

FINAL REGISTRATION REPORT

Part C

Confidential Information

Product code: **FLUDIO 025 GF**

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

FUNABEN® ŽEL 025 FS

Chemical active substance:

Fludioxonil, 25 g/L

Central Zone

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
06/2023	ZRMS assessment of dRR
10/2023	The final Registration Report

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CONFIDENTIAL DATA RELATING TO THE FORMU- LATED PRODUCT

Sufficient data on the identity of the plant protection product and the contained technical active substance(s) and formulant(s) are available.

Request for data confidentiality in accordance with Article 63 of Regulation (EU) No. 1107/2009

Synthos Agro Sp. z o. o. hereby requests data confidentiality for all the information listed in the attached document on the basis that this information is regarded as proprietary. This request takes into account the provision Article 63 of Regulation (EU) No. 1107/2009.

1 Identity of the Plant Protection Product

1.1 Producer of the plant protection product and of the active substances (KCP 1.2)

1.1.1 Producer(s) of the preparation (KCP 1.2)

Synthos Agro Sp. z o.o.
ul. Chemików 1
32-600 Oświęcim

1.1.2 Producer(s) of the active substance(s) (KCP 1.2)

Fludioxonil

1. Zhejiang Udragon Bioscience Co., Ltd
No.1 Fangjiadai Road,
Haiyan Economic Development Zone,
Haiyan, Zhejiang, 3614304,
China
2. Synthos Agro Sp. z o.o.
ul. Chemików 1
32-600 Oświęcim
Poland

1.1.3 Statement of purity (and detailed information on impurities) of the active substance(s) (KCP 1.2)

Fludioxonil

Minimum purity 950 g/kg
There are no relevant impurities.

RMS Comment:	Both active ingredient sources used are approved at EU level. Zhejiang Udragon Bioscience Co., Ltd source was assessed by DE and found equivalent (WRM 026100-00/00 Fludioxonil). The purity of a.s. from this source is 98%. Synthos Agro Sp. z o.o. was assessed by PL and found equivalent (HOR.ow.8205.59.2018). The purity of a.s from this source is 99%. Both equivalency reports are available on CIRCA.
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1.2 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.2.1 Composition of the plant protection product (KCP 1.4.1)

Table 1.2-1: Composition of FLUDIO 025 GF

Component	CAS no.	Trade name	Function	g/L	% w/w *
Fludioxonil	131341-86-1	-	Fungicide	pure 25	pure 2.36
				technical (98% purity) 25.6 25.5	technical (98% purity) 2.42 2.40
				technical (99% purity) 25.3	technical (99% purity) 2.38
Propylene glycol	57-55-6	Propylene glycol	Antifreeze	100	9.44
Agrilan 1015 (Alkoxyated Phosphate Ester)	Mixture of alkoxyated phosphate ester with propylene glycol and water.	Agrilan 1015	Dispersant agent	40	3.78
Poly(oxy-1,2-ethanediyl), alpha-sulfo-omega-[2,4,6-tris(1-phenylethyl)phenoxy]-, ammonium salt	119432-41-6	Soprophor 4D/384	Dispersant agent	20	1.89
Magnesium Aluminum Silicate	1302-78-9	Van Gel B	Thickener	3	0.28
Polydimethylsiloxane emulsion	Mixture of: - Glycerine (CAS 56-81-5; 5-10%) - Siloxane Polyalkyleneoxide (1-5%) - Polyalkylene Glycol (10-30%) - Silica Filled, Silicone Oil (10-30%) - Water (CAS 7732-18-5; 60-100%)	SAG 1572/PLS PL/19KG	Antifoaming agent	2	0.19
Proxel GXL	Mixture of: - 1,2-benzizotiazol-3(2H)-on (CAS 2634-33-5; 10-20%) - Sodium hydroxide (CAS 1310-73-2; 5-10%)	Proxel GXL	Preservative	1	0.09
Xantan gum	11138-66-2	Rhodopol 23	Thickener	1.5	0.14
JK 303 (Hydroxypropyl guar; Guar gum, 2-hydroxypropyl ether)	39421-75-5	Guarsafe JK 303	Thickener, rheology modifier	6	0.57
Lamfix SK/ETMA SK (an	-	Lamfix SK/	Thickener	20	1.89

Component	CAS no.	Trade name	Function	g/L	% w/w *
aqueous solution of low molecular weight cellulose ether)		ETMA SK			
3-hydroxy-N-(o-tolyl)-4-[(2,4,5-trichlorophenyl)azo]naphthalene-2-carboxamide	Mixture of: - 6535-46-2 - 135-61-5	Irgalite Red L 3865	Colorant	100	9.44
Demineralised water	7732-18-5	-	Solvent	740	69.87

* Based on the density of the formulation = 1.063 g/mL

This product does not contain any of the formulants listed in Annex III to Regulation (EC) No 1107/2009 (not even as an unintentional impurity in an amount greater than 0.1% by weight).

