REGISTRATION REPORT

Part A

Risk Management

Product code: ALD1202

Product name(s): JULIETTA GARDEN

Active Substance(s):

***Saccharomyces cerevisiae* LAS02,**

1×10^{13} CFU/kg

COUNTRY: FRANCE

Interzonal and Southern zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE
(new application)
Amateur

Applicant: Agrauxine

Date: 2019/02/22

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PART A – Risk Management

The company Agrauxine has requested a marketing authorisation in France for the product JULIETTA GARDEN (product code: ALD1202), containing 1 10^{13} CFU/Kg (960.8 g/Kg) of *Saccharomyces cerevisiae* strain LAS02 for use as a fungicide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to JULIETTA (ALD1202) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of JULIETTA GARDEN (ALD1202) have been made using endpoints agreed in the EU peer review(s) of *Saccharomyces cerevisiae* strain LAS02.

This document describes the specific conditions of use and labelling required for France for the registration of JULIETTA GARDEN (ALD1202).

Appendix 1 of this document provides a copy of the French Decision.

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

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

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of Agrauxine's application to market JULIETTA GARDEN (ALD1202) in France as a fungicide (product uses described under point 2.3) for amateur uses. France acted as an interzonal (Greenhouse uses) and zonal (field uses) Rapporteur Member State (izRMS) 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. *Saccharomyces cerevisiae* strain LAS02 is a low risk active substance and is the only active substance of JULIETTA GARDEN (ALD1202), therefore JULIETTA GARDEN (ALD1202)shall be authorized as a low risk plant protection product if compliant with article 47.

1.2 Active substance approval

***Saccharomyces cerevisiae* strain LAS02**

Commission Implementing Regulation (EU) 2016/952 of 15 June 2016 approving the low-risk active substance *Saccharomyces cerevisiae* strain LAS02 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.
Specific provisions of Regulation (EU) No 540/2011 were as follows : For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on Saccharomyces cerevisiae strain LAS02, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that Saccharomyces cerevisiae strain LAS02 is to be considered as a potential sensitizer. Conditions of use shall include risk mitigation measures, where appropriate. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer.
An EFSA conclusion is available (EFSA Journal 2015; 13(12): 4322).

A Review Report is available (SANCO/12457/2015 rev 0, 19 May 2016).

1.3 Regulatory approach

The present application (2017-1901) 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 European Union, taking into account the worst-case uses ("risk envelope approach")[1] – the highest application rates over the European Union. When risk mitigation measures were necessary, they are adapted to the situation in France.

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

The French Order of 4th May 2017[2] provides that:
- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight hours for indoor uses.

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

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009[3], implementing regulations, and French regulations.

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

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011[4], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[5] provides that:
- an authorisation granted for a "reference" crop applies also for "linked" crops, unless formally stated in the Decision
- the "reference" and "linked" crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "linked" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those "linked" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[6] is to supply "minor" crops with registered plant protection products.

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

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[1] SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5

[2] 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

[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

[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

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

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

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

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of JULIETTA GARDEN (ALD1202), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

2 Provided upon requested DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	JULIETTA GARDEN (ALD1202)
Authorisation number	2190011
Function	Fungicide
Low risk (article 47)	Yes
Applicant	Agrauxine
Composition	1 x 10^{13} CFU/kg *Saccharomyces cerevisiae* strain LAS02
Formulation type (code)	Water-dispersible granule (WG)
Packaging	Bags PET-ALU-PE (2.5 g and 25 g) Bags PET-Al-PAO-PE (75 g ; 125 g ; 250 g ; 500 g ; 1250 g)

2.2 Classification and labelling

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

Physical hazards	-	
Health hazards	no classification for human health	
Environmental hazards	no classification for environment	
Hazard pictograms		
Signal word	None	
Hazard statements	-	
Precautionary statements –	***For the P phrases, refer to the extant legislation***	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)		Contains *Saccharomyces cerevisiae.* Micro-organisms may have the potential to provoke sensitising reactions" The product should not be used by subjects affected by immunodeficiency or in treatment with immunosuppressive agents.

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

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

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

	Do not discharge into the sink, gutter or any other water source, the non-used container leftovers and the sprayer washing water.
	To protect aquatic organisms apply at least 5 metres[7] away from any surface water bodies (well, pond, stream, river…) for field uses.

