

REGISTRATION REPORT

Part A

Risk Management

Product code: DAENERYS

Active substance:
tebuconazole, 430 g/L

COUNTRY: FRANCE

Zonal and Interzonal

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: Rotam Agrochemical Europe Ltd.

Date: 15/09/2021

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PART A – Risk Management

The company Rotam Agrochemical Europe Ltd. has requested the marketing authorisation in France for the product DAENERYS, containing 430 g/L tebuconazole, for use as a fungicide.

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

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

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 Rotam Agrochemical Europe Ltd.'s application to market DAENERYS in France as a fungicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for outdoor uses and as an interzonal Rapporteur Member State (izRMS) for indoor uses 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 and European Union.

1.2 Active substance approval

Tebuconazole

COMMISSION IMPLEMENTING REGULATION (EU) No 921/2014 of 25 August 2014 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance tebuconazole.

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

PART A

Only uses as fungicide may be authorised.

PART B

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

- the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment;
- the dietary exposure of consumers to the tebuconazole (triazole) metabolites;
- the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil or climatic conditions, in particular as regards the occurrence in groundwater of the metabolite 1,2,4-triazole;
- the protection of granivorous birds and mammals and herbivorous mammals and must ensure that the conditions

of authorisation include, where appropriate, risk mitigation measures;

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

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

An EFSA conclusion is available (EFSA Journal 2014; 12(1):3485).

A Review Report is available (SANCO/171/08 - rev 2, 11 July 2014).

1.3 Regulatory approach

The present application (2015-2229) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) in the context of the zonal procedure for all Member States of the Southern zone for outdoor uses and of European Union for indoor uses [under protection], taking into account the worst-case uses (“risk envelope approach”)¹ – the highest application rates over the Southern Zone for the outdoor uses and the European Union for indoor uses. When risk mitigation measures were necessary, they are adapted to the situation in France.

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

The French Order of 4 May 2017² provides that:

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

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

The current document (RR) based on Anses’s assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009³, implementing regulations, and French regulations.

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

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011⁴, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014⁵ provides that:

- an authorisation granted for a “reference” crop applies also for “linked” crops, unless formally stated in the Decision

¹ SANCO document “risk envelope approach”, European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the “risk envelope approach”; SANCO/11244/2011 rev. 5

² Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l’utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l’article L. 253-1 du code rural et de la pêche maritime, modifié par l’arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l’utilisation de produits phytopharmaceutiques
<https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGR1632554A/jo/texte> ;
<https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

³ 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

⁴ 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

⁵ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGR1407093A/jo>

- 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 extrapolation⁶ is to supply “minor” crops with registered plant protection products.

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

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

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of DAENERYS, 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.

⁶ SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	DAENERYS.
Authorisation number	N/A : no marketing authorisation granted
Function	Fungicide.
Applicant	Rotam Agrochemical Europe Ltd.
Composition	430 g/L tebuconazole.
Formulation type (code)	Suspension concentrate (SC).
Packaging	N/A : no marketing authorisation granted

2.2 Classification and labelling

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

Physical hazards	-	
Health hazards	Reproductive toxicity, category 2.	
Environmental hazards	Hazardous to the aquatic environment, chronic, hazard category 1.	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H361d	Suspected of damaging the unborn child.
	H410	Very toxic to aquatic life with long-lasting effects.
Precautionary statements –	<i>For the P phrases, refer to the extant legislation</i>	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	EUH208	Contains CMIT/MIT. May produce an allergic reaction.

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

2.2.1 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:

N/A : no marketing authorisation granted

2.2.2 Other phrases linked to the preparation

N/A : no marketing authorisation granted

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 (outdoor uses) and izRMS (indoor uses). 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.

PPP (product name/code):	DAENERYS	Formulation type:	SC ^(a, b)
Active substance 1:	tebuconazole	Conc. of as 1:	430 g/L ^(c)
Safener:	-	Conc. of safener:	- ^(c)
Synergist:	-	Conc. of synergist:	- ^(c)
Applicant:	Rotam Agrochemical Europe Ltd	Professional use:	☒
Zone(s):	southern/interzonal ^(d)	Non-professional use:	☐
Verified by MS:	yes		
Field of use:	fungicide		

GAP rev. 1, date: 2021-09

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, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses)													
1	FR	Globe artichoke (CYUSC)	F	Leveillula taurica (LEVETA) Powdery mildew	Foliar spray	BBCH 40 Onwards (beginning of attack, first symptoms visible)	a) 1 b) 3	7-10	a) 0.3 b) 0.9	a) 129 b) 387	800 - 1000	7	Not acceptable (MRL, worker exposure, groundwater contamination and aquatic organisms)

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, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
2	FR	Asparagus (ASPOF)	F	<i>Puccinia asparagi</i> (PUCCAS) Asparagus rust <i>Stemphylium vesicarium</i> (PLEOAL) Purple spot	Foliar spray	BBCH 40 Onwards (begin of attack, first symptoms visible)	a) 1 b) 3	7-10	a) 0.3 b) 0.9	a) 129 b) 387	800 - 1000	n.a.	Not acceptable (groundwater contamination and aquatic organisms)
3	FR	Olive (OLVEU)	F	<i>Cycloconium oleaginum</i> (CYCLOL) Peacock spot	Foliar spray	BBCH 00-50 Before flowering (up to mid- March)	a) 1 b) 1	-	a) 0.437 b) 0.437	a) 188 b) 188	500 - 1250	n.a.	Not acceptable (worker and operator exposure, groundwater contamination and aquatic organisms)
4	FR	Rice, paddy (ORYSP)	F	<i>Pyricularia oryzae</i> (PYRIOR) Rice blast <i>Cochliobolus miyabeanus</i> (<i>Helminthosporium</i> <i>oryzae</i>) (COCHMI) Brown spot	Foliar spray	BBCH 30-69 June-Mid September	a) 1 b) 3	14	a) 0.6 b) 1.8	a) 258 b) 774	200 - 400	n.a.	Not acceptable (MRL, birds, mammals, aquatic organisms)
5	FR	Stone fruit (Apricots, Peaches & Plums)	F	<i>Monilia laxa</i> (MONILA)	Foliar spray	BBCH 57-60 (Pre-blossom)	a) 1 b) 1	-	a) 0.523 b) 0.523	a) 225 b) 225	1000 - 1500	14	Not acceptable (operator and worker exposure, MRL, groundwater contamination and aquatic organisms)

