

REGISTRATION REPORT
Part A
Risk Management

Product code: K-PHOS
Product name: K-PHOS
Chemical active substance:
Potassium phosphonates, 730 g/L

Interzonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE
(New application)

Applicant: Xeda International S.A.
2020/05/29

Table of Contents

1	Details of the application	4
1.1	Application background	4
1.2	Letters of Access	5
1.3	Justification for submission of tests and studies	5
1.4	Data protection claims	5
2	Details of the authorisation decision	5
2.1	Product identity	5
2.2	Conclusion	6
2.3	Substances of concern for national monitoring	6
2.4	Classification and labelling	6
2.4.1	Classification and labelling under Regulation (EC) No 1272/2008	6
2.4.2	Standard phrases under Regulation (EU) No 547/2011	6
2.4.3	Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)	6
2.5	Risk management	6
2.5.1	Restrictions linked to the PPP	7
2.5.2	Specific restrictions linked to the intended uses	7
2.6	Intended uses (only NATIONAL GAP)	8
3	Background of authorisation decision and risk management	11
3.1	Physical and chemical properties (Part B, Section 2)	11
3.2	Efficacy (Part B, Section 3)	11
3.3	Methods of analysis (Part B, Section 5)	12
3.3.1	Analytical method for the formulation	12
3.3.2	Analytical methods for residues	12
3.4	Mammalian toxicology (Part B, Section 6)	12
3.4.1	Acute toxicity	13
3.4.2	Operator exposure	13
3.4.3	Worker exposure	14
3.4.4	Bystander and resident exposure	15
3.5	Residues and consumer exposure (Part B, Section 7)	15
3.6	Environmental fate and behaviour (Part B, Section 8)	16
3.7	Ecotoxicology (Part B, Section 9)	16
3.8	Relevance of metabolites (Part B, Section 10)	17
4	Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)	17
5	Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation.....	17
5.1.1	Post-authorisation monitoring.....	17

5.1.2	Post-authorisation data requirements	17
Appendix 1	: Copy of the product authorisation.....	18
Appendix 2	Copy of the product label.....	23
Appendix 3	Letter of Access	24

PART A

RISK MANAGEMENT

1 Details of the application

The company Xeda International S.A. has requested a marketing authorisation in France for the product K-PHOS, containing 730 g/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 K-PHOS where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of K-PHOS 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 K-PHOS.

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 Xeda International S.A.'s application to market K-PHOS in France as a fungicide (product uses described under point 2.3). France acted as interzonal Rapporteur Member State (izRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the European Union.

The present application (2018-3779) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) in the context of the zonal procedure for all Member States of the European Union, taking into account the worst-case uses ("risk envelope approach")¹ – the highest application rates applied for in the European Union. 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

the applicant has provided equivalent studies to those essential for approval of the active substance potassium phosphonates via a data matching table (DMT).

1.3 Justification for submission of tests and studies

According to the applicant: “*Based on the intended application and composition of the product, new tests and studies were considered necessary to evaluate and demonstrate efficacy and toxicity of the product for the intended uses*”.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of K-PHOS, 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	K-PHOS.
Product name in MS	K-PHOS.
Authorisation number	N/A : no marketing authorisation granted
Low risk (article 47)	No.
Function	Fungicide.
Applicant	Xeda International S.A.
Active substance(s) (incl. content)	Potassium phosphonates, 730 g/L.
Formulation type	Soluble concentrate [SL].
Packaging	N/A : no marketing authorisation granted Professional user.
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 K-PHOS resulted in the decision **to refuse** 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 extant legislation</i>
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use [EUH401].

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

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

N/A : no marketing authorisation granted

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

N/A : no marketing authorisation granted

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 2017⁴ 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, modifié par l'arrêté du 27 décembre 2019 : <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

- 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

N/A : no marketing authorisation granted

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):

⁵ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGR1407093A/jo>

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

K-PHOS
Part A - National Assessment
FRANCE

2.6 Intended uses (only NATIONAL GAP)

Please note:

When the conclusion is “not acceptable” or “not finalised”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.

