

REGISTRATION REPORT

Part A

Risk Management

**Product code: Fosetyl-Al 50% + Folpet 25%
+ Cymoxanil 4% WG**

Product name: MAGMA TRIPLE WG

Chemical active substances:

fosetyl-aluminium, 500 g/kg

folpet, 250 g/kg

cymoxanil, 40 g/kg

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

New application

Applicant: Industrias Afrasa S.A.

Date: 2020/08 /11 (Decision)

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PART A

RISK MANAGEMENT

1 Details of the application

The company INDUSTRIAS AFRASA S.A. has requested a marketing authorisation in France for the product MAGMA TRIPLE WG (PRODUCT CODE: FOSETYL-AL 50% + FOLPET 25% + CYMOXANIL 4% WG), containing 500 g/kg fosetyl-aluminium¹, 250 g/kg folpet¹ and 40 g/kg cymoxanil¹, as a fungicide for professional uses.

Appendix 1 of this document provides a copy of the product authorisation.

Appendix 2 of this document contains a copy of the product label (draft as proposed by the applicant).

1.1 Application background

The present registration report concerns the evaluation of INDUSTRIAS AFRASA S.A.'s new application concerning the product MAGMA TRIPLE WG (PRODUCT CODE: FOSETYL-AL 50% + FOLPET 25% + CYMOXANIL 4% WG) in France (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 Member States (MSs) of the Southern zone.

The present application (2016-1028) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009², the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")³. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of MAGMA TRIPLE WG (PRODUCT CODE: FOSETYL-AL 50% + FOLPET 25% + CYMOXANIL 4% WG) has been made using endpoints agreed in the EU peer reviews of fosetyl, folpet and cymoxanil. It also includes assessment of data and information related to MAGMA TRIPLE WG (PRODUCT CODE: FOSETYL-AL 50% + FOLPET 25% + CYMOXANIL 4% WG) where those data have not been considered in the EU peer review process.

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 risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011⁴, and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

¹ 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

² REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

³ 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](#)

⁴ 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

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This document also describes the specific conditions of use and labelling required for France for the registration of MAGMA TRIPLE WG.

1.2 Letters of Access

The applicant has provided letters of access for the active substances. These letters of access are available upon request.

1.3 Justification for submission of tests and studies

According to the applicant: “*Test and studies submitted are required in order to fulfil the requirements of EC Regulation 1107/2009*”.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of MAGMA TRIPLE WG (PRODUCT CODE: FOSETYL-AL 50% + FOLPET 25% + CYMOXANIL 4% WG)), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

Product code	Fosetyl-Al 50% + Folpet 25% + Cymoxanil 4% WG
Product name in MS	MAGMA TRIPLE WG
Authorisation number	2200347
Kind of use	Professional use
Low risk product (article 47)	No
Function	Fungicide
Applicant	INDUSTRIAS AFRASA S.A.
Active substance(s) (incl. content)	Fosetyl-Al, 500 g/kg Folpet, 250 g/kg Cymoxanil, 40 g/kg
Formulation type	Water-dispersible granule [WG]
Packaging	Bags: PET/Al/LDPE ⁵ (40 g, 100 g, 250 g, 500 g, 1 kg, 2 kg, 2.5 kg, 3 kg, 5 kg)
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None

⁵ PET/Al/LDPE : Polyethylene terephthalate / aluminium / low-density polyethylene

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Recommended tank mixtures	None
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2.2 Conclusion DAMM

The evaluation of the application for MAGMA TRIPLE WG (PRODUCT CODE: FOSETYL-AL 50% + FOLPET 25% + CYMOXANIL 4% WG) resulted in the decision to grant an authorisation. Taking into account the above assessment, an authorisation **can be granted** as proposed in Appendix 1 – Copy of the product decision.




2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Skin sensitisation, category 1. Eye irritation, category 2. Carcinogenicity, category 2. Reproductive toxicity, category 2. Hazardous to the aquatic environment - Acute Hazard, category 1. Hazardous to the aquatic environment - Chronic Hazard, category 2.
Hazard pictograms:	   GHS07 GHS08 GHS09
Signal word:	Warning.
Hazard statement(s):	H317: May cause an allergic skin reaction. H319: Causes serious eye irritation. H351: Suspected of causing cancer. H361fd: Suspected of damaging fertility or the unborn child. H400: Very toxic to aquatic life. H411: Toxic to aquatic life with long-lasting effects.
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation.</i>
Additional labelling phrases:	-

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

2.4.2 Standard phrases under Regulation (EU) No 547/2011

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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.
	For other restrictions refer to 2.5.

