REGISTRATION REPORT

Part A

Risk Management

Product code: MCW-432

Product name(s): AMPERA

Active Substance(s):

Tebuconazole, 133 g/L

Prochloraz, 267 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: **ADAMA France S.A.S.**

Date: **20/09/2017**

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PART A – Risk Management

The company ADAMA France S.A.S. has requested marketing authorisation in France for the product AMPERA (MCW-432), containing 133 g/L tebuconazole and 267 g/L prochloraz for use as a fungicide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to AMPERA (MCW-432) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of AMPERA (MCW-432) have been made using endpoints agreed in the EU peer review of both tebuconazole and prochloraz.

This document describes the specific conditions of use and labelling required for France for the registration of AMPERA (MCW-432).

Appendix 1 of this document provides a copy of the French Decision.

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

Appendix 3 of this document is a copy of the letter(s) of Access.

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of ADAMA France S.A.S.'s application to market AMPERA (MCW-432) in France as a fungicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Tebuconazole

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. Commission Implementing Regulation (EU) No 921/2014 of 25 August 2014 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance tebuconazole.
Specific provisions of Regulation (EU) No 540/2011 were as follows : PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on tebuconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment; — the dietary exposure of consumers to the tebuconazole (triazole) metabolites; — the protection of granivorous birds and mammals and herbivorous mammals and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures. — the protection of aquatic organisms and must ensure that conditions of authorisation include risk mitigation

measures such as buffer zones, where appropriate.

The Member States concerned shall request the submission of further information to confirm the risk assessment for birds and mammals. They shall ensure that the notifier at whose request tebuconazole has been included in this Annex provide such information to the Commission by 31 August 2011 at the latest.

The Member States concerned shall ensure that the notifier submits to the Commission further information addressing the potential endocrine disrupting properties of tebuconazole within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, of Community agreed test guidelines.

The following regulation was not published at the date of dossier's submission.

Specific provisions of Commission Implementing Regulation (EU) No 921/2014 were as follows :

PART A

Only uses as fungicide and plant growth regulator may be authorised.

PART B

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on tebuconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account.

In this overall assessment Member States must pay particular attention to:

— the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment;

— the dietary exposure of consumers to the tebuconazole (triazole) metabolites;

— the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil or climatic conditions, in particular as regards the occurrence in groundwater of the metabolite 1,2,4-triazole;

— the protection of granivorous birds and mammals and herbivorous mammals and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures;

— the protection of aquatic organisms and must ensure that conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate.

The Member States concerned shall ensure that the notifier submits to the Commission further information addressing the potential endocrine disrupting properties of tebuconazole within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, of Community agreed test guidelines.

An EFSA conclusion is available (EFSA Scientific Report (2008) 176, 1-109; EFSA Journal 2014; 12(1): 3485).

A Review Report is available (SANCO/171/08 – rev. 1, 9 September 2008 [Inclusion]; SANCO/171/08 – rev. 2, 11 July 2014 [Conditions of approval])

Please note that the dossier was submitted prior to the publications in 2014.

Prochloraz

Commission Implementing Regulation (EU) No 1143/2011 of 10 November 2011 approving the active substance prochloraz, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 and Commission Decision 2008/934/EC

Specific provisions of Regulation (EU) No 1143/2011 were as follows :

PART A

Only uses as fungicide may be authorised. In the case of outdoor uses, rates shall not exceed 450 g/ha per

application.

PART B

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on prochloraz, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 September 2011, shall be taken into account.

In this overall assessment Member States:

(a) shall pay particular attention to the protection of operators and workers and shall ensure that conditions of use include the application of adequate personal protective equipment, where appropriate;

(b) shall pay particular attention to the risk to aquatic organisms, and shall ensure that conditions of authorisation include risk mitigation measures, where appropriate;

(c) shall pay particular attention to the long-term risk to mammals and shall ensure that conditions of authorisation include risk mitigation measures, where appropriate.

The applicants shall submit confirmatory information as regards:

(1) comparison and verification of the test material used in the mammalian toxicity and ecotoxicity dossiers against the specification of the technical material;

(2) the environmental risk assessment for the metal complexes of prochloraz;

(3) the potential endocrine disrupting properties of prochloraz on birds.

The notifier shall submit to the Commission, the Member States and the Authority the information set out in points 1 and 2 by 31 December 2013 and the information set out in point 3 within 2 years after the adoption of the pertinent OECD test guidelines on endocrine disruption.

An EFSA conclusion is available (EFSA Journal 2011; 9(7): 2323).

A Review Report is available (SANCO/11959/2011 final rev 4, 19 May 2016).

1.3 Regulatory approach

The present application (2014-0090) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)[1] in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[2] – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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

The French Order of 4th May 2017[3] provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, drift buffer zones may be reduced under some circumstances as explained in Appendix 3 of the above-mentioned French Order.

The current document (RR) based on Anses's assessment of the application submitted for this product is in

[1] French Food Safety Agency, Afssa, before 1 July 2010

[2] SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5

[3] Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte

compliance with Regulation (EC) no 1107/2009[4], implementing regulations, and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail.

