

# FINAL REGISTRATION REPORT

## Part A

### Risk Management

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

Product names: **DISFERA 90 EC/ LIPOSTAR 90 EC**

Chemical active substance:

Difenoconazole, 90 g/L

Central Zone

Zonal Rapporteur Member State: **Poland**

CORE ASSESSMENT Poland

(authorization)

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

Submission date: 01/2024

Update: 05/2024, 07/2024

MS Finalisation date: 08/2024, 10/2024; 11/2024; **04/2025**

## Version history

When	What
01/2024	Initial dRR
05/2024	Additional information in point: 3.8.6.
07/2024	ZRMs evaluated submitted dRR by Applicant
07/2024	Physicochemical data after one year of storage
08/2024	zRMS evaluation of the 1-year shelf life study
10/2024	Post-comment zRMS verification (fRR)
11/2024	The final RR after the second round of commenting
04/2025	The Final Registration Report after correction

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# **PART A**

## **RISK MANAGEMENT**

### **1 Details of the application**

This application was submitted by company Synthos Agro Sp. z o.o., ul Chemików 1, 32-600 Oświęcim, Poland.

The information, data and assessments provided in Registration Report, Parts B includes assessment of data and information relating to SNS-F-11 where that data has not been considered in the EU review. Otherwise assessments for the safe use of SNS-F-11 have been made using endpoints agreed in the EU review of difenoconazole.

#### **1.1 Application background**

The application is submitted for registration of plant protection product SNS-F-11 in Poland according to art. 33 of Regulation 1107/2009. The product has not been previously evaluated in any country from Central Zone of Europe according to Uniform Principles. The zRMS is Poland.

The application is for the approval of SNS-F-11 an emulsifiable concentrate (EC) containing 90 g/L of difenoconazole for use as a fungicide in cereal crops and oilseed rape to control fungal diseases.

#### **1.2 Letters of Access**

Not submitted.

#### **1.3 Justification for submission of tests and studies**

The Applicant has conducted and submitted own studies on SNS-F-11 which are sufficient to evaluate of the product. Data protection claims and a list of submitted test reports and study are included in each section of dRR for SNS-F-11 and in Part C.

#### **1.4 Data protection claims**

All data submitted in Part C are confidential.

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4, on all references specified in Sections 1-10 of Part B in the form of "List of data submitted in support of the evaluation".

## 2 Details of the authorization decision

### 2.1 Product identity

Product code	SNS-F-11
Product name in MS	DISFERA 90 EC, LIPOSTAR 90 EC
Authorization number	-
Function	Fungicide
Applicant	Synthos Agro
Active substance(s) (incl. content)	Difenoconazole: 90 g/L
Formulation type	Emulsifiable concentrate [EC]
Packaging	Size and packaging type for professional users: 0.25 L, 0.5 L, 1 L HDPE bottle 0.25 L, 0.5 L, 1 L PE/PA bottle 5 L, 10 L, 20 L HDPE canister 5 L, 10 L PE/PA canister
Coformulants of concern for national authorizations	Not applicable
Restrictions related to identiy	Not applicable
Mandatory tank mixtures	Not applicable
Recommended tank mixtures	Not applicable

### 2.2 Conclusion

The evaluation of the application for SNS-F-11 (DISFERA 90 EC/ LIPOSTAR 90 EC) resulted in the decision to grant the authorization.

Physical and chemical properties: Data gap – 2 years shelf life study. Expected date of completion of the study and the final report - approx. July 2025. Provisional authorisation for 2 years is possible and proposed.

Efficacy section:

All uses claimed in the GAP table were accepted by ZRMs on the basis on submitted documentation.

Metabolism and Residues:

Uses are accepted.

The fate and behaviour section:

Assessment is accepted for all crops presented in GAP. No risk for groundwater is expected following applications of DISFERA 90 EC / LIPOSTAR 90 EC.

Ecotoxycology section:

The use of this plant protection product **DISFERA 90 EC** according to recommendations is accepted in PL. However, the comparison of formulation **DISFERA 90 EC** and **SCORE 250 EC** should be provided by Applicant. (in this case these formulation DISFERA 90 EC and SCORE 250 EC 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 provided a comparison of products DIS-

FERA 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.~~

~~On the other hand, the risk assessment based on the studies for bees should be considered when GD for Bees, 2013 is implemented at EU level.~~ The Applicant delivered supplement risk assessment for bees in accordance with EFSA 2013. The risk assessment was accepted by zRMS.

Evaluators verified whether the co-formulants contained in plant protection product SNS-F-11 are listed in Annex III to Regulation (EC) No 1107/2009 and/or could be considered unacceptable based on the criteria indicated in the Annex to the Commission Implementing Regulation (EU) 2023/574 of 13 March 2023.

Based on the currently available MSDSs and other information provided by applicant or manufacturer of co-formulant, the product SNS-F-11 does not contain any unacceptable co-formulant/ingredient listed in the Commission Regulation (EU) 2021/383 amending Annex III to Regulation (EC) No 1107/2009.

According to the current knowledge and available information none of the co-formulants in the plant protection product SNS-F-11 meets the Annex to Regulation (EU) 2023/574 criteria for identification of co-formulants that are unacceptable for inclusion in a plant protection products. Taking this into account, none of the co-formulants/ingredients in this product is considered to be a candidate for inclusion in Annex III of Regulation (EU) 1107/2009.

Detailed assessment of co-formulants according to Article 3 of Regulation (EU) 2023/574 can be found in the dRR Part C and in the Annex to Part C (confidential)..

## 2.3 Substances of concern for national monitoring

National monitoring data is not available/known to the applicant.

## 2.4 Classification and labelling

### 2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard classes, categories:	Acute Tox. 4 (Inhalation) Carc. 2, H351 Skin Irrit. 2 Eye Dam. 1 Aquatic Chronic 1
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	GHS05, GHS07, GHS08, GHS09,
Signal word:	Danger
Hazard statements:	H332 Harmful if inhaled. H351 Suspected of causing cancer H315 Causes skin irritation H318 Causes serious eye damage.

	H410: Very toxic to aquatic life with long lasting effects.
Precautionary statements:	<p><b>Warning section of the label (first page):</b></p> <p><b>P261</b> Avoid breathing vapours/ spray.  <b>P280</b> Wear protective gloves/<del>protective clothing</del> and eye protection/face protection.  <b>P308+P313</b> IF exposed or concerned: Get medical advice/attention.  <b>P305+P351+P338</b> IF IN EYES Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  <b>P302 + P352</b> IF ON SKIN: Wash with plenty of water  <b>P304+P340</b> IF INHALED: Remove person to fresh air and keep comfortable for breathing.</p> <p>Other section of the label:  P270 Do not eat, drink or smoke when using this product.  P271 Use only outdoors or in a well-ventilated area.  P264 Wash hands thoroughly after handling.  P362 + P364 Take off contaminated clothing and wash it before reuse.  P405 Store locked up.  P501 Dispose of contents/ container to an approved waste disposal plant.</p> <p>And P280 as follows:  <i>„Stosować rękawice ochronne, odzież ochronną oraz ochronę oczu lub twarzy w trakcie przygotowywania cieczy roboczej oraz odzież roboczą w trakcie wykonywania zabiegu.”</i>  “Wear protective gloves, protective clothing and eye/face shield during mixing/loading and work wear during application”.</p> <p>Section First Aid:  P308+P313 IF exposed or concerned: Get medical advice/attention  P305+P351+P338 IF IN EYES Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P310 Immediately call a POISON CENTER/doctor.  P302 + P352 IF ON SKIN: Wash with plenty of water.  P332 + P313 If skin irritation occurs: Get medical advice/ attention.  P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.  P312 Call a POISON CENTRE/doctor if you feel unwell.</p> <p>P273: Avoid release to the environment.  P501: Dispose of contents/ container to an approved waste disposal plant.</p>
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Special rule for labelling of plant protection product (PPP):

EUH401	To avoid risks to man and the environment, comply with the instructions for use.
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**See Part C for justifications of the classification and labelling proposals.**

## 2.4.2 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).
SPe3	To protect aquatic organisms respect a: <b>Winter triticale, winter wheat</b>



	<p>1m buffer zone with vegetative filter strip and 50% spray drift reduction, or                  2 m buffer zone with vegetative filter strip</p> <p><b>Winter rape</b>                  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.</p> <p><b>Spring oilseed rape</b>                  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.</p> <p><b>Linseed (common flax)</b>                  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.</p> <p><b>Poppy seeds</b>                  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.</p> <p><b>Mustard seeds</b>                  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.</p> <p><b>Gold of pleasure seeds</b>                  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.</p> <p><b>Sunflower seeds</b>                  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.</p> <p><b>Sovabeans</b>                  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.</p>
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#### 2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

Not applicable.

### 2.5 Risk management

#### 2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
respective code if available	AOEM: None OPEX ver 1.0.1: Winter wheat, Winter triticale: None Minor uses according to Article 51: Work wear (arms, body and legs covered)  Since SNS-F-11 is classified as Carc.2, H351, Eye Dam. 1, H318 and Skin Irrit. 2, H315, the operator should wear protective clothes, eye protection or face protection and protective gloves when handling the concentrated product.
Worker protection:	
respective code if available	None
Integrated pest management (IPM)/sustainable use:	
None	Not applicable
Environmental protection	
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	<p><b>To protect aquatic organisms respect a:</b></p> <p><b>Winter triticale, winter wheat</b>  1m buffer zone with vegetative filter strip and 50% spray drift reduction, or  2 m buffer zone with vegetative filter strip</p> <p><b>Winter rape</b>  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.</p> <p><b>Spring oilseed rape</b>  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.</p> <p><b>Linseed (common flax)</b>  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.</p> <p><b>Poppy seeds</b>  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.</p> <p><b>Mustard seeds</b>  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.</p> <p><b>Gold of pleasure seeds</b>  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.</p> <p><b>Sunflower seeds</b>  1m buffer zone with vegetative filter strip and 50% spray drift reduction, or</p>

	2m buffer zone with vegetative filter strip and 25% spray drift reduction, or 3m buffer zone with vegetative filter strip.  <b>Soyabeans</b> 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.
Other specific restrictions	
None	Not applicable

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
None	Not applicable

## 2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
None	Not applicable	Not applicable
Environmental protection:		Relevant for use no.
respective code if available	The product may not be applied in or in the immediate vicinity of surface or coastal waters. Irrespective of this, the minimum buffer zone from surface waters must be adopted	1-10

## 2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code): SNS-F-11 Formulation type: EC  
Active substance : Difenoconazole Conc. of as 1: 90 g/L  
Applicant: Synthos Agro Sp. z o.o. Professional use: ☒  
Zone: Central Non professional use: ☐  
Verified by MS: No

GAP rev. 1, date: 01/2024

Field of use: Fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safen- er/synergist per ha <sup>(f)</sup>
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applica- tions (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha  a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	PL	Winter wheat	F	<i>Zymoseptoria tritici</i>  <i>Blumeria graminis tritici</i> / <i>Blumeria graminis</i>  <i>Puccinia triticina</i> / <i>Puccin- ia recondite</i>  <i>Pyrenophora tritici- repentis</i>  <i>Parastagonospora no- dorum</i>	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	NR*	
2	PL	Winter tritcale		<i>Zymoseptoria tritici</i>	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	NR*	

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safen- er/synergist per ha ( <sup>(f)</sup> )
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applica- tions (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		
				<i>Blumeria graminis tritici/</i> <i>Blumeria graminis</i>  <i>Puccinia triticina/ Puccin- ia recondite</i>  <i>Parastagonospora no- dorum</i>									
3	PL	Winter oilseed rape	F	<i>Leptosphaeria maculans</i>  <i>Sclerotinia sclerotiorum</i>	Foliar spray	BBCH 32-39 (spring)  BBCH 60-65 (spring)	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*	
<b>Minor uses according to Article 51</b>													
4	PL	Spring oilseed rape	F	<i>Leptosphaeria maculans</i>  <i>Sclerotinia sclerotiorum</i>	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*	
5	PL	Linseed (common flax)	F	<i>Leptosphaeria maculans</i>  <i>Sclerotinia sclerotiorum</i>	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*	
6	PL	Poppy seeds	F	<i>Leptosphaeria maculans</i>  <i>Sclerotinia sclerotiorum</i>	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*	
7	PL	Mustard seeds	F	<i>Leptosphaeria maculans</i>	Foliar	BBCH 32-39	1	-	a) 1.0 L/ha	a) Difenoconazole 90 g	200-	NR*	

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safen- er/synergist per ha <sup>(f)</sup>
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applica- tions (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		
				<i>Sclerotinia sclerotiorum</i>	spray	BBCH 60-65			b) 1.0 L/ha a) 1.15 L/ha b) 1.15 L/ha	b) Difenconazole 90 g a) Difenconazole 103.5 g b) Difenconazole 103.5 g	300		
8	PL	Gold of pleasure seeds	F	<i>Leptosphaeria maculans</i>  <i>Sclerotinia sclerotiorum</i>	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) Difenconazole 90 g b) Difenconazole 90 g a) Difenconazole 103.5 g b) Difenconazole 103.5 g	200- 300	NR*	
9	PL	Sunflower seeds	F	<i>Alternaria spp.</i>  <i>Leptosphaeria lindquistii</i> <i>Sclerotinia sclerotiorum</i>	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) Difenconazole 90 g b) Difenconazole 90 g a) Difenconazole 103.5 g b) Difenconazole 103.5 g	200- 300	NR*	
10	PL	Soyabeans	F	<i>Cercospora sojina</i> <i>Cercospora Kikuchi</i> <i>Sclerotinia sclerotiorum</i>	Foliar spray	BBCH 32 -65	1	-	a) 1.15 L/ha b) 1.15 L/ha	a) Difenconazole 103.5 g b) Difenconazole 103.5 g	200- 300	NR*	

**Remarks table heading:**

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008

(c) g/kg or g/l

(d) Select relevant

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

(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

\*NR – PHI is not relevant (commercial harvest)

<b>Remarks columns:</b>	1	Numeration necessary to allow references	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
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	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	10	For specific uses other specifications might be possible, e.g.: g/m <sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	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.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	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.

### 3 Background of authorization decision and risk management

#### 3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of cloudy, homogenous light brown liquid, with a characteristic odour. It is not explosive, has no oxidising properties. The product has a flash point of 71.0°C. It has a self ignition temperature of 359°C. In aqueous solution, it has a pH value around 6.65 at 20°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C, neither the active ingredient con-tent nor the technical properties were changed.

The stability data indicate a 2 years shelf life study at ambient temperature when stored in HDPE is ongoing (expected date of completion of the study and the final report - approx. July 2025). Its technical characteristics are acceptable for an EC formulation.

The intended concentration of use is 1 L/ha to 1.15 L/ha (0.33-0.58% v/v).  
Not intended for use in tank mixes.

#### 3.2 Efficacy (Part B, Section 3)

SNS-F-11 is an emulsifiable concentrate (EC) containing 90 g/L difenoconazole.

Active substance - difenoconazole is a systemic fungicide with preventive and curative action. Absorbed by the leaves, with acropetal and strong translaminar translocation. Difenoconazole is a broad – spectrum triazole fungicide. As a systemic sterol demethylation inhibitor, difenoconazole is highly effective against the diseases caused by various fungi infecting cereals targeting ergosterol biosynthesis by inhibiting the fungal enzyme sterol-1-4-a-demethylase. Given its ability to control various fungal diseases, difenoconazole has been extensively used in a wide range of crops in many countries.

Tested product SNS-F-11 showed high efficacy in winter wheat (SEPTTR, ERYSGR/ERYSGT, PUCCRE/PUCCRT, PYRNTR, LEPTNO), winter triticale (SEPTTR, ERYSGR/ERYSGT, PUCCRE/PUCCRT, LEPTNO) and winter rape (LEPTMA, SLESC).

#### 3.3 Efficacy data

**Preliminary studies:** Difenoconazole was developed as part of ongoing research into triazoles fungicides, which are known for their broad-spectrum activity and ability to inhibit ergosterol biosynthesis in fungi. It was introduced to the market in the late of 1980s. Since its introduction, difenoconazole has been registered and approved for use in many countries worldwide. Regulatory approvals are based on extensive testing for efficacy, safety and environmental impact. Over the decades, difenoconazole has been widely adopted by farmers and growers due to its effectiveness in controlling a broad range of fungal diseases across various crops, including cereals, fruits, vegetables and ornamentals. Initially available as a solo active ingredient, difenoconazole has also been formulated in combination with other fungicides to enhance its spectrum of activity and resistance management capabilities. As integrated pest management (IPM) practices have become more prevalent, difenoconazole has been incorporated into these programs to provide a balanced approach to disease control, combining chemical, biological and cultural methods.



So, it can be concluded that DISFERA 90 EC / LIPOSTAR 90 EC formulations are already registered and currently used in Europe. Therefore, no preliminary range-findings have been performed. Difenonazole is a well-known as an active ingredient, therefore it is justified to drop preliminary range findings tests in the opinion of ZRMs.

**MED (minimum effective dose):** The minimum effective dose (MED) of difenoconazole for winter wheat, winter triticale and winter oilseed rape can vary depending on the specific product and local guidelines. However, general application rates for these crops are typically within the following ranges: 125-250 grams of active ingredient per hectare (g a.i./ha). Product should be applied at the first signs of disease or as a preventive measure based on disease forecasting models. However, submitted trials prove that 90 grams of difenoconazole per hectare against fungal disease in winter wheat and winter triticale and against LEPTMA in winter oilseed rape is efficacy and dose of 103.5 grams of difenoconazole against SCLESC in winter oilseed rape.

In order to provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least two lower dose(s) than recommended dose. During field trials Applicant used different doses of fungicide DISFERA 90 EC / LIPOSTAR 90 EC (product code: SNS-F-11) containing difenoconazole (90 g/L) as an active compound. So, in the appropriate research of efficacy were tested differ doses and to register was chosen the lowest effective, which is in line to EPPO 1/225 (2). All trails were carried out under GP conditions by officially recognized testing organizations. Tested product was applied at intended dose rate and lower and higher rate.

On winter oilseed rape following doses were studied: 0.7 L/ha; 0.98 L/ha; 1.0 L/ha and 1.12 L/ha/1.15 L/ha against SCLESC and LEPTMA. Those doses were applied once a season. The most effective against SCLESC was dose 1.12/1.15 L/ha and against LEPTMA – dose 0.98 L/ha/1.0 L/ha.

PEST	Number of trials	Level of infestation of untreated control (%)	Efficacy of SNS-F-11		
			0.7 L/ha	0.98 L/ha / 1.0 L/ha	1.12 L/ha / 1.15 L/ha
SCLESC	8	21.8 (10.0-35.0)	56.5	73.5	82.7
LEPTMA	7	29.9 (9.1-68.8)	57.8	84.0	87.5

Dose 0.7 L/ha; 0.98 L/ha and 1.12 L/ha was studied in trials carried out in 2022 against LEPTMA (3 trials) and SCLESC (4 trials). Dose 0.7 L/ha; 1.0 L/ha and 1.15 L/ha was studied in trials performed in 2023 against LEPTMA (4 trials) and SCLESC (4 trials). In the opinion of ZRMs trials against LEPTMA with studied dose 0.98 and 1.0 L/ha can be used for assessment the efficacy of dose 1.0 L/ha. The difference in the active dose per hectare was only 2%. Also, no differences in effectiveness was found between the two doses (0.98 L/ha and 1.0 L/ha). All trials were characterized by sufficient level of infestation (>5%). It can be concluded that SNS-F-11 effectively control LEPTMA at dose 1.0 L/ha. In the opinion of ZRMs, trials with studied dose 1.12 and 1.15 L/ha can be used for assessment the efficacy of dose 1.15 L/ha against SCLESC. The differences in the active dose per hectare was only 2.6%. Also, no differences in effectiveness was found between the two doses (1.12 L/ha and 1.15 L/ha). All trials were characterized by sufficient level of infestation (>5%). It can be concluded that SNS-F-11 effectively control SCLESC at dose 1.15 L/ha.

On winter wheat against SEPTTR, ERYSGT/ERYSGR, PUCCRT/PUCCRE, PYRNTR, LEPTNO and winter triticale against SEPTTR, ERYSGT/ERYSGR, PUCCRT/PUCCRE and LEPTNO following doses were studied: 0.8 L/ha (0.8N), 1.0 L/ha (N recommended) and 1.3 L/ha (1.3N).The most effective against studied fungal diseases was dose 1.0 L/ha applied twice a season.

*winter wheat:*

PEST	Number of	Level of infestation of untreated	Efficacy of SNS-F-11
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	trials	control (%)	0.8 L/ha	1.0 L/ha	1.3 L/ha
SEPTTR	16	18.0 (5.0-34.5)	64.1	82.7	87.1
ERYSGT/ERYSGR	12	13.7 (7.8-23.3)	66.9	86.5	92.4
PUCCRT/PUCCRE	5	9.2 (6.5-11.3)	65.2	90.8	92.3
PYRNTR	5	11.8 (9.4-20.1)	67.7	81.4	85.1
LEPTNO	5	15.5 (10.0 - 27.5)	71.8	90.0	92.4

All trials were characterized by sufficient level of infestation (>5%). It can be concluded that SNS-F-11 effectively control SEPTTR, ERYSGT/ERYSGR, PUCCRT/PUCCRE, PYRNTR and LEPTMA at dose 1.0 L/ha.

