REGISTRATION REPORT

Part A

Risk Management

Product code: ARY-0534-004

Product name: EVITO T

Active substances:

tebuconazole, 250 g/L

fluoxastrobin, 180 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: ARYSTA LIFESCIENCE

Date: 2019-10-29

Table of Contents

PART A – Risk Management

The company ARYSTA LIFESCIENCE has requested a new application in France for the product EVITO T (product code: ARY-0534-004), containing 250 g/L tebuconazole and 180 g/L fluoxastrobin, for use as a fungicide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to EVITO T (ARY-0534-004) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of EVITO T (ARY-0534-004) have been made using endpoints agreed in the EU peer reviews of both tebuconazole and fluoxastrobin.

This document describes the specific conditions of use and labelling required for France for the registration of EVITO T (ARY-0534-004).

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 ARYSTA LIFESCIENCE's application to market EVITO T (ARY-0534-004) in France as a fungicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Tebuconazole

Commission Implementing Regulation (EU) No 921/2014 of 25 August 2014 amending Implementing Regulation (EC) No 540/2011 as regards the conditions of approval of the active substance tebuconazole.
Specific provisions of Regulation (EU) No 921/2014 were as follows : PART A Only uses as fungicide and plant growth regulator may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on tebuconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment; — the dietary exposure of consumers to the tebuconazole (triazole) metabolites; the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil or climatic conditions, in particular as regards the occurrence in groundwater of the metabolite 1,2,4-triazole; — the protection of granivorous birds and mammals and herbivorous mammals and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures.

— the protection of aquatic organisms and must ensure that conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate. The Member States concerned shall ensure that the notifier submits to the Commission further information addressing the potential endocrine disrupting properties of tebuconazole within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, of Community agreed test guidelines.
An EFSA conclusion is available (EFSA Journal 2014; 12(1): 3485). A Review Report is available (SANCO/171/08 rev 2, 9 September 2008; 11 July 2014).

Fluoxastrobin

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.
Specific provisions of Regulation (EU) No 540/2011 were as follows : PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fluoxastrobin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator safety, in particular when handling the undiluted concentrate. Conditions of use shall include adequate protective measures, such as wearing a face shield, — the protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate, — the levels of residues of the metabolites of fluoxastrobin, when straw from treated areas is used as animal feeding stuff. Conditions of use shall include restrictions for feeding to animals, where appropriate, — the risk of accumulation in the soil surface, if the substance is used in perennial crops or in succeeding crops in crop rotation. Conditions of use shall include risk mitigation measures, where appropriate. The concerned Member States shall request the submission of: — data to allow a comprehensive aquatic risk assessment to be made taking into account spray drift, run-off, drainage and the effectiveness of potential risk mitigation measures, — data on toxicity of non-rat metabolites if straw from treated areas is to be used as feedstuff. They shall ensure that the notifier at whose request fluoxastrobin has been included in this Annex provide such studies to the Commission within two years from the approval.
An EFSA conclusion is available (EFSA Journal 2007; 102, 1-84. A Review Report is available (SANCO/3921/07- final, 28 September 2012).

1.3 Regulatory approach

The present application (2015-5700) 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, taking into account the worst-case uses ("risk envelope approach")[1] – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

[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

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

The French Order of 4 May 2017[2] provides that:
- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight hours for indoor uses.

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

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009[3], implementing regulations, and French regulations.

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

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011[4], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[5] provides that:
- an authorisation granted for a "reference" crop applies also for "linked" crops, unless formally stated in the Decision
- the "reference" and "linked" crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "linked" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those "linked" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[6] 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 EVITO T (ARY-0534-004), 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 letters of access for both tebuconazole and fluoxastrobin.

