b) 2.35 kg/ha	100 / 1000	1	Not acceptable Only uses of Systemic Resistance Inducer acceptable in France
14	FR	Grapevine and Table grape VITVI	Fn	<i>Botrytis cinerea</i> BOTRCI	Foliar spray	BBCH12 to BBCH89.	a) 5 b) 5	7	a) 0.25 kg/ha b) 1.25 kg/ha	a) 0.24 kg/ha b) 1.18 kg/ha	100 / 1000	1	Not acceptable Only uses of Systemic Resistance Inducer acceptable in France
15	FR	Grapevine and Table grape VITVI	Fn	Systemic Resistance Inducer (demonstrated on powdery mildew UNCINE, downy mildew PLASVI and Botrytis BOTRCI)	Foliar spray	BBCH12 to BBCH89	a) 10 b) 10	7	a) 0.25 kg/ha b) 2.5 kg/ha	a) 0.24 kg/ha b) 2.35 kg/ha	100 / 1000	1	Acceptable
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	Cucurbits with edible peel	Gn	Powdery mildew ERYSCI PODOXA	Foliar spray	BBCH12 to BBCH89	a) 8 b) 8	7	a) 0.5 kg/ha b) 4 kg/ha	a) 0.47 kg/ha b) 3.8 kg/ha	100 / 1000	1	Not acceptable Only uses of Systemic Resistance Inducer acceptable in France
2	FR	Cucurbits with edible peel	Gn, Fn	Systemic Resistance Inducer (demonstrated on powdery mildew ERYSCI, PODOXA)	Foliar spray	BBCH12 to BBCH89	a) 8 b) 8	7	a) 0.5 kg/ha b) 4 kg/ha	a) 0.47 kg/ha b) 3.8 kg/ha	100 / 1000	1	Acceptable
5	FR	Lettuce LACSA and other salads	Gn	Downy mildew	Foliar spray	BBCH12 to BBCH89	a) 8 b) 8	7	a) 0.75 kg/ha b) 6 kg/ha	a) 0.71 kg/ha b) 5.65 kg/ha	100 / 1000	1	Not acceptable Only uses of Systemic Resistance Inducer acceptable in France
6	FR	Lettuce LACSA and other salads	Gn, Fn	Systemic Resistance Inducer (demonstrated on downy mildew BREMLA)	Foliar spray	BBCH12 to BBCH89	a) 8 b) 8	7	a) 0.75 kg/ha b) 6 kg/ha	a) 0.71 kg/ha b) 5.65 kg/ha	100 / 1000	1	Acceptable

7	FR	Strawberry FRASS	Gn	<i>Botrytis cinerea</i> BOTRCI	Foliar spray	BBCH12 to BBCH89	a) 8 b) 8	7	a) 0.75 kg/ha b) 6 kg/ha	a) 0.71 kg/ha b) 5.65 kg/ha	100 / 1000	1	Not acceptable Only uses of Sys- temic Resistance Inducer acceptable in France
8	FR	Strawberry FRASS	Gn, Fn	Systemic Resistance Inducer (demonstrated on <i>Botrytis cinerea</i> BOTRCI)	Foliar spray	BBCH12 to BBCH89	a) 8 b) 8	7	a) 0.75 kg/ha b) 6 kg/ha	a) 0.71 kg/ha b) 5.65 kg/ha	100/1000	1	Acceptable
9	FR	Tomato LYPES and Eggplant	Gn	<i>Botrytis cinerea</i> BOTRCI	Foliar spray	BBCH12 to BBCH89	a) 10 b) 10	7	a) 0.5 kg/ha b) 5 kg/ha	a) 0.47 kg/ha b) 4.7 kg/ha	100 / 1000	1	Not acceptable Only uses of Sys- temic Resistance Inducer acceptable in France
10	FR	Tomato LYPES and Eggplant	Gn, Fn	Systemic Resistance Inducer (demonstrated on Tomato Botry- tis cinerea BOTRCI)	Foliar spray	BBCH12 to BBCH89	a) 8 b) 8	7	a) 0.5 kg/ha b) 4 kg/ha	a) 0.47 kg/ha b) 3.8 kg/ha	100 / 1000	1	Acceptable

