FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

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

Product names:

DISFERA 90 EC / LIPOSTAR 90 EC

Chemical active substance:

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: 07/2024; 10/2024; 11/2024; 04/2025

Version history

When	What
01/ 2024	Initial dRR
05/2024	Additional informations in points: 9.1.1.6; 9.10; A.2.6, and Appendix 1 concerns new ecotoxicological studies for non target plants
07/2024	zRMS evaluation
10/2024	The Final Registration Report
11/2024	The final RR after the second round of commenting
04/2025	The Final Registration Report after correction

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9 Ecotoxicology (KCP 10)

Table 9.2-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
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**						
					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			**Birds**	**Mammals**	**Aquatic organisms**	**Bees**	**Non-target arthropods**	**Soil organisms**	**Non-target plants**
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	A	R	A	A	C	A
2	PL	Winter triticale		*Zymoseptoria tritici* *Blumeria graminis tritici/ Blumeria graminis* *Puccinia triticina/*	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	A	R	A	A	C	A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
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**						
					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			**Birds**	**Mammals**	**Aquatic organisms**	**Bees**	**Non-target arthropods**	**Soil organisms**	**Non-target plants**
				Puccinia recondite *Parastagonospora nodorum*																
3	PL	Winter oilseed 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	A	R	A	A	C	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	A	R	A	A	C	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	A	R	A	A	C	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) Difenocon-	200-300	NR*		A	A	R	A	A	C	A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
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**						
					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			**Birds**	**Mammals**	**Aquatic organisms**	**Bees**	**Non-target arthropods**	**Soil organisms**	**Non-target plants**
										azole 103.5 g										
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	A	R	A	A	C	A
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	A	R	A	A	C	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	A	R	A	A	C	A
9	PL	Sunflower seeds	F	*Alternaria spp.*	Foliar spray	BBCH 32-39	1	-	a) 1.0 L/ha b) 1.0 L/ha	a) Difenoconazole 90 g b) Difenocon-	200-300	NR*		A	A	R	A	A	C	A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
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**						
					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			**Birds**	**Mammals**	**Aquatic organisms**	**Bees**	**Non-target arthropods**	**Soil organisms**	**Non-target plants**
				Leptosphaeria lindquistii *Sclerotinia sclerotiorum*		BBCH 60-65			a) 1.15 L/ha b)1.15 L/ha	azole 90 g a) Difenoconazole 103.5 g b) Difenoconazole 103.5 g										
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	A	R	A	A	C	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 – 21 "Conclusion"

A	Acceptable, Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

Remarks table:

(1) Numeration necessary to allow references
(2) Use official codes/nomenclatures of EU
(3) For crops, the EU and Codex classifications (both) should be used; where 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

Section Ecotoxicology: The risk assessment for all uses in GAP in terms of soil organisms should be considered at MSs level.

9.1.1 Overall conclusions

9.1.1.1 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

Birds and Mammals

The calculated TER values, for recommended scenarios, all exceed the trigger values of 10 for acute risk and 5 for long-term risk. There was also no negative effects regarding to drinking water exposure and effect of secondary poisoning, indicating that the risk to birds and mammals is acceptable following use of SNS-F-11 according to the proposed use pattern.

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

An estimation of risk indicate low risk for aquatic organism in each range of assessed issues. Calculations conducted due to the influence of SNS-F-11 due to the acute and long-term toxicity did not indicate any hazardous properties and danger for aquatic organisms.

Taking into consideration Step 4 calculations for SNS-F-11 – use in winter cereals (winter wheat, winter triticale), following risk mitigation measures should be applied:

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

Taking into consideration Step 4 calculations for SNS-F-11 – use in winter oilseed rape, (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans), following risk mitigation measures should be applied:

- 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

9.1.1.3 Effects on bees (KCP 10.3.1)

The HQ values are lower than the trigger of 50, indicating low risk to bees from difenoconazole following applications of SNS-F-11. Calculation conducted for SNS-F-11 regarding to the oral and contact toxicity also confirm no risk for bees due to the use that formulation: achieved values are lower than 50.

Therefore a low risk to bees is expected from the application of SNS-F-11 following application according to the proposed GAP. According to EU Reg. 284 /2009, the chronic toxicity study for adult bees, and the chronic test for larvae were submitted, same as the acute contact and oral tests for bumblebees.

The Applicant delivered supplement risk assessment for bees in accordance with EFSA 2013. The risk assessment was accepted by zRMS.

First tier chronic evaluation of the risk to adult bees exposed to difenconazole resulted with ETR value above the trigger in some scenario indicating potentially unacceptable risk:

- chronic risk assessment in treated crop, weeds and next crop for scenario for cereals;

- chronic risk assesment in treated crop and weeds for scenario oilseed rape, sunflower, flax and poppy, linseed and mustard seed.

No data enabling refinement of the risk was available. We agree that it is difficult to determine chronic toxicity to bees in this case because the laboratory study for Disfera 90 EC used limit tests and therefore no specific dose causing toxicity has been identified. Nevertheless, since the EFSA Bee Guidance Document is yet to be implemented (2013), this result should be treated as indication of area that should be covered in the future, once the guidance document is officially noted and accepted. Further assessments from chronic exposure could be required at national level. The chronic risk assessment for bees should be considered by MSs level.

9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)

$HQ_{in\text{-}field}$ and $HQ_{off\text{-}field}$ values for *A. rhopalosiphi* and *T. pyri* are below the ESCORT 2 trigger of 2. The Tier I laboratory studies showed acceptable in-field and off-field effects from foliar applications of SNS-F-11 for *Aphidius rhopalosiphi* and *Typhlodromus pyri* for the use in winter cereals (winter wheat, winter triticale) and winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans).

9.1.1.5 Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)

An estimation of risk indicate low risk for earthworms and microbial activity in soil in each range of assessed issues.

For earthworm, TER_{LT} values for active substance – difenconazole, for use in winter cereals, and for formulation SNS-F-11 for use is winter rape, being slight below trigger value of 5. According to the expert opinion from the PPR TC 58 (28-30.06.2021), difenoconazole at a rate of 250 g a.s./ha did not result in sustaining adverse effects on a natural earthworm population after a period of one year. As above, an application of SNS-F-11 in respect of the GAP should not represent an long-term risk to earthworm and the other soil macrofauna.

9.1.1.6 Effects on non-target terrestrial plants (KCP 10.6)

SNS-F-11 as fungicide does not have any effects to terrestrial non-target plants. There is a low risk to non-target flora after application of SNS-F-11 as proposed. Based on risk assessment regarding effects of SNS-F-11~~difenoconazole~~ on non-target terrestrial plants, no risk mitigation needed.

9.1.1.7 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Tests on other non-target species are not required.

9.1.2 Grouping of intended uses for risk assessment

The following table documents the grouping of the intended uses to support application of the risk envelope approach (according to SANCO/11244/2011).

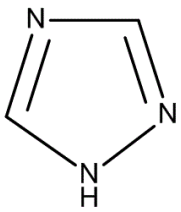
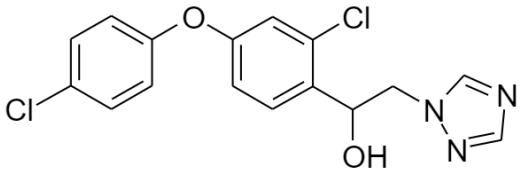
Table 9.2-2: Critical use pattern of SNS-F-11 grouped according to dose

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)

9.1.3 Consideration of metabolites

A list of metabolites found in environmental compartments is provided below. The need for conducting a metabolite-specific risk assessment in the context of the evaluation of SNS-F-11 is indicated in the table.

Table 9.2-3 Metabolites of Difenoconazole

Metabolite	Chemical structure	Molar mass [g/mol]	Maximum observed occurrence in compartments	Risk assessment required
CGA 71019 1,2,4-triazole		69	Soil: 23.4% Surface water: 9.6%	YES
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%	YES

zRMS comments:
Information regarding difenoconazole metabolites provided in Table 9.1-3 is in line with data reported in EFSA.

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Avian toxicity studies have been carried out with difenoconazole and its relevant metabolites. Full details of these studies are provided in the EFSA Journal 2011;9(1):1967, and respective EU DAR and related documents.

However, the provision of further data on the SNS-F-11 is not considered essential, because of low risk of difenoconazole to birds provided in previous studies. The risk to birds from the proposed uses of SNS-F-11 will be assessed using the endpoints for difenoconazole.

Table 9.2-1: Endpoints and effect values relevant for the risk assessment for birds

Species	Substance	Exposure System	Results	Reference
Japanese quail (*Coturnix japonica*)	difenoconazole	Oral 1 d Acute	**LD50 > 2000** mg/kg bw	EFSA Journal 2011;9(1):1967
Mallard duck (*Anas platyrhynchos*)	difenoconazole	Dietary 5 d Short-term	5 d LC_{50} >349	EFSA Journal 2011;9(1):1967
Bobwhite quail (*Colinusn virginianus*)	difenoconazole	Dietary Reproductive toxicity	**NOEL = 9.71** mg/kg bw/d	EFSA Journal 2011;9(1):1967
Mallard duck (*Anas platyrhynchos)*	Plant metabolite CGA131013	Dietary 5 d Short-term	LDD_{50} = > 1342 mg/kg bw/d LC_{50} >5000 mg/kg feed	EFSA Journal 2011;9(1):1967

9.2.1.1 Justification for new endpoints

Endpoints for difenoconazole were presented in EFSA Journal 2011;9(1):1967 and Draft Assessment Report (Vol. 3, Annex B, B.9).

9.2.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

9.2.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive screening/first-tier risk assessments are summarised in the following tables.

Table 9.2-2: Screening step assessment of the acute and long-term/reproductive risk for birds due to the use of SNS-F-11 in winter cereals (winter wheat, winter triticale)

Intended use	Winter cereals
Active substance/product	difenoconazole
Application rate (g/ha)	2 × 90
Acute toxicity (mg/kg bw)	> 2000 > 349

TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Winter cereal	Small omnivorous bird	158.8	1.2	17.15	>114.3 >20.35
Reprod. toxicity (mg/kg bw/d)	9.71				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Winter cereal	Small omnivorous bird	64.8	1.4 x 0.53	4.32	**2.24**

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-3: Screening step assessment of the acute and long-term/reproductive risk for birds due to the use of SNS-F-11 in winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans)

Intended use	**Winter oilseed rape**				
Active substance/product	difenoconazole				
Application rate (g/ha)	1 × 103.5				
Acute toxicity (mg/kg bw)	> 2000 > 349				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Winter rape	Small omnivorous bird	158.8	1	16.4	>122 > 21.28
Reprod. toxicity (mg/kg bw/d)	9.71				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Winter rape	Small omnivorous bird	64.8	1 x 0.53	3.55	**2.7**

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-4: Tier 1 assessment of the long-term/reproductive risk for birds due to the use of SNS-F-11 in winter cereals (winter wheat, winter triticale)

Intended use	**Winter cereals**				
Active substance/product	difenoconazole				
Application rate (g/ha)	2 × 90				
Reprod. toxicity (mg/kg bw/d)	9.71				
TER criterion	5				
Crop scenario Growth stage	**generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cereals BBCH 30-39	Small omnivorous bird "lark"	5.4	1.4 x 0.53	0.36	27

Cereals BBCH >40	Small omnivorous bird "lark"	3.3	1.4 x 0.53	0.22	44

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-5: Tier 1 assessment of the long-term/reproductive risk for birds due to the use of SNS-F-11 winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans)

Intended use	**Winter oilseed rape**
Active substance/product	difenoconazole
Application rate (g/ha)	1 x 103.5
Reprod. toxicity (mg/kg bw/d)	9.71
TER criterion	5

Crop scenario Growth stage	**generic focal species**	**SV_m**	**$MAF_m \times TWA$**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Winter rape BBCH 30-39	Small omnivorous bird "lark"	3.3	1 x 0.53	0.18	54
Winter rape BBCH ≥40	Small omnivorous bird "lark"	2.7	1 x 0.53	0.15	65
Winter rape BBCH 30-39	Medium herbivorous/granivorous bird „pigeon"	1.1	1 x 0.53	0.06	162
Winter rape BBCH ≥40	Medium herbivorous/granivorous bird „pigeon"	0.9	1 x 0.53	0.05	194

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

zRMS comments: zRMS accept the toxicity endpoints for difenconazole according to EFSA Conclusion Report 2011; 9(1):1967. The toxicity data for acute and long-term risk were agreed at the EU level. For acute risk assessment, the short-term dietary LDD_{50} = 349 mg/kg bw/d was also taken into account. In addition the metabolite, CGA131013, is formed in plants. According to the RMS, the risk assessment for metabolite - CGA131013 is not necessary. The risk assessment for the active substance difenconazole will cover the risk for the metabolite - CGA131013.

Justification:
The short-term avian LC_{50} for CGA131013 is > 1342 mg/kg b.w./day, and therefore clearly has a lower dietary toxicity to birds compared to the parent compound difenoconazole, for which a 5-day LC_{50} value of >349 mg/kg bw/day has been determined. Since the acute and long-term risk assessments below demonstrate acceptable risk to the parent compound, the ecological risks from potential exposure to this metabolite are expected to be negligible, thus CGA131013 will not be considered further in the risk assessment, which is in line with the residue definition for difenoconazole. Negligible exposure to this metabolite is expected when applied by foliar spray.

9.2.2.2 Higher-tier risk assessment

Not relevant.

9.2.2.3 Drinking water exposure

When necessary, the assessment of the risk for birds due to uptake of contaminated drinking water is conducted for a small granivorous bird with a body weight of 15.3 g (*Carduelis cannabina*) and a drinking water uptake rate of 0.46 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

Leaf scenario

Since SNS-F-11 is not a product for spray applications / not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

With a K(f)oc of 3760, difenoconazole belongs to the group of more sorptive substances. Here, the maximum use rate of 2 x 90 g a.s./ha (MAF= 1.4) is used (it covers the risk for birds from other intended use – winter oilseed rape = 1x 103.5 g sa/ha, MAF=1)(see 9.1.2).

Effective application rate (x MAF) (g/ha)=	90 x 1.4 =126		
Acute toxicity (mg/kg bw)=	> 2 000 >349	quotient=	<0.063 0.36
Reprod. toxicity (mg/kg bw/d)=	9.71	quotient=	13

The resulting ratio falls below the trigger of 3 000 indicating that further assessment of the acute and long term risk to birds from drinking water from puddles is not required for difenoconazole.

zRMS comments: Agreed.

9.2.2.4 Effects of secondary poisoning

The log Pow of difenoconazole is 4.4 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

Risk assessment for earthworm-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous birds is assessed for a bird of 100 g body weight with a daily food consumption of 104.6 g. Bioaccumulation in earthworms is estimated based on predicted concentrations in soil. Here, the 21-day time-weighted average soil PEC's following: 2 x 90 g a.s./ha application to winter cereals and 1 x 103 g a.s./ha application to winter oilseed rape were used.

Table 9.2-3: Assessment of the risk for earthworm-eating birds due to exposure to difenoconazole via bioaccumulation in earthworms (secondary poisoning) for the intended use in winter cereals (winter wheat, winter triticale)

Parameter	difenoconazole	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.046	According to table 8.7-3, dRR section B8
log P_{ow} / P_{ow}	4.4/ 25119	EFSA J 2011; 9(1):1967
Koc	3760	Mean value. EFSA J 2011; 9(1):1967
foc	0.02	Default
BCF_{worm}	4.02	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.12 \times P_{ow}) / foc \times Koc$
PEC_{worm}	0.185	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.194	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	9.71	EFSA J 2011; 9(1):1967
TER_{lt}	50	TERlt >5, No risk,

TER values shown in bold fall below the relevant trigger.

Table 9.2-7: Assessment of the risk for earthworm-eating birds due to exposure to difenoconazole via bioaccumulation in earthworms (secondary poisoning) for the intended use in winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans)

Parameter	difenoconazole	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.027	According to table 8.7-4, dRR section B8
log P_{ow} / P_{ow}	4.4/ 25119	EFSA J 2011; 9(1):1967
Koc	3760	Mean value. EFSA J 2011; 9(1):1967
foc	0.02	Default
BCF_{worm}	4.02	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.12 \times P_{ow}) / foc \times Koc$
PEC_{worm}	0.11	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.113	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	9.71	EFSA J 2011; 9(1):1967
TER_{lt}	86	TERlt >5, No risk,

TER values shown in bold fall below the relevant trigger.

zRMS comments: Agreed.

Risk assessment for fish-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous birds is assessed for a bird of 1000 g body weight with a daily food consumption of 159 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water. Here, the 21-day time-weighted average Surface water PEC's following: 2 x 90 g a.s./ha application to winter cereals and 1 x 103 g a.s./ha application to winter oilseed rape, were used.

Table 9.2-8: Assessment of the risk for fish-eating birds due to exposure to difenoconazole via bioaccumulation in fish (secondary poisoning) for the intended use in winter cereals (winter wheat, winter triticale)

Parameter	difenoconazole	comments
PEC_{sw} (twa = 21 d) (mg/L)	0.01	According to table 8.9-5, dRR section B8
BCF_{fish}	330	Measured value (EFSA J 2011; 9(1):1967
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	3.3	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.524	$DDD = PEC_{fish} \times 0.159$
NOEL (mg/kg bw/d)	9.71	EFSA J 2011; 9(1):1967
TER_{lt}	18.5	TERlt >5, No risk,

TER values shown in bold fall below the relevant trigger.

Table 9.2-9: Assessment of the risk for fish-eating birds due to exposure to difenoconazole via bioaccumulation in fish (secondary poisoning) for the intended use in winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans)

Parameter	difenoconazole	comments
PEC_{sw} (twa = 21 d) (mg/L)	0.005	According to table 8.9-6, dRR section B8
BCF_{fish}	330	Measured value (EFSA J 2011; 9(1):1967
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	1.65	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.262	$DDD = PEC_{fish} \times 0.159$
NOEL (mg/kg bw/d)	9.71	EFSA J 2011; 9(1):1967
TER_{lt}	37.1	TERlt >5, No risk,

TER values shown in bold fall below the relevant trigger.

zRMS comments: Agreed.

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.2.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.2.4 Overall conclusions

According to the screening and first-tier risk assessment for uses in winter cereals (winter wheat, winter triticale), and winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans) all calculated TER_{acute} and $TER_{long\ term}$ values for active substance- difenoconazole are greater than the Annex VI trigger of 10 and 5, respectively. It shows that SNS-F-11, presents no unacceptable acute and long-term risk to birds according to the intended uses on winter

cereals and winter oilseed rape. Additionally, no unacceptable risk was observed to earthworm-eating and fish-eating birds according to the intended uses of SNS-F-11.

zRMS comments: Agreed. TER values exceed the relevant triggers indicating that **DISFERA 90 EC** does not pose an unacceptable risk to birds following applications according to recommended use pattern.

9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

9.3.1 Toxicity data

Mammalian toxicity studies have been carried out with difenoconazole and metabolite. Full details of these studies are provided in the EFSA Journal 2011;9(1):1967, and respective EU DAR and related documents.

However, the provision of further data on the formulation SNS-F-11 is not considered essential, because risk assessment can be conducted based on data for active substances. The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.3-1: Endpoints and effect values relevant for the risk assessment for mammals

Species	Substance	Exposure System	Results	Reference
Rat	difenoconazole	Oral 1 d Acute	LD_{50} >1453 mg/kg bw/d	EFSA Journal 2011;9(1):1967
Rat	difenoconazole	Long- term Reproductive toxicity Two-generation study	NOAEL = 17.3 mg/kg bw/d	EFSA Journal 2011;9(1):1967

9.3.1.1 Justification for new endpoints

Not relevant, as there is no deviation to the EU agreed endpoints. The acute and long-term risk assessments on mammals for the plant metabolite CGA131013 are covered by the acute and log-term risk assessments of the parental difenoconazole.

9.3.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Mammals and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

9.3.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

Table 9.3-2: Screening step assessment of the acute and long-term/reproductive risk for mammals due to the use of SNS-F-11 in winter cereals (winter wheat, winter triticale)

Intended use	**Winter cereals**
Active substance/product	difenoconazole

Application rate (g/ha)	2 × 90				
Acute toxicity (mg/kg bw)	1453				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Winter cerealc	Small herbivorous mammal	118.4	1.2	12.8	113.5
Reprod. toxicity (mg/kg bw/d)	17.3				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Winter oilseed rape	Small herbivorous mammal	48.3	1.4 x 0.53	3.2	5.4

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-3: Screening step assessment of the acute and long-term/reproductive risk for mammals due to the use of SNS-F-11 in winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans)

Intended use	**Winter oilseed rape**				
Active substance/product	difenoconazole				
Application rate (g/ha)	1 × 103.5				
Acute toxicity (mg/kg bw)	1453				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Winter cerealc	Small gerbivorous mammal	118.4	1	12.3	118.1
Reprod. toxicity (mg/kg bw/d)	17.3				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Winter oilseed rape	Small herbivorous mammal	48.3	1 x 0.53	2.65	6.52

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

zRMS comments: Agreed. TER values exceed the relevant triggers indicating that **DISFERA 90 EC** does not pose an unacceptable acute and long-term risk to mammals following applications according to recommended use pattern.