---

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 https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte

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/AGRG1407093A/jo

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)	EVITO T (ARY-0534-004)
Authorisation number	Not applicable
Function	Fungicide
Applicant	Arysta LifeScience
Composition	250 g/L tebuconazole 180 g/L fluoxastrobin
Formulation type (code)	Suspension concentrate (SC)
Packaging	N/A: not registered in France.

2.2 Classification and labelling

2.2.1 Classification and labelling in accordance with Regulation (EC) No 1272/2008

Physical hazards	-	
Health hazards	Eye irritation, category 2. Carcinogenicity, category 2. Reproductive toxicity, category 2.	
Environmental hazards	Hazardous to the aquatic environment, Acute Hazard, Category 1. Hazardous to the aquatic environment, Chronic Hazard, Category 1.	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H319	Causes serious eye irritation.
	H351	Suspected of causing cancer.
	H361d	Suspected of damaging the unborn child.
	H400	Very toxic to aquatic life.
	H410	Very toxic to aquatic life with long-lasting effects.
Precautionary statements –	***For the P phrases, refer to the extant legislation***	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	EUH208	Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.

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

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

N/A: not registered in France.

2.2.3 Other phrases linked to the preparation

N/A: not registered in France.

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" or "not finalised", the intended use is highlighted in grey and the main reason(s) reported in the remarks.
When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.
Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 2019-10-29

PPP (product name/code):	**EVITO T (ARY-0534-004)**	Formulation type:	**SC** [a, b]
Active substance 1:	Tebuconazole	Conc. of a.s. 1:	**250/L** [c]
Active substance 2:	Fluoxastrobin	Conc. of a.s. 2:	**180/L** [c]
Safener:	n.a	Conc. of safener:	n.a
Synergist:	n.a	Conc. of synergist:	n.a
Applicant:	**Arysta LifeScience**	Professional use:	☒
Zone(s):	southern	Non-professional use:	☐
Verified by MS:	yes		
Field of use:	fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	**Major crops:** Oil seed rape **Minor crops:** Rape plant, mustard seed**,** gold-of-pleasure, poppy seed, linseed, Lin fibre	F	*Sclerotinia sclerotiorum*	Foliar application	61 - 70 BBCH	1	-	0.8 L/ha	0.144 + 0.200	200-400	56	**Not acceptable** (aquatic organisms and bees)

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/L
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No 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
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 RISK MANAGEMENT

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

3.1.1 Physical and chemical properties

EVITO T (ARY-0534-004) 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 free-flowing off-white liquid, with no specific odour. It is not explosive and has no oxidising properties. The product is neither flammable (flash point > 100 °C), nor auto-flammable. In aqueous solution (1 %), it has a pH value of 7.7 at 20 °C. There is no effect of low and high temperatures on the stability of the formulation, since after seven days at 0 °C and 14 days at 54 °C, neither the active substances' content nor the technical properties were changed. The stability data indicate a shelf life of at least two years at ambient temperature when stored in HDPE. As the formulation is a suspension concentrate, the HDPE/EVOH packaging may also be considered acceptable. The technical characteristics are acceptable for an SC formulation.

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

The packaging must be rinsed at least twice before its disposal.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methodology for the determination of the active substances in the formulation is available and validated. As the active substances fluoxastrobin and tebuconazole do not contain relevant impurities, no pertinent analytical method is required.

3.1.2.2 Analytical methods for residues

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

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

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

<table>
<tr><td colspan="4">Active substance: tebuconazole</td></tr>
<tr><td>ADI</td><td colspan="2">0.03 mg/kg bw/d</td><td rowspan="2">Efsa (2008)</td></tr>
<tr><td>ARfD</td><td colspan="2">0.03 mg/kg bw</td></tr>
<tr><td>AOEL</td><td colspan="2">0.03 mg/kg bw/d</td><td>Dir 08/125</td></tr>
<tr><td rowspan="3">Dermal absorption</td><td colspan="3">Based on an in vitro human study performed on the formulation:</td></tr>
<tr><td></td><td>Concentrate (tested)
250 g/L</td><td>Diluted formulation (tested)
0.5 g/L</td></tr>
<tr><td>In vitro (human) %</td><td>0.6</td><td>20</td></tr>
<tr><td></td><td></td><td>Concentrate
(used in formulation)
250 g/L</td><td>Spray dilution
(used in formulation)
0.5 g/L</td></tr>
</table>