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011[5], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[6] provides that:

- an authorisation granted for a "reference" crop applies also for "linked" crops, unless formally stated in the Decision
- the "reference" and "linked" crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "linked" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those "linked" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[7] is to supply "minor" crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of AMPERA (MCW-432), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

The applicant has provided the supporting data in Document K; the ownership of the data is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7. A copy of the letter(s) of access is reproduced in Part A, Appendix 3.

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

[5] COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

[6] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

[7] SANCO document "guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs": SANCO/ 7525/VI/95 - rev.9

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	AMPERA (MCW-432)
Authorisation number	2170757
Function	fungicide
Applicant	ADAMA FRANCE S.A.S.
Composition	133 g/L tebuconazole 267 g/L prochloraz
Formulation type (code)	Emulsion, oil in water [EW]
Packaging	Bottle HDPE/EVOH (1 L) Cans HDPE/EVOH (5 L) Cans HDPE/LDPE/PA (10 L)

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

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

Physical hazards	-	
Health hazards	Acute toxicity (oral), Hazard Category 4 Eye irritation, Hazard Category 2 Reproductive toxicity, Hazard Category 2	
Environmental hazards	Hazardous to the aquatic environment — Acute Hazard, Category 1 Hazardous to the aquatic environment — Chronic Hazard, Category 1	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H302	Harmful if swallowed
	H319	Causes serious eye irritation
	H361d	Suspected of damaging the unborn child
	H400	Very toxic to aquatic life
	H410	Very toxic to aquatic life with long lasting effects.
Precautionary statements –	***For the P phrases, refer to the extant legislation***	

Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	EUH208	Contains 2-Ethylhexyl-S-Lactate.May produce an allergic reaction.

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

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

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	To protect aquatic organisms respect an unsprayed vegetated buffer zone of 5 metres[8] to surface water bodies.
Spa1	To avoid the development of resistances to prochloraz and tebuconazole the number of applications of the AMPERA (MCW-432) preparation is limited to 1 application maximum per crop cycle. In order to better manage the risks of resistance on the plot treated with AMPERA (MCW-432), it is recommended to follow the limitations of use per chemical group recommended by ARVALIS-Institut du végétal, INRA, ANSES *(Note commune "Resistances aux fongicides : Céréales à pailles 2015 »: [Resistance to fungicides: Straw cereals – 2015]).*

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment[9]: refer to the Decision in Appendix 1 for the details
Re-entry period[10]: 24 hours
Pre-harvest interval[11]: Wheat: F- Application must be made at growth stage BBCH 69 at the latest. Rye, Barley and Oat: F- Application must be made at growth stage BBCH 49 at the latest.
-
The label may include the following recommendations: - the interest of AMPERA (MCW-432) is to control a disease complex The label must reflect the conditions of authorisation.

[8] The legal basis for this is **Titre III Article 11** of the French Order of 12 September 2006 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

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

[10] The legal basis for this is **Titre I Article 3** of the French Order of 12 September 2006 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

[11] According to the French Order of 12 September 2006, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.
Use should be crossed out when the applicant no longer supports this use.

GAP rev. , date: 2017-september-20

PPP (product name/code)	**AMPERA (MCW-432)**	**Formulation type:**	**EW**
active substance 1	**tebuconazole**	**Conc. of as 1:**	**133 g/L**
active substance 2	**prochloraz**	**Conc. of as 2:**	**267 g/L**
active substance 3	**-**	**Conc. of as 3:**	**-**
safener	**-**	**Conc. of safener:**	**-**
synergist	**-**	**Conc. of synergist:**	**-**
Applicant:	**ADAMA FRANCE S.A.S.**	**professional use**	☒
Zone(s):	**southern**	**non professional use**	☐
Verified by MS: yes/no			

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 or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/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)													
1	France	Barley	F	Net blotch **PYRNTE**, Leaf blotch **RHYNSE**, rust, **PUCCHD & PUCCST** powdery mildew, **ERYSGH**	foliar spraying, overall	BBCH 31-49	a) 1 b) 1	-	a) 1.2 L/ha b) 1.2 L/ha	a) 159.6 / 320.4 b) 159.6 / 320.4	100-300	F	**acceptable**
2	France	Oat	F	Crown rust **PUCCCO**, powdery mildew **ERYSGA**	foliar spraying, overall	BBCH 31-49	a) 1 b) 1	-	a) 1.2 L/ha b) 1.2 L/ha	a) 159.6 / 320.4 b) 159.6 / 320.4	100-300	F	**acceptable**
3	France	Rye	F	Leaf blotch	foliar	BBCH 31-49	a) 1	-	a) 1.2 L/ha	a) 159.6 / 320.4	100-	F	**acceptable**

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 or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
				Leaf blotch **RHYNSE**, Brown rust **PUCCRR**	spraying, overall		b) 1		b) 1.2 L/ha	b) 159.6 / 320.4	300		**acceptable**
4	France	Wheat, Triticale, spelt	F	Brown rust **PUCCRT**, Septoria **SEPTSS** , powdery mildew **ERYSGT**, Fusarium **FUSASS & MONGNI,** Yellow rust **PUCCST**	foliar spraying, overall	BBCH 31-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 199.5 / 400.5 b) 199.5 / 400.5	100-300	F	**acceptable**

Remarks table heading:

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

Remarks columns:

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

3 RISK MANAGEMENT

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties

The formulation AMPERA (MCW-432) is an emulsion, oil in water formulation (EW). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a lightly yellowish liquid, with a slightly organic smell. It is not explosive and has no oxidizing properties. The product has a flash point of 94°C. It has a self-ignition temperature of 275°C. In aqueous solution of 1%, it has a pH value of 8.22 at 20°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in 1L HDPE/EVOH bottle. Its technical characteristics are acceptable for a EW formulation.

