

FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: **FLUDIO 025 GF**

Product names: **FLUDIO ŻEL 025 FS/**

FUNABEN® ŻEL 025 FS

Chemical active substance:

Fludioxonil, 25 g/L

Central Zone

Zonal Rapporteur Member State: **Poland**

CORE ASSESSMENT

(authorization)

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

Submission date: **01/2023**

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

Version history

When	What
01/2023	Initial dRR
06/2023	Initial zRMS assessment
10/2023	Final Registration Report

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7 Metabolism and residue data (KCA section 6)

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.

7.1 Summary and zRMS Conclusion

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 not 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

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation with code name FLUDIO 025 GF are presented in Table 7.1-1. They have been selected from the individual GAPs in the Central Zone for winter wheat, spring wheat, winter triticale, winter rye, winter barley, spring barley. A list of all intended uses within the Central zone is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0,01 mg/kg for fludioxonil as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of fludioxonil residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, zRMS (Poland) agrees with the authorization of the intended uses.

According to available data, no specific mitigation measures should apply.

Data gaps

none

Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7		8				9			10	11
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applications (min)	kg as/hL min max	g as/100 kg seeds max	g as/ha min max		
1	Winter rye	PL	FLUDIO 025 GF	F	<i>Fusarium spp.</i> <i>Urocystis occulta</i>	FS	Fludioxonil 25 g/L	Seed treatment	BBCH 00	1	-	-	5 g as/100 kg seeds	Fludioxonil 5 – 10 g	n.a.	200 mL/100 kg seeds Sowing rate: 100 – 200 kg seeds/ha A
2	Winter wheat	PL	FLUDIO 025 GF	F	<i>Fusarium spp.</i> <i>Monographella nivalis</i> <i>Tilletia caries</i>	FS	Fludioxonil 25 g/L	Seed treatment	BBCH 00	1	-	-	5 g as/100 kg seeds	Fludioxonil: 7,5-12,5g	n.a.	200 ml/100 kg seeds Sowing rate: 150-250 kg seeds/ha A
3	Winter barley	PL	FLUDIO 025 GF	F	<i>Fusarium spp.</i> <i>Monographella nivalis</i> <i>Pyrenophora graminea</i>	FS	Fludioxonil 25 g/L	Seed treatment	BBCH 00	1	-	-	5 g as/100 kg seeds	Fludioxonil: 6-10g	n.a.	200 ml/100 kg seeds Sowing rate: 120-200 kg seeds/ha A
4	Winter triticale	PL	FLUDIO 025 GF	F	<i>Fusarium spp.</i>	FS	Fludioxonil 25 g/L	Seed treatment	BBCH 00	1	-	-	5 g as/100 kg seeds	Fludioxonil 5 – 10 g	n.a.	200 ml/100 kg seeds

																Sowing rate (triticale): 100-200 kg seeds/ha A
6	Spring wheat	PL	FLUDIO 025 GF	F	<i>Fusarium spp.</i> <i>Tilletia caries</i>	FS	Fludioxonil 25 g/L	Seed treatment	BBCH 00	1	-	-	5 g as/100 kg seeds	Fludioxonil: 7,5-12,5g	n.a.	200 ml/100 kg seeds Sowing rate: 150-250 kg seeds/ha A
7	Spring barley	PL	FLUDIO 025 GF	F	<i>Fusarium spp.</i>	FS	Fludioxonil 25 g/L	Seed treatment	BBCH 00	1	-	-	5 g as/100 kg seeds	Fludioxonil: 6-10g	n.a.	200 ml/100 kg seeds Sowing rate: 120-200 kg seeds/ha A

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** Use also code numbers according to Annex I of Regulation (EU) No 396/2005

*** 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

Explanation for Column 11 “Conclusion”

A	Exposure acceptable without risk mitigation measures, safe use
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

7.1.2 Summary of the evaluation

The preparation with code name FLUDIO 025 GF is composed of fludioxonil.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of fludioxonil

Reference value	Source	Year	Value	Study relied upon	Safety factor
Fludioxonil					
ADI	EFSA	2007	0.37 mg/kg bw/day	2-year rat	100
ARfD	EFSA	2007	-	Not necessary	-

7.1.2.1 Summary for fludioxonil

Table 7.1-3: Summary for fludioxonil

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Winter rye	Yes	Yes	Yes	Yes	Yes	No	No
2	Winter wheat	Yes	Yes (6 trials)	Yes	Yes	Yes		No
3	Winter barley	Yes	Yes	Yes	Yes	Yes		No
4	Winter triticale	Yes	Yes	Yes	Yes	Yes		No
5	Spring wheat	Yes	Yes	Yes	Yes	Yes		No
6	Spring barley	Yes	Yes	Yes	Yes	Yes		No

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

As residues of fludioxonil do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

7.1.2.2 Summary for FLUDIO 025 GF

Table 7.1-4: Information on FLUDIO 025 GF (KCA 6.8)

Crop	PHI for FLUDIO 025 GF proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for FLUDIO 025 GF proposed by zRMS	zRMS Comments (if different PHI proposed)
		Fludioxonil		
Winter rye	NR	Yes	NR	
Winter wheat	NR	Yes	NR	
Winter barley	NR	Yes	NR	
Winter triticale	NR	Yes	NR	
Spring wheat	NR	Yes	NR	
Spring barley	NR	Yes	NR	

NR: not relevant

* Purpose of withholding period to be specified

** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Waiting periods before planting succeeding crops

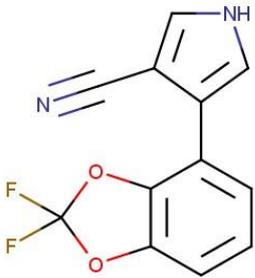
Not relevant.

