

REGISTRATION REPORT

Part A

Risk Management

Product name(s): ANL-F002

Active Substance(s):

Potassium hydrogen carbonate – 4.25 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: AGRONATURALIS LTD

Date: 2017-09-27

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PART A – Risk Management

The company AGRONATURALIS LTD has requested marketing authorisation in France for the product ANL-F002 (Any other liquid: AL), containing 4.25 g/L of potassium hydrogen carbonate 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 ANL-F002 where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of ANL-F002 have been made using endpoints agreed in the EU peer review of Potassium hydrogen carbonate.

This document describes the specific conditions of use and labelling required for France for the registration of ANL-F002

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 AGRONATURALIS LTD's application to market ANL-F002 in France as a fungicide (product uses described under point 2.3). France acted as a zonal (zRMS) Rapporteur Member State, for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Potassium hydrogen carbonate

Commission Implementing Regulation (EU) No 540/2011 of 14 August 2012 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance potassium hydrogen carbonate.

Specific provisions of Regulation (EU) No 540/2011 were as follows :

PART A

Only uses as fungicide and insecticide may be authorised.

PART B

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on potassium hydrogen carbonate (SANCO/2625/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 July 2012 shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to honeybees. Conditions of use shall include, where appropriate, risk mitigation measures.

An EFSA conclusion is available (EFSA Journal 2012;10(1):2524 [36 pp.]).

A Review Report is available (SANCO/2625/08 – final rev.1 13 July 2012). (SANCO/2625/08 – rev. 1 04 July 2008)

1.3 Regulatory approach

The present application (2015-6604) 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 Southern zone / European Union, taking into account the worst-case uses (“risk envelope approach”)² – the highest application rates over the Southern Zone / 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 2017³ 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 1107/2009⁴, 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 546/2011⁵, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

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.

1.4 Data protection claims

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 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/AGR1632554A/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/AGR1407093A/jo>

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

Where protection for data is being claimed for information supporting registration of ANL-F002, 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

Not necessary: the applicant has provided sufficient data to show that access is not required.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	ANL-F002
Authorisation number	2170861
Function	Fungicide
Applicant	AGRONATURALIS LTD
Composition	4,25 g/L Potassium hydrogen carbonate
Formulation type (code)	Any other liquid (AL)
Packaging	HDPE bottles of 500 mL, 750 mL and 1 L (with trigger spray)

2.2 Classification and labelling

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

Physical hazards	-
Health hazards	-
Environmental hazards	-
Hazard pictograms	-
Signal word	-
Hazard statements	-
Precautionary statements –	<i>For the P phrases, refer to the extant legislation</i>
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	

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 hole the non-used container leftovers.
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2.2.3 Other phrases linked to the preparation

Wear suitable personal protective equipment; refer to the Decision in Appendix 1 for the details
Re-entry period: Until the complete drying of the treated area
Pre-harvest interval: 1 days

Other mitigation measures:

The label may include the following recommendations:

- Do not store in a room where the temperature may exceed 40 °C.
- Shake before applying, after storage at low temperatures

The label must reflect the conditions of authorisation.

2.3 Product uses

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

PPP (product name/code): <ANL-F002> Formulation type: AL^(a, b)
Active substance 1: <Potassium hydrogen carbonate> Conc. of as 1: 4,25 g/L^(c)
Applicant: AGRONATURALIS LTD Professional use: ☐
Zone(s): Southern^(d) Non professional use: ☒
Verified by MS: yes
Field of use: fungicide

