FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: **SNS-F-11**

Product names:

DISFERA 90 EC / LIPOSTAR 90 EC

Chemical active substance(s):

Difenoconazole, 90.0 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT Poland

(authorization)

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

Submission date: **01/2024**

MS Finalisation date: 06/2024; 10/2024; 11/2024

Version history

When	What
01/ 2024	Initial dRR
06/2024	zRMS evaluation
10/2024	The Final Registration Report
11/2024	The final RR after the second round of commenting

Table of Contents

8 Fate and behaviour in the environment (KCP 9)

8.1 Critical GAP and overall conclusions

Table 8.1-1: Critical use pattern of the SNS-F-11

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, Fnp G, Gn, Gnp 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 (groundwater)**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Winter wheat	F	*Zymoseptoria tritici* *Blumeria graminis tritici/ Blumeria graminis* *Puccinia triticina/ Puccinia recondite* *Pyrenophora tritici-repentis* *Parastagonospora nodorum*	Foliar spray	BBCH 33-55 (spring)	2	14-21 days	a) 1.0 L/ha b) 2.0 L/ha	a) Difenoconazole 90 g b) Difenoconazole 180 g	200 – 300			A
2	PL	Winter triticale		*Zymoseptoria tritici* *Blumeria graminis tritici/ Blumeria graminis* *Puccinia triticina/ Puc-*	Foliar spray	BBCH 33-55 (spring)	2	14-21 days	a) 1.0 L/ha b) 2.0 L/ha	a) Difenoconazole 90 g b) Difenoconazole 180 g	200 – 300			A

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, Fnp G, Gn, Gnp 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 (groundwater)**
					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			
				cinia recondite *Parastagonospora nodorum*										
3	PL	Winter rape	F	*Leptospharia maculans*	Foliar spray	BBCH 32-39 (spring)	1		a) 1.0 L/ha b) 1.0 L/ha	a) Difenoconazole 90 g b) Difenoconazole 90 g	200-300			A
				Sclerotinia sclerotiorum	Foliar spray	BBCH 60-65 (spring)	1		a) 1.15 L/ha b) 1.15 L/ha	a) Difenoconazole 103.5 g b) Difenoconazole 103.5 g	200-300			A
Minor uses according to Article 51														
4	PL	Spring oilseed rape	F	*Leptospharia maculans* *Sclerotinia sclerotiorum*	Foliar spray	BBCH 32-39 BBCH 60-65	1	-	a) 1.0 L/ha b) 1.0 L/ha a) 1.15 L/ha b) 1.15 L/ha	a) Difenoconazole 90 g b) Difenoconazole 90 g a) Difenoconazole 103.5 g b) Difenoconazole 103.5 g	200-300	NR*		A
5	PL	Linseed (common flax)	F	*Leptospharia maculans* *Sclerotinia sclerotiorum*	Foliar spray	BBCH 32-39 BBCH 60-65	1	-	a) 1.0 L/ha b) 1.0 L/ha a) 1.15 L/ha b) 1.15 L/ha	a) Difenoconazole 90 g b) Difenoconazole 90 g a) Difenoconazole 103.5 g b) Difenoconazole 103.5 g	200-300	NR*		A
6	PL	Poppy seeds	F	*Leptospharia maculans* *Sclerotinia sclerotiorum*	Foliar spray	BBCH 32-39 BBCH 60-65	1	--	a) 1.0 L/ha b) 1.0 L/ha a) 1.15 L/ha b) 1.15 L/ha	a) Difenoconazole 90 g b) Difenoconazole 90 g a) Difenoconazole 103.5 g b) Difenoconazole 103.5 g	200-300	NR*		A

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, Fnp G, Gn, Gnp 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 (groundwater)**
					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			
7	PL	Mustard seeds	F	*Leptospharia maculans* *Sclerotinia sclerotiorum*	Foliar spray	BBCH 32-39 BBCH 60-65	1	-	a) 1.0 L/ha b) 1.0 L/ha a) 1.15 L/ha b) 1.15 L/ha	a) Difenoconazole 90 g b) Difenoconazole 90 g a) Difenoconazole 103.5 g b) Difenoconazole 103.5 g	200-300	NR*		A
8	PL	Gold of pleasure seeds	F	*Leptospharia maculans* *Sclerotinia sclerotiorum*	Foliar spray	BBCH 32-39 BBCH 60-65	1	-	a) 1.0 L/ha b) 1.0 L/ha a) 1.15 L/ha b) 1.15 L/ha	a) Difenoconazole 90 g b) Difenoconazole 90 g a) Difenoconazole 103.5 g b) Difenoconazole 103.5 g	200-300	NR*		A
9	PL	Sunflower seeds	F	*Alternaria spp.* *Leptosphaeria lindquistii* *Sclerotinia sclerotiorum*	Foliar spray	BBCH 32-39 BBCH 60-65	1	-	a) 1.0 L/ha b) 1.0 L/ha a) 1.15 L/ha b)1.15 L/ha	a) Difenoconazole 90 g b) Difenoconazole 90 g a) Difenoconazole 103.5 g b) Difenoconazole 103.5 g	200-300	NR*		A
10	PL	Soyabeans	F	*Cercospora sojina* *Cercospora Kikuchi* *Sclerotinia sclerotiorum*	Foliar spray	BBCH 32-65	1	-	a) 1.15 L/ha b)1.15 L/ha	a) Difenoconazole 103.5 g b) Difenoconazole 103.5 g	200-300	NR*		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

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

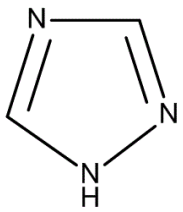
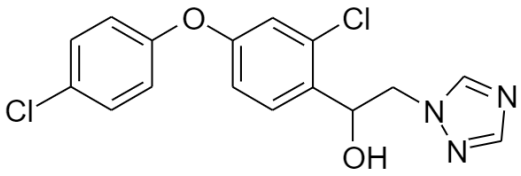
1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

Table 8.1-2: Critical use pattern of SNS-F-11 grouped according to dose

Grouping according to dose		
Group	**Intended uses**	**Maximal dose**
1	**Main crop:**Winter cereals (Winter wheat, Winter triticale)	1 l/ha (2 applications)
2	**Main crop:** Winter oilseed rape, **Minor crop:** Spring oilseed rape, Linseed, Poppy seeds, Mustard seeds, Gold of pleasure seeds, Sunflower seeds, Soyabeans	1.15 l/ha (1 application)

8.2 Metabolites considered in the assessment

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

Metabolite	Molar mass [g/mol]	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
CGA 71019 1,2,4-triazole	69		Soil: 23.4% Surface water: 9.6%	PEC_{gw}: leaching potential to groundwater PEC_{soil}: risk for soil organisms PEC_{sw}: risk for aquatic organisms
CGA 205375 1-[2-[2-chloro-4-(4-chlorophenoxy)-phenyl]-2-1H[1,2,4]triazol-yl]-ethanol	350		Soil: 11.9% Surface water: 11.6% Sediment: 11.6%	PEC_{gw}: leaching potential to groundwater PEC_{soil}: risk for soil organisms $PEC_{sw/sed}$: risk for aquatic organisms

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.

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

Reference to:

1. Conclusion on the peer review of the pesticide risk assessment of the active substances difenoconazole (EFSA (2011);9(1):1967).
2. Draft Assessment Reports for active substance difenoconazole (Vol. 3, Annex B, B.8).

