

REGISTRATION REPORT

Part A

Risk Management

Product code: AGX12

Product name(s): ARGICAL PRO

**Chemical active substance(s):
aluminium silicate (kaolin), 990g/kg**

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(Label extension)

Applicant: AGS MINERAUX

Date: 19/11/2019

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PART A

RISK MANAGEMENT

1 Details of the application

The company AGS MINERAUX has requested a marketing authorisation in France for the product ARGICAL PRO (product code: AGX12), containing 990g/kg aluminium silicate (kaolin)¹ as an insecticide for professional uses.

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

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

Appendix 3 of this document is Letter of Access.

1.1 Application background

The present registration report concerns the evaluation of AGS MINERAUX's application submitted to market ARGICAL PRO (AGX12) in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the label extension of this product in France and in other Member States (MSs) of the Southern zone.

The present applications (2016-0021 & 2017-0939) were evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009², the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")³. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of ARGICAL PRO (AGX12) have been made using endpoints agreed in the EU peer review of aluminium silicate (kaolin). It also includes assessment of data and information related to ARGICAL PRO (AGX12) where those data have not been considered in the EU peer review process.

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 risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

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

This document also describes the specific conditions of use and labelling required for France for the

¹ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.

² 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.

³ 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.

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.

registration of ARGICAL PRO (AGX12).

1.2 Letters of Access

Not necessary: active substance data are not protected anymore.

1.3 Justification for submission of tests and studies

Justification submitted by the applicant : “New efficacy and practical value trials were performed in order to get these uses extensions. No other kind of trial and/or studies were necessary.”

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of ARGICAL PRO (AGX12), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

Product code	AGX12
Product name in MS	ARGICAL PRO
Authorisation number	2120158
Kind of use	Professional use
Low risk product (article 47)	No
Function	Insecticide
Applicant	AGS MINERAUX
Active substance(s) (incl. content)	aluminium silicate (kaolin), 990g/kg
Formulation type	Wettable powder (WP)
Packaging	Packaging not changed
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for ARGICAL PRO (AGX12) resulted in the decision **to grant** the label extension.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

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

Classification not changed.

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

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.
	For other restrictions refer to 2.5

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

None.

2.5 Risk management

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

The French Order of 4 May 2017 ⁵ provides that:

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

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

Finally, the French Order of 26 March 2014⁶ provides that:

- an authorisation granted for a “reference” crop applies also for “related” crops, unless formally stated in the Decision
- the “reference” and “related” crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “related” ones are undertaken even if not clearly requested by the applicant in

⁵ Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRGI632554A/jo/texte>.

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

their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁷ is to supply “minor” crops with registered plant protection products.

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

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

2.5.1 Restrictions linked to the PPP

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

The applicant is required to comply with the current applicable standard for clothing type PPE (ISO EN 27065)⁸.

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details
	The formulation is not potentially toxic by inhalation nor by oral route. In case of repeated and prolonged exposure, the use of a filter mask FFP2 is recommended compulsory during activity on a treated field.
Bystander and resident protection	
	Respect an unsprayed zone of 10 meters from the last treated row and areas where bystanders or residents could be present for grapevine, citrus trees, stone fruits and pome fruits.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
SPe 3	To protect aquatic organisms respect an unsprayed buffer zone of 5 meters to surface water bodies.
SPe 3	To protect non-target arthropods respect an unsprayed buffer zone of 5 meters to non-agricultural land.
Other specific restrictions	
Re-entry period	6 hours.
Agricultural recommendations	The use of ARGICAL PRO (AGX12) between fruit set and harvest can lead to a thin white deposit on the surface of grapes which can impact the visual quality of harvested fruits. A particular care should be given to the application nearby almost harvested crops as a whitish deposit can impact the visual quality of those crops.

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

⁸ Protective clothing – Performance requirements for protective clothing worn by operators applying pesticides and for re-entry workers. EN ISO 27065:2017.

The other conditions of use specified in the previous évaluations are not changed.

2.5.2 Specific restrictions linked to the intended uses

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

None.

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2.6 Intended uses (only NATIONAL GAP)

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. Those uses are then granted in France.

