

FINAL REGISTRATION REPORT

Part B

Section 1: Identity

Section 2: Physical and chemical properties

Section 4: Further information

Detailed summary of the risk assessment

Product code: **FLUDIO 025 GF**

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

FUNABEN[®] ŻEL 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,**

Update: **05/2023**

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	The final Registration Report

Table of Contents

1	Section 1: Identity of the plant protection product.....	4
1.1	Applicant (KCP 1.1)	4
1.2	Producer of the plant protection product and of the active substances (KCP 1.2)	4
1.2.1	Producer(s) of the preparation	4
1.2.2	Producer(s) of the active substance(s)	4
1.2.3	Statement of purity (and detailed information on impurities) of the active substance(s).....	4
1.2.3.1	Fludioxonil.....	4
1.3	Trade names and producer's development code numbers for the preparation (KCP 1.3).....	4
1.4	Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)	5
1.4.1	Composition of the plant protection product (KCP 1.4.1).....	5
1.4.2	Information on the active substance(s) (KCP 1.4.2).....	5
1.4.3	Information on safeners, synergists and co-formulants (KCP 1.4.3).....	5
1.5	Type and code of the plant protection product (KCP 1.5).....	5
1.6	Function (KCP 1.6)	5
2	Section 2: Physical, chemical and technical properties of the plant protection product	6
3	Section 3 is presented as a separate document	16
4	Section 4: Further information on the plant protection product	17
4.1	Packaging and Compatibility with the Preparation (KCP 4.4)	17
Appendix 1	Lists of data considered in support of the evaluation.....	21
Appendix 2	Additional data on the physical, chemical and technical properties of the active substance.....	27
A 2.1	Fludioxonil.....	27

Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are:

- 2 years ambient shelf life study (it is proposed to grant authorisation for 2 years)

1 Section 1: Identity of the plant protection product

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

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

1.1 Applicant (KCP 1.1)

Name: Synthos Agro sp. z o.o.
Address: ul. Chemików 1
32-600 Oświęcim
Poland

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

1.2.1 Producer(s) of the preparation

Confidential information or data are provided separately (Part C).

1.2.2 Producer(s) of the active substance(s)

Confidential information or data are provided separately (Part C).

1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

1.2.3.1 Fludioxonil

Fludioxonil min. 950 g/kg

1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name: FLUDIO ŻEL 025 FS / FUNABEN® ŻEL 025 FS
Company code number: FLUDIO 025 GF

1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

Table 1.4-1: Active substance and variant of the active substance

Active substance / variant	Declared content of the pure active substance / variant (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L)	Technical content** (%w/w)
Fludioxonil	25 g/L	22.5 – 27.5 g/L	25.6 26.3	2.42 2.48

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers

** Based on the density of the formulation = 1.063 g/mL (Note: only applies if a liquid formulation – delete this comment if not needed)

Table 1.4-2: Safener and synergists

Neither safener nor synergists were used in the formulation.

Table 1.4-3: Relevant impurities

CONFIDENTIAL information - data provided separately (Part C).

1.4.2 Information on the active substance(s) (KCP 1.4.2)

Table 1.4-4: Information on Fludioxonil

Type	Name/Code Number
ISO common name	Fludioxonil
CAS No.	131341-86-1
EC No.	Not allocated 603-476-3
CIPAC No.	522

1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

Table 1.4-5: Information on safeners/ synergists / co-formulant

CONFIDENTIAL information is provided separately (Part C).

1.5 Type and code of the plant protection product (KCP 1.5)

Type: FS (Flowable concentrate for seed treatment)

[Code: FS]

1.6 Function (KCP 1.6)

Seed treatment

2 Section 2: Physical, chemical and technical properties of the plant protection product

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of homogenous red liquid, with a soft characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable/ hasn't got the flash point up to the boiling point. It has a self ignition temperature of 650°C. In aqueous solution, it has a pH value around 7.55 at 20°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 1 year at ambient temperature when stored in HDPE. 2 years ambient shelf life study is ongoing. Its technical characteristics are acceptable for a FS formulation.

