REGISTRATION REPORT

Part A

Risk Management

Product name: VITIPEC GOLD WG ADVANCE

Active Substances:

fosetyl-aluminium, 500 g/kg

folpet, 250 g/kg

cymoxanil, 40 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: SAPEC AGRO S.A.

Date: 10/06/2016

Table of Contents

PART A – Risk Management

The company SAPEC AGRO S.A. has requested marketing authorisation in France for the product VITIPEC GOLD WG ADVANCE, containing 500 g/kg fosetyl-aluminium, 250 g/kg folpet and 40 g/kg cymoxanil 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 VITIPEC GOLD WG ADVANCE where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of VITIPEC GOLD WG ADVANCE have been made using endpoints agreed in the EU peer review of fosetyl-aluminium, folpet and cymoxanil.

This document describes the specific conditions of use and labelling required for France for the registration of VITIPEC GOLD WG ADVANCE.

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 SAPEC AGRO S.A.'s application to market VITIPEC GOLD WG ADVANCE in France as a fungicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

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. Commission Implementing Regulation (EU) No 678/2014 of 19 June 2014 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances clopyralid, cyprodinil, fosetyl, pyrimethanil and trinexapac.
Specific provisions of regulation 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). Review Reports are available (SANCO/10015/06 final, 4 April 2006 [Annex I inclusion]; (SANCO/10015/06 final, 20 November 2012 [confirmatory data]).

Folpet

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. Commission Implementing Regulation (EU) 2015/404 of 11 March 2015 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances beflubutamid, captan, dimethoate, dimethomorph, ethoprophos, fipronil, folpet, formetanate, glufosinate, methiocarb, metribuzin, phosmet, pirimiphos-methyl and propamocarbe.
Specific provisions of regulation were as follows : PART A Only uses as fungicide may be authorised. PART B In assessing applications to authorise plant protection products containing folpet for uses other than winter wheat Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted. 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 folpet, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 29 September 2006 shall be taken into account. In this overall assessment Member States must pay particular attention to: — operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment; — the dietary exposure of consumers in view of future revisions of Maximum Residue Levels; — the protection of birds, mammals, aquatic and soil organisms. Conditions of authorisation should include risk mitigation measures. The Member States concerned shall request the submission of further studies to confirm the risk assessment for birds, mammals and earthworms. They shall ensure that the notifiers at whose request folpet 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 (2009) 297, 1-80). A Review Report is available (SANCO/10032/2006 rev 5, 11 July 2008).

Cymoxanil

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 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 cymoxanil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment; — the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions; — the protection of aquatic organisms and must ensure that the conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate
An EFSA Conclusion is available (EFSA Scientific Report (2008) 167, 1-116). A Review Report is available (SANCO/179/08 - final rev 1, 9 July 2010).

1.3 Regulatory Approach

The present application (2013-0884) 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.

According to the French law and procedures, specific conditions of use are set out in the Decision letter.
The French Order of 12 September 2006[3] 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-

[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] http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000425570

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 1107/2009[4], 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 546/2011[5], and are expressed as "acceptable" or "not acceptable" / "not finalised" in accordance with those criteria.

Finally, the French Order of 26 March 2014[6] 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 extrapolation[7] 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.

1.4 Data Protection Claims

Where protection for data is being claimed for information supporting registration of VITIPEC GOLD WG ADVANCE, 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

The applicant has provided the supporting data in Document K; the ownership of the data is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7. A copy of the letter(s) of access is reproduced in Part A, Appendix 3.

2 DETAILS OF THE AUTHORISATION

2.1 Product Identity

Product name (code)	VITIPEC GOLD WG ADVANCE
Authorisation number	-
Function	fungicide

[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

Applicant	SAPEC AGRO S.A.
Composition	500 g/kg fosetyl-aluminium 250 g/kg folpet 40 g/kg cymoxanil
Formulation type (code)	water-dispersible granule (WG)
Packaging	Polyethylene terephthalate/aluminium/polyethylene (PET/Al/PE) bags containing 300 g product Paper/low density PE sack containing 12 kg product

2.2 Classification and Labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

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

Physical hazards	-	
Health hazards	Acute toxicity (inhal.), hazard category 4 Carcinogenicity category 2 Skin sensitisation, category 1 Reproductive toxicity, category 2	
Environmental hazards	Hazardous to the aquatic environment — chronic hazard, category 2	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H332	Harmful if inhaled.
	H351	Suspected of causing cancer (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)
	H317	May cause an allergic skin reaction
	H361fd	Suspected of damaging fertility. Suspected of damaging the unborn child.
	H411	Toxic to aquatic life with long lasting effects.
Precautionary statements –	***For the P phrases, refer to the extant legislation***	

Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	-	

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

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

2.2.4 N/AOther phrases linked to the preparation

The exposures of operators and workers are not acceptable.	
Re-entry period[8]: N/A	
Pre-harvest interval[9]:	N/A
Other mitigation measures: N/A	
The label may include the following recommendations: N/A	

[8] The legal basis for this is **Titre I Article 3** of the French Order of 12 September 2006 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

[9] According to the French Order of 12 September 2006, 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 the 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.

