REGISTRATION REPORT

Part A

Risk Management

Product code: TRESINE (SAP 884F)

Active Substances: Azoxystrobin 80 g/kg + Dimethomorph 80 g/kg + Folpet 400 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: ASCENZA France

Date: 22/03/2019

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PART A – Risk Management

The company ASCENZA France has requested marketing authorisation in France for the product TRESINE (formulation code: SAP 884F), containing 400 g/kg folpet, 80 g/kg dimethomorph and 80 g/kg azoxystrobin 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 TRESINE (SAP 884F) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of TRESINE (SAP 884F) have been made using endpoints agreed in the EU peer reviews of folpet, dimethomorph and azoxystrobin.

This document describes the specific conditions of use and labelling required for France for the registration of TRESINE (SAP 884F).

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 ASCENZA France's application to market TRESINE (SAP 884F) 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

Folpet

Regulations Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.
Specific provisions of regulation were as follows : PART A Only uses as fungicide can be authorised. PART B In assessing applications to authorise plant protection products containing folpet for uses other than winter wheat Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted. 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 folpet, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 29 September 2006 shall be taken into account. In this overall assessment Member States must pay particular attention to:

— operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment; — the dietary exposure of consumers in view of future revisions of Maximum Residue Levels; — the protection of birds, mammals, aquatic and soil organisms. Conditions of authorisation should include risk mitigation measures. The Member States concerned shall request the submission of further studies to confirm the risk assessment for birds, mammals and earthworms. They shall ensure that the notifiers at whose request folpet has been included in this Annex provide such studies to the Commission within two years from the approval.
An EFSA conclusion is available (EFSA Scientific Report (2009) 297, 1-80). A Review Report is available (SANCO/10032/2006 rev 5, 11 July 2008).

Dimethomorph

Regulations Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.
Specific provisions of regulation were as follows : PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on dimethomorph, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 24 November 2006 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment; — to the protection of birds, mammals and aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate.
An EFSA conclusion is available (EFSA Scientific Report (2006) 82, 1-69). A Review Report is available (SANCO/10040/06 rev 3, 24 November 2006).

Azoxystrobin

Commission Implementing Regulation (EU) No 703/2011 of 20 July 2011 approving the active substance azoxystrobin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

Specific provisions of regulation were as follows :

PART A

Only uses as fungicide may be authorised.

PART B

For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on azoxystrobin and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account.

In this overall assessment Member States shall pay particular attention to:

(1) the fact that the specification of the technical material as commercially manufactured must be confirmed and

supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and

verified against this specification of the technical material;

(2) the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions;

(3) the protection of aquatic organisms. The Member States must ensure that the conditions of authori-

sation include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of confirmatory information as regards the risk assessment on groundwater and aquatic organisms.

The notifier shall submit to the Member States, the Commission and the Authority such information by 31 December 2013

An EFSA conclusion is available (EFSA Journal 2010; 8(4): 1542).

A Review Report is available (SANCO/11027/2011 rev 3, 20 March 2015).

1.3 Regulatory approach

The present application (2018-1117) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)[1] in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[2] – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

According to the French law and procedures, specific conditions of use are set out in the Decision letter.
The French Order of 4 May 2017[3] provides that:

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

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

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

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

[3] 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

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009[4], implementing regulations and French regulations.

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

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011[5], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

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

- an authorisation granted for a "reference" crop applies also for "linked" crops, unless formally stated in the Decision
- the "reference" and "linked" crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "linked" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those "linked" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[7] is to supply "minor" crops with registered plant protection products.