9.3.2.2 Higher-tier risk assessment

Not relevant.

9.3.2.3 Drinking water exposure

When necessary, the assessment of the risk for mammals due to uptake of contaminated drinking water is conducted for a small omnivorous mammal with a body weight of 21.7 g (*Apodemus sylvaticus*)

and a drinking water uptake rate of 0.24 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

With a K(f)oc of 3760, difenoconazole belongs to the group of more sorptive substances. Here, the maximum use rate of 2 x 90 g a.s./ha (MAF= 1.4) is used (it covers the risk for mammals from other intended use – winter oilseed rape = 1x 103.5 g sa/ha, MAF=1)(see 9.1.2).

Effective application rate (g/ha) =	90x1.4= 126		
Acute toxicity (mg/kg bw) =	1453	quotient =	0.086
Reprod. toxicity (mg/kg bw/d) =	17.3	quotient =	7.28

The resulting ratio falls below the trigger of 3 000 indicating that further assessment of the acute and long term risk to mammals from drinking water from puddles is not required for difenoconazole.

zRMS comments: Agreed.

9.3.2.4 Effects of secondary poisoning

The log Pow of difenoconazole is 4.4 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

Risk assessment for earthworm-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous mammals is assessed for a small mammal of 10 g body weight with a daily food consumption of 12.8 g. Bioaccumulation in earthworms is estimated based on predicted concentrations in soil.

Here, the 21-day time-weighted average soil PEC's following: 2 x 90 g a.s./ha application to winter cereals and 1 x 103 g a.s./ha application to winter oilseed rape were used.

Table 9.3-4: Assessment of the risk for earthworm-eating mammals due to exposure to difenoconazole via bioaccumulation in earthworms (secondary poisoning) for the intended use in winter cereals (winter wheat, winter triticale)

Parameter	difenoconazole	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.046	According to table 8.7-3, dRR section B8
log P_{ow} / P_{ow}	4.4/ 25119	EFSA J 2011; 9(1):1967
Koc	3760	Mean value. EFSA J 2011; 9(1):1967
foc	0.02	Default
BCF_{worm}	4.02	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$

Parameter	difenoconazole	comments
		= (0.84 + 0.12 × P_{ow}) / foc × Koc
PEC_{worm}	0.185	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.194	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	17.3	EFSA J 2011; 9(1):1967
TER_{lt}	89	TERlt >5, No risk,

TER values shown in bold fall below the relevant trigger.

zRMS comments: Agreed.

Table 9.3-5: Assessment of the risk for earthworm-eating mammals due to exposure to difenoconazole via bioaccumulation in earthworms (secondary poisoning) for the intended use in winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans)

Parameter	difenoconazole	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.027	According to table 8.7-4, dRR section B8
log P_{ow} / P_{ow}	4.4/ 25119	EFSA J 2011; 9(1):1967
Koc	3760	Mean value. EFSA J 2011; 9(1):1967
foc	0.02	Default
BCF_{worm}	4.02	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ = (0.84 + 0.12 × P_{ow}) / foc × Koc
PEC_{worm}	0.11	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.113	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	17.3	EFSA J 2011; 9(1):1967
TER_{lt}	153	TERlt >5, No risk,

TER values shown in bold fall below the relevant trigger.

zRMS comments: Agreed.

Risk assessment for fish-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous mammals is assessed for a mammal of 3000 g body weight with a daily food consumption of 425 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water. Here, the 21-day time-weighted average Surface water PEC's following: 2 x 90 g a.s./ha application to winter cereals and 1 x 103 g a.s./ha application to winter oilseed rape were used.

Table 9.3-6: Assessment of the risk for fish-eating mammals due to exposure to difenoconazole via bioaccumulation in fish (secondary poisoning) for the intended use in in winter cereals (winter wheat, winter triticale)

Parameter	difenoconazole	comments
PEC_{sw} (twa = 21 d) (mg/L)	0.01	According to table 8.9-5, dRR section B8

BCF_{fish}	330	Measured value (EFSA J 2011; 9(1):1967
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	3.3	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.47	$DDD = PEC_{fish} \times 0.142$
NOEL (mg/kg bw/d)	17.3	
TER_{lt}	37	

TER values shown in bold fall below the relevant trigger.

Table 9.3-7: Assessment of the risk for fish-eating mammals due to exposure to difenoconazole via bioaccumulation in fish (secondary poisoning) for the intended use in in winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans)

Parameter	difenoconazole	comments
PEC_{sw} (twa = 21 d) (mg/L)	0.005	According to table 8.9-5, dRR section B8
BCF_{fish}	330	Measured value (EFSA J 2011; 9(1):1967
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	1.65	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.23	$DDD = PEC_{fish} \times 0.142$
NOEL (mg/kg bw/d)	17.3	
TER_{lt}	75	

TER values shown in bold fall below the relevant trigger.

zRMS comments: Agreed.

9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.3.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.3.4 Overall conclusions

According to the screening risk assessment for winter cereals (winter wheat, winter triticale), and winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans) all calculated TER_{acute} and $TER_{long\ term}$ values for active substance- difenoconazole are greater than the trigger of 10 and 5, respectively. It shows that SNS-F-11, presents no unacceptable acute and long-term risk to mammals according to the intended uses on winter cereals and winter oilseed rape. Additionaly, no unacceptable risk was observed to earthworm-eating and fish-eating mammals according to the intended uses of SNS-F-11.

zRMS comments: Agreed. TER values exceed the relevant triggers indicating that **DISFERA 90 EC** does not pose an unacceptable risk to mammals following applications according to recommended use pattern.

9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

(KCP 10.1.3)

Not relevant.

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with difenoconazole and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on aquatic organisms of SNS-F-11 were not evaluated as part of the EU assessment of difenoconazole. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.5-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – difenoconazole and relevant metabolites

Species	Substance	Exposure System	Results	Reference
Oncorhynchus mykiss	difenoconazole	96 h, s	LC_{50} = 1.1 mg a.s./L $_{mm}$	EFSA Journal 2011;9(1):1967
Pimephales promelas	difenoconazole	Full life-cycle test	**NOEC = 0.0036 mg/L**	EFSA supporting publication 2014:EN-680
Oncorhynchus mykiss	CGA 205375	96 h, s	LC_{50} = 0.74 mg a.s./L $_{mm}$	EFSA Journal 2011;9(1):1967
Oncorhynchus mykiss	CGA 71019	96 h, s	LC_{50} = 498 mg a.s./L $_{mm}$	EFSA Journal 2011;9(1):1967
Oncorhynchus mykiss	CGA 71019	28 d, s	NOEC = 3.2 mg a.s./L $_{mm}$	EFSA Journal 2011;9(1):1967
Pimephales promelas	difenoconazole	34 d, f	NOEC = 0.0076 mg a.s./L $_{mm}$	EFSA Journal 2011;9(1):1967
Mysidopsis bahia	difenoconazole	96 h, f	**EC_{50} = 0.15 mg a.s./L**	EFSA Journal 2011;9(1):1967
Daphnia magna	difenoconazole	48h, s	EC_{50} = 0.77 mg a.s./L $_{mm}$	EFSA Journal 2011;9(1):1967
Daphnia magna	difenoconazole	21 d, f	**NOEC = 0.0056mg a.s./L $_{mm}$**	EFSA Journal 2011;9(1):1967
Daphnia magna	CGA 205375	48h, s	EC_{50} = 1.4 mg a.s./L $_{mm}$	EFSA Journal 2011;9(1):1967
Daphnia magna	CGA 71019	48h, s	EC_{50} > 100 mg a.s./L $_{mm}$	EFSA Journal 2011;9(1):1967
Scenedesmus subcapitatus	difenoconazole	72 h, s	**E_bC_{50} = 0.032 mg a.s./L $_{mm}$** NOEC = 0.0086 mg/l	EFSA Journal 2011;9(1):1967
Selenastrum capricornutum	CGA 205375	96 h, s	E_rC_{50} = 3.09 mg a.s./L $_{mm}$ E_bC_{50} = 1.23 mg a.s./L $_{mm}$	EFSA Journal 2011;9(1):1967
Selenastrum capricornutum	CGA 71019	96 h, s	E_rC_{50} > 31mg a.s./L $_{mm}$ E_yC_{50} = 8 mg a.s./L $_{mm}$	EFSA Journal 2011;9(1):1967
Chironomus riparius	difenoconazole	28 d, spiked	**$NOEC_{water}$ = 0.015**	EFSA Journal

Species	Substance	Exposure System	Results	Reference
		sediment	**mg a.s./L $_{nom}$** $NOEC_{sediment}$ = 50 mg a.s./kg sed	2011;9(1):1967
Chironomus riparius	CGA 205375	28 d, spiked sediment	$NOEC_{water}$ = 0.4 mg a.s./L $_{nom}$ $NOEC_{sediment}$ = 10 mg a.s./kg sed	EFSA Journal 2011;9(1):1967

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations; im: based on initial measured concentrations

Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – SNS-F-11

Species	Substance	Exposure System	Results	Reference
Oncorhynchus mykiss	SNS-F-11	96 h, s	LC_{50} = 13.45mg/L $_{nom}$ LC_{50} =1.097 mg a.s/L	Czarnecka M., 2023, W-45-22
Daphnia magna	SNS-F-11	48 h, s	EC_{50} = 9.11 mg/L $_{nom}$	Hodorek G., 2023, W-41-22
Pseudokirchneriella subcapitata	SNS-F-11	72 h, s	E_rC_{50} = 30.43 mg/L $_{nom}$ E_yC_{50} = 8.46 mg/L $_{nom}$	Hodorek G., 2023, W-42-22

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations

9.5.1.1 Justification for new endpoints

According to COMMISSION REGULATION (EU) No 284/2013 of 1 March 2013, for formulated products, at least studies for fish, invertebrates and algae must be performed.

9.5.2 Risk assessment

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the "Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009", as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).

The relevant global maximum FOCUS Step 1, 2 and 3 PEC_{SW} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the table below. Since the product SNS-F-11 shows a lot lower toxicity than active substances difenoconazole, the risk assessment is performed with appropriate endpoint obtained in studies with this active substance.

In the following table, the ratios between predicted environmental concentrations in surface water bodies (PEC_{SW}, PEC_{SED}) and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended use for each FOCUS scenario and each organism group.

Table 9.5-3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of SNS-F-11 in winter cereals (winter wheat, winter triticale)

Group	PEC-	Fish acute	Fish	Inverteb.	Inverteb.	Inverteb.	Algae	Sed. dwell.

	max		prolonged	acute	acute	prolonged		prolonged
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Mysidopsis bahia***	***Daphnia magna***	***Daphnia magna***	***Desmodesmus subspicatus***	***Chironomus riparius***
Endpoint (µg/L)		1100	3.6	150	770	5.6	32	15
AF		100	10	100	100	10	10	10
RAC (µg/L)		11	0.36	1.5	7.7	0.56	3.2	1.5
FOCUS Scenario								
Step 1	11.630	**1.057**	**32.306**	**7.753**	**1.510**	**20.768**	**3.634**	**7.753**
Step 2								
N- Europe	**1.830**	0.166	**5.083**	**1.220**	0.238	**3.268**	0.572	**1.220**
N- Europe	**1.840**	0.167	**5.111**	**1.227**	0.239	**3.286**	0.575	**1.227**
S- Europe	**3.350**	0.305	**9.306**	**2.233**	0.435	**5.982**	**1.047**	**2.233**
S- Europe	**2.590**	0.235	**7.194**	**1.727**	0.336	**4.625**	0.809	**1.727**
Step 3								
D1/ditch	**0.5044**	0.046	**1.401**	0.336	0.066	0.901	0.158	0.336
D1/stream	**0.4212**	0.038	**1.170**	0.281	0.055	0.752	0.132	0.281
D2/ditch	**0.5099**	0.046	**1.416**	0.340	0.066	0.911	0.159	0.340
D2/stream	**0.4372**	0.040	**1.214**	0.291	0.057	0.781	0.137	0.291
D3/ditch	**0.4951**	0.045	**1.375**	0.330	0.064	0.884	0.155	0.330
D4/pond	0.02218	0.002	0.062	0.015	0.003	0.040	0.007	0.015
D4/stream	**0.4076**	0.037	**1.132**	0.272	0.053	0.728	0.127	0.272
D5/pond	0.02636	0.002	0.073	0.018	0.003	0.047	0.008	0.018
D5/stream	**0.4308**	0.039	**1.197**	0.287	0.056	0.769	0.135	0.287
D6/ditch	**0.4969**	0.045	**1.380**	0.331	0.065	0.887	0.155	0.331
R1/pond	**0.0846**	0.008	0.235	0.056	0.011	0.151	0.026	0.056
R1/stream	**0.4159**	0.038	**1.155**	0.277	0.054	0.743	0.130	0.277
R3/stream	**0.4549**	0.041	**1.264**	0.303	0.059	0.812	0.142	0.303
R4/stream	**0.6946**	0.063	**1.929**	0.463	0.090	**1.240**	0.217	0.463

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of SNS-F-11 in winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans)

Group	**PECmax**	**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Mysidopsis bahia***	***Daphnia magna***	***Daphnia magna***	***Desmodesmus subspicatus***	***Chironomus riparius***
Endpoint (µg/L)		1100	3.6	150	770	5.6	32	15
AF		100	10	100	100	10	10	10

RAC (µg/L)		11	0.36	1.5	7.7	0.56	3.2	1.5
FOCUS Scenario								
Step 1	6.69	0.608	**18.583**	**4.460**	0.869	**11.946**	**2.091**	**4.460**
Step 2								
N- Europe	1.12	0.102	**3.111**	0.747	0.145	**2.000**	0.350	0.747
N- Europe	1.12	0.102	**3.111**	0.747	0.145	**2.000**	0.350	0.747
S- Europe	2.02	0.184	**5.611**	**1.347**	0.262	**3.607**	0.631	**1.347**
S- Europe	1.57	0.143	**4.361**	**1.047**	0.204	**2.804**	0.491	**1.047**
Step 3								
D2/ditch	**0.6523**	0.059	**1.812**	0.435	0.085	**1.165**	0.204	0.435
D2/stream	**0.5424**	0.049	**1.507**	0.362	0.070	0.969	0.170	0.362
D3/ditch	**0.6455**	0.059	**1.793**	0.430	0.084	**1.153**	0.202	0.430
D4/pond	0.0222	0.002	0.062	0.015	0.003	0.040	0.007	0.015
D4/stream	**0.4826**	0.044	**1.341**	0.322	0.063	0.862	0.151	0.322
D5/pond	0.02224	0.002	0.062	0.015	0.003	0.040	0.007	0.015
D5/stream	**0.5162**	0.047	**1.434**	0.344	0.067	0.922	0.161	0.344
R1/pond	0.04231	0.004	0.118	0.028	0.005	0.076	0.013	0.028
R1/stream	**0.4253**	0.039	**1.181**	0.284	0.055	0.759	0.133	0.284
R3/stream	**0.598**	0.054	**1.661**	0.399	0.078	**1.068**	0.187	0.399

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 71019 for each organism group based on FOCUS Steps 1 calculations for the use of SNS-F-11 in winter cereals (winter wheat, winter triticale) and winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans)

Group	**PECmax**	**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Algae**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Selenastrum capricornutum***
Endpoint (µg/L)		498000	3200	100000	13000
AF		100	10	100	10
RAC (µg/L)		4980	320	1000	1300
FOCUS Scenario					
winter cereals					
Step 1	3.03	0.0006	0.0095	0.0030	0.0023
Winter oilseed rape					
Step 1	1.74	0.0003	0.0054	0.0017	0.0013

Table 9.5-6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 71019 for each organism group based on FOCUS Steps 1 calculations for the use of SNS-F-11 in winter cereals (winter wheat, winter triticale) and winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans)

Group	**PECmax**	**Fish acute**	**Inverteb. acute**	**Algae**	**Sed. dwell. prolonged**

Test species		***Oncorhynchus mykiss***	***Daphnia magna***	***Selenastrum capricornutum***	***Chironomus riparius***
Endpoint (µg/L)		740	1400	1230	400
AF		100	100	10	10
RAC (µg/L)		7.4	14	123	40
FOCUS Scenario					
winter cereals					
Step 1	2.38	0.322	0.170	0.019	0.060
winter oilseed rape					
Step 1	1.37	0.185	0.098	0.011	0.034

For the intended uses in winter cereals, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms:

- *Pimephales promela*, with NOEC = 3.6 µg/L, in 11 STEP 3 scenario (D1 ditch, D1 stream D2 ditch, D2 stream, D3 ditch, D4 stream, D5 stream, D6 ditch, R1 stream, R3 stream, R4 stream)
- *Daphnia magna*, with NOEC 5.6 µg/L in one STEP 3 scenario (R4 stream) Therefore, further assessment is necessary. PEC/RAC ratio were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies.

For the intended uses in winter oilseed rape, calculated PEC/RAC ratios also did not indicate an acceptable risk for the most sensitive group of aquatic organisms:

- *Pimephales promela*, with NOEC = 3.6 µg/L, in 7 STEP 3 scenario (D2 ditch, D2 stream, D3 ditch, D4 stream, D5 stream, R1 stream, R3 stream)
- *Daphnia magna*, with NOEC 5,6 µg/L in three STEP 3 scenario (D2 ditch, D3 ditch, R3 stream). Therefore, further assessment is necessary. PEC/RAC ratio were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies.

Table 9.5-7: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for difenoconazole based on FOCUS Step 4 calculations and toxicity data for *Pimephales promelas and Daphnia magna* with mitigation of spray drift and run-off for the use of SNS-F-11 in winter cereals (winter wheat, winter triticale)

Intendend use		**Winter cereals (winter wheat, winter triticale)**					
Active substance		**Difenoconazole**					
Application rate (g/ha)		**2 x 90**					
Group				***Pimephales promelas***		***Daphnia magna***	
RAC (µg/L)				**0.36**		**0.56**	
No-spray buffer (m)		1	2	1	2	1	2
Vegetated filter strip (m)		1	2	1	2	1	2
Nozzle reduction	**FOCUS Scenario**	**PECmax**		**PEC/RAC ratio**			
0%	D1 ditch	-	0.2931	-	0.81	-	-

Intendend use		**Winter cereals (winter wheat, winter triticale)**					
Active substance		**Difenoconazole**					
Application rate (g/ha)		**2 x 90**					
Group				***Pimephales promelas***		***Daphnia magna***	
RAC (µg/L)				**0.36**		**0.56**	
No-spray buffer (m)		1	2	1	2	1	2
Vegetated filter strip (m)		1	2	1	2	1	2
Nozzle reduction	**FOCUS Scenario**	**PECmax**		**PEC/RAC ratio**			
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**	-	-	-
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	-	0.46
25%		0.3301	-	0.92	-	0.59	-

Intendend use		**Winter cereals (winter wheat, winter triticale)**					
Active substance		**Difenoconazole**					
Application rate (g/ha)		**2 x 90**					
Group				***Pimephales promelas***		***Daphnia magna***	
RAC (µg/L)				**0.36**		**0.56**	
No-spray buffer (m)		1	2	1	2	1	2
Vegetated filter strip (m)		1	2	1	2	1	2
Nozzle reduction	**FOCUS Scenario**	**PECmax**		**PEC/RAC ratio**			
50%		0.2949	-	0.82	-	0.44	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-8: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for difenoconazole based on FOCUS Step 4 calculations and toxicity data for *Daphnia magna* with mitigation of spray drift and run-off for the use of SNS-F-11 in winter rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans)

Intendend use		**Winter rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans)**								
Active substance		**Difenoconazole**								
Application rate (g/ha)		**1 x 103.5**								
Group					*Pimephales promelas*			*Daphnia magna*		
RAC (µg/L)					**0.36**			**0.56**		
	No-spray buffer (m)	1	2	3	1	2	3	1	2	3
	Vegetated filter strip (m)	1	2	3	1	2	3	1	2	3
Nozzle reduction	**FOCUS Scenario**	**PECmax**			**PEC/RAC ratio**					
0%	D2 ditch	-	-	0.2759	-	-	0.76	-	-	0.49
25%		-	0.2894	-	-	0.80	-	-	0.51	-
50%		0.3259	-	-	0.91	-	-	0.58	-	-
75%		0.1628	-	-	0.45	-	-	0.29	-	-
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	-	-	0.48
25%		-	0.2864	-	-	0.79	-	-	0.51	-
50%		0.3225	-	-	0.89	-	-	0.57	-	-
75%		0.1611	-	-	0.45	-	-	0.28	-	-

0%	D4 stream	-	-	0.2753	-	-	0.76	-	-	0.49
25%		-	0.2887	-	-	0.80	-	-	0.51	-
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	-	-	0.61
25%		-	0.3577	-	-	0.99	-	-	0.63	-
50%		**0.4028**	-	-	**1.11**	-	-	0.71	-	-
75%		0.2012	-	-	0.58	-	-	0.35	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

D3, D4, R1 are scenarios specific to Poland

9.5.3 Overall conclusions

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

zRMS comments: Agreed. The evaluation of the risk for aquatic organisms was performed in accordance with the recommendations of the "Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters" (EFSA Journal 2013;11(7):3290). The ratios between predicted environmental concentrations in surface water bodies (PEC_{SW}, PECSED) and regulatory acceptable concentrations (RAC) for a.s.- difenoconazole and difenoconazole metabolites CGA 71019 and 205375 based on the worst case for aquatic organisms were <1 indicating acceptable risk to aquatic organisms with applying:
– use in winter cereals (winter wheat, winter triticale):
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 (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds,

sunflower seeds, soybeans):
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
The risk assessment for aquatic organisms should be considered by MSs level.

