REGISTRATION REPORT

Part A

Risk Management

Product code: A74021

Product name(s): SCORE

Chemical active substance(s):

Difenoconazole, 250 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

Label extension according to Art. 51

Minor uses

Applicant: SYNGENTA FRANCE S.A.S.

Date: 2021-02-08

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PART A – Risk Management

The company SYNGENTA FRANCE SAS has requested a label extension in France for the SCORE (formulation code: A74021) according to article 51 Regulation (EC) no 1107/2009[1]

This document describes the specific conditions of use and labelling required for extension of the registration of SCORE (A74021) containing difenoconazole in France.

The conclusions of the risk assessment are based on the already existing registration of the preparation in France. Therefore, the evaluation of the current application is limited to the points not covered by the existing registration.

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

SCORE (A74021) is an emulsifiable concentrate (EC) product containing 250 g/L of difenoconazole, for use as a fungicide for the control of various pests. The aim of this registration application is to gain a label extension for crops of apricots, mangoes and passion fruit.

The complete GAP for the national application in France is provided below, under point 2.3.

1.2 Active substance approval

difenoconazole

Commission Implementing Regulation (EU) No 1100/2011 of 31 October 2011 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substances dicamba, difenoconazole, and imazaquin
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 difenoconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.
An EFSA conclusion is available (EFSA Journal 2011; 9(1): 1967, 17 December 2010). A Review Report is available (SANCO/830/08 rev. 3, 18 May 2020).

[1] 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

1.3 Regulatory approach

The present applications (n°2017-0578 and n°2019-1279) were evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)[2].

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

Since the application is intended for use in France only, the draft Part A was not circulated for comments.

According to the French law and procedures, specific conditions of use are set out in the Decision letter.
The French Order of 4th 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 m;
- unless formally stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

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

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A 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) N°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

There is no new data submitted with this application.

1.5 Letter(s) of access

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2 French Food Safety Agency, Afssa, before 1 July 2010

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, modifié par l'arrêté du 27 décembre 2019.

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

Not relevant for this application.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	SCORE (A74021)
Authorisation number	8800841
Function	fungicide
Applicant	SYNGENTA FRANCE SAS
Composition	250 g/L difenoconazole
Formulation type (code)	Emulsifiable concentrate (EC)
Packaging	Not relevant for extension of authorisation according article 51.

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not relevant for extension of authorisation according article 51.

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

Not relevant for extension of authorisation according article 51.

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

Refer to the decision of product authorisation.

2.2.4 Other phrases linked to the product

Wear suitable personal protective equipment[7]: refer to the Decision of product authorisation.
Re-entry period[8] : refer to the decision of product authorisation.
Pre-harvest interval[9] : o Apricots : 7 days o Mangoes : 7 days o Passion fruit : 14 days
Other mitigation measures :
Spe 3 To protect aquatic organisms respect an unsprayed buffer zone of 20 meters to surface water bodies for the uses on apricots, mangoes and passion fruit.
Bystander and resident protection :For uses on apricots, mangoes and passion fruits, respect an unsprayed zone of 10

[7] If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture
[8] The legal basis for this is **Titre I Article 3** of the French Order of 4th May 2017concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]
[9] According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

meters from the last treated raw and : - areas where bystanders are present during treatment - areas where residents could be present
The label must reflect the conditions of authorisation.

2.3 Restrictions linked to the PPP

The applicant is required to comply with the current applicable standard for PPEs, more specifically standard ISO EN 27065[10] for clothing type PPE

2.4 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.
When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.
Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 2021-02-08

PPP (product name/code):	SCORE / A74021	Formulation type:	Emulsifiable concentrate (EC) (a, b)
Active substance 1:	difenoconazole	Conc. of a.s. 1:	250 g/L (c)
Safener:	/	Conc. of safener:	/
Synergist:	/	Conc. of synergist:	/
Applicant:	SYNGENTA FRANCE SAS	Professional use:	☒
Zone(s):	Southern Zone (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)	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		e.g. g safener/synergist per ha (f)
Minor uses according to Article 51 (zonal uses)													

