

REGISTRATION REPORT

Part A

Risk Management

Product code: FOSETYL-AL 80% WG

Product name: KEYFOL WG

Active Substance(s): Fosetyl-Al, 800 g/kg

COUNTRY: FRANCE

Southern Zone & Interzonal

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: INDUSTRIAL QUIMICA KEY S.A.

Date: 20/02/2018

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PART A – Risk Management

The company INDUSTRIAL QUIMICA KEY S.A. has requested marketing authorisation in France for the product KEYFOL WG (product code: FOSETYL-AL 80% WG), containing 800 g/kg fosetyl-Al for use as a fungicide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to KEYFOL WG (FOSETYL-AL 80% WG) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of KEYFOL WG (FOSETYL-AL 80% WG) have been made using endpoints agreed in the EU peer review(s) of fosetyl-Al.

This document describes the specific conditions of use and labelling required for France for the registration of KEYFOL WG (FOSETYL-AL 80% WG).

Appendix 1 of this document provides a copy of the French Decision.

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

Appendix 3 of this document is a copy of the letter(s) of Access.

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of INDUSTRIAL QUIMICA KEY S.A.'s application to market KEYFOL WG (FOSETYL-AL 80% WG) in France as a fungicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for field uses 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. France acted as an interzonal Rapporteur Member State (izRMS) for greenhouse uses 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.

1.2 Active substance approval

Fosetyl-Aluminium

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.

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

PART A

Only uses as fungicide may be authorised.

PART B

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fosetyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 April 2006 shall be taken into account.

In this overall assessment Member States:

— must pay particular attention to the protection of birds, mammals, aquatic organisms and non-target arthropods.

Conditions of authorisation should include risk mitigation measures, where appropriate, such as buffer zones.

The concerned Member States shall request the submission of further studies to confirm the risk assessment for non-target arthropods, in particular with regard to in-field recovery, and for herbivorous mammals. They shall ensure that the notifier at whose request fosetyl has been included in this Annex provide such studies to the

Commission within two years from the approval.

An EFSA conclusion is available (EFSA Scientific Report (2005) 54, 1-79).

A Review Report is available (SANCO/10015/06 final, 20 November 2012).

1.3 Regulatory approach

The present application (2014-3278) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)¹ in the context of the zonal procedure for all Member States of the Southern zone for field uses and European Union for greenhouse uses, taking into account the worst-case uses (“risk envelope approach”)² – the highest application rates over the Southern Zone for field uses and European Union for greenhouse uses. When risk mitigation measures were necessary, they are adapted to the situation in France.

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

The French Order of 4th May 2017³ provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight hours for indoor uses.

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

The current document (RR) based on Anses’s assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009⁴, implementing regulations, and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail.

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011⁵, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

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

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

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “linked” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those “linked” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁷ is to supply “minor” crops with registered plant

¹ French Food Safety Agency, Afssa, before 1 July 2010

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

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

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

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

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

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

protection products.

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

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

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of KEYFOL WG (FOSETYL-AL 80% WG), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

Provided.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	KEYFOL WG (FOSETYL-AL 80% WG)
Authorisation number	2171242
Function	Fungicide
Applicant	INDUSTRIAL QUIMICA KEY S.A.
Composition	800 g/kg fosetyl-Al
Formulation type (code)	Water dispersible granule (WG)
Packaging	LDPE/PETmet/PP ⁸ (300 g, 600 g, 1 kg, 5 kg)

2.2 Classification and labelling

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

Physical hazards	-	
Health hazards	Serious eye damage, Hazard Category 1	
Environmental hazards	-	
Hazard pictograms		
Signal word	Danger	
Hazard statements	H318	Causes serious eye damage.
Precautionary statements –	<i>For the P phrases, refer to the extant legislation</i>	

⁸ LDPE/PETmet/PP: Low-density polyethylene / simple metallic polyethylene terephthalate / polypropylene.

Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	EUH208	Contains 2,4,7,9-tetramethyldec-5-yne-4,7-diol. May produce an allergic reaction.
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See Part C for justifications of the classification and labelling proposals.