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)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
6	FR	Stone fruit (Apricots, Peaches & Plums)	F	<i>Monilia fructigena</i> (MONIFG)	Foliar spray	BBCH 81-87 (Pre-harvest)	a) 1 b) 1	-	a) 0.523 b) 0.523	a) 225 b) 225	1000 - 1500	14	Not acceptable (operator and worker exposure, MRL, groundwater contamination and aquatic organisms)
7	FR	Wheat (TRZAX)	F	<i>Erysiphe graminis</i> (ERYSGR) Powdery mildew <i>Puccinia recondita</i> (PUCCRT) Brown rust <i>Puccinia striiformis</i> (PUCCSI) Yellow rust <i>Septoria tritici</i> (SEPTTR) Septoria	Foliar spray	BBCH 30-61 (spring-summer)	a) 1 b) 1	-	a) 0.6 b) 0.6	a) 258 b) 258	200 - 400	35	Not acceptable (groundwater contamination and aquatic organisms)
8	FR	Wheat (TRZAX)	F	<i>Fusarium</i> spp. (FUSASP) Fusarium ear blight	Foliar spray	BBCH 61-69 (spring-summer)	a) 1 b) 1	-	a) 0.6 b) 0.6	a) 258 b) 258	200 - 400	35	Not acceptable (groundwater contamination and aquatic organisms)

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)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
9	FR	Barley (HORVX)	F	<i>Erysiphe graminis</i> (ERYSGR) Powdery mildew <i>Rhynchosporium secalis</i> (RHYNSE) Leaf blotch <i>Puccinia hordei</i> (PUCCHD) brown rust <i>Puccinia striiformis</i> (PUCST) Yellow rust <i>Helminthosporium teres</i> (PYRNTE) Net blotch	Foliar spray	BBCH 30-61 (spring-summer)	a) 1 b) 1	-	a) 0.6 b) 0.6	a) 258 b) 258	200 - 400	35	Not acceptable (groundwater contamination and aquatic organisms)
10	FR	Grapevine (VITVI)	F	<i>Guignardia bidwellii</i> (GUIGBI) black rot	Foliar spray	BBCH 13-77	a) 1 b) 2	14	a) 0.2 b) 0.4	a) 86 b) 172	200 - 1000	14	Not acceptable for table grapes (worker and consumer exposure, groundwater contamination and aquatic organisms)
													Not acceptable for wine grapes (worker exposure, MRL, groundwater contamination and aquatic organisms)
11	FR	Grapevine (VITVI)	F	<i>Pseudopeziza tracheiphila</i> (PSPZTR) rot brenner <i>Uncinula necator</i> (UNCINE)	Foliar spray	BBCH 13-77	a) 1 b) 2	14	a) 0.25 b) 0.50	a) 108 b) 216	200 - 1000	14	Not acceptable for table grapes (worker and consumer exposure, groundwater contamination and aquatic organisms)

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, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
				Powdery mildew									Not acceptable for wine grapes (worker exposure, MRL, groundwater contamination and aquatic organisms)
Interzonal uses (indoor uses)													
1	FR	Cucumber (CUMSA), Courgette/Zucchini (CUUPG)	G	<i>Erysiphe cichoracearum</i> (ERYSCI) <i>Sphaerotheca fuliginea</i> (PODOXA) Powdery mildew	Foliar spray	BBCH 13-79 Begin of attack, first symptoms visible	a) 1 b) 4	7-10	a) 0.3 b) 1.2	a) 129 b) 516	500 - 1000	3	Not acceptable (worker exposure) Gherkin and other cucurbits with edible skin also unacceptable for the MRL
2	FR	Squash (CUUPE)	G	<i>Erysiphe cichoracearum</i> (ERYSCI) <i>Sphaerotheca fuliginea</i> (PODOXA) Powdery mildew	Foliar spray	BBCH 13-79 Begin of attack, first symptoms visible	a) 1 b) 4	7-10	a) 0.3 b) 1.2	a) 129 b) 516	500 - 1000	3	Not acceptable (worker exposure, MRL)
3	FR	Melon (CUMME), Melon, water (CITLA), Pumpkin (CUUMA),	G	<i>Erysiphe cichoracearum</i> (ERYSCI) <i>Sphaerotheca fuliginea</i> (PODOXA) Powdery mildew	Foliar spray	BBCH 13-79 Begin of attack, first symptoms visible	a) 1 b) 4	7-10	a) 0.3 b) 1.2	a) 129 b) 516	500 - 1000	7 3 (melon)	Not acceptable (operator exposure)
4	FR	Sweet pepper (CPSAN), Tomato (LYPES)	G	<i>Leveillula taurica</i> (LEVETA) Powdery mildew	Foliar spray	BBCH 13-79 Begin of attack, first symptoms visible	a) 1 b) 3 (tomato) 4 (pepper)	7-10	a) 0.3 b) 0.9 - 1.2	a) 129 b) 387 - 516	500 - 1000	3	Not acceptable (worker exposure MRL, efficacy)

Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/L	(f)	No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
Remarks columns:	1	Numeration necessary to allow references	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
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	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)	9	Minimum interval (in days) between applications of the same product
	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	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	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.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	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.	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

DAENERYS is a suspension concentrate (SC). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a white liquid, without characteristic odour. It is not explosive and has no oxidising properties. The product has no flash point and has a self-ignition temperature of > 500 °C. In a 1 % aqueous solution, it has a pH value of 7.7 at 20.2 °C. There is no effect of low and high temperatures on the stability of the formulation, since after seven days at 0 °C and 14 days at 54 °C, neither the active substance content nor the technical properties were changed. The stability data indicate a shelf life of at least two years at ambient temperature when stored in F-HDPE and HDPE. The technical characteristics are acceptable for an SC formulation.

The phrase “The container must be rinsed at least twice before disposal” should be added to the label.

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

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methods for the determination of the active substance in the formulation are available and validated. As the active substance tebuconazole does not contain any relevant impurity, no analytical method is required.

3.1.2.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report and this dossier and validated for the determination of residues of tebuconazole in plants (high-water-, high-oil- and dry-content-matrices), soil, water (surface and drinking) and air.

Analytical methods for the determination of residues of tebuconazole in foodstuffs of animal origin are not necessary.

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

Active substance: tebuconazole			
ADI	0.03 mg kg bw/d		EU (01/09/2009)
ARfD	0.03 mg/kg bw		
AOEL	0.03 mg/kg bw/d		
Dermal absorption	Based on an <i>in vitro</i> human study performed on the formulation or on a similar formulation (using a triple-pack approach; <i>pro rata</i> correction) or default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (tested) 443 g/L	Diluted formulation (tested) 2.4 g/L
	<i>In vitro</i> (human) %		
		Concentrate (used in formulation) 442.7 g/L	Spray dilution (used in formulation) 2.43 g/L
	Dermal absorption endpoints %	2	12

3.1.3.1 Acute Toxicity

DAENERYS, containing 430 g/L tebuconazole, has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitiser.