GAP rev. 1, date: 2016-06-10

PPP (product name/code)	**VITIPEC GOLD WG ADVANCE**	**Formulation type:**	**water-dispersible granule (WG)**
active substance 1	**fosetyl-aluminium**	**Conc. of a.s. 1:**	**500 g/kg**
active substance 2	**folpet**	**Conc. of a.s. 2:**	**250 g/kg**
active substance 3	**cymoxanil**	**Conc. of a.s. 3:**	**40 g/kg**
Applicant:	**SAPEC AGRO S.A.**	**professional use**	☒
Zone(s):	**southern EU**	**non-professional use**	☐

Verified by MS: **yes**

Crop and/ or situation (a)	**Zone**	**Product code**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Formulation**		**Application**			**Application rate per treatment**			**PHI (days)** (l)	**Remarks:** (m)
					Type (d-f)	**Conc. of as** (i)	**method kind** (f-h)	**growth stage & season** (j)	**number min max** (k)	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		

Crop and/ or situation **(a)**	**Zone**	**Product code**	**F G or I (b)**	**Pests or Group of pests controlled (c)**	**Formulation**		**Application**			**Application rate per treatment**			**PHI (days) (l)**	**Remarks: (m)**
					Type (d-f)	**Conc. of as (i)**	**method kind (f-h)**	**growth stage & season (j)**	**number min max (k)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
Grapes	France	50% fosetyl Al + 25%folpet + 4% cymoxanil	F	*Plasmopara viticola*	WG	50% 25% 4%	Tractor-mounted boom spraying	BBCH 53 – 85 (wine grape) **BBCH 53-69 (table grape)**	3	0.15 + 0.75 + 0.012 - 0.75 + 0.375 + 0.06	200-1000	1.5 + 0.75 + 0.12	28 (wine grape) **F BBCH 69 (table grape)**	3 kg product/ha 12-14 days between applications **Not acceptable (operator and worker exposures)**

Remarks:
(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at 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
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) 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

The formulation VITIPEC GOLD WG ADVANCE is a brown water-dispersible granule with uncharacteristic odour. All studies have been performed in accordance with the current requirements. It is not explosive and has no oxidising properties. It has a self-ignition temperature of 314 °C and is not flammable. In aqueous solution (1 %), its pH is 3.5 at 20 °C. Stability data indicate a shelf life of at least two years at ambient temperature (PET/Al/PE; OPP [oriented polypropylene]/PET/PE, OPP/Al/PE and LDPE). Its technical characteristics are acceptable for a water-dispersible granule formulation except for the results of resistance tests on the granules, which showed that wear was outside acceptable limits. This was taken into account in the risk evaluation for operators and workers.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methods for the determination of the active substances in the formulation are available and validated.

As the relevant impurities (perchloromethylmercaptan [PCMM] and carbon tetrachloride [tetrachloromethane]) are by-products of the manufacturing process for folpet and as such cannot be formed by storage of the formulation, an analytical method for the determination of relevant impurities in the formulation is not necessary.

3.1.2.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report and in this dossier and validated for the determination of residues of folpet, cymoxanil and fosetyl-aluminium in plants (acidic), soil, water (surface and drinking) and air. Analytical methods for the determination of residues of the active substances in foodstuffs of animal origin are not necessary.

- A confirmatory method for the determination of folpet residue in acidic crops is required post-authorisation.

To update the dossier and to be in accordance with SANCO 825/00/rev 8.1, the following analytical methods are required for the re-registration of the active substance fosetyl-aluminium:

- A confirmatory method for the determination of phosphonic acid in soil and surface water and a fully-validated method for the determination of phosphonic acid in drinking water.

The active substances are 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

3.1.3.1 Acute Toxicity

VITIPEC GOLD WG ADVANCE has a low acute oral and dermal toxicity. It is not irritant to skin and eyes of rabbits. It is classifiable for inhalational toxicity and skin sensitisation.