GAP rev. 1, date: 2019-11-19

PPP (product name/code): ARGICAL PRO / AGX12

Formulation type: WP ^(a, b)

Active substance 1: aluminium silicate (kaolin)

Conc. of a.s. 1: 990 g/kg ^(c)

Applicant: AGS MINERAUX

Professional use: ☒

Zone(s): Southern Zone ^(d)

Non-professional use: ☐

Verified by MS: Yes

Field of use: Insecticide

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 applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	Stone fruits (apricots, peaches, nectarines, plum, cherry) and Pome fruits (pome, quince, Chinese pear)	F	Winter stages Aphids	Spray	BBCH 91-57	5 (1 + 4)	21	a) 50 then 30 b) 170	a) 50 kg a.s./ha b) 170 kg a.s./ha	500- 1000 (2)	F (BBCH 57)	Acceptable
2	FR	Pear trees	F	Pear psylla <i>Cacopsylla pyri</i>	Spray	BBCH 00-57	5 (1 + 4)	21	a) 50 then 30 b) 170	a) 50 kg a.s./ha b) 170 kg a.s./ha	500- 1000 (2)	F (BBCH 57)	Acceptable
3	FR	Citrus trees	F	Green leafhopper <i>Asymmetrasca decedens</i>	Spray	BBCH 81-89 First application after first capture	5 (1 + 4)	21	a) 50 then 30 b) 170	a) 50 kg a.s./ha b) 170 kg a.s./ha	500- 1000 (2)	1	Acceptable

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4	FR	Grapevine (VITVI)	F	Green leafhopper (<i>Empoasca vitis</i>) EMPOFL	Foliar spray	1 st application: beginning of targets flight	6	3	a) 20 kg/ha b) 120 kg/ha	a) 19.8 kg a.s./ha b) 118.8 kg a.s./ha	100 / 300	3	Acceptable
Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR).					(d)	Select relevant.					
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008.					(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.					
	(c)	g/kg or g/l.					(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.					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 Background of authorisation decision and risk management

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

The physico-chemical properties of the formulation ARGICAL PRO (AGX12) have been evaluated taken into account the concentration of uses (concentration from 3% w/v to 5% w/v) and considered acceptable during the registration of this formulation.

The concentrations of uses claimed in the two extensions of uses (concentration from 3% w/v to 10% w/v and 6.6% w/v to 20% w/v) are not covered by the previous assessment.

To update the dossier, suspensibility and spontaneity of dispersion tests at 20% w/v should be provided in post-authorisation.

3.2 Efficacy (Part B, Section 3)

ARGICAL PRO (AGX12) efficacy level is considered as partial and variable for all the claimed uses. However it is considered as acceptable considering kaolin mode of action (physical barrier).

ARGICAL PRO (AGX12) phytotoxicity level is considered as negligible for all intended uses.

The risks of negative impact on yield, quality, cider and wine making process and propagation are considered as negligible. The use of ARGICAL PRO (AGX12) between fruit set and harvest can lead to a thin white deposit on the surface of grapes which can impact the visual quality of harvested fruits.

The risk of negative impact on adjacent crops is considered as acceptable. A particular care should be given to the application nearby almost harvested crops as a whitish deposit can impact the visual quality of those crops.

Considering the absence of data, a particular care should be given to the ARGICAL PRO (AGX12) application conditions in the frame of IPM.

The risk of resistance development or appearance to kaolin is considered as very low.

3.3 Methods of analysis (Part B, Section 5)

Kaolin is a natural component of soil and therefore, no analytical method is necessary for the determination of residues of kaolin in plants (dry, high wet, oily and acidic matrices), food of animal origin, soil, water (surface and drinking) and air.

3.4 Mammalian toxicology (Part B, Section 6)

Mammalian toxicology

Endpoints used in risk assessment

Active Substance: Aluminium silicate (Kaolin)		
ADI	No data available – not required ⁹	Efsa (2012)
ARfD	No data available – not required ⁵⁸	
AOEL	No suitable data available to set an AOEL ⁵⁸ . Inhalation exposure limit (IEL) of 36.6mg/day derived from WEL-TWA value of 2 mg/m ³ (8hours) based on a potential for pneumoconiosis after chronic inhalation exposure.	
Dermal absorption	Not necessary based on its physico-chemical properties (peer review EFSA 2012).	

