

REGISTRATION REPORT

Part A

Risk Management

Product code: FBR-1

Product name(s): FBR-C

Chemical active substance(s):

Potassium phosphonates, 726g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: Fitosanitarios Bajo Riesgo AIE

Date: 27/09/2019

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PART A

RISK MANAGEMENT

1 Details of the application

The company Fitosanitarios Bajo Riesgo AIE has requested a marketing authorisation in France for the product FBR-C (product code: FBR-1), containing 726g/L potassium phosphonates, as a fungicide for professional uses.

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 information, data and assessments provided in the Registration Report, Part B include assessment of further data or information as required at national registration by EU regulations. It also includes assessment of data and information related to FBR-C (FBR-1) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of FBR-C (FBR-1) have been made using endpoints agreed in the EU peer review of potassium phosphonates.

This document describes the specific conditions of use and labelling required for France for the registration of FBR-C (FBR-1).

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 contains a copy of the Letter(s) of Access.

1.1 Application background

The present registration report concerns the evaluation of Fitosanitarios Bajo Riesgo AIE's application to market FBR-C (FBR-1) in France as a fungicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

The present application (2016-2580) 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 Southern zone, taking into account the worst-case uses ("risk envelope approach")¹ – the highest application rates applied for in the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009², 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 on the acceptability of risk are based on the criteria provided in Regulation (EU)

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

² 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.

No 546/2011³, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

1.2 Letters of Access

Not necessary: the applicant has provided equivalent studies to those essential for approval of the active substance potassium phosphonates via a data matching table (DMT) and a letter of Access. The data matching table has been assessed by RMS (France) which considered it as incomplete in April 2019.

1.3 Justification for submission of tests and studies

According to the applicant: « This dossier relies on new test and studies providing data and information specific to the formulation FBR-C (FBR-1) as required by the EU regulations and are therefore considered necessary for first authorization. ».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration fo FBR-C (FBR-1), 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	FBR-1
Product name in MS	FBR-C
Authorisation number	2190316
Low risk (article 47)	No
Function	Fungicide
Applicant	Fitosanitarios Bajo Riesgo AIE
Active substance(s) (incl. content)	Potassium phoshonates, 726g/L
Formulation type	Soluble concentrate (SL)
Packaging	High Density PolyEthylene containers (60 mL ; 120 mL ; 250 mL ; 500 mL ; 1 L ; 5 L ; 10 L ; 20 L ; 25 L ; 200 L ; 220 L ; 1000 L)
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

³ [COMMISSION REGULATION \(EU\) No 546/2011 of 10 June 2011 implementing Regulation \(EC\) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products](#)

2.2 Conclusion

The evaluation of the application for FBR-C (FBR-1) resulted in the decision **to grant** the authorisation.

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

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	-
Hazard pictograms:	-
Signal word:	-
Hazard statement(s):	-
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation</i>

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

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 ⁴ 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;

⁴ 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>.

- 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 2014⁵ 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 “related” ones are undertaken even if not clearly requested by the applicant in 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 extrapolation⁶ 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:

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details
Bystander and resident protection:	
	For foliar spray, respect an unsprayed zone of 10 meters from the last treated row and areas where bystanders or residents could be present.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres with a 5-metre permanent planted buffer strip to surface water bodies for uses stone fruits.
Other specific restrictions	
Re-entry period	6 hours

⁵ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRGI407093A/jo>.

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

Storage	-
Risk mitigation measure	Limit the use of products containing fungicidal active substances that may lead to the presence of phosphonic acid in harvested products to a total of: - 10 kg equivalent of phosphonic acid per hectare per year on stone fruits.
Agricultural recommendations	-

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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FRANCE version

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France. When the conclusion is “not acceptable”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.

GAP rev. 1, date: 2019-09-27

PPP (product name/code): FBR-C (product code: FBR-1)
Active substance 1: Potassium phosphonates
Safener: -
Synergist: -
Applicant: FITOSANITARIOS BAJO RIESGO AIE
Zone(s): Southern Zone ^(d)
Verified by MS: **Yes**
Field of use: Fungicide

Formulation type: Soluble concentrate (SL) ^(a, b)
Conc. of a.s. 1: 726g/L ^(c)
Conc. of safener: -
Conc. of synergist: -
Professional use: ☒
Non-professional use: ☐