3.1.3.2 Operator Exposure

Operator exposure to vine has been assessed with the BBA model against the AOEL of 5 mg/kg bw/d for fosetyl-Al, 0.1 mg/kg bw/d for folpet and 0.01 mg/kg bw/d for cymoxanil.
The dermal absorption values of fosetyl-Al used for risk assessment are 25 % for the non-diluted and 75 % for the diluted respectively (default values based on the guidance on dermal absorption, EFSA 2012).

The dermal absorption values of folpet used for risk assessment are 2 % and 9 % for the non-diluted and diluted, respectively (based on an *in vitro* study on human skin using a similar formulation).
The dermal absorption value of cymoxanil used for risk assessment is 75 % for the non-diluted and diluted (default value based on the guidance on dermal absorption, EFSA 2012).

The risk for the operator using VITIPEC GOLD WG ADVANCE on grape is not acceptable. With a tractor-mounted/trailed broadcast air-assisted sprayer and a hand-held sprayer with a working coverall and gloves during the mix/loading and application phase the figures are 5.9 % and 2.9 % of fosetyl-Al's AOEL, 20 % and 12 % of folpet's AOEL and **243 % and 127 % of cymoxanil's AOEL** for tractor-mounted/trailed broadcast air-assisted sprayer and a hand-held sprayer respectively).

3.1.3.3 Bystander Exposure

Bystander exposures were estimated using EUROPOEM 2[10]. Based on this estimation it can be concluded that there is no undue risk to any bystander after accidental short-term exposure to VITIPEC GOLD WG ADVANCE (bystander exposure for the use on grape represents 1.4 % of fosetyl-Al's AOEL, 4.4 % of folpet's AOEL and 55 % of cymoxanil's AOEL).

The exposure of residents to folpet via the air represents < 3 % of folpet's AOEL and ADI for adults and children.
The exposure of residents to cymoxanil via the air represents < 0.1 % of cymoxanil's AOEL and ADI for adults and children.

3.1.3.4 Worker Exposure

The worker exposure to vine represents 13.5 % of fosetyl- Al's AOEL, 41 % of folpet's AOEL and 540 % of cymoxanil's AOEL with a working coverall and gloves. **The risk is considered unacceptable**.

3.1.4 Residues and Consumer Exposure

3.1.4.1 Residues

Primary crop metabolisms were sufficiently investigated to define residue of fosetyl, folpet and cymoxanil for enforcement and risk assessment purposes in the crop(s) under consideration.

Regarding the magnitude of residues in grapes, a sufficient number of residue trials is available to support the intended GAPs in France. These data allow it to be considered that no MRL exceedence will result from the intended uses (with a latest time of application of BBCH 69 on table grape).

The effects of processing on the nature of fosetyl residues have been investigated. Data on the effect of processing on the amount of residue have been submitted, but not considered for risk assessment. For folpet, hydrolysis studies showed that folpet is widely converted into phthalimide; besides, processing studies allowed derivation of transfer factors for the production of wine and grape juice. As for cymoxanil, residues did not exceed the trigger value of 0.1 mg/kg in grapes and therefore the effect of industrial and/or household processing is not required.

Residues in succeeding crops are not required as grape is a perennial crop.

As grape is not fed to animals, livestock metabolism and livestock feeding studies are not necessary.

[10] Bystander exposure to pesticides – Report of the bystander working group, Europoem II Project, Fair3 CT96-1406, December 2002, 1-43.

3.1.4.2 Consumer exposure

The toxicological profiles of fosetyl, folpet and cymoxanil were evaluated at EU level, which resulted in the proposal of ADIs (3 mg/kg for fosetyl-Al, 2.8 mg/kg for fosetyl, 2.9 mg/kg for phosphonic acid, 0.1 mg/kg for folpet, 0.013 mg/kg for cymoxanil) and ARfDs (0.2 mg/kg for folpet, 0.08 mg/kg for cymoxanil) that were considered in the framework of this evaluation. For fosetyl-Al, an ARfD was not deemed necessary.

Chronic consumer exposure resulting from the uses proposed in the framework of this application was calculated for the three active substance. Based on EFSA PRIMo (rev2), chronic and acute exposures were considered acceptable for all groups of consumers.

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

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment of the formulation has been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU evaluation were used to calculate Predicted Environmental Concentrations (PECs) for the three 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 PECs of fosetyl-aluminium, folpet, cymoxanil and their metabolites in soil, surface water and groundwater has 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 evaluation or agreed in the assessment based on new data provided.

PECsoil and PECsw derived for the three active substances and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PECgw for the three active substances and their metabolites do not exceed the trigger of 0.1 µg/L. 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 DT_{50} calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.6 Ecotoxicology

3.1.6.1 Effects on Terrestrial Vertebrates

The obtained TER values for birds and terrestrial vertebrates are above the trigger of 10 for acceptable acute risk, and of 5 for acceptable long-term risk.

