

REGISTRATION REPORT

Part A

Risk Management

Product code: (A9424B)

Product name: SPYRALE

Active Substance(s):
difenoconazole, 100 g/L
fenpropidin, 375 g/l

COUNTRY:
FRANCE

NATIONAL ASSESSMENT
Application for a label extension
according to Art. 51
-
Minor uses

Applicant: SYNGENTA FRANCE S.A.S.

Date: 2017-01-24

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PART A – Risk Management

The company SYNGENTA FRANCE S.A.S has requested a label extension according to article 51 in France for the product SPYRALE (A9424B).

This document describes the specific conditions of use and labelling required for extension of the registration of SPYRALE (A9424B) containing difenoconazole and fenpropidin in France.

The risk assessment conclusions 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

SPYRALE (A9424B) is an emulsifiable concentrate formulation (EC) containing 100 g/L of difenoconazole and 375 g/L of fenpropidin, for use as a fungicide for the control of leaf spot disease. The aim of this registration application is to gain a label extension for crops of beet for seed production.

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

1.2 Active substance approval

Fenpropidin

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 fenpropidin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 March 2008 shall be taken into account.

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

- the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment,
- the protection of aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zone.

The Member States concerned shall request the submission of:

- information to further address the long-term risk to herbivorous and insectivorous birds arising from the use of fenpropidin.

They shall ensure that the notifier provides such confirmatory data and information to the Commission within two years from the approval

An EFSA conclusion is available (EFSA Scientific Report (2007) 124, 1-84.)

A Review Report is available (SANCO/3784/08 – rev.2, 20 November 2012).

Difenoconazole

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 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.

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

- the protection of aquatic organisms.

Conditions of use shall include adequate risk mitigation measures, where appropriate.

An EFSA conclusion is available (EFSA Journal 2011;9(1):1967 [71 pp.])

A Review Report is available (SANCO/830/08 – rev.3, 13 December 2013).

1.3 Regulatory approach

The present application (n°2017-1749) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)¹.

The current document based on Anses' assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009², 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 2017³ 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°546/2011⁴, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

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

- an authorisation granted for a « reference » crop applies also for “linked” crops unless formally stated in the decision
- 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

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

² 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

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 <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGR1632554A/jo/texte>

⁴ COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

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

conclusion is reached on the acceptability of the intended uses on those “linked” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁶ is to supply “minor” crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant. The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

1.4 Data protection claims

There is no new data submitted with this application.

1.5 Letter(s) of access

Not relevant for this application.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	SPYRALE (A9424B)
Authorisation number	9300487
Function	Fungicide
Applicant	SYNGENTA FRANCE S.A.S
Composition	100 g/L difenoconazole, 375 g/L fenpropidin
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 authorization.

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

2.2.4 Other phrases linked to the preparation

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 : not relevant.
○ Crops for seed production should not be used as food or feed. Other mitigation measures: refer to the previous risk assessment of product (dossier n°2012-0606) authorisation.
The label must reflect the conditions of authorisation.

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 2017 concerning 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.

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 RMS. Those uses are then granted in France.

When the conclusion is “not acceptable” or “not finalised”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.

When a use is “acceptable” with GAP restrictions, the modifications of the GAP are in bold.

Use should be crossed out when the applicant no longer supports this use.

PPP (product name/code) **SPYRALE (A9424B)**

Difenoconazole

fenpropidin

Applicant:

Syngenta

Zone(s):

France

Formulation type: **EC**

Conc. of as 1: **100 g/L**

Conc. of as 1: **375 g/l**

professional use ☒

non professional use ☐

Verified by MS: **yes**

1	2	3	4	5	6	7	8	9	10	11	12	13
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G 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 (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	FR	Beet for seed production	F	Leaf spot disease (<i>Ramularia</i> <i>sp.</i> , <i>Puccinia sp.</i> , <i>Cercospora</i> <i>sp.</i> , <i>Erysiphe betae</i>)	Foliar	BBCH 50 - 59	a) 2 b) 2	a) 1 L/ha b) 2 L/ha	a) 100 g difenoconazol/ha 375 g fenpropidin/ha b) 200 g difenoconazol/ha 750 g fenpropidin/ha	300	--	Acceptable Restrictions (see 2.2.4)

Remarks:

- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
- (c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
- (f) All abbreviations used must be explained
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated

- (i) g/kg or g/l
- (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- (k) The minimum and maximum number of application possible under practical conditions of use must be provided
- (l) PHI - minimum pre-harvest interval
- (m) Remarks may include: Extent of use/economic importance/restrictions

3 RISK MANAGEMENT

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

3.1.1 Physical and chemical properties

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 preparation 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 details of personal protective equipment for operators and workers, refer to the Decision of product authorisation.

3.1.4 Residues and Consumer Exposure

Not relevant for this application (seed production). However crops for seed production should not be used as food or feed items.

3.1.5 Environmental fate and behaviour

According to previous risk assessments performed by Anses, no unacceptable risk for groundwater is expected. Similar mitigation measures as defined for previous risk assessment apply.

3.1.6 Ecotoxicology

According to previous risk assessments performed by Anses, no unacceptable risk for terrestrial and aquatic non-target organisms is expected. Similar mitigation measures as defined for previous risk assessment apply.

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

No further information is required.

Appendix 1 – Copy of the French Decision



Décision relative à une demande d'extension d'usage d'un produit phytopharmaceutique

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

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

*Vu la demande d'extension d'usage mineur du produit phytopharmaceutique **SPYRALE***

de la société SYNGENTA FRANCE SAS

enregistrée sous le n°2017-1749

Vu les conclusions de l'évaluation de l'Anses du 7 décembre 2017,

L'autorisation de mise sur le marché du produit référencé ci-après **est étendue** à compter de la présente décision aux usages fixés par 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.



