FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: SHA 7216 A

Product name: CIAZ

Chemical active substances:

Boscalid, 233 g/L
Difenoconazole, 66 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: August 2021

MS Finalisation date: 01.2022; updated:12.2022

Version history

When	What
August 2021	dRR prepared by the Applicant
January 2022	Draft assessment of dRR performed by the zRMS
November 2022	Applicant update
December 2022	The Aplicant updated was assessment

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8 Fate and behaviour in the environment (KCP 9)

zRMS comments:
All comments and conclusions of the zRMS are presented in grey commenting boxes. 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.

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)	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			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	CEU	**Winter wheat**	F	*Septoria spp.*	Foliar spray	BBCH 30-59	a) 2 b) 2	14	a) 1.5 b) 3	a) 0.35 boscalid + 0.1 difenoconazole b) 0.7 boscalid + 0.2 difenoconazole	200-400	-		
2	CEU	**Winter wheat**	F	*Puccinia spp.*	Foliar spray	BBCH 30-59	a) 2 b) 2	14	a) 1.5 b) 3	a) 0.35 boscalid + 0.1 difenoconazole b) 0.7 boscalid + 0.2 difenoconazole	200-400	-		
3	CEU	**Winter wheat**	F	*Fusarium spp.*	Foliar spray	BBCH 39-59	a) 2 b) 2	14	a) 1.5 b) 3	a) 0.35 boscalid + 0.1 difenoconazole b) 0.7 boscalid + 0.2 difenoconazole	200-400	-		

* 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 Boscalid 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	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	EU (N/S)	**Grape**	F	*Botrytis*	Spraying	68-81	1	-	-	0.6	1000-1600	28	-
2	EU	**Oilseed rape**	F	*Sclerotinia, Alternaria, Phoma*	Spraying	30, 63-65	2	4-6 weeks	-	0.25	200-400	-	-
3	EU (N/S)	**Peas**	F	*Botrytis, Sclerotinia*	Spraying	60-69	2	7-10	-	0.5	400	7	-
4	EU (N/S)	**Beans**	F	*Botrytis, Sclerotinia*	Spraying	60-69	2	7-10	-	0.5	300	7	-

* 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

Table 8.1-3: 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	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	EU (N/S)	**Pome fruit**	F	*Podosphaera leucotricha*	High volume spray or mist	Spray programme	a) 4 b) 4	10-14	-	a) 0.01875 b) 0.05625	500-1500	28	-

				Venturia inaequalis	blower	beginning at flowering (BBCH 61)				a) 0.0375 b) 0.0750	500-1000	14	
2	EU (N/S)	**Carrot**	F	*Alternaria dauci* *Erysiphe heraclei*	High volume spray	First application at BBCH 42/43	a) 3 b) 3	14	-	0.125	100-500	14	-
3	EU (N/S)	**Wheat**	F	*Fusarium spp.* *Tilletia spp.*	Seed treatment	BBCH 00	a) 1 b) 1	NA	-	a) 0.005 b) 0.012	-	-	Kg as/ha rate depends on seeding rate
4	EU (N/S)	**Barley**	F	*Pyrenophorma granimea*	Seed treatment	BBCH 00	a) 1 b) 1	NA	-	a) 0.005 b) 0.012	-	-	Kg as/ha rate depends on seeding rate
5	EU (N/S)	**Triticale**	F	*Fusarium spp.* *Tilletia spp.*	Seed treatment	BBCH 00	a) 1 b) 1	NA	-	a) 0.005 b) 0.012	-	-	Kg as/ha rate depends on seeding rate
6	EU (N/S)	**Rye**	F	*Fusarium spp.* *Urocystis occula*	Seed treatment	BBCH 00	a) 1 b) 1	NA	-	a) 0.005 b) 0.012	-	-	Kg as/ha rate depends on seeding rate
7	EU (N/S)	**Oats**	F	*Ustillago avenae* *Pyrenphora avenae* *Cochliobolus sativum* *Fusarium culmorum* *Gibberella avenacea* *Pythiul ultimum*	Seed treatment	BBCH 00	a) 1 b) 1	NA	-	a) 0.005 b) 0.012	-	-	Kg as/ha rate depends on seeding rate

* 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

8.2 Metabolites considered in the assessment

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

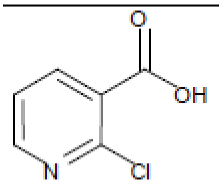
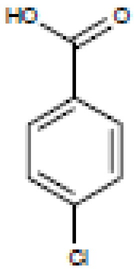
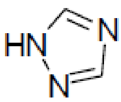
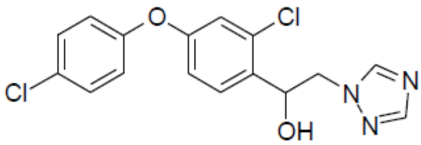
Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
M510F47	157.6		Soil: anaerobic conditions. 2.6 % after 3 d, 6 % after 62 d, 5.9 % after 90 d, 6.7 % after 120 d	-
M510F64	156.56		Sediment: under outdoor conditions. 7.3 % after 7 d 9 % after 14 d 9.4 % after 30 d 1.9 % after 120 d	-

Table 8.2-2: Metabolites of Difenoconazole potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
1,2,4-triazole (CGA 71019)	69.065 g/mol		Soil: 23.4% Water/sediment: 9.6% (worst case assumption calculated by RMS)	PEC_{gw}: leaching potential to groundwater PEC_{soil}: if not covered by EU assessment $PEC_{sw/sed}$: if not covered by EU assessment
Difenoconazole-alcohol (CGA 205375)	350 g/mol		Soil: 11.9% Water/sediment: 11.6%	PEC_{gw}: leaching potential to groundwater PEC_{soil}: if not covered by EU assessment $PEC_{sw/sed}$: if not covered by EU assessment

Comments zRMS:
Information regarding boscalid metabolites provided in Table 8.2-1 is in line with data reported Review Report, 2008 and information regarding difenoconazole metabolites provided in Table 8.2-2 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)

8.3.1.1 Boscalid and its metabolites

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

Boscalid, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH ($CaCl_2$)**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Bruch West	Loamy sand	7.4	20	40	108	360	-	-	-	y/Germany, 2002; Review Report, 2008
Li 35 b	Loamy sand	6.6	20	40	322	-	-	-	-	
Lufa 2.2	Loamy sand	5.6	20	40	384	-	-	-	-	
US soil	Sandy loam	7.0	20	40	376	-	-	-	-	
Minto (Canada)	Loam	7.7	20	40	133	442	-	-	-	
Median (n=5)					322					
Geometric mean (n=5)					**232**					
pH-dependency:					No					

8.3.1.2 Difenoconazole and its metabolites

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

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	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	SFO	
Geomean loam (n=2)					111	368	**111**			
-	Sandy loam	5.0	20	40	123[3]	409	**123**	0.913	SFO	y/ EFSA Journal
-	Silt loam	7.2	20	48	456[3]	>>273	456	0.892	SFO	

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**
-	Silt loam	7.2	30	48	175[1]	>>178[1]	-	0.977	SFO	2011;9(1):1967
-	Silt loam	7.2	20	24	709[1, 3]	>>281[1]	-	0.855	SFO	
-	Silt loam	7.2	20	48	345[3]	>>281	345	0.973	SFO	
-	Silt loam	7.2	10	48	602[1, 3]	>>281[1]	-	0.952	SFO	
-	Silt loam	7.2	20	48	83	277	83	0.950	SFO	
Geomean silt loam (n=3)					235	> 277	**235**			
-	Loam	7.2	20	22	136[1]	452[1]	-	0.986	SFO	y/ EFSA Journal 2011;9(1):1967
-	Loam	7.2	10	43	338[1, 3]	> 1000[1]	-	0.993	SFO	
-	Loam	7.2	20	43	53	175	**53**	0.995	SFO	
-	Loam sterile	7.2	20	43	>1000[1,3]	>1000[1]	-	-	SFO	
-	Sandy loam	7.4	20	40	149	496	**136**	0.977	SFO	
-	Sandy loam/loamy sand	7.5	20	40	186	617	**177**	0.939	SFO	
-	Silty clay loam	6.7	20	40	187	620	**151**	0.972	SFO	
Geometric mean (n=7)					136	>390	**130**			
Median (n=7)					149	≥409	136			
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] DT_{50} value extrapolated beyond the durations of the study

