REGISTRATION REPORT

Part A

Risk Management

Product code: FAZ09

Product name(s): DAYCYM WP

Active Substance(s):

Cymoxanil, 40 g/kg

Mancozeb, 465 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: United Phosphorus Ltd. (UPL)

Date: 13/05/2016

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PART A – Risk Management

The company United Phosphorus Ltd. has requested marketing authorisation in France for the product DAYCYM WP (formulation code: FAZ09), containing 40 g/kg cymoxanil and 465 g/kg mancozeb 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 DAYCYM WP where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of DAYCYM WP have been made using endpoints agreed in the EU peer review of both cymoxanil and mancozeb.

This document describes the specific conditions of use and labelling required for France for the registration of DAYCYM WP.

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 United Phosphorus Ltd's application to market DAYCYM WP 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

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 Journal (2008) 167; 1-116). A Review Report is available (SANCO/179/08 – final rev. 1, 9 July 2010).

Mancozeb

Regulations 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.
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, 1 July 2009).

1.3 Regulatory approach

The present application (2012-1185) 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.

[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

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-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 DAYCYM WP, 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.

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

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	DAYCYM WP (FAZ09)
Authorisation number	2160204
Function	Fungicide
Applicant	United Phosphorus Ltd
Composition	40 g/kg cymoxanil 465 g/kg mancozeb
Formulation type (code)	Wettable powder (WP)
Packaging	Paper/ Polyethylene bag (12 kg)

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[8] to adjacent surface water bodies.

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment[9]: refer to the Decision in Appendix 1 for the details
Re-entry period[10]: 48 hours
Pre-harvest interval[11]: • Potatoes : 7 days
Other mitigation measures: Alternate the active substances with different modes of action. Agitation should be maintained during the application.
The label may include the following recommendations: The label must reflect the conditions of authorisation.

[8] 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]

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

[10] 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]

[11] 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, 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: 2016-05-13

PPP (product name/code)	**DAYCYM WP (FAZ09)**	**Formulation type:**	**WP**
active substance 1	**cymoxanil**	**Conc. of as 1:**	**40 g/kg**
active substance 2	**mancozeb**	**Conc. of as 2:**	**465 g/kg**
Applicant:	**United Phosphorus Ltd.**	**professional use**	☒
Zone(s):	**southern**	**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)**	**g as/hL min max**	**water L/ha min max**	**g as/ha min max**		
Grapes (wine and table grapes)	France		F	Downy mildew (*Plasmopara viticola*)	WP	cymoxanil 4% mancozeb 46.5%	Spraying	From 3rd leaves unfolded to berries ripening (BBCH 13 to 85)	4	7 - 10	C: 12 - 60 M: 139.5 - 697.5	200 – 1000	C: 120 M: 1395	28	**Not acceptable (risk for worker)**

Potatoes	France		F	Late blight (*Phytophthora infestans*)	WP	cymoxanil 4% mancozeb 46.5%	Spraying	From first basal side shoot visible to 50% of the leaves brownish (BBCH 21 to 95)	**6**	7 - 10	C: 10 - 50 M: 116.2 – 581.25	200 - 1000	C: 100 M: 1162.5	7	**PPP application rate : 2.5 kg/ha Acceptable for 6 applications to limit the risk of resistance**

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 FAZ09 (DAYCYM WP) is a wettable powder product (WP). All studies have been performed in accordance with the current requirements. The appearance of the formulation is blue to green powder. It is not explosive and has no oxidizing properties. It is not flammable and auto-flammable at ambient temperature. In aqueous solution at 1 %, its pH is 6.2 at 20°C. Stability data indicate a shelf life of at least 2 years at ambient temperature (Paper with HDPE inner layer). Its technical characteristics are acceptable for a WG formulation; nevertheless, a mention will be added in the label indicating that the agitation should be maintained during the application as required by the GAP.
The formulation is not classified for the physical-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 impurities in the formulation are available and validated.

