REGISTRATION REPORT

Part A

Risk Management

Product code: Cymoxanil 4% + Mancozeb 46.5% WG

Product name(s): CIMOPEC M WG ADVANCE

Active Substances:

mancozeb, 465 g/kg

cymoxanil, 40 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: SAPEC AGRO SA

Date: 29/04/2016

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PART A – Risk Management

The company SAPEC AGRO S.A. has requested marketing authorisation in France for the product CIMOPEC M WG ADVANCE (formulation code: Cymoxanil 4% + Mancozeb 46.5% WG; containing 465 g/kg mancozeb 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 CIMOPEC M WG ADVANCE where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of CIMOPEC M WG ADVANCE have been made using endpoints agreed in the EU peer reviews of both mancozeb and cymoxanil.

This document describes the specific conditions of use and labelling required for France for the registration of CIMOPEC M 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 CIMOPEC M 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

Mancozeb

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 762/2013 of 7 August 2013 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb, MCPA, MCPB and metiram.
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 mancozeb, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 June 2005 shall be taken into account. Member States must pay particular attention to the potential for groundwater contamination when the active substance is applied in regions with vulnerable soils and/or extreme climatic conditions. Member States must pay particular attention to the residues in food and evaluate the dietary exposure of consumers.

Member States must pay particular attention to the protection of birds, mammals, aquatic organisms and non-target arthropods and ensure that the conditions of authorisation include risk mitigation measures. Member States shall request the submission of further studies to confirm the risk assessment for birds and mammals and for developmental toxicity. They shall ensure that the notifiers at whose request mancozeb has been included in this Annex provide such studies to the Commission within two years from the approval. Regulation (EU) No 762/2013 extended the approval's expiry date to 31 January 2018.
There is no definitive EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance. A Review Report is available (SANCO/4058/2001 rev 4.4, July 2009).

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 (2012-2574, 2014-0286 and 2014-0301) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) in the context of the zonal procedure for all Member States of the Southern Zone, taking into account the worst-case uses ("risk envelope approach") – 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[1] 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.

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[2], 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[3], and are expressed as "acceptable" or "not acceptable"/"not finalised" in accordance with those criteria.

Finally, the French Order of 26 March 2014[4] 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[5] 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 CIMOPEC M 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.

[1] http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000425570
[2] REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
[3] COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products
[4] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo
[5] SANCO document "guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs": SANCO/ 7525/VI/95 - rev.9

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	CIMOPEC M WG ADVANCE (Cymoxanil 4% + Mancozeb 46.5% WG)
Authorisation number	2160268
Function	Fungicide
Applicant	SAPEC AGRO S.A.
Composition	465 g/kg mancozeb 40 g/kg cymoxanil
Formulation type (code)	Water-dispersible granule (WG)
Packaging	Polyethylene terephthalate/polyethylene sachet containing 300 g product Paper/low-density polyethylene/paper sack containing 15 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	Sensitisation — Skin, Hazard Category 1 Serious eye damage/eye irritation, Hazard Category 2 Reproductive toxicity, Hazard Category 2	
Environmental hazards	Hazardous to the aquatic environment — Acute Hazard, Category 1 Hazardous to the aquatic environment — Chronic Hazard, Category 1	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H317	May cause an allergic skin reaction.
	H319	Causes serious eye irritation.
	H361fd	Suspected of damaging fertility. Suspected of damaging the unborn child.
	H400	Very toxic to aquatic life.

	H410	Very 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

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 50 metres[6] to surface water bodies

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment[7]: refer to the Decision in Appendix 1 for the details
Re-entry period[8]: 48 hours
Pre-harvest interval[9]: - Potato: 7 days, - Tomato: 7 days
Other mitigation measures: -
The label must reflect the conditions of authorisation.

[6] The legal basis for this is **Titre III Article 11** 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]

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

[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 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.

GAP rev. 1, date: 2016-04-29

PPP (product name/code)	**CIMOPEC M WG ADVANCE/ Cymoxanil 4% + Mancozeb 46.5% WG**	**Formulation type:**	**Water-dispersible granule/WG**
		Conc. of as 1:	**465 g/kg**
active substance 1	**mancozeb**	**Conc. of as 2:**	**40 g/kg**
active substance 2	**cymoxanil**		
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)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Grapes	FR	Cymoxanil 4% + Mancozeb 46.5% WG	F	*Plasmopara viticola*	WG	Cym 40 + Man 465 g/kg	Overall spray	BBCH 18-77	5	7-12 days	Cym 0.012 + Man 0.1395 Cym 0.120+ Man 1.395	100-1000	Cym 0.120 + Man 1.395	**28 days**	3 kg product/ha **Not acceptable (risk to operators and workers)**

Potato	FR	Cymoxanil 4% + Mancozeb 46.5% WG	F	*Plasmopara viticola*	WG	Cym 40 + Man 465 g/kg	Overall spray	BBCH 15-81	5	7-10 days	**Cym 0.013 + Man 0.0145** **Cym 0.025 + Man 0.291**	400-800	**Cym 0.100 + Man 1.162**	7 days	2.5 kg product/ha Acceptable **(The intended application rate of 3 kg/ha is not justified. Reduction of the rate to 2.5 kg/ha is proposed)**
Tomato	FR	Cymoxanil 4% + Mancozeb 46.5% WG	**F**	*Plasmopara viticola*	WG	Cym 40 + Man 465 g/kg	Overall spray	BBCH 12-81	5	14 days	Cym 0.010 + Man 0.116 Cym 0.025 + Man 0.291	400-1000	Cym 0.100 + Man 1.162	**7 days**	2.5 kg product/ha **Not acceptable for workers)**
Tomato, eggplant	FR	Cymoxanil 4% + Mancozeb 46.5% WG	**F**	*Plasmopara viticola*	WG	Cym 40 + Man 465 g/kg	Overall spray	BBCH 12-81	5	14 days	Cym 0.012 + Man 0.1395 Cym 0.03 + Man 0.349	400-1000	Cym 0.100 + Man 1.162	**7 days**	2.5 kg product/ha **Acceptable risk for worker only in case of mechanical harvest**

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 CIMOPEC M WG ADVANCE (Cymoxanil 4% + Mancozeb 46.5% WG) is a water-dispersible granule (WG). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the formulation is that of a light-brown granule, with uncharacteristic odour. It is not explosive and has no oxidising properties. It has a self-ignition temperature of 251 °C and is not flammable. In aqueous solution at 1 %, its pH is 5.3 at 25 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active substances' 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 PET/PE. As the formulation is WG, all packaging can be considered acceptable.
Its technical characteristics are acceptable for a WG formulation.

