REGISTRATION REPORT

Part A

Risk Management

Product code: HAG 300 04 F

Product name(s): PRIAM TOP

Active Substance:

Tebuconazole, 250 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: HELM AG

Date: 26/08/2016

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PART A – Risk Management

The company HELM AG has requested marketing authorisation in France for the product PRIAM TOP (formulation code: HAG 300 04 F), containing 250 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 review. It also includes assessment of data and information relating to PRIAM TOP where that data have not been considered in the EU review process. Otherwise assessments for the safe use of PRIAM TOP have been made using endpoints agreed in the EU review of tebuconazole.

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

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 HELM AG's application to market PRIAM TOP (HAG 300 04 F) in France as a fungicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Tebuconazole

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. 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 the 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 tebuconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment; — the dietary exposure of consumers to the tebuconazole (triazole) metabolites — the protection of granivorous birds and mammals and herbivorous mammals and must ensure that the conditions

of authorisation include, where appropriate, risk mitigation measures. — the protection of aquatic organisms and must ensure that conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate. The Member States concerned shall request the submission of further information to confirm the risk assessment for birds and mammals. They shall ensure that the notifier at whose request tebuconazole has been included in this Annex provide such information to the Commission by 31 August 2011 at the latest. The Member States concerned shall ensure that the notifier submits to the Commission further information addressing the potential endocrine disrupting properties of tebuconazole within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, of Community agreed test guidelines.
An EFSA conclusion is available (EFSA Journal 2014; 12(1): 3485). A Review Report is available (SANCO/171/08 – rev. 1, 9 September 2008 [Inclusion]; SANCO/171/08 – rev. 2, 11 July 2014 [Conditions of approval]).

1.3 Regulatory Approach

The present application (2012-1163) 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], 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) No546/2011[5], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria. In some cases, the use may be considered "not finalised" based on the data submitted in the dossier, however decision may considers additional criteria.

[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

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

- an authorization 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 this French order. .

Then, at FR level, possible extrapolation of submitted data and corresponding assessment from "reference" crops to linked ones are assessed even if not clearly intended by applicant in the dRR, and a conclusion is reached on acceptability of intended uses on those linked crops. The aim of this order, mainly based on EU document on residue data extrapolation [7] is to supply minor crops with registered PPP.

Then, GAPs table (§2.3.) and decision may include uses on crops not clearly intended by applicant.

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 PRIAM TOP, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

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

2 DETAILS OF THE AUTHORISATION

2.1 Product Identity

Product name (code)	PRIAM TOP (HAG 300 04 F)
Authorisation number	2150253
Function	Fungicide
Applicant	HELM AG
Composition	250 g/L tebuconazole
Formulation type (code)	Oil-in-water emulsion (EW)
Packaging	High-density polyethylene (HDPE) (1, 5, 10, 120, 220 or 820 litres)

2.2 Classification and Labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Physical hazards	-

[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

Health hazards	Xn	Harmful
Environmental hazards	N	Dangerous for the environment

Risk phrases	R41	Risk of serious damage to eyes
	R63	Possible risk of harm to the unborn child
	R51/53	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
Safety phrases	S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
	S36/37/39	Wear suitable protective clothing, gloves and eye/face protection
	S61	Avoid release to the environment. Refer to special instructions/safety data sheet

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

Physical hazards	-	
Health hazards	Reproductive toxicity category 2 Serious eye damage Category 1	
Environmental hazards	Aquatic Chronic 2	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H361d	Suspected of damaging the unborn child.
	H318	Causes serious eye damage.
	H411	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)		

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 1	To protect groundwater/soil organisms do not apply this or any other product containing tebuconazole more than once per year on winter and spring cereals.
SPe 1	To protect groundwater/soil organisms do not apply this or any other product containing tebuconazole more than twice per year on grapevines (wine grape).
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres to surface water bodies[8] including a permanent vegetative buffer strip of 5 metres to surface water bodies for spring cereals and grapevines (wine grape).
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 20 metres to surface water bodies[9] including a permanent vegetative buffer strip of 20 metres to surface water bodies for winter cereals.

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment[10]: refer to the Decision in Appendix 1 for the details		
Re-entry period[11]: 24 hours		
Pre-harvest interval[12]:	Cereals (barley, oats, wheat, triticale): 35 days	Wine grape: 14 days
Other mitigation measures:-		
Include any request for modification(s) of the draft label: - -		

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

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

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

[11] 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]

[12] 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 an use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.