The intended concentration of use is ~~120 mL to~~ 200 mL/100 kg seeds.

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

Classification

Aquatic Chronic 2 - H411: Toxic to aquatic life with long lasting effects

Labelling

Pictograms:

GHS 09 - Environment

Signal words:

No signal word is used

Notifier Proposals for Risk and Safety Phrases (KCP 12)

Hazard Statements:

H411: Toxic to aquatic life with long lasting effects

Precautionary Statements:

Prevention:

P273 - Avoid release to the environment

Response:

P391 - Collect spillage.

Disposal:

P501 - Dispose of contents/container to an approved waste disposal plant.

Compliance with FAO specifications:

No FAO specification exist for fludioxonil.

Formulation used for tests

The product used in the tests has the same composition as the one cited in Part C.

Table 2-1: Physical, chemical and technical properties of the plant protection product

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	OPPTS 830.6301-04	FLUDIO 025 GF, batch no. SNS-F-06-22	Homogenous red liquid of soft characteristic odour.	Y	Jarosław Kupiec, M.Sc., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-59/21; Warsaw; April 2022	Accepted.
Explosive properties (KCP 2.2.1)	EC A.14	FLUDIO 025 GF, batch no. SNS-F-06-22	FLUDIO 025 GF does not have explosive properties.	Y	Daniel Buczkowski, PhD, DSc., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BW-02/22; Warsaw; April 2022	In the impact sensitivity test, no explosion occurred. In the thermal sensitivity (Koenen) test no explosion occurred. Accepted.
Oxidizing properties (KCP 2.2.2)	EC A.21	FLUDIO 025 GF, batch no. SNS-F-06-22	FLUDIO 025 GF has not got the oxidizing properties.	Y	Paulina Flasińska MSc., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BC-07/22; Warsaw; March 2022	During the test no spontaneous ignition was noted; the pressure did not reach the critical value of 2070 kPa. The formulation is not oxidising. Accepted.
Flash point (KCP 2.3.1)	EC A.9	FLUDIO 025 GF, batch no. SNS-F-06-22	FLUDIO 025 GF hasn't got the flash point up to the boiling point.	Y	Paulina Flasińska MSc., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BC-07/22; Warsaw; March 2022	The test was performed with the Pensky-Martens closed-cup apparatus. No flash point up to the boiling point of 98°C. The formulation is not flammable. Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																		
Flammability (KCP 2.3.2)	Not applicable. It is not a solid or gas plant protection product.																							
Self-heating (KCP 2.3.3)	EC A.15	FLUDIO 025 GF, batch no. SNS-F-06-22	FLUDIO 025 GF has not got the auto-ignition temperature up to 650°C.	Y	Paulina Flasińska MSc., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BC-07/22; Warsaw; March 2022	Accepted.																		
Acidity or alkalinity and pH (KCP 2.4.1)	Not applicable. It is not a plant protection product which is acidic (pH < 4) or alkaline (pH > 10).					Accepted.																		
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	FLUDIO 025 GF, batch no. SNS-F-06-22	pH undiluted: 7.69 pH 1 % solution: 7.55	Y	Jarosław Kupiec, M.Sc., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-59/21; Warsaw; April 2022	Accepted.																		
Viscosity (KCP 2.5.1)	OECD 114		Non-Newtonian liquid: <table style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th></th> <th colspan="2">Temperature</th> </tr> <tr> <th>shear rate:</th> <th>20°C</th> <th>40°C</th> </tr> </thead> <tbody> <tr> <td>5.0 s⁻¹</td> <td>3928.5 mPa ·s</td> <td>3054.7 mPa ·s</td> </tr> <tr> <td>10.0 s⁻¹</td> <td>2438.2 mPa ·s</td> <td>1953.8 mPa ·s</td> </tr> <tr> <td>25.0 s⁻¹</td> <td>1295.3 mPa ·s</td> <td>1051.5 mPa ·s</td> </tr> <tr> <td>50.0 s⁻¹</td> <td>800.3 mPa ·s</td> <td>646.0 mPa ·s</td> </tr> </tbody> </table>				Temperature		shear rate:	20°C	40°C	5.0 s ⁻¹	3928.5 mPa ·s	3054.7 mPa ·s	10.0 s ⁻¹	2438.2 mPa ·s	1953.8 mPa ·s	25.0 s ⁻¹	1295.3 mPa ·s	1051.5 mPa ·s	50.0 s ⁻¹	800.3 mPa ·s	646.0 mPa ·s	The viscosity was determined by using of Brookfield Test Method. The formulation is a non-Newtonian liquid. The formulation does not pose an aspiration hazard. Accepted.
	Temperature																							
shear rate:	20°C	40°C																						
5.0 s ⁻¹	3928.5 mPa ·s	3054.7 mPa ·s																						
10.0 s ⁻¹	2438.2 mPa ·s	1953.8 mPa ·s																						
25.0 s ⁻¹	1295.3 mPa ·s	1051.5 mPa ·s																						
50.0 s ⁻¹	800.3 mPa ·s	646.0 mPa ·s																						
Surface tension (KCP 2.5.2)	OECD 115	37.14 mN/m (at 20°C)	The surface tension of the formulation was tested using the ring method. The product is surface active. Accepted.																					
Relative density	OECD 109		At 20°C At 40°C			Accepted.																		