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Difenoconazole and its metabolites

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

Difenoconazole, Laboratory studies, aerobic conditions										
Soil type	**g/ha[1]**	**pH**	**t.°C**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Method of calculation**	**Evaluated on EU level; Reference**
loam	141	7.2	20	40	104	345	64	0.999	SFO	Yes, EFSA Journal 2011;9(1):1967
loam	143	7.2	20	40	118	392	72	0.998	SFO	
Geometric mean, loam (n=2)					**111**	**368**	**111**			
sandy loam	75	5.0	20	40	**123[4]**	409	**123**	0.913	SFO	
silt loam	750	7.2	20	48	456[4]	>>273	456	0.892	SFO	
silt loam	750	7.2	30	48	175[2]	>>178[2]	-	0.977	SFO	
silt loam	750	7.2	20	24	709[2,4]	>>281[2]	-	0.855	SFO	
silt loam	750	7.2	20	48	345[4]	>>281	345	0.973	SFO	
silt loam	750	7.2	10	48	602[2,4]	>>281[2]	-	0.952	SFO	
silt loam	75	7.2	20	48	83	277	83	0.950	SFO	
Geometric mean, silt loam (n=3)					**235**	>277	**235**			
loam	128	7.2	20	22	136[3]	452[2]	-	0.986	SFO	
loam	128	7.2	10	43	338[2,4]	>1000[2]	-	0.993	SFO	
loam	12.8	7.2	20	43	**53**	175	**53**	0.995	SFO	
Loam ster-ile	128	7.2	20	43	>1000[2,4]	>1000[2]	-	-	SFO	
sandy loam	193	7.4	20	40	**149**	496	**136**	0.977	SFO	
sandy loam/ loamy sand	193	7.5	20	40	**186**	617	**177**	0.939	SFO	
Silty clay loam	193	6.7	20	40	**187**	620	**151**	0.972	SFO	

Difenoconazole, Laboratory studies, aerobic conditions										
Soil type	**g/ha[1]**	**pH**	**t.ºC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Method of calculation**	**Evaluated on EU level; Reference**
Geometric mean (n=7)					136	390	**130**			
Median (n=7)					149	≥409	136			

[1] Test concentration re-calculated into corresponding g a.s./ha dose for comparison with the representative uses.
[2] Values not included in the mean/median because they were obtained from test at 10/30ºC, dry moisture or sterile conditions.
[3] In case the same soil was tested under standard conditions, the variations in temperature and moisture were not considered for mean/median values of normalised data.
[4] DT_{50} value extrapolated beyond the durations of the study.

Table 8.3-2: Summary of aerobic degradation rates for CGA 71019 - laboratory studies

CGA 71019, Laboratory studies, aerobic conditions									
Soil type	**pH**	**t.ºC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Method of calculation**	**Evaluated on EU level; Reference**
sandy loam	6.4	20	40	6.3	21	5.0	0.75	SFO	EFSA Journal 2011;9(1):1967
loamy sand	5.8	20	40	9.9	33	9.9	0.81	SFO	
silt loam	6.7	20	40	12	41	8.2	0.95	SFO	
Geometric mean				**9.1**	**30.5**	**7.4**			
Median				9.9	33	7.7			

Table 8.3-3: Summary of aerobic degradation rates for CGA 205375 - laboratory studies

CGA 205375, Laboratory studies, aerobic conditions									
Soil type	**pH**	**t.ºC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Method of calculation**	**Evaluated on EU level; Reference**
sandy loam	7.4	20	40	93	309	85	0.980	SFO	EFSA Journal 2011;9(1):1967
Sandy loam/ loamy sand	7.5	20	40	83	275	79	0.995	SFO	
silt loam	5.8	20	40	**152**	504	123	0.996	SFO	
Geometric mean				106	350	**94**			
Median				93	309	85			

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

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

Table 8.3-4: Summary of anaerobic degradation rates for CGA 71019 and CGA 205375 - laboratory studies

Soil type	pH	t.°C	MWHC %	DT_{50} (d)	DT_{90} (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Method of calculation	Evaluated on EU level; Reference
CGA 71019									EFSA Journal 2011;9(1):1967
silt loam	7.3	20	flooded	**81**	268	-	0.972	SFO	
CGA 205375									
Sandy loam/ loamy sand	7.5	20	flooded	**213**	706	-	0.986	SFO	

8.4 Field studies (KCP 9.1.1.2)

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

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

Reference to:

1. Conclusion on the peer review of the pesticide risk assessment of the active substances difenoconazole (EFSA (2011);9(1):1967).
2. Draft Assessment Reports for active substance difenoconazole (Vol. 3, Annex B, B.8).

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

8.4.1.1 Difenoconazole.

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

Difenoconazole, field studies										
Soil type (indicate if bare or cropped soil was used)		**Location**	**g/ha[1]**	**pH**	**Depth (cm)[2]**	**DT_{50} (d) actual**	**DT_{90}(d) actual**	**Chi^2 (%)**	**DT_{50} (d) Norm. 20°C**	**Method of calculation**
silt loam	bare	Germany	>>250	7.4	0-20	160	532	18.6	-	SFO
silt loam	bare	Germany	500	6.6	0-10	20	68	13.0	-	SFO
loamy sand	bare	Germany	500	6.2	0-10	59	195	18.3	-	SFO
silt loam	bare	Germany	500	6.8	0-20	64	211	14.1	-	SFO
loamy sand	bare	Germany	500	5.6	0-10	61	202	14.8	-	SFO
sandy loam	bare	Germany	750	6.0	0-20	**265**	879	18.6	-	SFO
silt loam	bare	Germany	750	6.0	0-20	242	802	20.9	-	SFO
silt loam	bare	Germany	750	5.7	0-20	118	394	21.8	-	SFO
clay loam	bare	Switzer-land	125	7.3	0-10	83	277	-	-	SFO
Geometric mean						**92**	305			

Median	83	277	
Maximum	**265**	879	

[1] Treatment rate (g a.s./ha) used in studies. 2 Indicates depth considered.
[2] Indicates depth considered

ZRMS comments:

1,2,4-triazole (confirmatory data) - modelling endpoints

Kinetic parameters	Method of calculation	Evaluated on EU level y/n/ Reference
$DegT_{50}$ - fast = 1.68 d Proportion - fast = 0.489 $DegT_{50}$ - slow = 60.5 d Proportion - slow = 0.511	DFOP	Yes: EFSA (2011-2013)[1] 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

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

8.4.2.1 Difenoconazole

No accumulation observed after up to 10 years use under the following conditions: 10-year 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-year study in northern 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-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-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).

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 substances.

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

Reference to:

[1] In: CTGB work instruction: Implementation of bi-phasic kinetics for 1,2,4-triazole in PEARL/GeoPEARL

1. Conclusion on the peer review of the pesticide risk assessment of the active substances difenoconazole (EFSA (2011);9(1):1967).
2. Draft Assessment Reports for active substance difenoconazole (Vol. 3, Annex B, B.8).

8.5.1 Difenoconazole and its metabolites

Table 8.5-1: Summary of soil adsorption for difenoconazole

Difenoconazole						
Soil type	**OC (%)**	**pH (-)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
sand	0.36	7.9	12.8	3870	0.74	Yes/ 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	
Arithmetic mean			40	**3760**	0.85	
Median			41	3495	0.87	
Geomean (n=8)				**2943**		
pH-dependency			No			

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

CGA 71019						
Soil type	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
silty clay	0.70	8.8	0.83	120	0.90	Yes/ EFSA Journal 2011; 9(1):1967
clay loam	1.74	6.9	0.75	43	0.83	
silty clay loam	0.70	7.0	0.72	104	0.92	
sandy loam	0.81	6.9	0.72	89	1.02	
Arithmetic mean			0.75	**89**	0.91	
Median			0.74	82	0.91	
Geometric mean:			-	83		
pH-dependency			No			

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

CGA 205375						
Soil type	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
loamy sand	2.17	5.7	118	5440	0.81	Yes/

CGA 205375						
Soil type	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
silty clay loam	1.16	6.6	45.5	3920	0.76	EFSA Journal 2011; 9(1):1967
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	
Arithmetic mean			51	**2980**	0.76	
Median			44	1930	0.76	
Geomean (n=5)				**2661**		
pH-dependency			No			

8.5.2 Column leaching (KCP 9.1.2.1)

During the study with elution of 200 mm and time period of 2 days, difenoconazole did not move out of the zone of application in any of four soils tested.

8.5.3 Lysimeter studies (KCP 9.1.2.2)

Studies with the formulation were not performed. Not submitted, not required for difenoconazole.

8.5.4 Field leaching studies (KCP 9.1.2.3)

Studies with the formulation were not performed. Not submitted, not required for difenoconazole.

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.

The degradation of difenoconazole were evaluated during the EU review.

Reference to:

1. Conclusion on the peer review of the pesticide risk assessment of the active substances difenoconazole (EFSA (2011);9(1):1967).
2. Draft Assessment Reports for active substance difenoconazole (Vol. 3, Annex B, B.8).

8.6.1 Difenoconazole and its metabolites

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

Difenoconazole

Distribution of total radioactivity in Pond/River systems (20ºC): Max. in water 88/80% day 0.

Decreased to 20/32% by day 3 and to <10% by day 7/14.