Remarks table heading:

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

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 authorisation 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)

ROMEO GARDEN (ALD1901) is a wettable powder (WP). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is a beige wettable powder formulation with a malty odour. It is not explosive and has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 219°C. In aqueous solution (1%), it has a pH value 3.21 at 21°C. The product is stable for 2 weeks at 54 °C in opaque white plastic flasks (LDPE) with red stopper packaging; neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in kraft bags. As the formulation is wettable powder, as the stability was performed on opaque white plastic flasks (LDPE) and kraft bags packaging, the PET bag and HDPE pot packaging can be considered as compatible with the formulation. Its technical characteristics are acceptable for a wettable powder formulation.

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

3.2 Efficacy (Part B, Section 3)

The efficacy level of ROMEO GARDEN (ALD1901) is considered as partial and variable for all the claimed uses. Optimal conditions of use should be precised.

However it is considered as acceptable considering the kind of product with an induction of systemic resistance mode of action. Given the mode of action and the level of efficacy of the ROMEO GARDEN (ALD1901), **only the uses of systemic resistance inducer plants were kept.**

The phytotoxicity level of ROMEO GARDEN (ALD1901) is considered as negligible for all the claimed uses.

The risks of negative impact on yield, quality, transformation processes, propagation, succeeding crops, adjacent crops are considered as negligible.

The risk of resistance development or appearance to cerevisane is considered as very low for the claimed uses.

Restrictions: -

Resistance monitoring data: -

Post-authorization data: -

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical method for the determination of the microbial active substance in the formulation is available and validated.

Analytical methods for the determination of microbial contaminants according to OECD 65 are available and validated.

3.3.2 Analytical methods for residues

Analytical methods for the determination of residues are not necessary as MRL for active substance are not needed (cerevisane is on Annex IV to Regulation (EC) No 396/2005).

According to the EFSA conclusions, for the shelf life, data on active substance content (markers), contaminants (according to the proposed levels and methods as given in the OECD Issue Paper (2011) on Microbial Contaminant Limits for Microbial Pest Control Products) are required. Moreover, acidity of the preparation before and after 2 years of storage at ambient temperature is required.

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

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Active substance	ADI mg/kg.bw/d	ArfD mg/kg.bw	AOEL mg/kg.bw/d	Classification
Cerevisane	Not relevant			Not classified

Cerevisane is a low risk substance, the derivation or reference values were not needed.

Positive cases of respiratory sensitisation have been reported in humans exposed to *Saccharomyces cerevisiae* (EFSA Journal 2014;12(6):3583).

3.4.1 Acute toxicity

ROMEO GARDEN (ALD1901) containing 941 g/kg cerevisane has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye.

3.4.2 Operator exposure

The French study 2005 dedicated to amateur use is not suitable for calculating a risk assessment for operators on the base of a not existing dose-effect relation. The preparation is considered safe for operators based on the low toxicity profile and the application.

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

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.

3.4.3 Worker exposure

ROMEO GARDEN (ALD1901) is intended to be used by amateurs during home garden application. In this case of the non-professional user, the worker is also the user of the product.

Cerevisane is a low risk substance, it is not expected an unacceptable risk for the worker.

3.4.4 Bystander and resident exposure

Following the above given reasons for abstaining from an estimation of operator risk assessment, this also applies with regard to bystanders and residents. As regard the application method, bystander and residential exposure is supposed to be negligible for field uses.

As regard the application method (greenhouse), bystander and residential exposure is not considered relevant for greenhouse uses.

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

Selection of critical uses and justification

Cerevisane is listed on Annex IV to Regulation (EC) No 396/2005 and therefore has an MRL exemption. No further assessment is required on metabolism and residues.