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.6.1)			Absolute 1.063 g/mL 1.053 g/mL Relative 1.063 g/mL 1.053 g/mL			
Bulk density (KCP 2.6.2)	Not applicable. It is not a plant protection product in the form of powder or granules.					
Storage Stability after 14 days at 54° C (KCP 2.7.1)	OPPTS 830.6301-04	FLUDIO 025 GF, batch no. SNS-F-06-22	Homogenous red liquid of soft characteristic odour.	Y	Jarosław Kupiec, M.Sc., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-59/21; Warsaw; April 2022	The formulation was stored in original packages (1 litre HDPE). The test temperature varied between 53.4°C and 54.3°C. The change of a.s. content after the storage was 3.7%. There was no change to the properties of the formulation after the storage. The packaging remained stable. See KCP 2.8.3.1 comment regarding suspensibility results. Accepted.
	CIPAC MT 75.3		pH undiluted: 7.45 pH 1 % solution: 7.34			
	CIPAC MT 184.1		Suspension stability: 120 mL/880 mL: 97.81% 200 mL/800 mL: 98.98%			
	CIPAC MT 185		Wet sieve test: Residue in 75 µm sieve: 0.15%			
	CropLife International Technical Monograph no. 17		Package stability: The shape and colour of the 1 litre HDPE package were stable. No visible leaking in the package. Negligible mass change (0.03%).			
HPLC	Fludioksonil content: 2.26% (23.97 g/L)					
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	Not applicable. The product is chemically and physically stable after storage for 14 days at 54° C.					
Minimum content after heat stability testing (KCP 2.7.3)	HPLC	FLUDIO 025 GF, batch no. SNS-F-06-22	Fludioksonil content: 2.26% (23.97 g/L)	Y	Jarosław Kupiec, M.Sc., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-59/21;	The change of a.s. content after the storage was 3.7%. Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
					Warsaw; April 2022	
Effect of low temperatures on stability (KCP 2.7.4)	OPPTS 830.6301-04	FLUDIO 025 GF, batch no. SNS-F-06-22	Homogenous red liquid of soft characteristic odour.	Y	Jarosław Kupiec, M.Sc., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-59/21; Warsaw; April 2022	The test temperature varied between -0.8 °C and 0.1°C. The change of a.s. content after the storage was 0.2%. No separation, no crystallization, and the formulation remained homogenous. Accepted.
	CIPAC MT 75.3		pH undiluted: 7.74 pH 1 % solution: 7.36			
	CIPAC MT 184.1		Suspension stability: 120 mL/880 mL: 99.33% 200 mL/800 mL: 99.12%			
	CIPAC MT 185		Wet sieve test: Residue in 75 µm sieve: 0.15%			
	HPLC		Fludioksonil content: 2.33% (24.82 g/L)			
Ambient temperature shelf life (KCP 2.7.5)	OPPTS 830.6301-04	FLUDIO 025 GF, batch no. SNS-F-06-22	Physical state color and odour: Initial: Homogenous red liquid of soft characteristic odour. After 1 year: Homogenous red liquid of soft characteristic odour After 2 years: the study is ongoing	Y	Jarosław Kupiec, M.Sc., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-59/21; Warsaw; April 2022	The formulation was stored for 1 year in original packages (1 litre HDPE). The test temperature varied between 19.1°C and 21.2°C. The change of a.s. content after storage (1 year) was 1.3%. There was no change to the properties of the formulation after the storage. The packaging remained stable (no change of shape or colour; mass change 0.01%). See KCP 2.8.3.1 comment regarding sensibility results.
	CIPAC MT 75.3		Initial: pH undiluted: 7.45 pH 1 % solution: 7.34 After 1 year: pH undiluted: 7.28 pH 1 % solution: 7.12 After 2 years: the study is ongoing			
	CIPAC MT 184.1		Suspension stability: Initial: 120 mL/880 mL: 97.91% 200 mL/800 mL: 99.71% After 1 year: 120 mL/880 mL: 99.39% 200 mL/800 mL: 100.34%			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	CIPAC MT 185		After 2 years: the study is ongoing Wet sieve test: Initial: Residue in 75 µm sieve: 0.20% After 1 year: Residue in 75 µm sieve: 0.10% After 2 years: the study is ongoing			Accepted.
	CropLife International Technical Monograph no. 17		Package stability: After 1 year: The shape and colour of the 1 litre HDPE package were stable, negligible mass change After 2 years: the study is ongoing			
	HPLC		Initial: Fludioksonil content: 2.34% After 1 year: Fludioksonil content: 2.37% After 2 years: the study is ongoing			
Shelf life in months (if less than 2 years) (KCP 2.7.6)	Not applicable. Proposed shelf life is not less than 2 years.					
Wettability (KCP 2.8.1)	Not applicable. It is not a solid plant protection product, which is diluted for use.					
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	FLUDIO 025 GF, batch no. SNS-F-06-22	200 ml/800 mL: 4.0 mL after 1 min 0.0 mL after 12 min	Y	Jarosław Kupiec, M.Sc., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-59/21; Warsaw; April 2022	Standard CIPAC Water D was used. For FS formulation the performance of the test is not required if the product is not to be diluted before use. The physicochemical tests were performed for both uses: without dilution and with dilution. The final recommended use is without dilution,