Given the short DisT50 from water <1% of applied difenoconazole was estimated to remain in the water column after 7 and 14 days.

Distribution of Difenoconazole in Pond/River systems (8ºC):

Max. in water 83/87% day 0. Decreased to 15/36% by day 3 and to 2.3/12% by day 14.

Max. in sediment 99.8/96.5% day 42.

Metabolites identified (20ºC, 14C-chlorophenyl label):

CGA 205375 max. 4.9% in pond system (days 32 and 127),

max. 11.6-11.4% in river system (days 90-183).

Yes/ EFSA Journal 2011;9(1):1967

Water / sediment system	pH water phase	pH sed	t°C	DT_{50}/DT_{90} whole sys. Degradation	St. (r^2)	DT_{50}/DT_{90} water Dissipation	St.(r^2)	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
Pond	-	6.9	20	ca 324/>1000	0.998	1.0 / 3.3	0.987	-		SFO
River	-	7.2	20	ca 307/>1000	0.999	2.0 / 6.6	0.968	-		SFO
Geometric mean				**315** / >1000		1.1 / 4.6		-		

Table 8.6-2: Summary of observed metabolites

CGA 205375 Water/sediment system	Distribution of CGA 205375 in Pond/River systems: Max. in water 97/96% day 0. Decreased to <10% by day 7/14. Max. in sediment 91/87% day 62/28. Metabolites identified (14C-triazole label): CGA 71019 max. 3.2% in pond system (day 148), max. 14.1% in river system (day 148).	Yes/ EFSA Journal 2011;9(1):1967

Water / sediment system	pH water phase	pH sed	t.°C	DT_{50}/DT_{90} whole sys. Degradation	St. (r^2)	DT_{50}/DT_{90} water Dissipation	St. (r^2)	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
Pond	7.97	7.09	20	ca 630/>1000	0.765	1.4 / 4.7	0.958	-		SFO
River	8.1	7.46	20	ca 301/>1000	0.932	3.1/ 10.2	0.985	-		SFO
Geometric mean				**Ca 435**/ >1000		2.1 / 6.9		-		

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

8.7.1 Justification for new endpoints

There are no deviations from the EU agreed endpoints. PEC_{soil} was calculated according to endpoints for difenoconazole obtained from EFSA (2011);9(1):1967.

8.7.2 Active substance and relevant metabolites

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

Use No.	1	2
Crop	**Winter cereal [a]**	**Winter rape[a]**
Application rate (g Difenoconazole/ha)	1l/ha 90g/ha	1-1.15l/ha 103.5g/ha
Number of applications/interval	2/14-21	1/-
Crop interception (%)	80[b]	80[b]
Depth of soil layer (relevant for plateau concentration) (cm)	5 ($PEC_{S, initial}$)/20 ($PEC_{s,plateau}$)	
Models used for calculation	Simple calculation model (SFO) , (also in accordance with ESCAPE model, version 2)	

a simulations for winter cereals cover both: the uses in winter wheat and winter triticale.
Simulation for winter rape cover the uses in: spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans
b worst case interception rate for the proposed BBCH stages

Table 8.7-2: Input parameter for active substance and relevant metabolites for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT_{50} (days)	Value in accordance to EU endpoint y/n/ Reference
Difenoconazole	406	-	265	Y/EFSA Journal 2011;9(1):1967
CGA 71019	69	23.4	12	/EFSA Journal 2011;9(1):1967 (CRD, 2014: EFSA)
CGA 205375	350	11.9	152	/EFSA Journal 2011;9(1):1967

PEC_{soil} of metabolites

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

PECs (initial) = (Max. PECs (parent) x Max. metabolite occurrence x Molar weight fraction)/100

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

Where:

A_{perent} - Application rate of the parent

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

8.7.2.1 Difenoconazole and its metabolites

Table 8.7-3: PEC_{soil} for difenoconazole on winter cereals (winter wheat, winter triticale):

PEC_{soil} (mg/kg) Application: 90 g/ha		Winter cereals			
		Difenoconazole			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.024	0.024	0.047	0.047
Short term	24h	0.024	0.024	0.047	0.047
	2d	0.024	0.024	0.047	0.047
	4d	0.024	0.024	0.047	0.047
Long term	7d	0.024	0.024	0.046	0.047
	14d	0.023	0.024	0.045	0.046
	21d	0.023	0.024	0.045	0.046
	28d	0.023	0.023	0.044	0.045
	50d	0.021	0.023	0.042	0.044
	100d	0.019	0.021	0.036	0.041
Plateau concentration (20 cm) After 10 year		0.008			
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.055			

Table 8.7-4: PEC_{soil} for difenoconazole on winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soy-abeans)

PEC_{soil} (mg/kg) Application: 103.5 g/ha		Winter oilseed rape	
		Difenoconazole	
		Single application	
		Actual	TWA
Initial		0.028	0.028
Short term	24h	0.028	0.028
	2d	0.027	0.028
	4d	0.027	0.027
Long term	7d	0.027	0.027
	14d	0.027	0.027
	21d	0.026	0.027
	28d	0.026	0.027
	50d	0.024	0.026

	100d	0.021	0.024
Plateau concentration (20 cm) After 10 year		0.004	
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.032	

PEC_{soil} of metabolites

Table 8.7-5: PEC_{soil} for CGA 71019 and CGA 205375 on winter cereals (winter wheat, winter triticale)

PEC_{soil} (mg/kg)		Winter cereals							
		CGA 71019				CGA 205375			
		Single application		Multiple applications		Single application		Multiple applications	
		Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
Initial		0.001	0.001	0.001	0.001	0.002	0.002	0.005	0.005
Short term	24h	0.001	0.001	0.001	0.001	0.002	0.002	0.005	0.005
	2d	0.001	0.001	0.001	0.001	0.002	0.002	0.005	0.005
	4d	0.001	0.001	0.001	0.001	0.002	0.002	0.005	0.005
Long term	7d	0.001	0.001	0.001	0.001	0.002	0.002	0.005	0.005
	14d	0.000	0.001	0.001	0.001	0.002	0.002	0.004	0.005
	21d	0.000	0.001	0.000	0.001	0.002	0.002	0.004	0.005
	28d	0.000	0.000	0.000	0.001	0.002	0.002	0.004	0.004
	50d	0.000	0.000	0.000	0.000	0.002	0.002	0.004	0.004
	100d	0.000	0.000	0.000	0.000	0.002	0.002	0.003	0.004
Plateau concentration (20 cm) After 10 year		Not relevant since DT50 < 90				0.000			
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.001				0.006			

Table 8.7-6: PEC_{soil} for CGA 71019 and CGA 205375 on winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans)

Winter oilseed rape					
PEC_{soil} (mg/kg) Application: 12.5 g/ha		CGA 71019		CGA 205375	
		Single application		Single application	
		Actual	TWA	Actual	TWA
Initial		0.001	0.001	0.003	0.003
Short term	24h	0.001	0.001	0.003	0.003
	2d	0.001	0.001	0.003	0.003
	4d	0.001	0.001	0.003	0.003

Long term	7d	0.001	0.001	0.003	0.003
	14d	0.000	0.001	0.003	0.003
	21d	0.000	0.001	0.003	0.003
	28d	0.000	0.001	0.002	0.003
	50d	0.000	0.000	0.002	0.003
	100d	0.000	0.000	0.002	0.002
Plateau concentration (20 cm) After 10 year		Not relevant since DT50 < 90		0.000	
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.001		0.003	

8.7.2.2 PEC_{soil} of SNS-F-11

Table 8.7-7: PEC_{soil} for SNS-F-11 on winter cereals and winter rape

Formulation	crop	Maximum use rate (g SNS-F-11/ha)[a]	$PEC_{s,initial}$ (mg SNS-F-11kg)[b]
SNS-F-11	Winter cereal	1110	**0.296**
SNS-F-11	Winter rape	1276.5	**0.34**

[a]The formulation contain only 1 a.s, components are considered to dissipate rapidly after application, therefore only one application is taken into consideration. The rate of formulation was based on a specific density of 1.11 g/ml with a maximum application od 1L/ha for winter cereals and 1.15 L/ha for winter rape assuming 80% crop interception
[b] Calculated as:

$$PEC_{s,in}\left[\frac{\mathrm{mg}}{\mathrm{kg}}\right] = \frac{\mathrm{A} \times (1 - I)}{\mathrm{z} \times \mathrm{bd}_{soil} \times 10}$$

ZRMS comments:

zRMS agrees with the submitted calculation of PECs for difenconazole and its metabolites. The used endpoints were agreed at the EU level: DT_{50} for difenoconazole and its metabolite CGA205375 (EFSA, 2011) and for CGA71019/1,2,4-triazole (EFSA, 2011, 2013).
The PECs were assessed in accordance with proposed pattern use in GAP.
These values will be used in further risk assessment.