The formulation is not classified for the physico-chemical aspect.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

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

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 cymoxanil and mancozeb in plants (matrices with high water content and acidic matrices, soil, water (surface and drinking) and air.

The active substances are neither toxic nor very toxic, hence no analytical method is required for the determination of residues in biological fluids.

The following data are still missing and must be provided in post-authorisation:
An analytical method (with confirmatory data) and its ILV for the determination of residues of cymoxanil in foodstuffs of animal origin (muscle, fat, liver/kidney, eggs and milk)

The following data are still missing and should be provided at the renewal of the mancozeb approval:
An analytical method (with confirmatory data) and its ILV for the determination of residues of mancozeb in foodstuffs of animal origin (muscle, fat, liver/kidney, eggs and milk) or an ILV of the method Toledo, 2011.

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

Cymoxanil 4% + Mancozeb 46.5 WG (CIMOPEC M WG ADVANCE) containing 40 g/kg of cymoxanil and 465 g/kg of mancozeb has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin but is irritating to the rabbit eye and is a skin sensitiser

The formulation is classified as shown in Section 2.2.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G[10]	Equipment	Application rate kg product/ha (g a.s./ha)	Spray dilution (L/ha)	Model
Potato	F	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	3 (1395 g/ha of mancozeb and 120 g/ha of cymoxanil)	400-800	BBA
Grape vine	F	Tractor-mounted/trailed broadcast air-assisted sprayer / Hand-held sprayer: hydraulic nozzles. Outdoor, high-level target	3 (1395 g/ha of mancozeb and 120 g/ha of cymoxanil)	100-1000	BBA
Tomato	F	Tractor-mounted/trailed boom sprayer, hydraulic nozzles / Lance	2.5 (1162.5 g/ha of mancozeb and 100 g/ha of cymoxanil)	1000	BBA

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

Crop	Equipment	PPE and/or working coverall	% AOEL cymoxanil	% AOEL mancozeb
Potato	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	Working coverall and gloves during mixing/loading and application	57	11
Grape vine	Tractor-mounted/trailed broadcast air-assisted sprayer		**187**	14
Grape vine	Hand-held sprayer: hydraulic nozzles. Outdoor, high-level target		92	20
Tomato	Tractor-mounted/trailed boom sprayer, hydraulic nozzles		47	9.4

Estimation of operator exposure (for the uses that showed percentages of AOEL under 100 % when calculated substance by substance) have also been calculated for combined exposure with the protection factors used for PPE (90 % for working coverall and gloves).

According to the model calculations, it can be concluded that the risk for the operator using Cymoxanil 4% + Mancozeb 46.5 WG is unacceptable with a working coverall (90 % protection factor) and gloves during mixing/loading and application for the intended use on grape vine with a tractor-mounted/trailed broadcast air-assisted sprayer.

[10] Open field or glasshouse

The risk for the operator using Cymoxanil 4% + Mancozeb 46.5 WG is acceptable with a working coverall (90 % protection factor) and gloves during mixing/loading and application for the intended uses on grape vine, potato and tomato with a hand-held sprayer

A cumulative risk assessment has been performed using a tiered approach for uses on grape vine with a hand-held sprayer, on tomatoes and on potatoes. The calculated hazard index (HI) is under 1 for potato and tomatoes. However, it is over 1 for grape vines with a hand-held sprayer. Therefore a refined risk assessment was necessary and this was performed with specific target organ/system AOEL for each active substance. The result shows that HIs for all target organ/systems are less than 1. Therefore, the risk is acceptable.

3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to be 44.4 % of the AOEL of cymoxanil and 3.9 % of the AOEL of mancozeb for the worst case (grape vine).
Tier 2 of combined exposure shows the following:

% AOEL [Hazard Quotient (HQ)]		**Sum of hazard quotients (Σ HQ) or hazard index (HI)**
Mancozeb	**Cymoxanil**	
3.9 (0.039)	44.4 (0.444)	0.483

It is concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to Cymoxanil 4% + Mancozeb 46.5 WG.

Resident exposure assessment was carried out according to the publication of Martin et al. 2008 and shows an exposure below the respective AOELs of cymoxanil and mancozeb.

According to French organisations accredited for air quality monitoring, cymoxanil has been found at concentrations up to 3.22 ng cymoxanil/m³ in the air. Consequently, a risk assessment has been carried out for the resident via the air. Based on these data, the respiratory exposure of residents near the treatment areas was estimated at less than 1 % of cymoxanil's ADI and AOEL.

3.1.3.4 Worker Exposure

Workers may have to enter treated areas after treatment for crop inspection/harvesting activities. Therefore, estimation of worker exposure was calculated according to EUROPOEM II.
Potato:
Exposure is estimated as 36 % of the AOEL of cymoxanil and 0.5 % of the AOEL of mancozeb.
Grape vine:
Exposure is estimated as 432 % of the AOEL of cymoxanil and 5.7 % of the AOEL of mancozeb.
Tomato (field):
Exposure is estimated as 120 % of the AOEL of cymoxanil and 1.6 % of the AOEL of mancozeb.
However, with mechanical harvesting, no exposure of workers is expected.

Conclusions:
Potato:
It is concluded that without taking into account a re-entry period [i.e., 48 hours], there is no unacceptable risk anticipated for workers wearing a working coverall and gloves, when re-entering crops treated with Cymoxanil 4% + Mancozeb 46.5 WG.

Grape vine:
It is concluded that without taking into account a re-entry period [i.e., 48 hours], there is an unacceptable risk anticipated for workers wearing a working coverall and gloves, when re-entering crops treated with Cymoxanil 4% + Mancozeb 46.5 WG.
Tomato:
It is concluded that there is no unacceptable risk anticipated for workers using mechanical harvesting in crops treated with Cymoxanil 4% + Mancozeb 46.5 WG. However, manual harvesting would not be acceptable.

3.1.4 Residues and Consumer Exposure

3.1.4.1 Residues

Primary crop metabolisms were sufficiently investigated to define residue of both active substances for enforcement and risk assessment purposes in the crops under consideration.