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

1,2,4-triazole (CGA 71019), Laboratory studies, aerobic conditions									
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 fast phase (d)**	**DT50 slow phase (d)**	**g**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Laacherhof AXXa	Sandy loam	6.4	20	40	0.9	59.2	0.683	DFOP	y/ CRD, UK, December 2013, Briefing note for the 13 December 2013 SCFAH, Agenda Item Pt. A 06.01- Amended DT50 values for the 1,2,4-triazole metabolite (corrected DT50 values of 0.7 and 46.4 days are reported for slow and fast phase, respectively).
BBA 2.2	Loamy sand	5.8	20	40	1.5	24.6	0.580	DFOP	
Laacherhof A III	Silt loam	6.7	20	40	0.8	20.6	0.443	DFOP	

1,2,4-triazole (CGA 71019), Laboratory studies, aerobic conditions									
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 fast phase (d)**	**DT50 slow phase (d)**	**g**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
				Geometric mean (n=3)	**1.0**	**67.1**	0.569		
				pH-dependency:	No				

Table 8.3-4: Summary of aerobic degradation rates for CGA 205375 - laboratory studies

CGA 205375, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Schanz	Sandy loam	7.4	20	40	93	309	85	0.980	SFO	y/ EFSA Journal 2011;9(1): 1967
Pappelacker	Sandy loam/loamy sand	7.5	20	40	83	275	79	0.995	SFO	
Senozan	Silt loam	5.8	20	40	152	504	123	0.996	SFO	
						Geometric mean (n=3)	**94**			
				pH-dependency:	No					

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

8.3.2.1 Boscalid and its metabolites

Table 8.3-2: Summary of anaerobic degradation rates for Boscalid - laboratory studies

Boscalid, Laboratory studies, anaerobic conditions										
Soil name	**Soil type**	**pH ($CaCl_2$)**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Bruch West	Loamy sand	7.4	20	Flooded	261	-	-	-	-	y/Germany, 2002; Review Report, 2008
Bruch West	Loamy sand	7.4	20	Flooded	345	-	-	-	-	
						Geom. mean (n=2)	**300**			
						pH-dependency: y/n	No			

The metabolite M510F47 become detectable under anaerobic conditions, in which degradation is slowed (*Germany, 2002*).

8.3.2.2 Difenoconazole and its metabolites

Table 8.3-5: Summary of anaerobic degradation rates for Difenoconazole - laboratory studies

Difenoconazole, Laboratory studies, anaerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
-	Loam	7.2	20	Flooded	Stable		-	-	-	y/ EFSA Journal 2011;9(1):1967
Geometric mean / Median					-	-	-			

Table 8.3-6: Summary of anaerobic degradation rates for 1,2,4-triazole (CGA 71019) - laboratory studies

1,2,4-triazole (CGA 71019), Laboratory studies, anaerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
-	Silt loam	7.3	20	Flooded	81	268	-	0.972	SFO	y/ EFSA Journal 2011;9(1):1967
Geometric mean/ Median					-	-	-			

Table 8.3-7: Summary of anaerobic degradation rates for CGA 205375 - laboratory studies

CGA 205375, Laboratory studies, anaerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
-	Sandy loam/loamy sand	7.5	20	Flooded	213	706	-	0.986	SFO	y/ EFSA Journal 2011;9(1):1967
Geometric mean / Median					-	-	-			

8.4 Field studies (KCP 9.1.1.2)

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

8.4.1.1 Boscalid and its metabolites

Triggering endpoints

Table 8.4-1: Summary of aerobic degradation rates for Boscalid - field studies: Triggering endpoints

Boscalid, Field studies – Triggering endpoints									
Soil type	**Location**	**pH ($CaCl_2$)**	**Depth (cm)**	**DissT50 (d) actual**	**DT90 (d) actual**	**Kinetic parameters**	**St. (x^2)**	**Method of calculation**	**Evaluated on EU level y/n/ Reference**
Silty loam	Germany, Stetten	7.5	-	90 49 28	-	-	-	-	y/Germany, 2002; Review Report, 2008
Silty sand	Germany, Schifferstadt	5.4	-	208 175 147	-	-	-	-	
Sandy loam	Spain, Manzanilla	7.4	-	27	-	-	-	-	
Sandy loam	Spain, Alcala del Rio	7.7	-	78	-	-	-	-	
Loamy sand	Germany, Grossharrie	6.1	-	144	-	-	-	-	
Loamy sand	Sweden, Bjärred	5.5	-	-	-	-	-	-	
			Maximum (n=9)	**208**	-				

Modelling endpoints

Table 8.4-2: Summary of aerobic degradation rates for Boscalid - field studies: Modelling endpoints

Boscalid, Field studies – Modelling endpoints						
Soil type	**Location**	**pH (x)**	**Depth (cm)**	**DT50 (d) 20°C**	**Fit, Kinetic**	**Evaluated on EU level y/n/ Reference**
Silty loam	Germany, Stetten	7.5	-	106	-	y/ Germany, 2002; Review Report, 2008
Silty sand	Germany, Schifferstadt	5.4	-	212	-	
Sandy loam	Spain, Manzanilla	7.4	-	-	-	
Sandy loam	Spain, Alcala del Rio	7.7	-	-	-	

Boscalid, Field studies – Modelling endpoints						
Soil type	**Location**	**pH (x)**	**Depth (cm)**	**DT50 (d) 20°C**	**Fit, Kinetic**	**Evaluated on EU level y/n/ Reference**
Loamy sand	Germany, Grossharrie	6.1	-	98	-	
Geometric mean (n=3)				**130**		
Arithmetic mean (n=3)				139		
pH-dependency:				No		

8.4.1.2 Difenoconazole and its metabolites

Triggering endpoints

Table 8.4-1: Summary of aerobic degradation rates for Difenoconazole - field studies: Triggering endpoints

Difenoconazole, Field studies – Triggering endpoints									
Soil type	**Location**	**pH**	**Depth (cm)**	**DissT50 (d) actual**	**DT90 (d) actual**	**Chi2 (%)**	**DT50 (d) norm 20°C**	**Method of calculation**	**Evaluated on EU level y/n/ Reference**
Silt loam	Germany	7.4	0-20	160	532	18.6	-	SFO	y/ EFSA Journal 2011;9(1):1967
Silt loam	Germany	6.6	0-10	20	68	13.0	-	SFO	
Loamy sand	Germany	6.2	0-10	59	195	18.3	-	SFO	
Silt loam	Germany	6.8	0-20	64	211	14.1	-	SFO	
Loamy sand	Germany	5.6	0-10	61	202	14.8	-	SFO	
Sandy loam	Germany	6.0	0-20	265	879	18.6	-	SFO	
Silt loam	Germany	6.0	0-20	242	802	20.9	-	SFO	
Silt loam	Germany	5.7	0-20	118	394	21.8	-	SFO	
Clay loam	Switzerland	7.3	0-10	83	277	-	-	SFO	
Maximum (n=9)				**265**	**879**				

Table 8.4-2: Summary of aerobic degradation rates for 1,2,4 Triazole - field studies: Triggering endpoints

1,2,4-triazole, Field studies – Triggering endpoints									
Soil type	**Location**	**pH**	**Depth (cm)**	**DissT50 (d) actual**	**DT90 (d) actual**	**Kinetic parameters**	**St. (x^2)**	**Method of calculation**	**Evaluated on EU level y/n/ Reference**
Silt loam	Germany	6.4	0-30	7.8	366.7	FOMC	15.2	-	y/ CRD, UK, December 2013, Briefing note for the 13 December 2013 SCFAH, Agenda Item Pt. A 06.01- Amended DT50
Silty clay loam	Italy	7.6	0-40	21.2	207.4	DFOP	10.7	-	
Sandy loam	UK	7.4	0-40	6.8	109.3	DFOP	17.8	-	