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

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methods for the determination of active substances and relevant impurity (2,3,7,8 TCDD) in the formulation are available and validated.

3.1.2.2 Analytical methods for residues

Tebuconazole
Analytical methods are available in the monograph/this dossier and validated for the determination of residues of Tebuconazole in plants (acidic, dry, high oil and high water content plants), food of animal origin, soil, water (surface and drinking) and air.

Prochloraz
Analytical methods are available in the monograph/this dossier and validated for the determination of residues of Prochloraz in plants (dry, high acid, high oil and high water content plants), food of animal origin, soil, water (surface and drinking) and air.

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

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

<table>
<tr><td colspan="5">Active Substance: TEBUCONAZOLE</td></tr>
<tr><td>ADI</td><td colspan="3">0.03 mg kg bw/d</td><td rowspan="3">EU 2009</td></tr>
<tr><td>ARfD</td><td colspan="3">0.03 mg/kg bw/d</td></tr>
<tr><td>AOEL</td><td colspan="3">0.03 mg/kg bw/d</td></tr>
<tr><td rowspan="3">Dermal absorption</td><td colspan="4">Based on an in vitro rat/human study performed on a similar formulation; values from the in vitro human study are retained to set dermal absorption:</td></tr>
<tr><td></td><td>Concentrate (tested)</td><td colspan="2">Diluted formulation (tested)</td></tr>
<tr><td></td><td>133 g/L</td><td>0.71 g/L</td><td>0.25 g/L</td></tr>
<tr><td></td><td>In vitro (rat) %</td><td>3.7</td><td>39.7</td><td>41.9</td></tr>
</table>

	In vitro (human) %	**0.7**	18.1	**19.6**
		Concentrate (used in formulation) 133 g/L	Spray dilution (used in formulation) 0.27 g/L	
	Dermal absorption endpoints %	**0.7**	**-**	**20**

Active Substance: **PROCHLORAZ**			
ADI	0.01 mg kg bw/d		EU 2012
ARfD	0.025 mg/kg bw/d		
AOEL	0.02 mg/kg bw/d		
Dermal absorption	Based on an *in vitro* rat/human study performed on formulation. Values from the *in vitro* human study are retained to set dermal absorption and a *pro rata* correction has been done for spray dilution:		
		Concentrate (tested) 267 g/L	Diluted formulation (tested) 0.67 g/L
	In vitro (rat) %	2.29	28.1
	In vitro (human) %	0.92	24.4
		Concentrate (used in formulation) 267 g/L	Spray dilution (used in formulation) 0.53 g/L
	Dermal absorption endpoints %	**1**	**30**

3.1.3.1 Acute Toxicity

AMPERA (MCW-432) containing 133 g/L tebuconazole and 267 g/L prochloraz has a low toxicity in respect to acute inhalation and dermal toxicity and is not irritating to the rabbit skin and not a skin sensitiser. However, AMPERA (MCW-432) has a toxicity by oral it is irritating to eye.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G[12]	Equipment	Application rate
Cereals	F	Tractor mounted/trailed boom sprayer, hydraulic nozzles	1.5 L/ha (199.5 g tebuconazole/ha; 400.5 g prochloraz/ha)

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

Crop	Equipment	PPE and/or working coverall	% AOEL tebuconazole	% AOEL prochloraz

[12] Open field or glasshouse

Cereals	Tractor mounted/trailed boom sprayer, hydraulic nozzles	Working coverall and gloves during mixing/loading and application	11	48

According to the model calculations, it can be concluded that the risk for the operator using AMPERA (MCW-432) is acceptable with a working coverall (90% protection factor) and gloves during mixing/loading and application.

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

3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to 1.2 % of the AOEL of tebuconazole and 5.1 % of the AOEL of prochloraz.
It is concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to AMPERA (MCW-432).

3.1.3.4 Resident Exposure

The currently available data (2001-2006) in the report of the ORP (French pesticides residues observatory) show a range of values, reaching the maximum value for tebuconazole of 4.77 ng/m³ and 1.4 ng/m³ (maximum daily and weekly measurements, respectively). Based on these data, the respiratory exposure of people living near sprayed areas was estimated to be below 0.1 % of the ADI and the AOEL of the tebuconazole for an adult and child.
For prochloraz, the maximum value is 0.1 ng/m^3 (maximum daily measurement), the respiratory exposure of people living near sprayed is estimated to below 0.1% of the ADI and the AOEL of prochloraz for an adult and child.

3.1.3.5 Worker Exposure

Workers may have to enter treated areas after treatment for crop inspection activities. Therefore, estimation of worker exposure was calculated according to EUROPOEM II. Exposure is estimated to 6.8 % of the AOEL of tebuconazole and 31 % of the AOEL of prochloraz with working coverall and gloves.
It is concluded that without taking into account a re-entry period, there is no unacceptable risk anticipated for workers wearing a working coverall and gloves, when re-entering crops treated with AMPERA (MCW-432).