2.2.3 Other phrases linked to the preparation

Re-entry period[8]: Wait until the treated zone or plants have dried
Pre-harvest interval[9]: 1day
Other mitigation measures: - The formulation must not be stored at a temperature higher than 20 °C. - It has to be noted that it should be avoided to tank mix JULIETTA GARDEN (ALD1202)with fungicide products and that particular attention should be paid to the timing between applications of JULIETTA GARDEN (ALD1202)and other fungicide product
The label may include the following recommendations: - As efficacy is variable and partial on *monilia* spp, precise optimal conditions of use - Precise optimal conditions of use of the product in regard to other fungicides treatments - Do not mix with other fungicides - Contains *Saccharomyces cerevisiae*. Micro-organisms may have the potential to provoke sensitising reactions The label must reflect the conditions of authorisation.

[7] The legal basis for this is **Titre III Article 12** 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]

[8] The legal basis for this is **Titre I Article 3** 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]

[9] According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

2.3 Product uses

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

GAP rev. , date: 2019-02-22

PPP (product name/code):	**JULIETTA GARDEN/ ALD1202**	Formulation type:	**WG** [a, b]
Active substance 1:	Saccharomyces cerevisiae LAS02	Conc. of as 1:	**960,8 g/kg (1×10^{13} CFU/kg)** [c]
Safener:	Nc	Conc. of safener:	nc [c]
Synergist:	Nc	Conc. of synergist:	nc [c]
Applicant:	**Agrauxine**	Professional use:	☐
Zone(s):	interzonal [d]	Non professional use:	☒
Verified by MS:	Yes		
Field of use:	Fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f] RMS CONCLUSION
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	FR	Stone fruits (Peach, Apricot, Nectarine, Plum tree)	F	*Monilinia sp.* MONILA, MONIFG, MONIFC	Spraying	BBCH 51 to 89	a) 8 b) 8	7 days	a) 2.5 b) 20	a) 2.4 kg 2.5×10^{13} CFU b) 19.22 kg 2.0×10^{14} CFU	100-1500	1	**Acceptable**
2	FR	Grapevine & Table grape VITVI	F	*Botrytis cinerea* BOTRCI	Spraying	BBCH 60 to 89	a) 6 b) 6	7 days	a) 2.5 b) 15	a) 2.4 kg 2.5×10^{13} CFU b) 14.41 kg 1.5×10^{14} CFU	100-1000	1	**Acceptable**

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f] RMS CONCLUSION
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
3	FR	Small fruits (Raspberry, Blackberries, Blackcurrant, Blueberry, Currant, and other berries)	F	*Botrytis cinerea* BOTRCI	Spraying	BBCH 12 to 89	a) 8 b) 8	7 days	a) 2.5 b) 20	a) 2.4 kg 2.5×10^{13} CFU b) 19.22 kg 2.0×10^{14} CFU	100-1500	1	**Acceptable**
4	FR	Tomato LYPES, Eggplant SOLME,	G	*Botrytis cinerea* BOTRSP, BOTRCI	Spraying	BBCH 12 to 89	a) 8 b) 8	7 days	a) 2.5 b) 15	a) 2.4 kg 2.5×10^{13} CFU b) 14.41 kg 1.5×10^{14} CFU	100-1000	1	**Acceptable**
5	FR	Pepper CPSAN Gombo ABMES	G	*Botrytis cinerea* BOTRSP, BOTRCI	Spraying	BBCH 12 to 89	a) 8 b) 8	7 days	a) 2.5 b) 20	a) 2.4 kg (2.5×10^{13} CFU) b) 19.22 kg (2.0×10^{14} CFU)	100-1000	1	**Acceptable**
6	FR	Strawberry FRASS	G	*Botrytis cinerea* BOTRCI	Spraying	BBCH 12 to 89	a) 8 b) 8	7 days	a) 2.5 b) 20	a) 2.4 kg 2.5×10^{13} CFU b) 19.22 kg 2.0×10^{14} CFU	100-1300	1	**Acceptable**

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, 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:**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		e.g. g safener/synergist per ha (f) RMS CONCLUSION
7	FR	Small fruits (Raspberry, Blackberries, Blackcurrant, Blueberry, Currant, and other berries)	G	*Botrytis cinerea* BOTRCI	Spraying	BBCH 12 to 89	a) 8 b) 8	7 days	a) 2.5 b) 20	a) 2.4 kg 2.5×10^{13} CFU b) 19.22 kg 2.0×10^{14} CFU	100-1300	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
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
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.
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/m^3 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 RISK MANAGEMENT

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

3.1.1 Physical and chemical properties

JULIETTA GARDEN (ALD1202) is a wettable granule formulation (WG). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a light ivory wettable granule formulation with yeast odour. It is not explosive and has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 200°C. In aqueous solution (1%), it has a pH value of 5.80 at ambient temperature. The product is stable for 36 months at 20°C in commercial packaging; neither the active ingredient content nor the technical properties were changed.