Regarding the magnitude of residues, a sufficient number of residue trials is available to support the intended GAPs in France. These data allow it to be considered that there will not be residue levels above the extant MRLs for wine grapes, table grapes, potatoes and tomatoes as a result of the intended uses.

As residues of cymoxanil do not exceed the trigger value of 0.1 mg/kg in grapes, potatoes and tomatoes, there is no need to investigate the effect of industrial and/or household processing. As for mancozeb, a hydrolysis study showed that under pasteurisation, sterilisation and cooking processes, mancozeb is converted into ethylene-thio-urea (ETU). Magnitude of residue studies showed that wine production leads to a decrease of mancozeb residues and an increase of ETU residues. Transfer factors were calculated and were used to refine the risk assessment for mancozeb and ETU.

Residues in succeeding crops have been sufficiently investigated; it is very unlikely that residues of cymoxanil and mancozeb will be present in succeeding crops.

For cymoxanil, the residue data on potatoes do not modify the dietary burden for animals. According to an animal metabolism study, no significant residue levels of cymoxanil are expected in ruminants or pig commodities when crops are treated according to the intended GAPs. Therefore, it can be concluded that extant MRLs will not be exceeded.

For mancozeb, considering the dietary burden and based on the intended and already authorised uses, significant intake above the trigger value of 0.1 mg/kg dry matter was calculated for livestock. According to livestock feeding studies, no residue level of mancozeb above the extant MRLs are expected in animal commodities when crops are treated according to the intended GAPs, except in bovine liver, for which the exposure would lead to an MRL proposal of 0.1 mg/kg in liver. This figure is above the current MRL of 0.05* mg/kg.

However, since:
- the review of the existing MRLs for mancozeb is ongoing in the framework of Article 12(2),
- potato is not the main contributor to the exposure of livestock,
- the risk assessment carried out with the potential MRL of 0.1 mg/kg does not lead to an unacceptable consumer exposure,

the intended uses can be considered acceptable.

3.1.4.2 Consumer exposure

The toxicological profiles of cymoxanil, mancozeb and ETU were evaluated at EU level, which resulted in the proposal of ADIs (0.013 mg/kg for cymoxanil, 0.05 mg/kg for mancozeb, 0.002 mg/kg for ETU) and ARfDs (0.08 mg/kg for cymoxanil, 0.6 mg/kg for mancozeb and 0.05 mg/kg for ETU) that were considered in the framework of this evaluation.

Chronic consumer exposure resulting from the uses proposed in the framework of this application was calculated for both active substances as well as for ETU. Based on EFSA PRIMo (rev2), chronic and acute exposures were considered acceptable for all groups of consumers.
According to the 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 have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU peer reviews were used to calculate PECs 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 cymoxanil and mancozeb and their metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU review or agreed in the assessment based on new data provided.

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

PECgw for cymoxanil, mancozeb and their metabolites do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000[11]. 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.

Implications for labelling resulting from environmental fate assessment: None.

3.1.6 Ecotoxicology

3.1.6.1 Effects on Terrestrial Vertebrates

The risk assessment for terrestrial vertebrates was conducted according to the recommendations of the EFSA Guidance[12] on Risk Assessment for Birds and Mammals.
The tier 1 acute TER values for cymoxanil, mancozeb and formulated product are in excess of the trigger value of 10. The tier 1 or refined chronic TER values for cymoxanil and mancozeb are in excess of the trigger value of 5. Thus the risk for birds and mammals following applications of "Cymoxanil 4% + Mancozeb 46.5% WG" (CIMOPEC M WG ADVANCE) can be considered acceptable for all intended uses.

[11] Guidance document on the assessment of the relevance of metabolites in groundwater of substance regulated under Council directive 94/414/EEC. Sanco/2000-rev10-final, 25 February 2003
[12] Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA: EFSA Journal 2009; 7(12): 1438

3.1.6.2 Effects on Aquatic Species

Risk assessments show that the risk to aquatic organisms following application of "Cymoxanil 4% + Mancozeb 46.5% WG" can only be considered acceptable with a 50-metre unsprayed buffer zone is applied for all the intended uses.

3.1.6.3 Effects on Bees and Other Arthropod Species

Honey bees
All the hazard quotients are below the HQ trigger value of 50 indicating that the risk to bees from the use as a spray application in grapes of "Cymoxanil 4% + Mancozeb 46.5% WG" can be considered acceptable.

Terrestrial non-target arthropods
Considering the extended test on Aphidius rhopalosiphi, the aged residue test on Typhlodromus pyri and the studies on two additional species conducted with "Cymoxanil 4% + Mancozeb 46.5% WG", the in-field risk for non-target arthropods can be considered acceptable. An aged residue study conducted with A. rhopalosiphi must be submitted to confirm the in-field risk assessment. A 5-metre buffer zone is necessary to protect non-target arthropods for the use in vineyards only.

3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms

The calculations show that acute and long-term TER values are in excess of the corresponding trigger values of 10 and 5, respectively, for each of the active substances indicating that the acute and chronic risk to earthworms following the use of "Cymoxanil 4% + Mancozeb 46.5% WG" can be considered acceptable for all intended uses.

3.1.6.5 Effects on organic matter breakdown

Not required: the TER_{LT} for earthworms was above the trigger value of 5, and no effects on micro-organisms > 25% were observed.

3.1.6.6 Effects on Soil Non-target Micro-organisms

Considering that the effects of each active substance to soil microbial activity (carbon and nitrogen transformations) are lower than 25 % at rates significantly higher than the proposed rate with "Cymoxanil 4% + Mancozeb 46.5% WG", no study on the effects of this product on soil microbial activity was deemed necessary. The risk to soil micro-organisms can be considered acceptable.

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

The TER values are greater than the trigger value of 5 for "Cymoxanil 4% + Mancozeb 46.5% WG". The risk to non-target plants following the use of this product can be considered acceptable for all intended uses.