3.1.2.2 Analytical methods for residues

Analytical methods are available in the monograph and in this dossier and validated for the determination of residues of mancozeb and cymoxanil in plants (matrices with high water content and acidic matrices), food of animal origin, soil, water (surface and drinking) and air.
To update the dossier, the following data are required post-authorisation:
- An analytical method and its ILV for the determination of residues of mancozeb in foodstuff of animal origin.
- An ILV for the determination of residues of cymoxanil in foodstuff of animal origin.
- A confirmatory method for the determination of residues of cymoxanil in foodstuff of animal origin.

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

DAYCYM WP (FAZ09) has a low toxicity in respect to acute oral, dermal, and inhalation route. It not skin irritant. However, it is classified for eye irritation and skin sensitisation.

3.1.3.2 Operator Exposure

Operator exposure was assessed against the AOEL agreed in the EU review (0.01 mg a.s./kg bw/d and 0.035 mg a.s./kg bw/d for cymoxanil and mancozeb, respectively).
The dermal absorption values used during the assessments are:
- 0.24% for non-diluted and diluted formulations for mancozeb,
- 0.3% and 23% for non-diluted and diluted formulations, respectively for cymoxanil.

Operator exposure was modelled using the German model. According to the model calculations, it can be concluded that the risk for the operator using DAYCYM WP on:

- Potatoes (boom sprayer), is acceptable with the use of gloves and working coverall during mixing-loading and application. The operator exposure represents 68.8% and 38% of mancozeb's AOEL and cymoxanil's AOEL, respectively.
- grape (air-assisted sprayer) is acceptable with the use of gloves and working coverall during mixing-loading and application. The operator exposure represents 42.9% and 83% of mancozeb's AOEL and cymoxanil's AOEL, respectively.
- grape (hand-held sprayer), is acceptable with the use of gloves working coverall during mixing-loading and application. The operator exposure represents 64.1% and 52% of mancozeb's AOEL and cymoxanil's AOEL, respectively.

A cumulative risk assessment has been performed using a tiered approach for both uses. The calculated hazard index (HI) are under 1 for potato and vines.

The applicant recommends the operators to wear:

For tractor-mounted boom sprayer:

- ***for mixing/loading***

- Gloves (nitrile, EN 374-3);
- Working coveralls 65% polyester / 35% cotton; minimum 230 g/m²; with water repellent treatment;
- Long-sleeved aprons of Category III Type 3;
- Respiratory protection: half-mask (EN 140) with a P3 filter (EN143) or A2P3 filter (EN 14387);
- Glasses or face shield (CE, EN 166 "sigle 3");

- **during application – low application**

If application with tractor without cab

- Working coveralls 65% polyester / 35% cotton; minimum 230 g/m²; with water repellent treatment;
- Disposable nitrile gloves during application and in the case of an intervention on application equipment (EN 374-2);
- When exposed to sprayed droplets, wear a half-mask particulate filter certified EN 149 or a half mask certified EN 140 with a particle filter P3 certified EN 143;

If application with tractor with a cab

- Working coveralls 65% polyester / 35% cotton; minimum 230 g/m²; with water repellent treatment;
- Disposable nitrile gloves (EN 374-2) in the case of an intervention on application equipment, but not inside the cab. In the case of an intervention on application equipment, it should be noted that gloves should be worn only outside the tractor cab and stored after use outside the cab;

- **for equipment cleaning**

- Gloves (nitrile, EN 374-3) ;
- Working coveralls 65% polyester / 35% cotton; minimum 230 g/m²; with water repellent treatment
- Long-sleeved aprons of Category III Type 3.
- Goggles or face shield certified EN 166 with frame marking 3.

3.1.3.3 Bystander Exposure

Calculation was performed with the calculations from the EUROPOEM II model. It was concluded that bystander exposure was low and did not exceed the AOEL for the intended use (worst-case: grapes; represents 2.2% and 17% of mancozeb's and cymoxanil's AOEL, respectively).