Assessment

7.2 Fludioxonil

General data on fludioxonil are summarized in the table below (last updated 01/2023)

Table 7.2-1: General information on fludioxonil

Active substance (ISO Common Name)	Fludioxonil
IUPAC	4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile
Chemical structure	
Molecular formula	C ₁₂ H ₆ F ₂ N ₂ O ₂
Molar mass	248.2 g/mol
Chemical group	Phenylpyrrole fungicide
Mode of action (if available)	Non-systemic with long residual activity. Inhibits transport-associated phosphorylation of glucose, reducing mycelial growth. Osmotic signal transduction.
Systemic	No
Company (ies)	Syngenta Crop Protection
Rapporteur Member State (RMS)	Denmark
Approval status	Approved Date of (01/11/2008) and reference to decision (COMMISSION DIRECTIVE 07/XX/EC - REGULATION (EU) No 540/2011)
Restriction	Only uses as fungicide may be authorised.
Review Report	SANCO/2818/07– rev. 2 10/09/2007
Current MRL regulation	Reg. (EU) 2022/1264
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Yes (EFSA, 2007 – see reference list)
EFSA Journal: conclusion on article 12	Yes (EFSA, 2011 and EFSA, 2019 – see reference list)
Current MRL applications on intended uses	Reg. (EU) 2022/1264 none

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.2-2: Summary of stability data achieved at $\leq -18^{\circ}\text{C}$ (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Wheat (grain)	High starch content	24 months	DAR, 2005
Corn (grain)	High starch content	24 -27 months	DAR, 2005
Potato	High starch content	24 -27 months	DAR, 2005
Wheat (straw)	High water content	24 months	DAR, 2005
Tomato	High water content	24 months	DAR, 2005
Apple	High water content	24 months	DAR, 2005
Rapeseed	High oil content	24 months	DAR, 2005
Grape	High acid content	28.5 months	DAR, 2005
Animal Products			
Ruminant	Muscle	12 months	DAR, 2005
Ruminant	Liver	12 months	DAR, 2005
Milk cattle	Milk	12 months	DAR, 2005
Poultry	Eggs	12 months	DAR, 2005

Conclusion on stability of residues during storage

The storage stability of fludioxonil has been determined in crops covering water-, oil and starch-containing materials, in the accordance with EU guidelines. The stability in raw products under freezer storage conditions (-16 or below) was at least 24 month for plants samples and 12 months for animal products.

Storage stability of metabolites determined as 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid (CGA 192155) was not demonstrated but considering that the residue definition is based on a common moiety obtained after oxidation of the extracts, it is unlikely that the residue will hydrolyse even further (DAR, 2005).

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

Not applicable.

Conclusion on stability of residues in sample extracts

Not applicable. The samples were analyzed on the same day as the extracts were prepared.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

References:

Draft Assessment Report (DAR). Initial risk assessment provided by the rapporteur Member State Denmark for the existing active substance fludioxonil, 2005, Denmark. Annex B.7 Residues.

Review of the existing maximum residue levels (MRLs) for fludioxonil according to Article 12 of Regulation (EC) No 396/2005, EFSA Journal, 2011. 9(8): 2335.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	Grape	[Pyrrole-4- ¹⁴ C]-fludioxonil	Foliar treatment, F	0.500 kg a.s./ha	3	0.5 h, 26 days after 1 st application; 0.5 h, 14 days, 35 days after 3 rd application	-	DAR, 2005 EFSA, 2011
	Peach	[Phenyl-U- ¹⁴ C]-fludioxonil	Foliar treatment, F	0.84 or 8.40 kg a.s./ha (total) 8.40 kg a.s./ha (total)	3 2	28 DAT 30, 114 DAT	-	DAR, 2005 EFSA, 2011
Leafy vegetables	Lettuce	[Pyrrole-4- ¹⁴ C]-fludioxonil	Foliar treatment, F	0.200 kg a.s./ha/application	3	1 h, 6 and 13 days after the last application	-	DAR, 2005 EFSA, 2011
Root and tuber vegetables	Potato	[Pyrrole-4- ¹⁴ C]-fludioxonil	Seed treatment, F	2.5 g a.s./100 kg seed	1	71 DAT and at harvest	-	DAR, 2005 EFSA, 2011
	Onion	[Phenyl-U- ¹⁴ C]-fludioxonil	Foliar treatment, F	0.124 kg a.s./ha (1X treatment) and 6.169 kg a.i./ha (5X treat-	2	28 DAT	-	DAR, 2005 EFSA, 2011

				ment)				
Pulses and oilseeds	Cotton	[Pyrrole-4- ¹⁴ C]-fludioxonil	Foliar treatment, G	2.50 g a.s./100 kg seed 5.0 g a.s./100 kg seed	1	186 DAT		DAR, 2005 EFSA, 2011
	Soybean	[Pyrrole-4- ¹⁴ C]-fludioxonil	Foliar treatment, G	5.0 g a.s./100 kg seed	1	28, 38, 133 DAT		DAR, 2005 EFSA, 2011
Cereals	Wheat	[Pyrrole-4- ¹⁴ C]-fludioxonil	Seed treatment, F	6.4 g a.s./100 kg seeds and 7.3 g a.i./100 kg seed	1	48, 83, 106 DAT.	-	DAR, 2005 EFSA, 2011
	Rice	[Pyrrole-4- ¹⁴ C]-fludioxonil	Seed treatment, F	6.5 g a.s./100 kg seed	1	38, 76, 152 DAT	-	DAR, 2005 EFSA, 2011

Summary of plant metabolism studies reported in the EU

The metabolism of fludioxonil has been investigated after foliar application in grapes, lettuce, tomatoes and green onions as well as after seed treatment in potatoes, wheat, rice, cotton and soybean.

After foliar treatment, at plant maturity, parent fludioxonil represents by far the major constituent of the residue even for PHIs up to 35 days. The metabolic pattern includes a large number of metabolites. The metabolic pattern is similar in all crops and proceeds mainly through oxidation with subsequent conjugation of metabolites with sugars. Additionally, cleavage of the pyrrole ring results in the formation of 2,2-difluoro-benzo[1,3]dioxole metabolites.

After seed treatment uptake and translocation of fludioxonil from the treated seed is low. In wheat grain, TRR are 0.003 mg/kg after seed application of radiolabelled fludioxonil at a rate exceeding by 50 % the proposed representative use rate. In straw, TRR are below 0.02 mg/kg. Therefore, no significant residue in cereal food and feed items resulting from seed treatment is expected.

The proposed residue definition for monitoring is parent fludioxonil. Metabolism in fruit crops and leafy vegetables after foliar application does not result in metabolite formation adding a significant contribution to the toxicological burden. As this may be different in other commodities such as green onions, the expert meeting agreed that the residue definition for risk assessment should include the parent compound and all metabolites containing the 2,2-difluoro-benzo[1,3]dioxole-4-carboxylic moiety, to cover potential uses of fludioxonil in other commodities not addressed during the peer-review. A specific residue definition for the use of fludioxonil as seed treatment is not considered necessary given the extremely low residue level generated by this mode of application and considering the low toxicity of the parent compound. For the considered representative uses, the conversion factor between residue definitions for monitoring and risk assessment is 1 (EFSA, 2007; DAR, 2005).