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

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

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of TRESINE (SAP 884F), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

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

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	TRESINE SAP 884F
Authorisation number	N/A : no marketing authorisation granted
Function	fungicide
Applicant	ASCENZA FRANCE

[4] REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

[5] COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

[6] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

[7] SANCO document "guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs": SANCO/ 7525/VI/95 - rev.9

Composition	400 g/kg folpet 80 g/kg dimethomorph 80 g/kg azoxystrobin
Formulation type (code)	Water dispersible granule [Code: WG]
Packaging	N/A : not registered in France

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

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

Physical hazards	No classification required	
Health hazards	Acute Toxicity 4 Skin Sensitisation 1 Eye Irritation 2 Carcinogenicity 2	
Environmental hazards	Aquatic Chronic 1 Aquatic Acute 1	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H332	Harmful if inhaled.
	H317	May cause an allergic skin reaction
	H319	Causes serious eye irritation
	H351	Suspected of causing cancer.
	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)	-	

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

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

N/A: no marketing authorisation granted/withdrawn

2.2.4 Other phrases linked to the preparation

N/A: no marketing authorisation granted/withdrawn

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When the conclusion is "not acceptable" the intended use is highlighted in grey and the main reason(s) reported in the remarks.

GAP rev. 1, date: 2019/03/22

PPP (product name/code):	**TRESINE (SAP 884F)**	Formulation type:	**WG** [a, b]
Active substance 1:	azoxystrobin	Conc. of as 1:	**80 g/kg** [c]
Active substance 2:	dimethomorph	Conc. of as 2:	**80 g/kg** [c]
Active substance 3:	folpet	Conc. of as 3:	**400 g/kg** [c]
Applicant:	**ASCENZA FRANCE**	Professional use:	☒
Zone(s):	southern [d]	Non professional use:	☐
Verified by MS:	yes		

Field of use: fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		e.g. g safener/synergist per ha [f]
1	FR	Wine Grapes	F	Downy mildew (*Plasmopara viticola*) Powdery mildew (*Uncinula necator*) Black-Rot (*Guignardia bidwellii*)	Foliar spray	BBCH 18-77	3	12-14	a) 2.5 b) 7.5	a) 0.2 + 0.2 + 1.0 b) 0.6 + 0.6 + 3.0	100 - 1000	28	Product : 2.5 kg/ha **Not acceptable (Efficacy)**

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey,

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 RISK MANAGEMENT

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

3.1.1 Physical and chemical properties

The formulation TRESINE (SAP 884F) is a Water Dispersible Granule formulation (WG). All studies have been performed in accordance with the current requirements. The appearance of the formulation is solid brown granules with uncharacteristic odour. It is not explosive and has no oxidizing properties. It has a self-ignition temperature of 360-366°C. In aqueous solution (1%), its pH is 6.3 at 25°C. Stability data indicate a shelf life of at least 2 years at ambient temperature in the commercial packagings. Its technical characteristics are acceptable for a WG formulation.

The formulation is not classified for the physical-chemical part.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methods for the determination of active substances and relevant impurities (toluen and Z-isomer, tetrachloromethane, perchloromethyl mercaptan) in the formulation are available and validated.

3.1.2.2 Analytical methods for residues

Analytical methods are available in the monographs/this dossier and validated for the determination of residues of azoxystrobin, dimethomorph and folpet in plants, soil, water (surface and drinking) and air. Analytical methods for the determination of residues of azoxystrobin, dimethomorph and folpet in foodstuff of animal origin are not necessary.

It should be provided for the reapproval of the active substances folpet and dimethomorph:

- a confirmatory method for determination of folpet in plants (high acid content commodities)
- a confirmatory method for determination of dimethomorph in surface water
- a confirmatory method for determination of azoxystrobin in surface water

The active substance dimethomorph is neither irritating, nocive, toxic nor very toxic, hence no analytical method is required for the determination of residues in air.

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

The active substance azoxystrobin is toxic (T), therefore it should be provided an analytical method for the determination of residues of azoxystrobin in tissues and body fluids, validated according the EU guidance SANCO 825/00 rev 8.1.

