REGISTRATION REPORT

Part A

Risk Management

Product code: IR6141 M WG

Product name: MICENE PRO WG

Active substances:

benalaxyl-M, 40 g/kg

mancozeb, 650 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: ISAGRO S.p.A.

Date: 03/10/2018

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PART A – Risk Management

The company ISAGRO S.p.A. has requested marketing authorisation in France for the product MICENE PRO WG (product code: IR6141 M WG), containing 40 g/kg benalaxyl-M and 650 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 MICENE PRO WG (IR6141 M WG) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of MICENE PRO WG (IR6141 M WG) have been made using endpoints agreed in the EU peer reviews of both benalaxyl-M and mancozeb.

This document describes the specific conditions of use and labelling required for France for the registration of MICENE PRO WG (IR6141 M WG).

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 ISAGRO S.p.A.'s application to market MICENE PRO WG (IR6141 M WG) in France as a fungicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Benalaxyl-M

Commission Implementing Regulation (EU) No 1175/2013 of 20 November 2013 approving the active substance benalaxyl-M, in accordance with Regulation (EC) No 1107/09 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.
Specific provisions of Regulation (EU) No 1175/2013 were as follows: 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 benalaxyl-M, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of workers at re-entry, — the risk to groundwater from the metabolites BM-M2 (N-(malonyl)-N-(2,6-xylyl)-DL-alanine) and BM-M3 (N-(malonyl)-N-(2,6-xylyl)-D-alanine), when the substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of use shall include risk mitigation measures, where appropriate.
An EFSA conclusion is available (EFSA Journal 2013;11(4):3148). A Review Report is available (SANCO/12079/2013 rev 1 3 October 2013).

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.
Specific provisions of Regulation (EU) No 540/2011 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 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 (2012-1143) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)[1] in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[2] – the highest application rates over the Southern zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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

The French Order of 4th May 2017[3] provides that:
- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight 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.

[1] French Food Safety Agency, Afssa, before 1 July 2010
[2] SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5
[3] Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte

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 MICENE PRO WG (IR6141 M WG), 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

Not necessary for benalaxyl-M : the applicant has provided sufficient data to show that access is not required.

For mancozeb, the applicant has provided letter(s) of access.

[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

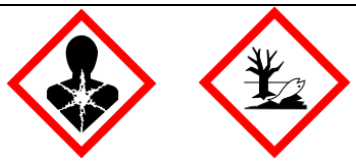
2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	MICENE PRO WG (IR6141 M WG)
Authorisation number	-
Function	Fungicide
Applicant	ISAGRO S.p.A.
Composition	40 g/kg benalaxyl-M 650 g/kg mancozeb
Formulation type (code)	Water-dispersible granules (WG)
Packaging	Polyester/aluminium/low-density polyethylene bags (1 kg) Polyester/aluminium/polyamide/low-density polyethylene bags (2.5 kg, 5 kg or 10 kg) High-density polyethylene containers (4 kg) Paper/low-density polyethylene bags (20 kg or 25 kg)

2.2 Classification and labelling

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

Physical hazards	-	
Health hazards	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	H361d	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.

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

N/A: Not registered in France.

2.2.3 Other phrases linked to the preparation

N/A: Not registered in France.

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" or "not finalised", the intended use is highlighted in grey and the main reason(s) reported in the remarks.

GAP rev. 1, date: 2018-10-03

PPP (product name/code)	**MICENE PRO WG (IR6141 M WG)**	**Formulation type:**	**WG**
active substance 1	**benalaxyl-M**	**Conc. of a.s. 1:**	**40 g/kg**
active substance 2	**mancozeb**	**Conc. of a.s. 2:**	**650 g/kg**
Applicant:	**ISAGRO S.p.A.**	**professional use**	☒
Zone(s):	**southern EU**	**non-professional use**	☐
Verified by MS:	**yes**		

Crop and/ or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number max (k)	interval between applications	kg a.s./hL min max	water L/ha min max	g a.s./ha min max		
Potato	France	IR6141 M WG	F	*Phytophthora infestans Alternaria solani*	WG	40 BM + 650 MZB	Foliar Spraying	21-39	**2**	7-10 days	0.010 – 0.033 + 0.163 – 0.542	300 - 1000	100 + 1625	7	**Not acceptable (no sufficient environmental data -risk of ground-water contamination)**
Tomato				*Phytophthora infestans*				21-79	3					3	**Not acceptable (no sufficient environmental data - risk of ground-water contamination and risk to aquatic organisms)**
Onion / Shallot / Garlic				*Peronospora destructor*				41-48	3					28	**Not acceptable (no sufficient environmental data - risk of ground-water contamination and risk to aquatic organisms)**

BM = benalaxyl-M MZB = mancozeb

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

MICENE PRO WG (IR6141 M WG) is a yellowish water-dispersible granule formulation, with faint aromatic odour. It contains 40 g/kg benalaxyl-M and 650 g/kg mancozeb. All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The formulation is not explosive, has no oxidising properties and is not flammable. It has a self-ignition temperature of 395 °C. In aqueous solution (1%), it has a pH value of 7.22. There is no effect of low and high temperatures on the stability of the formulation, since after seven days at 0 °C and 14 days at 54 °C, neither the active substances' content nor the technical properties were changed.