*winter triticale:*

PEST	Number of trials	Level of infestation of untreated control (%)	Efficacy of SNS-F-11		
			0.8 L/ha	1.0 L/ha	1.3 L/ha
SEPTTR	5	16.7 (8.6-33.5)	57.5	84.3	94.0
ERYSGT/ERYSGR	5	18.5 (5.8-30.2)	65.9	83.2	95.5
PUCCRE/PUCCRT	3	12.9 (6.1-20.0)	83.1	96.6	98.8
LEPTNO	2	10.7 (10.0 - 11.3)	67.1	83.8	90.4

All trials were characterized by sufficient level of infestation (>5%). It can be concluded that SNS-F-11 effectively control SEPTTR, ERYSGT/ERYSGR, PUCCRT/PUCCRE and LEPTMA at dose 1.0 L/ha.

**Based on the results from 36 valid efficacy trials (16-winter wheat, 5-winter triticale, 15-winter oilseed rape), a dose response was shown. Supported by the trials and by the knowledge of difenoconazole – which is already registered and in common use – a minimum effective rate of 1.0 L/ha for winter wheat against SEPTTR, ERYSGR/ERYSGT, PUCCRT/PUCCRE, PYRNTR and LEPTNO and winter triticale against SEPTTR, PUCCRE/PUCCRT, ERYSGR/ERYSGT, LEPTNO applied max. twice a season and winter oilseed rape against LEPTMA applied once a season. For winter oilseed rape against SCLESC a dose 1.15 L/ha applied once a season is recommended.**

**Efficacy:** Difenoconazole is highly effective against fungal diseases in winter wheat, winter triticale and winter oilseed rape. Fungicides with difenoconazole helps in reducing the incidence and severity of fungal diseases, contributing to improved grain quality and yield. Details of experiment are presented above by Applicant. All used methodology is in line with GEP rules. Applicant submitted in total 36 valid trials carried out on winter wheat (16 trials), winter triticale (5 trials) and winter oilseed rape (15 trials) carried out in two growing seasons (2022 and 2023). All trials were carried out in Poland (N-E EPPO zone).

We are dealing with the active substances used commonly for many years in many countries. We must emphasize that each pest should be representative by sufficient number of field efficacy trials (at least 6 for major pests and 3 for minor pest).

The following efficacy scale was used during trials:

- L – limiting the occurrence (0-60% efficacy);
- ME – moderately efficacy (60-80%);
- E – efficiently (>80% efficacy).

*Cereals:* Fungal diseases may affect cereals in different ways. Only diseases severity assessments with sufficient disease pressure were averaged in summary tables by applicant and ZRMs. Trials were conducted in line to EPPO 1/26. During submitted trials, Applicant properly studied effect against *Erysiphe graminis* (ERYSGR/ ERYSGT) on winter wheat and winter triticale, *Puccinia recondite* (PUCCRE/PUCCRT) on winter wheat and winter triticale, *Mycosphaerella graminicola*, *anamorfa Septoria tritici* (SEPTTR) on winter wheat and *Phaeosphaeria nodorum* (LEPTNO) on winter wheat and

winter triticale.

*Winter oilseed rape*: Fungal infection on oilseed rape can affect different parts of the plants, such as: leaves, bracts, stems, pods and roots. Only disease severity assessments with sufficient disease pressure (set up 5%) were averaged in summary tables. Trials were conducted in line to EPPO 1/78. Applicant properly studied effect of SNS-F-11 on *Sclerotinia sclerotirum* (SCLESC) and *Leptosphaeria maculans* (LEPTMA) on winter oilseed rape.

- *winter oilseed rape*  
✓ *against SCLESC*

PEST	Number of trials	Level of infestation of untreated control (%)	Efficacy of SNS-F-11 at 1.12 / 1.15 L/ha	St. ref. product	
				TORES 250 EC at 0.5 L/ha	DIFO 250 EC / DIFCOR 250 EC at 0.5 L/ha
SCLESC	8	21.8 (10.0-35.0)	82.7	77.6	78.8

All trials were characterized by sufficient level of infestation (at least 5%). Number of trials is acceptable. Applicant presented 8 valid trials for this major fungal disease in winter oilseed rape. It can be concluded that SNS-F-11 at recommended dose 1.15 L/ha effectively control SCLESC on winter oilseed rape. Results were better than st. ref. products used during trials. Efficacy assessments were made on leaf (average eff. from 3 trials – 81.0%) and stem/root (average eff. from 6 trials – 83.55%). Product is recommended for use in spring at BBCH 60-65 of winter oilseed rape at dose 1.15 L/ha. Preventive application during the early flowering stage provides significant control of the disease, helping to protect crop health and its yield.

- ✓ *against LEPTMA*

PEST	Number of trials	Level of infestation of untreated control (%)	Efficacy of SNS-F-11 at 0.98 / 1.0 L/ha	St. ref. product		
				PORTER 250 EC at 0.6 L/ha	TORES 250 EC at 0.6 L/ha	TORES250 EC at 0.5 L/ha
LEPTMA	7	29.9 (9.1-68.8)	84.0	70.7	80.2	86.9

All trials were characterized by sufficient level of infestation (at least 5%). Number of trials is acceptable. Applicant presented 7 valid trials for this major fungal disease in winter oilseed rape. It can be concluded that SNS-F-11 at recommended dose 1.0 L/ha effectively control LEPTMA on winter oilseed rape. Results were slightly better than st. ref. products used during trials. Efficacy assessments were made on leaf (average eff. from 5 trials – 86.58%) and stem/root (average eff. from 4 trials – 78.23%). Efficacy leaves and stem/root was at level: 82.41%. Product is recommended for use in spring at BBCH 32-39 of winter oilseed rape at dose 1.0 L/ha. For optimal control, difenoconazole should be applied when the first signs of the disease are detected. At BBCH 32-39, it helps in controlling early infections and reducing inoculum levels, thereby protecting the plant during critical growth phases.

- *winter wheat:*

PEST	Number of trials	Level of infestation of untreated control (%)	Efficacy of SNS-F-11 at 1.0 L/ha	St. ref. product		
				PORTER 250 EC at 0.6 L/ha	TORES 250 EC at 0.6 L/ha	TORES 250 EC at 0.5 L/ha
SEPTTR	16	18.0 (5.0-34.5)	82.7	83.3	85.5	86.8
ERYSGT/ERYSGR	12	13.7 (7.8-23.3)	86.5	90.0	92.0	89.2
PUCCRT/PUCCRE	5	9.2 (6.5-11.3)	90.8	84.7	95.5	87.9
PYRNTR	5	11.8 (9.4-20.1)	81.4	80.7	83.3	77.0
LEPTNO	5	15.5 (10.0 - 27.5)	90.0	90.5	82.7	93.9

All trials were characterized by sufficient level of infestation (>5%). It can be concluded that SNS-F-11 effectively control SEPTTR, ERYSGT/ERYSGR, PUCCRT/PUCCRE, PYRNTR and LEPTMA at dose 1.0 L/ha in winter wheat. All studied fungal diseases are major fungal diseases in winter wheat, so at least 6 valid trials are required for each one. Applicant presented enough number of trials against SEPTTR and ERYSGR/ERYSGT. However, in the opinion of ZRMS also PUCCRT/PUCCRE, PYRNTR and

LEPTNO should be accepted in the GAP table and label project on the basis on 5 valid trials. In special cases, when the research results are consistent, a reduction to 5 studies conducted over 2 seasons is possible. Applicant carried out trials in two growing seasons (2022 and 2023) and results were consistent, so reduction of number of trials is possible in the opinion of ZRMs. Difenonazole is highly effective against Brown Rust (*Puccinia recondita*), Stagonospora Nodorum Blotch (*Phaeosphaeria nodorum*), and Tan Spot (*Pyrenophora tritici-repentis*) in winter wheat. Applications during the spring, specifically from growth stages BBCH 33 to BBCH 55, provide significant control of these diseases. The fungicide's preventive and curative properties ensure healthy crop development and improved yield, making it a valuable component of integrated disease management strategies. In Poland 18 PPPs with difenoconazole are registered in Poland against PUCCRE/PUCCRT, 6 PPPs against PYRNTR and 6 PPPs against LEPTNO. So, efficacy of difenoconazole against those fungal diseases is known.

• **winter triticales:**

PEST	Number of trials	Level of infestation of untreated control (%)	Efficacy of SNS-F-11 at 1.0 L/ha	st. reference product	
				PORTER 250 EC at 0.6 L/ha	TORES 250 EC at 0.5 L/ha
SEPTTR	5	16.7 (8.6-33.5)	84.3	89.0	93.1
ERYSGT/ERYSGR	5	18.5 (5.8-30.2)	83.2	91.0	94.1
PUCCRE/PUCCRT	3	12.9 (6.1-20.0)	96.6	96.9	99.1
LEPTNO	2	10.7 (10.0 - 11.3)	83.8	90.4	83.8

All trials were characterized by sufficient level of infestation (>5%). It can be concluded that SNS-F-11 effectively control SEPTTR, ERYSGT/ERYSGR, PUCCRT/PUCCRE and LEPTMA at dose 1.0 L/ha. ERYSGT/ERYSGR, LEPTNO and PUCCRE/PUCCRT are major fungal diseases and SEPTTR is a minor disease in winter triticales. At least 6 valid trials are required for major diseases and at least 3 for minor diseases. Applicant submitted 5 trials against SEPTTR and ERYSGT/ERYSGR. Number of trials against SEPTTR is acceptable. In the opinion of ZRMs limited/ reduced number of trials against ERYSGR/ERYSGT can be acceptable. Also, extrapolation results from winter wheat is possible. It can be concluded that SNS-F-11 effectively control SEPTTR and ERYSGR/ERYSGT in winter triticales at recommended dose (1.0 L/ha). Also, limited number of trials against PUCCRE/PUCCRT (3 trials) and LEPTNO (2 trials) should be accepted on the basis on the possibility of extrapolating results from winter wheat. It can be concluded that SNS-F-11 at recommended dose (1.0 L/ha) effectively control PUCCRE/PUCCRT and LEPTNO on winter triticales. Difenonazole is highly effective against PUCCRE/PUCCRT, LEPTNO and ERYSGR/ERYSGT in winter triticales. Applications during the spring, specifically from growth stages BBCH33 to BBCH 55, provide significant control of these diseases. In Poland, 18 PPPs with difenoconazole against PUCCRE/PUCCRT, 12 PPS against ERYSGR/ERYSGT and 3 PPPs against LEPTNO are registered and commonly used. So, efficacy of difenoconazole against those fungal diseases is already known.

Also, all mentioned in the GAP table and label minor uses can be accepted in line to Article 51 without any trials. Those accepted minor uses are: spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds against against *Leptosphaeria maculans* and *Sclerotinia sclerotiorum*; sunflower seeds against *Alternaria spp.*, *Leptosphaeria lindquistii* and *Sclerotinia sclerotiorum*; soybeans against *Cercospora sojae*, *Cercospora Kikuchi* and *Sclerotinia sclerotiorum*.

### 3.3.1 Information on the occurrence or possible occurrence of the development of resistance

Difenonazole is an ergosterol biosynthesis inhibitor from the chemical class of the triazoles (FRAC group 3) blocking the demethylation of eburicol. It is active on a broad range of plant pathogens on many crop plants. Due to the supposed oligo-generic mechanism of resistance the risk is estimated as medium by the Fungicide Resistance Action Committee (FRAC, [www.frac.info](http://www.frac.info)).

Difenoconazole is a demethylation inhibitor (DMI) fungicide, which shares its mode of action with other sterol biosynthesis inhibitors. It belongs to FRAC MOA Code G1 Group Code 3 which are considered at medium risk to fungicide resistance development. A resistance management strategy is required. SNS-F-11 with the triazole difenoconazole as active ingredient should be used in tank mixes and / or spray programs in alternation with fungicides with different MoA's and azole compounds.

The agronomic risk for active ingredients which include SNS-F-11 is estimated as medium for difenoconazole.

The resistance management is coordinated by FRAC recommendations. Applying the anti-resistance use recommendations, development of resistance can be considerably decreased or avoided. The restriction should be put on the label.

The Fungicide Resistance Action Committee (FRAC) has made the following general recommendations to minimize the risk of resistance occurring to the SBI fungicides (of which the DMI's are one class):

- ✓ repeated application of SBI fungicides alone should not be used on the same crop in one season against a high-risk pathogen in areas of high disease pressure for that particular pathogen.
- ✓ for crop/pathogen situations where repeated spray applications (e.g. orchard crops/Powdery mildew) are made during the season, alternation (block sprays or in sequence) or mixtures with an effective non cross-resistant fungicide are recommended.
- ✓ where alternation or the use of mixtures is not feasible because of lack of effective or compatible non-cross-resistant partner fungicides, then input of SBI's should be reserved for critical parts of the season or crop growth stage.
- ✓ if DMI or amine performance should decline and sensitivity testing has confirmed the presence of less sensitive forms, SBI's should only be used in mixture or alternation with effective non cross resistant partner fungicides.
- ✓ the introduction of the new classes of chemistry offers new opportunities for more effective resistance management. The use of different mode of actions should be maximized for the most effective resistance management strategies.
- ✓ users must adhere to the manufacturers' recommendations. In many cases, reports of "resistance" have, on investigation, been attributed to cutting recommended rates of use, or to poor or mistimed application.
- ✓ fungicide input is only one aspect of crop management. Fungicide use does not replace the need for resistant crop varieties, good agronomic practice, plant hygiene/sanitation.

The lack of proper rotation of active substances and the use of too low doses are associated with the phenomenon of resistance formation. The use of so-called sub-threshold doses at the limit of their effective effectiveness (often repeatedly in crop rotation) and the use of substances that under certain conditions due to the mode of action may have lower effectiveness promotes the phenomenon of resistance formation. A lower dose or intervention use of a substance whose strength is preventive action limits the effectiveness and duration of action of such a product. In practice, resistance of known disease culprits to commonly and readily used groups of substances such as strobilurins or SDHI has been confirmed. Only full doses and properly selected tank mixtures provide the required high efficacy with a sufficiently long duration of action. Because of its specificity and the wide spectrum of pathogens from virtually all groups that it controls, difenoconazole is a good tool for building programs to limit the development of resistance to fungicides from other chemical groups.

Resistance to fungicides among key fungal pathogens of winter wheat and winter triticale has been documented in Europe. Here is an overview of resistance cases for several significant pathogens:



- ✓ ***Zymoseptoria tritici*** (Septoria tritici blotch): resistance to fungicides, especially triazoles (DMI fungicides like difenoconazole) and Qols (strobilurins), has been observed in *Zymoseptoria tritici*. This pathogen has shown reduced sensitivity to these fungicides across various European regions, making it challenging to control with chemical treatments alone. Research has documented that this pathogen has developed mutations in the CYP51 gene, which encodes the target enzyme for triazoles fungicides. These mutations reduce the efficacy of difenoconazole, necessitating the use of alternative fungicides and integrated management strategies.
- ✓ ***Blumeria graminis s. sp. tritici*** (Powdery mildew): Resistance to difenoconazole and other triazoles has been reported in *Blumeria graminis f. sp. tritici*. This pathogen has developed mechanisms such as target site modifications and enhanced efflux, which lower the effectiveness of triazole fungicides, including difenoconazole. The resistance challenges have led to the adoption of integrated approaches that combine chemical, biological and cultural practices.
- ✓ ***Puccinia triticina*** (Leaf rust): While specific cases of difenoconazole resistance in *Puccinia triticina* are less documented compared to other pathogens, there are concerns about potential resistance development due to the extensive use of triazoles fungicides. Monitoring and management practices are crucial to prevent resistance emergence.
- ✓ ***Pyrenophora tritici-repentis*** (Tan spot): There have been reports of reduced sensitivity to difenoconazole in *Pyrenophora tritici-repentis*. This pathogen has shown variability in response to fungicides, with some isolates exhibiting resistance. The development of resistance management strategies, such as rotating fungicides with different modes of action, is essential to maintain control over this pathogen.
- ✓ ***Parastagonospora nodorum*** (Stagonospora nodorum blotch): Cases of resistance to difenoconazole in *Parastagonospora nodorum* have been reported, although they are less common. Reduced sensitivity in some isolates suggests that continuous monitoring and the implementation of integrated disease management strategies are necessary to manage resistance and ensure effective control.
- ✓ ***Leptosphaeria maculans*** (Phoma stem canker): resistance to difenoconazole in *Leptosphaeria maculans*, the causative agent of phoma stem canker in winter oilseed rape, has been observed. Studies indicate that while difenoconazole remains somewhat effective, the pathogen has shown variable responses to triazoles fungicides due to genetic mutations and diverse pathogen populations. This variability necessitates integrated disease management strategies, including crop rotation and resistant cultivars.
- ✓ ***Sclerotinia sclerotiorum*** (Sclerotinia stem rot): responsible for sclerotinia stem rot, has also shown signs of resistance to difenoconazole. The effectiveness of difenoconazole can be inconsistent due to the pathogen's broad host range and genetic diversity. Research highlights the need for an integrated approach combining chemical treatments with cultural practices such as optimizing planting density and using resistant varieties to manage the disease.

#### **Management strategies:**

- ✓ **Fungicide rotation:** use different classes of fungicides to reduce resistant pressure
- ✓ **Integrated pest management (IPM):** combine fungicide applications with cultural practices and resistant varieties
- ✓ **Monitoring and early detection:** regularly scout fields to detect early signs of resistance and adjust management practices accordingly
- ✓ **Combination treatments:** using mixtures of fungicides to delay resistance development

It can be stated that, if DISFERA 90 EC / LIPOSTAR 90 EC is used according to the use instructions and under consideration of the proposed anti-resistant modifiers, the resistance risk of the target pathogens to develop resistance to DISFERA 90 EC / LIPOSTAR 90 EC is considered medium to high but can be reduced by adherence of the management strategy.

The agronomic risk is estimated as medium for difenoconazole.

The resistance management is coordinated by FRAC recommendations. Applying the anti-resistance use recommendations, development of resistance can be considerably decreased or avoided. The restrictions should be put on the label.

### 3.3.2 Adverse effects on treated crops

#### Phytotoxicity of product.

The phytotoxicity trials about tested plant protection product (fungicide) have been carried out in accordance with EPPO Guidelines (1/181 (4)). The conduct of the field work is principally compliant with “Good Agricultural Practice” and in accordance with EPPO Guidelines PP 1/135.

The trials were performed with the use of different agricultural practice in Poland. All presented trials were performed with the use of cultivars, differing in growth strength as well as soil and water requirements. The appropriate experimental design was applied. In all trials studied product was compared to the standard reference products. Statistical analysis of the data was performed. Also, quality of yield was evaluated in all submitted trials.

Selectivity trials and studied dose 2N for fungicide were not required, which is in accordance with EPPO 1/135 (3).

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 rape was performed visually by comparing the condition of the plants in the plots treated with fungicide in comparison to untreated plots (no fungicides). The intensity of damage to the plant was expressed as a percentage (0%-no symptoms of phytotoxic effects of fungicide, 100% - total destruction).

**Table 3.3-1: Phytotoxicity of SNS-F-11 and reference standard to winter wheat**

Number of trials with...		Efficacy trials (16 trials)		
		SNS-F-11	PORTER 250 EC	TORES 250 EC
		1.3N, 1.0N, 0.8N	1N	1N
Maximum of phytotoxicity recorded during the trials	0% to 5%	14	14	14
	>5% to 10%	2	2	2
	>10% to 15%	-	-	-
	>15 %	-	-	-
Level of symptoms at the last assessments	0% to 5%	16	16	16
	>5% to 10%	-	-	-
	>10% to 15%	-	-	-
	>15 %	-	-	-

16 efficacy trials were carried out on winter wheat in Poland in 2022 and 2023 on different varieties of winter wheat. In 2 trials were observed phytotoxicity symptoms. This symptoms were classified as chlorosis. All observed phytotoxicity symptoms were classified in the range of 5-10% and were observed after

first application of SNS-F-11 and standards products in experiments located in the same voivodeship in Poland. The wheat varieties used in these experiments were Joker and Findus. In experiments carried out in other locations in Poland were performed with use of the same varieties of wheat - no phytotoxicity symptoms was observed. The first application of SNS-F-11 and the reference products was made at a similar time, i.e. on April 18, 2023 and April 21, 2023. During subsequent phytotoxicity assessments, i.e. during the second application of SNS-F-11 and the standards, no phytotoxic effects were observed, similarly as in the case of last assessment performed up to 3 weeks after the second application of the all products. For this reason, observed phytotoxicity effect (chlorosis) was transient and was not caused by the applied products (SNS-F-11 and standard products) or the weather conditions prevailing after the application (low temperature). Observed phytotoxicity effect (chlorosis) was transient and did not negatively affect the quality of the yield, green leaf area, moisture content, vigour of plant or the effectiveness of SNS-F-11 and standard products. To eliminate potential phytotoxicity effect for the end user, the registration label will include a warning to not to use SNS-F-11 when the daily air temperature does not exceed 12 °C.

In 15 trials, no adverse effects in regard to phytotoxicity and vigour were observed in any efficacy trials treated with SNS-F-11. Furthermore, harvest results from winter wheat trials demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either.