[10] *Protective clothing – Performance requirements for protective clothing worn by operators applying pesticides and for re-entry workers. EN ISO 27065:2017*

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)	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		e.g. g safener/synergist per ha [f]
1	FR	Apricot (PRNAR)	F	Monilinia: *Monilia laxa* (MONILA), *Monilia fructigena* (MONIFG), *Monilia fructicola* (MONIFC)	spraying	BBCH 60-73	a) 2 b) 2	7	a) 0.3 L/ha b) 0.6 L/ha	a) 75 g sa/ha b) 150 g sa/ha	500-1500	7	**Acceptable**
2	FR	Apricot (PRNAR)	F	Powdery mildew: *Sphaerotheca pannosa var persicae* (SPHRPP), *Sphaerotheca pannosa* (SPHRPP), *Podosphaera tridactyla* (PODOTR)	spraying	BBCH 60-73	a) 2 b) 2	7	a) 0.3 L/ha b) 0.6 L/ha	a) 75 g sa/ha b) 150 g sa/ha	500-1500	7	**Acceptable**
3	FR	Mangoes (MNGIN)	F	Powdery mildew: *Oïdium mangiferae* (OIDIMA)	Spraying	BBCH 69-89	a) 2 b) 2	14	a) 0.45 L/ha b) 0.90 L/ha	a) 112.5 g sa/ha b) 225 g sa/ha	700-1500	7	**Acceptable**
4	FR	Mangoes (MNGIN)	F	Anthracnose: *Pestalotiopsis psidii, Glomerella cingulata, Colletotrichum sp., Botryodiplodia sp.* (PESPSP, PESPPS, GLOMCI, COLLSP, PHYORH, BOTDSP)	Spraying	BBCH 71-89	a) 2 b) 2	14	a) 0.45 L/ha b) 0.90 L/ha	a) 112.5 g sa/ha b) 225 g sa/ha	700-1500	7	**Acceptable**
5	FR	Passion fruit (PAQCO, PAQED, PAQQU)	F	Septoria: *Septoria passifloricola* (SEPTPA)	Spraying	BBCH 71-81	a) 2 b) 2	10	a) 0.20 L/ha b) 0.40 L/ha	a) 50 g sa/ha b) 100 g sa/ha	200-1000	14	**Acceptable**
Minor uses according to Article 51 (interzonal uses)													
-													

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/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

Not relevant for extension of authorisation according article 51.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Not relevant for extension of authorisation according article 51.

3.1.2.2 Analytical methods for residues

Further data for this application are not necessary.

3.1.3 Mammalian Toxicology

The risks for operators, bystanders, residents and workers related to this extension of claimed use are covered by assessment performed during the previous assessment of the product.

The product is already registered in France. If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents will not be expected for uses on passion fruit.

Concerning mangoes uses (0,45 L/ha), the risks for operators, bystanders and workers are not covered by previous assessments at 0.3 L/ha on peaches, plums, cherries and 0.15 L/ha on apples.

Risk assessment for mangoes uses must be carried on.

3.1.3.1 Operator exposure

Considering proposed uses, operator systemic exposure was estimated using the EFSA model[11]:

		difenoconazole	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL (RVNAS)[12]**
Tractor mounted boom spray application outdoors to high crops Application rate: 0.45 L/ha or 0.1125 kg difenoconazole/ha			
EFSA Operator Model (75th quantile regression) Body weight: 60 kg	Work wear and gloves during mixing and loading and application	0.0022	1.4%

According to the model calculations, it can be concluded that the risk for the operator using A7402T is acceptable with a working coverall and gloves during mixing/loading and application.

3.1.3.2 Worker exposure

Workers may have to enter into treated areas after treatment for crop searching, reaching and picking task..
Therefore, estimation of worker exposure was calculated according to EFSA model. Exposure is summarised below:

[11] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)
[12] RVNAS : Reference value non acutely toxic active substances.

		difenoconazole	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AAOEL**
Searching, reaching and picking Outdoor Work rate: 8 hours/day DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		2 x 0.1125 kg a.s./ha	
Body weight: 60 kg	Work wear (arms, body and legs covered) TC: 2250 cm²/person/h	0.0075	4.7%

It is concluded that there is no unacceptable risk anticipated for the worker.