2.2.2 Other phrases in compliance with Regulation (EU) No 547/2011

The authorisation of the preparation is linked for professional uses only to the following conditions:

SP 1	Do not contaminate water with the product or its container. Do not clean application equipment near surface water. Avoid contamination via drains from farmyards and roads.
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres ⁹ with an unsprayed vegetated buffer zone of 5 metres to surface water bodies for the outdoor uses.

2.2.3 Other phrases linked to the preparation

Wear suitable personal protective equipment ¹⁰ : refer to the Decision in Appendix 1 for the details		
Re-entry period ¹¹ : 24 hours		
Pre-harvest interval ¹² :	Wine and table grapes	28 days
	Tomato, eggplant (indoor, outdoor)	3 days
	Lettuce (outdoor)	15 days
	Cucumber and other cucurbits with edible peel (indoor)	3 days
Other mitigation measures:		
- 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: - o 10 kg equivalent of phosphonic acid per hectare per year on grapes, - o 9 kg equivalent of phosphonic acid per hectare per year on cucumber and other cucurbits with edible peel, - o 12 kg equivalent of phosphonic acid per hectare per year on tomatoes and eggplant, - o 7 kg equivalent of phosphonic acid per hectare per year on lettuce.		
The label must reflect the conditions of authorisation.		

⁹ The legal basis for this is **Titre III Article 12** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

¹⁰ If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

¹¹ The legal basis for this is **Titre I Article 3** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

¹² According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

2.3 Product uses

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

When a use is “acceptable” with GAP restrictions, the modifications of the GAP are in bold.

Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 2018-02-20

PPP (product name/code): **KEYFOL WG (FOSETYL-AL 80% WG)**
Active substance 1: fosetyl-AI
Applicant: **INDUSTRIAL QUIMICA KEY S.A.**
Zone(s): southern & interzonal ^(d)
Verified by MS: yes
Field of use: fungicide

Formulation type: **WG** ^(a, b)
Conc. of as 1: **800 g/kg** ^(c)
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: 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 or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	France	Grapes	F	<i>Plasmopara viticola</i>	Foliar Spraying	BBCH 12 to PHI	3	10	a) 2.5 b) 7.5	a) 2 b) 6	600- 1000	28	Acceptable
2	France	Tomato and eggplant	F	<i>Phytophthora infestans</i>	Foliar Spraying	BBCH 10 to PHI	4	10	a) 2.5 b) 10	a) 2 b) 8	300- 1000	3	Acceptable
3	France	Lettuce*	F	<i>Bremia lactucae</i>	Foliar Spraying	BBCH 10 to PHI	4	10	a) 2.5 b) 10	a) 2 b) 8	300- 1000	15	Acceptable (for lettuce)

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 ⁽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 or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
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	France	Cucumber and other cucurbits with edible peel	G	<i>Pseudoperonospora cubensis</i>	Foliar Spraying	BBCH 10 to PHI	4	10	a) 2.5 b) 10	a) 2 b) 8	300- 1000	3	Acceptable
2	France	Tomato and eegplant	G	<i>Phytophthora infestans</i>	Foliar Spraying	BBCH 10 to PHI	4	10	a) 2.5 b) 10	a) 2 b) 8	300- 1000	3	Acceptable

* According to the French catalogue of uses, the use “lettuce” also includes the following minor crops : escarole, escarole, broad leaves endive, lamb’s lettuce , salad, rocket salad and other lettuce-type salads

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/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
			13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

3 RISK MANAGEMENT

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties

KEYFOL WG (FOSETYL-AL 80% WG) is a white solid, with mild odour, water dispersible granule, containing 800 g/kg of fosetyl-Al. All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The formulation is not explosive and has no oxidising properties. It is not flammable and has a self- ignition temperature above 400 °C. In aqueous solution (1 %), it has a pH value of 3.1 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 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 LDPE/PETmet/PP packaging. The formulation's technical characteristics are acceptable for a WG formulation and it is not classified for the physico-chemical aspect. Studies are in progress for the determination of suspensibility, spontaneity of dispersion and persistent foaming at maximum use rate, before and after storage procedure. **Results are required in post authorisation within 2 years.**

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

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

3.1.2.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report (DAR) and in this dossier and are validated for the determination of residues of fosetyl-Al in plants (high water content, acidic), food of animal origin, soil, water (surface and drinking) and air.