GAP rev. , date: 2017-09-27

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, Gp n 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)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applicatio ns (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)													
1	FR	Grapes (wine and table)	Fn	Powdery mildew (<i>Uncinula necator</i>)	Foliar spray	BBCH 15 - 89	a) 5 b) 5	7	a) 1000 L/ha b) 5000 L/ha	a) 4,25 kg/ha b) 21,25 kg/ha	NA	1	acceptable
2	FR	Grapes (wine and table)	Fn	<i>Botrytis cinerea</i>	Foliar spray	BBCH 61-89	a) 5 b) 5	8	a) 1000 L/ha b) 5000 L/ha	a) 4,25 kg/ha b) 21,25 kg/ha	NA	1	acceptable
3	FR	Pome fruits	Fn	Apple scab – <i>Venturia inaequalis</i> Pear scab – <i>Venturia pirina</i>	Foliar spray	March – October BBCH 07 - 89	a) 5 b) 5	8	a) 1000 L/ha b) 5000 L/ha	a) 4,25 kg/ha b) 21,25 kg/ha	NA	1	acceptable
4	FR	Peach Nectarine Apricot	Fn	<i>Monilinia fructicola</i> MONIFC <i>Monilinia fructigena</i>	Foliar spray	May - September BBCH 79 - 89	a) 3 b) 3	3	a) 1000 L/ha b) 5000 L/ha	a) 4,25 kg/ha b) 12,75 kg/ha	NA	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, Gp n 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)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applicatio ns (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		
				MONIFG <i>Monilinia laxa</i> MONILA									
5	FR	Blackcurrants Redcurrants Raspberry	Fn	Powdery mildew (<i>Podosphaera</i> sp., <i>Sphaerotheca</i> sp.)	Foliar spray	BBCH 10 - 87	a) 5 b) 5	7	a) 1000 L/ha b) 5000 L/ha	a) 4,25 kg/ha b) 21,25 kg/ha	NA	1	acceptable
10	FR	Vegetables, herbs, flowers (for seed production only)	Fn	Powdery mildew	Foliar spray	BBC 10-89	a) 6 b) 6	7	a) 600 L/ha b) 3600 L/ha	a) 2,55 kg/ha b) 15,3 kg/ha	NA	NA	acceptable
Interzonal uses (uses in greenhouses and field)													
6	FR	Strawberry	Fn/ Gn	Powdery mildew (<i>Sphaerotheca macularis</i> ; <i>Podosphaera aphanis</i>)	Foliar spray	BBCH 10-85	a) 6 b) 6	8	a) 600 L/ha b) 3600 L/ha	a) 2,55 kg/ha b) 15,3 kg/ha	NA	1	acceptable
7	FR	Tomato Aubergine Pepper	Fn/ Gn	Powdery mildew (<i>Leveillula taurica</i> ; <i>Erysiphe</i> sp.)	Foliar spray	BBC 10-89	a) 6 b) 6	7	a) 600 L/ha b) 3600 L/ha	a) 2,55 kg/ha b) 15,3 kg/ha	NA	1	acceptable
8	FR	Cucumber Courgette	Fn/ Gn	Powdery mildew (<i>Erysiphe cichoracearum</i> ; <i>Sphaerotheca fuliginea</i>)	Foliar spray	BBC 10-89	a) 6 b) 6	7	a) 600 L/ha b) 3600 L/ha	a) 2,55 kg/ha b) 15,3 kg/ha	NA	1	acceptable
9	FR	Herbs	Fn/ Gn	Powdery mildew	Foliar spray	BBC 10-89	a) 6 b) 6	7	a) 600 L/ha b) 3600 L/ha	a) 2,55 kg/ha b) 15,3 kg/ha	NA	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, Gp n 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)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applicatio ns (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		
11	FR	Rose	Fn/ Gn	Powdery mildew (<i>Podosphaera pannosa</i>)	Foliar spray	Leaves BBCH 41-49 Flower buds BBCH 51-59	a) 5 b) 5	7	a) 1000 L/ha b) 5000 L/ha	a) 4,25 kg/ha b) 21,25 kg/ha	NA	NA	acceptable
12	FR	Ornamentals: -Hardwood and shrub -Pot plants (e.g. Amelanchier) -Cut foliage (e.g. Euonymus)	Fn/ Gn	Powdery mildew	Foliar spray	Young foliage	a) 5 b) 5	7	a) 1000 L/ha b) 5000 L/ha	a) 4,25 kg/ha b) 21,25 kg/ha	NA	NA	acceptable
13	FR	Ornamentals: -Pot plants (e.g. Chrysanthemums) -Cut flowers (e.g. Gerbera, Daisy)	Fn/ Gn	Powdery mildew	Foliar spray	Flowers, young and mature foliage	a) 6 b) 6	7	a) 600 L/ha b) 3600 L/ha	a) 2,55 kg/ha b) 15,3 kg/ha	NA	NA	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)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applicatio ns (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		