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

3.1.3.6 Relevance of metabolites

None.

3.1.4 Residues and Consumer Exposure

Overall conclusion

The available data are considered sufficient for risk assessment. An exceedance of the current MRL for prochloraz and tebuconazole as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of prochloraz and tebuconazole residues resulting from the uses proposed in the framework of this application are unlikely to present a public health concern.
As far as consumer health protection is concerned, France agrees with the authorization of the intended use(s).

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

Data gaps

/

Data required in post-authorization

For prochloraz:

- A stability study for residues on straw should be provided in post-authorization

- 3NEU and 3 SEU trials conducted on one cereal with a side-by-side comparison of two formulation types (EC and EW) should be provided in post-registration.

Summary of the evaluation

The preparation AMPERA (MCW-432) is composed of prochloraz and tebuconazole

Summary for prochloraz

Table -1: Summary for prochloraz

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EU) No 520/2011	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
	Wheat	Yes	Yes (13 NEU and 11 SEU) but side-by-side comparison trials of formulations EW and EC should be provided in post-registration	Yes	Yes	Yes	No	No	A stability storage on straw should be provided in post-registration
	Rye	Yes	Yes	Yes	Yes	Yes		No	By extrapolation from wheat data
	Barley and oat	Yes	Yes (11 NEU and 20 SEU) but side-by-side comparison trials of formulations EW and EC should be provided in post-registration	Yes	Yes	Yes		No	Oat by extrapolation from barley data

* 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 prochloraz residues have been investigated. Data on effects of processing on the amount of residue have been submitted.
These data were 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 (for dairy cattle and beef cattle). Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore necessary, but considering that uses under consideration are already registered in EU, this will be achieved in the framework of article 12 of Regulation (EC) No 396/2005.

Summary for tebuconazole

Table -2: Summary for tebuconazole

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg 2016/1	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
	Wheat	Yes	Yes (12 NEU and 9 SEU)	Yes	Yes	Yes	No	No	
	Rye	Yes	Yes	Yes	Yes	Yes		No	Rye by extrapolation from wheat data
	Barley and oat	Yes	Yes (19 NEU and 11 SEU)	Yes	Yes	Yes		No	Oat by extrapolation from barley data

* 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 tebuconazole residues have been investigated. Data on effects of processing on the amount of residue have been submitted.
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, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Summary for AMPERA (MCW-432)

Table -3: Information on AMPERA (MCW-432) (KCA 6.8)

Crop	PHI for AMPERA (MCW-432) proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for AMPERA (MCW-432) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Prochloraz	Tebuconazole		
Wheat	F** (BBCH 69)	Yes	Yes	F** (BBCH 69)	
Rye	F** (BBCH 49)	Yes	Yse	F** (BBCH 49)	
Barley and oat	F** (BBCH 49)	Yes	Yes	F** (BBCH 49)	

NR: not relevant

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

Waiting periods before planting succeeding crops

Not relevant.

3.1.5 Environmental fate and behaviour

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

The PEC of tebuconazole, prochloraz 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 review or agreed in the assessment based on new data provided.

PEC soil and PECsw derived for the active substances and their metabolites are used for the eco-toxicological risk assessment, and mitigation measures are proposed.

PECgw for tebuconazole, prochloraz and their metabolites do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000 [13]. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

Based on vapour pressure, information on volatilisation from plants and soil, and DT50 calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.6 Ecotoxicology

The ecotoxicological risk assessment of the formulation AMPERA (MCW-432) was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review for active substance and its metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

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

Risk mitigation measures are needed: no spray vegetated buffer zone of 5 meters to protect aquatic organisms for spring and winter cereals.

3.1.7 Efficacy

Considering all the data submitted:

- the efficacy of AMPERA (MCW-432) is considered as satisfying for all intended uses but as tebuconazol and prochloraz present complementary efficacy spectra, the interest of AMPERA (MCW-432) is to control a disease complex,
- the selectivity of AMPERA (MCW-432) is considered as satisfying on all claimed crops,
- the potential impact on quality, yield, parts of plants used for propagating purposes, processing procedures, succeeding and adjacent crops is considered as acceptable,
- the risk of resistance development is considered as low to high depending on diseases but the limitation of 1 application per year makes it acceptable. A resistance monitoring has to be set up and trials in characterized

[13] 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.

resistance situations have to be made for prochloraz and tebuconazol on wheat septoria and powdery mildew and helminthosporiose of barley. The resistance monitoring program set up for EPOPEE can be considered as relevant for AMPERA (MCW-432). All new data that may modify the risk should be transmitted to the competent authorities.

