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REGISTRATION REPORT

Part A

Risk Management

Product code: MCW 710 SC

Product name: CUSTODIA

Active substances:

azoxystrobin, 120 g/L

tebuconazole, 200 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: ADAMA France

Date: 2018-02-02

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PART A – Risk Management

The company ADAMA France has requested marketing authorisation in France for the product CUSTODIA (product code: MCW 710 SC), containing 120 g/L azoxystrobin and 200 g/L tebuconazole, 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 CUSTODIA (MCW 710 SC) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of CUSTODIA (MCW 710 SC) have been made using endpoints agreed in the EU peer review of both azoxystrobin and tebuconazole.

This document describes the specific conditions of use and labelling required for France for the registration of CUSTODIA (MCW 710 SC).

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 letters of Access.

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of ADAMA France's application to market CUSTODIA (MCW 710 SC) 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

Azoxystrobin

Commission Implementing Regulation (EU) No 703/2011 of 20 July 2011 approving the active substance azoxystrobin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.
Specific provisions of Regulation (EU) No 703/2011 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 azoxystrobin and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (1) the fact that the specification of the technical material as commercially manufactured must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material; (2) the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions;

(3) the protection of aquatic organisms. The Member States must ensure that the conditions of authorisation include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of confirmatory information as regards the risk assessment on groundwater and aquatic organisms. The notifier shall submit to the Member States, the Commission and the Authority such information by 31 December 2013.
An EFSA conclusion is available (EFSA Journal 2010; 8(4): 1542) and the Outcome of the consultation with Member States, applicant and EFSA on the pesticide risk assessment of confirmatory data submitted for the active substance azoxystrobin (EFSA supporting publication 2014: EN-718). A Review Report is available (SANCO/11027/2011 Rev 3, 20 March 2015).

Tebuconazole

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 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 Journal 2014; 12(1): 3485). A Review Report is available (SANCO/171/08 – rev. 2, 11 July 2014).

1.3 Regulatory approach

The present application (2015-6285) 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

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

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 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 CUSTODIA (MCW 710 SC), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

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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

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

1.5 Letters of Access

Not necessary for tebuconazole *per se*: the applicant has provided sufficient data to show that access is not required.

For the triazole metabolite data, a letter of access from the Triazole Derivative Metabolite Group (TDMG) has been submitted.

The applicant has provided the supporting data in Document K for azoxystrobin; 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 letters of access is reproduced in Part A, Appendix 3.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	CUSTODIA (MCW 710 SC)
Authorisation number	2180001
Function	Fungicide
Applicant	ADAMA France
Composition	120 g/L azoxystrobin 200 g/L tebuconazole
Formulation type (code)	Suspension concentrate (SC)
Packaging	High density polyethylene (HDPE) bottles or containers holding 1 L, 5 L, 10 L or 20 L product High density polyethylene/polyamide (HDPE/PA) containers holding 10 L or 20 L product

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) No 1272/2008

Physical hazards	-	
Health hazards	Acute oral toxicity, Hazard Category 4 Reproductive toxicity, Hazard Category 2	
Environmental hazards	Hazardous to the aquatic environment, Chronic, Hazard Category 1	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H302	Harmful if swallowed.
	H361d	Suspected of damaging the unborn child.
	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)	EUH 208	Contains 1,2-benzisothiazol-3(2H)-one. 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).
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres[8] to surface water bodies for uses on winter rapeseeds and winter canola .
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres with an unsprayed planted buffer zone of 5 metres to surface water bodies for uses on spring rapeseeds and spring canola .

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]: 48 hours
Pre-harvest interval[11]: 56 days
Other mitigation measures: - Rinse the packaging at least four times before disposal.
The label may include the following recommendations: - EUH 208: Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction. The label must reflect the conditions of authorisation.

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

[9] 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 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

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

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, 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.