The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.2.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G ⁷	Equipment	Application rate L product/ha (g a.s./ha)	Spray dilution (L/ha)	Model
Cucumber , Squash , Zucchini, Melon, Pumpkin, watermelon	G	Lance	0.3 (129)	500	BBA
Pepper , Tomato					
Globe artichoke, Asparagus	F	Tractor-mounted/trailed boom sprayer, hydraulic nozzles – 20 ha	0.3 (129)	800	BBA
Rice, paddy; wheat, barley	F	Tractor-mounted/trailed boom sprayer, hydraulic nozzles – 20 ha	0.6 (258)	200	BBA
Olive	F	Hand-held sprayer, hydraulic nozzles Outdoor, high-level target	0.437 (188)	500	BBA
Olive	F	Tractor-mounted/trailed broadcast air-assisted sprayer – 8 ha	0.437 (188)	500	BBA
Stone fruit (Apricots, Peaches & Plums)	F	Tractor-mounted/trailed broadcast air-assisted sprayer – 8 ha	0.523 (225)	1000	BBA

⁷ Open field or glasshouse

Crop	F/G ⁷	Equipment	Application rate L product/ha (g a.s./ha)	Spray dilution (L/ha)	Model
Grapevine	F	Tractor-mounted/trailed broadcast air-assisted sprayer – 8 ha	0.251 (108)	200	BBA

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

Crop	Equipment	PPE and/or working coverall	% AOEL tebuconazole
Cucumber, Squash, Zucchini, Melon, Pumpkin, watermelon	Hand-held sprayer (15 L tank), hydraulic nozzles, Outdoor, low-level target	Working coverall and gloves during mixing/loading and application	348
Pepper , Tomato	Hand-held sprayer, hydraulic nozzles Outdoor, high-level target	Working coverall and gloves during mixing/loading and application	40.5
Globe artichoke, Asparagus	Tractor-mounted/trailed boom sprayer, hydraulic nozzles – 20 ha	Working coverall and gloves during mixing/loading and application	24.6
Rice, paddy	Tractor-mounted/trailed boom sprayer, hydraulic nozzles – 20 ha	Working coverall and gloves during mixing/loading and application	30.1
Olive	Hand-held sprayer, hydraulic nozzles Outdoor, high-level target	Working coverall and gloves during mixing/loading and application	62.9
Olive	Tractor-mounted/trailed broadcast air -assisted sprayer – 8 ha	Working coverall and gloves during mixing/loading and application	121.4
Stone fruit (Apricots, Peaches & Plums)	Tractor-mounted/trailed broadcast air-assisted sprayer – 8 ha	Working coverall and gloves during mixing/loading and application	145.3
Grapevine	Tractor-mounted/trailed broadcast air-assisted sprayer – 8 ha	Working coverall and gloves during mixing/loading and application	68

According to the model calculations, it may be concluded that the risk for the operator using DAENERYS is acceptable with a working coverall (90 % protection factor) and gloves during mixing/loading and application for all crops, **except for stone fruit and olives in the field plus cucumber, squash, zucchini, melon and pumpkin in greenhouses.**

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

3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to be up to 78.9 % of the AOEL of tebuconazole.

It may be concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to DAENERYS.

3.1.3.4 Worker Exposure

Estimation of worker exposure was calculated according to EUROPOEM II. Exposure is less than 100 % of the AOEL of tebuconazole for asparagus and cereals in the field and for low-level crops in greenhouses. **Exposure is estimated to be 129 %, 188 %, 162 %, 225 % and 131 % of the AOEL of tebuconazole for globe artichoke, olive, grapevine, stone fruit trees and high-level crops in greenhouses, respectively, when PPE are worn.**

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

3.1.3.5 Resident Exposure

Residential exposure was assessed according to Martin *et al.* Exposure is estimated to be up to 24.79 % of the AOEL of tebuconazole. It may be concluded that there is no unacceptable risk to the resident exposed to DAENERYS.

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

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

3.1.4 Residues and Consumer Exposure

Outdoor uses:

The data available are considered sufficient for risk assessment for table olive, olive for oil production, apricot, peach, wheat and barley. No exceedance of the current MRL for tebuconazole as laid down in Reg. (EU) No 396/2005 is expected for these crops.

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

As far as consumer health protection is concerned, France as zRMS agrees with the authorisation of the uses mentioned above.

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

Moreover, considering triazole-derivative metabolites (TDMs: triazole acetic acid (TAA), triazole alanine (TA), 1,2,4-triazole (1,2,4-T) and triazole lactic acid (TLA)), the zRMS could not propose a dietary risk assessment similar to the ones proposed by EFSA in the “Peer review of the Pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted” (EFSA Journal 2018; 16(7):5376), because data gaps have been identified by EFSA and the zRMS. Nevertheless, France as zRMS is of the opinion that the chronic and short-term intakes of TDMs residues resulting from the uses proposed in the framework of this application are unlikely to present a public health concern.

Data required in post-authorisation:

- Additional residue trials on asparagus (4 NEU and 4 SEU), olive (8 SEU), rice (8 SEU), wheat (8 SEU and 4 NEU), barley (8 SEU and 4 NEU), globe artichoke (4 NEU) and grape vine (8 NEU) supporting the intended

GAP, with analysis of 1,2,4-T, TA, TAA and TLA have to be provided in post registration.

- Additional southern residue trials on peach (4) supporting the intended GAP, with analysis of TA, TAA and TLA have to be provided in post registration.

Data gaps relevant for the risk assessment to cover the complete group of triazole-derivate metabolites:

- 1) Storage stability data on 1,2,4-T, TA and TAA in high-acid-content commodities; on 1,2,4-T in high-protein-content commodities and on TLA in cereal straw, and covering the maximum storage time interval of the residue samples of the residue trials in primary and rotational crops.
- 2) Poultry and ruminant feeding studies conducted with TLA or, alternatively, metabolism studies performed in accordance with the current recommendations as a surrogate to these feeding studies, to determine the magnitude of TLA residues in products of animal origin.

Summary of the evaluation

Summary for tebuconazole

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EU) 2017/626	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	Globe artichoke	Yes	Yes for SEU No for FR	Yes	Yes	No	No	-	-
2	Asparagus	Yes	Not necessary	Yes	NR	Yes		-	-
3	Table olive	Yes	Yes	Yes	Yes	Yes		No	
3	Olive for oil production	Yes	Yes	Yes	Yes	Yes		No	-
4	Rice (paddy)	Yes	Yes	Yes	Yes	No		-	-
5, 6	Wheat	Yes	Yes	Yes	Yes	Yes		No	
7	Barley	Yes	Yes	Yes	Yes	Yes		No	
8, 9	Table grape	Yes	Yes	Yes	Yes	Yes		Yes**	
8, 9	Wine grape	Yes	Yes for SEU No for FR	Yes	Yes	Yes		No	
10, 11	Apricot, Peach	Yes	Yes	Yes	Yes	Yes		No	
10, 11	Plum	Yes	No	Yes	Yes	Yes		-	-

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

NR: not relevant

** The use of tebuconazole on table grape is not supported anymore by the main applicant since an acute risk for the consumer was identified.