PL (D3, D4, R1 are scenarios specific to Poland)
The ratios between predicted environmental concentrations in surface water bodies (PEC_{SW}, PECSED) and regulatory acceptable concentrations (RAC) for a.s.- difenoconazole and difenoconazole metabolites CGA 71019 and 205375 based on the worst case for aquatic organisms were <1 indicating acceptable risk to aquatic organisms in Poland with applying:
– use in winter cereals (winter wheat, winter triticale):
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 (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soybeans):
:
1m buffer zone with vegetative filter strip and 50% spray drift reduction, or
2m buffer zone with vegetative filter strip and 25% spray drift reduction, or
3m buffer zone with vegetative filter strip

9.6 Effects on bees (KCP 10.3.1)

9.6.1 Toxicity data

Studies on the toxicity to bees have been carried out with difenoconazole. Full details of these studies are provided in the respective EU Draft Assessment Report and related documents.

Effects on bees of SNS-F-11 were not evaluated as part of the EU assessment of difenoconazole. New data submitted with this application are listed in **Błąd! Nie można odnaleźć źródła odwołania.** and summarised in Appendix 2.

Table 9.6-1: Endpoints and effect values relevant for the risk assessment for bees

Species	Substance	Exposure System	Results	Reference
Apis mellifera	difenoconazole	Oral	LD_{50} > 177 µg/bee	EFSA Journal 2011;9(1):1967
Apis mellifera	difenoconazole	Contact	LD_{50} > 100 µg/bee	EFSA Journal 2011;9(1):1967
Apis mellifera	SNS-F-11	Oral	LD_{50} >300 µg/bee LD_{50} > 24.46 µg a.i./ bee	D. Kapa, 2023, B-05-23
Apis mellifera	SNS-F-11	Contact	LD_{50} >300 µg/bee LD_{50} > 24.46 µg a.i./ bee	D. Kapa, 2023, B-06-23
Apis mellifera	SNS-F-11	Chronic oral	LDD_{50} > 19.7 µg/bee	A. Wojciech, 2023, B-04-23
Apis mellifera	SNS-F-11	Larval chronic test	NOED ≥100 µg/larva	A. Wojciech, 2023, B-01-23
Bombus terrestris	SNS-F-11	Oral	LD_{50} >200 µg/bumblebee LD_{50} > 16.3 µg a.i./ bumblebee	A. Wojciech, 2023, B-02-23

Species	Substance	Exposure System	Results	Reference
Bombus terrestris	SNS-F-11	Contact	LD_{50} >200 µg/bumblebee LD_{50} > 16.3 µg a.i./ bumblebee	A. Wojciech, 2023, B-03-23

9.6.1.1 Justification for new endpoints

Not relevant.

9.6.2 Risk assessment

The evaluation of the risk for bees was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002).

Formulas used to calculation:

$$Q_{HO} = \frac{Single\ application\ rate\ [^{g}/_{ha}]}{LD_{50}}$$

$$Q_{HC} = \frac{Single\ application\ rate\ [^{g}/_{ha}]}{LD_{50}}$$

9.6.2.1 Hazard quotients for bees

Table 9.6-2: First-tier assessment of the risk for bees due to the use of difenoconazole and SNS-F-11 in winter cereals (winter wheat, winter triticale)

Intended use	**Winter cereals**		
Active substance	difenoconazole		
Application rate (g/ha)	2 x 90		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	177	90	0.508
Contact toxicity	100		0.900
Product	SNS-F-11		
Application rate (g/ha)	2 x 1100		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	300	1110*	3.7
Contact toxicity	300		3.7

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.
* Based on the density of the formulation = 1.111 g/mL

Table 9.6-3: First-tier assessment of the risk for bees due to the use of difenoconazole and SNS-F-11 in winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans)

Intended use	**Winter oilseed rape**		
Active substance	difenoconazole		
Application rate (g/ha)	1 x 103.5		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	177	103.5	0.58
Contact toxicity	100		1.03
Product	SNS-F-11		
Application rate (g/ha)	2 x 1276.5		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	300	1276.5*	4.25
Contact toxicity	300		4.25

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.
* Based on the density of the formulation = 1.111 g/mL

9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies)

Not relevant.

9.6.3 Effects on bumble bees

Although Bumblebee acute oral and contact studies, are not required under Regulation (EC) No 1107/2009, they were provided for SNS-F-11. Obtained endpoint for this studies are summarized below.

Table 9.6-4: Endpoints and effect values relevant for the risk assessment for bumblebees

Species	Substance	Exposure System	Results	Reference
Bombus terrestris	SNS-F-11	Oral	LD_{50} >200 µg/bumblebee LD_{50} > 16.3 µg a.i./ bumblebee	A. Wojciech, 2023, B-02-23
Bombus terrestris	SNS-F-11	Contact	LD_{50} >200 µg/bumblebee LD_{50} > 16.3 µg a.i./ bumblebee	A. Wojciech, 2023, B-03-23

Table 9.6-5: First-tier assessment of the risk for bumble bees due to the use of SNS-F-11 in winter cereals (winter wheat, winter triticale) and winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sun-flower seeds, soyabeans)

Intended use	**Winter cereals**
Active substance	SNS-F-11
Application rate (g/ha)	2 x 1100

Test design	LD_{50} (lab.) (µg/bee)	Single application rate (g/ha)	Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$
Oral toxicity	200	1110*	5.55
Contact toxicity	200		5.55
Intended use	**Winter oilseed rape**		
Product	SNS-F-11		
Application rate (g/ha)	1 x 1265		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	200	1276.5*	6.38
Contact toxicity	200		6.38

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.
* Based on the density of the formulation = 1.111 g/mL

9.6.4 Effects on solitary bees

Not relevant.

9.6.5 Overall conclusions

The risk assessment was performed in accordance with the SANCO guidance, 2002. The hazard quotients are below the trigger values considering SANCO guidance, indicating that the active substance and formulation pose an acceptable risk to bees following application according to the proposed GAP. Calculation conducted for SNS-F-11 regarding to the oral and contact toxicity confirm no risk for bees and bumblebees due to the use that formulation: achieved values are lower than 50. Furthermore studies for bees chronic oral toxicity and bees larval toxicity for SNS-F11 were submitted.

zRMS comments: Agreed. The HQ values are lower than the trigger of 50, indicating low risk to bees from following application of **DISFERA 90 EC.** Therefore a low risk to bees is expected from the application of **DISFERA 90 EC** following application according to the proposed GAP. According to EU Reg. 284/2009, the chronic toxicity study for adult bees, and the chronic test for larvae were submitted, same as the acute contact and oral tests for bumblebees. The studies were accepted by zRMS. The risk assessment based on this study should be considered when GD for Bees, 2013 is implemented at EU level. Thus, concerned Member States must decide on the consideration of data requirements and the risk assessment at national level.

UPDATED 10/2024

RISK ASSESMENT FOR BEES ACCORDING TO EFSA 2013

On the basis of the current Regulation, the risk assessment for bees has been carried out in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology" as provided by the Commission services (SANCO/10329/2002 rev.2 (final), 17 October 2002). Although the approach for risk assessment for bees according to EFSA 2013 is not yet harmonised in Poland, the notifier completes the dossier with a Tier 1 risk assessment for bees according to EFSA 2013. Risk assessment is presented in tables below.

Winter cereals 2x 1L/ha (2x 90 g a.s/ha)				
Risk quotient	**scenario**	**BBCH**	**Honeybee**	
			HQ/ETR	**trigger**
HQ contact	treated crop	30 - 39	7.4	42
	treated crop	≥ 40	7.4	42
	weeds	30 - 39	2.2	42
	weeds	≥ 40	1.8	42
	field margin	30 - 39	0.2	42
	field margin	≥ 40	0.2	42
ETRacute adult oral	treated crop	30 - 39	0.01	0.2
	treated crop	40 - 69	0.01	0.2
	weeds	30 - 39	0.01	0.2
	weeds	40 - 69	0.01	0.2
	field margin	30 - 39	0.00	0.2
	field margin	40 - 69	0.00	0.2
	adjacent crop	30 - 39	0.00	0.2
	adjacent crop	40 - 69	0.00	0.2
	next crop	30 - 39	0.01	0.2
	next crop	40 - 69	0.01	0.2
ETRchronic adult oral	treated crop	30 - 39	**0.07**	0.03
	treated crop	40 - 69	**0.07**	0.03
	weeds	30 - 39	**0.12**	0.03
	weeds	40 - 69	**0.07**	0.03
	field margin	30 - 39	0.00	0.03
	field margin	40 - 69	0.00	0.03
	adjacent crop	30 - 39	0.00	0.03
	adjacent crop	40 - 69	0.00	0.03
	next crop	30 - 39	**0.04**	0.03
	next crop	40 - 69	**0.04**	0.03
ETRlarvae	treated crop	30 - 39	0.00	0.2
	treated crop	40 - 69	0.00	0.2
	weeds	30 - 39	0.02	0.2
	weeds	40 - 69	0.01	0.2
	field margin	30 - 39	0.00	0.2
	field margin	40 - 69	0.00	0.2

	adjacent crop	30 - 39	0.00	0.2
	adjacent crop	40 - 69	0.00	0.2
	next crop	30 - 39	0.01	0.2
	next crop	40 - 69	0.01	0.2

Oilseed rape x 1L/ha (1x 90 g a.s/ha)*				
Risk quotient	**scenario**	**BBCH**	**Honeybee**	
			HQ	**trigger**
HQ contact	treated crop	30 - 39	3.7	42
	weeds	30 - 39	1.1	42
	field margin	30 - 39	0.1	42
ETRacute adult oral	treated crop	30 - 39	0.03	0.2
	weeds	30 - 39	0.00	0.2
	field margin	30 - 39	0.00	0.2
	adjacent crop	30 - 39	0.00	0.2
	next crop	30 - 39	0.00	0.2
ETRchronic adult oral	treated crop	30 - 39	**0.23**	0.03
	weeds	30 - 39	**0.04**	0.03
	field margin	30 - 39	0.00	0.03
	adjacent crop	30 - 39	0.00	0.03
	next crop	30 - 39	0.02	0.03
ETRlarvae	treated crop	30 - 39	0.04	0.2
	weeds	30 - 39	0.01	0.2
	field margin	30 - 39	0.00	0.2
	adjacent crop	30 - 39	0.00	0.2
	next crop	30 - 39	0.00	0.2

*The same results were obtained for sunflower, flox and poppy, linseed and mustard seed.

Oilseed rape 1.15 L/ha (1x 103.5 g a.s/ha)*				
Risk quotient	**scenario**	**BBCH**	**Honeybee**	
			HQ	**trigger**
HQ contact	treated crop	≥ 40	4.2	42
	weeds	≥ 40	1.1	42
	field margin	≥ 40	0.1	42
ETRacute adult oral	treated crop	40 - 69	0.03	0.2
	weeds	40 - 69	0.00	0.2

	field margin	40 - 69	0.00	0.2
	adjacent crop	40 - 69	0.00	0.2
	next crop	40 - 69	0.00	0.2
ETRchronic adult oral	treated crop	40 - 69	**0.27**	0.03
	weeds	40 - 69	**0.03**	0.03
	field margin	40 - 69	0.00	0.03
	adjacent crop	40 - 69	0.00	0.03
	next crop	40 - 69	0.03	0.03
ETRlarvae	treated crop	40 - 69	0.05	0.2
	weeds	40 - 69	0.01	0.2
	field margin	40 - 69	0.00	0.2
	adjacent crop	40 - 69	0.00	0.2
	next crop	40 - 69	0.00	0.2

*The same results were optained for sunflower, flox and poppy, linseed and mustard seed.

It is difficult to determine chronic toxicity to bees because the laboratory study for SNS-F-11 used limit tests and therefore no specific dose causing toxicity has been identified. The concentration of difenoconazole in SNS-F-11 is low (90 g a.s/L), therefore the amounts of formulation used in laboratory studies have to be very high and are not always completely ingested by bees. For this reason, it is very often difficult to administer higher doses in laboratory studies with a low concentration product. For this type of product, field studies are likely to provide a better indication of true toxicity.

The chronic oral toxicity endpoint for SNS-F-11 was set as LDD_{50} > 19.7 µg/bee/day. Risk Assesment according to the EFSA 2013 shows the value slightly above trigger for:

- chronic risk assessment in treated crop, weeds and next crop for scenario for cereals;
- chronic risk assesment in treated crop and weeds for scenario for oilseed rape, sunflower, flax and poppy, linseed and mustard seed.

Due to the low concentration of difenoconazole in SNS-F-11 formulation and the low ingested dose by bees (only 19.7 (µg formulation/bee/day) of 30 (µg formulation/bee/day)), it is not possible to obtain sufficient information on the chronic toxicity of SNS-F-11 to bees. It is likely that further studies with a higher formulation dose or a field study will be required.

Furthermore, on the basis of the additional trials carried out by the notifier in the field of Phacelia for the evaluation of difenoconazole residues in honey for another formulation TORES 250 EC (Kurek-Molenda M., 2023), it can be concluded that there is no effect on bees in terms of mortality and behaviour at the doses used: 150 g s.a/ha and 2x 125 g s.a/ha. The experiment was carried out during flowering at BBCH 61- 65 and can be considered as a worst case scenario (see Section 7 Metabolism and Residue).

Comments RMS: The risk assessment performed based on EFSA 2013 guidance was accepted by zRMS. First tier chronic evaluation of the risk to adult bees exposed to difenconazole resulted with ETR value above the trigger in some scenario indicating potentially unacceptable risk:

- chronic risk assessment in treated crop, weeds and next crop for scenario for cereals;
- chronic risk assesment in treated crop and weeds for scenario oilseed rape, sunflower, flax and poppy, linseed and mustard seed.

No data enabling refinement of the risk was available. We agree that it is difficult to determine chronic toxicity to bees in this case because the laboratory study for Disfera 90 EC used limit tests and therefore no specific dose causing toxicity has been identified. Nevertheless, since the EFSA Bee Guidance Document is yet to be implemented (2013), this result should be treated as indication of area that should be covered in the future, once the guidance document is officially noted and accepted. Further assessments from chronic exposure could be required at national level. The chronic risk assessment for bees should be considered by MSs level.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

Studies on the toxicity to non-target arthropods have been carried out with difenoconazole. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target arthropods of SNS-F-11 were not evaluated as part of the EU assessment of difenoconazole. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.7-1: Endpoints and effect values relevant for the risk assessment for non-target arthropods

Species	Substance	Exposure System	Results	Reference
Typhlodromus pyri (protonymphs)	SNS-F-11	Laboratory test glass plates (2D)	LR_{50} = 1.724 L/ha (1724 ml/ha) ER_{50} = 1.849 L/ha (1849 ml/ha)	D. Kapa, 2023, B-42-23
Aphidius rhopalosiphi (adults)	SNS-F-11	Laboratory test glass plates (2D)	LR_{50} = 1.173 L/ha (1173 ml/ha) ER_{50} = 1.324 L/ha (1324 ml/ha)	A. Wojciech, 2023, B-43-23

9.7.1.1 Justification for new endpoints

Not relevant.

9.7.2 Risk assessment

The evaluation of the risk for non-target arthropods was performed in accordance with the rec-

ommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2. According to the obtained results, endpoints are presented in [ml/ha], therefore this unit was used in "in field" and "off field" calculations.

9.7.2.1 Risk assessment for in-field exposure

The following formulas were used to "in field" calculations (according to ESCORT 2):

$$\mathrm{PER_{in-field}} = \text{max. single application rate } \left[\frac{\mathrm{ml}}{\mathrm{ha}}\right] \times \mathrm{MAF}$$

$$\mathrm{HQ_{in-field}} = \frac{\mathrm{PER_{in-field}} \left[\frac{\mathrm{ml}}{\mathrm{ha}}\right]}{\mathrm{LR_{50}} \left[\frac{\mathrm{ml}}{\mathrm{ha}}\right]}$$

Table 9.7-2: First tier assessment of the in-field risk for non-target arthropods due to the use of SNS-F-11 in winter cereals (winter wheat, winter triticale)

Intended use	**Winter cereals**
Active substance/product	SNS-F-11
Application rate (ml/ha)	2 x 1000 (min. interval: 14 days)
MAF	1.7

Test species Tier I	**LR_{50} (lab.) (ml/ha)**	**$PER_{in-field}$ (ml/ha)**	**$HQ_{in-field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	1724	1700	0.98
Aphidius rhopalosiphi	1173		1.45

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment.
Criteria values shown in bold breach the relevant trigger.

Table 9.7-3: First tier assessment of the in-field risk for non-target arthropods due to the use of SNS-F-11 in winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans)

Intended use	**Winter oilseed rape**
Active substance/product	SNS-F-11
Application rate (ml/ha)	1 x 1150
MAF	1

Test species Tier I	**LR_{50} (lab.) (ml/ha)**	**$PER_{in-field}$ (ml/ha)**	**$HQ_{in-field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	1724	1150	0.67
Aphidius rhopalosiphi	1173		0.98

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment.
Criteria values shown in bold breach the relevant trigger.

9.7.2.2 Risk assessment for off-field exposure

The following formulas were used to "in field" calculations (according to ESCORT 2):

$$\mathrm{PER_{off-field}} = \text{max. single application rate } \left[\frac{\mathrm{ml}}{\mathrm{ha}}\right] \times \mathrm{MAF} \times \left(\frac{\text{drift factor}}{\mathrm{VDF}}\right)$$

$$\text{corrected } \mathrm{PER_{off-field}} = \mathrm{PER_{off-field}} \times \mathrm{CF}$$

$$\mathrm{HQ_{off-field}} = \frac{\text{corr. } \mathrm{PER_{off-field}} \left[\frac{\mathrm{ml}}{\mathrm{ha}}\right]}{\mathrm{LR_{50}} \left[\frac{\mathrm{ml}}{\mathrm{ha}}\right]}$$

Table 9.7-4: First- tier assessment of the off-field risk for non-target arthropods due to the use of SNS-F-11 in winter cereals (winter wheat, winter triticale)

Intended use	**winter cereals**
Active substance/product	SNS-F-11
Application rate (ml/ha)	2 x 1000
MAF	1.7
Drift rate (%)	2.77% (1m)
vdf	10 (Tier 1)

Test species Tier I	**LR_{50} (lab.) (ml/ha)**	**Drift rate**	**$PER_{off-field}$ (ml/ha)**	**CF**	**$HQ_{off-field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	1724	0.027	4.59	10	0.026
Aphidius rhopalosiphi	1173				0.039

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

Table 9.7-4: First- tier assessment of the off-field risk for non-target arthropods due to the use of SNS-F-11 in winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans)

Intended use	**winter oilseed rape**
Active substance/product	SNS-F-11
Application rate (ml/ha)	1 x 1150
MAF	1
Drift rate (%)	2.77% (1m)
vdf	10 (Tier 1)

Test species Tier I	**LR_{50} (lab.) (ml/ha)**	**Drift rate**	**$PER_{off-field}$ (ml/ha)**	**CF**	**$HQ_{off-field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	1724	0.027	3.105	10	0.018
Aphidius rhopalosiphi	1173				0.026

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

9.7.2.3 Risk mitigation measures

No risk mitigation needed.

9.7.3 Overall conclusions

According to results of studies for for *Typhlodromus pyri* and *Aphidius rhopalosiphi* and risk assessment, using SNS-F-11 following according to the proposed GAP, SNS-F-11 poses no risk for non-target arthropods. $HQ_{in\text{-}field}$ and $HQ_{off\text{-}field}$ values for *A. rhopalosiphi* and *T.pyri* are below the ESCORT 2 trigger of 2.

zRMS comments: Agreed. The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2. The calculations of the risk assessment for in – field for two indicator species *Typhlodromus pyri* and *Aphidius rhopalosiphi* based on laboratory studies were accepted by zRMS. Finally, the risk in-field for NTA is considered acceptable (HQ values were below 2 for these species). The risk off-field for NTA for laboratory test for *A.rhopalosiphi* and *T.pyri* is considered acceptable (HQ values were below 2 for these species).