The maximum PEC_S values for active substance and its metabolites are presented in following table:

Crop	**PECact/PEC acc (mg/kg) Difenconazole**	**PECact (mg/kg) CGA-205375**	**PECact (mg/kg) CGA-71019 (1,2,4-triazole)**	**PECact (mg/kg) Formulation**
Winter OSR	0.028	0.001	0.003	0.340
Winter cereals	0.047	0.002	0.001	0.296

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

8.8.1 Justification for new endpoints

There are no deviations from the EU agreed endpoints. SNS-F-11 was not assessed as representative formulation. PEC_{GW} was calculated, using FOCUS PEARL v 5.5.5, FOCUS PELMO v 6.6.4, according to endpoints for difenoconazole and their metabolites obtained from EFSA Journal 2011; 9(1):1967 and submitted for SNS-F-11.

8.8.2 Active substance and relevant metabolites (KCP 9.2.4.1)

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

Use No.	**1**	**2**
Crop	**Winter cereals** (winter wheat, winter triticale)	**Winter oilseed rape** (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans)
Application rate (g Difenoconazole/ha)	90	103.5
Number of applications/interval (d)	2/14-21	1/-
Relative application date	10 days before emergence	
Crop interception (%)	80	80
Frequency of application	Annual	Annual
Models used for calculation	FOCUS PEARL v 5.5.5, FOCUS PELMO v 6.6.4	FOCUS PEARL v 5.5.5, FOCUS PELMO v 6.6.4

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

Application dates (absolute)			
Crop / **Scenario**	**Winter cereals**	**Winter oilseed rape**	
	BBCH 33	**BBCH 32**	**BBCH 60**
Chateaudun	20.04	15.03	20.04
Hamburg	07.05	20.04	05.05
Jokioinen	18.05	-	-
Kremsmünster	28.04	17.04	05.05
Okehampton	23.04	11.04	30.04
Piacenza	24.03	11.03	15.04
Porto	08.02	09.01	20.04

Application dates (absolute)			
Crop / Scenario	Winter cereals	Winter oilseed rape	
	BBCH 33	BBCH 32	BBCH 60
Sevilla	11.01	-	-
Thiva	25.01	-	-

8.8.2.1 Difenoconazole and its metabolites

Table 8.8-3: Input parameters related to active substance difenoconazole and CGA 71019 and CGA 205375 for PEC_{gw} calculations

Parameter	Compounds			Value in accordance with EU endpoint y/n/ Reference
	Difenoconazole	CGA 71019	CGA 205375	
Physico-Chemical parameters				
Molecular weight [g mol^{-1}]	406,3	69	350	Y/ EFSA Journal 2011; 9(1):1967
Water solubility [mg L^{-1}]	15 (pH 7, 25 °C)	730 (25 °C)	100 (25 °C)	Y/ EFSA Journal 2011; 9(1):1967
Molar enthalpy of dissolution [kJ mol^{-1}]	27	27	27	FOCUS default
Saturated vapor pressure [Pa]	$3{,}32 \times 10^{-8}$ (25 °C)	$3{,}4 \times 10^{-1}$ (25 °C)	$5{,}0 \times 10^{-6}$ (25 °C)	Worst case assumption.
Molar enthalpy of vaporization [kJ mol^{-1}]	95	95	95	FOCUS default
Diffusion coefficient in water [m^2 d^{-1}]	4.3×10^{-5} (20°C)	4.3×10^{-5} (20°C)	4.3×10^{-5} (20°C)	FOCUS default
Diffusion coefficient in gas [m^2 d^{-1}]	0.43 (20°C)	0.43 (20°C)	0.43 (20°C)	FOCUS default
Degradation in soil				
DT_{50} soil [d] (geomean)	130	7,4	94	EFSA Journal 2011; 9(1):1967
Temperature correction function Reference temperature Q10	20 2.58	20 2.58	20 2.58	FOCUS default
Molar activation energy [kJ mol^{-1}]	65.4	65.4	65.4	FOCUS default
Moisture correction function Reference moisture [-] Moisture exponent [-]	pF 2 0.7	pF 2 0.7	pF 2 0.7	FOCUS default
Sorption to soil				
$K_{f,om}$ [mL g^{-1}] (mean Koc/1.724)	2180,6	51,6	1728,2	Y/ EFSA Journal 2011; 9(1):1967
Freundlich exponent 1/n [-]	0.85	0,9	0,8	Y/ EFSA Journal 2011; 9(1):1967
Method of sorption subroutine	*pH independent*			

Parameter	Compounds			Value in accordance with EU endpoint y/n/ Reference
	Difenoconazole	CGA 71019	CGA 205375	
description				
Crop/ Management related parameters				
Crop uptake factor [-]	0	0	0	Worst case assumption

Table 8.8-4: PEC_{gw} difenoconazole and its metabolites on winter cereals (winter wheat, winter triticale)(with FOCUS PEARL 5.5.5)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Difenoconazole	CGA 71019	CGA 205375
Winter cereals BBCH 33	Châteaudun	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001	< 0.001
	Porto	< 0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001

Table 8.8-5: PEC_{gw} difenoconazole and its metabolites on winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans)(with FOCUS PEARL 5.5.5)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Difenoconazole	CGA 71019	CGA 205375
Winter oilseed rape BBCH 32	Chateaudun	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001	< 0.001
	Porto	< 0.001	< 0.001	< 0.001
Winter oilseed rape BBCH 60	Chateaudun	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001	< 0.001
	Porto	< 0.001	< 0.001	< 0.001

Table 8.8-6: PEC_{gw} difenoconazole and its metabolites on winter cereals (winter wheat, winter triticale) (with FOCUS PELMO 6.6.4)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Difenoconazole	CGA 71019	CGA 205375
Winter cereals BBCH 33	Châteaudun	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001	< 0.001
	Porto	< 0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001

Table 8.8-7: PEC_{gw} difenoconazole and its metabolites on winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sun-flower seeds, soyabeans (with FOCUS PELMO 6.6.4)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Difenoconazole	CGA 71019	CGA 205375
Winter oilseed rape BBCH 32	Chateaudun	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001	< 0.001
	Porto	< 0.001	< 0.001	< 0.001
Winter oilseed rape BBCH 60	Chateaudun	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001	< 0.001
	Porto	< 0.001	< 0.001	< 0.001

The PEC_{gw} were calculated for the highest applications rate recommended for use in winter cereals applied for 90 g s.a./ha (2 app.) and in winter oilseed rape applied for 103.5 g s.a./ha (1app.). Obtained PEC_{gw} of difenoconazole and its metabolites in each scenario and for the recommended use of SNS-F-11 in winter cereals and winter rape are significant below the trigger value of 0.1 µg/L and therefore the use of this plant protection product according to recommendations does not pose a risk of groundwater contamination.

ZRMS comments:

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

The 80th percentile groundwater concentrations PECgw 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

There are no deviations from the EU agreed endpoints. SNS-F-11 was not assessed as representative formulation. PEC_{SW} was calculated according to endpoints for Difenoconazole and submitted for SNS-F-11.