The stability data indicate a shelf life of at least two years at ambient temperature when stored in polyester/aluminium/polyethylene bags. Since the preparation is a solid formulation, compatibility is considered acceptable with all the requested packaging.

The technical characteristics are acceptable for a WG formulation, except for suspensibility and attrition. Suspensibility for mancozeb is outside of the acceptable range and therefore the spray mixture should be agitated during application. For attrition, results are below 98 % and sizes of dust should be determined after an attrition test. However, this test is not necessary to conclude on human health issues. Therefore, no further data are required. The formulation is not classified for the physico-chemical aspect.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methods for the determination of the active substances and the relevant impurity (ethylene thiourea [ETU] from technical mancozeb) in the formulation are available and validated.

3.1.2.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report (DAR) and in this dossier and validated for the determination of residues of benalaxyl-M and mancozeb in plants (high-water-content and acidic crops), foodstuffs of animal origin, soil, water (surface and drinking) and air.

An analytical method is available in the DAR and in this dossier and validated for the determination of residues of ETU in tissues and body fluids.

3.1.3 Mammalian Toxicology

Active substance: **benalaxyl-M**			
ADI	0.04 mg/kg body weight/day		EU 2014
ARfD	Not applicable		
AOEL	0.06 mg/kg body weight/day		
Dermal absorption	Based on *in vivo* rat study performed on the formulation (which is the representative formulation of the active substance):		
		Concentrate (tested) 8 g/L (0.08 mg/cm²)	Diluted formulation (tested) 0.1 g/L (0.001 mg/cm²)
	In vivo (rat) %	2.5	29
		Concentrate (used in formulation) 40 g/kg	Spray dilution (used in formulation) 0.1 g/L
	Dermal absorption endpoints %	**2.5**	**29**

Active substance: **mancozeb**			
ADI	0.05 mg/kg body weight/day		EU 2006
ARfD	0.6 mg/kg body weight		
AOEL	0.035 mg/kg body weight/day		
Dermal absorption	Based on an *in vivo* rat study performed on a similar formulation (representative formulation of the active substance) :		
		Concentrate (tested) 1200 g/L	Diluted formulation (tested) 1.4 g/L
	In vivo (rat) %	0.11	0.24
		Concentrate (used in formulation) 650 g/kg	Spray dilution (used in formulation) 1.625 g/L
	Dermal absorption endpoints %	**0.11**	**0.24**

3.1.3.1 Acute Toxicity

MICENE PRO WG (IR6141 M WG), containing 40 g/kg benalaxyl-M and 650 g/kg mancozeb has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitiser.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G[8]	Equipment	Application rate kg/L product/ha (g a.s./ha)	Spray dilution (L/ha)	Model
Potato/tomato/onion	F	Vehicle-mounted	2.5 kg product/ha (100 g benalaxyl-M/ha and 1625 g mancozeb/ha)	300-1000	BBA (German model)
Tomato	G	Manual Knapsack			

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

Crop	Equipment	PPE and/or working coverall	% AOEL benalaxyl-M	% AOEL mancozeb
Potato/ tomato/onion	Vehicle-mounted	Working coverall and gloves during mixing/loading and application	7	95
Tomato	Manual Knapsack		7	7

According to the model calculations, it can be concluded that the risk for the operator using MICENE PRO WG (IR6141 M WG) is acceptable with a working coverall (90 % protection factor) and gloves during mixing/loading and application.

For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

[8] Open field or glasshouse

3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to be 0.4 % of the AOEL of benalaxyl-M and 1 % of the AOEL of mancozeb.

It may be concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to MICENE PRO WG (IR6141 M WG).

3.1.3.4 Worker Exposure

Workers may have to enter treated areas after treatment for crop inspection/harvesting activities. Therefore estimation of worker exposure was calculated according to EUROPOEM II. Exposure is estimated to be 19 % of the AOEL of benalaxyl-M and 5 % of the AOEL of mancozeb.

It may be concluded that without taking into account a re-entry period, there is no unacceptable risk anticipated for workers wearing a working coverall and gloves, when re-entering crops treated with MICENE PRO WG (IR6141 M WG).

For details of personal protective equipment for workers, refer to the Decision in Appendix 1.