Overall conclusion

According to COMMISSION REGULATION (EU) 2016/143 of 18 January 2016 as regards cerevisane, the Authority concluded that the inclusion of that substance in Annex IV to Regulation (EC) No 396/2005 is appropriate. Cerevisane is listed on Annex IV to Regulation (EC) No 396/2005 and therefore has an MRL exemption. No further assessment is required on metabolism and residues and no safety concern was identified regarding the use of ROMEO GARDEN (ALD1901).

The product ROMEO GARDEN (ALD1901) is composed of cerevisane.

Summary for cerevisane

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1-2	Cucurbits with edible peel	Not required	Not required	Not required	Not required	Not applicable	No	No
3-5	Cucurbits with inedible peel							
5-6	Lettuce and other salads							
7-8	Strawberry							
9-10	Tomato and Eggplant							
12-15	Grapevine and table grape							

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

Cerevisane is included in Annex IV of Regulation (CE) No 396/2005 that groups active substances for which no MRL are necessary no specific studies are required. Therefore no addition data are required to

support the intended uses of ROMEO GARDEN (ALD1901).

Summary for ROMEO GARDEN (ALD1901)

Information on ROMEO GARDEN (ALD1901) (KCA 6.8)

Crop	PHI for ROMEO GARDEN (ALD1901) proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for ROMEO GARDEN (ALD1901) proposed by zRMS	zRMS Comments (if different PHI proposed)
		cerevisane		
Cucurbits with edible peel	0 days	NR	1 day	According to EU guidelines (European Commission, 1997g) a 1 day PHI is proposed for the intended uses on all edible crops under evaluation.
Cucurbits with inedible peel				
Lettuce and other salads				
Strawberry				
Tomato and Eggplant				
Grapevine and table grape				

NR: not relevant

* Purpose of withholding period to be specified

** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Waiting periods before planting succeeding crops

Not relevant

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

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Cerevisane is considered as a **low-risk active substance** (Commission Regulation (EC) No 2015/553). Appropriate endpoints from the EU review were used to calculate PECs for the active substance for the intended use patterns. The endpoints established in the EU conclusions (EFSA, 2014) were used in calculations.

The formulated product ROMEO GARDEN (ALD1901) was considered for Annex I inclusion of the active substance.

Cerevisane is made of inert cell wall of *Sacharomyces cerevisiae* (no cell living). Cerevisane can be considered degradable in the environment. The degradation of cerevisane releases protein material, lipid material and organic matter, which are all natural components in the soil. The dead cell biological material contained in the active substance does not only occur as residues of this yeast but also originates from

other living matter and thereby contributing to background levels. Therefore, no soil exposure calculation is needed.

In view of available data and in accordance with the EU assessment, no unacceptable risk of groundwater contamination is expected after the application of ROMEO GARDEN (ALD1901) for the intended uses.

PEC_{SW} derived for the active substance are used for the eco-toxicological risk assessment.

3.7 Ecotoxicology (Part B, Section 9)

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

Cerevisane is approved as a low-risk active substance (Commission Regulation (EC) No 2015/553).

Based on the guidance documents, the risks for birds, mammals, aquatic organisms, bees and other non-target arthropods, earthworms, other soil macro-organisms and soil micro-organisms and terrestrial plants are acceptable for the intended uses.

The risk to aquatic organisms following the intended use of ROMEO GARDEN (ALD1901) can be considered acceptable with the following mitigation measures:

- To protect aquatic organisms apply at least 5 meters away from any surface water bodies (well, pond, stream, river...) for the outdoor uses.

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

Not applicable.

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

5.1.1 Post-authorisation monitoring

No further information is required.

5.1.2 Post-authorisation data requirements

The French Decision requests the submission of post-authorisation confirmatory pieces of information within 24 months regarding:

- Active substance content (markers), contaminants (according to the proposed levels and methods as given in the OECD Issue Paper (2011) on Microbial Contaminant Limits for Microbial Pest Control Products)
- Acidity of the preparation before and after 2 years of storage at ambient temperature is required.

