

REGISTRATION REPORT

Part A

Risk Management

Product code: IR6141 M WG

Product name: SIDECAR 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 SIDECAR 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 SIDECAR WG (IR6141 M WG) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of SIDECAR 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 SIDECAR 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 SIDECAR 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 1107/2009 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 (2012-1141) 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 2017³ 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.

The current document (RR) based on Anses’s assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009⁴, implementing regulations, and French regulations.

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/AGRGI632554A/jo/texte>

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

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 546/2011⁵, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014⁶ 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 extrapolation⁷ 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 SIDECAR 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.

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/AGRGI407093A/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)	SIDECAR WG (IR6141 M WG)
Authorisation number	2180330
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 bags (2.5 kg, 5 kg or 10 kg) High-density polyethylene containers (4 kg) Paper/ low-density polyethylene bags sacks (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 - Category 2	
Environmental hazards	Hazardous to the aquatic environment - Acute Hazard Category 1 Hazardous to the aquatic environment - Chronic Hazard Category 1	
Hazard pictograms		
Signal word	Warning	
Hazard statements	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 –	<i>For the P phrases, refer to the extant legislation</i>	
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.
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SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 50 metres ⁸ to surface water bodies.
SPe 3	To protect non-target arthropods, respect an unsprayed buffer zone of 5 metres to non-agricultural land.
SPe 3	To protect non-target plants, respect an unsprayed buffer zone of 20 metres to non-agricultural land.
SPa 1	To avoid the build-up of resistance of grape downy mildew [<i>Plasmopara viticola</i>] to benalaxyl-M, do not apply this product more than twice per year on grape. To manage the risk of resistance with SIDECAR WG (IR6141 M WG), it is recommended to follow the limitations of use by chemical family recommended in the official French advice on managing resistance to diseases of grapes ⁹ .

2.2.3 Other phrases linked to the preparation

Wear suitable personal protective equipment ¹⁰ : refer to the Decision in Appendix 1 for the details
Re-entry period ¹¹ : 48 hours
Pre-harvest interval ¹² : 42 days
Other mitigation measures: - Maintain agitation of the spray mixture during application.
The label must include the following recommendations: It must be made clear that the product must be applied for the control of <i>Guignardia bidwelli</i> and <i>Pseudopeziza tracheiphila</i> only in the case of mutual protection against <i>Plasmopara viticola</i> .
The label must reflect the conditions of authorisation.

⁸ The legal basis for this is **Titre III Article 12** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

⁹ Available at http://draaf.centre-val-de-loire.agriculture.gouv.fr/IMG/pdf/Note_technique_commune_Vigne_2017_Vdef_cle8e7ec3.pdf

¹⁰ If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

¹¹ The legal basis for this is **Titre I Article 3** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

¹² According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France. When the conclusion is “not acceptable” 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)
active substance 1
active substance 2
Applicant:
Zone(s):
Verified by MS:

SIDECAR WG (IR6141 M WG)
benalaxyl-M
mancozeb
ISAGRO S.p.A.
southern EU
yes

Formulation type: WG
Conc. of a.s. 1: 40 g/kg
Conc. of a.s. 2: 650 g/kg
professional use
non-professional use

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 applicatio ns	kg a.s./hL min max	water L/ha min max	g a.s./ha min max		
Grape	France	IR6141 M	F	<i>Plasmopara viticola</i> / <i>Guignardia bidwellii</i> <i>Pseudopeziza tracheiphila</i> ¹³	WG	40 BM + 650 MZB	Foliar Spraying	40-73	2	10-14 days	0.010 – 0.050 + 0.163 – 0.813	200 - 1000	100 + 1625	42	Acceptable
Grape	France	IR6141 M	F	<i>Cryptosporella viticola</i> ¹⁴	WG	40 BM + 650 MZB	Foliar Spraying	05-12	2	10-14 days	0.010 – 0.050 + 0.163 – 0.813	200 - 1000	100 + 1625	42	Not acceptable (efficacy)

BM = benalaxyl-M MZB = mancozeb

¹³ red fire or rotbrenner disease

¹⁴ black knot or dead-arm

- 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

SIDECAR 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 were 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 a polyester/aluminium/polyethylene bag. Since the product 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 out 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 the human health section. 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

Endpoints used in risk assessment:

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 an <i>in vivo</i> rat study performed on the formulation (which is the representative formulation of the active substance):	Concentrate (tested) 8 g/L (0.08 mg/cm ²)	Diluted formulation (tested) 0.1 g/L (0.001 mg/cm ²)
	<i>In vivo</i> (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 <i>in vivo</i> 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
	<i>In vivo</i> (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

SIDECAR 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 type	F/G ¹⁵	Equipment <i>Application method</i>	Maximum application rate	Minimum volume water (L/ha)
Grape	F	Vehicle-mounted/manual knapsack <i>Upward spraying</i>	2.5 kg product/ha (100 g benalaxyl-M/ha and 1625 g mancozeb/ha)	200

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

Crop	Equipment	PPE and/or working coverall	% AOEL benalaxyl-M	% AOEL mancozeb
Grape	Vehicle-mounted <i>Upward spraying</i>	Working coverall and gloves during mixing/loading and application	14	50
	Manual knapsack <i>Upward spraying</i>		9	75

According to the model calculations, it may be concluded that the risk for the operator using SIDECAR WG (IR6141 M WG) is acceptable with a working coverall and gloves during mixing/loading and application.