Acute toxicity

ARGICAL PRO (AGX12) containing 990g/kg aluminium silicate (Kaolin) 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 sensitiser

Operator Exposure

Summary of critical use patterns (worst cases): Crop	F/G ¹⁰	Equipment	Application rate kg product/ha (g as/ha)	Spray dilution (L/ha)	Model
Stone fruits	F	Vehicle mounted/ <i>Upward spraying</i>	50 (49500) 30 (29700)	500	EFSA
Pome fruits	F	Vehicle mounted/ <i>Upward spraying</i>	50 (49500) 30 (29700)	500	EFSA
Pear trees	F	Vehicle mounted/ <i>Upward spraying</i>	50 (49500) 30 (29700)	500	EFSA
Citrus trees	F	Vehicle mounted/ <i>Upward spraying</i>	50 (49500) 30 (29700)	500	EFSA
Grapevines	F	Vehicle mounted/ <i>Upward spraying</i>	20 (19800)	100	EFSA

Considering proposed uses, operator systemic exposure was estimated using the EFSA model:

Crop	Equipment	PPE and/or working coverall	% IELV Kaolin
Stone fruits	Vehicle mounted	Working coverall	43,41 36,65
Pome fruits	Vehicle mounted	Working coverall	43,41 36,65
Pear trees	Vehicle mounted	Working coverall	43,41 36,65
Citrus trees	Vehicle mounted	Working coverall	43,41 36,65
Grapevines	Vehicle mounted	Working coverall	32,09

⁹ EFSA Journal 2012;10(1):2517.

¹⁰ Open field or glasshouse.

According to the model calculations, it can be concluded that the risk for the operator using ARGICAL PRO (AGX12) is acceptable with a working coverall (90% protection factor).

Bystander Exposure

EFSA model (w/o AAOEL): Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set¹¹.

Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): “No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.”

Resident Exposure

EFSA model: Residential exposure was assessed according to EFSA model. An acceptable risk was determined for residents (adult and/or child) when mitigation measures such as a buffer zone of 10 meters are taken:

Case 1: Pome fruit 50 kg product/ha, 1 application (cover stone fruit and citrus fruit)

Model (AOEM) - All pathways (mean)	% IELV Kaolin
Resident (children)	2.33
Resident (adults)	0.50

ZNT : 10 mètres Sans buses anti-dérives	Kaolin		
	DT ₅₀ (days)	30	
	DFR (µg/cm ² /kg a.s./ha)	3	
	Application rate (kg a.s./ha)	49.5	
	Pathways (percentile)	Total absorbed dose (mg/kg bw/day)	% AOEL
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0162704	2.67
	Vapour (75 th)	0.00107	0.18
	Deposits (75 th)	0	0
	Re-entry (75 th)	0	0
	Sum (mean)	0.0142413	2.33
Resident adult Body weight: 60 kg	Drift (75 th)	0.003465	0.57
	Vapour (75 th)	0.00023	0.04
	Deposits (75 th)	0	0
	Re-entry (75 th)	0	0
	Sum (mean)	0.003035	0.50

¹¹ Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

Case 2: Pome fruit 30kg product/ha, 4 application (cover stone fruit and citrus fruit)

Model (AOEM) - All pathways (mean)	%IELV Kaolin
Resident (children)	1.47
Resident (adults)	0.31

ZNT : 10 mètres Sans buses anti-dérives	Kaolin		
	DT ₅₀ (days)	30	
	DFR (µg/cm ² /kg a.s./ha)	3	
	Application rate (kg a.s./ha)	29.7	
	Pathways (percentile)	Total absorbed dose (mg/kg bw/day)	% AOEL
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0097623	1.60
	Vapour (75 th)	0.00107	0.18
	Deposits (75 th)	0	0
	Re-entry (75 th)	0	0
	Sum (mean)	0.0089728	1.47
Resident adult Body weight: 60 kg	Drift (75 th)	0.002079	0.34
	Vapour (75 th)	0.00023	0.04
	Deposits (75 th)	0	0
	Re-entry (75 th)	0	0
	Sum (mean)	0.0137416	0.31

Case 3: Grapes 20kg product/ha, 6 application

Model (AOEM) - All pathways (mean)	% IELV Kaolin
Resident (children)	4.49
Resident (adults)	0.96

ZNT : 10 mètres Sans buses anti-dérives	Kaolin		
	DT ₅₀ (days)	30	
	DFR (µg/cm ² /kg a.s./ha)	3	
	Application rate (kg a.s./ha)	19.8	
	Pathways (percentile)	Total absorbed dose (mg/kg bw/day)	% AOEL
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0325409	5.33
	Vapour (75 th)	0.00107	0.18
	Deposits (75 th)	0	0
	Re-entry (75 th)	0	0
	Sum (mean)	0.0274126	4.49
Resident adult Body weight: 60 kg	Drift (75 th)	0.00693	1.14
	Vapour (75 th)	0.0138	0.04
	Deposits (75 th)	0	0
	Re-entry (75 th)	0	0
	Sum (mean)	0.00584	0.96

Worker Exposure

The inhalation exposure of dried formulation is not expected for workers. Therefore, the re-entry exposure was not considered to be a concern.

