

# FINAL REGISTRATION REPORT

## Part A

### Risk Management

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; 02/2024; 05/2024;**

## Version history

When	What
01/2023	Initial dRR
04/2023	Updated calculation for exposure assessment
05/2023	Physicochemical data after one year of storage
06/2023	ZRMS evaluated dRR submitted by Applicant.
10/2023	Final Registration Report
02/2024	Efficacy section corrected fRR in line to comments from MRiRW
03/2024	Updated GAP table, label, KCP 3.2 (addition of water during usage).
05/2024	ZRMs assessed the addition of usage water during seed treatment application
06/2024	<del>An anonymized version has been compiled</del>

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# **PART A**

## **RISK MANAGEMENT**

### **1 Details of the application**

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.

This application was submitted by company Synthos Agro Sp. z o. o., ul. Chemików 1, 32-600 Oświęcim, Poland.

The information, data and assessments provided in Registration Report, Parts B includes assessment of data and information relating to FLUDIO 025 GF where that data has not been considered in the EU review. Otherwise assessments for the safe use of FLUDIO 025 GF have been made using endpoints agreed in the EU review of fludioxonil.

#### **1.1 Application background**

The application is submitted for registration of plant protection product FLUDIO 025 GF in Poland according to art. 33 of Regulation 1107/2009. The product has not been previously evaluated in any country from Central Zone of Europe according to Uniform Principles. The zRMS is Poland.

The application is for the approval of FLUDIO 025 GF which is a flowable concentrate for seed treatment [code FS] containing 25 g/L of fludioxonil for use as a seed treatment in cereal crops to control fungal diseases.

#### **1.2 Letters of Access**

Not submitted.

#### **1.3 Justification for submission of tests and studies**

The Applicant has conducted and submitted own studies on FLUDIO 025 GF which are sufficient to evaluate of the product. Data protection claims and a list of submitted test reports and study are included in each section of dRR for FLUDIO 025 GF and in Part C.

#### **1.4 Data protection claims**

All data submitted in Part C are confidential.

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4, on all references specified in Sections 1-7 of Part B in the form of "List of data submitted in support of the evaluation".

## 2 Details of the authorization decision

### 2.1 Product identity

Product code	FLUDIO 025 GF
Product name in MS	FLUDIO ŽEL 025 FS, FUNABEN® ŽEL 025 FS
Authorization number	-
Function	Fungicide
Applicant	Synthos Agro Sp. z o o.
Active substanc (incl. content)	Fludioxonil 25 g/L
Formulation type	Flowable concentrate for seed treatment (FS)
Packaging	Size and packaging type for professional users: <b>0.2 L, 0.25 L</b> PE/LDPE/HDPE tube <b>0.3 L</b> HDPE cartridge <b>0.2 L, 0.4 L, 0.5 L, 0.8 L, 1 L, 1.2 L, 2 L</b> PP bucket <b>5 L, 10 L, 20 L</b> HDPE canister <b>200 L</b> PE/HDPE drum <b>1000 L</b> HDPE/PE/PE-HD container
Coformulants of concern for national authorizations	Not applicable
Restrictions related to identiy	Not applicable
Mandatory tank mixtures	Not applicable
Recommended tank mixtures	Not applicable

### 2.2 Conclusion

#### Physical and chemical properties section:

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

For the formulation FLUDIO ŽEL FS (FUNABEN® ŽEL 025 FS) following tests were performed for neat formulation and formulation diluted in water:

- pH of formulation; pH of 1% solution (before storage)
- the persistence of foaming: with a dilution of 20% v/v (before storage)
- wet sieve: with a dilution of 1% w/v (before and after storage)
- suspensibility: with dilutions of 12% v/v and 20% v/v (before and after storage)
- stability of formulation: without dilution (before and after storage)
- adhesion to seeds: without dilution and with a dilution of 25% v/v (before storage)
- distribution to seed: without dilution and with a dilution of 25% v/v (before storage)
- active substance loading: without dilution and with a dilution of 25% v/v (before storage)

The results of the test were acceptable, therefore the use of the formulation both without dilution and with dilution up to 25% v/v is acceptable.

#### Efficacy section:

FLUDIO ŻEL 025 FS, FUNABEN® ŻEL 025 FS can be granted in Poland according to accepted GAP table and label project.

ZRMs accepted the addition of usage water during seed treatment application (0-800 ml of water per 100 kg of seeds).

#### Metabolism and residues:

The evaluation of the application for FLUDIO 025 GF resulted in the decision to grant the authorization.

All uses applied for were authorised.

#### Fate and ecotoxicology:

The evaluation of the application for product name FLUDIO ŻEL 025 FS, FUNABEN ŻEL 025 FS resulted in the decision to grant the authorization.

## 2.3 Substances of concern for national monitoring

National monitoring data is not available/known to the applicant.

## 2.4 Classification and labelling

### 2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class, categories:	Aquatic Chronic 2
---------------------------	-------------------

The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	<b>GHS09</b>
Signal word:	No signal word is used
Hazard statement(s):	<b>H411: Toxic to aquatic life with long lasting effects</b>
Precautionary statement(s):	Other section of the label: P270 – Do not eat, drink or smoke when using this product.  And P280 as follows: Operator: „Stosować odzież roboczą (kombinezon) oraz rękawice ochronne w trakcie przygotowywania cieczy roboczej, zaprawiania, pakowania zaprawionych ziaren oraz czyszczenia sprzętu.” “Wear work wear (coverall) nad protective gloves during mixing/loading, seed treatment, seed packing and cleaning.”  Worker: „Stosować odzież roboczą (kombinezon) oraz rękawice ochronne w czasie kontaktu z zaprawionym ziarnem” “Wear work wear (coverall) nad protective gloves during during contact with treated seeds”.

	<p>Section “First aid”: P101: If medical advice is needed, have product container or label at hand</p> <p><b>P273 - Avoid release to the environment</b> <b>P391 - Collect spillage.</b> <b>P501 - Dispose of contents/container to an approved waste disposal plant.</b></p>
Additional labelling phrases:	<b>To avoid risks to man and the environment, comply with the instructions for use. [EUH401]</b>
	<b>Contains 1,2-benzisothiazol-3(2H)-one and 3-hydroxy-2'-methyl-2-naphthanilide . May produce an allergic reaction. [EUH208]</b>

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
EUH 208	Contains 1,2-benzisothiazol-3(2H)-one and 3-hydroxy-2'-methyl-2-naphthanilide . May produce an allergic reaction.

See Part C for justifications of the classification and labelling proposals.

#### 2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe5	To protect birds/mammals the product must be entirely incorporated in the soil; ensure that the product is also fully incorporated at the end of rows.
SPe6	To birds/mammals remove spillages.

#### 2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

### 2.5 Risk management

#### 2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

<b>Operator protection:</b>	
respective code if available	There is no risk for operator health based on the exposure estimation. However, due to the model limitations and the possibility of underestimation it is recommended to: “Wear work wear (coverall) nad protective gloves during mixing/loading, seed treatment, seed packing and cleaning.”
<b>Worker protection:</b>	
respective code if available	There is no risk for operator health based on the exposure estimation. However, due to the model limitations and the possibility of underestimation it is recommended t:o “Wear work wear (coverall) nad protective gloves during during contact with treated seeds.”



Integrated pest management (IPM)/sustainable use:	
respective code if available	The risk of resistance has to be indicated on the package and in the instructions of use. Particularly measures for an appropriate risk management have to be declared.
Environmental protection	
respective code if available	FLUDIO 025 GF is safe for environment when using according to recommendation (GAP)
Other specific restrictions	
respective code if available	No other requirements

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
	The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration is applied.

## 2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Environmental protection:		Relevant for use no.
respective code if available	The product may not be applied in or in the immediate vicinity of surface or coastal waters. Irrespective of this, the minimum buffer zone from surface waters stipulated by state law must be observed.	1-6

## 2.6 Intended uses (only NATIONAL GAP)

GAP, 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) <sup>(a, b)</sup>  
Active substance 1: Fludioxonil Conc. of as 1: 25 g/L <sup>(c)</sup>  
Applicant: Synthos Agro Sp. z o.o. Professional use: ☒  
Zone: central <sup>(d)</sup> 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. <sup>(e)</sup>	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: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha <sup>(f)</sup>
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval 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 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	0-1.6 L/ha		200 mL/100 kg seeds  Sowing rate: 100 – 200 kg seeds/ha  The addition of using water during seed treatment application was accepted (recom- mended 0-800 ml per 100 kg of seeds).
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	0-2.0 L/ha		200 ml/100 kg seeds  Sowing rate: 150-250 kg seeds/ha  The addition of using water during seed

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	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: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval 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		
													treatment application was accepted (recom- mended 0-800 ml per 100 kg of seeds).
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	0-1.6 L/ha		200 ml/100 kg seeds  Sowing rate: 120-200 kg seeds/ha  The addition of using water during seed treatment application was accepted (recom- mended 0-800 ml per 100 kg of seeds).
4	PL	Winter triticale	F	<i>Fusarium spp.</i>	Seed treatment	BBCH 00	1	-	0.2-0.4 L/ha	Fludioxonil 5 – 10 g	0-1.6 L/ha		200 ml/100 kg seeds  Sowing rate (triticale): 100-200 kg seeds/ha  The addition of using water during seed treatment application was accepted (recom- mended 0-800 ml per 100 kg of seeds).
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	0-2.0 L/ha		200 ml/100 kg seeds  Sowing rate: 150-250 kg seeds/ha  The addition of using water during seed treatment application was accepted (recom- mended 0-800 ml per 100 kg of seeds).

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	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: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha <sup>(f)</sup>
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval 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		
6	PL	Spring barley	F	<i>Fusarium spp.</i>	Seed treatment	BBCH 00	1	-	0,24-0,4 L/ha	Fludioxonil: 6- 10g	0-1.6 L/ha		200 ml/100 kg seeds Sowing rate: 120-200 kg seeds/ha  The addition of using water during seed treatment application was accepted (recom- mended 0-800 ml per 100 kg of seeds).

**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 ap-  
 plication  
 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/m<sup>3</sup> 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

### 3 Background of authorization decision and risk management

#### 3.1 Physical and chemical properties (Part B, Section 2)

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 200 mL/100 kg of seeds.

#### 3.2 Efficacy (Part B, Section 3)

FLUDIO 025 GF a flowable concentrate for seed treatment [code: FS] containing fludioxonil (25 g/L). Active substance – fludioxonil is a non-systemic fungicide used for the treatment of crops (particularly cereals, fruits and vegetables, and ornamental plants; often in combination with another fungicide). It is a fungicide that interferes with glucose transport across fungal membranes.

During visual observation no effects of the measure on non-target organisms were found.

Tested product FLUDIO 025 GF showed high efficacy in winter rye (UROCO, FUSASP), winter barley (PYRNGR, FUSASP, MONGNI), spring barley (FUSASP), spring wheat (FUSASP, TILLCA), winter wheat (MONGNI, FUSASP, TILLCA) and winter triticale (FUSASP).

#### Justification for the possibility of adding water during the use of the product

The draft label attached to the application for authorization of plant protection product FLUDIO 025 GF (trade names: FLUDIO ŽEL 025 FS and FUNABEN GEL 025 FS) dated January 5, 2023 did not take into account the addition of water during seed treatment. However, due to common agricultural practice and the possibility of making the treatment easier for the farmer, it has been proposed to include in the label the possibility of adding water to the treated grain in a quantity of 0 to 800 ml. The addition of water improves seed treatment of winter wheat, spring wheat, winter triticale, winter rye, winter barley and spring barley.

#### A. Justification from the scope of the Efficacy Section

The efficacy of the FLUDIO 025 GF seed treatment was tested in various crops, such as: winter wheat, spring wheat, winter triticale, winter rye, winter barley and spring barley. In the case of barley, the efficacy in control of diseases after treating grains with FLUDIO 025 GF with the addition of water (800 ml) was also tested. Barley grains have a compact structure, with high starch content and are often covered with glumes. For this reason, it is considered one of the most difficult grains to treat compared to grains of other crops. Therefore, in the efficacy tests performed, an additional combination was proposed, in which the seeds were treated with FLUDIO 025 GF with the addition of water (800 ml). The conducted efficacy tests showed comparable efficacy in control of winter barley diseases: leaf stripe of barley (*Pyrrenophora graminea*), snow mold (*Monographella nivalis*) and *Fusarium* after using the FLUDIO 025 GF

at a dose of 200 ml/100 kg of grains without and with the addition of water (800 ml of water per 100 kg of grains). The differences between the efficacy of FLUDIO 025 GF at a dose of 200 ml/100 kg of grain without and with the addition of water are statistically insignificant, as presented in Table 1.

**Table 1. Summary of efficacy results in winter barley cultivation.**

Disease	Efficacy	
	Without water addition	With water addition (800 ml)
<i>Pyrenophora graminea</i>	87.0%	86.6%
<i>Fusarium spp.</i>	83.3%	89.7%
<i>Monographella nivalis</i>	83.2%	87.3%

In all diseases indicated in Table 1, the amount of the active substance fludioxonil used for seed treatment does not change. When using 200 ml of seed dressing per 100 kg of grain, without or with water (800 ml), the active substance content is 6 to 10 g, at the assumed winter barley sowing rate of 120 to 200 kg of grain per hectare.

## B. Justification from the scope of the Physicochemical properties Section

Physicochemical properties of FLUDIO 025 GF were also tested for the diluted (800 ml of water) and undiluted versions. The tested parameters are consistent with the requirements set out in the guideline „Guidance document for the generation and evaluation of data on the physical, chemical and technical properties of plant protection products under Regulation (EC) No. 1107/2009” (SANCO/10473/2003 – rev.5).

The *Seed loading*, *Adhesion to treated seeds* and *Determination of seed-to-seed uniformity of distribution for liquid seed-treatment formulations* studies performed for various seed materials, without and with water (800 ml), indicate no significant statistical differences. A summary of the results is provided below in Tables 2, 3 and 4.

**Table 2. Summary of Seed loading test results for FLUDIO 025 GF.**

Cultivation	Seed loading (method efficacy)	
	Without water addition	With water addition (800 ml)
Wheat	93.4%	95.7%
Rye	92.2%	96.0%
Triticale	90.2%	93.2%
Barley	93.3%	93.9%
Oat	92.3%	94.7%

**Table 3. Summary of the results of the Adhesion to treated seeds study for FLUDIO 025 GF.**

Adhesion to treated seeds	
Without water addition	With water addition (800 ml)
92.0%	98.2%

**Table 4. Summary of the results of the Determination of seed-to-seed uniformity of distribution for liquid seed-treatment formulations study for FLUDIO 025 GF.**

Determination of seed-to-seed uniformity of distribution for liquid seed-treatment formulations	
Without water addition	With water addition (800 ml)
homogeneous	homogeneous

The availability of seed treatments with recommendations for adding water depends on factors such as the specific needs of the crop, the type of treatment, and the preference of growers or agricultural specialists. Some seed treatments are formulated as concentrates the need to be diluted with water before application, while others are designed to be used directly without additional water. Overall, while seed treatments with recommendations for adding water are available, they represent a portion of the seed treatment market and the choice of treatment depends on various factors and the farmic practices employed.

Adding water to the seed treatment can have various impacts on its effectiveness, depending on the type of treatment, its chemical composition, and the application conditions.

In the case of some types of treatments, adding an excess of water can lead to the dissolution of active substances or other components of the treatment, which can reduce its effectiveness.

Adding water can help evenly distribute the treatment on the surface of the seeds, which in turn can increase protection against diseases.

Water can facilitate the adhesion of the treatment to the surface of the seeds, which can improve the adherence and durability of the treatment on the seeds.

In some cases, adding water can help the active substances of the treatment penetrate better into the structure of the seeds, which can increase its effectiveness.

Adding water can affect application conditions such as viscosity and spraying properties, which can impact the uniformity of seed coverage with the treatment.

Moistening seeds during seed treatment can also aid the germination process, especially if the soil is dry or conditions are unfavorable for germination.

It is important to note that excess water can also lead to decreased treatment effectiveness or other negative effects, so it is important to maintain the proper ratio of water to treatment and to follow the label's recommendations.

ZRMs accepted usage of water during application of FLUDIO ŽEL 025 FS / FUNABEN ŽEL 025 FS. Accepted and recommended water volume is 0-800 ml per 100 kg of seeds which correspond to water volume used during some efficacy trials carried out on for ex. on winter barley seeds. In all diseases indicated in Table 1, the amount of the active substance fludioxonil used for seed treatment does not change. When using 200 ml of seed dressing per 100 kg of grain, without or with water (800 ml), the active substance content is 6 to 10 g, at the assumed winter barley sowing rate of 120 to 200 kg of grain per hectare. Efficacy with water addition and without water addition was comparable against *Pyrenophora graminea*, *Fusarium spp.* and *Monographella nivalis*. In the opinion of ZRMs results only for winter barley seeds in the case of adding or not water for seed treatment application can be accepted. As, Applicant noted the barley grains have a compact structure, with high starch content and are often covered with glumes. For this reason, it is considered one of the most difficult grains to treat compared to grains of other crops. So, extrapolated results to other cereals should be accepted. Also, many PPPs registered as a seed treatment are recommended for using water as the same water volume as a tested product – FLUDIO ŽEL 025 FS / FUNABEN ŽEL 025 FS.

Applicant presented results for summary of seed loading test results for FLUDIO 025 GF, summary of the results of the adhesion to treated seeds study for FLUDIO 025 GF and summary of the results of the determination of seed-to-seed uniformity of distribution for liquid seed-treatment formulations study for FLUDIO 025 GF. All results were comparable for using water and without water application.

**In the opinion of ZRMS in the GAP table and label for FLUDIO ŽEL 025 FS / FUNABEN ŽEL 025 FS the possibility of adding water to the treated grain in a quantity of 0 to 800 ml can be accepted.**

### 3.3 Efficacy data

**Preliminary studies** have not been conducted because the active substance – fludioxonil is known and has long been used in the protection of plants. The effect of the active substances is well known and sufficient large scale efficacy trials are available to evaluate the effectiveness of FLUDIO 025 GF. Therefore



preliminary tests are not described and not required.

The efficacy of reduced rates of FLUDIO 025 GF for diseases control in winter rye (UROCOC, FUSASP), winter barley (PYRNGR, FUSASP, MONGNI), spring barley (FUSASP), spring wheat (FUSASP, TILLCA), winter wheat (MONGNI, FUSASP, TILLCA) and winter triticale (FUSASP) was investigated in field tests carried out in 2021. In the appropriate researches of efficacy were tested several doses and to register was chosen the lowest effective. All researches were conducted according to EPPO standard PP 1/225 '*Minimum effective dose*'.

#### **MED (Minimum effective dose)**

To provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least two lower dose(s) than recommended dose. In the appropriate research of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance to EPPO 1/225 (2).

During field tests Applicant used different doses (120 ml/100 kg seed – 0,6 N; 160 ml/100 kg seed – 0,8 N and 200 ml/100 kg seed – N recommended) of seed treatment product – FLUDIO ŽEL 025 FS / FUNABEN ŽEL (product code: FLUDIO 025 GF) containing fludioxonil (25 g/L). So, in the appropriate research of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance with EPPO 1/225 (2).

In total, Applicant submitted 32 trials carried out on: spring cereals (7) – spring barley (3) and spring wheat (4) and winter cereals (25) – winter rye (7), winter barley (9), winter wheat (7) and winter triticale (2). In some reports, several diseases were tested at the same time, so the number of tests performed on individual crops is not equal to the number of tests for individual fungal diseases.

What is more, seed treatments products containing active ingredient –fludioxonil (25 g/L) have been allowed to use for many years. Also, in the literature of crop protection vast amounts of information can be found on efficacy of the plant protection products containing fludioxonil as an active compound.

Therefore, **the submitted documentation can be observed as acceptable in the opinion of Evaluator. Recommended dose 200 ml / 100 kg seed effectively control all studied fungal diseases.** In all trials level of infestation was at acceptable level.

- **winter rye** (7 trials), **winter barley** (9 trials), **spring wheat** (2 trials), **spring barley** (3 trials), **winter wheat** (7 trials), **winter triticale** (2 trials) / **FUSASP** as a result, the proposed rate of 200 ml/ 100 kg seeds should be considered the minimum effective dose to deliver broad spectrum control of FUSASP under a wide range of environmental conditions.
- **winter rye** (7 trials) / **UROCOC** as a result, the proposed rate of 200ml/ 100 kg seeds should be considered the minimum effective dose to deliver broad spectrum control of UROCOC under a wide range of environmental conditions.
- **winter barley** (6 trials), **winter wheat** (6 trials) / **MONGNI** - as a result, the proposed rate of 200 ml/ 100 kg seeds should be considered the minimum effective dose to deliver broad spectrum control of MONGNI under a wide range of environmental conditions.
- **winter barley** (7 trials) / **PYRNGR** as a result, the proposed rate of 200ml/ 100 kg seeds should be considered the minimum effective dose to deliver broad spectrum control of PYRNGR under a wide range of environmental conditions.
- **spring wheat** (4 trials), **winter wheat** (7 trials) / **TILLCA** as a result, the proposed rate of 200ml/ 100 kg seeds should be considered the minimum effective dose to deliver broad spectrum control of TILLCA under a wide range of environmental conditions.

#### **EFFICACY:**

Details of experiment are presented above by Applicant. All used methodology is in accordance with GEP rules, in exception of EPPO 1/181 (4). However, Applicant has made the appropriate explanation for



carrying out the survey only in one growing season, which was accepted by Evaluator.

Applicant submitted in total 32 field trials showing the results in research into product efficacy carried out during one growing season (2021) in winter cereals (25 trials) and spring cereals (7 trials). Those efficacy trials were performed in North-East EPPO zone in Poland. The number of trials is sufficient and fulfil EPPO requirements for a major crop: winter wheat (7 trials), winter barley (9 trials), winter rye (7 trials). In the case of other cereals for which limited number of trials was presented: spring barley (3 trials), spring wheat (4 trials) and winter triticale (2 trials) the main case is the number of trials for each fungal disease. Only against FUSASP in winter triticale and spring wheat not sufficient number of trials is presented. However, results against FUSASP on winter wheat can be extrapolate for winter triticale and spring wheat. So, all claimed uses in GAP table can be accepted. Detailed assessment will be presented later for each disease separately.

Following varieties of winter and spring cereals were studied during field trials:

- winter triticale – 2 varieties (Gringo, Grenado),
- spring barley – 3 varieties (Xanthe, Finish, Ella),
- winter barley – 9 varieties (Cakri, U-313, Igri, SY 216-464, Titus, C 62, Zenek, Sandra, Kosmos),
- winter wheat – 7 varieties (Plejada, Arkadia-2 trials, Zyta, Opoka, Fidelius, Tobak),
- winter rye – 7 varieties (Dańkowskie Hadron, Dukato, Dańkowskie Granat, Dańkowski Diament, Dańkowsie Rubin, Słowiańskie, Tur F1),
- spring wheat – 4 varieties (MHR Jutrzenka, Rusalka, Atrakcja, Quintus).