3.1.7 Efficacy

The product complies with the Uniform Principles.
Considering the data submitted:
- on downy mildew of grape:

- ✓ The efficacy of CIMOPEC M WG ADVANCE at 3 kg/ha is considered satisfactory;
- ✓ the selectivity of CIMOPEC M WG ADVANCE up to 3 kg/ha is considered satisfactory;
- ✓ the risk of negative impact (on yield, quality, propagation, succeeding and adjacent crops) is considered negligible;
- ✓ the risk of negative impact on wine-making negligible;

- ✓ the risk of resistance developing or appearing is considered moderate, so management measures are necessary. The one submitted by the applicant (5 applications maximum per year, use in a programme of fungicides, are acceptable and reduce the risk;
- ✓ the curative effect of cymoxanil in association with mancozeb was not demonstrated. Data must be provided post-authorisation according a specific study plan (described in the Part B of the Registration report).

- on late blight of potato:

- ✓ The intended application rate of 3 kg/ha is not justified. Reduction of the rate to 2.5 kg/ha is proposed;
- ✓ the efficacy of CIMOPEC M WG ADVANCE (Cymoxanil 4% + Mancozeb 46.5% WG) at 3 kg/ha is considered satisfactory based on expert knowledge;
- ✓ the selectivity of CIMOPEC M WG ADVANCE up to 3 kg/ha is considered satisfactory;
- ✓ the risk of negative impact (on yield, quality, propagation, succeeding and adjacent crops) is considered negligible;
- ✓ the risk of resistance developing or appearing is considered low when the number of applications is reduced to 5 and when the product is integrated in a programme of disease control.

- on late blight of tomato:

- ✓ The intended application rate of 2.5 kg/ha is justified;
- ✓ the efficacy of CIMOPEC M WG ADVANCE at 2.5 kg/ha is considered satisfactory based on expert knowledge;
- ✓ the selectivity of CIMOPEC M WG ADVANCE up to 2.5 kg/ha is considered satisfactory;
- ✓ risk of negative impact (on yield, quality, processing; propagation, succeeding crops and adjacent crops) is considered negligible;
- ✓ the risk of resistance developing or appearing is considered moderate. Management measures are necessary; the one submitted by the applicant (3 applications maximum per crop, use in a programme of fungicides) is acceptable and reduces the risk.

3.2 Conclusions arising from French assessment

Uses in tomato and potato:

Taking into account the above assessment, an authorisation can be granted as proposed in Appendix 1 – Copy of the product Decision.

Use in grapevine

Taking into account the above assessment, an authorisation cannot be granted **because the risks to operators and workers are not acceptable.** 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

A plan for monitoring the appearance of resistance to cymoxanil must be undertaken for potato late blight. The competent authorities need only be informed of any changes compared with the current resistance situation.

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 analytical method (with confirmatory data) and its ILV for the determination of residues of cymoxanil in foodstuffs of animal origin (muscle, fat, liver/kidney, eggs and milk).
- An aged residue test with *Aphidius rhopalosiphi* using CIMOPEC M WG ADVANCE.

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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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 ***CIMOPEC M WG ADVANCE***

de la société *SAPEC AGRO S.A.*

enregistrée sous le *n°2012-2574*

Vu les conclusions de l'évaluation du 10 mars 2016,

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.

CIMOPEC M WG ADVANCE
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Informations générales sur le produit	
Nom du produit	CIMOPEC M WG ADVANCE
Type de produit	Produit de référence
Titulaire	SAPEC AGRO S.A. Parque das Naçoes, Departamento Tecnico Alameda dos Oceanos, Lote 1.06.1.1 - D2 1990-207 Lisbonne PORTUGAL
Formulation	Granulé dispersable (WG)
Contenant	465 g/kg - mancozèbe 40 g/kg - cymoxanil
Numéro d'intrant	957-2012.01
Numéro d'AMM	2160268
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 31 janvier 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 29 AVR. 2016

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

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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**
Sachets en polyéthylène téréphtalate / polyéthylène	300 g
Sacs en papier / polyéthylène basse densité / papier	15 kg

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	**Mention de danger**
Sensibilisation cutanée, catégorie 1	H317 : Peut provoquer une allergie cutanée
Lésions oculaires graves/irritation oculaire, catégorie 2	H319 : Provoque une sévère irritation des yeux
Toxicité pour la reproduction, catégorie 2	H361fd : Susceptible de nuire à la fertilité. Susceptible de nuire au fœtus
Dangers pour le milieu aquatique - Danger aigu, catégorie 1	H400 : Très toxique pour les organismes aquatiques
Dangers pour le milieu aquatique - Danger chronique, catégorie 1	H410 : Très toxique pour les organismes aquatiques, entraine des effets néfastes à long terme
Pour les phrases P se référer à la règlementation 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.**	

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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 Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
16953200 Tomate*Trt Part.Aer.*Mildiou(s)	**2,5 kg/ha**	**3/an**	entre les stades BBCH 12 et BBCH 81	7	50	-	-	-
Uniquement autorisé si la récolte est mécanique. L'utilisation du produit n'est pas autorisée pour une récolte manuelle, en raison de risques inacceptables pour le travailleur.								
15653201 Pomme de terre*Trt Part.Aer.*Mildiou(s)	**2,5 kg/ha**	**5/an**	entre les stades BBCH 15 et BBCH 81	7	50	-	-	-
Dose d'application revendiquée de 3 kg/ha non justifiée.								

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	5/an	28
Motivation du refus : L'usage est refusé en raison des risques inacceptables pour l'opérateur et le travailleur.			

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Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

Il convient de rappeler que 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 complémentaires comme les protections individuelles.

En tout état de cause, 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 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 - Pulvérisation vers le bas**

  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).

Pour le travailleur, porter

- Combinaison de travail (cotte en coton/polyester 35 %/65 % - grammage d'au moins 230 g/m²) avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-3 en cas de contact avec la culture traitée.

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Délai de rentrée
48 heures en application de l'arrêté du 12 septembre 2006.

Respect des limites maximales de résidus (LMR)

Les conditions d'utilisation de la préparation, compte tenu des bonnes pratiques agricoles critiques proposées pour chaque usage figurant dans la liste des usages autorisés, 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 50 mètres par rapport aux points d'eau.

Exigences complémentaires post-autorisation

A défaut de transmission de ces données dans les délais impartis à compter de la date de la présente décision, la présente décision pourra être retirée ou modifiée.