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: RMS conclusions e.g. g safener/synergist per ha (i)
					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	Grapevine	F	Mildew	Foliar spray	BBCH 15-18	6	10	a) 4 b) 24	a) 2.904 b) 17.424	600- 1000	14	Not acceptable (Risk for worker and MRL exceedance)
2	FR	Grapevine	F	Mildew	Foliar spray	BBCH 15-18	5	20	a) 4 b) 20	a) 2.904 b) 14.520	600- 1000	14	Not relevant (covered by use n°1)

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3		Citrus	F	<i>Phytophthora spp.</i>	Drip irrigation and Foliar spray (Drip irrigation for the 1 st to 5 th applications and foliar spray for the last application)	From April until November	6 1 st : April 2 nd : April-May 3 rd : July 4 th : September 5 th : September 6 th : October-November	15	a) 1 st : 8 2 nd : 6 3 rd : 8 4 th : 6 5 th : 8 6 th : 5 b) 41	a) 1 st : 5.808 2 nd : 4.356 3 rd : 5.808 4 th : 4.356 5 th : 5.808 6 th : 3.630 b) 29.776	1 st -5 th : 10000 6 th : 2500	14	Not acceptable (MRL exceedance)
4		Citrus	F	<i>Phytophthora spp.</i>	Drip irrigation and Foliar spray	From July until November	4 1 st : July 2 nd : September 3 rd : September 4 th : October-November Applied traditional fungicide at the beginning of the season	15	a) 1 st -3 rd : 6 4 th : 5 b) 23	a) 1 st : 4.356 2 nd : 4.356 3 rd : 4.356 4 th : 3.630 b) 16.698	1 st -3 th : 10000 4 th : 2500	14	Not relevant (covered by use n°1)
5		Stone fruits	F	<i>Phytophthora spp.</i>	Drip irrigation	Between BBCH 32 and BBCH 91	3	14	a) 10 b) 30	a) 7.26 b) 21.78	1000	14	Acceptable only on peach and nectarine trees: do not cumulate foliar sprays and drip application on a same crop Not acceptable (MRL exceedance) on apricot, cherry, plum and mirabelle plum trees

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6		Stone fruits	F	<i>Phytophthora spp.</i>	Foliar spray	Between BBCH 32 and BBCH 91	3	14	a) 4 b) 12	a) 7.26 b) 8.712	600	14	Acceptable only on peach and nectarine trees. do not cumulate foliar sprays and drip application on a same crop Not acceptable (MRL exceedance) on apricot, cherry, plum and mirabelle plum trees
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Remarks table heading:

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

Remarks columns:

1 Numeration necessary to allow references.
2 Use official codes/nomenclatures of EU Member States.
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure).
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application.
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

(d) Select relevant.
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.
(f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application.
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product.
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
13 PHI - minimum pre-harvest interval.
14 Remarks may include: Extent of use/economic importance/restrictions.

3 Background of authorisation decision and risk management

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

The product FBR-C (FBR-1) is colourless liquid with a characteristic odour. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. It is not explosive and has no oxidizing properties. The product has a flash point higher than 130°C. It has a self ignition temperature higher than 590°C. In aqueous solution (1%), its has a pH value 5.7 at ambient temperature. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°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 container.—Its technical characteristics are acceptable for a soluble concentrate formulation. The formulation is not classified for the physical-chemical part.

3.2 Efficacy (Part B, Section 3)

Considering the data provided:

- FBR-C (FBR-1) efficacy is considered as acceptable for all intended uses. However, the dose rate was not justified for all intended uses.
- FBR-C (FBR-1) risk of phytotoxicity is considered as negligible for all intended uses.
- FBR-C (FBR-1) risk of adverse effect on quality, yield and adjacent crops are considered as acceptable. However, no data was provided on the risk of adverse effect on wine making process. Therefore, **evaluation is not possible for wine grape**.
- The risk of resistance appearance or development to potassium phosphonates does not require setting up a monitoring program.

3.3 Methods of analysis (Part B, Section 5)

Analytical method for the determination of active substance in the formulation is available and validated. As the active substance potassium phosphonates does not contain relevant impurity, no analytical method is required.

Analytical methods are available in the monograph and in this dossier and validated for the determination of residues of potassium phosphonates in plants (acidic and high water content crops), food of animal origin, soil, water (surface and drinking) and air.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Active Substance: Potassium phosphonate		
ADI	2.25 mg/kg body weight/d	EU (2013)
ARfD	Not applicable	

AOEL	5 mg/kg body weight/d		
AAOEL	Not applicable		
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (used in formulation) 726g/L	Spray dilution (used in formulation) 3.63 /L
	Dermal absorption endpoints %	25%	75%
Oral absorption	100%		

3.4.1 Acute toxicity

FBR-C (FBR-1) containing 726g/L potassium phosphonate 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.