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

3.1.2 Methods of analysis

3.1.2.1 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.

3.1.2.2 Analytical methods for residues

Analytical methods for the determination of residues are not necessary as no residue definition.

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

Active substance	**ADI** mg/kg.bw/d	**ArfD** mg/kg.bw	**AOEL** mg/kg.bw/d	**Classification**
Saccharomyces cerevisiae Strain LAS02	Not relevant for microorganisms			Micro-organisms may have the potential to provoke sensitising reactions.

The derivation or reference values were not needed based on the absence of toxicity, infectivity and pathogenicity indications of the micro-organism.

3.1.3.1 Acute Toxicity

JULIETTA GARDEN (ALD1202) containing 960.8 g/kg (i.e. 1.10^{13} CFU/kg) of *Saccharomyces cerevisiae* LAS02 has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye. The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.2.

3.1.3.2 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.

Since *Saccharomyces cerevisiae* may be responsible for opportunist infection in sever immunocompromised people, the product should not be used by subjects affected by immunodeficiency or in treatment with immunosuppressive agents.

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

3.1.3.3 Bystander 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.
For greenhouse uses, bystander and residential exposure is not considered relevant.

3.1.3.4 Worker Exposure

JULIETTA GARDEN (ALD1202) 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. The micro-organism is neither toxic or infectious or pathogenic in mammals, it is not expected an unacceptable risk for the worker.

3.1.4 Residues and Consumer Exposure

Saccharomyces cerevisiae LAS02 is included in Annex IV to Regulation (EC) No 396/2005.
On the basis of the data presented, JULIETTA GARDEN (ALD1202) used according to the proposed GAP does not expose the consumer to viable or non-viable yeast. Chronic and acute consumer risks are considered acceptable.

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. *Saccharomyces cerevisiae* LAS02 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 values for the active substance for the intended use patterns. The endpoints established in the EU conclusions (EFSA, 2015) were used in calculations.

The PEC value of active substance in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with the endpoints established in the EU conclusions (EFSA, 2015).

PEC soil and PECsw values derived for the active substance are calculated, but they are not used for the ecotoxicological risk assessment in this specific case. No unacceptable risk of groundwater contamination is expected for the intended uses.

3.1.6 Ecotoxicology

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.

Saccharomyces cerevisiae LAS02 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.

3.1.7 Efficacy

The efficacy level of JULIETTA GARDEN (ALD1202) is considered as partial and variable for the use against *Monilia sp.* on stone fruit. However, it is considered as acceptable for this kind of product based on microorganism.
The efficacy level of JULIETTA GARDEN (ALD1202) is considered as acceptable for the other uses.
The phytotoxicity level of JULIETTA GARDEN (ALD1202) is considered as satisfactory for all the claimed uses.

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

3.2 The risk of resistance development or appearance to *Saccharomyces cerevisiae* strain LAS02 is considered as very low.Conclusions arising from French assessment

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

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

No further information is required.

3.4.2 Post-authorisation data requirements

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

3.4.3 Provide the result of the test of the persistent foam after long-term storage 36 months at 20 ° CLabel amendments

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

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

Appendix 1 – Copy of the French Decision

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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 règlementaire,

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

de la société	*AGRAUXINE*
enregistrée sous le	*n°2017-1901*

Vu les conclusions de l'évaluation de l'Anses du 10 janvier 2019,

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.

JULIETTA GARDEN
AMM n°2190011

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Informations générales sur le produit	
Nom du produit	JULIETTA GARDEN
Type de produit	Produit de référence
Titulaire	AGRAUXINE 137 rue Gabriel Péri 59700 MARCQ-EN-BAROEUL France
Formulation	Granulé dispersable (WG)
Contenant	1.10^{13} UFC/kg - *Saccharomyces cerevisiae* souche LAS02
Numéro d'intrant	635-2017.01
Numéro d'AMM	2190011
Fonction	Fongicide
Gamme d'usage	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 6 juillet 2032.