Détail de la demande post autorisation	Délai (mois)	Récurrence (mois)
Fournir une méthode et sa validation inter-laboratoires pour la détermination des résidus de cymoxanil dans les denrées d'origine animale (muscle, graisse, foie, rein, œufs et lait).	24	-
Fournir une étude sur résidus vieillis sur *Aphidius rhopalosiphi* réalisée avec la préparation CIMOPEC M WG ADVANCE.	24	-
Un plan de surveillance des apparitions de résistance au cymoxanil devrait être conduit pour le mildiou de la pomme de terre. Il conviendrait d'informer les autorités compétentes uniquement en cas de changement par rapport au contexte de résistance actuel.	-	-

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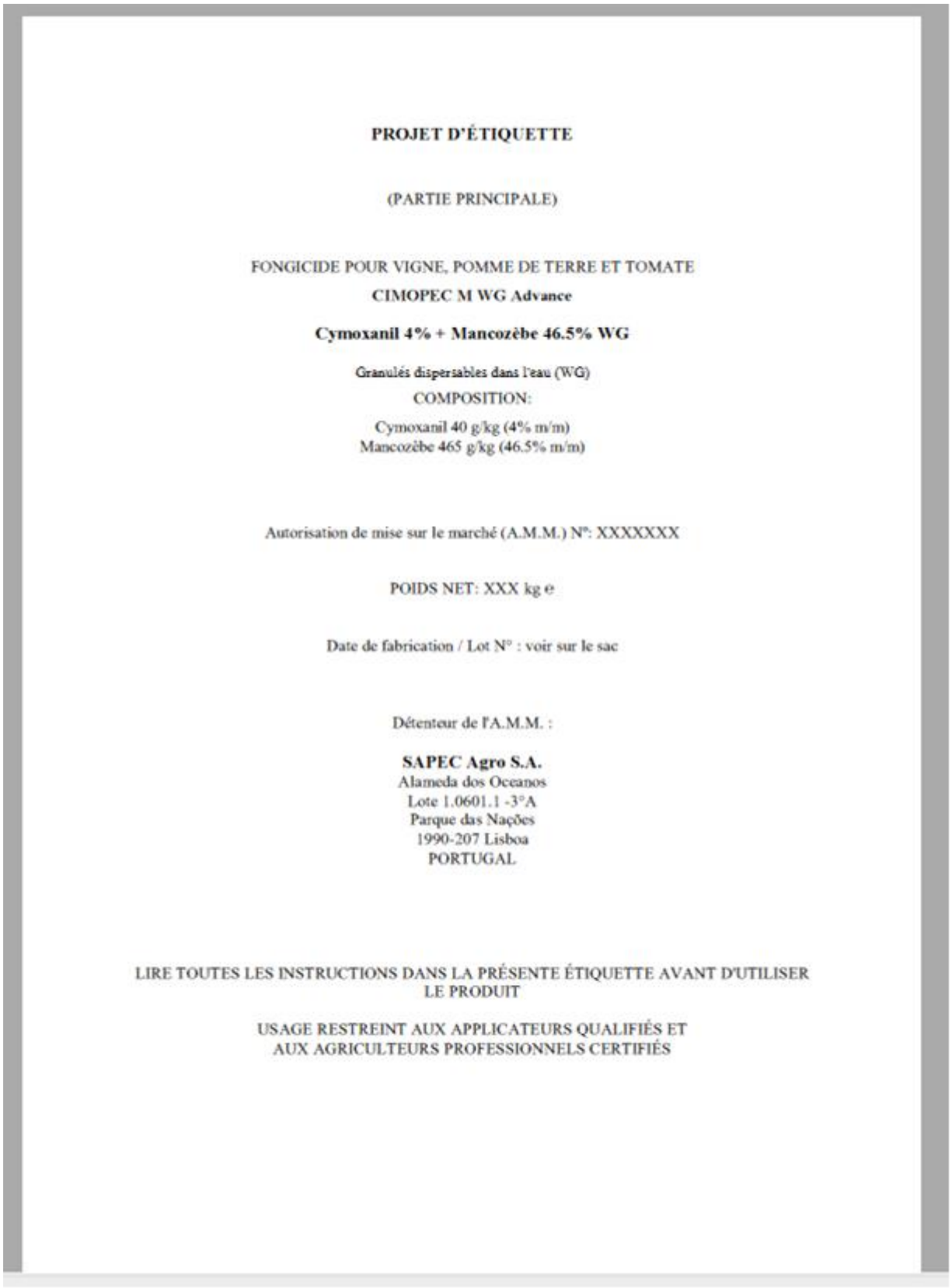
Appendix 2 – Copy of the draft product label as proposed by the applicant



PROJET D'ÉTIQUETTE

(PARTIE PRINCIPALE)

FONGICIDE POUR VIGNE, POMME DE TERRE ET TOMATE

CIMOPEC M WG Advance

Cymoxanil 4% + Mancozèbe 46.5% WG

Granulés dispersables dans l'eau (WG)

COMPOSITION:

Cymoxanil 40 g/kg (4% m/m)
Mancozèbe 465 g/kg (46.5% m/m)

Autorisation de mise sur le marché (A.M.M.) N°: XXXXXXX

POIDS NET: XXX kg e

Date de fabrication / Lot N° : voir sur le sac

Détenteur de l'A.M.M. :

SAPEC Agro S.A.
Alameda dos Oceanos
Lote 1.0601.1 -3°A
Parque das Nações
1990-207 Lisboa
PORTUGAL

LIRE TOUTES LES INSTRUCTIONS DANS LA PRÉSENTE ÉTIQUETTE AVANT D'UTILISER LE PRODUIT

USAGE RESTREINT AUX APPLICATEURS QUALIFIÉS ET AUX AGRICULTEURS PROFESSIONNELS CERTIFIÉS

(PARTIE GAUCHE)
ÉTIQUETTE DE SÉCURITÉ

Xn - Nocif

N- Dangereux pour l'environnement

CIMOPEC M WG Advance
Contient du cymoxanil et du mancozèbe. Peut déclencher une réaction allergique.

R36 **Irritant pour les yeux.**
R43 **Peut entraîner une sensibilisation par contact avec la peau.**
R63 **Risque possible pendant la grossesse d'effets néfastes pour l'enfant.**
R50/53 **Très toxique pour les organismes aquatiques, peut entraîner des effets néfastes à long terme pour l'environnement aquatique.**

S23 Ne pas respirer les aérosols.
S24/25 Éviter le contact avec la peau et les yeux.
S36/37 Porter un vêtement de protection et des gants appropriés.
S60 Éliminer le produit et son récipient comme un déchet dangereux.
S61 Éviter le rejet dans l'environnement. Consulter les instructions spéciales/la fiche de données de sécurité.

