REGISTRATION REPORT

Part A

Risk Management

Product code: Cymoxanil 6% + Mancozeb 70% WP

Product name(s): MICEXANIL

Active Substance(s):

Cymoxanil, 60 g/kg

Mancozeb, 700 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: OXON Italia S.p.A

Date: 22/07/2016

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PART A – Risk Management

The company OXON Italia S.p.A has requested marketing authorisation in France for the product MICEXANIL (formulation code: Cymoxanil 6% + Mancozeb 70% WP), containing 60 g/kg cymoxanil and 700 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 MICEXANIL where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of MICEXANIL have been made using endpoints agreed in the EU peer reviews of both cymoxanil and mancozeb.

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

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 OXON Italia S.p.A's application to market MICEXANIL 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 Scientific Report (2008) 167, 1-116). A Review Report is available (SANCO/179/08 - final rev 1, 9 July 2010).

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.
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).

1.3 Regulatory approach

The present application (2012-1105) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)[1] in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[2] – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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

[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

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" 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 MICEXANIL, 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 letters 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)	MICEXANIL (Cymoxanil 6% + Mancozeb 70% WP)
Authorisation number	2150441
Function	Fungicide
Applicant	OXON Italia S.p.A
Composition	Cymoxanil 60 g/kg Mancozeb 700 g/kg
Formulation type (code)	Wettable powder (WP)
Packaging	polyester / aluminium / polyethylene (5 kg) polyester/adhesive/polyethylene (1 kg) paper/polyethylene bags (4.5 kg, 5 kg, 10 kg, 20 kg, 25 kg) paper (kraft) (1.5 kg)

2.2 Classification and Labelling

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

Physical hazards	-	
Health hazards	Sensitisation — Skin, Hazard Category 1 Reproductive toxicity, Hazard Category 2	
Environmental hazards	Hazardous to the aquatic environment — Acute Hazard, Category 1 Hazardous to the aquatic environment — Chronic Hazard, Category 2	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H317	May cause an allergic skin reaction.
	H361fd	Suspected of damaging fertility. Suspected of damaging the unborn child.
	H400	Very toxic to aquatic life
	H411	Toxic to aquatic life with long lasting effects
Precautionary statements –	***For the P phrases, refer to the extant legislation***	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	-	-

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

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

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 50 metres to surface water bodies[8]
Spa 1	To avoid the build-up of potato blight resistance do not apply this preparation or any other product containing cymoxanil or active substance having the same mode of action, more than 6 applications/crop/season on potatoes.

[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]

2.2.3 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]:	Potato: 7 days
The label must reflect the conditions of authorisation.	

[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, 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.

GAP rev. 1, date: 2015-07-22

PPP (product name/code):	MICEXANIL (Cymoxanil 6% + Mancozeb 70% WP)	Formulation type:	WP [a, b]
Active substance 1:	cymoxanil	Conc. of a.s. 1:	60 g/kg [c]
Active substance 2:	mancozeb	Conc. of a.s. 2:	700 g/kg [c]
Applicant:	Oxon Italia S.p.A	Professional use:	☒
Zone(s):	southern EU[d]	Non professional use:	☐
Verified by MS:	yes		
Field of use:	fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	FR	Potato	F	*Phytophthora infestans*	Overall spraying	BBCH 21-85	6 (7 days)	a) 1.5-2 kg/ha b) 9-12 kg/ha	a) 0.09-0.12 CYM 1.05-1.4 MZ b) 0.54-0.72 CYM 6.3-8.4 MZ	200-400	7	No sufficient data to support 2 kg/ha
1	FR	Potato	F	*Phytophthora infestans*	Overall spraying	BBCH 21-85	6 (7-10 days)	a) 1.7 kg/ha b) 10.4 kg/ha	b) 0.102 CYM 1.19 MZ b) 0.612 CYM 7.14 MZ	200-400	7	Reduction of the dose rate to 1.7 kg/ha (in reference to the similar preparations registered in France)

1	2	3	4	5	6	7	8	9	10	11	12	13
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
2	FR	Grape	F	*Plasmopara viticola, Guignardia bidwelli*	Overall spraying	BBCH 11-85	~~5~~ 4 (7 days)	a) 2 kg/ha b) 8 ~~10~~ kg/ha	a) 0.12 CYM 1.4 MZ b) 0.48 ~~0.6~~ CYM 5.6 ~~7.0~~ MZ	200-350	28	**Not acceptable (cumulative risk for workers)** Reduction of the number of application (in reference to the similar registered preparation)

CYM: cymoxanil, MZ: mancozeb

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 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 Cymoxanil 6% + Mancozeb 70% WP (MICEXANIL) is a wettable powder (WP). All studies have been performed in accordance with the current requirements. The appearance of the formulation is a homogeneous yellow powder with a characteristic odour. It is not explosive and has no oxidising properties. It has a self-ignition temperature of 375 °C but is not highly flammable at ambient temperature. In aqueous solution (at 1 %), its pH is 6.7 at room temperature. Stability data indicate a shelf life of at least 2 years at ambient temperature (polyester/aluminium/polyethylene). Its technical characteristics are acceptable for a WP formulation.

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

The final report of the ongoing two-year shelf-life study should be provided post-authorisation

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 (ethylene thiourea [ETU]) in the formulation are available and validated.

3.1.2.2 Analytical methods for residues

Analytical methods are available in the monograph (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, acidic matrices), food of animal origin, soil, water (surface and drinking) and air.
Nevertheless, the following data should be provided in post-authorisation:

- An analytical method and its ILV for the determination of residues of cymoxanil in foodstuffs of animal origin
- A confirmatory method for the determination of cymoxanil in soil.
- A confirmatory analytical method for the determination of mancozeb in water (surface and drinking)

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

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

MICEXANIL (Cymoxanil 6% + Mancozeb 70% WP), containing 60g/kg of cymoxanil and 700 g/kg of mancozeb, has a low acute oral and dermal toxicity, a low acute toxicity by inhalation, and is not irritating to the rabbit eye and skin. It has been found to be a dermal sensitiser.

3.1.3.2 Operator Exposure

Operator exposure for the grape and potato uses has been assessed with the BBA model against the AOEL of 0.01 mg/kg bw/d for cymoxanil and 0.035 mg/kg bw/d for mancozeb.