However, in case of repeated and prolonged exposure, the use of a filter mask FFP2 is recommended compulsory during activity on a treated field.

Combined exposure

Not necessary.

Relevance of metabolites

No metabolites assessment is required.

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

Overall conclusion

The data available are considered sufficient for risk assessment.

Aluminium silicate is included in Annex IV of Regulation (EC) No 396/2005 amended by Regulation (EC) No 839/2008 containing a list of active substances for which maximum residue levels (MRLs) are not required. The toxicological profile of aluminium silicate was evaluated at EU level. The proposal of an ADI and of an ARfD was not deemed necessary.

Indeed, aluminium silicate is an inert substance and is not taken up by plants. This substance is a stable inorganic compound and is naturally present in the environment. Its chemical composition is similar to common clay. Once released it is expected to be stable in the environment and undistinguishable from clay minerals naturally present in soil. Moreover, aluminium silicate is also allowed as a food additive.

As a result, no MRLs are set for aluminium silicate and consequently, an exceedance of the current MRL for as laid down in Reg. (EU) 396/2005 is not expected.

As far as consumer health protection is concerned, France **agrees with the authorization of the intended uses.**

According to available data, no specific mitigation measures should apply.

Data gaps

Noticed data gaps are: -

Summary of the evaluation

The preparation ARGICAL PRO (AGX12) is composed of aluminium silicate (kaolin).

Summary for aluminium silicate

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
	Stone fruits (apricots, peaches, nectarines) and Pome fruits	Yes	Yes	Yes	Yes	Yes	No	No	

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Use- No.*	Crop	Plant me- tabolism covered?	Sufficient residue trials?	PHI suffi- ciently sup- ported?	Sample storage covered by sta- bility data?	MRL com- pliance	Chronic risk for consumers identified?	Acute risk for con- sumers identified?	Comments
	(pome, pears)								
	Pear trees	Yes	Yes	Yes	Yes	Yes		No	
	Citrus trees	Yes	Yes	Yes	Yes	Yes		No	
	Grapes (ta- ble and wine)	Yes	Yes	Yes	Yes	Yes		No	

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

Aluminium silicate is included in Annex IV of Regulation (EC) No 396/2005 amended by Regulation (EC) No 839/2008 containing a list of active substances for which maximum residue levels (MRLs) are not required. Therefore no additional data are required to support the intended use of ARGICAL PRO (AGX12).

The effects of processing on the nature of aluminium silicate residues have not been investigated. Indeed, aluminium silicate is non-toxic, inert and will not become bio-available when ingested.

Residues in succeeding crops have not been investigated and studies are not required taking into account the behavior of the active substance. It is very unlikely that residues will be present in succeeding crops.

No dietary burden calculations have been performed. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Summary for ARGICAL PRO (AGX12)

Information on ARGICAL PRO (AGX12) (KCA 6.8)

Crop	PHI for ARGICAL PRO (AGX12) proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for ARGICAL PRO (AGX12) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Aluminium silicate (kaolin)		
Stone fruits (apricots, peaches, nectarines) and Pome fruits (pome, pears)	N/A	NR	N/A	/
Pear trees	N/A	NR	N/A	/
Citrus trees	N/A	NR	N/A	/
Grapes (table and wine)	N/A	NR	N/A	/

NR: not relevant

N/A: not applicable

* Purpose of withholding period to be specified

Waiting periods before planting succeeding crops

Not relevant.

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

The fate and behaviour in the environment of the formulation have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review were used to calculate PECs, when relevant, for the active substance for the intended use patterns. As mentioned in EFSA conclusion (2012), aluminium silicate is a stable inorganic compound. Its chemical composition is similar to common clay. Once released it is expected to be stable in the environment and undistinguishable from clay minerals naturally present in soil.

The PEC of aluminium silicate in soil, surface water has been assessed according to Efsa conclusion (2012) and the endpoints established in the EU.