Conclusion on metabolism in primary crops

Uptake and translocation of fludioxonil from the treated seed were very low. This was expected for a non-systemic chemical.

Plant residue definition for monitoring: Fludioxonil.

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

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

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Considering fludioxonil application in wheat, succeeding or rotational crop studies are not required as well, as field residue trials have shown that in all wheat plant parts at maturity (whole plants, straw and grains) no fludioxonil residue exceeded the LOQ.

Table 7.2-4: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Lettuce	[pyrrole- ¹⁴ C]	Soil spraying, F	0.750	90	50 % and 100 % maturity		EFSA, 2011
Root and tuber vegetables	Sugar beets	[pyrrole- ¹⁴ C]	Soil spraying, F	0.750	140, 320, 345	25%, 50% and 100 % maturity		EFSA, 2011
	Turnips	[pyrrole- ¹⁴ C]	Soil spraying, F	0.124	33, 90	100 % maturity		EFSA, 2011
	Radishes	[pyrrole- ¹⁴ C]	Soil spraying, F	0.062	32, 90	100 % maturity		EFSA, 2011
		[phenyl - ¹⁴ C]	Soil spraying, F	1.117	30, 90, 210	100 % maturity		EFSA, 2011
Pulses and oilseeds	Mustard	[pyrrole- ¹⁴ C]	Soil spraying, F	0.124	33, 90	100 % maturity		EFSA, 2011
		[pyrrole- ¹⁴ C]	Soil spraying, F	0.062	32, 90	100 % maturity		EFSA, 2011
		[phenyl - ¹⁴ C]	Soil spraying, F	1.117	30, 90, 210	100 % maturity		EFSA, 2011
Cereals	Winter wheat	[pyrrole- ¹⁴ C]	Soil spraying, F	0.750	140, 320, 345	25% and 100 % maturity		EFSA, 2011
	Spring wheat	[pyrrole- ¹⁴ C]	Soil spraying, F	0.124	33, 90	25%, 50% and 100 % maturity		EFSA, 2011
		[pyrrole- ¹⁴ C]	Soil spraying, F	0.062	32, 90	25%, 50% and 100 % maturity		EFSA, 2011
		[phenyl]	Soil	1.117	30, 90, 210	25%,		EFSA,

		- ¹⁴ C]	spraying, F			50% and 100 % maturity		2011
	Corn	[pyrrole- ¹⁴ C]	Soil spraying, F	0.750	140, 320, 345	25%, 50% and 100 % maturity		EFSA, 2011

* Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Summary of plant metabolism studies reported in the EU

Four metabolism studies in rotational crop studies were submitted on lettuce, winter and spring wheat, sugar beets, corn, mustard, turnips, radishes (DAR, 2005). The available studies are summarized in Table 7.2-4. Significant TRR levels were only identified in radish samples (30 DAT, 1.117 kg a.s./ha) and in wheat samples (30 DAT, 0.124 and 1.117 kg a.s./ha); in all other crops TRR levels never exceeded 0.01 mg/kg. The highest TRR levels were observed in wheat straw (0.355 mg/kg) and radish tuber (0.135 mg/kg). Parent fludioxonil accounted for 0.016 mg/kg in radish tubers and CGA 192155 accounted for 0.015 mg/kg in wheat straw. Other metabolites were tentatively identified as CGA 26537814, CGA 30810315, CGA 34035116, CGA 22773117 and CGA 26076618, none of which accounted for more than 0.05 mg/kg each. EFSA concluded in the framework of the peer review that the metabolic pathway of fludioxonil in rotational crops is similar to that in primary crops and no formation of new metabolites was observed (EFSA, 2007).

Conclusion on metabolism in rotational crops

The same residue definition of as for primary crops applies to the rotational crops.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Conclusion on nature of residues in processed commodities

According to EU OECD guidelines, processing studies on wheat (grains and other plant products) are not required, as fludioxonil residues in grains, straw and whole plants are <0.1 mg/kg (DAR, 2005).

7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.2-5: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	<u>Seed treatment:</u> Cereals (wheat) <u>Foliar treatment:</u> Fruits (grapes and peach); Fruiting vegetables (tomatoes); Bulb vegetables (onion); Leafy vegetables (lettuce)
Rotational crops covered	Leafy vegetables: lettuce and mustard. Cereals: wheat and corn. Root/tuber: turnips, sugar beet and radish.

Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Not applicable. Residues in grains, straw and whole plants of cereals are <0.1 mg/kg
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Fludioxonil Reg. (EU) 2022/1264
Plant residue definition for risk assessment	Sum of fludioxonil and its metabolites, which can be oxidised to metabolite CGA 192155 (2,2-difluoro-benzo[1,3]dioxole-4-carboxylic acid) (EFSA, 2007)
Conversion factor from enforcement to RA	1 for cereals after seed treatment, fruits and leafy vegetables (EFSA, 2007)

7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

No new data submitted in the framework of this application.

According to the EU OECD guideline, metabolism studies in domestic animals are not required because the residues in wheat samples (grain, straw and silage) are below the LOQ.

However, two metabolism studies were presented at European level (DAR, 2005).

Table 7.2-6: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	[pyrrole-4- ¹⁴ C]-fludioxonil	2	3.5 mg fludioxonil/kg bw/day	4	Milk	daily	DAR, 2005 EFSA, 2007
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	[pyrrole-4- ¹⁴ C]-fludioxonil	5	6.3 mg fludioxonil/kg bw/day	8	Eggs	daily	DAR, 2005 EFSA, 2007
						Excreta	daily	
						Tissues	at sacrifice	

Summary of plant metabolism studies reported in the EU

Metabolism studies in livestock are not required because residues in wheat grain and straw were below the LOQ. However, metabolism studies were conducted in lactating goats and laying hens and were presented at EU level.

Identification of metabolites indicated that the major metabolic pathways were similar in both species, and based on the hydroxylation of the pyrrole and benzodioxol rings followed by conjugation reactions. In hens, further reactions involve the opening of the pyrrole ring. In the goat study, parent flu-

dioxonil was identified as the major component of the TRR in liver and fat. In kidneys the major components were identified as the glucuronide conjugates of the mono-hydroxylated fludioxonil. In the hen study, the sulphate conjugate of the N-hydroxylated fludioxonil was the major component of the residue in egg yolks and thigh muscle. In egg whites and liver, the major metabolites resulted from the opening of the oxidised pyrrole ring. Parent compound was major in breast muscle (EFSA Scientific Report, 2007).

