REGISTRATION REPORT

Part A

Risk Management

Product code: Bordeaux Mixture 15% + Fosetyl-Al 18% WP

Product name: TUTOR 18-15

Chemical active substances:

Copper (in the form of Bordeaux mixture), 150 g/kg
Fosetyl-aluminium, 180 g/kg

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: MANICA S.P.A

Date: 28/12/2018

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PART A
RISK MANAGEMENT

1 Details of the application

The company MANICA S.P.A has requested a marketing authorisation in France for the product TUTOR 18-15 (formulation code: Bordeaux Mixture 15% + Fosetyl-Al 18% WP), containing 150 g/kg copper (in the form of Bordeaux mixture) and 180 g/kg fosetyl-aluminium, as a fungicide for professional uses.

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 addenda for France. The information, data and assessments provided in the Registration Report, Part B include assessment of further data or information as required at national registration by EU regulations. It also includes assessment of data and information related to TUTOR 18-15 (Bordeaux Mixture 15% + Fosetyl-Al 18% WP) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of TUTOR 18-15 (Bordeaux Mixture 15% + Fosetyl-Al 18% WP) have been made using endpoints agreed in the EU peer reviews of copper and fosetyl-Al.

This document describes the specific conditions of use and labelling required for France for the registration of TUTOR 18-15 (Bordeaux Mixture 15% + Fosetyl-Al 18% WP).

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).

Appendix 3 of this document contains a copy of the Letter(s) of Access.

1.1 Appendix 4 of this document provides the list of data considered for national authorisation. Application background

The present registration report concerns the evaluation of MANICA S.P.A.'s application to market TUTOR 18-15 (Bordeaux Mixture 15% + Fosetyl-Al 18% WP) in France as a fungicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

The present application (2016-1775) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) 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")[1] – the highest application rates applied for in the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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[2], 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.

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[1] 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

[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

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011[3], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

1.2 Letters of Access

The applicant is the owner of the copper and TUTOR 18-15 (Bordeaux Mixture 15% + Fosetyl-Al 18% WP) data.

The applicant has provided letter(s) of access for fosetyl-Al data.

1.3 Justification for submission of tests and studies

According to the applicant:

"*The studies submitted have been performed to demonstrate the safe use of Bordeaux Mixture 15% + Fosetyl 18% WP as a fungicide in orchards (citrus, apples, pears, peaches), grapes, fruiting vegetables (tomato, aubergines, cucumbers, melon), potato and ornamentals*".

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of TUTOR 18-15 (Bordeaux Mixture 15% + Fosetyl-Al 18% WP), 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	Bordeaux Mixture 15% + Fosetyl 18% WP
Product name in MS	TUTOR 18-15
Authorisation number	N/A Product not rergistered in France
Low risk (article 47)	No
Function	Fungicide
Applicant	MANICA S.P.A.
Active substance(s) (incl. content)	Copper, 150 g/kg (in the form of Bordeaux mixture) Fosetyl-Al, 180 g/kg
Formulation type	Wettable powder [WP]
Packaging	N/A: no marketing authorisation granted
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

[3] 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

2.2 Conclusion

The evaluation of the application for TUTOR 18-15 (Bordeaux Mixture 15% + Fosetyl-Al 18% WP) resulted in the decision to **refuse the authorisation**.

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:	Eye irritation, Hazard Category 2 Hazardous to the aquatic environment — Chronic Hazard, Category 1
Hazard pictograms:	 SGH07 SGH09
Signal word:	Warning
Hazard statement(s):	H319: Causes serious eye irritation. H410: Very toxic to aquatic life with long lasting effects.
Precautionary statement(s):	***For the P phrases, refer to the extant legislation***
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

N/A : no marketing authorisation granted

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 2017 [4] 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

[4] 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

is 5 metres;
- 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 2014[5] 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 "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 extrapolation[6] 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

N/A : no marketing authorisation granted

2.5.2 Specific restrictions linked to the intended uses

None.

[5] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo
[6] SANCO document "guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs": SANCO/ 7525/VI/95 - rev.9

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green).
When the conclusion is "not acceptable" the intended use is highlighted in grey and the main reason(s) reported in the remarks.

GAP rev. 1, date: 28/12/2018

PPP (product name/code):	Bordeaux Mixture 15% + Fosetyl 18% WP / TUTOR 18-15	Formulation type:	WP [a, b]
Active substance 1:	copper (in the form of Bordeau mixture)	Conc. of a.s. 1:	150 g/kg [c]
Active substance 2:	fosetyl-Al	Conc. of a.s. 2:	180 g/kg [c]
Safener:	-	Conc. of safener:	- [c]
Synergist:	-	Conc. of synergist:	- [c]
Applicant:	MANICA S.P.A.	Professional use:	☒
Zone(s):	southern [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 and/ 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:**
					Method / Kind	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 / max		e.g. g safener/synergist per ha [f]