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 **ROMEO GARDEN***

*de la société **AGRO-LEVURES ET DERIVES SAS***

*enregistrée sous le **n°2017-0114***

Vu les conclusions de l'évaluation de l'Anses du 17 mai 2018,

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	ROMEO GARDEN	
Type de produit	Deuxième gamme	
Titulaire	AGRO-LEVURES ET DERIVES 137 rue Gabriel Péri 59700 MARCQ-EN-BAROEUL FRANCE	
Formulation	Poudre mouillable (WP)	
Contenant	941 g/kg - cerevisane	
Produit de référence	Nom commercial	ROMEO
	N° AMM	2170654
Numéro d'intrant	9984-2017.01	
Numéro d'AMM	2180275	
Fonction	Stimulateur des défenses naturelles	
Gamme d'usages	Amateur / emploi autorisé dans les jardins	
Mention particulière	Produit à faible risque au sens de l'article 47 du règlement (CE) 1107/2009	

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. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 23 avril 2031.

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 13 JUL. 2018

Le Directeur Général


Roger GENET



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
Sacs multicouches thermo-scellés en polyéthylène téréphtalate / aluminium / polyéthylène basse densité	1,25 g ; 2,5 g ; 5 g ; 10 g ; 12,5 g ; 20 g ; 25 g

Les sacs multicouches en papier / polyéthylène basse densité de 2,5 et 5 kg, les pots en polyéthylène haute densité de 125, 250, 500 et 1000 g et les seaux en polypropylène / polyéthylène basse densité de 2 et 4 kg sont refusés car ils ne permettent pas de garantir une exposition minimale de l'utilisateur non professionnel.

Classification du produit
La classification retenue est la suivante : Sans classement.
Pour les phrases P se référer à la réglementation en vigueur.
Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.



Liste des usages autorisés

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitee aquatique (mètres)	Zone Non Traitee arthropodes non cibles (mètres)	Zone Non Traitee plantes non cibles (mètres)	Mention abeilles
00516001 Concombre*Trt Part.Aer.* Stimul. Déf. naturelles	5 g/100 m ³	8/an	entre les stades BBCH 12 et BBCH 89	1	5	-	-	-
Egalement autorisé sous abri. Efficacité montrée sur oidium. Intervalle minimum entre les applications : 7 jours.								
01125023 Fraisier*Trt Part.Aer.* Stimul. Déf. naturelles	7,5 g/100m ²	8/an	entre les stades BBCH 12 et BBCH 89	1	5	-	-	-
Egalement autorisé sous abri. Efficacité montrée sur pourriture grise. Intervalle minimum entre les applications : 7 jours.								
01128015 Laitue*Trt Part.Aer.* Stimul. Déf. naturelles	7,5 g/100m ²	8/an	entre les stades BBCH 12 et BBCH 89	1	5	-	-	-
Egalement autorisé sous abri. Efficacité montrée sur mildiou. Intervalle minimum entre les applications : 7 jours.								
00516002 Melon*Trt Part.Aer.* Stimul. Déf. naturelles	5 g/100 m ²	8/an	entre les stades BBCH 12 et BBCH 89	1	5	-	-	-
Egalement autorisé sous abri. Efficacité montrée sur oidium. Intervalle minimum entre les applications : 7 jours.								
01146031 Tomate*Trt Part.Aer.* Stimul. Déf. naturelles	5 g/100 m ²	8/an	entre les stades BBCH 12 et BBCH 89	1	5	-	-	-
Egalement autorisé sous abri. Efficacité montrée sur pourriture grise. Intervalle minimum entre les applications : 7 jours.								
00901063 Vigne*Trt Part.Aer.* Stimul. Déf. naturelles	2,5 g/100m ²	10/an	entre les stades BBCH 12 et BBCH 89	1	5	-	-	-
Efficacité montrée sur mildiou, oidium et pourriture grise. Intervalle minimum entre les applications : 7 jours.								