GAP rev. 1, date: 2016-08-26

PPP (product name/code) **PRIAM TOP (HAG 300 04 F)**
Active substance **tebuconazole** **Conc. of a.s.: 250 g/L**

Applicant: **HELM AG** **professional use** ☒
Zone(s): **southern EU**

Verified by MS: Yes

Crop and/ or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		

Barley, wheat, triticale, oats	Southern	HAG 300 04 F	F	*Puccinia coronata, Rhynchosporium secalis, Fusarium sp., Puccinia recondita f. sp. tritici, Puccinia recondita,*	EW	250	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 30-79 (at infestation beginning or warning)	2	21	0.0833 – 0.166	150 - 300	250	28	Not compliant (risk to groundwater, resistance)
Barley, wheat, triticale, oats	France	HAG 300 04 F	F	*Puccinia coronata, Rhynchosporium secalis, Fusarium sp., Puccinia recondita f. sp. tritici, Puccinia recondita,*	EW	250	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 30-79 (at beginning **of infection** or warning)	**1**	21	0.0833 – 0.166	150 - 300	250	**35**	Application rate of product : 1 L/ha Number of treatments reduced, to protect groundwater and to reduce resistance risk. PHI adjusted to reflect the supporting residues trials.
Vineyard	Southern	HAG 300 04 F	F	*Erysiphe* necator	EW	250	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 55-79 (at infestation beginning or warning)	3	14	0.01 – 0.033	300-1000	100	14	Not compliant (risk to groundwaters)
Vineyard **(Wine grape only)**	France	HAG 300 04 F	F	*Erysiphe necator*	EW	250	Tractor-mounted sprayer, broadcast, ground-directed spraying	BBCH 55-79 (at beginning **of infection** or warning)	**2**	14	0.01 – 0.033	300-1000	100	14	Application rate of product : 0,4 L/ha Number of treatments reduced, to protect groundwater and to reduce resistance risk. Wine grape only.

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/L
(j) Growth stage at 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
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) 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 PRIAM TOP (HAG 300 04 F) is an oil-in-water emulsion (EW). All studies have been performed in accordance with the current requirements. The appearance of the formulation is a clear liquid with a slight yellow tint and an odour similar to amines. It is not explosive and has no oxidising properties. It has a self-ignition temperature of 265 °C and no flash point below the boiling point of 110°C. In aqueous solution at 1 % dilution, its pH is 7.54 at 20 °C. Stability data indicate a shelf life of at least 2 years at ambient temperature (HDPE). Its technical characteristics are acceptable for an EW formulation.

The formulation is not classified for the physical-chemical aspect

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methods for the determination of active substance in the formulation are available and validated.

3.1.2.2 Analytical methods for residues

Analytical methods are available in this dossier and validated for the determination of residues of tebuconazole in plants (acidic matrices, cereal and dry products and fatty products), food of animal origin, soil, water (surface and drinking) and air.

To update the dossier:

According to the definition proposed in EFSA conclusion, an analytical method and its ILV to allow the determination of tebuconazole, hydroxyl-tebuconazole and their conjugates in foodstuffs of animal origin (muscle, fat, liver/kidney, eggs and milk).
A certificate of supply for the radiolabelled internal standard used in the analytical method for the determination of tebuconazole in soil.
A confirmatory method for the determination of tebuconazole in soil, as the original method is not highly specific.

The active substance is 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

HAG 300 04 F (PRIAM TOP) containing 250 g/L tebuconazole, has a low acute oral and dermal toxicity. It is not irritating to rabbit skin, but causes irreversible effects on the eye. It does not induce dermal sensitisation. Due to its physico-chemical properties, no acute inhalation test was required.

Considering the classification of the non-active ingredients, the active substance and the results of acute toxicity studies, PRIAM TOP (HAG 300 04 F) requires the toxicological classification shown in Section 2.2 above.

3.1.3.2 Operator Exposure

The product is intended to be used on barley, wheat, triticale, oats and grape vineyards as a fungicide.

Estimations of potential operator exposure have been undertaken for tebuconazole using the list of intended uses (refer to GAP table above) and the BBA model, taking into account a protection factor of 90 % for the working coverall.

The estimates were compared with the following data from the approval of tebuconazole or studies provided in this dossier.