1.2.2 Information on co-formulants (KCP 1.4.3)

Comment of zRMS:	None of the co-formulants is listed in Annex III to Regulation (EC) No 1107/2009.
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Trade names: **Propylene glycol**
Chemical name: 99% Propan-1,2-diol
Components: >99.8% propan-1,2-diol
CAS number: 57-55-6
Relevant EC number: 200-338-0
Function: Antifreeze

Trade names: **Agrilan 1015**
Chemical name: -
Components: Mixture of alkoxyated phosphate ester with propylene glycol and water
CAS number: -
Relevant EC number: -
Function: Dispersant agent

Trade names: **Soprophor 4D/384**
Chemical name: Poly(oxy-1,2-ethanediyl), alpha-sulfo-omega-[2,4,6-tris(1-phenylethyl)phenoxy]-, ammonium salt
Components: 95-99% of poly(oxy-1,2-ethanediyl), alpha-sulfo-omega-[2,4,6-tris(1-phenylethyl)phenoxy]-, ammonium salt
CAS number: 119432-41-6
Relevant EC number: 601-612-6
Function: Dispersant agent

Trade names: **Van Gel B**
Chemical name: Magnesium Aluminum Silicate, Smectite clay, Bentonite
Components: 100% smectite-group minerals (CAS: 12199-37-0; EC: 235-374-6)
CAS number: 1302-78-9
Relevant EC number: 215-108-5
Function: Thickener

Trade names: **SAG 1572**
Chemical name: Polydimethylsiloxane emulsion,
Components: < 5-10% Glycerine CAS no. 56-81-5; 1-5% Siloxane Polyalkyleneoxide; 10-30% Polyalkylene Glycol; 10-30% Silica Filled, Silicone Oil; 60-100% Water CAS 7732-18-5
CAS number: -
Relevant EC number: -

Function: Antifoaming agent

Trade names: **Proxel GXL**

Chemical name: mixture contained 10-20% 1,2-benzisotiazol-3(2H)-on CAS 2634-33-5; 5-10% Sodium hydroxide CAS 1310-73-2

Components: -

CAS number: 2634-33-5

Relevant EC number: 220-120-9

Function: preservative

Trade names: **Rhodopol 23**

Chemical name: Xanthan Gum

Components: 80-90% xanthan Gum, CAS 11138-66-2

CAS number: 11138-66-2

Relevant EC number: 234-394-2

Function: Thickener

Trade names: **Guarsafe JK 303**

Chemical name: Hydroxypropyl guar; Guar gum, 2-hydroxypropyl ether

Components: 99% Hydroxypropyl guar; Guar gum, 2-hydroxypropyl ether, CAS 39421-75-5; 1% ethanol, CAS 64-17-5

CAS number: 39421-75-5

Relevant EC number: -

Function: Thickener, rheology modifier

Trade names: **ETMA SK (Lamfix SK)**

Chemical name: Aqueous solution of low molecular weight cellulosic ether

Components: contain max. 400 ppm of 1,2-benzisotiazol-3(2H)-on; 1,2-benzisotiazolin-3-on, CAS: 2634-33-5

CAS number: -

Relevant EC number: -

Function: Thickener

Trade names: **Irgalite Red L 3865**

Chemical name: 3-hydroxy-N-(o-tolyl)-4-[(2,4,5-trichlorophenyl)azo]naphthalene-2-carboxamide CAS 135-61-5 6535-46-2

Components: 3-hydroxy-N-(o-tolyl)-4-[(2,4,5-trichlorophenyl)azo]naphthalene-2-carboxamide CAS 6535-46-2; <1% 3-hydroxy-2'-methyl-2-naphthanilide CAS 135-61-5

CAS number: 6535-46-2

Relevant EC number: 229-440-3

Function: Colorant

Trade names: -

Chemical name: Water

Components: -

CAS number: 7732-18-5

Relevant EC number: 231-791-2

Function: Solvent

1.2.3 Description of formulation process (KCP 1.4.3)

Production process consists of mixing of active substance with co-formulants. No additional impurities of toxicological concern are formed.

1.2.4 Description of the analytical methods for the determination of relevant formulators (KCP 5.1.1)

Determination of co-formulants are not required by Regulation 1107/2009.

1.3 Data on Formulants

1.3.1 Material safety data sheets (KCP 1.4.3)

Copies of the Material Safety Data Sheets (MSDS) of the co-formulants are attached to registration documentation for FLUDIO 025 GF.