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

3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to be 3% of the AOEL of benalaxyl-M and mancozeb.

¹⁵ Open field or glasshouse

It may be concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to SIDECAR 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 29% of the AOEL of benalaxyl-M and 7% 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 SIDECAR 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. Any exceedence of the current MRLs for benalaxyl-M and mancozeb as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and 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 authorisation 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

SIDECAR 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) 520/2011	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
/	Grape	Yes	Yes (21 N + 25 S)	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. These data were not considered for risk assessment.

Grape is not a rotated crop and is not fed to livestock.

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
/	Grape	Yes	Yes (10 N + 21 S)	Yes	Yes	Yes	No	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.

Grape is not a rotated crop and is not fed to livestock.

Information on SIDECAR WG (IR6141 M WG)

Crop	PHI for IR6141 M WG proposed 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		
Grape	42 days	Yes	Yes	42 days	

NR: not relevant

* Purpose of withholding period to be specified

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.

PEC_{soil} and PEC_{sw} values derived for the active substances and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PEC_{gw} values for both active substance and their metabolite do not occur at levels exceeding those mentioned in Regulation (EC) 1107/2009 and guidance document SANCO 221/2000 on metabolites in groundwater. 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 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.

Risk mitigations measures are required in order to protect aquatic organisms, non-targets arthropods and non-target plants.

3.1.7 Efficacy

Considering the data submitted:

- the efficacy level of SIDECAR WG (IR6141 M WG) is considered satisfactory for all the requested uses, with the exception of use on *Cryptosporrella viticola* (black knot or dead-arm).
- the phytotoxicity level of SIDECAR WG (IR6141 M WG) is considered negligible for all the requested uses.
- the risks of negative impact on yield, quality, transformation processes and following crops are considered negligible.
- there is a risk of resistance developing or appearing to benalaxyl-M for downy mildew, requiring monitoring and the setting-up of efficacy trials in situations of characterised resistance. To avoid the development of resistance of downy mildew to benalaxyl-M, the number of applications is limited to two per crop cycle on grape. Resistance monitoring and efficacy trials in situations of characterised resistance should be put in place.

Restrictions:

SPa 1: To avoid the development of resistance of downy mildew to benalaxyl-M, the number of applications is limited to two per crop cycle on grapevine. To manage the risk of resistance with SIDECAR WG (IR6141 M WG) it is recommended to follow the limitations of use by chemical group recommended by the official guidance¹⁶ on resistance management on grapevine diseases.

Resistance monitoring data:

Monitoring of resistance to benalaxyl M should be put in place on downy mildew (one monitoring for all products based on benalaxyl-M). Efficacy trials in situations of characterised resistance to benalaxyl-M must also be put in place on downy mildew with at least the modalities benalaxyl-M alone and mancozeb alone each applied at the same rate of active substance that that results from IR6141 M at the intended rate. Any new information which would change the resistance risk analysis should immediately be provided to Anses (France).

Post-authorisation data: -

Information on label recommendation:

The product must be applied for the control of *Guignardia bidwelli* and *Pseudopeziza tracheiphila* only in the case of mutual protection against downy mildew (*Plasmopara viticola*).

¹⁶ Reference cited in Section 2.2.2

3.2 Conclusions arising from French assessment

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

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

Monitoring of resistance to benalaxyl M should be put in place for downy mildew (one monitoring programme for all products based on benalaxyl-M). Any new information which would change the resistance risk analysis should immediately be provided to Anses (France).

3.4.2 Post-authorisation data requirements

- Efficacy trials in situations of characterised resistance to benalaxyl-M must also be put in place on downy mildew with at least the modalities benalaxyl-M alone and mancozeb alone each applied at the same rate of active substance than the results from the product at the intended rate.

3.4.3 Label amendments

The draft label proposed by the applicant in Appendix 2 may be corrected with consideration of any new element under points 2.2.1 (or 2.2.2), 2.2.3 and 2.2.4.

The label shall reflect the detailed conditions stipulated in the Decision.

Appendix 1 – Copy of the French Decision



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 réglementaire,

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

de la société ISAGRO SPA

enregistrée sous le n°2012-1141

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

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.



Informations générales sur le produit	
Noms du produit	SIDECAR WG CAPRI 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	40 g/kg - béalaxyl-M 650 g/kg - mancozèbe
Numéro d'intrant	9912-2012.01
Numéro d'AMM	2180330
Fonction	Fongicide
Gamme d'usage	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 2020.

