# REGISTRATION REPORT

## Part A

## Risk Management

**Product code: ALD1202**

**Product name: JULIETTA**

**Active Substance:**

***Saccharomyces cerevisiae* strain LAS02, $1\times10^{13}$ CFU/kg**

**COUNTRY: FRANCE**

**Interzonal and Southern zone**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(new application)**

**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 (product code: ALD1202), containing 1 $10^{13}$ CFU[1]/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 (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 (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 (ALD1202) in France as a fungicide (product uses described under point 2.3). 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 (ALD1202), therefore JULIETTA (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 :<br>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.<br>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).<br>A Review Report is available (SANCO/12457/2015 rev 0, 19 May 2016). |

[1] CFU: colony forming unit

### 1.3 Regulatory approach

The present application (2017-1900, 2018-0618) 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")[2] – 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[3] 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[4], 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[5], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[6] 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[7] 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

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

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

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

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

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

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

mitigation measures.

### 1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of JULIETTA (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

Provided as requested.

## 2 DETAILS OF THE AUTHORISATION

### 2.1 Product identity

| | |
|---|---|
| **Product name (code)** | JULIETTA (ALD1202) |
| **Authorisation number** | 2190010 |
| **Function** | Fungicide |
| **Low risk (art 47)** | Yes |
| **Applicant** | Agrauxine |
| **Composition** | 1 x $10^{13}$ CFU/kg (960,8 g/kg technical product) *Saccharomyces cerevisiae* strain LAS02. |
| **Formulation type (code)** | Water-dispersible granule (WG) |
| **Packaging** | PET-ALU-PE bags (2.5 g, 12,5 g and 25 g)<br>PET-ALU-OPA-PE bags (75g, 125g, 250g, 500g, 1250g )<br>PET-ALU-OPA-PE bags (2.5 kg, 5 kg and 10 kg) |

### 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"<br><br>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 professional uses only to the following conditions:

| | |
|---|---|
| SP 1 | Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads). |
| SPe 3 | To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres[8] to surface water bodies for outdoor uses. |
| | For greenhouse applications, avoid direct outflow to the environment. |

### 2.2.3 Other phrases linked to the preparation

| |
|---|
| Wear suitable personal protective equipment[9]: refer to the Decision in Appendix 1 for the details. |
| Re-entry period[10]: 6 hours in field or 8 hours in greenhouse. |
| Pre-harvest interval[11]: Not necessary |
| Other mitigation measures:<br>- The formulation must not be stored at a temperature higher than 20 °C.<br>- It has to be noted that it should be avoided to tank mix JULIETTA (ALD1202)with fungicide products and that particular attention should be paid to the timing between applications of JULIETTA (ALD1202) and other fungicide product |
| The label may include the following recommendations:<br>- Contains *Saccharomyces cerevisiae*. Micro-organisms may have the potential to provoke sensitising reactions<br>- As efficacy is variable and partial on *monilia* spp, precise optimal conditions of use<br>- Precise optimal conditions of use of the product in regard to other fungicides treatments<br>- Do not mix with other fungicides<br><br>The label must reflect the conditions of authorisation. |

[8] 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]

[9] If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

[10] 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]