The dermal absorption values of cymoxanil used for risk assessment are 1 and 19 % for the undiluted and diluted respectively (based on an in vitro study on human and rat skin and an in vivo study on rat undertaken with a similar formulation).

The dermal absorption values of mancozeb used for risk assessment are 0.11 % and 0.24 % for the undiluted and diluted (based on an in vivo study on rat undertaken with a similar formulation).

The risk for the operator using MICEXANIL on potato is acceptable with a tractor mounted/trailed boom sprayer: hydraulic nozzles, with a working coverall and gloves during the mix/loading and application phase (82 % and 42 % of mancozeb's AOEL and cymoxanil's AOEL respectively).

The risk for the operator using MICEXANIL on grape is acceptable with a tractor mounted/trailed broadcast air assisted sprayer, with a working coverall and gloves during the mix/loading and application phases (43 % and 71 % of mancozeb's AOEL and cymoxanil's AOEL respectively).

3.1.3.3 Bystander Exposure

The bystander exposure for the potato use represents 1 % of mancozeb's AOEL and 1.8 % of cymoxanil's AOEL. The risk is considered acceptable.

The bystander exposure for the grape use represents 2.3 % of mancozeb's AOEL and 14.3 % of cymoxanil's AOEL. The risk is considered acceptable.

3.1.3.4 Worker Exposure

The worker exposure to potato represents 0.5 % of mancozeb's AOEL and 11 % of cymoxanil's AOEL with a working coverall and gloves. The risk for workers is considered acceptable.

The worker exposure to vine represents 6 % of mancozeb's AOEL and 137 % of cymoxanil's AOEL with a working coverall and gloves. The risk for workers is considered unacceptable.

The applicant recommends the operators to wear a working coveralls 65 % polyester / 35 % cotton; minimum 230 g/m²; with water-repellent treatment. It should also be recommended to wear gloves (nitrile, EN 374-3) in cases where there will be contact with the treated crop.

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 in crops under consideration.

Regarding the magnitude of residues, a sufficient number of residue trials are available to support the intended GAPs in France. These data allow it to be considered that residue levels above the extant MRLs for wine grapes, table grapes and potatoes will not result from the 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. As for mancozeb, a hydrolysis study showed that under pasteurisation, sterilisation and cooking processes mancozeb is converted into ETU. Magnitude of residue

studies showed that wine processing 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 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 dietary burden and based on the intended and already authorized uses, significant intake above the trigger value of 0.1 mg/kg dry matter (dm) 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 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 conduct to an unacceptable consumer exposure,

the intended uses can be considered acceptable.

3.1.4.2 Consumer exposure

The toxicological profile 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 context 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 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, and mitigation measures are proposed.

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

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review for active substances and their metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Based on the guidance documents, the risks for birds, mammals, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms are acceptable for the intended uses.

For aquatic organisms, the risks for use on grape and potato are acceptable when a buffer zone of 50 metres is applied.

3.1.6.1 Effects on Terrestrial Vertebrates

3.1.7 Efficacy

- ✓ **Downy mildew of grapevine (*Plasmopara viticola*)**

After evaluation, it was concluded that submitted data on efficacy and adverse or unintended side effects are generally in compliance with the Uniform Principles.

The proposed dose rate of the preparation “60 g/kg of cymoxanil + 700 g/kg of mancozeb (WP)” (MICEXANIL) against *P. viticola* of grapevine is 1.6-2 kg/ha. In France, the requested dose is 2 kg/ha. Moreover, the dose rate of registered products in France containing “60 g/kg of cymoxanil + 700 g/kg of mancozeb (WP)” is 2 kg/ha to control of P. viticola of grapevine. Based on the above, the zRMS suggests that 2 kg/ha is the minimum effective dose.

The recommended maximum number of applications is 4 (instead of the 5 requested), with an interval of 7-10 days.

No adverse effects on the quality of plant and plant products, on the processing procedure and on the yield of treated plants and plant products are expected when “60 g/kg of cymoxanil + 700 g/kg of mancozeb (WP)” is used according to the proposed GAP.

No symptoms of phytotoxicity, no adverse effects on parts of plant used for propagating purposes, no impact on succeeding crops and on other plants, including adjacent crops, are expected when “60 g/kg of cymoxanil + 700 g/kg of mancozeb (WP)” is used according to the proposed GAP.

Resistance: The maximum number of applications per cropping season as defined in the intended GAP, should be considered by the different Member States (MSs). The number of applications of registered products in France containing 60 g/kg of cymoxanil + 700 g/kg of mancozeb is limited to maximum 4 applications to control *P. viticola* of grapevine. Based on the above, the zRMS suggests a reduction of the maximum number of applications (from 5 to 4), considering that fewer applications per cropping season should be applied.

Moreover, to prevent the risk of resistance development, the applicant must continue the present monitoring and communicate any changes of the current context of resistance to the competent authorities.

As no data were provided to demonstrate that the preliminary trials were undertaken in situations with characterised resistance, two years' trials results must be submitted to demonstrate the curative action of cymoxanil.

- ✓ **Black rot of grapevine (*Guignardia bidwelli)***

After evaluation, it was concluded that submitted data on efficacy and adverse or unintended side effects are generally in compliance with the Uniform Principles.

The proposed dose rate of the product "60 g/kg of cymoxanil + 700 g/kg of mancozeb (WP)" against *G. bidwelli* on grapevine is 2 kg/ha. The recommended maximum number of applications is 4 (instead of the 5 requested), with an interval of 7 days.

No adverse effects on the quality of plant and plant products, on the processing procedure and on the yield of treated plants and plant products are expected when "60 g/kg of cymoxanil + 700 g/kg of mancozeb (WP)" is used according to the proposed GAP. No symptoms of phytotoxicity, no adverse effects on parts of plant used for propagating purposes, no impact on succeeding crops and on other plants including adjacent crops are expected either.

Resistance: The maximum number of applications per cropping season as defined in the intended GAP, should be considered by the different MSs. The number of applications of registered products in France containing 60 g/kg of cymoxanil + 700 g/kg of mancozeb is limited to maximum 4 applications to control *G. bidwelli*. Based on the above, the zRMS suggests reduction of the maximum number of applications, (from 5 to 4), considering that fewer applications per cropping season should be applied.