9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

9.8.1 Toxicity data

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with difenoconazole and its relevant metabolites. Full details of these studies are provided in the respective EU Draft Assessment Report and related documents.

Effects on earthworms of SNS-F-11 were not evaluated as part of the EU assessment of difenoconazole. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.8-1: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)

Species	Substance	Exposure System	Results	Reference
Eisenia fetida	difenoconazole	56 d, chronic, reproduction	No reliable data, assessment based on representative formulation studies	EFSA Journal 2011;9(1):1967
Eisenia fetida	difenoconazole	56 d, chronic, reproduction	NOEC = 0.5 mg/kg dry soil (repro) **$NOEC_{corr}$[1] = 0.25 mg/kg dry soil**	Difenoconazole Addendum Annex B 9 Confirmatory data_revised September 2014
Eisenia fetida	CGA 71019	28 d, chronic, reproduction	**NOEC[3] = 1 mg/kg dw**	EFSA Journal 2011;9(1):1967
Eisenia fetida	CGA 205375	56 d, chronic, reproduction	NOEC = 9.6 mg/kg dw **$NOEC_{corr}$[2] = 4.8 mg/kg dw**	Difenoconazole Addendum Annex B 9 Confirmatory data_revised September 2014

Species	Substance	Exposure System	Results	Reference
Eisenia fetida	SNS-F-11	56 d, chronic, reproduction	EC_{10}= 11.6 mg/kg dw $EC_{10\ corr}$= 5.8 mg/kg dw **NOEC = 3.2 mg/kg dw** **$NOEC_{corr}$[1] = 1.6 mg/kg dw**	Wróbel A., 2023/ G-09-23
Folsomia candida	Difenoconazole	28 d, chronic, reproduction	NOEC = 500 mg as/kg dw **$NOEC_{corr}$[1] = 250 mg/kg dw***	EFSA Journal 2011;9(1):1967
Folsomia candida	CGA 71019	28 d, chronic, reproduction	**NOEC[3] = 1.8 mg as/kg dw**	EFSA Journal 2011;9(1):1967
Folsomia candida	CGA 205375	28 d, chronic, reproduction	NOEC = 2.4 mg as/kg dw **$NOEC_{corr}$[2] = 1.2 mg/kg dw**	Difenoconazole Addendum Annex B 9 Confirmatory data_revised September 2014
Field studies				
Not required				
Litter bag test				
Not required				

* Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002.
1) Difenoconazole Log Pow = 4.4 (>2)
3) CGA205375 Log Pow = 3.8 (>2)
2) CGA71019 Log Pow = -1 (<2)

9.8.1.1 Justification for new endpoints

9.8.2 Risk assessment

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

9.8.2.1 First-tier risk assessment

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, tables 8.7-3 to 8.7-7. According to the assessment of environmental-fate data, multi-annual accumulation in soil is considered for difenoconazole and CGA 205375.

As stated in Commission Regulation EU No 284/2013 of 1 March 2013, "For plant protection products applied as a foliar spray, data on the relevant two non-target arthropod species might be taken into account for a preliminary risk assessment. If effects do not occur on these species, testing on *Folsomia candida* and *Hypoaspis aculeifer* are not required." The formulated product SNS-F-11 is applied as a foliar spray treatment. As demonstrated above, a low in-field and off-field risk is demonstrated for non-target arthropods - such as - *Typhlodromus pyri*, *Aphidius rhopalosiphi* (standard laboratory studies) in

cereals (2 x 90 g s.a./ha) and winter oilseed rape (1 x 103.5 g s.a./ha). Therefore, the risk assessment for macroorganisms other than earthworms is not required. In addition, however, the risk assessment for *Folsomia candida* based on the data for active substance difenoconazole and metabolites CGA771019 and CGA 205375 from EFSA Scientific Report, 2011 and "Difenoconazole Addendum Annex B 9 Confirmatory data_revised September 2014", was performed .

Table 9.8-1: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of SNS-F-11 in winter cereals (winter wheat, winter triticale)

Chronic effects on earthworms			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
difenoconazole	0.25	0.055	**4.54**
CGA 71019	1.0	0.001	1000
CGA 205375	4.8	0.006	800
SNS-F-11	1.6	0.296	5.4
Chronic effects on other soil macro- and mesofauna- *folsomia candida*			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
difenoconazole	250	0.055	4545
CGA 71019	1.8	0.001	1800
CGA 205375	1.2	0.006	200

Table 9.8-2: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of SNS-F-11 in winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans)

Chronic effects on earthworms			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
difenoconazole	0.25	0.032	7.8
CGA 71019	1.0	0.001	1000
CGA 205375	4.8	0.003	1600
SNS-F-11	1.6	0.34	**4.7**
Chronic effects on other soil macro- and mesofauna- *folsomia candida*			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
difenoconazole	250	0.032	7812
CGA 71019	1.8	0.001	1800
CGA 205375	1.2	0.003	333

TER values shown in bold fall below the relevant trigger.

TER_{LT} values for active substance – difenconazole, for use in winter cereals, and for formulation SNS-F-11 for use is winter rape, being slight below trigger value of 5, respectively: 4.54, and 4.7 (tabels 9.8-1 and 9.8-2). However, as discussed in the PPR TC 58 (28-30.06.2021), the field study on the difenoconazole formulation SCORE 250 EC (Hamberger 2015) with the NOEC of 1 L product/ha (corresponding to 250 g a.s./ha) was agreed by experts. It was, demonstrated in a field study that the application of difenoconazole at a rate of 250 g a.s./ha did not result in sustaining adverse effects on a natural earthworm population after a period of one year. Experts opinion from PPR TC 58 (28-30.06.2021) confirms the assessment that no unacceptable risk is expected for earthworms at the proposed application rates of SNS-F-11: 90 g a.s./ha for winter cereals and 103.5 g s.a./ha for winter oilseed rape.

zRMS comments:

Winter cereals
TER_{LT} value for active substance – difenconazole is slight below trigger value of 5, (**being 4.54**), indicating further refinement for winter cereals. Therefore, the applicant provided the risk assessment for the product **DISFERA 90 EC**. The TER_{LT} for ppp (converted to the a.s.-difenconazole) for earthworm is above trigger of 5, indicating acceptable risk for earthworm. Therefore, it is concluded that the active substance do not pose long-term risk to earthworms and other soil macro- and mesofauna when applied according to the proposed uses rates in winter cereals. The risk assessment for earthworms for winter cereals should be considered by MSs level.

Winter oilseed rape
The TER_{LT} for ppp for earthworm is slight below trigger value of 5 (**being 4.7**), indicating further refinement for winter oilseed rape for earthworm. The Applicant for refinement risk assessment referred to the field study on the difenoconazole formulation SCORE 250 EC (Hamberger 2015) with the NOEC of 1 L product/ha (corresponding to 250 g a.s./ha) was agreed by experts in the PPR TC 58. It was, demonstrated in a field study that the application of difenoconazole at a rate of 250 g a.s./ha did not result in sustaining adverse effects on a natural earthworm population after a period of one year. However, a detailed comparison of these formulations has not been presented (***in this case these formulation are probably comparable - it is the same type of EC formulation and DISFERA 90 EC contains less active substance inside than Sore 250 EC***). The Applicant should present a comparison of these products for confirmation with justification. The risk assessment for earthworms for winter cereals should be considered by MSs level.

9.8.2.2 Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

TER_{LT} values for active substance – difenconazole, for use in winter cereals, and for formulation SNS-F-11 for use is winter oilseed rape, being slight below trigger value of 5, but according to the expert opinion from the PPR TC 58 (28-30.06.2021), difenoconazole at a rate of 250 g a.s./ha did not result in sustaining adverse effects on a natural earthworm population after a period of one year. As above, an application of SNS-F-11 in respect of the GAP should not represent an long-term risk to earthworm and the other soil macrofauna.

zRMS comments: Agreed. However, a detailed comparison of these formulations Disfera 90 EC nad Score 250 EC should be submitted by Applicant (***in this case these formulation are probably compara-***

ble - it is the same type of EC formulation and DISFERA 90 EC contains less active substance inside than Sore 250 EC). The risk assessment for earthworms for winter cereals should be considered by MSs level. The Applicant provided a comparison of products **DISFERA 90 EC** and **Sore 250 EC** for confirmation with justification. The justification was accepted by zRMS. The documents - dRR B9, dRR B0 and Part A and Part C was updated by zRMS. On the basis of the above comparison, it can be stated that ***DISFERA 90 EC*** is much less toxic or, in the worst case scenario, has the same level of toxicity as **SCORE 250 EC. It should be considered by MSs level.**

Winter cereals
TER_{LT} value for active substance – difenconazole is slight below trigger value of 5, (**being 4.54**), indicating further refinement for winter cereals. Therefore, the applicant provided the risk assessment for the product **DISFERA 90 EC**. The TER_{LT} for ppp (converted to the a.s.-difenconazole) for earthworm is above trigger of 5, indicating acceptable risk for earthworm. Therefore, it is concluded that the active substance do not pose long-term risk to earthworms and other soil macro- and mesofauna when applied according to the proposed uses rates in winter cereals. The risk assessment for earthworms for winter cereals should be considered by MSs level.

Winter oilseed rape
The TER_{LT} for ppp for earthworm is slight below trigger value of 5 (**being 4.7**), indicating further refinement for winter oilseed rape for earthworm. The Applicant for refinement risk assessment referred to the field study on the difenoconazole formulation SCORE 250 EC (Hamberger 2015) with the NOEC of 1 L product/ha (corresponding to 250 g a.s./ha) was agreed by experts in the PPR TC 58. It was, demonstrated in a field study that the application of difenoconazole at a rate of 250 g a.s./ha did not result in sustaining adverse effects on a natural earthworm population after a period of one year. However, a detailed comparison of these formulations has not been presented (***in this case these formulation are probably comparable in ecotoxicology point of view - it is the same type of EC formulation and DISFERA 90 EC contains less active substance inside than Sore 250 EC***). The Applicant should present a comparison of these products for confirmation with justification. The risk assessment for earthworms for winter cereals should be considered by MSs level.

Macroorganisms other than earthworms

As stated in Commission Regulation EU No 284/2013 of 1 March 2013, "For plant protection products applied as a foliar spray, data on the relevant two non-target arthropod species might be taken into account for a preliminary risk assessment. If effects do not occur on these species, testing on *Folsomia candida* and *Hypoaspis aculeifer* are not required." The formulated product **DISFERA 90 EC** is applied as a foliar spray treatment. As demonstrated above, a low in-field and off-field risk is demonstrated for non-target arthropods - such as - *Typhlodromus pyri*, *Aphidius rhopalosiphi* (standard laboratory studies) in cereals (2 x 90 g s.a./ha) and winter oilseed rape (1 x 103.5 g s.a./ha). Therefore, the risk assessment for macroorganisms other than earthworms is not required. The risk assessment for macroorganisms other than earthworms for winter cereals should be considered by MSs level.

The risk assessment for earthworms and other soil macro- and mesofauna should be considered by MSs level.

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

Studies on effects soil microorganisms have been carried out with difenoconazole, and its metabolites. Full details of these studies are provided in the respective EU DAR and related documents. Effects on soil microorganisms of SNS-F-11 were not evaluated as part of the EU assessment of difenoconazole. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.9-1: Endpoints and effect values relevant for the risk assessment for soil microorganisms

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	difenoconazole	28 d, aerobic silty loam	< 25% effect at day 28 at 1.67 and 16.7 mg a.s./kg dw soil in silty loam, 60% increase in loamy sand	EFSA Journal 2011;9(1):1967
N-mineralisation	CGA 71019	28 d, aerobic sandy loam	<25% effect at day 28 at 0.035 and 0.353 mg a.s./kg dw soil	EFSA Journal 2011;9(1):1967
N-mineralisation	CGA 205375	28 d, aerobic sandy loam	<25% effect at day 28 at 0.09 and 0.22 mg a.s./kg dw soil	EFSA Journal 2011;9(1):1967
N-mineralisation	SNS-F-11	28 d, aerobic agricultural soil	<25% effect at day 28 at 1.16 and 5.80 mg test item/kg dry	Pieczka P., 2023/ G-23-22

9.9.1.1 Justification for new endpoints

Not relevant.

9.9.2 Risk assessment

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, tabels 8.7-3 to 8.7-7 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8.2).

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of SNS-F-11 in winter cereals (winter wheat, winter triticale)

Intended use	Winter cereals		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
difenoconazole	16.7 (at 28 days)	0.055	Yes
CGA 71019	0.35 (at 28 days)	0.001	Yes
CGA 205375	0.22 (at 28 days)	0.006	Yes
SNS-F-11	5.8 (at 28 days)	0.296	Yes

Table 9.9-3: Assessment of the risk for effects on soil micro-organisms due to the use of SNS-F-11 in winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans)

Intended use	Winter oilseed rape

N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
difenoconazole	16.7 (at 28 days)	0.032	Yes
CGA 71019	0.35 (at 28 days)	0.001	Yes
CGA 205375	0.22 (at 28 days)	0.003	Yes
SNS-F-11	5.8 (at 28 days)	0.34	Yes

9.9.3 Overall conclusions

On the basis of results it was assessed that SNS-F-11 in considered applications does not pose unacceptable risk to soil microorganisms.

zRMS comments: Agreed. The risk of **DISFERA 90 EC**, difenoconazole and their relevant metabolites to soil micro-organisms was evaluated by comparison of the maximum concentrations with effects ≤ 25% derived from laboratory tests, with maximum PEC_{soil}.

All the effect levels exceeded the relevant PEC_{soil} values, indicating that the risk to soil micro-organisms is acceptable following the use of **DISFERA 90 EC** according to the proposed use pattern.

9.10 Effects on non-target terrestrial plants (KCP 10.6)

9.10.1 Toxicity data

Studies on the toxicity to non-target terrestrial plants have been carried out with difenoconazole. Full details of these studies are provided in the respective EU DAR and related documents.
Effects of SNS-F-11 on non-target plants were not evaluated as part of the EU review of difenoconazole. Therefore all relevant data and assessments are provided here and are considered adequate.
SNS-F-11 as fungicide does not have any effects to terrestrial non-target plants. There is a low risk to non-target flora after application of SNS-F-11 as proposed.

According to the Section 3 (Efficacy) the lack of phytotoxicity symptoms caused by used of the SNS-F-11, during the field trials suggest that product application in accordance with label recommendation shall not adversely impact on succeeding crops.

There was a total of 36 efficacy trials in which phytotoxicity assessment was carried out on winter wheat (16 trials), winter triticale (5 trials), and winter rape (15 trials). Trials were performed during two different growing season (2022 and 2023), in exception for winter triticale (trials only from 2023).

The evaluation of phytotoxicity effects was done according to EPPO Standard 1/135 (4) of fungicides applied on crops of winter wheat, winter triticale and winter oilseed rape was performed visually by comparing the condition of the plants in the plots treated with fungicide in comparison to untreated plots (no fungicides).

In all trials, no adverse effects caused by used of the SNS-F-11 in regard to phytotoxicity and vigour were observed. Furthermore, harvest results from winter wheat, winter triticale, and winter rape demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either. Details concern efficacy trials are summarized in section B3, and in the table below:

Table 9.10-1: Details concern phytotoxicity in efficacy trials of SNS-F-11 in growing seasons 2022-2023

Crop	Winter wheat	Winter triticale	Winter rape
Dose	1.3N, 1.0N, 0.8N	1.3N, 1.0N, 0.8N	1.15N, 1.0N, 0.6N
Number of trials	16	5	15
Phytotoxicity effect	no adverse effects caused by use of the SNS-F-11 in regard to phytotoxicity and vigour were observed, no detrimental effect on yield		

~~Difenoconazole is used as a fungicide on a wide range of crop groups and does not cause crop phytotoxicity. SNS-F-11 is a fungicide containing about 8% of the active substance difenoconazole so it is possible to extrapolate data concerning effects on non-target plants from the active substance- difenoconazole, as a worst case.~~

~~Table 9.10-2: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants~~

~~Species~~	~~Substance~~	~~Exposure System~~	~~Results~~	~~Reference~~
~~*Avena sativa*, *Brassica napus*, *Glycine maxima*~~	~~difenoconazole~~	~~21 d Seedling emergence, 21 d Vegetative vigour~~	~~ER_{50} emergence >10 mg as/kg dw soil (incorporation)~~	~~EFSA Journal 2011;9(1):1967; DAR, B.9 (2006)~~
~~*Brassica napus; Avena fatua; Beta vulgaris; Zea mays; Glycina max.; Allium cepa*~~	~~difenoconazole (as SCORE 250EC)~~		~~ER_{50} emergence>100 g as/ha, (spray application) ER_{50} vegetative vigour>100 g as/ha, (spray application)~~	

~~m: monocotyledonous; d: dicotyledonous~~

Effects on non-target terrestrial plants of SNS-F-11 were not evaluated as part of the EU assessment of difenoconazole. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.10 Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants

Species	Substance	Exposure System	Results	Reference
Helianthus annuus$_d$ *Brassica oleracea* $_d$ *Pisum sativum.* $_d$	SNS-F-11	21 d Seedling emergence	ER_{50} plant weight > 2600 g/ha ER_{50} plant weight > 2600 g/ha ER_{50} plant weight > 2600 g/ha	Gierbuszewska A. /2024/ G-47-24

Species	Substance	Exposure System	Results	Reference
Daucus carota $_d$ *Allium cepa* $_m$ *Avena sativa* $_m$			$ER_{50\ plant\ weight}$ > 2600 g/ha $ER_{50\ plant\ weight}$ > 2600 g/ha $ER_{50\ plant\ weight}$ > 2600 g/ha	
Helianthus annuus$_d$ *Brassica oleracea* $_d$ *Pisum sativum.* $_d$ *Daucus carota* $_d$ *Allium cepa* $_m$ *Avena sativa* $_m$	SNS-F-11	21 d Vegetative vigour	$ER_{50\ plant\ weight}$ > 2600 g/ha $ER_{50\ plant\ weight}$ > 2600 g/ha $ER_{50\ plant\ weight}$ > 2600 g/ha $ER_{50\ plant\ weight}$ > 2600 g/ha $ER_{50\ plant\ weight}$ > 2600 g/ha $ER_{50\ plant\ weight}$ > 2600 g/ha	Pieczka P. /2024/ G-46-24

m: monocotyledonous; d: dicotyledonous

9.10.1.1 Justification for new endpoints

Not relevant.

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

9.10.2.2 Tier-2 risk assessment (based on dose-response data)

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area.

~~**Table 9.10-3: Assessment of the risk for non-target plants due to the use of SNS-F-11 in winter cereals (winter wheat, winter triticale)**~~

~~**Intended use**~~	~~**Winter cereals**~~				
~~**Active substance/product**~~	~~SNS-F-11~~				
~~**Application rate (g/ha)**~~	~~2 × 90 g s.s/ha~~				
~~**MAF**~~	~~1.7~~				
~~**Test species**~~	~~**ER_{50} (g/ha)**~~		~~**Drift rate (%)**~~	~~**$PER_{off\text{-}field}$ (g/ha)**~~	~~**TER criterion: TER ≥ 5**~~
~~*Brassica napus; Avena fatua; Beta vulgaris; Zea mays; Glycina max.;Allium cepa*~~	~~Vegetative vigour~~	~~100~~	~~2.72~~	~~4.16~~	~~24.03~~
	~~Seedling emergence~~	~~100~~			

~~MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.~~

~~**Table 9.10-4: Assessment of the risk for non-target plants due to the use of SNS-F-11 in winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans)**~~

~~**Intended use**~~	~~**Winter oilseed rape**~~
~~**Active substance/product**~~	~~SNS-F-11~~
~~**Application rate (g/ha)**~~	~~1 × 103.5 g s.s/ha~~
~~**MAF**~~	~~1~~

Test species	ER_{50} (g/ha)		Drift rate (%)	$PER_{off-field}$ (g/ha)	TER criterion: TER ≥ 5
Brassica napus; Avena fatua; Beta vulgaris; Zea mays; Glycina max.; Allium cepa	Vegetative vigour	100	2.72	2.82	35.4
	Seedling emergence	100			

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The following formulas were used to calculations (according to SANCO/10329/2002 rev.2 final, 2002):

Calculate PER off-field:

$$PER_{off-field}\left[\frac{ml}{ha}\right] = \text{max. single application rate}\left[\frac{ml}{ha}\right] \times MAF \times \text{Drift rate}$$

Calculate TER (based on lowest ER_{50}):

$$TER = \frac{ER_{50}\left[\frac{ml}{ha}\right]}{PER_{off-field}\left[\frac{ml}{ha}\right]}$$

Table 9.10-3: Assessment of the risk for non-target plants due to the use of SNS-F-11 in winter cereals (winter wheat, winter triticale)

Intended use	**Winter cereals**				
Active substance/product	SNS-F-11				
Application rate (g/ha)	2 × 1000 ml/ha				
MAF	1.7				
Test species	**ER_{50} (ml/ha)**		**Drift rate**	**$PER_{off-field}$ (ml/ha)**	**TER criterion: TER ≥ 5**
Helianthus annuus$_{d,}$ *Brassica oleracea*$_{d,}$ *Pisum sativum*$_{d}$ *Daucus carota*$_{d,}$ *Allium cepa*$_{m,}$ *Avena sativa* $_{m}$	Vegetative vigour	2600	2.72% (0.0277)	47.09	55.2
	Seedling emergence	2600			

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.10-4: Assessment of the risk for non-target plants due to the use of SNS-F-11 in winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans)

Intended use	**Winter oilseed rape**				
Active substance/product	SNS-F-11				
Application rate (g/ha)	1 × 1150 ml/ha				
MAF	1				
Test species	**ER_{50} (ml/ha)**		**Drift rate**	**$PER_{off-field}$ (ml/ha)**	**TER criterion: TER ≥ 5**
Helianthus annuus$_{d,}$ *Brassica oleracea*$_{d,}$ *Pisum sativum*$_{d}$ *Daucus carota*$_{d,}$ *Allium cepa*$_{m,}$ *Avena sativa* $_{m}$	Vegetative vigour	2600	2.72% (0.0277)	31.85	81.6
	Seedling emergence	2600			

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold

fall below the relevant trigger.