3.1.3.2 Bystander exposure

Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set[13].
Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): "*No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure*."

3.1.3.2 Resident exposure

Residential exposure was assessed according to EFSA model. An acceptable risk was determined for residents (adult and child) with a buffer zone of 10 meters and without drift reduction technology.

		difenoconazole	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to high crops Buffer zone: 10m Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		2 x 0.1125 kg a.s./ha	
Resident child Body weight: 10 kg	**Sum (mean)**	0.0029	1.8%
Resident adult Body weight: 60 kg	**Sum (mean**)	0.0012	0.75%

It is concluded that there is no unacceptable risk anticipated for the bystander and the resident.

3.1.4 Residues and Consumer Exposure

[13] Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

The applicant submitted new residue trials on apricots in the framework of this application which were data already assessed by EFSA[14] in 2017 in the frame of a request for MRL modification on apricot).

The applicant submitted new residue trials on mangoes and passion fruit in the framework of this application.

Apricots:

The studies on apricots are summarised in the Table below.

Crop (trial GAPs)	Region/ indoor(a)	Residue levels observed in the supervised residue trials (b) (mg/kg)	Comments	HR (c) (mg/kg)	STMR (d) (mg/kg)	Current EU MRL Reg. (EU) 2019/552 (mg/kg)	MRL compliance
Apricots (2x112.5 g/ha, PHI 7 days)	SEU	0.10, 0.14, 0.16,0.16, 0.17,0.3, 0.35, 0.37	MRL OECD: 0.65/0.7 (unrounded/ rounded) Underlined: higher residues at a longer PHI of 10 days	0.37	0.17	0.7	Yes

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Individual residue levels considered for MRL calculation are reported in ascending order and refer to difenoconazole only. Residues of TDMs are not reported.
(c): HR: Highest residue level according to the residue definition for risk assessment.
(d): STMR: Median residue level according to residue definition for risk assessment.

Apricots are major crop in SEU (**SANCO 7525/VI/95 rev. 10.3)** and are grown in south of France only. Therefore, 8 SEU residue trials are required. Available residue trials were conducted in SEU and support intended GAP (2 x 75 g a.s./ha PHI 7 days for France) even if they were performed according to more critical GAP.

The data submitted show that no exceedance of the MRLs will occur.

The data available are considered sufficient for risk assessment. An exceedance of the current MRL for difenoconazole as laid down in Reg. (EU) 396/2005 is not expected.

The short-term intake of difenoconazole residues resulting from the uses proposed in the framework of this application are unlikely to present a public health concern.

Using PRIMo rev. 3, an unacceptable chronic risk for consumer is identified (116 % ADI). Since intended use on apricots is not a major contributor to the exposure (use on apricots lead to 0.65% of ADI for DE child). Moreover, active substance approval re-assessment is in progress at EU level and it will confirm that no unacceptable chronic risk for consumer is expected.
According to available data, no specific mitigation measures should apply.

Moreover, considering triazole derivative metabolite (TDMs: triazole acetic acid (TAA), triazole alanine (TA), 1,2,4-triazole (1,2,4-T) and triazole lactic acid (TLA)), no analysis of TDMs occur in provided residue trials. However, the conclusions of the assessment published by EFSA 2018 as part of the confirmatory data on common metabolites of triazoles (TDM), based on the available information, do not identify a risk to the consumer for the active substance difenoconazole. As a conclusion, no risk for the consumer is expected but additional data is required in post authorisation.

Mangoes:

The studies on mangoes are summarised in the Table below.

[14] Reasoned opinion on the modification of the existing maximum residue levels for difenoconazole in various crops», EFSA Journal 2017, 15(7):4893 [33 p.]