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, 22 FEV. 2019

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

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ANNEXE I : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	**Contenance**
Sachets en polyéthylène téréphtalate / aluminium / polyéthylène	2,5 g ; 25 g
Sacs en polyéthylène téréphtalate / aluminium / polyamide orienté/ polyéthylène	75 g ; 125 g ; 250 g ; 500 g ; 1250 g

Classification du produit
La classification retenue est la suivante : Sans classement.
Pour les phrases P se référer à la règlementation 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.**

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
12153208 Cassissier*Trt Part.Aer.* Pourriture grise	**2,5 g/10 m²**	**8/an**	entre les stades BBCH 12 et BBCH 89	1	5	-	-	-
	Également autorisé sous abri Intervalle minimum entre les applications : 7 jours							
16553201 Fraisier*Trt Part.Aer.* Pourriture grise et sclérotinioses	**2,5 g/10 m²**	**8/an**	entre les stades BBCH 12 et BBCH 89	1	-	-	-	-
	Uniquement autorisé sous abri. Efficacité montrée sur pourriture grise. Intervalle minimum entre les applications : 7 jours							
12353205 Framboisier*Trt Part.Aer.* Pourriture grise	**2,5 g/10 m²**	**8/an**	entre les stades BBCH 12 et BBCH 89	1	5	-	-	-
	Également autorisé sous abri. Intervalle minimum entre les applications : 7 jours							
12553233 Pêcher*Trt Part.Aer.* Monilioses	**2,5 g/10 m²**	**8/an**	entre les stades BBCH 51 et BBCH 89	1	5	-	-	-
	Intervalle minimum entre les applications : 7 jours							

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Liste des usages autorisés
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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
16863201 Poivron*Trt Part.Aer.* Pourriture grise et sclérotinioses	**2,5 g/10 m²**	**8/an**	entre les stades BBCH 12 et BBCH 89	1	-	-	-	-
	Uniquement autorisé sous abri. Efficacité montrée sur pourriture grise Intervalle minimum entre les applications : 7 jours							
12653204 Prunier*Trt Part.Aer.* Monilioses	**2,5 g/10 m²**	**8/an**	entre les stades BBCH 51 et BBCH 89	1	5	-	-	-
	Intervalle minimum entre les applications : 7 jours							
16953203 Tomate*Trt Part.Aer.* Pourriture grise et sclérotinioses	**2,5 g/10 m²**	**8/an**	entre les stades BBCH 12 et BBCH 89	1	-	-	-	-
	Uniquement autorisé sous abri. Efficacité montrée sur pourriture grise Intervalle minimum entre les applications : 7 jours							
12703205 Vigne*Trt Part.Aer.* Pourriture grise	**2,5 g/10 m²**	**6/an**	entre les stades BBCH 60 et BBCH 89	1	5	-	-	-
	Intervalle minimum entre les applications : 7 jours							

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Conditions d'emploi du produit

Stockage et manipulation du produit

- Ne pas utiliser par des personnes fortement immunodéprimées ou sous traitement immunosuppresseur.
- Ne pas stocker le produit dans un local où la température peut dépasser 20°C.

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

- Attendre le séchage complet de la zone traitée.

Respect des limites maximales de résidus (LMR)

Le délai avant récolte est fixé à 1 jour en fonction des pratiques agricoles sur la culture et afin de limiter l'exposition potentielle des consommateurs.

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 sacs 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)	Récurrence (mois)
Fournir le résultat du test de la persistance de la mousse après stockage à long terme à 20°C.	36	-

Recommandations relatives à l'étiquette du produit

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

- Contient du *Saccharomyces cerevisiae*. Peut provoquer des réactions de sensibilisation.
- L'efficacité du produit étant variable et partielle pour les usages moniliose sur "pêcher" et "prunier", préciser les conditions optimales d'utilisation.
- Ne pas utiliser en mélange avec un produit fongicide.
- Préciser les conditions d'utilisation optimales du produit par rapport aux applications de produits fongicides.

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

AGRAUXINE

JULIETTA GARDEN®

JULIETTA GARDEN contient une levure vivante destinée à la protection des fruits à noyau (pêcher, nectarine, abricotier, prunier) contre la moniliose; la vigne et le raisin de table contre le botrytis; les tomates, aubergines, fraisiers et petits fruits (framboisier, mûrier, cassissier, myrtillier, groseillier et autres baies) contre le botrytis.

Granulés Dispersibles (WG)
Fongicide

contient 961g/kg de S.cerevisiae LAS 02 ($1x10^{13}$UFC/kg)

AMM. No. XXXXXXX
Détenteur de l'AMM:
Agrauxine,
4 rue Henri Becquerel
49070 Beaucouzé, France

JULIETTA GARDEN

Autorisé comme produit phytopharmaceutique à faible risque conformément au règlement (CE) n°1107/2009

Distribué par : Agrauxine, 4 rue Henri Becquerel, 49070 Beaucouzé, France

N° de lot et date de production: voir emballage
A utiliser avant : voir emballage
2.5 g

JULIETTA GARDEN

LIRE L'ETIQUETTE AVANT UTILISATION. NE PAS RESPECTER LES CONDITIONS D'EMPLOI PRECONISEES SUR L'ETIQUETTE PEUT CONSTITUER UNE INFRACTION. RESPECTER LES BONNES PRATIQUES PHYTOSANITAIRES.