9.10.2.3 Higher-tier risk assessment

Not relevant.

9.10.2.4 Risk mitigation measures

No risk mitigation needed.

9.10.3 Overall conclusions

Based on risk assessment regarding effects on non-target terrestrial plants, no risk mitigation needed. On the basis of the obtained results it was proved that the test item SNS-F-11 had no impact on the vegetative vigour and seedling emergence of monocotyledonous and dicotyledonous plants.

zRMS comments: Agreed. Calculations in terms of risk assessment for non-target plants are accepted by RMS. No additional calculations are needed. Acceptable risks are expected due to application of **DISFERA 90 EC** in the intended uses. No buffer zone is required.

9.11 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Not relevant.

9.12 Monitoring data (KCP 10.8)

No additional data.

9.13 Classification and Labelling

Acute Category 1: Since studies results shows that for each type of organism (fish, invertebrates, algae), LC_{50}/EC_{50} is higher than 1 mg of product per liter. Therefore, product should not be classified as Aquatic Acute 1.

Chronic Category 1

Relevant toxicity/basis for classification	Chronic based on toxicity data of the a.s.: *Pimephales promelas* **NOEC = 0.0036 mg/L** *Daphnia magna* **NOEC = 0.0056mg a.s./L** mm

CLASSIFICATION	
Hazard classes, categories:	Aquatic Chronic 1
LABELLING	
Hazard pictograms:	 GHS09

Signal word:	Warning
Hazard statements:	H410 – Very toxic to aquatic life with long lasting effects
Precautionary statements:	P273 – Avoid release to the environment. P391 - Collect spillage. P501 - Dispose of contents/container to an approved waste disposal plant.

zRMS comments: Agreed. The zRMS agrees with the proposed chronic classification as Aquatic Chronic 1 (H410), achieved using the summation method and based on the harmonized classification of the active substance difenoconazole.

Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe 3	To protect aquatic organisms respect a: -For 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 -For 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

zRMS comments: Agreed.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2	Hodorek Grażyna	2023	SNS-F-11 Daphnia magna, Acute Immobilisation Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: W-41-22 GLP, Unpublished	N	Synthos AGRO Sp z o.o.
KCP 10.2	Hodorek Grażyna	2023	SNS-F-11 Raphidocelis subcapitata SAG 61.81 (formerly Pseudokirchneriella subcapitata), Growth inhibition test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: W-42-22 GLP, Unpublished	N	Synthos AGRO Sp z o.o.
KCP 10.2	Czarnecka Małgorzata	2023	SNS-F-11 Rainbow trout, Acute Toxicity Testing Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: W-45-22 GLP, Unpublished	Y	Synthos AGRO Sp z o.o.
KCP 10.3.1	Wojciech Agnieszka	2023	SNS-F-11 Honeybees (Apis mellifera L.), Larval Toxicity Test, Repeated Exposure Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: B-01-23 GLP, Unpublished	N	Synthos AGRO Sp z o.o.
KCP 10.3.1	Wojciech Agnieszka	2023	SNS-F-11 Honeybees (Apis mellifera L.), Chronic Oral Toxicity Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: B-04-23 GLP, Unpublished	N	Synthos AGRO Sp z o.o.

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 10.3.1	Wojciech Agnieszka	2023	SNS-F-11 Bumbleebees (Bombus spp.), Acute Oral Toxicity Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: B-02-23 GLP, Unpublished	N	Synthos AGRO Sp z o.o.
KCP 10.3.1	Wojciech Agnieszka	2023	SNS-F-11 Bumblebees (Bombus spp.), Acute Contact Toxicity Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: B-03-23 GLP, Unpublished	N	Synthos AGRO Sp z o.o.
KCP 10.3.1	Kapa Dominik	2023	SNS-F-11 Honeybees (Apis mellifera L.), Acute Oral Toxicity Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: B-05-23 GLP, Unpublished	N	Synthos AGRO Sp z o.o.
KCP 10.3.1	Kapa Dominik	2023	SNS-F-11 Honeybees (Apis mellifera L.), Acute Contact Toxicity Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: B-06-23 GLP, Unpublished	N	Synthos AGRO Sp z o.o.
KCP 10.3.2	Kapa Dominik	2023	A laboratory test for evaluating the effects of SNS-F-11 on the predatory mite, Typhlodromus pyri (Sch.) Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: B-42-23 GLP, Unpublished	N	Synthos AGRO Sp z o.o.
KCP 10.3.2	Wojciech Agnieszka	2023	A laboratory test for evaluating the effects of SNS-F-11 on the parasitic wasp, Aphidius rhopalosiphi (De Stefani-Perez) Study code: B-43-23	N	Synthos AGRO Sp z o.o.

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**
			Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: B-43-23 GLP, Unpublished		
KCP 10.4	Wróbel Anna	2023	SNS-F-11 Earthworm Reproduction Test (Eisenia andrei) Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: G-09-23 GLP, Unpublished	N	Synthos AGRO Sp z o.o.
KCP 10.5	Pieczka Paweł	2023	SNS-F-11 Soil Microorganisms: Nitrogen Transformation Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: G-23-22 GLP, Unpublished	N	Synthos AGRO Sp z o.o.
KCP 10.6	Gierbuszewska Aneta	2024	SNS-F-11 Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: G-47-24 GLP, Unpublished	N	Synthos AGRO Sp z o.o.
KCP 10.6	Pieczka Paweł	2024	SNS-F-11 Terrestrial Plant Test: Vegetative Vigour Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: G-46-24 GLP, Unpublished	N	Synthos AGRO Sp z o.o.

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
KCP 10.1.1	[redacted]	1983a	A dietary LC_{50} study in the mallard with CGA 131013 [redacted] non GLP, Unublished	Y	Syngenta
KCP 10.1.1	[redacted]	1988b	11 - day acute dietary LC 50 study with CGA 169374 technical in mallard ducklings [redacted] GLP, Unpublished	Y	Syngenta
KCP 10.1.1	[redacted]	2000	Difenoconazole: A reproduction study with northern bobwhite. [redacted] GLP, Unpublished	Y	Syngenta
KCP 10.1.1	[redacted]	1993	Acute oral toxicity study with CGA 169374 technical in Japanese Quail [redacted] GLP, Unpublished	Y	Syngenta
KCP 10.1.1	[redacted]	1990	CGA169374 tech.: Toxicity and reproduction study in Mallard ducks. [redacted] GLP, Unpublished	Y	Syngenta
KCP 10.1.2	[redacted]	1987	CGA 169374 technical: Acute oral toxicity study in rats GLP	Y	Syngenta
KCP 10.1.2	[redacted]	1983	Triazole alanine: Teratogenicity Study in the Rat GLP	Y	Syngenta
KCP 10.1.2	[redacted]	1988	CGA-169374 technical: A two generation reproductive study in albino rats GLP	Y	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 10.1.2	[redacted]	1982	Triazolylalanine (THS 2212), Acute Toxicity Studies Non GLP	Y	Syngenta
KCP 10.1.2	[redacted]	1992	A two generation reproductive toxicity study in rats [redacted] GLP, Published	Y	Syngenta
KCP 10.2	Bell, G.	1995	1,2,4-triazole: acute toxicity to *Daphnia magna*. report no. ENVIR/95/52 Syngenta File No 169374/2620 GLP, Unpublished	N	Syngenta
KCP 10.2	[redacted]	2002	1,2,4-triazole juvenile growth test, fish (*Oncohrynchus mykiss*) [redacted] GLP, Unpublished	Y	Syngenta
KCP 10.2	Confirmatory data 2014	2009	Difenoconazole Life cycle test with the fathead minnow (Pimephales promelas) Syngenta Crop Protection AG, Basel, Switzerland Syngenta File No CGA169374_10441 GLP, Unpublished	Y	Syngenta
KCP 10.2	Forbis, A.D.	1988a	Acute toxicity of CGA 169374 to Daphnia magna Syngenta File no. CGA169374/0021 GLP, Unpublished	N	Syngenta
KCP 10.2	Forbis, A.D.	1988b	Chronic toxicity of CGA 169374 to Daphnia magna under flow through test conditions Syngenta File no. CGA169374/0022 GLP, Unpublished	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 10.2	Grade, R.	1993b	Report on the growth inhibition test of CGA 169374 tech. to green algae (*Scenedesmus subcapitatus).* report no. 938153 Syngenta File No 169374/0860 GLP, Unpublished	N	Syngenta
KCP 10.2	Grade, R.	2001	Toxicity test of CGA 211391 (metabolite of CGA 169374 on sediment-dwelling Chironomus riparius (syn. Chironomus thummi) under static conditions. Syngenta report no 2003511 Syngenta File No 211391/001 GLP, Unpublished	N	Syngenta
KCP 10.2	[redacted]	1993a	Report on the prolonged toxicity test of CGA169374 tech. to rainbow trout. [redacted]	N	Syngenta
KCP 10.2	Palmer, S.J., et al.	2001b	1,2,4-triazole: A 96-hours toxicity test with the fresh water alga (*Slenastrum capricornutum).* report no. 528A-101 Syngenta file no 71019/0044 GLP, Unpublished	N	Syngenta
KCP 10.2	Rufli H	1989	Alga Growth inhibition test of CGA 169374 to Green Algae(Scenedesmus supsicatus). Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No 881699; Syngenta File N° CGA169374/0026 GLP, Unpublished	N	Syngenta
KCP 10.2	Swarbrick, R.H.	2001a	CGA 205375 – Acute toxicity to rainbow trout (*Oncorhynchus mykiss*) GLP, Unpublished	Y	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 10.2	Surprenant, D.C.	1987b	The toxicity of CGA 169374 to fathead minnow (*Pimephales promelas*) embryo and larva. Report No. BW-87-5-2339 Syngenta File No. 169374/0018 GLP, Unpublished	Y	Syngenta
KCP 10.2	[redacted]	1990a	Acute toxicity of CGA169374 to rainbow trout under flow-through conditions [redacted] GLP, Unpublished	Y	Syngenta
KCP 10.2	Surprenant, D.C.	1990b	CGA169374 techn. Toxicity to Fathead Minnow (*Pimephales promelas*) embryos and larvae. Novartis AG, Basel, Switzerland. Syngenta File N° CGA169374/0020 GLP, Unpublished	N	Syngenta
KCP 10.2	Surprenant, D.C.	1990c	CGA169374 Acute toxicity to mysid shrimp (mysidopsis bahia) under flow- through conditions. Springborn Laboratories Inc. USA report no. 89-2-293 Syngenta file No 169374/0023 GLP, Unpublished	N	1990b
KCP 10.2	Swarbrick, R.H.	2001b	CGA 205375: Toxicity to the green alga *Selenastrum capricornutum.* report no. BL7203/B Syngenta File No 205375/0015 GLP, Unpublished	N	Syngenta
KCP 10.2	Swarbrick, R.H.	2002	CGA 205375: Acute toxicity to *Daphnia magna*	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
			report no. BL7202/B Syngenta File No 205375/0012 GLP, Unpublished		
KCP 10.2	Van der Kolk, J.	1999	CGA 169374: Chronic effects on midge larvae (*Chironomus riparius*) in water/sediment system report no. 97-192-1008 Syngenta File No 169374/1816 GLP, Unpublished	N	Syngenta
KCP 10.3.1	Grieg-Smith, P.W.	1990	Acute contact and oral toxicity of CGA 169374 to the honey-bee. report No. C89/0370 Syngenta File No. 169374/0029 GLP, Unppublished	N	Syngenta
KCP 10.3.2	Grimm, C.	1999	Toxicity of CGA 169374 EC 250 (A-7402 G) to the predacious mite *Typhlodromus pyri* Scheuten (Acari: Phytoseiidae) under extended laboratory conditions. report No 983929, Syngenta No. CGA 169374/1981) GLP, Unpublished	N	Syngenta
KCP 10.3.2	Kleiner, R.	2000a	Acute dose response toxicity of CGA 169374 EC (A-7402G) to the cereal aphid [arasitoid Aphidius rhapalosiphi (Destefani-Perez) under laboratory conditions. report number 99 10 48 083 Syngenta File No. CGA 169374/2095 GLP, Unpublished	N	Syngenta
KCP 10.3.2	Kleiner, R.	2001	Acute dose-response toxicity of CGA 169374 EC (A-7402G) to the predatory mite, Typhlodromus pyri (Scheuten), under laboratory conditions. report number 99 10 48 084	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 No. CGA 169374/2131 GLP, Unpublished		
KCP 10.4	Batsher, R.	2002	Acute toxicity of CGA 205375 (metabolite of CGA 169374) to the earthworm *Eisenia foetida* in a 14-day test. RCC Ltd. report no. 812092, Syngenta File No 205375/0011 GLP, Unpublished	N	Syngenta
KCP 10.4	Ehlers, H.A.	2000	Effects of 1,2,4-triazole on reproduction and growth of earthworms *Eisenia foetida* (Savigny 1826) in artificial soil. report no. 7781022 Syngenta File No 64250/4385 GLP, Unpublished	N	Syngenta
KCP 10.4	Heimbach, F.	1986	Acute toxicity of 1,2,4-triazole (technical) to earthworms. Bayer, report No. HBF/RG59 Syngenta File No 71019/0021 GLP, Unpublished	N	Syngenta
KCP 10.4	Suprenant, D.C.	1987c	Fourteen-day toxicity test exposing earthworm (*Eisenia foetida*) to CGA 169374. report no. 87-9-2494 Syngenta File No 169374/0027 GLP, Unpublished	N	Syngenta
KCP 10.4	Friedrich, S.	2011	Difenoconazole tech. – Sublethal Toxicity to the Earthworm Eisenia fetida in Artificial Soil with 5 % Peat Syngenta Crop Protection AG, Basel,Switzerland	N	Syngenta/ confirmatory data

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**
			BioChem Agrar, Gerichshain, Germany, 11 10 48 072 S Syngenta File No CGA169374_10511 GLP, Unpublished		
KCP 10.4	Friedrich, S.	2006	CGA211391 (Difenoconazole metabolite): Sublethal toxicity to the earthworm Eisenia fetida Syngenta Crop Protection AG, Basel, Switzerland BioChem agrar, Gerichshain, Germany, 06 10 48 058, Syngenta File No CGA205375/0030 GLP, Unpublished	N	Syngenta/ confirmatory data
KCP 10.4	Friedrich, S.	2006	Difenoconazole (CGA169374) EC (250) (A7402T): Sublethal toxicity to the earthworm *Eisenia fetida* Syngenta Report No.: T000733-04 GLP, Unpublished	N	Syngenta/ confirmatory data
KCP 10.4	Friedrich, S.	2006	CGA211391 (difenoconazole metabolite): Effects on the reproduction of the collembolans *Folsomia candida*, Report No. 06 10 48 059, BioChem agrar GmbH, Gerichshain, Germany, 12 May – 09 June 2006 Syngenta File No.CGA205375/0029 GLP, Unpublished	N	Syngenta/ confirmatory data
KCP 10.5	Ellgehausen, H.	1990	The effects of CGA 169374 on the activity of soil microbes. report 89EH08 Syngenta File No 169374/0289 GLP, Unpublished	N	Syngenta
KCP 10.5	Seyfried, B.	2002	The effects of CGA 205375 (metabolite of CGA 169374) on soil respiration and nitrification. report no. 808176 Syngenta File No 205375/0019 GLP, Unpublished	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 10.5	Volkel, W.	2000	The effects of CGA 71019 on soil respiration and nitrification. report no. 763367 Syngenta File No 71017/0042 GLP, Unpublished	N	Syngenta
KCP 10.6	Balluff, M.	2004	CGA169374 (Difenconazole): A toxicity test to determine the effects on seedling emergence and growth of three species of plants Syngenta Crop Protection AG, Basel, Switzerland GAB Biotechnologie GmbH, Niefern, Germany, Report No 20033067/S1-FGSE; Syngenta File N° CGA169374/2423 GLP, Unpublished	N	Syngenta
KCP 10.6	Walder, L	2000	Herbicide profiling test to evaluate the phytotoxicity of CGA 169374 250 EC (A-7402 G) to terrestrial non-target higher plants. Novartis Crop Protection, Stein, Switzerland. report No. SMQ 99003 (Syngenta No. CGA 169374/2029) Unpublished	N	Syngenta

Appendix 2 Detailed evaluation of the new studies

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

A 2.1.3 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

A 2.2 KCP 10.2 Effects on aquatic organisms

A 2.2.1 KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

zRMS comment:	Study was carried out according to appropriate OECD 203 and all validity criteria were met. Deviation from the study: No deviations. The validity criteria: ❖ the mortality in the control was 0% at exposure termination (should not exceed 10% or 1 fish if less than 10 fish are used); ❖ dissolved oxygen concentrations were within the range of 88– 99% of air saturation value (obligatory ≥60% of air saturation value). In opinion zRMS, above deviations did not affect the study results. In spent samples during renewals and spent at exposure termination, the determined concentrations of difenoconazole were in the range of 83.1–91.6% of the nominal concentration. Therefore, the concentrations of difenoconazole were stable under test conditions. **The study is considered acceptable.** **Agreed endpoints:**

Endpoint values based on the nominal test item concentrations - definitive test

Endpoint values [mg/L]	Time of exposure			
	24 h	48 h	72 h	96 h
LC_{50}*	>25.0	13.45 (10.28-17.61)	13.45 (10.28-17.61)	13.45 (10.28-17.61)
NOEC**	---	11.36	---	11.36
LOEC**	---	25.0	---	25.0

(-) – 95% confidence interval
* Calculations of LC_{50} values were made according to [15], version 3.30 [SOP/W/68]
** Calculations of NOEC/LOEC values were made according to [15], version 2.10 [SOP/W/68]

Endpoint values based on the nominal concentrations of difenoconazole - definitive test

Endpoint values [mg/L]	Time of exposure			
	24 h	48 h	72 h	96 h
LC_{50}*	>2.040	1.097 (0.838-1.436)	1.097 (0.838-1.436)	1.097 (0.838-1.436)
NOEC**	---	0.926	---	0.926
LOEC**	---	2.04	---	2.04

(-) – 95% confidence interval
* Calculations of LC_{50} values were made according to [15], version 3.30 [SOP/W/68]
** Calculations of NOEC/LOEC values were made according to [15], version 2.10 [SOP/W/68]

Study 1

Reference:	KCP 10.2.1
Report:	SNS-F-11, Rainbow trout, Acute Toxicity Testing Study code: W-45-22, 2023
Guideline(s):	OECD Guideline No. 203 (2019)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No
Materials and methods:	• Rainbow trout (Oncorhynchus mykiss Walb.), age: approximately 2 months, average weight: 0.73 g ± 0.09 g, average body length: 4.64 cm ± 0.20 cm (excluding control) • Semi-static system with daily renewals (96 h of exposure), one replicate of the test item concentration and control, seven fish in each aquarium, the ratio of fish weight per volume (10 L) was 0.51 g/L.