3.1.6.2 Effects on Aquatic Species

The risk assessment for aquatic organisms was carried out by comparing the worst-case PECsw values with the acute and long-term toxicity endpoints.

The risk for aquatic organisms is acceptable if a buffer zone of 5m including a vegetative filter strip of 5m to water bodies is respected. Furthermore a vegetative buffer strip of 5 m to limit the risk of eutrophication from increase of phosphorus concentrations in water bodies due to fosetyl-Al is necessary.

3.1.6.3 Effects on Bees and Other Arthropod Species

Bees

All the hazard quotients are below 50, indicating that the active substances and the formulation pose an acceptable risk to bees. Therefore an acceptable risk to bees is expected from the application of VITIPEC GOLD WG ADVANCE according to the recommended use pattern.

Other non-target arthropods

VITIPEC GOLD WG ADVANCE						
Aphidius rhopalosiphi (Tier II, 2D)	> 6900	6900	42.0	< 1	0.001	< 1
Typhlodromus pyri (Tier II, 2D)	4881			1.4	0.004	

It is not possible to conclude to an acceptable risk for non-target arthropods following the application of the formulation FOSETYL + FOLPEL + CYMOXANIL (50+25+4) SAPEC WG according to the application patterns (HQ for *T. pyri* estimated to be 1.4 and thus higher than the trigger of 1). However, the HQ value for *T. pyri* is close to the trigger value. In addition, all actives substances are quickly degraded (DT_{50} soil: folpet 4.3 days; fosetyl 3 hours; cymoxanil 1.3 days) and it is possible to assume that, due to the rapid degradation of active substances, a potential recovery of the affected populations of arthropods could occur within an acceptable period (within 1 year). However, as this potential of recovery is not clearly demonstrated by data and because no data on additional species was provided by the applicant, despite a request for additional data made by the zRMS, a buffer zone of 20 m from non-agricultural land is considered required to conclude to an acceptable risk for non-target arthropods.

3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms

The acute and chronic TER values for VITIPEC GOLD WG ADVANCE active substances and metabolites are greater to than the triggers of 10 and 5, respectively, indicating an acceptable risk to earthworms following application of VITIPEC GOLD WG ADVANCE for the proposed use.

3.1.6.5 Effects on organic matter breakdown

No studies on effects on soil microbial activity were carried out with VITIPEC GOLD WG ADVANCE, since the three active substances are not expected to pose a risk to soil microflora, and are not expected to show any synergistic or additive effects.
This supports the conclusion that under field conditions, use of VITIPEC GOLD WG ADVANCE at the proposed rates poses no unacceptable risk to non-target soil micro-organisms.

3.1.6.6 Effects on Soil Non-target Micro-organisms

No studies on effects on soil microbial activity were carried out with VITIPEC GOLD WG ADVANCE, since the three active substances are not expected to pose a risk to soil microflora, and are not expected to show any synergistic or additive effects.
This supports the conclusion that under field conditions, use of VITIPEC GOLD WG ADVANCE at the proposed rates poses no unacceptable risk to non-target soil micro-organisms.

3.1.6.7 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna)

VITIPEC GOLD WG ADVANCE poses no unacceptable risk to terrestrial non-target plants in off-crop areas following the proposed uses.

3.1.7 Efficacy

Table: Conclusion of France for efficacy section

Crops	Maximum application rate per treatment	Maximum number of applications per crop	Interval between applications (days)	Pre-harvest interval (days)	Conclusion of France for efficacy section	Remarks
Grape (table and wine) * treatment of the above-ground crop parts * downy mildew(s)	3 kg/ha	3	12-14	42	Compliant	-

The request for marketing authorisation of VITIPEC GOLD WG ADVANCE was submitted by SAPEC AGRO S.A. France is zRMS, Italy, Spain and Portugal are cMS.

The product complies with the Uniform Principles.

Considering the data submitted:

- ✓ The efficacy of VITIPEC GOLD WG ADVANCE can be considered satisfactory for grape.
- ✓ The selectivity of VITIPEC GOLD WG ADVANCE is considered satisfactory.
- ✓ The risk of negative impact (yield, quality, transformation processes, propagation, succeeding and adjacent crops) is considered negligible.
- ✓ The possible occurrence or the development of resistance can be considered low to moderate. Resistance monitoring is requested.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation **cannot be granted because of unacceptable operator and worker exposures**. A copy of the Decision issued can be found 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

N/A

3.4.2 Post-authorisation data requirements

N/A

3.4.3 Label amendments (see label in Appendix 2):

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

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RÉPUBLIQUE FRANÇAISE

anses
agence nationale de sécurité sanitaire alimentation, environnement, travail

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 règlementaire,

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

de la société *SAPEC AGRO S.A.*

enregistrée sous le *n°2013-0884*

Vu les conclusions de l'évaluation du 14 mars 2016,

Considérant les risques inacceptables pour les opérateurs et les travailleurs,

Considérant qu'il ne peut 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.