GAP rev., date: 2018-02-02

PPP (product name/code):	**CUSTODIA (MCW 710 SC)**	Formulation type:	**SC** [a, b]
Active substance 1:	azoxystrobin	Conc. of a.s. 1:	**120 g/L** [c]w
Active substance 2:	tebuconazole	Conc. of a.s. 2:	**200 g/L** [c]
Applicant:	**ADAMA France**	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**	**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)	L 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)													
1	FR	Rapeseeds, canola seeds (winter and spring)	F	*Sclerotinia*, *Alternaria*, powdery mildew	Foliar spray	BBCH 58-73	a) 1 b) 1	(-) (-)	a) 1.0 b) 1.0	a) 120 + 200 b) 120 + 200	100 / 400	56	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

CUSTODIA (MCW 710 SC) is a suspension concentrate (SC). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a white homogeneous liquid with a characteristic odour. It is not explosive and has no oxidising properties. The product has no flash point and has a self-ignition temperature of 500 C. In aqueous solution (1 % dilution), it has a pH value of 6.5 at 20 C. There is no effect of low and high temperatures on the stability of the formulation, since after seven days at 0 C and 14 days at 54 C, neither the active substances' content nor the technical properties were changed. The stability data indicate a shelf life of at least two years at ambient temperature when stored in HDPE. As the stability testing was performed on HDPE packaging, the HDPE/PA packaging can be considered acceptable too. The technical characteristics are acceptable for an SC formulation.

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

3.1.2 Methods of analysis

An analytical method for the determination of the active substances in the formulation is available and validated.

As the active substance tebuconazole does not contain any relevant impurity, no analytical method is required.

Analytical methods for the determination of the relevant impurity of azoxystrobin (toluene) and the Z-isomer of azoxystrobin in the formulation are available and validated.

Analytical methods are available in the Draft Assessment Report (DAR)/this dossier and validated for the determination of residues of azoxystrobin in plants (high-water-, high–acid-, high-fat-content and dry commodities), foodstuffs of animal origin, soil, water (surface and drinking) and air.

An Inter-Laboratory Validation (ILV) of the analytical method DFG S19 (Daneva, E., Wiesner, F., 2008) for the determination of azoxystrobin in high-oil–content commodities is required post-authorisation.

The active substance azoxystrobin is toxic (T), therefore an analytical method is available in this dossier for the determination of its residues in tissues and body fluids.

Analytical methods are available in the DAR/this dossier and validated for the determination of residues of tebuconazole in plants (high-oil–content commodities), foodstuffs of animal origin, soil, water (surface and drinking) and air.

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

3.1.3 Mammalian Toxicology

The following endpoints were used for risk assessment:

<table>
<tr><td colspan="4">Active substance: azoxystrobin</td></tr>
<tr><td>ADI</td><td colspan="2">0.2 mg/kg body weight/day</td><td rowspan="3">UE 2012</td></tr>
<tr><td>ARfD</td><td colspan="2">Not applicable</td></tr>
<tr><td>AOEL</td><td colspan="2">0.2 mg/kg body weight/day</td></tr>
<tr><td rowspan="5">Dermal absorption</td><td colspan="3">Based on an in vitro human study performed on formulation according to guidance on dermal absorption (EFSA 2012):</td></tr>
<tr><td></td><td>Concentrate (tested) 120 g/L</td><td>Spray dilution (tested) 0.3 g/L</td></tr>
<tr><td>In vitro (human) %</td><td>1 %</td><td>5 %</td></tr>
<tr><td></td><td>Concentrate
(used in formulation) 120 g/L</td><td>Spray dilution
(used in formulation) 0.3 g/L</td></tr>
<tr><td>Dermal absorption endpoints %</td><td>1</td><td>5</td></tr>
</table>

Active substance: **tebuconazole**			
ADI	0.03 mg/kg body weight/day		UE 2009
ARfD	0.03 mg/kg body weight		
AOEL	0.03 mg/kg body weight/day		
Dermal absorption	Based on an *in vitro* human study performed on formulation according to guidance on dermal absorption (EFSA 2012):		
		Concentrate (tested) 150 g/L	Spray dilution (tested) 0.5 g/L
	In vitro (human) %	3 %	17 %
		Concentrate (used in formulation) 200 g/L	Spray dilution (used in formulation) 0.5 g/L
	Dermal absorption endpoints %	3	17

3.1.3.1 Acute Toxicity

The product CUSTODIA (MCW 710 SC) has a low acute inhalational and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitiser. It is harmful if swallowed.