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						therefore the test is not required. Accepted.
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184.1		120 mL/880 mL: 97.91% 200 mL/800 mL: 99.71%			Standard CIPAC Water D was used. The concentrations used were 14% v/v and 25%. For FS formulation, if the product is not to be diluted before use, evidence is required that the formulation is homogeneous. The physicochemical tests were performed for both uses: without dilution and with dilution. The final recommended use is without dilution. In all stability tests (accelerated storage, low temp., ambient temp.), the formulation remained homogenous. Accepted.
Spontaneity of dispersion (KCP 2.8.3.2)	Not applicable. It is not a water dispersible plant protection product.					
Dispersion stability (KCP 2.8.3.3)	Not applicable. It is not a water dispersible plant protection product.					
Degree of dissolution and dilution stability	Not applicable. It is not a water soluble plant protection product.					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.4)						
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	Not applicable. It is not a solid plant protection product.					
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	FLUDIO 025 GF, batch no. SNS-F-06-22	Residue in 75 µm sieve: 0.20%	Y	Jarosław Kupiec, M.Sc., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-59/21; Warsaw; April 2022	Accepted.
Dust content (KCP 2.8.5.2.1)	Not applicable. It is not a granular plant protection product.					
Particle size of dust (KCP 2.8.5.2.2)	Not applicable. It is not a granular plant protection product.					
Attrition (KCP 2.8.5.3)	Not applicable. It is not a plant protection product in the form of granules or tablets which are loose packed.					
Hardness and integrity (KCP 2.8.5.4)	Not applicable. It is not a plant protection product in the form of tablets.					
Emulsifiability (KCP 2.8.6.1)	Not applicable. It is not a plant protection product, which exist as emulsion in the spray tank.					
Emulsion stability (KCP 2.8.6.2)	Not applicable. It is not a plant protection product, which exist as emulsion in the spray tank.					
Re-emulsifiability (KCP 2.8.6.3)	Not applicable. It is not a plant protection product, which exist as emulsion in the spray tank.					
Flowability (KCP 2.8.7.1)	Not applicable. It is not a granular plant protection product.					
Pourability (KCP 2.8.7.2)	CIPAC MT 148.1	FLUDIO 025 GF, batch no. SNS-F-	A = 9.75% Not applicable to the container and use instruction.	N	Paleń P., Synthos Agro Sp. z o.o.;	The formulation has a high viscosity and