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ 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/synergist per ha [f]
					Method / Kind	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 / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1a	FR	**Wine grapes**	F	*Plasmopara viticola*	Air blast sprayer	Pre flowering to harvest (BBCH 15 to 85)	a.- 5 b.- 5	8	a) 5.0 b) 25.0	Fosetyl-Al a) 900 b) 4500 Copper a) 750 b) 3750	300-1000	20	**Not acceptable** (operator, worker, copper MRL)
1b	FR	**Table grapes**	F	*Plasmopara viticola*	Air blast sprayer	Pre flowering to harvest (BBCH 15 to 85)	a.- 5 b.- 5	8	a) 5.0 b) 25.0	Fosetyl-Al a) 900 b) 4500 Copper a) 750 b) 3750	300-1000	**28**	**Not acceptable** (operator, worker)
2	FR	Apple, pear and other minor pome fruits (MABSD, PYUCO, CYDOB, MSPGE, PYUPC, MABSY)	F	Bacterial disease (*Pseudomonas syringae*), *Venturia inaequalis, Venturia pyrina, Nectria galligena*	Air blast sprayer	Pre flowering period (BBCH 03-59)	a.- 2 b.- 2	12	a) 4.5 b) 9.0	Fosetyl-Al a) 810 b) 1620 Copper a) 675 b) Maximum limit of 1300 g Cu/ha/year	600-1000	n.d.	**Not acceptable** (operator, worker, fosetyl-Al MRL, efficacy)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ 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/synergist per ha [f]
					Method / Kind	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 / max		
3	FR	Apple, pear and other minor pome fruits (MABSD, PYUCO, CYDOB, MSPGE, PYUPC, MABSY)	F	Bacterial disease (*Pseudomonas syringae*), *Venturia inaequalis, Venturia pyrina, Nectria galligena*	Air blast sprayer	Post flowering period (BBCH 59-80)	a.- 3 b.- 3	8	a) 1.5 b) 4.5	Fosetyl-Al a) 270 b) 810 Copper a) 225 b) 675	600-1000	40	**Not acceptable** (fosetyl-Al MRL, efficacy)
4	FR	Peach, nectarine, apricot (PRNPS, PRNAR, PRNCE, PRNDO, PRNJP, PRNPN, PRNDS)	F	*Taphrina deformans, Coryneum beijerinckii*,*Polystigma sp*, bacterial diseases	Air blast sprayer	Before staring leaves falling to pre-flowering (BBCH 90-99 and 03-53)	a.- 4 b.- 4	10	a) 5.0 b) 20.0	Fosetyl-Al a) 900 b) 3600 Copper a) 750 b) Maximum limit of 1300 g Cu/ha/year	600-1000	n.a.	**Not acceptable** (operator, worker, MRL, efficacy for *Coryneum beijerinckii* and bacterial diseases) **Not acceptable** for *Taphrina deformans* (efficacy)
5	FR	Potato	F	*Phytophthora infestans*	Field crop sprayer	From transplanting to pre-harvest period (BBCH 13-79)	a.- 5 b.- 5	8	a) 5.0 b) 25.0	Fosetyl-Al a) 900 b) 4500 Copper a) 750 b) 3750	600-1000	20	**Not acceptable** (operator, fosetyl-Al and copper MRL; efficacy)
6	FR	Cucumber, melon and other cucurbits with edible and non-edible peel (CUMSA, CUUPG, CUMSG, CUMME, CITLA, CUUMA)	F	*Pseudoperonospora cubensis*	Field crop sprayer	From transplanting to pre-harvest period (BBCH 13-79)	a.- 5 b.- 5	8	a) 5.0 b) 25.0	Fosetyl-Al a) 900 b) 4500 Copper a) 750 b) 3750	600-1000	20	**Not acceptable** (operator, fosetyl-Al MRL, efficacy)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (e)	**Member state(s)**	**Crop and/ 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/synergist per ha (f)
					Method / Kind	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 / max		
7	FR	Citrus (CIDSI, CIDLI, CIDGR, CIDRE, CIDLM, FOLJA)	F	*Phytophthora* spp., *Deuterophoma tracheiphila*, *Colletotrichum gloeosporioides*, *Gloeosporium limetticolum*	Air blast sprayer	Pre -Post flowering to pre-harvest (BBCH 90-50 and 71-80)	a.- 5 b.- 5	8	a) 5.0 b) 25.0	Fosetyl-Al a) 900 b) 4500 Copper a) 750 b) Maximum limit of 1300 g Cu/ha/year	800-1000	20	**Not acceptable** (operator, worker) **Not acceptable** for *Phytophthora citricola spp*, (efficacy)

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No 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
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorisation decision and risk management

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

TUTOR 18-15 (Bordeaux Mixture 15% + Fosetyl-Al 18% WP) is a wettable powder (WP). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a blue powdered solid, with a mild odour. The formulation is not explosive and has no oxidising properties. It is not flammable and has a self-ignition temperature of 198.8 °C. In aqueous solution (1 %), it has a pH value around 6-7 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 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 commercial packaging (metallic bags/inner plastic PE). The formulation's technical characteristics are acceptable for a wettable powder (WP) formulation.

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

The following data would have been required to update the dossier:
- Suspensibility at the minimum and maximum concentrations of use;
- The test of wettability performed at the maximum concentration of use;
- The test of persistence of foam performed at the minimum and maximum concentrations of use;
- The wet sieve test performed with a sieve of 75 µm.

Only recognized origins from HELM can be used.

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

- The efficacy level of TUTOR 18-15 (Bordeaux Mixture 15% + Fosetyl-Al 18% WP) is considered satisfactory (demonstrated through efficacy trials) for the requested uses against *Plasmopara viticola* on grapes and *Deuterophoma tracheiphila, Colletotrichum gloeosporioides and Gloeosporium limetticolum* on citrus fruits;

- Given the lack of data and no possible extrapolation from previously authorised uses, the evaluation of the efficacy cannot be assessed on the following uses:
    - *Taphrina deformans* on peach;
    - *Phytophthora infestans* on potato;

- Given the lack of data and no possible extrapolation from previously authorised uses or because of an efficacy level considered to be insufficient, the evaluation cannot be considered compliant on the following uses:
    - *Venturia sp.*, *Nectria galligena* and bacterial disease (*Pseudomonas syringae*) on pome fruits;
    - *Coryneum beijerinckii* and bacterial diseases on peach, nectarine and apricot;
    - *Pseudoperonospora cubensis* on cucurbits with edible and non-edible peel;
    - Crown and root rot (*Phytophthora citricola*), *Deuterophoma tracheiphila* and *Colletotrichum gloeosporioides* on citrus;

- The phytotoxicity level of TUTOR 18-15 (Bordeaux Mixture 15% + Fosetyl-Al 18% WP) is considered acceptable for all the requested uses;

- The risks of negative impact on yield, propagation, succeeding and adjacent crops are considered negligible. Risk (linked to copper) on the wine-making process and on the quality of pome fruits (russeting) and table grapes (spotting on berries for applications after fruit set) for application at sensitive growth stages are known. Nonetheless, as regards to the wine-making process, in the absence of specific data with TUTOR 18-15 (Bordeaux Mixture 15% + Fosetyl-Al 18% WP), a risk of negative impact cannot be excluded;

- The risk of resistance developing or appearing to fosetyl-Al does not require monitoring for the requested uses.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical methods for the determination of the active substance Bordeaux mixture and the relevant impurities (lead, cadmium, arsenic) are available and validated.

3.3.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report (DAR) and in this dossier, and are validated for the determination of residues of copper in plants, water and soil.