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,

03 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)



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 multicouches en polyester / aluminium / polyéthylène basse densité	1 kg
Sacs multicouches en polyester / aluminium / polyamide / polyéthylène basse densité	2,5 kg ; 5 kg ; 10 kg
Bidons en polyéthylène haute densité	4 kg
Sacs multicouches en papier / polyéthylène basse densité	20 kg ; 25 kg

Classification du produit	
La classification retenue est la suivante :	
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 réglementation 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.	



Liste des usages autorisés

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
12703206 Vigne*Trt.Part.Aer.*Black rot	2,5 kg/ha	2/an	entre les stades BBCH 40 et BBCH 73	42	50	5	20	-
	Intervalle minimum entre les applications : 10 jours. 2 applications maximum par cycle cultural. Uniquement pour une lutte conjointe contre le mildiou de la vigne.							
12703203 Vigne*Trt.Part.Aer.*Mildiou(s)	2,5 kg/ha	2/an	entre les stades BBCH 40 et BBCH 73	42	50	5	20	-
	Intervalle minimum entre les applications : 10 jours. 2 applications maximum par cycle cultural.							
12703207 Vigne*Trt.Part.Aer.*Rougeot parasitaire	2,5 kg/ha	2/an	entre les stades BBCH 40 et BBCH 73	42	50	5	20	-
	Intervalle minimum entre les applications : 10 jours. 2 applications maximum par cycle cultural. Uniquement pour une lutte conjointe contre le mildiou de la vigne.							

SIDECAR WG
AMM n°2180330



Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12703202 Vigne*Trt Part.Aer.*Excoriose	2,5 kg/ha	2/an	42
Motivation du refus : L'usage est refusé au motif que la substance active bénalaxy-M n'a pas d'action sur l'excoriose.			

SIDE CAR WG
AMM n°2180330



Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- 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 individuelles.
- le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage).
- les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

Pour l'opérateur, porter

Dans le cadre d'une application manuelle à l'aide d'un pulvérisateur à dos :

• pendant le mélange/chargement

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de protection de catégorie III type 4.

• pendant l'application

- Combinaison de protection de catégorie III type 4 avec capuche ;
- Bottes de protection certifiées EN 13 832-3 ;
- Gants en nitrile certifiés EN 374-3.

• pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de protection non tissée de catégorie III type 4.

Dans le cadre d'une application à l'aide d'un pulvérisateur pneumatique :

• 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.

• pendant l'application

Si application avec tracteur avec cabine

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

Si application avec tracteur sans cabine

- Combinaison de protection de catégorie III type 4 avec capuche ;
- 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.

Délai de rentrée en application de l'arrêté du 4 mai 2017

- 48 heures.

Respect des limites maximales de résidus (LMR)

Pour chaque usage figurant dans la liste des usages autorisés, les conditions d'utilisation du produit 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 arthropodes non cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente.
- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 50 mètres en bordures des points d'eau.

Protection de la flore

- SPe 3 : Pour protéger les plantes non cibles, respecter une zone non traitée de 20 mètres par rapport à la zone non cultivée adjacente.

Gestion des résistances

- Spa 1 : Pour éviter le développement de résistances du mildiou de la vigne à la substance bénomyl-M, le nombre d'application du produit est limité à 2 applications maximum par cycle cultural sur vigne.
- Afin de gérer les risques de résistance avec le produit, il est recommandé de suivre les limitations d'emploi par groupe chimique préconisées par la note relative à la gestion des résistances des maladies de la vigne.

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)
Mettre en place un suivi de la résistance du mildiou au bénomyl-M. Fournir aux autorités compétentes toute nouvelle information susceptible de modifier l'analyse de risque de résistance pour l'ensemble des usages.	-	-
Mettre en place des essais d'efficacité en situation de résistance caractérisée au bénomyl-M et au mancozèbe pour le mildiou de la vigne.	-	-

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

SIDECAR WG

SYSTEMIC AND PROTECTANT FUNGICIDE FOR THE CONTROL OF
MILDEW ON GRAPE

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

Distributed by:



Produced by:



CHARACTERISTICS

SIDECAR 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: grapes, 42 days

Harmful to aquatic organisms.

DIRECTIONS FOR USE AND RATES

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

GRAPE

Against **Downy Mildew** (*Plasmopara viticola*), **Black Rot** (*Guignardia bidwellii*), dose 2,5 kg/ha

SIDECAR WG is to be used as foliar application in a preventive disease control program. Make the first application at beginning of flowering (BBCH 60). Subsequent sprays must be carried out at 10-14 days interval according to the disease pressure.

Under severe disease risk, reduce the interval between two consecutive applications to 10-12 days.

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 SIDECAR 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 SIDECAR WG must be reduced to 10 days on grape.

LABEL

Appendix 3 – Letter(s) of Access

Provided upon request.