REGISTRATION REPORT

Part A

Risk Management

Product code: MCW 706

Product name(s): MARACAS

Active Substance(s):

Epoxiconazole, 50 g/L

Prochloraz, 225 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: ADAMA FRANCE SAS

Date: 27/04/2016

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PART A – Risk Management

The company ADAMA FRANCE SAS has requested marketing authorisation in France for the product MARACAS (MCW 706), containing 50 g/L epoxiconazole and 225 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 review. It also includes assessment of data and information relating to MARACAS where that data have not been considered in the EU review process. Otherwise assessments for the safe use of MARACAS have been made using endpoints agreed in the EU review of both epoxiconazole and prochloraz.

This document describes the specific conditions of use and labelling required for France for the registration of MARACAS.

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 SAS's application to market MARACAS 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

Epoxiconazole

Regulations Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.
Specific provisions of regulation 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 epoxiconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 July 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate, — the dietary exposure of consumers to the epoxiconazole (triazole) metabolites, — the potential for long-range transport via air, — the risk to aquatic organisms, birds and mammals. Conditions of authorisation shall include risk mitigation measures, where appropriate.

The Member States concerned shall ensure that the notifier submits to the Commission further studies addressing the potential endocrine disrupting properties of epoxiconazole within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, of Community agreed test guidelines. The Member States concerned shall ensure that the notifier presents to the Commission not later than 30 June 2009 a monitoring programme to assess the long-range atmospheric transport of epoxiconazole and related environmental risks. The results of this monitoring shall be submitted as a monitoring report to the Commission by 31 December 2011 at the latest. The concerned Member States shall ensure that the notifier submits within two years from the approval, at the latest, information on residues of epoxiconazole metabolites in primary crops, rotational crops and products of animal origin and information to further address the long-term risk to herbivorous birds and mammals.
An EFSA conclusion is available (EFSA Scientific Report (2008) 138, 1-80). A Review Report is available (SANCO/136/08 final, 28 September 2010).

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 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 rev 2, 27 September 2011).

1.3 Regulatory Approach

The present application (2012-2919) 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 in the decision letter.
The French Order of 12 September 2006[3] provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is 5 m;
- unless formally stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision making process in France. However, 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' 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 regulatory compliance are based on the criteria indicated in Regulation (EU) No546/2011[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.

[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] http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000425570
[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

The decision, as duplicated 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 MARACAS, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

Not necessary for epoxiconazole: the applicant has provided equivalent studies to the notifier's Annex II dossier. Not necessary for prochloraz: the applicant has provided sufficient data to show that access is not required.

IRVITA has access to different studies of BASF, a copy of the exchange letter(s) is reproduced in Part A, Appendix 3.

2 DETAILS OF THE AUTHORISATION

2.1 Product Identity

Product name (code)	MARACAS (MCW 706)
Authorisation number	2150853
Function	Fungicide
Applicant	ADAMA FRANCE SAS
Composition	225 g/L epoxiconazole, 50 g/L prochloraz
Formulation type (code)	EC
Packaging	HDPE/EVOH (1 L, 5 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	Eye irritation, category 2 Carcinogenocity, category.2 Reproductive toxicity, category 1B	
Environmental hazards	Aquatic acute category 1 Aquatic chronic category 1	
Hazard pictograms		
Signal word	Danger	
Hazard statements	H319	Causes serious eye irritation.
	H351	Suspected of causing cancer
	H360Df	May damage the unborn child. Suspected of damaging fertility
	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-Ethyl hexyl 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).
SPe 3	To protect aquatic organisms respect an unsprayed buffer zone of 5 meters including a vegetative filter strip of 5 meters to surface water bodies on crops treated once.
SPe 3	To protect aquatic organisms respect an unsprayed buffer zone of 20 meters including a vegetative filter strip of 20 meters to surface water bodies on crops treated twice.

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment[8]: refer to the decision in Appendix 1 for the details
Re-entry period[9]: 24 hours
Pre-harvest interval[10]: - Wheat, triticale : F – last application at GS BBCH 59 - Barley, oat, rye : F – last application at GS BBCH 49
Other mitigation measures: - To prevent the occurrence of residues in succeeding crops, a waiting period of 120 days after last treatment is necessary before planting or sowing another crop (except for cereals and other crops on which prochloraz is registered and an MRL is set a level higher than LOQ).
The label must include the following statement: "EUH208: Contains 2-ethyl hexyl lactate. May produce an allergic reaction." The label must reflect the conditions of authorisation.

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

[9] 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]

[10] 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 the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.
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. 1, date: 2016-04-27

PPP (product name/code):	MARACAS/MCW 706	Formulation type:	EC [a, b]
Active substance 1:	epoxiconazole	Conc. of as 1:	50 g/L [c]
Active substance 2:	prochloraz	Conc. of as 2:	225 g/L [c]
Applicant:	ADAMA FRANCE SAS	Professional use:	☒
Zone(s):	southern [d]	Non professional use:	☐
Verified by MS:	yes		

Field of use: fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** 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 or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