**Table 3.3-2: Phytotoxicity of SNS-F-11 and reference standard to winter triticale**

Number of trials with...		Efficacy trials (5 trials)		
		SNS-F-11	PORTER 250 EC	TORES 250 EC
		1.3N, 1.0N, 0.8N	1N	1N
Maximum of phytotoxicity recorded during the trials	0% to 5%	5	5	5
	>5% to 10%	-	-	-
	>10% to 15%	-	-	-
	>15 %	-	-	-
Level of symptoms at the last assessments	0% to 5%	5	5	5
	>5% to 10%	-	-	-
	>10% to 15%	-	-	-
	>15 %	-	-	-

5 trials of efficacy were carried out on winter triticale in Poland in 2023 on different varieties. No phytotoxicity symptoms caused by SNS-F-11 at the highest dose rate of 1.3 L/ha was observed. No adverse effects in regard to phytotoxicity and vigour were observed in any efficacy trials treated with SNS-F-11. Furthermore, harvest results from winter wheat trials demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either.

**Table 3.3-3: Phytotoxicity of SNS-F-11 and reference standard to winter rape (LEPTMA)**

Number of trials with...		Efficacy trials (7 trials)		
		SNS-F-11	PORTER 250 EC	TORES 250 EC
		1.15N, 1.0N, 0.6N	1N	1N, 1.2N
Maximum of phytotoxicity rec-	0% to 5%	7	7	7



Number of trials with...		Efficacy trials (7 trials)		
		SNS-F-11	PORTER 250 EC	TORES 250 EC
		1.15N, 1.0N, 0.6N	1N	1N, 1.2N
Recorded during the trials	>5% to 10%	-	-	-
	>10% to 15%	-	-	-
	>15 %	-	-	-
Level of symptoms at the last assessments	0% to 5%	7	7	7
	>5% to 10%	-	-	-
	>10% to 15%	-	-	-
	>15 %	-	-	-

7 trials of efficacy were carried out on winter rape in Poland in 2022 and 2023 on different varieties. No phytotoxicity symptoms caused by SNS-F-11 at the highest dose rate of 1.15 L/ha was observed. No adverse effects in regard to phytotoxicity and vigour were observed in any efficacy trials treated with SNS-F-11. Furthermore, harvest results from winter rape trials demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either.

**Table 3.3-4: Phytotoxicity of SNS-F-11 and reference standard to winter rape (SCLESC)**

Number of trials with...		Efficacy trials (7 trials)		
		SNS-F-11	DIFO 250 EC/DIFCOR 250 EC	TORES 250 EC
		0.6N, 0.9N, 1N	1N	1N
Maximum of phytotoxicity recorded during the trials	0% to 5%	8	8	8
	>5% to 10%	-	-	-
	>10% to 15%	-	-	-
	>15 %	-	-	-
Level of symptoms at the last assessments	0% to 5%	8	8	8
	>5% to 10%	-	-	-
	>10% to 15%	-	-	-
	>15 %	-	-	-

8 trials of efficacy were carried out on winter rape in Poland in 2022 and 2023 on different varieties. No phytotoxicity symptoms caused by SNS-F-11 at the highest dose rate of 1.15 L/ha was observed. No adverse effects in regard to phytotoxicity and vigour were observed in any efficacy trials treated with SNS-F-11. Furthermore, harvest results from winter rape trials demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either.

To eliminate potential phytotoxicity effect for the end user, the registration label will include a warning to not use SNS-F-11 when the daily air temperature does not exceed 12°C. In conclusion, no negative effects of the product – SNS-F-11 is to be expected when at the intended rate and used according to label's recommendations.

### Effect on the yield:

ZRMs, agree with Applicant. SNS-F-11 containing difenoconazole (90 g/L) applied at recommended dose for winter oilseed rape, winter wheat and winter triticale and even higher than recommended in winter wheat and winter triticale did not significantly affect the crop yield.

The data obtained in trials harvested demonstrated that FNS-F-11 containing difenoconazole (90 g/L) is as safe to the treated crops as the reference products used in the trials.

Below, ZRMs presented detailed results from field trials about impact of SNS-F-11 on the yield (on the basis on 36 trials).

#### ✓ winter wheat

Trial ID	Variety	Ass. Type	Unit	Untreated Mean	SNS-F-11		Reference products		
					1.0 L/ha	1.3 L/ha	PORTER 250 EC at 0.6 L/ha	TORES 250 EC at 0.6 L/ha	TORES 250 EC at 0.5 L/ha
					of product per 100 kg seeds				
					% rel.	% rel.	% rel.	% rel.	% rel.
119 F/2022	Tobak	Yield	t/ha	7.00	7.25	7.45	7.24	7.56	n.s.
SF22PZ306W	Arkadia	Yield	t/ha	5.73	6.60	6.66	7.24	6.62	n.s.
SF22PZ307W	Euforia	Yield	t/ha	6.71	6.86	7.06	6.94	7.25	n.s.
SGS/2022/069/PL01	Lavantus	Yield	t/ha	8.20	9.89	10.02	9.70	9.86	n.s.
SGS/2022/069/PL02	Opoka	Yield	t/ha	7.45	8.42	8.40	8.43	8.32	n.s.
SGS/2022/069/PL03	Findus	Yield	t/ha	6.97	7.81	7.96	7.80	8.01	n.s.
SGS/2022/069/PL04	Joker	Yield	t/ha	6.27	7.30	7.47	7.31	7.43	n.s.
63 F/2023	Patras	Yield	t/ha	9.59	10.12	10.15	9.88	ns	10.03
SF23PZ302W	Julius	Yield	t/ha	7.29	8.09	7.58	8.27	ns	7.67
SF23PZ309Z	Belissa	Yield	t/ha	7.05	7.80	7.77	8.12	ns	7.85
SF23PZ310Z	Euforia	Yield	t/ha	6.68	7.31	7.22	7.74	ns	7.38
SGS/2023/041/PL01	Yukon	Yield	t/ha	7.35	8.66	9.14	9.13	ns	9.17
SGS/2023/041/PL02	Findus	Yield	t/ha	9.67	10.22	10.40	10.26	ns	10.44
SGS/2023/041/PL04	Joker	Yield	t/ha	6.9	7.9	7.9	7.7	ns	8.0
SGS/2023/041/PL05	Euforia	Yield	t/ha	7.55	8.66	8.67	8.68	ns	8.68
SGS/2023/041/PL06	Arkadia	Yield	t/ha	6.92	8.46	8.58	7.97	ns	8.43
Average from 16 trials		Yield	t/ha	7.33	8.21	8.28	8.40	7.86	8.63

Submitted trials are sufficient for winter wheat. Impact on yield was assessed during 16 trials carried out on winter wheat in Poland. Yield from untreated plot – 7.33 t/ha and yield from field treated by SNS-F-11 was at level 8.21 t/ha (1.0 L/ha – N recommended) and 8.28 t/ha (1.3 L/ha which corresponds to 1.3N). Yield from field treated by st. reference products was: 8.40 t/ha (Porter 250 EC at 0.6 L/ha), 7.86 t/ha (Tores 250 EC at 0.6 L/ha) and 8.63 t/ha (Tores 250 EC at 0.5 L/ha).

#### ✓ winter triticale

Trial ID	Variety	Ass. Type	Unit	Untreated Mean	SNS-F-11		Reference products		
					1.0 L/ha	1.3 L/ha	PORTER 250 EC at 0.6 L/ha	TORES 250 EC at 0.6 L/ha	TORES 250 EC at 0.5 L/ha
					of product per 100 kg seeds				
					% rel.	% rel.	% rel.	% rel.	% rel.
SGS/2023/089/PL01	Liborious	Yield	t/ha	7.05	7.74	7.90	7.86	ns	7.90
SGS/2023/089/PL02	Tadeus	Yield	t/ha	6.55	7.07	7.21	7.15	ns	7.17
SGS/2023/089/PL03	Rotondo	Yield	t/ha	6.95	7.44	7.57	7.46	ns	7.65
SGS/2023/089/PL04	Twingo	Yield	t/ha	7.17	7.78	7.87	7.77	ns	7.80
SGS/2023/089/PL05	Medalion	Yield	t/ha	7.34	7.49	7.38	7.34	ns	7.35
Average from 5 trials:		Yield	t/ha	7.01	7.50	7.59	7.52	ns	7.57

Submitted trials are sufficient for winter triticale. Impact on yield was assessed during 5 efficacy trials carried out on winter triticale in Poland. Yield from untreated plot – 7.01 t/ha and yield from field treated by SNS-F-11 was at level 7.50 t/ha (1.0 L/ha – N recommended) and 7.59 t/ha (1.3 L/ha which corresponds to 1.3N). Yield from field treated by st. reference products was: 7.52 t/ha (Porter 250 EC at 0.6 L/ha) and 7.57 t/ha (Tores 250 EC at 0.5 L/ha).

#### ✓ winter oilseed rape

Ass.	Untreated	SNS-F-11	Reference products
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Trial ID	Variety	Type	Unit	-	0.98 L/ha /1.0 L/ha	1.12 L/ha/ 1.15 L/ha	PORTER 250 EC at 0.6 L/ha	TORES 250 EC at 0.6 L/ha	TORES 250 EC at 0.5 L/ha	DIFO 250 EC / DIFCOR 250 EC at 0.5 L/ha
					of product per 100 kg seeds					
					% rel.	% rel.	% rel.	% rel.	% rel.	% rel.
100 F/2022	Alibaba	Yield	t/ha	3.20	3.66	3.73	3.70	3.81	ns	ns
SGS/2022/070/PI03	Exotter	Yield	t/ha	3.86	4.97	4.98	4.98	5.00	ns	ns
SGS/2022/070/PL04	SY Ilona	Yield	t/ha	3.40	4.65	4.70	4.39	4.40	ns	ns
101 F/2022	Architekt	Yield	t/ha	4.45	5.36	5.47	ns	ns	5.14	5.17
SF22RZ307W	Graf	Yield	t/ha	2.90	3.20	3.02	ns	ns	3.17	3.22
SGS/2022/070/PL01	Galileus	Yield	t/ha	3.20	4.81	4.69	ns	ns	4.59	4.64
SGS/2022/070/PI02	Artemis	Yield	t/ha	4.75	5.83	5.93	ns	ns	5.31	5.56
31 F/2023	Architekt	Yield	t/ha	2.92	3.34	3.36	3.41	ns	3.46	ns
SGS/2023/042/PL01	Absolut	Yield	t/ha	3.0	3.6	3.5	3.4	ns	3.5	ns
SGS/2023/042/PL02	Sienna	Yield	t/ha	3.50	4.2	4.4	3.8	ns	4.4	ns
SGS/2023/042/PL03	Derrick	Yield	t/ha	3.35	3.64	3.89	4.08	ns	3.83	ns
32 F/2023	Hevelius	Yield	t/ha	3.50	3.86	4.39	ns	ns	4.16	4.20
SGS/2023/043/PL01	Bonanaza	Yield	t/ha	3.0	3.5	3.7	ns	ns	3.6	3.6
SGS/2023/043/PL02	Memori CS	Yield	t/ha	3.3	3.9	4.2	ns	ns	4.0	4.2
SGS/2023/043/PL03	Alabama	Yield	t/ha	3.03	3.38	3.39	ns	ns	3.36	3.37
Average from 15 trials:		Yield	t/ha	3.42	4.13	4.22	3.97	4.40	4.04	4.25

Submitted trials are sufficient for winter oilseed rape. Impact on yield was assessed during 15 efficacy trials carried out on winter oilseed rape in Poland. Yield from untreated plot – 3.42 t/ha and yield from field treated by SNS-F-11 was at level 4.13 t/ha (1.0 L/ha – N recommended) and 4.22 t/ha (1.3 L/ha which corresponds to 1.3N). Yield from field treated by st. ref. products was: 3.97 t/ha (Porter 250 EC at 0.6 L/ha), 4.40 t/ha (Tores 250 EC at 0.6 L/ha), 4.04 t/ha (Tores 250 EC at 0.5 L/ha) and 4.25 t/ha (Difo 250 EC/ Difcor 250 EC at 0.5 l/ha).

**There are almost no significant differences in yield between SNS-F-11 and the references products. Overall, these results confirms that there is no risk for negative side effects on yield of the treated cereals (winter wheat, winter triticale) and winter oilseed rape.**

#### Effect on the quality of yield:

In all trials no detrimental effect on the quality of yield was recorded at the proposed dose rate and even at higher than recommended (on the basis on winter wheat and winter triticale). For winter oilseed rape – only dose N recommended was studied, no higher doses were studied. Application of SNS-F-11 provided a quality of yield similar to the untreated plots and to those treated with the reference products. No significant differences were observed between untreated and treated plots and also between the tested product and the standard products. Parameters such as moisture [%], weight of 1000 grains [g], protein content [%], GLA [%] and hectolitre mass grains [kg/hl] for cereals (wheat, triticale) and thousand seed weight [g], moisture [%] and oil content [%] for winter oilseed rape.

#### **Moisture [%]**

✓ *winter wheat* (14 trials)

Trial ID	Variety	Ass. Type	Unit	Untreated Mean	SNS-F-11		Reference products		
					1.0 L/ha	1.3 L/ha	PORTER 250 EC at 0.6 L/ha	TORES 250 EC at 0.6 L/ha	TORES 250 EC at 0.5 L/ha
					of product per 100 kg seeds				
					% rel.	% rel.	% rel.	% rel.	% rel.
119 F/2022	Tobak	Moisture	%	ns	ns	ns	ns	ns	ns
SF22PZ306W	Arkadia	Moisture	%	11.28	13.50	13.59	13.04	14.27	ns
SF22PZ307W	Euforia	Moisture	%	12.18	12.35	12.39	12.23	12.18	ns
SGS/2022/069/PL01	Lavantus	Moisture	%	12.50	12.90	13.00	13.20	13.10	ns
SGS/2022/069/PL02	Opoka	Moisture	%	13.40	13.50	13.50	13.50	13.40	ns
SGS/2022/069/PL03	Findus	Moisture	%	13.10	13.10	12.90	13.00	13.10	ns
SGS/2022/069/PL04	Joker	Moisture	%	13.30	13.20	13.40	13.40	13.30	ns
63 F/2023	Patras	Moisture	%	ns	ns	ns	ns	ns	ns
SF23PZ302W	Julius	Moisture	%	16.03	16.38	16.23	16.15	ns	16.33
SF23PZ309Z	Belissa	Moisture	%	13.95	14.18	14.12	14.10	ns	14.02

SF23PZ310Z	Euforia	Moisture	%	13.20	13.20	13.40	13.80	ns	13.50
SGS/2023/041/PL01	Yukon	Moisture	%	12.90	12.90	12.90	12.90	ns	12.90
SGS/2023/041/PL02	Findus	Moisture	%	12.90	12.80	12.80	12.70	ns	12.80
SGS/2023/041/PL04	Joker	Moisture	%	13.50	13.60	13.50	13.50	ns	13.50
SGS/2023/041/PL05	Euforia	Moisture	%	12.50	12.50	12.50	12.50	ns	12.50
SGS/2023/041/PL06	Arkadia	Moisture	%	12.36	15.12	15.38	14.22	ns	15.13
Average from 16 trials		Moisture	%	13.08	13.52	13.54	13.48	13.23	12.34

No negative effect on moisture content was noted for any tested dose rate of SNS-F-11 in any of trials carried out on winter wheat. Comparing SNS-F-11 with standard reference products, no statistically significant differences were noted for moisture content in the majority of trials.

✓ *winter triticale* (5 trials)

Trial ID				Untreated -	SNS-F-11		Reference products		
					1.0 L/ha	1.3 L/ha	PORTER 250 EC at 0.6 L/ha	TORES 250 EC at 0.6 L/ha	TORES 250 EC at 0.5 L/ha
					of product per 100 kg seeds				
Ass. Type	Variety	Unit	Mean	% rel.	% rel.	% rel.	% rel.	% rel.	% rel.
Moisture	Liborious	%	12.8	12.8	12.8	12.8	ns	12.8	12.8
Moisture	Tadeus	%	12.3	12.4	12.3	12.3	ns	12.4	12.4
Moisture	Rotondo	%	13.1	13.1	13.2	13.0	ns	13.0	13.0
Moisture	Twingo	%	12.6	12.6	12.6	12.7	ns	12.6	12.6
Moisture	Medalion	%	12.5	12.7	12.6	12.5	ns	12.6	12.6
Average from 5 trials:		Mositure	%	12.66	12.72	12.70	12.66	ns	12.68

No negative effect on moisture content was noted for any tested dose rate of SNS-F-11 in any of trials carried out on winter triticale. Comparing SNS-F-11 with standard reference products, no statistically significant differences were noted for moisture content in the majority of trials.

✓ *winter oilseed rape* (11 trials)

Trial ID				Untreated -	SNS-F-11		Reference products			
					0.98 L/ha /1.0 L/ha	1.12 L/ha/ 1.15 L/ha	PORTER 250 EC at 0.6 L/ha	TORES 250 EC at 0.6 L/ha	TORES 250 EC at 0.5 L/ha	DIFO 250 EC / DIFCOR 250 EC at 0.5 L/ha
					of product per 100 kg seeds					
Ass. Type	Variety	Unit	Mean	% rel.	% rel.	% rel.	% rel.	% rel.	% rel.	% rel.
ns	100 F/2022	Alibaba	Moisture	%	ns	ns	ns	ns	ns	ns
Moisture	SGS/2022/070/PI03	Exotter	%	7.4	7.4	7.5	7.5	7.5	ns	ns
Moisture	SGS/2022/070/PL04	SY Ilona	%	8.7	8.5	8.6	8.6	8.6	ns	ns
Moisture	101 F/2022	Architekt	%	ns	ns	ns	ns	ns	ns	ns
Moisture	SF22RZ307W	Graf	%	8.00	8.03	7.98	ns	ns	8.10	8.03
Moisture	SGS/2022/070/PL01	Galileus	%	6.2	6.1	6.1	ns	ns	6.0	6.1
Moisture	SGS/2022/070/PI02	Artemis	%	8.2	8.6	8.5	ns	ns	8.5	8.6
Moisture	31 F/2023	Architekt	%	ns	ns	ns	ns	ns	ns	ns
Moisture	SGS/2023/042/PL01	Absolut	%	7.4	7.4	7.5	7.5	ns	7.5	ns
Moisture	SGS/2023/042/PL02	Sienna	%	8.7	8.7	8.8	8.7	ns	8.7	ns
Moisture	SGS/2023/042/PL03	Derrick	%	7.4	7.1	7.3	7.4	ns	7.3	ns
Moisture	32 F/2023	Hevelius	%	ns	ns	ns	ns	ns	ns	ns
Moisture	SGS/2023/043/PL01	Bonanaza	%	8.6	8.6	8.6	ns	ns	8.6	8.6
Moisture	SGS/2023/043/PL02	Memori CS	%	8.3	8.4	8.4	ns	ns	8.4	8.3
Moisture	SGS/2023/043/PL03	Alabama	%	9.0	8.8	9.0	ns	ns	8.9	8.9
Average from 15 trials:		Moisture	%	7.99	7.97	8.03	7.94	8.05	8.00	8.09

No negative effect on moisture content was noted for any tested dose rate of SNS-F-11 in any of trials carried out on winter oilseed rape. Comparing SNS-F-11 with standard reference products, no statistically significant differences were noted for moisture content in the majority of trials.

Hectolitre mass grains [kg/hl]

✓ *winter wheat* (5 trials)

Ass.	Untreated	SNS-F-11	Reference products
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Trial ID	Variety	Type	Unit	-	1.0 L/ha	1.3 L/ha	PORTER 250 EC at 0.6 L/ha	TORES 250 EC at 0.6 L/ha	TORES 250 EC at 0.5 L/ha
					of product per 100 kg seeds				
					% rel.	% rel.	% rel.	% rel.	% rel.
119 F/2022	Tobak	HMG	kg/hl	ns	ns	ns	ns	ns	ns
SF22PZ306W	Arkadia	HMG	kg/hl	79.58	80.33	80.65	80.48	80.53	ns
SF22PZ307W	Euforia	HMG	kg/hl	79.39	79.73	79.58	79.55	79.75	ns
SGS/2022/069/PL01	Lavantus	HMG	kg/hl	ns	ns	ns	ns	ns	ns
SGS/2022/069/PL02	Opoka	HMG	kg/hl	ns	ns	ns	ns	ns	ns
SGS/2022/069/PL03	Findus	HMG	kg/hl	ns	ns	ns	ns	ns	ns
SGS/2022/069/PL04	Joker	HMG	kg/hl	ns	ns	ns	ns	ns	ns
63 F/2023	Patras	HMG	kg/hl	ns	ns	ns	ns	ns	ns
SF23PZ302W	Julius	HMG	kg/hl	77.05	76.55	76.90	77.00	ns	76.88
SF23PZ309Z	Belissa	HMG	kg/hl	77.24	76.85	77.12	77.10	ns	77.01
SF23PZ310Z	Euforia	HMG	kg/hl	77.02	76.95	77.12	77.23	ns	76.89
SGS/2023/041/PL01	Yukon	HMG	kg/hl	ns	ns	ns	ns	ns	ns
SGS/2023/041/PL02	Findus	HMG	kg/hl	ns	ns	ns	ns	ns	ns
SGS/2023/041/PL04	Joker	HMG	kg/hl	ns	ns	ns	ns	ns	ns
SGS/2023/041/PL05	Euforia	HMG	kg/hl	ns	ns	ns	ns	ns	ns
SGS/2023/041/PL06	Arkadia	HMG	kg/hl	ns	ns	ns	ns	ns	ns
Average from 16 trials		HMG	kg/hl	78.06	78.08	78.27	78.28	80.14	76.93

No negative effect on hectolitre mass grains [g/hl] was noted for any tested dose rate of SNS-F-11 in any of trials carried out on winter wheat. Comparing SNS-F-11 with standard reference products, no statistically significant differences were noted for hectolitre mass grains in the majority of trials.