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

No PEC_{GW} were deemed necessary (Efsa, 2012) and no unacceptable risk of groundwater contamination is expected for the intended uses.

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.

3.7 Ecotoxicology (Part B, Section 9)

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

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

3.8 Relevance of metabolites (Part B, Section 10)

Not relevant.

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

The active substance aluminium silicate is not approved as a candidate for substitution, therefore a comparative assessment is not foreseen.

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

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

5.1.1 Post-authorisation monitoring

None.

5.1.2 Post-authorisation data requirements

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

- suspensibility and spontaneity of dispersion tests at 20% w/v.

Appendix 1 Copy of the product authorisation



Décision relative à une demande d'extension d'usages 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 les demandes d'extensions d'usages majeurs du produit phytopharmaceutique **ARGICAL PRO***

de la société AGS MINERAUX

enregistrées sous les n°2016-0021 et 2017-0939

Vu les conclusions de l'évaluation de l'Anses du 21 octobre 2019,

L'autorisation de mise sur le marché du produit référencé ci-après **est étendue** aux usages décrits dans la présente décision.

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	
Noms du produit	ARGICAL PRO ARGI NATURE
Type de produit	Produit de référence
Titulaire	AGS MINERAUX LA GARE 17270 CLERAC France
Formulation	Poudre mouillable (WP)
Contenant	990 g/kg – silicate d'aluminium
Numéro d'intrant	2120262
Numéro d'AMM	2120158
Fonction	Insecticide
Gamme d'usage	Professionnel

L'échéance de validité de la présente décision correspond à celle de l'autorisation du produit.

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

A Maisons-Alfort le,

19 NOV. 2019

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

ANNEXE I : Modalités d'autorisation du produit

Liste des nouveaux 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 arthropodes non ciblés (mètres)	Zone Non Traitée arthropodes non ciblés (mètres)	Zone Non Traitée plantes non ciblés (mètres)	Mention abeilles
12053119 Agrumes*Trt.Part.Aer.* Cicadelles, cercopoides et psylles	50 kg/ha	5/an	entre les stades BBCH 81 et BBCH 89	1	5	5	-	-
	Efficacité montrée sur cicadelles. Première application à la dose maximale de 50 kg/ha suivie, au plus, de quatre applications à la dose maximale de 30 kg/ha. Intervalle minimum entre les applications : 21 jours.							
12203102 Cerisier*Trt.Part.Aer.* Pucerons	50 kg/ha	5/an	entre les stades BBCH 91 et BBCH 57	F (BBCH 57)	5	5	-	-
	Première application à la dose maximale de 50 kg/ha (après la récolte des fruits) suivie, au plus, de quatre applications à la dose maximale de 30 kg/ha. Intervalle minimum entre les applications : 21 jours. 5 applications maximum par an et par culture pour contrôler l'ensemble des ravageurs.							
12553122 Pêcher*Trt.Part.Aer.* Pucerons	50 kg/ha	5/an	entre les stades BBCH 91 et BBCH 57	F (BBCH 57)	5	5	-	-
	Première application à la dose maximale de 50 kg/ha (après la récolte des fruits) suivie, au plus, de quatre applications à la dose maximale de 30 kg/ha. Intervalle minimum entre les applications : 21 jours.							

Liste des nouveaux 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 arthropodes non cibles (mètres)	Zone Non Traitée plantés non cibles (mètres)	Mention abeilles
12613116 Pommier*Trt Part.Aer.* P.sylle(s)	50 kg/ha	5/an	entre les stades BBCH 00 et BBCH 57	F (BBCH 57)	5	-	-
Uniquement sur poirier. Première application à la dose maximale de 50 kg/ha (après la récolte des fruits) suivie, au plus, de quatre applications à la dose maximale de 30 kg/ha. Intervalle minimum entre les applications : 21 jours.							
12603150 Pommier*Trt Part.Aer.* Pucerons	50 kg/ha	5/an	entre les stades BBCH 91 et BBCH 57	F (BBCH 57)	5	-	-
Uniquement sur pommier, cognassier et nashi. Première application à la dose maximale de 50 kg/ha (après la récolte des fruits) suivie, au plus, de quatre applications à la dose maximale de 30 kg/ha. Intervalle minimum entre les applications : 21 jours.							
12653110 Prunier*Trt Part.Aer.* Pucerons	50 kg/ha	5/an	entre les stades BBCH 91 et BBCH 57	F (BBCH 57)	5	-	-
Première application à la dose maximale de 50 kg/ha (après la récolte des fruits) suivie, au plus, de quatre applications à la dose maximale de 30 kg/ha. Intervalle minimum entre les applications : 21 jours.							
12703119 Vigne*Trt Part.Aer.* Cicadelles	20 kg/ha	6/an	-	3	5	-	-
Efficacité montrée sur <i>Empoasca vitis</i> . 1 ^{ère} application au début du vol des cibles. Intervalle minimum entre les applications : 3 jours.							



Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

Les équipements de protection individuelle ci-après sont applicables à tous les usages du produit.

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 cadre d'une application avec 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 (3) à porter par-dessus la combinaison précitée ;
- Demi-masque certifié (EN 140) équipé d'un filtre P3 (EN143) ou A2P3 (EN 14387) ;

• pendant l'application

Si application avec tracteur avec cabine

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 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 4 avec capuche ;
- Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;
- En cas d'exposition aux gouttelettes pulvérisées, porter un demi-masque filtrant à particules (EN 149) ou un demi-masque (EN 140) équipé d'un filtre à particules P3 (EN 143) ;

• 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 (3) à porter par-dessus la combinaison précitée.



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.
- En cas d'exposition répétée ou prolongée aux poussières lors d'une activité sur une culture préalablement traitée, porter un demi-masque filtrant conforme à la norme NF EN149 Classe : FFP2.

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

- 6 heures.

Protection des personnes présentes et des résidents

Respecter une distance d'au moins 10 mètres entre le dernier rang traité et l'espace susceptible d'être fréquenté par des personnes présentes ou des résidents pour les usages sur "vigne", "agrumes", Cerisier*Trt.Part.Aer.* Pucerons, "pêcher", "pommier" et "prunier".

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 mètres par rapport aux points d'eau.
- SPe 3 : Pour protéger les arthropodes non-cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente pour les usages en arboriculture.
- Pour protéger les abeilles et les autres insectes pollinisateurs, ne pas appliquer sur les cultures en période de floraison. Ne pas appliquer en présence d'abeilles ou d'autres insectes pollinisateurs.

Exigences complémentaires post-autorisation

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

Détail de la demande post autorisation	Délai (mois)	Réurrence (mois)
Fournir la détermination de la suspensibilité à la concentration maximale.	24	-
Fournir les résultats de la dispersion à la concentration maximale.	24	-

Appendix 2 Copy of the product label

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

ARGICAL PRO

COMPOSITION : Kaolin 99%
 TYPE DE FORMULATION : Poudre mouillable (WP)
 HOMOLOGATION : n° 2120158 détenue par AGS minéraux
 CLASSEMENT : Sans classement.

Produit réservé à usage professionnel

P270 : Ne pas manger, boire ou fumer en manipulant ce produit

P102 : Tenir hors de portée des enfants.

P260 : Ne pas respirer les poussières

EUH401 - Respectez les instructions d'utilisation pour éviter les risques pour l'homme 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.].

Spe3 – Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.

Spe3 - Pour protéger les arthropodes et les plantes non cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente.

Spe8 – Pour protéger les abeilles et autres insectes pollinisateurs, ne pas appliquer durant la floraison. Ne pas utiliser en présence d'abeilles.

Limites maximales de résidus : le kaolin ou silicate d'aluminium fait partie des substances proposées à l'inclusion de l'annexe IV du règlement (CE) n°396/2005. Par conséquent, aucune fixation de LMR n'a été jugée nécessaire pour cette substance.

Détenteur de l'homologation : AGS Minéraux - 17270 CLERAC - Téléphone 05 46 04 57 07

TABEAU DES USAGES ET DOSES D'EMPLOI HOMOLOGUES : (traitement des parties aériennes)

AGX12 / ARGICAL PRO
 Part A - National Assessment
 FRANCE version

Usages	Dose maximale d'emploi	Nombre maximal d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée Plantes non cibles (mètres)
Cerisier *Trt Part.Aer.* Mouches		1	Début véraison	na	5	5
Olivier*Trt Part.Aer.* Mouche		6		28	5	5
Pommier*Trt Part Aer* Pucerons		5	BBCH 91-92 and/or BBCH 54-57	28	5	5
Pommier, Poirier, Cognassier, Nashi ①						
Pêcher*Trt Part.Aer.*Pucerons		5	BBCH 91-92 and/or BBCH 54-57	28	5	5
Pêcher, Nectarinier, Abricotier ①						