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017⁶ provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres for products applied through spraying or dusting;
- unless otherwise 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, non-spraying buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

Finally, the French Order of 26 March 2014⁷ provides that:

- an authorisation granted for a “reference” crop applies also for “related” crops, unless formally stated in the Decision
- the “reference” and “related” 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 “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁸ 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.

2.5.1 Restrictions linked to the PPP

The authorisation of the PPP is linked to the following conditions:

⁶ 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, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

⁷ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo>

⁸ SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

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The applicant is required to comply with the current applicable standard for clothing type PPE (ISO EN 27065)⁹.

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 20 metres including an unsprayed planted buffer zone of 5 metres to surface water bodies
SPe 3	To protect non-target arthropods, respect an unsprayed buffer zone of 5 metres to non-agricultural land.
Other specific restrictions	
Re-entry period	6 days.
bystander and resident protection	Respect an unsprayed zone of 10 meters from the last treated raw and : - areas where bystanders are present during treatment - areas where residents could be present at least 50% drift reduction noozles should be used.
Risk mitigation measures	Limit the use of products containing fungicidal active substances that may lead to the presence of phosphonic acid in harvested products to a total of 10 kg equivalent of phosphonic acid per hectare per year on grapes.
Risk mitigation measures	Apply only with a tractor with a closed cab (category 4 according to standard EN 15695-1-2).

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

⁹ Protective clothing – Performance requirements for protective clothing worn by operators applying pesticides and for re-entry workers. EN ISO 27065:2017

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2.6 Intended uses (only NATIONAL GAP)

Please note:

When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.

GAP rev. 1, date: 2020-08-11

PPP (product name/code): MAGMA TRIPLE WG (PRODUCT CODE: FOSETYL-AL 50% + FOLPET 25% + CYMOXANIL 4% WG)/
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WG ^(a, b)

Active substance 1: Fosetyl-Al

Conc. of a.s. 1: 500 g/kg ^(c)

Active substance 2: Folpet

Conc. of a.s. 2: 250 g/kg ^(c)

Active substance 3: Cymoxanil

Conc. of a.s. 3: 40 g/kg ^(c)

Applicant: Industrias Afrasa S.A.

Professional use: ☒

Zone(s): Southern Zone ^(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	14
Use- No. ^(e)	Member state(s)	Crop or situation (crop destination/purpose of crop)	F, Fn, Fpn G, Gn, Gpn 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/synergis per ha (^(f))
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	Grape	F	<i>Plasmopara viticola</i>	Tractor- mounted sprayer	BBCH 61-75	a) 1 b) 1	-	a) 2 b) 2	a) 1000 (fos) + 500 (fol) + 80 (cim) b) 1000 (fos) + 500 (fol) + 80 (cim)	300 / 500	28	Acceptable only for application with a tractor with a closed cab (category 4 according to standard EN 15695-1-2).

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Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(f)	No authorisation 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	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
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	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)	9	Minimum interval (in days) between applications of the same product
	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	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	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.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
	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.	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 Background of authorisation decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

MAGMA TRIPLE WG (PRODUCT CODE: FOSETYL-AL 50% + FOLPET 25% + CYMOXANIL 4% WG) is a water-dispersible granule (WG). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a brown solid, with mild odour. The product is not explosive, has no oxidising properties and is not flammable. It has a self-ignition temperature above 400 °C. In 1 % aqueous solution, it has a pH value of 3.4 at 20 °C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active substance 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/LDPE bags. As the formulation is a WG, all the different packaging types may be considered acceptable. The technical characteristics are acceptable for a WG formulation.