Table : Summary of data supporting the intended uses of A7402T and conformity to existing MRL

Commodity	F or G	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)[a]	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL Reg. (EU) 2018/832 (mg/kg) and SANTE/11196/2018)	MRL compliance
Mangoes	Field	Outside EU (Brazil)	Trials GAP: 3 x 0.125 kg a.s./ha, PHI 7 d **2 x 0.025, 0.035, 0.04**	**0.03**	**0.04**	**0.094**	**0.1**	**Yes**

(a): Definition of residue for enforcement and risk assessment are the same: difenoconazole

Mango is a minor crop (**SANCO 7525/VI/95 rev. 10.3)** and therefore require four trials in world. Available residue trials were conducted in Brazil and support intended GAP in this submission (2 x 112.5 g a.s./ha PHI 7 days for France) even if they were performed according to more critical GAP.

It is therefore concluded that sufficient trials are available to support the proposed use of A7402T on mangoes.

The data submitted show that no exceedance of the MRLs will occur. The uses are considered acceptable.

Passion fruit:

The studies on passion fruits are summarised in the Table below.

Table 3.1-2: Summary of data supporting the intended uses of A7402T and conformity to existing MRL

Commodity	F or G	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)[a]	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL Reg. (EU) 2018/832 (mg/kg) and SANTE/11196/2018	MRL compliance
Passion fruit	Field	Outside EU (Brazil)	Trials 4 x 0.03 kg a.s./ha, PHI 7 d **ND, 2 x <0.01, 0.04** Trials GAP: 4 x 0.1 kg a.s./ha, PHI 14 d **<0.02**	**0.010**	**0.04**	**0.07**	**0.1**	**Yes**

(a): Definition of residue for enforcement and risk assessment are the same: difenoconazole

Passion fruit is a minor crop (**SANCO 7525/VI/95 rev. 10.3)** and therefore require four trials in world. Available residue trials were conducted in Brazil and support intended GAP in this submission: 2 x 50 g a.s./ha PHI 14 days for France.

It is therefore concluded that sufficient trials are available to support the proposed use of A7402T on passion fruits.

The data submitted show that no exceedance of the MRLs will occur. The uses are considered acceptable.

As a conclusion, the data available are considered sufficient for risk assessment. An exceedance of the current MRLs for difenoconazole as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of difenoconazole residues resulting from the uses proposed in the framework of this application are unlikely to present a public health concern.

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

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

Moreover, considering triazole derivative metabolite (TDMs: triazole acetic acid (TAA), triazole alanine (TA), 1,2,4-triazole (1,2,4-T) and triazole lactic acid (TLA)), no analysis of TDMs occur in provided residue trials. However, the conclusions of the assessment published by EFSA 2018 as part of the confirmatory data on common metabolites of triazoles (TDM), based on the available information, do not identify a risk to the consumer for the active substance difenoconazole. As a conclusion, no risk for the consumer is expected but additional data is required in post authorisation.

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. The risk assessment for this minor extension of uses is covered by the risk assessment provided for the major uses in SCORE (A74021) (2012-0465). Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

Similar mitigation measures as defined for previous risk assessment apply.

3.1.6 Ecotoxicology

The risk for this minor extension of uses for non-target organisms is covered by the risk assessment provided for the major uses in SCORE (A74021) (2012-0465). Thus, the risk for non-target organisms is acceptable for all non-target organisms and mitigation measures are required for aquatic organisms.

3.1.7 Efficacy

According to Article 51 of Regulation (EC) No 1107/2009, the efficacy assessment and the absence of any phytotoxicity risk on the crop is not necessary.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, **an authorisation can be granted** as proposed in Appendix 1 – Copy of the product Decision.

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

3.3.1 Post-authorisation data requirements

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

- 8 additional southern residue trials on apricots supporting intended GAP with analysis of TDMs (1,2,4-T, TA, TAA, TLA) have to be provided in post registration.
- 4 additional southern residue trials on mangoes supporting intended GAP with analysis of TDMs (1,2,4-T, TA, TLA, TAA) have to be provided in post registration.
- 4 additional southern residue trials on passion fruit supporting intended GAP with analysis of TDMs (1,2,4-T, TA, TLA, TAA) have to be provided in post registration.