8.9.2 Difenoconazole, relevant metabolites and the formulation (KCP 9.2.5)

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

Plant protection product	**SNS-F-11**	
Use No.	**1**	**2**
Crop	Winter cereal	Winter rape
Application rate (g as/ha)	difenoconazole: 90	difenoconazole: 103.5
Number of applications/interval (d)	2/14-21	1/0
Application window	N-Europe and S-Europe March – May and Jun-Sep (relevant for STEP 1 and 2 only)	N-Europe and S-Europe March – May and Jun-Sep (relevant for STEP 1 and 2 only)
Application method	Foliar spraying	Foliar spraying
Models used for calculation	FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3, FOCUS SWAN v5.0.1,	

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for $PEC_{sw/sed}$ calculations for the application of SNS-F-11

Crop	**Scenario**	**Application window used in modelling**
	D1	03.04- 08.07
	D2	13.04- 16.07

Crop	Scenario	Application window used in modelling
Winter cereals BBCH 33-55	D3	26.04- 07.08
	D4	28.03- 05.07
	D5	21.03- 04.06
	D6	20.02- 22.04
	R1	29.04- 02.07
	R3	24.03- 31.05
	R4	04.02- 27.05
Winter oilseed rape BBCH 32-65	D1	-
	D2	20.03- 20.06
	D3	02.03- 03.06
	D4	11.03- 16.06
	D5	08.03- 19.05
	D6	-
	R1	19.04- 02.06
	R3	11.03- 28.04
	R4	-

8.9.2.1 Difenoconazole and its metabolites

$PEC_{sw/sed}$

Table 8.9-3 Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments (EFSA Journal)

Compound	Ecotoxicology lowest regulatory acceptable concentration
Difenoconazole	**0.36 µg/L** Endpoint driving the aquatic risk assessment: ***Pimephales promelas* chronic NOEC = 0.0036 mg a.s./L** (regulatory concentration including a safety factor of 10 = 0.00036 mg a.s./L).
CGA 71019	**320 µg/L** Endpoint driving the aquatic risk assessment: **fish chronic NOEC = 3.2 mg a.s./L** (regulatory concentration including a safety factor of 10 = 0.32 mg a.s./L)..
CGA 205375	**7.4 µg/L** Endpoint driving the aquatic risk assessment: **fish acute EC_{50} = 0.74 mg a.s./L** (regulatory concentration including a safety factor of 100 = 0.0074 mg a.s./L).

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

Compound	Difenoconazole	CGA 71019	CGA 205375	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	406.3	69	350	Y/ EFSA Journal 2011; 9(1):1967

Compound	Difenoconazole	CGA 71019	CGA 205375	Value in accordance to EU endpoint y/n/ Reference
Saturated vapour pressure (Pa)	3.32 x 10^{-8} (25ºC) Set to 0	0	0	Y/ EFSA Journal 2011; 9(1):1967
Water solubility (mg/L)	15 (25 ^{0}C)	730 (25 ^{0}C)	100 (25 ^{0}C)	Y/ EFSA Journal 2011; 9(1):1967
Diffusion coefficient in water (m²/d)	4.3 x 10^{-5}	4.3 x 10^{-5}	4.3 x 10^{-5}	default
Diffusion coefficient in air (m²/d)	0.43	0.43	0.43	default
K_{foc} (mL/g)	3759,4	89	2979,4	Y/ EFSA Journal 2011; 9(1):1967
Freundlich Exponent 1/n	0,85	0,9	0,8	Y/ EFSA Journal 2011; 9(1):1967
Plant Uptake	0	0	0	Y/ EFSA Journal 2011; 9(1):1967
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	0.05 (MACRO) 0.50 (PRZM)	0.05 (MACRO) 0.50 (PRZM)	Y/ EFSA Journal 2011; 9(1):1967
$DT_{50,soil}$ (d)	130	7,4	94	Y/ EFSA Journal 2011; 9(1):1967
$DT_{50,water}$ (d)	315,5	1000	465,5	Y/ EFSA Journal 2011; 9(1):1967
$DT_{50,sed}$ (d)	315,5	1000	465,5	Y/ EFSA Journal 2011; 9(1):1967
$DT_{50,whole\ system}$ (d)	315,5	1000	465,5	Y/ EFSA Journal 2011; 9(1):1967
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 23,4 Total system: 9,6	Soil: 9,7 Total system: 11,6	Y/ EFSA Journal 2011; 9(1):1967
Formation fraction in soil:	-			

$PEC_{sw/sed}$

Table 8.9-5: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for difenoconazole following multiple application(s) of SNS-F-11 to winter cereals (winter wheat, winter triticale)

FOCUS Scenario	Waterbody	Max PEC_{sw} (µg/L)*	Day nr(since start simulation)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	11.63	0	Spraydrift, run-off, drainage	10.05	384.66
Step 2						
Northern Europe	March-May	1.83	18	Spraydrift, run-off, drainage	1.71	65.43
Northern Europe	Jun-Sep	1.84	18		1.71	65.43

FOCUS Scenario	Waterbody	Max PEC_{sw} (µg/L)*	Day nr(since start simulation)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Southern Europe	March-May	3.35	18		3.18	121.95
Southern Europe	June- Sep	2.59	18		2.44	93.69
Step 3						
D1	ditch	**0.5044**	115	drainage	0.1788	2.432
D1	stream	**0.4212**	115		0.005142	0.1001
D2	ditch	**0.5099**	143		0.2156	2.396
D2	stream	**0.4372**	127		0.1073	1.429
D3	ditch	**0.4951**	139		0.05273	0.6501
D4	pond	0.02218	150		0.01752	0.3648
D4	stream	**0.4076**	250		0.002369	0.04530
D5	pond	0.02636	112		0.02066	0.3882
D5	stream	**0.4308**	112		0.002679	0.04130
D6	ditch	**0.4969**	73		0.05954	0.7984
R1	pond	0.08460	198	run-off and erosion	0.07537	2.388
R1	stream	**0.4159**	113		0.03829	8.497
R3	stream	**0.4549**	42		0.03086	7.282
R4	stream	**0.6946**	171		0.07596	11.41

* single applications should be marked.
** twa-time as required by ecotox

$PEC_{sw/sed}$

Table 8.9-6: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for difenoconazole following single application(s) of SNS-F-11 to winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soy-abeans)

FOCUS Scenario	Waterbody	Max PEC_{sw} (µg/L)*	Day nr(since start simulation)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	6.69	0	Spraydrift, run-off, drainage	5.78	221.18
Step 2						
Northern Europe	March-May	1.12	4	Spraydrift, run-off, drainage	1.03	39.6
Northern Europe	Jun-Sep	1.12	4		1.03	39.6
Southern Europe	March-May	2.02	4		1.91	73.31
Southern Europe	June- Sep.	1.57	4		1.47	56.45
Step 3						
D2	ditch	**0.6523**	91	drainage	0.1178	1.582
D2	stream	**0.5424**	91		0.003580	0.05879

FOCUS Scenario	Waterbody	Max PEC_{sw} (µg/L)*	Day nr(since start simulation)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
D3	ditch	**0.6455**	61		0.02510	0.3785
D4	pond	0.02220	78		0.01600	0.2527
D4	stream	**0.4826**	78		0.000922	0.01513
D5	pond	0.02224	67		0.01638	0.2682
D5	stream	**0.5162**	67		0.000916	0.01520
R1	pond	0.04231	113	run-off and erosion	0.03432	1.115
R1	stream	**0.4253**	57		0.01841	3.353
R3	stream	**0.5980**	52		0.01482	1.879

* single applications should be marked.
** twa-time as required by ecotox

FOCUS Step 4

Table 8.9-5: Global maximum PEC_{sw} values for Difenoconazole, following multiple applications of SNS-F-11 in winter cereals (winter wheat, winter triticale) according to the central EU zone GAP according to surface water Step 4

Intendend use		Winter cereals (winter wheat, winter triticale)			
Active substance		Difenoconazole STEP 4			
Application rate (g/ha)		2 x 90			
Group				RAC (µg/L) 0.36	
RAC (µg/L)					
No-spray buffer (m)		1	2	1	2
Vegetated filter strip (m)		1	2	1	2
Nozzle reduction	FOCUS Scenario	PECmax (µg/L)		PEC/RAC ratio	
0%	D1 ditch	-	0.2931	-	0.81
25%		**0.3782**	-	**1.05**	-
50%		0.2519	-	0.69	-
0%	D1 stream	-	0.3335	-	0.93
25%		**0.4301**	-	**1.19**	-
50%		0.2865	-	0.79	-
0%	D2 ditch	-	0.2963	-	0.823
25%		**0.3823**	-	**1.061**	-
50%		0.2546	-	0.707	-
0%	D2 stream	-	0.3462	-	0.96
25%		**0.4465**	-	**1.24**	-
50%		0.2975	-	0.82	-
0%	D3 ditch	-	0.2878	-	0.80
25%		**0.3713**	-	**1.03**	-