A cumulative risk assessment has been performed using a tiered approach for vine (worst case). The calculated hazard quotient (HQ) is under 1.

According to the model calculations, it can be concluded that the risk for the bystander for the intended use of DAYCYM WP is acceptable.

3.1.3.4 Worker Exposure

Worker exposure to DAYCYM WP was evaluated in grapes and potatoes. It was concluded that worker exposure in grapes did exceed the AOEL using a working coverall and gloves (166% and 5.7% of cymoxanil's and mancozeb's AOEL, respectively). Worker exposure for potatoes did not exceed the AOEL using a working coverall and gloves (12% and 0.4% of cymoxanil's and mancozeb's AOEL, respectively).
It is concluded that there is an unacceptable risk anticipated for the worker wearing working coverall and gloves in grapes and no unacceptable risk anticipated for the worker wearing working coverall and gloves in potatoes.

3.1.4 Residues and Consumer Exposure

3.1.4.1 Residues

Primary crop metabolisms were sufficiently investigated to define residue of cymoxanil and mancozeb for enforcement and risk assessment in crops under consideration.

Regarding the magnitude of residues in grapes and potatoes, a sufficient number of residue trials are available to support the intended GAPs in France and in Southern zone. These data allowed to estimate the expected residue concentrations in grapes and potatoes, and to confirm that no MRL exceedance will result from intended uses.

As residues of cymoxanil do not exceed the trigger value of 0.1 mg/kg in potatoes and grapes, there is no need to investigate the effect of industrial and/or household processing.
For mancozeb, studies showed that under pasteurization, sterilization and cooking processes mancozeb is converted into ethylenethiourea (ETU). In processed potatoes, level of mancozeb is below the LOQ. Transfer factors were calculated for ETU but they do not exceed the trigger value of 0.02 mg.kg.

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. Therefore, it can be concluded that there is still no need to propose residue definition for foods of animal origin as well as MRL.
For mancozeb, considering dietary burden and based on the intended and already authorized uses, significant intake above the trigger value of 0.1 mg/kg DM was calculated for livestock. According to livestock feeding studies, no residue level of mancozeb over the in force 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 that is above the current MRL of 0.05* mg/kg.

However, since:
- the review of the existing MRLs for mancozeb is ongoing in the frame 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 conduct to an unacceptable consumer exposure,

The intended uses can be considered as acceptable.

3.1.4.2 Consumer exposure

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

Chronic consumer exposure resulting from the uses assessed in the framework of this application was calculated for both active substances. Based on EFSA PRIMo (rev2), chronic and acute exposures were considered as 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 review 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 of cymoxanil and mancozeb 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 review or agreed in the assessment based on new data provided.
The results for PEC soil and PECsw for the active substances and their metabolites are used for the eco-toxicological risk assessment. One may note that mitigation measures are proposed in order to protect aquatic organisms (see section 6).
PECgw for cymoxanil and mancozeb 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 DT50 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

Birds

The risk assessment for birds is carried out according to the 'EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009)[12] and considering the EU agreed endpoints of cymoxanil and mancozeb.
The TER values, calculated for recommended scenarios, all exceed the trigger values of 10 for acute risk and 5 for long-term risk, indicating that the risk to birds[13] is acceptable following use of FAZ09 (DAYCYM WP) according to the proposed use patterns.

Terrestrial vertebrates (other than birds)

The risk assessment for mammals is carried out according to the EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009) and considering the EU agreed endpoints of cymoxanil, mancozeb and data on the formulation FAZ02.
The TER values, calculated for recommended scenarios, all exceed the trigger values of 10 for acute and 5 for long-term risk, thus indicating acceptable risk to mammals[12] from the proposed use of FAZ09.

3.1.6.2 Effects on Aquatic Species

The risk assessment for aquatic organisms is carried out according to the Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001) and considering the EU agreed endpoints of cymoxanil and mancozeb, their metabolites and data on the formulation FAZ02 and FAZ011 used as surrogate for FAZ09.