EU End-points and endpoints used in this risk assessment for tebuconazole

End-Point	**Active substance agreed endpoints**
Dermal penetration	Concentrate: 1.2 % Spray dilutions: 25.5 % Based on *in vitro* study using human skin The study was carried out with the current formulation, see KIIIA 7.6.2/01
AOEL	0.03 mg/kg bw/d 1 year dog, (Safety Factor 100), supported by developmental mouse study (SF 300) (EFSA Scientific Report (2008) 176, 1-109)

According to the model calculations, it can be concluded that the risk for the operator using PRIAM TOP (HAG 300 04 F) is acceptable with the use of coverall (90 % protection factor) and without other personal protective equipment.

The following personal protective equipment are recommended by applicant:

Operator

- For mixing/loading

- Nitrile gloves certified EN 374-3;
- Working coverall 65 % polyester / 35 % cotton; minimum 230 g/m²; with water-repellent treatment;
- Long-sleeved apron, Category III Type PB3 worn over the coverall proposed above [not proposed by the applicant];
- Goggles or face shield certified according to EN 166 standard with frame marking 3 [proposed by the applicant and according to the classification].

- For application _ Downward spraying (cereals)

If application with tractor with cab
- Working coverall 65 % polyester / 35 % cotton; minimum 230 g/m²; with water-repellent treatment;
- Disposable nitrile gloves certified EN 374-2 in the case of an intervention on application equipment, but not inside the cab. In the case of an intervention on application equipment, it should be noted that gloves should be worn only outside the tractor cab and stored after use outside the cab

If application with tractor without cab

- Working coverall 65 % polyester / 35 % cotton; minimum 230 g/m²; with water-repellent treatment;
- Disposable nitrile gloves certified EN 374-2 in the case of an intervention on application equipment;
- Goggles or face shield certified according to EN 166 standard with frame marking 3.

● For application _ Upward spraying (grape)

If application with tractor with cab

- Working coverall 65 % polyester / 35 % cotton; minimum 230 g/m²; with water-repellent treatment;
- Disposable nitrile gloves certified EN 374-2 in the case of an intervention on application equipment, but not inside the cab. In the case of an intervention on application equipment, it should be noted that gloves should be worn only outside the tractor cab and stored after use outside the cab.

If application with tractor without cab

- Protective coverall category III Type 4 with hood;
- Disposable nitrile gloves certified EN 374-2 during application and in the case of an intervention on application equipment;
- Goggles or face shield certified according to EN 166 standard with frame marking 3.

● For equipment cleaning

- Nitrile gloves certified EN 374-3;
- Working coverall 65 % polyester / 35 % cotton; minimum 230 g/m²; with water-repellent treatment;
- Long-sleeved apron, Category III Type PB3 worn over the coverall proposed above [not recommended by the applicant]

- Goggles or face shield certified according to EN 166 standard with frame marking 33.1.3.3

3.1.3.3 Bystander Exposure

Bystander exposure to HAG 300 04 F was performed according to the EUROPOEM II. Based on this calculation, it is concluded that there is no undue risk to the bystander after incidental short-term exposure to HAG 300 04 F.

3.1.3.4 Worker Exposure

Workers enter treated areas after treatment for vine crop maintenance activities or harvesting; estimation of worker exposure was calculated according to EUROPOEM II. Based on this calculation, it is concluded that there is no unacceptable risk anticipated for the worker wearing gloves and working clothes, when re-entering crops treated with HAG 300 04 F

If the worker has to perform tasks on the treated crops, the following PPE are recommended:

- Working coverall 65 % polyester / 35 % cotton; minimum 230 g/m²; with water-repellent treatment.
- Nitrile gloves certified EN 374-3 (if in direct contact with the treated crop);

3.1.4 Residues and Consumer Exposure

3.1.4.1 Residues

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

Regarding the magnitude of residues in grapes, a sufficient number of residue trials are available to support the intended GAPs in Southern Europe. These data allowed to estimate the expected residue concentrations in the relevant plant commodities, and to confirm that no MRL exceedance will result from intended uses.
As only 6 northern trials conducted with a SC formulation are available to support the intended GAPs in France, 4 comparative trials between the SC and the EW formulations are required in post-registration. Moreover, these trials have to be conducted in the northern zone at the intended GAPs in order to complete the data package.
Regarding the magnitude of residues in cereals, a sufficient number of residue trials are available to support all the intended GAPs in Southern Europe, except in France for which the uses are proposed only for a PHI of 35 days instead of 28 days. These data allowed to estimate the expected residue concentrations in the relevant plant commodities, and to confirm that no MRL exceedance will result from intended uses.