Analytical methods are available in the DAR and in this dossier, and are validated for the determination of residues of fosetyl-Al in plants (acidic- and high-water-content), foodstuffs of animal origin, soil, water (surface and drinking) and air.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment:

<table>
<tr><td colspan="4">Active substance: copper (in the form of Bordeaux mixture)</td></tr>
<tr><td>ADI</td><td colspan="2">0.15 mg/kg bw/d</td><td rowspan="3">EU (2009)</td></tr>
<tr><td>ARfD</td><td colspan="2">Not relevant</td></tr>
<tr><td>AOEL</td><td colspan="2">0.072 mg/kg bw/d</td></tr>
<tr><td rowspan="5">Dermal absorp-tion</td><td colspan="3">Based on an in vitro human study performed on several formulations containing copper in different forms *</td></tr>
<tr><td></td><td>Concentrate (tested)</td><td>Diluted formulation (tested)</td></tr>
<tr><td>In vitro (human) %</td><td>1</td><td>9</td></tr>
<tr><td></td><td>Concentrate (used in formulation)</td><td>Spray dilution (used in formulation)</td></tr>
<tr><td>Dermal absorption endpoints %</td><td>1</td><td>9</td></tr>
</table>

* The dermal absorption values are those accepted after the peer review of copper compounds (EFSA Journal 2018;16(1):5152,

119 pp. doi:10.2903/j.efsa.2018.5152)

Active substance: **fosetyl-Al**			
ADI	3 mg/kg bw/d		EU (2007)
ARfD	Not relevant		
AOEL	5 mg/kg bw/d		
Dermal absorption	Based on default values (EFSA GD dermal absorption 2012)		
		Concentrate (tested) 500 g/kg	Diluted formulation (tested) 1 g/L
	In vitro (human) %	1	1
		Concentrate (used in formulation) 180 g/kg	Spray dilution (used in formulation) 0.27 g/L
	Dermal absorption endpoints %	**25**	**75**

3.4.1 Acute toxicity

TUTOR 18-15 (Bordeaux Mixture 15% + Fosetyl-Al 18% WP), containing 150 g/kg copper (in the form of Bordeaux mixture) and 180 g/kg fosetyl-Al, has a low acute oral, inhalational and dermal toxicity. It is not irritating to the rabbit skin but is irritating to the rabbit eye. It is not a skin sensitiser.

The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.4.1.

3.4.2 Operator exposure

Summary of critical use patterns (worst cases):

Crop	F/G[7]	Equipment	Application rate kg product/ha (g a.s./ha)	Spray dilution (L/ha)	Model
Grapes	F	Vehicle-mounted upward spraying	5 (750 g/ha Cu) (900 g/ha fosetyl-Al)	300-1000	EFSA
Pome fruit	F	Vehicle-mounted upward spraying	4.5 (675 g/ha Cu) (810 g/ha fosetyl-Al)	600-1000	EFSA
Pome fruit	F	Vehicle-mounted upward spraying	1.5 (225 g/ha Cu) (270 g/ha fosetyl-Al)	600-1000	EFSA
Stone fruit	F	Vehicle-mounted upward spraying	5 (750 g/ha Cu) (900 g/ha fosetyl-Al)	600-1000	EFSA
Potato	F	Vehicle-mounted downward spraying	5 (750 g/ha Cu) (900 g/ha fosetyl-Al)	600-1000	EFSA
Fruiting vegetables (melon, cucumber)	F	Vehicle-mounted downward spraying	5 (750 g/ha Cu) (900 g/ha fosetyl-Al)	600-1000	EFSA
Citrus	F	Vehicle-mounted upward spraying	5 (750 g/ha Cu) (900 g/ha fosetyl-Al)	800-1000	EFSA

[7] Open field or glasshouse

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

Crop	Equipment	PPE and/or working coverall	% AOEL Bordeaux mixture	% AOEL fosetyl-Al (5 mg/kg bw/d)	*% AOEL fosetyl-Al (1 mg/kg bw/d) (EFSA 2018)*
Grapes	Vehicle-mounted upward spraying	Working coverall and gloves during mixing/loading and application	119	5.4	*27*
Pome fruit (4.5 kg/ha)	Vehicle-mounted upward spraying	Working coverall and gloves during mixing/loading and application	114	5.4	*27*
Pome fruit (1.5 kg/ha)	Vehicle-mounted upward spraying	Working coverall and gloves during mixing/loading and application	73	2.3	*11*
Stone fruit	Vehicle-mounted upward spraying	Working coverall and gloves during mixing/loading and application	119	5.4	*27*
Potato	Vehicle-mounted downward spraying	Working coverall and gloves during mixing/loading and application	159	6.4	*32*
Melon, cucumber,	Vehicle-mounted downward spraying	Working coverall and gloves during mixing/loading and application	159	6.4	*32*
Citrus	Vehicle-mounted upward spraying	Working coverall and gloves during mixing/loading and application	119	5.4	*27*

According to the model calculations, it may be concluded **that the risk for the operator using TUTOR 18-15 (Bordeaux Mixture 15% + Fosetyl-Al 18% WP) is unacceptable with a working coverall (90 % protection factor) and gloves during mixing/loading and application, except for treating pome fruit with the modified maximum rate of 1.5 kg product/ha**.

Remark: the new AOEL value proposed by EFSA for fosetyl-Al (AOEL = 1 mg/kg bw/d) does not change the conclusion of the operator exposure assessment, including for acute operator exposure assessment.

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

3.4.3 Worker exposure

Workers may have to enter treated areas after treatment for crop inspection, and manual tasks such as picking, reaching, harvesting activities. Therefore estimation of worker exposure was calculated according to the EFSA model.

Crop	Task	PPE and/or working coverall	% AOEL Bordeaux mixture	% AOEL fosetyl-Al 5 mg/kg bw/d	*% AOEL fosetyl-Al 1 mg/kg bw/d (EFSA 2018)*
Grapes	Hand harvesting	Working coverall	1354	195	*975*
Pome fruit (4.5 kg/ha)	Searching, reaching, picking	Working coverall and gloves	133	21	*107*

Crop	Task	PPE and/or working coverall	% AOEL Bordeaux mixture	% AOEL fosetyl-Al 5 mg/kg bw/d	*% AOEL fosetyl-Al 1 mg/kg bw/d (EFSA 2018)*
Pome fruit (1.5 kg/ha)	Searching, reaching, picking	Working coverall and gloves	45	6.4	*32*
Stone fruit	Searching, reaching, picking	Working coverall and gloves	247	36	*178*
Potato	Inspection	Working coverall	47	6.8	*34*
Melon	Picking	Working coverall and gloves	78	11	*56*
Citrus	Searching, reaching, picking	Working coverall and gloves	302	43	*217*

It may be concluded that, without taking into account a re-entry period:

- **there is an unacceptable risk anticipated for workers wearing a working coverall and gloves, when re-entering grapes, pome fruit (4.5 kg product/ha), stone fruit and citrus crops treated with TUTOR 18-15 (Bordeaux Mixture 15% + Fosetyl-Al 18% WP)**.
- there is no unacceptable risk anticipated for workers wearing a working coverall, when re-entering potato crops and for workers wearing working coverall and gloves when re-entering, melon and pome fruit (1.5 kg product/ha) crops treated with TUTOR 18-15 (Bordeaux Mixture 15% + Fosetyl-Al 18% WP).