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

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

- The efficacy of MAGMA TRIPLE WG (PRODUCT CODE: FOSETYL-AL 50% + FOLPET 25% + CYMOXANIL 4% WG) is considered satisfactory for the requested use at an application rate of 3 kg product/ha. The application rate of 2 kg/ha requested by the applicant is considered acceptable. Nevertheless, the curative effect of cymoxanil and its usefulness in the association has not been fully demonstrated. Efficacy data should therefore be provided to show the usefulness of cymoxanil in the product.
- The level of phytotoxicity of MAGMA TRIPLE WG (PRODUCT CODE: FOSETYL-AL 50% + FOLPET 25% + CYMOXANIL 4% WG) is considered negligible.
- The risk of negative impact (on yield, quality, transformation processes, succeeding and adjacent crops) is considered negligible.
- There is a risk of resistance appearing or developing to cymoxanil for grape downy mildew: this requires monitoring. To manage the risk of resistance with MAGMA TRIPLE WG (PRODUCT CODE: FOSETYL-AL 50% + FOLPET 25% + CYMOXANIL 4% WG) it is recommended to follow the limitations of use by chemical group recommended by the French official advice¹⁰ on resistance management on grapevine.

3.3 Methods of analysis (Part B, Section 5)

¹⁰ Note Technique Commune Gestion de la résistance, maladies de la vigne : mildiou, oïdium, pourriture grise, available at <https://www.vege-phyl.fr/nos-activites/commissions/maladies/>

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3.3.1 Analytical method for the formulation

Analytical methodology for the determination of the active substances in the formulation is available and validated. As the active substances fosetyl and cymoxanil do not contain any relevant impurity, no pertinent analytical method is required.

Analytical methodology for the determination of the relevant impurities of the active substance folpet has been submitted and validated.

3.3.2 Analytical methods for residues

Fosetyl:

Analytical methods are available in the RAR and in this dossier, and are validated for the determination of residues of fosetyl-Al in plants (acidic crops), soil, water (surface and drinking) and air.

Folpet:

Analytical methods are available in the Draft Assessment Report (DAR) and validated for the determination of residues of folpet in plants (acidic crops), foodstuffs of animal origin, soil, water (surface and drinking) and air.

Cymoxanil:

Analytical methods are available in the DAR and validated for the determination of residues of cymoxanil in plants (acidic and high-water-content), soil, water (surface and drinking) and air.

Analytical methods for the determination of residues of fosetyl-Al, folpet and cymoxanil in foodstuffs of animal origin are not necessary.

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

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Active substance: fosetyl-Al			
ADI	3 mg/kg bw/d		EU (2007)
ARfD	Not applicable		
AOEL	5 mg/kg bw/d		
AAOEL	None		
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (used in formulation) 500 g/kg	Spray dilution (used in formulation) 2 g/L
	Dermal absorption endpoints %	25	75

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Oral absorption	100	
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Active substance: folpet			
ADI	0.1 mg/kg bw/d		EU (2007)
ARfD	0.2 mg kg bw		
AOEL	0.1 mg/kg bw/d		
AAOEL	None		
Dermal absorption	Based on an <i>in vitro</i> human study performed on a similar formulation:		
		Concentrate (used in formulation) 250 g/kg	Spray dilution (used in formulation) 1 g/L
	Dermal absorption endpoints %	2	6
Oral absorption	100		

Active substance: cymoxanil			
ADI	0.013 mg/kg bw/d		EU (2009)
ARfD	0.08 mg/kg bw		
AOEL	0.01 mg/kg bw/d		
AAOEL	None		
Dermal absorption	Based on an <i>in vitro</i> human study performed on the formulation:		
		Concentrate (tested) 40.8 g/kg	Diluted formulation (tested) 0.12 g/L
	<i>In vitro</i> (human) %	3	54
		Concentrate (used in formulation) 40 g/kg	Spray dilution (used in formulation) 0.16 g/L
	Dermal absorption endpoints %	3	54
Oral absorption	100		

3.4.1 Acute toxicity

MAGMA TRIPLE WG, containing 500 g/kg fosetyl-Al, 250 g/kg folpet and 40 g/kg cymoxanil, has a low acute oral, inhalational and dermal toxicity. It is irritating to the rabbit eye but not to the rabbit skin, and is a skin sensitiser.