✓ *winter triticale*

This parameter was not studied in winter triticale.

✓ *winter oilseed rape*

This parameter was not studied in winter oilseed rape.

Thousand seed weight [g]

✓ *winter wheat* (16 trials)

Trial ID	Variety	Ass. Type	Unit	Untreated -	SNS-F-11		Reference products		
					1.0 L/ha	1.3 L/ha	PORTER 250 EC at 0.6 L/ha	TORES 250 EC at 0.6 L/ha	TORES 250 EC at 0.5 L/ha
					of product per 100 kg seeds				
				% rel.	% rel.	% rel.	% rel.	% rel.	
119 F/2022	Tobak	TGW	g	35.36	35.46	36.79	36.93	36.31	ns
SF22PZ306W	Arkadia	TGW	g	44.57	48.92	50.25	48.40	49.42	ns
SF22PZ307W	Euforia	TGW	g	42.26	44.47	44.26	44.26	45.02	ns
SGS/2022/069/PL01	Lavantus	TGW	g	41.36	42.19	43.07	43.07	42.44	ns
SGS/2022/069/PL02	Opoka	TGW	g	46.29	50.38	50.36	50.30	50.09	ns
SGS/2022/069/PL03	Findus	TGW	g	40.58	44.34	45.85	43.62	43.79	ns
SGS/2022/069/PL04	Joker	TGW	g	40.77	44.02	44.72	43.58	44.09	ns
63 F/2023	Patras	TGW	g	51.84	52.46	53.14	52.82	ns	53.55
SF23PZ302W	Julius	TGW	g	46.30	46.31	46.64	44.82	ns	45.50
SF23PZ309Z	Belissa	TGW	g	44.51	45.61	45.67	45.72	ns	45.83
SF23PZ310Z	Euforia	TGW	g	42.80	43.30	43.50	43.60	ns	43.20
SGS/2023/041/PL01	Yukon	TGW	g	39.15	42.39	42.23	41.81	ns	41.50
SGS/2023/041/PL02	Findus	TGW	g	40.45	41.89	42.31	41.88	ns	42.45
SGS/2023/041/PL04	Joker	TGW	g	40.91	44.02	45.64	43.68	ns	44.28
SGS/2023/041/PL05	Euforia	TGW	g	39.08	42.31	41.51	41.48	ns	41.98
SGS/2023/041/PL06	Arkadia	TGW	g	39.76	41.19	41.66	41.13	ns	41.81
Average from 16 trials		TGW	g	42.25	44.33	44.85	44.20	44.45	44.46

No negative effect on thousand seed weight [g] was noted for any tested dose rate of SNS-F-11 in any of trials carried out on winter wheat. Comparing SNS-F-11 with standard reference products, no statistically significant differences were noted for thousand seed weight in the majority of trials.

✓ *winter triticale* (5 trials)

Trial ID	Variety	Ass. Type	Unit	Untreated -	SNS-F-11		Reference products		
					1.0 L/ha	1.3 L/ha	PORTER 250 EC at	TORES 250 EC at	TORES 250 EC at

				Mean			0.6 L/ha	0.6 L/ha	0.5 L/ha
					of product per 100 kg seeds				
					% rel.	% rel.	% rel.	% rel.	% rel.
SGS/2023/089/PL01	Liborious	TGW	g	39.79	42.12	43.04	42.51	ns	42.64
SGS/2023/089/PL02	Tadeus	TGW	g	40.15	41.20	41.66	41.27	ns	41.34
SGS/2023/089/PL03	Rotondo	TGW	g	38.47	40.91	41.18	41.37	ns	41.55
SGS/2023/089/PL04	Twingo	TGW	g	38.94	42.05	42.14	42.06	ns	42.01
SGS/2023/089/PL05	Medalion	TGW	g	37.50	67.50	88.80	87.50	ns	86.30
Average from 5 trials:				38.97	46.96	51.37	50.94	ns	50.77

No negative effect on thousand seed weight [g] was noted for any tested dose rate of SNS-F-11 in any of trials carried out on winter triticale. Comparing SNS-F-11 with standard reference products, no statistically significant differences were noted for thousand seed weight in the majority of trials.

✓ *winter oilseed rape* (5 trials)

Trial ID				Variety	Ass. Type	Unit	Untreated -	SNS-F-11		Reference products			
								0.98 L/ha /1.0 L/ha	1.12 L/ha/ 1.15 L/ha	PORTER 250 EC at 0.6 L/ha	TORES 250 EC at 0.6 L/ha	TORES 250 EC at 0.5 L/ha	DIFO 250 EC / DIFCOR 250 EC at 0.5 L/ha
Mean	% rel.	% rel.	% rel.	% rel.	% rel.	% rel.							
of product per 100 kg seeds													
100 F/2022	Alibaba	TGW	g	4.09	4.63	4.66	4.80	4.36	ns	ns			
SGS/2022/070/PI03	Exotter	TGW	g	ns	ns	ns	ns	ns	ns	ns			
SGS/2022/070/PL04	SY Ilona	TGW	g	ns	ns	ns	ns	ns	ns	ns			
101 F/2022	Architekt	TGW	g	3.87	4.18	4.26	ns	ns	4.20	4.12			
SF22RZ307W	Graf	TGW	g	4.88	5.30	4.89	ns	ns	5.07	5.22			
SGS/2022/070/PL01	Galileus	TGW	g	ns	ns	ns	ns	ns	ns	ns			
SGS/2022/070/PI02	Artemis	TGW	g	ns	ns	ns	ns	ns	ns	ns			
31 F/2023	Architekt	TGW	g	5.25	5.34	5.34	5.43	ns	5.37	ns			
SGS/2023/042/PL01	Absolut	TGW	g	ns	ns	ns	ns	ns	ns	ns			
SGS/2023/042/PL02	Sienna	TGW	g	ns	ns	ns	ns	ns	ns	ns			
SGS/2023/042/PL03	Derrick	TGW	g	ns	ns	ns	ns	ns	ns	ns			
32 F/2023	Hevelius	TGW	g	3.87	4.18	4.28	ns	ns	4.20	4.12			
SGS/2023/043/PL01	Bonanaza	TGW	g	ns	ns	ns	ns	ns	ns	ns			
SGS/2023/043/PL02	Memori CS	TGW	g	ns	ns	ns	ns	ns	ns	ns			
SGS/2023/043/PL03	Alabama	TGW	g	ns	ns	ns	ns	ns	ns	ns			
Average from 15 trials:					TGW	g	4.39	4.73	4.69	5.12	4.36	4.71	4.49

No negative effect on thousand seed weight [g] was noted for any tested dose rate of SNS-F-11 in any of trials carried out on winter oilseed rape. Comparing SNS-F-11 with standard reference products, no statistically significant differences were noted for thousand seed weight in the majority of trials.

**Oil content [%]**

✓ *winter wheat*

This parameter was not studied in winter wheat.

✓ *winter triticale*

This parameter was not studied in winter triticale.

✓ *winter oilseed rape* (15 trials)

Trial ID	Variety	Ass. Type	Unit	Untreated - Mean	SNS-F-11		Reference products			
					0.98 L/ha /1.0 L/ha	1.12 L/ha/ 1.15 L/ha	PORTER 250 EC at 0.6 L/ha	TORES 250 EC at 0.6 L/ha	TORES 250 EC at 0.5 L/ha	DIFO 250 EC / DIFCOR 250 EC at 0.5 L/ha
					% rel.	% rel.	% rel.	% rel.	% rel.	% rel.
100 F/2022	Alibaba	Oil	%	48.48	48.49	48.32	49.12	48.43	ns	ns
SGS/2022/070/PI03	Exotter	Oil	%	42.30	42.90	42.60	42.70	42.70	ns	ns

SGS/2022/070/PL04	SY Ilona	Oil	%	42.70	43.10	42.90	43.00	43.00	ns	ns
101 F/2022	Architekt	Oil	%	49.34	49.69	49.70	ns	ns	49.32	49.67
SF22RZ307W	Graf	Oil	%	46.25	46.85	46.43	ns	ns	46.25	46.70
SGS/2022/070/PL01	Galileus	Oil	%	38.6	40.1	40.1	ns	ns	40.7	40.4
SGS/2022/070/PL02	Artemis	Oil	%	43.2	42.9	43.1	ns	ns	43.0	43.1
31 F/2023	Architekt	Oil	%	49.82	49.85	49.69	49.95	ns	50.42	ns
SGS/2023/042/PL01	Absolut	Oil	%	42.3	42.9	42.6	42.7	ns	42.7	ns
SGS/2023/042/PL02	Sienna	Oil	%	42.4	42.5	42.5	42.6	ns	42.6	ns
SGS/2023/042/PL03	Derrick	Oil	%	41.6	41.7	41.8	42.3	ns	42.0	ns
32 F/2023	Hevelius	Oil	%	50.22	50.11	50.14	ns	ns	50.27	50.35
SGS/2023/043/PL01	Bonanaza	Oil	%	43.5	43.5	43.8	ns	ns	43.6	43.5
SGS/2023/043/PL02	Memori CS	Oil	%	43.1	43.2	43.1	ns	ns	43.1	43.1
SGS/2023/043/PL03	Alabama	Oil	%	42.4	43.3	42.9	ns	ns	42.7	42.7
Average from 15 trials:		Oil	%	44.41	44.74	44.65	44.62	44.71	44.72	44.94

No negative effect on oil content was noted for any tested dose rate of SNS-F-11 in any of trials carried out on winter oilseed rape. Comparing SNS-F-11 with standard reference products, no statistically significant differences were noted for oil content in the majority of trials.

#### GLA (retained green leaf)

✓ *winter wheat* (6 trials)

Trial ID	Variety	Ass. Type	Unit	Untreated - Mean	SNS-F-11		Reference products		
					1.0 L/ha	1.3 L/ha	PORTER 250 EC at 0.6 L/ha	TORES 250 EC at 0.6 L/ha	TORES 250 EC at 0.5 L/ha
					of product per 100 kg seeds				
					% rel.	% rel.	% rel.	% rel.	% rel.
119 F/2022	Tobak	GLA	%	40.0	56.25	60.00	61.25	52.50	ns
SF22PZ306W	Arkadia	GLA	%	ns	ns	ns	ns	ns	ns
SF22PZ307W	Euforia	GLA	%	ns	ns	ns	ns	ns	ns
SGS/2022/069/PL01	Lavantus	GLA	%	47.5	37.5	55.0	47.5	50.0	ns
SGS/2022/069/PL02	Opoka	GLA	%	62.5	86.3	86.3	86.3	86.3	ns
SGS/2022/069/PL03	Findus	GLA	%	21.3	80.0	85.0	87.5	82.5	ns
SGS/2022/069/PL04	Joker	GLA	%	30.0	92.5	93.8	88.8	91.3	ns
63 F/2023	Patras	GLA	%	41.25	51.25	57.50	63.75	ns	58.75
SF23PZ302W	Julius	GLA	%	ns	ns	ns	ns	ns	ns
SF23PZ309Z	Belissa	GLA	%	ns	ns	ns	ns	ns	ns
SF23PZ310Z	Euforia	GLA	%	ns	ns	ns	ns	ns	ns
SGS/2023/041/PL01	Yukon	GLA	%	ns	ns	ns	ns	ns	ns
SGS/2023/041/PL02	Findus	GLA	%	ns	ns	ns	ns	ns	ns
SGS/2023/041/PL04	Joker	GLA	%	ns	ns	ns	ns	ns	ns
SGS/2023/041/PL05	Euforia	GLA	%	ns	ns	ns	ns	ns	ns
SGS/2023/041/PL06	Arkadia	GLA	%	ns	ns	ns	ns	ns	ns
Average from 16 trials		GLA	%	40.43	67.30	72.93	72.52	72.52	58.75

No negative effect on retained green leaf was noted for any tested dose rate of SNS-F-11 in any of trials carried out on winter wheat. Comparing SNS-F-11 with standard reference products, no statistically significant differences were noted for retained green leaf in the majority of trials.

✓ *winter tritcale* (5 trials)

Trial ID	Variety	Ass. Type	Unit	Untreated - Mean	SNS-F-11		Reference products		
					1.0 L/ha	1.3 L/ha	PORTER 250 EC at 0.6 L/ha	TORES 250 EC at 0.6 L/ha	TORES 250 EC at 0.5 L/ha
					of product per 100 kg seeds				
					% rel.	% rel.	% rel.	% rel.	% rel.
SGS/2023/089/PL01	Liborius	GLA	%	25.00	60.00	60.00	55.00	ns	60.00
SGS/2023/089/PL02	Tadeus	GLA	%	11.30	40.00	60.00	55.00	ns	60.00
SGS/2023/089/PL03	Rotondo	GLA	%	47.50	78.80	87.50	80.00	ns	90.00
SGS/2023/089/PL04	Twingo	GLA	%	47.50	83.80	83.80	83.80	ns	83.80
SGS/2023/089/PL05	Medalion	GLA	%	37.50	67.50	88.80	87.50	ns	86.30
Average from 5 trials:		GLA	%	33.76	66.02	76.02	72.26	ns	76.02

No negative effect on retained green leaf was noted for any tested dose rate of SNS-F-11 in any of trials carried out on winter tritcale. Comparing SNS-F-11 with standard reference products, no statistically



significant differences were noted for retained green leaf in the majority of trials.

✓ *winter oilseed rape*

This parameter was not studied in winter oilseed rape.

**Protein content [%]**

✓ *winter wheat* (2 trials)

Trial ID	Variety	Ass. Type	Unit	Untreated - Mean	SNS-F-11		Reference products		
					1.0 L/ha	1.3 L/ha	PORTER 250 EC at 0.6 L/ha	TORES 250 EC at 0.6 L/ha	TORES 250 EC at 0.5 L/ha
					of product per 100 kg seeds				
					% rel.	% rel.	% rel.	% rel.	% rel.
119 F/2022	Tobak	Protein	%	11.29	11.88	11.81	11.77	11.38	ns
SF22PZ306W	Arkadia	Protein	%	ns	ns	ns	ns	ns	ns
SF22PZ307W	Euforia	Protein	%	ns	ns	ns	ns	ns	ns
SGS/2022/069/PL01	Lavantus	Protein	%	ns	ns	ns	ns	ns	ns
SGS/2022/069/PL02	Opoka	Protein	%	ns	ns	ns	ns	ns	ns
SGS/2022/069/PL03	Findus	Protein	%	ns	ns	ns	ns	ns	ns
SGS/2022/069/PL04	Joker	Protein	%	ns	ns	ns	ns	ns	ns
63 F/2023	Patras	Protein	%	9.10	9.14	9.73	9.70	ns	9.29
SF23PZ302W	Julius	Protein	%	ns	ns	ns	ns	ns	ns
SF23PZ309Z	Belissa	Protein	%	ns	ns	ns	ns	ns	ns
SF23PZ310Z	Euforia	Protein	%	ns	ns	ns	ns	ns	ns
SGS/2023/041/PL01	Yukon	Protein	%	ns	ns	ns	ns	ns	ns
SGS/2023/041/PL02	Findus	Protein	%	ns	ns	ns	ns	ns	ns
SGS/2023/041/PL04	Joker	Protein	%	ns	ns	ns	ns	ns	ns
SGS/2023/041/PL05	Euforia	Protein	%	ns	ns	ns	ns	ns	ns
SGS/2023/041/PL06	Arkadia	Protein	%	ns	ns	ns	ns	ns	ns
Average from 16 trials		Protein	%	10.20	10.51	10.77	10.74	11.38	9.29

No negative effect on protein content was noted for any tested dose rate of SNS-F-11 in any of trials carried out on winter wheat. Comparing SNS-F-11 with standard reference products, no statistically significant differences were noted for protein content in the majority of trials.

✓ *winter triticale*

This parameter was not studied in winter triticale

✓ *winter oilseed rape*

This parameter was not studied in winter oilseed rape.

**There are almost no significant differences in the quality of yield between SNS-F-11 and the reference products. Overall, these results confirms that there is no risk for negative side effects on the quality of the treated cereals (winter wheat and winter triticale) and winter oilseed rape.**

### 3.3.3 Observations on other undesirable or unintended side-effects

**Effects on transformation processes:** Difenoconazole can impact on the transformation processes in cereals and oilseed rape by enhancing growth, improving photosynthesis and nutrient uptake, increasing yield and its quality and supporting diseases resistance and stress tolerance. Difenoconazole helps maintain leaf area and chlorophyll content. Fungicide application reduces root infections, allowing for better nutrient absorption which leads to improved vigor and yield. For example in oilseed rape with reduced diseases pressure, plants can allocate nutrients more efficiently towards reproductive organs, enhancing seed quality and soil content.

Difenoconazole is a fungicide widely used in agriculture to protect crops, including cereals and winter oilseed rape from fungal diseases. Its impact on the transformation processes such as baking, fermenting or other processing can vary depending on several factors.

*Baking process* (cereals). The primary concern with difenoconazole in baking is the potential for pesticide residues in the final product. Baking typically involves high temperatures, which can degrade some pesticides residues, but not completely eliminate them.



*Fermenting process* (cereals and oilseed). Difenoconazole residues could potentially affect yeast activity during fermentation. While yeast can tolerate some level of residues, higher concentrations might inhibit fermentation, leading to lower efficiency in processes such as bread making, beer brewing or bioethanol production. During fermentation, chemical changes can occur, which might transform difenoconazole into different compounds. These transformations could either reduce the toxicity or create new metabolites.

*Oil processing* (winter oilseed rape). The presence of difenoconazole in oilseed rape could influence the quality of the extracted oil. While the refining process may reduce pesticide residues, complete elimination is not guaranteed.

The presence of difenoconazole residues in cereals and winter oilseed rape is a significant concern for food safety and environmental health. Difenoconazole is systemic, meaning it can be absorbed and translocated within the plant. Residue level can depend on the timing of application relative to the harvest. The degradation rate of difenoconazole in plants can be influenced by environmental conditions such as temperature, humidity and sunlight. Some food processing methods can reduce pesticide residues. For example, washing, peeling and cooking can decrease difenoconazole levels in cereals and oilseed rape products. Detailed information about remains of the active substance – difenoconazole is presented in Section 7 (part B).

**Impact on propagating purposes:** The use of difenoconazole fungicide can have various effects on the propagating purposes of cereals and winter oilseed rape. Propagation, which includes the processes of seed production, seed quality and subsequent germination can be influenced by fungicide application in several ways. Fungicide application can lead to the production of higher-quality seeds with better physical and biochemical properties. Healthier plants are likely to produce seeds with higher nutritional content and better storage qualities. Effective disease management can result in seeds with higher oil content and better fatty acid profiles, which is crucial for the economic value of oilseed rape. On the basis of literature data, there is no direct evidence suggesting that difenoconazole affects genetic properties of seeds. While difenoconazole residues are generally within safe limits if used according to label, it is essential to ensure that residues do not negatively affect seed quality of germination. So, it can be stated that difenoconazole fungicide has several positive effects on the propagating purposes of cereals and oilseed rape by enhancing seed health, quality, and germination rates. It contributes to higher seed yields and better seeding vigor. In line to Table 2 from EPPO 1/135 (4) – no studies for propagation are required in the case of SNS-F-11. The use of difenoconazole on winter wheat and winter triticale during BBCH 33-55 and winter oilseed rape during BBCH 32-39 provides significant benefits in disease control, growth enhancement, and yield and quality improvement. Effective application at these critical growth stages ensures healthier plants, better stress tolerance and improved agricultural outputs.

**Impact on succeeding crops:** Difenoconazole has a relatively moderate half-life in soil, typically ranging from several weeks to a few months, depending on soil type, moisture, temperature and microbial activity. It degrades primarily through microbial activity and chemical hydrolysis. Factors such as higher temperatures and adequate soil moisture can accelerate the degradation process. Some crops may be more sensitive to difenoconazole residues than others. For example, root vegetables and legumes might show different tolerance levels compared to cereals or oilseed rape. To mitigate negative effects, it is important to follow best practices such as adhering to recommended pre-harvest intervals and implementing integrated pest management strategies.

**Impact on other plants including adjacent crops:** The impact of difenoconazole fungicide on adjacent crops can be influenced by various factors including application methods, environmental conditions and the sensitivity of neighboring crops. Establishing buffer zones or untreated areas between treated fields and adjacent crops can help reduce the risk or drift. Broadleaf plants, including vegetables and certain legumes, may be more sensitive to difenoconazole compared to cereals and grasses. Exposure during critical growth stages (ex. flowering) can have more pronounced negative effects on adjacent crops, potentially leading to yield losses or quality issues. Difenoconazole can leach through soil, especially in sandy or low organic matter soils, potentially reaching the root zones of adjacent crops. Practices such as maintaining proper soil health and structure can mitigate this risk. Heavy rainfall or irrigation can cause runoff containing difenoconazole to move into adjacent fields, affecting nearby crops. Using precision

application techniques such as targeted spraying and appropriate equipment can minimize off-target movement of difenoconazole. Applying fungicides during favorable weather conditions (low wind, moderate temperatures) can reduce the risk of drift and volatilization. Maintaining untreated buffer zones between treated fields and adjacent crops can help protect sensitive plants from exposure. The use of difenoconazole fungicide can impact adjacent crops through mechanism such as spray drift, volatilization, leaching and runoff. Sensitive crops may experience phytotoxicity, growth inhibition and yield reduction if exposed. Implementing best practices such as precision application, establishing buffer zones, using physical barriers and regular monitoring can help mitigate these impacts and protect adjacent crops.