Crop	Target	Dose rate in L/ha	Number of appli.	zRMS opinion	Comments
		FR			
Wheat	PSDCHE	1.5	1	acceptable	Monitoring + trials in resistance situation for SEPTSS & ERYSGT
	ERYSGT				
	SEPTSS				
	FUSASS – MONGNI				
	PUCCRT				
	PUCCST				
Barley	ERYSGH	1.2	1	Favourable	Monitoring + trials in resistance situation for PYRNTE
	PUCCHD				
	PUCCST				
	PYRNTE				
	RHYNSE				
Oat	ERYSGA	1.2	1	Favourable	-
	PUCCCO				
Rye	PUCCCR	1.2	1	Favourable	-
	RHYNSE				
Triticale	ERYSGR	1.5	1	Favourable	-
	PUCCRT				
	SEPTSSL				

3.2 Conclusions arising from French assessment

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

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

- A resistance monitoring has to be set up and trials in characterized resistance situations have to be made for prochloraz and tebuconazole on wheat septoria and powdery mildew and helminthosporiose of barley. The resistance monitoring program set up for EPOPEE can be considered as relevant for AMPERA (MCW-432).
- All new data that may modify the risk should be transmitted to the competent authorities
- . Several azole active substances can be applied on a same field. Considering that 1,2,4-triazole can be formed from most of these azole active substances, an exceedance of the regulatory limit of 0.1 µg/L cannot be excluded. In order to ensure that the regulatory limit in groundwater is not exceeded for 1,2,4-triazole, all applicants of azole-based products are requested to set up a groundwater monitoring dedicated to this metabolite within two years.

3.4.2 Post-authorisation data requirements

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

- An inter-laboratory validation of the method (Sahvorost N., Class T. (2014) document: R-35859) for the determination of residues of tebuconazole in foodstuffs of animal origin;
- A stability study on straw for prochloraz;
- 3NEU and 3 SEU trials conducted on one cereal with a side-by-side comparaison of two formulation types (EC and EW) for prochloraz;

3.4.3 Label amendments

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

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

Appendix 1 – Copy of the French Decision

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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 et les demandes associées du produit phytopharmaceutique ***AMPERA***

de la société	*ADAMA FRANCE S.A.S.*
enregistrées sous les	*n°2014-0090 ; 2014-0106 ; 2015-6182 ; 2016-1389 ; 2017-0447 et 2017-0448*

Vu les conclusions de l'évaluation de l'Anses du 4 août 2017,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France pour les usages et dans les conditions précisés dans la présente décision et ses annexes.

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

Avertissement :

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

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Informations générales sur le produit	
Noms du produit	AMPERA PANAMA AGATA EPOPEE NEO NEBRASKA NEO
Type de produit	Produit de référence
Titulaire	ADAMA FRANCE S.A.S. 6/8 avenue de la Cristallerie 92316 Sèvres Cedex FRANCE
Formulation	Emulsion de type aqueux (EW)
Contenant	267 g/L - prochloraze 133 g/L - tébuconazole
Numéro d'intrant	680-2014.01
Numéro d'AMM	2170757
Fonction	Fongicide
Gamme d'usages	Professionnel

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active qui arrivera à échéance le plus tôt. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 août 2020.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) 1107/2009, dans les trois mois suivant le renouvellement de l'approbation de la substance active, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance de la durée nécessaire pour mener à bien l'examen et adopter une décision sur le renouvellement.

La présente décision peut être retirée ou modifiée avant cette échéance si des éléments le justifient.

A Maisons-Alfort, le 20 SEP. 2017

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 : 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**
Bouteilles en polyéthylène haute densité / éthylène d'alcool vinylique	1 L
Bidons en polyéthylène haute densité / éthylène d'alcool vinylique	5 L
Bidons en polyéthylène haute densité / polyéthylène basse densité / polyamide	10 L

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	**Mention de danger**
Toxicité aiguë par voie orale - Catégorie 4	H302 : Nocif en cas d'ingestion
Lésions oculaires graves et irritation oculaire - Catégorie 2	H319 : Provoque une sévère irritation des yeux
Toxique pour la reproduction - Catégorie 2	H361d : Susceptible de nuire au fœtus
Dangers pour le milieu aquatique - Danger aigu, catégorie 1	H400 : Très toxique pour les organismes aquatiques
Dangers pour le milieu aquatique - Danger chronique, catégorie 1	H410 : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme
EUH208 : Contient du 2-éthyl hexyl lactate. Peut produire une réaction allergique.	
Pour les phrases P se référer à la règlementation en vigueur.	
Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.	

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Liste des usages autorisés

En l'absence de 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
15103206 Avoine*Trt Part.Aer.*Oïdium(s)	**1,2 L/ha**	**1/an**	entre les stades BBCH 31 et BBCH 49	F (BBCH 49)	5 (dont DVP 5)	-	-	-
	1 application par culture sur l'ensemble du complexe de maladies.							
15103231 Avoine*Trt Part.Aer.*Rouille couronnée	**1,2 L/ha**	**1/an**	entre les stades BBCH 31 et BBCH 49	F (BBCH 49)	5 (dont DVP 5)	-	-	-
	1 application par culture sur l'ensemble du complexe de maladies.							
00108036 Blé*Trt Part.Aer.*Fusariose à microdochium	**1,5 L/ha**	**1/an**	entre les stades BBCH 31 et BBCH 69	F (BBCH 69)	5 (dont DVP 5)	-	-	-
	1 application par culture sur l'ensemble du complexe de maladies.							
15103202 Blé*Trt Part.Aer.*Fusarioses	**1,5 L/ha**	**1/an**	entre les stades BBCH 31 et BBCH 69	F (BBCH 69)	5 (dont DVP 5)	-	-	-
	1 application par culture sur l'ensemble du complexe de maladies.							
15103209 Blé*Trt Part.Aer.*Oïdium(s)	**1,5 L/ha**	**1/an**	entre les stades BBCH 31 et BBCH 69	F (BBCH 69)	5 (dont DVP 5)	-	-	-
	1 application par culture sur l'ensemble du complexe de maladies.							
15103214 Blé*Trt Part.Aer.*Rouille(s)	**1,5 L/ha**	**1/an**	entre les stades BBCH 31 et BBCH 69	F (BBCH 69)	5 (dont DVP 5)	-	-	-
	1 application par culture sur l'ensemble du complexe de maladies.							
15103221 Blé*Trt Part.Aer.*Septoriose(s)	**1,5 L/ha**	**1/an**	entre les stades BBCH 31 et BBCH 69	F (BBCH 69)	5 (dont DVP 5)	-	-	-
	1 application par culture sur l'ensemble du complexe de maladies.							