3.1.3.2 Operator Exposure

The summary of critical use patterns (worst cases) is followed:

Crop	F/G[12]	Equipment	Application rate L product/ha (g a.s./ha)	Spray dilution (L/ha)	Model
Oilseed rape	F	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	1 L/la (120 g azoxystrobin/ha) (200 g tebuconazole/ha)	100-400	BBA

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

Crop	Equipment	PPE and/or working coverall	% AOEL azoxystrobin	% AOEL tebuconazole
Oilseed rape	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	Working coverall and gloves during mixing/loading and application	0.3	10

According to the model calculations, it may be concluded that the risk for the operator using CUSTODIA (MCW 710 SC) 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 be 0.05 % of the AOEL of azoxystrobin and 1 % of the AOEL of tebuconazole.

It may be concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to CUSTODIA (MCW 710 SC).

[12] Open field or glasshouse

3.1.3.4 Worker Exposure

Workers may have to enter treated areas after treatment for crop harvesting activities. Therefore, estimation of worker exposure was calculated according to EUROPOEM II. Exposure is estimated to be 2 % of the AOEL of azoxystrobin and 57 % of the AOEL of tebuconazole.

It may be concluded that without taking into account a re-entry period, there is no unacceptable risk anticipated for workers not wearing PPE, when re-entering crops treated with CUSTODIA (MCW 710 SC).

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

3.1.3.5 Resident Exposure

Residential exposure was assessed according to Martin *et al*.

Exposure is estimated to be 2 % for adults and 4 % for children of the AOEL of azoxystrobin. Exposure is estimated to be 14 % for adults and 27 % for children of the AOEL of tebuconazole.

It may be concluded that there is no unacceptable risk to the resident exposed to CUSTODIA (MCW 710 SC).

Based on the currently available data (2001-2006) in the report of the ORP (French pesticides residues observatory), the respiratory exposure of people living near sprayed areas was estimated, as follows:

		azoxystrobin	
		% ADI	% AOEL
Maximum daily measurement (0.95 ng/m^3)	Adult	< 0.000%	< 0.000%
	Child	< 0.000%	< 0.000%
Maximum weekly measurement (1.2 ng/m^3)	Adult	< 0.000%	< 0.000%
	Child	< 0.000%	< 0.000%

		tebuconazole	
		% ADI	% AOEL
Maximum daily measurement (4.77 ng/m^3)	Adult	0.006	0.006
	Child	0.009	0.009
Maximum weekly measurement (1.4 ng/m^3)	Adult	0.002	0.002
	Child	0.003	0.003

3.1.4 Residues and Consumer Exposure

The available data are considered sufficient for risk assessment purposes. Any exceedence of the current MRLs for azoxystrobin and tebuconazole as laid down in Regulation (EU) 396/2005 is not expected.

The chronic and short-term intakes of the active substances' 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 uses.

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

3.1.5 Environmental fate and behaviour

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

The predicted environmental concentration (PEC) values of azoxystrobin, tebuconazole and their metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard

FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PEC soil and PEC surface water values derived for the active substances and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PEC groundwater values for azoxystrobin, tebuconazole and their metabolites do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009 and guidance document SANCO 221/2000 on the relevance of metabolites in groundwater. One azoxystrobin metabolite, R234886, was found in groundwater monitoring at a concentration greater than 0.1 µg/L: (maximum concentration 0.101µg/L). However, this metabolite is not toxicologically relevant.

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.

3.1.6 Ecotoxicology

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

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

There is no unacceptable risk to aquatic organisms when an unsprayed buffer zone of five metres is applied for winter rapeseeds and canola seeds use.

There is no unacceptable risk to aquatic organisms when an unsprayed planted buffer zone of five metres is applied for spring rapeseeds and canola use.