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

<table>
<tr><td colspan="4">Active Substance: Azoxystrobin</td></tr>
<tr><td>ADI</td><td>0.2 mg kg bw/d</td><td colspan="2">EU agreed endpoint</td></tr>
<tr><td>ARfD</td><td>Non necessary</td><td colspan="2">EU agreed endpoint</td></tr>
<tr><td>AOEL</td><td>0.2 mg/kg bw/d</td><td colspan="2">EU agreed endpoint</td></tr>
<tr><td rowspan="2">Dermal absorption</td><td colspan="3">Default values according to guidance on dermal absorption (Efsa 2012):</td></tr>
<tr><td></td><td>Concentrate
(used in formulation)
80 g/L</td><td>Spray dilution
(used in formulation)
0.2 g/L</td></tr>
</table>

	Dermal absorption endpoints %	**25**	**75**

Active Substance: **Dimethomorph**			
ADI	0.05 mg kg bw/d	EU agreed endpoint	
ARfD	0.6 mg/kg bw/d	EU agreed endpoint	
AOEL	0.15 mg/kg bw/d	EU agreed endpoint	
Dermal absorption	Default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (used in formulation) 80 g/L	Spray dilution (used in formulation) 0.2 g/L
	Dermal absorption endpoints %	**25**	**75**

Active Substance: **Folpet**			
ADI	0.1 mg kg bw/d	EU agreed endpoint	
ARfD	0.2 mg/kg bw/d	EU agreed endpoint	
AOEL	0.1 mg/kg bw/d	EU agreed endpoint	
Dermal absorption	Based on an in vitro/vivo rat/human study performed on formulation or on a similar formulation (*pro rata* correction) (Efsa 2012):		
		Concentrate (tested) 800 g/L	Spray dilution (tested) 3.2 g/L
	In vitro (rat) %	2.6	4.9
	In vitro (human) %	0.4	1.4
		Concentrate (used in formulation) 400 g/L	Spray dilution (used in formulation) 0.8 g/L
	Dermal absorption endpoints %	**1,4**	**6**

3.1.3.1 Acute Toxicity

TRESINE (SAP 884F) containing 80 g/kg azoxystrobin, 80 g/kg dimethomorph and 400 g/kg folpet has a low toxicity in respect to acute oral, dermal toxicity but a high toxicity in respect to acute inhalation, and is irritating to the rabbit eye but is not irritating to the rabbit skin and is a skin sensitizer.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G[8]	Equipment	Application rate kg product/ha (g as/ha)	Spray dilution (L/ha)	Model
Grape	F	Tractor mounted/trailed broadcast air-assisted sprayer	2,5 kg/ha (200 g Azoxystrobin/ha + 200 g Dimethomorph/ha + 1000 g Folpet/ha)	100	BBA
Grape	F	Hand-held sprayer	2,5 kg/ha (200 g Azoxystrobin/ha + 200 g Dimethomorph/ha + 1000 g Folpet/ha)	100	BBA

[8] Open field or glasshouse

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

Crop	Equipment	PPE and/or working coverall	% AOEL Azoxystrobin	% AOEL Dimethomorph	% AOEL Folpet
Grape	Tractor mounted/trailed broadcast air-assisted sprayer	Working coverall and gloves during mixing/loading and application	20	27	19
Grape	Hand-held sprayer	Working coverall and gloves during mixing/loading and application	10	14	12

According to the model calculations, it can be concluded that the risk for the operator using TRESINE (SAP 884F) is acceptable with a working coverall (90% protection factor) and gloves during mixing/loading and application.

Nature of protective clothing and PPE for the operator:

- **Tractor-mounted broadcast air assisted sprayer:**

- **For mixing/loading**
  - Nitrile gloves certified EN 374-3;
  - Working coverall 65% polyester / 35% cotton; minimum 230 g/m²; with water repellent treatment;
  - Long-sleeved apron, Category III Type PB3 worn over the coverall proposed above;
- ***For application* _ Upward spraying**

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

  If application with tractor without cab
  - Protective coverall category III Type 4 with hood;
  - Disposable nitrile gloves certified EN 374-2 during application and in the case of an intervention on application equipment;
- **For equipment cleaning**
  - Nitrile gloves certified EN 374-3;
  - Working coverall 65% polyester / 35% cotton; minimum 230 g/m²; with water repellent treatment;
  - Long-sleeved apron, Category III Type PB3 worn over the coverall proposed above.

