

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: **SNS-F-11**

Product names: **DISFERA 90 EC/LIPOSTAR 90 EC**

Chemical active substance:

Difenoconazole 90 g/l

Central Zone

Zonal Rapporteur Member State: **Poland**

CORE ASSESSMENT

(authorization)

Applicant: **Synthos Agro Sp. z o.o.**

Submission date: 01/2024

MS Finalisation date: 07/2024; 10/2024; 11/2024

Version history

When	What
01/2024	Initial submission.
07/2024	ZRMs evaluated dRR submitted by Applicant.
10/2024	The Final Registration Report
11/2024	The final RR after the second round of commenting

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

On 1 January 2014 data protection period for active substance **Difenoconazole** has been terminated. Taking into account above applicant shall be exempted from supplying the test and study in accordance with Article 34 of Regulation (EC) No. 1107/2009.

0.1.2 Details of zRMS(s) and concerned MS

Documentation submitted only in Poland.

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
Central zone	Poland	Not applicable

0.1.3 Regulatory history of the active(s)

0.1.3.1 Difenoconazole

Table 0.1-2: Summary of regulatory history of CAS No: 119446-68-3

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 540/2011 Reg. (EU) 2023/2592
RMS	ES
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/01/2009
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	-

Status	
Date of final Commission (re-registration) deadline (Step 2)	-
Current expiration of approval	15/03/2026
Low risk substance or Candidate for Substitution?	CfS

Issues that need to be considered as part of the EU approval are listed below.

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

- the protection of aquatic organisms.

The SANCO report for Difenoconazole (SANCO/830/08 – rev. 3 13 December 2013, 18 May 2020) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 07 January 2011.

Table 0.1-3: Information on minimum purity of Difenoconazole

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
940 g/kg	For minimum purity of active substance see part C For details regarding specification of the active substance see also in part C minimum purity of active substance: 960 g/Kg Equivalence report available: Y RMS: AT (2022)

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

** If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

0.1.4 Regulatory history of the product

Not relevant as the product has not yet been authorised

0.2 zRMS conclusion

Uses to be considered safe on the basis of EU methodology:

<p>Efficacy section: all</p> <p>Toxicology section: all</p> <p>Residues section: all</p> <p>Environmental fate section: all</p> <p>Ecotoxicology section:</p> <p>The use of this plant protection product DISFERA 90 EC according to recommendations is accepted at national level. However, the comparison of formulation DISFERA 90 EC and SCORE 250 EC should be provided by Applicant. The Applicant provided a comparison of products DISFERA 90 EC and Sore 250 EC for confirmation with justification. The justification was accepted by zRMS. The documents -</p>
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dRR B9, dRR B0 and Part A and Part C was updated by zRMS. On the basis of the above comparison, it can be stated that *DISFERA 90 EC* is much less toxic or, in the worst case scenario, has the same level of toxicity as *SCORE 250 EC*. It should be considered by MSs level.

The Applicant delivered supplement risk assessment for bees in accordance with EFSA 2013. The risk assessment was accepted by zRMS. It should be considered by MSs level.

Uses to be considered non-safe on the basis of EU methodology:

Efficacy section: none
Toxicology section: none
Residues section: none
Environmental fate section: none
Ecotoxicology section: none

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant CMS:

none

Conclusions:

Efficacy section:

DISFERA 90 EC / LIPOSTAR 90 EC (product code: SNS-F-11) can be granted in Poland in line to accepted GAP table and label project.

Fate and behaviour section:

The fate and behaviour assessment is accepted for all crops (1-10) presented in GAP. No risk for groundwater is expected following applications of DISFERA 90 EC / LIPOSTAR 90 EC.

Mammalian toxicology section:

Classification of the product SNS-F-11 : Carc. 2 (H351), Acute Tox 4 (H332), Eye Dam.1 (H318), Skin Irrit. 2 (H315). Taking into account the classification of the product (Carc.2, H251, Eye Dam. 1, H318, Skin Irrit. 2, H315), protective clothing, eye/face protection and protective gloves are mandatory when handling undiluted product.