Remark: the new AOEL value proposed by EFSA for active substance fosetyl-Al (AOEL = 1 mg/kg bw/d) does not change the conclusion of the operator exposure assessment.

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

3.4.4 Bystander and resident exposure

Bystander exposure:

No bystander risk assessment is required for products that do not have significant acute toxicity potential. There is no acute AOEL (AAOEL) assessed for the active substances Bordeaux mixture and fosetyl-Al; exposure in this case will be determined by exposure over a longer duration. Bystander exposure is then considered covered by resident exposure.

N.B.: EFSA proposed an acute AOEL of 1 mg/kg bw/d for fosetyl-Al (EFSA Journal 2018;16(6):5307 2018).

A bystander risk assessment has been calculated using EFSA model taking into consideration this proposed toxicity reference value (TRV). In a risk envelope approach, exposure is estimated to be 41 % and 23 % of the AOEL for a child and adult respectively.

Resident exposure:

Residential exposure was assessed according to the EFSA model.

In a risk envelope approach, exposure is estimated to be 79 % and 42 % of the AOEL of Bordeaux mixture for a child and adult respectively.
Exposure is estimated to be less than 11 % and 6 % of the AOEL of fosetyl-Al for a child and adult respectively.

Remark: The new AOEL value proposed by EFSA for active substance fosetyl-Al (AOEL= 1 mg/kg bw/d) does not change the conclusion of the resident exposure assessment.

3.4.5 Combined exposure

A cumulative assessment for operators and bystanders has been performed. At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity. Only the scenarios presenting an acceptable risk with individual active substances are evaluated in the light of combined exposure (pome fruit with application rates of 1.5 kg/ha).

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

Application scenario	Equipment	PPE	Active substance	Estimated exposure / AOEL (HQ)	Estimated exposure / AOEL (HQ) (EFSA 2018)
Pome fruit (1.5 kg/ha) 225 g Bordeaux mixture/ha 270 g fosetyl-Al/ha					
Operators	Vehicle mounted upward spraying	Working coverall and gloves during mixing/loading and application	**Bordeaux mixture**	0.73	0.73
			fosetyl-Al	0.023	0.11
		Cumulative risk operators (HI)		**0.75**	**0.84**
Residents (child)		No PPE	**Bordeaux mixture**	**0.15**	**0.15**
			fosetyl-Al	**0.018**	**0.091**
		Cumulative risk bystanders (HI)		**0.17**	**0.24**
Bystanders		No PPE	**Bordeaux mixture**	-	-
			fosetyl-Al	-	0.06
		Cumulative risk bystanders (HI)		**-**	**0.06**
Worker		Working coverall and gloves	**Bordeaux mixture**	0.45	0.45

			fosetyl-Al	0.064	0.32
		Cumulative risk workers (HI)		**0.51**	**0.77**

The Hazard Index is less than 1. Therefore combined exposure to both active substances in TUTOR 18-15 (Bordeaux Mixture 15% + Fosetyl-Al 18% WP) is not expected to present a risk for operators, workers, residents or bystanders for the use on pome fruit with an application rate of 1.5 kg/ha.

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

The data available are considered sufficient for risk assessment. Any exceedence of the current MRLs for copper and fosetyl-Al as laid down in Reg. (EU) 396/2005 is not expected for grapes (table and wine) and citrus.

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

As far as consumer health protection is concerned, France agrees with the authorisation of the intended use on citrus. Alternative GAPs than the intended one are proposed for grapes in the framework of the dossier.

Toxicological reference values for the dietary risk assessment of copper (Bordeaux mixture) and fosetyl-Al:

Reference value	Source	Year	Value	Study relied upon	Safety factor
Bordeaux mixture – copper					
ADI[(a)(b)]	EFSA	2008	0.15 mg Cu/kg bw/day	WHO value of 0.15 mg Cu/kg bw/day for children (based on human data) Supported by 1-year dog study	no safety factor 100
ARfD	EFSA	2008	Not applicable		
Fosetyl-Al - Fosetyl					
ADI	Dir 06/64	--	3.0		
ARfD	Dir 6/64	--	Not applicable		
Fosetyl-Al					
ADI	EFSA	2005	3 mg/kg bw/d	2 year rat and dog	
ARfD			Not necessary		
Fosetyl					
ADI	EFSA	2005	2.8 mg/kg/ bw/d	Calculated, from the fosetyl-Al ADI using an appropriate molecular weight conversion	
ARfD			Not necessary		
Phosphonic acid					
ADI	EFSA	2005	3.9 mg/kg bw/d	117 week rat	
		2012b	2.25 mg/kg bw/d		
ARfD		2005	Not necessary		

(a) It was felt by the meeting of experts that the term "ADI" was not adequate to copper as an essential micronutrient essential for life; the term "upper limit" was considered as more appropriate. (EFSA Scientific Report (2008) 187, 1-101 - Conclusion on the peer review of copper compounds)
(b) Initially in the draft assessment report, the rapporteur Member State proposed to base the ADI on the 1-year dog study. The experts agreed that it should be mentioned that copper (I) and (II) variants are a specific situation, in which it is justified to set reference values based on human data, as they are more relevant than the animal data. (EFSA Scientific Report (2008) 187, 1-101 - Conclusion on the peer review of copper compounds).

Summary for copper (Bordeaux mixture):

Use-No.*	Crop	Plant metabolism covered	Sufficient residue trials	PHI sufficiently supported	Sample storage covered by stability data	MRL compliance	Chronic risk for consumers identified	Acute risk for consumers identified	Comments
1	Grapes (table and wine)	Yes	Yes	Yes	Yes	Yes	No	Not relevant	**EU CTF GAP proposed for wine grapes**
2	Apple, pear, quince, medlars, nashi, loquat *BBCH 03-59*	Yes	Yes	Yes	Yes	Yes			-
3	Apple, pear, quince, medlars, nashi, loquat *BBCH 59-80*	Yes	**No** for apple and pear **Yes** for quince, medlar, loquat, and others	Yes	Yes	Yes			**Apple and pear not supported**
4	Peach, apricot, nectarine	Yes	Yes	Yes	Yes	Yes			-
5	Potato	Yes	**No**	Yes	Yes	Yes			**Not supported**
6	Melon, watermelon, pumpkin and other cucurbits with inedible peel	Yes	Yes	Yes	Yes	Yes			-
7	Citrus (grapefruit, orange, lemon, lime, mandarin) *BBCH 90-50*	Yes	Yes	Yes	Yes	Yes			-
7	Citrus (grapefruit, orange, lemon, lime, mandarin) *BBCH 71-80*	Yes	Yes	Yes	Yes	Yes			-
6	Cucumber, courgette, gherkins and other cucurbits with edible peel	Yes	Yes	Yes	Yes	Yes			**EU CTF GAP proposed**

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

Regarding the magnitude of residues in pome fruits and stone fruits treated at vegetative growth stage (after harvest and/or before flowering), no additional copper content linked to treatment is expected in fruits, and hence residue trials are not required.