The following efficacy scale was used:

- L – limiting (0-60% efficacy)
- ME – moderately efficiency (60-80%)
- E – efficiently (>80%)

We are dealing with the active substances used commonly for many years in many countries. We must emphasize that each pest should be representative by sufficient number of field efficacy tests (at least 6 for major pest and at least 3 for minor pest).

#### WINTER CEREALS:

- **winter wheat:**
- ✓ **TILLCA (śnieć cuchnąca)** – 7 trials – major pest – number of trials is sufficient. All trials were characterized by sufficient level of infestation (at least 5% is required). **It can be concluded that FLUDIO 025 GF effectively control (96,8%) TILLCA on winter wheat at recommended dose (200 ml/100 kg seed).** Lower doses 120 ml/100 kg seed (eff. 87.1%) and 160 ml / 100 kg seed (eff. 93.6%) were also characterized by very good efficiency, comparable to st. ref product (eff. 97.9%). According to the proposal results, the dose of 120 mL /100 kg seed of FLUDIO 025 GF provided the optimum overall control and should be considered as effective against TILLCA, for which activity of FLUDIO 025 GF is claimed. However, in practice, farmer/user perform one treatment to protect crops during the growing season from a broader spectrum of seed borne and soil-borne disease. For this reason, 200 mL/100 kg seed is recommended. This dose is also recommended in plant protection products registered for today in Poland, that contain the tested active substance.
- ✓ **FUSASP (zgorzel siewek)** – 7 trials – major pest – number of trials is sufficient. All trials were characterized by sufficient level of infestation (at least 5% is required). **It can be concluded that FLUDIO 025 GF effectively control (80,2% eff.) FUSASP on winter wheat at recommended dose (200 ml/ 100 kg seed).** Lower doses 120 ml/100 kg seed (eff. 55.6%) and 160 ml / 100 kg seed (eff. 67,3%) were characterized by worse efficiency than recommended dose and st. ref. product (79.8% eff.).
- ✓ **MONGNI (pleśń śniegowa)** – 6 trials – ~~minor~~ major pest – number of trials is sufficient. All trials were characterized by sufficient level of infestation (at least 5% is required). **It can be concluded that FLUDIO 025 GF effectively control (80,5% eff.) MONGNI at recommended dose (200 ml/100 kg seed) on winter wheat.** Lower doses 120 ml/100 kg seed (eff. 54,5%) and 160 ml / 100 kg seed (eff.

68,0%) were characterized by worse efficiency than recommended dose and st. ref. product (84,7% eff.).

- **winter triticale:**

- ✓ **FUSASP (zgorzel siewek)** – 2 trials – major pest – number of trials is not sufficient. However, extrapolation results from winter wheat is possible. So, FUSASP in winter triticale can be accepted. All trials were characterized by sufficient level of infestation (at least 5% is required). **It can be concluded that FLUDIO 025 GF effectively control (91,0% eff.) FUSASP at recommended dose (200 ml/100 kg seed) on winter triticale.** Lower doses 120 ml/100 kg seed (eff. 62,1%) and 160 ml / 100 kg seed (eff. 75,5%) were characterized by worse efficiency than recommended dose and st. ref. product (90,7% eff.).

- **winter barley:**

- ✓ **PYRNGR (pasistość liści jęczmienia)** – 7 trials – major pest – number of trials is sufficient. All trials were characterized by sufficient level of infestation (at least 5% is required). **It can be concluded that FLUDIO 025 GF effectively control (87,0% eff.) PYRNGR at recommended dose (200 ml/100 kg seed) on winter barley.** Lower doses 120 ml/100 kg seed (eff. 76,5%) and 160 ml / 100 kg seed (eff. 82,5%) were also characterized by very good efficiency, comparable to st. ref product (eff. 87,2%). According to the proposal results, the dose of 160 ml / 100 kg seed of FLUDIO 025 GF provided the optimum overall control and should be considered as effective against PYRNGR, for which activity of FLUDIO 025 GF is claimed. However, in practice, farmer/user perform one treatment to protect crops during the growing season from a broader spectrum of seed borne and soil-borne disease. For this reason, 200 mL/100 kg seed is recommended. This dose is also recommended in plant protection products registered for today in Poland, that contain the tested active substance.
- ✓ **MONGNI (pleśń śniegowa)** – 6 trials – ~~minor~~ **major** pest – number of trials is sufficient. All trials were characterized by sufficient level of infestation (at least 5% is required). **It can be concluded that FLUDIO 025 GF effectively control (83,2% eff.) MONGNI at recommended dose (200 ml/100 kg seed) on winter barley.** Lower doses 120 ml/100 kg seed (eff. 73,0%) and 160 ml / 100 kg seed (eff. 79,8%) were characterized by worse efficiency than recommended dose and st. ref. product (90,2% eff.).
- ✓ **FUSASP (zgorzel siewek)** – 7 trials – major pest – number of trials is sufficient. All trials were characterized by sufficient level of infestation (at least 5% is required). **It can be concluded that FLUDIO 025 GF effectively control (83,3% eff.) FUSASP at recommended dose (200 ml/100 kg seed) on winter barley.** Lower doses 120 ml/100 kg seed (eff. 55,9%) and 160 ml / 100 kg seed (eff. 68,4%) were characterized by worse efficiency than recommended dose and st. ref. product (84,0% eff.).

- **winter rye:**

- ✓ **UROCOC (głownia żdźbłowa)** – 7 trials – minor pest – number of trials is sufficient. All trials were characterized by sufficient level of infestation (at least 5% is required). **It can be concluded that FLUDIO 025 GF effectively control (98,7% eff.) UROCOC on winter rye at recommended dose (200 ml/ 100 kg seed).** Lower doses 120 ml/100 kg seed (eff. 94,1%) and 160 ml / 100 kg seed (eff. 97,5%) were also characterized by very good efficiency, comparable to st. ref product (eff. 98,7%). According to the proposal results, the dose of 120 mL /100 kg seed of FLUDIO 025 GF provided the optimum overall control and should be considered as effective against UROCOC, for which activity of FLUDIO 025 GF is claimed. However, in practice, farmer/user perform one treatment to protect crops during the growing season from a broader spectrum of seed borne and soil-borne disease. For this reason, 200 mL/100 kg seed is recommended. This dose is also recommended in plant protection products registered for today in Poland, that contain the tested active substance.
- ✓ **FUSASP (zgorzel siewek)** – 7 trials – major pest – number of trials is sufficient. All trials were characterized by sufficient level of infestation (at least 5% is required). **It can be concluded that FLUDIO 025 GF effectively control (85,6% eff.) FUSASP on winter rye at recommended dose (200 ml / 100 kg seed).** Lower doses 120 ml/100 kg seed (eff. 56,1%) and 160 ml / 100 kg seed (eff. 68,4%) were characterized by worse efficiency than recommended dose and st. ref. product (79,5%

eff.).

#### SPRING CEREALS:

- **spring wheat:**
- ✓ **TILLCA (śnieć cuchnąca)** – 4 trials – minor pest – number of trials is sufficient. **It can be concluded, on the basis on 4 valid trials, that FLUDIO 025 GF effectively control (91,5% eff.) TILLCA on spring wheat at recommended dose (200 ml/100 kg seed).** Lower doses 120 ml/100 kg seed (eff. 70,8%) and 160 ml / 100 kg seed (eff. 81,7%) were also characterized by very good efficiency, comparable to st. ref product (eff. 91,5%). According to the proposal results, the dose of 160 ml / 100 kg seed of FLUDIO 025 GF provided the optimum overall control and should be considered as effective against TILLCA, for which activity of FLUDIO 025 GF is claimed. However, in practice, farmer/user perform one treatment to protect crops during the growing season from a broader spectrum of seed borne and soil-borne disease. For this reason, 200 mL/100 kg seed is recommended. This dose is also recommended in plant protection products registered for today in Poland, that contain the tested active substance.
- ✓ **FUSASP (zgorzel siewek)** – 2 trials - minor pest – number of trials is not sufficient. However, extrapolation results from winter wheat are possible. Level of infestation was at acceptable level (>5%) in all trials. **It can be concluded that FLUDIO 025 GF effectively control (88,0% eff.) FUSASP on spring wheat at recommended dose (200 ml / 100 kg seed).** Lower doses 120 ml/100 kg seed (eff. 67,5%) and 160 ml / 100 kg seed (eff. 75,5%) were characterized by worse efficiency than recommended dose and st. ref. product (90,0% eff.).
- **spring barley:**
- ✓ **FUSASP (zgorzel siewek)** – 3 trials - ~~minor~~ major pest – number of trials is not sufficient. All trials were characterized by sufficient level of infestation (at least 5% is required). **Extrapolation results from winter wheat is possible. Winter wheat was represented by sufficient number of trials against FUSASP, so extrapolation results to spring barley is possible on the basis on 3 trials carried out on spring barley against this disease. It can be concluded that FLUDIO 025 GF effectively control (85,5% eff.) FUSASP on spring barley at recommended dose (200 ml / 100 kg seed).** Lower doses 120 ml/100 kg seed (eff. 70,5%) and 160 ml / 100 kg seed (eff. 79,2%) were characterized by worse efficiency than recommended dose and st. ref. product (88,9% eff.).

In all efficacy trials standard reference products were used. The efficacy of the tested seed treatment was comparable or even slightly higher than the standard products.

#### 3.3.1 Information on the occurrence or possible occurrence of the development of resistance

Fludioxonil, is used as a seed treatment or sprayed against foliar diseases or as post-harvest fungicide against a broad variety of fungi. Fludioxonil is usually applied as a mixture with the AP cyprodinil, which is considered the most effective fungicide against Botrytis. Like the dicarboximides, fludioxonil interferes with the Bos1- and MAP kinase-dependent osmoregulation pathway, but cross-resistance between these fungicides is rarely observed in the field. In sensitive cells, fludioxonil hyperactivates the pathway, which leads to a futile hyperosmolarity response, followed by glycerol accumulation and growth inhibition. Laboratory-induced mutations in the Bos1 histidine kinase confer high levels of resistance against both fludioxonil and iprodione; however, these mutants show poor growth and are hypersensitive to high osmolarity, and such strains usually do not survive in the field. In fact, fludioxonil is exceptional among the site-specific fungicides used against Botrytis because highly resistant field strains are very rarely found. In contrast, strains with resistance to fludioxonil and iprodione have been observed in field populations of *Alternaria brassicicola* and *Penicillium* spp. The proportion of *Botrytis cinerea* field isolates resistant to fludioxonil and other phenylpyrroles is very low. Very few resistant isolates have been detected in Switzerland and France. Thanks to the low resistance frequency and the fact that fludioxonil is mostly used a formulated combination with

cyprodinil (Switch) efficacy is very high. In regions where fludioxonil is used by itself (Champagne) a strict alternation with botrycides of other chemical groups is in place in order to manage resistance development and gram efficacy.

Applicant proposed strategy against developing resistance, in accordance with the general recommendations made by FRAC:

- Use in alternation with fungicides with a different mode of action
- Use as recommended on the label. Do not use reduced doses.
- Application should be as a protective application.
- Use other measures such as resistant varieties, good agronomic practice

The abundance of the requirements within the good agricultural practice is necessary. The resistance management should be coordinated by FRAC recommendations. Applying the anti-resistance use recommendations, development of resistance can be considerably decreased or avoided. The restriction should be put on the label.

Since the agronomic factors influencing the risk of resistance development tend to vary between the member states, the individual and detailed assessment of the resistance risk (Evaluation of the Agromonic risk of resistance, Management of resistance) should be decided on national level.

The Applicant should provide a resistance risk assessment in accordance with EPPO PP 1/213. The zRMS would consider that inherent risk of resistance developing to fludioxonil is quite low. To minimize occurrence of resistance product should be used strictly in accordance with the instructions on the label. Therefore, in the opinion of Evaluator the product should be applied in recommended dosage and (if possible) fungicides of other chemical structure and different mode of action should be also applied.

### 3.3.2 Adverse effects on treated crops

Phytotoxicity assessment of the tested product – FLUDIO 025 GF was made at the same time as studies of its effectiveness. Moreover, additional studies of selectivity were performed to check the influence of testes seed treatment on crop grains. Phytotoxicity assessment was carried out with the use of different cultivars (commercially grown varieties) which is compliant with PP 1/135 Phytotoxicity assessment.

A total of 60 phytotoxicity trials (32 efficacy trials and ~~24~~ 28 selectivity trials) were carried out in 2021 in different regions in Poland on different cultivars of winter wheat (7 efficacy trials and 5 selectivity trials), winter rye (7 efficacy trials and 5 selectivity trials), winter barley (9 efficacy trials and 5 selectivity trials), winter triticale (2 efficacy trials and 5 selectivity trials), spring wheat (4 efficacy trials and 4 selectivity trials), spring barley (3 efficacy trials and 4 selectivity trials). The annexes (5 reports for winter wheat, 5 for winter barley, 5 for winter rye and 5 for winter triticale) to selectivity trials were not counted as a new selectivity trials. Also, Applicant presented 14 quality trials against impact on protein content (winter wheat-5 trials, winter rye – 5 trials, spring barley – 4 trials). Those quality trials were also not counted as a selectivity trials.

### 3.3.3 Observations on other undesirable or unintended side-effects

The phytotoxicity trials about tested plant protection product (seed treatment) have been carried out in accordance with EPPO Guidelines (in exception of EPPO 1/181 (4). However, this exception was accepted by Evaluator. The conduct of the field work is principally compliant with “Good Agricultural Practice” and in accordance with EPPO Guidelines PP 1/135.

The trials were performed with the use of different agricultural practice in Poland (North-East EPPO zone). Those trials were performed with the use of cultivars, differing in growth strength as well as soil and water requirements. The appropriate experimental design was applied. In all trials studied product was compared to the standard reference products. Statistical analysis of the data was performed. Also, quality of yield was evaluated in some trials.

Both EU Directive 91/414 (EU, 1991) and EPPO PP 1/226 (3) – Number of efficacy trials requires testing phytotoxicity at normal (N) and double (2N) recommended dose. However, EPPO 1/135 (3) – Phytotoxicity assessment states: ‘EPPO Standards on fungicides, insecticides and plant growth regulators or seed treatments, on the other hand, include only a relatively simple special section on phytotoxicity assessment, because, for these types of plant protection products, phytotoxic effects will be less frequent’. Selectivity trials were not required, which is in accordance with EPPO 1/135 (3).

In efficacy trials FLUDIO 025 GF was tested in three doses: 1N (200 mL/100 kg seeds), 0.8N (160 mL/100 kg seeds), 0.6N (120 mL/100 kg seeds) and reference product – MAXIM 025 FS at the rate 200 mL/100 kg seeds with 800 mL of water.

In selectivity trials, two doses of tested product were examined: 1N (200 mL/100 kg seeds) and 1.5N (300 mL/100 kg seeds), as well as two doses of the reference product: 1N (200 mL/100 kg seeds+800 mL of water), and 1.5N (300 mL/100 kg seeds + 800 mL of water).

Applicant submitted in total 32 efficacy trials in which phytotoxicity effect was assessed:

- winter cereals (25 trials): winter wheat (7 trials), winter rye (7 trials), winter barley (9 trials), winter triticale (2 trials)
- spring cereals (7 trials): spring wheat (4 trials) and spring barley (3 trials).

Applicant submitted in total 28 selectivity trials in which phytotoxicity effect was assessed at N and 1.5 N dose:

- winter cereals (20 trials): winter wheat (5 trials), winter rye (5 trials), winter barley (5 trials), winter triticale (5 trials)
- spring cereals (8 trials): spring wheat (4 trials) and spring barley (4 trials)

**During the research, the visual observation, there were no impact on the measure of cultivation of spring and winter wheat, spring and winter barley, winter rye and winter triticale. No signs of phytotoxicity effect were observed in all trials.**

Submitted documentation is acceptable. There were not observed any phytotoxicity symptoms caused by FLUDIO 025 GF at the highest dose rate of 300 ml of product + 800 ml of water/ 100 kg seeds was recorded in all trials. No signs of phytotoxicity effects were observed in all trials.

FLUDIO ŽEL 025 FS / FUNABEN ŽEL (product code: FLUDIO 025 GF) containing fludioxonil (25 g/L) applied at dose rates higher than the recommended rate did not significantly affect the crop yield and its quality.

### IMPACT ON THE YIELD:

FLUDIO ŽEL 025 FS / FUNABEN ŽEL (product code: FLUDIO 025 GF) containing fludioxonil (25 g/L) applied at dose rates higher than the recommended rate did not significantly affect the crop yield.

**The data obtained in trials harvested demonstrate that FLUDIO ŽEL 025 FS / FUNABEN ŽEL (product code: FLUDIO 025 GF) containing fludioxonil (25 g/L) is as safe to the crop as the reference products used in the trials.**

Below, ZRMs presented detailed results from field trials about impact of FLUDIO ŽEL 025 FS / FUNABEN ŽEL (product code: FLUDIO 025 GF) on the yield (on the basis on 28 selectivity trials):

✓ **Winter wheat**

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Žel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
58 F/2022	PL	2021	Zyta	Yield	t/ha	4,77	5,86	5,69	5,67	5,66
59 F/2022	PL	2021	Opoka	Yield	t/ha	6,10	6,70	6,50	6,73	6,63
60 F/2022	PL	2021	Arkadia	Yield	t/ha	5,88	6,21	6,29	6,35	6,33
61 F/2022	PL	2021	Fideliuss	Yield	t/ha	5,56	5,50	6,39	6,36	6,28
62 F/2022	PL	2021	Tobak	Yield	t/ha	6,19	7,09	7,45	7,45	7,44



Impact on the yield was assessed in 5 trials carried out on winter wheat in PL (N-E). No negative effect was observed during trials.

✓ **Winter barley**

Trial ID	Country	Year	Variety	Ass. Type	Unit	Mean	Untreated	Fludio Żel 025 FS		Maxim 025 FA	
								200 ml	300 ml	200 ml	300 ml
								of product per 100 kg seeds			
								% rel.	% rel.	% rel.	% rel.
301_SYNTH_FF22JZ301W	PL	2021	Bažant	Yield	t/ha	5,56		5,64	6,58	5,98	6,10
302_SYNTH_FF22JZ302W	PL	2021	Bartosz	Yield	t/ha	6,01		6,12	7,08	6,67	6,78
303_SYNTH_FF22JZ303W	PL	2021	Brosza	Yield	t/ha	5,56		5,64	6,58	5,98	6,10
327_SYNTH_FF22JZ304W	PL	2021	Kosmos	Yield	t/ha	4,36		4,58	5,09	4,44	4,57
328_SYNTH_FF22JZ305W	PL	2021	Gloria	Yield	t/ha	4,18		5,12	4,35	4,27	4,73

Impact on the yield was assessed in 5 trials carried out on winter barley in PL (N-E). No negative effect was observed during trials.

✓ **Winter triticale**

Trial ID	Country	Year	Variety	Ass. Type	Unit	Mean	Untreated	Fludio Żel 025 FS		Maxim 025 FA	
								200 ml	300 ml	200 ml	300 ml
								of product per 100 kg seeds			
								% rel.	% rel.	% rel.	% rel.
307_SYNTH_FF22TZ301W	PL	2021	Avokado	Yield	t/ha	7,53		8,56	8,09	8,37	7,87
308_SYNTH_FF22TZ303W	PL	2021	Rotondo	Yield	t/ha	6,39		6,80	6,81	6,78	6,75
309_SYNTH_FF22TZ304W	PL	2021	Grenado	Yield	t/ha	6,28		6,34	6,47	6,70	6,86
341_SYNTH_FF22TZ305W	PL	2021	Trapero	Yield	t/ha	4,55		4,85	4,99	5,04	4,70
342_SYNTH_FF22TZ306W	PL	2021	Kasyno	Yield	t/ha	4,72		5,42	5,53	5,67	5,67

Impact on the yield was assessed in 5 trials carried out on winter triticale in PL (N-E). No negative effect was observed during trials.

✓ **Winter rye**

Trial ID	Country	Year	Variety	Ass. Type	Unit	Mean	Untreated	Fludio Żel 025 FS		Maxim 025 FA	
								200 ml	300 ml	200 ml	300 ml
								of product per 100 kg seeds			
								% rel.	% rel.	% rel.	% rel.
35 F/2022	PL	2021	Dukato	Yield	t/ha	8,15		8,38	8,27	8,15	8,08
36 F/2022	PL	2021	SU Forsetti	Yield	t/ha	9,08		9,43	9,00	8,89	9,22
37F/2022	PL	2021	Dańkowskie Rubin	Yield	t/ha	6,39		6,63	6,23	6,57	6,33
38F/2022	PL	2021	Dańkowskie Granat	Yield	t/ha	6,97		6,85	6,85	6,98	6,89
39F/2022	PL	2021	Dańkowskie Diament	Yield	t/ha	6,49		6,73	6,97	6,65	6,65

Impact on the yield was assessed in 5 trials carried out on winter rye in PL (N-E). No negative effect was observed during trials.

✓ **Spring wheat**

Trial ID	Country	Year	Variety	Ass. Type	Unit	Mean	Untreated	Fludio Żel 025 FS		Maxim 025 FA	
								200 ml	300 ml	200 ml	300 ml
								of product per 100 kg seeds			
								% rel.	% rel.	% rel.	% rel.
314_SYNTH_FF22PJ301W	PL	2021	Telimena	Yield	t/ha	6,32		6,53	6,61	6,47	6,69
315_SYNTH_FF22PJ302W	PL	2021	Ostka Smolicka	Yield	t/ha	5,87		6,25	6,14	6,42	6,33
343_SYNTH_FF22PJ303W	PL	2021	Arabella	Yield	t/ha	3,24		3,55	3,24	3,5	3,55
344_SYNTH_FF22PJ304W	PL	2021	Jarlanka	Yield	t/ha	2,98		3,87	4,19	3,91	4,04

Impact on the yield was assessed in 4 trials carried out on spring wheat in PL (N-E). No negative effect was observed during trials.

✓ **Spring barley**

Ass. Type	Untreated	Fludio Żel 025 FS	Maxim 025 FA
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Trial ID	Country	Year	Variety	Unit	Mean	of product per 100 kg seeds			
						200 ml	300 ml	200 ml	300 ml
						% rel.	% rel.	% rel.	% rel.
80 F_2022	PL	2021	Ella	Yield	t/ha	5,05	5,18	5,05	5,08
81 F_2022	PL	2021	Stratus	Yield	t/ha	5,39	5,43	5,47	5,39
82 F_2022	PL	2021	MHR Krajan	Yield	t/ha	4,79	4,81	4,84	4,82
83 F_2022	PL	2021	Pausitan	Yield	t/ha	4,87	4,89	5,03	4,81

Impact on the yield was assessed in 4 trials carried out on spring barley in PL (N-E). No negative effect was observed during trials.