3.1.4 Residues and Consumer Exposure

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs for benalaxyl-M and mancozeb as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of benalaxyl-M and mancozeb residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, France agrees with the authorization of the proposed uses.

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

Data gaps: none.

Data required post-authorisation: none.

Summary of the evaluation

MICENE PRO WG (IR6141 M WG) contains benalaxyl-M and mancozeb.

Summary for benalaxyl-M

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EU) No 520/2011	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
/	Potato	Yes	Yes (3N + 3S)	Yes	Yes	Yes	No	No	Zero residue situation
/	Tomato	Yes	Yes (8N + 11S)	Yes	Yes	Yes		No	
/	Onion, shallot, garlic	Yes	Yes (6N + 10S)	Yes	Yes	Yes		No	

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

The effects of processing on the nature of benalaxyl-M residues have not been investigated. Data on effects of processing on the amount of residue have been submitted for grapes only. These data were not considered for risk assessment.
No data on residues in succeeding crops have been sufficiently investigated (assuming that benalaxyl-M and benalaxyl have very similar behaviour in soil) taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.
Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin are therefore not necessary.

Summary for mancozeb

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EU) 2017/171	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
/	Potato	Yes	Yes (14N + 11S)	Yes	Yes	Yes	No	No	
/	Tomato	Yes	Yes (12N + 8S)	Yes	Yes	Yes		No	
/	Onion, shallot, garlic	Yes	Yes (8N + 8S)	Yes	Yes	Yes		No	

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

The effects of processing on the nature of mancozeb residues have been investigated. Data on effects of processing on the amount of residue have been submitted. These data were considered for risk assessment.
No data on residues in succeeding crops are required, based on the rapid biodegradation of parent and metabolites in soil.
Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin are therefore not necessary.

Information on MICENE PRO WG (IR6141 M WG)

Crop	PHI for IR6141 M WG requested by applicant	PHI/withholding period* sufficiently supported for		PHI for IR6141 M WG proposed by zRMS	zRMS Comments (if different PHI proposed)
		Benalaxyl-M	Mancozeb		
Potato	7 days	Y	Y	7 days	
Tomato	3 days	Y	Y	3 days	
Onion, shallot, garlic	28 days	Y	Y	28 days	

* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Waiting periods before planting succeeding crops

Not relevant.

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate predicted environmental concentration (PEC) values for the active substances and their metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC values of benalaxyl-M, mancozeb and their metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PECsoil values derived for the active substances and their metabolites are used for the ecotoxicological risk assessment.

When available, PECsw values derived for the active substances are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PECgw values for benalaxyl-M, mancozeb and their respective metabolites cannot be validated based on the available information supplied in the core assessment. **Therefore, an unacceptable risk of groundwater contamination cannot be excluded for all the requested uses**.

Based on vapour pressure, information on volatilisation from plants and soil, and DT_{50} calculation, no significant contamination of the air compartment is expected for the requested 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 conclusions for the 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 and terrestrial plants are acceptable for the intended uses.

For aquatic organisms, as no data on PECsw are available for the requested uses on tomato and onion-like crops (see Part B, section 5 and zRMS comment 10.2), **the risk is therefore considered to be non-finalised.**

Risk mitigation measures are required to protect aquatic organisms, non-target arthropods and non-target plants.

3.1.7 Efficacy

Considering the data submitted:

- The efficacy level of MICENE PRO WG (IR6141 M WG) is considered satisfactory for all the requested uses.
- The phytotoxicity level of MICENE PRO WG (IR6141 M WG) is considered negligible for all the requested uses.
- The risks of negative impact on yield, quality, multiplication, following and adjacent crops are considered negligible.
- There is a risk of resistance developing or appearing to benalaxyl-M for late blight of potato, requiring monitoring. **To avoid the development of resistance of late blight of potato to benalaxyl-M, the number of applications is also limited to two per crop cycle on potato.**

Restrictions: None

Resistance monitoring data: None

Post-authorisation data: None

3.2 Conclusions arising from French assessment

Taking into account the above assessment, **an authorisation cannot be granted (environmental risk)**. A copy of the decision issued can be found in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

N/A: Not registered in France.

3.4.2 Post-authorisation data requirements

N/A: Not registered in France.

3.4.3 Label amendments

N/A: Not registered in France.

Appendix 1 – Copy of the French Decision

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anses

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 ***MICENE PRO WG***

de la société *ISAGRO SPA*

enregistrée sous le *n°2012-1143*

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

Considérant que les paramètres d'entrée utilisés ne couvrent pas la période d'application revendiquée, un risque inacceptable de contamination des eaux souterraines ne peut être exclu,

Considérant qu'en conséquence, les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 ne sont pas remplies,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas autorisée** en France.