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

Residues in succeeding crops have been sufficiently investigated, it is very unlikely that residues will be present in succeeding crops. Nevertheless, the studies on the nature and magnitude of tebuconazole residues in rotational crops indicate that triazole derivative metabolites might be of concern in rotational crops. Noting that these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment would be performed for TDMs in rotational crops as soon as the confirmatory data requested for triazole compounds in the framework of Regulation 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their triazole derivative metabolites is available.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

- **Four comparative residues trials using EW and SC formulations, conducted in northern Europe according to the proposed GAP, to demonstrate the equivalence of these two formulation types.**

3.1.4.2 Consumer exposure

The toxicological profile of tebuconazole was evaluated at EU level, which resulted in the proposal of ADI (0.03 mg/kg for tebuconazole) and ARfDs (0.03 mg/kg for tebuconazole) that were considered in the frame of this evaluation.
Chronic consumer exposure resulting from the uses proposed in the framework of this application was calculated for active substance. 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 the active substance and its metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC of tebuconazole and its 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.

The results for PEC soil and PECsw for the active substance and its metabolites are used for the ecotoxicological risk assessment.

For the intended uses on cereals, PECgw values are below to the trigger value of 0.1 µg/L for tebuconazole (maximum value below 0.001 µg/L).

For the intended uses on cereals, PECgw for the metabolite 1,2,4-triazole were above the trigger of 0.1 µg/L for one scenario (maximum value of 0.283 µg/L) at least. Since metabolite 1,2,4-triazole is considered as relevant according to the document SANCO/221/2000, mitigation measures were provided, considering one application per year. In these conditions, PECgw for the relevant metabolite 1,2,4-triazole are below the value of 0.1 µg/L for all scenarios (maximum value of 0.091 µg/L). No unacceptable risk of groundwater contamination is expected when tebuconazole is applied no more than once a year on cereals.

For the intended uses on grapevines, PECgw for the metabolite 1,2,4-triazole were above the trigger of 0.1 µg/L for one scenario (maximum value of 0.137 µg/L) at least. Since metabolite 1,2,4-triazole is considered as relevant according to the document SANCO/221/2000, mitigation measures were provided, considering two applications per year. In these conditions, PECgw for the relevant metabolite 1,2,4-triazole are below the value of 0.1 µg/L for all scenarios (maximum value of 0.091 µg/L). No unacceptable risk of groundwater contamination is expected when tebuconazole is applied no more than twice a year on grapevines.

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.

Use on cereals

SPe1: To protect groundwater do not apply this or any other product containing tebuconazole more than once a year on cereals.

Use on grapevines

SPe1: To protect groundwater do not apply this or any other product containing tebuconazole more than twice a year on grapevines.

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)[13] and considering the EU agreed endpoints of tebuconazole.
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 is acceptable following use of PRIAM TOP (HAG 300 04 F) 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 tebuconazole, its metabolites (1,2,4-triazole, HWG 1608-pentanoic-acid and HWG 1608-lactone) and data on the formulation HAG 300 04 F.
The TER values using worst-case PECsw values for HAG 300 04 F, tebuconazole and its metabolites (1,2,4-triazole, HWG 1608-pentanoic-acid and HWG 1608-lactone) exceed the relevant triggers, indicating that the risk to aquatic organisms is acceptable following use of PRIAM TOP (HAG 300 04 F) according to the proposed use patterns :

-winter cereals, 2 applications: 20 metres buffer zone combined with a 20-metre vegetative buffer strip
-spring cereals, 2 applications: 5 metres buffer zone combined with a 5-metre vegetative buffer strip
-grapevines, 3 applications: 5 metres buffer zone combined with a 5-metre vegetative buffer strip.

3.1.6.3 Effects on Bees and Other Arthropod Species

The risk assessment for bees is carried out according to the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002) and considering the EU agreed endpoints of tebuconazole and the formulation HAG 300 04 F.

All hazard quotients for PRIAM TOP (HAG 300 04 F) and tebuconazole are less than 50, indicating that the risk to bees is acceptable following use of PRIAM TOP (HAG 300 04 F) according to the proposed use pattern.

The risk assessment for non target arthropods is carried out according to the Guidance Document ESCORT 2 and considering the endpoints of the formulation HAG 300 04 F.

The in-field foliar HQ values are below the trigger value indicating that the risk to in-field non target arthropods following use of PRIAM TOP (HAG 300 04 F) according to the proposed use pattern is acceptable.

3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms

The risk assessment for earthworms is carried out according to the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002) and considering the EU agreed endpoints of tebuconazole, metabolites (1,2,4-triazole, HWG 1608-pentanoic-acid and HWG 1608-lactone) and the formulation HAG 300 04 F.