[12] European Food Safety Authority; Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA. EFSA journal 2009; 7(12):1438. [139 pp.]
[13] from direct dietary exposure, drinking water and secondary poisoning.

The TER values using worst-case PEC_{SW} values for cymoxanil and mancozeb, theirs metabolites exceed the relevant triggers, indicating that the risk to aquatic organisms is acceptable following use of FAZ09 (DAYCYM WP) according to the proposed use patterns with respect of:

- A buffer zone of 80 m for grapes,
- A buffer zone of 50 m for potatoes,

3.1.6.3 Effects on Bees and Other Arthropod Species

Bees

The risk assessment for bees is carried out according to the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002) and considering the EU agreed endpoints of cymoxanil and mancozeb and data on the formulation FAZ11 used as surrogate for FAZ09.

All the hazard quotients for cymoxanil, mancozeb and FAZ09 are less than 50, indicating that the risk to bees is acceptable following use of FAZ09 according to the proposed use pattern.

Other non-target arthropods

The risk assessment for non-target arthropods is carried out according to the Guidance Document ESCORT 2 and considering the EU agreed endpoints of the formulation FAZ11 used as surrogate for FAZ09.

A higher tier risk assessment has been conducted with the available extended laboratory studies conducted using FAZ11 with *Typhlodromus pyri, Aphidius rhopalosiphi* and *Aleochahra bilineata*. Based on these data an acceptable in-field risk to *A.bilineata* and *A. rhopalosiphi* can be concluded. However for *T. Pyri* the in-field foliar HQ values are above the trigger value for indicating that the risk to in-field non-target arthropods may not be acceptable following use of FAZ09 according to the proposed use pattern. Toxicity is driven by mancozeb for which effects are observed for the highly sensitive predatory mite species, *T. pyri* and not to other arthropods such as spiders, beetles, predatory heteroptera, or parasitic hymenoptera. The results of fields study with *T. pyri* from dossier DITHANE-45 showed that no adverse effects were observed. Therefore the risk for *T. pyri* and other non-target arthropods is considered acceptable.

The off-crop HQ values are below the trigger value indicating that the risk to off-crop non-target arthropods is acceptable following use of FAZ09 according to the proposed use patterns.

3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms

Earthworms

The risk assessment for bees is carried out according to the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002) and considering the EU agreed endpoints of cymoxanil, mancozeb, theirs metabolites and the formulation FAZ11 used as surrogate for FAZ09.

The acute and chronic TER values for FAZ09, cymoxanil, mancozeb and theirs metabolites are greater than the triggers of 10 and 5 respectively, indicating that the risk to earthworms is acceptable following use of FAZ09 according to the proposed use pattern.

3.1.6.6 Effects on Soil Non-target Micro-organisms

Cymoxanil and mancozeb are not expected to pose an unacceptable risk to other soil non-target macro-organisms following the recommended use of FAZ09, and no soil non-target macro-organisms studies are required.

3.1.7 Efficacy

The product complies with the Uniform Principles.

Considering the data submitted:

- on late blight of potato

- The efficacy of DAYCYM WP at 2.5 kg/ha is considered as satisfactory.

- The selectivity of DAYCYM WP at 2.5 kg/ha is considered as satisfactory.
- The risk of negative impact (yield, quality, propagation, succeeding crops, adjacent crops) is considered as negligible.
- The risk of resistance development or appearance is considered as low when the number of application is reduced to 6 and when the product is integrated in a program of disease control.

- on downy mildew of grape

- The efficacy of DAYCYM WP at 3 kg/ha is considered as satisfactory.
- The selectivity of DAYCYM WP at 3 kg/ha is considered as satisfactory.
- The risk of negative impact (yield, quality, propagation, succeeding crops, adjacent crops) is considered as negligible.
- The risk of resistance development or appearance is considered as medium. So measures of management are necessary. The one submitted by the applicant (4 applications max per season, use in a program of fungicide are acceptable and reduced the risk.