1,2,4-triazole, Field studies – Triggering endpoints									
Soil type	**Location**	**pH**	**Depth (cm)**	**DissT50 (d) actual**	**DT90 (d) actual**	**Kinetic parameters**	**St. (x^2)**	**Method of calculation**	**Evaluated on EU level y/n/ Reference**
Loam	Spain	5.8	0-30	28.1	717.6	DFOP	13.3	-	values for the 1,2,4-triazole metabolite
			Maximum (n=4)	**28.1**	**717.6**				

Modelling endpoints

Table 8.4-2: Summary of aerobic degradation rates for Difenoconazole - field studies: Modelling endpoints

Difenoconazole, Field studies – Modelling endpoints									
Soil type	**Location**	**pH**	**Depth (cm)**	**DissT50 (d) actual**	**DT90 (d) actual**	**Chi2 (%)**	**DT50 (d) norm 20°C**	**Method of calculation**	**Evaluated on EU level y/n/ Reference**
Silt loam	Germany	7.4	0-20	160	532	18.6	-	SFO	y/ EFSA Journal 2011;9(1):1967
Silt loam	Germany	6.6	0-10	20	68	13.0	-	SFO	
Loamy sand	Germany	6.2	0-10	59	195	18.3	-	SFO	
Silt loam	Germany	6.8	0-20	64	211	14.1	-	SFO	
Loamy sand	Germany	5.6	0-10	61	202	14.8	-	SFO	
Sandy loam	Germany	6.0	0-20	265	879	18.6	-	SFO	
Silt loam	Germany	6.0	0-20	242	802	20.9	-	SFO	
Silt loam	Germany	5.7	0-20	118	394	21.8	-	SFO	
Clay loam	Switzerland	7.3	0-10	83	277	-	-	SFO	
			Geometric mean (n=9)	**92**	**305**				

Table 8.4-4: Summary of aerobic degradation rates for 1,2,4 Triazole - field studies: Modelling endpoints

1,2,4 Triazole (CGA 71019), Field studies - Modelling endpoints									
Soil type	**Location**	**pH**	**Depth (cm)**	**DT50 (d) 20°C pF2/10kPa Fast phase**	**DT50 (d) 20°C pF2/10kPa Slow phase**	**g**	**St. (x^2)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Silt loam	Germany	6.4	0-30	2.5	70.7	0.655	18.8	DFOP	y/ CRD, UK, December 2013, Briefing note for the 13 December 2013 SCFAH, Agenda Item Pt. A 06.01- Amended DT50 values for the 1,2,4-triazole metabolite
Silty clay loam	Italy	7.6	0-40	1.4	59.8	0.364	10.6	DFOP	
Sandy loam	UK	7.4	0-40	0.5	25.1	0.458	18.1	DFOP	
Loam	Spain	5.8	0-30	4.6	126.0	0.489	12.7	DFOP	

1,2,4 Triazole (CGA 71019), Field studies - Modelling endpoints									
Soil type	**Location**	**pH**	**Depth (cm)**	**DT50 (d) 20°C pF2/10kPa Fast phase**	**DT50 (d) 20°C pF2/10kPa Slow phase**	**g**	**St. (x^2)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Geometric mean (n=4) (arithmetic mean for “g” value)				**1.68**	**60.5**	0.489			

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Boscalid	Two soil accumulation studies were peer review (Review Report 2008): - Germany, 1999-2003 (loamy sand/sandy loam): Application to vines (3 x 700 g a.s./ha = 2100 g a.s./ha); measured maximum plateau: mean 2900 g a.s./ha (138% of applied rate) - Germany 1998-2004 (sandy loam): 3-year rotation with vegetables (2100 g as/ha), vegetables (1700 g as/ha) and cereals (no application); measured maximum: 2545 g a.s./ha (150% of applied rate in the preceding year).
Difenoconazole	No accumulation observed after up to 10 years use under the following conditions: - 10-year study in Switzerland (sandy loam): 7 years application of 125 g/ha to wheat, 2-year application of 125 g/ha to rape and 1 year 3 x 125 g/ha to sugar beet. Takin 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-year study in Northern Italy (sandy loam): Annual application on 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-year study in Northern 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-year study in UK (sandy loam and clay) 3-year application 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).

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.

8.5.1 Boscalid and its metabolites

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

Boscalid							
Soil name	**Soil type***	**OC (%)**	**pH ($CaCl_2$)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
LUFA 2.2	Sand / loamy sand	2.5	5.8	27.8	1110	0.875	y/Germany, 2002; Review Report, 2008
Bruch West	Loamy sand	1.5	7.5	7.6	507	0.870	
Li 35b	Loamy sand	1.1	6.5	6.5	594	0.839	
USA 538-30-5	Loamy sand	0.4	5.8	3.9	987	0.887	
USA 538-31-2	Silty loamy sand	0.5	5.2	3.3	655	0.860	
Canada 95024	Sandy loam	3.4	7.5	26.4	776	0.851	
Geometric mean (n=6)					**742.6**	-	
Arithmetic mean (n=6)					-	0.864	
pH-dependency:					No		

8.5.2 Difenoconazole and its metabolites

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

Difenoconazole							
Soil name	**Soil type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
-	Sand	0.36	7.9	12.8	3870	0.74	y/ EFSA Journal 2011;9(1):1967
-	Sandy loam	1.98	7.8	63.0	3520	0.76	
-	Silt loam	1.74	6.5	54.8	3470	0.85	
-	Silty clay loam	0.67	6.9	47.2	7730	0.91	
-	Clay	2.79	5.9	97.8	3470	0.89	
-	Sand	0.52	6.5	2.1	400	0.80	
-	Silt loam	0.58	7.5	35.0	5660	0.88	
-	Sandy loam	0.58	8.5	11.5	1960	0.94	
Geomean (n=8)				25	**2943**	-	
Arithmetic mean (n=8)					-	0.85	
pH-dependency:				No			

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

1,2,4-triazole (CGA 71019)							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Alpaugh	Silty clay	0.70	8.8	0.833	120	0.897	y/ CRD, UK, December 2013, Briefing note for the 13 December 2013 SCFAH, Agenda Item Pt. A 06.01-Amended DT50 values for the 1,2,4-triazole metabolite
Hollister	Clay loam	1.74	6.9	0.748	43	0.827	
Lakeland	Sand	0.12	4.8	0.234	202	0.885	
Lawrencewill	Silty clay loam	0.70	7.0	0.722	104	0.922	
Pachappa	Sandy loam	0.81	6.9	0.720	89	1.016	
Geomean (n=4, excluding the very low OC sand that was considered not representative of agricultural soils)					**83.***		
Arithmetic mean (n=4, excluding the very low OC sand that was considered not representative of agricultural soils)						0.916	
pH-dependency:					No		

* calculated by Applicant the geometric mean Kfoc from the EU agreed individual values.

Table 8.5-3: Summary of soil adsorption/desorption for CGA 205375

CGA 205375							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
-	Loamy sand	2.17	5.7	118	5440	0.81	y/ EFSA Journal 2011;9(1):1967
-	Silty clay loam	1.16	6.6	45.5	3920	0.76	
-	Clay	2.63	6.7	44.1	1680	0.76	
-	Sandy loam	1.17	6.8	22.6	1930	0.72	
-	Loam	1.22	7.6	23.6	1930	0.77	
Geomean (n=5)				41.7	**2661**		
Arithmetic mean (n=5)				-		0.76	
pH-dependency:				No			

8.5.3 Column leaching (KCP 9.1.2.1)

Boscalid	**Colum leaching:** Not required.
	Aged residues leaching: 0% radioactivity in leachate.
Difenoconazole	**Column leaching:** Eluation (mm): 200 mm Time period: 2 d Difenoconazole did not move out of the zone of application in any of four soils tested. Study used only to support results from adsorption/desorption tests.