Respecter les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement.

Délai de rentrée : 48 h après traitement.

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* les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

SPe3 Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.

Fabriqué par : SAPEC AGRO S.A.
Avenida do Rio Tejo, Herdade das Praias, 2910-440 SETÚBAL, PORTUGAL
Tél. : +351 265 710 120

Fiche de données de sécurité disponible sur : www.quickfds.fr
En cas d'urgence, appelez le 15 ou le centre antipoison (Paris : 01 40 05 48 48) puis signalez vos symptômes au réseau **Phyt'attitude, n° vert 0 800 887 887** (appel gratuit depuis un poste fixe).

Les limites maximales de résidus sont consultables à l'adresse suivante :
http://ec.europa.eu/sanco_pesticides/public/index.cfm

Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur et aux recommandations des guides officiels des bonnes pratiques.
Consulter le site: http://e-phy.agriculture.gouv.fr

RECOMMANDATIONS EN CAS D'INTOXICATION OU D'ACCIDENT

Mesures de premiers secours

Éloigner la personne de la zone contaminée.
Enlever immédiatement les vêtements contaminés ou imprégnés avec le produit.
Rincer l'œil abondamment avec de l'eau pendant plusieurs minutes; ne pas oublier d'enlever les lentilles de contact.
Laver immédiatement et abondamment les zones contaminées avec de l'eau et du savon pendant plusieurs minutes.
Ne faire administrer aucune substance par voie orale.
En cas d'ingestion, NE PAS faire vomir.
Maintenir la victime au repos.
Maintenir le corps à la bonne température.
Contrôler le rythme respiratoire ; pratiquer la respiration artificielle si nécessaire.
Si la personne est inconsciente, l'allonger sur un côté, avec la tête en position plus basse que le reste du corps, et les genoux demi-fléchis.
Emmener la victime à l'hôpital et, si possible, apporter l'étiquette ou le contenant du produit pour le montrer au médecin.
NE JAMAIS LAISSER LA VICTIME SEULE.

Mesures pour diminuer les risques pendant les manipulations

L'opérateur doit porter des gants appropriés en nitrile et une protection respiratoire type A2P3 pendant la phase de préparation de la bouillie et lors du remplissage de la cuve. Il doit porter des gants, une protection respiratoire type A2P3 et une combinaison adaptée lors de l'application. Il est nécessaire de choisir une combinaison possédant un indice de protection au moins de type 4 lors des traitements sur les cultures de pommes de terre et de tomates.
Lors de l'utilisation d'appareils d'application manuels et/ou à dos dans les vignes et dans les parcelles de tomates (culture en plein champ), l'opérateur doit porter des gants appropriés et une protection respiratoire type A2P3 pendant la phase de préparation de la bouillie et de remplissage de la cuve du pulvérisateur. Il doit porter des gants, un masque de protection A2P3, une combinaison adaptée et des bottes en caoutchouc résistant aux produits chimiques lors de l'application.
Lors de l'utilisation d'appareils d'application manuels et/ou à dos dans des serres de tomates, l'opérateur doit porter des gants appropriés et une protection respiratoire type A2P3 pendant la phase de préparation de la bouillie et de remplissage de la cuve du pulvérisateur. Pendant l'application il doit s'équiper de gants, d'une combinaison imperméable adaptée aux produits chimiques et porter par-dessus une combinaison en coton, des bottes adaptées ainsi qu'une protection respiratoire de type A2P3.
Règle standard : ne pas rentrer dans les parcelles traitées tant que les dépôts de bouillie de traitement à la surface des feuilles n'ont pas complètement séché. Les travailleurs doivent porter des gants appropriés "protection chimique".

Gestion des emballages vides : Une fois le produit utilisé, son emballage vide devient un déchet dangereux. Rincer les emballages vides trois fois et verser l'eau de rinçage dans la cuve du pulvérisateur. Réutilisation ou incinération de l'emballage interdit.
Éliminer les emballages vides et les produits non utilisables en respectant la réglementation en vigueur et via les collectes organisées par les distributeurs partenaires de la filière ADIVALOR (consulter le site www.adivalor.fr ou appeler le 0810 12 18 85).

(PARTIE DROITE)

MODE D'EMPLOI

CARACTÉRISTIQUES

Le cymoxanil fait partie de la classe des fongicides azotés aliphatiques. Il agit par voie foliaire et est doté d'une action protectrice préventive et curative. Il possède une action de contact ainsi qu'une action systémique locale (action pénétrante), et inhibe également la sporulation des champignons.
Le mancozèbe appartient au groupe des fongicides dithio-carbamates. Il agit par contact et au niveau de plusieurs sites différents (action fongicide multi-sites).

La combinaison des deux fongicides [cymoxanil 4% + mancozèbe 46,5%] confère au mélange un large spectre d'action fongicide de contact et pénétrant avec en particulier une activité contre *Plasmopara viticola* en vigne et contre *Phytophthora infestans* pour les cultures de pommes de terre et de tomates.

LES DOSES ET LES CONSEILS D'UTILISATION

Appliquer en pulvérisation foliaire de façon à obtenir une bonne pénétration du produit et afin d'obtenir une couverture complète de toute les parties végétatives de la culture. Les traitements doivent être effectués au cours de périodes favorables à l'activité du champignon. Les cadences d'application et le nombre maximal de traitements par saison sont indiqués dans le tableau ci-dessous.

Les doses et les volumes de bouillie recommandés sont les suivants:

Culture	Cible	Dose homologuée	Volumes de bouillie	Nombre max. de traitements / an	Intervalles entre les traitements	Délai avant récolte
Vigne	Mildiou	3.0 kg/ha	100-1000 L/ha	5	7-12 jours	28 jours pour le raisin de table 56 jours pour le raisin destiné à la vinification
Pomme de terre	Mildiou	3.0 kg/ha	400-800 L/ha	5	7-10 jours	7 jours
Tomate	Mildiou	3.0 kg/ha	400-1000 L/ha	5	14 jours	3 jours pour les tomates fraîches, 28 jours pour les tomates destinées à l'industrie

Sur tomate, CIMOPEC M WG Advance peut s'utiliser en plein champ ou sous serre.