For citrus and table grapes, a sufficient number of residue trials is available to support all the intended GAPs in France.

For wine grapes, a sufficient number of residue trials is available to support all the intended GAPs in SEU except in France. For France, the EU CTF GAP is proposed for wine grapes.

For cucurbits with edible peel and cucurbits with non-edible peel, a sufficient number of residue trials is available to support the EU CTF cGAP (as fall-back) GAP in France.

For apple and pear (post-flowering) and potatoes, the number of available residue trials is not sufficient to support the intended GAP on these crops in France. However, the use on other pome fruits, which includes quince, medlar, nashi and loquat, is sufficiently supported by available data on copper.

Since copper is a mineral compound, there is no need to investigate the effects of industrial and/or household processing on the nature of the residue. Data on effects of processing on the amount of residue have been submitted, and processing factors have been defined and considered to refine consumer risk assessment.

Residues in succeeding crops have not been investigated. However, copper occurs naturally in soils. Copper can be used applied as fertiliser, and is also added to soil when spreading sewage sludge, animal manure and urban compost as part of normal agricultural practice. Finally, copper is a contact fungicide/bactericide. As a result, studies for residues in succeeding crops are not relevant.

Considering dietary burden and based on the intended uses, modification of the intake was calculated for livestock. However, the maximum daily intake defined for copper as a feed additive according to the Regulation (EC) n° 479/2006 (06/03/23)[8] is not exceeded. The extant MRLs in foodstuffs of animal origin are not always compliant with the level of copper that can be reached in animal tissues. Therefore, in the framework of Article 12, the extant MRLs of these commodities should be modified.

Chronic consumer exposure resulting from copper background in all food commodities and from water was calculated according to the EFSA PRIMo (rev2) model. Considering uses of copper as plant protection products, chronic exposure remains acceptable for all groups of consumers (maximum 77.54 % ADI for WHO cluster B).

[8] COMMISSION REGULATION (EC) No 479/2006 of 23 March 2006 as regards the authorisation of certain additives belonging to the group compounds of trace elements

Summary for fosetyl-Al:

Use-No.*	Crop	Plant metabolism covered	Sufficient residue trials	PHI sufficiently supported	Sample storage covered by stability data	MRL compliance	Chronic risk for consumers identified	Acute risk for consumers identified
1	Grapes	Yes	Yes (12 SEU trials and 9 NEU trials)	Yes	Yes	Yes	No	No
2-3	Apple, pear, quince, medlars, nashi, loquat	Yes	**No**	N.A	N.A	N.A	N.A	N.A
4	Peach, nectarine, apricot	Yes	**No**	N.A	N.A	N.A		
5	Potato	Yes	**No**	N.A	N.A	N.A		
6	Cucumber, melon and other cucurbits	Yes	**N**	N.A	N.A	N.A		
7	Citrus	Yes	Yes (17 SEU trials)	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 fosetyl-Al residues have been investigated. Data on effects of processing on the amount of residue have been submitted for citrus and grapes. These data were not considered for risk assessment.

Residues in succeeding crops have been sufficiently investigated 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, 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 could be necessary. Taking into account this detail, a specific mitigation measure on citrus pomace is recommended.

Summary for TUTOR 18-15 (Bordeaux Mixture 15% + Fosetyl-Al 18% WP):

Crop	PHI for product requested by applicant	PHI/withholding period* sufficiently supported for		PHI for product proposed by zRMS	zRMS Comments (if different PHI proposed)
		Copper	Fosetyl-Al		
Grapes	20 days	Yes	**No**	28	Available residue data on grape support a PHI of 28 days
Apple, Pear	NR (pre-flowering)	-	-	-	**Use not supported**
	40 days (post-flowering)	-	-	-	**Use not supported**

Crop	PHI for product requested by applicant	PHI/withholding period* sufficiently supported for		PHI for product proposed by zRMS	zRMS Comments (if different PHI proposed)
		Copper	Fosetyl-Al		
Peach	n.a.	-	-	-	**Use not supported**
Potato	20 days	-	-	-	**Use not supported**
Melon and other cucurbits	20 days	-	-	-	**Use not supported**
Citrus	20 days	Yes	Yes	20 days	-

NR: not relevant

* 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 the 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 the active substances and the metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

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

PECgw values for active substances and their metabolites do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009 and guidance document SANCO 221/2000[9]. 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 DT_{50} 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 endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

3.7.1 Effects on terrestrial vertebrates

Applications of the product TUTOR 18-15 (Bordeaux Mixture 15% + Fosetyl-Al 18% WP) according to

[9] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev10-final, 25 February 2003.

the GAP, present no unacceptable risk to birds and mammals.

3.7.2 Effects on aquatic species

TUTOR 18-15 (Bordeaux Mixture 15% + Fosetyl-Al 18% WP) applications present an acceptable risk to aquatic organisms with the following mitigation measures to reduce exposure due to spray drift (including reduction of number of applications to reduce the risk to earthworms); 20 metres planted buffer is necessary to reduce run-off for all uses:

Crops	**Mitigation measures**
Grapes	20 metres buffer zone and 90 % drift-reducing nozzles 50 metres buffer zone and NO drift-reducing nozzles for 4 applications per year
Pear early and late applications.	20 metres buffer zone and 75 % drift-reducing nozzles 50 metres buffer zone and NO drift-reducing nozzles for a maximum application of 1300 g Cu/ha/year
Peach	50 metres buffer zone and 75 % drift-reducing nozzles 50 metres buffer zone and NO drift-reducing nozzles for a maximum application of 1300 g Cu/ha/year
Citrus	50 metres buffer zone and 75 % drift-reducing nozzles for 4 applications per year 50 metres buffer zone and NO drift-reducing nozzles for a maximum application of 1300 g Cu/ha/year
Potato and fruiting vegetables	5 metres buffer zone and 90 % drift-reducing nozzles 30 metres buffer zone and NO drift-reducing nozzles for 4 applications per year

Note that to avoid eutrophication from the use of fosetyl-Al, an unsprayed buffer zone of 5 metres with a planted buffer strip of 5 metres to adjacent surface bodies is necessary for all uses. This risk would be addressed by the above requirements.