Results and discussion:	The endpoint values were determined on the basis of the nominal test item concentrations and the nominal concentrations of difenoconazole [1]. Based on the generated results the LCx values were determined by Spearman-Karber method and Fisher's Exact Binomial Test with Bonferroni Correction. The calculations and statistical analysis were done using ToxRat Professional computer software (Appendix 1)
Conclusion:	The endpoint values based on the nominal test item concentrations after 96 h of exposure: LC50/96 h is 13.45 mg/L (95% confidence interval: 10.28 – 17.61). LOEC for survival is 25.0 mg/L. NOEC for survival is 11.36 mg/L The endpoint values based on the nominal concentrations of difenoconazole after 96 h of exposure: LC50/96 h is 1.097 mg/L (95% confidence interval: 0.838 – 1.436). LOEC for survival is 2.040 mg/L. NOEC for survival is 0.926 mg/L

Study 2

zRMS comment:	Study was carried out according to appropriate OECD 201 and all validity criteria were met. Deviation from the study: No deviations. The validity criteria: ❖ the biomass in the control increased by a factor of 158.2 within the 72-hour test period (criterion: at least a 16-fold growth), ❖ the coefficient of variation of the mean specific growth rate after the 72-hour test period (exposure initiation – exposure termination) in the control culture was 0.7% (criterion: it must not exceed 7%), ❖ the mean coefficient of variation for the section-by-section growth rate in the control culture was 12.2% (criterion: it must not exceed 35%). At exposure termination, the determined concentrations of difenoconazole were in the range of 80.1 – 109.8% of the nominal concentration. Therefore, the concentrations of difenoconazole were stable under test conditions **The study is considered acceptable.** **Agreed endpoints:**

Growth rate endpoint values based on the nominal test item concentrations, definitive test

Endpoint value [mg/L]	Time of exposure:		
	24 h	48 h	72 h
E_rC_{50}	n.d.	>40	30.43 (26.86 – 34.27)
E_rC_{20}	n.d.	14.05 (12.56 – 15.73)	11.89 (10.81 – 13.07)
E_rC_{10}	n.d.	7.46 (6.66 – 8.35)	7.27 (6.60 – 8.02)
LOEC	n.d.	3.9	3.9
NOEC	n.d.	1.2	1.2

(-) – 95% confidence interval
n.d. – not determined
Calculations were made according to [9], [SOP/W/68]

Yield endpoint values based on the nominal test item concentrations, definitive test

Endpoint value [mg/L]	Time of exposure:		
	24 h	48 h	72 h
E_yC_{50}	n.d.	13.37 (10.45 – 17.08)	8.46 (7.00 – 10.23)
E_yC_{20}	n.d.	5.05 (4.14 – 6.17)	3.80 (3.27 – 4.45)
E_yC_{10}	n.d.	3.03 (2.45 – 3.74)	2.51 (2.13 – 2.95)
LOEC	>40	3.9	1.2
NOEC	≥40	1.2	0.4

(–) – 95% confidence interval
n.d. – not determined
Calculations were made according to [9], [SOP/W/68]

Reference: KCP 10.2.1

Report: SNS-F-11 *Raphidocelis subcapitata* SAG 61.81 (formerly *Pseudokirchneriella subcapitata*), Growth inhibition test
Study code: W-42-22, 2023

Guideline(s): OECD Guideline No. 201 (2006)/ EU method C.3.

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study): No

Materials and methods:

- The unicellular freshwater green algae, *Raphidocelis subcapitata* (formerly *Pseudokirchneriella subcapitata (*Korshikov*)* Hindák, *Selenastrum capricornutum* Prinz) SAG 61.81

- 72 hours of exposure; three replicates per each test item concentration; six replicates per control; a background for each treatment; initial algal cell density: 1 x 104 cells/mL

Results and discussion: The endpoint values were determined on the basis of the nominal test item concentrations [1, 2]. The lowest observed effect concentration (LOEC) and the no observed effect concentration (NOEC) were estimated on the basis of statistical analyses. To conduct statistical analyses, the ToxRat Professional Version 3.3.0 commercial software was used (Appendix 1). The endpoint values are presented below.

Conclusion: The endpoint values based on nominal test item concentrations are given below:
The ErC50/72 h value is 30.43 mg/L (95% confidence interval: 26.86 – 34.27).
The LOEC/72 h value for growth rate is 3.9 mg/L.
The NOEC/72 h value for growth rate is 1.2 mg/L.
The EyC50/72 h value is 8.46 mg/L (95% confidence interval: 7.00 – 10.23).
The LOEC/72 h value for yield is 1.2 mg/L.
The NOEC/72 h value for yield is 0.4 mg/L.

Study 3

Reference: KCP 10.2.1

Report: SNS-F-11 *Daphnia magna,* Acute Immobilisation Test
Study code: W-41-22, 2023

Guideline(s): OECD Guideline No. 202 (2004)/ EU method C.2.

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study): No

Materials and methods:

- The unicellular freshwater green algae, *Raphidocelis subcapitata* (formerly *Pseudokirchneriella subcapitata (*Korshikov*)* Hindák, *Selenastrum capricornutum* Prinz) SAG 61.81
- 72 hours of exposure; three replicates per each test item concentration; six replicates per control; a background for each treatment; initial algal cell density: 1 x 104 cells/mL

Results and discussion:	The endpoint values were determined based on the nominal test item concentrations [1]. The endpoint values were calculated with a probit analysis using linear max. likelihood regression. The lowest observed effect concentration (LOEC) and the no observed effect concentration (NOEC) were estimated on the basis of statistical analysis. To make calculations and to conduct statistical analysis, the ToxRat Professional commercial software was used (Appendix 1) [7], [SOP/W/68]. The endpoint values are presented below.
Conclusion:	The endpoint values based on nominal test item concentrations are given below: The ErC50/72 h value is 30.43 mg/L (95% confidence interval: 26.86 – 34.27). The LOEC/72 h value for growth rate is 3.9 mg/L. The NOEC/72 h value for growth rate is 1.2 mg/L. The EyC50/72 h value is 8.46 mg/L (95% confidence interval: 7.00 – 10.23). The LOEC/72 h value for yield is 1.2 mg/L. The NOEC/72 h value for yield is 0.4 mg/L.

Study 3

Reference:	KCP 10.2.1
Report:	SNS-F-11 *Raphidocelis subcapitata* SAG 61.81 (formerly *Pseudokirchneriella subcapitata*), Growth inhibition test Study code: W-42-22, 2023
Guideline(s):	OECD Guideline No. 201 (2006)/ EU method C.3.
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No
Materials and methods:	• The unicellular freshwater green algae, *Raphidocelis subcapitata* (formerly *Pseudokirchneriella subcapitata (*Korshikov*)* Hindák, *Selenastrum capricornutum* Prinz) SAG 61.81 • 72 hours of exposure; three replicates per each test item concentration; six replicates per control; a background for each treatment; initial algal cell density: 1 x 104 cells/mL

Results and discussion: The endpoint values were determined on the basis of the nominal test item concentrations [1, 2]. The lowest observed effect concentration (LOEC) and the no observed effect concentration (NOEC) were estimated on the basis of statistical analyses. To conduct statistical analyses, the ToxRat Professional Version 3.3.0 commercial software was used (Appendix 1). The endpoint values are presented below.

Conclusion: The endpoint values based on nominal test item concentrations are given below:

The ErC50/72 h value is 30.43 mg/L (95% confidence interval: 26.86 – 34.27).

The LOEC/72 h value for growth rate is 3.9 mg/L.

The NOEC/72 h value for growth rate is 1.2 mg/L.

The EyC50/72 h value is 8.46 mg/L (95% confidence interval: 7.00 – 10.23).

The LOEC/72 h value for yield is 1.2 mg/L.

The NOEC/72 h value for yield is 0.4 mg/L.

zRMS comment:	Study was carried out according to appropriate OECD 202 and all validity criteria were met. Deviation from the study: No deviations. The validity criteria: ❖ the percentage of immobilisation of *Daphnia magna* in the control was 0% (criterion: not more than 10%), ❖ the dissolved oxygen concentrations in the test vessels were within the range of 7.6 – 8.6 mg/L (criterion: not less than 3 mg/L). In samples at exposure termination, the determined concentrations of difenoconazole were in the range of 84.7 – 89.5% of the nominal concentration. Therefore, the concentrations of difenoconazole were stable during 48 h under test conditions. **The study is considered acceptable.** **Agreed endpoints:**

Endpoint values based on the nominal test item concentrations, definitive test

Endpoint values [mg/L]	Time of exposure	
	24 h	48 h
EC_{50}	10.52 (n.d.)	9.11 (7.48 – 11.10)
EC_{20}	9.15 (n.d.)	6.63 (4.74 – 7.99)
EC_{10}	8.51 (n.d.)	5.61 (3.62 – 6.95)
LOEC	10.3	10.3
NOEC	4.7	4.7

Calculations were made according to [7], [SOP/W/68].
(-) - 95% confidence interval

n.d. – not determined (due to matemathical reasons)

Study 4

Reference:	KCP 10.2.1
Report:	SNS-F-11 *Daphnia magna*, Acute Immobilisation Test Study code: W-41-22, 2023
Guideline(s):	OECD Guideline No. 202 (2004)/ EU method C.2.
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No
Summary:	Immobilisation of *Daphnia magna* exposed to the test item, SNS-F-11 was investigated during a 48-hour static test. The definitive test was performed with a test item concentrations of 50, 22.7, 10.3, 4.7, 2.1 and 0.97 mg/L plus the control. The test was performed in glass beakers of 150 mL capacity, containing 100 mL of either the test item concentrations or the control per replicate. Four replicates were used for the test item concentrations and the control, each with five *Daphnia magna*. The *Daphnia magna* were observed for immobilisation and any abnormal behavior or appearance after 24 and 48 h of exposure. The *Daphnia magna* were considered immobile if they showed no ability to swim within 15 seconds after gentle swirling of the test vessel. In the control, no immobilisation of *Daphnia magna* was observed during exposure. At exposure termination in the test item concentration of 4.7, 10.3, 22.7 and 50 mg/L, the immobilisation of *Daphnia magna* was 5,

60, 100, 100%, respectively. No abnormal behavior of *Daphnia magna* was observed during exposure. The concentrations of difenoconazole were chemically determined using the high performance liquid chromatography (HPLC) with Diode Array Detection. Samples of all test item concentrations and the control collected at exposure initiation and at exposure termination were chemically determined. At exposure initiation, the determined concentrations of difenoconazole were in the range of 84.5 – 92.4% of the nominal concentration. The results confirm that the test item concentrations were prepared correctly. At exposure termination, the determined concentrations of difenoconazole were in the range of 84.7 – 89.5% of the nominal concentration. Therefore, the concentrations of difenoconazole were stable under test conditions.

The endpoint value was determined based on the nominal test item concentration.

Materials and methods: The study was performed according to the OECD Guideline for the Testing of Chemicals No. 202 (2004): '*Daphnia* sp., Acute Immobilisation Test', EU Method C.2. '*Daphnia* sp., Acute Immobilisation Test', the standard operating procedure SOP/W/21: *Daphnia* sp., acute immobilisation test and the Study Plan.

Results and discussion: The endpoint value based on nominal test item concentration:

The EC_{50}/48-h value is 9.11 mg/L (95% confidance limits: 7.48 mg/L-11.10 mg/L)

The EC_{20}/48-h value is 6.63 mg/L (95% confidance limits: 4.74 mg/L - 7.99 mg/L)

The EC_{10}/48 h value is 5.61 mg/L (95% confidance limits: 3.62 mg/L - 6.95 mg/L)

The LOEC is 10.3 mg/L

The NOEC is 4.7 mg/L

A 2.2.2 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

A 2.3 KCP 10.3 Effects on arthropods

A 2.3.1 KCP 10.3.1 Effects on bees

A 2.3.1.1 KCP 10.3.1.1 Acute toxicity to bees

zRMS comment:

Study was carried out according to appropriate OECD 213 and all validity criteria were met.

Deviation from the study: No deviations.

The validity criteria:
– the mortality for the control was 6.7% at the end of the experiment (criterion: it must not exceed 10%).
– the LD_{50}/24 h of the reference item (dimethoate) was 0.117 µg a.i./bee (95% confidence limit: 0.047 – 0.165 a.i./bee), (criterion: 0.1 – 0.35 µg a.i./bee).

The study is considered acceptable.
Agreed endpoints:

Dose [µg/bee]	Number of tested bees [no.]	Mortality after 48 h after the beginning of the treatment			LD_{50} [µg/bee]	Difenoconazole [µg a.i./bee]
		Total				
		[no.]	[%]	[%][a]		
0.0 (Control)	30	2	6.7	–	> 300.0	> 24.46
122.9	30	0	0.0	-7.1*		
153.6	30	0	0.0	-7.1*		
192.0	30	0	0.0	-7.1*		
240.0	30	3	10.0	3.6		
300.0	30	5	16.7	10.7		

[a]: mortality was corrected according to Abbott's equation [9]

*: the negative value means that the mortality in the tested dose was lower than in the control group

A 2.3.1.1.1 KCP 10.3.1.1.1 Acute oral toxicity to bees

Study 1

Reference:	KCP 10.3.1.1.1
Report:	SNS-F-11 Honeybees (*Apis mellifera* L.), Acute Oral Toxicity Test Study code: B-05-23, 2023
Guideline(s):	OECD Guideline No. 213 (1998) and the EU Method C.16. (2008)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No
Materials and methods:	**Biological test system:** the honeybee, *Apis mellifera* L., strain: carnica **Age**: approximately 3 weeks

Source: an apiary at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna

Test item doses:

122.9, 153.6, 192.0, 240.0 and 300.0 µg test item/bee and a control (0.0 µg/bee)

Reference item doses: 0.1, 0.2 and 0.4 µg a.i./bee

Results and discussion: The LD_{50} (median lethal dose) oral is a statistically derived single dose of a test or reference item that can cause death in 50 per cent of biological test systems when administered by the oral route. The LD_{50} is expressed in µg of the test item per bee or in µg of the active ingredient contained in the reference item per bee. It was calculated with the Probit analysis (linear max. likelihood regression) using ToxRat Proffesional software, version 3.3.0

LD_{50} [µg/bee] >300

difenoconazole [µg a.i./bee] >24.46

Conclusion: The median lethal doses LD_{50}/24 h and LD_{50}/48 h are higher than the highest dose used in the test, i.e. 300.0 µg/bee, i.e. > 24.46 µg a.i./bee.

Study 2

zRMS comment:

Study was carried out according to appropriate OECD 247 and all validity criteria were met.

Deviation from the study: The test was performed according to the OECD Guideline for the Testing of Chemicals No. 247 (2017): Bumblebee, Acute Oral Toxicity Test', other references given in section 9 and the SOP's listed in section 10 of the report. In the study following deviation occurred. According to the OECD Guideline No. 247 it is recommended to use plastic syringes for the test item administration. However, in the experiment they were replaced by calibrated glass pipettes. This deviations had no impact on the quality, integrity and final results of the study.

The validity criteria:
− Mortality of the control group was 0.0% at the end of the test (criterion: ≤ 10%).
− Mortality in the toxic reference item group (dimethoate) at the end of the test was 93.3% (criterion: ≥ 50%).

The study is considered acceptable.

Agreed endpoints:

Dose		Number of tested bumblebees [no.]	Mortality after 48 h		LD_{50}/48 h	
Test item [µg/ bumble-bee]	Difenoconazole [µg a.i. / bumblebee]		[no.]	[%]	Test item [µg/ bumblebee]	Difenoconazole [µg a.i. / bumble-bee]
Control		50	0	0.0	> 200.0	> 16.3
200.0	16.3	50	0	0.0		
Reference item: dimethoate						
Dose [µg/bumblebee]	4.0	30	28	93.3	–	

Reference:	KCP 10.3.1.1.1
Report:	SNS-F-11 Bumblebees (*Bombus* spp.), Acute Oral Toxicity Test Study code: B-02-23, 2023
Guideline(s):	OECD Guideline No. 213 (1998) and the EU Method C.16. (2008)
Deviations:	Yes, According to the OECD Guideline No. 247 it is recommended to use plastic syringes for the test item administration. However, in the experiment they were replaced by calibrated glass pipettes. This deviations had no impact on the quality, integrity and final results of the study
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No
Materials and methods:	− species: the bumblebee, *Bombus* spp. − source: commercial supplier: Koppert Polska sp. z o.o. − age: adult worker bumblebees (from 3 different families for the definitive test) Bumblebees were taken from healthy families consisting of 60 – 80 individuals.
Results and discussion:	At exposure initiation, in the fresh test item sample, the concentration of difenoconazole was 100.6% of the nominal concentration. The results confirm that the test item concentration was prepared correctly. The median lethal doses for the test item (LD50/24 h, LD50/48 h) are higher than the dose used in the test, i.e. > 200.0 µg test item/bumblebee i.e. > 16.3 µg difenoconazole/bumblebee. Dose-effect curves showing the influence of the test item on mortality after 24 and 48 hours of exposure are not given due to the lack of mortality. The percentage of mortality after 48 h hours of exposure to the reference item at the dose of 4.0 µg/bumblebee was 93.3% (Table 9). During the experiment sublethal effects (toxic symptoms) in the group treated with the reference item were no observed.
Conclusion:	The median lethal doses LD_{50}/24 h and LD_{50}/48 h are higher than the highest dose used in the test, i.e. 300.0 µg/bee, i.e. > 24.46 µg a.i./bee.

zRMS comment:	Study was carried out according to appropriate OECD 214 and all validity criteria were met. Deviation from the study: According to the Guideline No. 214/ EU Method C.17., the honeybees may be anesthetized with carbon dioxide for application of the test item. Anesthesia was replaced with mechanical immobilisation. The mentioned deviation had not effect on the results of the study. The validity criteria: − the mortality for the control was 0.0% after 48 h (criterion: it must not exceed 10.0%), − the LD_{50}/24 h of the reference item (dimethoate) was 0.221 µg a.i./bee (criterion:

0.10 – 0.30 µg a.i./bee).

The study is considered acceptable.
Agreed endpoints:

Dose [µg/bee]	Number of tested bees [no.]	Mortality after 48 h of exposure		LD_{50}	
		Total		Test item [µg/bee]	Difenoconazole [µg a.i./ bee]
		[no.]	[%]		
0.0 (water control)	30	0	0.0	> 300.0	> 24.46
0.0 (1% (*w/v*) surfactant control)	30	0	0.0		
122.9 + 1% (*w/v*) surfactant	30	0	0.0		
153.6 + 1% (*w/v*) surfactant	30	0	0.0		
192.0 + 1% (*w/v*) surfactant	30	0	0.0		
240.0 + 1% (*w/v*) surfactant	30	0	0.0		
300.0 + 1% (*w/v*) surfactant	30	0	0.0		

KCP 10.3.1.1.2 Acute contact toxicity to bees

Study 1

zRMS comment:

Study was carried out according to appropriate OECD 246 and all validity criteria were met.

Deviation from the study: The test was performed according to the OECD Guideline for Testing of Chemicals No. 246 (2017): Bumblebee, Acute Contact Toxicity Test', other references given in section 9 and the SOP's listed in section 10 of the report. According to the OECD Guideline No. 246 the bumblebees may be anesthetized with carbon dioxide or chilled for the application of the test item. Anesthesia with carbon dioxide or chilling was replaced with mechanical immobilisation. This deviation had no impact on the quality, integrity and final results of the study.

The validity criteria:
− Mortality of the control groups was 0.0% at the end of the test (criterion: ≤ 10%).
− Mortality in the toxic reference item group (dimethoate) at the end of the test was 83.3% (criterion: ≥ 50%).

The study is considered acceptable.
Agreed endpoints:

Dose		Number of tested bumble-bees [no.]	Mortality after 48 h		LD_{50}/48 h	
Test item [µg/ bumble-bee]	Difenoconazole [µg a.i. / bumblebee]		[no.]	[%]	Test item [µg/ bumble-bee]	Difenoconazole [µg a.i. / bumblebee]
Control + 1% surfactant		50	0	0.0	> 200.0	> 16.3
200.0 + 1% surfactant	16.3	50	0	0.0		
Reference item: dimethoate + 1% surfactant						
Dose [µg/bumblebee]	10.0	30	25	83.3	–	

Reference: KCP 10.3.1.1.2

Report: SNS-F-11 Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test
Study code: B-06-23, 2023

Guideline(s): OECD Guideline No. 214 (1998) and the EU Method C.17. (2008)

Deviations: Yes, However, According to the Guideline No. 214/ EU Method C.17., the honeybees may be anesthetized with carbon dioxide for application of the test item. Anesthesia was replaced with mechanical immobilisation

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study): No

Materials and methods: **Biological test system:** the honeybee, *Apis mellifera* L., strain: carnica

Age: approximately 3 weeks

Source: an apiary at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna

Test item doses:

122.9, 153.6, 192.0, 240.0 and 300.0 µg test item/bee and a control (0.0 µg/bee)

Reference item doses: 0.1, 0.2 and 0.4 µg a.i./bee

Results and discussion: The LD50 (median lethal dose) contact, is a statistically derived single dose of a substance that can cause death in 50 per cent of biological test system when administered by contact route. The LD50 is expressed in µg test item per bee or in µg of the active ingredient contained in the reference item per bee. It was calculated with the log-probit method

LD_{50} [µg/bee] >300

difenoconazole [µg a.i./bee] >24.46

Conclusion: The median lethal doses LD_{50}/24 h and LD_{50}/48 h are higher than the high-

est dose used in the test, i.e. 300.0 µg/bee, i.e. > 24.46 µg a.i./bee.

zRMS comment:

Study was carried out according to appropriate OECD 246 and all validity criteria were met.