The active substance is neither toxic nor very toxic hence no analytical method is required for the determination of residues in biological fluids and tissues.

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

Active Substance: fosetyl-Al			
ADI	3 mg/kg bw/d		EU 2007
ARfD	Not applicable		
AOEL	5 mg/kg bw/d		
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (used in formulation) 800 g/L	Spray dilution (used in formulation) 2.4 g/L
	Dermal absorption endpoints %	25	75

3.1.3.1 Acute Toxicity

KEYFOL WG (FOSETYL-AL 80% WG) containing 800 g/kg of fosetyl-Al has a low acute oral, inhalational and dermal toxicity. The product is not irritating to the rabbit skin and is not a skin sensitizer, but it is irritating to the rabbit eye.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G	Equipment	Application rate kg/L product/ha (g as/ha)	Spray dilution (L/ha)	Model
Grape (worst case scenario for open fields)	F	Tractor mounted/ trailed broadcast air-assisted sprayer	3 kg product/ha (2.4 kg as/ha)	600-1000 L/ha	BBA (German Model)
Tomato/ cucumber (worst case scenario for greenhouses application)	G	Hand held sprayer: hydraulic nozzles. Outdoor, high level target	3 kg product/ha (2.4 kg as/ha)	300-1000 L/ha	BBA (German Model)

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

Crop	Equipment	PPE and/or working coverall	% AOEL fosetyl
Grape (worst case scenario for open fields)	Tractor mounted/ trailed broadcast air-assisted sprayer	Working coverall and gloves during mixing/loading and application	10%
Tomato/ cucumber (worst case scenario for greenhouses application)	Hand held sprayer: hydraulic nozzles. Outdoor, high level target	Working coverall and gloves during mixing/loading and application	5%

According to the model calculations, it can be concluded that the risk for the operator using KEYFOL WG (FOSETYL-AL 80% WG) is acceptable with a working coverall (90% protection factor) and gloves during mixing/loading and application.

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

3.1.3.3 Bystander Exposure

For field application (worst case scenario: grape), bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to be 0.7 % of the AOEL of fosetyl-Al.

For greenhouse application, bystander exposure is not likely to occur when the proposed greenhouse crops (tomato and cucumber) are treated. Therefore, no evaluation of bystander exposure has been performed.

It is concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to KEYFOL WG (FOSETYL-AL 80% WG).

3.1.3.5 Worker Exposure

For field application (worst case scenario: grape), workers may have to enter treated areas after treatment for crop harvesting activities. Therefore, estimation of worker exposure was calculated according to EUROPOEM II. Exposure is estimated to be 22 % of the AOEL of fosetyl-Al (with PPE).

For greenhouse application (tomato, cucumber), workers may have to enter treated areas after treatment for crop harvesting activities. Therefore, estimation of worker exposure was calculated according to EUROPOEM II. Exposure is estimated to be 73 % of the AOEL of fosetyl-Al.

It is concluded that without taking into account a re-entry period, there is no unacceptable risk anticipated for workers wearing a working coverall and gloves, when re-entering crops treated with KEYFOL WG (FOSETYL-AL 80% WG).

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

3.1.4 Residues and Consumer Exposure

The data available are considered sufficient for risk assessment. Any exceedance of the current MRL for fosetyl-Al as laid down in Reg. (EU) 396/2005 is not expected.

Concerning the intended use on lettuce, in the absence of information on the open or closed feature of lettuces leaves on which the tests were carried out, extrapolation to other salads is not possible.

The chronic and short-term intakes of phosphonic acid and fosetyl residues are unlikely to present a public health concern.