### IMPACT ON THE QUALITY OF YIELD:

Applicant submitted in total 28 selectivity trials in which phytotoxicity effect was assessed at N and 1.5 N dose:

- winter cereals (20 trials): winter wheat (5 trials), winter rye (5 trials), winter barley (5 trials), winter triticale (5 trials)
- spring cereals (8 trials): spring wheat (4 trials) and spring barley (4 trials).

FLUDIO ŽEL 025 FS / FUNABEN ŽEL (product code: FLUDIO 025 GF) containing fludioxonil (25 g/L) applied at dose rates higher than the recommended rate did not significantly affect the quality of crop yield.

The data obtained in trials harvested demonstrate that FLUDIO ŽEL 025 FS / FUNABEN ŽEL (product code: FLUDIO 025 GF) containing fludioxonil (25 g/L) is as safe to the crop as the reference products used in the trials.

Below, ZRMs presented detailed results from field trials about impact of FLUDIO ŽEL 025 FS / FUNABEN ŽEL (product code: FLUDIO 025 GF) on the quality yield (on the basis on 28 selectivity trials and 14 quality trials about impact on protein content):

#### ✓ Winter wheat

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Žel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							% rel.	% rel.	% rel.	% rel.
1 J/2022	PL	2021	Zyta	protein	%DM	13,55	13,18	13,00	13,13	13,11
2 J/2022	PL	2021	Opoka	protein	%DM	11,10	10,90	10,95	10,88	11,06
3 J/2022	PL	2021	Arkadia	protein	%DM	10,86	10,85	11,04	11,27	10,71
4 J/2022	PL	2021	Fidelius	protein	%DM	11,16	10,04	10,65	10,85	10,04
5 J/2022	PL	2021	Tobak	protein	%DM	11,67	11,21	11,05	11,88	11,05

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Žel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							% rel.	% rel.	% rel.	% rel.
58 F/2022	PL	2021	Zyta	TGW	g	40,47	41,27	40,90	41,25	41,32
59 F/2022	PL	2021	Opoka	TGW	g	40,91	40,71	40,63	41,00	40,73
60 F/2022	PL	2021	Arkadia	TGW	g	41,16	41,84	42,22	42,05	41,73
61 F/2022	PL	2021	Fidelius	TGW	g	39,17	41,13	41,32	40,85	41,38
62 F/2022	PL	2021	Tobak	TGW	g	31,83	31,45	30,81	31,97	30,74

No negative impact on protein content (%) – 5 trials and TGW (g) – 5 trials was observed during trials carried out on winter wheat.

#### ✓ Winter barley

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Žel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							% rel.	% rel.	% rel.	% rel.
301_SYNTH_FF22JZ301W	PL	2021	Bazant	protein	%DM	14,30	14,93	14,35	14,48	14,45
302_SYNTH_FF22JZ302W	PL	2021	Bartos	protein	%DM	13,45	13,60	13,13	13,53	13,15

303_SYNTH_FF22JZ303W	PL	2021	Brosza	protein	%DM	14,30	14,93	14,35	14,48	14,45
327_SYNTH_FF22JZ304W	PL	2021	Kosmos	protein	%DM	13,95	13,20	13,30	13,18	13,63
328_SYNTH_FF22JZ305W	PL	2021	Gloria	protein	%DM	15,00	14,40	14,83	14,50	15,00

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Żel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
301_SYNTH_FF22JZ301W	PL	2021	Bazant	TGW	g	43,2	43,10	42,71	42,95	43,45
302_SYNTH_FF22JZ302W	PL	2021	Bartos	TGW	g	51,85	52,81	49,08	53,58	51,60
303_SYNTH_FF22JZ303W	PL	2021	Brosza	TGW	g	43,32	43,10	42,71	42,95	43,45
327_SYNTH_FF22JZ304W	PL	2021	Kosmos	TGW	g	51,55	51,97	50,88	51,76	50,75
328_SYNTH_FF22JZ305W	PL	2021	Gloria	TGW	g	55,39	57,47	55,98	55,35	54,91

No negative impact on protein content (%) – 5 trials and TGW (g) – 5 trials was observed during trials carried out on winter barley.

✓ **Winter triticale**

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Żel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
307_SYNTH_FF22TZ301W	PL	2021	Avokado	protein	%DM	11,63	11,65	11,85	11,68	11,65
308_SYNTH_FF22TZ303W	PL	2021	Rotondo	protein	%DM	12,20	12,05	12,38	12,00	12,30
309_SYNTH_FF22TZ304W	PL	2021	Grenado	protein	%DM	11,08	11,15	11,13	10,95	11,20
341_SYNTH_FF22TZ305W	PL	2021	Trapero	protein	%DM	13,95	13,95	14,23	13,90	14,38
342_SYNTH_FF22TZ306W	PL	2021	Kasyno	protein	%DM	11,75	11,43	11,40	11,73	11,43

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Żel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
307_SYNTH_FF22TZ301W	PL	2021	Avokado	TGW	g	51,56	49,85	50,57	51,58	51,52
308_SYNTH_FF22TZ303W	PL	2021	Rotondo	TGW	g	44,41	45,96	43,40	44,97	42,26
309_SYNTH_FF22TZ304W	PL	2021	Grenado	TGW	g	38,76	38,21	39,15	38,09	38,68
341_SYNTH_FF22TZ305W	PL	2021	Trapero	TGW	g	39,37	39,64	41,12	39,78	40,09
342_SYNTH_FF22TZ306W	PL	2021	Kasyno	TGW	g	46,96	45,58	45,48	45,72	47,05

No negative impact on protein content (%) – 5 trials and TGW (g) – 5 trials was observed during trials carried out on winter triticale.

✓ **Winter rye**

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Żel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
18 J/2022	PL	2021	Dukato	protein	%DM	7,91	8,27	8,61	8,26	8,41
19J/2022	PL	2021	SU Forsetti	protein	%DM	7,23	7,68	7,49	7,13	7,53
20J/2022	PL	2021	Dańkowskie Rubin	protein	%DM	8,28	8,11	8,24	8,33	8,25
21J/2022	PL	2021	Dańkowskie Granat	protein	%DM	8,74	8,33	8,38	8,55	8,46
22J/2022	PL	2021	Dańkowskie Diament	protein	%DM	8,80	8,68	8,89	9,46	8,58

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Żel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
35 F/2022	PL	2021	Dukato	TGW	g	31,83	31,45	30,81	31,97	30,74
36 F/2022	PL	2021	SU Forsetti	TGW	g	29,74	27,92	29,53	30,41	28,94
37F/2022	PL	2021	Dańkowskie Rubin	TGW	g	28,02	29,10	29,95	29,30	27,74
38F/2022	PL	2021	Dańkowskie Granat	TGW	g	28,64	27,74	29,40	28,65	28,05
39F/2022	PL	2021	Dańkowskie Diament	TGW	g	n.a	n.a	n.a	n.a	n.a



No negative impact on protein content (%) – 5 trials and TGW (g) – 5 trials was observed during trials carried out on winter rye.

✓ **Spring wheat**

Trial ID	Country	Year	Variety	Ass. Type	Unit	Mean	Untreated	Fludio Žel 025 FS		Maxim 025 FA	
								200 ml	300 ml	200 ml	300 ml
								of product per 100 kg seeds			
								% rel.	% rel.	% rel.	% rel.
314_SYNTH_FF22PJ301W	PL	2021	Telimena	protein	%DM	12,78		12,93	12,90	13,13	13,08
315_SYNTH_FF22PJ302W	PL	2021	Ostka Smolicka	protein	%DM	12,85		12,63	12,68	12,83	12,80
343_SYNTH_FF22PJ303W	PL	2021	Arabella	protein	%DM	11,45		11,60	11,13	11,48	11,20
344_SYNTH_FF22PJ304W	PL	2021	Jarlanka	protein	%DM	14,15		14,10	13,98	14,08	14,08

Trial ID	Country	Year	Variety	Ass. Type	Unit	Mean	Untreated	Fludio Žel 025 FS		Maxim 025 FA	
								200 ml	300 ml	200 ml	300 ml
								of product per 100 kg seeds			
								% rel.	% rel.	% rel.	% rel.
314_SYNTH_FF22PJ301W	PL	2021	Telimena	TGW	g	42,63		41,94	41,93	42,37	42,66
315_SYNTH_FF22PJ302W	PL	2021	Ostka Smolicka	TGW	g	39,13		39,74	40,63	42,54	38,93
343_SYNTH_FF22PJ303W	PL	2021	Arabella	TGW	g	36,48		36,87	36,58	36,75	36,99
344_SYNTH_FF22PJ304W	PL	2021	Jarlanka	TGW	g	37,95		37,54	37,18	37,10	36,11

No negative impact on protein content (%) – 4 trials and TGW (g) – 4 trials was observed during trials carried out on spring wheat.

✓ **Spring barley**

Trial ID	Country	Year	Variety	Ass. Type	Unit	Mean	Untreated	Fludio Žel 025 FS		Maxim 025 FA	
								200 ml	300 ml	200 ml	300 ml
								of product per 100 kg seeds			
								% rel.	% rel.	% rel.	% rel.
7J/2022	PL	2021	Ella	protein	%DM	11,73		11,69	11,30	11,10	11,39
8J/2022	PL	2021	Stratus	protein	%DM	11,77		12,16	12,11	11,52	11,84
9J/2022	PL	2021	MHR Kraján	protein	%DM	11,82		11,71	12,08	12,11	12,33
10J/2022	PL	2021	Pausitan	protein	%DM	11,72		11,58	11,64	11,52	11,70

Trial ID	Country	Year	Variety	Ass. Type	Unit	Mean	Untreated	Fludio Žel 025 FS		Maxim 025 FA	
								200 ml	300 ml	200 ml	300 ml
								of product per 100 kg seeds			
								% rel.	% rel.	% rel.	% rel.
80 F_2022	PL	2021	Ella	TGW	g	43,60		43,47	44,01	44,78	45,63
81 F_2022	PL	2021	Stratus	TGW	g	41,13		40,66	41,25	42,11	40,12
82 F_2022	PL	2021	MHR Kraján	TGW	g	37,99		36,80	37,08	36,88	35,90
83 F_2022	PL	2021	Pausitan	TGW	g	38,52		38,28	38,83	38,22	38,38

No negative impact on protein content (%) – 4 trials and TGW (g) – 4 trials was observed during trials carried out on spring barley.

## EFFECT ON TRANSFORMATION PROCESSES

EPPO PP 1/243 (1) states that the absence of detectable residues could form the basis of an argument to address this aspect. The remains of FLUDIO ŽEL 025 FS / FUNABEN ŽEL (product code: FLUDIO 025 GF) containing fludioxonil (25 g/L) should be presented in Part B, Section 7.

In this dossier, the information provided by the Applicant are limited. No residues above the LOD are expected because of the application regime – seed treatment – and based on the results of the residue trials provided. Still, no phytotoxicity symptoms occurring during the field trials suggest that product application in accordance with label recommendation has no negative impact on parts of plant used for propagating purposes. Also, this active compound –fludioxonil is known and commercially used in Poland (zRMS) and other countries from EU. Therefore, it is not expected to adversely affect the processing operations in the opinion of Evaluator.

## IMPACT ON TREATED PLANTS OR PLANTS PRODUCTS TO BE USED FOR PROPAGA-

**TION**

Information provided by the Applicant was limited due to fact that there is no information available pointing to presence of any limitations to using fludioxonil. Also, no phytotoxicity symptoms occurring during the field trials suggested that product (FLUDIO 025 GF) application in accordance with label recommendation has no negative impact on parts of plant used for propagating purposes.

Applicant presented results for impact of FLUDIO ŻEL 025 FS / FUNABEN ŻEL (product code: FLUDIO 025 GF) on the germination rate and energy after 1 month after the treatment under laboratory conditions.

Below, ZRMs presented results carried out on winter and spring cereals.

✓ **Winter wheat**

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Żel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
58 F/2022	PL	2021	Zyta	Germination energy	%	98,50	96,50	97,00	97,00	97,50
59 F/2022	PL	2021	Opoka	Germination energy	%	96,00	97,50	95,50	98,00	99,50
60 F/2022	PL	2021	Arkadia	Germination energy	%	93,50	97,00	95,50	95,50	96,50
61 F/2022	PL	2021	Fidelius	Germination energy	%	98,00	96,50	94,50	97,00	95,50
62 F/2022	PL	2021	Tobak	Germination energy	%	98,00	97,50	95,00	98,00	96,00

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Żel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
58 F/2022	PL	2021	Zyta	Germination rate	%	98,50a	97,00a	98,00a	98,00a	97,50a
59 F/2022	PL	2021	Opoka	Germination rate	%	97,50a	97,50a	97,00a	98,00a	99,50a
60 F/2022	PL	2021	Arkadia	Germination rate	%	98,50a	98,00a	99,00a	97,50a	98,00a
61 F/2022	PL	2021	Fidelius	Germination rate	%	99,00a	98,00a	98,00a	98,00a	97,00a
62 F/2022	PL	2021	Tobak	Germination rate	%	98,00a	99,00a	97,50a	98,00a	99,00a

✓ **Winter barley**

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Żel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
301_SYNTH_FF22JZ301W	PL	2021	Bažant	Germination energy	%	82,3	73,8	67,3	25,8	22,3
302_SYNTH_FF22JZ302W	PL	2021	Bartosz	Germination energy	%	74,5	47,5	49,3	19,5	12,8
303_SYNTH_FF22JZ303W	PL	2021	Brosza	Germination energy	%	83,5	53,3	45,0	47,5	22,0
327_SYNTH_FF22JZ304W	PL	2021	Kosmos	Germination energy	%	n.a.	n.a.	n.a.	n.a.	n.a.
328_SYNTH_FF22JZ305W	PL	2021	Gloria	Germination energy	%	92,8	87,0	82,5	45,3	42,5

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Żel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
301_SYNTH_FF22JZ301W	PL	2021	Bažant	Germination rate	%	89,8	85,0	82,5	72,0	60,3
302_SYNTH_FF22JZ302W	PL	2021	Bartosz	Germination rate	%	84,8	73,8	76,3	57,5	47,0
303_SYNTH_FF22JZ303W	PL	2021	Brosza	Germination rate	%	88,0	65,8	60,0	67,3	44,3
327_SYNTH_FF22JZ304W	PL	2021	Kosmos	Germination rate	%	n.a.	n.a.	n.a.	n.a.	n.a.
328_SYNTH_FF22JZ305W	PL	2021	Gloria	Germination rate	%	98,0	95,5	95,8	77,0	72,5

✓ **Winter triticales**

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Żel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
307_SYNTH_FF22TZ301W	PL	2021	Avokado	Germination energy	%	96,5	96,3	94,0	88,3	91,3
308_SYNTH_FF22TZ303W	PL	2021	Rotondo	Germination energy	%	99,3	98,5	99,0	93,5	91,3
309_SYNTH_FF22TZ304W	PL	2021	Grenado	Germination energy	%	96,3	94,5	94,0	91,3	89,3
341_SYNTH_FF22TZ305W	PL	2021	Trapero	Germination energy	%	97,5	96,3	92,0	80,3	70,0
342_SYNTH_FF22TZ306W	PL	2021	Kasyno	Germination energy	%	94,5	88,5	86,3	58,5	37,8

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Żel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
307_SYNTH_FF22TZ301W	PL	2021	Avokado	Germination rate	%	98,0	97,8	95,5	94,8	94,5

308_SYNTH_FF22TZ303W	PL	2021	Rotondo	Germination rate	%	99,8	99,5	99,8	98,0	98,0
309_SYNTH_FF22TZ304W	PL	2021	Grenado	Germination rate	%	96,3	95,3	94,5	94,0	93,0
341_SYNTH_FF22TZ305W	PL	2021	Trapero	Germination rate	%	98,0	96,8	94,3	88,3	88,0
342_SYNTH_FF22TZ306W	PL	2021	Kasyno	Germination rate	%	97,0	89,5	89,8	65,5	51,8

✓ **Winter rye**

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Żel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
35 F/2022	PL	2021	Dukato	Germination energy	%	81,5	86,5	82,0	77,0	73,0
36 F/2022	PL	2021	SU Forsetti	Germination energy	%	90,0	88,5	86,0	83,5	84,5
37F/2022	PL	2021	Dańkowskie Rubin	Germination energy	%	92,5	85,0	80,5	83,0	81,0
38F/2022	PL	2021	Dańkowskie Granat	Germination energy	%	87,0	82,5	84,5	80,0	80,0
39F/2022	PL	2021	Dańkowskie Diament	Germination energy	%	69,0	71,0	70,5	54,5	51,5

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Żel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
35 F/2022	PL	2021	Dukato	Germination rate	%	93,5	94,5	92,5	89,0	84,0
36 F/2022	PL	2021	SU Forsetti	Germination rate	%	90,5	89,3	89,0	86,5	87,0
37F/2022	PL	2021	Dańkowskie Rubin	Germination rate	%	94,0	89,0	84,5	85,0	87,0
38F/2022	PL	2021	Dańkowskie Granat	Germination rate	%	88,5	84,0	87,0	84,0	84,0
39F/2022	PL	2021	Dańkowskie Diament	Germination rate	%	73,5	80,0	74,0	61,0	62,0

✓ **Spring wheat**

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Żel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
314_SYNTH_FF22PJ301W	PL	2021	Telimena	Germination energy	%	96,5	95,5	94,5	93,3	88,3
315_SYNTH_FF22PJ302W	PL	2021	Ostka Smolicka	Germination energy	%	95,8	92,0	91,3	89,3	89,8
343_SYNTH_FF22PJ303W	PL	2021	Arabella	Germination energy	%	98,5	97,5	97,5	83,5	82,0
344_SYNTH_FF22PJ304W	PL	2021	Jarlanka	Germination energy	%	97,5	96,8	98,3	96,0	95,3

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Żel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
314_SYNTH_FF22PJ301W	PL	2021	Telimena	Germination rate	%	97,0	96,3	96,5	95,5	94,0
315_SYNTH_FF22PJ302W	PL	2021	Ostka Smolicka	Germination rate	%	96,3	92,8	92,8	91,3	90,8
343_SYNTH_FF22PJ303W	PL	2021	Arabella	Germination rate	%	98,8	97,8	98,8	88,5	89,8
344_SYNTH_FF22PJ304W	PL	2021	Jarlanka	Germination rate	%	97,8	97,3	98,8	97,8	97,3

✓ **Spring barley**

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Żel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
80 F_2022	PL	2021	Ella	Germination energy	%	66,00	67,50	53,50	60,00	41,50
81 F_2022	PL	2021	Stratus	Germination energy	%	73,00	65,00	60,50	75,50	73,00
82 F_2022	PL	2021	MHR Krajan	Germination energy	%	86,50	78,00	68,00	76,50	68,50
83 F_2022	PL	2021	Pausitan	Germination energy	%	80,50	74,00	66,50	64,00	71,00

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Żel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
80 F_2022	PL	2021	Ella	Germination rate	%	90,50	88,00	82,00	83,00	81,50
81 F_2022	PL	2021	Stratus	Germination rate	%	91,00	88,00	82,00	86,50	84,50
82 F_2022	PL	2021	MHR Krajan	Germination rate	%	90,00	88,00	85,00	86,00	83,50
83 F_2022	PL	2021	Pausitan	Germination rate	%	84,50	86,50	82,50	83,50	81,50

Also, plant emergence was assessed during those trials. No negative effects was observed. Below, ZRMs presented detailed results about plant emergence rate. In some trials, the average emergency rate was higher as compared to untreated object.

✓ **Winter wheat**

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Żel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
58 F/2022	PL	2021	Zyta	rel. check	%	100	102	106	111	101
59 F/2022	PL	2021	Opoka	rel. check	%	100	94	98	92	99
60 F/2022	PL	2021	Arkadia	rel. check	%	100	99	101	99	97
61 F/2022	PL	2021	Fidelius	rel. check	%	100	97	97	97	101
62 F/2022	PL	2021	Tobak	rel. check	%	100	96	102	99	104

✓ **Winter barley**

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Żel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
301_SYNTH_FF22JZ301W	PL	2021	Bazant	rel. check	%	100	99,8	100,5	99,8	94,1
302_SYNTH_FF22JZ302W	PL	2021	Bartosz	rel. check	%	100	100,3	103,6	96,0	97,2
303_SYNTH_FF22JZ303W	PL	2021	Brosza	rel. check	%	100	100,8	103,4	105,1	101,5
327_SYNTH_FF22JZ304W	PL	2021	Kosmos	rel. check	%	n.a.	n.a.	n.a.	n.a.	n.a.
328_SYNTH_FF22JZ305W	PL	2021	Gloria	rel. check	%	100	112,1	116,5	119,9	124,1

✓ **Winter triticale**

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Żel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
307_SYNTH_FF22TZ301W	PL	2021	Avokado	rel. check	%	100	106,7	107,6	106,3	105,3
308_SYNTH_FF22TZ303W	PL	2021	Rotondo	rel. check	%	100	101,7	101,2	107,6	102,3
309_SYNTH_FF22TZ304W	PL	2021	Grenado	rel. check	%	100	101,3	101,5	106,5	104,8
341_SYNTH_FF22TZ305W	PL	2021	Trapero	rel. check	%	100	97,7	99,5	90,1	106,4
342_SYNTH_FF22TZ306W	PL	2021	Kasyno	rel. check	%	100	112,1	116,5	119,9	124,1

✓ **Winter rye**

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Żel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
35 F/2022	PL	2021	Dukato	rel. check	%	100	112	84	77	82
36 F/2022	PL	2021	SU Forsetti	rel. check	%	100	98	100	104	104
37 F/2022	PL	2021	Dańkowskie Rubin	rel. check	%	100	91	90	80	90
38 F/2022	PL	2021	Dańkowskie Granat	rel. check	%	100	116	112	104	112
39 F/2022	PL	2021	Dańkowskie Diament	rel. check	%	100	111	105	106	102

✓ **Spring wheat**

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Żel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
314_SYNTH_FF22PJ301W	PL	2021	Telimena	rel. check	%	100	96,8	100,6	103,3	95,8
315_SYNTH_FF22PJ302W	PL	2021	Ostka Smolicka	rel. check	%	100	109,1	103,4	111,5	108,3
343_SYNTH_FF22PJ303W	PL	2021	Arabella	rel. check	%	100	98,7	98,4	97,6	102,1
344_SYNTH_FF22PJ304W	PL	2021	Jarlanka	rel. check	%	100	109,2	100,9	92,0	100,5

✓ **Spring barley**

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Żel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
80 F_2022	PL	2021	Ella	rel. check	%	100	101	102	101	96,0
81 F_2022	PL	2021	Stratus	rel. check	%	100	94,0	98,0	94,0	97,0
82 F_2022	PL	2021	MHR Krajani	rel. check	%	100	104	100	108	106
83 F_2022	PL	2021	Pausitan	rel. check	%	100	105	104	105	106

Applicant presented in the annexes to selectivity trials for winter cereals the results for grain germinability or germination rate and energy after 12 months after seed treatments. Below, ZRMs presented detailed results for grain germinability or germination rate and germination energy after 12 months after the treatments under laboratory conditions.