[11] 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/ ALD1202** | Formulation type: | **WG** [a, b] |
| Active substance 1: | Saccharomyces cerevisiae LAS02 | Conc. of as 1: | **960,8 g/kg ($1 \times 10^{13}$ 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**<br><br>**(crop destination / purpose of crop)** | **F, Fn, Fpn G, Gn, Gpn or I** | **Pests or Group of pests controlled**<br><br>(additionally: developmental stages of the pest or pest group) | **Application** | | | | **Application rate** | | | **PHI** (days) | **Remarks:**<br><br>e.g. g safener/synergist per ha [f]<br><br>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<br><br>a) max. rate per appl. b) max. total rate per crop/season | Water L/ha<br><br>min / max | | |
| 1 | FR | Stone fruits<br>(Peach, Apricot, Nectarine, Plum tree) | F | *Monilinia sp.*<br>MONILA, MONIFG, MONIFC | Spraying | BBCH 51 to 89 | a) 8<br>b) 8 | 7 days | a) 2.5<br>b) 20 | a) 2.4 kg<br>$2.5 \times 10^{13}$ CFU<br>b) 19.22 kg<br>$2.0 \times 10^{14}$ CFU | 100-1500 | 1 | **Acceptable** |
| 2 | FR | Grapevine & Table grape<br>VITVI | F | *Botrytis cinerea*<br>BOTRCI | Spraying | BBCH 60 to 89 | a) 6<br>b) 6 | 7 days | a) 2.5<br>b) 15 | a) 2.4 kg<br>$2.5 \times 10^{13}$ CFU<br>b) 14.41 kg<br>$1.5 \times 10^{14}$ 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**<br><br>**(crop destination / purpose of crop)** | **F, Fn, Fpn G, Gn, Gpn or I** | **Pests or Group of pests controlled**<br><br>(additionally: developmental stages of the pest or pest group) | **Application** | | | | **Application rate** | | | **PHI** (days) | **Remarks:**<br><br>e.g. g safener/synergist per ha [f]<br><br>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<br><br>a) max. rate per appl. b) max. total rate per crop/season | Water L/ha<br><br>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<br>b) 8 | 7 days | a) 2.5<br>b) 20 | a) 2.4 kg $2.5 \times 10^{13}$ CFU<br>b) 19.22 kg $2.0 \times 10^{14}$ CFU | 100-1500 | 1 | **Acceptable** |
| 4 | FR | Tomato LYPES, Eggplant SOLME, | G | *Botrytis cinerea* BOTRSP, BOTRCI | Spraying | BBCH 12 to 89 | a) 8<br>b) 8 | 7 days | a) 2.5<br>b) 15 | a) 2.4 kg $2.5 \times 10^{13}$ CFU<br>b) 14.41 kg $1.5 \times 10^{14}$ CFU | 100-1000 | 1 | **Acceptable** |
| 5 | FR | Pepper CPSAN<br>Gombo ABMES | G | *Botrytis cinerea* BOTRSP, BOTRCI | Spraying | BBCH 12 to 89 | a) 8<br>b) 8 | 7 days | a) 2.5<br>b) 20 | a) 2.4 kg ($2.5 \times 10^{13}$ CFU)<br>b) 19.22 kg ($2.0 \times 10^{14}$ CFU) | 100-1000 | 1 | **Acceptable** |
| 6 | FR | Strawberry FRASS | G | *Botrytis cinerea* BOTRCI | Spraying | BBCH 12 to 89 | a) 8<br>b) 8 | 7 days | a) 2.5<br>b) 20 | a) 2.4 kg $2.5 \times 10^{13}$ CFU<br>b) 19.22 kg $2.0 \times 10^{14}$ 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**<br><br>**(crop destination / purpose of crop)** | **F, Fn, Fpn G, Gn, Gpn or I** | **Pests or Group of pests controlled**<br><br>(additionally: developmental stages of the pest or pest group) | **Application** | | | | **Application rate** | | | **PHI** (days) | **Remarks:**<br><br>e.g. g safener/synergist per ha (f)<br><br>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<br><br>a) max. rate per appl. b) max. total rate per crop/season | Water L/ha<br><br>min / max | | |
| 7 | FR | Small fruits (Raspberry, Blackberries, Blackcurrant, Blueberry, Currant, and other berries) | G | *Botrytis cinerea* BOTRCI | Spraying | BBCH 12 to 89 | a) 8<br>b) 8 | 7 days | a) 2.5<br>b) 20 | a) 2.4 kg<br>$2.5 \times 10^{13}$ CFU<br>b) 19.22 kg<br>$2.0 \times 10^{14}$ 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/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 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 (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 (ALD1202) containing 960.8 g/kg (i.e. $1.10^{13}$ CFU/kg) *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 EFSA model is not suitable for calculating a risk assessment for operators on the base of a not existing dose-effect relation.