Moreover, to prevent the risk of resistance development, the applicant must continue the present monitoring and communicate any changes of the current context of resistance to the competent authorities.

- ✓ **Late blight of potato (*Phytophthora infestans*)**

After evaluation, it was concluded that submitted data on efficacy and adverse or unintended side effects are generally in compliance with the Uniform Principles.

The proposed dose rate of the product "60 g/kg of cymoxanil + 700 g/kg of mancozeb (WP)" against *P. infestans* on potato is 1.7 kg/ha (instead of 1.5-2 kg/ha). In France, the dose rate of registered products containing 60 g/kg of cymoxanil + 700 g/kg of mancozeb is 1.7 kg/ha to control of *P. infestans* on potato. Based on the above, the zRMS suggests that 1.7 kg/ha is the minimum effective dose.

The recommended maximum number of applications is 6, with an interval of 7 days.

No adverse effects on the quality of plant and plant products, on the processing procedure and on the yield of treated plants and plant products are expected when "60 g/kg of cymoxanil + 700 g/kg of mancozeb (WP)" is used according to the proposed GAP. No symptoms of phytotoxicity, no adverse effects on parts of plant used for propagating purposes, no impact on succeeding crops and on other plants including adjacent crops are expected either.

Resistance: The maximum number of applications per cropping season as defined in the intended GAP, should be considered by the different MSs. The number of applications of registered products in France containing 60 g/kg of cymoxanil + 700 g/kg of mancozeb is limited to a maximum of 6 applications to control *P. infestans* on potato. Moreover, to prevent the risk of resistance development, the applicant must implement risk-management measures and monitor *P. infestans* on potato and communicate any change of the current context of resistance to the competent authorities.

Conclusion for France

Crops	Maximum application rate per treatment	Maximum number of application per use	Maximum number of application per crop	Conclusion for efficacy section	Remarks
Potato * *Phytophthora infestans*	1,5 - 2 kg/ha **(Reduction to 1.7 kg/ha for France)**	**6**	**6**	**Acceptable**	Reduction of the dose rate to 1.7 kg/ha (in reference to the similar registered product SARMAN M WP)
Table and wine grape * *Plasmopara viticola*	1,6 - 2 kg/ha (2 kg/ha for France)	~~5~~ **4**	~~5~~ **4**	**Acceptable**	Reduction of the number of applications (with reference to the similar registered product SARMAN M WP) Post-authorisation data on the usefulness of cymoxanil
Table and wine grape * *Guignardia bidwelli*	2 kg/ha	~~5~~ **4**	~~5~~ **4**	**Acceptable**	Reduction of the number of applications (with reference to the similar registered product SARMAN M WP)

3.2 Conclusions arising from French assessment

Use in potatoes:
Taking into account the above, an authorisation can be granted as proposed in Appendix 1 – Copy of the product decision.

Use in grapes: The cumulative risk to workers is not acceptable.
Taking into account the above, an authorisation cannot 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

It will be necessary to establish or continue:

- the monitoring of resistance to *Phytophthora infestans* of potato.

Any new information likely to modify the assessment of risk of resistance must be provided to the competent authorities, for all uses.

3.4.2 Post-authorisation data requirements

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

- The final report of the two-year shelf-life study at ambient temperature.
- An analytical method and its ILV for the determination of cymoxanil residues in foodstuffs of animal origin.
- A confirmatory method for the determination of cymoxanil in soil.
- A confirmatory analytical method for the determination of mancozeb in water (surface and drinking).

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 new elements 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 ***MICEXANIL***

de la société *OXON ITALIA SPA*

enregistrée sous le *n°2012-1105*

Vu les conclusions de l'évaluation du 22 mai 2015,

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.

MICEXANIL
AMM n°2150441

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Informations générales sur le produit	
Nom du produit	MICEXANIL
Type de produit	Produit de référence
Titulaire	OXON ITALIA SPA Via Sempione 195 20016 PERO ITALIE
Formulation	Poudre mouillable (WP)
Contenant	60 g/kg - cymoxanil 700 g/kg - mancozèbe
Numéro d'intrant	978-2012.01
Numéro d'AMM	2150441
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 22 JUIL. 2016

Le Directeur Général

Roger GENET

MICEXANIL
AMM n°2150441

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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**
Sacs en papier (kraft)	1,5 kg
Sacs en papier / polyéthylène basse densité	4,5 kg - 5 kg - 10 kg - 20 kg - 25 kg
Sacs en polyester / adhésif / polyéthylène basse densité	1 kg
Sachets en polyester / aluminium / polyéthylène basse densité	5 kg

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	**Mention de danger**
Toxicité pour la reproduction, catégorie 2	H361fd : Susceptible de nuire à la fertilité. Susceptible de nuire au fœtus
Sensibilisation cutanée, catégorie 1	H317 : Peut provoquer une allergie cutanée
Dangers pour le milieu aquatique - Danger aigu, catégorie 1	H400 : Très toxique pour les organismes aquatiques
Dangers pour le milieu aquatique - Danger chronique, catégorie 2	H411 : Toxique pour les organismes aquatiques, entraîne des effets 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)	**1,7 kg/ha**	**6/an**	entre les stades BBCH 21 et BBCH 85	7	50	-	-	-
	- Intervalle entre les applications : 7 - 10 jours. - Le nombre d'applications de la préparation et de toute autre préparation à base de substance active ayant le même mode d'action que le cymoxanil est limité à 6 applications maximum par campagne et par culture.							

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12703206 Vigne*Trt Part.Aer.*Black rot	2 kg/ha	4/an	28
	Motivation du refus : Les risques sanitaires pour les travailleurs sont considérés comme inacceptables.		
12703203 Vigne*Trt Part.Aer.*Mildiou(s)	2 kg/ha	4/an	28
	Motivation du refus : Les risques sanitaires pour les travailleurs sont considérés comme inacceptables.		

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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

- **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).

- **Pendant l'application - Pulvérisation vers le bas (pulvérisateur à rampe)**

  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.