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 or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	France	Wheat	F	Eye spot	Boom sprayer Foliar spray	BBCH 30-59	a) 1 (NR) b) 1 (NR)		a) 2.0 L b) 2.0 L	a) E: 100 g P: 450 g b) E: 100 g P: 450 g	100 – 300	F	*the efficacy of MARACAS is considered as acceptable but only for treatment on a diseases complex*
2	France	Wheat	F	Yellow rust Brown rust Septoria	Boom sprayer Foliar spray	BBCH 30-59	a) 1 (NR) b) 1 (NR)		a) 2.0 L b) 2.0 L	a) E: 100 g P: 450 g b) E: 100 g P: 450 g	100 – 300	F	
3	France	Barley	F	Helminthosporium sp. Rhynchosporium sp. Dwarf leaf Rust/Yellow rust	Boom sprayer Foliar spray	BBCH 31-49: A1: BBCH 31-39 A2: BBCH 39-49	a) 2 (14 days) b) 2 (14 days)		a) 2.0 L b) 4.0 L	a) E: 100 g P: 450 g b) E: 200 g P: 900 g	100 – 300	F	
5	France	Oat	F	Powdery mildew Crown Rust	Boom sprayer Foliar spray	BBCH 31-49: A1: BBCH 31-39 A2: BBCH 39-49	a) 2 (14 days) b) 2 (14 days)		a) 2.0 L b) 4.0 L	a) E: 100 g P: 450 g b) E: 200 g P: 900 g	100 – 300	F	
7	France	Rye	F	Rhynchosporium sp. Brown rust	Boom sprayer Foliar spray	BBCH 31-49: A1: BBCH 31-39 A2: BBCH 39-49	a) 2 (14 days) b) 2 (14 days)		a) 2.0 L b) 4.0 L	a) E: 100 g P: 450 g b) E: 200 g P: 900 g	100 – 300	F	
9	France	Triticale	F	Eye spot	Boom sprayer	BBCH 30-59	a) 1 (NR)		a) 2.0 L	a) E: 100 g	100 – 300	F	

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:**
					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 or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		e.g. g safener/synergist per ha [f]
				Powdery mildew Rhynchosporium sp Brown rust Yellow rust Septoria	Foliar spray		b) 1 (NR)		b) 2.0 L	P: 450 g b) E: 100 g P: 450 g			

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 MARACAS (MCW 706) is an emulsifiable concentrate (EC). All studies have been performed in accordance with the current requirements. The appearance of the formulation is that of a homogeneous translucent orange liquid, free form visible suspended matter and sediment with a faint chemical odour. It is not explosive and has no oxidizing properties. It has a self-ignition temperature of 276°C and a flash point >79°C. In aqueous solution (1%), its pH is 7.3 at 23°C. Stability data indicate a shelf life of at least 2 years at ambient temperature (HDPE/EVOH). Its technical characteristics are acceptable for an emulsifiable concentrate (EC) formulation.

3.1.2 Methods of analysis

Analytical methods for the determination of active substances and relevant impurities in the formulation are available and validated.
As relevant impurities (PCDDs and PCDFs) are by-product of the manufacturing process for prochloraz and as such cannot be formed by storage of the formulation, an analytical method for the determination of relevant impurities in the formulation is not necessary.

Analytical methods are available in the monographs/this dossier and validated for the determination of residues of prochloraz and epoxiconazole in plants (wheat, triticale, rye, oat, barley), 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

3.1.3.1 Acute Toxicity

MARACAS (MCW 706) was of low acute toxicity by oral, dermal route or via inhalation. MARACAS was not irritating to rabbit skin and was irritating to the eyes. In a M&K test with guinea pigs, MARACAS was not a skin sensitizer.

3.1.3.2 Operator Exposure

Operator exposure to cereals has been performed according to the German model BBA. According to the model and the classification of MARACAS, PPE have to be worn.

An additional evaluation has been performed with the German model with similar entry parameters in the model as presented in the dRR; According to the model calculations, it can be concluded that the risk for the operator using MARACAS is acceptable with a working coverall (90% protection factor) and gloves during mixing/loading and application.

Tractor-mounted/trailed boom sprayer: hydraulic nozzles: with this consideration the estimation of operator exposure represented 42% of the AOEL of prochloraz and 20% of the AOEL of epoxiconazole with working coverall and with gloves during mixing/loading and application.

A cumulative risk assessment has been performed using a tiered approach for MCW 706. The calculated hazard index (HI), estimated by summing the hazard quotients ($\sum$QR) for each active substance, is under 1 for cereals.

3.1.3.3 Bystander Exposure

Bystander exposure has been calculated according to EUROPOEM II model and is acceptable (4.6% of the AOEL of prochloraz and 2.1% of the AOEL of epoxiconazole).

A cumulative risk assessment has been performed using a tiered approach for MCW 706. The calculated hazard index (HI), estimated by summing the hazard quotients (∑QR) for each active substance, is under 1 for cereals.

3.1.3.4 Worker Exposure

Worker exposure is acceptable according to EUROPOEM II model only with PPE (27% of the AOEL of prochloraz and 11.7% of the AOEL of epoxiconazole).

A cumulative risk assessment has been performed using a tiered approach for MCW 706. The calculated hazard index (HI), estimated by summing the hazard quotients (∑QR) for each active substance, is under 1 for cereals.

3.1.4 Residues and Consumer Exposure

3.1.4.1 Residues

Primary crop metabolisms were sufficiently investigated to define residue of both active substances for enforcement and risk assessment in crops under consideration.

Regarding the magnitude of residues in wheat, triticale, rye, barley and oat, a sufficient number of residue trials are available to support the intended GAPs in France. These data confirm that no MRL exceedance will result from intended uses.

The effects of processing on the nature of prochloraz residues have been investigated. Data on effect of processing on the amount of residue have been submitted and considered for risk assessment for prochlroaz.

Residues in succeeding crops have been sufficiently investigated. The following mitigation is proposed: to prevent the occurrence of residues in succeeding crops: "a waiting period of 120 days after last treatment is necessary before planting or sowing another crop (except for cereals and other crops on which prochloraz is registered and an MRL is set a level higher than LOQ)".

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.

Feed commodities may represent a significant source of exposure to epoxiconazole residues for animals. Livestock metabolism studies in lactating goats and laying hens are available and based on the metabolic pattern in animal tissues the residue definition for monitoring can be restricted to the parent compound. Feeding studies in dairy cows are available and comply with MRLs in matrix of animal origin.

