

REGISTRATION REPORT

Part A

Risk Management

Product code: FOSETYL-AL 80% WG

Product name(s):

GOLBEX WG

Chemical active substance(s):

Fosetyl-Al, 800 g/kg

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(Label extension)

Applicant: EXCLUSIVAS SARABIA S.A.

Date: 2019-03-13

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PART A

RISK MANAGEMENT

1 Details of the application

The company EXCLUSIVAS SARABIA S.A. has requested marketing authorisation in France for the product GOLBEX WG (formulation code: FOSETYL-AL 80% WG), containing 800 g/kg fosetyl-Al for use as a fungicide for professional uses.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-10 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 GOLBEX 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 GOLBEX WG (FOSETYL-AL 80% WG) have been made using endpoints agreed in the EU peer review of fosetyl-Al.

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

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

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

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

1.1 Application background

The present registration report concerns the evaluation of EXCLUSIVAS SARABIA S.A.'s application to market GOLBEX 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 this request and assessed the application submitted for the label extension of this product in France and in other MSs of the Southern zone.

The present application (2016-3942) 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, taking into account the worst-case uses ("risk envelope approach")² – the highest application rates over 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 1107/2009³, 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.

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 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

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

1.2 Letters of Access

The applicant has provided letter(s) of access.

1.3 Justification given by the applicant for submission of tests and studies

According to the applicant:

“This is an application for an extension of use of the formulated product FOSETYL-AL 80% in pome fruits.

New tests with the formulation have been performed regarding efficacy on pome fruit crops, residues on pome fruits and ecotoxicology (effects on bees).”

1.4 Data protection claims

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

⁴ COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

2 Details of the authorisation decision

2.1 Product identity

Product code	FOSETYL-AL 80% WG
Product name in MS	GOLBEX WG
Authorisation number	2171243
Low risk (article 47)	No
Function	Fungicide
Applicant	EXCLUSIVAS SARABIA S.A.
Active substance(s) (incl. content)	Fosetyl-Al, 800 g/kg
Formulation type	Water dispersible granule [WG]
Packaging	LDPE/PETmet/PP ⁵ bags (300g, 600g, 1kg or 5kg) professional user
Coformulants of concern for national authorisations	None
Restrictions related to identity	None
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for GOLBEX WG (FOSETYL-AL 80% WG) resulted in the decision to grant the authorization.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

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

Classification not changed.

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
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⁵ LDPE/PETmet/PP: Low-density polyethylene / simple metallic polyethylene terephthalate / polypropylene.

	For other restrictions refer to 2.5
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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 4th May 2017⁶ provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres;
- unless formally 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, drift 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 2014⁷ 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 extrapolation⁸ 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

⁶ 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>

⁷ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo>

⁸ SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
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.
Other specific restrictions	
Re-entry period	24 hours
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: o 14 kg equivalent of phosphonic acid per hectare per year on pome fruits,

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.

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]

2.6 Intended uses (only NATIONAL GAP)

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

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.

PPP (product name/code): GOLBEX WG / FOSETYL AL 80% WG
Active substance 1: fosetyl-Al
Applicant: EXCLUSIVAS SARABIA S.A.
Zone(s): southern ^(d)
Verified by MS: **Yes**

GAP rev. 2, date: 2019-03-13
Formulation type: WG ^(a, b)
Conc. of as 1: 800 g/kg ^(c)
Professional use: ☒
Non professional use: ☐

Field of use: fungicide

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: developmen- tal 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	kg 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	Pome fruits	F	Foot rot (<i>Phytophthora spp.</i>)	Foliar spraying	1 st application: April-May 2 nd application: June-July 3 rd application: October BBCH 91-77	a) 3 b) 3	30	a) 3 b) 9	a) 2.4 b) 7.2	800- 1000	15	Acceptable Demonstrated on <i>Phytophthora cactorum</i>
2	FR	Pome fruits	F	Bacteriose (<i>Pseudomonas syringae</i>)	Foliar spraying	At petal fall BBCH 69-71	a) 2 b) 2	30	a) 3 b) 9	a) 2.4 b) 7.2	800- 1000	15	Acceptable

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmen- tal 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	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
													For an interval between applications of 30 days, the maximum number of application cannot exceed 2 applications as part of good agricul- tural practices

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:

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.