3.7.3 Effects on bees

Application of TUTOR 18-15 (Bordeaux Mixture 15% + Fosetyl-Al 18% WP) at the maximum proposed rate presents no unacceptable contact and oral risks to honey bees. Results of higher-tier outdoor cage studies and a semi-field tunnel test with copper confirm that the risks to bees due to the use of the product can be considered acceptable. However, according to new requirements of Reg. (EU) No. 284/2013, a chronic toxicity study of the formulation TUTOR 18-15 (Bordeaux Mixture 15% + Fosetyl-Al 18% WP) for adult bees and data on effects on development of bees should have been submitted by the applicant as exposure of bees to the formulation during the flowering period cannot be excluded. Therefore, the risk to bees cannot be completely finalised and mitigation measures such as “to protect bees and other pollinating insects, do not apply during flowering” should be set at Member State level.

3.7.4 Effects on other arthropod species other than bees

In-field and off-field HQ values for the two indicator species *Aphidius rhopalosiphi* and *Typhlodromus pyri* are below the trigger value of 1.0. As a consequence, adverse effects on non-target arthropods are not likely to follow the use of TUTOR 18-15 (Bordeaux Mixture 15% + Fosetyl-Al 18% WP) at the maximum rate applied to the crops.

3.7.5 Effects on soil organisms

A reproduction test has been performed in earthworms with TUTOR 18-15 (Bordeaux Mixture 15% + Fosetyl-Al 18% WP) and the TER value has been above the trigger value of 5.

According to the new requirement of the Regulation (EU) n° 284/2013, chronic studies (on soil organisms other than earthworms) are required for *Folsomia candida* and *Hypoaspis aculeifer*.

However, according to the same Regulation, when no effects are identified for non-target arthropods, *i.e.* an acceptable risk has been identified without the need to perform a study taking into account recovery (risk acceptable with Tier I and II studies), studies on *F. candida* and *H. aculeifer* are then not required. Therefore, it is the zRMS's opinion in this case that no studies are required.

The potential long-term risk of the product is based on the latest Efsa conclusions (2013) in which a Regulatory Acceptable Concentration (RAC) of 4 kg Cu/ha per year was set based on a field study. Therefore, uses for which the total annual rate is higher than 4 kg Cu/ha should have their number of applications reduced.

The TER_{LT} values for other non-target soil organisms are below the trigger value of 5, leading to the conclusion of a potential risk to macro-organisms. However, a litter-bag study is included in a field study and presented in the DAR, showing no effects on leaf litter degradation due to Copper Hydroxide WP applied at 16 kg Cu/ha. Available bibliographic data detailed in the DAR indicate that soil macro-organisms are relatively more tolerant to copper than earthworms. The risk to soil macro-organisms can then be considered to be covered by that on earthworms, and therefore be considered acceptable at the annual rate of 4 kg Cu/ha/year.

3.7.6 Effects on non-target terrestrial plants

Based on a literature review, the Efsa conclusions (2013) stated that the risk to terrestrial non-target plants due to copper was considered low. Fosetyl-Al is not toxic for plants either. The product is therefore not expected to pose unacceptable risk to terrestrial non-target plants.

3.8 Relevance of metabolites (Part B, Section 10)

Not relevant.

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

TUTOR 18-15 (Bordeaux Mixture 15% + Fosetyl-Al 18% WP) contains copper compounds (Bordeaux mixture) which is approved as a candidate for substitution because it fulfils two PBT (Persistent, Bio-accumulable, Toxic) criteria;

Preliminary Step / Request for derogation from comparative assessment:

The information submitted to comply with Article 50(3) of Regulation (EC) No 1107/2009 is considered acceptable.

Where it is necessary to acquire experience first through using the product in practice for some of the

requested uses, comparative assessment will not be put in place for any of the requested uses in the framework of the current application.

In such cases, the authorisation would be granted once only, for a period not exceeding five years.

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 the relevant summary under point 3 “Background of authorisation decision and risk management”.

5.1.1 Post-authorisation monitoring

None.

5.1.2 Post-authorisation data requirements

None

Appendix 1 Copy of the product authorisation

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Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) N° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et règlementaire,

Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique ***TUTOR 18-15***

de la société *MANICA S.P.A.*

enregistrée sous le *n°2016-1775*

Vu les conclusions de l'évaluation de l'Anses du 20 décembre 2018,

Considérant que le manque d'essais résidus fournis pour certains usages ne permet pas d'exclure un risque de dépassement de la limite maximale de résidus en cuivre et en fosétyl,

Considérant que l'estimation des expositions, liées à l'utilisation du produit sur certains usages, est supérieure au niveau acceptable d'exposition au cuivre pour les opérateurs et les travailleurs,

Considérant le manque de données d'efficacité pour certains usages,

Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 sont respectées,

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

TUTOR 18-15
AMM n°-

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anses
agence nationale de sécurité sanitaire alimentation, environnement, travail

Informations générales sur le produit	
Nom du produit	TUTOR 18-15
Type de produit	Produit de référence
Titulaire	MANICA S.P.A. Via all'Adige, 4 (loc, Borgo Sacco), 38068 ROVERETO (Trento), Italie
Formulation	Poudre mouillable (WP)
Contenant	150 g/kg – cuivre (sous forme de bouillie bordelaise) 180 g/kg – fosétyl-Al
Numéro d'intrant	517-2016.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usage	Professionnel

A Maisons-Alfort le, 28 DEC. 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)

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ANNEXE I : Conditions de mise sur le marché demandées

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12053204 Agrumes*Trt Part.Aer.* Chancre du collet	5 kg/ha	5/an	20
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les opérateurs et les travailleurs. L'usage est refusé en raison du manque de données d'efficacité.		
12053200 Agrumes*Trt Part.Aer.* Maladies diverses	5 kg/ha	5/an	20
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les opérateurs et les travailleurs.		
12053201 Agrumes*Trt Part.Aer.* Maladies du feuillage	5 kg/ha	5/an	20
	Motivation du refus : L'usage est refusé puisqu'il est couvert par l'usage N°12053200. L'usage est refusé en raison d'un risque d'effet nocif pour les opérateurs et les travailleurs.		
16323204 Concombre*Trt Part.Aer.* Mildiou(s)	5 kg/ha	5/an	20
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les opérateurs et en raison d'un manque d'essais résidus ne permettant pas d'exclure le risque de dépassement des limites maximales de résidus en fosétyl-Al. L'usage est refusé en raison du manque de données d'efficacité.		