PPP (product name/code):	K-PHOS	Formulation type:	GAP rev. 1, date: 2020-05-29
Active substance 1:	Potassium phosphonates	Conc. of a.s. 1:	Soluble concentrate (SL) ^(a, b)
Safener:	-	Conc. of safener:	730 g/L ^(c)
Synergist:	-	Conc. of synergist:	- ^(c)
Applicant:	Xeda International S.A.	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	Interzonale ^(d)	Non-professional use:	<input type="checkbox"/>
Verified by MS:	Yes		
Field of use:	fungicide		

K-PHOS

Part A - National Assessment
FRANCE

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/Ki nd	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 or kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
1	FR, ES, PT, IT, EL	<i>Citrus</i>	I	<i>Geotrichum</i> spp. <i>Penicillium</i> spp.	Dipping, Drenching	Post-harvest	1	-	0.3 – 0.5 L/hL	219 – 365 g a.s/hL	-	-	Not acceptable (MRL, efficacy)
2a	BE, FR, NL	Chicory, leaf production	I	Pythiaceae	Spraying on the col- lar of the roots.	Post-harvest	1	-	60 mL/m ² /5 L spraying	0.876 g a.s./hL	-	-	Not acceptable (MRL) Efficacy demonstrated on <i>Phytophthora</i> spp.
2b	BE, FR, NL	Chicory, leaf production	I	Pythiaceae	Addition in the nu- trient solu- tion during the forcing of chicory.	Post-harvest	1	-	60 mL/hL	43.8 g a.s./hL	-	-	Not acceptable (MRL, efficacy)
2c	BE, FR, NL	Chicory, root production	I	Stimulator of natural defences	Foliar Spraying	Post-harvest	1	-	60 mL/m ² /5 L	0.876 g a.s./hL	-	-	Use not relevant (no foliar spraying on post-harvest root)
2d	BE, FR, NL	Chicory, root production	I	Stimulator of natural defences	Foliar Spraying	Post-harvest	1	-	60 mL/hL	43.8 g a.s./hL	-	-	Use not relevant (no foliar spraying on post-harvest root)

K-PHOS

Part A - National Assessment
FRANCE

Remarks table heading:	(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008 (c) g/kg or g/l	(d) Select relevant (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1 (f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
Remarks columns:	<p>1 Numeration necessary to allow references</p> <p>2 Use official codes/nomenclatures of EU Member States</p> <p>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)</p> <p>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</p> <p>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.</p> <p>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.</p>	<p>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</p> <p>8 The maximum number of application possible under practical conditions of use must be provided.</p> <p>9 Minimum interval (in days) between applications of the same product</p> <p>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.</p> <p>11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).</p> <p>12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".</p> <p>13 PHI - minimum pre-harvest interval</p> <p>14 Remarks may include: Extent of use/economic importance/restrictions</p>

3 Background of authorisation decision and risk management

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

All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is that of a light translucent white liquid. It is not explosive and has no oxidising properties. The product has a flash point above 200 °C. It is not self-igniting. In aqueous solution, it has a pH value around 7.1 at 20 °C. There is no effect of low and high temperatures on the stability of the formulation, since after seven days at 0 °C and 14 days at 54 °C, neither the active substance content nor the technical properties were changed. After one minute, no foam was formed, meaning that K-PHOS is not a foaming product.

The stability data indicate a shelf life of at least two years at ambient temperature when stored in HDPE. However, a slight deposit is noticed after 24 months and it should be recommended to shake the product before use.

The technical characteristics are acceptable for a SL formulation.