The effects of processing on the nature of tebuconazole residues have been investigated. Data on effects of processing on the amount of residue have been submitted.

The processing factor calculated for grapes were considered for risk assessment.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops. 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 be performed for TDMs in rotational crops as soon as the confirmatory data requested for triazole compounds in the framework of Directive 91/414/EEC have been evaluated and a general methodology on the risk assessment of triazole compounds and their TDMs 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.

The triazole derivative metabolites (TDM) triazole acetic acid (TAA), triazole alanine (TA), 1,2,4-triazole (1,2,4-T) and triazole lactic acid (TLA), are common metabolites of the triazole-containing fungicides. Tebuconazole belongs to this group of fungicides.

Considering these TDMs, France as zRMS could not proposed a dietary risk assessment similar to the one proposed by EFSA in the “Peer review of the Pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted” (EFSA Journal 2018; 16(7):5376) because data gaps have been identified. Nevertheless, the zRMS is of the opinion that the chronic and short-term in-takes of TDMs residues resulting from the use proposed in the framework of this application are unlikely to present a public health concern.

Post registration data (residue trials) are required to complete the data set assessed (i.e., confirmatory data).

Summary for DAENERYS

Crop	PHI for DAENERYS requested by applicant	PHI/ Withholding period* sufficiently supported for	PHI for DAENERYS proposed by zRMS	zRMS Comments (if different PHI proposed)
		Tebuconazole		
Globe artichoke	7 days	-	-	Use not supported (MRL exceedance).
Asparagus	F*	Yes	F*	-
Table olive	F*	Yes	F*	-
Olive for oil production	F*	Yes	F*	
Rice (paddy)	F*	-	-	Use not supported (MRL exceedance).
Wheat	35 days	Yes	35 days	-
Barley	35 days	Yes	35 days	-
Table grape	14 days	Yes	14 days	Acute risk cannot be excluded
Wine grape	14 days	Yes	14 days (SEU except FR)	Use not supported in FR (not enough trials).
Apricot, Peach	14 days	Yes	14 days	-
Plum	14 days	-		Use not supported (not enough trials).

NR: not relevant

* Purpose of withholding period to be specified

** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Waiting periods before planting succeeding crops: Not relevant.

Indoor uses:

The data available are considered sufficient for risk assessment for cucumber, courgette (zucchini and squash), tomato and cucurbits inedible peel. No exceedance of the current MRL for tebuconazole as laid down in Reg. No (EU) 396/2005 is expected for these crops.

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

As far as consumer health protection is concerned, France as zRMS agrees with the authorisation of the uses mentioned above.

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

Moreover, considering triazole derivative metabolite (TDMs: triazole acetic acid (TAA), triazole alanine (TA), 1,2,4-triazole (1,2,4-T) and triazole lactic acid (TLA)), the zRMS could not propose a dietary risk assessment similar to the ones proposed by EFSA in the “Peer review of the Pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted” (EFSA Journal 2018; 16(7):5376) because data gaps have been identified. Nevertheless, the zRMS is of the opinion that the chronic and short-term intakes of TDMs residues resulting from the use proposed in the framework of this application are unlikely to present a public health concern.

Data required post-authorisation (indoor uses):

- Additional indoor residue trials on melon (8) and cucumber or zucchini (8) supporting intended GAP, with analysis of 1,2,4-T, TA, TLA and TAA must be provided, to support uses on melon, cucumber, squash, zucchini, watermelon and pumpkin.
- A processing study on tomato.

Data gaps relevant for the risk assessment to cover the complete group of triazole derivate metabolites:

- 1) Storage stability data on 1,2,4-T, TA and TAA in high-acid-content commodities; on 1,2,4-T in high-protein-content commodities and on TLA in cereal straw, and covering the maximum storage time interval of the residue samples of the residue trials in primary and rotational crops.
- 2) Poultry and ruminant feeding studies conducted with TLA or, alternatively, metabolism studies performed in accordance with the current recommendations as a surrogate to these feeding studies, to determine the magnitude of TLA residues in products of animal origin.

Summary of the evaluation

Summary for tebuconazole

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EU) 2017/626	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	Cucumber, Zucchini, Squash	Yes	Yes	Yes	Yes	Yes	No	No	-
1	Melon	Yes	Yes	Yes	Yes	Yes		No	-
2	Pumpkin, Watermelon, Other cucurbits with inedible peel	Yes	Yes	Yes	Yes	No		-	-

Use- No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EU) 2017/626	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
3	Tomato	Yes	Yes	Yes	Yes	Yes		No	New GAP proposed (3 x 129 g a.s./ha, PHI 3 d) Processing study required post- authorisation
3	Pepper	Yes	Yes	Yes	Yes	No		-	-

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
NR: not relevant

The submitted overdosed trials on tomato cannot be used to cover the intended GAP. Consequently the alternative GAP of 3 x 129 g a.s./ha is proposed by zRMS (BBCH and PHI remain unchanged).

The effects of processing on the nature of tebuconazole residues have been investigated. Data on effects of processing on the amount of residue have been submitted.

These data were not considered for risk assessment.

For tomato, the effect of industrial and/or household processing needs to be investigated, as residues of tebuconazole exceed the trigger values defined in Reg. (EU) No 283/2013. Therefore a processing study on tomato is required post-authorisation.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops. Nevertheless, the studies on the nature and magnitude of tebuconazole residues in rotational crops indicate that TDMs may 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 be performed for TDMs in rotational crops as soon as the confirmatory data requested for triazole compounds in the framework of Directive 91/414/EEC have been evaluated and a general methodology on the risk assessment of triazole compounds and their TDMs is available.

None of the intended indoor uses are fed to livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Considering these TDMs, zRMS could not proposed a dietary risk assessment similar to the one pro-posed by EFSA in the “Peer review of the Pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted” (EFSA Journal 2018; 16(7):5376) because data gaps have been identified. Nevertheless, zRMS is of the opinion that the chronic and short-term intakes of TDMs residues resulting from the use proposed in the framework of this application are unlikely to present a public health concern.

Post-authorisation data (residue trials) are required to complete the data set assessed (confirmatory data).

Summary for DAENERYS

Crop	PHI for DAENERYS requested by applicant	PHI/withholding period* sufficiently supported for tebuconazole	PHI for DAENERYS proposed by zRMS	zRMS Comments (if different PHI proposed)
Cucumber, Zucchini	3 days	Yes	3 days	
Melon	3 days	Yes	3 days	
Pumpkin, Watermelon, Other cucurbits with inedible peel	7 days	Yes	7 days	
Tomato	3 days	Yes	3 days	
Pepper	3 days	-	-	Use not supported (MRL exceedance).