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

Other fungicide active substances than fosetyl-Al authorized on grapes, tomatoes, lettuce and cucumber (potassium phosphonates or disodium phosphonate) can lead to the presence of phosphonic acid in harvested products. The accumulated use of these active substances on the same plots could lead to an exceedance of the in force MRLs. In consequence, it is recommended to limit the use of products containing these substances to a total of:

- 10 kg equivalent of phosphonic acid per hectare per year on grapes;
- 9 kg equivalent of phosphonic acid per hectare per year on cucumber and other cucurbits with edible peel;
- 12 kg equivalent of phosphonic acid per hectare per year on tomatoes and eggplant;
- 7 kg equivalent of phosphonic acid per hectare per year on lettuce.

Summary for fosetyl-Al

Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg 2016/1003	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
Grape	Yes	Yes (9 SEU + 12 NEU)	Yes	Yes	Yes	No	No	
Tomato	Yes	Yes (8 indoor + 4 SEU)	Yes	Yes	Yes		No	Outdoor and protected
Lettuce	Yes	Yes (8 SEU + 8 NEU)	Yes	Yes	Yes		No	
Cucumber	Yes	Yes (8	Yes	Yes	Yes		No	protected

Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg 2016/1003	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
		indoor)						only

The effects of processing on the nature of fosetyl-Al and phosphonic acid residues have been investigated. Data on effects of processing on the amount of residue have been submitted. These data were not considered for risk assessment.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Summary for KEYFOL WG (FOSETYL-AL 80% WG)

Information on KEYFOL WG (FOSETYL-AL 80% WG)

Crop	PHI for KEYFOL WG (FOSETYL-AL 80% WG) proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for KEYFOL WG (FOSETYL-AL 80% WG) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Fosetyl-Al		
Grape	28 days	Yes	28 days	
Tomato	3 days	Yes	3 days	
Lettuce	15 days	Yes	15 days	
Cucumber	3 days	Yes	3 days	

* Purpose of withholding period to be specified

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate predicted environmental concentration (PEC) values for the active substances and their 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 fosetyl-Al 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 conclusions or agreed in the assessment based on new data provided.

PEC soil and PEC_{sw} derived for fosetyl-Al and its metabolite phosphonic acid are used for the ecotoxicological risk assessment and mitigation measures are proposed. According to the classification proposed in document OECD¹³, the PEC_{sw} obtained for the intended field uses meet the classification “eutrophic” (annual concentration in water: > 35 µg/L). To protect the aquatic ecosystems and limit the risk of eutrophication, should be respected an unsprayed

¹³ OECD (1982) Eutrophication of Waters. Monitoring, Assessment and Control.

buffer zone of 5 metres to surface water bodies and a permanent vegetative buffer strips of 5 metres-width to the edge of surface water bodies.

PEC_{gw} for fosetyl-Al and its metabolite do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009 and guidance document SANCO 221/2000¹⁴. Therefore, 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.

3.1.6 Ecotoxicology

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance and its metabolite 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.

To confirm the absence of any unacceptable risk to non-target arthropods, zRMS considers that an aged residues study with *Typhlodromus pyri* should be provided in post-registration.

3.1.7 Efficacy

Considering the data provided :

- KEYFOL WG (FOSETYL-AL 80% WG) efficacy is considered satisfactory for all intended uses.
- KEYFOL WG (FOSETYL-AL 80% WG) risk of phytotoxicity is considered to be negligible.
- The risks of negative impact on yield, quality, wine making process, propagation, succeeding and adjacent crops are considered to be acceptable.
- The risk of resistance appearance or development to fosetyl-Al does not require any monitoring program.

¹⁴ 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.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation can be granted for grapes, cucumber and other cucurbits with edible peel, tomato and eggplant and lettuce (except other salads) as proposed in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

No further information is required.

3.4.2 Post-authorisation data requirements

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

- An aged residues study with *Typhlodromus pyri*.
- Studies for the determination of suspensibility, spontaneity of dispersion and persistent foaming at maximum use rate, before and after storage procedure.