✓ **Winter wheat**

**379 days after application**

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Żel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
Aneks_58 F/2022	PL	2021	Zyta	Germination rate	%	80,0	83,0	74,0	80,0	70,0
Aneks_59 F/2022	PL	2021	Opoka	Germination rate	%	98,0	91,0	93,0	91,0	96,0
Aneks_60 F/2022	PL	2021	Arkadia	Germination rate	%	96,0	98,0	96,0	93,0	89,0
Aneks_61 F/2022	PL	2021	Fidelius	Germination rate	%	97,0	97,0	98,0	95,0	88,0
Aneks_62 F/2022	PL	2021	Tobak	Germination rate	%	98,0	99,0	98,0	98,0	99,0

**375 days after application**

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Żel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
Aneks_58 F/2022	PL	2021	Zyta	Germination energy	%	67,0	72,0	67,0	75,0	65,0
Aneks_59 F/2022	PL	2021	Opoka	Germination energy	%	94,0	86,0	76,0	82,0	89,0
Aneks_60 F/2022	PL	2021	Arkadia	Germination energy	%	88,0	90,0	88,0	85,0	81,0
Aneks_61 F/2022	PL	2021	Fidelius	Germination energy	%	92,0	93,0	90,0	82,0	82,0
Aneks_62 F/2022	PL	2021	Tobak	Germination energy	%	93,0	97,0	91,0	83,0	90,5

✓ **Winter barley**

**Grain germinability after 4 days after sowing**

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Żel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
Aneks_301_SYNTH_FF22JZ301W	PL	2021	Bažant	Grain germinability	%	62,5	57,0	43,8	22,0	11,8
Aneks_302_SYNTH_FF22JZ302W	PL	2021	Bartosz	Grain germinability	%	37,8	33,8	29,0	12,5	7,5
Aneks_303_SYNTH_FF22JZ303W	PL	2021	Brosza	Grain germinability	%	74,8	64,5	64,3	38,8	36,5
Aneks_327_SYNTH_FF22JZ304W	PL	2021	Kosmos	Grain germinability	%	98,8	98,0	96,0	81,5	93,0
Aneks_328_SYNTH_FF22JZ305W	PL	2021	Gloria	Grain germinability	%	95,5	86,0	66,0	81,3	82,5

**Grain germinability after 7 days after sowing**

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Żel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
Aneks_301_SYNTH_FF22JZ301W	PL	2021	Bažant	Grain germinability	%	80,3	75,5	65,3	54,3	45,0
Aneks_302_SYNTH_FF22JZ302W	PL	2021	Bartosz	Grain germinability	%	57,3	49,3	43,8	35,3	31,0
Aneks_303_SYNTH_FF22JZ303W	PL	2021	Brosza	Grain germinability	%	83,5	77,3	77,5	64,3	59,5
Aneks_327_SYNTH_FF22JZ304W	PL	2021	Kosmos	Grain germinability	%	100	98,5	98,8	95,5	97,0
Aneks_328_SYNTH_FF22JZ305W	PL	2021	Gloria	Grain germinability	%	98,5	95,8	72,5	94,5	96,5

✓ **Winter triticale**

**Grain germinability after 4 days after sowing**

Trial ID	Country	Year	Variety	Ass. Type	Unit	Untreated Mean	Fludio Żel 025 FS		Maxim 025 FA	
							200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
Aneks_307_SYNTH_FF22TZ301W	PL	2021	Avokado	Grain germinability	%	94,5	94,5	90,3	79,8	80,8
Aneks_308_SYNTH_FF22TZ303W	PL	2021	Rotondo	Grain germinability	%	99,5	98,8	97,5	94,3	92,8
Aneks_309_SYNTH_FF22TZ304W	PL	2021	Grenado	Grain germinability	%	92,5	87,3	91,8	89,5	84,5
Aneks_341_SYNTH_FF22TZ305W	PL	2021	Trapero	Grain germinability	%	98,8	97,5	96,5	97,5	90,8
Aneks_342_SYNTH_FF22TZ306W	PL	2021	Kasyno	Grain germinability	%	85,8	90,0	78,5	84,5	82,8

**Grain germinability after 8 days after sowing**

Ass. Type	Untreated	Fludio Żel 025 FS	Maxim 025 FA
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Trial ID	Country	Year	Variety	Ass. Type	Unit	Mean	200 ml	300 ml	200 ml	300 ml
							of product per 100 kg seeds			
							% rel.	% rel.	% rel.	% rel.
Aneks_307_SYNTH_FF22TZ301W	PL	2021	Avokado	Grain germinability	%	95,8	97,0	93,5	88,0	88,5
Aneks_308_SYNTH_FF22TZ303W	PL	2021	Rotondo	Grain germinability	%	99,5	99,5	98,0	96,8	96,8
Aneks_309_SYNTH_FF22TZ304W	PL	2021	Grenado	Grain germinability	%	94,3	90,5	92,5	92,8	89,3
Aneks_341_SYNTH_FF22TZ305W	PL	2021	Trapero	Grain germinability	%	99,0	98,3	98,5	98,8	93,5
Aneks_342_SYNTH_FF22TZ306W	PL	2021	Kasyno	Grain germinability	%	87,8	92,0	83,5	85,8	84,8

✓ **Winter rye**

**375 days after application**

Trial ID	Country	Year	Variety	Ass. Type	Unit	Mean	Untreated	Fludio Żel 025 FS		Maxim 025 FA	
								200 ml	300 ml	200 ml	300 ml
								of product per 100 kg seeds			
								% rel.	% rel.	% rel.	% rel.
Aneks_35 F/2022	PL	2021	Dukato	Germination rate	%	64,5	76,0	69,0	45,5	28,0	
Aneks_36 F/2022	PL	2021	SU Forsetti	Germination rate	%	86,0	68,0	66,5	50,0	53,5	
Aneks_37F/2022	PL	2021	Dańkowskie Rubin	Germination rate	%	89,0	75,0	74,0	42,0	43,0	
Aneks_38F/2022	PL	2021	Dańkowskie Granat	Germination rate	%	67,5	61,0	61,5	41,5	26,0	
Aneks_39F/2022	PL	2021	Dańkowskie Diament	Germination rate	%	60,0	62,5	47,0	32,0	26,0	

**372 days after application**

Trial ID	Country	Year	Variety	Ass. Type	Unit	Mean	Untreated	Fludio Żel 025 FS		Maxim 025 FA	
								200 ml	300 ml	200 ml	300 ml
								of product per 100 kg seeds			
								% rel.	% rel.	% rel.	% rel.
Aneks_35 F/2022	PL	2021	Dukato	Germination energy	%	48,5	53,0	46,5	24,0	16,0	
Aneks_36 F/2022	PL	2021	SU Forsetti	Germination energy	%	88,5	58,0	56,0	43,0	37,5	
Aneks_37F/2022	PL	2021	Dańkowskie Rubin	Germination energy	%	83,5	59,5	61,5	30,0	26,0	
Aneks_38F/2022	PL	2021	Dańkowskie Granat	Germination energy	%	58,0	52,0	56,5	25,5	15,5	
Aneks_39F/2022	PL	2021	Dańkowskie Diament	Germination energy	%	57,0	57,0	41,0	25,0	21,5	

No studies on the germination ability after 12 months of storage have been presented for spring cereals. In the case of winter barley, it was found that the germination capacity of the grains after 4 and 7 days in the facility using Fludio 025 GF at the recommended dose of 200 ml did not differ significantly compared to the control. For winter rye, in two studies (36 F/2022 and 37 F/2022), after 12 months from treatment, a significant reduction in germination parameters was observed after applying the tested Fludio 025 GF as well as the comparator Maxim 025 FS. The negative effect was higher with the st. ref. product. In the case of winter triticale, after applying Fludio 025 GF at doses of 200 ml and 300 ml, germination capacity under laboratory conditions did not differ significantly from the control. For winter wheat, after 12 months from treatment, no negative impact of the tested Fludio 025 GF fungicide on germination parameters (energy and capacity) was observed.

Given that reduced germination capacity of treated seeds after prolonged storage (12 months) was observed in some studies, and there are no relevant studies for spring cereals, it seems justified not to change the proposed label wording of the product: *'If there is a need to store seed grain for the next season, germination capacity should be tested before sowing'* in the opinion of ZRMs.

### IMPACT ON SUCCEEDING AND ADJACENT CROPS

The Applicant initially did not provide a sufficient level of information to address the impact on succeeding crops in accordance with EPPO PP 1/207. Predicted concentration of fludioxonil in soil (PECsoil) should be shown in report B, Section 5.

The submitted data and lack of phytotoxicity symptoms recorded during the field trials suggested that product (FLUDIO 025 GF) application in accordance with label recommendation shall not adversely impact on succeeding crops.

Also, the Applicant did not submit the results of the trials on possible impact on adjacent crops. The information collected in previous section and lack of phytotoxicity symptoms recorded during the field trials suggested that product application in accordance with label recommendation has no negative impact on adjacent crops.

Lack of any information's and submitted data against impact on succeeding and adjacent crops was accepted by ZRMs. Normally no special data for fungicides or PPP for seed treatment are prepared and submitted for that point if no persistence of the product is known or in discussion.

## **EFFECTS ON BENEFICIAL AND OTHER NON-TARGET ORGANISMS**

Efficacy evaluator did not evaluate the studies to beneficial and other non-target organisms presented by the applicant. Reference should be made to the Ecotoxicology assessment. Moreover, for details concerning adverse effects on beneficial and other non-target organisms see Part B9 of the dossier (ecotoxicological data).

### **3.4 Methods of analysis (Part B, Section 5)**

It was confirmed that chromatographic methods of determination of the active compound (fludioxonil) are specific. No interference was observed. The validation parameters (specificity, linearity, repeatability and recovery) are within the acceptance range and fulfil EU requirements given in SANCO/3030/99 rev.5.

#### **3.4.1 Analytical method for the formulation**

With respect to toxicological, eco-toxicological or environmental aspects FLUDIO 025 GF does not contain any relevant formulants. Therefore, a special analytical method and validation is not needed.

#### **3.4.2 Analytical methods for residues**

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

Data gaps:

- ILV method for drinking water (post registration requirement)
- Methods for body fluids and tissues (post registration requirement):

Commodity/crop	Supported/ Not supported
Cereals	Supported

### **3.5 Mammalian toxicology (Part B, Section 6)**

#### **3.5.1 Acute toxicity**

FLUDIO 025 GF does not contain any substances classified as:

- acute dermal toxicity,
- acute inhalation toxicity,
- respiratory sensitizer,
- germ cell mutagenic,
- cancerogenic,
- toxic on reproduction,
- toxic on specific target organs (single exposure, repeat exposure),
- aspiration hazard.

Based on *in vitro* studies, FLUDIO 025 GF is neither irritating to eye nor corrosive to skin. The calculations performed in accordance to the additivity formula confirm that the product is not a skin/eye irritant it is also not a skin sensitizer.



Taking into account the content of the product FLUDIO 025 GF, and based on the calculations performed in accordance to the additivity formula, the product does not require classification in regards to acute toxicity.

FLUDIO 025 GF contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction [EUH208].

### 3.5.2 Operator exposure

Operator exposure was assessed against the AOELs agreed in the EU review of fludioxonil (0.59 mg/kg bw/day).

Default values of dermal absorption for FLUDIO 025 GF according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) and SANTE/2018/10591 (rev.1 24 October 2018) are 50% for concentrate and 50% for dilution. FLUDIO 025 GF is water based formulation.

Operator exposure was modelled using the Seed-TROPEX model.

According to the model calculations, it can be concluded that the risk for the operator using FLUDIO 025 GF on cereals is acceptable without the use of personal protective equipment. However, it is recommended to use suitable protective gloves and clothing when performing seed treatment related activities with FLUDIO 025 GF.

According to the model calculations, it can be concluded that the risk for the operator using undiluted FLUDIO 025 GF on cereals at up to 2 L/ton is acceptable without the use of personal protective equipment. The % AOEL for FLUDIO 025 GF is equal to 58.3%. In the case of use diluted product on cereals, the risk is acceptable without the use of personal protective equipment. The % AOEL for FLUDIO 025 GF is equal to 29.5 % for an operator working with the concentrated formulation and using no PPE. When PPE is used, the % AOEL for an operator performing all tasks during a working shift and when handling the diluted formulation decreases to 15.1 %.

According to the results of estimations, the use of FLUDIO 025 GF containing fludioxonil (25 g/L) using mechanical seed treatment machines of continuous movement with closed mixing chamber, **causes acceptable health risk for unprotected operator wearing work wear (with long sleeved and long trousers)**. The exposure to fludioxonil amounts to the value lower than the AOEL set for this substance. However, due to the model limitations and the possibility of underestimation, evaluator suggests to equip the operator with protective gloves.

Thus, the following sentence regarding the use of PPE is recommended by the evaluator to be placed in the label:

*„Stosować odzież roboczą (kombinezon) oraz rękawice ochronne w trakcie przygotowywania cieczy roboczej, zaprawiania, pakowania zaprawionych ziaren oraz czyszczenia sprzętu.”*

### 3.5.3 “Wear work wear (coverall) nad protective gloves during mixing/loading, seed treatment, seed packing and cleaning.” Worker exposure

Worker exposure was assessed against the AOELs agreed in the EU review of fludioxonil (0.59 mg/kg bw/day).

Default values of dermal absorption for FLUDIO 025 GF according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) and SANTE/2018/10591 (rev.1 24 October 2018) are 50% for concentrate and 50% for dilution. FLUDIO 025 GF is water based formulation.

According to the results of estimations, the exposure to fludioxonil (25 g/L) contained in the product FLUDIO 025 GF during sowing of treated seeds, **causes acceptable health risk for unprotected worker wearing work wear (with long sleeved and long trousers)**. The exposure to fludioxonil amounts to the



value lower than the AOEL set for this substance. However, the protective gloves are strongly recommended for worker during sowing activities (opening sacks, filling the tanks of a sowing machine). The recommendation of using PPE by the worker should be placed on the label of the product. The evaluator suggests the following sentence regarding the use of PPE to be placed in the label:

„Stosować odzież roboczą (kombinezon) oraz rękawice ochronne w czasie kontaktu z zaprawionym ziarnem”

“Wear work wear (coverall) nad protective gloves during during contact with treated seeds”.

### 3.5.4 Bystander and resident exposure

The AAOEL value for the fludioxonil is not allocated. Consequently, it is assumed that the estimation of bystander exposure is covered by the calculation of resident exposure towards the active substance.

Due to the method of application of product (treatment on mobile equipment, usually done outside) the bystander/resident exposure to the active substance is possible. Hence, the estimation of exposure for this group of people is justified. However, it is not expected that exposure value of bystander/resident will exceed those of operators and workers.

According to the results of estimations provided by the Applicant, the exposure to fludioxonil contained in the FLUDIO 025 GF according to the list of intended uses presented in GAP Table, causes acceptable health risk for bystander and resident (adult and child) based on SeedTROPEX model.

## 3.6 Residues and consumer exposure (Part B, Section 7)

### 3.6.1 Residues

#### Storage stability

No new data submitted in the framework of this application. Stability of fludioxonil residues when stored deep frozen was assessed in plant and animal matrices during the EU Review of fludioxonil.

Fludioxonil was demonstrated to be stable upon storage at  $\leq 20^{\circ}\text{C}$  for at least 24 months in commodities of high water (tomato, apple, fresh peas, maize forage), high acid (grapes), and high oil (rape-seed, corn oil) content as well as in dry/starch (cereal grains, maize grains, potato tubers) commodities and other matrices (straw, corn meal, sorghum hay). Animal matrices are stable for at least 12 months (EFSA, 2007, 2011).

#### Metabolism in plants and animals

No new data are submitted in the framework of this application.

Residue definition for enforcement: fludioxonil (Reg. (EU) 2022/1264).

Residue definition for risk assessment: Sum of fludioxonil and its metabolites oxidised to metabolite 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid (CGA 192155), expressed as fludioxonil.

For cereals (seed treatment), fruits and leafy vegetables, pulses and oilseeds, the conversion factor between residue definitions for monitoring and risk assessment is 1.

#### Magnitude of residues in plants

Proposed GAPs: seed treatment

Winter rye: 5 – 10 g as/ha

Winter wheat: 7,5-12,5g as/ha

Winter barley: 6 – 10 g as/ha as/ha

Winter triticale: 5 – 10 g as/ha as/ha

Spring wheat: 7,5-12,5g as/ha

Spring barley: 6 – 10 g as/ha as/ha

PHI – not required

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application (6 trials).

Trials GAP: seed treatment, 1 x 5 g as/100 kg seeds

Residues: 6 x < 0.01 mg/kg (LOQ)

The number of trials is sufficient as to support the use of fludioxonil in cereals according to the proposed GAPs in Central Zone (residues are below LOQ).

The residues arising from the proposed use will not exceed the MRLs for cereals set at 0.01 mg/kg (Reg. (EU) 2022/1264).

Extrapolation from wheat to triticale, barley and rye in case of seed treatment is possible (SAN-TE/2019/12752).

#### Magnitude of residues in livestock

There is no risk for animal MRL to be exceeded. Residues are below LOQ. The calculated dietary burdens for all groups of livestock were not found to exceed the trigger value considering the proposed uses. Additional studies are no required.

#### Processing studies

Additional tests are not required. Residues are below LOQ.

#### Magnitude of residues in representative succeeding crops

EFSA Journal 2019;17(8):5812:

*Based on the rotational crop study (bare soil: 1.5N to rate of the adjusted GAP) fludioxonil residues above the LOQ of 0.01 mg/kg are not expected to occur in rotational crops when fludioxonil is applied according to the proposed GAP. EU GAP for wheat is: 0.005- 0.00875 kg as/ha.*

Additional study is not required.

Waiting period before planting following succeeding crops: not required.

#### Effect on the residue level in pollen and bee product

The studies of fludioxonil effect on the residue level in pollen and bee products are not required. Plants covered by the GAP are not melliferous plants according to the guideline SAN-TE/11956/2016 rev. 9.

#### Consumer risk assessment

The proposed uses do not represent unacceptable chronic risks for the consumer.

#### **Conclusion:**

According to the available data, the intended uses on cereals are considered acceptable.

Proposed PHI: not required.

### 3.6.2 Consumer exposure

TMDI calculation below (EFSA PRIMo revision 3.1).

Consumer risk assessment taking into account Reg. (EU) 2022/1264

TMDI (% ADI) according to EFSA PRIMo	61 % (NL toddler) – 15% Apples
IEDI (% ADI) according to EFSA PRIMo	See TMDI
IESTI (% ARfD) according to EFSA PRIMo*	Not need to be assessed
NESTI (% ARfD) **	Not need to be assessed

The proposed uses of fludioxonil in the formulation FLUDIO 025 GF do not represent unacceptable acute and chronic risks for the consumer.

## 3.7 Environmental fate and behaviour (Part B, Section 8)

The predicted environmental concentrations (PEC values) in soil, surface water, sediment and groundwater are provided in Part B, Section 8. The long-term concentrations are based on results obtained for the active substance contained in the formulation. Calculated PEC values demonstrates that the FLUDIO 025 GF is safe for the environment.

### 3.7.1 Predicted environmental concentrations in soil (PEC<sub>soil</sub>)

The PECs of fludioxonil and metabolites in soil, has been assessed assuming that active substances is evenly distributed in the top 5 cm soil horizon with a soil bulk density 1.5 g/cm<sup>3</sup> and DT<sub>50</sub> value established in the EFSA peer review. Calculations were performed for the bare soil with max. dose (0.5 L/ha). The calculated values of PECs for each compound were accepted.

### 3.7.2 Predicted environmental concentrations in groundwater (PEC<sub>gw</sub>)

The PECs of fludioxonil and their metabolites in groundwater were calculated using values established in the EFSA peer review with FOCUS PEARL and FOCUS PELMO. The PEC<sub>gw</sub> were calculated for the highest application rate recommended for use in winter wheat applied for 12.5 g a.s./ha in bare soil. Obtained PEC<sub>gw</sub> of fludioxonil and metabolites in each scenario and for the recommended use of FLUDIO 025 GF in winter and spring cereals are significant below the trigger value of 0.1 µg/L and therefore the use of this plant protection product according to recommendations does not pose a risk of groundwater contamination.

Consequently, there is no need for toxicological assessment.

### 3.7.3 Predicted environmental concentrations in surface water (PEC<sub>sw</sub>)

The PECs of fludioxonil and its metabolites in surface water were calculated using values established in the EFSA peer review. Since results obtained from STEP1-2 v.3.2. showed no risk for aquatic life after application of FLUDIO 025 GF, no more calculations were needed.

### 3.7.4 Predicted environmental concentrations in air (PEC<sub>air</sub>)

The vapour pressure at 25 °C of the active substance fludioxonil is < 10<sup>-5</sup> Pa and the Henry's Law Con-

stant is  $5.4 \times 10^{-5}$  Pa.m<sup>3</sup>/mol. Hence the fludioxonil is regarded as non-volatile.

### **3.8 Ecotoxicology (Part B, Section 9)**

An estimation of risk indicate acceptable risk for each organisms of each range of assessed issues, taking into consideration adequate mitigation measures.

#### **3.8.1 Effects on terrestrial vertebrates**

An estimation of risk indicate low risk for birds and other terrestrial vertebrates of each range of assessed issues. Calculations conducted due to the influence of FLUDIO 025 GF due to the acute and long-term toxicity and reproductive did not indicate any hazardous properties and danger. There was also no negative effects regarding to drinking water exposure and effect of secondary poisoning. There is no influence to evaluated organism regarding to dangerous to food poisoning.

To protect birds/mammals the product must be entirely incorporated in the soil; ensure that the product is also fully incorporated at the end of rows.

To protect birds/mammals remove spillages.

#### **3.8.2 Effects on aquatic species**

An estimation of risk indicate low risk for aquatic organism of each range of assessed issues. Calculations conducted due to the influence FLUDIO 025 GF due to the acute and long-term toxicity did not indicate any hazardous properties and danger for aquatic organisms.

#### **3.8.3 Effects on bees**

The evaluation of the risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SAN-CO/10329/2002 rev.2 (final), October 17, 2002). The risk assessment for bees was carried out regarding oral and dermal toxicity endpoints and individual application rates.

An estimation of risk indicate low risk for bees of each range of assessed issues. Calculations conducted due to the influence FLUDIO 025 GF due to the acute oral and contact toxicity did not indicate any hazardous properties and danger.

#### **3.8.4 Effects on other arthropod species other than bees**

The calculations present an acceptable risk to non-target arthropods, after application of FLUDIO 025 GF.