**Effects on beneficial and other non-target organisms:** Detailed studies on the possible adverse effects to beneficial organisms are presented in Ecotoxicology Section (B9). Below, ZRMs from efficacy section presents only literature data about possible impact on beneficial and non-target organisms. It is known that the use of difenoconazole can have various effects on beneficial and non-target organisms. Difenoconazole can affect the diversity and activity of soil microbial communities, including bacteria, fungi and actinomycetes. Difenoconazole may negatively affect nitrogen-fixing bacteria such as *Rhizobium* species, which form symbiotic relationships with legumes. Non-target plants, particularly broadleaf species, may experience phytotoxic effects if exposed to difenoconazole through drift, volatilization or soil residues. Symptoms can include leaf chlorosis, necrosis, stunted growth and reduced reproductive success. Although difenoconazole is not highly toxic to bees, sub-lethal effects such as altered foraging behavior or reduced brood development could occur if bees are exposed to residues. Beneficial predatory and parasitic insects, such as lady beetles, lacewings and parasitoid wasps can be affected by difenoconazole if they consume contaminated prey or come into direct contact with this fungicide. Difenoconazole can enter water bodies through leaching and runoff, potentially impacting aquatic ecosystems. Contamination of water bodies can affect fish, amphibians and aquatic invertebrates. Birds and mammals can be exposed to residues through ingestion of treated plants, seeds or contaminated water. Although difenoconazole has low acute toxicity to birds and mammals, chronic exposure to residues could have sub-lethal effects. Difenoconazole fungicide can impact beneficial and non-target organisms, including soil microorganisms, non-target plants, beneficial insects, aquatic organisms, soil fauna, birds and mammals. These effects can be direct, such as toxicity, or indirect such as disruption of food webs and habitats. Implementing integrated pest management practices, establishing buffer zones, conserving habitats and conducting regular monitoring can mitigate these impacts and promote sustainable agricultural practices.

### 3.4 Methods of analysis (Part B, Section 5)

It was confirmed that chromatographic methods of determination of the active compound (difenoconazole) and its impurity (toluene) are specific. No interference was observed. The validation parameters (linearity, LOQ, repeat-ability and accuracy) are within the acceptance range and fulfil EU requirements given in SAN-CO/3030/99 rev.5.

#### 3.4.1 Analytical method for the formulation

With respect to toxicological, ecotoxicological or environmental aspects SNS-F-11 does not contain any relevant formulants. Therefore, a special analytical method and validation is not needed.

#### 3.4.2 Analytical methods for residues

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

Commodity/crop	Supported/ Not supported
Cereals	Supported
Oilseeds	Supported

### 3.5 Mammalian toxicology (Part B, Section 6)

#### 3.5.1 Acute toxicity

The classification of the formulation SNS-F-11 is based on toxicological data of individual ingredients of the mixture (additivity formula) and *in vitro* data.

Type of test, species, model system (Guideline)	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD <sub>50</sub> oral (calculation method)	None	Calculation method
LD <sub>50</sub> dermal (calculation method)	None	Calculation method
LC <sub>50</sub> inhalation (calculation method)	Acute Tox 4 (H332)	Calculation method
Skin irritation, <i>in vitro</i> / Reconstructed Human Epidermis (OECD 431)	Not corrosive	Krakowian D.
Skin irritation (calculation method)	Skin Irrit. 2 (H315)	Calculation method
Eye irritation, <i>in vitro</i> / Reconstructed human Cornea-like Epithelium (RhCE) (OECD 492)	Eye Dam. 1 (H318)	Krakowian D.
Eye irritation, Isolated Chicken Eye (OECD 438)		Toczko M.
Skin sensitisation (calculation method)	None	Calculation method

#### 3.5.2 Operator exposure

According to the estimation based on Calcualtor OPEX version v.1.0.1, the use of SNS-F-11 containing difenoconazole (90 g/kg) causes acceptable health risk for:

- unprotected operator (no PPE) (arms, body and legs covered) during mixing/loading and application in the case of tractor mounted boom spray application in winter wheat and winter triticales;
- Operator equipped with work wear (arms, body and legs covered) during mixing/loading and application in the case of tractor mounted boom spray application in winter rape, spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans.

However, taking into account the classification of the product (Eye Dam. 1, H318, Skin Irrit. 2, H315), eye/face protection and protective gloves are mandatory when handling undiluted product.

Consequently, the following sentence regarding the use of PPE is recommended by the evaluator to be placed in the label:

„Stosować rękawice ochronne, ochronę oczu lub twarzy oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy roboczej oraz odzież roboczą w trakcie wykonywania zabiegu.”  
“Wear protective gloves, eye/face shield and work wear (coverall) during mixing/loading and work wear during application”.

### 3.5.3 Worker exposure

According to the estimation results, the use of SNS-F-11 containing difenoconazole (90 g/kg) causes acceptable health risk for a unprotected worker assuming 2 hour working day (inspection, irrigation). However, bearing in minds the hygienic rules, the use of protective gloves is recommended when entering treated area.

Following sentence is recommended by the evaluator to be placed in the section of precautions for the workers:

„Stosować rękawice ochronne oraz odzież roboczą podczas wchodzenia na teren poddany opryskowi .”  
“Wear protective gloves and work wear when entering treated area.”

### 3.5.4 Bystander and resident exposure

The AAOEL value for difenoconazole is not allocated. Consequently, it is assumed that the estimation of bystander exposure is covered by the calculation of resident exposure towards the active substance. The results of exposure estimations demonstrate that the use of SNS-F-11 according to the list of intended uses presented in the GAP Table and anticipating the introduction of buffer zone presented (2-3m), cause acceptable health risk for bystander/resident (adult and child).

## 3.6 Residues and consumer exposure (Part B, Section 7)

### 3.6.1 Residues

#### Storage stability

##### Difenoconazole

Residues of difenoconazole in tomato fruit, potato tubers, cottonseed, cottonseed oil, cottonseed meal, wheat forage, wheat straw and wheat grain will be stable for at least 24 months, in lettuce head, soybeans, whole bananas, eggs, milk, poultry breast and beef liver for at least 12 months and at least 10 months in blood, fat, milk and tissues from dairy cattle when stored at <-18°C. CGA 205375 was shown to be stable in animal commodities for at least 10 months stored at <-18°C.

New residue trials submitted in the framework of this application (winter wheat) are valid with regard to storage stability data.

The storage stability data of difenoconazole and TDMs in oilseed rape and honey are not required, as the samples were tested within 30 days of sampling.

#### Metabolism in plants and animals

EU endpoints:

Plant residue definition for monitoring Difenoconazole Reg. (EU) 2019/552

Plant residue definition for risk assessment separate residue definitions (Difenoconazole,

SANCO/830/08 – rev. 3, 13 December 2013, 18 May 2020:

- 1) Difenoconazole
- 2) TA and TLA, since these compounds share the same toxicity;
- 3) TAA
- 4) 1,2,4-T

Animal residue definition for monitoring: difenoconazole Reg. (EU) 2019/552

Animal residue definition for risk assessment

- 1) Difenoconazole
- 2) TA and TLA, since these compounds share the same toxicity;
- 3) TAA
- 4) 1,2,4-T

#### **Magnitude of residues in plants**

Spring and winter oilseed rape, Linseed (common flax), Poppy seeds, Mustard seeds, Gold of pleasure seeds, Sunflower seeds, Soyabeans

Proposed GAP (Spring oilseed rape, Linseed (common flax), Poppy seeds, Mustard seeds, Gold of pleasure seeds, Sunflower seeds):

1 application, BBCH 32-39, 90 g as/ha

or

1 application, BBCH 60-65, 103.5 g as/ha

Proposed GAP (Soyabeans)

1 application, BBCH 60-65, 103.5 g as/ha

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. Trials are acceptable.

Trials GAP: 1x 108 g, BBCH 65, PHI not relevant (commercial harvest)

Seeds:

E: Difenoconazole: 8x <0.01

RA: Difenoconazole: 8x <0.01

1,2,4-T: 8x <0.01

TA: 0.87, 0.40, 0.67, 0.48, 3.80, 0.16, 0.30, 0.73

TAA: 0.01, 3x<0.01, 0.01, 3x<0.01

TLA: 0.04, 0.02, 0.03, 0.02, 0.17, <0.01, 2x 0.02

Sufficient number of trials are available. Extrapolation from oilseed rape to linseed (common flax), poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans is possible (SAN-TE/2019/12752 Rev01). The residues arising from the proposed use will not exceed the MRLs for difenoconazole established for proposed uses (Reg. (EU) 2019/552).

Oilseeds	mg/kg
Linseeds	0.2
Poppy seeds	0.05*
Sunflower seeds	0.05*
Rapeseeds/canola seeds	0.5

Soyabeans	0.1
Mustard seeds	0.2
Gold of pleasure seeds	0.05*

\*- LOQ

Winter wheat, Winter triticale

**Proposed GAP:**

2 applications, interval: 14, BBCH 33-55, 90 g as/ha

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. Trials are acceptable.

**Trials GAP:**

Trials GAP: 2x 150 g as/ha, BBCH 33-55, PHI 62d

E: Difenoconazole: 8x < 0.0025 mg/kg

RA: Difenoconazole: 8x < 0.0025 mg/kg

1,2,4-T: 8x < 0.004 mg/kg

TA: 8x < 0.0025 mg/kg

TAA: 8x < 0.004 mg/kg

TLA: 8x < 0.004 mg/kg

Sufficient number of trials are available. Extrapolation from wheat to triticale is possible. The residues arising from the proposed use will not exceed the MRLs for difenoconazole established for proposed uses (0.1 mg/kg, Reg. (EU) 2019/552).

**Magnitude of residues in livestock**

Information provided by the applicant are sufficient. There is no risk for animal MRL to be exceeded

Additional studies are not required.

**Magnitude of residues in processed commodities**

Processing studies for difenoconazole are not required.

Processing studies data for TDMs were submitted and evaluated at EU level as confirmatory data for triazole derivative metabolites (Triazole Derivative Metabolites Addendum – Confirmatory Data, 2018). Additional studies are not required.

**Magnitude of residues in representative succeeding crops**

Waiting periods before planting following succeeding crops: not required.

**Other / special studies**

Oilseed rape is a melliferous crop foraged by bees. A study to determine the residues in honey and bee products is required.

Therefore, a studies determining the residue levels of difenoconazole and triazole derivative metabolites in honey was performed in accordance with SANTE/11956/2016 rev. 9. The study was conducted using Phacelia tanacetifolia as a crop with high melliferous capacity under semi-field conditions and at four different locations in Poland and Germany.

Residue studies in honey in the Northern Zone in Poland and Germany showed that the level of difenoconazole and triazole derivative metabolites was below LOQ (0.01 mg/kg). The studies showed no negative impact on the life processes and health of the bee family.

The currently established MRL for difenoconazole in honey and other apiculture products is 0.05 mg/kg. The use of the product SNS-F-11 in the cultivation of winter rapeseed during flowering in accordance

with the proposed GAP does not pose a risk of exceeding the currently established MRL in honey and other apiculture products.

### 3.6.2 Consumer exposure

#### Difenoconazole

TMDI (% ADI) according to EFSA PRIM ver. 3.1.	96 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo ver. 3.1.	See TMDI
IESTI (% ARfD) according to EFSA PRIMo ver. 3.1.	Wheat: 0.09 % (based on results for children) Soybeans: 0.01% (based on results for children) Rapeseeds/canola seeds: 0.01% (based on results for children) Linseeds: 0.01% (based on results for children)  Wheat/milling (flour): 0.1% (based on results for children) Wheat/milling (wholemeal)-baking: 0.0% (based on results for children) Soybeans/soya drink: 0.0% (based on results for children) Soyabeans/boiled: 0.0% (based on results for children) Rapeseeds/oils: 0.0% (based on results for children)
NTMDI (% ADI) **	Not required
NEDI (% ADI)**	Not required
NESTI (% ARfD) **	Not required

#### 1,2,4- Triazole (1,2,4-T)

TMDI (% ADI) according to EFSA PRIM ver. 3.1.	0,4 % (based on GEMS/Food G06)
IEDI (% ADI) according to EFSA PRIMo ver. 3.1.	See TMDI
IESTI (% ARfD) according to EFSA PRIMo ver. 3.1.	Wheat: 0.1 % (based on results for children) Sunflower seeds: 0.03% (based on results for children) Soybeans: 0.02% (based on results for children) Rapeseeds/canola seeds: 0.01% (based on results for children) Linseeds: 0.01% (based on results for children) Mustard seeds: 0.01% (based on results for children)  Wheat/milling (flour): 0.1% (based on results for children) Wheat/milling (wholemeal)-baking: 0.1% (based on results for children) Soybeans/soya drink: 0.0% (based on results for children) Soyabeans/boiled: 0.0% (based on results for children) Rapeseeds/oils: 0.0% (based on results for children)
NTMDI (% ADI) **	Not required
NEDI (% ADI)**	Not required
NESTI (% ARfD) **	Not required

#### Triazole alanine (TA) and Triazole lactic acid (TLA)

TMDI (% ADI) according to EFSA PRIM ver. 3.1.	0.6% (based on GEMS/Food G11)
IEDI (% ADI) according to EFSA PRIMo ver. 3.1.	See TMDI
IESTI (% ARfD) according to EFSA PRIMo ver. 3.1.	Sunflower seeds: 0.5% (based on results for children)



	Soybean: 0.4% (based on results for children) Rapeseeds/canola seeds: 0.2% (based on results for children) Linseeds: 0.2% (based on results for children) Mustard seeds: 0.2% (based on results for children) Wheat: 0.05% (based on results for children)  Soyabeans/soya drink: 0.7% (based on results for children) Sunflower seeds/oils: 0.4% (based on results for children) Soyabeans/boiled: 0.2% (based on results for children) Rapeseeds/oils: 0.1% (based on results for children) Wheat/milling (flour): 0.0% (based on results for children) Wheat/milling (whole meal)-baking: 0.0% (based on results for children)
NTMDI (% ADI) **	Not required
NEDI (% ADI)**	Not required
NESTI (% ARfD) **	Not required

### Triazole acetic acid (TAA)

TMDI (% ADI) according to EFSA PRIM ver. 3.1.	0.0% (based on GEMS/Food G10)
IEDI (% ADI) according to EFSA PRIMo ver. 3.1.	See TMDI
IESTI (% ARfD) according to EFSA PRIMo ver. 3.1.	Wheat: 0.01% (based on results for children) Sunflower seeds: 0.01% (based on results for children) Soyabeans: 0.00% (based on results for children) Rapeseeds/canola seeds: 0.00% (based on results for children) Linseeds: 0.00% (based on results for children) Mustard seeds: 0.00% (based on results for children)  Wheat/milling (flour): 0.00% (based on results for children) Soyabeans/soya drink: 0.00% (based on results for children) Wheat/milling (whole meal)-baking: 0.00% (based on results for children) Sunflower seeds/oils: 0.00% (based on results for children) Soyabeans/boiled: 0.00% (based on results for children) Rapeseeds/oils: 0.00% (based on results for children)
NTMDI (% ADI) **	Not required
NEDI (% ADI)**	Not required
NESTI (% ARfD) **	Not required

The proposed uses of difenoconazole in the formulation SNS-F-11 do not represent unacceptable acute and chronic risks for the consumer.

### 3.7 Environmental fate and behaviour (Part B, Section 8)

The predicted environmental concentrations (PEC values) in soil, surface water, sediment and groundwater are provided in Part B, Section 8. The long-term concentrations are based on results obtained for the active substance contained in the formulation. Calculated PEC values demonstrates that the SNS-F-11 is safe for the environment.



### 3.7.1 Predicted environmental concentrations in soil (PEC<sub>soil</sub>)

The PEC<sub>soil</sub> values were calculated for a single application in winter oilseed rape (1 x 1.15 L/ha) and for the double application in winter cereals (2 x 1 L/ha). Crop interception at this growth stage is 80% according „Generic Guidance for Tier 1 FOCUS Ground Water Assessments” (Version: 2.2; May 2014). Furthermore, the PEC<sub>s,initial</sub> values assuming incorporation into a 5 cm soil layer with a density of 1.5 g/cm<sup>3</sup>. For the calculations of active substance and its relevant metabolites, the worst-case (maximum) normalized laboratory DT<sub>50</sub> values were used.

### 3.7.2 Predicted environmental concentrations in groundwater (PEC<sub>gw</sub>)

The Predicted Environmental Concentrations (PEC<sub>gw</sub>) of difenoconazole and their metabolites: CGA 71019 and CGA 205375, were calculated with FOCUS PEARL (v 5.5.5.) and FOCUS PELMO (v. 6.6.4.) on the basis of EU agreed endpoints that were summarized at EU level.

The PEC<sub>gw</sub> were calculated for both application rates: 2 x 1 L/ha recommended for use in winter cereals (*winter wheat, winter triticales*), and 1 x 1.15 L/ha recommended for use in winter oilseed rape (*oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans*).

Nine scenarios were taken into consideration for use in winter cereals: Châteaudun, Hamburg, Kremsmünster (scenarios important for Poland) and Okehampton, , Jokioinen, Piacenza, Porto, Sevilla and Thiva.

Six scenarios were taken into consideration for use in winter oilseed rape: Châteaudun, Hamburg, Okehampton, Kremsmünster, Piacenza and Porto.

Obtained PEC<sub>gw</sub> for difenoconazole, and their metabolites: CGA 71019 and CGA 205375 in each scenario and for the recommended use of SNS-F-11 are significant below the trigger value of 0.1 µg/L and therefore the use of this plant protection product according to recommendations does not pose a risk of groundwater contamination.

### 3.7.3 Predicted environmental concentrations in surface water (PEC<sub>sw</sub>)

PEC<sub>sw</sub> was calculated according to endpoints for difenoconazole and submitted for SNS-F-11. The Predicted Environmental Concentrations in surface water has been calculated for active substances and their metabolites. Taking into consideration risk mitigation calculations for SNS-F-11 use in winter cereals and winter oilseed rape, and **minor crops** following risk mitigation measures should be applied:

- For use in winter cereals:
  - **Winter triticales, winter wheat**
    - 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: (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soyabeans)**
  - 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.**

- Spring oilseed rape  
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.

- Linseed (common flax)  
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.

- Poppy seeds  
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.

- Mustard seeds  
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.

- Gold of pleasure seeds  
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.

- Sunflower seeds  
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.

- Soyabeans  
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.

### 3.7.4 Predicted environmental concentrations in air (PEC<sub>air</sub>)

The vapour pressure at 20 °C of the active substance difenoconazole is  $< 10^{-5}$  Pa and the Henry's Law Constant is  $9.0 \times 10^{-7}$  Pa.m<sup>3</sup>/mol. Hence the difenoconazole is regarded as non-volatile.

### 3.8 Ecotoxicology (Part B, Section 9)

#### 3.8.1 Effects on terrestrial vertebrates

An estimation of risk indicate low risk for birds and mammals for proposed uses in winter cereals (winter wheat and winter triticale) and winter oilseed rape (spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, soybeans). 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.

#### 3.8.2 Effects on aquatic species

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).

##### **PL (D3, D4, R1 are scenarios specific to Poland)**

The ratios between predicted environmental concentrations in surface water bodies (PEC<sub>sw</sub>, PEC<sub>SED</sub>) 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

Taking into consideration risk mitigation calculations for SNS-F-11 use in winter cereals and winter oilseed rape, and minor crops following risk mitigation measures should be applied:

– For use in winter cereals:

Winter triticale, winter wheat

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: (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.

- Spring oilseed rape

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.

- Linseed (common flax)

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.

- Poppy seeds

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.

- Mustard seeds

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.

- Gold of pleasure seeds

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.

- Sunflower seeds

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.

- Soyabeans

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.

### 3.8.3 Effects on bees

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 (SAN-CO/10329/2002 rev.2 (final), October 17, 2002). Calculation conducted for SNS-F-11 regarding to the oral and contact toxicity 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 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.

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.

### 3.8.4 Effects on other arthropod species other than bees

*A. rhopalosiphi* and *T. pyri* are organisms used to designation the initial assessment.  $HQ_{in-field}$  and  $HQ_{off-field}$  values for *A. rhopalosiphi* and *T. pyri* are below the ESCORT 2 trigger of 2. The calculations present an acceptable risk to non-target arthropods, after spray application of SNS-F-11.

### 3.8.5 Effects on soil organisms

The calculated chronic TER for formulation for use is winter oilseed 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.

**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 comparable - 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<sub>LT</sub> 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<sub>LT</sub> 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<sub>LT</sub> 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.**

### 3.8.6 Effects on non-target terrestrial plants

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, on non-target terrestrial plants, no risk mitigation needed.

### **3.8.7 Effects on other terrestrial organisms (Flora and Fauna)**

Not relevant.

### **3.9 Relevance of metabolites (Part B, Section 10)**

The groundwater metabolites of difenoconazole: CGA 71019, CGA 205375, are considered as non-relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10, since their predicted concentration in the groundwater do not exceed the concentration of 0.1 µg/L.

## **4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)**

SNS-F-11 contains difenoconazole which is approved as a candidate for substitution because two of PBT. As a conclusion of the comparative assessment uses in winter oilseed rape, winter wheat and winter triticale and minor uses presented at GAP table in 2.6 are not suitable for substitution. More details are provided in the comparative assessment document for the SNS-F-11 product.