3.1.4.2 Consumer exposure

The toxicological profile of prochloraz and epoxiconazole were evaluated at EU level, which resulted in the proposal of ADIs (0.01 mg/kg for prochloraz and 0.008 mg/kg for epoxiconazole) and ARfDs (0.025 mg/kg for prochloraz and 0.023 mg/kg for epoxiconazole) that were considered in the frame of this evaluation.
Chronic and acute consumer exposure resulting from the uses proposed in the framework of this application was calculated for both active substances. Based on EFSA PRIMo (rev2), chronic and acute exposures were considered as acceptable for all groups of consumers.

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment of the formulation has been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review were used to calculate PECs for epoxiconazole, prochloraz 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 epoxiconazole, prochloraz and their metabolites in soil, surface water and groundwater has 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 epoxiconazole, prochloraz and their metabolites are used for the eco-toxicological risk assessment, and mitigation measures are proposed.

PECgw for epoxiconazole, prochloraz and their metabolites do not exceed the trigger of 0.1 µg/L for all FOCUS scenarios. 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

3.1.6.1 Effects on Terrestrial Vertebrates

The risk assessment for birds and mammals is carried out according to the 'EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009)[11] and considering the EU agreed endpoints of epoxiconazole and prochloraz.
The TER values, calculated for recommended scenarios, all exceed the trigger values of 10 for acute risk and 5 for long-term risk, indicating that the risk to birds and mammals[12] is acceptable following use of MARACAS (MCW 706) according to the proposed use patterns.

3.1.6.2 Effects on Aquatic Species

The risk assessment for aquatic organisms is carried out according to the Guidance Document on Aquatic Ecotoxicology (Sanco/3268/2001) and considering the EU agreed endpoints of epoxiconazole, prochloraz, their metabolites and data on the formulation MARACAS.
The TER for epoxiconazole exceed the relevant triggers, indicating that the risk to aquatic organisms is acceptable following use of MARACAS according to the proposed use patterns with respect of a 20 m buffer zone and 20 m vegetative strip.
The TER for prochloraz exceed the relevant triggers, indicating that the risk to aquatic organisms is acceptable following use of MARACAS according to the proposed use patterns with respect of a 5 m buffer zone and 5 m vegetative strip.

3.1.6.3 Effects on Bees and Other Arthropod Species

Based on the guidance documents, the risks for bees and other non-target arthropods are acceptable for the intended uses.

3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms

The risk assessment for earthworms and other soil macro-organisms is carried out according to the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002) and considering the EU agreed endpoints of epoxiconazole, prochloraz, their metabolites and data on the formulation MARACAS.
The TER values for prochloraz, its metabolite, the formulation and the acute TER values for epoxiconazole are greater than the triggers values, indicating that the risk to earthworms and other soil macro-organisms is acceptable according to the proposed uses pattern.
The long-term TER values for epoxiconazole are below the trigger of 5 indicating a potential risk to earthworms and other soil macro-organisms.
However, field studies were performed with epoxiconazole. No negative impact on earthworm populations or other soil non-target macro-organisms is expected from

3.1.6.5 Effects on Soil Non-target Micro-organisms

The risk of MARACAS to soil micro-organisms was evaluated by comparison of no-effect concentrations, derived from laboratory tests, with PECS.

[11] European Food Safety Authority; Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA. EFSA journal 2009; 7(12):1438. [139 pp.]
[12] from direct dietary exposure, drinking water and secondary poisoning.

The no effect levels exceed the relevant PECS values, indicating that the risk to soil micro-organisms is acceptable following use of MARACAS according to the proposed use pattern.

3.1.6.6 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna)

The risk assessment for non-target plants is carried out according to the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002) and considering the endpoints of the formulation MARACAS.
The application of MARACAS does not cause unacceptable effects on non-target terrestrial plants when applied at a maximum application rate of 2 L formulation/ha.

3.1.7 Efficacy

Considering the data submitted :
- the efficacy of MARACAS is considered as acceptable. On wheat, MARACAS can be applied against eye spot, but only when a diseases complex is present
- the selectivity of MARACAS is considered as acceptable,
- the risk of negative impact (yield, quality, transformation processes, propagation, adjacent and succeeding crops) is considered as acceptable.
- the risk of resistance development or appearance is considered as low to high depending on the disease. For OLIMSP, SEPTTR, ERYSGR and PYRNTE, diseases for which the risk can be considered as moderate to high, the applicant will have to set up or to pursue resistance monitorings to the active substances epoxiconazole and prochloraz. For these diseases, the applicant also will have to provide efficacy trials in situation of characterized resistance towards epoxiconazole and prochloraz. Any new information that may alter the risk of resistance will have to be provided to the competent authorities for all uses.

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

For OLIMSP, SEPTTR, ERYSGR and PYRNTE, diseases for which the risk can be considered as moderate to high, the applicant will have to set up or to pursue resistance monitorings to the active substances epoxiconazole and prochloraz. For these diseases, the applicant also will have to provide efficacy trials in situation of characterized resistance towards epoxiconazole and prochloraz. Any new information that may alter the risk of resistance will have to be provided to the competent authorities for all uses.

3.4.2 Post-authorisation data requirements

The French decision requests the submission of post-authorisation confirmatory pieces of information within 24 months regarding:
- A stability study of prochloraz residues in the straw.

Different active substances of the triazole family may be applied to the same plot. As the 1,2,4-triazole metabolite is common to most of these substances, it cannot be excluded that the regulatory value of 0,1 µg/L may be exceeded. To ensure compliance with the regulatory threshold value of 1,2,4-triazole in groundwater, all authorisation holders of triazole-based products must put in place specific monitoring for this metabolite within 24 months.