When the potential sensitising properties are considered and appropriate protection equipment is worn (gloves, coverall and respiratory mask), 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.
For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

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

#### 3.1.3.4 Worker Exposure

The micro-organism is neither toxic or infectious or pathogenic in mammals, it is not expected an unacceptable risk for the worker wearing appropriate protection equipment.
For details of personal protective equipment for workers, refer to the Decision in Appendix 1.

### 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 (ALD1202) used according to the proposed GAP does not expose the consumer to viable or non-viable virus. 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 for the active substance for the intended use patterns. The endpoints established in the EU conclusions (EFSA, 2015) were used in calculations

The PEC 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 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.

For glasshouse application (covered crops), zRMS considers the risk assessment covers by the one performed for open-field applications. According to the OCDE guidance (2012 12 ) and EFSA guidance (EFSA Journal 2014;12(3):3615), only the discharge to surface water should be also considered for permanent structures. No further calculation was provided by the notifier. Therefore, the following mitigation measure should be recommended: “Avoid direct outflow to the environment”.

### 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).

[12] Guidance to the environmental safety evaluation of microbial biocontrol agents; Series on Pesticides; No. 67; NV/JM/MONO(2012)1OECD

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

### 3.1.7 Efficacy

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

- The phytotoxicity level of JULIETTA (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.
- The risk of resistance development or appearance to *Saccharomyces cerevisiae* strain LAS02 is considered as very low.

## 3.2 Conclusions arising from French assessment

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

## 3.3 Substances of concern for national monitoring

No information stated.

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

### 3.4.1 Post-authorisation monitoring

No further information is required.

### 3.4.2 Post-authorisation data requirements

The French Decision requests the submission of post-authorisation confirmatory pieces of information within 36 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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anses
agence nationale de sécurité sanitaire alimentation, environnement, travail

# 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 et la demande associée du produit phytopharmaceutique* ***JULIETTA***

*de la société* *AGRAUXINE*

*enregistrées sous les* *n°2017-1900 et 2018-0618*

*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*
*AMM n°2190010*

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anses
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| Informations générales sur le produit | |
|---|---|
| **Noms du produit** | JULIETTA<br>HIVA |
| **Type de produit** | Produit de référence |
| **Titulaire** | AGRAUXINE<br>137 rue Gabriel Péri<br>59700 MARCQ-EN-BAROEUL<br>France |
| **Formulation** | Granulé dispersable (WG) |
| Contenant | $1.10^{13}$ UFC/kg - *Saccharomyces cerevisiae* souche LAS02 |
| **Numéro d'intrant** | 634-2017.01 |
| **Numéro d'AMM** | 2190010 |
| **Fonction** | Fongicide |
| **Gamme d'usage** | Professionnel |
| **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 [qui arrivera. 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** |
| Sacs en polyéthylène téréphtalate / aluminium / polyéthylène | 2,5 g ; 12,5 g ; 25 g |
| Sacs en polyéthylène téréphtalate / aluminium / polyamide orienté / polyéthylène | 2,5 kg ; 5 kg ; 10 kg ; 75 g ; 125 g ; 250 g ; 500 g ; 1250 g |