Intendend use		**Winter cereals (winter wheat, winter triticale)**			
Active substance		**Difenoconazole STEP 4**			
Application rate (g/ha)		**2 x 90**			
Group				**RAC (µg/L) 0.36**	
RAC (µg/L)					
No-spray buffer (m)		1	2	1	2
Vegetated filter strip (m)		1	2	1	2
Nozzle reduction	**FOCUS Scenario**	**PECmax (µg/L)**		**PEC/RAC ratio**	
50%		0.2473	-	0.68	-
0%	D4 stream	-	0.3228	-	0.89
25%		**0.4163**	-	**1.15**	-
50%		0.2773	-	0.77	-
0%	D5 stream	-	0.3412	-	0.94
25%		**0.4400**	-	**1.22**	-
50%		0.2931	-	0.81	-
0%	D6 ditch	-	0.2888	-	0.8
25%		**0.3726**	-	**1.035**	-
50%		0.2482	-	0.69	-
0%	R1 stream	-	0.08604	-	0.24
25%		0.3296	-	0.92	-
50%		0.2196	-	0.61	-
0%	R3 stream	-	0.3602	-	1.00
25%		**0.4646**	-	**1.29**	-
50%		0.3095	-	0.86	-
0%	R4 stream	-	0.2569	-	0.71
25%		0.3301	-	0.92	-
50%		0.2949	-	0.82	-

Table 8.9-6: Global maximum PEC_{sw} values for Difenoconazole, following single application of SNS-F-11 in winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans) according to the central EU zone GAP according to surface water Step 4

Intendend use		**Winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans)**					
Active substance		**Difenoconazole STEP 4**					
Application rate (g/ha)		**1 x 103.5**					
Group					**RAC (µg/L) 0.36**		
RAC (µg/L)							
No-spray buffer (m)		1	2	3	1	2	3
Vegetated filter strip (m)		1	2	3	1	2	3
Nozzle reduction	**FOCUS Scenario**	**PECmax (µg/L)**			**PEC/RAC ratio**		
0%	D2 ditch	-	-	0.2759	-	-	0.76
25%		-	0.2894	-	-	0.80	-
50%		0.3259	-	-	0.91	-	-
75%		0.1628	-	-	0.45	-	-
0%	D2 stream	-	-	0.3094	-	-	0.85
25%		-	0.3245	-	-	0.90	-
50%		**0.3653**	-	-	**1.01**	-	-
75%		0.1825	-	-	0.50	-	-
0%	D3 ditch	-	-	0.2730	-	-	0.76
25%		-	0.2864	-	-	0.79	-
50%		0.3225	-	-	0.89	-	-
75%		0.1611	-	-	0.45	-	-
0%	D4 stream	-	-	0.2753	-	-	0.76
25%		-	0.2887	-	-	0.80	-
50%		0.3250	-	-	0.90	-	-
75%		0.1624	-	-	0.45	-	-
0%	D5 stream	-	-	0.2944	-	-	0.81
25%		-	0.3088	-	-	0.86	-
50%		0.3476	-	-	0.96	-	-
75%		0.1737	-	-	0.48	-	-
0%	R1 stream	-	-	0.2426	-	-	0.67
25%		-	0.2544	-	-	0.70	-
50%		0.2864	-	-	0.79	-	-
75%		0.1431	-	-	0.39	-	-
0%	R3 stream	-	-	0.3411	-	-	0.94

25%		-	0.3577	-	-	0.99	-
50%		**0.4028**	-	-	**1.11**	-	-
75%		0.2012	-	-	0.58	-	-

In Step 4 the SWAN model was used. Taking into consideration risk mitigation calculations for SNS-F-11 use in winter cereal and winter oilseed rape, following risk mitigation measures should be applied:

Taking into consideration Step 4 calculations for SNS-F-11 following risk mitigation measures should be applied:

– use in winter cereals:

1m buffer zone with vegetative filter strip and 50% spray drift reduction, or

2 m buffer zone with vegetative filter strip

– use in winter rape:

1m buffer zone with vegetative filter strip and 75% spray drift reduction, or

2m buffer zone with vegetative filter strip and 25% spray drift reduction, or

3m buffer zone with vegetative filter strip

Metabolites of difenoconazole

Table 8.9-4: FOCUS Step 1 PEC_{sw} and PEC_{sed} for CGA 71019 following multiple application(s) to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Day nr (since start simulation)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
320 µg/L						
Step 1	---	3.03	0	Spraydrift, run-off, drainage	2.96	2.69

Table 8.9-7: FOCUS Step 1 PEC_{sw} and PEC_{sed} for CGA 71019 following multiple application(s) to winter oilseed rape

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Day nr (since start simulation)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
320 µg/L						
Step 1	---	1.74	0	Spraydrift, run-off, drainage	1.7	1.55

Table 8.9-8: FOCUS Step 1 PEC_{sw} and PEC_{sed} for CGA 205375 following multiple application(s) to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Day nr (since start simulation)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
7.4 µg/L						
Step 1	---	2.38	0	Spraydrift, run-off, drainage	2.2	66.81

Table 8.9-9: FOCUS Step 1 PEC_{sw} and PEC_{sed} for CGA 205375 following multiple application(s) to winter oilseed rape

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Day nr (since start simulation)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
7.4 µg/L						
Step 1	---	1.37	0	Spraydrift, run-off, drainage	1.26	38.41

8.9.2.2 $PEC_{sw/sed}$ of SNS-F-11

SNS-F-11 was not assessed as representative formulation. PEC_{SW} was calculated according to endpoints for Difenoconazole and submitted for SNS-F-11.

ZRMS comments:

The submitted PECsw/sed assessment was accepted. The application dates 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).
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.

zRMS agrees with PECsw calculated at formulation.
The relevant PECsw and PECsed 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	Difenoconazole
Direct photolysis in air	Not relevant
Quantum yield of direct phototransformation	Difenoconazole: 0.0155 (in water) CGA 205375: 0.0266 (in water)
Photochemical oxidative degradation in air	DT_{50} 5 hours derived by the Atkinson method (AOP 1.85). OH (12 h) concentration assumed: 1.5 x 10 6 radicals/cm3.
Volatilisation	Vapour pressure (Pa): 3.32E-8

	Henry's Law Constant (Pa.m3/mol): 9.0E-7 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).
Metabolites	No potentially volatile metabolites

The vapour pressure at 20 °C of the active substance difenoconazole is < 10^{-5} Pa and the Henry's Law Constant is 9.0 x 10^{-7} Pa.m3/mol. Hence the difenoconazole is regarded as non-volatile.

No additional studies have been performed. There was no need to calculate PECa due to low volatility of Difenoconazole. Expected to be negligible.

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

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 9.1	Atkins, R.H.	1991a	CGA 169374, Soil adsorption/desorption of 14C-CGA-169374 by the batch equilibrium method. Novartis Crop Protection AG, Basel, Switzerland. PTRL East, Inc., Richmond, United States, Report No 495. GLP; Not Published Syngenta File N° CGA169374/0477	N	SYNGENTA
KCP 9.1	Atkins, R.H.	1991b	Hydrolysis of 14C CGA169374 at pH 5, 7 and 9. Novartis Crop Protection AG, Basel, Switzerland. PTRL East, Inc., Richmond, United States, Report No 494. GLP; Not Published Syngenta File N° CGA169374/0488	N	SYNGENTA
KCP 9.1	Atkins, R.H.	1994	CGA 169374, Soil surface photolysis of Phenyl-14C-CGA-169374 under artificial sunlight. Novartis Crop Protection AG, Basel, Switzerland.	N	SYNGENTA