16753208 Melon*Trt Part.Aer.* Mildiou(s)	5 kg/ha	5/an	20
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les opérateurs et en raison d'un manque d'essais résidus ne permettant pas d'exclure le risque de dépassement des limites maximales de résidus en fosétyl-Al. L'usage est refusé en raison du manque de données d'efficacité.		
12553303 Pêcher*Trt Part.Aer.* Bactérioses	5 kg/ha	4/an	-
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les opérateurs et les travailleurs et en raison d'un manque d'essais résidus ne permettant pas d'exclure le risque de dépassement des limites maximales de résidus en fosétyl-Al. L'usage est refusé en raison du manque de données d'efficacité.		
12553203 Pêcher*Trt Part.Aer.* Cloque(s)	5 kg/ha	4/an	-
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les opérateurs et les travailleurs et en raison d'un manque d'essais résidus ne permettant pas d'exclure le risque de dépassement des limites maximales de résidus en fosétyl-Al. L'usage est refusé en raison du manque de données d'efficacité.		
12553232 Pêcher*Trt Part.Aer.* Coryneum et polystigma	5 kg/ha	4/an	-
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les opérateurs et les travailleurs et en raison d'un manque d'essais résidus ne permettant pas d'exclure le risque de dépassement des limites maximales de résidus en fosétyl-Al. L'usage est refusé en raison du manque de données d'efficacité.		

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anses

15653201 Pomme de terre* Trt Part.Aer.*Mildiou(s)	5 kg/ha	5/an	20
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les opérateurs et en raison d'un manque d'essais résidus ne permettant pas d'exclure le risque de dépassement des limites maximales de résidus en fosétyl-Al et en cuivre. L'usage est refusé en raison du manque de données d'efficacité.		
12603301 Pommier*Trt Part.Aer.* Bactérioses	4,5 kg/ha	2/an	-
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les opérateurs et les travailleurs et en raison d'un manque d'essais résidus ne permettant pas d'exclure le risque de dépassement des limites maximales de résidus en fosétyl-Al. L'usage est refusé en raison du manque de données d'efficacité.		
	1,5 kg/ha	3/an	40
	Motivation du refus : L'usage est refusé en raison d'un manque d'essai résidu ne permettant pas d'exclure le risque de dépassement des limites maximales de résidus en fosétyl-Al. L'usage est refusé en raison du manque de données d'efficacité.		
12603201 Pommier*Trt Part.Aer.* Chancre européen	4,5 kg/ha	2/an	-
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les opérateurs et les travailleurs et en raison d'un manque d'essais résidus ne permettant pas d'exclure le risque de dépassement des limites maximales de résidus en fosétyl-Al. L'usage est refusé en raison du manque de données d'efficacité.		
	1,5 kg/ha	3/an	40
	Motivation du refus : L'usage est refusé en raison d'un manque d'essai résidu ne permettant pas d'exclure le risque de dépassement des limites maximales de résidus en fosétyl-Al. L'usage est refusé en raison du manque de données d'efficacité.		

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12603203 Pommier*Trt Part.Aer.* Tavelure(s)	1,5 kg/ha	3-/an	40
	Motivation du refus : L'usage est refusé en raison d'un manque d'essais résidus ne permettant pas d'exclure le risque de dépassement des limites maximales de résidus en fosétyl-Al. L'usage est refusé en raison du manque de données d'efficacité.		
	4,5 kg/ha	2/an	-
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les opérateurs et les travailleurs et en raison d'un manque d'essais résidus ne permettant pas d'exclure le risque de dépassement des limites maximales de résidus en fosétyl-Al. L'usage est refusé en raison du manque de données d'efficacité.		
12703203 Vigne*Trt Part.Aer.* Mildiou(s)	5 kg/ha	5/an	20
	Motivation du refus : L'usage est refusé avec un délai avant récolte de 20 jours en raison d'un risque d'effet nocif pour les opérateurs et les travailleurs et en raison d'un manque d'essais résidus ne permettant pas d'exclure le risque de dépassement des limites maximales de résidus en cuivre. L'usage est refusé avec un délai avant récolte de 28 jours en raison d'un risque d'effet nocif pour les opérateurs et les travailleurs.		

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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.

TUTOR 18-15 WP

Numéro AMM : XXXXXX

Poudre mouillable (WP) contenant 18 % de Fosetyl Al et 15% de cuivre sous forme bouillie bordelaise

Le **TUTOR 18-15 WP** est un fongicide contenant 18% de Fosetyl Al e 15% de cuivre métal. Il est autorisé pour lutter contre certaines maladies fongiques et bactériennes de la vigne, pommier, poire, peche, pomme de terre, melon et agrumes.

  **ATTENTION**	**TUTOR 18-15 WP (contient 18% fosetyl Al et 15% de cuivre métal issu de la bouillie bordelaise)** H319: Provoque une grave irritation oculaire. H400: Très toxique pour les organismes aquatiques. H410 : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme. P260 Ne pas respirer les poussières. P264 Se laver soigneusement après manipulation. P273: Eviter le rejet dans l'environnement. P280: Porter des lunettes de protection. P305+P351+ P338: EN CAS DE CONTACT AVEC LES YEUX: rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer. P337 + P313: I Si l'irritation oculaire persiste: consulter un médecin. P501: Eliminer le contenu/récipient selon la règlementation en vigueur. 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. EUH401: Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement **En cas d'urgence, appeler le 15 ou le centre antipoison puis signalez vos symptômes au réseau Phyt'attitude, n° vert 0 800 887 887 (appel gratuit depuis un poste fixe)**

	Un produit de : **MANICA S.p.A.** Tél. : + 00 39 0464 433 705 Via all'Adige, 4 Fax : + 00 39 0464 437 224 38068 ROVERETO (Trento) ITALIE

CONDITIONS D'EMPLOI :

TUTOR 18-15 WP est autorisée sur les cultures et aux doses suivantes.

Culture	Maladie	Dose
Vigne	Mildiu	4-6 kg /ha
Pommier (pre floraison)	Tavelure, Chancre européen, Bactériose pseudomonas	3-4 kg /ha
Pommier (post floraison)	Tavelure, Chancre européen, Bactériose pseudomonas	1,5 kg/ha
Poirier (pre floraison)	Tavelure	3-4 kg/ha
Poirier (post floraison)	Tavelure	1,5 kg/ha
Pêcher	Cloque, Maladie criblée (coryneum), Bacterioses	5-6 kg/ha
Pomme de terre	Mildiu	5-6 kg/ha
Melon	Mildiu	5-6 kg/ha
Agrumes	Gommose parasitaire, Anthracnose	4-5 kg/ha

Le **TUTOR 18-15 WP** est un fongicide a base de fosétyl al et de la bouilie bordelaise qui a une action soit préventive soit curative contre le mildiou de la vigne, d'autres maladies fongiques et avec une action collaterale bactériostatique due au cuivre. L'activité systémique de ce produit permet de protéger la nouvelle végétation qui se développe pendant l'intervalle entre un traitement et l'autre. La présence de la bouillie bordelaise donne a la préparation une persistance remarquable grâce à laquelle le produit est difficilement lixivié par la pluie après le traitement. La synergie entre les deux principes actifs permet soit l'action fungicide soit l'action bactériostatique avec des doses de cuivre métallique réduit par hectare.