ROMEO GARDEN
AMM n°2180275

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Liste des usages refusés				
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)	
01101036 Cultures légumières*Trt Part.Aer.*Stimul. Def. naturelles	7 g/100m ²	8/an	1	
Motivation du refus : L'usage est refusé car il est considéré comme redondant avec les usages n°00516001, 01128015, 00516002. et 01146031, aucune information supplémentaire n'ayant été fournie pour les autres cultures légumières.				
16323203 Concombre*Trt Part.Aer.*Oidium(s)	5 g/100m ²	8/an	1	
Motivation du refus : L'usage est refusé car il est considéré comme non pertinent. L'usage est couvert par l'usage n°00516001.				
16553201 Fraisier*Trt Part.Aer.*Pourriture grise et sclérotioses	7,5 g/100m ²	8/an	1	
Motivation du refus : L'usage est refusé car il est considéré comme non pertinent. L'usage est couvert par l'usage n°01125023.				
16603207 Laitue*Trt Part.Aer.*Mildiou(s)	7,5 g/100m ²	8/an	1	
Motivation du refus : L'usage est refusé car il est considéré comme non pertinent. L'usage est couvert par l'usage n°01128015.				
16753205 Melon*Trt Part.Aer.*Oidium(s)	5 g/100m ²	8/an	1	
Motivation du refus : L'usage est refusé car il est considéré comme non pertinent. L'usage est couvert par l'usage n°00516002.				
16953203 Tomate*Trt Part.Aer.*Pourriture grise et sclérotioses	5 g/100m ²	8/an	1	
Motivation du refus : L'usage est refusé car il est considéré comme non pertinent. L'usage est couvert par l'usage n°01146031.				

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Liste des usages refusés				
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)	
12703203 Vigne*Trt Part.Aer.*Mildiou(s)	2,5 g/100m²	10/Jan	1	
Motivation du refus : L'usage est refusé car il est considéré comme non pertinent. L'usage est couvert par l'usage n°00901063.				
12703204 Vigne*Trt Part.Aer.*Oidium(s)	2,5 g/100m²	10/Jan	1	
Motivation du refus : L'usage est refusé car il est considéré comme non pertinent. L'usage est couvert par l'usage n°00901063.				
12703205 Vigne*Trt Part.Aer.*Pourriture grise	2,5 g/100m²	5/Jan	1	
Motivation du refus : L'usage est refusé car il est considéré comme non pertinent. L'usage est couvert par l'usage n°00901063.				

ROMEO GARDEN
AMM n°2180275

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Conditions d'emploi du produit

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

- Pour protéger les organismes aquatiques, ne pas appliquer à moins de 5 mètres d'un point d'eau (puits, bassin, mare, ruisseau, rivière, fossé...).

Exigences complémentaires post-autorisation

A défaut de transmission de ces données dans les délais impartis à compter de la date de la présente décision, la présente décision pourra être retirée ou modifiée.

Détail de la demande post autorisation	Délai (mois)	Réurrence (mois)
Déterminer la teneur en substance active (marqueurs) et en contaminants microbiens avant et après 2 ans de stockage à température ambiante.	24	-
Déterminer l'acidité du produit avant et après 2 ans de stockage à température ambiante.	24	-

Recommandations relatives à l'étiquette du produit

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

- L'efficacité du produit étant variable et partielle, préciser les conditions optimales d'utilisation.

Appendix 2 Copy of the product label

Copy of the draft product label as proposed by the applicant

CORE DRAFT LABEL

AGRO-LEVURES ET DÉRIVÉS SAS

**ROMEO
GARDEN®**

ROMEO GARDEN® est un Stimulateur des Défenses Naturelles des plantes pour la protection de la vigne, raisin de table, cucurbitacées, fraisiers, tomates, laitues et autres salades contre diverses maladies fongiques (mildiou, oïdium, botrytis).