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3.4.2 Operator exposure

Summary of critical use patterns (worst cases):

Crop type	F/G ¹¹	Equipment <i>Application method</i>	Maximum application rate kg product/ha (g a.s./ha)	Maximum volume wa- ter (L/ha)
Grapes	F	Vehicle-mounted <i>Upward spraying</i>	2 kg MAGMA TRIPLE WG/ha (fosetyl-Al: 1000 g/ha folpet: 500 g/ha cymoxanil: 80 g/ha)	500

Considering the proposed uses, operator systemic exposure was estimated using the EFSA model¹²:

Crop	Equipment	PPE and/or working cover- all	% AOEL fosetyl-Al	% AOEL folpet	% AOEL cymoxanil
Grapes	Vehicle-mounted <i>Upward spraying</i>	Working coverall and gloves during mixing/load- ing and application	3.4	10	110
		Working coverall and gloves during mixing/load- ing and application <u>and</u> <u>closed cab</u>	0.36	2.1	16

According to the model calculations, it may be concluded that the risk for the operator using MAGMA TRIPLE WG (PRODUCT CODE: FOSETYL-AL 50% + FOLPET 25% + CYMOXANIL 4% WG) is acceptable with a working coverall and gloves during mixing/loading and application and **with the use of a closed cab (category 4 according to Standard NF EN-15695-1-2).**

3.4.3 Worker exposure

Workers may have to enter treated areas after treatment for crop hand-harvesting or searching, reaching and picking activities. Therefore, estimation of worker exposure was calculated according to the AOEM model. Exposure is estimated to be 53 % of the AOEL of fosetyl-Al, 12 % of the AOEL of folpet and 34 % of cymoxanil with PPE (work-wear only) **taking into account a re-entry period of at least 5.5 days**¹³.

It may be concluded that there is no unacceptable risk anticipated for the worker.

¹¹ Open field or glasshouse

¹² AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014;12 (10):3874)

¹³ An acceptable value of 5.5 days re-entry time was calculated, corresponding to a Hazard Index of 0.99. It was rounded to 6 days for practical reasons and being protective

3.4.4 Bystander exposure

Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e., no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set¹⁴.

Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): “No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.”

3.4.5 Resident exposure

Residential exposure was assessed according to the EFSA model¹⁵ incorporating a distance of 10 metres from the spray boom and a drift reduction technology. An acceptable risk was determined for residents (adult and child).

Model (AOEM) - All pathways (mean)	% AOEL fosetyl-Al	% AOEL folpet	% AOEL cymoxanil
Resident (children)	3.42	4.46	71.53
Resident (adults)	1.89	2.07	35.88

3.4.6 Combined exposure

Currently no EU-harmonised guidance is available on the risk assessment of combined exposure to multiple active substances. Most assessment approaches used up to now make use of the Hazard Index (HI) concept. It is therefore suggested to use this as a first-tier assessment.

A cumulative assessment for operators, bystanders/residents and workers was performed. At the first tier, combined exposure was calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity.

Hazard quotients (HQ) for each active substance and the HI (sum of hazard quotients) are:

Population groups and PPE		Active substance	Estimated exposure/AOEL (HQ)
Operators	Working coverall and gloves during mixing/loading & application + <u>closed cab</u> during application	fosetyl-Al	0.0036
		folpet	0.0205
		cymoxanil	0.1594

¹⁴ Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

¹⁵ EFSA Journal 2014;12(10):3874

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	Cumulative risk operators (HI)		0.1835
Bystanders /Residents	Children - All pathways (mean) Buffer zone: 10 m Vehicle with drift-reduction	fosetyl-Al	0.0342
		folpet	0.0446
		cymoxanil	0.7153
	Cumulative risk bystanders/residents (child) (HI)		0.7941
	Adults - All pathways (mean) Buffer zone: 10 m Vehicle with drift-reduction	fosetyl-Al	0.0189
		folpet	0.0207
		cymoxanil	0.3588
	Cumulative risk bystanders/residents (adult) (HI)		0.3984
Worker	Working coverall and <u>re-entry period</u> of 5.5 days ¹⁶	fosetyl-Al	0.53
		folpet	0.12
		cymoxanil	0.34
	Cumulative risk workers (HI)		0.99

The Hazard Index is < 1. Thus, combined exposure to all active substances in MAGMA TRIPLE WG (PRODUCT CODE: FOSETYL-AL 50% + FOLPET 25% + CYMOXANIL 4% WG) is not expected to present a risk for operators, workers, residents and bystanders, taking into account the mitigation measures mentioned above. No further refinement of the assessment is required.

3.5 Residues and consumer exposure (Part B, Section 7)

The data available are considered sufficient for risk assessment. No exceedence of the current MRL as laid down in Reg. (EU) 396/2005 is expected on grapes.

The chronic and short-term intakes of fosetyl-Al, folpet and cymoxanil residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, France as zRMS agrees with the authorisation of the intended uses.