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		06-24	Plant protection product is not intended to be removed from the packaging by pouring.		AGRO/44/22; Oświęcim, December 2022	therefore it will not be poured from the packaging. The proposed packagings for formulation are buckets, canisters, cartridges, and tubes. To empty the packaging, the user will need to use a spatula, stick, or spoon to remove the entire product from the packaging. Appropriate instructions have been proposed on the label. Accepted.
Dustability following accelerated storage (KCP 2.8.7.3)	Not applicable. It is not a plant protection product in the form of dustable powder.					
Physical compatibility of tank mixes (KCP 2.9.1)	Not applicable. Tank mixes are not recommended.					
Chemical compatibility of tank mixes (KCP 2.9.2)	Not applicable. Tank mixes are not recommended.					
Adhesion to seeds (KCP 2.10.1)	CIPAC MT 194	FLUDIO 025 GF, batch no. SNS-F-06-22	Seeds treated with product with the addition of water: 98.2% Product applied directly to the seeds: 92.0%	N	Paleń P., Synthos Agro Sp. z o.o.; AGRO/4/21; Oświęcim, January 2022, June 2023	Accepted.
Distribution to seed (KCP 2.10.2)	CIPAC MT 175	FLUDIO 025 GF, batch no. SNS-F-06-22	Seed treatment procedure with water addition: Homogenous Seed treatment procedure without water addition	N	Paleń P., Synthos Agro Sp. z o.o.; AGRO/5/21;	There was a deviation from the MT 175 method: instead of