VITIPEC GOLD WG ADVANCE
AMM n°-

Page 1 sur 3

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Informations générales sur le produit	
Nom du produit	VITIPEC GOLD WG ADVANCE
Type de produit	Produit de référence
Titulaire	SAPEC AGRO S.A. Alameda dos Oceanos, Lote 1.0601.1-3° A, Parque das Naçöes, 1990-207 Lisboa PORTUGAL
Formulation	Granulé dispersable (WG)
Contenant	500 g/kg - fosétyl 250 g/kg - folpel 40 g/kg - cymoxanil
Numéro d'intrant	961-2013.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usages	Professionnel

A Maisons-Alfort, le 10 JUIN 2016

Françoise WEBER
Directrice générale adjointe des produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

VITIPEC GOLD WG ADVANCE
AMM n°-

Page 2 sur 3

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ANNEXE I : Conditions de mise sur le marché demandées

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12703203 Vigne*Trt Part.Aer.*Mildiou(s)	3 kg/ha	3/an	F (BBCH 69)
	Motivation du refus : Sur raisin de table Risques inacceptables pour les opérateurs et les travailleurs		
	3 kg/ha	3/an	28
	Motivation du refus : Sur raisin de cuve Risques inacceptables pour les opérateurs et les travailleurs		

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

VITIPEC GOLD WG ADVANCE

Granulés mouillables (WG). Contient 50% de Fosetyl-al, 25 % de Folpel et 4% de Cymoxanil

Fongicide contre le Mildiou de la vigne (*Plasmopara viticola*)

PRECAUTIONS A PRENDRE

Sécurité de l'applicateur :

PORTER UN VETEMENT DE PROTECTION APPROPRIE (COMBINAISON) lors de la manipulation du produit.
PORTER UN VETEMENT (COMBINAISON) ET DES GANTS DE PROTECTION APPROPRIES en cas de contact avec les surfaces contaminées.
PORTER UN VETEMENT (COMBINAISON), DES GANTS ET UN APPAREIL DE PROTECTION DU VISAGE (MASQUE DE PROTECTION) APPROPRIES lors de la manipulation du produit.
EN CAS D'ACCIDENT OU DE MALAISE consulter immédiatement un médecin (si possible lui montrer l'étiquette).

Stockage du produit :

Conserver le produit uniquement dans l'emballage d'origine bien fermé.
Bien rincer le récipient en utilisant un appareil de rinçage sous pression ou rincer à la main trois fois.
Ne pas re-utiliser le récipient.
En cas d'urgence, composer le 15 ou le centre anti-poison.

Numéro de lot : XXXXXX POIDS NET : XX kg

Stocker à l'abri du gel.

Distribué par :	**Homologation détenue par :**
SAPEC AGRO S.A Herdade das Praias, Apartado 11 E.C. Bonfim 2901-852 Sétubal PORTUGAL	SAPEC AGRO S.A Herdade das Praias, Apartado 11 E.C. Bonfim 2901-852 Sétubal PORTUGAL

VITIPEC GOLD WG ADVANCE. Granule mouillable (WG). Contient 50% de Fosetyl-Al, 25 % de Folpel et 4% de Cymoxanil

Xn - Nocif

R20	**Nocif par inhalation.**
R40	**Effet cancérogène suspecté preuves insuffisantes.**
R43	**Peut entraîner une sensibilisation par contact avec la peau.**
R51/53	**Toxique pour les organismes aquatiques. Peut entraîner des effets néfastes à long terme pour l'environnement aquatique.**

N – Dangereux pour l'environnement

S2	Conserver hors de portée des enfants.
S13	Conserver à l'écart des aliments et boissons y compris ceux pour animaux.
S20 /21	Ne pas manger, ne pas boire et ne pas fumer pendant l'utilisation.
S29	Ne pas jeter les résidus à l'égout
S36/37/39	Porter un vêtement de protection approprié, des gants et un appareil de protection des yeux ou du visage
S61	Éviter le rejet dans l'environnement. Consulter les instructions spéciales / la fiche de données de sécurité.