Exposure assessment:

Operator: Product causes acceptable health risk for:

- unprotected operator (no PPE) during mixing/loading and application in the case of tractor mounted boom spray application in winter wheat and winter triticale;
- operator equipped with work wear (arms, body and legs covered) during mixing/loading and application in the case of tractor mounted boom spray application in winter rape, spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soybeans.

Worker: The use of SNS-F-11 causes acceptable health risk for a unprotected worker assuming 2 hour working day (inspection, irrigation).

Bystander/resident: The use of SNS-F-11 according to the list of intended uses presented in the GAP Table and anticipating the introduction of buffer zone presented (2-3m), cause acceptable health risk for bystander/resident (adult and child).

Residues section:

Uses are accepted.

Ecotoxicology section: The use of this plant protection product **DISFERA 90 EC** according to recommendations is accepted at national level.

1. However, the comparison of formulation DISFERA 90 EC and SCORE 250 EC should be provided by Applicant.

(in this case these formulation DISFERA 90 EC and SCORE 250 EC are probably comparable in ecotoxicology point of view - it is the same type of EC formulation and DISFERA 90 EC contains less active substance inside than Sore 250 EC). The Applicant provided a comparison of products DISFERA 90 EC and Sore 250 EC for confirmation with justification. The justification was accepted by zRMS. The documents - dRR B9, dRR B0 and Part A and Part C was updated by zRMS. On the basis of the above comparison, it can be stated that *DISFERA 90 EC* is much less toxic or, in the worst case scenario, has the same level of toxicity as SCORE 250 EC. It should be considered by MSs level.

2. According to EU Reg. 284/2009, the chronic toxicity study for adult bees, and the chronic test for larvae were submitted, same as the acute contact and oral tests for bumblebees. The studies were accepted by zRMS. **The risk assessment based on these studies should be considered when GD for Bees, 2013 is implemented at EU level.** The Applicant delivered supplement risk assessment for bees in accordance with EFSA 2013. The risk assessment was accepted by zRMS. It should be considered by MSs level.

Appendix 1 ALL intended uses

GAP rev. 1, date: 01/2024

PPP (product name/code): SNS-F-11
Active substance: Difenoconazole
Applicant: Synthos Agro Sp. z o.o.
Zone(s): Central
Verified by MS: No
Field of use: Fungicide

Formulation type: EC)
Conc. of as 1: 90 g/L
Professional use: ☒
Non professional use: ☐

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: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val 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		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	PL	Winter wheat	F	<i>Zymoseptoria tritici</i> <i>Blumeria graminis tritici</i> / <i>Blumeria graminis</i> <i>Puccinia triticina</i> / <i>Puccin- ia recondite</i> <i>Pyrenophora tritici- repentis</i> <i>Parastagonospora no- dorum</i>	Foliar spray	BBCH 33-55 (spring)	2	14-21 days	a) 1.0 L/ha b) 2.0 L/ha	a) Difenonazole 90g b) Difenonazole 180 g	200 – 300	NR*	
2	PL	Winter triticale	F	<i>Zymoseptoria tritici</i>	Foliar spray	BBCH 33-55 (spring)	2	14-21 days	a) 1.0 L/ha b) 2.0 L/ha	a) Difenonazole 90g b) Difenonazole 180 g	200 – 300	NR*	