Informations générales sur le produit	
Nom du produit	SPYRALE
Type de produit	Produit de référence
Titulaire	SYNGENTA FRANCE SAS 12 Chemin de l'Hobit 31790 Saint Sauveur France
Formulation	Concentré émulsionnable (EC)
Contenant	100 g/L - difénoconazole 375 g/L - fenpropiidine
Numéro d'intrant	9300487
Numéro d'AMM	9300487
Fonction	Fongicide
Gamme d'usages	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

24 JAN. 2018

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)



ANNEXE I : Modalités d'autorisation du produit

Liste des usages autorisés							
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)
00607005 Porte graine - Betterave industrielle et fourragère* Trt Part.Aer.* Maladies des taches foliaires	1 L/ha	2/an	entre les stades BBCH 50 et BBCH 59	Non applicable	50 (dont DVP 20)	-	-

DVP : Dispositif Végétalisé Permanent.

SPYRALE
AMM n°9300487

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Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- 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 individuelles
- 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

• Pendant le mélange/chargement

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

• Pendant l'application

Si application avec tracteur avec cabine

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;

Si application avec tracteur sans cabine

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;

• Pendant le nettoyage du matériel de pulvérisation

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

Pour le travailleur, porter

- Une combinaison de travail tissée en polyester 65% / coton 35% avec un grammage d'au moins 230 g/m² ou plus avec traitement déperlant.



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

- 24 heures

Respect des limites maximales de résidus (LMR)

Ne pas utiliser les sous-produits des cultures porte-graines traitées en alimentation humaine ou animale.

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

Protection de la faune

La phrase :

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 50 mètres par rapport aux points d'eau comportant un dispositif végétalisé permanent non traité d'une largeur de 20 mètres en bordure des points d'eau, dans le cas de 2 applications de 1 L/ha entre les stades BBCH 39 et BBCH 49.

Est remplacée par :

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 50 mètres par rapport aux points d'eau comportant un dispositif végétalisé permanent non traité d'une largeur de 20 mètres en bordure des points d'eau, dans le cas de 2 applications de 1 L/ha effectuées après le stade BBCH 39.

La phrase :

- SPe 2 : Pour protéger les organismes aquatiques, ne pas appliquer la préparation SPYRALE sur sols artificiellement drainés, dans le cas de 2 applications de 1 L/ha entre les stades BBCH 39 et BBCH 49.

Est remplacée par :

- SPe 2 : Pour protéger les organismes aquatiques, ne pas appliquer le produit SPYRALE sur sols artificiellement drainés, dans le cas de 2 applications de 1 L/ha après le stade BBCH 39.

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

SPYRALE (AMM n° 9300487) Extension d'usage sur betterave porte graine – Projet d'étiquette

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

Etiquette DOS ou Pavé réglementaire :

CULTURES AUTORISEES, UNIQUEMENT :	CIBLES	DOSES AUTORISEES	DELAI AVANT RECOLTE
Betterave industrielle	Cercosporiose	1 L/ha	28 jours
	Oïdium	1 L/ha	28 jours
	Ramulariose	1 L/ha	28 jours
	Rouille	1 L/ha	28 jours
Betterave fourragère	Cercosporiose	1 L/ha	28 jours
	Oïdium	1 L/ha	28 jours
	Ramulariose	1 L/ha	28 jours
	Rouille	1 L/ha	28 jours
Betterave porte graine	Cercosporiose	1 L/ha	-
	Oïdium	1 L/ha	-
	Ramulariose	1 L/ha	-
	Rouille	1 L/ha	-

Condition d'emploi réglementaire:

Dans le cas de 2 applications de 1 L/ha : respecter une ZNT aquatique de 50 m dont 20 m de DVP et ne pas appliquer sur sols artificiellement drainés. Dans le cas d'une seule application de 0,9 L/ha : respecter une ZNT aquatique de 20 m dont 5 m de DVP. L'application du produit dans les conditions d'1 application annuelle à 0,9 L/ha, permet de limiter les mesures de protection des organismes aquatiques.

Etiquette Livret (page 3 du PDF joint) :

CULTURES AUTORISEES, UNIQUEMENT :	CIBLES	DOSES AUTORISEES	NOMBRES MAX. D'APPLICATIONS	Délai Avant Récolte ou Période d'application	ZNT ^{**}	DVP ^{***}
Betterave industrielle	Cercosporiose Oïdium Ramulariose Rouille	1 L/ha	2	28 jours	Dans le cas de 2 applications de 1 L/ha : respecter une ZNT aquatique de 50 m Dans le cas d'une seule application de 0,9 L/ha : respecter une ZNT aquatique de 20 m	Dans le cas de 2 applications de 1 L/ha : 20 mètres en bordure des points d'eau temporaires ou permanents Dans le cas d'une seule application de 0,9 L/ha : 5 mètres en bordure des points d'eau temporaires ou permanents
Betterave fourragère	Cercosporiose Oïdium Ramulariose Rouille	1 L/ha	2	28 jours		
Betterave porte graine	Cercosporiose Oïdium Ramulariose Rouille	1 L/ha	2	-		

^{*} Avec accord de l'organisme

^{**} Zone Non Traitee

^{***} Dispositif Végétalisé Permanent non traité

Appendix 3 – Letter(s) of Access

Not applicable