	Dermal absorption endpoints %	**0.6**	**20**

Active substance: **fluoxastrobin**			
ADI	0.015 mg/kg bw/d		EU (2008)
ARfD	0.3 mg/kg bw		
AOEL	0.03 mg/kg bw/d		
Dermal absorption	Based on an *in vitro* human study performed on the formulation:		
		Concentrate (tested) 180 g/L	Diluted formulation (tested) 0.36 g/L
	In vitro (human) %	0.3	14
		Concentrate (used in formulation) 180 g/L	Spray dilution (used in formulation) 0.36 g/L
	Dermal absorption endpoints %	**0.3**	**14**

3.1.3.1 Acute Toxicity

EVITO T (ARY-0534-004), containing 250 g/L tebuconazole and 180 g/L fluoxastrobin, has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin and not a skin sensitiser but is irritant to the eye.

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
Oilseed rape Rape plant, mustard seed, gold-of-pleasure, poppy seed, linseeds, Lin fibre	F	Tractor-mounted/trailed boom sprayer: hydraulic nozzles	0.8 L product/ha 144 g fluoxastrobin/ha 200 g tebuconazole/ha	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	% AOEL fluoxastrobin
Oilseed rape, rape plant, mustard seed, gold of pleasure, poppy seed, linseeds, Lin fibre	Tractor-mounted/trailed boom sprayer: hydraulic nozzles	Working coverall and gloves during mixing/loading and application	10	5.3

[7] Open field or glasshouse

According to the model calculations, it may be concluded that the risk for the operator using EVITO T (ARY-0534-004) is acceptable with a working coverall (90 % protection factor) and gloves during mixing/loading and application.

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

3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to be 1.1 % and 0.6 % of the AOEL of tebuconazole and fluoxastrobin, respectively.

It may be concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to EVITO T (ARY-0534-004).

3.1.3.4 Worker Exposure

Workers may have to enter treated areas after treatment for crop inspection activities. Therefore, estimation of worker exposure was calculated according to EUROPOEM II. Exposure is estimated to be 6.7 % and 3.4 % of the AOEL of tebuconazole and fluoxastrobin, respectively.

It may be concluded that without taking into account a re-entry period, there is no unacceptable risk anticipated for workers wearing a working coverall and gloves, when re-entering crops treated with EVITO T (ARY-0534-004).

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 the Martin *et al*, (2008) approach. Exposure is estimated to be 0.05 % and 0.02 % of the AOEL of tebuconazole and fluoxastrobin for adults, respectively and 0.09 % and 0.05 % of the AOEL of tebuconazole and fluoxastrobin for children, respectively (FMTC, 10 m, drift deposit of 0.29 %).

It may be concluded that there is no unacceptable risk to the resident exposed to EVITO T (ARY-0534-004).

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:

Tebuconazole		% ADI	% AOEL
Maximum daily measurement (4.77 ng/m³)	Adult	0.006	0.006
	Child	0.009	0.009
Maximum weekly measurement (1.4 ng/m³)	Adult	0.002	0.002
	Child	0.003	0.003

3.1.3.6 Combined exposure

A cumulative assessment for operators and workers was performed. At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity.