- **Hand-held sprayer_outdoor:**

- **For mixing/loading**
  - Nitrile gloves certified EN 374-3;
  - Protective coverall category III Type 4;
- **For application:**
  - Nitrile gloves certified EN 374-3;
  - Protective coverall category III Type 4 with hood;
  - Rubber boots certified EN 13 832-3;
- **For equipment cleaning**
  - Nitrile gloves certified EN 374-3;
  - Protective coverall category III Type 4.

3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to 5% of the AOEL of azoxystrobin, 6% of the AOEL of dimethomorph and 5% of the AOEL of folpet.

It is concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to TRESINE (SAP 884F).

3.1.3.4 Worker Exposure

Workers may have to enter treated areas after treatment for crop harvesting activities. Therefore, estimation of worker exposure was calculated according to EUROPOEM II. Exposure is estimated to 46 % of the AOEL of azoxystrobin, 62% of the AOEL of dimethomorph and 38% of the AOEL of folpet.

It is 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 TRESINE (SAP 884F).

Nature of protective clothing and PPE for the worker:

If the worker would have performed different tasks on the treated crops:

- Nitrile gloves certified EN 374-3;
- Working coverall 65% polyester / 35% cotton; minimum 230 g/m²; with water repellent treatment.

3.1.4 Residues and Consumer Exposure

3.1.4.1 Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation TRESINE (SAP 884F) are presented in paragraph 2.3 in part A.

3.1.4.2 Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 10 mg/kg for folpet, 3 mg/kg for dimethomorph and 2 mg/kg for azoxystrobin as laid down in Reg. (EU) No 396/2005 is not expected.

The chronic and the short-term intakes of folpet and dimethomorph residues and the chronic intake of azoxystrobin residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, France agrees with the authorization of the intended uses.

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

3.1.4.3 Summary of the evaluation

Summary for folpet

Use-No.*	**Crop**	**Plant metabolism covered?**	**Sufficient residue trials?**	**PHI sufficiently supported?**	**Sample storage covered by stability data?**	**MRL compliance** **Reg. (EU) No 251/2013**	**Chronic risk for consumers identified?**	**Acute risk for consumers identified?**	**Comments**
1	Wine grapes	Yes	Yes	Yes	Yes	Yes	No	No	-

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EU) No 251/2013	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
			(13N + 18S)						

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

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

These data were considered for risk assessment.

As the requested use is a perennial crop (grapes), it is not expected to be grown in rotation.

As grapes are not susceptible to enter in the livestock feeding, it is not required to calculate the dietary burden.

Summary for dimethomorph

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EU) N° 51/2014	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	Wine grapes	Yes	Yes (20N + 10S)	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

The effects of processing on the nature of dimethomorph 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.

As the requested use is a perennial crop (grapes), it is not expected to be grown in rotation.

As grapes are not susceptible to enter in the livestock feeding, it is not required to calculate the dietary burden.

Summary for azoxystrobin

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EU) N° 1040/2015	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	Wine grapes	Yes	Yes (11N + 21S)	Yes	Yes	Yes	No	No (ARfD not	-

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EU) N° 1040/2015	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
								necessary)	

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

The effects of processing on the nature of azoxystrobin 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.

As the requested use is a perennial crop (grapes), it is not expected to be grown in rotation.

As grapes are not susceptible to enter in the livestock feeding, it is not required to calculate the dietary burden.

Summary for SAP 884F

Crop	PHI for SAP 884F proposed by applicant	PHI/ Withholding period* sufficiently supported for			PHI for SAP 884F proposed by zRMS	zRMS Comments (if different PHI proposed)
		Folpet	Dimethomorph	Azoxystrobin		
Wine grapes	28 days	Yes	Yes	Yes	28 days	n.a.

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 of the formulation has been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review were used to calculate PECs for the active 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 for the 3 active substances and their metabolites in soil, surface water and groundwater has been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU review or agreed in the assessment based on new data provided.

The results for PEC soil and PECsw for the 3 active substances and their metabolites are used for the eco-toxicological risk assessment.

PECgw for azoxystrobin and its metabolites R401553 and R402173 do not exceed the trigger of 0.1 µg/L. PECgw for the metabolite R234886 do not exceed the trigger of 10 µg/L (not relevant metabolite according to SANCO/221/2000[9]).