NR: not relevant

* Purpose of withholding period to be specified

** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Waiting periods before planting succeeding crops: Not relevant.

3.1.5 Environmental fate and behaviour

Outdoor uses:

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate predicted environmental concentration (PEC) values for the active 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.

All intended uses (except rice)

PEC_{soil} values derived for tebuconazole and its metabolite have been assessed according to FOCUS guidance and are used for the ecotoxicological risk assessment.

Based on the information made available to the zRMS, groundwater and surface water exposure calculations could not be validated (see corresponding assessment in section 5).

No groundwater risk assessment conclusions can be drawn.

Uses on rice

PEC values are calculated according to MEC-RICE guidance.

PEC_{soil} and PEC_{sw} values derived for tebuconazole and its metabolite are used for the ecotoxicological risk assessment.

PEC_{GW} values for tebuconazole and its metabolite 1,2,4 triazole do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009 and guidance document SANCO 221/2000 when the product is applied in soils with clay content above 30 %. No unacceptable risk of groundwater contamination is expected for uses on rice in soils with clay content above 30 %.

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.

Several azole active substances may be applied on a same field. Considering that 1,2,4-triazole can be formed from most of these azole active substances, an exceedance of the regulatory limit of 0.1 µg/L cannot be excluded. In order to ensure that the regulatory limit in groundwater is not exceeded for 1,2,4-triazole, all applicants of azole-based products are requested to set up a groundwater monitoring dedicated to this metabolite within two years.

Indoor uses:

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate PEC values 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.

PEC_{soil} values for tebuconazole and its metabolite have been assessed according to FOCUS guidance documents with the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PEC_{sw} values for tebuconazole were calculated using the Dutch approach for greenhouse uses.

Both PEC_{soil} and PEC_{sw} values are used for the ecotoxicological risk assessment.

Considering the intended uses (greenhouse), exposure of groundwater compartment to the active substance and its metabolite is considered negligible. No PEC_{GW} calculations are deemed necessary.

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

Outdoor uses:

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

Based on the guidance documents, the risk was not finalised for aquatic organisms for leafy vegetables, cereals, orchards, rice and vineyards uses.

For rice use, the risks for birds and mammals were also not finalised.

For leafy vegetables, cereals, orchards and vineyards uses, the risks for birds and mammals are acceptable.

Based on the guidance documents, the risks for bees and other non-target arthropods, earthworms, other soil macro- and micro-organisms and terrestrial plants are acceptable for the leafy vegetables, cereals, orchards, rice and vineyards uses.

The current assessment is submitted to the new data requirement of the Regulation (EU) No 284/2013.

A chronic toxicity study of the formulated product to adult bees and a chronic toxicity study of the formulated product to larvae of bees should have been provided by the applicant. Such studies are not currently available. Therefore the product must not be applied during the flowering period.

The following mitigation measure, “To protect bees and other pollinating insects, do not apply during flowering” is considered in France. Mitigation measures may be adapted at national level.

Indoor uses:

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

No risk assessment was deemed necessary for exposure for birds, mammals, bees and other non-target arthropods, earthworms, other soil macro- and micro-organisms and terrestrial plants for glasshouse due to the very limited potential of exposure. Moreover, the risk assessment was acceptable for outdoor uses on leafy vegetable at same application rates (even if there were three applications outdoor vs four in glasshouses).

Based on the guidance documents, the risk assessment for aquatic organisms is acceptable for the intended uses without mitigation measures.

3.1.7 Efficacy

Considering the data submitted:

- The efficacy level of DAENERYS is considered satisfactory for all the requested uses, **except for powdery mildew of tomato and sweet pepper, for which there are insufficient data to finalise the assessment.**
- The phytotoxicity level of DAENERYS is considered negligible for all the requested uses.
- The risks of negative impact on yield, quality, transformation processes, propagation, succeeding and adjacent crops are considered negligible.
- There is a risk of resistance developing or appearing to tebuconazole for Septoria-type diseases of wheat (*Zymoseptoria tritici* - SEPTTR), powdery mildew of wheat (*Erysiphe graminis* - ERYSGR), *Fusarium* spp. on wheat, net blotch of barley (*Helminthosporium teres* - PYRNTE), ramularia leaf spot of barley (*Ramularia collo-cygni* - RAMUCC), powdery mildew of grapevine (*Uncinula necator* - UNCINE), powdery mildews of cucurbits and brown rots of stone fruits (*Monilia* sp. - MONISP). This requires monitoring of resistance.

To avoid the development of resistance of tebuconazole to powdery mildew of grapevine (*Uncinula necator*), the number of applications is limited to two per crop cycle.

On wheat, the number of applications of tebuconazole is limited to one per crop cycle because of tebuconazole resistance risk to Septoria-type diseases of wheat (*Z. tritici*). On barley, the number of applications of tebuconazole is limited to one per crop cycle because of the tebuconazole resistance risk to net blotch of barley (*H. teres*) and ramularia leaf spot (*R. collo-cygni* - RAMUCC).

Efficacy trials in situations of characterised resistance should be carried on *Z. tritici* of wheat, net blotch of barley (*H. teres*) and powdery mildew of grapevine (*U. necator*).

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation **cannot be granted**. A copy of the decision issued can be found 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

N/A : no marketing authorisation granted.

3.4.2 Post-authorisation data requirements

N/A : no marketing authorisation granted.

3.4.3 Label amendments

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

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

Appendix 1 - Copy of the French Decision



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

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

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

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

de la société	ROTAM AGROCHEMICAL EUROPE LIMITED
enregistrées sous les	n°2015-2229 et 2019-4236

Vu les conclusions de l'évaluation de l'Anses du 2 août 2021,

Considérant que, pour certains usages, il existe un risque de dépassement des limites maximales de résidus de la substance active et que l'utilisation du produit peut entraîner un risque d'effet nocif pour le travailleur, l'opérateur ou le consommateur,

Considérant qu'un risque d'effet inacceptable pour les oiseaux, et les mammifères, lié à l'utilisation du produit sur riz, ne peut être exclu,

Considérant qu'un risque d'effet inacceptable pour les organismes aquatiques, lié à l'utilisation en plein champ du produit, ne peut être exclu,

Considérant qu'un risque inacceptable de contamination des eaux souterraines, lié à l'utilisation en plein champ du produit, ne peut être exclu,

Considérant que les données disponibles ne permettent pas de déterminer l'efficacité du produit, pour les usages tomates-aubergines et poivrons,

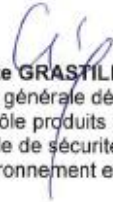
Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 sont respectées,