Hazard quotients (HQ) for each active substance and the hazard index (HI: sum of hazard quotients) are:

Application scenario	**Equipment**	**PPE**	**Active substance**	**Estimated exposure / AOEL (HQ)**
Operators	Tractor-mounted/trailed boom sprayer: hydraulic nozzles	Working coverall and gloves during mixing/loading and application	Tebuconazole	0.104
			Fluoxastrobin	0.05

		Cumulative risk operators (HI)		**0.15**
Workers	-	With PPE	Tebuconazole	0.067
			Fluoxastrobin	0.034
		Cumulative risk bystanders (HI)		**0.1**

The Hazard Index is < 1. Thus combined exposure to all active substances in EVITO T (ARY-0534-004) is not expected to present a risk for operators, bystanders or workers.

3.1.4 Residues and Consumer Exposure

The data available are not considered sufficient for risk assessment. An exceedence of the current MRL for tebuconazole and fluoxastrobin is not expected.

From the consumer safety aspect, France as zRMS agrees with the authorisation of the intended uses.

Summary of the evaluation
The preparation EVITO T (ARY-0534-004) contains tebuconazole and fluoxastrobin.

Table 1: 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	**Major crops:** Oil seed rape **Minor crops:** rape plant, mustard seed**,** gold-of-pleasure, poppy seed, linseeds	YES	YES	YES	YES	YES	NO	NO	

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

As residues of tebuconazole do not exceed the trigger values defined in Reg. (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was

calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin are therefore not necessary.

Table 2: Summary for fluoxastrobin

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EU) 2019/50	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	**Major crops:** Oil seed rape **Minor crops:** rape plant, mustard seed**,** gold-of-pleasure, poppy seed, linseeds	YES	YES	YES	YES	YES	NO	NO	

As residues of fluoxastrobin do not exceed the trigger values defined in Reg. (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

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

Summary for EVITO T (ARY-0534-004)

PRE-HARVEST INTERVAL (IN DAYS) FOR EACH RELEVANT CROP
Pre-harvest interval by crop

Table 3: Information on EVITO T (ARY-0534-004) (KCA 6.8)

Crop	PHI for EVITO T (ARY-0534-004) requested by applicant	PHI/withholding period* sufficiently supported for		PHI for EVITO T (ARY-0534-004) proposed by zRMS	zRMS Comments (if different PHI proposed)
		tebuconazole	fluoxastrobin		
Oilseed rape	56 days	YES	YES		

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).

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate predicted environmental concentration (PEC) values for the active substances and their metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.
The PEC values of tebuconazole, fluoxastrobin and their metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.
PECsoil and PECsw values derived for the active substances and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.
PECgw values for tebuconazole, fluoxastrobin and their metabolites do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009 and guidance document SANCO 221/2000 on the relevance of metabolites in groundwater. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.
Based on vapour pressure, information on volatilisation from plants and soil, and DT_{50} calculation, no significant contamination of the air compartment is expected for the intended uses.

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

3.1.6 Ecotoxicology

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

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

The risk to aquatic organisms following the intended use of EVITO T (ARY-0534-004) cannot be considered acceptable. Indeed, the refined regulatory acceptable concentration (RAC) proposed by the applicant is considered unsuitable for risk assessment following the EFSA aquatic guidance document. Therefore using toxicity data available it is not possible to finalise the risk assessment for the intended uses.
In addition, according to new requirements of Reg. No. 284/2013, a chronic toxicity study for adult bees and data on effects on development of bees should have been submitted by the applicant as exposure of bees to the formulation cannot be excluded. Indeed, according to the intended use, EVITO T (ARY-0534-004) would be sprayed during the flowering period of oilseed rape, which is a very attractive crop for bees. Therefore, it is not possible to conclude on the risk of the use of the formulation EVITO T (ARY-0534-004). Without these new studies the risk assessment for bees cannot be finalised.

3.1.7 Efficacy

Considering the data submitted:

- the efficacy level of EVITO T (ARY-0534-004) is considered satisfactory for all the requested uses.
- the phytotoxicity level of EVITO T (ARY-0534-004) is considered negligible for all the requested uses.
- the risks of negative impact on yield, quality, propagation, succeeding and adjacent crops are considered negligible.
- There is a risk of resistance developing or appearing to fluoxastrobin for *Sclerotinia sclerotiorum* on oilseed rape; this requires monitoring.