3.2 Conclusions arising from French assessment

Use in grape:

The exposure of worker is not acceptable.
Taking into account the above assessment, an authorisation cannot be granted as proposed in Appendix 1 – Copy of the product Decision.

Use in potato:

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

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

A survey of the resistance emergence of *Phytophthora infestans* to cymoxanil should be carried out by the applicant.

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 and its ILV for the determination of residues of mancozeb in foodstuff of animal origin.
- An ILV for the determination of residues of cymoxanil in foodstuff of animal origin.
- A confirmatory method for the determination of residues of cymoxanil in foodstuff of animal origin.

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 ***DAYCYM WP***

de la société *UPL France SAS*

enregistrée sous le *n°2012-1185*

Vu les conclusions de l'évaluation du 23 février 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.

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Informations générales sur le produit	
Nom du produit	DAYCYM WP
Type de produit	Produit de référence
Titulaire	UPL France SAS Energy Park, batiment 4, 5ème étage, 132-190 Boulevard de Verdun, 92400 Courbevoie FRANCE
Formulation	Poudre mouillable (WP)
Contenant	465 g/kg - mancozèbe 40 g/kg - cymoxanil
Numéro d'intrant	959-2012.01
Numéro d'AMM	2160204
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 qui arrivera à échéance le plus tôt. 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 13 MAI 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**
Sac double enveloppe en papier kraft / polyéthylène	12 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
15653201 Pomme de terre*Trt Part.Aer.*Mildiou(s)	**2,5 kg/ha**	**6/an**	entre les stades BBCH 21 et BBCH 95	7	50	-	-	
	- Respecter un intervalle de 7 à 10 jours entre 2 applications. - Le nombre d'applications accordé est limité à 6 en raison du risque de résistance.							

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	4/an	28
	Motivation du refus : L'usage est refusé en raison d'un risque inacceptable pour le travailleur.		

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Conditions d'emploi du produit

Stockage et utilisation du produit
Agiter énergiquement la bouillie contenant la préparation DAYCYM WP lors de l'application.

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 ;
- Protections respiratoires certifiées : demi-masque certifié (EN 140) équipé d'un filtre P3 (EN143) ou A2P3 (EN 14387) ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3).

- **Pendant l'application**

Si application avec tracteur avec cabine
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;

Si application avec tracteur sans cabine
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;
- En cas d'exposition aux gouttelettes pulvérisées, porter un demi-masque filtrant à particules (EN 149) ou un demi-masque (EN 140) équipé d'un filtre à particules P3 (EN 143).

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

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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.

Gestion des résistances
Alterner les substances actives à modes d'action différents.

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 d'analyse validée et sa Validation Inter-laboratoires (ILV) pour la détermination des résidus de mancozèbe dans les denrées d'origine animale. - une ILV pour la détermination des résidus de cymoxanil dans les denrées d'origine animale. - une méthode de confirmation de la méthode de détermination des résidus de cymoxanil dans les denrées d'origine animale.	24	-
Poursuivre le plan de surveillance des apparitions de résistance du mildiou de la pomme de terre au cymoxanil. Tout changement par rapport au contexte de résistance actuel devra être communiqué aux autorités compétentes.	-	-

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

DAYCYM WP

Fongicide pénétrant Vigne, Pomme de Terre et tomate

COMPOSITION :
40 % cymoxanil, 46,5 % de Mancozèbe

TYPE DE FORMULATION :
Poudre mouillable (WP)

HOMOLOGATION :

Xn – nocif

R36/37 : Irritant pour les yeux et les voies respiratoires.
R43 : Peut entraîner une sensibilisation par contact avec la peau.
R50/53 : Très toxique pour les organismes aquatiques, peut entraîner des effets néfastes à long terme pour l'environnement aquatique.
R63 : Risque possible pendant la grossesse d'effets néfastes pour l'enfant.