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



Informations générales sur le produit	
Nom du produit	DAENERYS
Type de produit	Produit de référence
Titulaire	ROTAM AGROCHEMICAL EUROPE LIMITED Hamilton House Mabledon Place LONDRES, WC1H 9BB Royaume-Uni
Formulation	Suspension concentrée (SC)
Contenant	430 g/L - tébuconazole
Numéro d'intrant	416-2015.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usage	Professionnel

A Maisons-Alfort, le 15 SEP. 2021


Charlotte GRASTILLEUR
Directrice générale déléguée
en charge du pôle produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

ANNEXE : Conditions de mise sur le marché demandées

Liste des usages refusés				
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)	
16103203 Artichaut*Trt Part.Aer.*Oidium(s)	0,3 L/ha	3/an	7	
Motivation du refus : L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus de la substance active, d'un risque d'effet nocif pour le travailleur et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques, ni d'exclure un risque inacceptable de contamination des eaux souterraines.				
16153203 Asperge*Trt Part.Aer.* Maladies des taches brunes	0,3 L/ha	3/an	-	
Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques, ni d'exclure un risque inacceptable de contamination des eaux souterraines.				
16153201 Asperge*Trt Part.Aer.*Rouille(s)	0,3 L/ha	3/an	-	
Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques, ni d'exclure un risque inacceptable de contamination des eaux souterraines.				
15103202 Blé*Trt Part.Aer.*Fusarioses	0,6 L/ha	1/an	35	
Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques, ni d'exclure un risque inacceptable de contamination des eaux souterraines.				

Liste des usages refusés				
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)	
15103209 Blé*Trt Part.Aer.*Oidium(s)	0,6 L/ha	1/an	35	
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques, ni d'exclure un risque inacceptable de contamination des eaux souterraines.			
15103214 Blé*Trt Part.Aer.*Rouille(s)	0,6 L/ha	1/an	35	
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques, ni d'exclure un risque inacceptable de contamination des eaux souterraines.			
15103221 Blé*Trt Part.Aer.*Septoriose(s)	0,6 L/ha	1/an	35	
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques, ni d'exclure un risque inacceptable de contamination des eaux souterraines.			
16323203 Cucurbitacées à peau comestible* Trt Part.Aer.*Oidium(s)	0,3 L/h	4/an	3	
	Motivation du refus : L'usage sous abri est refusé en raison d'un risque d'effet nocif pour le travailleur et d'un risque de dépassement des limites maximales de résidus de la substance active sur cornichon et autres cucurbitacées à peau comestibles.			
16753205 Cucurbitacées à peau non comestible* Trt Part.Aer.*Oidium(s)	0,3 L/ha	4/an	3	
	Motivation du refus : L'usage sous abri est refusé en raison d'un risque d'effet nocif pour l'opérateur.			

Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12503203 Olivier*Trt Part.Aer.* Maladies du feuillage	0,437 L/ha	1/an	35
15103226 Orge*Trt Part.Aer.* Helminthosporiose et ramulariose	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour le travailleur et l'opérateur, et au motif que les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques, ni d'exclure un risque inacceptable de contamination des eaux souterraines.		
	0,6 L/ha	1/an	35
15103225 Orge*Trt Part.Aer.*Oidium(s)	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques, ni d'exclure un risque inacceptable de contamination des eaux souterraines.		
	0,6 L/ha	1/an	35
15103229 Orge*Trt Part.Aer.*Rhynchosporiose	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques, ni d'exclure un risque inacceptable de contamination des eaux souterraines.		
	0,6 L/ha	1/an	35
15103205 Orge*Trt Part.Aer.*Rouille(s)	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques, ni d'exclure un risque inacceptable de contamination des eaux souterraines.		
	0,6 L/ha	1/an	35

Liste des usages refusés				
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)	
12553233 Pêcher - Abricotier*Trt Part.Aer.* Moniliose(s)	0,523 L/ha	1/an	14	
Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour le travailleur et l'opérateur, et au motif que les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques, ni d'exclure un risque inacceptable de contamination des eaux souterraines.				
16863203 Poivron*Trt Part.Aer.*Oidium(s)	0,3 L/ha	4/an	3	
Motivation du refus : L'usage sous abri est refusé en raison d'un risque de dépassement des limites maximales de résidus de la substance active, d'un risque d'effet nocif pour le travailleur et car les données disponibles ne permettent pas de déterminer l'efficacité du produit.				
12653204 Prunier*Trt Part.Aer.*Moniliose(s)	0,523 L/ha	1/an	14	
Motivation du refus : L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus de la substance active, d'un risque d'effet nocif pour le travailleur et l'opérateur et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques, ni d'exclure un risque inacceptable de contamination des eaux souterraines.				
00124010 Riz*Trt Part.Aer.* Maladies des feuilles, tiges et panicules	0,6 L/ha	3/an	-	
Motivation du refus : L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus de la substance active et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les oiseaux, les mammifères et les organismes aquatiques.				
16953206 Tomate - Aubergine*Trt Part.Aer.* Oidium(s)	0,3 L/ha	3/an	3	
Motivation du refus : L'usage sous abri est refusé en raison d'un risque d'effet nocif pour le travailleur et car les données disponibles ne permettent pas de déterminer l'efficacité du produit.				

Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12703206 Vigne*Trt Part.Aer.*Black rot	0,2 L/ha	2/an	14
Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour le travailleur ainsi que d'un risque de dépassement des limites maximales de résidus de la substance active sur raisin de cuve et d'un risque de d'effet nocif pour le consommateur sur raisin de table. De plus, les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques, ni un risque inacceptable de contamination des eaux souterraines.			
12703204 Vigne*Trt Part.Aer.*Oidium(s)	0,25 L/ha	2/an	14
Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour le travailleur ainsi que d'un risque de dépassement des limites maximales de résidus de la substance active sur raisin de cuve et d'un risque de d'effet nocif pour le consommateur sur raisin de table. De plus, les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques, ni un risque inacceptable de contamination des eaux souterraines.			
12703207 Vigne*Trt Part.Aer.*Rougeot parasitaire	0,25 L/ha	2/an	14
Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour le travailleur ainsi que d'un risque de dépassement des limites maximales de résidus de la substance active sur raisin de cuve et d'un risque de d'effet nocif pour le consommateur sur raisin de table. De plus, les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques, ni un risque inacceptable de contamination des eaux souterraines.			