Appendix 1 – Copy of the French Decision

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Décision relative à des demandes d'extensions d'usages 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 les demandes d'extensions d'usages mineurs du produit phytopharmaceutique ***SCORE***

de la société *SYNGENTA FRANCE SAS*

enregistrées sous les *n°2017-0578 et n°2019-1279*

Vu les conclusions de l'évaluation de l'Anses du 26 novembre 2020, relatives à la demande d'extension d'usages mineurs sur abricotier,

Vu les conclusions de l'évaluation de l'Anses du 26 novembre 2020, relatives à la demande d'extension d'usages mineurs sur fruits de la passion et manguier,

L'autorisation de mise sur le marché du produit référencé ci-après **est étendue** aux usages décrits dans la présente décision.

La présente décision s'applique sans préjudice des autres dispositions applicables.

Avertissement :

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.

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Informations générales sur le produit	
Noms du produit	SCORE BOGARD SCORENET MAVITA 250 EC
Type de produit	Produit de référence
Titulaire	SYNGENTA FRANCE SAS 1228 Chemin de l'Hobit 31790 Saint Sauveur France
Formulation	Concentré émulsionnable (EC)
Contenant	250 g/L - difénoconazole
Numéro d'intrant	8800841
Numéro d'AMM	8800841
Fonction	Fongicide
Gamme d'usage	Professionnel

L'échéance de validité de la présente décision correspond à celle de l'autorisation du produit.

La présente décision peut être retirée ou modifiée si des éléments le justifient.

A Maisons-Alfort, le 08 FEV. 2021

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)

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ANNEXE I : Modalités d'autorisation du produit

Liste des nouveaux usages autorisés
En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
00807009 Fruit de la passion* Trt Part.Aer.*Septoriose(s)	**0,2 L/ha**	**2/an**	entre les stades BBCH 71 et BBCH 81	14	20	-	-	-
	Usage autorisé dans le cadre de l'article 51 du règlement (CE) n°1107/2009. Intervalle minimum entre les applications : 10 jours.							
00810004 Manguier*Trt Part.Aer.* Anthracnose(s)	**0,45 L/ha**	**2/an**	entre les stades BBCH 71 et BBCH 89	7	20	-	-	-
	Deux applications maximum par culture sur l'ensemble du complexe de maladies. Usage autorisé dans le cadre de l'article 51 du règlement (CE) n°1107/2009. Intervalle minimum entre les applications : 14 jours.							
00810005 Manguier*Trt Part.Aer.* Oïdium(s)	**0,45 L/ha**	**2/an**	entre les stades BBCH 69 et BBCH 89	7	20	-	-	-
	Deux applications maximum par culture sur l'ensemble du complexe de maladies. Usage autorisé dans le cadre de l'article 51 du règlement (CE) n°1107/2009. Intervalle minimum entre les applications : 14 jours.							

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Liste des nouveaux usages autorisés
En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
12553233 Pêcher*Trt Part.Aer.* Monilioses	**0,3 L/ha**	**2/an**	entre les stades BBCH 60 et BBCH 73	7	20	-	-	-
	Uniquement sur abricotier. Deux applications maximum par culture sur l'ensemble du complexe de maladies. Usage autorisé dans le cadre de l'article 51 du règlement (CE) n°1107/2009. Intervalle minimum entre les applications : 7 jours.							
12553224 Pêcher*Trt Part.Aer.* Oïdium(s)	**0,3 L/ha**	**2/an**	entre les stades BBCH 60 et BBCH 73	7	20	-	-	-
	Uniquement sur abricotier. Deux applications maximum par culture sur l'ensemble du complexe de maladies. Usage autorisé dans le cadre de l'article 51 du règlement (CE) n°1107/2009. Intervalle minimum entre les applications : 7 jours.							

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Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

Il convient de rappeler que l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections complémentaires comme les protections individuelles.

En tout état de cause, le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage). Les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

Pour l'opérateur, porter

Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur pneumatique

• pendant le mélange/chargement

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3) ;

• pendant l'application

Si application avec tracteur avec cabine

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;

Si application avec tracteur sans cabine

- Combinaison de protection de catégorie III type 4 avec capuche ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) 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 NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité.