¹⁶ An acceptable value of 5.5 days re-entry time was calculated, corresponding to a Hazard Index of 0.99. It was rounded to 6 days for practical reasons and being protective (6 days re-entry time corresponds to a Hazard Index of 0.91)

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Information on MAGMA TRIPLE WG (PRODUCT CODE: FOSETYL-AL 50% + FOLPET 25% + CY-MOXANIL 4% WG)(KCA 6.8)

Crop	PHI for MAGMA TRIPLE WG (PRODUCT CODE: FOSETYL-AL 50% + FOLPET 25% + CY-MOXANIL 4% WG) requested by applicant	PHI/withholding period* sufficiently supported for			PHI for MAGMA TRIPLE WG proposed by zRMS	zRMS Comments (if different PHI proposed)
		fosetyl-Al	folpet	cymoxanil		
Grapes	28 days	Yes	Yes	Yes	28 days	

* Purpose of withholding period to be specified

Waiting periods before planting succeeding crops: Not relevant.

3.6 Environmental fate and behaviour (Part B, Section 8)

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 fosetyl, folpet, cymoxanil 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 fosetyl-Al, folpet, cymoxanil and their metabolites do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009.

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.

3.7 Ecotoxicology (Part B, Section 9)

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

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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, earthworms, other soil macro- and micro-organisms and terrestrial plants are acceptable for the intended uses.

The use of MAGMA TRIPLE WG, at the proposed label rates, poses an acceptable risk to aquatic organisms with mitigation measures such as a 20-metre unsprayed buffer zone to surface water bodies, including a planted buffer strip of 5 metres.

The use of MAGMA TRIPLE WG, at the proposed label rates, poses an acceptable risk to non-target arthropods other than bees with mitigation measures such as a 5-metre unsprayed buffer zone to non-agricultural land.

3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to environmental fate and behaviour above for conclusion on the risk of groundwater contamination.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

The active substances fosetyl-Al, folpet and cymoxanil are not approved as candidates for substitution; therefore a comparative assessment is not foreseen.

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

When the conclusions of the assessment is “Not acceptable”, please refer to relevant summary under point 3, “Background of authorisation decision and risk management”.

5.1.1 Post-authorisation monitoring

A monitoring of resistance to cymoxanil should be implemented on grapevine (one monitoring for all products based on cymoxanil). Any new information which would change the resistance risk analysis should immediately be provided to Anses (France). In all cases, a report on the results of the monitoring implemented should be provided at the time of the renewal of MAGMA TRIPLE WG's authorisation.

5.1.2 Post-authorisation data requirements

None.

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Appendix 1 Copy of the product authorisation DAMM



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 **MAGMA TRIPLE WG***

*de la société **INDUSTRIAS AFRASA S.A.***

*enregistrée sous le **n° 2016-1028***

Vu les conclusions de l'évaluation de l'Anses du 15 mai 2020,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France, sous réserve du respect de la composition du produit autorisée dans les conclusions de l'évaluation, pour les usages et dans les conditions précisés dans la présente décision et ses annexes.

La présente décision s'applique sans préjudice des autres dispositions applicables.

Avertissement :

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.

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Informations générales sur le produit	
Nom du produit	MAGMA TRIPLE WG
Type de produit	Produit de référence
Titulaire	INDUSTRIAS AFRASA S.A. Ciudad de Sevilla, 53Pol.ind. Fuente del Jarro, 46988 Paterna Valencia Espagne
Formulation	Granulé dispersable (WG)
Contenant	500 g/kg - fosétyl 250 g/kg - folpel 40 g/kg - cymoxanil
Numéro d'intrant	288-2016.01
Numéro d'AMM	2200347
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 30 avril 2022.

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 11 AOÛT 2020

Caroline SEMAILLE
 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 polyéthylène téréphtalate / aluminium / polyéthylène basse densité	40 g ; 100 g ; 250 g ; 500 g ; 1 kg ; 2 kg ; 2,5 kg ; 3 kg ; 5 kg

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	Mention de danger
Sensibilisants cutanés - Catégorie 1	H317 : Peut provoquer une allergie cutanée
Lésions oculaires graves - Catégorie 2	H319 : Provoque une sévère irritation des yeux
Cancérogénicité - Catégorie 2	H351 : Susceptible de provoquer le cancer
Toxiques pour la reproduction - Catégorie 2	H361fd : Susceptible de nuire à la fertilité. Susceptible de nuire au fœtus
Dangers pour le milieu aquatique - Danger aigu, catégorie 1	H400 : Très toxique pour les organismes aquatiques
Dangers pour le milieu aquatique - Danger chronique, catégorie 2	H411 : Toxique pour les organismes aquatiques, entraîne des effets 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.	