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

EVITO T (ARY-0534-004) contains tebuconazole wich is approved as a candidate for substitution because it meets two PBT criteria.

As a conclusion of the comparative assessment,

- In accordance with Articles 50(1d) and 51 of Regulation (EC) No 1107/2009, product substitution is not retained for minor uses against *Sclerotinia* at national level on rape plant, mustard seed, gold of pleasure, poppy seed, linseeds, flax,
- Use from GAP table on oil seed rape, major crop, against *Sclerotinia* is not suitable for substitution because the candidate substance is a significant component of the resistances management strategy.

3.4 Substances of concern for national monitoring

No information stated.

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

3.5.1 Post-authorisation monitoring

N/A: not registered in France.

3.5.2 Post-authorisation data requirements

N/A: not registered in France.

3.5.3 Label amendments

N/A: not registered in France.

Appendix 1 – Copy of the French Decision

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

anses

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 ***EVITO T***

de la société *ARYSTA LIFESCIENCE*

enregistrée sous le *n°2015-5700*

Vu les conclusions de l'évaluation de l'Anses du 23 août 2019,

Considérant qu'un risque inacceptable pour les organismes aquatiques et pour les abeilles ne peut être exclu,

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.

EVITO T
AMM n°-

Page 1 sur 3

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

anses

Informations générales sur le produit	
Nom du produit	EVITO T
Type de produit	Produit de référence
Titulaire	ARYSTA LIFESCIENCE Route d'Artix BP80 64150 NOGUERES France
Formulation	Suspension concentrée (SC)
Contenant	250 g/L - tébuconazole 180 g/L - fluoxastrobine
Numéro d'intrant	580-2015.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usage	Professionnel

A Maisons-Alfort le, 29 OCT. 2019

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

EVITO T
AMM n°-

Page 2 sur 3

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

anses

ANNEXE I : Conditions de mise sur le marché demandées

Liste des usages refusés			
Usages	**Dose d'emploi**	**Nombre maximum d'applications**	**Délai avant récolte (jours)**
15203202 Crucifères oléagineuses*Trt Part.Aer.* Sclérotiniose	0,8 L/ha	1/an	56
	Motivation du refus : L'usage est refusé au motif qu'un risque inacceptable pour les organismes aquatiques et pour les abeilles ne peut être exclu.		
00118016 Lin*Trt Part.Aer.* Pourriture grise et sclérotinioses	0,8 L/ha	1/an	56
	Motivation du refus : L'usage est refusé au motif qu'un risque inacceptable pour les organismes aquatiques et pour les abeilles ne peut être exclu.		
00122008 Pavot*Trt Part.Aer.* Pourriture grise et sclérotinioses	0,8 L/ha	1/an	56
	Motivation du refus : L'usage est refusé au motif qu'un risque inacceptable pour les organismes aquatiques et pour les abeilles ne peut être exclu.		

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

Septembre 2015

EVITO T
(AMM n°……)

Suspension concentrée contenant 250g/l tebuconazole et 180g/l fluoxastrobine

EVITO T est un fongicide à spectre large utilisé pour le contrôle du développement de la *Sclerotinia sclerotiorum* sur colza, moutarde, caméline, navette, pavot, lin fibre et lin

Contenu: litres **e**

Lot No. 00000
PROTEGER DU GEL

INFORMATIONS IMPORTANTES

POUR UN USAGE PROFESSIONNEL SEULEMENT COMME FONGICIDE AGRICOLE

Culture	**Dose individuelle maximale (litres produit/ha)**	**Nombre maximal d'application**	**Dernière application**
Cultures majeures: Colza	0.8	1 par culture	BBCH 70
Cultures mineures: Moutarde, caméline, navette, pavot, lin fibre, lin			