The acute and chronic TER values for HAG 300 04 F, tebuconazole and metabolites are greater than the triggers of 10 and 5 respectively, indicating that the risk to earthworms is acceptable following use of PRIAM TOP (HAG 300 04 F) according to the proposed use pattern.

Tebuconazole is not expected to pose an unacceptable risk to other soil non-target macro-organisms following the recommended use of HAG 300 04 F, and no soil non-target macro-organism studies are required.

3.1.6.5 Effects on organic matter breakdown

The risk of PRIAM TOP (HAG 300 04 F) to soil micro-organisms was evaluated by comparison of no-effect concentrations, derived from laboratory tests, with PECs.

The no effect levels exceed the relevant PECs values, indicating that the risk to soil micro-organisms is acceptable following use of PRIAM TOP (HAG 300 04 F) according to the proposed use pattern.

[13] European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA. EFSA Journal 2009; 7(12):1438. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu

3.1.6.6 Effects on Soil Non-target Micro-organisms

The risk of PRIAM TOP (HAG 300 04 F) to soil micro-organisms was evaluated by comparison of no-effect concentrations, derived from laboratory tests, with PEC_S.
The no effect levels exceed the relevant PEC_S values, indicating that the risk to soil micro-organisms is acceptable following use of PRIAM TOP (HAG 300 04 F) according to the proposed use pattern.

3.1.6.7 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 PRIAM TOP (HAG 300 04 F).
The application of PRIAM TOP (HAG 300 04 F) does not cause unacceptable effects on non-target terrestrial plants.

3.1.7 Efficacy

Considering the data submitted:

The efficacy of PRIAM TOP (HAG 300 04 F) is considered acceptable;
The selectivity of PRIAM TOP (HAG 300 04 F) is considered satisfactory;
The risk of negative impact (yield, quality, transformation processes, propagation, succeeding crops, adjacent crops) is considered negligible.
On cereals, the risk of resistance developing or appearing is considered high for SEPTTR, ERYSGR and PYRNGR. To reduce the selection pressure on the target pathogen and considering that it is a treatment in situations of disease complex (including SEPTTR, ERYSGR and PYRNGR), the number of applications per season and per crop of PRIAM TOP (HAG 300 04 F) must be restricted to one per year and per crop, for all uses on wheat and triticale.

On grapevine, the risk of resistance developing or appearing is considered moderate for UNCINE. The number of applications per season and per crop of PRIAM TOP (HAG 300 04 F) must be restricted to two (non-consecutive applications) per year and per crop, for all uses on grapevine (because of complex of diseases). Given the context of resistance to chemical groups in French vineyards**, the applicant must provide specific efficacy trials in situations where the level of resistance of powdery mildew to tebuconazole was characterised and corresponds to the monitoring data, to determine whether the efficacy of the product used solo is maintained at a sufficient level in these conditions.**

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

All authorisation holders of triazole-containing products must put in place dedicated monitoring for the relevant metabolite 1,2,4- triazole in groundwater, before summer 2017.

3.4.2 Post-authorisation data requirements

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

- An analytical method and its ILV to allow the determination of tebuconazole, hydroxyl-tebuconazole and their conjugates in foodstuffs of animal origin (muscle, fat, liver/kidney, eggs and milk).
- A certificate of supply for the radiolabelled internal standard used in the analytical method for the determination of tebuconazole in soil
- A confirmatory method for the determination of tebuconazole in soil, as the original method is not highly specific.
- Four comparative residues trials using EW and SC formulations, conducted in northern Europe according to the proposed GAP, to demonstrate the equivalence of these two formulation types.
- Specific efficacy trials in situations where the level of resistance of powdery mildew to tebuconazole has been characterised and corresponding to the monitoring and control data, to determine whether the efficacy of PRIAM TOP (HAG 300 04 F) is maintained at a sufficient level in these conditions.

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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anses
agence nationale de sécurité sanitaire alimentation, environnement, travail

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

PRIAM TOP

de la société *HELM AG*

enregistrée sous le *n°2012-1163*

Vu l'avis de l'ANSES du 22 mai 2015,

Vu la décision du directeur général de l'Anses du 6 août 2015,

Vu le recours gracieux formé par la société HELM AG,

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

La présente décision abroge et remplace la décision du 6 août 2015 et 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.