#### **3.8.5 Effects on soil organisms**

An estimation of risk indicate low risk for earthworms, other non-target soil organisms and microbial activity in soil in each range of assessed issues. Calculations conducted due to the influence of FLUDIO 025 GF due to the chronic toxicity did not indicate any hazardous properties and danger.

#### **3.8.6 Effects on non-target terrestrial plants**

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SAN-

CO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area.  
Based on risk assessment regarding effects on non-target terrestrial plants, no risk mitigation needed.

### **3.8.7 Effects on other terrestrial organisms (Flora and Fauna)**

Not relevant.

### **3.9 Relevance of metabolites (Part B, Section 10)**

The groundwater metabolites CGA 192155, CGA 265378 and CGA 339833 are considered as non-relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10, since their predicted concentration in the groundwater do not exceed the concentration of 0.1 µg/L.

## **4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)**

FLUDIO 025 GF contains fludioxonil which is approved as a candidates for substitution because two of PBT criteria.

As a conclusion of the comparative assessment, uses presented in GAP are not suitable for substitution because there is only few alternative modes of action available amongst alternative products and thus the chemical diversity remaining is not sufficient to minimise the occurrence of resistance.

FLUDIO 025 GF is a significantly safer alternative with significant economic and practical advantages.

## **5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization**

2 years ambient shelf life study results.
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## **Appendix 1 Copy of the product authorization**

MS assessor to insert details of the product authorization for MS country.

## Appendix 2 Copy of the product label

Sekcja fizyko-chemia: Dodano informację dot. techniki zaprawiania.

Sekcja skuteczność: Zaakceptowano zapisy proponowane przez Aplikanta. ~~Dodano informację nt. dobre-  
go zwalczania chorób grzybowych uwzględnionych w etykiecie.~~ Zamieszczono strategię przeciwdziałania  
rozwojowi odporności. Ponieważ jest to zaprawa, to niewymagana jest informacja nt. oddziaływania  
na rośliny następcze i sąsiadujące.

Zaakceptowano zapis dotyczący stosowania wody podczas zaprawiania nasion. Zalecana ilość wody: 0–  
800 ml/100 kg ziarna.

Metabolizm i pozostałości: brak uwag

Los i zachowanie w środowisku: bez uwag

Ekotoksykologia: bez uwag

**Posiadacz zezwolenia:**




### FLUDIO ŻEL 025 FS

#### Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:

**fludioksonil** (związek z grupy fenylopiroli) – 25 g/L

**Zezwolenie MRiRW nr R- .....**

	
H411	Działa toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH208	Zawiera 1,2-benzizotiazol-3-on oraz 3-hydrokso-N-(2-metylofenylo)-2-naftalenokarboksyamid. Może powodować wystąpienie reakcji alergicznej.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P273	Unikać uwalniania do środowiska.
P391	Zebrać wyciek.
P501	Zawartość/pojemnik usuwać do firm posiadających odpowiednie uprawnienia

#### OPIS DZIAŁANIA

FUNGICYD – zaprawa nasienna w formie płynnego koncentratu (FS) o działaniu powierzchniowym, przeznaczony do zaprawiania w prostych zaprawiarkach bębnowych ~~lub zaprawiarkach przystosowanych do zapraw ciekłych i zawieszinowych~~, ziarna siewnego zbóż ozimych i jarych w celu ochrony przed chorobami powodowanymi przez grzyby.

Zgodnie z klasyfikacją FRAC substancja czynna fludioksonil zaliczana jest do grupy 12.

## STOSOWANIE ŚRODKA

**Żyto ozime, jęczmień ozimy, jęczmień jary, pszenica ozima, pszenica jara, pszenżyto ozime**  
*Zgorzel siewek*

**Żyto ozime**  
*Głownia żdźbłowa żyta*

**Jęczmień ozimy**  
*Pasiastość liści jęczmienia*

**Jęczmień ozimy, pszenica ozima**  
*Pleśń śniegowa*

**Pszenica ozima, pszenica jara**  
*Śnieć cuchnąca*

**Maksymalna / zalecana dawka dla jednorazowego zastosowania:**  
200 ml środka / 100 kg ziarna siewnego.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Zalecana ilość wody: 0–800 ml/100 kg ziarna.

~~Uwzględnione w etykiecie choroby grzybowe charakteryzują się wysokim stopniem zwalczania. Skuteczność przeprowadzonych zabiegów powyżej 80%.~~

## ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ

1. Zaprawiać tylko dobrze oczyszczony materiał siewny.
2. Zaprawianie wykonać najlepiej bezpośrednio przed siewem.
3. Zaprawiony materiał powinien być dokładnie i równomiernie pokryty środkiem.
4. Zaprawiony materiał może być użyty wyłącznie do siewu. Nie wolno przeznaczać go na cele konsumpcyjne ani na paszę.
5. Zaprawiać tylko dobrze oczyszczony materiał siewny, o wysokiej energii kiełkowania. Nie zaprawiać ziarna siewnego o wilgotności powyżej 16%, ani uprzednio traktowanego inną zaprawą.
6. Zaprawione nasiona pozostawić po zaprawieniu w otwartych workach do momentu przeschnięcia.
7. Zaprawiony materiał przechowywać w grubych, papierowych, oznakowanych i szczelnie zamkniętych workach, w chłodnym, suchym i dobrze wietrzonym magazynie, z dala od żywności i pasz.
8. Jeżeli zachodzi konieczność przechowywania zaprawionego ziarna siewnego do następnego sezonu, należy zbadać przed siewem zdolność kiełkowania.
9. Przed użyciem środek dokładnie wymieszać.

Na opakowaniach zaprawianych nasion powinny zostać umieszczone następujące zwroty:

1. Jeżeli zachodzi konieczność przechowywania ziarna siewnego do następnego sezonu, należy zbadać przed siewem zdolność kiełkowania.



2. W celu ochrony ptaków i wolno żyjących ssaków:
- zaprawione nasiona muszą być całkowicie przykryte glebą,
  - upewnić się, że zaprawione nasiona są również całkowicie przykryte na końcach rzędów,
  - zebrać przypadkowo rozsypane nasiona.

Środek zawiera jedną substancję czynną: fludioksonil (związek fenylopirolowy (PP) – z grupy inhibitorów transdukcji sygnału, wg FRAC Grupa 12). W ramach strategii przeciwdziałania odporności sprawców chorób zaleca się m.in.:

- Stosować na przemian z fungicydami o innym sposobie działania
- Stosować zgodnie z zaleceniami na etykiecie.
- Nie stosować zmniejszonych dawek.
- Środek należy stosować ostrożnie.
- Stosować inne środki, takie jak odmiany odporne, dobra praktyka agronomiczna

## TECHNIKA ZAPRAWIANIA

Ściśle przestrzegać właściwego dawkowania środka.

Przed użyciem wstrząsnąć.

Zaprawiać w zaprawiarkach mechanicznych o ruchu ciągłym lub porcjowych, zgodnie z instrukcją obsługi danej zaprawiarki. Zaprawiać bez przerw w pracy zaprawiarki, aby uniknąć zasychania zaprawy. Przed rozpoczęciem zaprawiania zaprawiarkę poddać kalibracji.

Odmierzoną ilość środka wrzucić do obracającego się zbiornika zaprawiarki bębnowej wypełnionej ziarnem w zalecanej proporcji ilościowej, w razie potrzeby środek wybrać za pomocą np. szpatułki, pałeczki, łyżeczki. Zaprawiać z włączonym mieszadłem. Zaprawianie ziarna w zaprawiarkach przeprowadzać zgodnie z instrukcją obsługi danej zaprawiarki, ściśle przestrzegając zalecanego dawkowania środka. Po pracy aparaturę dokładnie wyczyścić zgodnie z instrukcją danej zaprawiarki. Zaprawiony materiał siewny powinien być dokładnie i równomiernie pokryty środkiem.

## POSTĘPOWANIE Z RESZTKAMI ZAWIESINY I MYCIE APARATURY

Resztki zawiesiny oraz wodę użytą do mycia zaprawiarki należy:

- jeżeli jest to możliwe, zużyć do sporządzenia zawiesiny podczas kolejnego zaprawiania lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Aparaturę dokładnie oczyścić i wymyć zgodnie z instrukcją danej zaprawiarki.

## WARUNKI BEZPIECZNEGO STOSOWANIA ŚRODKA

### ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

Stosować rękawice ochronne oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

Stosować rękawice ochronne (nitrylowe) i okulary ochronne.

**Środki ostrożności związane z ochroną środowiska naturalnego:**

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.  
Nie myć aparatury w pobliżu wód powierzchniowych.  
Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

W celu ochrony ptaków i wolno żyjących ssaków:

- zaprawione nasiona muszą być całkowicie przykryte glebą – upewnić się, że zaprawione nasiona są również całkowicie przykryte na końcach rzędów,
- zebrać przypadkowo rozsypane nasiona.

**Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta:**  
nie dotyczy.

**Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):**  
nie dotyczy.

**Okres od ostatniego zastosowania środka na rośliny przeznaczone na paszę do dnia, w którym zwierzęta mogą być karmione tymi roślinami (okres karencji dla pasz):**  
nie dotyczy.

**Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następnie:**  
nie dotyczy.

## **WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA**

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, w temperaturze nie niższej niż 0°C i nie wyższej niż 30°C.

Chronić przed światłem słonecznym.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.  
Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.  
Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

## **PIERWSZA POMOC**

Antidotum brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

Okres ważności: 2 lata

Data produkcji -

Zawartość netto

Sekcja fizyko-chemia: Dodano informację dot. techniki zaprawiania.  
Sekcja skuteczność: Zaakceptowano zapisy proponowane przez Aplikanta. ~~Dodano informację nt. dobrego zwalczania chorób grzybowych uwzględnionych w etykiecie.~~ Zamieszczono strategię przeciwdziałania rozwojowi odporności. Ponieważ jest to zaprawa, to niewymagana jest informacja nt. oddziaływania na rośliny następce i sąsiadujące.  
Zaakceptowano zapis dotyczący stosowania wody podczas zaprawiania nasion. Zalecana ilość wody: 0–800 ml/100 kg ziarna.  
Metabolizm i pozostałości: brak uwag  
Los i zachowanie w środowisku: bez uwag  
Ekotoksykologia: bez uwag

**Posiadacz zezwolenia:**




## FUNABEN® ŻEL 025 FS

### Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:

**fludioksonil** (związek z grupy fenylopiroli) – 25 g/L

**Zezwolenie MRiRW nr R- .....**

	
H411	Działa toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH208	Zawiera 1,2-benzizotiazol-3-on oraz 3-hydroksy-N-(2-metylofenylo)-2-naftalenokarboksyamid. Może powodować wystąpienie reakcji alergicznej.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P273	Unikać uwalniania do środowiska.
P391	Zebrać wyciek.
P501	Zawartość/pojemnik usuwać do firm posiadających odpowiednie uprawnienia

### OPIS DZIAŁANIA

FUNGICYD – zaprawa nasienna w formie płynnego koncentratu (FS) o działaniu powierzchniowym, przeznaczony do zaprawiania w prostych zaprawiarkach bębnowych ~~lub zaprawiarkach przystosowanych do zapraw ciekłych i zawieszinowych~~, ziarna siewnego zbóż ozimych i jarych w celu ochrony przed chorobami powodowanymi przez grzyby.

Zgodnie z klasyfikacją FRAC substancja czynna fludioksonil zaliczana jest do grupy 12.

## STOSOWANIE ŚRODKA

**Żyto ozime, jęczmień ozimy, jęczmień jary, pszenica ozima, pszenica jara, pszenżyto ozime**  
*Zgorzel siewek*

**Żyto ozime**  
*Głownia żdźbłowa żyta*

**Jęczmień ozimy**  
*Pasiastość liści jęczmienia*

**Jęczmień ozimy, pszenica ozima**  
*Pleśń śniegowa*

**Pszenica ozima, pszenica jara,**  
*Śnieć cuchnąca*

**Maksymalna / zalecana dawka dla jednorazowego zastosowania:**  
200 ml środka / 100 kg ziarna siewnego.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Zalecana ilość wody: 0–800 ml/100 kg ziarna.

~~Uwzględnione w etykiecie choroby grzybowe charakteryzują się wysokim stopniem zwalczania. Skuteczność przeprowadzonych zabiegów powyżej 80%.~~

## ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ

1. Zaprawiać tylko dobrze oczyszczony materiał siewny.
2. Zaprawianie wykonać najlepiej bezpośrednio przed siewem.
3. Zaprawiony materiał powinien być dokładnie i równomiernie pokryty środkiem.
4. Zaprawiony materiał może być użyty wyłącznie do siewu. Nie wolno przeznaczać go na cele konsumpcyjne ani na paszę.
5. Zaprawiać tylko dobrze oczyszczony materiał siewny, o wysokiej energii kiełkowania. Nie zaprawiać ziarna siewnego o wilgotności powyżej 16%, ani uprzednio traktowanego inną zaprawą.
6. Zaprawione nasiona pozostawić po zaprawieniu w otwartych workach do momentu przeschnięcia.
7. Zaprawiony materiał przechowywać w grubych, papierowych, oznakowanych i szczelnie zamkniętych workach, w chłodnym, suchym i dobrze wietrzonym magazynie, z dala od żywności i pasz.
8. Jeżeli zachodzi konieczność przechowywania ziarna siewnego do następnego sezonu, należy zbadać przed siewem zdolność kiełkowania.
9. Przed użyciem środek dokładnie wymieszać.

Środek zawiera jedną substancję czynną: fludioksonil (związek fenylopirolowy (PP) – z grupy inhibitorów transdukcji sygnału, wg FRAC Grupa 12). W ramach strategii przeciwdziałania odporności sprawców chorób zaleca się m.in.:

- Stosować na przemian z fungicydami o innym sposobie działania

- Stosować zgodnie z zaleceniami na etykiecie.
- Nie stosować zmniejszonych dawek.
- Środek należy stosować ochronnie.

Stosować inne środki, takie jak odmiany odporne, dobra praktyka agronomiczna.

## TECHNIKA ZAPRAWIANIA

Ściśle przestrzegać właściwego dawkowania środka.  
Przed użyciem wstrząsnąć.

Zaprawiać w zaprawiarkach mechanicznych o ruchu ciągłym lub porcjowych, zgodnie z instrukcją obsługi danej zaprawiarki. Zaprawiać bez przerw w pracy zaprawiarki, aby uniknąć zasychania zaprawy. Przed rozpoczęciem zaprawiania zaprawiarkę poddać kalibracji.

Odmierzoną ilość środka wrzucić do obracającego się zbiornika zaprawiarki bębnowej wypełnionej ziarnem w zalecanej proporcji ilościowej, w razie potrzeby środek wybrać za pomocą np. szpatułki, pałeczki, łyżeczki. Zaprawiać z włączonym mieszadłem. Zaprawianie ziarna w zaprawiarkach przeprowadzać zgodnie z instrukcją obsługi danej zaprawiarki, ściśle przestrzegając zalecanego dawkowania środka.

Po pracy aparaturę dokładnie wyczyścić zgodnie z instrukcją danej zaprawiarki

Zaprawiony materiał siewny powinien być dokładnie i równomiernie pokryty środkiem.

## POSTĘPOWANIE Z RESZTKAMI ZAWIESINY I MYCIE APARATURY

Resztki zawiesiny oraz wodę użytą do mycia zaprawiarki należy:

- jeżeli jest to możliwe, zużyć do sporządzenia zawiesiny podczas kolejnego zaprawiania lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Aparaturę dokładnie oczyścić i wymyć zgodnie z instrukcją danej zaprawiarki.

## WARUNKI BEZPIECZNEGO STOSOWANIA ŚRODKA

### ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

Stosować rękawice ochronne oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

Stosować rękawice ochronne (nitrylowe) i okulary ochronne.

### Środki ostrożności związane z ochroną środowiska naturalnego:

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.

Nie myć aparatury w pobliżu wód powierzchniowych.

Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

W celu ochrony ptaków i wolno żyjących ssaków:

- zaprawione nasiona muszą być całkowicie przykryte glebą – upewnić się, że zaprawione nasiona są również całkowicie przykryte na końcach rzędów,
- zebrać przypadkowo rozsiane nasiona.

**Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta:**  
nie dotyczy.

**Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):**  
nie dotyczy.

**Okres od ostatniego zastosowania środka na rośliny przeznaczone na paszę do dnia, w którym zwierzęta mogą być karmione tymi roślinami (okres karencji dla pasz):**  
nie dotyczy.

**Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następnie:**  
nie dotyczy.

## **WARUNKI PRZECCHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA**

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą.

Przechowywać w temperaturze nie niższej niż 0°C i nie wyższej niż 30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

## **PIERWSZA POMOC**

Antidotum brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

Okres ważności: 2 lata

Data produkcji -

Zawartość netto

## **Appendix 3 Letter of Access**

Letter(s) of access is/are classified as confidential and, thus, are not attached to this document.

## Appendix 4 Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

### 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	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	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	Y	Data/study report never submitted before to Poland	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	Y	Data/study report never submitted before to Poland	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	N	Y	Data/study report never submitted before to Poland	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	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 2.3.1	Paulina Flasińska	2022	Unpublished FLUDIO 025 GF Determination of flash point, auto-ignition temperature and oxidiz- ing properties. Study code number: BC-07/22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Warsaw, 2022 GLP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
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	Y	Data/study report never sub- mitted before to Poland	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 – Institute of Industrial Organic Chemistry Łukasiewicz Research Network – Institute of Industrial Organic Chemistry , 2022 GLP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	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	N	Y	Data/study report never sub- mitted before to Poland	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	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
			Warsaw, 2022 GLP Unpublished				
KCP 2.6.1	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	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z 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	Y	Data/study report never submitted before to Poland	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	Y	Data/study report never submitted before to Poland	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	N	Y	Data/study report never submitted before to Poland	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	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
			Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Warsaw, 2022 GLP Unpublished				
KCP 2.7.5	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	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
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	Y	Data/study report never submitted before to Poland	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	Y	Data/study report never submitted before to Poland	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	N	Y	Data/study report never submitted before to Poland	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	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
			storage. Study code number: BF – 59/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Warsaw, 2022 GLP Unpublished				
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	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 2.10.1 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	Y	Data/study report never submitted before to Poland	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	Y	Data/study report never submitted before to Poland	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	N	Y	Data/study report never submitted before to Poland	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	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
			Non – GLP Unpublished				
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	Y	Data/study report never submitted before to Poland	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. Study code number: AGRO/6/21 Synthos Agro Sp.z o.o. Oświęcim, 2022 Non – GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 5.1.1	Kupiec Jarosław, M.Sc.	2022	FLUDIO 025 GF Stage I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after low temperature storage. Jarosław Kupiec, M.Sc., 2022, Study code: BF-59/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 5.2	Wójcik, M. MSc Eng.	2022	DIFLUD 050 FS Determination of the residues of difenoconazole, triazole derivative metabolites and fludioxonil in grains and straw of winter wheat. Marcin Wójcik, MSc Eng, 2022 Study code: C-02-22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 5.2	Zaręba-Kozioł, M. PhD	2022	Validation of a method for determination of fludioxonil and its metabolite CGA192155 residues by Liquid Chromatography (LC-	N	Y	Data/study report never submitted before to Poland	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	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
			MS/MS) Monika Zaręba-Kozioł, PhD, 2022 Study code: PW-2022-02 Fertico Sp. z o.o. GLP Unpublished				
KCP 5.2	Wróbel A., MSc	2022	FLUDIO 025 GF Earthworm ( <i>Eisenia andrei</i> ) reproduction test. Anna Wróbel, MSc, 2022 Study code: G/23/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 5.2	Gierbuszewska, A., MSc	2022	FLUDIO 025 GF Collembolan ( <i>Folsomia candida</i> ) Reproduction Test. Aneta Gierbuszewska, MSc, 2022 Study code: G/24/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 5.2	Wróbel A., MSc	2022	FLUDIO 025 GF Predatory mite ( <i>Hypoaspis (Geolaelaps) aculeif- er</i> ) reproduction test in soil. Anna Wróbel, MSc, 2022 Study code: G/25/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 5.2	Hodorek G., MSc	2022	Fludio 025 GF <i>Daphnia magna</i> , Acute Immobilisation Test. Grażyna Hodorek, MSc, 2022 Study code: W/31/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 5.2	Hodorek G., MSc	2022	Fludio 025 GF <i>Raphidocelis subcapitata</i> SAG 61.81 (formerly <i>Pseudo-kirchneriella subcapitata</i> ), Growth inhibition test.	N	Y	Data/study report never sub- mitted before to Poland	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	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
			Grażyna Hodorek, MSc, 2022 Study code: W/32/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished				
KCP 5.2		2022	Fludio 025 GF Rainbow trout, Acute Toxicity Testing. Study code: W/33/21 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 5.2	Kulec-Płoszczyca, E., MSc	2022	FLUDIO 025 GF Bumblebees ( <i>Bombus</i> spp.), Acute Oral Toxicity Test. Elżbieta Kulec-Płoszczyca, MSc, 2022 Study code: B/67/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 5.2	Kulec-Płoszczyca, E., MSc	2022	FLUDIO 025 GF Bumblebees ( <i>Bombus</i> spp.), Acute Contact Toxicity Test. Elżbieta Kulec-Płoszczyca, MSc, 2022 Study code: B/68/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 5.2	Kulec-Płoszczyca, E., MSc	2022	FLUDIO 025 GF Honeybees ( <i>Apis mellifera</i> L.), Larval Toxicity Test, Repeated Exposure. Elżbieta Kulec-Płoszczyca, MSc, 2022 Study code: B/01/22 GLP Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 5.2	Kulec-Płoszczyca, E., MSc	2022	FLUDIO 025 GF Honeybees ( <i>Apis mellifera</i> L.), Chronic Oral Toxicity Test.	N	Y	Data/study report never submitted before to Poland	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	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
			Elżbieta Kulec-Płoszczyca, MSc, 2022 Study code: B/02/22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished				
KCP 6.2	Barbara Krzyżińska	2021	Biological efficacy expertise of fungicide seed treatment Fludio 025 GF for <i>Fusarium</i> spp., <i>Pyrenophora graminea</i> control in spring barley 91 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Published/Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Barbara Krzyżińska	2021	Biological efficacy expertise of fungicide seed treatment Fludio 025 GF for <i>Fusarium</i> spp., <i>Pyrenophora graminea</i> control in spring barley 92 F/2022 Institute of Plant Protection – National Research Institute, Sośnicowice Branch GEP Published/Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Cecylia Dreja	2021	Biological expertise of selectivity of seed treatment Fludio 025 GF in spring barley 80 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Published/Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Cecylia Dreja	2021	Biological expertise of selectivity of seed treatment Fludio 025 GF in spring barley 81 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Published/Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Cecylia Dreja	2021	Biological expertise of selecvtivity of seed treatment Fludio 025 GF in spring barley	N	Y	Data/study report never sub- mitted before to Poland	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	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
			82 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Published/Unpublished				
KCP 6.2	Cecylia Dreja	2021	Biological expertise of selecvtivity of seed treatment Fludio 025 GF in spring barley 83 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Published/Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Cecylia Dreja	2021	Analysis of quality parameters of spring barley seeds application of Fludio 025 GF 7 J/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Published/Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Cecylia Dreja	2021	Analysis of quality parameters of spring barley seeds application of Fludio 025 GF 8 J/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Published/Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Cecylia Dreja	2021	Analysis of quality parameters of spring barley seeds application of Fludio 025 GF 9 J/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Published/Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Cecylia Dreja	2021	Analysis of quality parameters of spring barley seeds application of Fludio 025 GF 10 J/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch	N	Y	Data/study report never sub- mitted before to Poland	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	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
			GEP Published/Unpublished				
KCP 6.2	Patrycja Płonka	2021	Biological efficacy expertise of fungicide seed treatment Fludio 025 GF for <i>Fusarium</i> spp. <i>Tilletia</i> caries control in spring wheat. 78 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Published/Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Patrycja Płonka	2021	Biological efficacy expertise of fungicide seed treatment Fludio 025 GF for <i>Fusarium</i> spp. <i>Tilletia</i> caries control in spring wheat. 79 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Published/Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krzysztof Kubiak	2021	Expertise of phytotoxicity of product Fludio 025 GF in spring wheat (Field studies – for registration purpose). 314/2022 Institute of plant protection – national research institute. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Published/Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krzysztof Kubiak	2021	Expertise of phytotoxicity of product Fludio 025 GF in spring wheat (Field studies – for registration purpose). 315/2022 Institute of plant protection – national research institute. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Agata Korbas	2021	Expertise of phytotoxicity of product Fludio 025 GF in spring wheat (Field studies – for registration purpose). 343/2022 Institute of plant protection – national research institute. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Agata Korbas	2021	Expertise of phytotoxicity of product Fludio 025 GF in spring	N	Y	Data/study report never sub-	Synthos Agro