Conclusion on metabolism in livestock

A residue definition is proposed for monitoring and risk assessment consisting in the sum of fludioxonil and all metabolites containing the 2,2-difluoro-benzo[1,3]dioxole-4-carboxylic moiety, expressed as fludioxonil. The setting of MRLs in animal products is not necessary (EFSA Scientific Report, 2007).

7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Table 7.2-7: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	Milk: 14 days
	Eggs: 5 days
Animal residue definition for monitoring	Fludioxonil - code 1000000 except 1040000 (Honey and other apiculture products) : sum of fludioxonil and its metabolites oxidized to metabolite 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid, expressed as fludioxonil (Reg. (EU) 2022/1264)
Animal residue definition for risk assessment	sum of fludioxonil and its metabolites oxidized to metabolite 2,2difluoro-benzo[1,3]dioxole-4 carboxylic acid (CGA 192155), expressed as fludioxonil (EFSA, 2011)
Conversion factor	None
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Not assessed

7.2.3 Magnitude of residues in plants (KCA 6.3)

7.2.3.1 Summary of European data and new data supporting the intended uses

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies are summarized in the Table below. The detailed assessment of these studies is presented in Appendix 2.

Table 7.2-8: Summary of EU reported and new data supporting the intended uses of FLUDIO 025 GF and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance		
Wheat straw → extrapolated to Rye straw Barley straw Triticale straw	New trials (Study No PB-2022-28)	N-EU	Trials GAP: seed treatment, 1 x 5g as/100 kg seeds, PHI: not relevant, outdoor E: 2 x <0.0001 mg/kg RA: 2 x <0.0001 mg/kg E and RA: 2 x < 0.01 mg/kg (LOQ)	N/A						
	New trials (Study No C-02-22)	N-EU	Trials GAP: seed treatment, 1 x 5g as/100 kg seeds, PHI: not relevant, outdoor E: 4 x < 0.0025 mg/kg RA: 4 x < 0.0025 mg/kg E and RA: 4 x < 0.01 mg/kg (LOQ)							
	Overall supporting data for cGAP	N-EU	E : 2 x <0.0001, 4 x <0.0025 RA: 2 x <0.0001, 4 x <0.0025 E and RA: 6 x < 0.01 mg/kg (LOQ)	E: 0.003 RA: 0.003 0.01	E: 0.003 RA: 0.003 0.01	0.01	0.01	Yes		
Wheat grain →	New trials (Study No	N-EU	Trials GAP: seed treatment, 1 x 5g as/100 kg seeds, PHI: not relevant, outdoor	N/A						

extrapolated to Rye grain Barley grain Triticale grain	PB-2022-28)		E: 2 x <0.0001 mg/kg RA: 2 x <0.0001 mg/kg E and RA: 2 x < 0.01 mg/kg (LOQ)					
	New trials (Study No C-02-22)	N-EU	Trials GAP: seed treatment, 1 x 5g as/100 kg seeds, PHI: not relevant, outdoor E: 4 x < 0.0025 mg/kg RA: 4 x < 0.0025 mg/kg E and RA: 4 x < 0.01 mg/kg (LOQ)					
	Overall supporting data for cGAP	N-EU	E : 2 x <0.0001, 4 x <0.0025 RA: 2 x <0.0001, 4 x <0.0025 E and RA: 6 x < 0.01 mg/kg (LOQ)	E: 0.003 RA: 0.003 0.01	E: 0.003 RA: 0.003 0.01	0.01	0.01	Yes

* Source of EU MRL: Reg. (EU) 2022/1264

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on wheat are considered acceptable, for outdoor uses.

According to appendix D of EU guidelines, extrapolation to rye, barley, triticale is possible with 4 trials (seed treatment) on wheat, which is the case here.

The data submitted show that no exceedance of the MRL will occur.

The uses are considered acceptable.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Table 7.2-9: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
2,2difluoro-benzo[1,3]dioxole-4 carboxylic acid (CGA 192155), expressed as fludioxonil				
Wheat, rye grain	0.01	Median residue (EFSA, 2011)	0.01	Highest residue (EFSA, 2011)
Barley, oat grain	0.01	Median residue (EFSA, 2011)	0.01	Highest residue (EFSA, 2011)
Wheat, rye bran	0.01	Median residue (EFSA, 2011)	0.01	Highest residue (EFSA, 2011)
Wheat, rye straw	0.04	Median residue (EFSA, 2011)	0.05	Highest residue (EFSA, 2011)
Barley, oat straw	0.04	Median residue (EFSA, 2011)	0.05	Highest residue (EFSA, 2011)

Table 7.2-10: Results of the dietary burden calculation (Animal model 2017)

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
2,2difluoro-benzo[1,3]dioxole-4 carboxylic acid (CGA 192155), expressed as fludioxonil					
Dairy cattle (all diets)	0,002	0,002	Wheat, milled byppts	0,04	No
Dairy cattle (dairy only)	0,002	0,002	Wheat, milled byppts	0,04	No
Lamb	0,003	0,003	Wheat, milled byppts	0,06	No
Ram/Ewe	0,002	0,002	Wheat, milled byppts	0,06	No
Swine (finishing)	0,001	0,001	Wheat, milled byppts	0,05	No

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Poultry layer (all diets)	0,002	0,002	Wheat, milled bypds	0,03	No
Poultry layer (layer only)	0,002	0,002	Wheat, milled bypds	0,03	No

* These categories correspond to those (formerly) assessed at EU level.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

The calculated dietary burdens for all groups of livestock were not found to exceed the trigger value of 0.1 mg/kg DM. Further investigation on residues is not required.

7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

7.2.5.1 Conclusion on processing studies

According to EU OECD guidelines, processing studies on wheat (grains and other plant products) are not required, as fludioxonil residues in grains, straw and whole plants are <0.1 mg/kg (DAR, 2005).

7.2.6 Magnitude of residues in representative succeeding crops

Conclusion on rotational crops studies

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues (see 7.2.2.2), no study dealing with magnitude of residues in succeeding crops is needed.

Studies investigating the potential for residues being present in rotational crops are not necessary considering that residues in any part of seed treated wheat plant are below the LOQ. The data indicate that the uptake from the soil of fludioxonil and related compounds is minimal and that the metabolic pathway is similar to that observed in primary crops. Plant-back restrictions and MRL for rotational crops do not need to be established (EFSA Scientific Report, 2007).

7.2.7 Other / special studies (KCA6.10, 6.10.1)

Effect on the residue level in pollen and bee products

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 SANTE/11956/2016 rev. 9.

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of FLUDIO 025 GF. Therefore, other special studies are not needed.

7.2.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

As ARfD was not deemed necessary, acute risk assessment is not relevant.

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-11: Input values for the consumer risk assessment

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
sum of fludioxonil and its metabolites oxidised to metabolite 2,2-difluoro-benzo[1,3] dioxole-4 carboxylic acid (CGA 192155), expressed as fludioxonil		
Rye grain	0.003 0.01	Median residue (Own studies, reports: PB-2022-28 and C-02-22) - LOQ
Wheat grain	0.003 0.01	Median residue (Own studies, reports: PB-2022-28 and C-02-22) - LOQ
Barley grain	0.003 0.01	Median residue (Own studies, reports: PB-2022-28 and C-02-22) - LOQ
Other plant and animal commodities	MRL Reg. (EU) 2022/1264	

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-12: Consumer risk assessment

TMDI calculation below (EFSA PRIMo revision 3.1).

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

TMDI (% ADI) according to EFSA PRIMo rev.3.1	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

~~Consumer risk assessment based on refined calculation mode (crops under GAP):~~

TMDI (% ADI) according to EFSA PRIMo	0.0 % (DK child) — 0.0% Rye
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

~~* include raw and processed commodities if both values are required for PRIMo~~

~~** if national model is available~~

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

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.4 References

Denmark, 2005. Draft Assessment Report. Rapporteur Member State: Denmark. Annex B.7 Residues, January 2005, revised July 2005.

EFSA (European Food Safety Authority), 2007. Conclusion regarding the peer review of the pesticide risk assessment of the active substance fludioxonil. EFSA Scientific Report 2007, 110: 1–85.

EFSA (European Food Safety Authority), 2011. Review of the existing maximum residue levels (MRLs) for fludioxonil according to Article 12 of Regulation (EC) No 396/200. EFSA Journal 2011, 9(8): 2335.

Denmark, 2005. Draft Assessment Report. Rapporteur Member State: Denmark. Annex B.7 Residues, January 2005, revised July 2005.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 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	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	Synthos Agro Sp. z o.o.
KCP 7.2.3	Zaręba-Kozioł M.	2022	Quantitative analysis of fludioxonil and its metabolite CGA192155 residues in winter wheat after one application of product Fludio 025 GF. Fertico Sp. z o.o., Report No PB-2022-28 GLP Unpublished	N	Synthos Agro 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	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	N	Synthos Agro

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			fludioxonil in grains and straw of winter wheat. Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Report No C-02-22		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	Owner
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	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	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 Novartis Crop Protection Inc., █ GLP Syngenta File No CGA173506/5001	N	Syngenta
KCP 7.2.1 (KCA 6.1)	Mair P.	1996	Stability of residues of CGA 173506 in grapes stored under deep freezer conditions Novartis Crop Protection AG, Basel, Switzerland	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			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	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	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	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	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	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	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Syngenta File No CGA173506/1128		
KCP 7.2.2 (KCA 6.2.1)	Fleischmann T.J	1991	Distribution of ¹⁴ C-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	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	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Gentile B.	1993	Metabolism of [4- ¹⁴ C-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	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Kennedy E.	1999	(Phenyl)-U- ¹⁴ C)-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	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	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 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 [¹⁴ C-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	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Nicollier G.	1991	Penetration, distribution and degradation of ¹⁴ C-pyrrole-CGA 173506 in field grape-vine Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 3/91 GLP Syngenta File No CGA173506/0151	N	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Nicollier G.	1993	Metabolism of ¹⁴ C-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	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Peffer R.C.	1999	[Phenyl-U- ¹⁴ C]-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	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Stingelin J.	2000	Uptake, distribution and metabolism of [pyrrole-4- ¹⁴ C] 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	Syngenta
KCP 7.2.2 (KCA 6.2.2-6.2.5)	█	1992a	Metabolism of [¹⁴ C-pyrrole] CGA 173506 in Goats F-00088, Amendment No. 1 GLP Syngenta File No CGA173506/0236	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 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	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	Syngenta
KCP 7.2.2 (KCA 6.2.2-6.2.5)	█	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 Syngenta File No CGA173506/0651	N	Syngenta
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	Syngenta
KCP 7.2.2 (KCA 6.6.1)	Gentile B.	1992	Outdoor confined accumulation study on rotational crops after bareground applicaion of 1-14C-Pyrroe) CGA 173506 Ciba-Geigy Ltd., Basel, Switzerland 89BG03PR1 GLP Syngenta File No CGA173506/0196	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	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 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	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	Syngenta

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	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	Owner

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Fludioxonil

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

Not required.

A 2.1.2 Nature of residues in plants, livestock and processed commodities

Not required.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Winter wheat

Table A 1: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, 2005)	1 (seed treatment)	5 g a.s./100 kg seed	Not applicable	BBCH 00	Not relevant
cGAP EU (Art. 12, EFSA, 2011)	1 (seed treatment)	5 g a.s./100 kg seed	Not applicable	BBCH 00	Not relevant
Intended cGAP (21FRT-53TRZAWFLDO; 21FRT-52TRZAWFLDO)	1 (seed treatment)	5 g a.s./100 kg seed	Not applicable	BBCH 00	Not relevant

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

A 2.1.3.1.1 Study 1

Comments of zRMS:	Study is accepted
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Reference: K.C.P. 7.3.2

Report **Field phase:** Tartanus M., 2022. Study number: 21FRT-53TRZAWFLDO. 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).
Analytical phase: Zaręba-Kozioł M., 2022. Study number: PW-2022-02. Validation study report. Analytical phase. Validation of a method for determination of fludioxonil and its metabolite CGA192155 residues by Liquid Chromatography (LC-MS/MS).
 Zaręba-Kozioł., 2022. Study number PB-2022-2. Final study report. Analytical phase. Quantitative analysis of fludioxonil and its metabolite CGA192155 residues in winter wheat after one application of product Fludio 025 GF.

Guideline(s): Test No. 509: Crop Field trial, OECD Guidelines for the Testing of Chemicals;
 Guidance document on pesticide analytical methods for risk assessment and post approval control and monitoring purposes (SANTE/2020/12830 rev.1)

Deviations: No

GLP: Yes

Acceptability: Yes

Two residue trials (harvest studies) of winter wheat, were carried out in Poland in 2021 - 2022. Trials consisted of one untreated (C) and treated (T) plot. Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial sites. Product Fludio 025 GF was applied 1-times (seed treatment) at a rate of 5 g of fludioxonil per 100 kg of seeds. Seed treatment were performed at BBCH 00. Samples of wheat grains and straw for analysis were collected at a normal commercial harvest at the beginning of August 2022 (01.08 – 02.08.2022). Samples were taken from untreated plot firstly than from treated plots. After harvesting samples were frozen and stored at the temperature $\leq -18^{\circ}\text{C}$ for approx. 3.5 months.

Analytical analysis of the samples was carried out on November 18, 2022.

The concentration of fludioxonil and its metabolite CGA192155 in winter wheat samples was chemically determined with a liquid chromatographic method coupled with mass spectrometry (LC-MS/MS). The method for each compound was validated in according to EC Guidance Documents SAN-TE/2020/12830, Rev.1.

Fludioxonil were verified for two ion transitions 247.0 > 180.0 (quantifier ion) and 247.0 > 126.0 (qualifier ion). The range of linearity of the analytical graph of fludioxonil varied from 0.0001 to 0.1 $\mu\text{g/ml}$ (0.0001 – 0.1 mg/kg). The linear coefficient r^2 was higher than 0.99. The recovery of the method was estimated for two fortification levels LOQ and 10x LOQ, e.i. 0.01 and 0.10 mg/kg. The mean extraction recovery levels and RSD in winter wheat grain and straw samples are presented in a table below:

Fludioxonil (247.0 >180.0) – quantifier ion			
Matrix	Fortification level [mg/kg]	Mean Recovery [%]	RSD [%]
Winter wheat (grain)	0.01	94.9368	4.3076
	0.1	101.1576	5.9489
Winter wheat (straw)	0.01	105.2916	2.8987
	0.1	106.5665	2.6590
Fludioxonil (247.0 >126.0) – qualifier ion			
Matrix	Fortification level [mg/kg]	Mean Recovery [%]	RSD [%]
Winter wheat (grain)	0.01	96.7939	4.9023
	0.1	102.0574	4.6236
Winter wheat (straw)	0.01	107.5979	4.3899
	0.1	106.9721	1.6055

Matrix effect was checked during the validation method. Assessment of matrix effects was performed by comparing the standard preparing in solution to standard preparing in blank matrix at concentration 0.01 mg/kg. The matrix effect was -1.34% (for transition 247.0 >180.0) and -2.91% (for transition 247.0 >126.0) for winter wheat grains and -20.33 % (for transition 247.0 >180.0) and -20.41% (for transition 247.0 >126.0) for winter wheat straw. The limit of quantification (LOQ) for fludioxonil was 0.01 mg/kg and the limit of detection was 0.0001 mg/kg.

CGA192155 were verified for two ion transitions 201.0 > 91.1 (quantifier ion) and 201.0 > 65.1 (qualifier ion). The range of linearity of the analytical graph of CGA192155 varied from 0.0001 to 0.1 $\mu\text{g/ml}$ (0.0001 – 0.1 mg/kg). The linear coefficient r^2 was higher than 0.99. The recovery of the method was estimated for two fortification levels LOQ and 10x LOQ, e.i. 0.01 and 0.10 mg/kg. The mean extraction recovery levels and RSD in winter wheat grain and straw samples are presented in a table below:

CGA192155 (201.0 > 91.1) – quantifier ion			
Matrix	Fortification level	Mean Recovery [%]	RSD [%]

	[mg/kg]		
Winter wheat (grain)	0.01	72.8282	3.3425
	0.1	82.0795	4.9346
Winter wheat (straw)	0.01	84.4140	7.2323
	0.1	92.3558	9.1039
CGA192155 (201.0 > 65.1) – qualifier ion			
Matrix	Fortification level [mg/kg]	Mean Recovery [%]	RSD [%]
Winter wheat (grain)	0.01	79.3576	5.6223
	0.1	82.0795	4.9346
Winter wheat (straw)	0.01	82.7643	8.5066
	0.1	89.8951	3.3920

Matrix effect was checked during the validation method. Assessment of matrix effects was performed by comparing the standard preparing in solution to standard preparing in blank matrix at concentration 0.01 mg/kg. The matrix effect was -10.34% (for transition 201.0 > 91.1) and 12.97% (for transition 201.0 > 65.1) for winter wheat grains and -10.49 % (for transition 201.0 > 91.1) and -12.77% (for transition 201.0 > 65.1) for winter wheat straw. The limit of quantification (LOQ) for fludioxonil was 0.01 mg/kg and the limit of detection was 0.0001 mg/kg.

Table A 2: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			g a.s./100 kg seed	Water (l/ha)	g a.s./hl				Fludioxonil	CGA192155		
21FRT- 53TRZAWFLDO- 01/Nowa Dzierż- nia/Poland/2021-2022	Winter wheat/Astoria	1. 15.10.2021 2. 24.05.2022- 04.06.2022 3. 01.08.2022	5 g a.s./100 kg seed	–	–	1 (seed treatment)	BBCH 00	Grains Straw	<LOD <LOD	<LOD <LOD	n.a.	
21FRT- 53TRZAWFLDO- 02/Błonie/Poland/2021- 2022	Winter wheat/ Hondia	1. 19.10.2021 2. 28.05.2022- 09.06.2022 3. 05.08.2022	5 g a.s./100 kg seed	–	–	1 (seed treatment)	BBCH 00	Grains Straw	<LOD <LOD	<LOD <LOD	n.a.	

LOD = 0.0001 mg/kg, LOQ = 0.01 mg/kg

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.3.1.2 Study 2

Comments of zRMS:	Study is accepted
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Reference:	K.C.P. 7.3.2
Report	<p>Field phase: Tartanus M., 2022. Study number: 21FRT-52TRZAWFLD. 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).</p> <p>Analytical phase: Diflud 050 FS. Study code C-02-22. Determination of the residues of difenoconazole, triazole derivative metabolites and fludioxonil in grains and straw of winter wheat.</p>
Guideline(s):	Test No. 509: Crop Field trial, OECD Guidelines for the Testing of Chemicals; Guidance document on pesticide analytical methods for risk assessment and post approval control and monitoring purposes (SANTE/2020/12830 rev.1)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Four residue trials (harvest studies) of winter wheat, were carried out in Poland in 2021 - 2022. Trials consisted of one untreated (C) and treated (T) plot. Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial sites. Product Diflud 050 FS was applied 1-times (seed treatment) at a rate of 5 g of fludioxonil per 100 kg of seeds. Seed treatment were performed at BBCH 00. Samples of wheat grains and straw for analysis were collected at a normal commercial harvest at the beginning of August 2022 (26.07.– 08.08.2022). Samples were taken from untreated plot firstly than from treated plots. After harvesting samples were frozen and stored at the temperature $\leq -18^{\circ}\text{C}$ for approx. 3 months.

Analytical analysis of the samples was carried out on November 9, 2022.

The concentration of fludioxonil and its metabolite CGA192155 in grains and straw of winter was chemically determined with a liquid chromatographic method with a liquid chromatographic method with mass spectrometer detection. The method for each compound was validated in according to EC Guidance Documents SANTE/2020/12830, Rev.1.

Fludioxonil were verified for two ion transitions 247.10 > 180.0 (quantitation transition) and 247.10 > 125.95 (confirmatory transition). The range of linearity of the analytical graph of fludioxonil varied from 0.5 to 50.0 $\mu\text{g/ml}$ (0.0025 – 0.25 mg/kg). The linear coefficient r^2 was higher than 0.99. The recovery of the method was estimated for two fortification levels LOQ and 10x LOQ, e.i. 0.01 and 0.10 mg/kg. The mean extraction recovery levels and RSD in winter wheat grain and straw samples are presented in a table below:

Fludioxonil (247.10 >180.0) – quantitation transition			
Matrix	Fortification level [mg/kg]	Mean Recovery [%]	RSD [%]
Winter wheat (grain)	0.01	104.5	5.5
	0.1	99.3	1.5
Winter wheat (straw)	0.01	98.3	5.5
	0.1	94.6	1.4
Fludioxonil (247.10 >125.95) – confirmatory transition			
Matrix	Fortification level [mg/kg]	Mean Recovery [%]	RSD [%]
Winter wheat (grain)	0.01	104.5	3.7
	0.1	101.1	2.2
Winter wheat (straw)	0.01	96.2	7.1
	0.1	96.8	2.6

Matrix effect was checked during the validation method. Assessment of matrix effects was performed by comparing the standard preparing in solution to standard preparing in blank matrix at concentration 2.0 ng/ml. The matrix effect was -1.4% (for transition 247.10 >180.0) and -1.5% (for transition 247.10 >125.95) for winter wheat grains and -4.0 % (for transition 247.10 >180.0) and 2.3% (for transition 247.10 >125.95) for winter wheat straw. The limit of quantification (LOQ) for fludioxonil was 0.01 mg/kg and the limit of detection was 0.0025 mg/kg.

CGA192155 were verified for two ion transitions 200.90 > 91.1 (quantitation transition) and 200.90 > 156.95 (confirmatory transition). The range of linearity of the analytical graph of CGA192155 varied from 0.5 to 50.0 ng/ml (0.0025 – 0.25 mg/kg). The linear coefficient r^2 was higher than 0.99. The recovery of the method was estimated for two fortification levels LOQ and 10x LOQ, e.i. 0.01 and 0.10 mg/kg. The mean extraction recovery levels and RSD in winter wheat grain and straw samples are presented in a table below:

CGA192155 (200.90 > 91.1) – quantitation transition			
Matrix	Fortification level [mg/kg]	Mean Recovery [%]	RSD [%]
Winter wheat (grain)	0.01	97.4	1.1
	0.1	97.0	1.3
Winter wheat (straw)	0.01	98.8	2.2
	0.1	97.6	1.0
CGA192155 (200.90 > 156.95) – confirmatory transition			
Matrix	Fortification level [mg/kg]	Mean Recovery [%]	RSD [%]
Winter wheat (grain)	0.01	95.6	1.3
	0.1	98.0	1.3
Winter wheat (straw)	0.01	94.8	2.6
	0.1	95.6	1.2

Matrix effect was checked during the validation method. Assessment of matrix effects was performed by comparing the standard preparing in solution to standard preparing in blank matrix at concentration 2.0 ng/ml. The matrix effect was -7.3% (for transition 200.90 >91.1) and 0.2% (for transition 200.90 > 156.95) for winter wheat grains and -0.5 % (for transition 200.90 >91.1) and -0.3% (for transition 200.90 > 156.95) for winter wheat straw. The limit of quantification (LOQ) for fludioxonil was 0.01 mg/kg and the limit of detection was 0.0025 mg/kg.

Table A 3: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./100 kg seeds	Water (l/ha)	g a.s./hl				Fludioxonil	CGA192155		
	(a)	(b)				(c)				(d)	(e)	
21FRT-52TRZAWFLD-01/ Krysk/Poland/2021-2022	Winter wheat/Astoria	1. 08.11.2021 2. 24.05.2022- 04.06.2022 3. 02.08.2022	5 g a.s/100 kg seeds	0.2		1 (seed treatment)	BBCH 00	Grains Straw	<LOD <LOD	<LOD <LOD	n.a.	
21FRT-52TRZAWFLD- 02/Stara Żelazna /Poland/2021-2022	Winter wheat/ Astoria	1. 03.11.2021 2. 28.05.2022- 07.06.2022 3. 26.07.2022	5 g a.s/100 kg seeds	0.2		1 (seed treatment)	BBCH 00	Grains Straw	<LOD <LOD	<LOD <LOD	n.a.	
21FRT-52TRZAWFLD- 03/Kocerany/Poland/2021- 2022	Winter wheat/ Hondia	1. 21.10.2021 2. 02.06.2022- 10.06.2022 3. 09.08.2022	5 g a.s/100 kg seeds	0.2		1 (seed treatment)	BBCH 00	Grains Straw	<LOD <LOD	<LOD <LOD	n.a.	
21FRT-52TRZAWFLD- 04/Skierniewice/Poland/2021- 2022	Winter wheat/ Euforia	1. 15.10.2021 2. 25.05.2022- 05.06.2022 3. 09.08.2022	5 g a.s/100 kg seeds	0.2		1 (seed treatment)	BBCH 00	Grains Straw	<LOD <LOD	<LOD <LOD	n.a.	

LOD = 0.0025 mg/kg, LOQ = 0.01 mg/kg

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.4 Magnitude of residues in livestock

Not required.

A 2.1.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

Not required.

A 2.1.6 Magnitude of residues in representative succeeding crops

Not required.

A 2.1.7 Other/Special Studies

Not required.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations



Fludioxonil			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	0,37	ARID (mg/kg bw):	not necessary
Source of ADI:	EFSA	Source of ARID:	EFSA
Year of evaluation:	2007	Year of evaluation:	2007

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

		No of diets exceeding the ADI : ---						Exposure resulting from		
Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
61%	NL toddler	225,17	15%	Apples	6%	Oranges	6%	Pears		0,0%
46%	DE child	171,93	17%	Apples	11%	Oranges	4%	Potatoes		0,0%
40%	NL child	147,35	9%	Sugar beet roots	8%	Apples	5%	Potatoes		0,0%
30%	IE adult	109,23	10%	Sweet potatoes	3%	Potatoes	3%	Oranges		0,0%
24%	FR child 3 15 yr	90,04	9%	Oranges	4%	Sugar beet roots	2%	Apples		0,0%
22%	DE women 14-50 yr	82,46	5%	Oranges	5%	Sugar beet roots	3%	Apples		0,0%
22%	FR toddler 2 3 yr	79,59	4%	Apples	4%	Oranges	3%	Sugar beet roots		0,0%
21%	SE general	78,75	6%	Potatoes	4%	Lettuces	2%	Oranges		0,0%
21%	UK toddler	76,91	5%	Oranges	5%	Potatoes	3%	Sugar beet roots		0,0%
21%	GEMS/Food G07	76,85	5%	Potatoes	4%	Oranges	3%	Lettuces		0,0%
20%	GEMS/Food G11	74,98	5%	Potatoes	2%	Apples	2%	Oranges		0,0%
20%	DE general	74,89	5%	Sugar beet roots	4%	Oranges	3%	Apples		0,0%
20%	ES child	73,25	6%	Oranges	5%	Lettuces	2%	Potatoes		0,0%
20%	GEMS/Food G10	72,99	4%	Potatoes	4%	Lettuces	3%	Oranges		0,0%
20%	GEMS/Food G06	72,47	3%	Tomatoes	3%	Oranges	3%	Oranges		0,0%
19%	GEMS/Food G08	68,93	5%	Potatoes	2%	Lettuces	2%	Apples		0,0%
18%	PT general	66,59	7%	Potatoes	3%	Potatoes	2%	Oranges		0,0%
18%	NL general	65,28	3%	Potatoes	3%	Sugar beet roots	3%	Oranges		0,0%
17%	ES adult	61,92	6%	Lettuces	3%	Oranges	1%	Potatoes		0,0%
16%	GEMS/Food G15	60,14	5%	Potatoes	2%	Oranges	1%	Apples		0,0%
16%	RO general	58,46	5%	Potatoes	2%	Apples	2%	Wine grapes		0,0%
15%	UK infant	57,21	4%	Potatoes	4%	Oranges	2%	Apples		0,0%
14%	FI 3 yr	52,85	6%	Potatoes	1%	Apples	1%	Mandarins		0,0%
14%	IT adult	49,98	4%	Lettuces	1%	Apples	1%	Peaches		0,0%
13%	IT toddler	49,36	3%	Lettuces	1%	Oranges	1%	Potatoes		0,0%
13%	DK child	48,11	3%	Potatoes	3%	Apples	2%	Lettuces		0,0%
12%	FI 6 yr	44,43	5%	Potatoes	0,9%	Lettuces	0,9%	Mandarins		0,0%
12%	FR infant	43,01	3%	Potatoes	2%	Apples	2%	Spinaches		0,0%
11%	FR adult	40,22	3%	Wine grapes	2%	Oranges	1%	Apples		0,0%
11%	PL general	39,86	5%	Potatoes	3%	Apples	0,7%	Tomatoes		0,0%
11%	UK vegetarian	39,29	2%	Oranges	2%	Potatoes	2%	Lettuces		0,0%
9%	LT adult	33,66	4%	Potatoes	3%	Apples	0,7%	Lettuces		0,0%
9%	UK adult	32,92	2%	Potatoes	2%	Oranges	1%	Lettuces		0,0%
8%	DK adult	30,27	2%	Potatoes	1%	Apples	1%	Wine grapes		0,0%
8%	FI adult	28,15	2%	Potatoes	2%	Lettuces	1%	Oranges		0,0%
2%	IE child	8,34	0,8%	Potatoes	0,4%	Apples	0,2%	Oranges		0,0%

Conclusion:
 The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
 The long-term intake of residues of Fludioxonil is unlikely to present a public health concern.
 DISCLAIMER: Dietary data from the UK were included in PRIMo when the UK was a member of the European Union.

A 3.2 IESTI calculations - Raw commodities – not relevant

Acute risk assessment /children				Acute risk assessment / adults / general population				Acute risk assessment /children			Acute risk assessment / adults / general population					
Details - acute risk assessment /children				Details - acute risk assessment/adults				Hide IESTI new calculations			Show IESTI new calculations					
As an ARID is not necessary/not applicable, no acute risk assessment is performed.								IESTI new calculations: The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.								
Show results for all crops																
Unprocessed commodities	Results for children No. of commodities for which ARID/ADI is exceeded (IESTI):				Results for adults No. of commodities for which ARID/ADI is exceeded (IESTI):				IESTI new Results for children No. of commodities for which ARID/ADI is exceeded (IESTI new):			IESTI new Results for adults No. of commodities for which ARID/ADI is exceeded (IESTI new):				
	---				---				---			---				
	IESTI				IESTI				IESTI new			IESTI new				
	Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	Expand/collapse list															
Total number of commodities exceeding the ARID/ADI in children and adult diets (IESTI calculation)								Total number of commodities found exceeding the ARID/ADI in children and adult diets (IESTI new calculation)								

A 3.3 IESTI calculations - Processed commodities – not relevant

Processed commodities	Results for children			Results for adults			Results for children			Results for adults					
	No of processed commodities for which ARID/ADI is exceeded (IESTI):			No of processed commodities for which ARID/ADI is exceeded (IESTI):			No of processed commodities for which ARID/ADI is exceeded (IESTI new):			No of processed commodities for which ARID/ADI is exceeded (IESTI new):					
	---			---			---			---					
	IESTI			IESTI			IESTI new			IESTI new					
	Highest % of ARID/ADI	Processed commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL /input for RA (mg/kg)
Expand/collapse list															
Conclusion:															

Appendix 4 Additional information provided by the applicant

Not required.