Remarks columns:	1	Numeration necessary to allow references					7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application					
	2	Use official codes/nomenclatures of EU Member States					8	The maximum number of application possible under practical conditions of use must be provided.					
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)					9	Minimum interval (in days) between applications of the same product					
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application					10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.					
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.					11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).					
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.					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

ANL-F002 is a liquid to be applied undiluted (ready to use product). 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 cloudy white and translucent liquid, with no strong odour. It is not explosive and has no oxidising properties. The product is not flammable. It has a self- ignition temperature of over 395°C. In aqueous solution (1% dilution), it has a pH value of 6.59 at 20°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 8 weeks at 40 °C, 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 HDPE packaging.

Its technical characteristics are acceptable for a ready-to-use liquid. The formulation is not classified for the physico-chemical aspect.

The formulation must be stored at a temperature below 40°C and must be shaken before use after storage at low temperature.

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.

To update the dossier, a test for the determination of persistent foaming is required in post-authorization.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methods for the determination of the relevant impurities in the formulation are available but not fully validated. To update the dossier, the absence of interferences in the product ANL-F002-2 should be demonstrated and the LOQs should be provided and should comply with the content limits set in the Regulation (EU) No 735/2012.

An analytical method for the determination of the active substance in the formulation is available. To update the dossier, a method fully validated for the quantitation of potassium is required in post-authorization.

3.1.2.2 Analytical methods for residues

Analytical methods for the determination of residues of potassium hydrogen carbonate in food of plant and animal origin and in the environment are not necessary.

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

Active Substance: Potassium hydrogen carbonate			
ADI	Not relevant		EU agreed endpoint (Efsa 2012)
ARfD	Not relevant		
AOEL	128 mg/kg bw/d (AOEL is not relevant according to EFSA peer review on potassium hydrogen carbonate. Therefore, the daily intake of potassium is used as a surrogate)		
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (used in formulation) 4.25 g/L	Spray dilution (used in formulation) x g/L
	Dermal absorption endpoints %	75	-

3.1.3.1 Acute Toxicity

ANL-F002 containing 4.25 g/L of potassium hydrogen carbonate has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is not a skin sensitizer.

The proposed packaging has been described in sufficient detail, and its compliance can therefore be finalised. In summary, compliance with the provisions of French regulation related to the use of certain plant protection products by non professional users is considered to be finalised.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G	Equipment	Application rate kg product/ha (g as/ha)	Spray dilution (L/ha)	Model
All crops	F/G	Manual spraying (ready to use)	1000 L product/ ha 4.25 kg as / ha	No dilution required	Amateur use (trigger spray surface treatment model)

Considering proposed uses, operator systemic exposure was estimated using the Amateur use (trigger spray surface treatment model):

Crop	Equipment	PPE and/or working coverall	% AOEL potassium hydrogen carbonate
All crops	Manual spraying (ready to use)	None	< 0,1

According to the model calculations, it can be concluded that the risk for the operator using ANL-F002 is acceptable without PPE.

3.1.3.3 Bystander and Resident Exposure

In the context of use by non-professionals, it is considered that the assessment for bystanders is covered by that for the operator.

As a conservative approach, Residential exposure was assessed according to the UK guidance for operator exposure for amateur (home&garden) pesticide. Exposure is estimated to be 1.38 % of the AOEL of potassium hydrogen carbonate.

It is concluded that there is no unacceptable risk to the resident exposed to ANL-F002.

3.1.3.4 Worker Exposure

ANL-F002 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. It will be necessary to ensure complete drying of the treated area or of treated plants before handling them.

3.1.4 Residues and Consumer Exposure

The plant protection product ANL-F002 is composed of potassium hydrogen carbonate. This active substance is approved under Regulation (EC) No 1107/2009. Potassium hydrogen carbonate is also included in Annexe IV to 396/2005/EC regulation, which includes those active substances where no MRL are required.