PRECAUTIONS D'EMPLOI

SP1: Ne pas contaminer l'eau avec le produit ou son emballage.
P102 Tenir hors de portée des enfants.
P103 Lire l'étiquette avant utilisation.
P234 Conserver uniquement dans l'emballage d'origine.
P501 Eliminer le contenu et son emballage en accord avec la règlementation nationale.

Conserver à l'écart de tout aliment et boisson y compris ceux pour les animaux.
Ne pas réutiliser l'emballage pour toute autre utilisation.

Respecter les instructions d'utilisation pour éviter tout risque pour l'homme et l'environnement.
Les Fiches de Données de Sécurité pour les utilisateurs professionnels sont disponibles sur demande (Fds-agx@agrauxine.fr ou Quick-FDS)

RECOMMANDATIONS D'EMPLOI:
IMPORTANT: Cette information fait partie intégrante de l'étiquette. Lire attentivement les instructions de cette section afin de garantir une utilisation sûre et efficace.

MODE D'ACTION

JULIETTA GARDEN contient une levure vivante dont le rôle est de protéger les fruits à noyau (pêcher, abricotier, nectarine, prunier) contre la moniliose, la vigne et le raisin de table contre le botrytis, les tomates, aubergines, fraisiers et autres petits fruits contre le botrytis. JULIETTA GARDEN fonctionne par compétition nutritive et spatiale contre les pathogènes.

TABLEAU DES USAGES

Culture	Maladie cible	Dose d'emploi par application ($g/10m^2$)	Nombre max d'applications/an	Délai avant récolte (DAR)
Fruits à noyau (pêcher, nectarine, abricotier, prunier) (champ)	Monilioses	2.5	8	0 j
Vigne et Raisin de table (champ)	Botrytis	2.5	6	0 j
Tomates, aubergines (sous serre)	Botrytis	2.5	8	0 j
Fraisiers (sous serre)	Botrytis	2.5	8	0 j
Petits fruits (*framboisier, myrtillier, mûrier, cassissier, groseillier et autres baies*) (champ, sous serre)	Botrytis	2.5	8	0 j

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

LIMITE MAXIMALE DE RESIDUS (LMR)
Aucune LMR existante (*Saccharomyces cerevisiae* LAS02 est inclue sur l'annexe IV)

RECOMMENDATIONS D'UTILISATION
JULIETTA GARDEN peut être utilisé en application foliaire sur vigne et raisin de table, fruits à noyau, tomates, aubergines, fraisiers, et petits fruits.
Application préventive en spray, avant un risque de contamination, puis tous les 7 à 14 jours en fonction de la pression de maladie.
En cas de développement de la maladie ou de forte pression, utiliser JULIETTA GARDEN en programme avec d'autres fongicides.
Appliquer un volume de bouillie suffisant pour assurer une couverture complète des fruits et de la végétation sans ruissellement.
Eviter toute application pendant les périodes de fortes températures.

PREPARATION DE BOUILLIE ET PULVERISATION
La levure doit être réactivée dans l'eau. Remplir par exemple un seau avec de l'eau, verser directement la quantité nécessaire de JULIETTA GARDEN. Agiter doucement jusqu'à dispersion complète.
Remplir à moitié la cuve avec de l'eau et mettre en marche le système d'agitation. Verser le mélange de JULIETTA GARDEN dans la cuve du pulvérisateur.
Compléter avec de l'eau jusqu'au volume requis. Maintenir l'agitation durant toute la durée de l'application.
Nettoyer soigneusement et rincer le pulvérisateur aussitôt après chaque utilisation de JULIETTA GARDEN.
Toujours s'assurer que le pulvérisateur est nettoyé selon les procédures standards de nettoyage, en bon état de fonctionnement et calibré avec précision selon les recommandations du fabricant du pulvérisateur.

MELANGES ET COMPATIBILITES
JULIETTA GARDEN peut être utilisé avec d'autres fongicides, herbicides, insecticides et fertilisants. Comme tous les mélanges n'ont pu être testés, s'assurer avec le distributeur de la compatibilité des mélanges. Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur et aux recommandations des bonnes pratiques agricoles.

STOCKAGE
Stocker dans son emballage d'origine, fermé, dans un endroit frais, sec et bien aéré. Conserver à l'abri du gel, des fortes températures, de l'humidité et de la lumière directe.
Durée de vie : voir emballage.

Appendix 3 – Letter(s) of Access

Provided upon request.