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
			PTRL East, Inc., Richmond, United States, Report No 791. GLP; Not Published Syngenta File N° CGA169374/1184		
KCP 9.1	Beidler, W.T.	1991	Stability of CGA 169374 residues in soil under freezer storage conditions for 2 years. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States, Report No ABR-90068. GLP; Not Published Syngenta File N° CGA169374/0451	N	SYNGENTA
KCP 9.1	Baumann, W.	1993	Report on the test for ready biodegradability of CGA 169374 tech. in the carbon dioxide evolution test. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Basel, Oekotoxikologie, Basel, Switzerland, Report No 933652. GLP; Not Published Syngenta File N° CGA169374/0813	N	SYNGENTA
KCP 9.1	Gonzalez-Valero, J.	1992a	CGA 169374 Degradation in soil under aerobic conditions at 20°C. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Basel, Oekotoxikologie, Basel, Switzerland, Report No 91-GJ-05. GLP; Not Published Syngenta File N° CGA169374/0606	N	SYNGENTA
KCP 9.1	Gonzalez-Valero, J.	1992b	Rate of degradation of 14C-CGA 169374 in aerobic soil at various conditions. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No 12-92. GLP; Not Published Syngenta File N° CGA169374/0713	N	SYNGENTA
KCP 9.1	Gonzalez-Valero, J.	1993	Metabolism of CGA 169374 Under Aerobic Conditions in Aquatic Systems. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No 34/92 91GJ04. GLP; Not Published Syngenta File N° CGA169374/0746	N	SYNGENTA
KCP 9.1	Harvey, B. R.	2004	Difenoconazole (CGA169374) Summary of degradation rates in European field dissipation and residue trials. Syngenta Crop Protection AG, Basel, Switzerland.	N	SYNGENTA

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Syngenta, Jealott's Hill, United Kingdom, Report No RAJ0208B. Not GLP; Not Published Syngenta File N° CGA169374/2429		
KCP 9.1	Hawkins, D.R.	1988	Soil adsorption and desorption of 1,2,4- Triazole. Novartis Crop Protection AG, Basel, Switzerland. Rohm and Haas, Philadelphia, United States, Report No 34S-88-27. GLP; Not Published Syngenta File N° CGA71019/0014	N	TRIAZOLE DERIVATIVE METABOLITE GROUP
KCP 9.1	Hennecke, D.	2002a	Quantum Yield of the photochemical degradation of CGA169374 in aqueous solution. Syngenta Crop Protection AG, Basel, Switzerland. Fraunhofer Institut für Umweltchemie und Oekotoxikologie, Schmallenberg, Germany, Report No SYN-001/7-05. GLP; Not Published Syngenta File N° CGA169374/2208	N	SYNGENTA
KCP 9.1	Hennecke, D.	2002b	Quantum yield of the photochemical degradation of CGA205375 in aqueous solution. Syngenta Crop Protection AG, Basel, Switzerland. Fraunhofer Institut für Umweltchemie und Oekotoxikologie, Schmallenberg, Germany, Report No SYN-001/7-05. GLP Not Published Syngenta File N° CGA205375/0017	N	SYNGENTA
KCP 9.1	Mamouni, A.	2000a	Degradation and metabolism of CGA169374 (14C-Triazole) in one soil incubated under aerobic conditions. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 738606. GLP; Not Published Syngenta File N° CGA169374/2101	N	SYNGENTA
KCP 9.1	Mamouni, A.	2000b	Degradation and metabolism of CGA 169374 (14C-Chlorophenyl) in one soil incubated under aerobic conditions. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 738617. GLP; Not Published	N	SYNGENTA

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
			Syngenta File N° CGA169374/2102		
KCP 9.1	Mamouni, A.	2002	Degradation of CGA169374 [14C-Chlorophenyl] in three Soils incubated under Aerobic Conditions. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 775438. GLP;Not Published Syngenta File N° CGA169374/2223	N	SYNGENTA
KCP 9.1	Mamouni, A	2003	[14C]-CGA71019: Anaerobic soil degradation. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 798660. GLP; Not Published Syngenta File N° CGA71019/0062	N	SYNGENTA
KCP 9.1	Mani, J.	1991a	Leaching mobel study with 14C-CGA 169374 in four soil under laboratory conditions. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No 23-91. GLP; Not Published Syngenta File N° CGA169374/0467	N	SYNGENTA
KCP 9.1	Shadrick, BA, Bloomberg, AM, Helfrich, KK	1999	Freezer Storage Stability of 1H-1,2,4- Triazole[3,5-14C] in Soil. Syngenta Crop Protection AG, Basel, Switzerland. Bayer Corporation, Kansas City, United States, Report No 108303. GLP; Not Published Syngenta File N° CGA71019/0068	N	SYNGENTA
KCP 9.1	Slangen, P.J.	2000	Degradation of 1,2,4-triazole in Three Soils under Aerobic Conditions. Novartis Crop Protection AG, Basel, Switzerland. NOTOX B.V., 'S Hertogenbosch, Netherlands, Report No NOTOX 278336. GLP; Not Published Syngenta File N° CGA64250/4345	N	TRIAZOLE DERIVATIVE METABOLITE GROUP
KCP 9.1	Spare, W.C.	1983	Determination of the hydrolysis rate constants of 1,2,4-H-Triazole (CGA 71019). Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States, Report No 83-E-074. Not GLP; Not Published Syngenta File N° CGA71019/0033	N	TRIAZOLE DERIVATIVE METABOLITE GROUP

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
KCP 9.1	Spare, W.C.	1988	CGA 169374, Adsorption/Desorption of 14C-CGA-169374. Novartis Crop Protection AG, Basel, Switzerland. Agrisearch Inc., Frederick, United States, Report No 12115. GLP; Not Published Syngenta File N° CGA169374/0476	N	SYNGENTA
KCP 9.1	Ulbrich, R.	1997	Metabolism of 14C labeled CGA 169374 in aquatic systems under aerobic conditions at 8°C. Novartis Crop Protection AG, Basel, Switzerland. Novartis Crop Protection AG, Basel, Switzerland, Report No 94UL03. GLP; Not Published Syngenta File N° CGA169374/1357	N	SYNGENTA
KCP 9.1	Van, Der Gaauw A.	2001	CGA 205375 [14C-Triazole]: Hydrolysis at three different pH Values. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 798658. GLP; Not Published Syngenta File N° CGA205375/0010	N	SYNGENTA
KCP 9.1	Van, der Gaauw A.	2002a	Aqueous Photolysis of CGA169374 [14C- Triazole] under Laboratory Conditions. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 815635. GLP; Not Published Syngenta File N° CGA169374/2209	N	SYNGENTA
KCP 9.1	Van, der Gaauw A.	2002b	Aqueous Photolysis of CGA205375 [14C- Triazole] under Laboratory Conditions. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 815657. GLP; Not Published Syngenta File N° CGA205375/0018	N	SYNGENTA
KCP 9.1	Völkel, W.	2000a	Degradation and metabolism of CGA 169374 (14C-Triazole) in one soil incubated under anaero-bic conditions. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 738630. GLP; Not Published Syngenta File N° CGA169374/2099	N	SYNGENTA
KCP 9.1	Völkel, W.	2000b	Degradation of CGA 169374 (14C-Triazole) in one soil incubated under various conditions.	N	SYNGENTA

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
			Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No738628. GLP; Not Published Syngenta File N° CGA169374/2100		
KCP 9.1	Völkel, W	2002a	Degradation of CGA205375 [14C-triazole] in three soils incubated under aerobic and anaerobic conditions. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 775451. GLP; Not Published Syngenta File N° CGA169374/2240	N	SYNGENTA
KCP 9.1	Volkel, W.	2002b	Adsorption/Desorption of CGA205375 [14C-Triazole] on Soils. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 798647. GLP; Not Published Syngenta File N° CGA205375/0013	N	SYNGENTA
KCP 9.1	Völkl, S.	2002c	CGA205375 [14C-Triazole]: Route and Rate of Degradation in Aerobic Aquatic Systems. Syngenta Crop Protection AG, Basel, Switzerland, Report No 798636. GLP; Not Published Syngenta File N° CGA205375/0016	N	SYNGENTA
KCP 9.1.1.2	Kühne-Thu, H.	1990a	Determination of residues of parent compound in soil after treatment with 'Difenaconazole EC 250' - field experiment. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No RR-2097-89. GLP (analytical phase); Not Published Syngenta File N° CGA169374/0335	N	SYNGENTA
KCP 9.1.1.2	Kühne-Thu, H.	1990b	Determination of residues of parent compound in soil after treatment with 'Difenaconazole EC 250' - field experiment. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No RR-2096-89. GLP (analytical phase); Not Published Syngenta File N° CGA169374/0336	N	SYNGENTA