Délai minimum de réentrée des travailleurs sur la parcelle : 48 heures après la fin de la pulvérisation.

N-DANGEREUX POUR L'ENVIRONNEMENT

S2 : Conserver hors de la portée des enfants.
S8 : Conserver le récipient à l'abri de l'humidité.
S3/9/49 : Conserver uniquement dans le récipient d'origine dans un endroit frais et bien ventilé.
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.
S24/25 : Eviter le contact avec la peau et les yeux.
S26 : En cas de contact avec les yeux, laver immédiatement et abondamment avec de l'eau et consulter un spécialiste.
S36/37 : Porter un vêtement de protection approprié et des gants appropriés.
S46 : En cas d'ingestion, consulter immédiatement un médecin et lui montrer l'emballage ou l'étiquette.
S60 : Eliminer le produit et son récipient comme un déchet dangereux.
S61 : Eviter le rejet dans l'environnement. Consulter les instructions spéciales/la fiche de donnée de sécurité.

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

SP1 – Ne pas polluer l'eau avec le produit ou son emballage. [Ne pas nettoyer le matériel d'application près des eaux de surface. Eviter la contamination via 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 20 mètres par rapport aux points d'eau.

En cas d'urgence, appelez le 15 ou le centre anti-poison puis signalez vos symptômes au réseau Phyt'attitude, numéro vert 0 800 887 887 (appel gratuit depuis un poste fixe).

La Fiche de Données de Sécurité peut être obtenue sur simple demande auprès de Cerexagri ou sur Internet à l'adresse suivante : www.quickFDS.com

USAGES ET DOSES D'EMPLOI HOMOLOGUES : (traitement des parties aériennes)

Culture/organisme nuisible	Dose	Nombre maximal d'applications/an	Délai avant récolte (DAR)	Zone non traitée (ZNT)
Vigne / mildiou (*Plamopara viticola*)	3 kg/ha	4	28 jours	20 m
Pomme de terre/mildiou (Phythopththora infestans)	2,5 kg/ha	8	7 jours	20 m
Tomate	2.5 kg/ha	5	3 consommation 10 industrie	20 m

MODE D'UTILISATION :

- **Mise en œuvre**

DAYCYM WP s'emploie aussi bien en pulvérisation mécanique qu'en pulvérisation pneumatique

1) Remplir à moitié d'eau la cuve du pulvérisateur.
2) Agiter le bidon et verser dans le pulvérisateur la quantité du produit nécessaire.
3) Mettre en agitation et compléter avec de l'eau.
4) Maintenir l'agitation pendant le traitement.
5) Utiliser le mélange immédiatement après sa préparation.

Lors de l'emploi :

Porter des gants et un vêtement de protection appropriés et un appareil de protection des yeux et du visage approprié pendant les opérations de mélange, de chargement et d'application.

En cas de projections accidentelles, se laver immédiatement. En cas d'irritation ou de malaise, appeler un médecin.
Ne pas traiter si présence de vent.
Eviter toute contamination de l'eau, spécialement celle liée à la dérive due au vent.

Après emploi :

Nettoyer le pulvérisateur avant et après le traitement.
Après utilisation, rincer abondamment les tuyauteries, jets et appareils de pulvérisation.

Vider et éliminer les emballages en respectant la réglementation.
Ne pas déverser les reliquats de produits et les eaux de rinçage dans les fossés, laes mares, les égouts ou les cours d'eau.
Eliminer les fonds de cuve conformément à la règlementation en vigueur.
Pour l'élimination des produits non utilisables, faire appel à une entre prise habilitée pour la collecte et l'élimination des produits dangereux.

- **Recommandations**

Destiné à combattre le mildiou de la pomme de terre de la tomate et de la vigne, DAYCYM WP doit être appliqué en fonction des recommandations des Avertissements Agricoles en respectant les stades préconisés dans le tableau ci-dessus.