PRIAM TOP
n°2150253

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Informations générales sur le produit	
Nom(s) du produit	PRIAM TOP
Type de produit	Produit de référence
Titulaire	HELM AG Crop Protection_Regulatory Affairs Europe/USA Nordkanalstrasse 28, 20097 Hamburg, Allemagne
Formulation	Emulsion de type aqueux (EW)
Contenant	250,0 g/L - tébuconazole
Numéro d'intrant	987-2012.01
Numéro d'AMM	2150253
Fonction(s)	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 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 26 AOUT 2016

Françoise WEBER
Directrice générale adjointe des produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

PRIAM TOP
n°2150253

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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 dans les emballages :	
Emballage	**Contenance**
Bouteille Polyéthylène haute densité	1 L
Bidon Polyéthylène haute densité	5 L 10L
Fût Polyéthylène haute densité	120 L 220 L
Cuve Polyéthylène haute densité	820 L

Classification du produit		
La classification retenue est la suivante :		
Catégorie de danger		**Mention de danger**
Toxicité pour la reproduction, catégorie 2		H361d : Susceptible de nuire au fœtus
Lésions oculaires graves/irritation oculaire, catégorie 1		H318 : Provoque des lésions oculaires graves
Dangers pour le milieu aquatique - Danger chronique, catégorie 2		H411 : Toxique pour les organismes aquatiques, entraîne des effets à long terme
Le titulaire de l'autorisation est responsable de la conformité de la fiche de données de sécurité avec la classification retenue ci-dessus, et de ses éventuelles évolutions.		

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Liste des usages autorisés								
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**
12703204 Vigne*Trt Part.Aer.*Oïdium(s)	0,4 L/ha	2 /an	-	14 jours	5	-	-	Sans objet
- Uniquement sur raisin de cuve - Non autorisé sur raisin de table : des données disponibles par ailleurs mettent en évidence un risque aigu inacceptable pour certains consommateurs								
15103231 Avoine*Trt Part.Aer.*Rouille couronnée	1 L/ha	1 /an	-	35 jours	20	-	-	Sans objet
15103202 Blé*Trt Part.Aer.*Fusarioses	1 L/ha	1 /an	-	35 jours	20	-	-	Sans objet
15103214 Blé*Trt Part.Aer.*Rouille(s)	1 L/ha	1 /an	-	35 jours	20	-	-	Sans objet
15103229 Orge*Trt Part.Aer.*Rhynchosporiose	1 L/ha	1 /an	-	35 jours	20	-	-	Sans objet

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Conditions d'emploi du produit

Délai de rentrée

24 heures en cohérence avec l'arrêté du 12 septembre 2006.

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

Dans le cadre de pulvérisation à l'aide de pulvérisateurs portés ou traînés à rampe ou pneumatiques ou des atomiseurs

- Pendant le mélange/chargement

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

- Pendant l'application - Pulvérisation vers le bas (céréales)

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

- Pendant l'application - Pulvérisation vers le haut (vigne)

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 ;

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- 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 protection de catégorie III type 4 avec capuche (non revendiquée par le notifiant) ou Combinaison de travail (revendication notifiant) ;
- Gants en nitrile certifiés EN 374-2 à usage unique pendant l'application et dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation.

- Pendant le nettoyage du matériel de pulvérisation

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

Pour le travailleur, porter

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

Respect des limites maximales de résidus (LMR)

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

- SPe 1 : Pour protéger les eaux souterraines, ne pas appliquer ce produit ou tout autre produit à base de tébuconazole plus de deux fois tous les ans sur vigne.

- SPe 1 : Pour protéger les eaux souterraines, ne pas appliquer ce produit ou tout autre produit à base de tébuconazole plus d'une fois tous les ans sur céréales d'hiver et de printemps.

- 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.

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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 céréales de printemps et vigne.

- 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 pour les usages sur céréales d'hiver.

Exigences complémentaires post-autorisation

Le titulaire de l'autorisation doit mettre en place un programme de suivi et transmettre à l'Anses un bilan de ce suivi selon les demandes citées ci-dessous.
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)
Une méthode et sa validation inter-laboratoires pour la détermination du tébuconazole, de l'hydroxy-tébuconazole et leurs conjugués dans les denrées d'origine animale (foie, rein, lait, œufs, muscle et graisse) ; Une attestation de fourniture sur demande du standard interne utilisé dans la méthode de détermination du tébuconazole dans le sol ainsi qu'une méthode de confirmation pour cette méthode non hautement spécifique.	24	-
Des essais d'efficacité spécifiques dans des situations où le niveau de résistance de l'oïdium au tébuconazole a été caractérisé et correspond aux données de suivi et de contrôle afin de déterminer si l'efficacité de la préparation est maintenue à un niveau suffisant dans ces conditions.	24	-
4 essais de comparaison des formulations EW/SC conduits dans la zone Nord de l'Europe et à la BPA revendiquée sur vigne	24	-
Afin de s'assurer du respect de la valeur seuil réglementaire du 1,2,4-triazole dans les eaux souterraines, il conviendra de mettre en place, par l'ensemble des pétitionnaires commercialisant des produits à base de triazoles, une surveillance dédiée de ce métabolite.	24	-

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

PRIAM® TOP

SYSTEMIC FUNGICIDE

Composition
250 g/L Tebuconazole

Formulation
EW – emulsion in water

Net Content: 1L - 820L

Batch n°.....