Pour le travailleur, porter

Une combinaison de travail (cotte en coton/polyester 35 %/65 % - grammage d'au moins 230 g/m²) avec traitement déperlant et, en cas de contact avec la culture traitée, des gants en nitrile certifiés EN 374-3.

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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

Spa 1 : Pour éviter le développement de résistances du mildiou de la pomme de terre à la substance active cymoxanil, le nombre d'applications de la préparation et de toute autre préparation à base de substance active ayant le même mode d'action est limité à 6 applications maximum par campagne et par culture.

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 le rapport final de l'étude en cours de réalisation concernant la stabilité au stockage pendant 2 ans, à température ambiante.	24	-
Fournir une méthode et sa validation inter-laboratoires pour la détermination des résidus du cymoxanil dans les denrées d'origine animale.	24	-
Fournir une méthode de confirmation pour la détermination des résidus de cymoxanil dans le sol.	24	-
Fournir une méthode de confirmation pour la détermination du mancozèbe dans l'eau (de surface et de boisson).	24	-
Mettre en place un 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.	-	-

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

MICEXANIL®

FONGICIDE PENETRANT VIGNE et POMME DE TERRE

NOM COMMERCIAL :	MICEXANIL
N° D'AMM :	
DÉTENTEUR DE L'AMM :	OXON ITALIA S.p.A., Via Sempione, 195, 20016 PERO (MI), Italy
TYPE D'ACTION :	Fongicide
FORMULATION :	Poudre mouillable (WP)
COMPOSITION :	6% cymoxanil 70% mancozèbe

Culture / organisme nuisible	Dose	Spécifications	ZNT	DAR (recommandé)
Vigne / mildiou, black rot	2,0 kg/ha	5 applications maximum	5 m	28 jours
Pomme de Terre / mildiou	1,5 – 2,0 kg/ha	6 applications maximum		7 jours

- Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur.
- Délai de rentrée : 48 heures.

PERFORMANCE / CONDITIONS D'EMPLOI

MICEXANIL est une association de deux matière actives, le cymoxanil et le mancozèbe, présentée sous la forme de poudre mouillable, pour lutter efficacement contre le mildiou et le black rot de la vigne ainsi que le mildiou de la pomme de terre.
MICEXANIL agit à la fois en surface et en profondeur, du fait du pouvoir pénétrant du cymoxanil.
MICEXANIL possède une bonne efficacité préventive sur le mildiou de la vigne, le traitement sera d'autant plus efficace qu'il sera réalisé le plus tôt possible après la pluie contaminatrice (délai maximum : 2 jours).

PÉRIODES ET DOSES D'EMPLOI

Effectuer des traitements préventifs en fonction des risques de développement de la maladie et selon les Avertissement Agricoles.
Traiter dès que les conditions climatiques sont favorables à l'évolution de la maladie.
En cas de lessivage, renouveler l'application.

VIGNE
Mildiou, black rot: 2,0 kg/ha
Appliquer en préventif tout le 10 jours (cadence 7-8 jours en case de risques élevés). Protéger la végétation dès le premiers risques de contamination et jusqu'à la véraison.

POMME DE TERRE
Mildiou : 1,5 – 2,0 kg/ha
Uniquement en préventif à la cadence de 7 jours. Protéger dès premiers risques de contamination et jusqu'au défanage.

PREPARATION / RECOMMANDATIONS

Verser la quantité nécessaire de **MICEXANIL** dans la cuve de l'appareil à demi remplie d'eau, compléter le remplissage en faisant fonctionner le système d'agitation.
MICEXANIL est utilisable dans tous les types de pulvérisateurs classiques à jet projeté et pneumatique. Vérifier le réglage du pulvérisateur et prendre soin de protéger toute la végétation notamment dans le cas de la vigne (feuilles et grappes). Bien refermer le sac après utilisation.

Xn - Nocif

N – Dangereux pour l'environnement

MICEXANIL
Contient : cymoxanil, mancozèbe

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

S24/25 Toxique par contact avec la peau
S37 Porter des gants appropriés
S57 Utiliser un récipient approprié pour éviter toute contamination du milieu ambiant.
S60 Eliminer le produit et son récipient comme un déchet dangereux.
SPe3 Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau

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

IMPORTANT :
Respectez les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduisez sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous les facteurs particuliers concernant votre exploitation tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces ...
Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de vente du Ministère de l'Agriculture.

PRECAUTIONS A PRENDRE

Elimination du produit et de son emballage

- Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.
- Réemploi de l'emballage interdit. Bien le vider.
- Eliminer les emballages vides via les collectes organisées par les distributeurs partenaires de filière ADIVALOR.
- Eliminer les fonds de cuve conformément à la réglementation en vigueur.

Poids net : **XX Kg**

Appendix 3 – Letter(s) of Access

PHYTEUROP

To the competent National Authorities
For the evaluation of Plant Protection Product
All relevant countries of the European Union

Réf : PK-20101215-02

Levallois-Perret, 15th December 2010

Objet : Letter of Access for the registration of products containing the active ingredient Cymoxanil

Dear Madam or Sir,

By this letter, **PHYTEUROP S.A.,** located 53 rue Raspail, 92594 Levallois Perret – France **("Phyteurop")** agrees that all data and studies, as listed in annex A of the present letter, owned by Phyteurop, may be referred to in the relevant country in order to grant the registration to:

OXON Italia S.p.A., located Via Sempione 195, 20016 PERO (MI), Italy ("**Oxon**"),

for Oxon's Cymoxanil-based formulated products ("**Products**").

The right to refer to these data and studies is subject to the following restrictions:

1) The right of referral only entitled **Oxon** to make use of or refer to such data and studies for the sole purpose of obtaining or maintaining any registrations of "**Products**" in the European Union ;
2) The right of referral only gives access to the data and studies specified in Annex A ;
3) The right of referral is granted to **Oxon** and Oxon's affiliates ;
4) Oxon and its affiliates shall keep the data and studies confidential.