Sur la vigne, 5 applications par saison peuvent être réalisées avec un intervalle de 8-10 jours entre chaque traitement. Le délai avant récolte est de 20 jours.

Sur les pommiers (pre floraison), 2 applications par saison peuvent être effectuées avec une cadence de 15 jours sans delai avant la récolte. En post floraison, 3 applications par saison peuvent être effectuées avec une cadence de 8-10 jours avec une délai avant récolte de 40 jours.

Sur les poirier (pre floraison), 2 applications par saison peuvent être effectuées avec une cadence de 12 jours sans delai avant la récolte. En post floraison, 3 applications par saison

peuvent être effectuées avec une cadence de 8-10 jours avec une délai avant récolte de 40 jours.

Sur les pêcher, 4 applications par saison peuvent être effectuées avec une cadence de 10-14 jours avec une délai avant récolte de 20 jours

Sur les pommes de terres, 5 applications par saison peuvent être effectuées avec une cadence de 8-10 jours. Le délai avant récolte est 20 jours.

Sur le melon, 5 applications par saison peuvent être effectuées avec une cadence de 8-10 jours. Le délai avant récolte est 20 jours.

Sur les agrumes, 5 applications par saison peuvent être effectuées avec une cadence de 8-12 jours. Le délai avant récolte est 20 jours.

PREPARATION DE LA BOUILLIE :

Verser la quantité requise de **TUTOR 18-15 WP** dans la cuve du pulvérisateur à moitié remplie d'eau, le système d'agitation fonctionnant.

Compléter avec le volume d'eau nécessaire à l'application en maintenant sous agitation.

RECOMMANDATIONS :

Il est recommandé de :

- traiter uniquement par temps calme,
- ne traiter que les cultures saines et non endommagées,
- prendre soin des cultures voisines.

PRECAUTIONS D'EMPLOI :

Stockage

Conserver les produits dans leur emballage d'origine, dans des locaux fermés à clé, hors de portée des enfants.

Conserver à l'écart des aliments et boissons, y compris ceux pour animaux.

Utilisation

PROTECTION DE L'OPERATEUR

Pour l'opérateur, porter :

Pour toutes les phases d'utilisation du TUTOR 18-15 WP

Porter un vêtement de travail couvrant de type combinaison de travail 35% coton/65% polyester (densité min 230 g/m² avec un traitement déperlant).

Pendant le mélange/chargement

- Porter un tablier ou blouse de protection catégorie III (TYPE PB [3]), à porter par-dessus la combinaison de travail
- Porter des gants réutilisables en nitrile (EN 374-3, catégorie 3)
- Porter des lunettes de sécurité (EN 166, catégorie 4)

Pendant l'application

Si application avec un tracteur sans cabine ou cabine ouverte

- Porter des gants en nitrile à usage unique (EN 374-3, catégorie 3)
- Porter des lunettes de sécurité (EN 166, catégorie 4)

Si application avec un tracteur avec cabine fermée et uniquement en cas d'intervention sur le matériel de pulvérisation

- Porter des gants en nitrile à usage unique (EN 374-3, catégorie 3)
- Porter des lunettes de sécurité (EN 166, catégorie 4)

Si application avec un pulvérisateur manuel

- Porter des gants en nitrile à usage unique (EN 374-3, catégorie 3)
- Porter des lunettes de sécurité (EN 166, catégorie 4)

Pour la phase de nettoyage

- Porter un tablier ou blouse de protection catégorie III (TYPE PB [3]), à porter par-dessus la combinaison de travail
- Porter des gants réutilisables en nitrile (EN 374-3, catégorie 3)
- Porter des lunettes de sécurité (EN 166, catégorie 4)

Pour protéger le travailleur, porter une combinaison de travail tissée en coton 35% / polyester 65% (densité minimum 230 g/m^2 avec traitement déperlant).

PRÉCAUTIONS D'EMPLOI

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

Pendant le stockage

• Conserver le produit uniquement dans l'emballage d'origine, dans un local phytopharmaceutique conforme à la réglementation en vigueur et fermé à clé, à l'abri de l'humidité, de la lumière et du gel, dans un endroit frais, aéré et ventilé, à l'écart des aliments et boissons y compris ceux pour animaux.

• Conserver hors de la portée des enfants.

Pendant la préparation de la bouillie et en cours d'application

• Ne pas manger, boire, fumer.

• Porter des gants, des vêtements de protection et un appareil de protection des yeux et du visage pendant toutes les opérations de mélange / chargement et de traitement (voir paragraphe « PROTECTION DE L'OPERATEUR»).

• Ne pas traiter en présence de vent (selon la réglementation en vigueur).

Les reliquats de produit (fond de cuve) sont dilués par rinçage en ajoutant dans la cuve du pulvérisateur un volume d'eau au moins égal à 5 fois le volume de ce fond de cuve. L'épandage de ce fond de cuve dilué est réalisé, jusqu'au désamorçage du pulvérisateur, sur la parcelle ou la zone venant de faire l'objet de l'application du produit en s'assurant que la dose totale appliquée au terme des passages successifs ne dépasse pas la dose maximale autorisée pour l'usage considéré.

Après utilisation

Emballage : éliminer les emballages via les collectes organisées par les distributeurs partenaires de la filière ADIVALOR (08 10 12 18 85, numéro Azur prix d'un appel local).

Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.

Les doses, usages, conditions et précautions d'emploi décrits ont été définis en fonction des caractéristiques du produit et des applications auxquelles il est destiné. Traitez en respectant ces recommandations selon la bonne pratique agricole tout en tenant compte, sous votre responsabilité, des facteurs particuliers liés à votre exploitation, tels que nature du sol, conditions météorologiques, méthodes culturales, variétés végétales, résistance des espèces... Ne pouvant contrôler le stockage, le transport, le mode d'utilisation, les façons culturales, le dosage, etc. et sachant que ces circonstances peuvent influencer l'action du produit et les réactions éventuelles de la culture, nous ne pouvons accepter aucune responsabilité en rapport avec une moindre efficacité ou des dommages qui pourraient résulter de l'application de notre produit. Le fabricant garantit la qualité du produit vendu dans son emballage d'origine ainsi que sa conformité à l'autorisation de vente du Ministère de l'Agriculture.

Appendix 3 Letter of Access

Provided upon request.