## **5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization**

Insert any data that the notifier needs to submit following authorization. As a rule, this is restricted to storage stability and monitoring data.

Insert the data that is still required for the evaluation of the product in the case where the product authorization is not granted.

## **Appendix 1    Copy of the product authorization**

MS assessor to insert details of the product authorization for MS country.



## Appendix 2 Copy of the product label

**Skuteczność:** W etykiecie śró DISFERA 90 EC oraz LIPOSTAR 90 EC doprecyzowano zapis zastosowania dla pszenżyta ozimego – zaakceptowano septoriozę paskowaną liści a nie ogólnie – septoriozy liści. Pozostałych zapisów w etykietach – nie zmieniano.

**Pozostałości:** Brak uwag

**Ekotoksykologia:** W przypadku uprawy rzepaku ozimego, w celu ochrony organizmów wodnych nie jest konieczne wyznaczenie zadarnionej strefy ochronnej od zbiorników i cieków wodnych.

W przypadku uprawy zbóż ozimych (pszenica ozima, pszenżyto ozime), w celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

- 1m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%, lub

- 2 m od zbiorników i cieków wodnych bez konieczności stosowania technik redukujących znoszenie cieczy użytkowej

W przypadku uprawy rzepaku ozimego, w celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

- 1m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%, lub

- 2m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 25%, lub

- 3 m od zbiorników i cieków wodnych bez konieczności stosowania technik redukujących znoszenie cieczy użytkowej

### **Rzepak jary, lnianka siewna**

w celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

☐ 1m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%, lub

☐ 2m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 25%, lub

☐ 3 m od zbiorników i cieków wodnych bez konieczności stosowania technik redukujących znoszenie cieczy użytkowej

### **Len zwyczajny – wykorzystywanie na olej, włókno oraz na nasiona**

w celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

☐ 1m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%, lub

☐ 2m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 25%, lub

☐ 3 m od zbiorników i cieków wodnych bez konieczności stosowania technik redukujących znoszenie cieczy użytkowej

#### **Mak lekarski**

w celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

- ☐ 1m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%, lub
- ☐ 2m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 25%, lub
- ☐ 3 m od zbiorników i cieków wodnych bez konieczności stosowania technik redukujących znoszenie cieczy użytkowej

#### **Gorczyca sarepska, gorczyca biała, gorczyca czarna**

w celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

- ☐ 1m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%, lub
- ☐ 2m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 25%, lub
- ☐ 3 m od zbiorników i cieków wodnych bez konieczności stosowania technik redukujących znoszenie cieczy użytkowej

#### **Słonecznik zwyczajny**

w celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

- ☐ 1m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%, lub
- ☐ 2m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 25%, lub
- ☐ 3 m od zbiorników i cieków wodnych bez konieczności stosowania technik redukujących znoszenie cieczy użytkowej

#### **Soja**

w celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

- ☐ 1m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%, lub
- ☐ 2m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 25%, lub
- ☐ 3 m od zbiorników i cieków wodnych bez konieczności stosowania technik redukujących znoszenie cieczy użytkowej

### Posiadacz zezwolenia:

Synthos Agro Spółka z o.o., 32-600 Oświęcim, ul. Chemików 1 ; tel. +48 33 847 47 77; e-mail: [rejestracja@synthosgroup.com](mailto:rejestracja@synthosgroup.com)


## DISFERA 90 EC

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

difenokonazol (związek z grupy triazoli) - 90 g/l (%)

### Zezwolenie MRiRW nr R –

	
<b>Niebezpieczeństwo</b>	
<b>H302</b> <b>H332</b> <b>H351</b> <b>H315</b> <b>H318</b> <b>H410</b>	<del>Działa szkodliwie po połknięciu.</del> Działa szkodliwie w następstwie wdychania Podejrzewa się, że powoduje raka Działa drażniąco na skórę. Powoduje poważne uszkodzenie oczu Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
<b>EUH401</b>	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
<b>P261</b> <b>P280</b> <del><b>P301+P312</b></del> <del><b>P330</b></del> <b>P304+P340</b> <b>P305+P351+P338</b> <del><b>P302+P352</b></del> <b>P273</b> <del><b>P501</b></del>	Unikać wdychania par/rozpylonej cieczy. Stosować rękawice ochronne, odzież ochronną, ochronę oczu lub ochronę twarzy. <del>W PRZYPADKU POŁKNIECIA: W przypadku złego samopoczucia skontaktować się z OŚRODKIEM ZATRUĆ lub lekarzem</del> <del>Wypłukać usta.</del> W PRZYPADKU DOSTANIA SIĘ DO DRÓG ODDECHOWYCH: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić mu warunki do swobodnego oddychania. W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać. <del>W PRZYPADKU KONTAKTU ZE SKÓRĄ: Umyć dużą ilością wody.</del> Unikać uwolnienia do środowiska. <del>Zawartość/pojemnik usuwać do upoważnionego odbiorcy odpadów.</del>

### OPIS DZIAŁANIA

FUNGICYD w formie koncentratu do sporządzania emulsji wodnej (EC) o działaniu układowym do stosowania zapobiegawczego i interwencyjnego w ochronie przed chorobami powodowanymi przez grzyby. Zgodnie z klasyfikacją FRAC substancja czynna difenokonazol zaliczana jest do grupy 3.

### STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieźnych lub ciągnikowych opryskiwaczy polowych, samobieźnych, ciągnikowych lub opryskiwaczy ręcznych.

### **Rzepak ozimy**

*Sucha zgnilizna kapustnych*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha.

Termin stosowania: Zabieg wykonać wiosną, w fazie wydłużania pędu głównego, widocznego 2-ego międzywęźla do fazy widocznego 9-ego międzywęźla lub więcej międzywęźli (BBCH 32-39, wiosna). Środek stosować zapobiegawczo lub natychmiast po zauważeniu pierwszych objawów chorób.

*Zgnilizna twardzikowa*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,15 l/ha.

Termin stosowania: Zabieg wykonać zapobiegawczo lub z chwilą pojawienia się pierwszych objawów choroby, od początku fazy kwitnienia do pełni kwitnienia (ok. 50% kwiatów otwartych) (BBCH 60-65, wiosna).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200 - 300 l/ha.

Zalecane opryskiwanie: drobnokropliste.

### **Pszenica ozima**

*Mączniak prawdziwy zbóż i traw, septorioza paskowana liści, rdza brunatna, brunatna plamistość liści, septorioza plew*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha

Termin stosowania: Środek stosować zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów chorób, od fazy 3 kolanka do pełni fazy kłoszenia (odslania się 50% kwiatostanu) (BBCH 33-55, wiosna). Środek stosować nie częściej niż 1-2 razy w sezonie, w odstępie co 14-21 dni. W przypadku konieczności wykonania dwóch zabiegów, pierwszy zabieg zaleca się wykonać do fazy początku narzmienia pochwy liściowej liścia flagowego (wczesna faza rozwoju kłosa) (BBCH 41), drugi natomiast od fazy, gdy odslania się 30% kwiatostanu do pełni fazy kłoszenia (odslania się 50% kwiatostanu) (BBCH 53-55).

Liczba zabiegów: 2

Odstęp między zabiegami: co najmniej 14 dni.

Zalecana ilość wody: 200-300 l/ha

Zalecane opryskiwanie: średniokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

### **Pszenżyto ozime**

*Mączniak prawdziwy zbóż i traw, rdza brunatna, ~~septorioza~~ septorioza paskowana liści, septorioza plew*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1.0 l/ha

Termin stosowania: Środek stosować zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów chorób, od fazy 3. kolanka do pełni fazy kłoszenia (odslania się 50% kwiatostanu) (BBCH 33-55, wiosna). Środek stosować nie częściej niż 1-2 razy w sezonie, w odstępie co 14-21 dni. W przypadku konieczności wykonania dwóch zabiegów, pierwszy zabieg zaleca się wykonać do fazy początku narzmienia pochwy liściowej liścia flagowego (wczesna faza rozwoju kłosa) (BBCH 41), drugi natomiast od fazy, gdy odslania się 30% kwiatostanu do pełni fazy kłoszenia (odslania się 50% kwiatostanu) (BBCH 53-55).

Liczba zabiegów: 2

Odstęp między zabiegami: co najmniej 14 dni.

Zalecana ilość wody: 200-300 l/ha

Zalecane opryskiwanie: średniokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

## **STOSOWANIE ŚRODKA OCHRONY ROŚLIN W UPRAWACH I ZASTOSOWANIACH MAŁOObszarowych**

**Odpowiedzialność za skuteczność działania i fitotoksyczność środka ochrony roślin  
stosowanego w uprawach małoobszarowych ponosi wyłącznie jego użytkownik**

### **Rzepak jary, Inianka siewna**

*Sucha zgnilizna kapustnych*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha.

Termin stosowania: Zabieg wykonać w fazie wydłużania pędu głównego, widocznego 2-ego międzywęźla do fazy widocznego 9-ego międzywęźla lub więcej międzywęźli (BBCH 32-39). Środek stosować zapobiegawczo lub natychmiast po zauważeniu pierwszych objawów chorób.

*Zgnilizna twardzikowa*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,15 l/ha.

Termin stosowania: Zabieg wykonać zapobiegawczo lub z chwilą pojawienia się pierwszych objawów chorób, od początku fazy kwitnienia do pełni kwitnienia (ok. 50% kwiatów otwartych) (BBCH 60-65).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200 - 300 l/ha.

Zalecane opryskiwanie: drobnokropliste.

### **Len zwyczajny – wykorzystanie na olej, włókno oraz na nasiona**

*Sucha zgnilizna kapustnych*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha.

Termin stosowania: Zabieg wykonać zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów choroby w fazie wydłużania pędu głównego, widocznego 2-ego międzywęźla do fazy widocznego 9-ego międzywęźla lub więcej międzywęźli (BBCH 32-39).

*Zgnilizna twardzikowa*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,15 l/ha.

Termin stosowania: Zabieg wykonać zapobiegawczo lub z chwilą pojawienia się pierwszych objawów chorób, od początku fazy kwitnienia do pełni kwitnienia (ok. 50% kwiatów otwartych) (BBCH 60-65).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200 - 300 l/ha.

Zalecane opryskiwanie: drobnokropliste.

### **Mak lekarski**

*Sucha zgnilizna kapustnych*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha.

Termin stosowania: Zabieg wykonać zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów choroby w fazie wydłużania pędu głównego, widocznego 2-ego międzywęźla do fazy widocz-

nego 9-ego międzywęźla lub więcej międzywęźli (BBCH 32-39).

*Zgnilizna twardzikowa*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,15 l/ha.

Termin stosowania: Zabieg wykonać zapobiegawczo lub z chwilą pojawienia się pierwszych objawów chorób, od początku fazy kwitnienia do pełni kwitnienia (ok. 50% kwiatów otwartych) (BBCH 60-65).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200 - 300 l/ha.

Zalecane opryskiwanie: drobnokropliste.

**Gorczyca sarepska, gorczyca biała, gorczyca czarna**

*Sucha zgnilizna kapustnych*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha.

Termin stosowania: Zabieg wykonać zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów choroby, w fazie wydłużania pędu głównego, widocznego 2-ego międzywęźla do fazy widocznego 9-ego międzywęźla lub więcej międzywęźli (BBCH 32-39).

*Zgnilizna twardzikowa*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,15 l/ha.

Termin stosowania: Zabieg wykonać zapobiegawczo lub z chwilą pojawienia się pierwszych objawów chorób, od początku fazy kwitnienia do pełni kwitnienia (ok. 50% kwiatów otwartych) (BBCH 60-65).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200 - 300 l/ha.

Zalecane opryskiwanie: drobnokropliste.

**Słonecznik zwyczajny**

*Alternarioza słonecznika*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha.

Termin stosowania: Zabieg wykonać zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów choroby, w fazie wydłużania pędu głównego, widocznego 2-ego międzywęźla do fazy widocznego 9-ego międzywęźla lub więcej międzywęźli (BBCH 32-39).

*Zgnilizna twardzikowa, czarna plamistość łodyg słonecznika*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,15 l/ha.

Termin stosowania: Zabieg wykonać zapobiegawczo lub z chwilą pojawienia się pierwszych objawów chorób, od początku fazy kwitnienia do pełni kwitnienia (ok. 50% kwiatów otwartych) (BBCH 60-65).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200 - 300 l/ha.

Zalecane opryskiwanie: drobnokropliste.

**Soja**

*Cerkosporioza (chwościk soi), purpurowa cerkosporioza soi*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,15 l/ha.

Termin stosowania: Zabieg wykonać zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów choroby, w fazie wydłużania pędu głównego, widocznego 2-ego międzywęźla do fazy widocz-

nego 9-ego międzywęzła lub więcej międzywęzli (BBCH 32-39).

#### *Zgnilizna twardzikowa*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,15 l/ha.

Termin stosowania: Zabieg wykonać zapobiegawczo lub z chwilą pojawienia się pierwszych objawów chorób, od początku fazy kwitnienia do pełni kwitnienia (ok. 50% kwiatów otwartych) (BBCH 60-65).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200 - 300 l/ha.

Zalecane opryskiwanie: drobnokropliste.

### **ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA**

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji): pszenica ozima, pszenżyto ozime, rzepak ozimy, rzepak jary, lnianka siewna, len zwyczajny, mak lekarski, gorczyca sarepska, gorczyca biała, gorczyca czarna, słonecznik zwyczajny, soja – nie dotyczy.

Okres od ostatniego zastosowania środka na rośliny przeznaczone na paszę do dnia, w którym zwierzęta mogą być karmione tymi roślinami (okres karencji dla pasz): pszenica ozima, pszenżyto ozime, rzepak ozimy, rzepak jary, lnianka siewna, len zwyczajny, mak lekarski, gorczyca sarepska, gorczyca biała, gorczyca czarna, słonecznik zwyczajny, soja – nie dotyczy.

1. Środek stosować w temperaturze powietrza powyżej 12°C.
2. Środek zawiera substancję czynną difenokonazol (związek triazolowy, fungicydy inhibitory biosyntezy steroli – inhibitory demetylacji (SBI – DMI), wg klasyfikacji FRAC grupa 3). W ramach strategii przeciwdziałania odporności zaleca się m. in. stosowanie środka:
  - w terminach i dawkach zgodnie z etykietą,
  - przemiennie ze środkami grzybobójczymi zawierającymi substancje czynne z innych grup, o odmiennym mechanizmie działania.

Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następnie:

w razie konieczności wcześniejszej likwidacji plantacji, nie stosować środków zawierających difenokonazol na rośliny uprawiane następnie w sezonie wegetacyjnym, w którym został uprzednio zastosowany środek.

### **SPORZĄDZANIE CIECZY UŻYTKOWEJ**

**Odmierzoną ilość środka wymieszać w osobnym naczyniu z 5-10 razy większą ilością wody do momentu uzyskania jednorodnej mieszaniny. Następnie mieszaninę wlać przez sito do zbiornika opryskiwacza napełnionego do połowy wodą (z włączonym mieszadłem), uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Opryskiwać z włączonym mieszadłem.**

Po wlaniu środka do zbiornika opryskiwacza nie wyposażonego w mieszadło hydrauliczne ciecz mechanicznie wymieszać.

W przypadku przerw w opryskiwaniu przed przystąpieniem do pracy dokładnie wymieszać ciecz użytkową w zbiorniku opryskiwacza.

Opróżnione opakowanie przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową.



## POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej należy:

- jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

Z wodą użytą do mycia aparatury postąpić tak, jak z resztkami cieczy użytkowej, stosując te same środki ochrony osobistej.

W przypadku mycia aparatury przy użyciu środków myjących przeznaczonych do tego celu z powstałymi popłuczynami należy postępować zgodnie z instrukcją dołączona do środka myjącego.

## ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

Unikać wdychania rozpylonej cieczy.

Stosować rękawice ochronne, ochronę oczu i twarzy oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin, w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

Dokładnie umyć ręce po użyciu.

Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.

## ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

W przypadku uprawy zbóż ozimych, w celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

### **Pszenica ozima, pszenżyto ozime:**

- 1m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%, lub
- 2 m od zbiorników i cieków wodnych bez konieczności stosowania technik redukujących znoszenie cieczy użytkowej

W przypadku uprawy rzepaku ozimego, w celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

- 1m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 75 50%, lub
- 2m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 25%, lub
- 3 m od zbiorników i cieków wodnych bez konieczności stosowania technik redukujących znoszenie cieczy użytkowej

### **Rzepak jary, Inianka siewna**

w celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

- 1m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%, lub
- 2m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 25%, lub
- 3 m od zbiorników i cieków wodnych bez konieczności stosowania technik redukujących znoszenie cieczy użytkowej

### **Len zwyczajny – wykorzystywanie na olej, włókno oraz na nasiona**

w celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

- 1m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%, lub
- 2m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 25%, lub
- 3 m od zbiorników i cieków wodnych bez konieczności stosowania technik redukujących znoszenie cieczy użytkowej

### **Mak lekarski**

w celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

- 1m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%, lub
- 2m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 25%, lub
- 3 m od zbiorników i cieków wodnych bez konieczności stosowania technik redukujących znoszenie cieczy użytkowej

### **Gorczyca sarepska, gorczyca biała, gorczyca czarna**

w celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

- 1m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%, lub
- 2m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 25%, lub
- 3 m od zbiorników i cieków wodnych bez konieczności stosowania technik redukujących znoszenie cieczy użytkowej

### **Słonecznik zwyczajny**

w celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

- 1m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%, lub
- 2m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących

- znoszenie cieczy użytkowej podczas zabiegu o 25%, lub
- 3 m od zbiorników i cieków wodnych bez konieczności stosowania technik redukujących znoszenie cieczy użytkowej

#### **Soja**

w celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

- 1m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%, lub
- 2m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 25%, lub
- 3 m od zbiorników i cieków wodnych bez konieczności stosowania technik redukujących znoszenie cieczy użytkowej

W okresie kwitnienia rzepaku oraz innych kwitnących upraw małoobszarowych zaleca się stosować środek poza okresami aktywności pszczoł.

### **WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA**

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- pod zamknięciem,
- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0°C - 30°C.

Chronić przed wilgocią.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

### **PIERWSZA POMOC**

Antidotum brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W przypadku narażenia lub styczości: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

W przypadku dostania się do dróg oddechowych: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić warunki do odpoczynku w pozycji umożliwiającej swobodne oddychanie.

W przypadku kontaktu ze skórą: umyć dużą ilością wody z mydłem.

W przypadku dostania się do oczu: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać. Natychmiast skontaktować się z OŚRODKIEM ZATRUCIE/lekarzem.

W przypadku połknięcia: Natychmiast skontaktować się z ośrodkiem zatruc/lekarzem. Wypłukać usta.

~~W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza.~~

Okres ważności – 2 lata  
Data produkcji -  
Zawartość netto -  
Nr partii –

**Posiadacz zezwolenia:**


Synthos Agro Spółka z o.o., 32-600 Oświęcim, ul. Chemików 1 ; tel. +48 33 847 47 77; e-mail: [rejestracja@synthosgroup.com](mailto:rejestracja@synthosgroup.com)

**LIPOSTAR 90 EC**

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:  
difenokonazol (związek z grupy triazoli) - 90 g/l (%)

**Zezwolenie MRiRW nr R –**

	
<b>Niebezpieczeństwo</b>	
H302 H332 H351 H315 H318 H410	Działa szkodliwie po połknięciu. Działa szkodliwie w następstwie wdychania. Podejrzewa się, że powoduje raka. Działa drażniąco na skórę. Powoduje poważne uszkodzenie oczu. Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P261 P280  P301+P312  P330	Unikać wdychania par/rozpylonej cieczy. Stosować rękawice ochronne, odzież ochronną, ochronę oczu lub ochronę twarzy. W PRZYPADKU POŁKNIECIA: W przypadku złego samopoczucia skontaktować się z OŚRODKIEM ZATRUĆ lub lekarzem Wyplukać usta.

P304+P340	W PRZYPADKU DOSTANIA SIĘ DO DRÓG ODDECHOWYCH: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić mu warunki do swobodnego oddychania.
P305+P351+P338	W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
P302+P352	W PRZYPADKU KONTAKTU ZE SKÓRĄ: Umyć dużą ilością wody.
P273	Unikać uwolnienia do środowiska.
P501	Zawartość/pojemnik usuwać do upoważnionej odbiorcy odpadów.

## OPIS DZIAŁANIA

FUNGICYD w formie koncentratu do sporządzania emulsji wodnej (EC) o działaniu układowym do stosowania zapobiegawczego i interwencyjnego w ochronie przed chorobami powodowanymi przez grzyby. Zgodnie z klasyfikacją FRAC substancja czynna difenokonazol zaliczana jest do grupy 3.

## STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych, samobieżnych, ciągnikowych lub opryskiwaczy ręcznych.

### Rzepak ozimy

*Sucha zgnilizna kapustnych*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha.

Termin stosowania: Zabieg wykonać wiosną, w fazie wydłużania pędu głównego, widocznego 2-ego międzywęźla do fazy widocznego 9-ego międzywęźla lub więcej międzywęźli (BBCH 32-39, wiosna). Środek stosować zapobiegawczo lub natychmiast po zauważeniu pierwszych objawów chorób.

*Zgnilizna twardzikowa*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,15 l/ha.