Philippe KUENEMANN
Directeur Recherche et Développement
Phyteurop
Tel.: 01 47 59 77 31 / e-mail : p.kuenemann@phyteurop.fr

Siège social et bureaux : 53, rue Raspail / 92594 LEVALLOIS-PERRET Cédex
Téléphone : 01 47 59 77 00 / Fax : 01 47 37 54 52 - 01 47 37 54 81 / www.phyteurop.com
S.A. au capital de 7 000 000 € - R.C. Nanterre B 666 580 352 - Code NAF 242 Z - N° Intracommunautaire TVA FR 29 666 580 352
Usine : Zone Industrielle / 49260 MONTREUIL-BELLAY / Téléphone : 02 41 83 42 42 / Télex 720 194 F SODEXI / Fax : 02 41 52 46 53
Bureau régional : "ATRIA" 5, boulevard de Prague / 30000 NIMES / Téléphone : 04 66 76 56 63 / Fax : 04 66 76 56 66

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To the competent National Authorities

For the evaluation of Plant Protection Product

All relevant countries of the EU Union.

24th February 2012

Declaration of Access to the Studies with products containing the Active Ingredient Cymoxanil.

With the present, we **SIPCAM UK Limited**, located at 4C Archway House, The Lanterns, Melbourn Street, Royston SG8 7BX – UK, hereby agree to give access to the efficacy studies listed in Appendix 1 to this Letter to **OXON ITALIA S.p.A.**, Via Sempione 195, Pero, Milan, Italy and its affiliate companies in the European Union.

OXON ITALIA S.p.A and its affiliates and customers, to which Oxon Italia gives access through specific letter of access, are entitled to make use of or refer to the above mentioned studies for the sole purpose of obtaining or maintaining any registrations of Cymoxanil 6% + Mancozeb 70% WP in the European Union.

Yours Sincerely,

Mr Bob Hend

Sipcam UK Ltd Registrations Manager

Appendix 1

Author, Company	Year	Title Source (where different from company) Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed yes/no	Owner
C.Harrison HND, Agrisearch UK Ltd	1998	**Title** Field study to evaluate the efficacy of two formulated products based on cymoxanil (SIP 4109 and SIP 40876) for the control of late blight on potatoes under irrigated conditions **Report No** : AK/3729/SP **GLP or GEP :** No **Published:** No	Yes	Sipcam UK
C.Harrison HND, Agrisearch UK Ltd	1997	**Title** Field study to evaluate the efficacy of a range of formulated products based on cymoxanil (SIP 4109, SIP 40876 and SIP 40875) for the control of late blight in potatoes under irrigated conditions **Report No:** AK/3304/SP **GLP or GEP:** No **Published:** No	Yes	Sipcam UK
A.Bailey, Agrisearch UK Ltd	1997	**Title** Field evaluation of the efficacy of SIP 4109, SIP 40876 and SIP 40875 for the control of late blight in potatoes under commercial conditions **Report No:** AP/3363/SP **GLP or GEP:** No **Published:** No	Yes	Sipcam UK
A.Bailey, Agrisearch UK Ltd	1997	**Title** Field study to evaluate the efficacy of two formulated products based on cymoxanil (SIP 4109 and SIP 40876) for the control of late blight in potatoes under commercial conditions **Report No:** AP/3842/SP **GLP or GEP:** No **Published:** No	Yes	Sipcam UK
J.Ridgway, Agrisearch UK Ltd	2000	**Title** Field study to evaluate the efficacy of PHYT 4109 for the control of late blight in potatoes under commercial conditions (1999) **Report No:** AP/4814/SP/99 **GLP or GEP** : Yes **Published:** No	Y	Sipcam UK/ Oxon
A.Bailey, Agrisearch UK Ltd	1996	**Title** Field study to evaluate the crop safety of SIP 4109, SIP 40876 and SIP 40875 in the absence of foliar blight on a range of cultivars of potato **Report No:** AP/3381/SP **GLP or GEP:** No **Published:** No	Yes	Sipcam UK

PHYTEUROP

To the competent National Authorities
For the evaluation of Plant Protection Product
All relevant countries of the EU Union

LETTER OF ACCESS

We **PHYTEUROP**, located at 53 rue Raspail 92594 Levallois-Perret Cedex – France, hereby agree to give access to the efficacy studies listed in Appendix 1 to this Letter and concerning the product **cymoxanil 6% + mancozeb 70% WP** to **OXON ITALIA S.p.A.**, Via Sempione 195, Pero, Milan, Italy and its affiliate companies in the European Union

OXON ITALIA S.p.A and its affiliates and customers, to which Oxon Italia gives access through specific letter of access, are entitled to make use of or refer to the above mentioned studies for the sole purpose of obtaining or maintaining any registrations of **cymoxanil 6% + mancozeb 70% WP** in the European Union.

At Levallois-Perret, the 27th of February 2012,

Guido CIMA
Directeur Général

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Appendix 1

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data pro-tection claimed Y/N	Owner
IIIA 6.1 Chapter 1	Staphyt	1999	C99RJA-MIL-1-SA Etude de l'efficacité de fongicides contre le mildiou de la vigne GEP Unpublished	Y	Phyteurop
IIIA 6.1 Chapter 1	Staphyt	1999	C99RJA-MIL-2-SA Etude de l'efficacité de fongicides contre le mildiou de la vigne GEP Unpublished	Y	Phyteurop
IIIA 6.1 Chapter 1	Viti R&D	1999	C99RJA-MIL-3-SA Evaluation de l'activité fongicide de différentes formulations contre le mildiou de la vigne en conditions de contamination artificielle GEP Unpublished	Y	Phyteurop
IIIA 6.1 Chapter 1	Staphyt	2000	C00RJA-MIL-4-SA Evaluer l'efficacité de produits fongicides sur le mildiou (Plasmopara viticola) après contamination artificielle sur vigne fructifère GEP Unpublished	Y	Phyteurop
IIIA 6.1 Chapter 1	Staphyt	2000	C00RJA-MIL-5-SA Evaluer l'efficacité de produits fongicides sur le mildiou (Plasmopara viticola) après contamination artificielle sur vigne fructifère GEP Unpublished	Y	Phyteurop
IIIA 6.1 Chapter 1	Viti R&D	2000	C00RJA-MIL-6-SA Evaluation de l'efficacité des préparations d'essai 1 4109 00, 1 4123 00, 1 4423 00 et 1 4424 00 contre le mildiou de la vigne GEP Unpublished	Y	Phyteurop
IIIA 6.1 Chapter 1	Phyteurop	2001	C01RJA-MIL-9-SA Dossier et Rapports d'essai biologique - 032 GEP Unpublished	Y	Phyteurop
IIIA 6.1 Chapter 1	Phyteurop	2001	C01RJA-MIL-10-SA Dossier et Rapports d'essai biologique - 222 GEP Unpublished	Y	Phyteurop
IIIA 6.1 Chapter 1	Phyteurop	2003	C03RJA-MIL-13-SA Dossier et Rapports d'essai biologique - 242 GEP Unpublished	Y	Phyteurop
IIIA 6.1 Chapter 1	Staphyt	2003	C03RJA-MIL-14-SA Homologuer deux nouvelles formules sous forme de granulés dispersibles contre le mildiou de la vigne. Essai conduit en conditions naturelles GEP Unpublished	Y	Phyteurop