3.4.3 Label amendments

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

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

Appendix 1 – Copy of the French Decision



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

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

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

*Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique **KEYFOL WG***

de la société INDUSTRIAL QUIMICA KEY S.A.

enregistrée sous le n°2014-3278

Vu les conclusions de l'évaluation de l'Anses du 1^{er} décembre 2017,

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

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

Avertissement :

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



Informations générales sur le produit	
Nom du produit	KEYFOL WG
Type de produit	Produit de référence
Titulaire	INDUSTRIAL QUIMICA KEY S.A. Avenida Cervera n°17 25300 TARREGA Espagne
Formulation	Granulé dispersable (WG)
Contenant	800 g/kg - fosétyl d'aluminium
Numéro d'intrant	9666-2014.01
Numéro d'AMM	2171242
Fonction	Fongicide
Gamme d'usages	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 avril 2019.

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 20 FEV. 2018

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



ANNEXE I : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	Contenance
Sacs multicouches en polyéthylène basse densité / polyéthylène téréphtalate métallisé / polypropylène	300 g ; 600 g ; 1 kg ; 5 kg

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	Mention de danger
Lésions oculaires graves et irritation oculaire - Catégorie 1	H318 : Provoque des lésions oculaires graves
EUH208 : Contient du 2,4,7,9-tetraméthyl-5-décyne-4,7-diol. Peut produire une réaction allergique.	
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.
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitee arthropodes non cibles (mètres)	Zone Non Traitee plantes non cibles (mètres)	Mention abeilles
16323204 Concombre*Trt Part.Aer.*Mildiou(s)	2,5 kg/ha	4/an	à partir du stade BBCH 10	3	-	-	-
	Uniquement autorisé sous abri. Intervalle minimum entre les applications : 10 jours.						
16603207 Laitue*Trt Part.Aer.*Mildiou(s)	2,5 kg/ha	4/an	à partir du stade BBCH 10	15	5 (dont DVP 5)	-	-
	Uniquement sur laitue. Intervalle minimum entre les applications : 10 jours.						
16953201 Tomate*Trt Part.Aer.*Mildiou(s)	2,5 kg/ha	4/an	à partir du stade BBCH 10	3	5 (dont DVP 5)	-	-
	Egalement autorisé sous abri. Intervalle minimum entre les applications : 10 jours.						
12703203 Vigne*Trt Part.Aer.*Mildiou(s)	2,5 kg/ha	3/an	à partir du stade BBCH 12	28	5 (dont DVP 5)	-	-
	Intervalle minimum entre les applications: 10 jours.						

DVP : Dispositif Végétalisé Permanent.

KEYFOL WG
AMM n°2171242

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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 à l'aide d'un pulvérisateur à dos

• pendant le mélange/chargement

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de protection de catégorie III type 4 ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3) ;

• pendant l'application

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de protection de catégorie III type 4 avec capuche ;
- Bottes de protection certifiées EN 13 832-3 ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3) ;

• pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de protection non tissée de catégorie III type 4
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3).

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

• pendant le mélange/chargement

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3) ;

• 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 ;

• 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 ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3).

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

• 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 ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3) ;

• 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 ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3).

Dans le cadre d'une application effectuée à l'aide d'une lance

• pendant le mélange/chargement

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de protection de catégorie III type 4 ou 3 (selon le niveau de protection recommandé pendant la phase d'application) ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3) ;

Ou

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3) ;

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

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de protection de catégorie III type 4 avec capuche ;
- Bottes de protection certifiées EN 13 832-3 ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3) ;

• pendant l'application : contact intense avec la végétation

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de protection de catégorie III type 3 avec capuche ;
- Bottes de protection certifiées EN 13 832-3 ;



- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3) ;

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

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de protection de catégorie III type 4 ou 3 (selon le niveau de protection recommandé pendant la phase d'application) ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3) ;

Ou

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3).

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 :

- 24 heures.