Usages	Dose maximale d'emploi	Nombre maximal d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée Plantes non cibles (mètres)
Cerisier *Trt Part.Aer.*Pucerons		5	BBCH 91-92 and/or BBCH 54-57	28	5	5
Pommier *Trt Part.Aer.*Psylle		5	BBCH 00-57	28	5	5
Poirier Psylle						
Agrumes *Trt Part.Aer.*Cicadelles, cercopides et psylles		5	BBCH 81-89	28	5	5
<i>Uniquement Cicadelles Oranger (CIDSJ), Citronnier (CIDLI), Pamplemoussier (CIDGR), Mandarinier (CIDRE), Clémentinier (CIDRE), Limettes (CIDLM) ①</i>						
Prunier*Trt Part.Aer.*Pucerons		5	BBCH 91-92 and/or BBCH 54-57	28	5	5
<i>Prunier (PRNDO), Jujube (ZIPJU) ①</i>						

① Usage obtenu à partir d'une culture de référence sans données de sélectivité sur les autres cultures rattachées, produit utilisable uniquement sous la responsabilité du producteur.

Protection de l'opérateur et du travailleur

-Pour protéger l'opérateur porter :

- Pendant le mélange/chargement :
 - Gants en nitrile certifiés EN 374-3. Bottes de protection certifiées EN 13 832-3. Combinaison de travail tissée en polyester 65 %/coton 35 % de 230 g/m² minimum avec traitement déperlant.
 - EPI partiel (blouse) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée.
 - Masque FFP2
 - Lunettes norme EN 166 (CE, sigle 3).

• Pendant l'application :

- Combinaison de travail cote en polyester 65 %/coton 35 % de 230 g/m² minimum avec un traitement déperlant. Bottes de protection certifiées EN 13 832-3 ;

Si application avec tracteur sans cabine:

- Gants en nitrile certifiés EN 374-3 à usage unique ;
- En cas de risque d'exposition à des particules pulvérisées, porter un demi-masque filtrant à particules (EN 149) ou demi-masque connecté à un filtre à particules (EN 140 + 143). Le masque doit être stocké à l'extérieur de la cabine.

Si application avec tracteur avec cabine :

- Combinaison de travail 65 % polyester/35 % coton de 230 g/m² minimum avec un traitement déperlant. Les gants en nitrile certifiés EN 374-3 à usage unique ne sont nécessaires que lors d'interventions sur le matériel de pulvérisation. Les

gants doivent être stockés à l'extérieur de la cabine. Lunettes norme EN 166 (CE, sigle 3) dans le cas d'une intervention sur le matériel ;

Si application avec une lance ou un pulvérisateur à dos :

- Gants en nitrile certifiés EN 374-3 réutilisables. Lunettes norme EN 166 (CE, sigle 3)
- Pendant le nettoyage du matériel de pulvérisation :
 - Gants en nitrile certifiés EN 374-3. Combinaison de travail tissée en polyester 65 %/coton 35 % de 230 g/m² minimum avec traitement déperlant.
 - EPI partiel (blouse) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée.
 - En cas de risque d'exposition à des particules pulvérisées, porter un demi-masque filtrant à particules (EN 149) ou demi-masque connecté à un filtre à particules (EN 140 + 143). Le masque doit être stocké à l'extérieur de la cabine.
 - Lunettes norme EN 166 (CE, sigle 3).

-Pour protéger le travailleur, porter des gants en nitrile certifiés EN 374-3 et une combinaison de travail tissée en polyester 65 %/coton 35 % de 230 g/m² minimum avec traitement déperlant.

AGRICULTURE BIOLOGIQUE :

Produit utilisable en agriculture biologique en application du RCE n° 834/2007.



EMBALLAGE :

Réemploi de l'emballage interdit. Bien le vider et l'éliminer via les collectes organisées par les distributeurs partenaires de la filière ADIVALOR.



IMPORTANT :

Respectez les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduisez, sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces ...

Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'AMM, délivrée par le Ministère de l'Agriculture, de l'Agroalimentaire et de la Forêt.

AGX12 / ARGICAL PRO
Part A - National Assessment
FRANCE version

Appendix 3 Letter of Access