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																		
			(direct procedure): Homogenous		Oświęcim, January 2022	performing extraction with 1 seed and 1 ml of solvent, extraction was done with 5 seeds and 5 ml of solvent. Seed treatment procedure with water addition (200 mL of product in 800 mL of water per 100 kg): absorbance=1.544; RSD=1.1%. Seed treatment procedure without water addition (direct procedure): absorbance=1.477; RSD=2.61%. Accepted.																		
Active substance loading (KCP 2.10.3)	HPLC	FLUDIO 025 GF, batch no. SNS-F-06-22	<table border="1"> <thead> <tr> <th></th> <th>with addition of 800 mL of water per 100 kg</th> <th>without addition of water per 100 kg</th> </tr> </thead> <tbody> <tr> <td>wheat</td> <td>95.7%</td> <td>93.4%</td> </tr> <tr> <td>rye</td> <td>96.0%</td> <td>92.2%</td> </tr> <tr> <td>triticale</td> <td>93.2%</td> <td>90.2%</td> </tr> <tr> <td>barley</td> <td>93.9%</td> <td>93.3%</td> </tr> <tr> <td>oat</td> <td>94.7%</td> <td>92.3%</td> </tr> </tbody> </table>		with addition of 800 mL of water per 100 kg	without addition of water per 100 kg	wheat	95.7%	93.4%	rye	96.0%	92.2%	triticale	93.2%	90.2%	barley	93.9%	93.3%	oat	94.7%	92.3%	N	Paleń P., Synthos Agro Sp. z o.o.; AGRO/6/21; Oświęcim, January 2022	The product was applied to seeds using Wintersteiger Hege 1-1 seed treater. Ca. 10 g of treated seeds were transferred into 300 mL Erlenmeyer flasks, 50 mL of solvent was added, and a closed flask was placed in a laboratory shaker for about 60 minutes. The prepared solution was then analysed. Accepted.
	with addition of 800 mL of water per 100 kg	without addition of water per 100 kg																						
wheat	95.7%	93.4%																						
rye	96.0%	92.2%																						
triticale	93.2%	90.2%																						
barley	93.9%	93.3%																						
oat	94.7%	92.3%																						

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Other/special studies (KCP 2.11)						

3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

4 Section 4: Further information on the plant protection product

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

Comment of zRMS:	In the accelerated stability study and shelf-life study (1 year), the formulation has been tested in its original commercial packaging (1 litre HDPE) and the packaging remained stable. Since the formulation is FS formulation (aqueous solution), it is possible, according to the guideline of the Ministry of Agriculture and Rural Development (Wytyczna w sprawie zasad zatwierdzania opakowań w środkach ochrony roślin), to extrapolate the results from HDPE packaging to another plastic packaging. Therefore, the proposed commercial packs are considered acceptable.
------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Packagings proposed for FLUDIO 025 GF are as follows:

0.2 L, 0.25 L	PE/LDPE/HDPE tube
0.3 L	HDPE cartridge
0.2 L, 0.4 L, 0.5 L, 0.8 L, 1 L, 1.2 L, 2 L	PP bucket
0.25 L, 0.5 L, 1 L	HDPE bottle
5 L, 10 L, 20 L	HDPE canister
200 L	PE/HDPE drum
1000 L	HDPE/PE/PE-HD container

Table 4.1-1: Packaging information for 0.2 litre tube

Type	Description
Material:	PE 7 (LDPE/HDPE)
Shape/size:	Tube / height 150 - 160 mm
Opening and closure:	45 – 55 mm diameter

Table 4.1-2: Packaging information for 0.25 litre tube

Type	Description
Material:	PE 7 (LDPE/HDPE) and COEX (SUGAR CANE/LDPE/HDPE)
Shape/size:	Tube / height 180 - 190 mm
Opening and closure:	45 – 55 mm diameter

Table 4.1-3: Packaging information for 0.3 litre cartridge

Type	Description
Material:	HDPE
Shape/size:	Cartridge / 210 – 220 mm x 48 - 50 mm
Opening and closure:	Cap, 12 - 16 mm diameter

Table 4.1-4: Packaging information for 0.25 litre bottle

Type	Description
Material:	HDPE

Type	Description
Shape/size:	Bottle / 60 – 65 mm x 125 – 130 mm
Opening and closure:	polyethylene screw cap, 40 – 55 mm diameter
Seal:	With liner or induction sealing
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-5: Packaging information for 0.5 litre bottle

Type	Description
Material:	HDPE
Shape/size:	Bottle / 72 – 74 mm x 179 – 181 mm
Opening and closure:	polyethylene screw cap, 40 – 50 mm diameter
Seal:	With liner or induction sealing
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-6: Packaging information for 1 litre bottle

Type	Description
Material:	HDPE and COEX (EVOH/HDPE)
Shape/size:	Bottle / 83 – 90 mm x 230 – 250 mm
Opening and closure:	polyethylene screw cap, 40 – 65 mm diameter
Seal:	With liner or induction sealing
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-7: Packaging information for 5 litre canister