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IIIA 6.1 Chapter 2	Staphyt	1999	C99RJA-BLA-1-SA Etude de l'efficacité de produits fongicides contre le black-rot de la vigne GEP Unpublished	Y	Phyteurop
IIIA 6.1 Chapter 2	Viti R&D	1999	C99RJA-BLA-2-SA Evaluation de l'activité fongicide de différentes formulations contre le black rot de la vigne en conditions de contamination artificielle GEP Unpublished	Y	Phyteurop
IIIA 6.1 Chapter 2	Staphyt	1999	C00RJA-BLA-3-SA Evaluer l'efficacité de produits fongicides sur Black-rot (Guignardia bidwellii) après contamination artificielle sur vigne fructifère GEP Unpublished	Y	Phyteurop
IIIA 6.1 Chapter 2	Viti R&D	2000	C00RJA-BLA-4-SA Evaluation de l'efficacité des préparations d'essai 1 4109 00, 1 4123 00, 1 4423 00 et 1 4424 00 contre le black rot de la vigne GEP Unpublished	Y	Phyteurop
IIIA 6.1 Chapter 2	Anadiag Prestagro	2001	C01RJA-BLA-7-SA Rapport final SIP 1 4423 00 Black rot Vigne GEP Unpublished	Y	Phyteurop
IIIA 6.1 Chapter 2	Staphyt	2001	C01RJA-BLA-8-SA Evaluer l'efficacité de produits fongicides contre le Black-rot (Guignardia bidwellii) après contamination artificielle sur vigne fructifère GEP Unpublished	Y	Phyteurop
IIIA 6.1 Chapter 2	Staphyt	2003	C03RJA-BLA-13-SA Etude de programmes fongicides contre Black rot sur vigne sous conditions artificielles GEP Unpublished	Y	Phyteurop
IIIA 6.1 Chapter 2	Staphyt	2003	C03RJA-BLA-14-SA Etude de programmes fongicides contre Black rot sur vigne sous conditions artificielles GEP Unpublished	Y	Phyteurop
IIIA 6.1 Chapter 2	INRA UMR SAVE	2011	C11RJA-BLA-15-SA Etude de l'efficacité des différentes formulations de la spécialité SARMAN M vis-à-vis du black-rot de la vigne - Unpublished	Y	Phyteurop
IIIA 6.1 Chapter 2	Syntech Research	2011	C11RJA-BLA-16-SA Efficacy of SARMAN M WP and SARMAN M WG against vine black rot GEP Unpublished	Y	Phyteurop

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IIIA 6.1 Chapter 2	Anadiag Prestagro	2011	C11RJA-BLA-17-SA Grape vine fungicide Black rot (Guignardia bidwellii) efficacy GEP Unpublished	Y	Phyteurop
IIIA 6.2.1 Chapter 1 Chapter 2	La Tapy	2010	C10RJA-COMPL-1-SA Essai marquages sur raisin de table avec cinq spécialités fongicides antimildiou - Année 2010 GEP Unpublished	Y	Phyteurop
IIIA 6.1.4 Chapter 1 Chapter 2	Staphyt	2011	C11RJA-COMPL-2-SA Etude des effets non intentionnels des préparations fongicides SARMAN M et SARMAN M WG sur l'élaboration et la qualité des moûts et des vins GEP Unpublished	Y	Phyteurop
IIIA 6.1.4 Chapter 1 Chapter 2	BNIC	2011	C10RJA-COMPL-8-SA Rapport d'essai - CEB 143 2010. Etude contractuelle des 3 fongicides 1 40283 00, SARMAN M WG, SARMAN MC WG GEP / GLP Unpublished	Y	Phyteurop
IIIA 6.1 Chapter 3	Sipcam-Phyteurop Aubry J-C.	1999	PF1 Rapport d'essai biologique **FSIP996120** Sipcam-Phyteurop, 01.40.99.040 (230) GEP Unpublished	N	Phyteurop
IIIA 6.1 Chapter 3	Sipcam-Phyteurop Testelin H.	1999	PF2 Rapport d'essai biologique **FSIP993549** Sipcam-Phyteurop, 01.40.99.040 (232) GEP Unpublished	N	Phyteurop
IIIA 6.1 Chapter 3	Staphyt Varret F., Willocq B.	2000	PF3 Efficacité fongicide pomme de terre - **FSIP003304** Staphyt, F 00 31 01 (01.40.00.015 / 090) GEP Unpublished	N	Phyteurop
IIIA 6.1 Chapter 3	Sipcam-Phyteurop Petit Y.	2000	PF4 Rapport d'essai biologique **FSIP004249** Sipcam-Phyteurop, 01.40.00.015 (088) GEP Unpublished	N	Phyteurop
IIIA 6.1 Chapter 3	Staphyt Varret F., Lecomte T.	2000	PF5 Efficacité fongicide pomme de terre - **FSIP004000** Staphyt, F 00 31 01 (01.40.00.015 / 091) GEP Unpublished	N	Phyteurop
IIIA 6.1 Chapter 3	SPV Culiez L., Dubois L.	2000	PF6 Compte-rendu d'essai officiel PV00061 - Mildiou de la pomme de terre SPV 62, **HM00276** Official Unpublished	N	Phyteurop