Pour le travailleur, porter

- Un EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 et, en cas de contact avec la culture traitée, des gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A).

Délai de rentrée en application de l'arrêté du 4 mai 2017

- 24 heures.

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Protection des personnes présentes et des résidents (au sens du règlement (UE) N°284/2013)

Pour les usages sur abricotier, "manguier" et "fruits de la passion", respecter une distance d'au moins 10 mètres entre le dernier rang traité et :
- l'espace fréquenté par les personnes présentes lors du traitement ;
- l'espace susceptible d'être fréquenté par des résidents.

Respect des limites maximales de résidus (LMR)

Pour chaque usage figurant dans la liste des usages autorisés, les conditions d'utilisation du produit permettent de respecter les limites maximales de résidus.

Protection de l'environnement (milieux, faune et flore)

Protection de la faune
- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 20 mètres par rapport aux points d'eau, pour les usages sur abricotier, "fruits de la passion" et "manguier".

Exigences complémentaires post-autorisation

A défaut de transmission de ces données dans les délais impartis à compter de la date de la présente décision, la présente décision pourra être retirée ou modifiée.

Détail de la demande post autorisation	Délai (mois)	Récurrence (mois)
Fournir 8 essais résidus sur abricotier, réalisés dans la zone sud de l'Europe, avec la détermination des métabolites 1,2,4-T, TA, TLA et TAA.	24	-
Fournir 4 essais résidus sur fruits de la passion, réalisés dans la zone sud de l'Europe, avec la détermination des métabolites 1,2,4-T, TA, TLA et TAA.	24	-
Fournir 4 essais résidus sur manguier, réalisés dans la zone sud de l'Europe, avec la détermination des métabolites 1,2,4-T, TA, TLA et TAA.	24	-

Recommandations relatives à l'étiquette du produit

Il est recommandé de faire figurer l'information suivante sur l'étiquette :
- Pour les usages mineurs dont l'autorisation a été accordée dans le cadre de l'article 51 du règlement (CE) n°1107/2009, l'attention de l'utilisateur est attirée sur les risques éventuels de phytotoxicité ou de manque d'efficacité.
  Avant tout emploi du produit, il est recommandé à l'utilisateur de s'assurer de son efficacité ou de l'absence de risques éventuels de phytotoxicité sur la culture.

Les autres modalités d'autorisation du produit restent inchangées.

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

SCORE (AMM n°8800841)
Extension d'usage sur abricotier
Projet d'étiquette

Les tableaux ci-dessous viennent se substituer aux tableaux de l'étiquette existante.

Etiquette DOS ou Pavé réglementaire :

CULTURES AUTORISEES :	CIBLES	DOSES AUTORISEES	DAR
Vigne, arbres fruitiers, fruits de la passion, cultures légumières, porte-graines, PPAMC, lin, ornementales	Voir tableau des usages à l'intérieur du livret		

Etiquette Livret (pages 3 à 5 du PDF joint) :

CULTURES AUTORISEES, UNIQUEMENT :	CIBLES	DOSES AUTORISEES	NOMBRES MAX. D'APPLICATIONS[1]	STADES MIN. D'APPLICATION	DAR[2]	ZNT AQUATIQUE[3] et DVP[4]
Vigne						
Vigne - raisin de cuve et raisin de table	Oïdium Black-rot Rougeot parasitaire (brenner)	0,2 L/ha *(Dose recommandée = 0,12 L/ha)*	2 / an et une 3ème application possible pour lutter spécifiquement contre le black rot	-	21 jours	5 m
Cultures fruitières						
Pommier Poirier Cognassier Nashi Pommette Néflier	Tavelure	0,15 L/ha	3 / an	-	21 jours	20 m
Pêcher Nectarinier, Abricotier	Oïdium Moniliose sur fleurs et rameaux	0,3 L/ha	2 /an	-	7 jours	20 m
Prunier	Moniliose sur fleurs et rameaux	0,3 L/ha	3 /an	-	10 jours	20 m
Cerisier	Moniliose sur fleurs et rameaux	0,3 L/ha	2 / an	-	7 jours	20 m
Cultures légumières						
Tomates *Plein champ et sous abri*	Pourriture des fruits Alternaria Cladosporiose	0,5 L/ha	3 / an	BBCH 19	7 jours	5 m (dont DVP 5 m)