3.4.2 Operator exposure

Summary of critical use patterns (worst cases):

Crop type	F/G ⁷	Equipment <i>Application method</i>	Maximum application rate kg as /ha	Minimum volume water (L/ha)
Grapes	F	Vehicle mounted <i>Upward spraying</i>	2.904	200
Citrus	F	Drip irrigation	5.808	200
Citrus	F	Vehicle mounted <i>Upward spraying</i>	3.630	200
Stone fruits	F	Drip irrigation	7.260	200
Stone fruits	F	Vehicle mounted <i>Upward spraying</i>	2.904	200

Considering proposed uses, operator systemic exposure was estimated using the EFSA model⁸:

Crop	Equipment	PPE and/or working coverall	% AOEL potassium phospho- nate
Grapes	Vehicle mounted <i>Upward spraying</i>	Working coverall and gloves during mixing/loading and application	9.83
Citrus	Drip irrigation	Working coverall and gloves during mixing/loading and application	0.36

⁷ Open field or glasshouse

⁸ AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014;12 (10):3874)

Citrus	Vehicle mounted <i>Upward spraying</i>	Working coverall and gloves during mixing/loading and application	12.27
Stone fruits	Drip irrigation	Working coverall and gloves during mixing/loading and application	0.44
Stone fruits	Vehicle mounted <i>Upward spraying</i>	Working coverall and gloves during mixing/loading and application	9.83

According to the model calculations, it can be concluded that the risk for the operator using FBR-C (FBR-1) is acceptable with a working coverall and gloves during mixing/loading and application.

For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

3.4.3 Worker exposure

Workers may have to enter treated areas after treatment for crop hand harvesting and searching, reaching, picking activities. The worker exposure to applications via drip irrigation is considered as negligible compared to the exposure to foliar applications and therefore applications via drip irrigation are well covered by these critical uses.

Therefore, estimation of worker exposure was calculated according to AOEM model:

		Potassium Phosphonates	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Grapes Vehicle-mounted/outdoors/high crops Application rate: 4 L/ha corresponding to 2904 g a.s./ha Number of applications: 6 Min. interval between applications : 10 days			
AOEM Body weight: 60 kg	no PPE	95.0172	1900.34
	+ type of PPE * (work wear)	31.9891	639.78
Grapes Vehicle-mounted/outdoors/high crops Application rate: 4 L/ha corresponding to 2904 g a.s./ha Number of applications: 5 Min. interval between applications : 20 days			
AOEM Body weight: 60 kg	no PPE	63.6229	1272.46
	+ type of PPE * (work wear)	21.4197	428.39
Citrus Vehicle-mounted/outdoors/high crops Application rate: 5 L/ha corresponding to 3630 g a.s./ha Number of applications: 1 Min. interval between applications : 365 days			
AOEM	no PPE	24.5025	490.05

Body weight: 60 kg	+ type of PPE * (work wear)	4.9005	98.01
	+ type of PPE * (work wear & gloves)	2.4503	49.01
Stone fruits Vehicle-mounted/outdoors/high crops Application rate: 4 L/ha corresponding to 2904 g a.s./ha Number of applications: 3 Min. interval between applications : 14 days			
AOEM Body weight: 60 kg	no PPE	44.0512	881.02
	+ type of PPE * (work wear)	8.8102	176.20
	+ type of PPE * (work wear & gloves)	4.4051	88.10

According to the EFSA model calculations, it can be concluded that the risk for the worker is not acceptable with PPE on grapevine.

Whereas, the risk for the operator is acceptable with PPE on stone fruits and citrus.

For details of personal protective equipment for workers, refer to the Decision in Appendix 1.

3.4.4 Bystander and resident exposure

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 set .

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.”

Residential exposure was assessed according to EFSA model.

The resident/bystander exposure to applications via drip irrigation is considered as negligible compared to the exposure to foliar applications and therefore applications via drip irrigation are well covered by these critical uses.