3.1.7 Efficacy

Considering the data submitted:

- The efficacy level of CUSTODIA (MCW 710 SC) is considered satisfactory for all requested uses.
- The phytotoxicity level of CUSTODIA (MCW 710 SC) is considered acceptable for all requested uses.
- The risks of negative impact on yield, quality, propagation, succeeding and adjacent crops are considered acceptable.
- There is a risk of resistance to azoxystrobin developing or appearing for *Sclerotinia* on rape; this requires monitoring.

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

CUSTODIA (MCW 710 SC) contains tebuconazole which is approved as a candidate for substitution because it meets two of the criteria to be considered as a PBT substance.

As a conclusion of the comparative assessment:

- Use against powdery mildew hasn't enough modes of action to keep a good control against resistances;
- To control *Sclerotinia* and other fungal diseases (*Alternaria*), tebuconazole is an important component of national resistance management strategy for the resistance control.

Consequently, substitution is not retained.

3.3 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.

3.4 Substances of concern for national monitoring

No information stated.

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

3.5.1 Post-authorisation monitoring

Monitoring of resistance to azoxystrobin in *Sclerotinia* should be put in place (one monitoring for all products based on azoxystrobin). Any new information which would change the resistance risk analysis should immediately be provided to French authorities. In all cases, a report on the results of the monitoring put in place should be provided at the time of the authorisation renewal for CUSTODIA (MCW 710 SC).

3.5.2 Post-authorisation data requirements

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

- An ILV of the analytical method DFG S19 (Daneva, E., Wiesner, F., 2008) for the determination of azoxystrobin in high-oil–content commodities.
- Several azole active substances can be applied on the same field. Considering that 1,2,4-triazole can be formed from most of these azole active substances, an exceedence 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 groundwater monitoring dedicated to this metabolite within two years.

3.5.3 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 réglementaire,

Vu la demande d'autorisation de mise sur le marché et la demande associée du produit phytopharmaceutique ***CUSTODIA***

de la société	*ADAMA FRANCE SAS*
enregistrées sous les	*n°2015-6285 et n°2015-6286*

Vu les conclusions de l'évaluation de l'Anses du 29 décembre 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.

CUSTODIA
AMM n°2160001

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Informations générales sur le produit	
Noms du produit	CUSTODIA ORIUS Z
Type de produit	Produit de référence
Titulaire	ADAMA FRANCE SAS 33 rue de Verdun 92156 SURESNES FRANCE
Formulation	Suspension concentrée (SC)
Contenant	120 g/L - azoxystrobine 200 g/L - tébuconazole
Numéro d'intrant	848-2015.01
Numéro d'AMM	2180001
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 02 FEV. 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 : 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	1 L
Bidons en polyéthylène haute densité	5 L ; 10 L ; 20 L
Bidons en polyéthylène haute densité / polyamide	10 L ; 20 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
Toxiques pour la reproduction - Catégorie 2	H361d : Susceptible de nuire au fœtus
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 de la 1,2-benzisothiazol-3(2H)-one. Peut produire une réaction allergique.	
Pour les phrases P se référer à la réglementation en vigueur.	
Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.	

CUSTODIA
AMM n°2180001

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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
15203201 Crucifères oléagineuses*Trt Part.Aer.*Maladies fongiques des siliques	1 L/ha	1/an	entre les stades BBCH 58 et BBCH 73	56	5	-	-	-
	Uniquement sur colza d'hiver et navette d'hiver. Une applications par culture pour contrôler l'ensemble des maladies.							
	1 L/ha	1/an	entre les stades BBCH 58 et BBCH 73	56	5 (dont DVP 5)	-	-	-
	Uniquement sur colza de printemps et navette de printemps. Une applications par culture pour contrôler l'ensemble des maladies.							
15203207 Crucifères oléagineuses*Trt Part.Aer.*Oïdium(s)	1 L/ha	1/an	entre les stades BBCH 58 et BBCH 73	56	5	-	-	-
	Uniquement sur colza d'hiver et navette d'hiver. Une applications par culture pour contrôler l'ensemble des maladies.							
	1 L/ha	1/an	entre les stades BBCH 58 et BBCH 73	56	5 (dont DVP 5)	-	-	-
	Uniquement sur colza de printemps et navette de printemps. Une applications par culture pour contrôler l'ensemble des maladies.							
15203202 Crucifères oléagineuses*Trt Part.Aer.*Sclérotiniose	1 L/ha	1/an	entre les stades BBCH 58 et BBCH 73	56	5	-	-	-
	Uniquement sur colza d'hiver et navette d'hiver. Une applications par culture pour contrôler l'ensemble des maladies.							
	1 L/ha	1/an	entre les stades BBCH 58 et BBCH 73	56	5 (dont DVP 5)	-	-	-
	Uniquement sur colza de printemps et navette de printemps. Une applications par culture pour contrôler l'ensemble des maladies.							