Type	Description
Material:	HDPE and COEX (PA/HDPE)
Shape/size:	Canister / 125 - 145 mm x 190 – 200 mm x 300 – 315 mm
Opening and closure:	polyethylene screw cap, 50 – 65 mm diameter
Seal:	With liner or induction sealing
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-8: Packaging information for 10 litre canister

Type	Description
Material:	HDPE
Shape/size:	Canister / 160 - 182 mm x 225 – 245 mm x 370 – 385 mm
Opening and closure:	polyethylene screw cap, 50 – 65 mm diameter
Seal:	With liner or induction sealing

Type	Description
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-9: Packaging information for 20 litre canister

Type	Description
Material:	HDPE
Shape/size:	Canister / 250 – 263 mm x 285 – 300 mm x 370 – 385 mm
Opening and closure:	polyethylene screw cap, 50 – 65 mm diameter
Seal:	With liner or induction sealing
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-10: Packaging information for 0.2 litre bucket

Type	Description
Material:	PP
Shape/size:	Bucket / heighth: 45 - 80 mm, upper diameter: 75 – 95 mm
Opening and closure:	polyethylene lid, 75 – 95 mm diameter
Seal:	seal, weld

Table 4.1-11: Packaging information for 0.4 litre bucket

Type	Description
Material:	PP
Shape/size:	Bucket / heighth: 65 - 100 mm, upper diameter: 94 – 120 mm
Opening and closure:	polyethylene lid, 94 – 120 mm diameter
Seal:	seal, weld

Table 4.1-12: Packaging information for 0.5 litre bucket

Type	Description
Material:	PP
Shape/size:	Bucket / heighth: 62 - 120 mm, upper diameter: 94 – 135 mm
Opening and closure:	polyethylene lid, 94 – 135 mm diameter
Seal:	seal, weld

Table 4.1-13: Packaging information for 0.8 litre bucket

Type	Description
Material:	PP
Shape/size:	Bucket / heighth: 100 - 125 mm, upper diameter: 115 – 135 mm
Opening and closure:	polyethylene lid, 115 – 135 mm diameter
Seal:	seal, weld

Table 4.1-14: Packaging information for 1 litre bucket

Type	Description
Material:	PP
Shape/size:	Bucket / heighth: 90 - 145 mm, upper diameter: 115 – 148 mm
Opening and closure:	polyethylene lid, 115 – 148 mm diameter
Seal:	seal, weld

Table 4.1-15: Packaging information for 1.2 litre bucket

Type	Description
Material:	PP
Shape/size:	Bucket / heighth: 130 - 135 mm, upper diameter: 130 – 135 mm
Opening and closure:	polyethylene lid, 130 – 135 mm diameter
Seal:	seal, weld

Table 4.1-16: Packaging information for 2 litre bucket

Type	Description
Material:	PP
Shape/size:	Bucket / heighth: 100 - 110 mm, upper diameter: 200 – 205 mm
Opening and closure:	polyethylene lid, 200 – 205 mm diameter
Seal:	seal, weld

Table 4.1-17: Packaging information for 200 litre drum

Type	Description
Material:	PE/HDPE
Shape/size:	cylindrical / approx. 580 mm diameter x 965 mm

Table 4.1-18: Packaging information for 1000 litre container

Type	Description
Material:	HDPE/ PE/PE HD
Shape/size:	Container / approx. 1152 mm x 1000 mm x 1200 mm
Opening and closure:	screw cap