An acceptable risk was determined for residents (adult and/or child) without mitigation measures:

Model (AOEM) - All pathways (mean)	% AOEL phosphonate de potassium
Resident (children)	42%
Resident (adults)	23%

According to the EFSA model calculations, it can be concluded that an acceptable risk was determined for residents (adult and/or child) when mitigation measures such as **a buffer zone of 10 meters are taken for foliar application.**

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

The available data are not considered sufficient to support the intended uses on citrus fruits and stone fruits other than peaches. Additionally, an exceedance of the current MRL of for potassium phosphonates (expressed as Fosetyl) as laid down in Reg. (EU) 396/2005 is expected for grapes.

The chronic intakes of potassium phosphonates residues are unlikely to present a public health concern. Since the setting of an ARfD was not deemed necessary for this active substance, no acute risk assessment was performed in the framework of this dossier.

As far as consumer health protection is concerned, France as zRMS agrees with the authorisation of the intended uses on peaches but disagrees with the authorisation of the intended uses on grapes, citrus fruits and stone fruits other than peaches. **On these crops do not apply (all phosphonic acid generating products considered) more than the equivalent of 10 kg/ha phosphonic acid.**

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

Data gaps

Noticed data gaps are:

- 4 additional SEU trials on oranges
- 6 additional SEU trials on mandarins
- A minimum of 4 SEU trials on apricots supporting each GAP intended on stone fruits
- Complete SEU data packages supporting the intended uses on cherries and plums (one data package per crop and per intended GAP)

Data required in post-authorization

None

Summary of the evaluation

The preparation FBR-C (FBR-1) is composed of potassium phosphonates.

Summary for FBR-C (FBR-1)

Table 1 : Information on FBR-C (FBR-1) (KCA 6.8)

Crop	PHI for FBR-C (FBR-1) proposed by applicant	PHI sufficiently supported for	PHI for FBR-C (FBR-1) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Potassium phosphonates		
Grapevines	14 days	No	None	MRL exceedance
Citrus	14 days	No	None	lack of supporting data
Peaches	14 days	Yes	14 days	-

Crop	PHI for FBR-C (FBR-1) proposed by applicant	PHI sufficiently supported for	PHI for FBR-C (FBR-1) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Potassium phosphonates		
Other stone fruits	14 days	No	None	MRL exceedance

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 for the active substance and its metabolites 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.

The PEC of active substance and its metabolite in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU review or agreed in the assessment based on new data provided.

PEC soil and PEC_{sw} derived for the active substance and its metabolite are used for the eco-toxicological risk assessment, and mitigation measures are proposed. For the active substance potassium phosphonates, the maximum PEC_{sw} values were higher than 35 µg of phosphorous equivalent/L (OECD, 1982⁹). So, there is a potential risk of eutrophication for the surface water.

PEC_{gw} for phosphonic acid do not occur at levels exceeding those mentioned in regulation EC 1107/2009, and in regulation Directive 98/83/CE¹⁰. Therefore, no unacceptable risk of groundwater contamination 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 and its metabolites 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 terrestrial plants are acceptable for the intended uses.

Risk mitigations are required for aquatic organisms:

For applications in grapes, stone fruits and citrus the long-term risk can be considered acceptable **if an unsprayed buffer zone of 5 m including 5 m vegetation filter strip is respected.**

⁹ O.E.C.D. 1982. Eutrophication of Waters. Monitoring, Assessment and Control. O.E.C.D. Paris. 154 pp.

¹⁰ Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev10-final, 25 February 2003.

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 potassium phosphonates 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 following data would have been required to update the dossier:

- The final report of the ILV for the determination of potassium phosphonates residues in foodstuff of animal origin ;
- Breakthrough data for method (Perboni A., 2016, report RAU-053-15).

Appendix 1 Copy of the product authorisation



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

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

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

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

*de la société **FITOSANITARIOS BAJO RIESGO AIE***

*enregistrée sous le **n°2016-2580***

Vu les conclusions de l'évaluation de l'Anses du 15 mai 2019,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France, sous réserve du respect de la composition du produit autorisée dans les conclusions d'évaluation, 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	FBR-C
Type de produit	Produit de référence
Titulaire	FITOSANITARIOS BAJO RIESGO AIE Serrat de la Creu, 15 08554 San Miguel De La Balenya-Seva (Barcelona) Espagne
Formulation	Concentré soluble (SL)
Contenant	726 g/L - phosphonates de potassium
Numéro d'intrant	747-2016.01
Numéro d'AMM	2190316
Fonction	Fongicide
Gamme d'usage	Professionnel

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 30 septembre 2024.