Formulation : Poudre mouillable (WP)

Contenant 941 g/kg de CEREVISANE

A.M.M. N°. XXXXXXX
Détenteur de l'A.M.M.:
Agro-Levures et Dérivés SAS,
137, rue Gabriel Péri
59700 Marcq-en-Barœul, France

ROMEO GARDEN®

"Autorisé en tant que produit phytopharmaceutique à faible risque conformément au règlement (CE) n° 1107/2009 "

Distribué par: xxxxx

N° de lot et date de fabrication : voir emballage

XX g e

Agro-Levures et Dérivés

Mars 2016

ALD1901

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ROMEO GARDEN®

LIRE L'ETIQUETTE AVANT EMPLOI. UTILISER CE PRODUIT D'UNE MANIÈRE INCOMPATIBLE AVEC L'ETIQUETTE PEUT ÊTRE UNE INFRACTION. RESPECTER LES BONNES PRATIQUES PHYTOSANITAIRES.

PRECAUTIONS D'EMPLOI

Utiliser des équipements de protection individuelle, y compris des gants pour l'hygiène

SP1: Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes

P101 En cas de consultation d'un médecin, garder à disposition le récipient ou l'étiquette.

P102 Conserver hors de la portée des enfants.

P103 Lire l'étiquette avant utilisation

P260 Ne pas respirer les poussières.

Ne pas réutiliser l'emballage.

Respecter les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement.

RECOMMANDATIONS D'EMPLOI

IMPORTANT : Cette information fait partie de l'étiquette du produit. Lire attentivement les instructions de cette section afin de garantir une utilisation sûre et efficace de ce produit.

MODE D'ACTION

ROMEO GARDEN® est Stimulateur des Défenses Naturelles des plantes (SDN) qui agit de façon préventive. Sa substance active (CEREVISANE) stimule fortement les mécanismes de défenses des plantes, et prépare ainsi la plante à se défendre contre des attaques fongiques.

Agro-Levures et Dérivés Mars 2016 ALD1901 Page 3 of 4

TABLEAU DES USAGES (GAP)

Culture	Champ / Serre	Maladie cible	Dose d'emploi (g/100m ²) par appli.	Nombre maximal d'application	Délai avant récolte (DAR)
Concombre (CUMSA) Courgette(CUUPG) Cornichon, et autres cucurbitacées à peau comestible	Serre	Oidium ERYSCI PODOXA	5	8	0 jour
Cucurbitacées	Serre	Stimulateur des Défenses Naturelles (démontré sur concombre et courgette, oidium ERYSCI, PODOXA)	5	8	0 jour
Melon (CUMME) Pastèque, Citrouille, et autres cucurbitacées à peau non comestible	Champ	Oidium ERYSCI PODOXA	5	8	0 jour
Cucurbitacées	Champ	Stimulateur des Défenses Naturelles (démontré sur melon oidium ERYSCI, PODOXA)	5	8	0 jour
Laitue (LACSA) et autres salades	Serre	Mildiou BREMLA	7.5	8	0 jour
Laitue (LACSA) et autres salades	Serre	Stimulateur des Défenses Naturelles (démontré sur laitue mildiou BREMLA, botrytis BOTRSP, et rhizoctone RHIZSO)	7.5	8	0 jour
Fraisier (FRASS)	Serre	<i>Botrytis cinerea</i> (BOTRCI)	7.5	8	0 jour
Fraisier (FRASS)	Serre	Stimulateur des Défenses Naturelles (démontré sur <i>Botrytis cinerea</i> BOTRCI)	7.5	8	0 jour
Tomate (LYPES) et Aubergine	Serre	<i>Botrytis cinerea</i> (BOTRCI)	5	10	0 jour
Tomate (LYPES) et Aubergine	Serre	Stimulateur des Défenses Naturelles (démontré sur Tomate <i>Botrytis cinerea</i> BOTRCI)	5	10	0 jour
Cultures légumières	Serre	Stimulateur des Défenses Naturelles (démontré sur - concombre oidium, - courgette oidium, - melon oidium, - laitue mildiou, botrytis et rhizoctone - fraisier botrytis - tomate botrytis)	5 – 7.5	8	0 jour
Vigne et raisin de table VITVI	Champ	Oidium UNCINE	2.5	10	0 jour
Vigne et raisin de table VITVI	Champ	Mildiou PLASVI	2.5	10	0 jour
Vigne et raisin de table VITVI	Champ	<i>Botrytis cinerea</i> BOTRCI	2.5	5	0 jour
Vigne et raisin de table VITVI	Champ	Stimulateur des Défenses Naturelles (démontré sur oidium UNCINE, mildiou PLASVI et botrytis BOTRCI)	2.5	10	0 jour