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

DAENERYS®
FONGICIDE
CEREALES (BLE, ORGE), RIZ, ARTICHAUTS, ASPERGE, OLIVIER de table
et cuve, PÊCHER, ABRICOTIER, PRUNIER, VIGNE de table et cuve
EN PLEIN CHAMP
ET
CONCOMBRE, COURGETTE, COURGE, MELON, CITROUILLE, PASTèque,
POIVRON ET TOMATE
EN SOUS ABRI / HORS DU CHAMP*

**Consulter les usages autorisés dans le livret*

Autorisation de Mise sur le Marché n° XXXXXX
Contient 430 g/L de tébuconazole (39.81%) - Suspension concentrée (SC)

RESERVE A UN USAGE EXCLUSIVEMENT PROFESSIONNEL



ATTENTION

H361d - Susceptible de nuire au fœtus.
H411 - Toxique pour les organismes aquatiques, et des effets néfastes à long terme.



P202 - Ne pas manipuler avant d'avoir lu et compris toutes les précautions de sécurité.

P273 - Éviter le rejet dans l'environnement.

P280 - Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage.

P308+P313 - EN CAS d'exposition prouvée ou suspectée: consulter un médecin.

P501 - Éliminer le contenu/récipient dans un point de collecte des déchets spéciaux ou dangereux.

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.]

SPe3 - Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 m par rapport aux points d'eau.

EUH 401 Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.

Délai de rentrée : 48 heures

Autres conditions d'utilisation et précautions d'usage : lire attentivement le livret.

Détenteur de l'A.M.M. :	Rotam Agrochemical Europe Ltd., Hamilton House, Mabledon Place London WC1H 9BB, Royaume-Uni
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Distributeur et EMB :	XXXXXXX
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En cas d'urgence, composer le 15 ou le 112 ou contacter le centre anti-poison le plus proche

Puis signalez vos symptômes au réseau Phyt'attitude, N° vert 0 800 887 887 (appel gratuit depuis un poste fixe).

250mL / 1L / 3L / 4L / 5L / 10L

Numéro de lot et date de production : voir emballage

® Marque déposée de Rotam

RÉEMPLOI DE L'EMBALLAGE INTERDIT

MODE D'ACTION

Le tébuconazole agit au niveau de la membrane du pathogène en inhibant la biosynthèse de l'ergostérol par blocage du processus de déméthylation. Ainsi que les autres triazoles, le tébuconazole appartient au groupe des Inhibiteurs de la Biosynthèse des Stérols. Le FRAC (Fungicide Resistance Action Committee) a classé le tébuconazole et les autres triazoles dans le groupe DMI (DeMethylation Inhibitors), SBI Class I.

Afin de diminuer le risque d'apparition ou de développement du phénomène de résistance, il est conseillé de se conformer aux recommandations suivantes :

- Appliquer **DAENERYS®** à sa dose homologuée.
- La mise en œuvre de programmes de traitements à doses réduites doit être prohibée car elle a pour conséquence une augmentation de la pression de sélection, phénomène qui peut conduire à la sélection de souches résistantes.
- Alternier des produits à mode d'action différent ou utiliser des spécialités associant des substances actives à mode d'action différent.

USAGES ET DOSES AUTORISEES

	Usage	Dose d'application	Nombre maximum d'application par an	Intervalle entre les applications (jours)	Stades d'application	Délai avant récolte	Volume d'eau (L/ha) Min / max
Cultures de plein champ							
Riz	Traitement des parties aériennes : Maladies des feuilles, tiges et panicules. Cet usage couvre à la fois les maladies Brunissage du riz (Pyricularia oryzae) et Helminthosporiose du riz (Cochliobolus miyabeanus) (Helminthosporium oryzae)	0.6 L/ha	3	14	BBCH 30 – BBCH 69	BBCH 69	200 – 400
Artichaut	Traitement des parties aériennes : Oïdium(s)	0,3 L/ha	3	7 - 10	A partir de BBCH 40	7 jours	800 - 1000
Asperge	Traitement des parties aériennes : Rouille(s), Maladies des tâches brunes	0,3 L/ha	3	7 - 10	A partir de BBCH 40	-	800 – 1000
Olivier de table et cuve	Traitement des parties aériennes : Maladie de l'œil de paon	0,43 L/ha	1	-	BBCH 00 – BBCH 50	-	500 - 1250
Pêcher , Abricotier	Traitement des parties aériennes : Monilioses	0,523 L/ha	1	-	BBCH 57 – BBCH 60 (pré-floraison)	14 jours	1000 - 1500

					BBCH 81 – BBCH 87 (avant récolte)		
Prunier	Traitement des parties aériennes : Monilioses	0,523 L/ha	1	-	BBCH 57 – BBCH 60 (pré- floraison) BBCH 81 – BBCH 87 (avant récolte)	14 jours	1000 - 1500
Vigne de table et de cuve	Traitement des parties aériennes : Black rot	0,2 L/ha	3	14	BBCH 13 - BBCH 77	14 jours	200 - 1000
	Traitement des parties aériennes : Rougeot parasitaire	0,25 L/ha					
Blé	Traitement des parties aériennes : Oïdium(s), Rouille(s), Septoriose(s),	0,6 L/ha	2	14	BBCH 30 - BBCH 61	35 jours	200 - 400
	Fusarioses		1	-	BBCH 61 – BBCH 69	35 jours	200 - 400
Orge	Traitement des parties aériennes : Oïdium(s), Rhynchosporiose, Helminthosporiose et ramulariose, Rouille(s)	0,6 L/ha	2	14	BBCH 30 – BBCH 61	35 jours	200 - 400
Cultures hors champ / sous abri							
Concombre, courge, courgette	Traitement des parties aériennes : Oïdium(s)	0,3 L/ha	4	7 – 10 jours	BBCH 13 – BBCH 79	3 jours	500 - 1000
Melon, Potiron, Citrouille, Pastèque	Traitement des parties aériennes : Oïdium(s)	0,3 L/ha	4	7 – 10 jours	BBCH 13 – BBCH 79	3 jours 7 jours : Pastèque et Potiron	500 - 1000
Poivron	Traitement des parties aériennes : Oïdium(s)	0,3 L/ha	4	7 – 10 jours	BBCH 13 – BBCH 79	3 jours	500 - 1000
Tomate	Traitement des parties aériennes : Oïdium(s)	0,3 L/ha	4	7 – 10 jours	BBCH 13 – BBCH 79	3 jours	500 - 1000

L'utilisation de ce produit sur ses usages autorisés n'est recommandée que sur les cultures et cibles indiquées ci-dessus.

Les limites maximales de résidus applicables dans les pays de l'Espace Economique Européen sont consultables à l'adresse suivante : <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database>. Pour les autres pays susceptibles d'importer les denrées issues des cultures traitées, il est de la responsabilité de l'utilisateur du produit et de l'exportateur des denrées d'assurer la conformité en matière de quantité de résidus.

MODE D'EMPLOI

En cas de stress hydrique marqué ou de fortes amplitudes thermiques, éviter de traiter les céréales mal implantées ou en situation de sol séchant.