Potassium and bicarbonates ions are naturally occurring in all environmental compartments, including plant tissues. It is therefore not possible to distinguish between the residues arising from the use of potassium hydrogen carbonate as a plant protection product and its natural presence in plants. Moreover, potassium hydrogen carbonate is approved as a food additive in the EU (E501). Potassium hydrogen carbonate was considered as « Generally Recognized As Safe » (GRAS) by US FDA.

In addition, for this active substance, no toxicological reference values were deemed necessary during the peer-review.

For all of these reasons, the use of ANL-F002 is not expected to induce an additional specific consumer exposure to potassium hydrogen carbonate.

Nevertheless, according to EU guidelines⁸, a 1 day PHI is proposed for all food intended uses.

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment of the formulation has been evaluated according to the requirements of Regulation (EC) No 1107/2009. No new studies are presented; all data were reviewed in the EU review (potassium hydrogen carbonate). Appropriate endpoints from the EU review (EFSA, 2012⁹) were used to calculate PECs in the core assessment for potassium hydrogen carbonate in soil for the intended use patterns.

Considering the packaging and the application method of the ready to use preparation ANL-F002 (low volume container (500, 750 or 1000 mL) with trigger spray), exposure of environmental compartments to active substance is considered negligible. Consequently, no risk assessment for the compartments surface water and groundwater is deemed necessary.

Based on vapour pressure, information on volatilisation from plants and soil, and DT50 calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.6 Ecotoxicology

Considering the packaging and the application method of the ready to use preparation ANL-F002 (low volume container (500, 750 or 1000 ml) with trigger spray), exposure of environmental compartments to active substance is considered negligible. Consequently, no risk assessment for environment and non-target organisms is deemed necessary.

3.1.7 Efficacy

Considering the data submitted:

- On the basis of data available for an equivalent preparation which are currently registered in France in a more concentrated version on same uses and same doses of potassium hydrogen carbonate, the efficacy and the selectivity of the preparation ANL-F002 is considered as acceptable in the claimed conditions.
- By extrapolation to data provided for an equivalent preparation, the risk of negative impact of the preparation ANL-F002 on yield, quality, transformation processes, propagation, non-target organisms, succeeding crops, adjacent crops is considered as negligible.
- The risk of resistance development or appearance of the preparation ANL-F002 is identical to the one of the equivalent preparation and is therefore considered as low.

⁸ EC (European Commission), 1997:. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010. Available online: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

⁹ Conclusion on the peer review of the pesticide risk assessment of the active substance potassium hydrogen carbonate. EFSA Journal 2012;10(1):2524. [36 pp.] doi:10.2903/j.efsa.2012.2524

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 12 months.

The following data would have been required to update the dossier:

- .Analytical methods for the determination of the relevant impurities in the formulation are available but not fully validated. The absence of interferences in the product ANL-F002-2 should be demonstrated and the LOQs should be provided and should comply with the content limits set in the Regulation (EU) No 735/2012.

3.4.3 Label amendments

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

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

Appendix 1 – Copy of the French Decision



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

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

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

*Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique **ANL-F002***

*de la société **AGRONATURALIS LIMITED***

*enregistrée sous le **n°2015-6604***

Vu les conclusions de l'évaluation de l'Anses du 25 août 2017,

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

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

Avertissement :

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



Informations générales sur le produit	
Nom du produit	ANL-F002
Type de produit	Produit de référence
Titulaire	AGRONATURALIS Ltd Suite B Crown House 2 SOUTHAMPTON ROAD RING WOOD HAMPSHIRE BH24 1HY ROYAUME UNI
Formulation	Autre liquide (AL)
Contenant	4,25 g/L - hydrogénocarbonate de potassium
Numéro d'intrant	996-2015.01
Numéro d'AMM	2170861
Fonction	Fongicide
Gamme d'usages	Amateur / emploi autorisé dans les jardins

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 août 2021.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) 1107/2009, dans les trois mois suivant le renouvellement de l'approbation de la substance active, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance de la durée nécessaire pour mener à bien l'examen et adopter une décision sur le renouvellement.