DVP : Dispositif Végétalisé Permanent.

CUSTODIA

AMM n°2180001

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Conditions d'emploi du produit

Stockage et manipulation du produit

- Rincer l'emballage au moins quatre fois avant son élimination.

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 ;

• pendant l'application - Pulvérisation vers le bas

Si application avec tracteur avec cabine

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage d'au moins 230 g/m² 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 d'au moins 230 g/m² 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.

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.

CUSTODIA
AMM n°2180001

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

Protection de l'environnement (milieux, faune et flore)
Protection de l'eau
- SP 1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination *via* les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

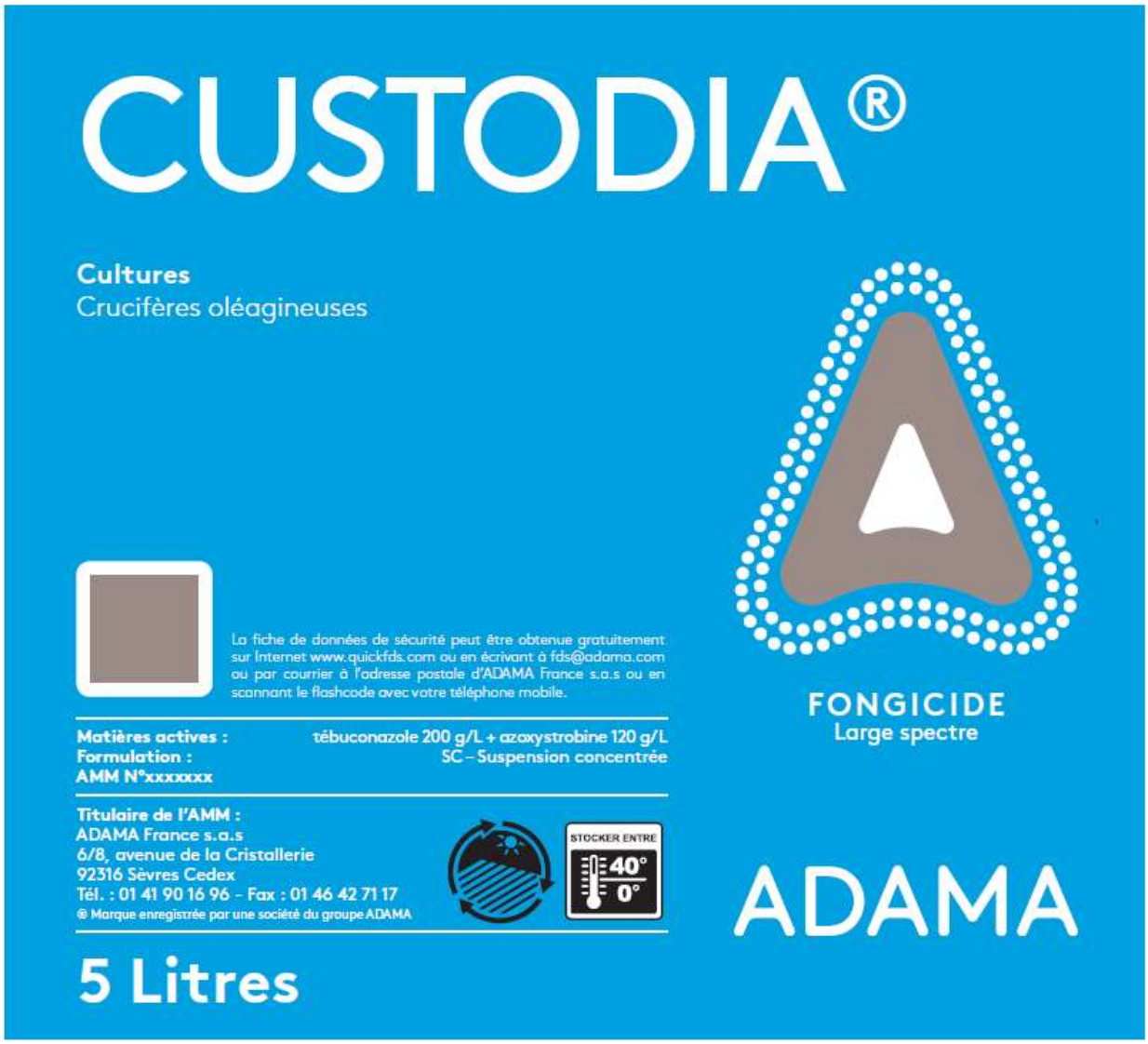
Protection de la faune
- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres comportant un dispositif végétalisé permanent non traité d'une largeur de 5 mètres en bordure des points d'eau pour les usages sur colza de printemps et navette de printemps.