Registration Owner :
HELM AG
Nordkanalstrasse 28
D-20097 Hamburg (Allemagne)
Tel.: 0049 40 2375 0

Distribué par ----------

CAREFULLY READ THE LABEL BEFORE USE

Mode of action
PRIAM® TOP is an organic triazole biocide that is effective against wood decay fungi. Tebuconazole is a systemic fungicide with preventive, curative and eradicant action against a wide range of pathogens on cereals, oilseed rape and vine. Tebuconazole belongs to the group of fungicides known as sterol demethylation inhibitors. This active ingredient acts as an inhibitor of sterol biosynthesis at the 14 α-demethylase step.

Registration n°: --------

USES TABLE

AUTHORIZED USES	RATE OF USE	NUMBER OF APPLICATIONS	PRE-HARVEST INTERVAL
Oat - Crown rust (*Puccinia coronata*)	1.0 L / ha	2	28 days
Barley – Leaf blotch (*Rhynchosoporium secalis*)	1.0 L / ha	2	28 days
Wheat – Fusariosis (*Fusarium sp.*)	1.0 L / ha	2	28 days
Wheat – Brown Rust (*Puccinia recondita*)	1.0 L / ha	2	28 days
Wheat – Yellow Rust (*Puccinia striiformis*)	1.0 L / ha	2	28 days
Triticale – Brown Rust (*Puccinia recondita*)	1.0 L / ha	2	28 days
Vine – Powdery mildew (*Uncinula necator*)	0.4 L / ha	3	14 days

For use in cereals respect a buffer zone of 10 m in combination with 10 m run-off reduction
For use in grapevine respect a 10 m buffer zone .

Use this product only in accordance with its labeling and in line with Good Agricultural Practices. PRIAM® TOP used in accordance with its labeling has no effect on vinification, transformation processes and wine organoleptic quality.

Maximum Residue Limits (MRL) available for consultation on the web site : http://e-phy.agriculture.gouv.fr

PREPARATION
Thoroughly shake the pack before use. Add the required quantity of PRIAM® TOP to the half-filled spray tank with the agitation system in operation and then fill to the required level. Continue agitation at all times during spraying and stoppages until the tank is completely empty. Spray immediately after mixing.

AUTHORIZED USES
Oat - Crown Rust (*Puccinia coronata*)
Rate: 1.0 L product/ha (i.e. 250 g ai/ha)
Application volume: 150 – 300 l/ha
Number of applications: 2 applications: 1st application at infestation beginning or warning. Not before BBCH 30 (more than 9 leaves unfolded). 2nd application when re-infestation occurred, 2-4 weeks later. Not after BBCH 79.

Barley – Leaf blotch (*Rhynchosoporium secalis*)
Rate: 1.0 L product/ha (i.e. 250 g ai/ha)

Application volume: 150 – 300 l/ha
Number of applications: 2 applications : 1st application at infestation beginning or warning. Not before BBCH 30 (more than 9 leaves unfolded). 2^{ns} application when re-infestation occurred, 2-4 weeks later. Not after BBCH 79.

Wheat – Fusariosis (*Fusarium sp.*)
Rate: 1.0 L product/ha (i.e. 250 g ai/ha)
Application volume: 150 – 300 l/ha
Number of applications: 2 applications at BBCH 61-65 (flowering) at warning.

Wheat – Brown Rust (*Puccinia recondita*)
Rate: 1.0 L product/ha (i.e. 250 g ai/ha)
Application volume: 150 – 300 l/ha
Number of applications: 2 applications: 1st application at infestation beginning or warning. Not before BBCH 30 (more than 9 leaves unfolded). 2^{ns} application when re-infestation occurred, 2-4 weeks later. Not after BBCH 79.