				<i>Blumeria graminis tritici/</i> <i>Blumeria graminis</i>									
				<i>Puccinia triticina/ Puccinia recondite</i>									
				<i>Parastagonospora nodorum</i>									
3	PL	Winter oilseed rape	F	<i>Leptosphaeria maculans</i> <i>Sclerotinia sclerotiorum</i>	Foliar spray	BBCH 32-39 (spring) BBCH 60-65 (spring)	1	-	a) 1.0 L/ha b) 1.0 L/ha a) 1.15 L/ha b) 1.15 L/ha	a) Difenconazole 90 g b) Difenconazole 90 g a) Difenconazole 103.5 g b) Difenconazole 103.5 g	200 – 300	NR*	
Minor uses according to Article 51													
4	PL	Spring oilseed rape	F	<i>Leptosphaeria maculans</i> <i>Sclerotinia sclerotiorum</i>	Foliar spray	BBCH 32-39 BBCH 60-65	1	-	a) 1.0 L/ha b) 1.0 L/ha a) 1.15 L/ha b) 1.15 L/ha	a) Difenconazole 90 g b) Difenconazole 90 g a) Difenconazole 103.5 g b) Difenconazole 103.5 g	200 – 300	NR*	
5	PL	Linseed (common flax)	F	<i>Leptosphaeria maculans</i> <i>Sclerotinia sclerotiorum</i>	Foliar spray	BBCH 32-39 BBCH 60-65	1	-	a) 1.0 L/ha b) 1.0 L/ha a) 1.15 L/ha b) 1.15 L/ha	a) Difenconazole 90 g b) Difenconazole 90 g a) Difenconazole 103.5 g b) Difenconazole 103.5 g	200 – 300	NR*	
6	PL	Poppy seeds	F	<i>Leptosphaeria maculans</i> <i>Sclerotinia sclerotiorum</i>	Foliar spray	BBCH 32-39 BBCH 60-65	1	-	a) 1.0 L/ha b) 1.0 L/ha a) 1.15 L/ha b) 1.15 L/ha	a) Difenconazole 90 g b) Difenconazole 90 g a) Difenconazole 103.5 g b) Difenconazole 103.5 g	200 – 300	NR*	
7	PL	Mustard seeds	F	<i>Leptosphaeria maculans</i> <i>Sclerotinia sclerotiorum</i>	Foliar spray	BBCH 32-39 BBCH 60-65	1	-	a) 1.0 L/ha b) 1.0 L/ha a) 1.15 L/ha b) 1.15 L/ha	a) Difenconazole 90 g b) Difenconazole 90 g a) Difenconazole 103.5 g b) Difenconazole 103.5 g	200 – 300	NR*	
8	PL	Gold of pleasure seeds	F	<i>Leptosphaeria maculans</i> <i>Sclerotinia sclerotiorum</i>	Foliar spray	BBCH 32-39 BBCH 60-65	1	-	a) 1.0 L/ha b) 1.0 L/ha a) 1.15 L/ha b) 1.15 L/ha	a) Difenconazole 90 g b) Difenconazole 90 g a) Difenconazole 103.5 g b) Difenconazole 103.5 g	200-300	NR*	
9	PL	Sunflower seeds	F	<i>Alternaria spp.</i>	Foliar spray	BBCH 32-39	1	-	a) 1.0 L/ha b) 1.0 L/ha	a) Difenconazole 90 g b) Difenconazole 90 g	200-300	NR*	

				<i>Leptosphaeria lindquistii</i> <i>Sclerotinia sclerotiorum</i>		BBCH 60-65			a) 1.15 L/ha b) 1.15 L/ha	a) Difenoconazole 103.5 g b) Difenoconazole 103.5 g			
10	PL	Soyabeans	F	<i>Cercospora sojina</i> <i>Cercospora Kikuchi</i> <i>Sclerotinia sclerotiorum</i>	Foliar spray	BBCH 32 -65	1	-	a) 1.15 L/ha b) 1.15 L/ha	a) Difenoconazole 103.5 g b) Difenoconazole 103.5 g	200- 300	NR*	

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, 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

*NR – PHI is not relevant (commercial harvest)

Section Ecotoxicology: The risk assessment for all uses in GAP in terms of soil organisms should be considered at MSs level.