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau pour les usages sur colza d'hiver et navette d'hiver.

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

Détail de la demande post autorisation	Délai (mois)	Récurrence (mois)
Mettre en place un suivi de la résistance à l'azoxystrobine (un seul suivi tous produits confondus) pour la sclérotiniose du colza. Fournir, aux autorités compétentes, toute nouvelle information susceptible de modifier l'analyse du risque de résistance.	-	-
Fournir une ILV de la méthode DFG S19 pour la détermination de l'azoxystrobine dans les denrées riches en huile.	24	-
Mettre en place un suivi dédié au métabolite 1,2,4-triazole afin de s'assurer du respect de la valeur seuil réglementaire de ce métabolite dans les eaux souterraines.	-	-

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



MODE D'ACTION – PROPRIÉTÉS

Custodia® est un fongicide à base de tébuconazole et d'azoxystrobine, à action préventive et curative contre un grand nombre de champignons pathogènes. Le tébuconazole agit par inhibition de la biosynthèse des stérols, tandis que l'azoxystobine agit sur la respiration et bloque la production d'énergie des champignons.

Il est efficace contre le sclérotinia, l'alternaria et l'oïdium des crucifères oléagineuses.

MODE D'EMPLOI

Usages et doses homologués :

Libellé de l'usage	Cultures associées pour le produit	Cibles associées pour le produit	Dose	Nombre d'applications	Délai avant récolte	Zone non traitée par rapport aux points d'eau
Crucifères oléagineuses*Trt Part.Aer.*Sclérotiniose	Colza Navette Navette sauvage	Sclérotiniose	1 L/ha	1 appli max/an	56 jours	5 mètres
Crucifères oléagineuses*Trt Part.Aer.*Oïdium(s)		Oïdium(s)				
Crucifères oléagineuses*Trt Part.Aer.*Maladies fongiques des siliques		Alternariose				

ADAMA France ne préconise l'utilisation de ce produit que sur les cultures et cibles mentionnées dans le tableau ci-dessus et, à ce titre, décline toute responsabilité concernant l'élargissement de son utilisation à d'autres cultures et cibles telles que prévues par le catalogue des usages fixé par l'arrêté du 26 mars 2014.

Ainsi, l'attention de l'utilisateur est attirée sur les risques éventuels de non-conformité de cet élargissement permis par ce catalogue.

Les Limites Maximales de Résidus sont consultables à l'adresse suivante :
http://ec.europa.eu/sanco_pesticides/public/index.cfm

Délai de rentrée des travailleurs sur la parcelle : 6 heures après traitement conformément à l'arrêté du 12 juin 2015 relatif à la mise sur le marché et à l'utilisation des produits visés à l'article L-253-1 du Code Rural.

Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur selon l'arrêté du 7 avril 2010 modifié par l'arrêté du 12 juin 2015.

Conditions d'emploi :

Custodia® s'utilise dans des volumes d'eau compris entre 100 et 400 L/ha.

Période d'emploi :

Sur colza, pour lutter de façon optimale contre le sclérotinia, il est préférable de réaliser le traitement au stade G1 (chute des premiers pétales).

PRÉCAUTIONS GÉNÉRALES

Equipements de protection individuels (EPI)

Pour protéger l'opérateur, porter :

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 (tablier ou blouse à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;

Pendant l'application :

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

Pendant le nettoyage du matériel de pulvérisation :

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

Pour protéger le travailleur s'il doit intervenir sur une parcelle traitée, porter des gants en nitrile certifiés EN 374-3 et une combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant.

Dans le cadre des bonnes pratiques agricoles :

Conditions de stockage : Conserver le produit dans son emballage d'origine, dans un local réservé à cet usage, à l'abri de la chaleur et à une température supérieure à 0°C.

Emballages vides : Réemploi de l'emballage interdit. Lors de l'utilisation du produit, bien vider et l'éliminer via les collectes organisées par les distributeurs partenaires de la filière ADIVALOR ou tout autre service de collecte spécifique. Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.

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 : Eloigner la victime de la zone dangereuse. Transporter la victime à l'air frais et selon les symptômes, consulter le médecin. En cas d'évanouissement, placer le sujet sur le côté en stabilisant la position, et consulter un médecin.

Contact avec la peau : Enlever immédiatement les vêtements sales et imbibés, les laver en profondeur à grande eau et avec du savon, en cas d'irritation de la peau (rougeurs, etc), consulter le médecin.

Contact avec les yeux : Ôter les verres de contact. Rincer abondamment à l'eau pendant plusieurs minutes. Si nécessaire, consulter le médecin.

Ingestion : Rincer soigneusement la bouche avec de l'eau. Faire boire abondamment de l'eau, consulter un médecin. Ne jamais faire avaler quoi que ce soit à une personne évanouie.

Mesures d'urgence :

En cas d'urgence, appeler le 15 ou le centre antipoison le plus proche de votre domicile. Présenter aux secours l'étiquette et la Fiche de Données de Sécurité. N° vert de PHYT'ATTITUDE (réseau de toxicovigilance agricole de la MSA) : Tél. 0 800 887 887.

IMPORTANT : Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduisez sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces, la pression parasitaire... Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de vente du Ministère de l'Agriculture. Compte-tenu de la diversité des législations existantes, il est recommandé, dans le cas où les denrées protégées ou issues de cultures protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur. ADAMA France s.a.s ne saurait être tenu en aucun cas responsable des conséquences inhérentes à toute copie (totale ou partielle) de cette étiquette, à sa diffusion ou son utilisation non autorisée.

CUSTODIA®

AMM N°xxxxxxx
SC – Suspension concentrée
tébuconazole 200 g/L (18,6%)
+ azoxystrobine 120 g/L (11,2%)

Attention
H302 : Nocif en cas d'ingestion.
H361d : Susceptible de nuire au foetus.
H410 : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.
EUH208: Contient de la 1,2-benziosothiazolin-3-one. Peut produire une réaction allergique.
EUH401 : Respecter les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.

Délai de rentrée des travailleurs sur la parcelle : 6h après traitement.
P102 : Tenir hors de portée des enfants.
P201 : Se procurer les instructions avant utilisation.
P270 : Ne pas manger, boire ou fumer en manipulant le produit.
P280 : Porter des gants de protection/ des vêtements de protection/ un équipement de protection des yeux/du visage.
P501 : Eliminer le contenu / récipient dans un centre de collecte des déchets dangereux ou spéciaux.

SP1 : Ne pas polluer l'eau avec le produit ou son emballage.
SPe3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.

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

Titulaire de l'AMM : ADAMA France s.a.s
6/8, avenue de la Cristallerie - 92316 Sèvres Cedex
Tél. : 01 41 90 16 96 - Fax : 01 46 42 71 17

Produit fabriqué en Israël

N° de lot	**VOIR SUR L'EMBALLAGE**
Date de fabrication	

Appendix 3 – Letters of Access

TDMG
Triazole Derivate Metabolite Group

11th November 2015

ANSES
DAMM – UIA
14 rue Pierre et Marie Curie
94701 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:

ADAMA France s.a.s
6/8 avenue de la Cristallerie
92316 Sèvres Cedex
France

for their plant protection product: **Custodia** (code MCW-710 SC)

with the active ingredients in a formulation containing: Tebuconazole 200 g/L + Azoxystrobin 120 g/L only.

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

1. The right of referral is solely granted to Adama France s.a.s. and is not transferable to any further companies or other legal or natural entities.
2. Reference to the data package can only be made for the registration of tebuconazole as an agrochemical.
3. 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.
4. Adama France s.a.s. 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.

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

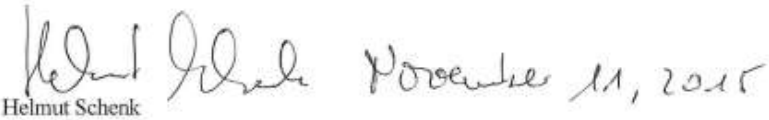
page 1

HC

5. This authorisation is valid only for such duration as there is a valid agreement between Adama France s.a.s. and TDMG.

On behalf of the TDMG

Yours sincerely,



November 11, 2015

Helmut Schenk
Chairman of the TDMG, Global Registration Manager

Bayer CropScience AG
BCS AG-R&D-GRA-RASM

Alfred-Nobel-Str. 50
D-40789 Monheim
Phone: +49 (0) 2173 38-3114
E-Mail: helmut.schenk@bayer.com

Delphine Plataux
Global Regulatory Manager
Tel: +41-61-323 75 83
delphine.plataux@syngenta.com
Syngenta Crop Protection AG
Schwarzwaldallee 215
CH-4058 Basel
Switzerland

ANSES
DAMM – UIA
14 rue Pierre et Marie Curie
94701 Maisons-Alfort Cedex
France

13th November 2015

Letter of Access for Azoxystrobin to the benefit of ADAMA France S.A.S.

Dear Sirs.

Syngenta Crop Protection AG Switzerland ("Syngenta") hereby authorizes the competent French authorities, to refer to the files, data, studies, summaries and assessments (hereinafter referred to as the "Dossier") owned and submitted by Syngenta (or our Affiliates) in support of the registration of Azoxystrobin Technical as an active ingredient or of Syngenta formulation/s containing Azoxystrobin in France, in order to grant registration to:

ADAMA France S.A.S.
6/8 avenue de la Cristallerie
92316 Sèvres Cedex
France

for their formulation **CUSTODIA (MCW-710-SC)** nominally containing 120 g/l Azoxystrobin + 200 g/l Tebuconazole (the "Formulation").

The above right to refer to the Dossier is subject to the following restrictions:

1. The right of referral only gives access to the Dossier of Azoxystrobin Technical.
2. The right of referral only gives access for the registration of the Formulation for uses on all agricultural crops (but excluding for the avoidance of doubt all uses for non-crop and non-agricultural applications).
3. The right of referral is solely granted to **ADAMA France S.A.S.**, and is not transferable to any further companies or other legal or natural entities.
4. **ADAMA France S.A.S.** is not authorized to receive any copies of the Dossier nor is it authorized to inspect or view the Dossier or any specific document in whole or in part.
5. This authorization is valid only for such duration as there is a valid agreement (including any prior termination notice period) relating to Azoxystrobin Technical in relation to **France** between **ADAMA Celsius B.V., Curaçao Branch** and Syngenta. **ADAMA Celsius B.V., Curaçao Branch** and **ADAMA France S.A.S.** have agreed to waive any rights and claims under this authorization upon termination of the underlying supply agreement, and consequently Syngenta shall be entitled to withdraw and revoke this letter of access at any time.

Yours sincerely.

Syngenta Crop Protection AG

Delphine Plataux
Global Regulatory Manager

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