La présente décision peut être retirée ou modifiée avant cette échéance si des éléments le justifient.

A Maisons-Alfort, le 27 SEP. 2017

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)

ANL-F002
AMM n°2170861

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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
Pulvérisateurs en polyéthylène haute densité	500 mL ; 750 mL ; 1 L

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitee arthropodes non cibles (mètres)	Zone Non Traitee plantes non cibles (mètres)	Mention abeilles
14053204 Arbres et arbustes*Trt Part.Aer.*Oidium(s)	100 mL/m² Intervalle minimum entre les applications : 7 jours Egalement autorisé sous abri	5/an	feuillage jeune	Non applicable	-	-	-
12153202 Cassissier*Trt Part.Aer.*Oidium(s)	100 mL/m² Intervalle minimum entre les applications : 7 jours	5/an	entre les stades BBCH 10 et BBCH 87	1	-	-	-
16323203 Concombre*Trt Part.Aer.*Oidium(s)	60 mL/m² Intervalle minimum entre les applications : 7 jours Egalement autorisé sous abri	6/an	entre les stades BBCH 10 et BBCH 89	1	-	-	-
17403202 Cultures florales et plantes vertes*Trt Part.Aer.*Oidium(s)	60 mL/m² Intervalle minimum entre les applications : 7 jours Egalement autorisé sous abri	6/an	flurs, feuillage jeune et mature	Non applicable	-	-	-
16553205 Fraisier*Trt Part.Aer.*Oidium(s)	60 mL/m² Intervalle minimum entre les applications : 8 jours Egalement autorisé sous abri	6/an	entre les stades BBCH 10 et BBCH 85	1	-	-	-
12353204 Framboisier*Trt Part.Aer.*Oidium(s)	100 mL/m² Intervalle minimum entre les applications : 7 jours	5/an	entre les stades BBCH 10 et BBCH 87	1	-	-	-
12553233 Pêcher*Trt Part.Aer.*Moniliose	100 mL/m² Intervalle minimum entre les applications : 3 jours	3/an	entre les stades BBCH 79 et BBCH 89	1	-	-	-
16863203 Poivron*Trt Part.Aer.*Oidium(s)	60 mL/m² Intervalle minimum entre les applications : 7 jours Egalement autorisé sous abri	6/an	entre les stades BBCH 10 et BBCH 89	1	-	-	-

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Liste des usages autorisés

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
12603203 Pommier*Trt Part.Aer.*Tavelure(s)	100 mL/m ² Intervalle minimum entre les applications : 8 jours	5/an	entre les stades BBCH 07 et BBCH 89	1	-	-	-
10993211 Porte graine - PPAMC, Florales et Potagères*Trt Part.Aer.*Oidium(s)	60 mL/m ² Intervalle minimum entre les applications : 7 jours	6/an	entre les stades BBCH 10 et BBCH 89	Non applicable	-	-	-
19993200 PPAMC*Trt Part.Aer.*Maladies fongiques	60 mL/m ² Intervalle minimum entre les applications : 7 jours Egalement autorisé sous abri	6/an	entre les stades BBCH 10 et BBCH 89	1	-	-	-
17303203 Rosier*Trt Part.Aer.*Oidium(s)	100 mL/m ² Intervalle minimum entre les applications : 7 jours Egalement autorisé sous abri	5/an	BBCH 41-49 BBCH 51-59	Non applicable	-	-	-
16953206 Tomate*Trt Part.Aer.*Oidium(s)	60 mL/m ² Intervalle minimum entre les applications : 7 jours Egalement autorisé sous abri	6/an	entre les stades BBCH 10 et BBCH 89	1	-	-	-
12703204 Vigne*Trt Part.Aer.*Oidium(s)	100 mL/m ² Intervalle minimum entre les applications : 7 jours	5/an	entre les stades BBCH 15 et BBCH 89	1	-	-	-
12703205 Vigne*Trt Part.Aer.*Pourriture grise	100 mL/m ² Intervalle minimum entre les applications : 8 jours	5/an	entre les stades BBCH 61 et BBCH 89	1	-	-	-

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Conditions d'emploi du produit

Stockage et manipulation du produit

- Ne pas stocker le produit dans un local où la température peut dépasser 40°C.
- Agiter avant l'application après un stockage à basse température.