	Aged residues leaching: Not submitted, not required.

8.5.4 Lysimeter studies (KCP 9.1.2.2)

Boscalid	Not submitted, not required.
Difenoconazole	Not submitted, not required.

8.5.5 Field leaching studies (KCP 9.1.2.3)

Boscalid	Not submitted, not required.
Difenoconazole	Not submitted, not required.

8.6 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.

8.6.1 Boscalid and its metabolites

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

Boscalid Distribution (max. water 17.4 % after 100 days, sediment 79.9 % after 100 days, plateau in sediment 217% after 8 years)										
Water/sediment system	**pH water/ sed.**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**Kinetic, Fit**	**DissT50 water (d)**	**DissT90 water (d)**	**Kinetic, Fit**	**DissT50 sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Pond system	8.5	>100	-	-	9	133	-	-	-	y/Germany, 2002; Review Report, 2008
River system	8.1	>100	-	-	3	43	-	-	-	
Geometric mean (n=2)		**>100**	**-**		**5.2**	75.62		-		-

The half-life of M510F64 in the water is 7-8 days (*Germany, 2002*).

8.6.2 Difenoconazole and its metabolites

Table 8.6-2: Summary of degradation in water/sediment of Difenoconazole

Difenoconazole Distribution in Pond/River system at 20 °C (max. in water 88/80% day 0, decreased to 20/32% by day 3 and to < 10% by day 7/14) **Difenoconazole Distribution in Pond/River system at 8 °C (max. in water 83/87% day 0, decreased to 15/36% by day 3 and to 2.3/12% by day 14 and max in sediment 99.8/96.5% day 42)**										
Water/ sediment system	**pH water/ sed.**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**St. (r^2)**	**DissT50 water (d)**	**DissT90 water (d)**	**St. (r^2)**	**DissT50 sed. (d)**	**Method of calculation**	**Evaluated on EU level y/n/ Reference**
Pond	- / 6.9	324	> 1000	0.998	1.0	3.3	0.987	-	SFO	y/ EFSA Journal 2011;9(1):1967
River	- / 7.2	307	> 1000	0.999	2.0	6.6	0.968	-	SFO	
Geomean (n=2)		**315**	**> 1000**		**1.1**	4.6		-		

Table 8.6-3: Summary of degradation in water/sediment of CGA 205375

CGA 205375 Distribution (in Pond/river systems: max. in water 97/96% day 0, decreased to <10% by day 7/14 and max. in sediment 91/87% day 62/28)										
Water/sediment system	**pH water/ sed.**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**St. (r^2)**	**DissT50 water (d)**	**DissT90 water (d)**	**St. (r^2)**	**DissT50 sed. (d)**	**Method of calculation**	**Evaluated on EU level y/n/ Reference**
Pond	7.97/7.09	630	> 1000	0.765	1.4	4.7	0.958	-	SFO	y/ EFSA Journal 2011;9(1): 1967
River	8.1/7.46	301	> 1000	0.932	3.1	10.2	0.985	-	SFO	
Geomean (n=2)		**435.5**	**> 1000**		**2.1**	6.9		-		

Table 8.6-4: Summary of observed metabolites

1,2,4-triazole (CGA 71019) **Water/sediment system**	Max in water/sediment: 9.6% (worst case assumption, calculated by RMS) Max in water/sediment 14.1% after 148 d (river system)	EFSA Journal 2011;9(1):1967
CGA 205375	Max in water/sediment: 11.6% after 90-183 d (river system)	

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

8.7.1 Justification for new endpoints

Not relevant as there is no deviation to EU agreed endpoints.

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

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

Use No.	1	2	3
Crop	**Winter wheat**		
Application rate (g as/ha)	Boscalid: 350 Difenoconazole: 100		
Number of applications/interval	2/14		
Crop interception* (%)	80		
Depth of soil layer (relevant for plateau concentration) (cm)	20 cm (tillage)		

*** According to the EFSA Guidance 3662**

Table 8.7-2: Input parameter for active substance(s) and relevant metabolite(s) for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
Boscalid	343.21	-	208 d (Maximum, field studies)	y/Review Report, 2008
Difenoconazole	406.3	-	265 (Worst case, longest unormalized DT_{50}, from field studies)	y/ EFSA Journal 2010;8(11):1967 and Triazole LoEP January 2013
1,2,4- triazole (CGA 71019)	69.1	23.4	k1 = 0.0632 d^{-1} (DT_{50} = 10.97 d) k2 = 0.002 d^{-1} (D_{T50} = 346.6 d*) g = 0.5732	
Difenoconazole alcohol (CGA 205375)	350	11.9	152 d (unormalized worst case form lab studies)	

* used for calculations

8.7.2.1 Boscalid and its metabolites

Table 8.7-3: PEC_{soil} for Boscalid on winter wheat

PEC_{soil} (mg/kg)		Winter wheat			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.093	-	0.182	-
Short term	24h	0.093	0.093	0.182	0.182
	2d	0.093	0.093	0.181	0.182
	4d	0.092	0.093	0.180	0.181
Long term	7d	0.091	0.092	0.178	0.180
	14d	0.089	0.091	0.174	0.178

	21d	0.087	0.090	0.170	0.176
	28d	0.085	0.089	0.166	0.174
	50d	0.080	0.096	0.155	0.169
	100d	0.067	0.079	0.131	0.155
Plateau concentration (20 cm) after year 4		-	-	0.020	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		-	-	0.202	-

8.7.2.2 Difenoconazole and its metabolites

Table 8.7-4: PEC_{soil} for Difenoconazole on winter wheat

PEC_{soil} (mg/kg)		Winter wheat			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.027	-	0.052	-
Short term	24h	0.027	0.027	0.052	0.052
	2d	0.027	0.027	0.052	0.052
	4d	0.026	0.027	0.052	0.052
Long term	7d	0.026	0.026	0.051	0.052
	14d	0.026	0.026	0.050	0.051
	21d	0.025	0.026	0.050	0.051
	28d	0.025	0.026	0.049	0.051
	50d	0.023	0.025	0.046	0.049
	100d	0.021	0.023	0.040	0.046
Plateau concentration (20 cm) after year 2		-	-	0.008	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		-	-	0.060	-

PEC_{soil} of metabolites

PEC_{soil} values for the metabolites were determined as for the parent with an application rate corrected taking into account the molecular weights (MW) and the maximum occurrence of the metabolite in soil as following:

Application $rate_{metabolite}$ = ($MW_{metabolite}$/ MW_{parent}) x (% maximum occurrence/100) x application $rate_{parent}$

The corresponding application rates for each metabolite are summarized in the table below.

Table 8.7-5: Corrected application rates for the metabolites

Metabolite	Application rate of the parent	MW_{parent}	$MW_{metabolite}$	Maximum occurrence in soil	Corrected application rate

	(g/ha)			(%)	(g/ha)
1,2,4-triazole	2 x 100	406.3	69.1	23.4	2 x 3.98
CGA 205375			350	11.9	2 x 10.25

The results of PEC_{soil} calculations are presented in the tables below.