Wheat – Yellow Rust (*Puccinia striiformis*)
Rate: 1.0 L product/ha (i.e. 250 g ai/ha)
Application volume: 150 – 300 l/ha
Number of applications: 2 applications: 1st application at infestation beginning or warning. Not before BBCH 30 (more than 9 leaves unfolded). 2^{ns} application when re-infestation occurred, 2-4 weeks later. Not after BBCH 79.

Triticale – Brown Rust (*Puccinia recondita*)
Dose: 1.0 L product/ha (i.e. 250 g ai/ha)
Application volume: 150 – 300 l/ha
Number of applications: 2 applications: 1st application at infestation beginning or warning. Not before BBCH 30 (more than 9 leaves unfolded). 2^{ns} application when re-infestation occurred, 2-4 weeks later. Not after BBCH 79.

Vine – Powdery mildew (*Uncinula necator*)
Rate: 0.4 L product/ha (i.e. 100 g ai/ha)
Application volume: 300 – 1000 l/ha
Number of applications: 3 applications at BBCH 55-79, at infestation beginning or warning

In order to achieve a better protection it is possible to associate PRIAM® TOP with a contact product in case of high disease pressure

APPLICATION
Use sufficient water to ensure thorough coverage of vines. Increase spray volume as vine growth increases. Considering the substance active distribution, one application on each side of each row is recommended.

CONDITIONS
On vine, do not apply under high temperatures. Tebuconazole characteristics in vine confer a high resistance to washing. From 1 hour after application, rain has no effect anymore on PRIAM® TOP.

TREATMENT PROGRAM
PRIAM® TOP achieves a high level of efficacy against powdery mildew on leaves and grapevine. Apply in a preventive spray schedule. Make the first application before bloom and continue applications using spray intervals of up to 21 days in low to moderate pressure. Use a 14 day spray interval when disease pressure is severe. PRIAM® TOP is a sterol demethylation inhibator (DMI) fungicide. It may be applied in a tank-mix or alternated (every other spray application) with a non-DMI fungicide as a resistance management strategy. Tank-mixing PRIAM® TOP with other DMI fungicides is not recommended. The following practices are essential to maintain effectiveness of PRIAM® TOP:

- Apply fungicides at label rate
- the total number of tebuconazole applications should not exceed that indicated on the label. The exclusive repeated use of tebuconazole based fungicides must be avoided.
- Apply fungicides during good conditions for spraying

STORAGE
Store in original container, keep container tightly closed in a dry and well-ventilated place. Store in a place authorized persons only and keep away from food, drink and animal feedingstuffs.

COMPATIBILITY
When used in mixture with another compound, the longer pre-harvest interval must be respected and the safety instructions for the more toxic product must be followed. In case of intoxication inform the physician of the nature of the mixture.

RESPONSABILITY
Who use this product is responsible for any damage derivating from using it in a manner that is inconsistent with the label. The respect of the recommendations above is essential to ensure the efficacy and to avoid damage to crops people and animals.

CLASSIFICATION
Toxicologie Xn – Harmful

Environment: N – Dangerous for the environment

RISK PHRASES
R 41 – Risk of serious damage to eyes
R 63 – Possible risk of harm to the unborn child
R 51/53 – Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

SAFETY PHRASES
S 26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
S 35 – This material and its container must be disposed of in a safe way
S 36/37/39 – Wear suitable protective clothing, gloves and eye/face protection
S 57 – Use appropriate container to avoid environmental contamination
S 61 - Avoid release to the environment. Refer to special instructions/ Safety data sheets.

To avoid risks to man and the environment, comply with the instructions for use

MEDICAL INFORMATIONS
In case of intoxication call a physician immediately.
Call a poison control centre immediately

Appendix 3 – Letter(s) of Access

TDMG
Triazole Derivate Metabolite Group

5th September 2013

Anses - DPr - UGAmm
253, av. du Général Leclerc
94700 Maisons Alfort
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 A and I B, 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:

Helm AG
Nordkanalstrasse 28
D-20097 Hamburg
Germany

for their plant protection product:

PRIAM TOP
containing 250 g/L Tebuconazole
in an EW formulation

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

1. The right of referral is solely granted to Helm AG 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.

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

page 1

3. Specifically excluded from the right of referral are the use of the data in the context of the Biocides Directive 98/8/EC and Commission Regulation 1896/2000.
4. The right of referral gives access to the file of data on **1,2,4-triazole** as environmental metabolite of parent triazole active ingredients.
5. Helm AG 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 authorities.
6. This authorisation is valid only for such duration as there is a valid agreement between Helm AG and TDMG.

On behalf of the TDMG

Yours sincerely,

September 5, 2013

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