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Liste des usages autorisés
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
15103226 Orge*Trt Part.Aer.*Helminthosporiose et ramulariose	**1,2 L/ha**	**1/an**	entre les stades BBCH 31 et BBCH 49	F (BBCH 49)	5 (dont DVP 5)	-	-	-
	1 application par culture sur l'ensemble du complexe de maladies. Efficacité montrée sur helminthosporiose.							
15103225 Orge*Trt Part.Aer.*Oïdium(s)	**1,2 L/ha**	**1/an**	entre les stades BBCH 31 et BBCH 49	F (BBCH 49)	5 (dont DVP 5)	-	-	-
	1 application par culture sur l'ensemble du complexe de maladies.							
15103229 Orge*Trt Part.Aer.*Rhynchosporiose	**1,2 L/ha**	**1/an**	entre les stades BBCH 31 et BBCH 49	F (BBCH 49)	5 (dont DVP 5)	-	-	-
	1 application par culture sur l'ensemble du complexe de maladies.							
15103205 Orge*Trt Part.Aer.*Rouille(s)	**1,2 L/ha**	**1/an**	entre les stades BBCH 31 et BBCH 49	F (BBCH 49)	5 (dont DVP 5)	-	-	-
	1 application par culture sur l'ensemble du complexe de maladies.							
15103232 Seigle*Trt Part.Aer.*Rhynchosporiose	**1,2 L/ha**	**1/an**	entre les stades BBCH 31 et BBCH 49	F (BBCH 49)	5 (dont DVP 5)	-	-	-
	1 application par culture sur l'ensemble du complexe de maladies.							
15103208 Seigle*Trt Part.Aer.*Rouille(s)	**1,2 L/ha**	**1/an**	entre les stades BBCH 31 et BBCH 49	F (BBCH 49)	5 (dont DVP 5)	-	-	-
	1 application par culture sur l'ensemble du complexe de maladies.							

DVP : Dispositif Végétalisé Permanent.

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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 à rampe :

• 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 ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3);

• pendant l'application - pulvérisation vers le bas

Si application avec tracteur avec cabine

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

Si application avec tracteur sans cabine

- Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;

• pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée.
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3).

Pour le travailleur, porter

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

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

- 48 heures.

Respect des limites maximales de résidus (LMR)

Pour chaque usage figurant dans la liste des usages autorisés, les conditions d'utilisation du produit permettent de respecter les limites maximales de résidus.

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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 5 mètres comportant un dispositif végétalisé permanent non traité d'une largeur de 5 mètres en bordure des points d'eau.

Gestion des résistances

- Spa 1 : Pour éviter le développement de résistances au prochloraze et au tébuconazole, le nombre d'applications du produit AMPERA est limité à 1 application maximum par campagne.

Afin de gérer au mieux les risques de résistance avec le produit AMPERA, il est recommandé de suivre les limitations d'emploi par groupe chimique préconisées par la note relative à la gestion des résistances des maladies des céréales à paille.

Exigences complémentaires post-autorisation

A défaut de transmission de ces données dans les délais impartis à compter de la date de la présente décision, la présente décision pourra être retirée ou modifiée.

Détail de la demande post autorisation	Délai (mois)	Récurrence (mois)
Fournir une validation inter-laboratoires de la méthode (Sahvorost N., Class T. (2014) document R-35859) pour la détermination des résidus de tébuconazole dans les denrées d'origine animale.	24	-
Fournir une étude de stabilité des résidus de prochloraze dans la paille.	24	-
Fournir 3 essais résidus Nord et 3 essais Sud de comparaison des formulations EC et EW sur une céréale, pour le prochloraze.	24	-
Mettre en place un suivi dédié au 1,2,4-triazole afin de s'assurer du respect de la valeur seuil règlementaire de ce métabolite dans les eaux souterraines.	24	-
Mettre en place un suivi de la résistance au prochloraze et au tébuconazole pour la septoriose et l'oïdium du blé et l'helminthosporiose de l'orge. Fournir, aux autorités compétentes, toute nouvelle information susceptible de modifier l'analyse du risque de résistance.	-	-
Mettre en place des essais d'efficacité en situation de résistance caractérisée au prochloraze et au tébuconazole pour la septoriose et l'oïdium du blé et l'helminthosporiose de l'orge.	-	-

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

FONGICIDE CÉRÉALES ET COLZA

Ampera®

EMULSION DE TYPE AQUEUX

Contient 133 g/L tébuconazole et 267 g/L prochloraz

AMM N°XXXXXXX délivrée le xx/xx/XXXX

MODE D'ACTION - PROPRIÉTÉS

AMPERA® est un fongicide qui associe les propriétés complémentaires du tébuconazole de la famille des triazoles à celles du prochloraz de la famille des imidazoles. Doté de propriétés systémiques et translaminaires, il agit également par contact d'une part, sur les principales maladies des feuilles et des épis des céréales et d'autre part, sur des maladies du colza (sclérotiniose et cylindrosporiose).