Ne pas traiter à partir d'une température de 30°C.

Après un stockage au froid, agiter avant emploi.

Préparation de la bouillie : Agiter la préparation avant emploi. **DAENERYS®** s'utilise en pulvérisation après dilution dans l'eau.

Remplir la cuve à 2/3 d'eau, mettre sous agitation, agiter le bidon et verser la quantité de **DAENERYS®** nécessaire puis compléter le remplissage.

Application : Utiliser un matériel adapté à la culture et au parasite à contrôler. Veiller à une répartition homogène de la bouillie sur l'ensemble de la végétation à traiter. Laisser l'agitateur en fonctionnement pendant le trajet et jusqu'à la fin de la pulvérisation.

RECOMMANDATIONS D'EMPLOI

Sur céréales, DAENERYS® s'utilise du stade redressement au stade floraison ; il peut être appliqué seul mais peut également s'intégrer à tout programme de protection. Généralement, **DAENERYS®** s'applique dès l'apparition des symptômes de la maladie ; sur fusarioses des épis, traiter dès le début de la floraison. Suivre les recommandations des bulletins d'Avertissements Agricoles diffusés par les SRPV.

MELANGES

Les mélanges extemporanés doivent être mis en oeuvre conformément à la réglementation en vigueur.

Pendant la floraison du colza, ne pas utiliser **DAENERYS®** en mélange avec des insecticides de la famille des pyréthrinoides.

PROTECTION DE L'OPERATEUR ET DU TRAVAILLEUR

Se laver les mains après toute manipulation/utilisation/intervention dans une parcelle préalablement traitée. Ne pas manger, boire, téléphoner ou fumer lors de l'utilisation du produit.

• **Pour l'opérateur,** porter dans le cadre d'une application effectuée à l'aide d'un pulvérisateur à rampe :

> pendant le mélange/chargement

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

> pendant l'application - Pulvérisation vers le bas

Si application avec tracteur avec cabine

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

PRECAUTIONS A PRENDRE

Avant l'application : Port de gants pendant le mélange et le chargement. Vérifier régulièrement et maintenir le bon état et le réglage du matériel d'application, surveiller le remplissage de la cuve du pulvérisateur et ajuster le volume de bouillie. Rincer les emballages trois fois, vider l'eau de rinçage dans la cuve.

Pendant l'application : Porter un vêtement de protection approprié, des gants et un appareil de protection des yeux et du visage. En cas de contact avec la peau et les yeux, laver immédiatement et abondamment avec de l'eau et consulter un spécialiste. Ne pas respirer les vapeurs, ni le brouillard de pulvérisation. Ne pas traiter les cours d'eau et fossés en eau. Appliquer la bouillie dans les cultures par temps calme, sans vent fort pour éviter, toute dérive de pulvérisation vers les fossés, cours d'eau, chemins, abords de ferme ou bâtiments. Appliquer les fonds de cuve après dilution.

Après l'application : Nettoyer les équipements de protection. Se laver les mains. Prendre une douche. Port d'un vêtement approprié par le travailleur entrant dans la parcelle après traitement.

À la fin de la période d'application du produit, l'intégralité de l'appareil (cuve, rampe, circuit, buses...) doit être rincée à l'eau claire. Le rinçage du pulvérisateur, l'épandage ou la vidange du fond de cuve et l'élimination des effluents doivent être réalisés conformément à la réglementation en vigueur.

PRÉVENTION ET GESTION DE LA 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, l'utilisateur doit raisonner en premier lieu les pratiques agronomiques et respecter les conditions d'emploi du produit. 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. En dépit du respect de ces règles, on ne peut pas exclure une altération de l'efficacité de cette préparation liée à ces phénomènes de résistance.

PREMIERS SOINS

S'éloigner de la zone dangereuse.

En cas de contact cutané : enlever tout vêtement souillé, rincer immédiatement et abondamment la peau sous l'eau du robinet. En cas d'irritation ou éruption cutanée, consulter un spécialiste.

En cas de projection dans les yeux : rincer immédiatement pendant 15 à 20 minutes sous un filet d'eau paupières ouvertes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Consulter un spécialiste.

En cas d'inhalation : en cas de trouble respiratoire, contacter sans délai les secours : le 15, le 112 ou un centre anti-poison.

En cas d'ingestion : rincer immédiatement la bouche avec de l'eau. Ne pas faire vomir sans avis médical. Contacter sans délai les secours : le 15, le 112 ou un centre anti-poison.

Dans tous les cas, si les symptômes persistent ou en cas de malaise, consulter un médecin et lui présenter l'étiquette et/ou la Fiche de Données de Sécurité.

En cas d'intoxication animale, contactez votre vétérinaire.

STOCKAGE DU PRODUIT

Conserver le produit uniquement dans son emballage d'origine, dans un local phytopharmaceutique conforme à la réglementation en vigueur, à l'écart des aliments et boissons, y compris ceux pour animaux. Conserver hors de la portée des enfants et des personnes non autorisées.

ELIMINATION DU PRODUIT ET DE SON EMBALLAGE

Réemploi de l'emballage interdit. Lors de l'utilisation du produit, bien vider et rincer le bidon à l'eau claire (rinçage manuel à 3 reprises en agitant le bidon rempli au 1/3 ou rinçage mécanique d'une durée minimale¹ de 30 secondes) en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur. Apporter les emballages ouverts, rincés et égouttés à votre service de collecte spécifique.

Pour l'élimination des produits non utilisables, conserver le produit dans son emballage d'origine. Interroger votre entreprise habilitée pour la collecte et l'élimination des déchets dangereux.

EN CAS DE DEVERSEMENT ACCIDENTEL

Se protéger (EPI) et sécuriser la zone.

Prévenir les pompiers (18 ou 112) en cas de danger immédiat pour l'environnement que vous ne pouvez gérer avec vos propres moyens. Collecter tout ce qui a pu être en contact avec le produit, terre souillée incluse.

Nettoyer le site et le matériel utilisé, en prenant soin de confiner les effluents générés par l'opération de nettoyage. Les éliminer selon la réglementation en vigueur.

Avertissement : Toute reproduction totale ou partielle de cette étiquette est interdite.

Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage. Ils 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 la responsabilité de l'utilisateur, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces... Le fabricant garantit la qualité du produit vendu dans son emballage d'origine et stocké selon les conditions préconisées, ainsi que sa conformité à l'Autorisation de Mise sur le Marché délivrée par les Autorités Compétentes françaises. Pour les denrées issues de cultures

protégées avec cette spécialité et destinées à l'exportation, il est de la responsabilité de l'exportateur de s'assurer de la conformité avec la réglementation en vigueur dans le pays importateur.

Appendix 3 – Letter(s) of Access

Not applicable.