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IIIA 6.1 Chapter 3	SPV Culiez L., Pinchon V.	2000	PF7 Compte-rendu d'essai officiel PV00061 - Mildiou de la pomme de terre SPV 80, **HM00277** Official Unpublished	N	Phyteurop
IIIA 6.1 Chapter 3	Sipcam- Phyteurop Testelin H.	2001	PF8 Rapport d'essai biologique **FSIP014249** Sipcam-Phyteurop, 01.40.01.034 (230) GEP Unpublished	N	Phyteurop
IIIA 6.1 Chapter 3	Sipcam- Phyteurop Aubry J-C.	2001	PF9 Rapport d'essai biologique **FSIP014270** Sipcam-Phyteurop, 01.40.01.034 (232) GEP Unpublished	N	Phyteurop
IIIA 6.1 Chapter 3	SPV Culiez L., Dubois L.	2001	PF10 Compte-rendu d'essai officiel PV00061 - Mildiou de la pomme de terre SPV 62, **HM01269** Official Unpublished	N	Phyteurop
IIIA 6.1 Chapter 3	SPV Culiez L., Pinchon V.	2001	PF11 Compte-rendu d'essai officiel PV00061 - Mildiou de la pomme de terre SPV 80, **HM01270** Official Unpublished	N	Phyteurop

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To the competent National Authorities
For the evaluation of Plant Protection Product
All relevant countries of the EU Union

CO-OWNERSHIP DECLARATION

Co-ownership declaration regarding efficacy studies in France with cymoxanil 6% + mancozeb 70% WP

We **PHYTEUROP**, located at 53 rue Raspail 92594 Levallois-Perret Cedex – France, hereby declare that the efficacy studies listed in Appendix 1 to this Declaration have been duly shared with OXON ITALIA S.p.A., located at Via Sempione 195, Pero, Milan – Italy.

OXON ITALIA S.p.A. is therefore entitled to use these efficacy studies in support of **cymoxanil 6% + mancozeb 70% WP** registrations.

The studies listed in Appendix 1 to this Declaration have to be considered co-owned by the two companies.

At Levallois-Perret, the 27th of February 2012,

Guido CIMA
Directeur Général

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IIIA 6.1 Chapter 1	Phyteurop	2010	C10RJA-MIL-15-SA SARMAN F, SARMAN M, 1 40423 00, 1 40424 00 / mildiou / vigne GEP Unpublished	Y	Phyteurop / Oxon
IIIA 6.1 Chapter 1	Phyteurop	2010	C10RJA-MIL-16-SA SARMAN F, SARMAN M, 1 40423 00, 1 40424 00 / mildiou / vigne GEP Unpublished	Y	Phyteurop / Oxon
IIIA 6.1 Chapter 1	Promovert	2010	C10RJA-MIL-17-SA Efficacité fongicide sur le mildiou de la vigne (dû à Plasmopara viticola) GEP Unpublished	Y	Phyteurop / Oxon
IIIA 6.1 Chapter 1	Staphyt	2010	C10RJA-MIL-18-SA Etude du comportement de différentes formulations à base de cymoxanil (Mancozèbe, Folpel, Mancozèbe + Cuivre) utilisées à leurs doses homologuées et à dose réduite dans le cadre de la lutte contre le mildiou GEP Unpublished	Y	Phyteurop / Oxon
IIIA 6.1 Chapter 1	Staphyt	2010	C10RJA-MIL-19-SA Etude du comportement de SARMAN F et de SARMAN M utilisé à différentes époques tout au long de la période de sensibilité de la vigne dans le cadre de programmes de lutte contre le mildiou GEP Unpublished	Y	Phyteurop / Oxon
IIIA 6.1 Chapter 1	Anadiag Prestagro	2010	C10RJA-MIL-20-SA Efficacité fongicide SARMAN F - SARMAN M Mildiou Vigne (Plasmopara viticola) GEP Unpublished	Y	Phyteurop / Oxon
IIIA 6.1 Chapter 1	Anadiag Prestagro	2010	C10RJA-MIL-21-SA Efficacité fongicide SARMAN F - SARMAN M Mildiou Vigne (Plasmopara viticola) GEP Unpublished	Y	Phyteurop / Oxon
IIIA 6.1 Chapter 1	Staphyt	2011	C11RJA-MIL-25-SA Evaluation of the efficacy of different mixtures based on cymoxanil applied at their registrated rate and at reduced rates during the whole period of sensibility to downy mildew of grapevines. GEP Unpublished	Y	Phyteurop / Oxon
IIIA 6.1 Chapter 1	Staphyt	2011	C11RJA-MIL-26-SA Evaluation of the efficacy of different mixtures based on cymoxanil when applied within 24 hours after a downy mildew infecting event. GEP Unpublished	Y	Phyteurop / Oxon

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IIIA 6.1 Chapter 1	Agrolis consulting	2011	C11RJA-MIL-28-SA Study efficacy of different formulations of Cymoxanil (+ Mancozeb, Folpet and Copper) on *Plasmopara viticola*. Comparison to standard REMILTINE S PEPITE at 3 Kg/ha. GEP Unpublished	Y	Phyteurop / Oxon
IIIA 6.1 Chapter 1	Biotek Agriculture	2011	C11RJA-MIL-34-SA The efficacy of SARMAN M, SARMAN M WG and SARMAN F for the control of downy mildew (*Plasmopara viticola*) on grapevine under artificial inoculation conditions GEP Unpublished	Y	Phyteurop / Oxon
IIIA 6.1 Chapter 1	Phyteurop	2011	C11RJA-MIL-35-SA SARMAN M, SARMAN F, SARMAN MC WG / Downy mildew / Vine grape GEP Unpublished	Y	Phyteurop / Oxon
IIIA 6.1 Chapter 1	Phyteurop	2011	C11RJA-MIL-36-SA SARMAN M, SARMAN M WG, SARMAN F, SARMAN MC WG / Downy mildew / Vine grape GEP Unpublished	Y	Phyteurop / Oxon
IIIA 6.2 Chapter 1	Biorizon	2011	C11RJA-MIL-46-SA Sensitivity to cymoxanil of grape downy mildew populations collected during 3 seasons (2009, 2010 and 2011) - Unpublished	Y	Phyteurop / Oxon
IIIA 6.1 Chapter 3	Biotek Agriculture Chambon J., Delabarre O.	2010	PF12 The efficacy of 1.40109.00 and 1.40423.00 against potato late blight ... Biotek Agriculture, BPE10/238/FGC - 40.10.T.079 - **FSIP101504** GEP Unpublished	Y	Phyteurop / Oxon
IIIA 6.1 Chapter 3	Staphyt Trouslard B., Willocq B.	2010	PF13 Etudier les performances techniques des préparations fongicides 1.40109.00 ... Staphyt, BTD-10-7621-FR01 - 40.10.T.074 - **FSIP107314** GEP Unpublished	Y	Phyteurop / Oxon
IIIA 6.1 Chapter 3	Prestagro Lefebvre S.	2010	PF14 Fungicide efficacy 1 40109 00 - 1 40423 00 downy mildew of potato Prestagro, P10PYF225LG67 - 40.10.T.074 - **FSIP103534** GEP Unpublished	Y	Phyteurop / Oxon