MODE D'EMPLOI

USAGES ET DOSES HOMOLOGUÉS :

Culture	Cible	Dose homologuée	Nombre d'applications	Intervalle minimal entre applications	Délai avant récolte	Zone non traitée par rapport aux points d'eau
Avoine	Oïdium Rouille couronnée	1.2 L/ha	2 applications max/an	14 jours	28 jours	20 m
Blé*	Septoriose	1.5 L/ha	Blé : 1 application max/an Triticale : 2 applications max/an	Blé : - Triticale : 14 jours	28 jours	20 m
	Rouilles	1.2 L/ha				
	Oïdium	Blé : 1.7 L/ha Triticale : 1.2 L/ha				
Blé* Uniquement blé	Fusarioses Fusarioses à microdochium	1.5 L/ha	1 application max/an	-		
Orge	Helminthosporiose Rhynchosporiose Oïdium Rouilles	1.2 L/ha	2 applications max/an	14 jours	28 jours	20 m
Seigle	Rhynchosporiose Rouilles	1.2 L/ha	2 applications max/an	14 jours	28 jours	20 m
Crucifères oléagineuses Uniquement colza et navette	Cylindrosporiose Sclérotinioses	1.5 L/ha	2 applications max/an	14 jours	56 jours	20 m

* La culture «blé» couvre «blé et triticale».

Délai de rentrée des travailleurs sur la parcelle : 24 heures après traitement conformément à l'arrêté du 12 septembre 2006 relatif à la mise sur le marché et à l'utilisation des produits visés à l'article L 253-1 du code rural.

Les Limites Maximales de Résidus sont consultables à l'adresse suivante : http://ec.europa.eu/sanco_pesticides/public/index.cfm
Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur selon l'arrêté du 7 avril 2010.

Conditions d'emploi :

Sur blés : Application aux stades redressement-montaison et épiaison-floraison.

Sur orges d'hiver et de printemps : Application sortie dernière feuille – sortie des barbes.

Sur colza : Sur sclérotiniose, application en prévention dès la chute des premiers pétales. Sur cylindrosporiose, application dès l'apparition des premiers symptômes.

Sélectivité :

Sur blé, l'application du produit peut dans certaines conditions engendrer des ponctuations sur le feuillage sans pour autant altérer le rendement. En cas de stress hydrique marqué et de fortes amplitudes thermiques, éviter de traiter les blés mal implantés et en situation de sols séchants.

Préparation de la bouillie :

Remplir le pulvérisateur à moitié et mettre l'agitation en marche. Introduire la dose voulue de **AMPERA®** et compléter d'eau.
Volume d'eau : 100 à 300 L/ha.
Consulter également le paragraphe Précautions générales.

PRÉCAUTIONS GÉNÉRALES

Dans le cadre des Bonnes Pratiques Agricoles :

Emballages vides : Réemploi de l'emballage interdit. Lors de l'utilisation du produit, bien vider et rincer le bidon en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur. Eliminer les emballages vides via les collectes organisées par les distributeurs partenaires de la filière ADIVALOR ou tout autre service de collecte spécifique.

Nettoyage de l'équipement : Ne pas laisser de bouillie prête à l'emploi dans le pulvérisateur. Eliminer les fonds de cuve et les eaux de rinçage conformément à la réglementation en vigueur. Eviter toute contamination des mares, puisards, ruisseaux, eaux souterraines ou de distribution ou
de tout autre point d'eau, par le produit, la bouillie de pulvérisation et les eaux de rinçage des emballages et équipements de traitement.

Premiers secours :

Inhalation : Amener la victime à l'air libre. Consulter un médecin en cas de troubles.

Contact avec la peau : Oter les vêtements touchés et laver les parties exposées de la peau au moyen d'un savon doux et d'eau, puis rincer à l'eau chaude.

Contact avec les yeux : En cas de contact avec les yeux, rincer immédiatement à l'eau claire durant 10-15 minutes. Consulter un ophtalmologiste.

Ingestion : Ne pas faire vomir. Rincer la bouche avec beaucoup d'eau. Ne jamais rien faire avaler par la bouche à une personne inconsciente. Si la respiration est difficile, administrer de l'oxygène. En cas d'arrêt de la respiration, pratiquer la respiration artificielle. Consulter un médecin immédiatement

Mesures d'urgence : En cas d'urgence, appelez le 15 ou le centre antipoison le plus proche de votre domicile. Présentez aux secours l'étiquette et la Fiche de Données de Sécurité. Ensuite, signalez vos symptômes au réseau "PHYT'ATTITUDE", n° vert 0 800 887 887 (appel gratuit depuis un poste fixe).