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

- In the absence of justification of the dose intended for the control of storage diseases in *Citrus* fruits, evaluation of the efficacy level of K-PHOS cannot be finalised for this intended use.
- **In the absence of justification of the dose intended for the control of chicory downy mildew by introduction in the nutrient solution during the forcing period, evaluation of the efficacy level of the K-PHOS cannot be finalised. However, efficacy is considered satisfactory for the control of chicory downy mildew by collar-directed spraying of roots. The outdoor use (foliar spraying) corresponding to the treatment of chicory during the root production phase does not appear relevant in the framework of this dossier, which focuses on indoor treatments only.**
- The phytotoxicity level of K-PHOS is considered negligible for the intended uses.
- The risks of negative impact on yield and quality are considered negligible.
- The risk of resistance appearing or developing to potassium phosphonates does not require any monitoring for the requested uses.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

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

3.3.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report (DAR) and validated for the determination of residues of potassium phosphonates (phosphonic acid) in plants (acidic and high-water-content crops). Since the proposed uses can be part animal feeding, a fully validated method with ILV for the determination of potassium phosphonates (phosphonic acid) in foodstuffs of animal origin is required post-authorisation. Additionally, as identified in the EFSA conclusions, a fully validated method should be provided post authorisation for the determination of potassium phosphonates (phosphonic acid) in soil and water (surface and drinking).

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Active Substance: Potassium phosphonates	
ADI	2.25 mg kg bw/d
ARfD	NA
AOEL	5 mg/kg bw/d
AAOEL	NA

Anses

K-PHOS
Part A - National Assessment
FRANCE

Dermal absorption	Based on Default value (EFSA Journal 2017; 15(6):4873)			
	<table border="1"> <tr> <td>Concentrate (used in formulation) 730 g/L</td><td>Spray dilution (used in formulation) 730 g/L</td></tr> </table>		Concentrate (used in formulation) 730 g/L	Spray dilution (used in formulation) 730 g/L
Concentrate (used in formulation) 730 g/L	Spray dilution (used in formulation) 730 g/L			
Dermal absorption endpoints %		10	50	
Oral absorption			100	

3.4.1 Acute toxicity

K-PHOS containing 730 g/L potassium phosphonates 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 sensitisier.

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)
Risk envelop	I	Drenching / Dipping	0.5 L K-Phos/ hL (3.6 kg potassium phosphonates/ha*)	/

* The concentration of the active substance in the treatment water is 0.120 kg as/t (technical content) (or 0.5L product/hL). Considering 10.000 L per cycle (1 cycle/day), 300 tons of plants are treated per day which gives an active substance loading of 36 kg per cycle or day: 36 kg as/day x 1 day/10 t = 3.6 kg as/t

⁷ Open field or glasshouse

K-PHOS
Part A - National Assessment
FRANCE

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

Only the exposure during mixing and loading (product without dilution) has been assessed. The application phase of the product (diluted product) depends on the application technique, in this case is automatic, therefore the presence of the applicator is not required.

Crop	Equipment	PPE and/or working coverall	% AOEL
citrus	Vehicule mounted : Mixing and loading only*	Working coverall and gloves during mixing/loading and application	2.64

* (*) According EFSA model, for the use citrus, operator treated 10 ha /day, (in post-harvest, treatment unit is tons (t) of treated fruit (instead of Ha in pre-harvest) therefore 10 t/day.

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

3.4.3 Worker exposure

Worker exposure may occur during the removal of rotten citrus fruits after storage and fruits may be packed manually after storage into the final boxes to be delivered to the market. Calculation of worker handling the treated fruit exposure was estimated by applicant according to the predictive model: "Calculation of the exposure of the postharvest phytosanitary treatments" (AEPLA-AGRUPPOST) .

Applicant considers penetration factor (with gloves) to be 1% whereas EFSA recommends a 10% penetration factor.

Under these conditions, worker exposition is unacceptable (189% AOEL) for large orange with the AEPLA-AGRUPPOST model proposed by the applicant.

Dermal exposure during post-harvest activities results primarily from sorting and packaging (bundling). Especially in the case of sorting, workers have to handle the harvested commodity with their hands, most often in a similar way as during harvesting but without any contact to foliage. Therefore, in a first attempt these post-harvest exposures could be considered at the most as comparable to exposure during harvesting.