Table 8.7-6: PEC_{soil} for 1,2,4-triazole (CGA71019) on winter wheat

PEC_{soil} (mg/kg)		Winter wheat			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.001	-	0.002	-
Short term	24h	0.001	0.001	0.002	0.002
	2d	0.001	0.001	0.002	0.002
	4d	0.001	0.001	0.002	0.002
Long term	7d	0.001	0.001	0.002	0.002
	14d	0.001	0.001	0.002	0.002
	21d	0.001	0.001	0.002	0.002
	28d	0.001	0.001	0.002	0.002
	50d	0.001	0.001	0.002	0.002
	100d	0.001	0.001	0.002	0.002
Plateau concentration (20 cm) after year 1		-	-	< 0.001	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		-	-	0.002	-

Table 8.7-7: PEC_{soil} for CGA 205375 on winter wheat

PEC_{soil} (mg/kg)		Winter wheat			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.003	-	0.005	-
Short term	24h	0.003	0.003	0.005	0.005
	2d	0.003	0.003	0.005	0.005
	4d	0.003	0.003	0.005	0.005
Long term	7d	0.003	0.003	0.005	0.005
	14d	0.003	0.003	0.005	0.005
	21d	0.002	0.003	0.005	0.005
	28d	0.002	0.003	0.005	0.005
	50d	0.002	0.002	0.004	0.005
	100d	0.002	0.002	0.003	0.004
Plateau concentration (20 cm)		-	-	< 0.001	-

after year 1				
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)	-	-	0.005	-

8.7.2.3 PEC$_{soil}$ of CIAZ

Since CIAZ is rapidly broken down into its constituent parts on contact with soil and/or crop material, it is appropriate to calculate the PEC_S following a single application only, using the following equation:

$$PEC_S\,(mg/kg) = \frac{\text{Application rate (g/ha)} \times (1 - F)}{100 \times \text{Soil depth (cm)} \times \text{Soil dry bulk density (g/cm}^3)}$$

Table 8.7-8: PEC$_{soil}$ for CIAZ on winter wheat

Preparation	Application rate (g/ha)	Crop interception (%)	PEC$_{act}$ (mg/kg)
Boscalid + Difenoconazole / Boscalid 23.3% + Difenoconazole 6.6% SC	2 x 1667*	80	0.889

* Based on density value of 1.111 g/mL

Comments zRMS:
Boscalid

PECs calculations have been accepted. The calculations cover proposed GAP. Soil Parameters used for the calculations were considered at the EU level. Accumulated concentration was calculated for the boscalid by assuming distribution of plateau concentration through either plough layer (20 cm annual crops). No PECsoil calculations were performed for metabolites of boscalid because metabolites were found in amounts greater than 10% of the applied parent (DAR 2002). The crop interception assumed in calculations is in line with the most recent version of the FOCUS Groundwater Guidance of 2014.
The exposure for the formulated product was recalculated by the zRMS and the same PEC$_{soil}$ was obtained. For this reason PEC$_{soil}$ were considered relevant for the soil risk assessment.

Boscalid: PECs = 0.182 (mg/kg)

Difenoconazole
PECs calculations have been accepted. Parameters used for the calculations were considered at the EU level. Accumulated concentration was calculated for the difenoconazole by assuming distribution of plateau concentration through either plough layer (20 cm annual crops). The crop interception assumed in calculations is in line with the most recent version of the FOCUS Groundwater Guidance of 2014.
PECs values are considered relevant for the soil risk assessment.

Difenoconazole: PECs = 0.052 (mg/kg)
Metabolite 1,2,4-triazole: PECs = 0.002(mg/kg)
Metabolite CGA 205375: PECs = 0.005(mg/kg)

CIAZ: PECs = 0.889 (mg/kg)

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

8.8.1 Justification for new endpoints

Not relevant as there is no deviation to EU agreed endpoints.

8.8.2 Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1)

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

Use No.	1	2	3
Crop	**Winter wheat**		
Application rate (g as/ha)	Boscalid: 350 Difenoconazole: 100		
Number of applications/interval (d)	2/14		
Crop interception (%)	80		
Frequency of application	annual		
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3		

It should be noted that as recommended in the Generic Guidance for Tier 1 FOCUS Ground Water Assessments (FOCUS 2011), a corrected application rate is calculated taking into account the interception by the crop canopy. Therefore, the substance is applied directly to the ground in the models, thus avoiding the internal interception routines in the models. The corrected application rate are 70 g Boscalid/ha and 20g Difenoconazole/ha.

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

Crop	**Scenario**	**Application dates***
Winter wheat	Châteaudun	15/04
	Hamburg	04/05
	Jokioinen	14/05
	Kremsmünster	24/04
	Okehampton	21/04
	Piacenza	19/03
	Porto	30/01
	Sevilla	06/01
	Thiva	18/01

*** First application according to AppDate v 3.05 (30 April 2019)**

8.8.2.1 Boscalid and its metabolites

Table 8.8-3: Input parameters related to active substance Boscalid for PEC_{gw} calculations

Compound	Boscalid	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	343.21	y/ Review Report, 2008
Water solubility (mg/L):	4.6 at 20°C	
Saturated vapour pressure (Pa):	7.2 x 10^{-7} at 20°C	
DT_{50} in soil (d)	208 d (Maximum, field studies)	
K_{foc} (mL/g)/K_{fom}	742.6 (geometric mean, n=6) / 430.7	
1/n	0.864 (arithmetic mean, n=6)	
Plant uptake factor	0	
Formation fraction	-	

Table 8.8-4: PEC_{gw} for Boscalid on winter wheat (with FOCUS PEARL 4.4.4/PELMO 5.5.3)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)	
		PEARL	PELMO
Winter wheat	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

8.8.2.2 Difenoconazole and its metabolites

Table 8.8-5: Input parameters related to active substance Difenoconazole and metabolites for PEC_{gw} calculations

Compound	Difenoconazole	1,2,4-triazole (CGA 71019)	CGA 205375	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	406.3	69.1	350	y/ SANCO/3049/99 + CRD, UK, 2013
Water solubility (mg/L):	15 at 25°C	730000 @ 20ºC	100 @ 20ºC	DAR, 2006

Compound	Difenoconazole	1,2,4-triazole (CGA 71019)	CGA 205375	Value in accordance with EU end-point y/n/ Reference*
	(12.46 at 20 °C)		(assumed value)	
Saturated vapour pressure (Pa):	3.32×10^{-8} at 25°C (1.73×10^{-8} at 20°C)	0	0	
DT_{50} in soil (d)	130 (geomean of lab data normalised pF2, 20°C, Q_{10} 2.2, n=7)	1.68 fast phase 60.5 slow phase 0.489 g (Geometric mean from new LoEP, 2011 normalized at 20°C and pF2)	94 (geomean of normalised data, 20°C, pF2, 10 kPa, n=3)	y/ EFSA Journal 2011;9(1):1967
Transformation rate	-	0.381902	0.381902	
K_{foc} (mL/g)/K_{fom}	2943 (geomean, n=8) / 1707.1	83.1 (geomean, n=4) / 48.2	2661 (geomean, n=5) / 1543.5	
1/n	0.85 (arithmetic mean, n=8)	0.916 (arithmetic mean, n=4)	0.76 (arithmetic mean, n=5)	
Plant uptake factor	0	0	0	
Formation fraction	-	1 from parent	1 from parent	

Following the briefing note regarding amended soil degradation end points for 1,2,4 Triazole, second tier modelling purposes was used. The simulation was performed using the geometric mean from the slow and fast phase, respectively. It was done in order to consider the biphasic kinetic of 1,2,4 Triazole. The simulation was therefore conducted for the fast degrading and the slow degrading compartment. One compartment was conducted with a half-life of 1.68 days, and another compartment was conducted with a degradation half-life of 60.5 days.

For biphasic degradation where the Freundlich exponent is not one a small error may occur when breaking the pesticide into two fractions. To avoid this, as a conservative approach, when splitting the metabolite into two fractions, the application rate should be doubled for input into the model and then the fast and slow PEC values should be summed together. Then the final total concentration should be divided by two. This approach was also considered in following assessment.

The results from the PEC groundwater modelling FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 for Difenoconazole and its soil metabolites for the relevant FOCUS groundwater scenarios are provided in the following tables. Detailed calculations are included in separate files provided in Registration Report.