Deviation from the study: The test was performed according to the OECD Guideline for Testing of Chemicals No. 246 (2017): Bumblebee, Acute Contact Toxicity Test', other references given in section 9 and the SOP's listed in section 10 of the report. According to the OECD Guideline No. 246 the bumblebees may be anesthetized with carbon dioxide or chilled for the application of the test item. Anesthesia with carbon dioxide or chilling was replaced with mechanical immobilisation. This deviation had no impact on the quality, integrity and final results of the study.

The validity criteria:
− Mortality of the control groups was 0.0% at the end of the test (criterion: ≤ 10%).
− Mortality in the toxic reference item group (dimethoate) at the end of the test was 83.3% (criterion: ≥ 50%).

The study is considered acceptable.
Agreed endpoints:

Dose		Number of tested bumble-bees [no.]	Mortality after 48 h		LD_{50}/48 h	
Test item [µg/ bumble-bee]	Difenoconazole [µg a.i. / bumblebee]		[no.]	[%]	Test item [µg/ bumble-bee]	Difenoconazole [µg a.i. / bumblebee]
Control + 1% surfactant		50	0	0.0	> 200.0	> 16.3
200.0 + 1% surfactant	16.3	50	0	0.0		
Reference item: dimethoate + 1% surfactant						
Dose [µg/bumblebee]	10.0	30	25	83.3	–	

Study 2

Reference:	KCP 10.3.1.1.2
Report:	SNS-F-11 Bumblebees (*Bombus* spp.), Acute Contact Toxicity Test Study code: B-03-23, 2023
Guideline(s):	OECD Guideline No. 246 (2017)
Deviations:	Yes, However, According to the Guideline No. 246, the bumblebees may be anesthetized with carbon dioxide for application of the test item. Anesthesia was replaced with mechanical immobilization. This deviation had no impact on the quality, integrity and final results of the study
GLP:	Yes
Acceptability:	Yes

Duplication (if vertebrate study):	No
Materials and methods:	− species: the bumblebee, *Bombus* spp. − source: commercial supplier: Koppert Polska sp. z o.o. − age: adult worker bumblebees Bumblebees were taken from healthy families consisting of 60 – 80 individuals.
Results and discussion:	At exposure initiation, in the fresh test item sample, the concentration of difenoconazole was 109.7% of the nominal concentration. The results confirm that the test item concentration was prepared correctly. The median lethal doses for the test item (LD50/24 h, LD50/48 h) are higher than the dose used in the test, i.e. > 200.0 µg test item/bumblebee, i.e. > (16.3 µg difenoconazole/bumblebee). Dose-effect curves showing the influence of the test item on mortality after 24 and 48 hours of exposure are not given due to the lack of mortality. The percentage of mortality after 4, 24 and 48 h hours of exposure to the reference item at the dose of 10.0 µg/bumblebee with 1% surfactant were 0.0, 60.0 and 83.3%
Conclusion:	The median lethal doses (LD_{50}/24 h, LD_{50}/48 h) are higher than the dose used in the test, i.e. > 200.0 µg test item/bumblebee i.e. > (16.3 µg difenoconazole/bumblebee).

zRMS comment:	Study was carried out according to appropriate OECD 245 and all validity criteria were met. Deviation from the study: none. The validity criteria: − At the end of the experiment average mortality of the control groups was 0.0% (criterion: it must not exceed 15%). − After 10 days of exposure corrected mortality of the honeybees exposed to the reference item at the concentration of 0.8 mg/kg (0.024 µg/bee/day) was 100% (criterion: it must be ≥ 50% on day 10 of exposure). **The study is considered acceptable.** **Agreed endpoints:**

Nominal test item concentration/ dose		Ingested[a] dose	Number of tested bees	Total mortality		LC_{50}	LDD_{50}
[µg/30 mg/day] [µg/bee/day]	[mg/kg]	[µg/bee/day]	[no]	No.	[%]	[mg/kg]	[µg/bee/day]
SNS-F-11							
0.0 (Control)			50	0	0.0	> 1000.0	> 19.7
30.0	1000.0	19.7	50	0	0.0		
Dimethoate (reference item)							
0.024	0.8	0.017	30	30	100.0	not determined	

[a]: ingested doses (dietary doses) were calculated on the basis of the concentrations of the test item / reference item and average sucrose solution consumption

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

Study 1

Reference:	KCP 10.3.1.2.
Report:	SNS-F-11 Honeybees (*Apis mellifera* L.), Chronic Oral Toxicity Test Study code: B-04-23, 2023
Guideline(s):	OECD Guideline No. 245 (2017)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No
Materials and methods:	**Biological test system:** the honeybee, *Apis mellifera* L., strain: carnica **Age**: freshly emerged worker honeybees (max. 2 days old) from the same queen-right colony **Source:** an apiary at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna
Results and discussion:	The validity criterion concerning mortality was met, because mortality in the control was 0.0% after 10 days of exposure [1]. The percentage of mortality of the honeybees exposed to the test item, SNS-F-11 at the concentration of 1000.0 mg/kg (i.e. 30.0 µg/30 mg/ day; dietary dose 19.7 µg/bee/day) after 10 days of exposure, was 0.0%. On the basis of the obtained mortality results the LC_{50} is higher than 1000.0 mg/kg, and the LDD_{50} value is higher than 19.7 µg/bee/day. The validity criterion concern-

ing mortality of the honeybees exposed to the reference item,dimethoate was met, because mortality was equal to 100.0% after 10 days of exposure. The results obtained in the reference item group showed that the insects were sensitive to dimethoate.

Conclusion:

Conclusions:

The LC_{50} is higher than 1000.0 mg/kg, and the LDD_{50} value is higher than 19.7 µg/bee/day.

A 2.3.1.3 KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages

zRMS comment:

Study was carried out according to appropriate OECD 239 and all validity criteria were met.

Deviation from the study: no deviation.

The validity criteria:
− Cumulative larval mortality in the control group was 13.9% at day 8 (D8) (criterion: ≤ 15%).
− Abbott corrected mortality of the larvae treated with the reference item at day 8 (D8) (dimethoate) was 87.1% (criterion: ≥ 50%).
− Emergence rate in the control group on D22 was 75.0% (criterion: ≥ 70%).

The study is considered acceptable.
Agreed endpoints:

Dose [µg test item/larva]	Concentration [mg test item/kg food]	Number of tested larvae [no.]	Total mortality (larval and pupal) on day 22 (D22)				
			Number [no.]	[%]	Corr[a] [%]	Number of emerged adults [No.]	Emergence rate [%]
Test item: SNS-F-11							
0.0 (Control)		36	9	25.0	–	27	75.0
100.0	649.4	36	12	33.3	11.1	24	66.7
ED_{50} [µg test item/larva]			> 100.0				
EC_{50} [mg/kg]			> 649.4				
NOED [µg test item/larva]			≥ 100.0				
NOEC [mg/kg]			≥ 649.4				
Reference item: Technical dimethoate mortality on day 22 (D22)							
7.39	48.0	36	36	100.0	100.0	not determined	

[a]: Mortality corrected according to the Abbott formula [7]

Study 1

Reference:	KCP 10.3.1.2.
Report:	SNS-F-11 Honeybees (*Apis mellifera* L.), Larval Toxicity Test, Repeated Exposure Study code: B-01-23, 2023
Guideline(s):	OECD Guideline No. 239 (2021)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No
Materials and methods:	− **species:** the honeybee, *Apis mellifera* L.; strain: carnica − **source:** an apiary at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna − age: one-day-old larvae, first instar (L1) Larvae were taken from three healthy, queen-right families (3 replicates) with known history and physiological status. Families had not been treated with chemical substances, such as antibiotics, anti-varroa, etc. for four weeks before the experiment
Results and discussion:	Mortality of the control group on day 8 (D8) of the test was 13.9% (criterion: ≤ 15%). The percentage of mortality of the honeybee larvae, exposed to the test item, SNS-F-11 at the cumulative dose of 100.0 µg test item/larva at D8, corrected using Abbott's formula [7], was (-3.2)*%. The percentage of larval mortality on D8 in the reference item group, corrected using Abbott's formula [7], was 87.1%. Pupal mortality of the control group on day 15 (D15) of the test was 25.0%. The percentage of mortality of the honeybee pupae corrected using Abbott's formula [7], exposed to the test item, SNS-F-11 at the cumulative dose of 100.0 µg/larva at D15 was (-14.8)%. The percentage of pupal mortality, corrected using Abbott's formula [7], on D15 in the reference item group was 100.0%. Cumulative mortality (larval and pupal) of the control group on day 22 (D22) of the test was 25.0%. The percentage of mortality of the honeybee pupae corrected using Abbott's formula [7], exposed to the test item, SNS-F-11 at the cumulative dose of 100.0 µg/larva at D22 was 11.1%. The emergence of adults (emergence rate) at the end of the test (on D22) in the control group was 75.0%. In the group treated with the test item at the cumulative dose of 100.0 µg test

item/larva the adult emergence rate was: 66.7%.

Conclusion: **Conclusions:**

The endpoint values for SNS-F-11 at the end of the assessment (D22):

- ED50 value is higher than 100.0 µg test item/larva,
- EC50 value is higher than 649.4 mg/kg,
- NOED value is higher than or equal to 100.0 µg test item/larva,
- NOEC value is higher than or equal to 649.4 mg/kg.

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

A 2.3.2 KCP 10.3.2 Effects on non- target arthropods other than bees

A 2.3.2.1 KCP 10.3.2.1 Standard laboratory testing for non-target arthropods

Study 1

zRMS comment:	Study was carried out according to the ESCORT 1 (Barrett K. L. et al., 1994) and the ESCORT 2 (Candolfi M. P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Blümel S. et al., 2000) and all validity criteria were met. Deviation from the study: The study was conducted according to the guidelines developed by the IOBC, BART and EPPO Joint initiative, SOP/B/23 and other procedures related to the study and the Study Plan. However, in the experimental part of the study the following deviation from the guidelines occurred. According to the guideline developed by the IOBC, BART, EPPO Joint Initiative, as a food source only pollen is used. However, in the experiment additional food in the form of the two-spotted spider mite (*T.urticae*) eggs, was used. Another food source prevents the mites from escaping from discs. A deviation from the Study Plan concerning study completion date occurred. According to the Study Plan the study should be completed in September 2023. However, it will complete in October 2023. Since the test guideline does not require the necessity of checking the concentration, homogeneity and stability of the test material, such analyses will not be carried out. The waiver of these analyses constitutes a deviation from the OECD Principles on Good Laboratory Practice Number 1. The obtained deviations had no impact on the quality, integrity and final results of the study. The validity criteria: − mortality of the control group was 0.0% on day 7 of exposure (criterion: a maximum of 20%), − mortality of the mites exposed to the reference item at the rate of 4.0 g/ha was

85.0% on day 7 of exposure (criterion: from 50 to 100%),
– the mean number of eggs per female in the control group was 8.56 (required: ≥ 4 eggs per female).

The study is considered acceptable.
Agreed endpoints:

Study group [application rate]	Parameter (endpoint)					
	Mortality (dead + escape mites)		Reproduction			
Test item [L/ha]	Total [%]	LR_{50} [L/ha]	Test item [L/ha]	Mean number of eggs per female (Rr) [no.]	Repro-duction reduction (Pr) [%]	ER_{50} [L/ha]
Control	0.0	–	Control	8.56	–	–
SNS-F-11						
0.30	0.0	1.724 *(1.537-1.961)***	0.30	8.65	(-1.0)*	1.849 *(1.201-8.784)***
0.45+	5.0		0.45+	6.06	29.2	
0.67+	6.7		0.67+	5.24	38.8	
1.01+	28.3		1.01+	5.16	39.8	
1.51+	43.3		1.51+	5.18	39.5	
2.27+	73.3		-	-	-	-
3.40+	73.3		-	-	-	-
$NOER_{mortality}$ [L/ha]	0.30		$NOER_{reproduction}$ [L/ha]			0.30
Reference item						
[g/ha]	Total [%]		Dimethoate			
4.0	85.0		not assessed			

*: the negative value means that in the tested rate there was higher cumulative mean reproduction value than in the control group
**: 95% confidence limits [10], [SOP/B/67]
+: statistically significant differences [10], [SOP/B/67]

Reference: KCP 10.3.2.1.

Report: SNS-F-11 A laboratory test for evaluating the effects of SNS-F-11 on the predatory mite, *Typhlodromus pyri* (Sch.)
Study code: B-42-23, 2023

Guideline(s): ESCORT 1 (Barrett K.L. et al., 1994)
ESCORT 2 (Candolfi M.P. et al., 2001) developed by the IOBC, BART, and EPPO Joint Initiative (Blumel S. et al., 2000)

Deviations: Yes,
According to the guideline developed by the IOBC, BART, EPPO Joint Initiative, as a food source only pollen is used. However, in the experiment additional food in the form of the two-spotted spider mite (*T. urticae*) eggs, was used. Another food source prevents the mites from escaping from discs.
A deviation from the Study Plan concerning study completion date occurred. According to the Study Plan the study should be completed in Sep-

	tember 2023. However, it will complete in October 2023. The obtained deviations had no impact on the quality, integrity and final results of the study.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No
Materials and methods:	**Biological test system:** the predatory mite, *Typhlodromus pyri* (Sch.), (Acari: *Phytoseiidae*) **– age:** 24-hour-old protonymphs **– source:** a laboratory culture at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Ecotoxicology Research Group; the culture was obtained from commercial breeder
Results and discussion:	In the definitive test, mortality of the control group after 7 days of exposure was 0.0%. After 7 days of exposure to SNS-F-11 at the rates of 0.30, 0.45, 0.67, 1.01, 1.51, 2.27 and 3.40 L/ha, the *T. pyri*, percentages of mortality, were 0.0, 5.0, 6.7, 28.3, 43.3, 73.3 and 73.3%, respectively. There were no statistically significant differences in mortality between the group treated with the test item at the rate 0.30 L/ha in comparison to the control group (Step-down Cochran-Armitage Test Procedure, p(trend) > Alpha, Alpha = 0.05). There were statistically significant differences in mortality between the group treated with the test item at the rates of 0.45, 0.67, 1.01, 1.51, 2.27 and 3.40 L/ha in comparison to the control group (Step-down Cochran-Armitage Test Procedure, p(trend) ≤ Alpha, Alpha = 0.05). On the basis of the obtained results the LR50 value is equal to 1.724 L/ha (*1.537-1.961 L/ha* with 95%-confidence limits). The $NOER_{mortality}$ value is equal to 0.30 L/ha. After 7 days of exposure to dimethoate at the rate of 4.0 g/ha mortality was 85.0%. Therefore, the validity criterion specified in the method description was met. The results obtained in the reference item group showed that the test organisms were sensitive to dimethoate.
Conclusion:	On the basis of the obtained results the LR_{50} value is equal to 1.724 L/ha (*1.537-1.961 L/ha* with 95%-confidence limits). The $NOER_{mortality}$ value is equal to 0.30 L/ha. On the basis of the obtained reproduction results, the ER_{50} value is equal to

1.849 L/ha (*1.201-8.784 L/ha* with 95%-confidence limits) and the $NOER_{re-production}$ value is equal to 0.30 L/ha.

Study 2

zRMS comment:	Study was carried out according to the ESCORT 1 (Barrett K. L. et al., 1994) and the ESCORT 2 (Candolfi M. P. et al., 2001) guidance documents and EPPO Joint Initiative (Mead-Briggs. et al., 2000) and all validity criteria were met. Deviation from the study: The experiment was performed according to the ESCORT 1 and the ESCORT 2 guidance documents, the guideline developed by the IOBC, BART, and EPPO Joint Initiative, the Standard Operating Procedure SOP/B/25: 'A laboratory test for evaluating the effects of plant protection products on the parasitic wasp, *Aphidius rhopalosiphi* (De Stephani-Perez)', other references given in section 9, the SOP's listed in section 10 of the report and the Study Plan. There were used barley variety "Ella" instead of variety "Kucyk", however, it did not influence the study course and results. Since the test guideline does not require the necessity of checking the concentration, homogeneity and stability of the test material, such analyses will not be carried out. The waiver of these analyses constitutes a deviation from the OECD Principles on Good Laboratory Practice Number 1. The validity criteria: –the mortality of the control group after 48 hours was 0.0% (criterion: a maximum of 13.0%), – mortality of the reference item group after 24 hours of the treatment was 95.0% (criterion: from 75 to 100%), – all wasps survived the 24-hour oviposition period (criterion: only wasps that survive oviposition can be examined for fecundity), – the mean number of mummies per female in the control group was 31.7 (criterion: a minimum of 5.0 mummies/female), – all wasps in the control group gave offspring (criterion: a maximum of 2 females giving no offspring). **The study is considered acceptable.** **Agreed endpoints:**

Study group	Test item: SNS-F-11					
	Mortality after 48 h		Reproduction after 12 days after the oviposition			
Test item [L/ha]	Total [%]	LR_{50} [L/ha]	Test item [L/ha]	Mean no. of mummies /female	Fecundity reduction Pr [%]	ER_{50} [L/ha]
Control (0.0)	0.0	1.173* (1.046 - 1.317)	Control (0.0)	31.7	–	1.324* (0.990 – 2.685)
0.30	2.5		0.30	28.4	10.5	
0.45	0.0		0.45+	23.5	25.8	
0.67+	25.0		0.67+	21.1	33.4	
1.01+	32.5		1.01+	18.3	42.2	
1.51+	67.5		1.51	-	-	
2.27+	87.5		2.27	-	-	
3.40+	97.5		3.40	-	-	
$NOER_{mortality}$ 0.45 [L/ha]			$NOER_{fecundity}$ 0.30 [L/ha]			
Reference item: dimethoate						
Rate [g/ha]			Mortality after 24 h Total [%]			
0.2			95.0			

+: Statistically significant differences between control and groups exposed to test item [10], [SOP/B/67],

*: ER_{50} and LR_{50} value (with 95% confidence limits) was estimated with the log-probit method (ToxRat Proffesional 3.3.0 computer software), [10]

Reference:	KCP 10.3.2.1.
Report:	SNS-F-11 A laboratory test for evaluating the effects of SNS-F-11 on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez) Study code: B-43-23, 2023
Guideline(s):	ESCORT 1 (Barrett K.L. et al., 1994) ESCORT 2 (Candolfi M.P. et al., 2001) developed by the IOBC, BART, and EPPO Joint Initiative (Mead-Briggs. et al., 2000)
Deviations:	Yes, There were used barley variety “Ella” instead of variety “Kucyk”, however, it did not influence the study course and results.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No
Materials and methods:	Test system: the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez); Hymenoptera: Braconidae, Aphiidinae – age: adult wasps (24 - 48 hours after emerging from mummies) – source: a laboratory culture at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, The Ecotoxicology Research Group; the culture was obtained from commercial breeder

Results and discussion: In the definitive test, mortality of the control group, after 48 hours, was 0.0%. After 48 hours of the exposure to SNS-F-11, at the rates 0.30, 0.45, 0.67, 1.01, 1.51, 2.27 and 3.40 L/ha, the percentages mortality of *A. rhopalosiphi* were 2.5, 0.0, 25.0, 32.5, 67.5, 87.5 and 97.5%, respectively. At the significance level of 0.05, there were statistically significant differences in mortality between the wasps exposed to the test item at rates: 0.67, 1.01, 1.51, 2.27 and 3.40 L/ha and the control group (Step-down Cochran Armitage Test Procedure, p(trend) ≤ Alpha). Based on the obtained mortality results it can be assumed that the LR_{50} is equal to 1.173 L/ha (95% confidence limit: *1.046 – 1.317* L/ha). The $NOER_{mortality}$ is equal to 0.45 L/ha of the test item. Mortality the wasps exposed to dimethoate (after 24 hours of exposure) at the rate of 0.2 g/ha was 95.0%. Therefore, the validity criterion specified in the method description was met. The results showed that the test organisms were sensitive to dimethoate. The fecundity assessment showed that the mean number of mummies per female in the control group was 31.7. As for the wasps treated with SNS-F-11 at the rates of 0.30, 0.45, 0.67, 1.01 the mean number of mummies per female were 28.4, 23.5, 21.1 and 18.3 respectively. Higher doses 1.51, 2.27 and 3.40 L/ha were not considered due to excess mortality 50%. Fecundity reduction (Pr) in the group treated with the test item at the rates of 0.30, 0.45, 0.67, 1.01 were 10.5, 25.8, 33.4 and 42.2%, respectively.

Conclusion: Based on the obtained mortality results it can be assumed that the LR_{50} is equal to 1.173 L/ha (95% confidence limit: *1.046 – 1.317* L/ha). The $NOER_{mortality}$ is equal to 0.45 L/ha of the test item.
Based on the obtained fecundity results it can be assumed that the ER_{50} is equal to 1.324 L/ha of the test item (95% confidence limit: *0.990 – 2.685* L/ha). The $NOER_{fecundity}$ is equal to 0.30 L/ha of the test item.