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

K-PHOS
Part A - National Assessment
FRANCE

Thus, zRMS proposes the following calculation using parameters given in the EFSA guidance¹

Systemic exposure (mg/d): DFR (mg/cm²) x AR (Kg as/ha) x TC (cm²/h) x T(h) x P x DA

Where:

DFR: 0.003 mg/cm² for an application rate (AR) of 1 kg as/ha (default value)

AR: 3.6 kg as/ha

TC: 22500 cm²/h (potential) for hand harvesting on tree fruits⁹

T: 8 hours/day

P (penetration factor): 0.1 (gloves and work wear)

DA (dermal absorption): 50%

Systemic exposure (mg/d) = 0.003 x 3.6 x 22500 x 8 x 0.1 x 0.5 = 97.2

Systemic exposure (mg/kg/day) = 97.2 / 60 = 1.62

Taking into account of the AOEL of 5 mg/kg bw/day for phosphonate potassium, the systemic exposure represents 32.4% of the AOEL when workers wearing gloves and work wear.

It is concluded that there is no unacceptable risk anticipated for the worker.

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

3.4.4 Bystander and resident exposure

No exposure to residents or bystanders is expected and therefore no pertinent risk assessment is considered necessary.

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

The data available are not considered sufficient to support the intended uses on *Citrus* and chicories. Consequently, compliance with the current MRLs for potassium phosphonates as laid down in Reg. (EU) 396/2005 could not be checked and the chronic and short-term intakes of potassium phosphonates residues could not be estimated. Therefore no assessment of the consumer risk could be performed.

⁹ 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

K-PHOS
Part A - National Assessment
FRANCE

As far as consumer health protection is concerned, France as izRMS disagrees with the authorisation of the intended uses.

Data gaps

Noticed data gaps are:

- Four additional trials on oranges: two in which the active substance is applied by dipping and two in which the active substance is applied by drenching.
- Four additional trials on mandarins: two in which the active substance is applied by dipping and two in which the active substance is applied by drenching.
- A complete data package on chicories.

Information on K-PHOS (KCA 6.8)

Crop	PHI for K-PHOS requested by applicant	PHI sufficiently supported for potassium phosphonates	PHI for K-PHOS proposed by izRMS	zRMS Comments (if different PHI proposed)
Citrus	None	No	None	Unacceptable use
Chicory	None	No	None	Unacceptable use

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

The intended use of K-PHOS is a post-harvest treatment of *Citrus* fruit and chicory indoors. No exposure of any environmental compartment is expected and therefore no risk assessment for environment or non-target species is considered necessary.

3.7 Ecotoxicology (Part B, Section 9)

The intended use of K-PHOS is a post-harvest treatment of *Citrus* fruit and chicory indoors. No exposure of any environmental compartment is expected and therefore no risk assessment for environment or non-target species is considered necessary.

K-PHOS
Part A - National Assessment
FRANCE

3.8 Relevance of metabolites (Part B, Section 10)

The intended use of K-PHOS is a post-harvest treatment of *Citrus* fruit and chicory indoors. No exposure of groundwater is expected.

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

N/A : no marketing authorisation granted

5.1.2 Post-authorisation data requirements

N/A : no marketing authorisation granted

K-PHOS
Part A - National Assessment
FRANCE

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 K-PHOS

de la société XEDA INTERNATIONAL
enregistrée sous le n°2018-3779

Vu les conclusions de l'évaluation de l'Anses du 1^{er} avril 2020,

Considérant que l'usage en plein champ sur chicorées pour une production de racines n'est pas jugé pertinent pour le produit,

Considérant le risque de dépassement des limites maximales de résidus en vigueur,

Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 sont respectées,

La mise sur le marché du produit phytopharmaceutique désigné ci-après n'est pas autorisée en France.