Table 8.8-6: PEC_{gw} for Difenoconazole and metabolites on winter wheat (with FOCUS PEARL 4.4.4)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Difenoconazole	1, 2, 4-triazole*	CGA 205375
Winter wheat	Châteaudun	< 0.001	0.005	< 0.001
	Hamburg	< 0.001	0.028	< 0.001
	Jokioinen	< 0.001	0.010	< 0.001
	Kremsmünster	< 0.001	0.018	< 0.001

	Okehampton	< 0.001	0.027	< 0.001
	Piacenza	< 0.001	0.014	< 0.001
	Porto	< 0.001	0.013	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	0.003	< 0.001

*** Sum of slow and fast phases divided by 2**

Table 8.8-7: PEC$_{gw}$ for Difenoconazole and metabolites on winter wheat (with FOCUS PELMO 5.5.3)

Crop	**Scenario**	**80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)**		
		Difenoconazole	**1, 2, 4-triazole***	**CGA 205375**
Winter wheat	Châteaudun	< 0.001	0.004	< 0.001
	Hamburg	< 0.001	0.032	< 0.001
	Jokioinen	< 0.001	0.013	< 0.001
	Kremsmünster	< 0.001	0.020	< 0.001
	Okehampton	< 0.001	0.028	< 0.001
	Piacenza	< 0.001	0.018	< 0.001
	Porto	< 0.001	0.023	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	0.002	< 0.001

*** Sum of slow and fast phases divided by 2**

Comments zRMS:

<u>Boscalid</u>

PECgw calculations have been accepted. The calculations cover proposed uses in GAP. The crop interception assumed in calculations is in line with the most recent version of the FOCUS Groundwater Guidance of 2014. In simulations PUF value of 0 was assumed for all compounds, in line with recommendations of the most recent version of the FOCUS Groundwater Guidance.

According to DAR and EFSA Journal 2011;9(1):1967 in field studies no metabolite was found in amounts greater than 10% of the applied parent, therefore no PECgw calculations are performed for metabolites of boscalid. No MACRO calculations was required (PECgw < 0.001µg/L).
Based on Focus PEARL and PELMO simulations. Calculated PECgw values are far below the threshold concentration of 0.1 µg/L for all scenarios and crops.
No unacceptable risk for groundwater was identified.

<u>Difenoconazole</u>

PECgw calculations have been accepted. The calculations cover proposed uses in GAP. The crop interception assumed in calculations is in line with the most recent version of the FOCUS Groundwater Guidance of 2014. Parameters used for the calculations were considered at the EU level. In simulations PUF value of 0 was assumed for all compounds, in line with recommendations of the most recent version of the FOCUS Groundwater Guidance. Calculated. PECgw values are far below the threshold concentration

of 0.1 µg/L for all modelled compounds for all crops and scenarios. No MACRO calculations was required (PECgw < 0.001µg/L).
Calculated PECgw values are far below the threshold concentration of 0.1 µg/L for all scenarios and crops.
No unacceptable risk for groundwater was identified.

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

8.9.1 Justification for new endpoints

Not relevant as there is no deviation to EU agreed endpoints.

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

Table 8.9-1: Input parameters related to application for $PEC_{SW/SED}$ calculations

Plant protection product	CIAZ		
Use No.	1	2	3
Crop	**Winter wheat**		
Application rate (kg as/ha)	Bodcalid: 0.35 Difenoconazole: 0.1		
Number of applications/interval (d)	2/14		
Application window	March-May (average interception)		
Application method	Foliar spray		
CAM (Chemical application method)	CAM 2		
Soil depth (cm)	4 cm		
Models used for calculation	FOCUS STEPS 1-2 v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3, SWAN v 5.0.0		

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for $PEC_{sw/sed}$ calculations for the application of CIAZ

Crop	Scenario	Application window used in modelling*
Winter wheat	D1	25/03 – 08/05
	D2	04/04 – 18/05
	D3	16/04 – 30/05
	D4	18/03 – 01/05
	D5	15/03 – 28/04
	D6	16/02 – 01/04
	R1**	24/04 – 07/06
	R3	19/03 – 02/05

Crop	Scenario	Application window used in modelling*
	R4	24/01 – 09/03

*** According to AppDate v3.05 (30 April 2019)**
****R1 scenario has been calculated separately because the application date has change on the new version of AppDate and the whole calculations were calculated with version v3.03 (only applicable for Boscalid calculations)**

8.9.2.1 Boscalid and its metabolites

Table 8.9-3: Input parameters related to active substance Boscalid for $PEC_{sw/sed}$ calculations STEP 1/2 and 3(/4) (if necessary)

Compound	Boscalid	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	343.21	
Saturated vapour pressure (Pa)	7.2×10^{-7} at 20°C	
Water solubility (mg/L)	4.6 at 20°C	
Diffusion coefficient in water (m²/d)	4.3×10^{-5}	default
Diffusion coefficient in air (m²/d)	0.43	default
K_{foc} (mL/g)	742.6 (geometric mean, n=6)	y/ Review Report, 2008
Freundlich Exponent 1/n	0.864 (arithmetic mean, n=6)	
Plant Uptake	0	
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	
$DT_{50,soil}$ (d)	208 d (maximum, field studies) 130.0 (geomean field studies, normalized to 20°C with Q_{10} of 2.2, n=3)	
$DT_{50,water}$ (d)	1000	
$DT_{50,sed}$ (d)	1000	
$DT_{50,whole\ system}$ (d)	1000	
Maximum occurrence observed (% molar basis with respect to the parent)	Sediment: 79.9	

$PEC_{sw/sed}$

Table 8.9-4: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for Boscalid following single/ multiple application(s) of CIAZ to winter wheat

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)	Max PEC_{sed} accumulative (µg/kg)*
Step 1	---	61.841 / 123.683	Runoff / drainage	59.842 / 119.684	435.331 / 894.064	944.668/ 1940.119

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)	Max PEC_{sed} accumulative (µg/kg)*
Step 2						
Northern Europe	March-May	11.190 / 21.491	Runoff / drainage	10.797 / 20.788	80.652 / 155.287	175.015 / 336.973
Southern Europe	March-May	20.445 / 39.580	Runoff / drainage	19.986 / 38.746	149.335 / 289.522	324.057 / 628.263
Step 3						
D1	ditch	8.093 / 16.140	Drainage	7.426 / 15.050	78.720 / 149.900	170.822 / 325.283
D1	stream	5.066 / 10.090	Drainage	4.586 / 9.284	44.800 / 83.840	97.216 / 181.933
D2	ditch	10.260 / 22.190	Drainage	4.714 / 10.180	60.600 / 119.400	131.502 / 259.098
D2	stream	6.404 / 13.840	Drainage	2.726 / 5.925	36.250 / 71.850	78.663 / 155.915
D3	ditch	2.215 / 1.939	Drainage	0.109 / 0.199	1.199 / 1.448	2.602 / 3.142
D4	pond	1.094 / 2.648	Drainage	1.058 / 2.560	9.496 / 21.360	20.606 / 46.351
D4	stream	1.637 / 3.468	Drainage	0.678 / 1.648	3.207 / 7.480	6.959 / 16.232
D5	pond	0.694 / 1.434	Drainage	0.651 / 1.351	8.200 / 17.720	17.794 / 38.452
D5	stream	1.784 / 2.387	Drainage	0.222 / 0.632	1.669 / 3.400	3.622 / 7.378
D6	ditch	2.977 / 4.937	Drainage	0.808 / 1.280	3.609 / 6.640	7.832 / 14.409
R1	pond	0.243/ 0.619	Runoff	0.215/ 0.549	2.313/ 5.354	5.019 / 11.618
R1	stream	1.688 / 4.751	Runoff	0.121 / 0.336	1.326 / 3.175	2.877 / 6.890
R3	stream	2.305 / 5.029	Runoff	0.120 / 0.268	2.372 / 5.389	5.147 / 11.694
R4	stream	3.281 / 7.416	Runoff	0.161 / 0.376	1.968 / 4.220	4.271 / 9.157

*** Plateau concentration in sediment after 8yr is 217%**

FOCUS Step 4

Table 8.9-5: Global maximum PEC_{sw} values for Boscalid, following single/multiple application(s) of CIAZ to winter wheat according to the central EU zone GAP according to surface water Step 4