Termin stosowania: Zabieg wykonać zapobiegawczo lub z chwilą pojawienia się pierwszych objawów choroby, od początku fazy kwitnienia do pełni kwitnienia (ok. 50% kwiatów otwartych) (BBCH 60-65, wiosna).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200 - 300 l/ha.

Zalecane opryskiwanie: drobnokropliste.

### Pszenica ozima

*Mączniak prawdziwy zbóż i traw, septorioza paskowana liści, rdza brunatna, brunatna plamistość liści, septorioza plew*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha

Termin stosowania: Środek stosować zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów chorób, od fazy 3 kolanka do pełni fazy kłoszenia (odslania się 50% kwiatostanu) (BBCH 33-55, wiosna). Środek stosować nie częściej niż 1-2 razy w sezonie, w odstępie co 14-21 dni. W przypadku konieczności wykonania dwóch zabiegów, pierwszy zabieg zaleca się wykonać do fazy początku nabrzmienia pochwy liściowej liścia flagowego (wczesna faza rozwoju kłosa) (BBCH 41), drugi natomiast od fazy, gdy odslania się 30% kwiatostanu do pełni fazy kłoszenia (odslania się 50% kwiatostanu) (BBCH 53-55).

Liczba zabiegów: 2

Odstęp między zabiegami: co najmniej 14 dni.

Zalecana ilość wody: 200-300 l/ha

Zalecane opryskiwanie: średniokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

### **Pszenżyto ozime**

*Mączniak prawdziwy zbóż i traw, rdza brunatna, ~~septoriozy~~ septorioza paskowana liści, septorioza plew*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1.0 l/ha

Termin stosowania: Środek stosować zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów chorób, od fazy 3. kolanka do pełni fazy kłoszenia (odslania się 50% kwiatostanu) (BBCH 33-55, wiosna). Środek stosować nie częściej niż 1-2 razy w sezonie, w odstępie co 14-21 dni. W przypadku konieczności wykonania dwóch zabiegów, pierwszy zabieg zaleca się wykonać do fazy początku nabrzmienia pochwy liściowej liścia flagowego (wczesna faza rozwoju kłosa) (BBCH 41), drugi natomiast od fazy, gdy odslania się 30% kwiatostanu do pełni fazy kłoszenia (odslania się 50% kwiatostanu) (BBCH 53-55).

Liczba zabiegów: 2

Odstęp między zabiegami: co najmniej 14 dni.

Zalecana ilość wody: 200-300 l/ha

Zalecane opryskiwanie: średniokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

## **STOSOWANIE ŚRODKA OCHRONY ROŚLIN W UPRAWACH I ZASTOSOWANIACH MAŁOObszarowych**

**Odpowiedzialność za skuteczność działania i fitotoksyczność środka ochrony roślin  
stosowanego w uprawach małoobszarowych ponosi wyłącznie jego użytkownik**

### **Rzepak jary, lnianka siewna**

*Sucha zgnilizna kapustnych*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha.

Termin stosowania: Zabieg wykonać w fazie wydłużania pędu głównego, widocznego 2-ego międzywęźla do fazy widocznego 9-ego międzywęźla lub więcej międzywęźli (BBCH 32-39). Środek stosować zapobiegawczo lub natychmiast po zauważeniu pierwszych objawów chorób.

*Zgnilizna twardzikowa*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,15 l/ha.

Termin stosowania: Zabieg wykonać zapobiegawczo lub z chwilą pojawienia się pierwszych objawów chorób, od początku fazy kwitnienia do pełni kwitnienia (ok. 50% kwiatów otwartych) (BBCH 60-65).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200 - 300 l/ha.

Zalecane opryskiwanie: drobnokropliste.

### **Len zwyczajny – wykorzystanie na olej, włókno oraz na nasiona**

*Sucha zgnilizna kapustnych*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha.

Termin stosowania: Zabieg wykonać zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych

objawów choroby w fazie wydłużania pędu głównego, widocznego 2-ego międzywęźla do fazy widocznego 9-ego międzywęźla lub więcej międzywęźli (BBCH 32-39).

#### *Zgnilizna twardzikowa*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,15 l/ha.

Termin stosowania: Zabieg wykonać zapobiegawczo lub z chwilą pojawienia się pierwszych objawów chorób, od początku fazy kwitnienia do pełni kwitnienia (ok. 50% kwiatów otwartych) (BBCH 60-65).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200 - 300 l/ha.

Zalecane opryskiwanie: drobnokropliste.

### **Mak lekarski**

#### *Sucha zgnilizna kapustnych*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha.

Termin stosowania: Zabieg wykonać zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów choroby w fazie wydłużania pędu głównego, widocznego 2-ego międzywęźla do fazy widocznego 9-ego międzywęźla lub więcej międzywęźli (BBCH 32-39).

#### *Zgnilizna twardzikowa*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,15 l/ha.

Termin stosowania: Zabieg wykonać zapobiegawczo lub z chwilą pojawienia się pierwszych objawów chorób, od początku fazy kwitnienia do pełni kwitnienia (ok. 50% kwiatów otwartych) (BBCH 60-65).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200 - 300 l/ha.

Zalecane opryskiwanie: drobnokropliste.

### **Gorczyca sarepska, gorczyca biała, gorczyca czarna**

#### *Sucha zgnilizna kapustnych*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha.

Termin stosowania: Zabieg wykonać zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów choroby, w fazie wydłużania pędu głównego, widocznego 2-ego międzywęźla do fazy widocznego 9-ego międzywęźla lub więcej międzywęźli (BBCH 32-39).

#### *Zgnilizna twardzikowa*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,15 l/ha.

Termin stosowania: Zabieg wykonać zapobiegawczo lub z chwilą pojawienia się pierwszych objawów chorób, od początku fazy kwitnienia do pełni kwitnienia (ok. 50% kwiatów otwartych) (BBCH 60-65).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200 - 300 l/ha.

Zalecane opryskiwanie: drobnokropliste.

### **Słonecznik zwyczajny**

#### *Alternarioza słonecznika*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha.

Termin stosowania: Zabieg wykonać zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych



objawów choroby, w fazie wydłużania pędu głównego, widocznego 2-ego międzywęźla do fazy widocznego 9-ego międzywęźla lub więcej międzywęźli (BBCH 32-39).

*Zgnilizna twardzikowa, czarna plamistość łodyg słonecznika*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,15 l/ha.

Termin stosowania: Zabieg wykonać zapobiegawczo lub z chwilą pojawienia się pierwszych objawów chorób, od początku fazy kwitnienia do pełni kwitnienia (ok. 50% kwiatów otwartych) (BBCH 60-65).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200 - 300 l/ha.

Zalecane opryskiwanie: drobnokropliste.

## Soja

*Cerkosporioza (chwościk soi), purpurowa cerkosporioza soi*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,15 l/ha.

Termin stosowania: Zabieg wykonać zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów choroby, w fazie wydłużania pędu głównego, widocznego 2-ego międzywęźla do fazy widocznego 9-ego międzywęźla lub więcej międzywęźli (BBCH 32-39).

*Zgnilizna twardzikowa*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,15 l/ha.

Termin stosowania: Zabieg wykonać zapobiegawczo lub z chwilą pojawienia się pierwszych objawów chorób, od początku fazy kwitnienia do pełni kwitnienia (ok. 50% kwiatów otwartych) (BBCH 60-65).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200 - 300 l/ha.

Zalecane opryskiwanie: drobnokropliste.

## ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji): pszenica ozima, pszenżyto ozime, rzepak ozimy, rzepak jary, lnianka siewna, len zwyczajny, mak lekarski, gorczyca sarepska, gorczyca biała, gorczyca czarna, słonecznik zwyczajny, soja – nie dotyczy.

Okres od ostatniego zastosowania środka na rośliny przeznaczone na paszę do dnia, w którym zwierzęta mogą być karmione tymi roślinami (okres karencji dla pasz): pszenica ozima, pszenżyto ozime, rzepak ozimy, rzepak jary, lnianka siewna, len zwyczajny, mak lekarski, gorczyca sarepska, gorczyca biała, gorczyca czarna, słonecznik zwyczajny, soja – nie dotyczy.

1. Środek stosować w temperaturze powietrza powyżej 12°C.
2. Środek zawiera substancję czynną difenokonazol (związek triazolowy, fungicydy inhibitory biosyntezy steroli – inhibitory demetylacji (SBI – DMI), wg klasyfikacji FRAC grupa 3). W ramach strategii przeciwdziałania odporności zaleca się m. in. stosowanie środka:
  - w terminach i dawkach zgodnie z etykietą,
  - przemiennie ze środkami grzybobójczymi zawierającymi substancje czynne z innych grup, o odmiennym mechanizmie działania.

Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następnie:

w razie konieczności wcześniejszej likwidacji plantacji, nie stosować środków zawierających difenokozol na rośliny uprawiane następnie w sezonie wegetacyjnym, w którym został uprzednio zastosowany środek.

## **SPORZĄDZANIE CIECZY UŻYTKOWEJ**

**Odmierzoną ilość środka wymieszać w osobnym naczyniu z 5-10 razy większą ilością wody do momentu uzyskania jednorodnej mieszaniny. Następnie mieszaninę wlać przez sito do zbiornika opryskiwacza napelnionego do połowy wodą (z włączonym mieszadłem), uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Opryskiwać z włączonym mieszadłem.**

Po wlaniu środka do zbiornika opryskiwacza nie wyposażonego w mieszadło hydrauliczne ciecz mechanicznie wymieszać.

W przypadku przerw w opryskiwaniu przed przystąpieniem do pracy dokładnie wymieszać ciecz użytkową w zbiorniku opryskiwacza.

Opróżnione opakowanie przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową.

## **POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY**

Resztki cieczy użytkowej należy:

- jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

Z wodą użytą do mycia aparatury postąpić tak, jak z resztkami cieczy użytkowej, stosując te same środki ochrony osobistej.

W przypadku mycia aparatury przy użyciu środków myjących przeznaczonych do tego celu z powstałymi popłuczynami należy postępować zgodnie z instrukcją dołączona do środka myjącego.

## **ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH**

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

Unikać wdychania rozpylonej cieczy.

Stosować rękawice ochronne, ochronę oczu i twarzy oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin, w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

Dokładnie umyć ręce po użyciu.

Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.

## **ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO**

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu

wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

W przypadku uprawy zbóż ozimych, w celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

**Pszenica ozima, pszenżyto ozime:**

- 1m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%, lub
- 2 m od zbiorników i cieków wodnych bez konieczności stosowania technik redukujących znoszenie cieczy użytkowej

W przypadku uprawy rzepaku ozimego, w celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

- 1m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 75 50%, lub
- 2m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 25%, lub
- 3 m od zbiorników i cieków wodnych bez konieczności stosowania technik redukujących znoszenie cieczy użytkowej

**Rzepak jary, lnianka siewna**

w celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

- 1m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%, lub
- 2m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 25%, lub
- 3 m od zbiorników i cieków wodnych bez konieczności stosowania technik redukujących znoszenie cieczy użytkowej

**Len zwyczajny – wykorzystywanie na olej, włókno oraz na nasiona**

w celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

- 1m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%, lub
- 2m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 25%, lub
- 3 m od zbiorników i cieków wodnych bez konieczności stosowania technik redukujących znoszenie cieczy użytkowej

**Mak lekarski**

w celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

- 1m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%, lub
- 2m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 25%, lub
- 3 m od zbiorników i cieków wodnych bez konieczności stosowania technik redukujących znoszenie cieczy użytkowej

### **Gorczyca sarepska, gorczyca biała, gorczyca czarna**

w celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

- 1m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%, lub
- 2m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 25%, lub
- 3 m od zbiorników i cieków wodnych bez konieczności stosowania technik redukujących znoszenie cieczy użytkowej

### **Słonecznik zwyczajny**

w celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

- 1m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%, lub
- 2m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 25%, lub
- 3 m od zbiorników i cieków wodnych bez konieczności stosowania technik redukujących znoszenie cieczy użytkowej

### **Soja**

w celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

- 1m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%, lub
- 2m od zbiorników i cieków wodnych, z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 25%, lub
- 3 m od zbiorników i cieków wodnych bez konieczności stosowania technik redukujących znoszenie cieczy użytkowej

W okresie kwitnienia rzepaku oraz innych kwitnących upraw małoobszarowych zaleca się stosować środki poza okresami aktywności pszczół.

## **WARUNKI PRZECHEWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA**

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- pod zamknięciem,
- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0°C - 30°C.

Chronić przed wilgocią.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

### **PIERWSZA POMOC**

Antidotum brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W przypadku narażenia lub styczości: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

W przypadku dostania się do dróg oddechowych: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić warunki do odpoczynku w pozycji umożliwiającej swobodne oddychanie.

W przypadku kontaktu ze skórą: umyć dużą ilością wody z mydłem.

W przypadku dostania się do oczu: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać. Natychmiast skontaktować się z OŚRODKIEM ZATRUCIE/lekarzem.

W przypadku połknięcia: Natychmiast skontaktować się z ośrodkiem zatruc/lekarzem. Wypłukać usta.

~~W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza.~~

Okres ważności – 2 lata

Data produkcji -

Zawartość netto -

Nr partii –

## **Appendix 3 Letter of Access**

## Appendix 4 Lists of data considered for national authorization

### 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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1	Kupiec J.	2023	SNS-F-11 Stage I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 13/23 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2023 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 2.2.1	Ołowski G.	2023	SNS-F-11 Determination of explosive properties Study code number: BW-02/23 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2023 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 2.2.2	Pachnicki P.	2023	SNS-F-11 Determination of flash point, auto-ignition temperature and oxidizing properties Study code number: BC-24/23 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2023 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 2.3.1	Pachnicki P.	2023	SNS-F-11 Determination of flash point, auto-ignition temperature and oxidizing properties	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Study code number: BC-24/23 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2023 GLP Unpublished				
KCP 2.3.3	Pachnicki P.	2023	SNS-F-11 Determination of flash point, auto-ignition temperature and oxidizing properties Study code number: BC-24/23 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2023 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 2.4.2	Kupiec J.	2023	SNS-F-11 Stage I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 13/23 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2023 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 2.5.1	Kupiec J.	2023	SNS-F-11 Stage I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 13/23 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2023 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 2.5.2	Kupiec J.	2023	SNS-F-11 Stage I: Determination of physicochemical properties of the initial preparation, after accelerated	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			and low temperature storage Study code number: BF – 13/23 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2023 GLP Unpublished				
KCP 2.6.1	Kupiec J.	2023	SNS-F-11 Stage I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 13/23 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2023 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 2.7.1	Kupiec J.	2023	SNS-F-11 Stage I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 13/23 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2023 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 2.7.3	Kupiec J.	2023	SNS-F-11 Stage I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 13/23 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2023 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 2.7.4	Kupiec J.	2023	SNS-F-11	N	Y	Data/study report never	Synthos Agro

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Stage I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 13/23 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2023 GLP Unpublished			submitted before to Poland	Sp. z o.o.
KCP 2.7.5	Łysik A.	2024	SNS-F-11 Stage II: Determination of physicochemical properties after one year of storage Study code number: BF – 13/23 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2024 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 2.8.2	Kupiec J.	2023	SNS-F-11 Stage I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 13/23 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2023 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 2.8.6.1	Kupiec J.	2023	SNS-F-11 Stage I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 13/23 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2023 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.8.6.2	Kupiec J.	2023	SNS-F-11 Stage I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 13/23 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2023 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 2.8.6.3	Kupiec J.	2023	SNS-F-11 Stage I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 13/23 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2023 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 2.11.1	Paleń P.	2023	SNS-F-11 Effectiveness of equipment cleaning procedure Study code number: AGRO/19/23 Synthos Agro Sp.z o.o. Oświęcim, 2023 Non – GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 2.11.2	Kupiec J.	2023	SNS-F-11 Stage I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 13/23 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2023 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.1	Kupiec J.	2023	SNS-F-11 Stage I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storageJarosław Kupiec, M.Sc., 2023 Study code: BF – 13/23 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 5.1.2	Wójcik M.	2022	Valor 250 EC: Determination of the residues of difenoconazole in winter wheat. Study code: C-08-21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry (Branch Pszczyna) Analytical phase, GLP Unpublished	N	Y	Data/study report submitted before to Poland (data protection still ongoing)	Synthos Agro Sp. z o.o.
KCP 5.1.2	Schernikau N.	2024	Determination of the residues of difenoconazole and triazole derivative metabolites in oilseed rape following one application of Tores 250 EC in four trials in Northern Europe 2023 Study code: S23-103661 Eurofins Agroscience Services Chem GmbH GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 5.1.2	Schernikau N., Kissmann H.	2024	Determination of the residues of difenoconazole and triazole derivative metabolites in oilseed rape following one application of SNS-F-11 in four trials in Poland 2023 Study code: S23-103662 Eurofins Agroscience Services Chem GmbH GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 5.1.2	Schernikau N.	2023	Determination of the residues of difenoconazole and triazoles derivative metabolites in honey following application of Tores 250 EC in four trials in Northern	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Europe 2023 Study code: SYT-2303 Eurofins Agroscience Services Chem GmbH GLP Unpublished				
KCP 5.1.2	Wróbel A.	2023	SNS-F-11 Earthworm reproduction test ( <i>Eisenia andrei</i> ) Study code: G-09-23 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry (Branch Pszczyna) GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 5.1.2	Hodorek G.	2023	SNS-F-11 <i>Raphidocelis subcapitata</i> SAG 61.81 (formerly <i>Pseudokirchneriella subcapitata</i> ), Growth inhibition test Study code: W-42-22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry (Branch Pszczyna) GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 5.1.2	Czarnecka M.	2023	SNS-F-11 Rainbow trout, Acute Toxicity Testing Study code: W-45-22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry (Branch Pszczyna) GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 5.2	Wojciech A.	2023	SNS-F-11 Honeybees ( <i>Apis mellifera</i> L.), Larval Toxicity Test, Repeated Exposure Study code: B-01-23 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry (Branch Pszczyna) GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 5.2	Wojciech A.	2023	SNS-F-11 Bumblebees ( <i>Bombus spp.</i> ), Acute Oral Toxicity Test	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Study code: B-02-23 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry (Branch Pszczyna) GLP Unpublished				
KCP 5.2	Wojciech A.	2023	SNS-F-11 Bumblebees ( <i>Bombus spp.</i> ), Acute Contact Toxicity Test Study code: B-03-23 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry (Branch Pszczyna) GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 5.2	Wojciech A.	2023	SNS-F-11 Honeybees ( <i>Apis mellifera L.</i> ), Chronic Oral Toxicity Test Study code: B-04-23 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry (Branch Pszczyna) GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 5.2	Hodorek G.	2023	SNS-F-11 <i>Daphnia magna</i> , Acute Immobilisation Test Study code: W-41-22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry (Branch Pszczyna) GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 5.2	Pieczka P.	2024	SNS-F-11 Terrestrial Plant Test: Vegetative Vigour Test Study code: G-46-24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry (Branch Pszczyna) GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 5.2	Gierbuszewska A.	2024	SNS-F-11 Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Study code: G-47-24	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Lukasiewicz Research Network – Institute of Industrial Organic Chemistry (Branch Pszczyna) GLP Unpublished				
KCP 6.2 KCP 6.4.3	Maczyńska A.	2022	Analysis of quality parameters of winter oilseed rape after application of SNS-F-11. 26 J/2022 Institute of Plant Protection – National Research Institute, Sosnowice Branch GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Maczyńska A.	2022	Biological efficacy expertise of fungicide SNS-F-11 (90 EC) for <i>Leptosphaeria maculans</i> control in winter oilseed rape. 100 F/2022 Institute of Plant Protection – National Research Institute, Sosnowice Branch GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krawczuk M.	2022	Efficacy evaluation of SNS-F-11 when applied into winter oilseed rape to control of <i>Plenodomus lingam</i> , Poland, 2022 SGS/2022/070/PL03 SGS Polska Sp. z o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krawczuk M.	2022	Efficacy evaluation of SNS-F-11 when applied into winter oilseed rape to control of <i>Plenodomus lingam</i> , Poland, 2022. SGS/2022/070/PL04 SGS Polska Sp. z o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Maczyńska A.	2022	Analysis of quality parameters of winter oilseed rape	N	Y	Data/study report never	Synthos Agro

