

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: **FLUDIO 025 GF**

Product names: **FLUDIO ŽEL 025 FS /**

FUNABEN® ŽEL 025 FS

Chemical active substance:

Fludioxonil, 25 g/L

Central

Zonal Rapporteur Member State: **Poland**

CORE ASSESSMENT

(authorization)

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

Submission date: **01/2023**

MS Finalisation date: **06/2023; 10/2023**

Version history

When	What
01/2023	Initial dRR
05/2023	Physicochemical data after one year of storage
06/2023	ZRMS assessment of dRR
10/2023	Final Registration Report

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0 Product background, regulatory context and GAP information

0.1 Introduction

Justification regarding the difference in the formulation type between the product code name - FLUDIO 025 GF and the product trade names - FLUDIO ŽEL 025 FS, FUNABEN® ŽEL 025 FS is presented in Part C.

The product code name FLUDIO 025 GF is used in all draft Registration Report.

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.

This dossier has been submitted in order to register new product.

On 1 November 2013 data protection period for existing active substance **Fludioxonil** 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

Not relevant as the product has not yet been authorised in any zone.

Table 0.1-1: Overview of zRMS and cMS

Not relevant as the product has not yet been authorised.

0.1.3 Regulatory history of the active(s)

0.1.3.1 Fludioxonil

Table 0.1-2: Summary of regulatory history of CAS No: 133-06-02

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 540/2011
RMS	FR
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.11.2008
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	31.10.2023
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:

- to the potential for groundwater contamination, in particular from the soil photolysis metabolites CGA 339833 and CGA 192155, in vulnerable zones,
- the protection of fish and aquatic invertebrates.

Conditions of authorisation should include risk mitigation measures, where appropriate.

The SANCO report for Fludioxonil (SANCO/2818/07-rev.2 – 10/09/2007) 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 17 August 2007.

Table 0.1-3: Information on minimum purity of Fludioxonil

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 *, **
950 g/kg	For minimum purity of active substance see part C For details regarding specification of the active substance see also in part C Equivalence report available: Yes, RMS DE for one source and PL for the second source.

* 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:

Efficacy section: all
Residues section: all
Mammalian toxicology section: all
Environmental fate and behavior section: all
Ecotoxicology section: all

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

Efficacy section: none
Residues section: none
Mammalian toxicology section: none
Environmental fate and behavior 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:

Residues section : none

All uses/ GAPs are covered by established MRLs

zRMS main conclusions:

Physical and chemical properties section:

2 years ambient shelf life study is ongoing and the results should be available February/March 2024.

Efficacy section:

FLUDIO ŽEL 025 FS, FUNABEN® ŽEL 025 FS can be granted in PL in line to accepted GAP table and label project.

Mammalian toxicology section:

The product FLUDIO 025 GF containing Fludioxonil, 25 g/L does not require classification in regards to acute toxicity. It causes no unacceptable health risk for operator, worker, bystander/resident if used in accordance to the applications indicated in the GAP Table.

Residues section:

All uses are accepted.

Environmental fate and behavior section:

All uses are accepted.

Ecotoxicology section:

All uses are accepted.

Appendix 1 ALL intended uses

GAP rev. 1, date: 01.2023

PPP (product name/code): FLUDIO ŽEL 025 FS, FUNABEN® ŽEL 025 FS/
FLUDIO 025 GF Formulation type: Flowable concentrate for seed treatment (FS)

Active substance 1: fludioxonil Conc. of as 1: 25 g/L

Applicant: Synthos Agro Sp. z o.o. Professional use: ☒

Zone: central Non professional use: ☐

Verified by MS: no

Field of use: fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. (e)	Mem- ber state(s)	Crop and/ or situation (crop destina- tion / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (i)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval be- tween applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/seaso n	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 rye	F	<i>Fusarium spp.</i> <i>Urocystis occulta</i>	Seed treatment	BBCH 00	1	-	0.2-0.4 L/ha	Fludioxonil 5 – 10 g	-		200 mL/100 kg seeds Sowing rate: 100 – 200 kg seeds/ha
2	PL	Winter wheat	F	<i>Fusarium spp.</i> <i>Monographella nivalis</i> <i>Tilletia caries</i>	Seed treatment	BBCH 00	1	-	0,3-0,5 L/ha	Fludioxonil: 7,5-12,5g	-		200 ml/100 kg seeds Sowing rate: 150-250 kg seeds/ha
3	PL	Winter barley	F	<i>Fusarium spp.</i> <i>Monographella nivalis</i> <i>Pyrenophora graminea</i>	Seed treatment	BBCH 00	1	-	0,24-0,4 L/ha	Fludioxonil: 6-10g	-		200 ml/100 kg seeds Sowing rate: 120-200 kg seeds/ha
4	PL	Winter tritcale	F	<i>Fusarium spp.</i>	Seed	BBCH 00	1	-	0.2-0.4	Fludioxonil 5 – 10 g	-		200 ml/100 kg seeds

					treatment				L/ha				Sowing rate (triticale): 100-200 kg seeds/ha
5	PL	Spring wheat	F	<i>Fusarium spp.</i> <i>Tilletia caries</i>	Seed treatment	BBCH 00	1	-	0,3-0,5 L/ha	Fludioxonil: 7,5-12,5g	-		200 ml/100 kg seeds Sowing rate: 150-250 kg seeds/ha
6	PL	Spring barley	F	<i>Fusarium spp.</i>	Seed treatment	BBCH 00	1	-	0,24-0,4 L/ha	Fludioxonil: 6-10g	-		200 ml/100 kg seeds Sowing rate: 120-200 kg seeds/ha

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

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.

(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.

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