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. 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

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	Contenance
Bouteilles en polyéthylène haute densité	60 mL ; 120 mL ; 250 mL ; 500 mL ; 1 L
Bidons en polyéthylène haute densité	5 L ; 10 L ; 20 L
Fûts en polyéthylène haute densité	25 L ; 200 L
Cuves en polyéthylène haute densité	220 L ; 1000 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 mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.							
Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traînée arthropodes non cibles (mètres)	Zone Non Traînée plantes non cibles (mètres)	Mention abeilles
12693201 Cultures fruitières* traitement des parties aériennes* champignons (pythiacées)	4 L/ha	3/an	entre les stades BBCH 32 et BBCH 91	14	5 (dont DVP 5)	-	-
	Uniquement sur pêcher et nectarinier. Efficacité montrée sur <i>Phytophthora</i> spp. Intervalle minimum entre les applications : 14 jours. Ne pas cumuler sur une même culture des applications foliaires et par irrigation. L'usage est refusé sur abricotier, cerisier, prunier et mirabellier en raison d'un risque de dépassement des limites maximales de résidus.						
00201025 Cultures fruitières*Trt Sol* Champignons (pythiacées)	10 L/ha	3/an	entre les stades BBCH 32 et BBCH 91	14	5 (dont DVP 5)	-	-
	Uniquement sur pêcher et nectarinier. Application uniquement par irrigation goutte à goutte. Efficacité montrée sur <i>Phytophthora</i> spp. Intervalle minimum entre les applications : 14 jours. Ne pas cumuler sur une même culture des applications foliaires et par irrigation. L'usage est refusé sur abricotier, cerisier, prunier et mirabellier en raison d'un risque de dépassement des limites maximales de résidus.						

DVP : Dispositif Végétalisé Permanent.

FBR-C

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Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12053204 Agrumes*Trt Part.Aer.* Chancres du collet	5 L/ha	1/an	14
	Motivation du refus : L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus.		
12052201 Agrumes*Trt Sol* Champignons (pythiacées)	6 L/ha	3/an	14
	Motivation du refus : L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus. L'usage à 3 applications à la dose de 8 L/ha et 2 applications à la dose de 6 L/ha est également refusé pour la même raison.		
12703203 Vigne*Trt Part.Aer.* Mildiou(s)	4 L/ha	5/an	14
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour le travailleur. Il est également refusé en raison d'un risque de dépassement des limites maximales de résidus. L'usage à 6 applications maximum par an est également refusé pour les mêmes raisons. L'usage est également refusé en raison de l'absence de données sur le risque d'impact négatif sur le processus de vinification.		

FBR-C

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Conditions d'emploi du produit

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 cadre d'une application effectuée 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 ;

• 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 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 ;

• 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.

Dans le cadre d'une application effectuée par le système d'irrigation en goutte à goutte

• 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 ;



• **pendant l'application**

Si intervention sur le matériel

- 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 ;

• **pendant le nettoyage du matériel d'application**

- 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.

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 applications en traitement des parties aériennes.

Respect des limites maximales de résidus (LMR)

Pour chaque usage figurant dans la liste des usages autorisés, les conditions d'utilisation du produit permettent de respecter les limites maximales de résidus.

Limiter les applications de produits contenant des substances susceptibles d'engendrer la présence de résidus d'acide phosphonique dans les produits récoltés à un total de :

- 10 kg d'équivalent d'acide phosphonique par hectare et par an sur "fruits à noyau".

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 comportant un dispositif végétalisé permanent non traité d'une largeur de 5 mètres en bordure des points d'eau.



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 l'évaluation du « breakthrough » pour la méthode des résidus de substance active dans l'air.	24	-
Fournir la méthode de validation inter laboratoires pour la détermination des résidus dans les denrées d'origine animale.	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.

Usages autorisés et doses :