PEC_{sw} (µg/L)	Scenario	STEP 4 Boscalid		
Nozzle reduction	Vegetative strip (m)	None	None	None
	No spray buffer (m)	1	10	20
None	D1 ditch	- / 16.140	- / 16.140	- / 16.140
50 %		- / 16.140	- / -	- / -
75 %		- / 16.140	- / -	- / -
90 %		- / 16.140	- / -	- / -
None	D2 ditch	- / 22.190	- / 22.190	- / 22.190

PEC_{SW} (µg/L)	**Scenario**	**STEP 4 Boscalid**		
Nozzle reduction	Vegetative strip (m)	None	None	None
	No spray buffer (m)	1	10	20
50 %		- / 22.190	- / -	- / -
75 %		- / 22.190	- / -	- / -
90 %		- / 22.190	- / -	- / -
None	D2 stream	- / 13.840	- / 13.840	- / 13.840
50 %		- / 13.840	- / -	- / -
75 %		- / 13.840	- / -	- / -
90 %		- / 13.840	- / -	- / -

8.9.2.2 Difenoconazole and its metabolites

Table 8.9-6: Input parameters related to active substance Difenoconazole and metabolites for $PEC_{sw/sed}$ calculations STEP 1/2 and 3(/4) (if necessary)

Compound	**Difenoconazole**	**1, 2, 4-triazole (CGA 71019)**	**CGA 205375**	**Value in accordance to EU endpoint y/n/ Reference**
Molecular weight (g/mol)	406.3	69.065	350	y/ EFSA Journal 2011;9(1):1967
Saturated vapour pressure (Pa)	3.32 x 10^{-8} at 25°C	not required for Step 1+2 / 0 at 20°C	not required for Step 1+2 / 0 at 20°C	
Water solubility (mg/L)	15 at 25°C	730000 @ 20ºC	100 @20ºC (assumed)	
Diffusion coefficient in water (m²/d)	4.3 x 10^{-5}	not required for Step 1+2	not required for Step 1+2	default
Diffusion coefficient in air (m²/d)	0.43	not required for Step 1+2	not required for Step 1+2	default
K_{foc} (mL/g)	2943/1707.1 (geomean, n=8)	83.1 (geomean, n=4) / 48.2	2661 (geomean, n=5) / 1543.5	-
Freundlich Exponent 1/n	0.85 (geomean, n=8)	not required for Step 1+2	not required for Step 1+2	-
Plant Uptake	0	not required for Step 1+2	not required for Step 1+2	-
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	not required for Step 1+2	not required for Step 1+2	default
$DT_{50,soil}$ (d)	130 (geomean of normalised data, pF2, 20°C, Q10 2.2, n=7)	60.5 d slow phase (worst-case between fast	94 (geomean of normalised data, pF2, 20°C, , n=3)	-

Compound	Difenoconazole	1, 2, 4-triazole (CGA 71019)	CGA 205375	Value in accordance to EU endpoint y/n/ Reference
		phase and slow phase, geomean of normalised data, 20°C, pF2, 10 kPa, n=4)		
$DT_{50,water}$ (d)	1000 (default)	1000 (worst case assumption)	1000 (default)	-
$DT_{50,sed}$ (d)	315.5 (geomean, n=2, degradation whole system)	1000 (worst case assumption)	435 (geomean, n=2, degradation whole system)	-
$DT_{50,whole\ system}$ (d)	315.5 (geomean, n=2)	1000 (worst case assumption)	435 (geomean, n=2)	-
Maximum occurrence observed (% molar basis with respect to the parent)	Sediment: 99.8	Soil: 23.4 Water: - Sediment: 9.6 Water/sediment: 9.6	Soil: 11.9 Water: - Sediment: 11.6 Water/sediment: 11.6	

$PEC_{sw/sed}$

According to EFSA Journal 2011;9(1):1967, the PEC_{sed} plateau was calculated as:

$$PEC_{sed}\ \text{plateau} = (\text{max. } PEC_{sed} \text{ after 1 year of treatment}) / (1 - e^{-k \times t})$$

Where: k = ln (2) / 315.5
t = 365 days

Table 8.9-7: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for Difenoconazole following single/ multiple applications of CIAZ to winter wheat

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d-$PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)	PEC_{sed} plateau (µg/kg)
Step 1	---	7.69 / 15.38	Runoff/drainage	6.82 / 13.63	204.28 / 408.55	370.39 / 740.77
Step 2						
Northern Europe	March-May	1.32 / 2.49	Runoff/drainage	1.22 / 2.33	36.58 / 69.54	66.33 / 126.09
Southern Europe	March-May	2.38 / 4.53	Runoff/drainage	2.27 / 4.33	67.72 / 129.57	122.79 / 234.93
Step 3						
D1	ditch	**0.636** / **0.562**	Drainage	0.053 / 0.201	0.694 / 2.328	1.258 / 4.221
D1	stream	0.495 / 0.472	Drainage	0.001 / 0.006	0.020 / 0.112	0.036 / 0.203
D2	ditch	**0.640** / **0.573**	Drainage	0.071 / 0.168	0.959 / 2.502	1.739 / 4.537
D2	stream	0.544 / 0.492	Drainage	0.008 / 0.125	0.160 / 1.713	0.290 / 3.106
D3	ditch	**0.634** / 0.555	Drainage	0.030 / 0.055	0.439 / 0.648	0.796 / 1.175

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Dominant entry route	21 d-PECsw,twa (µg/L)	Max PECsed (µg/kg)	PECsed plateau (µg/kg)
D4	pond	0.022 / 0.026	Drainage	0.016 / 0.021	0.231 / 0.408	0.419 / 0.740
D4	stream	0.468 / 0.419	Drainage	0.001 / 0.003	0.019 / 0.047	0.034 / 0.085
D5	pond	0.022 / 0.030	Drainage	0.016 / 0.024	0.260 / 0.423	0.471 / 0.767
D5	stream	0.506 / 0.483	Drainage	0.001 / 0.003	0.015 / 0.045	0.027 / 0.082
D6	ditch	**0.626** / 0.557	Drainage	0.013 / 0.067	0.207 / 0.856	0.375 / 1.552
R1	pond	0.027 / 0.066	Runoff	0.022 / 0.055	0.703 / 1.612	1.275 / 2.923
R1	stream	0.418 / 0.361	Runoff	0.011 / 0.030	1.603 / 3.805	2.906 / 6.899
R3	stream	**0.586** / 0.510	Runoff	0.010 / 0.023	1.512 / 2.673	2.741 / 4.847
R4	stream	0.419 / 0.546	Runoff	0.014 / 0.032	2.139 / 4.305	3.878 / 7.806

FOCUS Step 4

Table 8.9-8: Global maximum PECsw values for Difenoconazole, following single/multiple application(s) of CIAZ to winter wheat according to the central EU zone GAP according to surface water Step 4

PECsw (µg/L)	Scenario	STEP 4 Difenoconazole							
Nozzle reduction	Vegetative strip (m)	None					5*		
	No spray buffer (m)	5			10		5		
		Max PECsw (µg/L)	Max PECsed (µg/kg)	PECsed plateau (µg/kg)	Max PECsed (µg/kg)	PECsed plateau (µg/kg)	Max PECsw (µg/L)	Max PECsed (µg/kg)	PECsed plateau (µg/kg)
None	D1 ditch	0.172 / 0.146	- / -	- / -	- / -	- / -	- / -	- / -	- / -
	D1 stream	0.181 / 0.167	- / -	- / -	- / -	- / -	- / -	- / -	- / -
	D2 ditch	0.174 / 0.284	- / -	- / -	- / -	- / -	- / -	- / -	- / -
	D2 stream	0.199 / 0.179	- / -	- / -	- / -	- / -	- / -	- / -	- / -
	D3 ditch	0.172 / 0.144	- / -	- / -	- / -	- / -	- / -	- / -	- / -
	D4 stream	0.171 / 0.148	- / -	- / -	- / -	- / -	- / -	- / -	- / -
	D5 stream	0.185 / 0.171	- / -	- / -	- / -	- / -	- / -	- / -	- / -
	D6 ditch	0.170 / 0.145	- / -	- / -	- / -	- / -	- / -	- / -	- / -
	R1 stream	0.153 / 0.359	- / 3.797	- / 6.885	- / 3.795	- / 6.881	- / -	- / 2.319	- / 4.205
	R3 stream	0.214 / 0.309	- / -	- / -	- / -	- / -	- / -	- / -	- / -
	R4 stream	0.243 / 0.545	- / 4.287	- / 7.773	- / 4.282	- / 7.764	- / 0.356	- / 2.634	- / 4.776