MICENE PRO WG

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anses
agence nationale de sécurité sanitaire alimentation, environnement, travail

Informations générales sur le produit	
Nom du produit	MICENE PRO WG
Type de produit	Produit de référence
Titulaire	ISAGRO SPA Centro uffici San Siro Edificio D - ala 3 Via Caldera 21 20153 MILAN Italie
Formulation	Granulé dispersable (WG)
Contenant	650 g/kg - mancozèbe 40 g/kg - bénalaxyl-M
Numéro d'intrant	9913-2012.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usage	Professionnel

A Maisons-Alfort le, 0 3 OCT. 2018

Françoise WEBER
Directrice générale déléguée
en charge du pôle produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

MICENE PRO WG

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ANNEXE I : Conditions de mise sur le marché demandées

Classification du produit	
Catégorie de danger	**Mention de danger**
Toxiques pour la reproduction - Catégorie 2	H361d : 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, entraîne des effets néfastes à long terme
Pour les phrases P se référer à la règlementation en vigueur.	

MICENE PRO WG

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anses

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
16803201 Oignon*Trt Part.Aer.* Mildiou(s)	2,5 kg/ha	3/an	28
	Motivation du refus : L'usage est refusé en raison de l'absence d'éléments permettant d'exclure un risque inacceptable pour les organismes aquatiques et de contamination des eaux souterraines.		
15653202 Pomme de terre*Trt Part.Aer.* Maladies des taches brunes	2,5 kg/ha	2/an	7
	Motivation du refus : L'usage est refusé en raison de l'absence d'éléments permettant d'exclure un risque de contamination des eaux souterraines.		
15653201 Pomme de terre*Trt Part.Aer.* Mildiou(s)	2,5 kg/ha	2/an	7
	Motivation du refus : L'usage est refusé en raison de l'absence d'éléments permettant d'exclure un risque de contamination des eaux souterraines.		
16953201 Tomate*Trt Part.Aer.*Mildiou(s)	2,5 kg/ha	3/an	3
	Motivation du refus : L'usage est refusé en raison de l'absence d'éléments permettant d'exclure un risque inacceptable pour les organismes aquatiques et de contamination des eaux souterraines.		

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

MICENE PRO WG

SYSTEMIC AND PROTECTANT FUNGICIDE FOR THE CONTROL OF
MILDEW ON POTATO, TOMATO, ONION, SPRING ONION, SHALLOT, GARLIC

A Water Soluble Granules formulation containing
4% w/w Benalaxyl-M and 65% w/w Mancozeb

Distributed by:

Produced by:

ISAGRO (ITALY)

CHARACTERISTICS

MICENE PRO WG contains 4% of Benalaxyl-M and 65% of Mancozeb. Benalaxyl-M is a systemic fungicide for use on selected crops to control diseases caused by different species of Phycomycete family of fungi. Mancozeb is a contact fungicide effective against a wide range of fungal pathogens.

Pre harvest interval: potato, 7 days; tomato, 3 days; onion, spring onion, shallot and garlic, 28 days.

Harmful to aquatic organisms.

DIRECTIONS FOR USE AND RATES

MICENE PRO WG is to be used as foliar application in a preventive disease control program in the following crops.

POTATO

Against **Late blight** (*Phytophthora infestans*), dose 2,5 kg/ha

Make the first application when conditions for primary infection occur; in any case no later than beginning of crop cover along the row (BBCH 31). If a Blight warning is issued for the area, apply the first spray immediately, irrespective of the growth stage of the crop. Subsequent sprays shall be made at a 7-10 days interval according to the disease pressure.

TOMATO

Against **Late blight** (*Phytophthora infestans*), dose 2,5 kg/ha

Make the first application when conditions favourable to the disease development occur, in any case no later than beginning of flowering (first inflorescence, first flower open, BBCH 61).

ONION / SPRING ONION / SHALLOT / GARLIC

Against **Downy Mildew** (*Peronospora destructor*), dose 2,5 kg/ha.

Make the first spray as soon as conditions favourable to the disease development occur. Subsequent applications shall be made at a 7-10 days interval, according to the disease pressure.

GENERAL ADVICE ON THE APPLICATION

Use ground sprayers. Spray fans should overlap just before the top of the crop. Use a fine spray at high pressure to ensure complete cover of the foliage. Allow foliage to dry before applying MICENE PRO WG after rainfall or irrigation.

Apply in sufficient water to achieve thorough coverage of foliage.

The **application interval** can be determined by assessing the relative threat of Mildew to the crop. Mildew is favoured by warm temperatures and long periods of high relative humidity. Under these conditions the application timing between two consecutive applications of MICENE PRO WG must be reduced to 7 days on potato, tomato, and other vegetables.

Appendix 3 – Letter(s) of Access

Provided upon request.