LIRE L'ETIQUETTE AVANT UTILISATION. EN UTILISANT CE PRODUIT D'UNE MANIERE NON RECOMMANDEE PAR L'ETIQUETTE PEUT ETRE UNE INFRACTION. SUIVEZ LES CONDITIONS D'UTILISATION POUR UTILISER LES PRODUITS PHYTOSANITAIRES ;

Détenteur de l'autorisation
Arysta LifeScience SAS,
Route d'Artix
BP 80
64150 Noguères - France
Téléphone: 05 59 60 92 92

EVITO T (AMM n° ….)
Suspension concentrée contenant 250g/l tébuconazole (22,4 %) et 180g/l fluoxastrobine (16,4%)
Attention

H319: Catégorie 2 “Provoque une sévère irritation des yeux”

H361d: “Susceptible de nuire á la fertilité ou au fœtus”

H410: “Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme”

EUH208: Contient 1,2-Benzisothiazolin-3-one. Peut produire une réaction allergique.
EUH401: Respectez les instructions d’utilisation pour éviter les risques pour la santé humaine et l’environnement.
SP1: Ne pas contaminer l’eau avec le produit ou son contenant (Ne pas nettoyer l’équipement d’application à proximité d’eaux de surface / Eviter la contamination via les eaux de drainage des routes ou des fermes).
SPe3: Pour protéger les organismes aquatiques, respecter une bande de végétation sans traitement (zone non traitée) de 10 m en bordure des points d'eau.

PRECAUTIONS
P201: Se procurer les instructions avant utilisation.
P281: Utiliser l'équipement de protection individuel requis.
P308+P313: EN CAS d'exposition prouvée ou suspectée: Consulter un médecin.
P391: Recueillir le produit répandu
P405: Garder sous clef.
P501: Eliminer le contenu/récipient dans un centre spécialisé.

Protection de l’opérateur

- pendant le mélange/chargement
  - Gants en nitrile certifiés EN 374-3 ;
  - Bottes de protection conforme à la réglementation et selon la norme EN 13 832-3 ;
  - Lunettes de sécurité conforme à la réglementation et selon la norme EN 166 ;
  - 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
  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 ;
  - Bottes de protection conforme à la réglementation et selon la norme EN 13 832-3 ;

- 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 ;
- Bottes de protection conforme à la réglementation et selon la norme EN 13 832-3 ;
- 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 ;
  - Bottes de protection conforme à la réglementation et selon la norme EN 13 832-3 ;
  - Lunettes de sécurité conforme à la réglementation et selon la norme EN 166 ;
  - 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.

Protection des travailleurs

Dans les cas où le travailleur serait amené à intervenir sur les parcelles traitées, il est recommandé de porter une combinaison de travail tissée polyester 65 %/coton 35 % avec un grammage d'au moins 230 g/m² avec traitement déperlant.

Protection Environnementale

Ne pas contaminer les eaux de surfaces ou les fossés avec le produit chimique ou son emballage utilisé.
Une zone non traitée enherbée de 10m doit être présente.
NE PAS PERMETTRE LE CONTACT DIRECT DU SPRAY avec la zone non traitée lors de l'application, sauf si une évaluation du risque environnemental local (LERAP) permet une zone non traitée plus étroite, ou une zone de 1m entre l'application et le fossé sec lors de l'application.
Eviter d'appliquer en direction de l'eau.

Stockage et Enlèvement

GARDER ELOIGNE DE LA NOURRITURE, DES BOISSONS ET DES ALIMENTS POUR ANIMAUX.
GARDER ELOIGNE DE LA PORTEE DES ENFANTS.
GARDER DANS SON EMBALLAGE D'ORIGINE dans un endroit sûr, frais et bien ventilé, avec le couvercle bien refermé. Le produit doit être éloigné du gel et la température du lieu de stockage ne devrait pas excéder 25°C. Sous ces conditions, le produit peut rester stable durant deux (2) ans après la date de production.
RINCER MINITIEUSEMENT L'EMBALLAGE en utilisant un appareil de rinçage à pression ou en rinçant manuellement 3 fois. Ajouter des lavages au pulvérisateur au moment du remplissage et de la vidange du produit.