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1.2	Kühne-Thu, H.	1990c	Determination of residues of parent compound in soil after treatment with fungicide 'CGA169374 EC 250'. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No RR-2024-89. GLP (analytical phase); Not Published Syngenta File N° CGA169374/0341	N	SYNGENTA
KCP 9.1.1.2	Kühne-Thu, H.	1990d	Determination of residues of parent compound in soil after treatment with fungicide 'CGA169374 EC 250'. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No RR-2023-89. GLP (analytical phase); Not Published Syngenta File N° CGA169374/0342	N	SYNGENTA
KCP 9.1.1.2	Kühne-Thu, H.	1991a	Determination of residues of parent compound in soil after treatment with 'Difenaconazole EC 250' - Field experiment. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No RR-2040-89. GLP (analytical phase); Not Published Syngenta File N° CGA169374/0337	N	SYNGENTA
KCP 9.1.1.2	Kühne-Thu, H.	1991b	Determination of residues of parent compound in soil after treatment with 'Difenaconazole EC 250' - field experiment. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No RR-2039-89. GLP (analytical phase); Not Published Syngenta File N° CGA169374/0338	N	SYNGENTA
KCP 9.1.1.2	Kühne-Thu, H.	1992a	Determination of residues Difenoconazole in asparagus and soil - field trial - Italy. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No 2056-90.	N	SYNGENTA

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP (analytical phase); Not Published Syngenta File N° CGA169374/0695		
KCP 9.1.1.2	Kühne-Thu, H.	1992b	Determination of residues Difenoconazole in soil of sugar beet - field trial - Italy. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No 2054-90. GLP (analytical phase); Not Published Syngenta File N° CGA169374/0696	N	SYNGENTA
KCP 9.1.1.2	Kühne-Thu, H.	1992c	Determination of residues Difenoconazole in soil of sugar beet field - field trial - Italy. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No 2149-90. GLP (analytical phase); Not Published Syngenta File N° CGA169374/0694	N	SYNGENTA
KCP 9.1.1.2	Kühne-Thu, H.	2000	Long term study on fate and behaviour of Difenoconazole (CGA 169374) in soil in Switzerland. Novartis Crop Protection AG, Basel, Switzerland. Novartis Crop Protection AG, Basel, Switzerland, Report No 2031/89-98. GLP; Not Published Syngenta File N° CGA169374/0652	N	SYNGENTA
KCP 9.1.1.2	Molinari, G.P.	2002	Soil dissipation of Difenoconazole (Dissipazione nel suolo del fungicida Difenoconazole). Novartis Crop Protection AG, Basel, Switzerland. Report No CIBA/96/01. GLP; Not Published Syngenta File N° CGA169374/2044	N	SYNGENTA
KCP 9.1.1.2	Purdy, J.	1997	Dissipation and leaching movement of CGA 169374 residues in soil after application as a seed treatment on wheat seed. Novartis Crop Protection AG, Basel, Switzerland. Novartis Crop Protection Inc., Mississauga, Canada, Report No CER 05306/94. GLP; Not Published Syngenta File N° CGA169374/1423	N	SYNGENTA
KCP 9.1.1.2	Resseler, H	1992a	Field Dissipation of Difenaconazole. Test Report - Field Experiment. Ciba-Geigy GmbH, Frankfurt a.Main, Germany, Report No 96-88 B.	N	SYNGENTA

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Not GLP; Not Published Syngenta File N° CGA169374/2302		
KCP 9.1.1.2	Resseler, H.	1992b	Field dissipation of Difenoconazole. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy GmbH, Frankfurt a.Main, Germany, Report No 43-89B. Not GLP; Not Published Syngenta File N° CGA169374/0699	N	SYNGENTA
KCP 9.1.1.2	Resseler, H.	1992c	Field dissipation of Difenoconazole. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy GmbH, Frankfurt a.Main, Germany, Report No 45-89B. Not GLP; Not Published Syngenta File N° CGA169374/0700	N	SYNGENTA
KCP 9.1.1.2	Resseler, H.	1992d	Field dissipation of Difenoconazole. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy GmbH, Frankfurt a.Main, Germany, Report No 46-89B. Not GLP; Not Published Syngenta File N° CGA169374/0701	N	SYNGENTA
KCP 9.1.1.2	Resseler, H	2001a	Field Dissipation of Difenaconazole - Test Report - Field Experiment. Syngenta Agro GmbH, Frankfurt/Main, Germany, Report No 44-89B. Not GLP; Not Published Syngenta File N° CGA169374/2304	N	SYNGENTA
KCP 9.1.1.2	Resseler, H	2001b	Field Dissipation of Difenaconazole Test Report - Field Experiment. Syngenta Agro GmbH, Frankfurt/Main, Germany, Report No 40-90B. GLP; Not Published Syngenta File N° CGA169374/2306	N	SYNGENTA
KCP 9.1.1.2	Resseler, H	2001c	Field Dissipation of Difenaconazole Test Report - Field Experiment. Syngenta Agro GmbH, Frankfurt/Main, Germany, Report No 41-90B. GLP; Not Published Syngenta File N° CGA169374/2308	N	SYNGENTA
KCP 9.1.1.2	Resseler, H	2001d	Field Dissipation of Difenaconazole. test Report - Field Experiment. Syngenta Agro GmbH, Frankfurt/Main, Germany, Report No 42-90B. GLP;Not Published Syngenta File N° CGA169374/2310	N	SYNGENTA

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
KCP 9.1.1.2	Tack, T.J.	1995	The determination of Difenoconazole (CGA169374) residues in soil after successive applications of A7402G 250EC containing 250 g ai CGA 169374 applied as a foliar application to winter wheat and bare soil for three years. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No CSTR 01:11. GLP; Not Published Syngenta File N° CGA169374/1205	N	SYNGENTA
KCP 9.1.1.2	Walser, M.	1994	Field Dissipation of CGA 169374 after Bareground Application of [Phenyl-14C] CGA 169374 labelled Material. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No 92CN08. GLP; Not Published Syngenta File N° CGA169374/0920	N	SYNGENTA
KCP 9.1.1.2	Zelger, R.	2001	Ricerche sul comportamento dei residui di Difenoconazolo nel frutteto. Novartis Crop Protection AG, Basel, Switzerland. Report No Final report after 4th year incl. interi. Translation to English: Research into Difenoconazole Residue Behaviour in Fruit Growing. Not GLP; Not Published Syngenta File N° CGA169374/2043	N	SYNGENTA
KCP 9.2	Beulke, S. Brown, C.	2003	FOCUS Step 1-3 modelling to estimate predicted environmental concentrations in surface water (PECsw) and sediment (PECsed) for difenoconazole and its metabolites CGA205375 and 1,2,4-triazole following use on sugar beet, apple and carrots. Syngenta Crop Protection AG Not GLP, Not Published Syngenta File No CGA169374/2418	N	SYNGENTA
KCP 9.2	Takacs, M.	2006	Difenoconazole (CGA 169374): A European Fate Assessment using FOCUS Surface Water Scenarios at Steps 3 and 4 for Carrots and Apples Syngenta Jealotts Hill International Not GLP, Not Published Syngenta File No CGA169374/2821	N	SYNGENTA

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
KCP 9.2	Turner, N.L., Beulke, S.	2003	Estimation with FOCUS PEARL 2.2.2 of predicted concentrations of difenoconazole and its metabolites CGA205375 and 1,2,4-triazole in groundwater (PECGW) following application to sugar beet, sunflower, apple and carrot crops. Syngenta Crop Protection AG Not GLP, Not Published Syngenta File No CGA169374/2427	N	SYNGENTA
KCP 9.3	Mani, J.	1991b	Volatilization of CGA 169374 from soil under laboratory conditions. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No 13-91. GLP; Not Published Syngenta File N° CGA169374/0468	N	SYNGENTA
KCP 9.3.	Rordorf, B.	1992	Report on vapour pressure curve Ciba -Geigy Ltd., Basel, Switzerland Report No. PP-92-11P-VPC, 23.09.1992 GLP, not published Syngenta File N° 173506 / 207	N	SYNGENTA
KCP 9.3	Sandmeier, P.	1992	Volatilization of CGA169374 from plant and soil after postemergent application of 14C-triazole) labelled material on wheat under indoor conditions. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No 8-92. GLP; Not Published Syngenta File N° CGA169374/0651	N	SYNGENTA
KCP 9.3	Stamm, E.	1998	Atmospheric oxidation of Difenoconazole CGA 169374 by hydroxyl radicals; rate estimation. Novartis Crop Protection AG, Basel, Switzerland. Novartis Crop Protection AG, Basel, Switzerland, Report No 98SM18. Not GLP; Not Published Syngenta File N° CGA169374/1669	N	SYNGENTA

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the new Annex II studies

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