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.

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 des données démontrant l'absence d'interférences pour la détermination des impuretés pertinentes (plomb et arsenic) dans le produit ANL-F002 selon les méthodes USP 231 et USP 211 et préciser les limites de quantification de ces méthodes, qui doivent respecter les limites réglementaires fixées au niveau européen ajustées au niveau de concentration de la substance active dans le produit.	12	-

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

ANL-F002

Fongicide multicultures

PRODUITS POUR LES AMATEURS : Respecter les conditions d'emploi
Lire attentivement l'étiquette avant toute utilisation et respecter strictement les usages, doses, conditions et précautions d'emploi.

ANL-F002 (AMM No XXXXX)**« Emploi autorisé dans les jardins ».**

Fongicide

4,25 g/L de bicarbonate de potassium

Liquide destiné à être utilisé sans dilution (AL)

Conseils de prudence

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

P102 – Tenir hors de portée des enfants

P103 – Lire l'étiquette avant utilisation

P264 – Se laver soigneusement les mains après manipulation

P270 – Ne pas manger, boire ou fumer en manipulant le produit

P280 – Porter des gants de protection

P501 – Eliminer le contenu/récipient selon la législation en vigueur

Autres mentions

EUH401 – Respecter les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.

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

Conditions d'emploi

Attendre le séchage complet de la zone traitée ou des plantes avant leur manipulation.

Délai avant récolte : 0 jour

Zone non traitée : 5 mètres par rapport aux points d'eau

Le produit est exempt de Limite Maximale de Résidu

Utilisable en agriculture biologique conformément au règlement CE 834/2007

Information santé**Appel en cas d'urgence :** appeler le 15 ou le centre antipoison le plus proche (N° ORFILA :

01.45.42.59.59). Puis signalez vos symptômes au réseau Phyt'attitude, n° vert 0800 887 887 (appel gratuit depuis un poste fixe).

Fiche de sécurité du produit ANL-F002 disponible en appelant Agronaturalis au 04 32 52 93 53

PREMIERS SECOURS**En cas de contact avec les yeux :** Enlever les lentilles de contact si nécessaire. Rincer immédiatement avec de l'eau claire avec une faible pression et si possible tiède, en soulevant de temps en temps les paupières supérieures.**En cas de contact avec la peau :** Enlever les vêtements contaminés. Laver les parties exposées à l'eau.**En cas d'ingestion :** Ne pas faire vomir après ingestion. Si la personne est consciente, donner à boire. Ne jamais rien donner à ingérer à une personne inconsciente.

*Homologué par :***Agronaturalis Ltd**

Suite B, Crown House, 2 Southampton Road, BH24 1HY Ringwood, Royaume-Uni

Date de fabrication

: XXXXX;

N° de lot : XXXXX Quantité nette : XX mL

Présentation

ANL-F002 agit par contact et possède une action multi-site. Il est à appliquer de manière préventive ou stoppante. Polyvalent, il peut s'utiliser sur les légumes, les arbres fruitiers et les petits fruits ainsi que sur les plantes ornementales pour lutter contre oïdium, tavelure et pourriture grise.

Son mode d'action résulte d'une combinaison de facteurs : modification du pH, de la pression osmotique et perturbation de l'équilibre ionique des cellules du pathogène qui lui confère une bonne efficacité.

