

FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

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 submitted by Applicant
06/2023	dRR assessment by zRMS PL
10/2023	Final Registration Report

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8 Fate and behaviour in the environment (KCP 9)

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.

8.1 Critical GAP and overall conclusions

Table 8.1-1: Critical use pattern of the FLUDIO 025 GF

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I**	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/ synergist per ha	Conclusion
					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			PECgw
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Winter rye	F	<i>Fusarium spp.</i> <i>Urocystis occulta</i>	Seed treatment	BBCH 00	1	-	0.2-0.4 L/ha	Fludioxonil 5 – 10 g	-		200 mL/100 kg seeds Sowing rate: 100 – 200 kg seeds/ha	A
2	PL	Winter wheat	F	<i>Fusarium spp.</i> <i>Monographella nivalis</i> <i>Tilletia caries</i>	Seed treatment	BBCH 00	1	-	0,3-0,5 L/ha	Fludioxonil: 7,5-12,5g	-		200 ml/100 kg seeds Sowing rate: 150- 250 kg	A

													seeds/ha	
3	PL	Winter barley	F	<i>Fusarium spp.</i> <i>Monographella nivalis</i> <i>Pyrenophora graminea</i>	Seed treatment	BBCH 00	1	-	0,24-0,4 L/ha	Fludioxonil: 6-10g	-		200 ml/100 kg seeds Sowing rate: 120-200 kg seeds/ha	A
4	PL	Winter triticale	F	<i>Fusarium spp.</i>	Seed treatment	BBCH 00	1	-	0.2-0.4 L/ha	Fludioxonil 5 – 10 g	-		200 ml/100 kg seeds Sowing rate (triticale): 100-200 kg seeds/ha	A
5	PL	Spring wheat	F	<i>Fusarium spp.</i> <i>Tilletia caries</i>	Seed treatment	BBCH 00	1	-	0,3-0,5 L/ha	Fludioxonil: 7,5-12,5g	-		200 ml/100 kg seeds Sowing rate: 150-250 kg seeds/ha	A
6	PL	Spring barley	F	<i>Fusarium spp.</i>	Seed treatment	BBCH 00	1	-	0,24-0,4 L/ha	Fludioxonil: 6-10g	-		200 ml/100 kg seeds Sowing rate: 120-200 kg seeds/ha	A

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

** 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 15 “Conclusion”

A	Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS

N	No safe use
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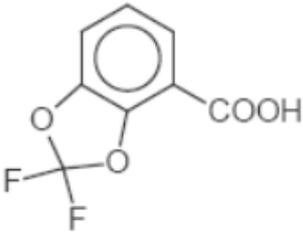
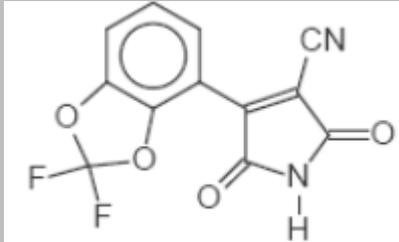
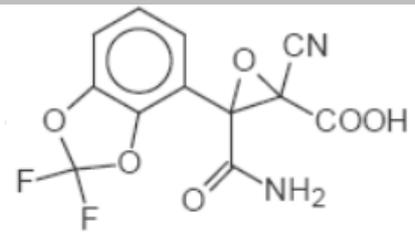
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|-------------------------------|---|---|
| Remarks table heading: | (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l | (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. |
| 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. | 7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m ³ 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 |

Table 8.1-2: Critical use pattern of FLUDIO 025 GF

Grouping according to application rate		
Group	Intended uses	Recommended dose rate
Bare soil (treated seed)	Winter and spring cereals (Wheat, Barley, Triticale, Rye)	0.12 – 0.5 l/ha

8.2 Metabolites considered in the assessment

Table 8.2-1: Metabolites of fludioxonil potentially relevant for exposure assessment

Metabolite	Molar mass [g/mol]	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
CGA 192155 (2,2-difluoro-benzo[1,3]dioxol-4-carbocyclic acid	202.1		Soil 11.7% Surface 17.3%	PEC _{soil} : risk for soil organisms PEC _{sw} : risk for aquatic organisms
CGA 265378* 4-(2,2-difluoro-benzo[1,3]dioxol-4-yl)-2,5-dioxo-2,5-dihydro-1H-pyrrole-3-carbonitrile	278.2		Soil 12.3 % Surface 3.8%/	PEC _{gw} : leaching potential to groundwater PEC _{soil} : risk for soil organisms
CGA 339833* 3-carbamoyl-2-cyano-3-(2,2-difluorobenzo[1,3]dioxol-4-yl)-oxirane-2-carbocyclic acid	312.2		Soil: 9.1% Surface: 1x10 ⁻⁶	PEC _{sw} : risk for aquatic organisms

*In accordance with EFSA Scientific Report (2007) 110, 1-85 the metabolites: CGA 339833 and CGA 192155 are relevant for foliar spray use only.

zRMS comment:

Information regarding fludioxonil metabolite CGA192155 is in line with EU agreed data reported in EFSA Scientific Report (2007) 110.

Rate of degradation in soil (KCP 9.1.1)

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

The degradation studies of fludioxonil were evaluated during the EU review.

Reference to:

1. Conclusion on the peer review of the pesticide risk assessment of the active substances fludioxonil (EFSA (2007) 110,1-85).
2. Draft Assessment Reports for active substance fludioxonil (Vol. 3, Annex B, B.8).

8.2.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.2.1.1 Fludioxonil and its metabolites

8.3.1.2.1 Fludioxonil (degradation in the dark):

EFSA (2007) 110,1-85)

DT50lab (20°C, aerobic): 119 – > 365 days, median 239 d, n= 13.

In details the results were as follow:

Sandy loam: DT50 236 days, $r^2 = 0.857$

Sandy loam: DT50 292 days, $r^2 = 0.813$

Sandy loam: DT50 272 days, $r^2 = 0.865$

Sandy loam: DT50 272 days, $r^2 = 0.795$

Sand: DT50 >365 days, $r^2 = 0.846$

Sandy loam: DT50 = 150 days, $r^2 = 0.983$

Sandy loam: DT50 = 253 days, $r^2 = 0.921$

Loamy sand: DT50 = 250 days, $r^2 = 0.941$

Silt loam: DT50 = 239 days, $r^2 = 0.977$

Silt loam: DT50 = 119 days, $r^2 = 0.983$

Silt loam: DT50 = 175 days, $r^2 = 0.991$

Silt loam: DT50 = 148 days, $r^2 = 0.991$

Silt loam: DT50 = 200 days, $r^2 = 0.980$

EFSA (2007) 110,1-85)

For FOCUS modelling, DT50 values normalised to standard conditions ie. 20°C and 100 % field capacity
DT50 = 100 – 569 days, median 164 days, n = 9

In details the results were as follow:

Sandy loam; 160 days; $r^2 = 0.813-865$, n = 3

Sandy loam; 186 days; $r^2 = 0.795$

Sand; 569 days; $r^2 = 0.846$

Sandy loam; 100 days; $r^2 = 0.983$

Sandy loam; 169 days; $r^2 = 0.921$

Loamy sand; 177 days; $r^2 = 0.941$

Silt loam; 151 days; $r^2 = 0.977$

Silt loam; 120 days $r^2 = 0.983 -0.991$, n = 3

Silt loam; 164 days; $r^2 = 0.980$

DT50lab (30°C, aerobic): 84 days, $r^2 = 0.968$

DT90lab (20°C, aerobic): 3.3 * 365 d, n=7

8.3.1.2.2 Fludioxonil (degradation in the light):

EFSA (2007) 110,1-85)

Above 0.5 mm: DT50: 0.86 and 2 d, n=2

Below 0.5 mm: DT50: 50 and 98 d, n=2

Combined one-compartment 1. order: DT50: 10 and 14 d, n=2.

8.3.1.2.3 CGA 192155 and CGA 339833 (degradation in the light):

EFSA (2007) 110,1-85)

CGA 192155: first order DT50lab 16, 16 and 24 d, n=3, r2 = 0.955 – 0.985. Mean value 19 d.
CGA 192155: DT90lab 52, 54 and 79 d, n=3, r2 = 0.955 – 0.985. Mean value 62 d.
CGA 339833: first order DT50lab 9, 12 and 16 d, n=3, r2 = 0.992 – 0.994. Mean value 12 d.
DT90lab 31, 40 and 53 d, n=3, , r2 = 0.992 – 0.994. Mean value 41 d.

8.3.1.2.3 CGA 265378 (degradation in the light):

From a soil photolysis study a worst case DT50 was estimated to be 19 d.

8.2.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Studies on the anaerobic degradation in soil have previously been evaluated within an EU peer review process. Under anaerobic conditions, there is practically no route of fludioxonil breakdown. The active substance is stable.

8.3 Field studies (KCP 9.1.1.2)

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

The degradation rates of fludioxonil were evaluated during the EU review.

Reference to:

- Conclusion on the peer review of the pesticide risk assessment of the active substances fludioxonil (EFSA (2007) 110,1-85).
- Draft Assessment Reports for active substance fludioxonil (Vol. 3, Annex B, B.8).

8.3.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

8.3.1.1 Fludioxonil

EFSA (2007) 110,1-85)

Spray on bare ground (first order kinetic):

France: DT50f = 15 d, DT90f = 49 d; n=1; r2 = 0.81

Germany: DT50f = 8-43 d, DT90f = 28-142 d; n=6; r2 = 0.71-0.85

Germany in details:

Sandy loam; DT50f = 28; r2 = 0.85

Sand; DT50f = 9; r2 = 0.78

sand to silt loam; DT50f = 8; r2 = 0.81

Loam; DT50f = 43; r2 = 0.78

silt loam; DT50f = 14; r2 = 0.71

silt loam; DT50f = 14; r2 = 0.82

Switzerland: DT50f = 16 d; n=1; r2 not stated

Photolysis field study on bare ground using a two-compartment first order model: Above 0.5 mm soil: DT50: 0.1 d, n=1 Below 0.5 mm soil:

DT50: 60 d, n=1 Using combined one-compartment 1. order kinetic:
DT50: 16 d, n=1.

Spray in grape vine (first order kinetic): Italy:

DT50f = 10 d, DT90f = 34 d; n=1; r2 = 0.99

DT50f in vine and bare ground (first order kinetic):

Median DT50 = 14 d, n=9 90th percentile DT50 = 31 d, n=9 **Worst case DT50 = 43 d**

8.3.2 Soil accumulation testing (KCP 9.1.1.2.2)

8.3.2.1 Fludioxonil

Does not accumulate continuously after repeated use over 8 years, foliar use in grape vine. Plateau reached after 4-6 years with a max concentration of 0.7 and 1.1 mg/ kg in 0-10 cm soil layer after application of 2x300 or 2x500 g as/ha/year respectively, declining to 0.23 - 0.37 mg/kg in the following years.

In two 5 year accumulation studies on grapevine (foliar use 2 x 300 g as/ha/year or 1-2x 500 gas/ha/year), the concentration reached a maximum of 2.0 mg/kg and 0.78 mg/kg in the year 3 and 4 respectively, and was declining to 1.35 mg/kg and 0.63 mg/kg within 5 and 3 years, respectively. The foliar use scenario is considered a worst case and covers for seed treatment use.

8.4 Mobility in soil (KCP 9.1.2)

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

The mobility studies of fludioxonil were evaluated during the EU review.

Reference to:

- Conclusion on the peer review of the pesticide risk assessment of the active substances fludioxonil (EFSA (2007) 110,1-85).
- Draft Assessment Reports for active substance fludioxonil (Vol. 3, Annex B, B.8).

8.4.1 Fludioxonil and its metabolites

EFSA (2007) 110,1-85)

Fludioxonil:

$K_{foc}(ads) = 12000-385000$, mean 145600, median 75000 mL/g OC, n=5

$K_f ads = 290-61000$, mean 14292, median 2100 mL/g soil, n=5

$1/n_{ads} = 0.81-1.19$, mean 1.00, median 0.95, n=5

CGA 192155 n=4

$K_{foc}(ads) = 11.7-42.4$, mean 23.5, median 19.9 mL/g OC

$K_{Fads} = 0.06-0.28$, mean 0.21, median 0.26 mL /g soil

$1/n_{ads} = 0.769-0.841$, mean 0.803, median 0.800

CGA-339833, n=4

$K_{foc}(ads) = 1.94-5.79$, mean 4.031, median 4.2 mL/g OC

$K_{Fads} = 0.011-0.109$, mean 0.06, median 0.06 mL /g soil

$1/n_{ads} = 0.072-1.08$, mean 0.7302, median 0.884

CGA 265378, unstable, rough estimates, n=4

$K_{oc} = 36-111$, mean 68.3, median 80 mL /g OC

$K_{Fads} = 0.646-0.829$, mean 0.749 mL/g soil

Due to fast degradation of CGA 265378 only the ratio of concentrations were determined and the adsorption coefficients were calculated from $K_d = C_{soil}/C_{water}$.

8.4.2 Column leaching (KCP 9.1.2.1)

During the study with elution of 200 mm and time period of 2 days in four types of soil, with fludioxonil total leachate residues were 0.02 – 0.1% of applied dose.

8.4.3 Lysimeter studies (KCP 9.1.2.2)

Studies with the formulation were not performed.

Standard soil columns with four different soils with unaged fludioxonil eluted with 200 mm artificial rain showed a leaching of 0.02-0.1% AR, confirming that fludioxonil is immobile in soil.

8.4.4 Field leaching studies (KCP 9.1.2.3)

Studies with the formulation were not performed.

Not submitted, not required for fludioxonil.

8.5 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

The degradation of fludioxonil was evaluated during the EU review.

Reference to:

- Conclusion on the peer review of the pesticide risk assessment of the active substances fludioxonil (EFSA (2007) 110,1-85).
- Draft Assessment Reports for active substance fludioxonil (Vol. 3, Annex B, B.8).

8.5.1 Fludioxonil and its metabolites

EFSA (2007) 110,1-85

Degradation in water/sediment in dark

DT50 water: 1-2 days

DT50 whole system: 451-699 days

DT90 whole system: > 1000 days

Distribution in water and sediments of metabolites: Unidentified metabolite fractions in sediment and water accounted for 0.1 – 6.2%

Degradation in water/sediment in light exposure

DT50 water: 1.7-1.8 days

DT90 water: 9.8-14.5 days

DT50 whole system: 18.8-25.2 days (geometric mean: 21.77d)

DT90 whole system: 133-148 days

DT50 sediment: 57.8-65.4 days
 DT90 sediment: 192-217

Distribution in water and sediments of metabolites:
 CGA 192155: 10.2-11.9% in water, 5.4-5.5% in sediment

8.6 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

8.6.1 Justification for new endpoints

There are no deviations from the EU agreed endpoints.
 PEC_{soil} was calculated according to endpoints for fludioxonil obtained from EFSA (2007) 110,1-85.

Table 8.6-1: Input parameters related to application for PEC_{soil} calculations

Use No.	1
Crop	Bare soil
Application rate (g as/ha)	Fludioxonil: 12.5
Number of applications/interval	1/0
Crop interception (%)	0
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm (no tillage)

Table 8.6-2: Input parameter for fludioxonil and relevant metabolites for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
Fludioxonil	248.2	-	569*	Y/ EFSA Scientific Report (2007) 110, 1-85
CGA 192155	202.1	11.7	24	Y/ EFSA Scientific Report (2007) 110, 1-85
CGA 265378	278.2	12.3	19	Y/ EFSA Scientific Report (2007) 110, 1-85
CGA 339833	312.2	9.1	16	Y/ EFSA Scientific Report (2007) 110, 1-85

* that according to EFSA Scientific Report (2007) 110, the maximum field soil DT₅₀ of 43 days should be used to calculate the soil exposure to fludioxonil. In this case of the Applicant used the maximum normalised laboratory DT₅₀ of 569 days as worst for in case seed treatment.

PEC_{soil} of metabolites

For the metabolites initial PEC_{soil} was calculated according to the following equation:

$$\text{PECs (initial)} = (\text{Max. PECs (parent)} \times \text{Max. metabolite occurrence} \times \text{Molar weight fraction})/100$$

$$A_{\text{metabolite}} = A_{\text{parent}} \times (\text{Max. metabolite occurrence} \times \text{Molar weight fraction})/100$$

Where:

- A_{parent} - Application rate of the parent
 $A_{\text{metabolite}}$ - Equivalent application rate of the metabolite [g/ha]

8.6.1.1 Fludioxonil and its metabolites

Table 8.6-3: PEC_{soil} for fludioxonil on bare soil

PEC_{soil} (mg/kg) Application: 12.5 g/ha		Bare soil	
		Single application	
		Actual	TWA
Initial		0.017	0.017
Short term	24h	0.017	0.017
	2d	0.017	0.017
	4d	0.017	0.017
Long term	7d	0.017	0.017
	14d	0.016	0.017
	21d	0.016	0.016
	28d	0.016	0.016
	50d	0.016	0.016
	100d	0.015	0.016
Plateau concentration (5cm) after 10 year		0.03	
$PEC_{\text{s,accumulation}}$ ($PEC_{\text{s,accumulation}} = PEC_{\text{s,ini}} + PEC_{\text{s,plateau}}$)		0.047	

Table 8.6-4: PEC_{soil} for CGA 192155 on bare soil

PEC_{soil} (mg/kg) Application: 1.19 mg/kg		Bare soil	
		Single application	
		Actual	TWA
Initial		0.002	0.002
Short term	24h	0.002	0.002
	2d	0.001	0.002
	4d	0.001	0.001
Long term	7d	0.001	0.001
	14d	0.001	0.001
	21d	0.001	0.001
	28d	0.001	0.001
	50d	0.000	0.001
	100d	0.000	0.001
Plateau concentration (5cm) after 20 year		Not relevant since DT50 < 90	

Table 8.6-5: PEC_{soil} for CGA 265378 on bare soil

PEC _{soil} (mg/kg) Application: 1.72 mg/kg		Bare soil	
		Single application	
		Actual	TWA
Initial		0.002	0.002
Short term	24h	0.002	0.002
	2d	0.002	0.002
	4d	0.002	0.002
Long term	7d	0.002	0.002
	14d	0.001	0.002
	21d	0.001	0.002
	28d	0.001	0.001
	50d	0.000	0.001
	100d	0.000	0.001
Plateau concentration (5cm) after 20 year		Not relevant since DT50 < 90	

Table 8.6-6: PEC_{soil} for CGA 339833 on bare soil

PEC _{soil} (mg/kg) Application: 1.43 mg/kg		Bare soil	
		Single application	
		Actual	TWA
Initial		0.002	0.002
Short term	24h	0.002	0.002
	2d	0.002	0.002
	4d	0.002	0.002
Long term	7d	0.001	0.002
	14d	0.001	0.001
	21d	0.001	0.001
	28d	0.001	0.001
	50d	0.000	0.001
	100d	0.000	0.000
Plateau concentration (5cm) after 20 year		Not relevant since DT50 < 90	

8.6.1.2 PEC_{soil} of FLUDIO 025 GF

Table 8.6-7: PEC_{soil} for FLUDIO 025 GF on bare soil

Active substance/ reparation	Application rate (g/ha)	PEC _{act} (mg/kg)	PEC _{twa21 d} (mg/kg)	PEC _{soil,plateau} (mg/kg)	PEC _{accu} = PE- Cact + PEC _{soil,plateau} (mg/kg)
Fludioxonil	12.5	0.017	0.016	0.030	0.047
FLUDIO 025 GF	531	0.71	-	-	-

zRMS comments:

Soil exposure has been calculated with consideration of the maximum application rate indicated in the GAP, covering intended uses of FLUDIO 025 FS.

According to EFSA Scientific Report (2007) 110, the maximum field soil DT₅₀ of 569 days was used to calculate the soil exposure to fludioxonil. Value taken into account by the Applicant represents worst case in terms of the soil accumulation potential and is thus agreed by the zRMS, especially it is more relevant for degradation of the active compound in the dark due to use as a seed treatment.

The photolytic metabolites: CGA 265378, CGA 192155 and CGA 339833 were considered relevant for soil exposure assessment due to max occurrence >10% AR. However, as FLUDIO 025 FS is applied as a seed treatment, soil photolysis will only marginally contribute to metabolism of fludioxonil in soil and for this reason photolytic metabolites do not have to be considered in soil exposure calculations.

Taking this into account, PEC_{soil} values provided in table 8.7-6- and 8.7-10 may be used for the risk assessment.

8.7 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

8.7.1 Justification for new endpoints

There are no deviations from the EU agreed endpoints.

FLUDIO 025 GF was not assessed as representative formulation. PEC_{GW} was calculated, using PEARL 5.5.5 and PELMO 6.6.4, according to endpoints for fludioxonil and its metabolites obtained from EFSA Journal 2007; 110, 1-85 and submitted for FLUDIO 025 GF.

Table 8.7-1: Input parameters related to application for PEC_{gw} calculations

Use No.	1
Crop	Bare soil
Application rate (g as/ha)	Fludioxonil 12.5
Number of applications/interval (d)	1/0

Relative application date	10 days before emergence
Crop interception (%)	0
Frequency of application	annual
Models used for calculation	FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4

8.7.1.1 Fludioxonil and its metabolites

Table 8.7-2: Input parameters related to active substance fludioxonil and its metabolites for PEC_{gw} calculations

Parameter	Compounds		Value in accordance with EU endpoint y/n/ Reference
	Fludioxonil	CGA 265378	
Physico-Chemical parameters			
Molecular weight [g mol ⁻¹]	248.2	278.2	Y/ EFSA Journal 2007; 110, 1-85;
Water solubility [mg L ⁻¹]	1.8	120	Y/ EFSA Journal 2007; 110, 1-85;
Saturated vapour pressure (Pa):	2.9E-7	8.4E-6	Y/ EFSA Journal 2007; 110, 1-85;
Molar enthalpy of dissolution [kJ mol ⁻¹]	27		FOCUS default
Molar enthalpy of vaporization [kJ mol ⁻¹]	95		FOCUS default
Diffusion coefficient in water [m ² d ⁻¹]	4.3 x 10 ⁻⁵ (20°C)		FOCUS default
Diffusion coefficient in gas [m ² d ⁻¹]	0.43 (20°C)		FOCUS default
Degradation in soil			
DT ₅₀ soil [d]	164	19	Y/ EFSA Journal 2007; 110, 1-85;
Temperature correction function	20°C		FOCUS default
Reference temperature	2.58		
Q10 -value			
Molar activation energy [kJ mol ⁻¹]	65.4		FOCUS default
Moisture correction function	pF 2		FOCUS default
Reference moisture [-]	0.7		
Moisture exponent [-]			
Exponent in moisture exponent	0.49		FOCUS default
Sorption to soil			
K _{foc} (mL/g)/K _{fom} K _{FOM} =K _{FOC} / 1.724	145000/ 84107	68/39.4	Y/ EFSA Journal 2007; 110, 1-85;
Freundlich exponent 1/n [-]	1.0	0.9	
Method of sorption subroutine description	<i>pH independent</i>		
Crop/ Management related parameters			
Plant uptake factor (TSCF)	0	0	Worst case assumption

Table 8.7-3: PEC_{gw} fludioxonil and its metabolites on bare soil (with FOCUS PEARL 5.5.5)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)	
		Fludioxonil	CGA 265378
Winter cereal	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
Thiva	< 0.001	< 0.001	
Spring cereal	Chateaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Porto	< 0.001	< 0.001

Table 8.7-4: PEC_{gw} fludioxonil and its metabolites on bare soil (with FOCUS PELMO 6.6.4)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)	
		Fludioxonil	CGA 265378
Winter cereal	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001
Spring cereal	Chateaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001

	Okehampton	< 0.001	< 0.001
	Porto	< 0.001	< 0.001

The PEC_{gw} were calculated for the highest application rate recommended for use in winter wheat applied for 12.5 g s.a./ha in bare soil. Obtained PEC_{gw} of fludioxonil and its metabolite 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.

zRMS comment:

Groundwater modelling has been performed using FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4. As all relevant Central Zone scenarios are defined for modelling performed for this crop is considered sufficiently protective for application to GAP.

The maximum application rate considered in performed simulations covers all intended application rates of FLUDIO 025 GF.

Input parameters presented in Table 8.8-2 are in line with the EU agreed endpoints reported in EFSA Scientific Report (2007) 110. The median value DT50 of 164 days recalculated (addendum 2, March 2007) in line with the recommendations and indications provided by MS experts' in PRAPeR 07 meeting was used in the modelling. In line with recommendations of the *Central Zone guidance document in area of Section 8 Working document of the Central Zone* in the authorisation of plant protection products, Section 8, Environmental fate and behaviour. Version 1, rev. 1, June 2018 MACRO simulations were not required, since PEC_{GW} values calculated using FOCUS PEARL and FOCUS PELMO were <0.001 µg/L.

Overall, based on the results of the performed groundwater modelling, no unacceptable leaching of fludioxonil at concentrations exceeding 0.1 µg/L is expected when FLUDIO 025 GF is used according to the GAP.

The additional groundwater modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

8.8 Predicted Environmental Concentrations in surface water (PEC_{sw}) (KCP 9.2.5)

8.8.1 Justification for new endpoints

There are no deviations from the EU agreed endpoints.
 FLUDIO 025 GF was not assessed as representative formulation. PEC_{sw} was calculated according to endpoints for fludioxonil and submitted for FLUDIO 025 GF.

8.8.2 Active substance, relevant metabolites and the formulation (KCP 9.2.5)

Table 8.8-1: Input parameters related to application for PEC_{sw/sed} calculations

Plant protection product	FLUDIO 025 GF
Use No.	1
Crop	Bare soil
Application rate (kg as/ha)	fludioksonil: 0.0125
Number of applications/interval (d)	1/0
Application window	N-Europe and S-Europe Oct-Feb and Mar-May
Application method	Not required for steps 1 and 2
CAM (Chemical application method)	Not required for steps 1 and 2
Soil depth (cm)	Not required for steps 1 and 2
Models used for calculation	FOCUS STEPS 1 - 2

8.8.2.1 Fludioxonil and its metabolites

Table 8.8-2: Input parameters related to active substance fludioxonil and its metabolites for PEC_{sw/sed} calculations STEP 1

Compound	Fludioxonil	CGA 192155	CGA 339833	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	248.2	202.10	312.2	Y/ EFSA Scientific Report (2007) 110
Water solubility (mg/L)	1.8	4900	31000	Y/ EFSA Scientific Report (2007) 110
K _{foc} (mL/g)	145000	23.5	4.0	Y/ EFSA Scien-

Compound	Fludioxonil	CGA 192155	CGA 339833	Value in accordance to EU end-point y/n/ Reference
				tific Report (2007) 110
DT _{50,soil} (d)	164	12.9	8.7	Y/ EFSA Scientific Report (2007) 110
DT _{50,water} (d)	22	1000	1000	Y/ EFSA Scientific Report (2007) 110
DT _{50,sed} (d)	1000	1000	1000	Y/ EFSA Scientific Report (2007) 110
DT _{50,whole system} (d)	14	1000	1000	Y/ EFSA Scientific Report (2007) 110
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil:11.7% Water/Sediment: 17.3 %	Soil:9.1 Water/Sediment: 0.000001%	Y/ EFSA Scientific Report (2007) 110

Table 8.8-3 Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments (EFSA Journal)

Compound	Ecotoxicology lowest regulatory acceptable concentration
Fludioxonil	0.5 µg/L
CGA 339833	1000 µg/L
CGA 192155	1000 µg/L

Table 8.8-4: FOCUS Step 1 PEC_{sw} and PEC_{sed} for fludioxonil following single application of FLUDIO 025 GF to bare soil

Scenario	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
FOCUS					
RAC = 0.5 µg/L					
Step 1	---	0.02	0	0.01	31.09

RAC: Regulatory acceptable concentration

Metabolites of fludioxonil

Table 8.8-5: FOCUS Step 1 PEC_{sw} and PEC_{sed} for CGA 192155 following single application of FLUDIO 025 GF to bare soil

Scenario	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
FOCUS					
RAC = 1000 µg/L					
Step 1	---	0.95	0	0.95	0.22

RAC: Regulatory acceptable concentration

Table 8.8-6: FOCUS Step 1 PEC_{sw} and PEC_{sed} for CGA 339833 following single application of FLUDIO 025 GF to bare soil

Scenario	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
FOCUS					
RAC = 1000 µg/L					
Step 1	---	0.47	0	0.47	0.02

RAC: Regulatory acceptable concentration

Since low risk for aquatic organisms is predicted for fludioxonil and its metabolites at Step 1, no additional calculations is required.

zRMS comment:

The PEC_{sw/sed} values were calculated by the Applicant for the intended use in GAP. Calculations for active substance and its metabolites performed by the Applicant are acceptable. The EU agreed endpoints were used. The CGA339833 metabolite formed via photolysis in water is not considered to be relevant for the surface water exposure assessment due to the type of application of FLUDIO 025 GF in seed treatment.

8.8.2.2 PEC_{sw/sed} of FLUDIO 025 GF

FLUDIO 025 GF was not assessed as representative formulation. PEC_{sw} was calculated according to endpoints for Fludioxonil and submitted for FLUDIO 025 GF.

8.9 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

Table 8.9-1 Summary of atmospheric degradation and behaviour

Compound	Fludioxonil
Direct photolysis in air	Not relevant
Quantum yield of direct phototransformation	Not relevant
Photochemical oxidative degradation in air	Latitude: standard season: standard Atkinson, 1.5x10 ⁶ OH radicals/cm ³ , 12 h day

	DT50 3.6 h
Volatilisation	Vapour pressure (Pa): 3.9E-7 Henry's Law Constant (Pa.m3/mol): 5.4E-5
Metabolites	No potentially volatile metabolites

The vapour pressure at 25 °C of the active substance fludioxonil is $< 10^{-5}$ Pa and the Henry's Law Constant is 5.4×10^{-5} Pa.m3/mol. Hence the fludioxonil is regarded as non-volatile.

zRMS comments:

Information regarding fate and behaviour in the air presented in Table 8.10-1 is in line with EU agreed data presented in EFSA Scientific Report (2007) 110.

As the vapour pressure of fludioxonil is below the trigger of 10^{-5} Pa, no significant volatilisation from soil and plant surfaces is expected and DT₅₀ in the air being < 2 days, fludioxonil is not expected to be subject to the long- or short-range transport.

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 9.2.4.1	---	2022	Estimations of the PEC _{gw} of Fludioxonil for the intended use as a seed treatment formulation non GLP Unpublished	N	
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	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	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	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, 2 April 2004. None GLP, unpublished RCC Study number 847909	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 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	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	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	SYNGENTA
KCP 9.1	Burton, S.D.	1996b	Soil adsorption/desorption of pyrrole-14C CGA 265378 by the batch equilibrium method Stillmeadow Inc., Texas, United States 2481 95, 16.08.1996 GLP, not published Syngenta File N° CGA265378/0003	N	SYNGENTA
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	SYNGENTA
KCP 9.1	Ellgehausen, H.	1992a	Degradation of CGA 173506 in two soils under aerobic conditions at 20°C Ciba-Geigy Ltd., Basel, Switzerland 91EH05, 04.02.1992 GLP, not published Syngenta File N° CGA173506/0141	N	SYNGENTA
KCP 9.1	Ellgehausen, H.	1992b	Degradation of CGA 173506 in one soil under aerobic conditions at two temperatures Ciba-Geigy Ltd., Basel, Switzerland 91EH08, 01.04.1992 GLP, not published	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
			Syngenta File N° CGA173506/0153		
KCP 9.1	Ellgehausen, H.	1992e	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	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	SYNGENTA
KCP 9.1	Gentile, B.	1991	Uptake, distribution and degradation of [4- ¹⁴ 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	SYNGENTA
KCP 9.1	Gentile, B.	1993	Field dissipation of CGA 173506 under two different environmental conditions after bare-ground application of [4- ¹⁴ C-Pyrrole] labeled material Ciba Geigy Ltd., Basel, Switzerland 89BG02PR3, 03.05.1993 GLP, not published Syngenta File N° CGA173506/0306	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	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	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
			Syngenta File N° CGA173506/0235		
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	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 Mod01AG02, 18.01.2002 Non-GLP not published Syngenta File N° CGA173506/5450	N	SYNGENTA
KCP 9.1	Hawking, D.R., et al	1991	The degradation of CGA 173506 in soil under aerobic, aerobic/anaerobic and sterile conditions at 25°C Huntington Research Centre GLP, Not published Syngenta File No CGA173506/0061	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	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	SYNGENTA
KCP 9.1	Hawkins, D.R. Kirkpatrick, D.	1991e	The mobility of CGA 173506 on soil columns Huntingdon Research Centre Ltd., Huntingdon, United Kingdom HRC CBG 486 90294,	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
	Shaw, D. Chan, S.C.		11.02.1991 GLP, not published Syngenta File N° CGA173506/0060		
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	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 Syngenta File N° CGA173506/1029	N	SYNGENTA
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	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	SYNGENTA
KCP 9.1	Kirkpatrick, D.	1994e	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	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	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, not published Syngenta File N° CGA173506/0524		
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	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 Syngenta File N° CGA173506/0519	N	SYNGENTA
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	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	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	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	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, not published Syngenta File N° CGA173506/0633		
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	SYNGENTA
KCP 9.1	Mair, P.	1995e	Determination of residues of CGA 173506 in soil – Field Trial Ciba-Geigy Ltd., Basel, Switzerland 2151/93, 22.05.1995 GLP, not published Syngenta File N° CGA173506/0614	N	SYNGENTA
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	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	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	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	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 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	SYNGENTA
KCP 9.1	Minet, U.	1994a	Degradation and Metabolism of 14C Pyrrole Labelled CGA 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	N	SYNGENTA
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	SYNGENTA
KCP 9.1	Minet, U.	1994e	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	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	SYNGENTA
KCP 9.1	Reichert, N.	1993a	Field soil dissipation rate determination of CGA 173506 RCC Umwelchemie GmbH & Co. KG, Rossdorf, Germany 324538, 09.11.1993 GLP, not published	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
			Syngenta File N° CGA173506/0430		
KCP 9.1	Reichert, N.	1993b	Field soil dissipation rate determination of CGA 173506 RCC Umweltechemie GmbH & Co. KG, Rossdorf, Germany 324527, 09.11.1993 GLP, not published Syngenta File N° CGA173506/0431	N	SYNGENTA
KCP 9.1	Reichert, N.	1993e	Field soil dissipation rate determination of CGA 173506 RCC Umweltechemie GmbH & Co. KG, Rossdorf, Germany 324516, 09.11.1993 GLP, not published Syngenta File N° CGA173506/0432	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	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	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	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	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	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 2037/93-02, 14.08.2001 GLP, not published Syngenta File N° CGA173506/0459		
KCP-9.1	Tribolet, R.	2001b	Long Term Residue Study with Fludioxonil (CGA 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	N	SYNGENTA
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	SYNGENTA
KCP-9.1	Ulbrich, R.	1999	Rate of degradation of Oxirane 3-14C-labelled CGA 339833 in various soils at 20°C Novartis Crop Protection AG, Basel, Switzerland 98UL01, 06.07.1999 GLP, not published Syngenta File N° CGA339833/0002	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	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	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	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 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, 07.01.1994 GLP, not published Syngenta File N° CGA173506/0413	N	SYNGENTA
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	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	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	SYNGENTA
KCP 9.3.	Widmer, H.	2001e	Vapour pressure of CGA 192155 Syngenta Crop Protection AG, Basel, Switzerland 2000WI37, 08.05.2001 GLP, not published Syngenta File N° CGA192155/0011	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 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
	There were no studies submitted relied on and not submitted by the Applicant.				

Appendix 2 Detailed evaluation of the new Annex II studies

Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data)