Culture	Cible	Mode d'application	Période	Nombre d'applications (intervalle)	Dose d'application (g/ha)	Valeur g d'eau (g/ha)	PHI	Remarques
Vigne	Mildiou	Pulvérisation foliaire	A partir de BBCH 15 - 18	4 (10)	4	200 - 1000	14	6 applications à partir de BBCH 15 - 18, suivies des traitements et produits utilisés habituellement à la fin d'un programme de lutte contre le mildiou
Vigne	Mildiou	Pulvérisation foliaire	A partir de BBCH 15 - 18	5 (20)	4	200 - 1000	14	Le programme consiste en l'alternance entre le produit FIB-AX et un produit à base de bisulfure d'arsène, utilisé pour lutter contre le mildiou
Agrumes	<i>Phytophthora</i> 225	Irrigation en souille-à-souille et pulvérisation foliaire*	D' avril à novembre	6 (15)**	1 ^{ère} : 8 2 ^{ème} : 6 3 ^{ème} : 8 4 ^{ème} : 6 5 ^{ème} : 8 6 ^{ème} : 5	1 ^{ère} - 5 ^{ème} : 10000 6 ^{ème} : 2500	14	*Contre la souille de la souille à la 5 ^{ème} application et pulvérisation foliaire pour la dernière application 1 ^{ère} 1 ^{ère} : Avril 2 ^{ème} : Avril - mai 3 ^{ème} : Juin 4 ^{ème} : Septembre 5 ^{ème} : Septembre 6 ^{ème} : Octobre - novembre
Agrumes	<i>Phytophthora</i> 225	Irrigation en souille-à-souille et pulvérisation foliaire*	D' avril à novembre	4 (15)**	1 ^{ère} - 3 ^{ème} : 6 4 ^{ème} : 5	1 ^{ère} - 3 ^{ème} : 10000 4 ^{ème} : 2500	14	*Contre la souille de la souille à la 3 ^{ème} application et pulvérisation foliaire pour la dernière application 1 ^{ère} 1 ^{ère} : Juillet 2 ^{ème} : Septembre 3 ^{ème} : Septembre 4 ^{ème} : Octobre - novembre
Arbustes à feuilles persistantes	<i>Phytophthora</i> 225	Irrigation en souille-à-souille et pulvérisation foliaire*	1 ^{ère} : BBCH 32 2 ^{ème} : BBCH 35 3 ^{ème} : BBCH 91	3 (14)	10	1000	-	Appliquer le fongicide habituel en début de saison
Arbustes à feuilles persistantes	<i>Phytophthora</i> 225	Pulvérisation foliaire	1 ^{ère} : BBCH 32 2 ^{ème} : BBCH 35	3 (14)	4	600	-	

Instructions d'utilisation :

Remplir à moitié le réservoir d'eau et commencer l'agitation. Verser la quantité de produit recommandée puis remplir le volume restant avec de l'eau.

Volume net : xv L

Date de production : xx/xx/xxxx

N° de lot : XXXX

**FBR-A
FONGICIDE**

Produit contenant 726 g/L de phosphonate de potassium

Pour un usage fongicide contre le mildiou sur vigne et les *Phytophthora* spp. sur agrumes et fruits à noyaux

Numéro d'autorisation: XXXXXX

Titulaire de l'autorisation :

Fitosanitarios Bajo Riesgo AIE

Serrat de la Creu, 15

08554 San Miguel De La Balenya-Seva (Barcelona)

Classification de la substance ou du mélange :

Le produit n'est pas classé en accord avec les exigences de la réglementation CLP (CE) n°1272/2008.

Précautions d'utilisation :

P264 : Se laver les mains soigneusement après manipulation.

SP280 : Porter des gants de protection ainsi que de vêtements de protection.

EUH 401 : Respecter les instructions d'utilisation pour éviter les risques pour la santé humaine et

l'environnement.

Exemple : Ne pas polluer l'eau avec le produit ou son emballage.

...pénétrer dans les cultures traitées

Numéro téléphonique d'urgence : +33 (0)1 45 42 59 59

Premiers secours :

En cas d'inhalation, Retirer le sujet de la zone d'émission et l'amener à l'air frais. Si les troubles se prolongent, consulter un médecin.

En cas d'ingestion, laver la bouche à l'eau puis boire abondamment. Ne pas provoquer de vomissement.

Consultez un médecin si vous ne vous sentez pas bien.

En cas de contact avec la peau, laver immédiatement la zone touchée à grande eau. Enlever les vêtements contaminés.

En cas de contact avec les yeux, laver immédiatement à grande eau pendant 15 minutes en maintenant les paupières ouvertes. En cas de port de lentilles de contact, les retirer puis continuer à rincer. Si les irritations persistent, consulter un médecin.

Conditions de stockage sûres :

Conservez le produit dans son emballage original dans un endroit frais, sec, et correctement ventilé.

Elimination du produit et de son emballage :

Éliminez le produit et son emballage en respectant les lois en vigueur.

Mode d'action :

FBR-A est un fongicide préventif à activité systémique. FBR-A a une action indirecte sur le renforcement du système de protection naturel de la plante et une action directe sur la prolifération des champignons par inhibition de la germination des spores.

Appendix 3 Letter of Access

Provided upon request.