PECgw for dimethomorph do not exceed the trigger of 0.1 µg/L.

PECgw for folpet and its metabolites do not exceed the trigger of 0.1 µg/L.

Therefore, no unacceptable risk of groundwater contamination is expected for the intended use.

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.

Implications for labelling resulting from environmental fate assessment:

There are no specific implications for labelling resulting from environmental assessment.

3.1.6 Ecotoxicology

3.1.6.1 Effects on Terrestrial Vertebrates

The risk assessment for terrestrial vertebrates was conducted according to the recommendations of the EFSA Guidance[10] on Risk Assessment for Birds and Mammals.

Birds

Acute and short term:

The acute TER values for azoxystrobin, dimethomorph and folpet are in excess of the corresponding trigger value indicating that their use as TRESINE (SAP 884F) does not lead to unacceptable risk for acute effects on small omnivorous birds at the screening step.

According to the Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA, short-term studies should not be conducted due to their scientific limitations and welfare issues. Therefore no calculations were undertaken for exposure of birds after use of TRESINE (SAP 884F).

Long term:

The long-term TER values, at screening step for azoxystrobin and dimethomorph, and at first tier for folpet, are greater than the trigger of 5, indicating acceptable long-term risk to birds from following application of TRESINE (SAP 884F) at all proposed label rates.

Risks assessments for secondary poisoning are conducted for folpet. This risk assessment demonstrates that the risk posed by secondary poisoning to fish eating birds and earthworms eating birds is acceptable.

The risk to birds from uptake of contaminated drinking water was also assessed and is considered that the risk is acceptable.

Wild mammals

Acute and short term:

The acute TER values of azoxystrobin, dimethomorph and folpet are in excess of the corresponding trigger value for small herbivorous mammals at the screening step indicating acceptable acute risk to this species.

According to the EU guidance document, short-term risk to mammals is not presented as it is covered by the long-term risk assessment.

[9] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. SANCO/221/2000-rev10-final, 25 February 2003.

[10] Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA: EFSA Journal 2009; 7(12): 1438

Long term:

For azoxystrobin, dimethomorph and folpet the long term TER values calculated according the worst case Tier 1 conditions are below the trigger of 5 for small herbivorous mammals for the proposed applications according to the GAP.

In a Tier 2, considering refinements using another focal species, a larger herbivorous species (lagomorph) for azoxystrobin and folpet, it is concluded that the long term and reproductive risk is acceptable for wild mammalian species from contaminated food items when TRESINE (SAP 884F) is applied according to the GAP.

A specific risk assessment for secondary poisoning is considered for folpet. This risk assessment demonstrates that the risk posed by secondary poisoning to fish eating mammals and earthworms eating mammals is acceptable.

The risk to mammals from uptake of contaminated drinking water was also assessed and is considered that the risk is acceptable.

3.1.6.2 Effects on Aquatic Species

Taking in account the results from the studies and the endpoints for the active substances, is possible to conclude that the formulation has similar toxicity to that seen with the active substances azoxystrobin, dimethomorph and folpet. It is therefore considered reasonable the use active substances aquatic substance data for the risk assessment evaluation.

A safe use for the application of TRESINE (SAP 884F) according to the proposed label uses is demonstrated if any of the following mitigation measures are taken into account:

- 20 m for grapes of non-sprayed buffer zone including 5 m of vegetative strip only for the following use: vineyard, 3 applications early.
- 20 m for grapes of non-sprayed buffer zone including 20 m of vegetative strip only for the following use: vineyard, 3 applications late.

3.1.6.3 Effects on Bees and Other Arthropod Species

Honey bees

All hazard quotients are below the HQ trigger value of 50 indicating an acceptable risk to bees from the use as a spray application in grapes.

Therefore, it can be considered an acceptable risk to honey bees.

Terrestrial non-target arthropods

The in-field hazard quotients (HQ) and the effects on reproduction were all below the trigger values recommended by ESCORT2 for all species investigated, thus indicating an acceptable risk to non-target arthropods following application of TRESINE (SAP 884F) for the proposed use.