1.3.2 Available toxicological data for each formulant (KCP 7.4)

Comments of zRMS:	The classification of individual formulants has been revised and supplemented whenever necessary. Provided classification is sufficient to perform product classification in accordance with additivity formula rules.
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Table 1.3-1: Toxicological data for each co-formulant

Formulant (Chemical name, CAS No.)	Content in the product		Classification	Consequence for the product classification (Y/N)
	g/L or g/kg	% w/w		
Fludioxonil CAS No. 131341-86-1	25.6 g/L	2.42	Aquatic Acute 1; H400	Y
			Aquatic Chronic 1, H410	Y
Propan-1,2-diol CAS No. 57-55-6	100 g/L	9.44	Not classified as hazardous product	N
Agrilan 1015 CAS No. -	40 g/L	3.78	Not classified as hazardous product	N
Poly(oxy-1,2-ethanediyl), alpha-sulfo-omega-[2,4,6-tris(1-phenylethyl)phenoxy]-, ammonium salt CAS No. 119432-41-6	20 g/L	1.89	Aquatic Chronic 3; H412 (Acc. ECHA notification: Eye Irrit. 2, H319)	N
Smectite-group minerals CAS No. 235-374-6 (included in Van Gel B)	3 g/L	0.28	Not classified as hazardous product	N
Glycerine CAS No. 56-81-5 (included in SAG 1572)	<0.2 g/L	0.04	Not classified as hazardous product	N
1,2-benzisotiazol-3(2H)-on CAS No. 2634-33-5 (included in PROXEL GXL)	<0.2 g/L	0.018	Acute Tox. 4; H302	N
			Skin Irrit.2; H315	N
			Eye Dam.1; H318	N
			Skin Sens.1; H317	N
			Aquatic Acute 1; H400	N

Formulant (Chemical name, CAS No.)	Content in the product g/L or g/kg % w/w		Classification	Consequence for the product classification (Y/N)
Sodium hydroxide CAS No. 1310-73-2 (included in PROXEL GXL)	<0.1 g/L	0.009	Skin Corr. 1A; H314	N Eye Irrit. 2; H319: 0,5 % ≤ C < 2 % Skin Corr. 1A; H314: C ≥ 5 % Skin Corr. 1B; H314: 2 % ≤ C < 5 % Skin Irrit. 2; H315: 0,5 % ≤ C < 2 %
Xanthan gum CAS No. 11138-66-2	1.5 g/L	0.14	Not classified as hazardous product (acc. ECHA notification: Skin Irrit. 2, H315 Eye Irrit. 2, H319)	N
JK 303 CAS No. -	6 g/L	0.57	Not classified as hazardous product	N
Lamfix SK CAS No. -	20 g/L	1.89	Not classified as hazardous product	N
3-hydroxy-2'-methyl-2-naphthanilide CAS No. 135-61-5 (included in Irgalite Red L 3865, ≥ 0 % - < 1 %)	1 g/L	0.0094	Skin Sens. 1A; H317	N
			Aquatic Chronic 2; H411	Y
Water CAS No. 7732-18-5	740 g/L	69.87	Not classified as hazardous product	N

2 Statement on the regulatory status of formulants

Table 1.3-1: Plant Protection Product

Formulation Inerts	CAS Number	EINECS	European Pharmacopoeia	Regulation EC 1333/2008	Regulation EC 1831/2003	Commission Decision 2019/701	Regulation EC 10/2011
Glikol propylenowy	57-55-6	Propylene glycol	Yes	Yes	-	Yes	Yes
Agrilan 1015	-	-	-	-	-	-	-
Soprophor 4D/384	119432-41-6	Poly(oxy-1,2-ethanediyl), alpha-sulfo-omega-[2,4,6-tris(1-phenylethyl)phenoxy]-, ammonium salt	-	-	-	-	-
Van Gel B	12199-37-0	Smectite-group minerals	-	-	-	-	-
SAG 1572	56-81-5	Polydimethylsiloxane emulsion	-	-	-	-	-
Proxel GXL	2634-33-5	-	-	-	-	-	-
Rhodopol 23	11138-66-2	Xanthan gum	Yes	Yes	-	-	Yes
JK 303	-	-	-	-	-	-	-
Lamfix SK	-	-	-	-	-	-	-
Irgalite Red L 3865	6535-46-2	3-hydroxy-N-(o-tolyl)-4-[(2,4,5-trichlorophenyl)azo]naphthalene-2-carboxamide	-	-	-	-	-
Water	7732-18-5	Water	Yes	-	-	Yes	Yes

3 Others

3.1 **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**

During initial stages of the project verification and selection of the formulation, it was decided that the properties of the product will be closest to the GF formulation (Gel for Seed Treatment). GF formulation was no longer supported at the time, but concept of the product hasn't met the criteria of any available formulations. After performing physicochemical studies, formulation selection was re-evaluated. Based on new information, *TECHNICAL MONOGRAPH n° 2, 7th Edition Revised March 2017* and FAO specifications *Manual on development and use of FAO and WHO specifications for pesticides*, FS (Flowable concentrate for seed treatment) formulation was selected.

Initial product code name FLUDIO 025 GF is used throughout all of the study reports and draft registration report.