Conditions d'emploi

Délai de rentrée des travailleurs dans la zone traitée : 48 heures après traitement

Spe3 - Pour protéger les organismes aquatiques, respecter une ZNT de 20 m par rapport aux points d'eau, avec un dispositif végétalisé non traité d'une largeur de 20 mètres en bordure des points d'eau.

SP1 - Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Eviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

Ne se débarrasser de ce produit et de son récipient qu'en prenant toutes les précautions d'usage.

Distributeur :

USAGES, DOSES, SPECIFICATIONS D'USAGE, DELAI AVANT RECOLTE (DAR), ZONE NON TRAITEE (ZNT).

Culture	Usage	Dose (kg/ha)	Nombre d'applications par an	DAR (jours)	ZNT (m)
Vigne	Mildiou *(Plasmopara viticola)*	3.0 kg/ha	3	28	20

RECOMMANDATIONS D'UTILISATION

Attention

VITIPEC GOLD WG ADVANCE contient du *Fosetyl- Al*, du *Folpel* et *Cymoxanil*. Par précaution, veiller à ne pas construire un programme anti-mildiou s'appuyant uniquement sur des produits contenant du *Cymoxanil*.
Pour plus d'information visitez le site Internet de «**F**ungicide **R**esistance **A**ction **C**ommittee » (www.frac.info).

Contrôle des maladies :

VITIPEC GOLD WG ADVANCE s'utilise en pulvérisation sur la vigne pour la lutte contre le mildiou (*Plasmopara viticola*).

VITIPEC GOLD WG ADVANCE est un mélange d'ingrédients actifs fongicides avec des caractéristiques différentes, qui allient l'action systémique ascendante et descendante du ***Fosétyl Al***, la protection par contact avec effet multisite du ***Folpel*** et à l'action pénétrante et curative du ***Cymoxanil***.

Périodes et doses d'emploi :
En préventif
La Vigne peut être traitée avec **VITIPEC GOLD WG ADVANCE** dès l'apparition de l'inflorescence (Stade BBCH 53) jusqu'à la véraison (BBCH 85). Se conformer aux bulletins de santé du végétal (BSV) publiés par les services officiels.
Ne pas dépasser 3 applications par an. Respecter une cadence de 12-14 jours entre applications D'une manière générale, cette durée de protection est obtenue entre deux traitements avec **VITIPEC GOLD WG ADVANCE** En cas de forte pression du mildiou, l'intervalle entre 2 traitements peut être ramené à 10 jours

A noter si un traitement de contact succède à un traitement avec **VITIPEC GOLD WG ADVANCE**, l'application de ce fongicide doit intervenir au plus tard 12 jours après **VITIPEC GOLD WG ADVANCE** (8 jours en cas de forte pression).

Intervention exceptionnelle en curatif :
La curativité du cymoxanil permet également de traiter la vigne avec **VITIPEC GOLD WG ADVANCE** dans les 1 à 2 jours après une contamination par le mildiou, dans la limite de 25% de la période d'incubation du parasite.sur attaque déclarée (taches de mildiou visibles), la limitation des dégâts peut être obtenue en appliquant **VITIPEC GOLD WG ADVANCE** dès que possible, puis en renouvelant la protection 5 à 6 jours après avec un fongicide curatif d'un autre mode d'action,

DOSE

VITIPEC GOLD WG ADVANCE doit être appliqué à 3.0 kg/ha dans 200 à 1000 litres d'eau par hectare.

Le mélange et la pulvérisation du produit

Bien mélanger avant l'utilisation. Remplir à moitié la cuve d'eau du pulvérisateur et ajouter la quantité indiquée de **VITIPEC GOLD WG ADVANCE** sous agitation. Ajouter la quantité d'eau restante en maintenant l'agitation lors de l'application.
Etant donnée les types de mode d'action des 3 matières actives (systémie pour le fosétyl-Al , action pénétrante pour le cymoxanil et action de contact pour le folpel), la technique de pulvérisation « face par face » sur chaque rang doit être privilégiée pour obtenir une efficacité maximale.

La bouillie ainsi obtenue devra être utilisée dans les 24 heures qui suivent sa préparation

Ne pas mélanger **VITIPEC GOLD WG ADVANCE** avec les produits à base de cuivre et les engrais foliaires contenant de l'azote.
Les mélanges doivent-être mis en œuvre conformément à la réglementation en vigueur et aux recommandations des guides de bonnes pratiques officiels.
Etant donnée les modes d'action des 3 matières actives (la technique de pulvérisation « face par face » sur chaque rang doit être privilégiée pour obtenir une efficacité maximale.