3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms

The calculations show that acute and long-term TER values are in excess of the corresponding trigger values of 10 and 5, respectively, for each of the active substances and the formulated product indicating that the use of TRESINE (SAP 884F) does not raise any concern for acute and long-term effects on earthworms and collembola.

3.1.6.6 Effects on Soil Non-target Micro-organisms

Considering the lack of effects of each active substance to soil microbial activity (carbon and nitrogen transformations) at rates significantly higher than the proposed rate with TRESINE (SAP 884F), no study on effects of TRESINE (SAP 884F) on soil microbial activity was deemed necessary.

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

The potential effects of TRESINE (SAP 884F) on vegetative vigour have been tested. None of the tested rates of the test product TRESINE (SAP 884F) affected the survival of any of the species and did not affected the final weight and final height of the species. The overall lowest NOER was estimated to be 8.0357 L product/ha based on nominal treatment levels.

Considering the highest rate tested and the maximum predicted exposure rate, the TER value is in excess of the trigger value of 5 for vegetative vigour.

Risk assessment demonstrated an acceptable risk to the active substances with no buffer zone required.

3.1.7 Efficacy

The interest of azoxystrobin in the product has not been demonstrated. 2 of 3 substances have widespread resistance situations in vine southern Europe, azoxystrobin for the mildew and the powdery mildew and dimetomorph for the mildew. This combination lead to apply at least one active substance without sufficient interest and lead to increase too the resistance phenomen.

Then, the interest of the combination of these three substances azoxystrobin, dimethomorph and folpet has not been demonstrated.

3.2 Conclusions arising from French assessment

The practical interest of the product is not demonstrated in France where the risk of resistance is high for 2 substances.

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 : not registered in France

3.4.2 Post-authorisation data requirements

N/A : not registered in France

3.4.3 Label amendments (see label in Appendix 2):

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

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

Appendix 1 – Copy of the French Decision

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agence nationale de sécurité sanitaire alimentation, environnement, travail

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

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

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

Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique ***TRESINE***

de la société *ASCENZA France*

enregistrée sous le *n°2018-1117*

Vu les conclusions de l'évaluation de l'Anses du 15 février 2019,

Considérant l'absence de justification de l'intérêt de l'azoxystrobine dans le produit,

Considérant le niveau de résistance élevée vis-à-vis du mildiou et de l'oïdium, pour deux des trois substances actives du produit,

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.

TRESINE
AMM n°-

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Informations générales sur le produit	
Nom du produit	TRESINE
Type de produit	Produit de référence
Titulaire	ASCENZA France 2/12 Chemin des Femmes, Immeuble l'Odyssée - Bâtiment A - 3ème étage, 91300 MASSY, France
Formulation	Granulé dispersable (WG)
Contenant	400 g/kg - folpel 80 g/kg - azoxystrobine 80 g/kg - diméthomorphe
Numéro d'intrant	9995-2018.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usage	Professionnel

A Maisons-Alfort le, 22 MARS 2019

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

TRESINE
AMM n°-

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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)
12703206 Vigne*Trt Part.Aer.* Black rot	2,5 kg/ha	3/an	28
	Motivation du refus : L'usage est refusé car l'intérêt de la substance active azoxystrobine dans le produit n'a pas été démontrée.		
12703203 Vigne*Trt Part.Aer.* Mildiou(s)	2,5 kg/ha	3/an	28
	Motivation du refus : L'usage est refusé car l'intérêt de la substance active azoxystrobine dans le produit n'a pas été démontrée. La situation de résistance est élevée pour les substances actives azoxystrobine et diméthomorphe.		
12703204 Vigne*Trt Part.Aer.* Oïdium(s)	2,5 kg/ha	3/an	28
	Motivation du refus : L'usage est refusé car l'intérêt de l'azoxystrobine dans le produit n'a pas été démontrée. La situation de résistance est élevée pour la substance active azoxystrobine.		