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IIIA 6.1 Chapter 3	SGS Marocchi A., Camus O.	2011	PF15 GEP trial report - Evaluation of efficacy of SARMAN M and SARMAN M WG ... SGS, 11 POT F PY RS 040 - 40.11.T.082 - **FSIP116883** GEP Unpublished	Y	Phyteurop / Oxon
IIIA 6.1 Chapter 3	Staphyt Trouslard B., Bordet M.	2011	PF16 Evaluation of the technical performances of fungicide preparations SARMAN M ... Staphyt, BTD-11-9127-FR02 - 40.11.T.082 - **FSIP119660** GEP Unpublished	Y	Phyteurop / Oxon
IIIA 6.1 Chapter 3	Staphyt Trouslard B., Willocq B.	2011	PF17 Evaluation of the technical performances of fungicide preparations SARMAN M ... Staphyt, BTD-11-9127-FR01 - 40.11.T.082 - **FSIP112665** GEP Unpublished	Y	Phyteurop / Oxon
IIIA 6.1 Chapter 3	SGS Marocchi A., Camus O.	2011	PF18 GEP trial report - Evaluation of efficacy of SARMAN M and SARMAN M WG ... SGS, 11 POT F PY RS 030 - 40.11.T.083 - **FSIP111463** GEP Unpublished	Y	Phyteurop / Oxon
IIIA 6.1 Chapter 3	Staphyt Trouslard B., Willocq B.	2011	PF19 Evaluation of the technical performances of fungicide preparations SARMAN M ... Staphyt, BTD-11-9125-FR01 - 40.11.T.082 - **FSIP113806** GEP Unpublished	Y	Phyteurop / Oxon
IIIA 6.1 Chapter 3	Staphyt Trouslard B., Bedu O.	2011	PF20 Evaluation of the technical performances of fungicide preparations SARMAN M ... Staphyt, BTD-11-9125-FR02 - 40.11.T.083 - **FSIP116502** GEP Unpublished	Y	Phyteurop / Oxon
IIIA 6.1 Chapter 3	Staphyt Trouslard B., Willocq B.	2010	PF23 Etudier les performances techniques de la préparation fongicide 1.40109.00 ... Staphyt, BTD-10-7513-FR01 - 40.10.T.075 - **FSIP106465** GEP Unpublished	Y	Phyteurop / Oxon
IIIA 6.1 Chapter 3	Prestagro Lefebvre S.	2010	PF24 Fungicide efficacy 1 40109 00 downy mildew of potato Prestagro, P10PYF226LG68 - 40.10.T.075 - **FSIP105335** GEP Unpublished	Y	Phyteurop / Oxon

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IIIA 6.1 Chapter 3	Phyteurop. Aubry J-C.	2010	PF25 Rapport d'essai biologique **FSIP102001** Phyteurop, 40.10.T.073 – 10.10.029 GEP Unpublished	Y	Phyteurop / Oxon
IIIA 6.1 Chapter 3	Phyteurop Testelin H.	2010	PF26 Rapport d'essai biologique **FSIP104329** Phyteurop, 40.10.T.073 – 10.10.023 GEP Unpublished	Y	Phyteurop / Oxon
IIIA 6.1.4 Chapter 3	Biotek Agriculture Soulier S.	2011	Evaluation of non-intentional effects of 1.40109.00 and 1.40423.0 on potatoes qualitative parameters and processed products Biotek Agriculture, BPE10/286/TGC GEP Unpublished	Y	Phyteurop / Oxon
IIIA 6.1.1 Chapter 3	Biorizon Giraud F.	2011	Evaluation of preventive and curative activity of products against late blight potato Biorizon, 11 24 / 04 P - Unpublished	Y	Phyteurop / Oxon

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INDUSTRIES LIMITED

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Ref.IIL/MCZ/FR/1502-51
Date: February 03, 2015
Page: 1 of 2

To
ANSES DPR UGAmm
253 Avenue du General Leclerc
94701 Maisons Alfort Cedex
FRANCE

Subject: INDOFIL's Letter of Access to Mancozeb protected data supporting registration of Micexanil 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, wish to extend access to

- Mancozeb study post-submitted in support of the registration of MANFIL 80 WP (Amm No. 2040019) in France listed in Appendix 1,.

for registration of following plant protection product of Oxon Italia SpA, Via Sempione 195, 20016 PERO, Italy in France, based on the condition that finished products will contain Mancozeb of Indofil's sources,

Product Name	Registration number	Composition	Registration Holder
Micexanil	To be assigned	Cymoxanil 6 + Mancozeb 70 % WP	Oxon Italia SpA, Italy

This access is neither transferable nor sub-assignable to any third party and is granted only with respect to the registration of applications mentioned above.

This letter does not authorize registration holder or its affiliates to receive copies of studies or any other documents owned by Indofil, nor does it authorize registration holder or its affiliates to inspect such studies or any such documents, 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

Narendra C. Rane
EVP – Agro International & SPCD Business

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APPENDIX I

Author	Study date	Title	GLP/GEP Study Y/N	Ref. No.
Miller, C.	2013	Mancozeb: Validation of methodology for the determination of residues in ground water, drinking water and surface water	Y	435-013

----- END OF APPENDIX I -----

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