Rognage
Le Fosétyl-al de **VITIPEC GOLD WG ADVANCE** protège les pousses formées entre 2 traitements.si un rognage est nécessaire, nous conseillons de le réaliser avant le traitement avec **VITIPEC GOLD WG ADVANCE**

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

Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de vente du Ministère de l'Agriculture.

Appendix 3 – Letter(s) of Access

Date: May 16, 2012

To

Anses - DPR - UGAmm
253 avenue du Général Leclerc
94701 MAISONS-ALFORT Cedex,
France

Subject: Letter of access to Cymoxanil protected data for plant protection products registrations in France

Dear Sir/Madam,

We, **Belchim Crop Protection NV/SA** with address at Neringstraat 15 B-1840 Londerzeel in Belgium and **Indofil Industries Limited** (formerly, Indofil Chemicals Company), having the Representative Office at Via Filippo Turati 6 -20121 Milan, Italy, with the Principal Office, located at Kalpataru Square, 4th floor, Kondivita Road, Off. Andheri Kurla Road, Andheri (E) – Mumbai 400 059, India declare that the **Cymoxanil post Annex I compliance dossier,** generated by both companies and submitted to the competent registration authorities, supports the following registration of **SAPEC AGRO S.A.,** Avenida do Rio Tejo - Herdade das Praias, 2910-440 Setúbal, Portugal in **France**:

Sr. No.	Trade name	Reg. No.	Composition	Reg. Holder
1	VITIPEC GOLD WG ADVANCE	To be assigned	Cymoxanil 4% + Folpet 25% + Fosetyl-Al 50% WG	SAPEC AGRO S.A. Avenida do Rio Tejo - Herdade das Praias 2910-440 Setúbal Portugal
2	VITIPEC WG ADVANCE	To be assigned	Cymoxanil 8% + Folpet 66% WG	

This letter is valid exclusively to support the above registrations and is not transferable and can not be used for other purpose than the evaluation of the above mentioned products.

Yours Sincerely,

Indofil Industries Limited

INDOFIL INDUSTRIES LIMITED ITALY

Narendra C. Rane
Vice President – Strategy & International Business

Belchim Crop Protection
Belchim Crop Protection
Technologielaan 7
B 1840 Londerzeel
Tel 0032 52 300906 Fax 0032 52 301135
BTW/TVA BE 0458.909.077
RPR/RPM Brussel/Bruxelles

Dr. Jacques Horsten
Global R & D Manager

Date: 5 April 2013

To whom it may concern

Re: Letter of access: Folpet

We **Belchim Crop Protection NV/SA** with address at Technologielaan 7, B-1840 Londerzeel, Brussels in Belgium and **Sapec Agro SA** with address at Avenida do Rio Tejo – Herdade das Praias, 2910-440 Setubal in Portugal declare that the Folpet Annex II dossier has been generated by both companies and submitted to the competent registration authorities. **Belchim Crop Protection NV/SA** and **Sapec Agro SA** through its undersigned, duly appointed representatives, herby grand to **Sapec Agro SA** the authority to reply on the Folpet Annex II dossier for the purpose of registration of the following product in France.

Trademarks	Composition	Formulation Type	Registration Number
VITIPEC GOLD WG ADVANCE	4% Cymoxanil + 25% Folpet + 50% Fosetyl-al	WG	--

This letter is valid exclusively to support the above registrations, is not transferable, can not be used for other purpose than the evaluation of the above mentioned product.

Yours sincerely

Belchim Crop Protection NV/SA

Dr. ir. Steven Van Pottelberge
Registration and Development Manager

Sapec Agro SA

Mr. João Estrela
Managing Director
SAPEC AGRO, S.A.

INDOFIL INDUSTRIES LIMITED

An ISO 9001 & 14001 Certified Company

Ref.: IIL/CYM/FR/134-14/129
Date: September 12, 2014

To
Anses – DPR – UGAmm
253 avenue du Général Leclerc
94701 MAISONS-ALFORT Cedex, France

Subject: Indofil's Letter of Access to Cymoxanil protected data in support of application for the plant protection product "VITIPEC GOLD WG ADVANCE" of Sapec Agro SA, Portugal in France.