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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
12703203 Vigne*Trt Part.Aer.*Mildiou(s)	2 kg/ha	1/an	entre les stades BBCH 61 et BBCH 75	28	20 (dont DVP 5)	5	-	-
Appliquer uniquement avec un tracteur avec cabine de catégorie 4 selon la norme EN 15695-1-2.								

DVP : Dispositif Végétalisé Permanent.

MAGMA TRIPLE WG
 AMM n°2200347

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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 effectuée à l'aide d'un pulvérisateur pneumatique ou d'un atomiseur

• 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

Application uniquement avec tracteur avec cabine de catégorie 4 selon la norme EN 15695-1-2

- 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.

• 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

- 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:

- 6 jours



Protection des personnes présentes et des résidents (au sens du règlement (UE) N°284/2013)

Respecter une distance d'au moins 10 mètres entre le dernier rang traité et :

- l'espace fréquenté par les personnes présentes lors du traitement ;
- l'espace susceptible d'être fréquenté par des résidents

et utiliser un matériel permettant une atténuation de la dérive d'au moins 50 %.

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.

Limiter les applications de produits contenant des substances actives susceptibles d'engendrer la présence de résidus d'acide phosphonique dans les produits récoltés à un total de 10 kg d'équivalent d'acide phosphonique par hectare et par an.

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 20 mètres comportant un dispositif végétalisé permanent non traité d'une largeur de 5 mètres par rapport aux points d'eau.

- SPe 3 : Pour protéger les arthropodes non cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente.

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 au cymoxanil (un seul suivi tous produits confondus) pour le mildiou de la vigne.		
Fournir, aux autorités compétentes, toute nouvelle information susceptible de modifier l'analyse du risque de résistance pour le mildiou de la vigne.	-	-

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Appendix 2 Copy of the product label

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.

PARTIE PRINCIPALE
<p style="text-align: center;">MAGMA TRIPLE WG</p> <ul style="list-style-type: none"> • FONGICIDE • GRANULES DISPERSIBLES DANS L'EAU • COMPOSITION: <ul style="list-style-type: none"> Fosétyl-Al 50% p/p (500 g/kg) Folpet 25% p/p (250 g/kg) Cymoxanil 4% p/p (40 g/kg) • Contient du folpet et du cymoxanil. Peut entraîner une réaction allergique • CONTENU NET: 40-100-250-500 g, 1-5 kg • No de REGISTRE: • LIRE ATTENTIVEMENT L'ÉTIQUETTE AVANT L'UTILISATION • USAGE RÉSERVÉ AUX FERMIERS ET APPLICATEURS PROFESSIONNELS • STOCKAGE: Garder le produit dans un endroit frais, sec et bien ventilé. <p>FABRICATION:</p> <p>N° de lot:</p> <p>Date de fabrication:</p> <p>Date d'expiration:</p> <p>ENREGISTRÉ et FABRIQUÉ PAR:</p> <p>INDUSTRIAS AFRASA, S.A.</p> <p>Ciudad de Sevilla, n° 53</p> <p>46988-Pol. Ind. Fuente del Jarro</p> <p>PATERNA (Valencia)</p> <p>Tel.: +34 96 132 17 00; Fax: +34 96 132 17 16;</p> <p>Email: afrasa@afrasa.es</p> <p>DISTRIBUÉ PAR:</p>
(PARTIE GAUCHE)

PRÉCAUTIONS:



AVERTISSEMENT

H317: Peut provoquer une allergie cutanée.
 H319: Provoque une sévère irritation des yeux.
 H351: Susceptible de provoquer le cancer.
 H361Df: Susceptible de nuire à la fertilité. Susceptible de nuire au fœtus.
 H410: Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.
 EUH401: Respecter les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.
 EUH 208: Contient du ~~cymoxanil~~ et du ~~folpet~~. Peut entraîner une réaction allergique.