Respect des limites maximales de résidus (LMR)

Limitier les applications de produits contenant des substances actives fongicides pouvant engendrer la présence d'acide phosphonique dans les produits récoltés, à un total de maximal de :

- 10 kg d'équivalent d'acide phosphonique par hectare et par an sur vigne ;
- 9 kg d'équivalent d'acide phosphonique par hectare et par an sur cucurbitacées à peau comestible ;
- 12 kg d'équivalent d'acide phosphonique par hectare et par an sur tomate et aubergine ;
- 7 kg d'équivalent d'acide phosphonique par hectare et par an sur laitue.

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

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 pour les usages en plein champ.

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 une étude sur résidus vieillis réalisée avec l'espèce <i>Typhlodromus pyri</i> .	24	-
Fournir les résultats des tests de suspensibilité et de persistance de la mousse à la concentration maximale d'utilisation (1% p/v) du produit avant et après 2 ans de stockage à température ambiante.	24	-

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

KEYFOL WG

Autorisation de Mise sur le Marché n°
Dé détenteur: INDUSTRIAL QUÍMICA KEY S.A., Av. Cervera, n°17; 25300 Tàrrega (Lleida) Espagne

FONGICIDE, granulés dispersables (WG) contenant 80% de Fosétyl-Al

Cultures, usages et doses d'emploi autorisées en traitement des parties aériennes :

Cultures	Usages	Nombre max. d'applications	Dose produit (g/hL)	Volume Litres de bouillie/ha	Dose produit (g/ha)	DAR (jours)
Vigne	contre mildiou (<i>Plasmopara viticola</i>)	3	250-300	600-1000	1500-3000	28
Concombre (serre)	contre mildiou (<i>Pseudoperonospora cubensis</i>)	4	250-300	300-1000	750-3000	3
Tomate (plein champ et serre)	contre mildiou (<i>Phytophthora infestans</i>)	4	250-300	300-1000	750-3000	3
Laitue (plein champ)	contre mildiou (<i>Bremia lactucae</i>)	4	250-300	300-1000	750-3000	15

Mode d'action: KEYFOL WG est une fongicide systémique qui présente une efficacité remarquable sur mildiou. Le fosétyl-Al pénètre et se répartit rapidement dans la plante. Sa systémie est montante et descendante. Il stimule les défenses naturelles des cultures contre le mildiou.

Mode d'emploi: Traitements préventifs suivant les avis des stations d'avertissements agricoles de votre région. Cadence. 10 jours.

Élimination du produit et de l'emballage : Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux. Éliminer les emballages vides via une collecte organisée par un service de collecte spécifique.

Contient du Fosétyl-Al



DANGER

H318 Provoque des lésions oculaires graves

H412 Nocif pour les organismes aquatiques, entraîne des effets néfastes à long terme.

P102 Tenir hors de portée des enfants

P273 Éviter le rejet dans l'environnement.

P280 Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage.

P305+351+338 EN CAS DE CONTACT AVEC LES YEUX : rincer avec précaution à l'eau pendant plusieurs minutes.

Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer.

P310 Appeler immédiatement un CENTRE ANTIPOISON ou un médecin.

P501 Éliminer le contenu/récepteur dans...

Respecter 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. Éviter la contamination via des systèmes d'évacuation des eaux à partir des cours de ferme ou des routes).

Détenteur: INDUSTRIAL QUÍMICA KEY S.A., Av. Cervera, n°17; 25300 Tàrrega (Lleida) Espagne
N° d'appel centre anti poison : 01 40 05 48 48

REMARQUES : Respectez les usages, doses, conditions et précautions d'emploi mentionnées sur l'emballage, qui ont été déterminés en fonction des caractéristiques et des applications pour lesquelles le produit 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 ces produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de mise sur le marché du Ministère de l'Agriculture.
La société ne sera pas responsable des pertes ou des dégâts occasionnés par une utilisation non conforme à ses recommandations. L'utilisateur assume tous les risques associés à un tel usage, non conforme à ces recommandations.

N° DE LOT : voir sur emballage

POIDS NET :

Appendix 3 – Letter(s) of Access

Provided.