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
			wheat (Field studies – for registration purpose). 344/2022 Institute of plant protection – national research institute. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished			mitted before to Poland	Sp. z o.o.
KCP 6.2	Barbara Krzyżińska	2021	Biological efficacy expertise of fungicide seed treatment Fludio 025 GF for <i>Fusarium spp.</i> , <i>Pyrenophora graminea</i> , <i>Monographella nivalis</i> (anam. <i>Microdochium nivale</i> ) control in winter barley. 19 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Barbara Krzyżińska	2021	Biological efficacy expertise of fungicide seed treatment Fludio 025 GF for <i>Fusarium spp.</i> , <i>Pyrenophora graminea</i> , <i>Monographella nivalis</i> (anam. <i>Microdochium nivale</i> ) control in winter barley. 20 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Barbara Krzyżińska	2021	Biological efficacy expertise of fungicide seed treatment Fludio 025 GF for <i>Fusarium spp.</i> , <i>Pyrenophora graminea</i> , <i>Monographella nivalis</i> (anam. <i>Microdochium nivale</i> ) control in winter barley. 21 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Barbara Krzyżińska	2021	Biological efficacy expertise of fungicide seed treatment Fludio 025 GF for <i>Fusarium spp.</i> , <i>Pyrenophora graminea</i> , <i>Monographella nivalis</i> (anam. <i>Microdochium nivale</i> ) control in winter barley. 22 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	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	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 6.2	Barbara Krzyżińska	2021	Biological efficacy expertise of fungicide seed treatment Fludio 025 GF for <i>Fusarium spp.</i> , <i>Pyrenophora graminea</i> , <i>Monographella nivalis</i> (anam. <i>Microdochium nivale</i> ) control in winter barley. 23 F/2022 Institute of Plant Protection – National Research Institute, Sos-nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Barbara Krzyżińska	2021	Biological efficacy expertise of fungicide seed treatment Fludio 025 GF for <i>Fusarium spp.</i> , <i>Pyrenophora graminea</i> , <i>Monographella nivalis</i> (anam. <i>Microdochium nivale</i> ) control in winter barley. 24 F/2022 Institute of Plant Protection – National Research Institute, Sos-nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krzysztof Kubiak	2021	Expertise of phytotoxicity of product Fludio 025 GF in winter barley (Field studies – for registration purpose). 301/2022 Institute of plant protection – national research institute. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krzysztof Kubiak	2021	Expertise of phytotoxicity of product FLUDIO 025 GF in winter barley (Field studies – for registration purpose). Annex to the report No. 301/2022 Institute of plant protection – national research institute. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krzysztof Kubiak	2021	Expertise of phytotoxicity of product Fludio 025 in winter barley (Field studies – for registration purpose) 302/2022 Institute of plant protection – national research institute. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krzysztof Kubiak	2021	Expertise of phytotoxicity of product Fludio 025 in winter barley	N	Y	Data/study report never sub-	Synthos Agro

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
			(Field studies – for registration purpose) Annex to the report No. 302/2022 Institute of plant protection – national research institute. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished			mitted before to Poland	Sp. z o.o.
KCP 6.2	Krzysztof Kubiak	2021	Expertise of phytotoxicity of product Fludio 025 in winter barley (Field studies – for registration purpose) 303/2022 Institute of plant protection – national research institute. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krzysztof Kubiak	2021	Expertise of phytotoxicity of product Fludio 025 in winter barley (Field studies – for registration purpose) Annex to the report No. 303/2022 Institute of plant protection – national research institute. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Agata Korbas	2021	Expertise on the phytotoxic effects of Fludio 025 GF in the cultiva- tion of winter barley. (Field studies – for registration purpose). 327/2022 Institute of plant protection – national research institute. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Agata Korbas	2021	Expertise on the phytotoxic effects of Fludio 025 GF in the cultiva- tion of winter barley. (Field studies – for registration purpose). Annex to the report No. 327/2022 Institute of plant protection – national research institute. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Agata Korbas	2021	Expertise on the phytotoxic effects of Fludio 025 GF in the cultiva- tion of winter barley. (Field studies – for registration purpose). 328/2022 Institute of plant protection – national research institute. Research	N	Y	Data/study report never sub- mitted before to Poland	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	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
			Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished				
KCP 6.2	Agata Korbas	2021	Expertise on the phytotoxic effects of Fludio 025 GF in the cultivation of winter barley. (Field studies – for registration purpose). Annex to the report No. 328/2022 Institute of plant protection – national research institute. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Joanna Pietryga	2021	Biological efficacy expertise of fungicide seed treatment Fludio 025 GF for <i>Fusarium spp.</i> , <i>Monographella nivalis</i> (anam. <i>Microdochium nivale</i> ), <i>Urocystis occulta</i> control in winter rye. 50 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Joanna Pietryga	2021	Biological efficacy expertise of fungicide seed treatment Fludio 025 GF for <i>Fusarium spp.</i> , <i>Monographella nivalis</i> (anam. <i>Microdochium nivale</i> ), <i>Urocystis occulta</i> control in winter rye. 51 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Joanna Pietryga	2021	Biological efficacy expertise on fungicide seed treatment Fludio 025 GF for <i>Fusarium spp.</i> , <i>Monographella nivalis</i> (anam. <i>Microdochium nivale</i> ), <i>Urocystis occulta</i> control in winter rye. 52 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Joanna Pietryga	2021	Biological efficacy expertise on fungicide seed treatment Fludio 025 GF for <i>Fusarium spp.</i> , <i>Monographella nivalis</i> (anam. <i>Microdochium nivale</i> ), <i>Urocystis occulta</i> control in winter rye. 53 F/2022	N	Y	Data/study report never submitted before to Poland	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	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
			Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished				
KCP 6.2	Joanna Pietryga	2021	Biological efficacy expertise on fungicide seed treatment Fludio 025 GF for <i>Fusarium spp.</i> , <i>Monographella nivalis</i> (anam. <i>Microdo- chium nivale</i> ), <i>Urocystis occulta</i> control in winter rye. 54 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krzysztof Kubiak	2021	Expertise of efficacy of product Fludio 025 GF in the control of fungal diseases in rye (Field studies – for registration purpose) 313/2022 Institute of plant protection – national research institute. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Agnieszka Mączyńska	2021	Analysis of quality parameters of winter rye seeds application of Fludio 025 GF 18 J/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Agnieszka Mączyńska	2021	Analysis of quality parameters of winter rye seeds application of Fludio 025 GF 19 J/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Agnieszka Mączyńska	2021	Analysis of quality parameters of winter rye seeds application of Fludio 025 GF 20 J/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch	N	Y	Data/study report never sub- mitted before to Poland	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	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
			GEP Unpublished				
KCP 6.2	Agnieszka Mączyńska	2021	Analysis of quality parameters of winter rye seeds application of Fludio 025 GF 21 J/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Agnieszka Mączyńska	2021	Analysis of quality parameters of winter rye seeds application of Fludio 025 GF 22 J/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Agnieszka Mączyńska	2021	Biological expertise of selectivity of seed treatment Fludio 025 GF in winter rye. 35 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Agnieszka Mączyńska	2021	Biological expertise of selectivity of seed treatment Fludio 025 GF in winter rye. Annex to trial report No. 35 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Agnieszka Mączyńska	2021	Biological expertise of selectivity of seed treatment Fludio 025 GF in winter rye. 36 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Agnieszka	2021	Biological expertise of selectivity of seed treatment Fludio 025 GF	N	Y	Data/study report never sub-	Synthos Agro

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
	Mączyńska		in winter rye. Annex to trial report No. 36 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished			mitted before to Poland	Sp. z o.o.
KCP 6.2	Agnieszka Mączyńska	2021	Biological expertise of selectivity of seed treatment Fludio 025 GF in winter rye. 37 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Agnieszka Mączyńska	2021	Biological expertise of selectivity of seed treatment Fludio 025 GF in winter rye. Annex to trial report No. 37 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Agnieszka Mączyńska	2021	Biological expertise of selectivity of seed treatment Fludio 025 GF in winter rye. 38 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Agnieszka Mączyńska	2021	Biological expertise of selectivity of seed treatment Fludio 025 GF in winter rye. Annex to trial report No. 38 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Agnieszka Mączyńska	2021	Biological expertise of selectivity of seed treatment Fludio 025 GF in winter rye. 39 F/2022 Institute of Plant Protection – National Research Institute, Sos-	N	Y	Data/study report never sub- mitted before to Poland	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	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
			nicowice Branch GEP Unpublished				
KCP 6.2	Agnieszka Mączyńska	2021	Biological expertise of selectivity of seed treatment Fludio 025 GF in winter rye. Annex to trial report No. 39 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Patrycja Płonka	2021	Biological efficacy expertise of fungicide seed treatment Fludio 025 GF for <i>Fusarium spp.</i> , <i>Tilletia caries</i> , <i>Monographella nivalis</i> ( <i>anam. Microdochium nivale</i> ) control in winter wheat. 63 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Patrycja Płonka	2021	Biological efficacy expertise of fungicide seed treatment Fludio 025 GF for <i>Fusarium spp.</i> , <i>Tilletia caries</i> , <i>Monographella nivalis</i> ( <i>anam. Microdochium nivale</i> ) control in winter wheat. 64 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Patrycja Płonka	2021	Biological efficacy expertise of fungicide seed treatment Fludio 025 GF for <i>Fusarium spp.</i> , <i>Tilletia caries</i> , <i>Monographella nivalis</i> ( <i>anam. Microdochium nivale</i> ) control in winter wheat. 65 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Patrycja Płonka	2021	Biological efficacy expertise of fungicide seed treatment Fludio 025 GF for <i>Fusarium spp.</i> , <i>Tilletia caries</i> , <i>Monographella nivalis</i> ( <i>anam. Microdochium nivale</i> ) control in winter wheat. 66 F/2022	N	Y	Data/study report never sub- mitted before to Poland	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	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
			Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished				
KCP 6.2	Patrycja Płonka	2021	Biological efficacy expertise of fungicide seed treatment Fludio 025 GF for <i>Fusarium spp.</i> , <i>Tilletia caries</i> , <i>Monographella nivalis</i> (anam. <i>Microdochium nivale</i> ) control in winter wheat. 67 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krzysztof Kubiak	2021	Expertise of efficacy of product Fludio 025 GF in the control of fungal diseases in winter wheat (Field studies – for registration purpose) 306/2022 Institute of plant protection – national research institute. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Angelika Szymura	2021	Analysis of quality parameters of winter wheat seeds application of Fludio 025 GF 1 J/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Angelika Szymura	2021	Analysis of quality parameters of winter wheat seeds application of Fludio 025 GF 2 J/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Angelika Szymura	2021	Analysis of quality parameters of winter wheat seeds application of Fludio 025 GF 2 J/2022 Institute of Plant Protection – National Research Institute, Sos-	N	Y	Data/study report never sub- mitted before to Poland	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	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
			nicowice Branch GEP Unpublished				
KCP 6.2	Angelika Szymura	2021	Analysis of quality parameters of winter wheat seeds application of Fludio 025 GF 3 J/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Angelika Szymura	2021	Analysis of quality parameters of winter wheat seeds application of Fludio 025 GF 4 J/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Angelika Szymura	2021	Analysis of quality parameters of winter wheat seeds application of Fludio 025 GF 5 J/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Angelika Szymura	2021	Biological expertise of selectivity of seed treatment Fludio 025 GF in winter wheat. 58 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Angelika Szymura	2021	Biological expertise of selectivity of seed treatment Fludio 025 GF in winter wheat. Annex to the report 58 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2	Angelika Szymura	2021	Biological expertise of selectivity of seed treatment Fludio 025 GF in winter wheat. 59 F/2022 Institute of Plant Protection – National Research Institute, Sosnowice Branch GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Angelika Szymura	2021	Biological expertise of selectivity of seed treatment Fludio 025 GF in winter wheat. Annex to the report 59 F/2022 Institute of Plant Protection – National Research Institute, Sosnowice Branch GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Angelika Szymura	2021	Biological expertise of selectivity of seed treatment Fludio 025 GF in winter wheat. 60 F/2022 Institute of Plant Protection – National Research Institute, Sosnowice Branch GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Angelika Szymura	2021	Biological expertise of selectivity of seed treatment Fludio 025 GF in winter wheat. Annex to the report 60 F/2022 Institute of Plant Protection – National Research Institute, Sosnowice Branch GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Angelika Szymura	2021	Biological expertise of selectivity of seed treatment Fludio 025 GF in winter wheat. 61 F/2022 Institute of Plant Protection – National Research Institute, Sosnowice Branch GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Angelika Szymura	2021	Biological expertise of selectivity of seed treatment Fludio 025 GF in winter wheat. Annex to the report 61 F/2022	N	Y	Data/study report never submitted before to Poland	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	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
			Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished				
KCP 6.2	Angelika Szymura	2021	Biological expertise of selectivity of seed treatment Fludio 025 GF in winter wheat. 62 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Angelika Szymura	2021	Biological expertise of selectivity of seed treatment Fludio 025 GF in winter wheat. Annex to the report 62 F/2022 Institute of Plant Protection – National Research Institute, Sos- nicowice Branch GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krzysztof Kubiak	2021	Expertise of phytotoxicity of product Fludio 025 GF in winter triticale (Field studies – for registration purpose) 307/2022 Institute of plant protection – national research institute. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krzysztof Kubiak	2021	Expertise of phytotoxicity of product Fludio 025 GF in winter triticale (Field studies – for registration purpose) Annex to the report No. 307/2022 Institute of plant protection – national research institute. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krzysztof Kubiak	2021	Expertise of phytotoxicity of product Fludio 025 GF in winter triticale (Field studies – for registration purpose) 308/2022 Institute of plant protection – national research institute. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP	N	Y	Data/study report never sub- mitted before to Poland	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	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 6.2	Krzysztof Kubiak	2021	Unpublished Expertise of phytotoxicity of product Fludio 025 GF in winter triticales (Field studies – for registration purpose) Annex to the report No. 308/2022 Institute of plant protection – national research institute. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krzysztof Kubiak	2021	Unpublished Expertise of phytotoxicity of product Fludio 025 GF in winter triticales (Field studies – for registration purpose) 309/2022 Institute of plant protection – national research institute. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krzysztof Kubiak	2021	Unpublished Expertise of phytotoxicity of product Fludio 025 GF in winter triticales (Field studies – for registration purpose) Annex to the report No. 309/2022 Institute of plant protection – national research institute. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Agata Korbas	2021	Unpublished Expertise on the phytotoxic effects of Fludio 025 GF in the cultivation of winter triticales (Field studies – for registration purpose) 341/2022 Institute of plant protection – national research institute. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Agata Korbas	2021	Unpublished Expertise on the phytotoxic effects of Fludio 025 GF in the cultivation of winter triticales (Field studies – for registration purpose) Annex to the report No. 341/2022 Institute of plant protection – national research institute. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Agata Korbas	2021	Unpublished Expertise on the phytotoxic effects of Fludio 025 GF in the cultivation of winter triticales (Field studies – for registration purpose)	N	Y	Data/study report never submitted before to Poland	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	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
			342/2022 Institute of plant protection – national research institute. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished				
KCP 6.2	Agata Korbas	2021	Expertise on the phytotoxic effects of Fludio 025 GF in the cultiva- tion of winter triticale (Field studies – for registration purpose) Annex to the report No. 342/2022 Institute of plant protection – national research institute. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Adam Szemendera	2021	The efficacy of FLUDIO 025 GF seed treatment in control of dis- eases in spring barley, Poland 2022. 28_01_F22_053 Fertico Sp. z o.o. GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Adam Szemendera	2021	The efficacy of FLUDIO 025 GF seed treatment in control of dis- eases in spring barley, Poland 2022. 28_01_F22_054 Fertico Sp. z o.o. GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Adam Szemendera	2021	The efficacy of FLUDIO 025 GF seed treatment in control of dis- eases in spring wheat, Poland 2022. 29_01_F22_055 Fertico Sp. z o.o. GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Adam Szemendera	2021	The efficacy of FLUDIO 025 GF seed treatment in control of dis- eases in spring wheat, Poland 2022. 29_01_F22_056 Fertico Sp. z o.o. GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Adam Szemendera	2021	The efficacy of FLUDIO 025 GF seed treatment in control of dis- eases in spring wheat, Poland 2022.	N	Y	Data/study report never sub- mitted before to Poland	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	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
			29_01_F22_056 Fertico Sp. z o.o. GEP Unpublished				
KCP 6.2	Adam Szemendera	2021	The efficacy of FLUDIO 025 GF seed treatment in control of dis- eases in winter triticale, Poland 2021. 332_01_F21_70 Fertico Sp. z o.o. GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Adam Szemendera	2021	The efficacy of FLUDIO 025 GF seed treatment in control of dis- eases in winter triticale, Poland 2021. 332_01_F21_71 Fertico Sp. z o.o. GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Adam Szemendera	2021	The efficacy of FLUDIO 025 GF seed treatment in control of dis- eases in winter wheat, Poland 2021. 332_01_F21_72 Fertico Sp. z o.o. GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Adam Szemendera	2021	The efficacy of FLUDIO 025 GF seed treatment in control of dis- eases in winter rye, Poland 2021. 332_01_F21_74 Fertico Sp. z o.o. GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Adam Szemendera	2021	The efficacy of FLUDIO 025 GF seed treatment in control of dis- eases in winter barley, Poland 2021. 332_01_F21_76 Fertico Sp. z o.o. GEP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Adam Szemendera	2021	The efficacy of FLUDIO 025 GF seed treatment in control of dis- eases in winter barley, Poland 2021. 332_01_F21_77 Fertico Sp. z o.o.	N	Y	Data/study report never sub- mitted before to Poland	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	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
			GEP Unpublished				
KCP 6.2	Adam Szemendera	2021	The efficacy of FLUDIO 025 GF seed treatment in control of diseases in winter barley, Poland 2021. 332_01_F21_78 Fertico Sp. z o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 7.1.4	Krakowian D.	2022	FLUDIO 025 GF. Reconstructed human Cornea-like Epithelium (RhCE) test method for identifying chemicals not requiring classification and labelling for eye irritation or serious eye damage Study code: EIT-06-21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 7.1.4	Krakowian D.	2022	FLUDIO 025 GF: In vitro Skin Corrosion: Reconstructed Human Epidermis Test Method. Study code: SCT-03-21. Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 7.2.3	Tartanus M.	2022	Magnitude of the residue of fludioxonil (131341-86-1) in winter wheat (Raw Agricultural Commodity – RAC) grown in open field conditions after one application of a formulated product Fludio 025 GF (seed treatment) – two harvest trials in Northern Europe – Poland (2021) Fertico Sp. z o.o., Report No 21FRT-53TRZAWFLDO GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 7.2.3	Zaręba-Kozioł M.	2022	Validation study report. Analytical phase. Validation of a method for determination of fludioxonil and its metabolite CGA192155 residues by Liquid Chromatography (LC-MS/MS) Fertico Sp. z o.o., Report No PW-2022-02 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 7.2.3	Zaręba-Kozioł M.	2022	Quantitative analysis of fludioxonil and its metabolite CGA192155	N	Y	Data/study report never sub-	Synthos Agro

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
			residues in winter wheat after one application of product Fludio 025 GF. Fertico Sp. z o.o., Report No PB-2022-28 GLP Unpublished			mitted before to Poland	Sp. z o.o.
KCP 7.2.3	Tartanus M.	2022	Magnitude of the residue of difenoconazole (CAS 119446-68-3) and fludioxonil (131341-86-1) in winter wheat (Raw Agricultural Commodity – RAC) grown in open field conditions after one application of a formulated product Diflud 050 FS (seed treatment) – four harvest trials in Northern Europe – Poland (2021) Fertico Sp. z o.o., Report No 21FRT-52TRZAWFLD GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 7.2.3	Wójcik M.	2022	Diflud 050 FS. Determination of the residues of difenoconazole, triazole derivative metabolites and fludioxonil in grains and straw of winter wheat. Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Report No C-02-22	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 10.2	Hodorek G.	2022	FLUDIO 025 GF: <i>Raphidocelis subcapitata</i> SAG 61.81 (formerly <i>Pseudokirchneriella subcapitata</i> ), Growth inhibition test W-32-21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 10.2	Hodorek G.	2022	FLUDIO 025 GF: <i>Daphnia magna</i> , acute immobilisation test W-31-21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 10.2		2022	FLUDIO 025 GF: <i>Rainbow trout</i> , acute toxicity test W-33-21 GLP Unpublished	Y	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 10.3.1	Kulec-Płoszczyca Elżbieta	2022	FLUDIO 025 GF: Honeybees ( <i>A. mellifera</i> ), Acute oral toxicity test B-03-22	N	Y	Data/study report never submitted before to Poland	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	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
			Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished				
KCP 10.3.1	Kulec-Płoszczyca Elżbieta	2022	FLUDIO 025 GF: Honeybees ( <i>A. mellifera</i> ), Acute contact toxicity test B-04-22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 10.3.1	Kulec-Płoszczyca Elżbieta	2022	FLUDIO 025 GF: Bumblebees ( <i>Bombus</i> spp.), Acute oral toxicity test B-67-21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 10.3.1	Kulec-Płoszczyca Elżbieta	2022	FLUDIO 025 GF: Bumblebees ( <i>Bombus</i> spp.), Acute contact toxicity test B-68-21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 10.3.1.2	Kulec-Płoszczyca Elżbieta	2022	FLUDIO 025 GF: Honeybees ( <i>A. mellifera</i> ), Chronic oral toxicity test B-02-22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 10.3.1.3	Kulec-Płoszczyca Elżbieta	2022	FLUDIO 025 GF: Honeybees ( <i>A. mellifera</i> ), Larval toxicity test - repeated B-01-22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna GLP	N	Y	Data/study report never submitted before to Poland	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	Verte-brate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 10.3.1.3	Kulec-Płoszczyca Elżbieta	2022	Unpublished FLUDIO 025 GF: Honeybees ( <i>A. mellifera</i> ), Acute Oral Toxicity Test B-03-22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 10.3.1.3	Kulec-Płoszczyca Elżbieta	2022	FLUDIO 025 GF: Honeybees ( <i>A. mellifera</i> ), Acute Contact Toxici- ty Test B-04-22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 10.3.2	Diáková Kateřina	2022	GLP laboratory study to determine effects of a plant protection product FLUDIO 025 GF on spiders of the genus <i>Pardosa</i> (Aranea, Lycosidae) Study code: 21/349 i2L Research Europe s.r.o. GLP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 10.3.2	Nácarová Jana	2022	GLP laboratory study to determine the effect of a plant protection product FLUDIO 025 GF on the entomophagous rove beetle <i>Aleo- chara bilineata</i> ; Study code: 21/350 i2L Research Europe s.r.o. GLP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 10.4	Gierbuszewska Aneta	2022	FLUDIO 025 GF: Collembolan ( <i>Folsomia candida</i> ) Reproduction Test G-24-21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never sub- mitted before to Poland	Synthos Agro Sp. z o.o.
KCP 10.4	Wróbel Anna	2022	FLUDIO 025 GF: Earthworm reproduction test ( <i>Eisenia andrei</i> ) G-23-21	N	Y	Data/study report never sub- mitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished				
KCP 10.4	Wróbel Anna	2022	FLUDIO 025 GF: Predatory mite ( <i>Hypoaspis (Geolaelaps) Aculeifer</i> ) reproduction test in soil G-25-21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 10.5	Gierbuszewska Aneta	2022	FLUDIO 025 GF: Soil Microorganisms: Nitrogen Transformation Test G-26-21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.