| **Classification du produit** |
|---|
| La classification retenue est la suivante :<br>Sans classement. |
| Pour les phrases P se référer à la règlementation en vigueur.<br><br>**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**<br>Cassissier*Trt Part.Aer.*<br>Pourriture grise | **2,5 kg/ha** | **8/an** | entre les stades BBCH 12 et BBCH 89 | 1 | 5 | - | - | - |
| | Egalement autorisé sous abri.<br>Intervalle minimum entre les applications : 7 jours | | | | | | | |
| **16553201**<br>Fraisier*Trt Part.Aer.*<br>Pourriture grise et sclérotinioses | **2,5 kg/ha** | **8/an** | entre les stades BBCH 12 et BBCH 89 | 1 | - | - | - | - |
| | Uniquement autorisé sous abri<br>Efficacité montrée sur pourriture grise.<br>Intervalle minimum entre les applications : 7 jours | | | | | | | |
| **12353205**<br>Framboisier*Trt Part.Aer.*<br>Pourriture grise | **2,5 kg/ha** | **8/an** | entre les stades BBCH 12 et BBCH 89 | 1 | 5 | - | - | - |
| | Egalement autorisé sous abri.<br>Intervalle minimum entre les applications : 7 jours | | | | | | | |
| **12553233**<br>Pêcher*Trt Part.Aer.*<br>Monilioses | **2,5 kg/ha** | **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

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 |
|---|---|---|---|---|---|---|---|---|
| **16863201**<br>Poivron*Trt Part.Aer.*<br>Pourriture grise et sclérotinioses | **2,5 kg/ha** | **8/an** | entre les stades BBCH 12 et BBCH 89 | 1 | - | - | - | - |
| | Uniquement autorisé sous abri.<br>Efficacité montrée sur pourriture grise.<br>Intervalle minimum entre les applications : 7 jours | | | | | | | |
| **12653204**<br>Prunier*Trt Part.Aer.*<br>Monilioses | **2,5 kg/ha** | **8/an** | entre les stades BBCH 51 et BBCH 89 | 1 | 5 | - | - | - |
| | Intervalle minimum entre les applications : 7 jours | | | | | | | |
| **16953203**<br>Tomate*Trt Part.Aer.*<br>Pourriture grise et sclérotinioses | **2,5 kg/ha** | **8/an** | entre les stades BBCH 12 et BBCH 89 | 1 | - | - | - | - |
| | Uniquement autorisé sous abri.<br>Efficacité montrée sur pourriture grise.<br>Intervalle minimum entre les applications : 7 jours | | | | | | | |
| **12703205**<br>Vigne*Trt Part.Aer.*<br>Pourriture grise | **2,5 kg/ha** | **6/an** | entre les stades BBCH 60 et BBCH 89 | 1 | 5 | - | - | - |
| | Intervalle minimum entre les applications : 7 jours | | | | | | | |

*JULIETTA*
*AMM n°2190010*

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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.

**Protection de l'opérateur et du travailleur**

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections individuelles ;
- le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage) ;
- les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

***Pour l'opérateur, porter***

**Dans le cas d'une application effectuée à l'aide d'une lance**

**• pendant le mélange/chargement**

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de protection de catégorie III type 4 ou 3 (selon le niveau de protection recommandé pendant la phase d'application) ;
- Demi-masque filtrant anti-aérosols certifié (EN 149) de classe FFP3 ou demi-masque certifié (EN 140) équipé d'un filtre anti-aérosols certifié (EN143) de classe P3 ;

OU

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;
- Demi-masque filtrant anti-aérosols certifié (EN 149) de classe FFP3 ou demi-masque certifié (EN 140) équipé d'un filtre anti-aérosols certifié (EN143) de classe P3 ;

**• pendant l'application : sans contact intense avec la végétation**

**Culture basse (< 50 cm)**

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- Bottes de protection certifiées EN 13 832-3 ;
- Demi-masque filtrant anti-aérosols certifié (EN 149) de classe FFP3 ou demi-masque certifié (EN 140) équipé d'un filtre anti-aérosols certifié (EN143) de classe P3 ;

**Culture haute (> 50 cm)**

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de protection de catégorie III type 4 avec capuche ;
- Bottes de protection certifiées EN 13 832-3 ;
- Demi-masque filtrant anti-aérosols certifié (EN 149) de classe FFP3 ou demi-masque certifié (EN 140) équipé d'un filtre anti-aérosols certifié (EN143) de classe P3 ;

**• pendant l'application : contact intense avec la végétation**

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de protection de catégorie III type 3 avec capuche;
- Bottes de protection certifiées EN 13 832-3 ;
- Demi-masque filtrant anti-aérosols certifié (EN 149) de classe FFP3 ou demi-masque certifié (EN 140) équipé d'un filtre anti-aérosols certifié (EN143) de classe P3 ;

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**• pendant le nettoyage du matériel de pulvérisation**

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de protection de catégorie III type 4 ou 3 (selon le niveau de protection recommandé pendant la phase d'application) ;
-Demi-masque filtrant anti-aérosols certifié (EN 149) de classe FFP3 ou demi-masque certifié (EN 140) équipé d'un filtre anti-aérosols certifié (EN 143) de classe P3 ;

OU

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;
- Demi-masque filtrant anti-aérosols certifié (EN 149) de classe FFP3 ou demi-masque certifié (EN 140) équipé d'un filtre anti-aérosols certifié (EN 143) de classe P3 ;

**Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur pneumatique**

**• pendant le mélange/chargement**

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3B) à porter par-dessus la combinaison précitée ;
- Demi-masque filtrant anti-aérosols certifié (EN 149) de classe FFP3 ou demi-masque certifié (EN 140) équipé d'un filtre anti-aérosols certifié (EN143) de classe P3.

**• pendant l'application**

*Si application avec tracteur avec cabine*

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage d'au moins 230 g/m² avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-3 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine.

*Si application avec tracteur sans cabine :*

- Combinaison de protection de catégorie III type 4B avec capuche ;
- Gants en nitrile certifiés EN 374-3 à usage unique pendant l'application et dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;
- Demi-masque filtrant anti-aérosols certifié (EN 149) de classe FFP3 ou demi-masque certifié (EN 140) équipé d'un filtre anti-aérosols certifié (EN143) de classe P3.

**• pendant le nettoyage du matériel de pulvérisation**

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3B) à porter par-dessus la combinaison précitée ;
- Demi-masque filtrant anti-aérosols certifié (EN 149) de classe FFP3 ou demi-masque certifié (EN 140) équipé d'un filtre anti-aérosols certifié (EN 143) de classe P3 ;

***Pour le travailleur, porter***

- Une combinaison de travail (cotte en coton/polyester 35 %/65 % grammage d'au moins 230 g/m²) avec traitement déperlant et, en cas de contact avec la culture traitée, des gants en nitrile certifiés EN 374-3.

**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.

*JULIETTA*
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***Délai de rentrée en application de l'arrêté du 4 mai 2017 :***
- 6 heures en plein champ et 8 heures pour les applications en milieu fermé.

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

***Protection de l'eau***
- SP 1 : 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.

***Protection de la faune***
- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 m par rapport aux points d'eau pour les usages en plein champ.

- Pour les applications sur des cultures hors sol : éviter le rejet direct des effluents dans l'environnement.

## 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 les informations suivantes sur l'étiquette :

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

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

AGRAUXINE

# JULIETTA

**JULIETTA is a living yeast to protect Stone fruits (peach, apricot, nectarine, plum tree) against monilia; Grapevine and Table Grape against botrytis; Tomato, Strawberry and Small fruits (raspberry, blackberries, blackcurrant, Blueberry, Currant and other berries) against botrytis.**

Wettable Granule (WG)
Fungicide

*containing 961g/kg of S.cerevisiae strain LAS 02 ($1x10^{13}$CFU/kg)*

**Approval. No. XXXXXXX**
**Approval holder:**
**Agrauxine,**
**4 rue Henri Becquerel**
**49070 Beaucouzé, France**

JULIETTA
authorised as a low-risk plant protection product according to regulation (CE) n°1107/2009

Distributed by: Agrauxine, 4 rue Henri Becquerel, 49070 Beaucouzé, France

Batch No. and manufacturing date: see packaging
Use before : see packaging
**5 kg**

## JULIETTA

**READ THE LABEL BEFORE USE. USING THIS PRODUCT IN A MANNER THAT IS INCONSISTENT WITH THE LABEL MAY BE AN OFFENCE. FOLLOW THE CODE OF PRACTICE FOR USING PLANT PROTECTION PRODUCTS.**

**SAFETY PRECAUTIONS**

SP1: Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
P102 Keep out of reach of children.
P103 Read label before use.
P234 Keep only in original container.
P501 Dispose of contents/containers in accordance with local and national regulation.