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 use rates claimed in the use extension (0.30 to 0.37%) are covered by the one previously assessed (0.3 to 1% w/v).

GOLBEX 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 temperatures 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.

The formulation 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.

3.2 Efficacy (Part B, Section 3)

Considering the data provided:

- GOLBEX WG (FOSETYL-AL 80% WG) efficacy is considered satisfactory for all the intended uses.
- GOLBEX WG (FOSETYL-AL 80% WG) risk of phytotoxicity is considered negligible for all intended uses.
- The risks of negative impact on yield, quality, cider making process, propagation and adjacent crops are considered negligible.
- The risk of resistance appearing or developing to fosetyl-Al does not require a monitoring program.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 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.

3.3.2 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), 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.

3.4 Mammalian toxicology (Part B, Section 6)

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

3.4.1 Acute toxicity

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

The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.4.1.

3.4.2 Operator exposure

Summary of critical use patterns (worst cases):

Crop	F/G ¹⁰	Equipment	Application rate kg/L product/ha (g as/ha)	Spray dilution (L/ha)	Model
Pome fruit	F	Tractor mounted/ trailed broadcast air- assisted sprayer	3 kg product/ ha (2.4 kg as/ ha)	800-1000	EFSA Model

Considering the proposed uses, operator systemic exposure was estimated using the EFSA model¹¹:

Crop	Equipment	PPE and/or working coverall	% AOEL fosetyl-Al
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¹⁰ Open field or glasshouse

¹¹ AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014;12 (10):3874)

Pome fruit	Tractor mounted/ trailed broadcast air-assisted sprayer	Working coverall and gloves during mixing/loading and application	8
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According to the model calculations, it can be concluded that the risk for the operator using GOLBEX WG (FOSETYL-AL 80% WG) is acceptable with a working coverall (90% protection factor) and gloves during mixing/loading and application.

3.4.3 Worker exposure

Workers may have to enter treated areas after treatment for crop harvesting activities. Therefore, estimation of worker exposure was calculated according to EFSA Model. Exposure is estimated to be 71 % of the AOEL of fosetyl-Al with PPE.

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 GOLBEX WG (FOSETYL-AL 80% WG) .

3.4.4 Bystander and resident exposure

In the absence of AAOEL determined for the active substance, it is considered that exposure of bystander is covered by exposure of resident.

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

Residential exposure was assessed according to EFSA Model. Exposure is estimated to be 17 % and 9 % of the AOEL of fosetyl-Al (for child and adult respectively).

It is concluded that there is no unacceptable risk to the resident exposed to GOLBEX WG (FOSETYL-AL 80% WG).

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

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 75 mg/kg for fosetyl-Al as laid down in Reg. (EU) No 396/2005 is not expected.

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

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

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

Toxicological reference values for the dietary risk assessment of fosetyl-Al, fosetyl and phosphonic acid:

Reference value	Source	Year	Value	Study relied upon	Safety factor
Fosetyl-Al					
ADI	EFSA	2005	3 mg/kg bw/d	2 year rat and dog	100

Reference value	Source	Year	Value	Study relied upon	Safety factor
ARfD			Not necessary		
Fosetyl					
ADI	EFSA	2005	2.8 mg/kg bw/d	Calculated, from the fosetyl-Al ADI using an appropriate molecular weight conversion	100
ARfD			Not necessary		
Phosphonic acid					
ADI	EFSA	2005	3.9 mg/kg bw/d	117 week rat	100
		2012b	2.25 mg/kg bw/d		
ARfD			2005	Not necessary	

Summary for fosetyl-Al

Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
Apple (int.btw app: 30days)*	Yes	Yes (8 NEU trials and 8 SEU trials)	Yes	Yes	Yes	No	No
Apple (int.btw app: 15days)		No data	No	N.A	N.A		

*Two GAP are requested for apple with a different interval between applications. Data are available only for the GAP with an interval of 30 days.

The effects of processing on the nature of fosetyl-Al 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.

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

Information on fosetyl-Al 80%WG:

Crop	PHI for GOLBEX WG (FOSETYL-AL 80% WG) proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for GOLBEX WG (FOSETYL-AL 80% WG) proposed by France	zRMS Comments (if different PHI proposed)
		Fosetyl-Al		
Apple	15 days	Yes	15 days	-

* Purpose of withholding period to be specified

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

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 values 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 OECD¹², the PEC_{sw} obtained for the intended uses meet the classification “hypereutrophic” (annual concentration in water: > 100 µg/L). To protect the aquatic ecosystems and limit the risk of eutrophication, should be respected an unsprayed 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 Council Directive 98/83/EC¹³. 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.