## List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2	Mair P.	1993	Determination of CGA 173506 in plant material, wine and soil by HPLC incl. validation data. NCP/Novartis Crop Protection AG, -, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No REM-133-04, 01/04/1993 Syngenta File N° CGA173506/0313	N	N	-	Syngenta

			GLP Not Published				
KCP 5.1.2	Mair P.	1996	Validation of Method REM 133.04. Determination of efficiency of extraction and accountability from 14C-Fludioxonil treated specimen (tomato) Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland Report No 110/96 Syngenta File No CGA173506/0778 GLP Not Published	N	N	-	Syngenta
KCP 5.1.2	Ross J.,	1991	Anal. method for the determination of CGA 169374 in wheat raw agricultural commodities by gas chromatography with nitrogen/phosphorus detection Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, United States, Report No AG-575A Syngenta File N° CGA169374/0450 GLP Not Published	N	N	-	Syngenta
KCP 5.1.2	■	1996	Independent Method Validation Ruggedness Trial for the Determination of Total Residues of CGA173506 and Metabolites in Animal Tissues, Milk and Eggs using Ciba-Geigy Method AG-616B entitled "Determination of Total Residues of CGA1735..." Novartis Crop Protection AG, Basel, Switzerland ■ Report No 96-0010 Syngenta File No CGA173506/0886 GLP Not Published	N	N	-	Syngenta
KCP 5.1.2	Tribolet R.,	2001	Validation of Method REM 133.04 by Analysis of Fortified Specimens (Plant Materials and Soil) for Fludioxonil (CGA173506) and Evaluation of Recoveries Syngenta Crop Protection AG, Basel, Switzerland Report No 210/01, 26/06/2001 Syngenta File N° CGA173506/5398 GLP Not Published	N	N	-	Syngenta
KCP 5.1.2	■	1996	Determination of total residues of CGA173506 and metabolites as CGA192155 in animal tissues, milk and eggs by high performance	N	N	-	Syngenta

			liquid chromatography with column switching Novartis Crop Protection AG, Basel, Switzerland █ Report No AG-616B Syngenta File No CGA173506/0733 GLP Not Published				
KCP 5.1.2	█	1994	Analytical method for the determination of CGA 169374 residues in dairy and poultry tissue, eggs and milk by gas chromatography Syngenta Crop Protection AG, Basel, Switzerland █ States, Report No AG-544A Syngenta File N° CGA169374/0933 Not GLP Not Published	N	N	-	Syngenta
KCP 5.2	█	2004	Independent Laboratory Validation of Residue Method REM 147.07 for the Determination of Difenconazole and CGA205375 in Animal Products Syngenta Crop Protection AG, Basel, Switzerland █, Report No SYN/DIF/04031 GLP Not Published Syngenta File N° CGA169374/2535	N	N	-	Syngenta
KCP 5.2	█	2004	Residue Method for the Determination of Residues of Difenconazole (CGA169374) and CGA 205375 in Animal Products. Final Determination by LC-MS/MS Syngenta Crop Protection AG, Basel, Switzerland █, Report No REM 147.07 Not GLP Not Published Syngenta File N° CGA205375/0021	N	N	-	Syngenta
KCP 5.2	Lakaschus, S.,	2005	Validation of Multi-Residue Method DFG S19 (L00.00-34) for the Determination of Residues of Fludioxonil in Different Plant Matrices With LC-MS/MS Detection Syngenta Crop Protection AG, Basel, Switzerland Dr. Specht & Partner Chem. Laboratorien GmbH, Hamburg, Germany Method/Validation No. SYN-0503V, 01 August 2005	N	N	-	Syngenta

			GLP, Not Published Syngenta File N° CGA173506/6497				
KCP 5.2	Mair,	1996	Validation of Method REM 133.04. Determination of efficiency of extraction and accountability from 14C-Fludioxonil treated specimen (tomato) Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland Report No 110/96 GLP, not published Syngenta File No CGA173506/0778	N			Syngenta
KCP 5.2	Reichert N.,	2006	Independent Laboratory Validation of the DFG Method S19 for The Determination of Residues of Fludioxonil in Plant Matrices (Kiwi and Avocado) Syngenta Crop Protection AG, Basel, Switzerland Institut Fresenius, Taunusstein, Germany Method/Validation No. IF-05/00362984, 26 January 2006 GLP, Not Published Syngenta File N° CGA173506/6772	N	N	-	Syngenta
KCP 5.2	Robinson N.J., Tummon O.J.,	2004	Residue Analytical Method for the Determination of Fludioxonil in Soil Syngenta Ltd., Jealott's Hill, UK, 02.07.2004 Study report number RAM 423/01 Not GLP, Not Published Syngenta archive No. CGA173506/5941	N	N	-	Syngenta
KCP 5.2	■■■■	2004b	Difenoconazole (CGA169374) and CGA205375: Validation of Residue Analytical Method REM 147.07 for the Determination of Residues in Animal Products Syngenta Crop Protection AG, Basel, Switzerland ■■■■, Report No RJ3478B GLP Not Published Syngenta File N° CGA205375/0020	N	N	-	Syngenta
KCP 5.2	Schulz H.,	2004	Independent Laboratory Validation of DFG Method S19 (Extended Revision) for the Determination of Residues of difenoconazole in/on plant matrices Syngenta Crop Protection AG, Basel, Switzerland Institut Fresenius, Taunusstein, Germany,	N	N	-	Syngenta



			Report No IF-04/00160619 GLP Not Published Syngenta File N° CGA169374/2507				
KCP 5.2	■■■■	2004a	Difenoconazole: Validation of the DFG Method S 19 (Extended Revision) for the Determination of Residues of Difenoconazole in Milk, Meat, Fat, Egg, Liver and Kidney Syngenta Crop Protection AG, Basel, Switzerland ■■■■, Report No SYN-0302V Az. G03-0024 GLP Not Published Syngenta File N° CGA169374/2443	N	N	-	Syngenta
KCP 5.2	■■■■	1996	Independent Method Validation Ruggedness Trial for the Determination of Total Residues of CGA173506 and Metabolites in Animal Tissues, Milk and Eggs using Ciba-Geigy Method AG-616B entitled "Determination of Total Residues of CGA1735..." Novartis Crop Protection AG, Basel, Switzerland ■■■■ Report No 96-0010 GLP, not published Syngenta File No CGA173506/0886	N	N	-	Syngenta
KCP 5.2	Tribolet R.,	1992	Sampling of air and determination of residues of parent compound by high performance liquid chromatography NCP/Novartis Crop Protection AG, Switzerland Ciba-Geigy Ltd., Basel, Switzerland Report No REM133-03, 15/12/1992 GLP, Not Published Syngenta File N° CGA173506/0234	N	N	-	Syngenta
KCP 5.2	Tribolet R.,	1992	Sampling of air and determination of residues of parent compound by gas chromatography Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No REM-147-02 Not GLP Not Published Syngenta File N° CGA169374/0722	N	N	-	Syngenta
KCP 5.2	Tribolet R.,	1996	Report on Special Study 102/96. Validation of method REM 147.02 in air, Validation by analytis of fortified specimens and determina-	N	N	-	Syngenta

			tion of recoveries Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No 102/96 GLP Not Published Syngenta File N° CGA169374/1192				
KCP 5.2	Tribolet R.,	1999a	Validation of Method REM 133.05 by Analysis of Fortified Water Specimens for Fludioxonil (CGA173506) and Evaluation of Recoveries Novartis Crop Protection AG, Basel, Switzerland Report No 212/99, 30/06/1999 GLP, Not Published Syngenta File N° CGA173506/5010	N	N	-	Syngenta
KCP 5.2	Tribolet R.,	1999b	Determination of Parent Compound by High Performance Liquid Chromatographie in Water CGA173506 – Fludioxonil Novartis Crop Protection AG, Basel, Switzerland Report No REM 133.05, 30/06/1999 GLP, Not Published Syngenta File N° CGA173506/5009	N	N	-	Syngenta
KCP 5.2	Tribolet R.,	2001	Validation of Method REM 133.04 by Analysis of Fortified Specimens (Plant Materials and Soil) for Fludioxonil (CGA173506) and Evaluation of Recoveries Syngenta Crop Protection AG, Basel, Switzerland Report No 210/01, 26/06/2001 GLP, Not Published Syngenta File N° CGA173506/5398	N	N	-	Syngenta
KCP 5.2	Tummon O.K.,	2004a	Difenoconazole. Validation of an Analytical Method for the Determination of Residues of Difenoconazole and CGA205375 in Soil Syngenta Crop Protection AG, Basel, Switzerland Syngenta, Jealott's Hill, United Kingdom, Report No RJ3459B GLP Not Published Syngenta File N° CGA169374/2501	N	N	-	Syngenta
KCP 5.2	Tummon O.K.,	2004b	Difenoconazole. Validation of an Analytical Method for the Determination of Residues of Difenoconazole in Air Syngenta Crop Protection AG, Basel, Switzerland Syngenta, Jealott's Hill, United Kingdom, Report No RJ3495B	N			Syngenta

			GLP Not Published Syngenta File N° CGA169374/2500				
KCP 5.2	■■■■	1996	Validation of “Draft” Analytical Method AG-616 for the Determination of Total Residues of CGA173506 and Metabolites as CGA192155 in Animal Tissues, Milk and Eggs Novartis Crop Protection AG, Basel, Switzerland ■■■■ Report No ABR-95063 GLP, not published Syngenta File No CGA173506/0732	N	N	-	Syngenta
KCP 5.2	■■■■	1996	Determination of total residues of CGA173506 and metabolites as CGA192155 in animal tissues, milk and eggs by high performance liquid chromatography with column switching Novartis Crop Protection AG, Basel, Switzerland ■■■■ Report No AG-616B Not GLP, not published Syngenta File No CGA173506/0733	N	N	-	Syngenta
KCP 7.2.1 (KCA 6.1)	Bass R.V.	1995	CGA 173506: Evaluation of residues, Stability in grain and straw under deep freeze storage conditions Novartis Crop Protection AG, Basel, Switzerland Hazleton Europe Ltd., Harrogate, North Yorkshire, United Kingdom, 621/7-1012 GLP Syngenta File No CGA173506/0589	N	N	-	Syngenta
KCP 7.2.1 (KCA 6.1)	Eudy L.W.	1997a	Stability of CGA-173506 fortified into corn, sorghum, and potato substrates under freezer storage conditions Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection Inc., Greensboro, USA, 115-93 GLP Syngenta File No CGA173506/1235	N	N	-	Syngenta
KCP 7.2.1 (KCA 6.1)	■■■■	1997b	Stability of CGA 173506 fortified into Meat, Milk and Egg samples under freezer storage conditions Novartis Crop Protection AG, Basel, Switzerland ■■■■ GLP Syngenta File No CGA173506/5001	N	N	-	Syngenta
KCP 7.2.1	Mair P.	1996	Stability of residues of CGA 173506 in grapes stored under deep	N	N	-	Syngenta

(KCA 6.1)			freezer conditions Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 131/93 GLP Syngenta File No CGA173506/0714				
KCP 7.2.1 (KCA 6.1)	Tribolet R.	2000a	Stability of residues of CGA 173506 (Fludioxonil) in Tomatoes under Freezer Storage Conditions. Syngenta AG, Basel, Switzerland, 222/98 GLP Syngenta File No CGA173506/5348	N	N	-	Syngenta
KCP 7.2.1 (KCA 6.1)	Tribolet R.	2000b	Stability of residues of CGA 173506 (Fludioxonil) in Apples under Freezer Storage Conditions. Syngenta AG, Basel, Switzerland, 221/98 GLP Syngenta File No CGA173506/5349	N	N	-	Syngenta
KCP 7.2.1 (KCA 6.1)	Tribolet R.	2000c	Stability of residues of CGA 173506 (Fludioxonil) in Peas and Rape Seed under Freezer Storage Conditions. Syngenta AG, Basel, Switzerland, 210/00 GLP Syngenta File No CGA173506/5508	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Close Ch.	1998a	14C-CGA-173506: Uptake and Distribution in cotton Following Seed Treatment at 5 g ai/100 kg Seed Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection Inc., Greensboro, USA, ABR-97032 GLP Syngenta File No CGA173506/1150	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Close Ch.	1998b	14C-CGA-173506: Uptake and Distribution in Cotton Following Seed Treatment at 2.5 g ai/100 kg Seed Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection Inc., Greensboro, USA, ABR-97034 GLP Syngenta File No CGA173506/1151	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Close Ch.	1998c	14C-CGA-173506: Uptake and distribution in Soybeans Following Seed Treatment at 5 g a.i./100 kg Seed Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection Inc., Greensboro, USA, ABR-97033 GLP Syngenta File No CGA173506/1128	N	N	-	Syngenta

KCP 7.2.2 (KCA 6.2.1)	Fleischmann T.J	1991	Distribution of 14C-CGA 173506 in rice resulting from seed treatment grown under greenhouse conditions Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, USA, ABR-90099 GLP Syngenta File No CGA173506/0078	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Gentile B.	1991	Uptake, distribution and degradation of 14-C-pyrrole CGA 173506 in field grown spring wheat after seed treatment Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 15-91 GLP Syngenta File No CGA173506/0101	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Gentile B.	1993	Metabolism of [4-14C-Pyrrole]CGA 173506 in Spring Wheat Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 27/92 GLP Syngenta File No CGA173506/0286	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Kennedy E.	1999	(Phenyl)-U-14C)-CGA 173506: Nature of the Residue in Green Onions Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection Inc., Greensboro, USA, 153-97 GLP Syngenta File No CGA173506/5079	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Krauss J.H.	1992	Distribution and degradation of CGA 173506 in greenhouse grown tomatoes after treatment with (14C-pyrrole)CGA 173506 labelled material Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 1-92 GLP Syngenta File No CGA173506/0152	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Krauss J.H.	1993	Distribution and Degradation of CGA 173506 in Field Grown Potato after Seed Treatment with [14C-Pyrrole]CGA 173506 Labelled Material Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 13-93 GLP Syngenta File No CGA173506/0308	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Nicollier G.	1991	Penetration, distribution and degradation of 14C-pyrrole-CGA 173506 in field grape-vine	N	N	-	Syngenta

			Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 3/91 GLP Syngenta File No CGA173506/0151				
KCP 7.2.2 (KCA 6.2.1)	Nicollier G.	1993	Metabolism of 14C-Pyrrole-CGA 173506 in Field Grape-Vine Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 8/93 GLP Syngenta File No CGA173506/0309	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Peffer R.C.	1999	[Phenyl-U-14C]-CGA-173506 : Nature of the Residue in Peaches Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection Inc., Greensboro, USA, 156-96 GLP Syngenta File No CGA173506/5080	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Stingelin J.	2000	Uptake, distribution and metabolism of [pyrrole-4-14C] CGA 173506 in field grown lettuce Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 98JS29 GLP Syngenta File No CGA173506/5281	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.2.2-6.2.5)	■■■■	1992a	Metabolism of [14C-pyrrole] CGA 173506 in Goats F-00088, Amendment No. 1 GLP Syngenta File No CGA173506/0236	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.2.2-6.2.5)	■■■■	1992b	Metabolism of [14C-pyrrole] CGA 173506 in chickens. F-00089, Amendment No. 1 and Amendment No. 2 GLP Syngenta File No CGA173506/0237	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.2.2-6.2.5)	■■■■	1996	CGA 173506 – Magnitude of the residues in meat and milk resulting from the feeding of three levels to dairy cattle. ABR-95095 GLP Syngenta File No CGA173506/0709	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.2.2-6.2.5)	Seim V.	1995	Biological phase report for CGA 173506 - Magnitude of the residues in meat and milk resulting from the feeding of three levels to dairy cattle. Part A: Biological Phase. BIOL-94016, Amendment 1 GLP	N	N	-	Syngenta

			Syngenta File No CGA173506/0651				
KCP 7.2.2 (KCA 6.6.1)	Close C.	1997	14C-CGA 173506: Uptake and Distribution of residues in confined rotational crops following treatment at 25 g a.i./Acre Ciba-GeigyCorp., Greensboro, United States. ABR-97005 GLP Syngenta file No CGA173506/0967	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.6.1)	Gentile B.	1992	Outdoor confined accumulation study on rotational crops after bare-ground applicaion of 1-14C-Pyrroe) CGA 173506 Ciba-Geigy Ltd., Basel, Switzerland 89BG03PR1 GLP Syngenta File No CGA173506/0196	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.6.1)	Joseph T.A.	1999	CGA 219417 and CGA 173506 – Field Accumulation in Rotational Crops Novartis Crop Protection Inc., Greensbro, United States 174-97 GLP Syngenta File No CGA21941/0930	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.6.1)	Thalacker F.W.	1996	14C-CGA-173506: Uptake and distribution of residues in confined rotational crops following treatment at 50g a.i./acre Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, USA, Corning Hazleton Inc., Madison, USA, CHW 6117-329 GLP not published Syngenta File No CGA173506/0731	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.6.1)	Thalacker F.W.	1999	[Phenyl-U-14C] CGA 173506 - Confined rotational crop study after soil application Novartis Crop Protection AG, Basel, Switzerland Covance Laboratories, Madison WI, USA, 117-97 GLP not published Syngenta File No CGA173506/5212	N	N	-	Syngenta
KCP 9.1	Abildt, U.	1991	Rate of degradation of CGA 173506 in aerobic soil at various conditions Ciba-Geigy Ltd., Basel, Switzerland 1-91, 22.08.1991 GLP, not published Syngenta File N° CGA173506/0112	N	N	-	Syngenta

KCP 9.1	Abildt, U.	1994	Rate and Quantum Yield of the direct Phototransformation of CGA 173506 under Laboratory Conditions in Water Ciba-Geigy Ltd., Basel, Switzerland 93UA02, 15.09.1994 GLP, not published Syngenta File N° CGA173506/0502	N	N	-	Syngenta
KCP 9.1	Adam, D.	1998	Anaerobic soil metabolism of 14C- Phenyl-CGA 173506 in a sandy loam/water system Novartis Crop Protection AG, Basel, Switzerland 97DA01, 27.11.1998 GLP, not published Syngenta File N° CGA173506/1397	N	N	-	Syngenta
KCP 9.1	Adam, A.	2004	[Pyrole-4-14C]CGA 173506: Route and degradation in water/sediment systems under light exposure. Syngenta Crop Protection. Environmental fate & Exposure Assessment, Wro-1058.7, 4002 Basel, 2April 2004. None GLP, unpublished RCC Study number 847909	N	N	-	Syngenta
KCP 9.1	Argento, J.C.	1994	Determination of residues of CGA 173506 in soil, (WP 50, A-7850 B, Vine + Soil, France Ciba-Geigy SA, Rueil-Malmaison, France OF93164, 28.11.1994 Non-GLP not published Syngenta File N° CGA173506/0534	N	N	-	Syngenta
KCP 9.1	Baumann, W.	1993	Report on the test for ready biodegradability of CGA 173506 tech. in the carbon dioxide evolution test Ciba-Geigy Ltd, Basel, Switzerland 933653, 07.09.1993 GLP, not published Syngenta File N° CGA173506/0353	N	N	-	Syngenta
KCP 9.1	Burton, S.D.	1996a	Soil adsorption/desorption of carboxyl- 14C-CGA 192155 by the batch equilibrium method Stillmeadow Inc., Texas, United States 1402-94, 16.08.1996 GLP, not published Syngenta File N° CGA192155/0003	N	N	-	Syngenta
KCP 9.1	Burton, S.D.	1996b	Soil adsorption/desorption of pyrrole- 14C-CGA 265378 by the batch equilibrium method	N	N	-	Syngenta