3.4.3 Label amendments (see label in Appendix 2):

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 du produit phytopharmaceutique ***MARACAS***

de la société *ADAMA FRANCE SAS*

enregistrée sous le *n°2012-2919*

Vu les conclusions de l'évaluation du 9 février 2016,

Vu la réclamation d'ADAMA FRANCE SAS du 18 février 2016,

Vu les éléments complémentaires transmis par la direction en charge de l'évaluation des produits règlementés de l'Anses le 8 mars 2016,

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.

MARACAS
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Informations générales sur le produit	
Nom du produit	MARACAS
Type de produit	Produit de référence
Titulaire	ADAMA FRANCE SAS 6/8 avenue de la Cristallerie, 92316 Sèvres Cedex FRANCE
Formulation	Concentré émulsionnable (EC)
Contenant	225 g/L - prochloraze 50 g/L - époxiconazole
Numéro d'intrant	962-2012.01
Numéro d'AMM	2150853
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. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 30 avril 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

27 AVR. 2016

Françoise WEBER
Directrice générale adjointe des 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 vinyl alcool	1 L
Bidons en polyéthylène haute densité / éthylène vinyl alcool	5 L
L'emballage « Bidons de 10 L en polyéthylène haute densité / polyamide » n'est pas autorisé en raison d'une manque de donnée.	

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	**Mention de danger**
Lésions oculaires graves/irritation oculaire, catégorie 2	H319 : Provoque une sévère irritation des yeux
Cancérogénicité, catégorie 2	H351 : Susceptible de provoquer le cancer
Toxicité pour la reproduction, catégorie 1B	H360Df : Peut nuire au fœtus. Susceptible de nuire à la fertilité
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, entraine 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	Délai avant récolte	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
15103214 Blé*Trt Part.Aer.*Rouille(s)	**2 L/ha**	**1/an**	BBCH 30 - 59	F (BBCH 59)	5 (dont DVP 5)	-	-	-
	Uniquement autorisé sur blé et triticale 1 application par an et par culture pour contrôler l'ensemble des maladies.							
15103221 Blé*Trt Part.Aer.*Septoriose(s)	**2 L/ha**	**1/an**	BBCH 30 - 59	F (BBCH 59)	5 (dont DVP 5)	-	-	-
	Uniquement autorisé sur blé et triticale 1 application par an et par culture pour contrôler l'ensemble des maladies.							
15103210 Blé*Trt Part.Aer.*Piétin verse	**2 L/ha**	**1/an**	BBCH 30 - 59	F (BBCH 59)	5 (dont DVP 5)	-	-	-
	Uniquement autorisé sur blé et triticale 1 application par an et par culture pour contrôler l'ensemble des maladies et pour lutte conjointe contre un complexe parasitaire.							
15103209 Blé*Trt Part.Aer.*Oïdium(s)	**2 L/ha**	**1/an**	BBCH 30 - 59	F (BBCH 59)	5 (dont DVP 5)	-	-	-
	Uniquement autorisé sur triticale. 1 application par an et par culture pour contrôler l'ensemble des maladies.							
15103220 Blé*Trt Part.Aer.*Rhynchosporiose	**2 L/ha**	**1/an**	BBCH 30 - 59	F (BBCH 59)	5 (dont DVP 5)	-	-	-
	Uniquement autorisé sur triticale. 1 application par an et par culture pour contrôler l'ensemble des maladies.							
15103208 Seigle*Trt Part.Aer.*Rouille(s)	**2 L/ha**	**2/an**	BBCH 31 - 49	F (BBCH 49)	20 (dont DVP 20)	-	-	-
	Intervalle entre applications : 14 jours 2 applications par an et par culture pour contrôler l'ensemble des maladies.							

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	Délai avant récolte	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
15103232 Seigle*Trt Part.Aer.*Rhynchosporiose	**2 L/ha**	**2/an**	BBCH 31 - 49	F (BBCH 49)	20 (dont DVP 20)	-	-	-
	Intervalle entre applications : 14 jours 2 applications par an et par culture pour contrôler l'ensemble des maladies.							
15103205 Orge*Trt Part.Aer.*Rouille(s)	**2 L/ha**	**2/an**	BBCH 31 - 49	F (BBCH 49)	20 (dont DVP 20)	-	-	-
	Intervalle entre applications : 14 jours 2 applications par an et par culture pour contrôler l'ensemble des maladies.							
15103229 Orge*Trt Part.Aer.*Rhynchosporiose	**2 L/ha**	**2/an**	BBCH 31 - 49	F (BBCH 49)	20 (dont DVP 20)	-	-	-
	Intervalle entre applications : 14 jours 2 applications par an et par culture pour contrôler l'ensemble des maladies.							
15103226 Orge*Trt Part.Aer.*Helminthosporiose et ramulariose	**2 L/ha**	**2/an**	BBCH 31 - 49	F (BBCH 49)	20 (dont DVP 20)	-	-	-
	Intervalle entre applications : 14 jours 2 applications par an et par culture pour contrôler l'ensemble des maladies.							
15103206 Avoine*Trt Part.Aer.*Oïdium(s)	**2 L/ha**	**2/an**	BBCH 31 - 49	F (BBCH 49)	20 (dont DVP 20)	-	-	-
	Intervalle entre applications : 14 jours 2 applications par an et par culture pour contrôler l'ensemble des maladies.							
15103231 Avoine*Trt Part.Aer.*Rouille couronnée	**2 L/ha**	**2/an**	BBCH 31 - 49	F (BBCH 49)	20 (dont DVP 20)	-	-	-
	Intervalle entre applications : 14 jours 2 applications par an et par culture pour contrôler l'ensemble des maladies.							

DVP : Dispositif Végétalisé Permanent.

MARACAS

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Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

Il convient de rappeler que 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 complémentaires comme les protections individuelles.

En tout état de cause, 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

- **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 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.

Pour le travailleur, porter

- Combinaison de travail (cotte en coton/polyester 35 %/65 % - grammage d'au moins 230 g/m²) avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-3 en cas de contact avec la culture traitée.

Délai de rentrée

24 heures en application de l'arrêté du 12 septembre 2006.

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Respect des limites maximales de résidus (LMR)

- Respecter un délai de 120 jours après la dernière application avant d'implanter une culture (excepté les cultures de céréales et autres cultures sur lesquelles la LMR du prochloraze n'est pas fixée à la limite de quantification).

- Les conditions d'utilisation de la préparation, compte tenu des bonnes pratiques agricoles critiques proposées pour chaque usage figurant dans la liste des usages autorisés, 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 dans le cas d'une application par culture.

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 20 mètres comportant un dispositif végétalisé permanent non traité d'une largeur de 20 mètres en bordure des points d'eau dans le cas de deux applications par culture.

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 étude de stabilité des résidus de prochloraze dans la paille.	24	-
Afin de s'assurer du respect de la valeur seuil règlementaire du 1,2,4-triazole dans les eaux souterraines, il conviendrait de mettre en place, un suivi dédié de ce métabolite.	24	-
Pour le piétin-verse, la septoriose à *Septoria tritici*, l'oïdium et l'helminthosporiose de l'orge, maladies pour lesquelles le risque de développement de la résistance est modéré à élevé, il conviendrait de : - mettre en place ou poursuivre les suivis de résistance aux substances actives époxiconazole et prochloraze ; - mettre en place des essais d'efficacité en situation de résistance caractérisée vis-à-vis de l'époxiconazole et du prochloraze.	-	-
Toutes nouvelles informations concernant la résistance aux substances actives époxiconazoles et prochloraze, devront être fournies aux autorités compétentes.	-	-

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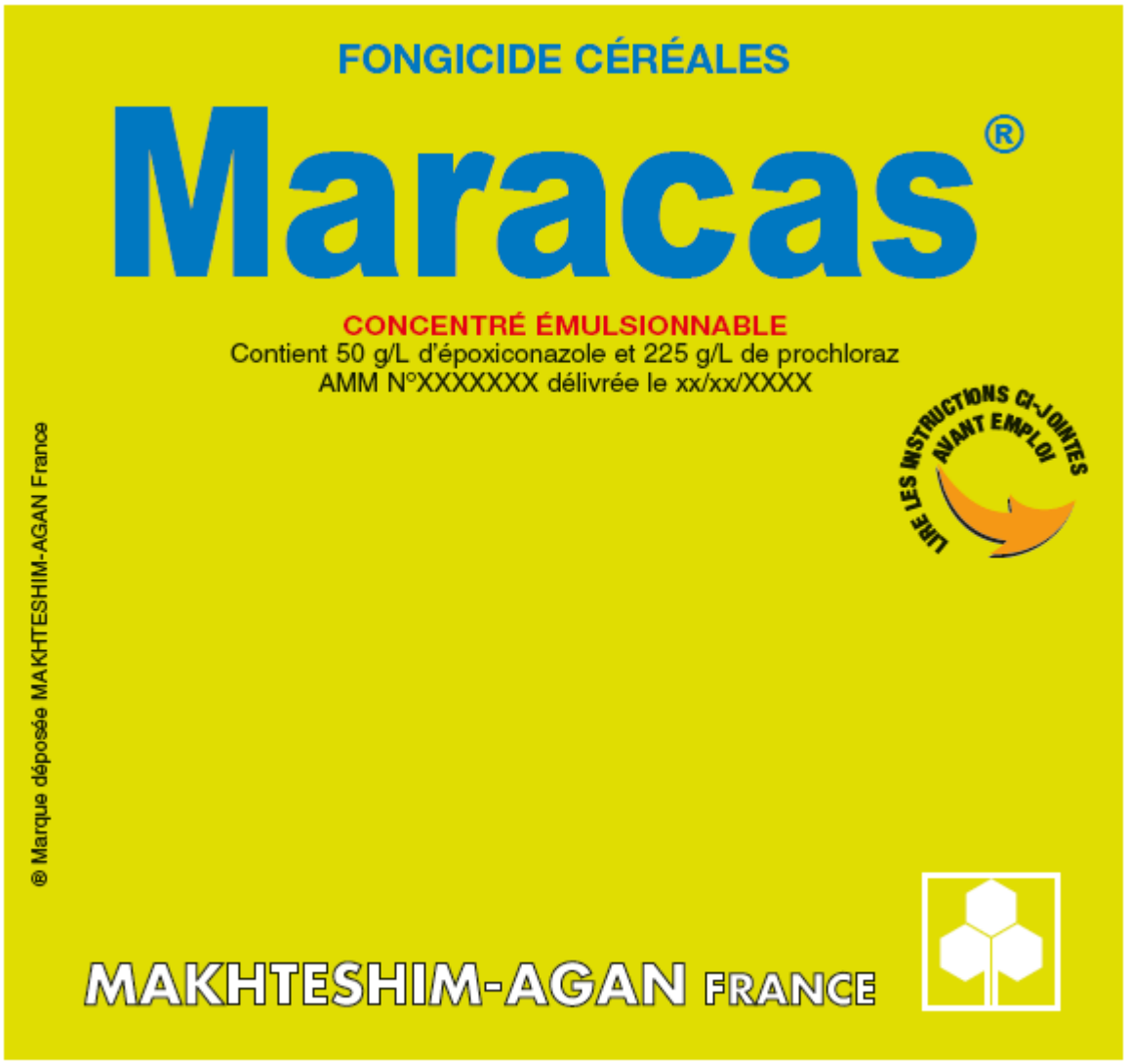
Appendix 2 – Copy of the draft product label as proposed by the applicant



Maracas®

AMM N° XXXXXXX

EC - concentré émulsionnable

Contient 50 g/L epoxiconazole (4,8 %) + 225 g/L prochloraz (21,4%)

Xn - nocif

N - Dangereux pour l'environnement

R36 : Irritant pour les yeux.
R40 : Effet cancérogène suspecté – preuves insuffisantes.
R50/53 : Très toxique pour les organismes aquatiques, peut entraîner des effets néfastes à long terme pour l'environnement aquatique.

Délai de rentrée des travailleurs sur la parcelle : 24h après traitement.

S2 Conserver hors de portée des enfants.
S13 Conserver à l'écart des aliments et boissons, y compris ceux pour animaux.
S20/21 Ne pas manger, ne pas boire et ne pas fumer pendant l'utilisation.
S26 En cas de contact avec les yeux, laver immédiatement et abondamment avec de l'eau et consulter un spécialiste.
S35 Ne se débarrasser de ce produit et de son emballage qu'en prenant toute précaution d'usage.
S36/37 Porter un vêtement de protection et des gants appropriés.
S61 Eviter le rejet dans l'environnement. Consulter les instructions spéciales / la fiche 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.

Homologué par :
MAKHTESHIM-AGAN France
2, rue Troyon
92316 Sèvres Cedex
Tél. : 01 41 90 16 96
Fax : 01 46 42 71 17

Aragonesas Agro, S.A.
Paseo de Recoletos, 16
28001 Madrid
Espagne

Produit fabriqué dans l'Union européenne

Volume net : **5 L**

Voir emballage

N° de lot et date de fabrication

Product Name :	MARACAS®
Country :	France
Package Size :	5 L
Label Code :	-
Label Dimensions :	140 (H) x 278 (W) mm
Label Date :	November 2012

MODE D'ACTION - PROPRIÉTÉS

MARACAS® est un fongicide systémique, préventif et curatif permettant le contrôle d'un grand nombre de maladies sur les céréales : blés, orges, triticale, seigle et avoine. **MARACAS®** est composé d'époxiconazole et de prochloraz, deux molécules issues de la famille des inhibiteurs de la synthèse de l'ergostérol, un des constituants de la membrane cellulaire des champignons. Elles sont complémentaires dans leur mode d'action et dans leur comportement vis-à-vis des maladies.

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	2 L/ha	2 applications max/an	14 jours d'intervalle	42 jours	20 mètres
Blé	Piétin verse Septoriose Rouille jaune Rouille brune	2 L/ha	1 application max/an	14 jours d'intervalle	42 jours	20 mètres
Orge	Helminthosporiose Rhynchosporiose Rouille jaune Rouille naine	2 L/ha	2 applications max/an	14 jours d'intervalle	42 jours	20 mètres
Seigle	Rhynchosporiose Rouille brune	2 L/ha	2 applications max/an	14 jours d'intervalle	42 jours	20 mètres
Triticale	Piétin verse Oïdium Septoriose Rouille jaune Rouille brune Rhynchosporiose	2 L/ha	1 application max/an	14 jours d'intervalle	42 jours	20 mètres

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 sur le site Internet de la Commission – Direction Générale Santé et protection du Consommateur à l'adresse suivante : http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=substance.selection

Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur et aux recommandations des guides de bonnes pratiques officiels. Consulter le site : http://e-phy.agriculture.gouv.fr

CONDITIONS D'EMPLOI :

Pour une meilleure efficacité, utiliser **MARACAS®** en application préventive. En cas de forte pression maladie, il peut être nécessaire de pratiquer une seconde application 14 jours après la première (sauf sur blé et triticale où une seule application est autorisée).

Sur Blé et Triticale : **MARACAS®** s'utilise du stade début montaison à fin épiaison (BBCH 30 à 59)

- Contre le piétin-verse : **MARACAS®** a une efficacité optimale lorsqu'il est appliqué avant que le piétin-verse n'attaque la tige, ce qui en général correspond à des traitements en début montaison, et en tous cas au plus tard au stade 1 nœud de la céréale (BBCH 31). Bien mouiller le bas des tiges.

Sur Avoine, Orge et Seigle : **MARACAS®** s'utilise du stade 1 noeud à fin montaison (BBCH 31 à 49).

Quantité de bouillie : de 100 à 300 L /ha.

PRÉPARATION DE LA BOUILLIE :
Remplir la cuve à moitié d'eau. Ajouter le produit, mélanger et compléter le volume du réservoir en évitant la formation de trop forts remous. Mettre ensuite le système d'agitation en action, avec modération.

PRÉCAUTIONS GÉNÉRALES :

GESTION DU RISQUE D'APPARITION DE RÉSISTANCE :
L'utilisation répétée, sur une même parcelle, de préparations à base de substances actives de la même famille chimique ou ayant le même mode d'action, peut conduire à l'apparition d'organismes résistants.
Pour réduire ce risque, il est conseillé d'alterner ou d'associer, sur une même parcelle, des préparations à base de substances actives de familles chimiques différentes ou à modes d'action différents, tant au cours d'une saison culturale que dans la rotation.

DANS LE CADRE DES BONNES PRATIQUES AGRICOLES :
Conditions de stockage : Conserver le produit dans son emballage d'origine, dans des locaux fermés à clé, à l'écart de tout aliment et boisson y compris ceux pour les animaux, et hors de portée des enfants. Les locaux doivent être frais et ventilés.
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.
Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'enlèvement des produits dangereux.
Nettoyage de l'équipement : Ne pas laisser de bouillie prêt à l'emploi dans le pulvérisateur. Eliminer les fonds de cuve et les eaux de rinçage conformément à la réglementation en vigueur. Eviter tout 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 :
Eloigner la personne atteinte de la zone de travail. La conduire dans un endroit bien aéré et la protéger de l'hypothermie. Ne rien administrer par voie orale et ne pas tenter de faire vomir, contacter le centre anti-poison ou un médecin.
Inhalation : Confère paragraphe consignes générales.
Contact avec la peau : Oter les vêtements souillés et laver à l'eau et au savon les parties contaminées du corps.
Contact avec les yeux : En cas de contact avec les yeux, laver immédiatement et abondamment avec de l'eau, maintenir les paupières ouvertes et consulter un spécialiste.
Ingestion : Confère paragraphe consignes générales. En cas d'ingestion, consulter un médecin et lui montrer l'emballage ou l'étiquette. Les vomissements peuvent provoquer des lésions pulmonaires.
Mesures d'urgence : En cas d'urgence, contacter le centre antipoison le plus proche de votre domicile ou appeler le 15. Présentez aux secours la fiche de données de sécurité. Puis signalez vos symptômes au réseau Phyt'attitude : tél. 0 800 887 887 (numéro vert).

RECOMMANDATIONS : Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage et qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduire sur ces bases la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous les facteurs particuliers concernant votre exploitation, telles 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 des législations existantes, il appartient à l'utilisateur, dans le cas où les denrées issues des cultures protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur. Makhteshim Agan ne saurait être tenu en aucun cas pour responsable des conséquences inhérentes à toute copie (totale ou partielle) de cette étiquette, à sa diffusion ou son utilisation non autorisée.

Appendix 3 – Letter(s) of Access

BASF
The Chemical Company

BASF SE, 67114 Limburgerhof, Deutschland

To whom it may concern

10.02.2009/ak
APD – Li 556
Dr. Jürgen Oldeweme
Tel.: 0621/60-27663
Fax: 0621/60-27487
E-mail: juergen.oldeweme@basf.com

Letter of Access for Generic Behavioural Ecology Data

- **Study Report BASF DocID 2006/1039415**
- **Grouping: Cereals, post-emergence, foliar stages**

BASF SE (the "**Grantor**") has been conducting behavioural field studies for certain wild birds and mammals in relation to certain crops and regions of Europe in order to generate generic behavioural ecology data in support of its plant protection products. These data are not targeted to any specific active substance.

The field studies were conducted on a crop/crop stage (pre-emergence/post-emergence) basis and are reported on the basis of several so-called groupings. The study report included in this Letter of Access is assigned to the grouping "cereals, post-emergence, foliar stages" (the "**Grouping**").

The generic behavioural ecology data contained in the study report:

are owned by the Grantor and have been filed by the Grantor in relation to the particular Grouping referenced above.

The Grantor hereby agrees that the aforementioned Study Report may be accessed by

Makhteshim Chemical Works Ltd., Beer Sheva 84100, Industrial Zone PO Box 60, 84100 Israel

The Company and its Affiliates may use the study report solely to support their individual product risk assessments in relation to plant protection products for which they are either (a) the registration applicant or (b) the holder of a registration.

BASF SE
Agrarzentrum Limburgerhof
67117 Limburgerhof, Deutschland

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Sitz der Gesellschaft: 67056 Ludwigshafen
Registergericht: Amtsgericht Ludwigshafen,
Eintragungsnummer: HRB 6000

Euro-Bankverbindung:
BASF Bank GmbH, 67056 Ludwigshafen
Konto-Nr. 400505, BLZ 520 200 00
IBAN DE67 5202 0000 0000 4005 05
SWIFT-BIC-Code WINBDE52XXX

Aufsichtsratsvorsitzender: Jürgen Strube

Vorstand: Jürgen Hambrecht, Vorsitzender;
Kurt Bock, Martin Brudermüller,
Hans-Ulrich Engel, John Feldmann,
Andreas Kreimeyer, Stefan Marcinowski,
Harald Schwager

BASF
The Chemical Company

Page 2 10.02.2009

To whom it may concern

Letter of Access for Generic Behavioural Ecology Data
- **Study Report BASF DocID 2006/1039415**
- **Grouping: Cereals, post-emergence, foliar stages**

For the purpose of this Letter of Access the term "Affiliate" means any business entity, which controls, is controlled by or is under common control with one of the Parties, as at the Effective Date or during the term of this Agreement; for the purposes of this definition, a business entity shall be deemed to "control" another entity if it beneficially owns, directly or indirectly, 50% or more of the outstanding voting securities or capital stock of such business entity or any other comparable equity or ownership interest with respect to a business entity other than a corporation. For the purposes of interpreting this Agreement an Affiliate shall not be treated as a third party.

The rights granted under this Letter of Access to refer to the Study Report are subject to the following restrictions:

1. The right of referral granted only applies to the Study Report explicitly mentioned in this Letter of Access and to no other data, report or dossier of the Grantor or any of its Affiliates.

2. The right of referral to the Study Report is strictly limited for the purposes described in this Letter of Access and there is no implied license to use or refer to the Study Report for any other purposes.

3. The right of referral is personal to the Company and its Affiliates and is neither sub-licensable nor transferable to any other person or legal entity.

4. The right of referral is only valid for as long as there is a valid agreement ("**Data Access Agreement**") between the Grantor and the Company in this regard; upon expiration or termination of such an agreement, the Grantor may at any time revoke the rights of referral granted herein and shall inform the competent registration authority accordingly.

The Study Report contains valuable information proprietary to the Grantor. Therefore, neither any registration authority nor the Company or any of its Affiliates shall be entitled to disclose the Study Report or any part of it to any third party nor to allow its use by any third party, unless the Grantor has given its prior written approval to such disclosure or use.