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

TRESINE®

Granulés dispersibles (WG)

contenant Azoxystrobine 8% + Dimétomorphe 8 % + Folpel 40 % WG

Fongicide anti-mildiou & Black Rot de la vigne,

Autorisation de Mise sur le Marché n° XXXXXX

« RÉSERVÉ À UN USAGE EXCLUSIVEMENT PROFESSIONNEL »

Homologué par:

SAPEC AGRO S.A.

Avenida do Rio Tejo - Herdade das Praias

2910-440 SETÚBAL - PORTUGAL

Tel: +351 265710100

Lot N°.....

Date de fabrication :

TRESINE
Granulés dispersibles contenant Azoxystrobine 8% + Dimétomorphe 8 % + Folpel 40 %
AMM n° XXXXXX

SGH07

SGH08

DANGER

SGH09

H332 **Nocif par inhalation.**
H319 **Provoque une sévère irritation des yeux.**
H351 **Susceptible de provoquer le cancer.**
H317 **Peut provoquer une allergie cutanée.**
H410 **Très toxique pour les organismes aquatiques, entraîne des effets à long terme.**

P102 Tenir hors de portée des enfants.
P260 Ne pas respirer les aérosols.
P262 Éviter tout contact avec les yeux, la peau ou les vêtements.
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.
P305 + 351 + 338 En cas de contact avec les yeux : rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer.
P308 + 313 En cas d'exposition prouvée ou suspectée: consulter un médecin.
P501 Éliminer le contenu/récipient conformément à la réglementation nationale.

Conditions d'emploi
Respectez les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement.
- Délai de rentrée des travailleurs sur la parcelle: 48 heures après traitement
-SP1 : 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 10 mètres comportant un dispositif végétalisé permanent en bordure des points d'eau.

Distributeur :

La fiche de données de sécurité est disponible sur demande chez votre fournisseur de produits phytopharmaceutiques et elle est également téléchargeable et imprimable à partir des sites www.sapecagro.fr et www.quickfds.com.

En cas d'urgence **appelez le n° 15 ou le Centre Anti-poison** (Paris : 01 40 05 48 48) puis signalez vos symptômes au réseau Phyt'attitude, n° vert 0 800 887 887 (appel gratuit depuis un poste fixe).

Fabriqué au PORTUGAL **Contenu : XX L e**

TRESINE ® -Marque déposée par SAPEC AGRO
SAPEC AGRO, S.A. Avenida do Rio Tejo - Herdade das Praias, 2910-440 Setúbal – Portugal

TRESINE ®
Azoxystrobine 8% + Dimétomorphe 8 % + Folpel 40%, WG

PRESENTATION ET MODE D'ACTION

TRESINE ® est un fongicide anti-mildiou qui est doté apporte:
- d'une action originale et complète sur le mildiouet le black-rot
- d'une longue persistance d'action

De plus TRESINE pénètre en moins d'une heure dans la plante, ce qui le met très vite à l'abri du lessivage. Il assure ainsi une excellente protection des feuilles et des grappes de vigne.
Enfin TRESINE ® diffuse dans les feuilles et vers les nouvelles pousses. Les jeunes infections sont ainsi stoppées.

Le diméthomorphe est une molécule diffusante. Le mode d'action biochimique du diméthomorphe n'est pas complètement élucidé, mais il agit en inhibant la biosynthèse des parois cellulaires. Le diméthomorphe est actif contre les mildious et autres maladies du genre *Phytophthora* ou *Plasmopara* (notamment *Plasmopara viticola*).

L'Azoxystrobine appartient à la famille chimique des strobilurines. Elle a un large spectre d'efficacité contre les différentes familles de champignons pathogènes. l'Azoxystrobine agit au niveau des `mitochondries par blocage de la respiration et arrêt de la production d'énergie. Elle agit sur la germination des spores, sur la croissance mycélienne et sur la sporulation. La pénétration dans ´la plante est translaminaire et systémique. L'action ´de l'Azoxystrobine est principalement protectrice; la matière active doit donc ` être appliquée de façon préventive. L'Azoxystrobine assure une protection prolongée contre de nouvelles infections, selon la maladie et le développement foliaire. L'Azoxystrobine en pénétrant dans la plante confère à SURCLASS une très longue persistance d'action : il peut assurer ainsi, en fonction de la croissance des pousses et du développement des maladies, une protection de plusieurs semaines. Enfin les parcelles de vigne traitées avec TRESINE restent vertes plus longtemps.