Usages et doses

Culture	Maladie	Dose d'emploi	Nombre maximum d'application par an
Pommier, poirier, cognassier, nashi, néflier, pommette	tavelure	100 mL/ m ²	5
Pêcher, abricotier, nectarinier	Monilioses sur fruit	100 mL/ m ²	3
Cassissier, groseillier, myrtillier, airelle Framboisier, mûres	oïdium	100 mL/ m ²	5
Vigne	Oïdium, pourriture grise (Botrytis)	100 mL/ m ²	5
Tomate, aubergine, poivron, piment, concombre, courgette, cornichon, pepino, physalis et baie de Goji	oïdium	60 mL/ m ²	6
Fraisier	oïdium	60 mL/ m ²	6
PPAMC	Maladies fongiques (oïdium)	60 mL/ m ²	6
Porte-graines (potagères, PPAMC, florales)	oïdium	60 mL/ m ²	6
Arbres et arbustes d'ornement (plantes ligneuses)	oïdium	100 mL/ m ²	5
Cultures florales et plantes vertes (plantes herbacées)	oïdium	60 mL/ m ²	6
Rosier	oïdium	100 mL/ m ²	5

Délai avant récolte : 0 jour

Périodes d'emploi

Appliquer pendant la période de végétation entre mars et septembre. Intervalle entre application minimum de 8 jours pour vigne et pommier, 3 jours pour pêcher et 7 jours pour les autres cultures. ANL-F002 s'utilise en applications préventives ou stoppantes (maximum de 12h suivant l'infection).

Une hygrométrie élevée pendant ou après l'application favorise l'efficacité.

Mode d'emploi

Produit prêt-à-l'emploi. Appuyer sur la gâchette et appliquer uniformément sur le feuillage et les fruits.

Recommandations et précautions d'emploi

Contre la tavelure, l'alternance avec d'autres spécialités est recommandée entre deux applications. En cas de pluie intense ou supérieure à 20 mm, il est nécessaire de renouveler le traitement pour assurer une bonne protection.

Avant de généraliser le traitement, faire un essai sur une petite partie de la plante pour s'assurer de l'absence de phytotoxicité.

Bien rincer les produits récoltés avant consommation.

Attention au risque de marquage sur le raisin (disparition de la pruine) ou sur les pommes (rugosités).

Ne pas appliquer lors de hautes températures dans les cultures maraîchères, cultures de fines herbes et baies et dans les serres. Il est recommandé d'appliquer ANL-F002 soit en matinée soit en soirée lorsque l'hygrométrie est élevée.

Equipements de protection individuels

Pour se protéger, l'opérateur doit porter des gants lors de l'utilisation du produit ANL-F002

Stockage

Stocker le produit dans son emballage d'origine dans un endroit frais et sec à une température ambiante supérieure à 0°C. Stocker le produit dans un local fermé à clé. Conserver hors de la portée des enfants. Conserver à l'écart des aliments et boissons, y compris ceux pour animaux.

Elimination

Emballage : réemploi interdit. Eliminer les produits non utilisables dans une déchetterie et les emballages vides et rincés dans la poubelle ménagère. Ne pas jeter les résidus dans les égouts et les cours d'eau.

Important

Respecter les usages, doses, conditions et précautions d'emploi mentionnées sur l'emballage. Elles ont été déterminées en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé.

GARANTIE ET LIMITES DE RESPONSABILITE

Le détenteur de l'autorisation de mise sur le marché (Agronaturalis Ltd) garantit que le produit ANL-F002 dans son emballage d'origine est conforme aux spécifications stipulées sur cette étiquette ainsi qu'à l'autorisation de mise sur le marché délivrée par les autorités compétentes (la « garantie »).

AGRONATURALIS LTD REJETTE TOUTE GARANTIE AUSSI BIEN EXPLICITE QU'IMPLICITE, Y COMPRIS MAIS SANS S'Y LIMITER, TOUTES LES LIMITES DE QUALITE MARCHANDE ET D'APTITUDE A ATTEINDRE UN RESULTAT PARTICULIER OU UN NIVEAU D'EFFICACITE MINIMUM.

Il est impossible d'éliminer tous les risques inhérents au produit. Les dommages à la culture,

les mauvaises performances ou tout autre conséquence indésirable peuvent résulter de facteurs tels que les conditions météorologiques exceptionnelles, la présence d'autres substances ou des

méthodes d'application ou d'utilisation du produit qui seraient différentes de celles strictement préconisées sur cette étiquette, ou de tout autre facteur.

Appendix 3 – Letter(s) of Access

Not applicable.