Ampera®
AMM N° XXXXXXX
EW - Emulsion de type aqueux
Contient 133 g/L tébuconazole (12.3%), 267 g/L prochloraz (24.6%)

Xn - nocif

N - Dangereux pour l'environnement

R22 : **Nocif en cas d'ingestion.**
R36 : **Irritant pour les yeux.**
R50/53 : **Très toxique pour les organismes aquatiques, peut entraîner des effets néfastes à long terme pour l'environnement aquatique.**
R63 : **Risque possible pendant la grossesse d'effets néfastes pour l'enfant.**

Délai de rentrée des travailleurs : 24h après traitement
S2 : Conserver hors de portée des enfants.
S13 : Conserver dans un endroit frais à l'écart des aliments et des boissons, y compris ceux pour animaux.
S20/21 : Ne pas manger, ne pas boire et ne pas fumer pendant l'utilisation.
S25 : Eviter le contact avec les yeux.
S26 : En cas de contact avec les yeux, laver immédiatement et abondamment avec de l'eau et consulter un spécialiste.
S36/37/39 : Porter un vêtement de protection approprié, des gants et un appareil de protection des yeux/du visage.
S46 : En cas d'ingestion, consulter immédiatement un médecin et lui montrer l'emballage ou l'étiquette.
S57 : Utiliser un récipient approprié pour éviter une contamination du milieu ambiant.
S61 : Eviter le rejet dans l'environnement. Consulter les instructions spéciales/ la fiche de données de sécurité.

Respecter les instructions d'utilisation pour éviter les risques pour l'homme et pour l'environnement.
SP1 : Ne pas polluer l'eau avec le produit ou son emballage.
SPe3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 20 mètres par rapport aux points d'eau. En cas de ruissellement possible sur la parcelle traitée, prévoir un dispositif végétalisé non traité d'une largeur de 20 m en bordure des points d'eau.

PRODUIT POUR LES PROFESSIONNELS : RESPECTER LES CONDITIONS D'EMPLOI.
Lire les instructions ci jointes avant emploi.

La fiche de données de sécurité peut être obtenue gratuitement sur Internet www.quickfds.com ou à partir de www.ma-france.com ou en écrivant à fds@ma-france.com ou par courrier à l'adresse postale de MAKHTESHIM-AGAN France ou en scannant le flashcode avec votre téléphone mobile.

Homologué par :
MAKHTESHIM-AGAN France
6/8, avenue de la Cristallerie
92316 Sèvres Cedex
Tél. : 01 41 90 16 96
Fax : 01 46 42 71 17

Responsable de l'emballage :
Makhteshim Chemical Works Ltd.
P.O.B. 60, Industrial Zone,
Beer-Sheva 84100
Israël

Produit fabriqué en Israël

Voir emballage

Volume net : **5 L**

N° de lot et date de fabrication

Appendix 3 – Letter(s) of Access

TDMG
Triazole Derivate
Metabolite Group

18th November 2013

Anses
Direction des Produits Reglementes
UGAmm
253, avenue de General Leclerc
94700 Maisons-Alfort Cedex
France

SUBJECT: Letter of Access to TDMG owned data on triazole metabolites

This letter is being submitted on behalf of the Triazole Derivative Metabolite Group ("TDMG") comprised of BASF SE, Bayer CropScience AG, Dow AgroSciences LLC, Isagro S.p.A. and Syngenta Crop Protection AG.

TDMG hereby agrees that the protected file of studies and study summaries on the triazole metabolites **1,2,4 triazole, triazole alanine, triazole acetic acid and triazole lactic acid** as listed in Appendix I and Appendix II, owned by TDMG and either submitted in support of the Step 2 EU registration of the active substance TEBUCONAZOLE or under general evaluation in the EU, may be referred to by you in order to support:

Makhteshim Agan France
6/8 Avenue de la Cristallerie
92316-Sevres Cedex
France

for their plant protection products:

MCW-432 Registration number: not applicable

with the active ingredients in an EW formulation containing 133 g/L tebuconazole and 267 g/L prochloraz.

The right to refer to the data package is subject to the following restrictions:

1. The right of referral is solely granted to Makhteshim Agan France and is not transferable to any further companies or other legal or natural entities.

BASF SE Bayer CropScience AG Dow AgroSciences LLC Isagro S.p.A. Syngenta Crop Protection AG

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2. Reference to the data package can only be made for the registration of tebuconazole as an agrochemical.
3. Specifically excluded from the right of referral are the use of the data in the context of the Biocides Directive 98/8/EC and Commission Regulation 1896/2000.
4. The right of referral only gives access to the file of data on **1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid** attached as dietary and environmental metabolites of triazole active ingredients.
5. Makhteshim Agan France is not authorised to receive any copies of the data package nor is it authorised to inspect or view the data package or any specific document in whole or in part filed with the Regulatory Authorities.
6. This authorisation is valid only for such duration as there is a valid agreement between Makhteshim Agan France and TDMG.

On behalf of the TDMG

Yours sincerely,

November 18, 2013

Helmut Schenk
Chairman of the TDMG, Global Registration Manager

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