Le Folpel apporte une protection par contact avec effet multisites agissant sur la germination des spores mildiou (*Plasmopara* sp., *Phytophthora* sp., *Bremia* sp.) et black-rot il dispose d'un effet partiel contre la pourriture grise (Botrytis cinerea (*Guignardia bidwelli*). Le Folpel appartient au groupe chimique des phtalimides. La matière active empêche la germination des spores et la formation du mycélium de certains champignons parasites avant leur pénétration dans les tissus végétaux.

USAGES, DOSES, SPECIFICATIONS D'USAGE, DELAI AVANT RECOLTE (DAR), ZONE NON TRAITEE (ZNT).

Culture	Cibles & Usages	Dose (kg/ha)	Nombre d'applications	DAR (jours)	ZNT (en m)
Vigne	Mildiou	2.5	3 non consécutives	28	10
	Oidium	2.5			
	Black-rot	2.5			

Les limites maximales de résidus sont disponibles sur le site : http://ec.europa.eu/sanco_pesticides/public/index.cfm

RECOMMANDATION D'UTILISATION

VIGNE

TRAITER EN PREVENTIF dès que les risques sont présents (suivre les Bulletins de Santé du Végétal).
Appliquer à une cadence jusqu'à 14 jours, à adapter en fonction de la pousse de la végétation et de la pression parasitaire. En cas de forte pression de la maladie ou de pousse active de la vigne, la cadence ne devra pas dépasser 12 jours.
Le nombre de traitement avec TRESINE ® doit être limité à 3.

- applications non consécutives.
- en préventif.
- pas en dernière application du programme.

Volume de bouillie par hectare, sur vigne :
- Pulvérisateur pneumatique : minimum 100 litres/ha
- Jet porté (aéroconvection) ou jet projeté : minimum 250 l/ha.

TRESINE ® s'applique de BBCH18 à BBCH 77 soit de 8 feuilles ou plus de la vigne à début de la fermeture de la grappe (les baies commencent à se toucher)

TRESINE ® et les fongicides à même mode d'action (QoI) doivent être appliqués sur une même parcelle, au plus trois fois par an.
Si l'année précédente cette recommandation n'a pas été suivie, ne pas dépasser deux traitements annuels de SURCLASS® WG ou de tout autre QoI.

CONDITIONS D'EMPLOI

Remplir la cuve au 3/4 du volume d'eau nécessaire.
Mettre l'agitation en marche avant de verser progressivement la quantité nécessaire de TRESINE, puis compléter avec de l'eau jusqu'au volume final.

Laisser l'agitateur en fonctionnement pendant le trajet et jusqu'à la fin de la pulvérisation. La bouillie ainsi obtenue devra être utilisée dans les 24 heures qui suivent sa préparation

Protection de l'utilisateur lors de la préparation de la bouillie : Gants en nitrile ou néoprène (EN 374), lunettes de sécurité, masque avec filtre A2 P3, bottes de protection marquage S5 ou P5, vêtements de travail de niveau de protection 4.

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

PRECAUTIONS D'EMPLOI

- Emballage :
    - Réemploi de l'emballage interdit ; rincer soigneusement le bidon en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur, ou dans la cuve de rinçage pour l'injection directe.
    - Éliminer les emballages vides *via* une collecte organisée par un service de collecte spécifique.
    - Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.

Important
Respecter les usages, doses, conditions et précautions d'emploi mentionnées sur l'emballage. Elles ont été déterminées en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé.

Conduisez sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces…

Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de vente du Ministère de l'Agriculture.

Compte tenu de la diversité des législations existantes, il est recommandé, dans le cas où les denrées issues des cultures protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur.

Appendix 3 – Letter(s) of Access

Letter(s) of access and, if necessary, an argumentation according to art. 62.4 of Reg (UE) No 1107/2009 have been submitted and are available under request.