P102: Tenir hors de portée des enfants
 P273: Éviter le rejet dans l'environnement.
 P280: Porter des gants de protection, des vêtements de protection, un équipement de protection des yeux et du visage.
 P391: Recueillir le produit répandu
 P308+P313: En cas d'exposition prouvée ou suspectée: consulter un médecin.
 P405: Garder sous clef.
 P501: Eliminer le contenu/récipient conformément à la réglementation locale

SP1: Ne pas polluer l'eau avec le produit ou son emballage. (Ne pas nettoyer le matériel d'application près des eaux de surface / Éviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.)

SPe 3: Pour protéger les organismes aquatiques, respecter une zone tampon de végétation de 10 mètres par rapport aux points d'eau.

Ne pas entrer dans une culture traitée avant que les dépôts de pulvérisation sur la surface des feuilles aient complètement séché, à moins de porter des vêtements de protection.

INFORMATION MÉDICALE

- Traiter les symptômes et contacter un centre anti-poison pour le meilleur traitement à suivre en cas d'hospitalisation.
 - Inhalation: Faire sortir la victime à l'air frais et à l'écart de la zone contaminée. En cas d'arrêt respiratoire, pratiquer la respiration artificielle. Si la victime est en état de choc, garder au chaud et au repos. Consulter immédiatement un médecin.
 - Ingestion: Ne jamais rien faire boire ou avaler. En cas d'ingestion, ne pas faire vomir. Consulter un médecin et lui montrer l'emballage ou l'étiquette.
 - CONTACT AVEC LA PEAU: Enlever les vêtements contaminés et les laver. Laver la peau avec de l'eau et du savon (pourvu qu'il n'y a pas de brûlures) pendant 15-20 minutes. Consulter un médecin si des symptômes apparaissent.
 - CONTACT AVEC LES YEUX: Rincer les yeux abondamment avec de l'eau pendant au moins 15 minutes, en soulevant les paupières avec les doigts afin de nettoyer complètement. Enlever les verres de contact, le cas échéant. Consulter immédiatement un médecin.
- Attention: Consulter un centre antipoison

NE PAS LAISSER LA VICTIME SEULE

EN CAS D'INTOXICATION, APPELER XXXXXXXX

PARTIE DROITE

MAGMA TRIPLE WG est un mélange de trois substances ayant une activité fongicide contre le mildiou (*Plasmopara viticola*) de la vigne. L'une des substances (Fosetyl-AI) a des propriétés systémiques inhibant toutes les phases du développement du champignon; le deuxième (Folpet) possède une activité protectrice empêchant la germination et la pénétration des suçoirs dans les tissus; et le troisième (Cymoxanil) a des propriétés systémiques locales inhibant la sporulation et le développement interne du champignon. Le produit est donc très efficace pour la prévention des attaques de mildiou et l'éradication des infections précoces.

USAGES AUTORISÉS :

- **Vigne:** *Plasmopara viticola*

DOSES D'UTILISATION

Application par pulvérisation:

- **Vigne:** appliquer le produit à une dose de 2 - 3 kg/ha en utilisant un volume d'eau de 300 à 1000 l/ha, du début de la floraison jusqu'à ce que les baies atteignent la taille d'un pois lorsque les grappes pendent (BBCH 61-75), avec un maximum de 3 applications par année et un intervalle entre applications de 10 à 14 jours.

DÉLAI AVANT RÉCOLTE

Délai avant récolte, entre les applications et la récolte des fruits et des plantes destinés à la consommation humaine ou animale: 28 jours pour la vigne.

AVERTISSEMENT

Les recommandations et les informations que nous fournissons sont le fruit d'études complètes et rigoureuses. Cependant, lors de l'utilisation du produit, plusieurs facteurs peuvent intervenir qui échappent à notre contrôle (préparation des mélanges, application, conditions climatiques etc.) La Compagnie garantit la composition, la formulation et le contenu. L'utilisateur sera responsable des dommages éventuels (manque d'efficacité, toxicité en général, résidus, etc.) en cas de non observation des instructions de l'étiquette.

RINCER TROIS FOIS VIGOREUSEMENT CHAQUE RÉCIPIENT UTILISÉ. VERSER L'EAU DE RINÇAGE DANS LE RÉSERVOIR DU PULVÉRISATEUR. LORSQUE VIDE, CE RÉCIPIENT EST UN RÉSIDU TOXIQUE. IL EST DE LA RESPONSABILITÉ DE L'UTILISATEUR DE RETOURNER LES RÉCIPIENTS VIDES À UN DES POINTS DE RÉCEPTION CONFORMÉMENT À LA RÉGULATION NATIONALE.