			Stillmeadow Inc., Texas, United States 2481-95, 16.08.1996 GLP, not published Syngenta File N° CGA265378/0003				
KCP 9.1	Burton, S.D.	1996d	Soil adsorption/desorption of (oxirane- 3-14C) CGA 339833 by the batch equilibrium method Stillmeadow Inc., Texas, United States 2694-96, 16.08.1996 GLP, not published Syngenta File N° CGA339833/0001	N	N	-	Syngenta
KCP 9.1	Ellgehausen, H.	1992a	Degradation of CGA-173506 in two soils under aerobic con- ditions at 20°C Ciba-Geigy Ltd., Basel, Switzerland 91EH05, 04.02.1992 GLP, not published Syngenta File N° CGA173506/0141	N	N	-	Syngenta
KCP 9.1	Ellgehausen, H.	1992b	Degradation of CGA 173506 in one soil under aerobic condi- tions at two temperatures Ciba-Geigy Ltd., Basel, Switzerland 91EH08, 01.04.1992 GLP, not published Syngenta File N° CGA173506/0153	N	N	-	Syngenta
KCP 9.1	Ellgehausen, H.	1992c	Leaching characteristics of aged soil residues of CGA 173506 in two soils after percolation of 508 mm artificial rain Ciba-Geigy Ltd., Basel, Switzerland 19-92 91EH06, 01.09.1992 GLP, not published Syngenta File N° CGA173506/0187	N	N	-	Syngenta
KCP 9.1	Ellgehausen, H.	1993	Leaching Characteristics of Aged Soil Residues of CGA 173506 in two Soils after Percolation of 200 mm Artificial Rainfall Ciba-Geigy Ltd., Basel, Switzerland 20/92 91EH07, 27.01.1993 GLP, not published Syngenta File N° CGA173506/0268	N	N	-	Syngenta

KCP 9.1	Gentile, B.	1991	Uptake, distribution and degradation of [4- <sup>14</sup> -C-pyrrole]-CGA 173506 in field grown spring wheat after seed treatment Ciba-Geigy Ltd., Basel, Switzerland 15-91, 17.06.1991 GLP, not published Syngenta File N° CGA173506/0101	N	N	-	Syngenta
KCP 9.1	Gentile, B.	1993	Field dissipation of CGA 173506 under two different environmental conditions after bareground application of [4- <sup>14</sup> C-Pyrrole]-labeled material Ciba-Geigy Ltd., Basel, Switzerland 89BG02PR3, 03.05.1993 GLP, not published Syngenta File N° CGA173506/0306	N	N	-	Syngenta
KCP 9.1	Giddings, J.M.	1993	CGA 173506: Outdoor aquatic microcosm study of the environmental fate and ecological effects Springborn Laboratories Inc., Wareham, United States 92-12-4548, 13.08.1993 GLP, not published Syngenta File N° CGA173506/0346	N	N	-	Syngenta
KCP 9.1	Gonzalez-Valero, J.	1992	Metabolism of CGA 173506 under aerobic conditions in aquatic systems Ciba-Geigy Ltd, Basel, Switzerland 91GJ03, 25.11.1992 GLP, not published Syngenta File N° CGA173506/0235	N	N	-	Syngenta
KCP 9.1	Greener, M	2001	Fludioxonil (CGA173506) Using FOCUS-PELMO to Model Soil Residues Following Use as a Seed Treatment on Winter Cereals and Peas in Europe Syngenta Jealott's Hill Research Centre, Bracknell, United Kingdom RAJ0091B, 13.12.2001 Non-GLP, not published Syngenta File N° CGA173506/5448	N	N	-	Syngenta
KCP 9.1	Gurney, A.	2001	Leaching behaviour of fludioxonil (CGA173506) and its metabolites CGA339833 and CGA192155 under the conditions of the FOCUS groundwater scenarios Syngenta Crop Protection AG, Basel, Switzerland	N	N	-	Syngenta

			Mod01AG02, 18.01.2002 Non-GLP not published Syngenta File N° CGA173506/5450				
KCP 9.1	Hawking, D.R., et. al	1991	The degradation of CGA 173506 in soil under aerobic, aerobic/anaerobic and sterile conditions at 25C Huntington Research Centre GLP, Not published Syngenta File No CGA173506/0061	N	N	-	Syngenta
KCP 9.1	Hawkins, D.R. Kirkpatrick, D. Shaw, D. Chan, S.C.	1991	The degradation of CGA 173506 in soil under aerobic, aerobic/anaerobic and sterile conditions at 25°C Huntingdon Research Centre Ltd., Huntingdon, United Kingdom HRC-CBG-485-90818, 11.02.1991 GLP, not published Syngenta File N° CGA173506/0061	N	N	-	Syngenta
KCP 9.1	Hawkins, D.R. Kirkpatrick, D. Shaw, D. Chan, S.C.	1991b	Adsorption/desorption of CGA 173506 with soil Huntingdon Research Centre Ltd., Huntingdon, United Kingdom 89CG05, 02.07.1991 GLP, not published Syngenta File N° CGA173506/0107	N	N	-	Syngenta
KCP 9.1	Hawkins, D.R. Kirkpatrick, D. Shaw, D. Chan, S.C.	1991c	The mobility of CGA 173506 on soil columns Huntingdon Research Centre Ltd., Huntingdon, United Kingdom HRC-CBG-486-90294, 11.02.1991 GLP, not published Syngenta File N° CGA173506/0060	N	N	-	Syngenta
KCP 9.1	Hawkins, D.R. Kirkpatrick, D. Shaw, D.	1991d	The hydrolytic stability of CGA 173506 Huntingdon Research Centre Ltd., Huntingdon, United Kingdom HRC-CBG-487-891775, 19.03.1991 GLP, not published Syngenta File N° CGA173506/0091	N	N	-	Syngenta
KCP 9.1	Kiffe, M.	1997	Migration of Fludioxonil in soil after seed treatment with (Pyrole-4-14C) CGA 173506 Novartis Crop Protection AG, Basel, Switzerland 97MK04, 06.10.1997 GLP, not published	N	N	-	Syngenta

			Syngenta File N° CGA173506/1029				
KCP 9.1	Kirkpatrick, D.	1994a	The photodegradation of CGA 173506 on soil (amended final report) Huntingdon Research Centre Ltd., Huntingdon, United Kingdom HRC CBG 516/901362, 11.11.1994 GLP, not published Syngenta File N° CGA173506/0523	N	N	-	Syngenta
KCP 9.1	Kirkpatrick, D.	1994b	Photolysis of [Phenyl-U-14C]CGA 173506 on the soil surface under laboratory conditions Huntingdon Research Centre Ltd., Huntingdon, United Kingdom CBG 610, 27.09.1994 GLP, not published Syngenta File N° CGA173506/0521	N	N	-	Syngenta
KCP 9.1	Kirkpatrick, D.	1994c	The Photodegradation of [Pyrole-4- 14C]CGA 173506 on soil and in water: Identification of photoproducts Huntingdon Research Centre Ltd., Huntingdon, United Kingdom CBG569A & CBG569B, 27.09.1994 GLP, not published Syngenta File N° CGA173506/0519	N	N	-	Syngenta
KCP 9.1	Kirkpatrick, D.	1994d	The photodegradation of CGA 173506 in water (amended final report) Huntingdon Research Centre Ltd., Huntingdon, United Kingdom HRC/CBG488/9098, 10.11.1994 GLP, not published Syngenta File N° CGA173506/0524	N	N	-	Syngenta
KCP 9.1	Kirkpatrick, D.	1994e	Photolysis of [Phenyl-U-14C]CGA 173506 in aqueous solution under laboratory conditions Huntingdon Research Centre Ltd., Huntingdon, United Kingdom CBG 609, 27.09.1994 GLP, not published Syngenta File N° CGA173506/0520	N	N	-	Syngenta
KCP 9.1	Kirkpatrick, D.	1994f	The Photodegradation of [Pyrole-4- 14C]CGA 173506 on soil and in water: Identification of photoproducts Huntingdon Research Centre Ltd., Huntingdon, United Kingdom CBG569A & CBG569B, 27.09.1994 GLP, not published	N	N	-	Syngenta

			Syngenta File N° CGA173506/0519				
KCP 9.1	Kirkpatrick, D.	1996	The photodegradation of CGA 173506 on soil and in water: co- chromatography of study samples with reference compounds Huntingdon Research Centre Ltd., Huntingdon, United Kingdom CBG 720, 17.04.1996 GLP, not published Syngenta File N° CGA173506/0724	N	N	-	Syngenta
KCP 9.1	Kissling, M.	1995a	Determination of Residues of CGA219417 and of CGA173506 in Strawberries and Soil And Determination of CGA249287 (Metabolite of CGA219417) in Soil After Application as WG 62.5 - Field Trial (Open Field) Ciba-Geigy Ltd., Basel, Switzerland 2110/94, 06.04.1995 GLP, not published Syngenta File N° CGA173506/1095	N	N	-	Syngenta
KCP 9.1	Mair, P.	1992	Determination of residues of CGA 173506 in soil - South Africa Ciba-Geigy Ltd., Basel, Switzerland 2017-91, 04.01.1992 GLP, not published Syngenta File N° CGA173506/0194	N	N	-	Syngenta
KCP 9.1	Mair, P.	1995a	Determination of residues of CGA 173506 in soil after direct application to soil planted with grapevine - field trial Ciba-Geigy Ltd., Basel, Switzerland 2093/93, 04.07.1995 GLP, not published Syngenta File N° CGA173506/0633	N	N	-	Syngenta
KCP 9.1	Mair, P.	1995b	Determination of residues of CGA 173506 in soil - Field Trial Ciba-Geigy Ltd., Basel, Switzerland 2150/93, 22.05.1995 GLP, not published Syngenta File N° CGA173506/0610	N	N	-	Syngenta
KCP 9.1	Mair, P.	1995c	Determination of residues of CGA 173506 in soil - Field Trial Ciba-Geigy Ltd., Basel, Switzerland 2151/93, 22.05.1995	N	N	-	Syngenta

			GLP, not published Syngenta File N° CGA173506/0614				
KCP 9.1	Mair, P.	1996a	Residues of CGA 173506 in Grapes and Soil after Four Applications of WP 50 Formulation - Long-term Field Trial, Switzerland Ciba-Geigy Ltd., Basel, Switzerland 2069/88-94, 06.03.1996 GLP, not published Syngenta File N° CGA173506/0712	N	N	-	Syngenta
KCP 9.1	Mair, P.	1996b	Residues of CGA 173506 in Grapes and Soil after Four Applications of WP 50 Formulation - Long-term Field Trial, Switzerland Ciba-Geigy Ltd., Basel, Switzerland 2070/88-94, 06.03.1996 GLP, not published Syngenta File N° CGA173506/0711	N	N	-	Syngenta
KCP 9.1	Mair, P.	1997	Long-Term Residue Study with Fludioxonil (CGA 173506) as Formulation WP 50 in Grapes in Switzerland Ciba-Geigy Ltd., Basel, Switzerland 2048/91-95, 16.12.1997 GLP, not published Syngenta File N° CGA173506/0318	N	N	-	Syngenta
KCP 9.1	Mair, P.	1998	Long-Term Residue Study with Cyprodinil (CGA 219417) and Fludioxonil (CGA 173506) in Grapes in Switzerland; Ciba-Geigy Ltd., Basel, Switzerland 2047/92-96, 04.02.1998 GLP, not published Syngenta File N° CGA173506/0320	N	N	-	Syngenta
KCP 9.1	Maffezzoni, M. Tournayre, J.C.	1991	Dissipation of CGA 173506, soil Ciba-Geigy SA, Rueil-Malmaison, France 18-91, 05.07.1991 Non-GLP, not published Syngenta File N° CGA173506/0133	N	N	-	Syngenta
KCP 9.1	Minet, U.	1994a	Degradation and Metabolism of 14C-Pyrrole-Labelled CGA	N	N	-	Syngenta

			173506 in Soil under Aerobic and Aerobic/Anaerobic Conditions at 20°C Ciba-Geigy Ltd., Basel, Switzerland 92MU01-1, 01.02.1994 GLP, not published Syngenta File N° CGA173506/0417				
KCP 9.1	Minet, U.	1994b	Degradation of 14C-Pyrrole-Ring-Labelled CGA 173506 in Two Soils under Aerobic Conditions at 20°C Ciba-Geigy Ltd., Basel, Switzerland 92MU01-2, 04.02.1994 GLP, not published Syngenta File N° CGA173506/0418	N	N	-	Syngenta
KCP 9.1	Minet, U.	1994c	Degradation and Metabolism of Phenyl-Labelled CGA 173506 in Soil under Aerobic Conditions at 20°C Ciba-Geigy Ltd., Basel, Switzerland 92MU02, 22.04.1994 GLP, not published	N	N	-	Syngenta
KCP 9.1	Purdy, J.	1998	Two soil dissipation trials to determine persistence and leaching movement of CGA 173506, CGA 329351 and their significant soil metabolites after application of Maxim XL as a seed treatment on field corn in central Canada Novartis Crop Protection Inc., Mississauga, Canada CER 04110/97, 15.10.1998 GLP, not published Syngenta File N° CGA173506/1277	N	N	-	Syngenta
KCP 9.1	Reichert, N.	1993a	Field soil dissipation rate determination of CGA 173506 RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany 324538, 09.11.1993 GLP, not published Syngenta File N° CGA173506/0430	N	N	-	Syngenta
KCP 9.1	Reichert, N.	1993b	Field soil dissipation rate determination of CGA 173506 RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany 324527, 09.11.1993 GLP, not published Syngenta File N° CGA173506/0431	N	N	-	Syngenta

KCP 9.1	Reichert, N.	1993c	Field soil dissipation rate determination of CGA 173506 RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany 324516, 09.11.1993 GLP, not published Syngenta File N° CGA173506/0432	N	N	-	Syngenta
KCP 9.1	Reischmann, F.J.	1994	Degradation of CGA 173506 in Soil under controlled laboratory Conditions Ciba-Geigy Ltd., Basel, Switzerland 93RF02, 27.04.1994 GLP, not published Syngenta File N° CGA173506/0488	N	N	-	Syngenta
KCP 9.1	Schmidt, E.	2001	Direct Phototransformation of CGA339833 in Water Solvias AG, Basel, Switzerland L01-008350, 20.12.2001 GLP, not published Syngenta File N° CGA339833/0018	N	N	-	Syngenta
KCP 9.1	Steinemann, A.	1995a	Estimation of the distribution of CGA 173506 on wheat seeds and in soil after sowing of dressed seeds Ciba-Geigy Ltd., Basel, Switzerland 17.02.1995 GLP, not published Syngenta File N° CGA173506/0551	N	N	-	Syngenta
KCP 9.1	Steinemann, A.	1995b	Uptake of CGA 173506 from dressed wheat seeds after sowing. 173506 FS 025 (A-8207 B) Novartis Crop Protection AG., Basel, Switzerland 95A94137ST, 02.02.1995 Non-GLP, not published Syngenta File N° CGA173506/0553	N	N	-	Syngenta
KCP 9.1	Tribolet, R.	2001a	Long Term Residue Study with Fludioxonil (CGA 173506) and Cyprodinil (CGA 219417) in or on Grapes and Soil in Switzerland Ciba-Geigy Ltd., Basel, Switzerland 2037/93-02, 14.08.2001 GLP, not published Syngenta File N° CGA173506/0459	N	N	-	Syngenta
KCP 9.1	Tribolet, R.	2001b	Long Term Residue Study with Fludioxonil (CGA	N	N	-	Syngenta



			173506) in or on Grapes and Soil in Switzerland Ciba-Geigy Ltd., Basel, Switzerland 2038/93-02, 14.08.2001 GLP, not published Syngenta File N° CGA173506/0460				
KCP 9.1	Ulbrich, R.	1998	Rate of degradation of 14C-Carbonyl labelled CGA 192155 in various soils at 20°C Novartis Crop Protection AG, Basel, Switzerland 97UL04, 19.10.1998 GLP, not published Syngenta File N° CGA192155/0005	N	N	-	Syngenta
KCP 9.1	Ulbrich, R.	1999	Rate of degradation of Oxirane-3-14C- labelled CGA 339833 in various soils at 20° Novartis Crop Protection AG, Basel, Switzerland 98UL01, 06.07.1999 GLP, not published Syngenta File N° CGA339833/0002	N	N	-	Syngenta
KCP 9.1	Van derGaauw, A.	2002	[U-Phenyl- 14C]-CGA 339833: Hydrolysis at three different pH Values RCC Ltd, Itingen, Switzerland 812621, 24.01.2002 GLP, not published Syngenta File N° CGA339833/0017	N	N	-	Syngenta
KCP 9.3.	Minet, U.	1993	Volatilization of CGA 173506 from Soil Surface under controlled Laboratory Conditions Ciba-Geigy Ltd., Basel, Switzerland 13/93, 11.10.1993 GLP, not published Syngenta File N° CGA173506/0358	N	N	-	Syngenta
KCP 9.3.	Rordorf, B.	1992	Report on vapour pressure curve Ciba -Geigy Ltd., Basel, Switzerland Report No. PP-92-11P-VPC, 23.09.1992 GLP, not published Syngenta File N° 173506 / 207	N	N	-	Syngenta
KCP 9.3.	Sandmeier, P.	1994	Volatilization of CGA 173506 from Bean Leaves under Indoor Conditions after Spray Application of 14-C labelled Material Ciba-Geigy Ltd., Basel, Switzerland 93PSA28,	N	N	-	Syngenta

			07.01.1994 GLP, not published Syngenta File N° CGA173506/0413				
KCP 9.3.	Stamm, E.	1999	Atmospheric oxidation of fludioxonil CGA 173506 by hydroxyl radicals, Rate estimation Novartis Crop Protection AG, Basel, Switzerland 98SM19, 04.01.1999 Non-GLP, not published Syngenta File N° CGA173506/1278	N	N	-	Syngenta
KCP 9.3.	Widmer, H.	2001a	Vapour pressure of CGA 339833 Syngenta Crop Protection AG, Basel, Switzerland 2000WI39, 25.04.2001 GLP, not published Syngenta File N° CGA339833/0012	N	N	-	Syngenta
KCP 9.3.	Widmer, H.	2001b	Vapour pressure of CGA 265378 Syngenta Crop Protection AG, Basel, Switzerland 2000WI38, 22.02.2001 GLP, not published Syngenta File N° CGA265378/0006	N	N	-	Syngenta
KCP 9.3.	Widmer, H.	2001c	Vapour pressure of CGA 192155 Syngenta Crop Protection AG, Basel, Switzerland 2000WI37, 08.05.2001 GLP, not published Syngenta File N° CGA192155/0011	N	N	-	Syngenta
KCP 10.1.1	██████	1990	The acute oral toxicity (LD50) of CGA173506 to the Mallard duck. Syngenta Report ██████ Unpublished GLP	Y	N	-	Syngenta
KCP 10.1.1	██████	1993b	The dietary toxicity (LC50) of CGA173506 to the bobwhite quail. Syngenta Report ██████ Unpublished GLP	Y	N	-	Syngenta
KCP 10.1.1	██████	1996a	Bobwhite quail dietary reproduction and tolerance studies. ████████████████████ Unpublished GLP	Y	N	-	Syngenta

KCP 10.1.2	██████	1991	Acute oral toxicity study of CGA-173506 Technical in rats (EPA Guidelines) Report No. ██████ Published GLP	Y	N	-	Syngenta
KCP 10.1.2	██████	1992	A two generation reproductive toxicity study in rats Report ██████ Published GLP	Y	N	-	Syngenta
KCP 10.2	██████	1997a	CGA 173506 technical – acute toxicity to rainbow trout, <i>Oncorhynchus mykiss</i> , under flow thru conditions ██████ Unpublished report no. ██████ GLP	Y	N	-	Syngenta
KCP 10.2	Grade, R.	2000a	Acute toxicity test of CGA 339833 (metabolite of CGA 173506) to the cladoceran <i>Daphnia magna</i> Straus in the static system. Syngenta unpublished report No. CGA339833/006 Unpublished report no 2003512 GLP	N	N	-	Syngenta
KCP 10.2	Grade, R	2000b	Growth inhibition of CGA 339833 (metabolite of CGA 173506) to gree algae, <i>Selenastrum capricornutum</i> ), under static conditions Syngenta unpublished report No. CGA339833/0004 GLP	N	N	-	Syngenta
KCP 10.2	██████	1994	CGA-173506, An early life-stage toxicity test with the fathead minnow ██████ Syngenta Unpublished report No. CGA173506/0416 Unpublished report No. ██████ GLP	Y	N	-	Syngenta
KCP 10.2	Hoberg, J.R.	1992	CGA-173506 technical – Toxicity to the fresh water green alga, <i>Selenastrum capricornutum</i> , Syngenta Unpublished report CGA173506/2043 GLP	N	N	-	Syngenta
KCP 10.2	██████	2000	Acute toxicity test of CGA 339833 (metabolite of CGA 173506) to rainbow trout ( <i>Oncorhynchus mykiss</i> ) under static conditions. ██████ Unpublished report ██████ GLP	Y	N	-	Syngenta
KCP 10.2	Suprenant, D.	1990a	CGA 173506 Technical – Acute toxicity to daphnids ( <i>Daphnia magna</i> ) under flow-through conditions.	N	N	-	Syngenta

			Syngenta Unpublished report CGA173506/0059 Unpublished report No. 89-05-2990				
KCP 10.3.1	Wainwright, M.	2001	Acute toxicity to Honey bee ( <i>Apis mellifera</i> ) Syngenta Unpublished report CGA173506/5376 GLP	N	N	-	Syngenta
KCP 10.4	Batscher, R.	2002	Acute toxicity of CGA 192155 (metabolite of CGA 173506) to the earthworm <i>Eisenia Fetida</i> in a 14-day test. Unpublished report No. 812068 GLP	N	N	-	Syngenta
KCP 10.4	Batscher, R.	2002a	Acute toxicity of CGA 265378 (metabolite of CGA 173506) to the earthworm <i>Eisenia Fetida</i> in a 14-day test. Unpublished report No. 812070 GLP	N	N	-	Syngenta
KCP 10.4	Friedrich, S.	2003	Fludioxonil (CGA 173506): Sublethal toxicity of the technical material to the earthworm <i>Eisenia fetida</i> . Syngenta Unpublished report CGA173506/5665. GLP	N	N	-	Syngenta
KCP 10.4	Rufli, H.	1989	Effect on Earthworm – Acute Toxicity to Earthworms. Syngenta Unpublished report CGA173506/0705 Report No. 953608 GLP	N	N	-	Syngenta
KCP 10.5	Schame, C. and Galicia, H.	1992	The effects of CGA 173506 on soil respiration and nitrification. Syngenta Unpublished report CGA173506/0193 Unpublished report no. 315843 GLP	N	N	-	Syngenta
KCP 10.5	Vokel, W.	2001	The effects of CGA 192155 (metabolite of CGA 173506) on soil respiration and nitrification. Syngenta Unpublished report CGA173506/0014 Unpublished report no. 808121 GLP	N	N	-	Syngenta
KCP 10.5	Vokel, W.	2002	The effects of CGA 265378 (metabolite of fludioxonil) on soil respiration and nitrification. Syngenta Unpublished report CGA173506/0012 Unpublished report no. 808198 GLP	N	N	-	Syngenta

The following tables are to be completed by MS

**List of data submitted by the applicant and not 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	Data protection claimed Y/N	Justification if data protection is claimed	Owner

**List of data relied on and not submitted by the applicant but necessary for evaluation**

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner