

FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: IN005B1570

Product name: ~~INDOFIL~~ Difenoconazole 250 G/L EC greener

Chemical active substance:

Difenoconazole, 250 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Article 33: Application for authorisation

Applicant: Indofil Industries (Netherlands) B.V.

Submission date: February 2022

MS Finalisation date: 10.2022; 05.2024; 07.2024;

Version history

When	What
February 2022	V0 – Original version from applicant Indofil Industries (Netherlands) B.V. for submission to z-RMS, Poland , in the frame of the PPP Authorization according to Article 33 of Regulation (EC) No. 1107/2009
October 2022	Initial evaluation by the zRMS
May 2024	Corrected version by zRMS after commenting
July 2024	Corrected version by zRMS after commenting III.

Table of Contents

8	Fate and behaviour in the environment (KCP 9).....	4
8.1	Critical GAP and overall conclusions.....	5
8.2	Metabolites considered in the assessment.....	8
8.3	Rate of degradation in soil (KCP 9.1.1).....	9
8.3.1	Aerobic degradation in soil (KCP 9.1.1.1)	9
8.3.2	Anaerobic degradation in soil (KCP 9.1.1.1).....	11
8.4	Field studies (KCP 9.1.1.2).....	12
8.4.1	Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1). ..	12
8.4.2	Soil accumulation testing (KCP 9.1.1.2.2)	12
8.5	Mobility in soil (KCP 9.1.2)	13
8.5.1	Column leaching (KCP 9.1.2.1).....	14
8.5.2	Lysimeter studies (KCP 9.1.2.2).....	14
8.5.3	Field leaching studies (KCP 9.1.2.3)	14
8.6	Degradation in water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)	14
8.7	Predicted Environmental Concentrations in soil (PEC _{soil}) (KCP 9.1.3)	15
8.7.1	Justification for new endpoints	15
8.7.2	Active substance(s) and relevant metabolite(s)	16
8.7.2.1	PEC _{soil} for the formulated product	19
8.8	Predicted Environmental Concentrations in groundwater (PEC _{gw}) (KCP 9.2.4)	20
8.8.1	Justification for new endpoints	20
8.8.2	Active substance and relevant metabolites (KCP 9.2.4.1).....	21
8.9	Predicted Environmental Concentrations in surface water (PEC _{sw}) (KCP 9.2.5)	26
8.9.1	Justification for new endpoints	26
8.9.2	Active substance, relevant metabolites and the formulation (KCP 9.2.5) ...	26
8.9.2.1	PEC _{sw/sed} for IN005B1570 DG250EC	43
8.10	Fate and behaviour in air (KCP 9.3, KCP 9.3.1)	45
Appendix 1	Lists of data considered in support of the evaluation.....	46
Appendix 2	Detailed evaluation of the new Annex II studies	48
Appendix 3	Additional information provided by the applicant (e.g. detailed modelling data).....	48

8 Fate and behaviour in the environment (KCP 9)

This document reviews the environmental fate studies and modelling for the product IN005B1570, an emulsifiable concentrate formulation containing 250 g/L difenoconazole for use on oilseed rape, pome fruit, carrot, cabbage, cauliflower, and broccoli. Difenoconazole was first included in Annex I to Directive 91/414/EEC by Commission Directive 2008/69/EC of 1 July 2008.

A full risk assessment according to Uniform Principles is provided which demonstrates that the product is safe for the environment. Where appropriate this document refers to the conclusion of the EU review for difenoconazole. This will be where:

- The active substance data are relied upon in the risk assessment of the formulation; or when
- the EU review concluded that the additional data/information should be considered at national re-registration.

The EFSA Scientific report for Difenoconazole (EFSA Scientific Report, 2011; 9(1):1967) is considered to provide the relevant review information or a reference to where such information can be found.

The Commission Implementation Regulation for Difenoconazole (540/2011) provides specific provisions under part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No. 1107/2009, the conclusion of the review report for difenoconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 March 2008.

In this overall assessment Member States must pay particular attention to:

- The operator safety in spray applications. Conditions of use shall include adequate protective measures.
- The protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied where appropriate.
- The protection of birds and small mammals. Risk mitigation measures shall be applied, where appropriate.

Conditions of use shall include risk mitigation measures, where appropriate.

Information on the detailed composition of IN005B1570 can be found in the confidential dossier of this submission (Registration Report – Part C).

8.1 Critical GAP and overall conclusions

Table 8.1-1: Critical use pattern of the formulated product

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, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ 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)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g 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	IE, DE, BE, UK, SI, PL, CZ, NL, AT, SI	BRSNW Oilseed rape	F	LEPTMA (Plenodomus lingam) LEPTBG (Plenodomus biglobosus) SCLECS (Sclerotinia sclerotiorum), ALTEBI (Alternaria brassicae)	foliar spray	Autumn and Spring applications BBCH 14-18 and BBCH 30-69	2 (1 in autumn and 1 in spring or 2 in autumn)	21 (but usually longer in practice)	a) 0.5 b) 1	a) 125 b) 250	100-500	NA	Half rate per treatment if 2 applications in autumn	A
2	PL, BE, SI, DE, UK, CZ, NL, AT, IE	MABSD, PYUCO (Apples, Pears)	F	VENTIN, VENTPI (Venturia inaequalis, Venturia pyrina) PODOLE [Powdery mildew (Podosphaera leucotricha)]	foliar spray	BBCH 57-84	3	7 (label: spray interval from 7 to 10 days)	a) 0,225 b) 0.9	a) 56,25 b) 225	100-1500 In DE max 500 L/ha per m of height	21		A
3	PL - DE, UK, CZ, BE, NL, AT, SI, IE	DAUCS (Carrot)	F	ALTEDA (Alternaria dauci, Alternaria radicina) ERYSHE (Oidium (Erysiphe heraclei)	foliar spray	from BBCH 39-40	3	14	a) 0.5 b) 1.5	a) 125 b) 375	200-1000	14		A
4	PL - DE, UK, CZ, BE, NL, AT, SI, IE	BRSOB (Cauliflower)	F	ALTEBI (Alternaria brassicicola) MYCOBR (Mycosphaerella brassicicola)	foliar spray	from BBCH 19	3	14	a) 0.5 b) 1.5	a) 125 b) 375	200-1000	14 or 21		A
5	PL - DE, UK, CZ,	BRSOK (Broccoli)	F	ALTEBI (Alternaria brassicicola)	foliar spray	from BBCH 19-21	3	7 - 10	a) 0.5 b) 1.5	a) 125 b) 375	200-1000	14		A

	BE, NL, AT, SI, IE			MYCOBR (Mycosphaerella brassicicola)										
6	PL - DE, UK, CZ, BE, NL, AT, SI, IE	BRSOL (Cabbage)	F	ALTEBI (Alternaria brassicicola) MYCOBR (Mycosphaerella brassicicola)	foliar spray	from BBCH 19	3	7 - 10	a) 0.5 b) 1.5	a) 125 b) 375	200-1000	14 or 21		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

Table 8.1-2: Assessed (critical) uses during approval of difenoconazole concerning the Section Environmental Fate

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					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	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	EU	Pome fruit	F	Podosphaera leucotricha, Venturia inaequalis	High vol spray or mist blower	Flowering (BBCH 61)	1-4	10	0.00375 – 0.0075	0.05625 0.0750	500/1500	28 14	-
2	EU	Carrot	F	Alternaria dauci, Erysiphe heraclei	High vol spray	BBCH 42	1-3	14	-	0.125	100/500	14	-
3	EU	Wheat	F	Fusarium spp., Tilletia spp.	Seed treatment	BBCH 00	1	-	0.03-0.06 kg as/tonne	0.012	-	-	-
4	EU	Barley	F	Pyrenophoma granimeae	Seed treatment	BBCH 00	1	-	0.03-0.06 kg as/tonne	0.012	-	-	-
5	EU	Triticale	F	Fusarium spp., Tilletia spp.	Seed treatment	BBCH 00	1	-	0.03-0.06 kg as/tonne	0.012	-	-	-
6	EU	Rye	F	Fusarium spp., Urocystis occulata	Seed treatment	BBCH 00	1	-	0.03-0.06 kg as/tonne	0.012	-	-	-
7	EU	Oats	F	Ustilago avenae Pyrenophora avenae Cochliobolus sativum Fusarium culmorum Gibberella avenacea Pythium ultimum	Seed treatment	BBCH 00	1	-	0.03-0.06 kg as/tonne	0.012	-	-	-

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

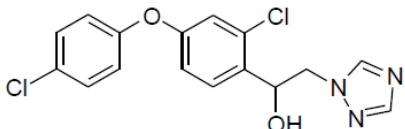
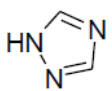
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

zRMS comments:

The dRR was prepared by Applicant. All comments and conclusions of the zRMS are presented in grey. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information is struck through and shaded for transparency. The corrected text is presented by yellow. The corrected after III RT in blue.

8.2 Metabolites considered in the assessment

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

Metabolite	Molar mass (g/mole)	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required
CGA-205375	350		Soil: 9.7% Water/Sediment: 11.6%	PEC _{gw} , PEC _{soil} , PEC _{sw/sed}
CGA 71019 (1,2,4-triazole)	69		Soil: 23.4% Water/Sediment: 9.6%	PEC _{gw} , PEC _{soil} , PEC _{sw/sed}

zRMS comments:

Information regarding difenoconazole metabolites provided in Table 8.2-1 is in line with data reported in EFSA Journal 2011;9(1):1967.

8.3 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.

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

The EU agreed kinetics end points for difenoconazole and its metabolites in aerobic soil are presented in the following tables.

Table 8.3-1: Summary of aerobic degradation rates for difenoconazole - laboratory studies

Soil name	Soil type	pH	Temp. (°C)	MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C/pF2	Chi ² (%)	Kinetic model	Evaluated at EU level y/n Reference
Not stated	Loam	7.2	20	40	111	368	111		SFO	Y EFSA Journal 2011;9(1):1967
Not stated	Sandy loam	5.0	20	40	123	409	123		SFO	
Not stated	Silt loam	7.2	20	48	235	>277	235		SFO	
Not stated	Loam	7.2	20	43	53	175	53		SFO	
Not stated	Sandy loam	7.4	20	40	149	496	136		SFO	
Not stated	Sandy loam/loamy sand	7.5	20	40	186	617	177		SFO	
Not stated	Silty clay loam	6.7	20	40	187	620	151		SFO	
Geometric mean:							130			
pH-dependency:							Not stated			

Table 8.3-1a: Summary of aerobic degradation rates for Difenoconazole - laboratory studies

Difenoconazole, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH	t.oC	MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) ² 20°C pF2/10kPa	Chi ² (%)	Kinetic model	Evaluated on EU level y/n/ Reference
-	Loam	7.2	20	40	104	345	64	0.999	SFO	y/ EFSA Journal 2011;9(1):1967
-	Loam	7.2	20	40	118	392	72	0.998		
Geomean loam (n=2)						111				
-	Sandy loam	5.0	20	40	123 ³	409	123	0.913	SFO	y/ EFSA Journal 2011;9(1):1967
-	Silt loam	7.2	20	48	456 ³	>>273	456	0.892		
-	Silt loam	7.2	30	48	175 ¹	>>178 ¹	-	0.977		
-	Silt loam	7.2	20	24	709 ^{1,3}	>>281 ¹	-	0.855		
-	Silt loam	7.2	20	48	345 ³	>>281	345	0.973		
-	Silt loam	7.2	10	48	602 ^{1,3}	>>281 ¹	-	0.952		
-	Silt loam	7.2	20	48	83	277	83	0.950		
Geomean silt loam (n=3)						235				
-	Loam	7.2	20	22	136 ¹	452 ¹	-	0.986	SFO	y/ EFSA Journal

Difenoconazole, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH	t.oC	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) ² 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
-	Loam	7.2	10	43	338 ^{1,3}	> 1000 ¹	-	0.993		2011;9(1):1967
-	Loam	7.2	20	43	53	175	53	0.995		
-	Loam sterile	7.2	20	43	>1000 ^{1,3}	>1000 ¹	-	-		
-	Sandy loam	7.4	20	40	149	496	136	0.977		
-	Sandy loam/loamy sand	7.5	20	40	186	617	177	0.939		
-	Silty clay loam	6.7	20	40	187	620	151	0.972		
Geometric mean (n=7)							130			
pH-dependency:							No			

¹ Values not included in the mean/median because they were obtained from test at 10/30°C, dry moisture or sterile conditions.

² In case the same soil was tested under standard conditions, the variations in temperature and moisture were not considered for mean/median values of normalized data

³ DT₅₀ value extrapolated beyond the durations of the study

zRMS comments:

The zRMS agrees with the selected endpoints. The geomeans were selected correctly and used instead of the arithmetic means for the DT₅₀.

Table 8.3-2: Summary of aerobic degradation rates for CGA 205375 - laboratory studies

Soil name	Soil type	pH	Temp. (°C)	MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C/pF2	Form. Fract	Chi ² (%)	Kinetic model	Evaluated at EU level y/n/ Reference
Not stated	Sandy loam	7.4	20	40	93	309	85	NC		SFO	Y EFSA Journal 2011;9(1):1967
Not stated	Sandy loam/loamy sand	7.5	20	40	83	275	79	NC		SFO	
Not stated	Silt loam	5.8	20	40	152	504	123	NC		SFO	
Geometric mean:							94				
pH-dependency:							Not stated				

NC = not calculated

Table 8.3-3: Summary of aerobic degradation rates for CGA 71019 (1,2,4-triazole) - laboratory studies

Soil name	Soil type	pH	Temp. (°C)	MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C/pF2	Form. Fract	Chi ² (%)	Kinetic model	Evaluated at EU level y/n Reference
Not stated	Sandy loam	6.4	20	40	6.3	21	5.0	NC		SFO	Y EFSA Journal 2011;9(1):1967
Not stated	Loamy sand	5.8	20	40	9.9	33	9.9	NC		SFO	
Not stated	Silt loam	6.7	20	40	12	41	8.2	NC		SFO	
Geometric mean:							7.4				
pH-dependency:							Not stated				

NC = not calculated

zRMS comments:

Soil degradation data presented in Tables 8.3-2 to 8.3-3 are in line with EU agreed endpoints presented in EFSA Journal 2011;9(1):1967. The Applicant did not presented aerobic degradation rates for CGA71019 (1,2,4-triazole) performed by CRD (UK) in January 2013.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

The EU agreed kinetics end points for difenoconazole and its metabolites in anaerobic soil are presented in the following table.

Table 8.3-4: Summary of anaerobic degradation rates for difenoconazole and its metabolites- laboratory studies

Soil name	Soil type	pH	Temp. (°C)	MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C/pF2	Chi² (%)	Kinetic model	Evaluated at EU level y/n Reference
Difenoconazole										Y EFSA Journal 2011;9(1):1967
Not stated	Loam	7.2	20	flooded	stable	stable	NA		NA	
CGA 205375										
Not stated	Silt loam	7.5	20	flooded	213	706	NA		SFO	
CGA 71019										
Not stated	Sandy loam/loamy sand	7.3	20	flooded	81	268	NA		SFO	

NA = not applicable

zRMS comments:

The information is in line with this reported in EFSA Journal 2011;9(1):1967.

8.4 Field studies (KCP 9.1.1.2)

Field studies with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

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

The EU agreed kinetics end points for difenoconazole in terrestrial field dissipation studies are presented in the following tables. No data are available for metabolites. Note that DegT₅₀ values (normalised to 20 °C/pF2) were not presented in the EFSA report.

Table 8.4-1: Summary of dissipation rates for difenoconazole - field studies

Location	Soil type	pH	Depth (cm)	DisT ₅₀ (d)	DisT ₉₀ (d)	Chi ² (%)	Kinetic model	Evaluated at EU level y/n Reference
Germany	Silt loam	7.4	0-20	160	532		SFO	Y EFSA Journal 2011;9(1):1967
Germany	Silt loam	6.6	0-10	20	68		SFO	
Germany	Loamy sand	6.2	0-10	59	195		SFO	
Germany	Silt loam	6.8	0-20	64	211		SFO	
Germany	Loamy sand	5.6	0-10	61	202		SFO	
Germany	Sandy loam	6.0	0-20	265	879		SFO	
Germany	Silt loam	6.0	0-20	242	802		SFO	
Germany	Silt loam	5.7	0-20	118	394		SFO	
Switzerland	Clay loam	7.3	0-10	83	277		SFO	
Maximum value:				265				
Geometric mean				92				Y EFSA Journal 2011;9(1):1967
pH-dependency:				No				

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

No accumulation of difenoconazole was observed in field studies conducted for up to 10 years at the following locations: Switzerland (one site, 10 years); N Italy (two sites, 4 years), UK (two sites, 3 years).

No accumulation observed after up to 10 years use under the following conditions: 10-yr study in Switzerland (sandy loam): 7 years appl. of 125 g/ha to wheat, 2 years appl. of 125 g/ha to rape and 1 year 3x125 g/ha to sugar beet. Taking crop interception (90% by wheat and sugar beet and 80% by rape, FOCUS GW) into account the “effective doses” would have been 12.5 g/ha for 7 years, 25 g/ha for 2 years and 37.5 g/ha for 1 year. 4-yr study in N Italy (sandy loam): Annual application to pome fruit at 250 g/ha. Assuming standard crop interception (50-65%, FOCUS GW) the annual “effective dose” would have been 87.5-125 g/ha. 4-yr study in N Italy (silt clay): Annual application to sugar beets at 202-241 g/ha. Assuming crop interception of 90% the “effective dose” would have been within 20-24 g/ha each year. 3-yr study in UK (sandy loam and clay): 3-yr appl. to winter wheat or bare ground, at 75 g/ha and

150 g/ha. Assuming 90% crop interception by wheat the net application rates would have been 7.5 and 15 g/ha. (this study considered as supplementary) (EFSA Journal 2011;9(1):1967).

Modelling endpoints

Normalised field aerobic degradation modelling endpoints for difenoconazole and metabolite CGA205375 are not available. Laboratory data were used instead.

8.5 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.

Table 8.5-1: Summary of soil adsorption/desorption for difenoconazole

Soil name	Soil type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated at EU level y/n Reference
Not stated	Sand	0.36	7.9	12.8	3870	0.74	Y EFSA Journal 2011;9(1):1967
Not stated	Sandy loam	1.98	7.8	63	3520	0.76	
Not stated	Silt loam	1.74	6.5	54.8	3470	0.85	
Not stated	Silty clay loam	0.67	6.9	47.2	7730	0.91	
Not stated	Clay	2.79	5.9	97.8	3470	0.89	
Not stated	Sand	0.52	6.5	2.1	400	0.80	
Not stated	Silt loam	0.58	7.5	35	5660	0.88	
Not stated	Sandy loam	0.58	8.5	11.5	1960	0.94	
Geometric mean:					2943		
Arithmetic mean:					3760	0.85	
pH-dependency:					No		

Table 8.5-2: Summary of soil adsorption/desorption for CGA 205375

Soil name	Soil type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated at EU level y/n Reference
Not stated	Loamy sand	2.17	5.7	118	5440	0.81	Y EFSA Journal 2011;9(1):1967
Not stated	Silty clay loam	1.16	6.6	45.5	3920	0.76	
Not stated	Clay	2.63	6.7	44.1	1680	0.76	
Not stated	Sandy loam	1.17	6.8	22.6	1930	0.72	
Not stated	Loam	1.22	7.6	23.6	1930	0.77	
Geometric mean:					2661		
Arithmetic mean:					2980	0.76	
pH-dependency:					No		

Table 8.5-3: Summary of soil adsorption/desorption for CGA 71019 1,2,4-triazole)

Soil name	Soil type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated at EU level y/n Reference
Not stated	Silty clay	0.7	8.8	0.83	120	0.90	Y EFSA Journal 2011;9(1):1967
Not stated	Clay loam	1.74	6.9	0.75	43	0.83	
Not stated	Silty clay loam	0.7	7	0.72	104	0.92	
Not stated	Sandy loam	0.81	6.9	0.72	89	1.02	
Geometric mean:					83		
Arithmetic mean:					89	0.92	
pH-dependency:					No		

zRMS comments:

Mobility information for difenoconazole and its metabolites presented in Tables 8.5-2 to 8.5-3 are in line with EFSA Journal 2011;9(1):1967.

8.5.1 Column leaching (KCP 9.1.2.1)

Difenoconazole did not move out of the zone of application in four soils following elution with 200 mm of water over two days.

8.5.2 Lysimeter studies (KCP 9.1.2.2)

No data submitted. Not required.

8.5.3 Field leaching studies (KCP 9.1.2.3)

No data submitted. Not required.

8.6 Degradation in 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.

Table 8.6-1: Summary of degradation of difenoconazole in water/sediment

Difenoconazole distribution (max. water = 88% after 0 days; max. sediment = 99.8 % after 42 days)												
Water/ sediment system	pH wat/ sed.	T (°C)	DegT50 tot syst. (d)	DegT90 tot syst. (d)	Kinetic Fit	DisT50 water (d)	DisT90 water (d)	Kinetic Fit	DisT50 sed. (d)	DisT90 sed. (d)	Kinetic Fit	Evaluated at EU level y/n Reference
Pond	-/6.9	20	324	>1000	SFO	1.0	3.3	SFO	NC	NC	NA	Y EFSA Journal 2011;9(1):1967
River	-/7.2	20	307	>1000	SFO	2.0	6.6	SFO	NC	NC	NA	
Geometric mean			315			1.1			NC			

NC = not calculated

NA = not applicable

Table 8.6-2: Summary of observed metabolites

CGA 205375 Water/sediment system	Max. in total water/sediment = 4.9 % after 127 days (pond), 11.6% after 90-183 days (river).	EFSA Journal 2011;9(1):1967
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Table 8.6-3: Summary of degradation of CGA 205375 in water/sediment (metabolite applied study)

Difenoconazole distribution (max. water = 97% after 0 days; max. sediment = 91 % after 62 days)												
Water/ sediment system	pH wat/ sed.	T (°C)	DegT50 tot syst. (d)	DegT90 tot syst. (d)	Kinetic Fit	DisT50 water (d)	DisT90 water (d)	Kinetic Fit	DisT50 sed. (d)	DisT90 sed. (d)	Kinetic Fit	Evaluated at EU level y/n Reference
Pond	8.0/ 7.1	20	630	>1000	SFO	1.4	4.7	SFO	NC	NC	NA	Y EFSA Journal 2011;9(1):1967
River	8.1/ 7.5	20	301	>1000	SFO	3.1	10.2	SFO	NC	NC	NA	
Geometric mean			435			2.1			NC			

NC = not calculated

NA = not applicable

Table 8.6-4: Summary of observed metabolites (from CGA 205375 applied study)

CGA 71019 1,2,4-triazole Water/sediment system	Max. in total water/sediment = 3.2 % after 148 days (pond), 14.1% after 148 days (river). Max. in water/sediment 9.6 % - worse case assumption calculated by RMS from CGA205375 water /sediment study	EFSA Journal 2011;9(1):1967
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8.7 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

8.7.1 Justification for new endpoints

The EU agreed endpoints were used (EFSA Journal 2011;9(1):1967).

8.7.2 Active substance(s) and relevant metabolite(s)

The relevant information related to application of the product are shown in the following table.

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

Use No.	1	2	4	7, 8, 9
Crop	Winter oilseed rape	Pome/stone fruit	Carrots	Leafy vegetables ^a
Application rate (g a.s./ha)	125	56.25	125	125
Number of apps/interval (d)	2 / 21	3 / 7	3 / 14	3 / 7
Crop growth stage (BBCH)	14-18	57-84	39-40	From 19
Crop interception (%)	40	60	60	25
Depth of soil layer relevant for plateau concentration (cm)	20	5	20	20

^a Cabbage, cauliflower, broccoli

The substance input parameters used for PEC_{soil} calculations are presented in the following table.

Table 8.7-2: Input parameter for difenoconazole and its metabolites for PEC_{soil} calculations

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT ₅₀ (days)	Value in accordance with EU endpoint y/n Reference
Difenoconazole	406	-	265 (longest field DT ₅₀ , SFO)	Y EFSA Journal 2011;9(1):1967 (CRD, 2014; EFSA 2018)
CGA 205375	350	11.9 (radiolabelled field)	152 (longest lab DT ₅₀ , SFO)	
CGA 71019	69	23.4 (lab. aerobic soil)	12.0 (longest lab DT ₅₀ , SFO) *DT50 = 11 d **DT50 = 346.6 d	

*DT50 = 11 d (CRD, 2014; EFSA 2018)

**DT50 = 346.6 d (CRD, 2014; EFSA 2018)

The PEC_{soil} values for difenoconazole and its metabolites are presented in the following tables. A soil depth of 5 cm and a soil density of 1.5 g/cm³ were used for all calculations. For calculations of plateau concentrations following multiple years of applications, a soil depth of 20 cm was used for all field crops (to account for tillage) and a soil depth of 5 cm was used for permanent crops (no tillage). The PEC_{accumulation} value was calculated by adding the initial PEC_{soil} value to the minimum plateau value (*i.e.* the PEC_{soil} immediately before each year's application).

Table 8.7-3: PEC_{soil} for difenoconazole following application to winter oilseed rape

PEC _{soil} (mg/kg)		Oilseed rape (2 x 125 g/ha, 21 d interval, 40% intercept)			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.100	-	0.195	-
Short term	24h	0.100	0.100	0.194	0.194
	2d	0.099	0.100	0.194	0.194
	4d	0.099	0.099	0.193	0.194
Long term	7d	0.098	0.099	0.191	0.193
	14d	0.096	0.098	0.188	0.191
	21d	0.095	0.097	0.184	0.189
	28d	0.093	0.096	0.181	0.188
	50d	0.088	0.094	0.171	0.182
	100d	0.077	0.088	0.150	0.171
Plateau conc. (20 cm) after year 6		-	-	0.079	-
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		-	-	0.227 (0.195 + 0.032)	-

Table 8.7-4: PEC_{soil} for difenoconazole following application to pome/stone fruit

PEC _{soil} (mg/kg)		Pome/stone fruit (3 x 56.25 g/ha, 7 d interval, 60% intercept)			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.030	-	0.088	-
Short term	24h	0.030	0.030	0.088	0.088
	2d	0.030	0.030	0.088	0.088
	4d	0.030	0.030	0.087	0.088
Long term	7d	0.029	0.030	0.087	0.088
	14d	0.029	0.029	0.085	0.087
	21d	0.028	0.029	0.084	0.086
	28d	0.028	0.029	0.082	0.085
	50d	0.026	0.028	0.078	0.083
	100d	0.023	0.026	0.068	0.078
Plateau conc. (5 cm) after year 7		-	-	0.144	-
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		-	-	0.145 (0.088 + 0.057)	-

Table 8.7-5: PEC_{soil} for difenoconazole following application to carrots

PEC _{soil} (mg/kg)		Carrots (3 x 125 g/ha, 14 d interval, 60% intercept)	
		Single application	Multiple applications

		Actual	TWA	Actual	TWA
Initial		0.067	-	0.193	-
Short term	24h	0.066	0.067	0.192	0.193
	2d	0.066	0.066	0.192	0.192
	4d	0.066	0.066	0.191	0.192
Long term	7d	0.065	0.066	0.189	0.191
	14d	0.064	0.065	0.186	0.189
	21d	0.063	0.065	0.183	0.188
	28d	0.062	0.064	0.179	0.186
	50d	0.058	0.062	0.169	0.181
	100d	0.051	0.059	0.148	0.170
Plateau conc. (20 cm) after year 5		-	-	0.078	-
$\text{PEC}_{\text{accumulation}} = (\text{PEC}_{\text{act}} + \text{PEC}_{\text{soil plateau}})$		-	-	0.225 (0.193 + 0.032)	-

Table 8.7-6: PEC_{soil} for difenoconazole following application to leafy vegetables

PEC _{soil} (mg/kg)		Leafy vegetables (3 x 125 g/ha, 7 d interval, 25% intercept)			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.125	-	0.368	-
Short term	24h	0.125	0.125	0.367	0.368
	2d	0.124	0.125	0.366	0.367
	4d	0.124	0.124	0.364	0.366
Long term	7d	0.123	0.124	0.362	0.365
	14d	0.121	0.123	0.355	0.362
	21d	0.118	0.122	0.349	0.358
	28d	0.116	0.121	0.342	0.355
	50d	0.110	0.117	0.323	0.345
	100d	0.096	0.110	0.283	0.324
Plateau conc. (20 cm) after year 8		-	-	0.150	-
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		-	-	0.428 (0.368 + 0.060)	-

PEC_{soil} for metabolites

The maximum PEC_{soil} values for metabolites were calculated from the maximum PEC_{soil} for the parent active substance by adjusting the value for molecular weight difference and maximum percentage of metabolite in soil.

Use	Max. PEC _{soil} for parent (mg/kg)	Maximum PEC _{soil} (mg/kg)			
		CGA-205375	CGA-71019 (1,2,4-triazole) EFSA Journal 2011;9(1):1967	CGA-71019* (1,2,4-triazole)	CGA-71019** (1,2,4-triazole)
Oilseed rape (2 x 125 g/ha, 21 d int., 40% intercept)	0.227	0.023	0.009	0.127	0.196
Pome/stone fruit (3 x 56.25 g/ha, 7 d int., 60% intercept)	0.145	0.015	0.006	0.085	0.125
Carrots (3 x 125 g/ha, 14 d int., 60% intercept)	0.225	0.023	0.009	0.137	0.197
Leafy veg. (3 x 125 g/ha, 7 d int., 25% intercept)	0.428	0.044	0.017	0.257	0.370

*DT50 = 11 d (CRD, 2014; EFSA 2018)

**DT50 = 346.6 d (CRD, 2014; EFSA 2018)

8.7.2.1 PEC_{soil} for the formulated product

The maximum single application rate (in g/ha) for the formulation IN005B1570 was calculated from the

density of 1.1401 g/mL. A soil depth of 5 cm and a bulk density of 1.5 g/cm³ were assumed. Time-dependent PEC_{soil} values are not required to be calculated for the formulation since it is considered to be rapidly separated into its individual components by transport and dissipation processes.

Table 8.7-8: PEC_{soil} for the formulation IN005B1570

Formulation	Crop	Application rate (L/ha)	Application rate (g FP/ha)	Interception (%)	PEC _{act} (mg/kg)
IN005B1570	Winter OSR	0.5	570.1	40	0.456
	Pome/stone fruit	0.225	256.5	60	0.137
	Carrots	0.5	570.1	60	0.304
	Leafy veg.	0.5	570.1	25	0.570

zRMS comments:

zRMS agrees with the submitted calculation of PECs for difenconazole and its metabolites. The used endpoints were agreed at the EU level: DT₅₀ for difenconazole and its metabolite CGA205375 (EFSA, 2011) and for CGA71019/1,2,4-triazole (EFSA, 2013) and [CRD, 2014; EFSA 2018](#).

The PECs were assessed in accordance with proposed pattern use in GAP.

These values will be used in further risk assessment.

Use	Max. PEC _{soil} for parent (mg/kg)	Maximum PEC _{soil} (mg/kg)			
		CGA-205375	CGA-71019 (1,2,4-triazole) EFSA Journal 2011;9(1):1967	CGA-71019* (1,2,4-triazole) DT50 = 11 d (CRD, 2014; EFSA 2018)	CGA-71019** (1,2,4-triazole) DT50 = 346.6 d (CRD, 2014; EFSA 2018)
Oilseed rape (2 x 125 g/ha, 21 d int., 40% intercept)	0.227	0.023	0.009	0.127	0.196
Pome/stone fruit (3 x 56.25 g/ha, 7 d int., 60% intercept)	0.145	0.015	0.006	0.085	0.125
Carrots (3 x 125 g/ha, 14 d int., 60% intercept)	0.225	0.023	0.009	0.137	0.197
Leafy veg. (3 x 125 g/ha, 7 d int., 25% intercept)	0.428	0.044	0.017	0.257	0.370

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

8.8.1 Justification for new endpoints

No new active substance data have been submitted as part of this application for authorisation/re-registration.

8.8.2 Active substance and relevant metabolites (KCP 9.2.4.1)

The PEC_{GW} values for difenconazole and its metabolites were calculated using FOCUS modelling. For each crop, all relevant scenarios were included including the following scenarios that are relevant for Central Europe: Châteaudun, Hamburg, Kremsmünster, Okehampton, Piacenza and Porto.

The application data for difenconazole are shown in the following table.

Table 8.8-1: Input parameters related to application for PEC_{gw} calculations

Use No.	1	2	4	5 - 11
Crop	Winter oilseed rape	Pome/stone fruit	Carrots	Cabbage ^a
Application rate (g as/ha)	125	56.25	125	125
Number of apps/interval (d)	2 / 21	3 / 7	3 / 14	3 / 7
Crop growth stage	(a) Autumn (BBCH 14-18) (b) Spring (BBCH 30-69)	BBCH 57-84	BBCH 39-40	From BBCH 19
Crop interception (%)	40	60	60	25
Soil deposition rate (g/ha)	75	22.5	50	93.75
Frequency of application	Every year	Every year	Every year	Every year
Models used for calculation	FOCUS PEARL v.5.5.5, FOCUS PELMO v.6.6.4, FOCUS MACRO v.5.5.4			

^a Also covers cauliflower, broccoli (leafy vegetables)

To define the application windows for Step 3 modelling, the AppDate (v3.06) software (M. Klein, 2019. Fraunhofer IME, Germany) was used, which calculates application dates based on growth development stages (BBCH) of each crop in the different FOCUS groundwater and surface water scenarios.

Table 8.8-2: Application dates used for groundwater risk assessment

Scenario	Application dates			
	Winter oilseed rape (2 x 125 g/ha, 21d, BBCH 14 or 30) ^a	Pome fruit (3 x 56.25 g/ha, 7d, BBCH 57)	Carrots (3 x 125 g/ha, 14d, BBCH 39)	Cabbage (3 x 125 g/ha, 7d, BBCH 19)
Châteaudun	(a) 14/09, 05/10 (b) 11/03, 01/04	12/05, 19/05, 26/05	24/04, 08/05, 22/05	27/05, 03/06, 10/06
Hamburg	(a) 09/09, 30/09 (b) 18/04, 09/05	06/06, 13/06, 20/06	24/04, 08/05, 22/05	27/05, 03/06, 10/06
Jokioinen	NR	20/05, 27/05, 03/06	08/09, 22/09, 06/10	25/08, 01/09, 08/09
Kremsmünster	(a) 09/09, 30/09 (b) 15/04, 06/05	06/06, 13/06, 20/06	24/04, 08/05, 22/05	27/05, 03/06, 10/06
Okehampton	(a) 21/08, 11/09 (b) 09/04, 30/04	20/05, 27/05, 03/06	NR	NR
Piacenza	(a) 12/10, 02/11 (b) 07/03, 28/03	12/05, 19/05, 26/05	NR	NR
Porto	(a) 30/09, 21/10 (b) 01/01, 22/01	27/05, 03/06, 10/06	04/05, 18/05, 01/06	08/05, 15/05, 22/05
Sevilla	NR	06/05, 13/05, 20/05	NR	25/04, 02/05, 09/05
Thiva	NR	27/05, 03/06, 10/06	19/04, 03/05, 17/05	26/09, 03/10, 10/10

^a Dates are shown for (a) BBCH 14 in autumn and (b) BBCH 30 in spring

The substance input parameters for the parent active substance and its metabolites are shown in the following table.

Table 8.8-3: Input parameters related to difenoconazole and its metabolites for PEC_{gw} calculations

Compound	Difenoconazole	CGA 205375	CGA 71019	Value in accordance with EU endpoint y/n Reference*
Molecular weight (g/mol)	406	350	69	Y
Water solubility (mg/L)	15 (25°C)	100 (estimate)	730	Y
Saturated vapour pressure (Pa)	3.32 x 10 ⁻⁸ (25°C)	0 (no data, default)	0 (no data, default)	Y
DT ₅₀ in soil (d) at pF2/20°C	130 (geomean lab, n = 7)	94 (geomean lab, n = 3)	7.4 (geomean lab, n = 3)	Y

Compound	Difenoconazole	CGA 205375	CGA 71019	Value in accordance with EU endpoint y/n Reference*
			The modelling endpoints for 1,2,4-triazole with the DFOP fast-phase DT ₅₀ of 1.68d and the slow-phase DT ₅₀ of 60.5d were used to calculations.	CRD, 2014; EFSA 2018
K _{oc} /K _{om} (mL/g)	2943 / 1707 (geomean, n = 8)	2661 / 1544 (geomean, n = 5)	83 / 48 (geomean, n = 4)	N (geomean values used according to EFSA guidance)
1/n	0.85 (arithmetic mean, n = 8)	0.76 (arithmetic mean, n = 5)	0.92 (arithmetic mean, n = 4)	Y
Plant uptake factor	0	0	0	Y
Formation fraction	NA	1 ^a	1 ^a	Y

^a default worst case

The 80th percentile PEC_{gw} values for difenoconazole and its metabolites calculated using FOCUS PELMO and FOCUS PEARL are presented in the following tables. FOCUS MACRO results for the Châteaudun scenario are presented later in this section.

Table 8.8-4: PEC_{gw} for difenoconazole and its metabolites following application to winter oilseed rape (FOCUS PELMO 6.6.4 and FOCUS PEARL v.5.5.5)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)					
		Difenoconazole		CGA 205375		CGA 71019	
		PELMO	PEARL	PELMO	PEARL	PELMO	PEARL
Winter oilseed rape (autumn app, 2 x 125 g/ha, 21d, BBCH 14)	Châteaudun	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001
	Hamburg	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001
	Kremsmünster	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001
	Okehampton	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001
	Piacenza	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001
	Porto	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001
Winter oilseed rape (spring app,	Châteaudun	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001
	Hamburg	0.000	0.000	0.000	0.000	0.000	0.000

2 x 125 g/ha, 21d, BBCH 30)		<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001
	Okehampton	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001
	Piacenza	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001
	Porto	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001

Table 8.8-5: PEC_{gw} for difenoconazole and its metabolites following application to pome fruit (FOCUS PELMO 6.6.4 and FOCUS PEARL v.5.5.5)

[illegible]

Table 8.8-6: PEC_{gw} for difenoconazole and its metabolites following application to carrots (FOCUS PELMO 6.6.4 and FOCUS PEARL v.5.5.5)

[illegible]

	Jokioinen	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001
	Kremsmünster	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001
	Porto	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001
	Thiva	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001

Table 8.8-7: PEC_{gw} for difenoconazole and its metabolites following application to cabbages (FOCUS PELMO 6.6.4 and FOCUS PEARL v.5.5.5)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)					
		Difenoconazole		CGA 205375		CGA 71019	
		PELMO	PEARL	PELMO	PEARL	PELMO	PEARL
Cabbage (3 x 125 g/ha, 7d, BBCH 19)	Châteaudun	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001
	Hamburg	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001
	Jokioinen	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001
	Kremsmünster	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001
	Porto	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001
	Sevilla	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001
	Thiva	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001	0.000 <0.001

The 80th percentile PEC_{gw} values for difenoconazole and its metabolites calculated using FOCUS MACRO with the Châteaudun scenario are presented in the following table.

Table 8.8-8: PEC_{gw} for difenoconazole and its metabolites calculated with FOCUS MACRO v.5.5.4 with the Châteaudun scenario

Crop	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
	Difenoconazole	CGA 205375	CGA 71019
Winter OSR (2 x 125 g/ha, 21d, BBCH 14, autumn)	0.000 <0.001	0.000 <0.001	0.000 <0.001
Winter OSR (2 x 125 g/ha, 21d, BBCH 30, spring)	0.000 <0.001	0.000 <0.001	0.000 <0.001
Pome fruit (3 x 56.25 g/ha, 7d, BBCH 57)	0.000 <0.001	0.000 <0.001	0.000 <0.001
Carrots (3 x 125 g/ha, 14d, BBCH 39)	0.000 <0.001	0.000 <0.001	0.000 <0.001

Cabbage (3 x 125 g/ha, 7d, BBCH 19)	0.000 <0.001	0.000 <0.001	0.000 <0.001
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zRMS comments:

The zRMS agrees with PEC_{gw} calculations performed by the Applicant.

The input parameters used in calculations were taken from the endpoints available in the EFSA conclusion on Difenconazole EFSA Journal 2011;9(1):1967. The geometric mean K_{foc} values are lower than arithmetic mean values and represent thus worst case in terms of the leaching potential, and consideration of geometric mean K_{foc} values are in line with current EFSA recommendations.

In simulations PUF value of 0 was assumed for all substances and interception according to the proposed BBCH of crops (guidance 2014).

The PEC_{gw} values (µ/L) of metabolite CGA 71019 (1,2,4-triazole) recalculated by RMS for all crop in proposed GAP confirmed that the limit values of 0.1 µg/L have not been exceeded. The modelling endpoints for 1,2,4-triazole with the DFOP fast-phase DT₅₀ of 1.68d and the slow-phase DT₅₀ of 60.5d were used to confirmation of calculations.

The 80th percentile groundwater concentrations PEC_{gw} for difenconazole and its metabolites are less than trigger value 0.1 µg/L.

No risk of groundwater contamination with difenconazole and its metabolites are expected when the product is applied according to Good Agricultural Practice.

Nevertheless, additional simulations may be required by the SMS that do not accept calculations performed using FOCUS models.

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

8.9.1 Justification for new endpoints

No new active substance data have been submitted as part of this application for authorisation/re-registration.

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

The PEC_{sw} and PEC_{sed} values for difenconazole and its metabolites were calculated using FOCUS modelling. A separate report was not produced and all inputs and procedures are described below.

FOCUS Step 1-2 in calculations were conducted for difenconazole and its two major metabolites. Further assessment at Step 3 and 4 was required for parent difenconazole only. The application data for difenconazole are shown in the following table.

Table 8.9-1: Input parameters related to application for PEC_{sw/sed} calculations

Use No.	1	2	4	5 - 11
Crop	Winter oilseed rape	Pome/stone fruit, early	Carrots	Leafy vegetables ^a
Application rate (g as/ha)	125	56.25	125	125

Number of apps/interval (d)	2 / 21	3 / 7	3 / 14	3 / 7
Crop growth stage (BBCH)	(a) Autumn (14-18) (b) Spring (30-69)	57-84	39-40	From 19
Application window (Step 1-2)	(a) Oct-Feb (b) Mar-May	Mar-May and Jun-Sep	Mar-May and Jun-Sep	Mar-May and Jun-Sep
Application method	Ground spray	Air blast	Ground spray	Ground spray
CAM (Chemical application method)	2 (foliar)	2 (foliar)	2 (foliar)	2 (foliar)
Soil depth (cm)	4	4	4	4
Models used for calculation	FOCUS SWASH v3.1; FOCUS PRZM v3.3.1; FOCUS MACRO v5.5.3; FOCUS TOXWA v3.3.1			

^a Cabbage, cauliflower, broccoli.

Note that for autumn applications to oilseed rape, the product is applied **either** as a single application of 125 g/ha **or** as a split application of 2 x 62.5 g/ha (with 21-day interval). A single application of 125 g/ha in autumn can be followed by a second application of 125 g/ha in spring.

To define the application windows for Step 3 modelling, the AppDate (v3.06) software (M. Klein, 2019. Fraunhofer IME, Germany) was used, which calculates application dates based on growth development stages (BBCH) of each crop in the different FOCUS groundwater and surface water scenarios.

Table 8.9-2: FOCUS Step 3 application data for PEC_{sw/sed} calculations for winter oilseed rape

Crop	Scenario	Application window used in modelling (Julian day)	
		Autumn application (BBCH 14)	Spring application (BBCH 30)
Winter OSR (1 x 125 g/ha in spring or autumn) or 2 x 62.5 g/ha in autumn, 21 d interval)	D2	22 Sep – 12 Nov (265 – 316)	10 Mar – 9 Apr (69 – 99)
	D3	9 Sep – 30 Oct (252 – 303)	21 Feb – 23 Mar (52 – 82)
	D4	10 Sep – 31 Oct (253 – 304)	1 Mar – 31 Mar (60 – 90)
	D5	27 Sep – 17 Nov (270 – 321)	1 Mar – 31 Mar (60 – 90)
	R1	11 Sep – 1 Nov (254 – 305)	15 Apr – 15 May (105 – 135)
	R3	12 Oct – 2 Dec (285 – 336)	7 Mar – 6 Apr (66 – 96)

Table 8.9-3: FOCUS Step 3 application data for PEC_{sw/sed} calculations for pome/stone fruit

Crop	Scenario	Application window used in modelling (Julian day)
Pome fruit (3 x 56.25 g/ha, 7 d interval, BBCH 57)	D3	6 Jun – 20 Jul (157 – 201)
	D4	11 Jun – 25 Jul (162 – 206)
	D5	12 May – 25 Jun (132 – 176)
	R1	6 Jun – 20 Jul (157 – 201)
	R2	16 Jun – 30 Jul (167 – 211)
	R3	12 May – 25 Jun (132 – 176)
	R4	6 May – 19 Jun (126 – 170)

Table 8.9-4: FOCUS Step 3 application data for $PEC_{sw/sed}$ calculations for carrots (FOCUS crop root vegetables)

Crop	Scenario	Application window used in modelling (Julian day)
Root vegetables (3 x 125 g/ha, 14 d interval, BBCH 39)	D3	4 Jun – 1 Aug (155 – 213)
	D6	2 Mar – 29 Apr (61 – 119)
	R1	30 May – 27 Jul (150 – 208)
	R2	20 Mar – 17 May (79 – 137)
	R3	2 Mar – 29 Apr (61 – 119)
	R4	2 Mar – 29 Apr (61 – 119)

Note that for carrots, the application window selected by AppDate resulted in the last application being made after the harvest date. Therefore, the window was amended so that the last possible application, based on the PHI stated in the GAP, was 14 days pre-harvest.

Table 8.9-5: FOCUS Step 3 application data for $PEC_{sw/sed}$ calculations for leafy vegetables

Crop	Scenario	Application window used in modelling (Julian day)
Leafy vegetables (3 x 125 g/ha, 7 d interval, BBCH 19)	D3	1 Jun – 15 Jul (152 – 196)
	D4	13 Jul – 26 Aug (194 – 238)
	D6	26 Sep – 9 Nov (269 – 313)
	R1	27 May – 10 Jul (147 – 191)
	R2	8 May – 21 Jun (128 – 172)
	R3	17 Apr – 31 May (107 – 151)*
	R4	17 Apr – 31 May (107 – 151)*

* Application window moved back 8 days to ensure that the last application was before harvest of the crop

The substance input parameters for the parent active substance and its metabolites are shown in the following table. If available, the agreed EFSA end points were selected. For sorption inputs, the geometric mean K_{oc} values were used (as recommended in current EFSA guidance), rather than the arithmetic mean values stated in the EFSA end points.

Because the K_{OC} values for difenoconazole and the CGA 205375 metabolite are greater than 2000 mL/g, the whole system water/sediment DT_{50} values were used for sediment and a default of 1000 days for water (as recommended in current EFSA guidance).

Table 8.9-6: Input parameters for difenoconazole and its metabolites for $PEC_{sw/sed}$ calculations (Step 1/2 and 3/4)

Compound	Difenoconazole	CGA 205375	CGA 71019	Value in accordance with EU endpoint y/n Reference
Molecular weight (g/mol)	406	350	69	Y
Water solubility (mg/L)	15 (25°C)	100 (estimate)	730	Y
Saturated vapour pressure (Pa)	3.32×10^{-8} (25°C)	0 (no data, default)	0 (no data, default)	Y
Diff. coeff. in water (m ² /d)	4.3×10^{-5}	Not required	Not required	Default
Diff. coeff. in air (m ² /d)	0.43	Not required	Not required	Default
K_{oc}/K_{om} (mL/g)	2943 / 1707 (geomean, n = 8)	2661 / 1544 (geomean, n = 5)	83 / 48 (geomean, n = 4)	N (geomean values used according to EFSA guidance)
1/n	0.85 (arithmetic mean, n = 8)	0.76 (arithmetic mean, n = 5)	0.92 (arithmetic mean, n = 4)	Y
Plant uptake factor	0	Not required	Not required	Y
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	Not required	Not required	Y
DT_{50} in soil (d) at pF2/20°C	130 (geomean lab, n = 7)	94 (geomean lab, n = 3)	7.4 (geomean lab, n = 3)	Y

Compound	Difenoconazole	CGA 205375	CGA 71019	Value in accordance with EU endpoint y/n Reference
			The modelling endpoints for 1,2,4-triazole with the DFOP fast-phase DT ₅₀ of 1.68d and the slow-phase DT ₅₀ of 60.5d were used to calculations.	CRD, 2014; EFSA 2018
DT _{50,water} (d)	1000 ^a (default)	1000 ^a (default)	1000 ^b (default)	Y
DT _{50,sed} (d)	315 (geomean whole system value, n = 2)	435 (geomean whole system value, n = 2)	1000 ^b (default)	Y
DT _{50,whole system} (d)	315 (geomean whole system value, n = 2)	435 (geomean whole system value, n = 2)	1000 ^b (default)	Y
Maximum occurrence (%)	NA	Soil: 9.7 Water/sediment: 11.6	Soil: 23.4 Water/sediment: 9.6	Y

^a default value for non-degrading compartment

^b default value (no data)

NA = not applicable

Difenoconazole: FOCUS Step 1 and 2 results

The results of the FOCUS Step 1-2 modelling for parent difenoconazole are presented in the following tables.

Table 8.9-7: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for difenoconazole following application to winter oilseed rape (2 x 125 g/ha, 21-day interval)

FOCUS Step	Multiple application		Single application	
	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)
Step 1	19.22	498.1	-	-
Step 2: N. Europe, Oct-Feb ^a	5.259	150.0	2.805	79.78
Step 2: N. Europe, Mar – May ^a	2.435	67.10	1.314	36.00
Step 2: S. Europe, Oct-Feb and Mar-May ^a	4.318	122.4	2.308	65.19

^a minimal crop cover (40% intercept)

Table 8.9-8: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for difenoconazole following application to pome/stone fruit - early application (3 x 56.5 g/ha, 7-day interval)

FOCUS Step	Multiple application		Single application	
	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)
Step 1	27.97	435.3	-	-
Step 2: N. Europe, Mar – May ^a	6.967	117.3	5.499	45.77
Step 2: N. Europe, Jun-Sep ^b	6.967	101.5	5.499	40.27
Step 2: S. Europe, Mar-May ^a	6.967	155.5	5.499	58.96
Step 2: S. Europe, Jun-Sep ^b	6.967	112.6	5.499	44.12

^a average crop cover (40% intercept)

^b full canopy (65% intercept)

Table 8.9-9: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for difenoconazole following application to carrots (3 x 125 g/ha, 14-day interval)

FOCUS Step	Multiple application		Single application	
	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)
Step 1	28.83	747.1	-	-
Step 2: N. Europe, Mar – May ^a	2.993	82.47	1.150	31.13
Step 2: N. Europe, Jun-Sep ^b	2.068	55.33	1.150	21.40
Step 2: S. Europe, Mar-May ^a	5.303	150.3	1.977	55.46
Step 2: S. Europe, Jun-Sep ^b	2.762	75.69	1.150	28.70

^a average crop cover (50% intercept)

^b full canopy (70% intercept)

Table 8.9-10: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for difenoconazole following application to leafy vegetables (3 x 125 g/ha, 7-day interval)

FOCUS Step	Multiple application		Single application	
	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)
Step 1	28.83	766.0	-	-
Step 2: N. Europe, Mar – May ^a	4.283	120.3	1.563	43.30
Step 2: N. Europe, Jun-Sep ^b	3.565	99.20	1.314	36.00
Step 2: S. Europe, Mar-May ^a	7.876	225.8	2.805	79.78
Step 2: S. Europe, Jun-Sep ^b	5.002	141.4	1.811	50.59

^a minimal crop cover (25% intercept)

^b average crop cover (40% intercept)

Difenoconazole: FOCUS Step 3 results

The results of the FOCUS Step 3 modelling for difenoconazole are presented in the following tables. In addition to multiple applications, Step 3 simulations were conducted with single applications to each crop, since this results in higher drift deposition due to the use of a higher percentile drift input. The FOCUS scenarios that are relevant to the EU Central Zone are D3, D4, D5, R1, R3 and R4. In the following tables, all available scenarios for each crop are presented but those that are not relevant for the Central Zone are shaded grey.

Table 8.9-11: FOCUS Step 3 PEC_{sw} and PEC_{sed} for difenoconazole following application to winter oilseed rape (1 x 125 g/ha or 2 x 62.5 g/ha, 21-day interval, autumn application)

FOCUS scenario	Water body	Max PEC _{sw} (µg/L)*		Dominant entry route	21d- PEC _{sw, tva} (µg/L)	Max PEC _{sed} (µg/kg)
		<u>Multiple^a</u>	<u>Single^b</u>			
D2	ditch	0.362	0.810	Drift	0.408	3.544
D2	stream	0.309	0.712	Drift	0.346	2.822
D3	ditch	0.346	0.790	Drift	0.092	0.837
D4	pond	0.018	0.027	Drift	0.022	0.377
D4	stream	0.294	0.681	Drift	0.014	0.149
D5	pond	0.018	0.027	Drift	0.022	0.345
D5	stream	0.317	0.734	Drift	0.020	0.210
R1	pond	0.049	0.048	Runoff	0.042	1.156
R1	stream	0.239	0.520	Drift	0.020	1.086
R3	stream	0.314	0.728	Drift	0.039	4.352

* Values exceeding the RAC of 0.36 µg/L are shown in **bold**

Shaded scenarios are not relevant for Central Zone

^a application rate = 2 x 62.5 g/ha ^b application rate = 1 x 125 g/ha

Table 8.9-12: FOCUS Step 3 PEC_{sw} and PEC_{sed} for difenoconazole following application to winter oilseed rape (1 x 125 g/ha in autumn + 1 x 125 g/ha in spring)

FOCUS scenario	Water body	Max PEC _{sw} (µg/L)*		Dominant entry route	21d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
		<u>Multiple</u>	<u>Single^a</u>			
D2	ditch	0.731	0.798	Drift	0.395	4.470
D2	stream	0.624	0.709	Drift	0.315	3.098
D3	ditch	0.690	0.785	Drift	0.080	0.784
D4	pond	0.026	0.027	Drift	0.022	0.571
D4	stream	0.589	0.623	Drift	0.012	0.133
D5	pond	0.026	0.027	Drift	0.022	0.503
D5	stream	0.635	0.627	Drift	0.017	0.184
R1	pond	0.057	0.033	Runoff	0.051	1.696
R1	stream	0.447	0.517	Drift	0.031	2.270
R3	stream	0.629	0.727	Drift	0.039	4.433

* Values exceeding the RAC of 0.36 µg/L are shown in **bold**

Shaded scenarios are not relevant for Central Zone

^a single application in spring (for single application in autumn see Table 8.9-)

Table 8.9-13: FOCUS Step 3 PEC_{sw} and PEC_{sed} for difenoconazole following application to pome/stone fruit - early application (3 x 56.5 g/ha, 7-d interval)

FOCUS scenario	Water body	Max PEC _{sw} (µg/L)*		Dominant entry route	21d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
		<u>Multiple</u>	<u>Single</u>			
D3	ditch	3.543	4.357	Drift	0.824	7.587
D4	pond	0.544	0.264	Drift	0.474	6.627
D4	stream	3.703	4.622	Drift	0.153	1.749
D5	pond	0.525	0.264	Drift	0.464	6.934
D5	stream	3.995	4.992	Drift	0.218	2.288
R1	pond	0.490	0.264	Drift	0.422	5.829
R1	stream	2.831	3.541	Drift	0.079	1.534
R2	stream	3.796	4.748	Drift	0.058	0.913
R3	stream	3.992	4.957	Drift	0.107	1.959
R4	stream	2.831	3.461	Drift	0.052	0.998

* Values exceeding the RAC of 0.36 µg/L are shown in **bold**

Shaded scenarios are not relevant for Central Zone

Table 8.9-14: FOCUS Step 3 PEC_{sw} and PEC_{sed} for difenoconazole following application to carrots (3 x 125 g/ha, 14-d interval)

FOCUS scenario	Water body	Max PEC _{sw} (µg/L)*		Dominant entry route	21d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
		<u>Multiple</u>	<u>Single</u>			
D3	ditch	0.575	0.787	Drift	0.055	0.782
D6	ditch	0.573	0.777	Drift	0.042	0.424
R1	pond	0.180	0.076	Runoff	0.164	5.149
R1	stream	0.545	0.518	Runoff	0.078	12.47
R2	stream	0.506	0.687	Drift	0.018	50.20
R3	stream	0.688	0.733	Drift	0.084	4.757
R4	stream	1.136	0.517	Runoff	0.209	10.84

* Values exceeding the RAC of 0.36 µg/L are shown in **bold**

Shaded scenarios are not relevant for Central Zone

Table 8.9-15: FOCUS Step 3 PEC_{sw} and PEC_{sed} for difenoconazole following application to leafy vegetables (3 x 125 g/ha, 7-d interval)

FOCUS scenario	Water body	Max PEC _{sw} (µg/L)*		Dominant entry route	21d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
		<u>Multiple</u>	<u>Single</u>			
D3	ditch	0.575	0.788	Drift	0.087	0.877
D4	pond	0.042	0.027	Drift	0.035	0.765
D4	stream	0.436	0.601	Drift	0.014	0.143
D6	ditch	0.640	0.779	Drainage	0.047	0.435
R1	pond	0.318	0.092	Runoff	0.300	8.377
R1	stream	0.554	0.520	Runoff	0.078	55.76
R2	stream	0.506	0.698	Drift	0.017	48.12
R3	stream	0.704	0.734	Drift	0.080	44.54
R4	stream	1.097	0.520	Runoff	0.225	11.52

* Values exceeding the RAC of 0.36 µg/L are shown in **bold**
Shaded scenarios are not relevant for Central Zone

Difenoconazole: FOCUS Step 4 results

The results of the FOCUS Step 4 modelling for difenoconazole are presented in the following tables.

Table 8.9-16: FOCUS Step 4 PEC_{sw} for difenoconazole following application to winter oilseed rape (1 x 125 g/ha or 2 x 62.5 g/ha, 21-day interval, autumn application)

Vegetative strip:		None					
No spray buffer:		5 m					
No. applications:		Multiple (2 x 62.5 g/ha)			Single (1 x 125 g/ha)		
Scenario	Water body	Max PEC _{sw} (µg/L)*	Entry route	Max PEC _{sed} (µg/kg)	Max PEC _{sw} (µg/L)*	Entry route	Max PEC _{sed} (µg/kg)
D2	ditch	0.189	Drainage	1.242	0.228	Drift	1.434
D2	stream	0.120	Drainage	0.604	0.262	Drift	1.174
D3	ditch	0.090	Drift	0.156	0.214	Drift	0.231
D4	pond	0.015	Drift	0.289	0.023	Drift	0.339
D4	stream	0.104	Drift	0.052	0.248	Drift	0.054
D5	pond	0.015	Drift	0.230	0.023	Drift	0.301
D5	stream	0.112	Drift	0.051	0.268	Drift	0.077
R1	pond	0.049	Runoff	1.130	0.048	Runoff	1.122
R1	stream	0.239	Runoff	1.078	0.230	Runoff	0.953
R3	stream	0.247	Runoff	4.346	0.270	Runoff	3.537

* Values exceeding the RAC of 0.36 µg/L are shown in **bold**
Shaded scenarios are not relevant for Central Zone

Table 8.9-17: FOCUS Step 4 PEC_{sw} for difenoconazole following application to winter oilseed rape (1 x 125 g/ha in autumn + 1 x 125 g/ha in spring) – 5 m spray buffer

Vegetative strip:		None				
No spray buffer:		5 m				
Scenario	Water body	Max PEC _{sw} (µg/L)*		Entry route	Max PEC _{sed} (µg/kg)	
		Multiple	Single ^a		Multiple	Single ^a
D2	ditch	0.462	0.217	Drainage	2.968	0.745
D2	stream	0.292	0.259	Drainage	1.536	0.785
D3	ditch	0.179	0.212	Drift	0.209	0.119
D4	pond	0.023	0.023	Drainage	0.514	0.255
D4	stream	0.208	0.228	Drift	0.085	0.021
D5	pond	0.022	0.023	Drift	0.436	0.273
D5	stream	0.224	0.229	Drift	0.065	0.007
R1	pond	0.056	0.032	Runoff	1.647	0.707
R1	stream	0.317	0.189	Runoff	2.259	1.544
R3	stream	0.386	0.265	Runoff	4.400	1.079

* Values exceeding the RAC of 0.36 µg/L are shown in **bold**

Shaded scenarios are not relevant for Central Zone

^a single application in spring (for single application in autumn see Table 8.9-)

Table 8.9-18: FOCUS Step 4 PEC_{sw} for difenoconazole following application to winter oilseed rape (1 x 125 g/ha in autumn + 1 x 125 g/ha in spring) – 10 m buffer

Vegetative strip:		10 m		
No spray buffer:		10 m		
Scenario	Water body	Max PEC _{sw} (µg/L)*	Entry route	Max PEC _{sed} (µg/kg)
		Multiple		Multiple
D2	ditch	0.462	Drainage	2.884
D2	stream	0.292	Drainage	1.448
D3	ditch	0.093	Drift	0.110
D4	pond	0.021	Drainage	0.411
D4	stream	0.108	Drift	0.079
D5	pond	0.016	Drift	0.316
D5	stream	0.116	Drift	0.034
R1	pond	0.026	Drift	0.776
R1	stream	0.144	Runoff	0.467
R3	stream	0.174	Runoff	0.857

* Values exceeding the RAC of 0.36 µg/L are shown in **bold**

Shaded scenarios are not relevant for Central Zone

^a single application in spring (for single application in autumn see Table 8.9-)

Table 8.9-19: FOCUS Step 4 PEC_{sw} for difenoconazole following application to pome/stone fruit - early application (3 x 56.5 g/ha, 7-d interval) – 20 m spray buffer

Vegetative strip:		None				
No spray buffer:		20 m				
Scenario	Water body	Max PEC _{sw} (µg/L)*		Entry route	Max PEC _{sed} (µg/kg)	
		Multiple	Single		Multiple	Single
D3	ditch	0.414	0.480	Drift	0.980	0.484
D4	pond	0.100	0.053	Drift	1.325	0.596
D4	stream	0.477	0.557	Drift	0.242	0.115
D5	pond	0.096	0.053	Drift	1.379	0.615
D5	stream	0.515	0.601	Drift	0.320	0.168
R1	pond	0.102	0.053	Drift	1.319	0.590
R1	stream	0.366	0.427	Drift	0.944	0.408
R2	stream	0.490	0.572	Drift	0.820	0.315
R3	stream	0.516	0.597	Drift	0.282	0.134
R4	stream	0.366	0.417	Drift	0.793	0.466

* Values exceeding the RAC of 0.36 µg/L are shown in **bold**

Shaded scenarios are not relevant for Central Zone

Table 8.9-20: FOCUS Step 4 PEC_{sw} for difenoconazole following application to pome/stone fruit - early application (3 x 56.5 g/ha, 7-d interval) – 25 m spray buffer

Vegetative strip:		None				
No spray buffer:		25 m				
Scenario	Water body	Max PEC _{sw} (µg/L)*		Entry route	Max PEC _{sed} (µg/kg)	
		Multiple	Single		Multiple	Single
D3	ditch	0.226	0.283	Drift	0.549	0.287
D4	pond	0.063	0.035	Drift	0.855	0.408
D4	stream	0.261	0.328	Drift	0.135	0.068
D5	pond	0.061	0.035	Drift	0.887	0.421
D5	stream	0.281	0.355	Drift	0.179	0.099
R1	pond	0.069	0.035	Drift	0.916	0.429
R1	stream	0.212	0.251	Drift	0.903	0.397
R2	stream	0.267	0.337	Drift	0.813	0.313
R3	stream	0.281	0.352	Drift	0.181	0.081
R4	stream	0.245	0.246	Drift	0.784	0.454

* Values exceeding the RAC of 0.36 µg/L are shown in **bold**

Shaded scenarios are not relevant for Central Zone

**Table 8.9-21: FOCUS Step 4 PEC_{sw} for difenoconazole following application to carrots
(3 x 125 g/ha, 14-d interval) – 10 m buffer**

Vegetative strip:		10 m				
No spray buffer:		10 m				
Scenario	Water body	Max PEC _{sw} (µg/L)*		Entry route	Max PEC _{sed} (µg/kg)	
		Multiple	Single		Multiple	Single
D3	ditch	0.080	0.113	Drift	0.118	0.079
D6	ditch	0.121	0.111	Drainage	0.075	0.034
R1	pond	0.075	0.034	Runoff	2.202	0.893
R1	stream	0.244	0.106	Runoff	2.156	1.001
R2	stream	0.095	0.133	Drift	7.916	2.891
R3	stream	0.314	0.142	Runoff	1.010	0.370
R4	stream	0.516	0.162	Runoff	2.418	0.924

* Values exceeding the RAC of 0.36 µg/L are shown in **bold**
Shaded scenarios are not relevant for Central Zone

**Table 8.9-22: FOCUS Step 4 PEC_{sw} for difenoconazole following application to carrots
(3 x 125 g/ha, 14-d interval) – 20 m buffer**

Vegetative strip:		20 m		
No spray buffer:		20 m		
Scenario	Water body	Max PEC _{sw} (µg/L)*	Entry route	Max PEC _{sed} (µg/kg)
		Multiple		Multiple
D3	ditch	0.041	Drift	0.062
D6	ditch	0.121	Drainage	0.047
R1	pond	0.039	Runoff	1.184
R1	stream	0.127	Runoff	0.807
R2	stream	0.049	Drift	2.718
R3	stream	0.164	Runoff	0.429
R4	stream	0.270	Runoff	1.048

* Values exceeding the RAC of 0.36 µg/L are shown in **bold**
Shaded scenarios are not relevant for Central Zone

Table 8.9-23: FOCUS Step 4 PEC_{sw} for difenoconazole following application to leafy vegetables (3 x 125 g/ha, 7-d interval) – 10 m buffer

Vegetative strip:		10 m				
No spray buffer:		10 m				
Scenario	Water body	Max PEC _{sw} (µg/L)*		Entry route	Max PEC _{sed} (µg/kg)	
		Multiple	Single		Multiple	Single
D3	ditch	0.080	0.113	Drift	0.132	0.087
D4	pond	0.034	0.017	Drainage	0.583	0.225
D4	stream	0.144	0.116	Drainage	0.137	0.036
D6	ditch	0.640	0.143	Drainage	0.220	0.047
R1	pond	0.135	0.040	Runoff	3.342	1.100
R1	stream	0.252	0.101	Runoff	8.815	3.301
R2	stream	0.095	0.135	Drift	7.531	3.123
R3	stream	0.318	0.142	Runoff	7.124	2.211
R4	stream	0.496	0.170	Runoff	2.366	0.853

* Values exceeding the RAC of 0.36 µg/L are shown in **bold**

Shaded scenarios are not relevant for Central Zone

Table 8.9-24: FOCUS Step 4 PEC_{sw} for difenoconazole following application to leafy vegetables (3 x 125 g/ha, 7-d interval) – 20 m buffer

Vegetative strip:		20 m		
No spray buffer:		20 m		
Scenario	Water body	Max PEC _{sw} (µg/L)*	Entry route	Max PEC _{sed} (µg/kg)
		Multiple		Multiple
D3	ditch	0.041	Drift	0.070
D4	pond	0.032	Drainage	0.484
D4	stream	0.144	Drainage	0.136
D6	ditch	0.640	Drainage	0.212
R1	pond	0.069	Runoff	1.758
R1	stream	0.132	Runoff	3.060
R2	stream	0.049	Drift	2.595
R3	stream	0.166	Runoff	2.498
R4	stream	0.260	Runoff	0.986

* Values exceeding the RAC of 0.36 µg/L are shown in **bold**

Shaded scenarios are not relevant for Central Zone

Metabolites of difenoconazole

The results of the FOCUS Step 1-2 modelling for the metabolites of difenoconazole are presented in the following tables.

Metabolite CGA-205375

Table 8.9-25: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for CGA-205375 following application to winter oilseed rape (2 x 125 g a.s./ha, 21-day interval)

FOCUS Step	Multiple application		Single application	
	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)
Step 1	3.594	90.73	-	-
Step 2: N. Europe, Oct-Feb ^a	0.984	25.71	0.527	13.74
Step 2: N. Europe, Mar – May ^a	0.429	10.98	0.231	5.899
Step 2: S. Europe, Oct-Feb and Mar-May ^a	0.799	20.80	0.428	11.13

^a minimal crop cover (40% intercept)

Table 8.9-26: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for CGA-205375 following application to pome/stone fruit – early application (3 x 56.5 g a.s./ha, 7-day interval)

FOCUS Step	Multiple application		Single application	
	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)
Step 1	3.931	70.24	-	-
Step 2: N. Europe, Mar – May ^a	0.716	14.59	0.550	5.560
Step 2: N. Europe, Jun-Sep ^b	0.716	11.76	0.550	4.575
Step 2: S. Europe, Mar-May ^a	0.910	21.38	0.550	7.924
Step 2: S. Europe, Jun-Sep ^b	0.716	13.74	0.550	5.265

^a average crop cover (40% intercept)

^b full canopy (65% intercept)

Table 8.9-27: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for CGA-205375 following application to carrots (3 x 125 g a.s./ha, 14-day interval)

FOCUS Step	Multiple application		Single application	
	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)
Step 1	5.392	136.1	-	-
Step 2: N. Europe, Mar – May ^a	0.526	13.46	0.198	5.027
Step 2: N. Europe, Jun-Sep ^b	0.345	8.651	0.133	3.283
Step 2: S. Europe, Mar-May ^a	0.978	25.47	0.363	9.386
Step 2: S. Europe, Jun-Sep ^b	0.481	12.25	0.182	4.591

^a average crop cover (50% intercept)

^b full canopy (70% intercept)

Table 8.9-28: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for CGA-205375 following application to leafy vegetables (3 x 125 g a.s./ha, 7-day interval)

FOCUS Step	Multiple application		Single application	
	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)
Step 1	5.392	136.1	-	-
Step 2: N. Europe, Mar – May ^a	0.782	20.24	0.281	7.206
Step 2: N. Europe, Jun-Sep ^b	0.640	16.49	0.231	5.899
Step 2: S. Europe, Mar-May ^a	1.489	39.03	0.527	13.74
Step 2: S. Europe, Jun-Sep ^b	0.923	24.00	0.330	8.514

^a minimal crop cover (25% intercept)

^b average crop cover (40% intercept)

Metabolite CGA-71019

Table 8.9-29: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for CGA-71019 following application to winter oilseed rape (2 x 125 g a.s./ha, 21-day interval)

FOCUS Step	Multiple application		Single application	
	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)
Step 1	4.246	3.518	-	-
Step 2: N. Europe, Oct-Feb ^a	0.722	0.598	0.505	0.418
Step 2: N. Europe, Mar – May ^a	0.307	0.254	0.212	0.176
Step 2: S. Europe, Oct-Feb and Mar-May ^a	0.584	0.483	0.407	0.337

^a minimal crop cover (40% intercept)

FOCUS Step	Multiple application		Single application	
	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)
Step 1	4.25	3.49	-	-
Step 2: N. Europe, Oct-Feb ^a	1.20	1.00	0.63	0.53
Step 2: N. Europe, Mar – May ^a	2.33	1.91	0.13	0.11
Step 2: S. Europe, Oct-Feb and Mar-May ^a	0.25	0.19	0.14	0.12

*minimal crop cover (40% intercept)

Table 8.9-30: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for CGA-71019 following application to pome/stone fruit – early application (3 x 56.5 g a.s./ha, 7-day interval)

FOCUS Step	Multiple application		Single application	
	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)
Step 1	3.122	2.567	1	1
Step 2: N. Europe, Mar – May ^a	0.398	0.324	0.172	0.140
Step 2: N. Europe, Jun-Sep ^b	0.317	0.257	0.135	0.110
Step 2: S. Europe, Mar-May ^a	0.591	0.485	0.260	0.213
Step 2: S. Europe, Jun-Sep ^b	0.373	0.304	0.160	0.131

^a average crop cover (40% intercept) ^b full canopy (65% intercept)

FOCUS Step	Multiple application		Single application	
	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)
Step 1	1.81	1.48	1	1
Step 2: N. Europe, Mar – May ^a	0.24	0.18	0.10	0.08
Step 2: N. Europe, Jun-Sep ^b	0.23	0.18	0.11	0.08
Step 2: S. Europe, Mar-May ^a	0.40	0.32	0.17	0.13
Step 2: S. Europe, Jun-Sep ^b	0.16	0.12	0.08	0.06

^a average crop cover (40% intercept) ^b full canopy (65% intercept)

Table 8.9-31: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for CGA-71019 following application to carrots (3 x 125 g a.s./ha, 14-day interval)

FOCUS Step	Multiple application		Single application	
	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)
Step 1	6.368	5.230	1	1
Step 2: N. Europe, Mar – May ^a	0.343	0.283	0.180	0.149
Step 2: N. Europe, Jun-Sep ^b	0.221	0.182	0.115	0.095
Step 2: S. Europe, Mar-May ^a	0.648	0.536	0.342	0.284
Step 2: S. Europe, Jun-Sep ^b	0.312	0.258	0.164	0.135

^a average crop cover (50% intercept) ^b full canopy (70% intercept)

FOCUS Step	Multiple application		Single application	
	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)
Step 1	3.50	2.86	1	1
Step 2: N. Europe, Mar – May ^a	0.31	0.25	0.12	0.10
Step 2: N. Europe, Jun-Sep ^b	0.19	0.15	0.08	0.06
Step 2: S. Europe, Mar-May ^a	0.37	0.30	0.14	0.12
Step 2: S. Europe, Jun-Sep ^b	0.28	0.23	0.11	0.09

^a average crop cover (50% intercept) ^b full canopy (70% intercept)

Table 8.9-32: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for CGA-71019 following application to leafy vegetables (3 x 125 g a.s./ha, 7-day interval)

FOCUS Step	Multiple application		Single application	
	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)
Step 1	6.368	5.277	1	1
Step 2: N. Europe, Mar – May ^a	0.573	0.474	0.264	0.216
Step 2: N. Europe, Jun-Sep ^b	0.466	0.386	0.212	0.176
Step 2: S. Europe, Mar-May ^a	1.108	0.918	0.505	0.418
Step 2: S. Europe, Jun-Sep ^b	0.680	0.563	0.310	0.257

^a minimal crop cover (25% intercept) ^b average crop cover (40% intercept)

FOCUS Step	Multiple application		Single application	
	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)
Step 1	3.50	2.86	1	1
Step 2: N. Europe, Mar – May ^a	0.48	0.40	0.18	0.14
Step 2: N. Europe, Jun-Sep ^b	0.33	0.27	0.12	0.09
Step 2: S. Europe, Mar-May ^a	0.96	0.79	0.34	0.28
Step 2: S. Europe, Jun-Sep ^b	0.48	0.40	0.18	0.14

^a minimal crop cover (25% intercept) ^b average crop cover (40% intercept)

8.9.2.1 PEC_{sw/sed} for IN005B1570 DG250EC

The PEC_{sw} for the formulation IN005B1570 was calculated using the SWASH drift calculator. The formulation will not remain intact in aquatic systems after application due to breakdown of its individual components, therefore, time-aged values are not relevant and only the initial (maximum) PEC_{sw} resulting from the highest single rate was calculated. Separate calculations were performed for field crops and tree crops using the FOCUS Step 3 default no-spray zones for leafy vegetables (representative of all field crops) and pome fruit (early application).

The maximum single use rate for IN005B1570 is 0.5 L/ha in field crops and 0.225 L/ha in pome/stone fruit. Based on the formulation density of 1.1401 g/mL, the application rates converted to g/ha are 570.1 g/ha for field crops and 256.5 g/ha for pome fruit.

The PEC_{sw} values for the formulation are presented in the following table.

Table 8.9-33: FOCUS Step 3 PEC_{sw} values for IN005B1570 following application to field crops and pome fruit

Crop	Application rate (g FP/ha)*	Max. PEC _{sw} (µg/L)		
		Ditch	Stream	Pond
Field crops	570.1	3.663	2.718	0.125
Pome fruit (early)	256.5	20.18	18.45	1.213

* Based on formulation density of 1.1401 g/mL

zRMS comments:

The submitted PEC_{sw}/sed assessment was accepted.

The application data were accepted.

All used endpoints for active substance and its metabolites were agreed at the EU level (EFSA, 2011 and EFSA, 2013 for 1,2,4-triazole) and was accepted.

The calculations have been done in accordance with FOCUS Surface water guidelines. Models Step 1 & 2 and Step 3 and Step 4 have been used. Drift, drainage and runoff as a main exposure route were considered. Relevant metabolites were taken into consideration in Step 1 and 2.

The degradation data according to data CRD (2014) for metabolite 1,2,4-triazole were used by zRMS for recalculated PEC_{se}/sed.

zRMS agrees with PEC_{sw} calculated at formulation.

The relevant PEC_{sw} and PEC_{sed} values for active substance and its metabolites are presented in the tables above.

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

Table 8.10-1 Summary of atmospheric degradation and behaviour

Compound	Difenconazole
Direct photolysis in air	Not available
Photochemical oxidative degradation in air	DT ₅₀ 5 hours derived by the Atkinson method (AOP 1.85). OH (12 h) concentration assumed: 1.5×10^6 radicals/cm ³ .
Volatilisation	Volatilisation from soil: <0.05% after 24 hours (measured as % ¹⁴ C in absorption trap) Volatilisation from plants and soil: <9% after 24 hours (measured as % loss).

The vapour pressure at 20 °C of the active substance difenconazole is < 10⁻⁵ Pa. Hence the active substance difenconazole is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance difenconazole due to volatilization with subsequent deposition is not required.

zRMS comments:

Based on data regarding atmospheric degradation and behaviour of difenconazole the risk of atmospheric pollution of active substance following the use of Difenconazole 250 EC is low.

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 XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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 XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	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
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Detailed evaluation of the new Annex II studies

No new studies submitted

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