Chicorée Witloof et chicorée à café - Production de racines	Rouille Oïdium Alternaria	0,5 L/ha	1 / an	-	30 jours	5 m
Asperge	Rouille *Stemphylium vesicarium*	0,5 L/ha	3 / an	Utilisation en post-récolte des turions et à partir du stade BBCH 39		5 m (dont DVP 5 m)
Carotte Céleri rave Cerfeuil tubéreux Panais Persil à grosse racine Raifort Topinambour Salsifis	Alternaria Maladie des taches foliaires Septoriose Oïdium	0,5 L/ha	3 / an	BBCH 39	14 jours	5 m
Céleri branche Fenouil	Septoriose	0,5 L/ha	3 / an	BBCH 39	14 jours	5 m
Chou de Bruxelles Chou pommé	Alternaria *Mycosphaerella brassicicola* Phoma lingam	0,5 L/ha	3 / an	BBCH 19	21 jours	5 m (dont DVP 5 m)
Chou-fleur Brocoli	Alternaria *Mycosphaerella brassicicola* Phoma lingam	0,5 L/ha	3 / an	BBCH 19	14 jours	5 m (dont DVP 5 m)
Chou vert (non pommé) Chou chinois	Alternaria *Mycosphaerella brassicicola* Phoma lingam	0,5 L/ha	3 / an	BBCH 19	21 jours	5 m (dont DVP 5 m)
Betterave potagère Feuilles de bettes	Cercosporiose Maladie des taches foliaires Ramulariose Rouille	0,5 L/ha	2 / an	BBBCH 39	28 jours	5 m
Cultures porte-graines						
Cultures florales porte-graine Cultures potagères porte-graine PPAMC(5) porte-graine *Plein champ et sous abri*	Phoma	0,5 L/ha	2 / an	BBBCH 39	-	5 m (dont DVP 5 m)
Légumineuses fourragères porte-graine *Plein champ et sous abri*	Rouille	0,5 L/ha	2 / an	BBBCH 39	-	5 m (dont DVP 5 m)

PPAMC[6]						
Fines herbes (persil, cerfeuil et feuilles de céleri) Infusions (feuilles, fleurs, racines) PPAM non alimentaires	Maladie des taches foliaires	0,5 L/ha	3 / an	BBBCH 39	14 jours	5 m (dont DVP 5 m)
Lin						
Lin oléagineux et lin textile	Phoma Oïdium Brunissure *(Polyspora linicola)* Septoriose	0,5 L/ha	2 / an	BBBCH 19	60 jours	5 m
Cultures ornementales						
Arbres et arbustes *Plein champ et sous abri*	Black-rot Brunissures Maladies des taches foliaires Moniliose des fleurs et rameaux Maladies des ramules et des aiguilles Oïdium	0,5 L/ha	2 par culture et par an	-	-	arbustes : 5 m arbres 5 m
Cultures florales et plantes vertes *Plein champ et sous abri*	Alternarioses Anthracnoses Cercosporioses Ramulariosses Oïdium Rouilles	0,5 L/ha	3 par culture et par an	-	-	5 m (dont DVP 5 m)
Rosiers *Plein champ et sous abri*	Maladies des taches noires *(Stemphylium)* Oïdium Rouille	0,5 L/ha	3 par culture et par an	-	-	5 m (dont DVP 5 m)

(1) Nombre maximal d'applications sur la culture afin de limiter les risques de résistances. (2) Délai avant récolte. (3) Zone non traitée par rapport à un point d'eau temporaire ou permanent. (4) Dispositif végétalisé permanent. (5) PPAMC : Plantes à Parfum, Aromatiques, Médicinales et Condimentaires.

Appendix 3 – Letter(s) of Access

Not applicable