K-PHOS
 Part A - National Assessment
 FRANCE



Informations générales sur le produit	
Nom du produit	K-PHOS
Type de produit	Produit de référence
Titulaire	XEDA INTERNATIONAL 1397 RN 7 ZAC LA CRAU 13670 SAINT ANDIOL France
Formulation	Concentré soluble (SL)
Contenant	730 g/L - phosphonates de potassium
Numéro d'intrant	823-2018.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usage	Professionnel

29 MAI 2020

A Maisons-Alfort le,

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 : Conditions de mise sur le marché demandées

Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
500 mL/hL	1/an	Non applicable
Motivation du refus : L'usage est refusé en raison d'un risque de dépassement des LMR en vigueur, ainsi qu'en l'absence de justification de la gamme de dose d'emploi revendiquée de 300 à 500 mL/hL.		
60 mL/m ²	1/an	Non applicable
Motivation du refus : L'usage est refusé en raison d'un risque de dépassement des LMR en vigueur. L'usage est également refusé à la dose revendiquée de 60 mL/hL en l'absence de justification de la dose d'emploi.		
60 mL/m ²	1/an	Non applicable
Motivation du refus : L'usage est refusé car une utilisation en plein champ sur chichorées n'est pas jugée pertinente pour le produit (usage en bâtiments fermés). L'usage est également refusé à la dose de 60 mL/hL au même motif.		

Appendix 2 Copy of the product label

K-PHOS

Numéro d'AMM : **xxxx**

UFI : **xxxx**

FONGICIDE pour le traitement post-récolte des pommes, poires et plants de chicons.

Type de formulation : Concentré soluble (SL)
Composant : Phosphonate de potassium, 730 g/L (50,7 % p/p)
RESERVE A UN USAGE EXCLUSIVEMENT PROFESSIONNEL
Conseils de prudence
P273 Eviter le rejet dans l'environnement
Autres mentions
EUH 401 Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.
SP1 Ne pas polluer l'eau avec le produit ou son emballage.
Détenteur d'autorisation de mise sur le marché (A.M.M.) :
XEDA INTERNATIONAL
1397 Route nationale 7
ZAC La Crau
13670 St Andiol/ France
Tél : + 33 4 90 90 23 23 - Fax : + 33 4 90 90 23 20

EN CAS D'URGENCE
Composer le 15 ou le 112 ou contacter le centre anti-poison le plus proche

Puis signaler vos symptômes au réseau Phyt'Attitude, N° Vert : 0800 887 887 (appel gratuit depuis un poste fixe).

Premiers soins

Après inhalation : Transférer la personne à l'air frais.

Après contact cutané : laver abondamment à l'eau et au savon. Laver les vêtements contaminés avant réutilisation.

Après contact oculaire : rincer avec précaution à l'eau pendant plusieurs

Après ingestion : appeler un CENTRE ANTIPOISON ou un médecin. NE PAS faire vomir.

Fiche de Données de Sécurité disponible sur : www.quickfds.com.

Le produit K-Phos est un fongicide destiné à être utilisé pour le traitement post-récolte des pommes, poires et plants de chicons. K-Phos est un concentré soluble contenant 730 g/L de Phosphonate de potassium. Cette matière active fait partie du groupe des phosphonates (FRAC P7) et agit de manière directe sur la respiration cellulaire et indirectement sur la stimulation des défenses naturelles des plantes.

Cultures	Cibles	Dose maximum d'emploi	Nombre maximum d'applications
<u>Agrumes</u> : Oranger, Citronnier, Pamplemoussier, Mandarinier, Clémentinier, Limettes	Maladies de conservation : <i>Phytophthora</i> <i>Penicillium</i>	300 - 500 ml/hL	1
<u>Chicorées</u> - Production de chicons : Endive	Champignons : <i>Phytophthora</i>	60 ml/m ² /5L de pulvérisation 60 ml/hL	1
<u>Chicorées</u> - Production de racines : Toutes racines de chicorées	Stimulation des défenses naturelles	60 ml/m ² /5L de pulvérisation 60 ml/hL	1

5 L

Numéro de lot/date de fabrication : voir sur l'emballage.

Réemploi de l'emballage interdit

Appendix 3 Letter of Access

Not applicable.