DAYCYM WP peut être utilisé dans le cadre d'un programme préventif ou curatif à la dose de 2,5 kg/ha sur pomme de terre et tomate ou 3 kg/ha sur vigne durant toute la période

végétative… Les traitements devront être appliqués en cadence de 7-10 jours, à adapter selon lac climatologie. La culture doit être ainsi protégée jusqu'à la destruction du feuillage. Il est conseillé de traiter par temps calme et lorsque le feuillage est sec. Eviter les situations de stress hydrique, les périodes de fortes amplitudes thermiques, des températures trop froides ou trop chaudes. Reporter le traitement si des pluies sont prévues dans les deux heures après l'application. DAYCYM WP doit être pulvérisé de façon homogène. Veiller à bien régler le pulvérisateur afin d'éviter toute dérive ainsi que les phénomènes de surdosage.

DAYCYM WP est un fongicide pénétrant qui contient du cymoxanil ce qui lui confère une action de rattrapage, durant la période d'incubation du mildiou, avant la sorite des taches de mildiou et au maximum dans les 48 heures suivant une pluie contaminatrice.

DAYCYM WP peut être appliqué sur raisin de cuve jusqu'à 4 semaines avant vendanges, la préparation ne générant pas d'effet sur les fermentations ni sur les qualités organoleptiques des vins à la dose préconisée. Sur raisin de table les applications seront arrêtées à partir de la nouaison pour éviter le marquage des baies.

Par précaution, il est conseillé de ne pas construire de programmes anti-mildiou s'appuyant uniquement sur des préparations à base de cymoxanil. Se référer aux actualisations annuelles des recommandations officielles (Ex : Note nationale mildiou de la vigne). Utiliser de préférence en conditions préventives et éviter de traiter en présence de taches de mildiou sporulantes.

Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur et aux recommandations des guides de bonnes pratiques officiels. Pour plus d'information, consulter le site : http//e-phy.agriculture.gouv.fr/

Dans tous les cas, il est recommandé d'effectuer des tests préalables de compatibilité physique.

STOCKAGE :

Ce produit doit être conservé dans son emballage d'origine fermé, à l'abri de la chaleur et du gel, dans des locaux frais et ventilés.

EMBALLAGE :

Réemploi de l'emballage interdit. Bien le vider et l'éliminer via les collectes organisées par les distributeurs partenaires de la filière ADIVALOR.

IMPORTANT :

Respectez les usages, doses, conditions et precautions d'emploi mentionnes sur l'emballage qui ont ete determines 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 facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces …

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

Détenteur de l'AMM :

12 KG

Appendix 3 – Letter(s) of Access

INDOFIL INDUSTRIES LIMITED

An ISO 9001 & 14001 Certified Company

Date: June 19, 2014
Ref.: IIL/MCZ/EU/1461

TO WHOM IT MAY CONCERN

Sub: Letter of Access for Mancozeb protected studies supporting Mancozeb based registrations of Cerexagri-UPL in the EU.

Dear Sir/Madam,

Indofil Industries Limited (Indofil), 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 and **Cerexagri S.A.S.**, Energy Park, Batiment 4, 5ème étage,132-190 Boulevard de Verdun, F-92400 Courbevoie, France (owned by United Phosphorus Ltd) (Cerexagri-UPL) have entered an agreement to form "The EU Mancozeb Task Force" for the purpose of obtaining and maintaining registrations of Mancozeb in the EU. With this agreement both the parties have accepted to jointly develop or acquire tests, studies or any other information in support of their registrations in the EU.

Under the provision of the agreement, Indofil allows Cerexagri-UPL to cite & refer the studies mentioned in the enclosed Appendix 1, owned by Indofil in support of Mancozeb based registrations & business of Cerexagri-UPL and its Affiliates and its third party customers in the EU.

In addition to this, Cerexagri-UPL may allow its affiliates and its third party customers to reference the study as mentioned in the Appendix 1 in order to maintain and obtain their registrations of plant protection products containing Mancozeb in the EU, produced by and purchased from Cerexagri-UPL.

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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