Préparation de la bouillie fongicide
Remplir la cuve du pulvérisateur avec ¾ du volume d'eau requis et mettre l'agitation en marche. Verser lentement la dose recommandée du produit à pulvériser dans la cuve du pulvérisateur tout en maintenant l'agitation pour obtenir un mélange homogène. Compléter la cuve avec la quantité d'eau nécessaire afin d'obtenir le volume requis. Ne pas préparer plus de bouillie qu'il n'est nécessaire.

Stades d'application
Vigne : traiter à partir du stade "8 feuilles étalées" et jusqu'au stade "début de la fermeture de la grappe" (BBCH 18 à 77)
Pomme de terre : traiter à partir du stade "5 feuilles étalées" et jusqu'au stade où les baies de la première infrutescence (tige principale) sont toujours vertes et où les graines sont claires (BBCH 15 à 81)
Tomate : traiter à partir du stade "2 feuilles étalées" et jusqu'au stade où 10% des fruits ont la coloration typique du fruit à maturité (BBCH 12 à 81)

Demandeur : SAPEC AGRO S.A.
Auteur: SAPEC AGRO, S.A.
Evaluator
Date

Stockage
Conserver le produit dans son emballage d'origine, dans un local fermé à clé, sec, frais et bien aéré.
Ne pas stocker la préparation à des températures extrêmes (éviter les températures inférieures à 0° C et supérieures à 35° C).
Stocker hors de portée des enfants.
Conserver à l'écart des aliments et boissons, y compris ceux destinés aux animaux.

RÉSISTANCE
Il existe un risque général d'apparition de maladies résistant aux fongicides. Afin de limiter ce risque, il convient de respecter les préconisations d'emploi de cette étiquette (dose, conditions d'application...) et, à chaque fois que c'est possible, de varier les substances chimiques et d'alterner avec des produits à mode d'action différent, tant au cours d'une saison culturale que dans la rotation.

AVERTISSEMENT: toutes les recommandations ci-dessus sont le résultat d'études approfondies et rigoureuses. Néanmoins, un certain nombre de facteurs hors de notre contrôle (mélange de produits, type et matériel d'application, climatologie, ...etc.) peuvent influencer les effets. La société garantit la composition, la formulation et le contenu de son produit. L'utilisateur sera tenu pour responsable de tout dommage causé (manque d'efficacité, toxicité d'une façon générale, résidus, etc.) en raison de l'inobservation totale ou partielle des instructions portées sur la présente étiquette du produit.

Demandeur : SAPEC AGRO S.A.
Auteur: SAPEC AGRO, S.A.
Evaluator
Date

Appendix 3 – Letter(s) of Access

MANCOZEB CONSORTIUM

600 13th Street, N.W.
Washington, D.C. 20005-3096

DOW AGROSCIENCES LLC

UNITED PHOSPHORUS LTD.

June 9, 2008

To Whom It May Concern

Re: Letter of Authorization For Indofil Chemicals Company to Rely On and Cite Certain additional Mancozeb Data and Information submitted by the Members of the Mancozeb European Consortium to address conditional listing of Mancozeb in Annex I as per commission directive 2005/72/EC dt. 22/10/2005

Dear Madam/Sir:

The Mancozeb Consortium consists of two companies, Dow AgroSciences, LLC, and Cerexagri, Inc. To achieve Annex I listing of Mancozeb, the Consortium and its members submitted mancozeb data and information including health, safety and use information (hereinafter collectively "Consortium Mancozeb Data and Information") to the Commission ("Commission") of the European Union ("EU") in response to certain EU directives and regulations including, but not limited to, Directive 91/414/EEC, and especially Commission Directive 2005/72/EC of 21 October amending Council directive 91/414/EEC. The Consortium has submitted additional Mancozeb Data and Information to address the conditions as listed in commission directive 2005/72/EC dt.22/10/2005.

The Consortium and its members have entered into a license agreement on April 7 Th 2006 with Indofil Chemicals Company ("Indofil"). Under the terms of that license, Indofil and its affiliates and customers are now hereby granted, solely for use in EU Member States, letters of access to rely on the Consortium Mancozeb Data and Information which had been submitted to the EU for the purpose of addressing conditional listing of Mancozeb in Annex I, The license granted to Indofil does not permit Indofil or its affiliates or customers to possess the Consortium Mancozeb Data and Information.

I trust that this letter is sufficient authorization to allow Indofil to rely on but not possess the aforementioned Mancozeb Data and Information in support of the registration and reregistration activities. If additional information or authorization is needed or should you have any questions, please contact me.

Very truly yours,

Edward M. Ruckert
Consultant to Mancozeb Consortium

WDC99 1577368-1.064967.0010

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.U.** Parque Empresarial Táctica, Calle Botiguers, nº 3, 4ª planta, 46980.Paterna (Valencia) Spain in **France**:

Sr. No.	Trade name	Reg. No.	Composition	Reg. Holder
1	POMBAL PLUS WG	To be assigned	Cymoxanil 2.67% + Fosetyl-Al 33.3% + Mancozeb 33.3% WG	SAPEC Agro, S.A.U. Parque Empresarial Táctica Calle Botiguers, nº 3, 4ª planta 46980.PATERNA (Valencia) Spain
2	CIMOPEC M WG Advance	To be assigned	Cymoxanil 4% + Mancozeb 46.5% 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 350806 Fax 0032 52 301135
BTW/TVA BE 0458.909.077
RPR/RPM Brussel/Bruxelles

Dr. Jacques Horsten
Global R & D Manager

INDOFIL INDUSTRIES LIMITED

CELEBRATING 50 Years

Ref. IIL/MCZ/FR/340
Date: May 8, 2012

To

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

Subject: Letter of access to Mancozeb protected data for plant protection products registration in France

Dear Sir/Madam,

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 manufacture and formulate Mancozeb in their plants in India, based on the following introductory statements:

- Indofil has signed a Mancozeb Data Access Agreement with Mancozeb Data Development Consortium which is owner of protected data as mentioned in Annex III of Review Report on active ingredient Mancozeb (SANCO/4058/2001 – Rev 4.4)
- The letter of authorization issued by Mancozeb Data Development Consortium, which entitle Indofil to extend access to all protected data in order to support all registrations owned by Indofil or Indofil's customers which contains Mancozeb of Indofil's origin, was already submitted.
- As per Review Report on active ingredient Mancozeb (SANCO/4058/2001/Rev4.4), Mancozeb produced by Indofil is identical to reference product mentioned in Review Report.
- The equivalence statement as per "Guidance Document on the Assessment of the Equivalence of Technical Materials of Substances Regulated under Council Directive 91/414/EEC" (SANCO/10597/2003 – Rev. 7 final 2 of 14 December 2005)" has also been submitted to rapporteur member state Italy.
- Pesticide Safety Directorate (Now Chemicals Regulation Directorate), UK on behalf of RMS Italy has evaluated the technical equivalence and confirmed the equivalence of INDOFIL's source of Mancozeb (manufactured at: Kolshet, Off Swami Vivekananda Road., Azad Nagar, Sandoz Baug P.O., Thane - 400 607 Maharashtra, India) with that of original notifiers.
- Italy, as the RMS has evaluated INDOFIL's additional manufacturing site of Mancozeb (Address: Plot No. Z7-1/Z8, SEZ Dahej Limited, SEZ Dahej, Taluka, Vagra, District Bharuch, Gujarat – 392 130, India) and concluded that mancozeb manufactured in the new site

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INDOFIL INDUSTRIES LIMITED

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Ref. IIL/MCZ/FR/340
Date: May 8, 2012

Dahej, India can be considered chemically equivalent to the Mancozeb source considered for Annex I inclusion.

On the merit of above Indofil wishes to extend the Mancozeb protected data access in support of the registrations mentioned in the enclosed Annexure 1, based on the condition the finished products will contain Mancozeb of Indofil sources:

This access is neither transferable nor sub-assignable and is granted only with respect to the application mentioned above. Any future application for registration of any other Mancozeb containing product will require a new letter of access.

This letter does not authorize SAPEC Agro, S.A.U., Spain or its affiliates to receive copies of studies or any other documents submitted by Indofil, nor does it authorize SAPEC Agro, S.A.U., Spain 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
Vice President - Strategy & International Business

CC: SAPEC Agro, S.A.U., Spain

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CELEBRATING 50 Years

Ref. IIL/MCZ/FR/340
Date: May 8, 2012

Annexure 1

Sr. No.	Trade name	Reg. No.	Composition	Reg. Holder
1	POMBAL PLUS WG	To be assigned	Cymoxanil 2.67% + Fosetyl-Al 33.3% +Mancozeb 33.3% WG	SAPEC Agro, S.A.U. Parque Empresarial Táctica Calle Botiguers, nº 3, 4ª planta 46980.PATERNA (Valencia) Spain
2	CIMOPEC M WG Advance	To be assigned	Cymoxanil 4% + Mancozeb 46.5% WG	

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INDOFIL
INDUSTRIES LIMITED

An ISO 9001 & 14001 Certified Company

Ref. IIL/CYM/FR/1407-19
Date: July 4, 2014

To

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

Subject: Letter of Access to Cymoxanil protected data in support of plant protection product, "CIMOPEC M WG Advance" in France.

Ref. CIMOPEC M WG Advance (n°2012-2574)

Dear Sir/Madam,

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 the access to studies as mentioned in enclosed **Appendix 1**, submitted for Indofil's plant protection product Moximate 505 WP (N° de dossier: 2011-6500) in France, in support of following registration application of **Sapec Agro S.A.**, Avenida do Rio Tejo – Herdade das Praias, 2910-440 Setubal, Portugal in France, with the condition that the finished product will contain Cymoxanil of Indofil source:

Sr. No.	Trade name	Composition	Reg. No.	Registration Holder
1	CIMOPEC M WG Advance	Cymoxanil 4% + Mancozeb 46.5% WG	To be assigned	Sapec Agro S.A, Portugal

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

This letter does not authorize Sapec Agro S.A., Portugal or its affiliates to receive copies of studies or any other documents submitted by Indofil nor does it authorize Sapec Agro S.A., 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

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INDOFIL INDUSTRIES LIMITED

An ISO 9001 & 14001 Certified Company

Ref. IIL/CYM/FR/1407-19
Date: July 4, 2014

Appendix 1

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

---------- End of the Appendix 1 ----------

INDOFIL INDUSTRIES LIMITED ITALY

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IIL/MCZ/FR/147-37
Date: July 4, 2014

To

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

Subject: Letter of Access to Mancozeb protected data in support of plant protection product, "CIMOPEC M WG Advance" in France.

Ref. CIMOPEC M WG Advance (n°2012-2574)

Dear Sir/Madam,

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 Mancozeb protected studies as mentioned in enclosed **Appendix 1**, post-submitted for our Manfil 80 WP (Amm no. 2040019) registration in France, in support of following registration application of **Sapec Agro S.A.**, Avenida do Rio Tejo – Herdade das Praias, 2910-440 Setubal, Portugal in France, with the condition that the finished product will contain Mancozeb of Indofil sources:

Sr. No.	Trade name	Composition	Reg. No.	Registration Holder
1	CIMOPEC M WG Advance	Cymoxanil 4% + Mancozeb 46.5% WG	To be assigned	Sapec Agro S.A, Portugal

Further, we would like to bring to your kind attention that the analytical method for the determination of Mancozeb residues in surface water is under development. We'll make the submission of the same in due course and provide its access to the aforementioned product by a separate access letter.

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

This letter does not authorize Sapec Agro S.A., Portugal or its affiliates to receive copies of studies or any other documents submitted by Indofil nor does it authorize Sapec Agro S.A., 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

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IIL/MCZ/FR/147-37
Date: July 4, 2014

APPENDIX 1

Author	Year	Title Reference/Report No. GLP or GEP status (where relevant) Published or unpublished	Data protection claimed Y/N	Owner
Meyer, M.	2009	Validation of analytical methods for the determination of residues of Mancozeb & ETU in Plant Materials Doc. No.: 432-013 GLP: Y, Published: No	Y	Indofil
Suresh, G.	2012	Independent Laboratory Validation for the Determination of Mancozeb residues in apple samples Doc. No.: 432-044 GLP: Y, Published: No	Y	Indofil
Suresh, G.	2012	Independent Laboratory Validation for the Determination of Mancozeb residues in bean samples Doc. No.: 432-045 GLP: Y, Published: No	Y	Indofil

---------- End of the Appendix 1 ----------

INDOFIL INDUSTRIES LIMITED ITALY

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