Dear Sir/Madam,

In response to your request towards the new requirement for the evaluation of VITIPEC GOLD WG ADVANCE, we, **INDOFIL INDUSTRIES LIMITED** (formerly, Indofil Chemicals Company), having the Representative Office at Via Filippo Turati 6 -20121 Milan, Italy, with the Principal Office, located at Kalpataru Square, 4th floor, Kondivita Road, Off. Andheri Kurla Road, Andheri (E) – Mumbai 400 059, India, wish to extend access to the following Cymoxanil protected study submitted by Indofil for Moximate 505 WP (N° de dossier: 2011-6500) in France,

Author	Year	Title Reference/Report No. GLP or GEP status (where relevant) Published or unpublished	Data protection claimed Y/N	Owner
Garofani, S.	2009	Validation of the analytical method for the determination of Cymoxanil residues in soil Doc. No.: 434-002 GLP: Y, Published: No	Y	Indofil / Belchim
Garofani, S.	2013	Validation of the analytical method for the Determination of Cymoxanil residues in soil - integration of the GLP study CH - 285/2008 with linearity and recovery tests using peak areas of qualifier ions Doc. No.: 434-004 GLP: Y, Published: No	Y	Indofil / Belchim

for the evaluation of registration of following plant protection product of **Sapec Agro SA**, Portugal in France, based on the condition the finished products will contain Cymoxanil of Indofil sources.

No.	Trade name	Reg. No.	Composition	Registration holder
1	**VITIPEC GOLD WG ADVANCE**	To be assigned	Cymoxanil 4% + Folpet 25% + Fosetyl-Al 50% WG	Sapec Agro SA, Portugal

This letter is valid exclusively to support the above mentioned registrations and is not transferable and cannot be used for other purpose than the evaluation of the above mentioned product.

This letter does not authorize Sapec Agro SA, Portugal or its affiliates to receive copies of studies or any other documents submitted by us nor does it authorize Sapec Agro SA, Portugal or its affiliates to inspect such studies or any such document, whether in whole or in part.

This authorization can be revoked at any time, should there be a material breach of the conditions defined in this letter.

Yours Sincerely,

For Indofil Industries Limited

INDOFIL INDUSTRIES LIMITED ITALY

Narendra C. Rane
Sr. Vice President – Strategy & International Business

ITALY OFFICE :
Via Filippo Turati, 6 - 20121 Milan (Italy)

INDIA OFFICE :
Kalpataru Square, 4th Floor, Kondivita Road,

INDOFIL
INDUSTRIES LIMITED

An ISO 9001 & 14001 Certified Company

Ref.: IIL/CYM/FR/1411-20
Date: November 04, 2014

To
Anses – DPR – UGAmm
253 avenue du Général Leclerc
94701 MAISONS-ALFORT Cedex, France

Subject: Indofil's Letter of Access to Cymoxanil protected data in support of registration application for the plant protection product "VITIPEC GOLD WG ADVANCE" of Sapec Agro SA, Portugal in France.

Dear Sir/Madam,

In response to your request towards the new requirement for the evaluation of VITIPEC GOLD WG ADVANCE, we, **INDOFIL INDUSTRIES LIMITED** (formerly, Indofil Chemicals Company), having the Representative Office at Via Filippo Turati 6 -20121 Milan, Italy, with the Principal Office, located at Kalpataru Square, 4th floor, Kondivita Road, Off. Andheri Kurla Road, Andheri (E) – Mumbai 400 059, India, wish to extend access to the following Cymoxanil protected study submitted by Indofil for Moximate 505 WP (N° de dossier: 2011-6500) in France,

Author	Year	Title Reference/Report No. GLP or GEP status (where relevant) Published or unpublished	Data protection claimed Y/N	Owner
Caine, J.	2010	Method validation- Determination of residues of IN-KQ960 in water Doc. No.: 435-002 GLP: Y Published: No	Y	Indofil / Belchim
Garofani, S.	2009	Validation of the analytical method for the determination of Cymoxanil residues in air Doc. No.: 436-001 GLP: Y Published: No	Y	Indofil / Belchim

for the evaluation of registration of following plant protection product of **Sapec Agro SA**, Portugal in France, based on the condition the finished products will contain Cymoxanil of Indofil sources.

No.	Trade name	Reg. No.	Composition	Registration holder
1	**VITIPEC GOLD WG ADVANCE**	To be assigned	Cymoxanil 4% + Folpet 25% + Fosetyl-Al 50% WG	Sapec Agro SA, Portugal

This letter is valid exclusively to support the above mentioned registrations and is not transferable and cannot be used for other purpose than the evaluation of the above mentioned product.

This letter does not authorize Sapec Agro SA, Portugal or its affiliates to receive copies of studies or any other documents submitted by us nor does it authorize Sapec Agro SA, Portugal or its affiliates to inspect such studies or any such document, whether in whole or in part.

This authorization can be revoked at any time, should there be a material breach of the conditions defined in this letter.

Yours Sincerely,

For Indofil Industries Limited

INDOFIL INDUSTRIES LIMITED ITALY

Narendra C. Rane
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