NE PAS REUTILISER LES EMBALLAGES POUR QUELCONQUE AUTRE UTILISATION.

MODE D'EMPLOI

IMPORTANT: Cette information est approuvée comme faisait partie de l'étiquette du produit. Toutes les instructions de cette section doivent être attentivement lues dans le but de pouvoir manipuler en toute sécurité, sereinement et efficacement le produit.

RESTRICTIONS

Eviter les dérives sur les cultures avoisinantes, car des dommages peuvent arriver surtout sur des plantes à feuilles larges.

RESISTANCE

La stratégie de management du risque pour réduire le risque de développement de résistance au produit EVITO T est basée sur plusieurs mesures. Même si ces stratégies sont présentées individuellement, un usage intégré de combinaison de différentes stratégies est possible, bénéfique et souvent implémenté:

- La combinaison de deux substances actives aux modes d'action différents.
- Maintenir le taux recommandé par l'étiquette. Ne pas utiliser de doses réduites. Il est possible que la réduction de la dose entraine le développement de résistance.
- Maximum d'une application par saison. Réduire le nombre de traitement par saison de croissance et appliquer seulement lorsque cela est nécessaire.
- Ajuster le volume de spray volume par acre en se basant sur la taille et le volume des cultures pour aboutir à la meilleure couverture d'application.
- Appliquer des fongicides seulement lorsque qu'il y'a de bonnes conditions d'application.
- Utiliser ensemble des programmes de pulvérisation avec des mélanges et séquences d'autres fongicides avec différents modes d'action.
- Avoir un management intégré des maladies. L'utilisation intégrée de tous types de contre-mesures contre les maladies qui frappent les cultures céréalières n'est pas seulement bénéfique sur le plan environnemental et économique, mais fait également partie d'une stratégie majeure pour éviter ou retarder les résistances aux fongicides. L'utilisation de variétés céréalières résistances aux maladies, les agents de contrôles biologiques et des utilisations hygiéniques appropriées, comme la rotation des cultures et la suppression des parties de plantes infectées, réduit les incidences de maladies et permet le remplacement des fongicides utilisés lors de applications. Cela permet dans les deux cas de réduire le potentiel de résistance spécifique à certains fongicides. Cela permet d'assurer qu'il n y'aura pas de changements défavorables dans la sensibilité d'une maladie à un produit.

CONTROLE DES MALADIES

EVITO T est un fongicide à spectre large utilisé pour le contrôle du développement de la *Sclerotinia sclerotiorum* sur colza, moutarde, caméline, navette, pavot, lin fibre et lin.

INFORMATIONS SPECIFIQUES AUX CULTURES

EVITO T peut être utilisé en toute sécurité sur toutes les variétés de colza, moutarde, caméline, navette, pavot, lin fibre et lin.

Période d'application

Pour la meilleure efficacité du contrôle des maladies, appliquer durant la floraison de BBCH 61 (10% des fleurs sur la grappe principale ouvertes) jusqu'à BBCH70 (chute des pétales).

Dose d'application

Appliquer 0.8 L/ha dans 200-400 d'eau/ha. Utiliser le plus haut volume d'eau pour les cultures denses.

MELANGE ET APPLICATION

Remplir à moitié le réservoir avec de l'eau propre et commencer l'agitation. Ajouter la quantité nécessaire d'EVITO T et ajouter le reste d'eau nécessaire.
Continuer l'agitation jusqu'à la fin de la pulvérisation.
Laver minutieusement le pulvérisateur après utilisation et rincer 3 fois avec de l'eau.

Appendix 3 – Letter(s) of Access

Provided upon request.