A 2.3.2.2 KCP 10.3.2.2. Extended laboratory testing, aged residue studies with non- target arthropods

A 2.3.2.3 KCP 10.3.2.3. Semi- field studies with non- target arthropods

A 2.3.2.4 KCP 10.3.2.4. Field studies with non-target arthropods

A 2.3.2.5 KCP 10.3.2.5. Other routes of exposure for non-target arthro-

pods

A 2.4 KCP 10.4 Effects on non-target soil meso- and macrofauna

A 2.4.1 KCP 10.4.1 Earthworms

A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

Study 1

zRMS comment:

Study was carried out according to OECD Guideline no. 222 (216) and all validity criteria were met.

Deviation from the study: No deviations occurred in the study.

The validity criteria:
• each replicate produced from 130 to 151 juveniles (142.4 mean) at the end of the exposure period (criterion: ≥ 30 juveniles by the end of the experiment),
• the coefficient of variation of reproduction was 6.0% (criterion: ≤ 30%),
• adult mortality over the initial 4 weeks of the experiment was 0.0% (criterion: ≤ 10%).

The study is considered acceptable.
Agreed endpoints:

Parameter	Value [mg test item/kg dry weight of artificial soil]	Value [mg of difenoconazole/kg dry weight of artificial soil]
EC_{10}	11.6 (5.2 – 26.0)	1.0 (0.4 – 2.1)
EC_{20}	33.9 (19.4 – 59.3)	2.8 (1.6 – 4.8)
EC_{50}	263.5 (178.5 – 388.8)	21.5 (14.6 – 31.7)
NOEC (reproduction)	3.2	0.3
LOEC (reproduction)	5.6	0.5
LC_{10}	> 1000.0	> 81.5
LC_{20}	>1000.0	>81.5
LC_{50}	> 1000.0	> 81.5
NOEC (survival)	≥ 1000.0	≥ 81.5
LOEC (survival)	> 1000.0	> 81.5

Reference: KCP 10.4.1.1.

Report: SNS-F-11 Earthworm Reproduction Test (*Eisenia andrei*)
Study code: B-09-23, 2023

Guideline(s): Guideline No. 222 (2016)

Deviations: No

GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No
Materials and methods:	Test system: the earthworm, *Eisenia andrei* obtained from a standard laboratory culture cultivated at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna, Ecotoxicology Research Group, Laboratory of Soil Organisms Toxicology Test design: test duration: 8 weeks; number of replicates: 4 replicates/concentration + 8 replicates/control; number of earthworms: 10 earthworms/replicate
Results and discussion:	At concentrations ranging from 3.2 to 1000.0 mg of the test item/kg dry weight of artificial soil, after 4 weeks of exposure to the test item, mortality of the adult earthworms was between 0.0 and 5.0%. In the control group no mortality of the adult earthworms was observed. The concentration of the test item causing 50% mortality of the adult earthworms (LC50) is higher than 1000 mg/kg dry weight of the artificial soil (i.e. 81.5 mg of difenoconazole/kg dry weight of the artificial soil). At the concentration of 100.0 mg/kg one earthworm was divided. In the other test concentrations no changes in the appearance (morphology) and behaviour of the living adult earthworms were noticed. At the concentrations 560.0 and 1000.0 mg/kg dry weight juvenile earthworms were less active in comparison to the control group. After 4 weeks of the exposure period of the test item at the concentrations ranging from 3.2 to 1000.0 mg/kg dry weight of artificial soil, the body weight increase was between 1.5 and 8.3%. As for the control group, the body weight increase was equal to 3.6%. After the application of the test item at the concentrations ranging from 3.2 to 1000.0 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 38.3 and 135.8 per replicate. The mean number of juveniles in the control group was equal to 142.4 per replicate.
Conclusion:	The endpoint values showing the impact of the test item on reproduction and survival of adult earthworms are presented in the table given below.

Parameter	**Value [mg test item/kg dry weight of artificial soil]**	**Value [mg of** difenoconazole/**kg dry weight of artificial soil]**

EC10	11.6 (5.2 – 26.0)	1.0 (0.4 – 2.1)
EC20	33.9 (19.4 – 59.3)	2.8 (1.6 – 4.8)
EC50	263.5 (178.5 – 388.8)	21.5 (14.6 – 31.7)
NOEC (reproduction)	3.2	0.3
LOEC (reproduction)	5.6	0.5
LC10	> 1000.0	> 81.5
LC20	>1000.0	>81.5
LC50	> 1000.0	> 81.5
NOEC (survival)	≥ 1000.0	≥ 81.5
LOEC (survival)	> 1000.0	> 81.5

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

A 2.4.2.1 KCP 10.4.2.1 Species level testing

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

Study 1

zRMS comment:	Study was carried out according to OECD Guideline no. 216 and all validity criteria were met. Deviation from the study: According the Guideline, the soil extraction should be conducted at 150 rpm for 60 min. However, in this study, the extraction was performed at 90 rpm and time duration between 18 to 24 hours. The modification resulted from the optimization of the nitrate extraction which showed that the extraction was more effective when the shaking rate was lower and the extraction lasted longer. These deviation did not affect the results of the study. Since the test guideline not require the necessity of checking the concentration, homogeneity and stability of the test item, such analyses were not carried out. The waiver of these analyses constitutes a derogation from the principles of Good Laboratory Practice. The validity criteria: The coefficients of variation (CV) in the control group were 8.8, 4.6, 0.3 and 3.7%, after 0, 7, 14 and 28 days of incubation. The validity criterion was met, because the variation between replicate control samples is less than 15%.

The study is considered acceptable.

Agreed endpoints:
On the basis of the results, it was concluded that **DISFERA 90 EC** at the concentrations corresponding to the PEC: 1.16 mg test item/kg dry weight of soil and 5 x PEC: 5.80 mg test item/kg dry weight of soil did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

Time interval [d]	Control					PEC					5xPEC				
	Replicate			Mean ± SD		Replicate			Mean ± SD		Replicate			Mean ± SD	
	I	II	III			I	II	III			I	II	III		
0 – 7	14.817	12.553	14.010	13.794	± 1.15	14.203	13.617	14.067	13.963	± 0.31	13.639	14.196	11.582	13.139	± 1.38
0 – 14	12.651	12.680	12.769	12.700	± 0.06	14.090	14.073	13.794	13.986	± 0.17	12.576	12.537	12.505	12.539	± 0.04
0 – 28	9.247	10.110	10.006	9.788	± 0.47	9.910	10.072	10.513	10.165	± 0.31	10.329	9.556	9.643	9.843	± 0.42

* - Rate of nitrate ions formation per a day = [(mg nitrate / kg of soil dry weight on sampling day 'a') - (mg nitrate / kg of soil dry weight on day 0)]/ 'a' day; 'a' = 7, 14 and 28 day

Reference: KCP 10.5.

Report: SNS-F-11 Soil Microorganisms: Nitrogen Transformation Test
Study code: B-23-22, 2023

Guideline(s): OECD Guideline No. 216 (2000)/EU Method C.21

Deviations: Yes
According the Guideline, the soil extraction should be conducted at 150 rpm for 60 min. However, in this study, the extraction was performed at 90 rpm and time duration between 18 to 24 hours. The modification resulted from the optimization of the nitrate extraction which showed that the extraction was more effective when the shaking rate was lower and the extraction lasted longer (point 3.4.4.4.). These deviation did not affect the results of the study.

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study): No

Materials and methods: Soil: Agricultural soil collected from a place belonging to the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna.
Test design: Three portions of soil (3 x 1500 g), i.e. one control group and two treated groups. The soil was enriched with the organic substrate, i.e. lucerne at dose of 5 g/kg dry weight of soil. After adding the deionized water, every portion was divided into three replicates (3 x 505 g). Exposure period: 28 days.

Results and discussion:	The difference in the nitrate formation rate between the control soil and the ones treated with the test item at the concentrations corresponding to the PEC: 1.16 mg test item/kg dry weight of soil and 5 x PEC: 5.80 mg test item/kg dry weight of soil did not exceed 25% on 28 day of analysis
Conclusion:	On the basis of the results, it was concluded that SNS-F-11 at the concentrations corresponding to the PEC: 1.16 mg test item/kg dry weight of soil and 5 x PEC: 5.80 mg test item/kg dry weight of soil did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants

A 2.6.1 KCP 10.6.1 Summary of screening data

A 2.6.2 KCP 10.6.2 Testing on non-target plants

Study 1

zRMS comment:	Study was carried out according to OECD Guideline no. 208 and all validity criteria were met. Deviation from the study: According to OECD Guideline No. 208 (2006), the light intensity should be 350 ± 50 µE/m2/s. However, these values are recommended for tests conducted in greenhouses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 208.7 and 250.0 µE/m2/s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing. The validity criteria: On the basis of the obtained results, it was stated that the following validity criteria of the study aimed at evaluating the impact of Disfera 90 EC on seedling emergence and seedling growth of terrestrial plants were met: - the seedling emergence in the control (validity criterion: at least 70%) was as follows: 95.2% – sunflower, 100.0% – cabbage, 100.0% – pea, 100.0% – carrot, 95.0% – onion, 95.0% – oats, - the mean survival of the emerged control seedlings was 100% for each tested plant species (validity criterion: 90%); - the control seedlings did not exhibit any visible phytotoxic effects; - environmental conditions for all plants of the same species were identical. **The study is considered acceptable.**

Agreed endpoints:

	Sunflower *Helianthus annuus*	Cabbage *Brassica oleracea var. capitata*	Pea *Pisum sativum*	Carrot *Daucus carota*	Onion *Allium cepa*	Oats *Avena sativa*
Emergence of plants						
ER_{50}	> 2600.0	> 2600.0	> 2600.0	> 2600.0	> 2600.0	> 2600.0
NOER	≥ 2600.0	≥ 2600.0	≥ 2600.0	≥ 2600.0	≥ 2600.0	≥ 2600.0
Survival of plants						
ER_{50}	> 2600.0*	> 2600.0*	> 2600.0*	> 2600.0*	> 2600.0*	> 2600.0
NOER	≥ 2600.0	≥ 2600.0	≥ 2600.0	≥ 2600.0	≥ 2600.0	≥ 2600.0
Shoot length						
ER_{50}	> 2600.0	> 2600.0	> 2600.0	> 2600.0	> 2600.0	> 2600.0
NOER	≥ 2600.0	≥ 2600.0	≥ 2600.0	≥ 2600.0	≥ 2600.0	≥ 2600.0
Shoot dry weight						
ER_{50}	> 2600.0	> 2600.0	> 2600.0	> 2600.0	> 2600.0	> 2600.0
NOER	1300.0	1300.0	≥ 2600.0	1300.0	≥ 2600.0	650.0
Plant damages						
ER_{50}	> 2600.0	> 2600.0	> 2600.0	> 2600.0	> 2600.0	> 2600.0
NOER	n.d.**	n.d.**	n.d.**	n.d.**	n.d.**	n.d.**

* no plants mortality occurred, therefore no statistical calculations were performed. The value is higher than 2600.0 mL/ha.
** - not determined

Reference: KCP 10.6.

Report: SNS-F-11 Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test
Study code: G-47-24

Guideline(s): OECD Guideline No. 208 (2006)

Deviations: Yes
According to OECD Guideline No. 208 (2006), the light intensity should be 350 ± 50 µE/m2/s. However, these values are recommended for tests conducted in greenhouses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 208.7 and 250.0 µE/m2/s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing. These deviation did not affect the results of the study.

GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No
Materials and methods:	**Test species:** sunflower (*Helianthus annuus*), cabbage (*Brassica oleracea var. capitata*), pea (*Pisum sativum*), carrot (*Daucus carota*), onion (*Allium cepa*), oats (*Avena sativa*) **Application rate [ml/ha]:** 81.3, 162.5, 325.0, 650.0, 1300.0, 2600.0 **Exposure termination:** 14 days after the emergence of 50% of the control seedlings **Test conditions :** temperature: 18.1 – 25.2°C, humidity: 46.1 – 76.8%, lighting: 16 h light : 8 h dark; light intensity: 208.7 – 250.0 µE/m2/s; carbon dioxide concentration: 361 – 386 ppm;
Results and discussion:	The ER_{50} and NOER values determined on the basis of emergence of plants, survival of plants, shoot length and shoot dry weight measurements and ER50 values for plant damages at the end of the exposure period expressed as mL of the test item/ha for all test species are given below.

Sunflower *Helianthus annuus*	**Cabbage** *Brassica oleracea var. capitata*	**Pea** *Pisum sativum*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Oats** *Avena sativa*
Emergence of plants					
ER50	> 2600.0	> 2600.0	> 2600.0	> 2600.0	> 2600.0	> 2600.0
NOER	≥ 2600.0	≥ 2600.0	≥ 2600.0	≥ 2600.0	≥ 2600.0	≥ 2600.0
Survival of plants					
ER50	> 2600.0*	> 2600.0*	> 2600.0*	> 2600.0*	> 2600.0*	> 2600.0
NOER	≥ 2600.0	≥ 2600.0	≥ 2600.0	≥ 2600.0	≥ 2600.0	≥ 2600.0
Shoot length					
ER50	> 2600.0	> 2600.0	> 2600.0	> 2600.0	> 2600.0	> 2600.0
NOER	≥ 2600.0	≥ 2600.0	≥ 2600.0	≥ 2600.0	≥ 2600.0	≥ 2600.0
Shoot dry weight					
ER50	> 2600.0	> 2600.0	> 2600.0	> 2600.0	> 2600.0	> 2600.0
NOER	1300.0	1300.0	≥ 2600.0	1300.0	≥ 2600.0	650.0
Plant damages					
ER50	> 2600.0	> 2600.0	> 2600.0	> 2600.0	> 2600.0	> 2600.0
NOER	n.d.**	n.d.**	n.d.**	n.d.**	n.d.**	n.d.**

Conclusion: On the basis of the obtained results it was proved that the test item i.e. SNS-F-11 had no impact on the process of growth of pea and onion. The test item had slightly impact on the cultivation of sunflower, cabbage, carrot and oats. Mortality of plants was not observed in cultivation of all tested species. Delayed emergence of plants in comparison to the control group was observed in cultivation of sunflower. On the basis of NOER, ER10, ER25 and ER50 values determined from the plant emergence during exposure period it was proved that the test item had no impact on seedling emergence of all tested species. On the basis of NOER, ER_{10}, ER_{25} and ER_{50} values determined from the survival of plants it was proved that the test item had no impact on survival of all tested plants.

On the basis of NOER, ER_{10}, ER_{25} and ER_{50} values determined from the shoot length it was proved that the test item did not inhibit process of growth of all tested species. On the basis of NOER, ER_{10}, ER_{25} and ER_{50} values determined from the shoot dry weight it was proved that the test item did not inhibit process of growth of pea and onion. The test item slightly inhibited process of growth of sunflower, cabbage, carrot and oats. During the exposure period, the phytotoxic symptoms of the test item were not observed in cultivation of all tested plants. The ER_{50} values for all test species were higher than 2600.0 mL/ha.

Study 2

zRMS comment:	Study was carried out according to OECD Guideline no. 227 and all validity criteria were met. Deviation from the study: According to OECD Guideline No. 227 (2006), the light intensity should be 350 ± 50 µE/m2/s. However, these values are recommended for tests conducted in greenhouses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 210.8 and 252.7 µE/m2/s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing. This deviation did not affect the results of the experiment. The validity criteria: On the basis of the obtained results. it was stated that the following validity criteria of the study aimed at evaluating the impact of SNS-F-11 on vegetative vigour of terrestrial plants were met: - the seedling emergence of plants (validity criterion: at least 70%) was as follows: 88.1 – 95.2% – sunflower,

88.1 – 95.2% – cabbage,
88.1 – 97.6% – pea,
82.5 – 95.0% – carrot,
87.5 – 100.0% – onion,
90.0 – 100.0% – oats.
- the mean plant survival of the control was 100% for all tested species (validity criterion: at least 90%).
- the control plants did not exhibit any visible phytotoxic symptoms.
- environmental conditions for all plants belonging to the same species were identical.

The study is considered acceptable.

Agreed endpoints:

	Sunflower *Helianthus annuus*	Cabbage *Brassica oleracea var. capitata*	Pea *Pisum sativum*	Carrot *Daucus carota*	Onion *Allium cepa*	Oats *Avena sativa*
Plant number at the end of the experiment						
ER_{50}	> 2600.00	> 2600.00	> 2600.00	> 2600.00	> 2600.00	> 2600.00
NOER	≥ 2600.00	≥ 2600.00	≥ 2600.00	≥ 2600.00	≥ 2600.00	≥ 2600.00
Shoot length						
ER_{50}	> 2600.00	> 2600.00	> 2600.00	> 2600.00	> 2600.00	> 2600.00
NOER	≥ 2600.00	≥ 2600.00	≥ 2600.00	≥ 2600.00	≥ 2600.00	≥ 2600.00
Plant dry weight						
ER_{50}	> 2600.00	> 2600.00	> 2600.00	> 2600.00	> 2600.00	> 2600.00
NOER	≥ 2600.00	650.00	≥ 2600.00	≥ 2600.00	≥ 2600.00	≥ 2600.00
Plant Damage						
ER_{50}	> 2600.00	> 2600.00	> 2600.00	> 2600.00	> 2600.00	> 2600.00
NOER	n.d.*	n.d.*	n.d.*	n.d.*	n.d.*	n.d.*

* not determined

Reference: KCP 10.6.

Report: SNS-F-11 Terrestrial Plant Test: Vegetative Vigour Test
Study code: G-46-24

Guideline(s): OECD Guideline No. 227 (2006)

Deviations: Yes
According to OECD Guideline No. 227 (2006), the light intensity should be 350 ± 50 µE/m2/s. However, these values are recommended for tests conducted in greenhouses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 210.8 and 252.7 µE/m2/s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suita-

ble for plant growing. These deviation did not affect the results of the study.

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study): No

Materials and methods: **Test species:** sunflower (*Helianthus annuus*), cabbage (*Brassica oleracea var. capitata*), pea (*Pisum sativum*), carrot (*Daucus carota*), onion (*Allium cepa*), oats (*Avena sativa*)

Application rate [ml/ha]: 81.3, 162.5, 325.0, 650.0, 1300.0, 2600.0

Test conditions : temperature: 20.0 – 25.4°C; humidity: 50.2 – 73.4%; lighting: 16 h light : 8 h dark; light intensity: 210.8 – 252.7 µE/m2/s; carbon dioxide concentration: 358 – 384 ppm

Results and discussion: The ER50 and NOER values determined on the basis of plants number at the end of the experiment, shoot length and shoot dry weight measurements and ER50 values for plant damages at the end of the exposure period expressed as mL of the test item/ha for all test species are given below.

Sunflower *Helianthus annuus*	**Cabbage** *Brassica oleracea var. capitata*	**Pea** *Pisum sativum*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Oats** *Avena sativa*
Plant number at the end of the experiment					
ER50	> 2600.00	> 2600.00	> 2600.00	> 2600.00	> 2600.00	> 2600.00
NOER	≥ 2600.00	≥ 2600.00	≥ 2600.00	≥ 2600.00	≥ 2600.00	≥ 2600.00
Shoot length					
ER50	> 2600.00	> 2600.00	> 2600.00	> 2600.00	> 2600.00	> 2600.00
NOER	≥ 2600.00	≥ 2600.00	≥ 2600.00	≥ 2600.00	≥ 2600.00	≥ 2600.00
Plant dry weight					
ER50	> 2600.00	> 2600.00	> 2600.00	> 2600.00	> 2600.00	> 2600.00
NOER	≥ 2600.00	650.00	≥ 2600.00	≥ 2600.00	≥ 2600.00	≥ 2600.00
Plant Damage					
ER50	> 2600.00	> 2600.00	> 2600.00	> 2600.00	> 2600.00	> 2600.00
NOER	n.d.*	n.d.*	n.d.*	n.d.*	n.d.*	n.d.*

* not determined

Conclusion: The test item. i.e. SNS-F-11, had a slight impact in cultivation of cabbage and onion. No influence was noticed in cultivation of sunflower, pea, carrot and oats. On the basis of NOER, ER_{10}, ER_{25} and ER_{50} values

determined from the plant number at the end of the experiment it was proved that the test item did not cause mortality of tested plant species. On the basis of NOER, ER10, ER25 and ER50 values determined from the shoot length it was proved that the test item did not inhibit the process of growth of all tested plant species. On the basis of NOER, ER10, ER25 and ER50 values determined from the shoot dry weight it was proved that the test item did not inhibit the process of growth of sunflower, pea, carrot and oats. Slight effect was noticed in cultivation of cabbage and onion. During the exposure period, some phytotoxic symptoms were noticed only in cultivation of cabbage.

A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants

A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

A 2.8 KCP 10.8 Monitoring data