***0.4 for Fractional reduction in run-off volume and flux and Fractional reduction in erosion mass and flux were used for strip vegetative simulation, according to the Austrian Environmental Agency AGES.**

Metabolites of Difenoconazole

Table 8.9-9 ~~8~~: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for 1,2,4-triazole following single/multiple applications to winter wheat

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	1.70 / 3.40	Runoff / drainage	1.68 / 3.37	1.41 / 2.82
Step 2					
Northern Europe	March-May	0.27 / 0.51	Runoff / drainage	0.27 / 0.51	0.23 / 0.42
Southern Europe	March-May	0.53 / 1.00	Runoff / drainage	0.53 / 0.99	0.44 / 0.83

Table 8.9-10 ~~9~~: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for CGA 205375 following single/multiple applications to winter wheat

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	1.58 / 3.15	Runoff / drainage	1.48 / 2.96	39.96 / 79.91
Step 2					
Northern Europe	March-May	0.26 / 0.49	Runoff / drainage	0.25 / 0.47	6.68 / 12.71
Southern Europe	March-May	0.49 / 0.93	Runoff / drainage	0.48 / 0.91	12.83 / 24.48

8.9.2.3 $PEC_{sw/sed}$ of CIAZ

The PEC_{SW} for Boscalid 23.3% + Difenoconazole 6.6% SC was calculated using the following equation:

$$PEC_{SW}\,(\mu g/L) = \frac{\%Drift_{90th\,\%ile} \times Application\,rate\,(g/ha)}{Water\,depth\,(cm) \times 10}$$

The application of CIAZ is 1.5 L/ha, corresponding to 1666.5 g/ha (taking into account a density of 1.111 g/cm^3) for winter wheat. The depth of the static water body was assumed to be 30 cm. The resulting maximum instantaneous PEC_{SW} value is presented in the table 8.9-10.

Table 8.9-11: PEC_{sw} for CIAZ following single application to winter wheat

Crop	Distance (m)	Drift (%)	Max PEC_{sw} (µg/L)
Winter wheat	1	2.77	15.39
		2.38	26.44

The PEC_{sed} for CIAZ was calculated using the following equation:

$$PEC_{sed}\,(\mu g/kg\,dw) = \frac{\%Drift_{90th\,\%ile} \times Application\ rate\ (g/ha) \times \%Active\ substance\ in\ sediment}{1000 \times sediment\ density\ (g/cm^3) \times sediment\ height\ (cm)}$$

The application of CIAZ is 1.5 L/ha, corresponding to 1666.5 g/ha (taking into account a density of 1.111 g/cm^3) for winter wheat. The maximum percentage of Boscalid in the sediment is 79.9 % and of Difenoconazole in the sediment is 99.8%. The height of the sediment was assumed to be 5 cm and the sediment density was assumed to be 1.3 g/cm^3. The resulting maximum instantaneous PEC_{sed} value is presented in the table 8.9-11.

Table 8.9-12: PEC_{sed} for CIAZ following single application to winter wheat

Crop	Distance (m)	Drift (%)	Active substance	% in sediment	Max PEC_{sed} (µg/kg) (based on maximum occurrence)
Winter wheat	1	2.77	Boscalid	79.9	56.74
		2.38			97.51
		2.77	Difenoconazole	99.8	70.88
		2.38			121.80

Comments zRMS:

Boscalid

PECsw/sed calculations have been accepted.
According to DAR and EFSA Journal 2011;9(1):1967 in field studies no metabolites were found in amounts greater than 10% of the applied parent, therefore no PECsw/sed calculations are performed for metabolites of boscalid.
The calculations cover proposed uses in GAP.

Difenoconazole

PECsw/sed calculations have been accepted.
The single sorption parameter values considered for the calculations were taken from the EFSA conclusion Difenoconazole, EFSA Journal 2011; 9(1): 1967. However, instead of the arithmetic mean of the Kfoc values listed by EFSA, the geometric mean of the Kfoc values for parent and its metabolites were considered in the assessment in accordance with the latest EFSA guideline (EFSA, 2014). For CGA71019 (1,2,4-triazole) the field soil degradation rates derived by the CRD (UK) in January 2013 were considered. As document by CRD (2013) was peer-reviewed and presents EU agreed data for 1,2,4-triazole, values used by the Applicant are valid and accepted.
The calculations cover proposed uses in GAP.

Additionally, the Applicant used for strip vegetative simulation according to the Austrian Environmental Agency AGES. However, according to the “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) it has been decided that“ other approaches for simulating run-off mitigation reductions are not recommended for the Core Assessment.

The approaches will be acceptable for national authorisations; such approaches should only be presented in National Assessment Report.”.

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	Boscalid
Direct photolysis in air	Photolytically stable in water. Photolysis in air not expected. Not stable under influencec of radicals.
Quantum yield of direct phototransformation	< 2.45 x 10^{-4}
Photochemical oxidative degradation in air	DT_{50}: < 1.1d AOPWIN Version 1.88, [OH radicals] = 8 x 10^{5} cm^{-3}
Volatilisation	Vapour pressure (Pa): 7.2 x 10^{-7} (20°C) Henry's Law Constant (Pa.m3/mol): 5.178 x 10^{-5}
Metabolites	-

The vapour pressure at 20 °C of the active substance Boscalid is < 10^{-5} Pa. Hence the active substance Boscalid is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Boscalid due to volatilization with subsequent deposition should not be considered.

Table 8.10-2 Summary of atmospheric degradation and behaviour

Compound	Difenoconazole
Direct photolysis in air	Not submitted, not required
Quantum yield of direct phototransformation	Difenoconazole: 0.0155 (in water) CGA 205375: 0.0266 (in water)
Photochemical oxidative degradation in air	DT50 (h): 5 hours derived by the Atkinson model (AOP 1.85) OH (12h) concentration assumed =1.5 x 10^{6} radicals/cm^{3}
Volatilisation	From soil: < 0.05% after 24 hours (measured as % ^{14}C in absorption trap). From plants and soil: < 9% after 24 hours (measured as % loss). Vapour pressure (Pa): 3.32 x 10^{-8} at 25°C (99.0%) Henry's Law Constant (Pa.m3/mol): 9.0 x 10^{-7} at 25°C
Metabolites	-

The vapour pressure at 20 °C of the active substance Difenoconazole is < 10^{-5} Pa. Hence the active substance Difenoconazole is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Difenoconazole due to volatilization with subsequent deposition should not be considered.

Comments zRMS:

Agreed with Applicant.

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
Input and output pliks from models subbmited only.					

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
All endpoints for the active substances (boscalid and difenoconazole) and its metabolites were taken from the EU review. -					-

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
None.					

Appendix 2 Detailed evaluation of the new Annex II studies

A 2.1 Study 1

Comments of zRMS:	Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information

Reference:	Data point
Report	Title, author(s), year, report No, document No, Authority registration No
Guideline(s):	Yes/No (If yes, give guidelines; If no, give justification, e.g., “ no guidelines available” or “ methods used comparable to guideline(s) xxx”)
Deviations:	Yes/No (If yes, describe deviations from test guidelines)
GLP:	Yes/No (If no, give justification, e.g., state that GLP was not compulsory at the time the study was performed)
Acceptability:	Yes/No/Supplementary

Materials and methods

Results and discussions

Conclusion

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

No additional information were provided.