Sincerely,

BASF SE

Name: Dr. Jürgen Oldeweme
Titel: Group Vice President

Name: Dr. Rainer Bahnemann
Title: Director

Bayer CropScience

To whom it may concern

Dr. Christine Nohl-Weiler

Global Regulatory Manager
Tel. +49 (0)2173 38 7386
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E-Mail: christine.nohlweiler@bayercropscience.com

2009-02-19

Bayer CropScience AG
Development
Global Regulatory Affairs
Alfred-Nobel-Str. 50
40789 Monheim
Germany
www.bayercropscience.com

Letter of Access for Generic Behavioural Ecology Data
- Study Report Bayer CropScience AG DocID M-252240-01-1
- Grouping: Maize, pre-emergence (seed treatments) and early post-emergence

Bayer CropScience AG (the "**Grantor**") has been conducting behavioural field studies for certain wild birds and mammals in relation to certain crops and regions of Europe in order to generate generic behavioural ecology data in support of their plant protection products. These data are not targeted to any specific active substance.

The field studies were conducted on a crop/crop stage (pre-emergence/post-emergence) basis and are reported on the basis of several so-called groupings. The study report included in this Letter of Access is assigned to the grouping "maize, pre-emergence, seed treatments and early post-emergence" (the "**Grouping**").

The generic behavioural ecology data contained in the study report:

are owned by the Grantor and/or its Affiliates and have been filed by the Grantor in relation to the particular Grouping referenced above.

The Grantor hereby agrees that the aforementioned Study Report may be accessed by

> MAKHTESHIM Chemical Works Ltd., Beer Sheva 84100 Industrial Zone, PO Box 60, 84100 Israel (the **"Company"**) and its Affiliates.

The Company and its Affiliates may use the Study Report to support their individual product risk assessments in relation to plant protection products for which they are either (a) the registration applicant or (b) the holder of a registration.

Bayer CropScience

Page 2 of 2

For the purpose of this Letter of Access the term "**Affiliate**" means any entity which, directly or indirectly, controls, is controlled by, or is under common control with the Grantor or the Company, respectively. An entity shall be deemed to "**control**" another entity if it beneficially owns, directly or indirectly, more than 50% of the voting stock or any other comparable equity or ownership interest with respect to an entity.

The rights granted under this Letter of Access to refer to the Study Report are subject to the following restrictions:

1. The right of referral granted only applies to the Study Report explicitly mentioned in this Letter of Access and to no other data, report or dossier of the Grantor or any of its Affiliates.
2. The right of referral to the Study Report is strictly limited for the purposes described in this Letter of Access and there is no implied license to use or refer to the Study Report for any other purposes.
3. The right of referral is personal to the Company and its Affiliates and is neither sub-licensable nor transferable to any other person or legal entity.
4. The right of referral is only valid for as long as there is a valid agreement between the Grantor and the Company in this regard; upon expiration or termination of such an agreement, the Grantor may at any time revoke the rights of referral granted herein and shall inform the competent registration authority accordingly.

The Study Report contains valuable information proprietary to the Grantor. Therefore, neither any registration authority nor any Company and its Affiliates shall be entitled to disclose the Study Report nor any part of it to any third party nor to allow its use by any third party, unless the Grantor has given its prior written approval to such disclosure or use.

Sincerely,
Bayer CropScience AG

Dr. Christine Nohl-Weiler
Global Regulatory Manager Fungicides

BASF
The Chemical Company

BASF Agro B.V., Arnhem (NL) - Wädenswil Branch

TO WHOM IT MAY CONCERN

August 31, 2012
Tim Hickling
Director
Tel. +41 44 781 99 50
Fax +41 44 781 96 48
tim.hickling@basf.com

Certificate of Ownership

Prochloraz : ownership of study from Heal & Beck referenced under BASF Doc ID C038443

This letter is to confirm that:

BASF Agro B.V. Arnhem (NL) Wädenswil Branch, Moosacherstr. 2, CH-8804 Au, Switzerland acquired from **Bayer Crop Science AG** the ownership of the following Study:

Sincerely,

BASF Agro B.V. Arnhem (NL) Wädenswil Branch

Tim Hickling
Director

Martin Bolinger
Manager Customer & Support Services

BASF Agro B.V., Arnhem (NL) Wädenswil Branch BASF Switzerland CH-8820 Wädenswil

BASF Agro B.V., Arnhem (NL) - Wädenswil Branch
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BASF
The Chemical Company

BASF Agro B.V., Arnhem (NL) - Wädenswil Branch

TO WHOM IT MAY CONCERN

- Curacao -

May 29, 2012
Tim Hickling
Director
Tel. +41 44 781 99 50
Fax +41 44 781 96 48
tim.hickling@basf.com

Letter of Co-Ownership

This letter is to confirm that:

Irvita Plant Protection N.V. ("IRVITA") a company organised and existing under the laws of Curacao, with registered address at Pos Cabai Office Park, Unit 13, P.O. Box 403, Curacao and incorporated in under no. 53211 ("IRVITA"), has acquired from **BASF Agro B.V., Arnhem (NL)** ("BASF"), co-ownership in and regulatory data use of the Study listed here below.

As a result of the above, IRVITA and BASF shall each be co-owner of the above-mentioned Study, and shall each be entitled to freely use and act with such Study in its discretion without any limitations and restrictions in time, place, volume of data or otherwise.

Yours faithfully,

BASF Agro B.V. Arnhem (NL) Wädenswil Branch

BASF Agro B.V., Arnhem (NL) Wädenswil Branch BASF Switzerland CH-8804 Au

Tim Hickling
Director

Alexander Hauk
Manager Global Sourcing & Contracting

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