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1	Jarosław Kupiec	2022	FLUDIO 025 GF Stage I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after low temperature storage. Study code number: BF – 59/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Warsaw, 2022 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.2.1	Daniel Buczkowski	2022	FLUDIO 025 GF Determination of explosive properties Study code number: BW-02/22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Warsaw, 2022 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.2.2	Paulina Flasińska	2022	FLUDIO 025 GF Determination of flash point, auto-ignition temperature and oxidizing properties. Study code number: BC-07/22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Warsaw, 2022 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.3.1	Paulina Flasińska	2022	FLUDIO 025 GF Determination of flash point, auto-ignition temperature and oxidizing properties. Study code number: BC-07/22	N	Synthos Agro Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Warsaw, 2022 GLP Unpublished		
KCP 2.4.2	Jarosław Kupiec	2022	FLUDIO 025 GF Stage I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after low temperature storage. Study code number: BF – 59/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Warsaw, 2022 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.5.1	Jarosław Kupiec	2022	FLUDIO 025 GF Stage I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after low temperature storage. Study code number: BF – 59/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Warsaw, 2022 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.5.2	Jarosław Kupiec	2022	FLUDIO 025 GF Stage I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after low temperature storage. Study code number: BF – 59/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Warsaw, 2022 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.6.1	Jarosław Kupiec	2022	FLUDIO 025 GF Stage I: Determination of physicochemical properties of the initial preparation, after accelerated storage	N	Synthos Agro Sp. z

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			and after low temperature storage. Study code number: BF – 59/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Warsaw, 2022 GLP Unpublished		o.o.
KCP 2.7.1	Jarosław Kupiec	2022	FLUDIO 025 GF Stage I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after low temperature storage. Study code number: BF – 59/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Warsaw, 2022 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.7.3	Jarosław Kupiec	2022	FLUDIO 025 GF Stage I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after low temperature storage. Study code number: BF – 59/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Warsaw, 2022 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.7.4	Jarosław Kupiec	2022	FLUDIO 025 GF Stage I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after low temperature storage. Study code number: BF – 59/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Warsaw, 2022 GLP Unpublished	N	Synthos Agro Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.7.5	Jarosław Kupiec	2023	FLUDIO 025 GF Stage II: Determination of physicochemical properties of the preparation after one year storage. Study code number: BF – 59/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Warsaw, 2023 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.8.2	Jarosław Kupiec	2022	FLUDIO 025 GF Stage I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after low temperature storage. Study code number: BF – 59/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Warsaw, 2022 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.8.3.1	Jarosław Kupiec	2022	FLUDIO 025 GF Stage I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after low temperature storage. Study code number: BF – 59/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Warsaw, 2022 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.8.5.1.2	Jarosław Kupiec	2022	FLUDIO 025 GF Stage I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after low temperature storage. Study code number: BF – 59/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Warsaw, 2022 GLP Unpublished	N	Synthos Agro Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.8.7.2	Piotr Paleń	2022	Pourability of plant protection product FLUDIO 025 GF Study code number: AGRO/44/22 Synthos Agro Sp.z o.o. Oświęcim, 2022 Non – GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.10.1/01	Piotr Paleń	2022	FLUDIO 025 GF Determination of adhesion to treated seeds of plant protection product. Study code number: AGRO/4/21 Synthos Agro Sp.z o.o. Oświęcim, 2022 Non – GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.10.1/02	Piotr Paleń	2023	Amendment No. 1 to the final report: FLUDIO 025 GF Determination of adhesion to treated seeds of plant protection product. Study code number: AGRO/4/21 Synthos Agro Sp.z o.o. Oświęcim, 2023 Non – GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.10.2	Piotr Paleń	2022	FLUDIO 025 GF Determination of seed-to-seed uniformity of distribution for liquid seed-treatment formulation. Study code number: AGRO/5/21 Synthos Agro Sp.z o.o. Oświęcim, 2022 Non – GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.10.3	Piotr Paleń	2022	FLUDIO 025 GF Seed loading – determination of the active substance content on treated seeds – validation of analytical procedure.	N	Synthos Agro Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Study code number: AGRO/6/21 Synthos Agro Sp.z o.o. Oświęcim, 2022 Non – GLP Unpublished		

Appendix 2 Additional data on the physical, chemical and technical properties of the active substance

A 2.1 Fludioxonil

No new or additional data.