LIMITES MAXIMALES DE RÉSIDUS (LMR)

Conformément au règlement (UE) 2016/143 de la Commission, cérévisane est exempté de LMR.

Délai de rentrée sur la parcelle traitée : attendre le séchage complet de la zone traitée.

ROMEO GARDEN®

RECOMMANDATIONS D'EMPLOI

ROMEO GARDEN® peut être utilisé en pulvérisation foliaire sur Vigne, Raisin de table et Cucurbitacées au champ, et sous serre sur Cucurbitacées, Salades, Tomates et Fraisier.

Appliquer en préventif strict, avant un risque de contamination.

Intervalle d'application : 7-10 jours en fonction de la pression de maladie.

En cas de développement de la maladie ou de forte pression, utiliser ROMEO® dans un programme avec d'autres fongicides (alternance ou mélange).

Appliquer un volume de bouillie suffisant pour assurer une couverture complète de la végétation sans lessivage :

- 2.5 g dans 10 L d'eau pour traiter 100 m² sur vigne
- 2.5 à 3.75 g dans 5 L d'eau pour traiter 50 m² sur légumes.

Si possible appliquer le produit sur chaque face des feuilles et de préférence tôt le matin. Éviter toute application pendant les périodes de fortes températures.

En cas de fortes pluies (risque de lessivage) suivant l'application, répéter l'application.

PRÉPARATION DE LA BOUILLIE ET PULVERISATION

Remplir à moitié la cuve avec de l'eau et mettre en marche l'agitation. Verser la quantité nécessaire de ROMEO GARDEN® dans la cuve du pulvérisateur. Remplir la cuve avec de l'eau au volume requis.

Maintenir l'agitation durant toute la durée de l'application.

Toujours s'assurer que le pulvérisateur est nettoyé selon les procédures standard de nettoyage, en bon état de fonctionnement et calibré avec précision selon les recommandations du fabricant du pulvérisateur.

MELANGES ET COMPATIBILITES

Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur et aux recommandations des guides de bonnes pratiques officiels.

Le produit est compatible avec la plupart des produits de protection des plantes (fongicides, insecticides, herbicides) et fertilisants. En cas de nouveau mélange, merci de vérifier préalablement la compatibilité physique dans un petit récipient. Il n'est cependant pas possible de garantir la compatibilité biologique de tous les mélanges.

STOCKAGE

Conservez l'emballage bien fermé dans un endroit sec et bien aéré. Toujours garder dans son emballage d'origine. Il est recommandé de stocker ROMEO GARDEN® hors du gel, des fortes température et protégé de la lumière directe et de l'humidité.

Durée de vie : 2 ans à compter de la date de fabrication (voir emballage).

Ce produit doit être utilisé uniquement en conformité avec les recommandations et les instructions données sur les étiquettes. L'utilisation dans toute autre circonstance est entièrement sous la responsabilité de l'utilisateur.

Appendix 3 Letter of Access

The letters of access are available and have been removed for confidentiality reasons.

Appendix 4 Lists of data considered for national authorisation

See attached documentation.