Keep away from food, drink and animal feeding stuffs.
Do not re-use container for any purpose.

**To avoid risks to man and the environment, comply with the instructions for use.**
**Safety data sheet available for professional user on request (Fds-agx@agrauxine.fr or Quick-FDS)**

**DIRECTIONS FOR USE**
**IMPORTANT: This information is approved as part of the Product Label. All instructions within this section must be read carefully in order to obtain safe and successful use of this product.**

**MODE OF ACTION**

JULIETTA contains a living yeast to protect Stone fruits (peach, apricot, nectarine, plum tree) against monilia, Grapevine and Table Grape against botrytis, Tomato, Strawberries and Small fruits against botrytis. JULIETTA works mainly through natural competition for space and nutrients with pathogens.

**GOOD AGRICULTURAL PRACTICE TABLE**

| Crop | Target disease | JULIETTA Application rate | Max. number of applications per year | Pre Harvest Interval (PHI) |
|---|---|---|---|---|
| Stone fruits *(peach, apricot, nectarine, plum tree)* (Field) | Monilia | 2.5 kg/ha | 8 | 0 day |
| Grapevine and Table Grape (Field) | Botrytis | 2.5 kg/ha | 6 | 0 day |
| Tomato (Indoor / Greenhouse) | Botrytis | 2.5 kg/ha | 8 | 0 day |
| Strawberry (Indoor / Greenhouse) | Botrytis | 2.5 kg/ha | 8 | 0 day |
| Small fruits ( *Raspberry, Blackberries, Blackcurrant, Blueberry, Currant and other berries*) (Field / Indoor / Greenhouse) | Botrytis | 2.5 kg/ha | 8 | 0 day |

Re-entry period on the treated area: wait until spray has dried.

**MAXIMUM RESIDUE LIMIT (MRL)**
No MRL is necessary (*Saccharomyces cerevisiae* LAS02 is Annex IV listed)

**DIRECTIONS FOR USE**

JULIETTA can be used via foliar spray in grapevine, table grape, stone fruits, strawberry, tomato and small fruits.
Apply preventively by spraying, before the development of the disease, and then every 7-14 days depending on the risk.
In case of development of disease or high pressure, JULIETTA should be used in program with other fungicides.
Apply a sufficient volume of mixture to make sure a complete coverage of fruits and vegetation without run-off:

- 2.5 kg/ha

**VARIETIES**
JULIETTA is crop safe. No symptoms of phytotoxicity were recorded on any of the tested crops and varieties.

**MIXING**
The yeast needs to be reactivated in water, for example Fill a bucket with water and pour the granules of JULIETTA directly in it. Agitate smoothly until complete dispersion.
Half fill the spray tank with clean water and start the re-circulation system. Pour the mixture of JULIETTA into the spray tank. Top up the spray tank with more clean water to the required level. Keep agitating during spraying operations.

**MIXTURES**
JULIETTA can be used in combination with other fungicides, herbicides, insecticides and fertilizers. As all mixtures could not be tested, first ensure with your distributor about the compatibility of the mixture. Mixtures should be made following the current legislation and the recommendations of Good Agricultural Practice.

**STORAGE**
Store in original container, tightly closed, in a fresh, dry and well-ventilated place. Protect from frost, moisture, and direct sunlight.
Shelf-life : see packaging.

**RESISTANCE**
The risk of development of resistance is limited considering the non-direct mode of action.

**CARE OF SPRAYER**
Immediately after each day use with JULIETTA, wash out the sprayer thoroughly with clean water, according to standard cleaning procedures.

**Appendix 3 – Letter(s) of Access**

Provided upon request.