3.7 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 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,

¹² OECD (1982) Eutrophication of Waters. Monitoring, Assessment and Control.

¹³ Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption

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

The active substance fosetyl-Al is not approved as a candidate of 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

5.1.1 Post-authorisation monitoring

None.

5.1.2 Post-authorisation data requirements

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Appendix 1 Copy of the product authorisation



Décision relative à une demande d'extension d'usages d'un produit phytopharmaceutique

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

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

*Vu la demande d'extension d'usage majeur du produit phytopharmaceutique **GOLBEX WG***

*de la société **EXCLUSIVAS SARABIA, S.A.***

*enregistrée sous le **n°2016-3942***

Vu les conclusions de l'évaluation de l'Anses du 11 juin 2018,

L'autorisation de mise sur le marché du produit référencé ci-après **est étendue** à compter de la présente décision aux usages fixés par la présente décision.

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

Avertissement :

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



Informations générales sur le produit	
Nom du produit	GOLBEX WG
Type de produit	Produit de référence
Titulaire	EXCLUSIVAS SARABIA, S.A. Cami de l'Albi rec nou s/n 25110 ALPICAT, LERIDA Espagne
Formulation	Granulé dispersable (WG)
Contenant	800 g/kg – fosétyl d'aluminium
Numéro d'intrant	9665-2014.01
Numéro d'AMM	2171243
Fonction	Fongicide
Gamme d'usage	Professionnel

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

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

A Maisons-Alfort le, **13 MARS 2019**

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

Liste des usages autorisés								
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.								
Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
12603301 Pommier*Trt Part.Aer.*Bactérioses	3 kg/ha	2/an	entre les stades BBCH 69 et BBCH 71	15	5 (dont DVP 5)	-	-	-
	Intervalle minimum entre les applications : 30 jours. Ne pas appliquer le produit plus de 2 fois par an et par culture durant la période végétative et avant la récolte. Diminution du nombre d'applications de 3 à 2 et augmentation de l'intervalle entre les applications de 15 à 30 jours conformément aux données résidus disponibles.							
12603214 Pommier*Trt Part.Aer.*Champignons (pythiacées)	3 kg/ha	3/an	entre les stades BBCH 91 et BBCH 77	15	5 (dont DVP 5)	-	-	-
	Intervalle minimum entre les applications : 30 jours. Efficacité montrée sur <i>Phytophthora cactorum</i> . Ne pas appliquer le produit plus de 2 fois par an et par culture durant la période végétative et avant la récolte.							

DVP : Dispositif Végétalisé Permanent.

GOLBEX WG
AMM n°2171243



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).

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)

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

- 14 kg d'équivalent d'acide phosphonique par hectare et par an sur pommier.

Protection de l'environnement (milieux, faune et flore)

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.

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.

GOLBEX WG

Autorisation de Mise sur le Marché n°
Détenteur: EXCLUSIVAS SARABIA S.A., Camí de l'Albi – Ptda. Rec Nou, s/n – Aptdo. Correos N° 9
25110 Alpicat, Lleida (Spagna) 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	600-1000	2500	28
Concombre (serre)	contre mildiou (<i>Pseudoperonospora cubensis</i>)	4	250	300-1000	2500	3
Tomate (plein champ et serre)	contre mildiou (<i>Phytophthora infestans</i>)	4	250	300-1000	2500	3
Laitue (plein champ)	contre mildiou (<i>Bremia lactucae</i>)	4	250	300-1000	2500	15
Pommier, poirier	contre champignons (pythiacées) (<i>Phytophthora cactorum</i>) et bactériose (<i>Pseudomonas syringae</i>)	3	300	800-1000	3000	15

Mode d'action: GOLBEX 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/réceptacle 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. Eviter la contamination via des systèmes d'évacuation des eaux à partir des cours de ferme ou des routes).

*Détenteur: EXCLUSIVAS SARABIA S.A., Camí de l'Albi – Pída. Rec Nou, s/n – Aptdo. Correos N° 9
25110 Alpicat, Lleida (Spagna) 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 of Access

Provided upon request.