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4.3			after application of SNS-F-11. 25 J/2022 Institute of Plant Protection – National Research Institute, Sosnicowice Branch GEP Unpublished			submitted before to Poland	Sp. z o.o.
KCP 6.2	Maczyńska A.	2022	Biological efficacy expertise of fungicide SNS-F-11 (90 EC) for <i>Sclerotinia sclerotiorum</i> control in winter oilseed rape. 101 F/2022 Institute of Plant Protection – National Research Institute, Sosnicowice Branch GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Danielewicz B.	2022	An evaluation of the efficacy TORES 250 EC and SNS-F-11 against fungal diseases in oilseed rape. 334/2022 Institute of plant protection – national research institute. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krawczuk M.	2022	Efficacy evaluation of SNS-F-11 when applied into winter oilseed rape to control of <i>Sclerotinia sclerotiorum</i> , Poland, 2022 SGS/2022/070/PL01 SGS Polska Sp. z o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krawczuk M.	2022	Efficacy evaluation of SNS-F-11 when applied into winter oilseed rape to control of <i>Sclerotinia sclerotiorum</i> , Poland, 2022 SGS/2022/070/PL02 SGS Polska Sp. z o.o.	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP Unpublished				
KCP 6.2	Płonka P	2022	Biological efficacy expertise of fungicide SNS-F-11 (90 EC) for <i>Blumeria graminis</i> ( <i>Erysiphe graminis</i> ), <i>Puccinia recondita</i> control in winter wheat. 119 F/2022 Institute of Plant Protection – National Research Institute, Sosnowice Branch GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Danielewicz B.	2022	An evaluation of the efficacy SNS-F-11 and Tores 250 EC against fungal diseases in winter wheat. 332/2022 Institute of plant protection – national research institute. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Danielewicz B.	2022	An evaluation of the efficacy SNS-F-11 and Tores 250 EC against fungal diseases in winter wheat. 333/2022 Institute of plant protection – national research institute. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krawczuk M.	2022	Efficacy evaluation of SNS-F-11 when applied into winter wheat to control of foliar diseases, Poland, 2022. SGS/2022/069/PL01 SGS Polska Sp. z o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krawczuk M.	2022	Efficacy evaluation of SNS-F-11 when applied into winter wheat to control of foliar diseases, Poland, 2022.	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			SGS/2022/069/PL02 SGS Polska Sp. z o.o. GEP Unpublished				
KCP 6.2	Krawczuk M.	2022	Efficacy evaluation of SNS-F-11 when applied into winter wheat to control of foliar diseases, Poland, 2022. SGS/2022/069/PL03 SGS Polska Sp. z o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krawczuk M.	2022	Efficacy evaluation of SNS-F-11 when applied into winter wheat to control of foliar diseases, Poland, 2022. SGS/2022/069/PL04 SGS Polska Sp. z o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2 KCP 6.4.3	Mączyńska A.	2023	Analysis of quality parameters of winter oilseed rape after application of fungicides SNS-F-11 (90 EC), Tores 250 EC. 2 J/2023 Institute of Plant Protection – National Research Institute, Sosnowice Branch GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Mączyńska A.	2023	Biological efficacy expertise of fungicides SNS-F-11 (90 EC), Tores 250 EC for <i>Leptosphaeria maculans</i> control in winter oilseed rape. 31 F/2023 Institute of Plant Protection – National Research Institute, Sosnowice Branch GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2 KCP 6.4.3	Mączyńska A.	2023	Analysis of quality parameters of winter oilseed rape after application of fungicide SNS-F-11 (90 EC).	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			3 J/2023 Institute of Plant Protection – National Research Institute, Sosnicowice Branch GEP Unpublished				
KCP 6.2	Maczyńska A.	2023	Biological efficacy expertise of fungicide SNS-F-11 (90 EC) for <i>Sclerotinia sclerotiorum</i> control in winter oilseed rape. 32 F/2023 Institute of Plant Protection – National Research Institute, Sosnicowice Branch GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Płonka P.	2023	Biological efficacy expertise of fungicides SNS-F-11 (90 EC), Tores 250 EC for <i>Blumeria graminis</i> ( <i>Erysiphe graminis</i> ), <i>Puccinia recondita</i> , <i>Zymoseptoria tritici</i> control in winter wheat. 63 F/2023 Institute of Plant Protection – National Research Institute, Sosnicowice Branch GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krawczuk M.	2023	Efficacy evaluation of SNS-F-11 containing the active substance: difenoconazole, in EC formulation. when applied into winter wheat to control of foliar diseases, Poland, 2023. SGS/2023/041/PL05 SGS Polska Sp. z o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krawczuk M.	2023	Efficacy evaluation of SNS-F-11 containing the active substance: difenoconazole, in EC formulation. when applied into winter wheat to control of foliar diseases, Poland, 2023.	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			SGS/2023/041/PL06 SGS Polska Sp. z o.o. GEP Unpublished				
KCP 6.2	Krawczuk M.	2023	Efficacy evaluation of SNS-F-11 containing the active substance: difenoconazole, in EC formulation. when applied into winter wheat to control of foliar diseases, Poland, 2023. SGS/2023/041/PL01 SGS Polska Sp. z o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krawczuk M.	2023	Efficacy evaluation of SNS-F-11 containing the active substance: difenoconazole, in EC formulation. when applied into winter wheat to control of foliar diseases, Poland, 2023. SGS/2023/041/PL02 SGS Polska Sp. z o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krawczuk M.	2023	Efficacy evaluation of SNS-F-11 containing the active substance: difenoconazole, in EC formulation. when applied into winter wheat to control of foliar diseases, Poland, 2023. SGS/2023/041/PL04 SGS Polska Sp. z o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Siekaniec Ł.	2023	Expertise of the effectiveness of fungicide SNS-F-11 90 EC and TORES 250 EC int the control fungal diseases in the cultivation of winter wheat, 323/2023 Institute of Plant Protection – National Research Institute, Research. Research Centre for Registration of	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Agrochemicals Fungicide Research Team GEP Unpublished				
KCP 6.2	Korbas A.	2023	Expertise of the effectiveness of fungicide SNS-F-11 90 EC and TORES 250 EC int the control fungal diseases in the cultivation of winter wheat, 319/2023 Institute of Plant Protection – National Research Institute, Research. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Siekaniec Ł.	2023	Expertise of the effectiveness of fungicide SNS-F-11 90 EC and TORES 250 EC int the control fungal diseases in the cultivation of winter wheat, 324/2023 Institute of Plant Protection – National Research Institute, Research. Research Centre for Registration of Agrochemicals Fungicide Research Team GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krawczuk M.	2023	Efficacy evaluation of SNS-F-11 containing the active substance: difenoconazole, in formulation EC when applied into winter oilseed rape to control of <i>Plenodomus lingam</i> , Poland, 2023 SGS/2023/042/PL01 SGS Polska Sp. z o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krawczuk M.	2023	Efficacy evaluation of SNS-F-11 containing the active substance: difenoconazole, in formulation EC when applied into winter oilseed rape to control of <i>Plenodomus lingam</i> , Poland, 2023 SGS/2023/042/PL02	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			SGS Polska Sp. z o.o. GEP Unpublished				
KCP 6.2	Krawczuk M.	2023	Efficacy evaluation of SNS-F-11 containing the active substance: difenoconazole, in formulation EC when applied into winter oilseed rape to control of <i>Plenodomus lingam</i> , Poland, 2023 SGS/2023/042/PL03 SGS Polska Sp. z o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krawczuk M.	2023	Efficacy evaluation of SNS-F-11 containing the active substance: difenoconazole, in formulation EC when applied into winter oilseed rape to control of <i>Sclerotinia sclerotiorum</i> . SGS/2023/043/PL01 SGS Polska Sp. z o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krawczuk M.	2023	Efficacy evaluation of SNS-F-11 containing the active substance: difenoconazole, in formulation EC when applied into winter oilseed rape to control of <i>Sclerotinia sclerotiorum</i> . SGS/2023/043/PL02 SGS Polska Sp. z o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krawczuk M.	2023	Efficacy evaluation of SNS-F-11 containing the active substance: difenoconazole, in formulation EC when applied into winter oilseed rape to control of <i>Sclerotinia sclerotiorum</i> . SGS/2023/043/PL03 SGS Polska Sp. z o.o. GEP	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 6.2	Krawczuk M.	2023	Efficacy evaluation of SNS-F-11 containing the active substance: difenoconazole, in EC formulation. when applied into winter triticale to control of foliar diseases, Poland, 2023. SGS/2023/089/PL01 SGS Polska Sp. z o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krawczuk M.	2023	Efficacy evaluation of SNS-F-11 containing the active substance: difenoconazole, in EC formulation. when applied into winter triticale to control of foliar diseases, Poland, 2023. SGS/2023/089/PL02 SGS Polska Sp. z o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krawczuk M.	2023	Efficacy evaluation of SNS-F-11 containing the active substance: difenoconazole, in EC formulation. when applied into winter triticale to control of foliar diseases, Poland, 2023. SGS/2023/089/PL03 SGS Polska Sp. z o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krawczuk M.	2023	Efficacy evaluation of SNS-F-11 containing the active substance: difenoconazole, in EC formulation. when applied into winter triticale to control of foliar diseases, Poland, 2023. SGS/2023/089/PL04 SGS Polska Sp. z o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krawczuk M.	2023	Efficacy evaluation of SNS-F-11 containing the active substance: difenoconazole, in EC formulation. when applied into winter triticale to control of foliar diseases, Poland, 2023. SGS/2023/089/PL04 SGS Polska Sp. z o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 6.2	Krawczuk M.	2023	Efficacy evaluation of SNS-F-11 containing the active substance: difenoconazole, in EC formulation. when applied into winter triticale to control of foliar diseases, Poland, 2023. SGS/2023/089/PL04 SGS Polska Sp. z o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			substance: difenoconazole, in EC formulation. when applied into winter triticale to control of foliar diseases, Poland, 2023. SGS/2023/089/PL05 SGS Polska Sp. z o.o. GEP Unpublished			submitted before to Poland	Sp. z o.o.
KCP 7.2.3. (KCA 6.3)	Figurski R.	2021	Magnitude of residue of difenoconazole (CAS 119446-68-3) in winter wheat (Raw Agricultural Commodity – RAC) grown in open field conditions after two applications of a formulated product Valor 250 EC – four harvest trials and four decline curve trials in Northern Europe – Poland (2021) Study code: 21FRT-32TRZAWDFKN Field phase, GLP Unpublished	N	Y	Data/study report submitted before to Poland (data protection still ongoing)	Synthos Agro Sp. z o.o.
KCP 7.2.3. (KCA 6.3)	Wójcik M.	2022	Valor 250 EC: Determination of the residues of difenoconazole in winter wheat. Study code: C-08-21 Analytical phase, GLP Unpublished	N	Y	Data/study report submitted before to Poland (data protection still ongoing)	Synthos Agro Sp. z o.o.
KCP 7.2.3. (KCA 6.3)	Kurek-Molenda M.	2023	Determination of the residues of difenoconazole and triazole derivative metabolites in/on outdoor winter oilseed rape after one application of SNS-F-11 in Poland in 2023. Study code: EU-23-1359 Field phase, GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 7.2.3. (KCA 6.3)	Schernikau N., Kissmann H.	2024	Determination of the residues of difenoconazole and triazole derivative metabolites in oilseed rape following one application of SNS-F-11 in four trials in Poland 2023. Study code: S23-103662 Analytical phase, GLP	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 7.2.3. (KCA 6.3)	Lines J.	2023	Study to generate samples of winter oilseed rape following one application of Tores 250 EC for subsequent residue analysis. 4 sites in Northern Europe 2023. Study code: S23-103623 Field phase, GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 7.2.3. (KCA 6.3)	Schernikau N.	2024	Determination of the residues of difenoconazole and triazole derivative metabolites in oilseed rape following one application of Tores 250 EC in four trials in Northern Europe 2023. Study code: S23-103661 Analytical phase, GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 7.2.7 (KCA 6.3)	Kurek-Molenda M.	2023	Honey residue study with difenoconazole on Phacelia after application of Tores 250 EC Poland 2023. Study code: EU-23-1667 Field phase, GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 7.2.7 (KCA 6.3)	Portail B.	2024	Study to generate samples of honey after two application of TORES 250 EC in <i>Phacelia tanacetifolia</i> for subsequent residue analysis at two sites in Germany in 2023. Study code: S23-103847 Field phase, GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 7.2.7 (KCA 6.3)	Schernikau N.	2023	Determination of the residues of difenoconazole and triazoles derivative metabolites in honey following application of Tores 250 EC in four trials in Northern Europe 2023. Study code: S23-103664 Analytical phase, GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 7.1.4	Krakowian D.	2023	SNS-F-11: <i>In vitro</i> Skin Corrosion: Reconstructed Human Epidermis Test Method. Krakowian D., 2023.	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Study code: SCT-01-23. Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished				
KCP 7.1.5	Krakowian D.	2023	SNS-F-11: Reconstructed human Cornea-like Epithelium (RhCE) test method for identifying chemicals not requiring classification and labelling for eye irritation or serious eye damage. Krakowian D., 2023. Study code: EIT-01-23. Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 7.1.5	Toczko M.	2023	SNS-F-11: Isolated Chicken Eye Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classifications for Eye Irritation or Serious Eye Damage. Sornat R., 2023, Study code: ICE-02-23. Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 10.2	Hodorek G.	2023	SNS-F-11 <i>Daphnia magna</i> , Acute Immobilisation Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: W-41-22 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 10.2	Hodorek G.	2023	SNS-F-11 <i>Raphidocelis subcapitata</i> SAG 61.81 (formerly <i>Pseudokirchneriella subcapitata</i> ), Growth inhibition test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Study code: W-42-22 GLP Unpublished				
KCP 10.2	■	2023	SNS-F-11 Rainbow trout, Acute Toxicity Testing Łukasiewicz Research Network – Institute of Industrial ■ Study code: W-45-22 GLP Unpublished	Y	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 10.3.1	Wojciech A.	2023	SNS-F-11 Honeybees ( <i>Apis mellifera</i> L.), Larval Toxicity Test, Repeated Exposure Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: B-01-23 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 10.3.1	Wojciech A.	2023	SNS-F-11 Honeybees ( <i>Apis mellifera</i> L.), Chronic Oral Toxicity Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: B-04-23 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 10.3.1	Wojciech A.	2023	SNS-F-11 Bumblebees ( <i>Bombus</i> spp.), Acute Oral Toxicity Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: B-02-23 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 10.3.1	Wojciech A.	2023	SNS-F-11 Bumblebees ( <i>Bombus</i> spp.), Acute Contact Toxicity Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Study code: B-03-23 GLP Unpublished				
KCP 10.3.1	Kapa D.	2023	SNS-F-11 Honeybees ( <i>Apis mellifera</i> L.), Acute Oral Toxicity Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: B-05-23 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 10.3.1	Kapa D.	2023	SNS-F-11 Honeybees ( <i>Apis mellifera</i> L.), Acute Contact Toxicity Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: B-06-23 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 10.3.2	Kapa D.	2023	A laboratory test for evaluating the effects of SNS-F-11 on the predatory mite, <i>Typhlodromus pyri</i> (Sch.) Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: B-42-23 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 10.3.2	Wojciech A.	2023	A laboratory test for evaluating the effects of SNS-F-11 on the parasitic wasp, <i>Aphidius rhopalosiphi</i> (De Stefani-Perez) Study code: B-43-23 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: B-43-23 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 10.4	Wróbel A.	2023	SNS-F-11 Earthworm Reproduction Test ( <i>Eisenia andrei</i> )	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: G-09-23 GLP Unpublished				
KCP 10.5	Pieczka P.	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	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 10.6	Pieczka P.	2024	SNS-F-11 Terrestrial Plant Test: Vegetative Vigour Test Study code: G-46-24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry (Branch Pszczyna) GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Synthos Agro Sp. z o.o.
KCP 10.6	Gierbuszewska A.	2024	SNS-F-11 Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Study code: G-47-24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry (Branch Pszczyna) GLP Unpublished	N	Y	Data/study report never submitted before to Poland	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**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCP 5.1.2	Wurz R.E.M.	1994	Analytical method for the determination of CGA 169374 residues in dairy and poultry tissue, eggs and milk by gas chromatography Syngenta Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, United States, Report No AG-544A Syngenta File N° CGA169374/0933 Not GLP Not Published	N	N	-	Syngenta
KCP 5.2	Benazeraf L.	2004	Independent Laboratory Validation of Residue Method REM 147.07 for the Determination of Difenconazole and CGA205375 in Animal Products Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergèze, France, Report No SYN/DIF/04031 GLP Not Published Syngenta File N° CGA169374/2535	N	N	-	Syngenta
KCP 5.2	Crook S. J.	2004	Residue Method for the Determination of Residues of Difenconazole (CGA169374) and CGA 205375 in Animal Products. Final Determination by LC-MS/MS Syngenta Crop Protection AG, Basel, Switzerland Syngenta, Jealott's Hill, United Kingdom, Report No REM 147.07 Not GLP Not Published Syngenta File N° CGA205375/0021	N	N	-	Syngenta
KCP 5.2	Ryan J.	2004b	Difenconazole (CGA169374) and CGA205375: Validation of Residue Analytical Method REM 147.07 for the Determination of Residues in Animal Products Syngenta Crop Protection AG, Basel, Switzerland Syngenta, Jealott's Hill, United Kingdom,	N	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report No RJ3478B GLP Not Published Syngenta File N° CGA205375/0020				
KCP 5.2	Schulz H.	2004	Independent Laboratory Validation of DFG Method S19 (Extended Revision) for the Determination of Residues of difenoconazole in/on plant matrices Syngenta Crop Protection AG, Basel, Switzerland Institut Fresenius, Taunusstein, Germany, Report No IF-04/00160619 GLP Not Published Syngenta File N° CGA169374/2507	N	N	-	Syngenta
KCP 5.2	Steinhauer S.	2004a	Difenoconazole: Validation of the DFG Method S 19 (Extended Revision) for the Determination of Residues of Difenoconazole in Milk, Meat, Fat, Egg, Liver and Kidney Syngenta Crop Protection AG, Basel, Switzerland Dr. Specht & Partner Chem. Laboratorien GmbH, Hamburg, Germany, Report No SYN-0302V Az. G03-0024 GLP Not Published Syngenta File N° CGA169374/2443	N	N	-	Syngenta
KCP 5.2	Tribolet R.	1990	CGA 169374, Determination of residues of parent compound by gas liquid chromatography (GLC), potable water Novartis Crop Protection AG, Switzerland Ciba-Geigy Ltd., Basel, Switzerland Report No REM-147-01 Not GLP, Not Published Syngenta File N° CGA169374/0055	N	N	-	Syngenta
KCP 5.2	Tribolet R.	1992	Sampling of air and determination of residues of parent compound by high performance liquid chromatography NCP/Novartis Crop Protection AG, Switzerland Ciba-Geigy Ltd., Basel, Switzerland	N	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report No REM133-03, 15/12/1992 GLP, Not Published Syngenta File N° CGA173506/0234				
KCP 5.2	Tribolet R.	1992	Sampling of air and determination of residues of parent compound by gas chromatography Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No REM-147-02 Not GLP Not Published Syngenta File N° CGA169374/0722	N	N	-	Syngenta
KCP 5.2	Tribolet R.	1996	Report on Special Study 102/96. Validation of method REM 147.02 in air, Validation by analysis of fortified specimens and determination of recoveries Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No 102/96 GLP Not Published Syngenta File N° CGA169374/1192	N	N	-	Syngenta
KCP 5.2	Tribolet R.	1999a	Determination of parent compound by gas chromatography, Water Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No REM 147.05 Not GLP Not Published Syngenta File N° CGA169374/1783	N	N	-	Syngenta
KCP 5.2	Tribolet R.	1999b	Validation of method 147.05 by Analysis of Fortified Water Specimens for Difenoconazole (CGA 169374) and Evaluation of Recoveries Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No 226/98	N	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Not Published Syngenta File N° CGA169374/1782				
KCP 5.2	Tummon O.J.	2004a	Difenoconazole. Validation of an Analytical Method for the Determination of Residues of Difenoconazole and CGA205375 in Soil Syngenta Crop Protection AG, Basel, Switzerland Syngenta, Jealott's Hill, United Kingdom, Report No RJ3459B GLP Not Published Syngenta File N° CGA169374/2501	N	N	-	Syngenta
KCP 5.2	Tummon O.J.	2004b	Difenoconazole. Validation of an Analytical Method for the Determination of Residues of Difenoconazole in Air Syngenta Crop Protection AG, Basel, Switzerland Syngenta, Jealott's Hill, United Kingdom, Report No RJ3495B GLP Not Published Syngenta File N° CGA169374/2500	N	N	-	Syngenta
KCP 7.2.1 (KCA. 6.1)	Beidler WT.	1991a	Stability of CGA-169374 residues in potatoes under freezer storage conditions for 2 years. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-90070. GLP, Published. Syngenta File No CGA 169374/0453	N	N	-	Syngenta
KCP 7.2.1 (KCA. 6.1)	Beidler WT.	1991b	Stability of CGA-169374 residues in potatoes under freezer storage conditions for 2 years. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-90069. GLP, Published. Syngenta File No CGA 169374/0452	N	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.2.1 (KCA. 6.1)	Beidler WT.	1992	Stability of CGA-169374 residues in lettuce, soybeans and wheat forage under freezer storage conditions for one year. Syngenta Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-91024. GLP, Published. Syngenta File No CGA 169374/0617	N	N	-	Syngenta
KCP 7.2.1 (KCA. 6.1)	Kühne-Thu H.	1994	Residue stability of CGA-169374 (difenoconazole) in banana (whole fruit) under freezer storage conditions. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd. Basel, Switzerland. Report No 125/93. GLP, Published. Syngenta File No CGA 169374/0934	N	N	-	Syngenta
KCP 7.2.1 (KCA. 6.1)	Hayworth CG.	1998	Stability of CGA-169374 fortified into wheat and cotton substrates under freezer conditions. Novartis Crop Protection AG, Basel, Switzerland. Novartis Crop Protection Inc., Greensboro, United States Report No ABR-98061. GLP, Published. Syngenta File No CGA 169374/1644	N	N	-	Syngenta
KCP 7.2.1 (KCA. 6.1)	Wurz REM.	1993a	Storage stability study of CGA-169374 in dairy and poultry tissues, eggs and milk under freezer storage conditions. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-93012. GLP, Published. Syngenta File No CGA 169374/0795	N	N	-	Syngenta
KCP 7.2.1 (KCA. 6.1)	■■■■■	2000	Residue of difenoconazole (CGA 169374) and its metabolite CGA 205375 in milk, blood, and tissues (muscle, fat, liver, kidney) of dairy cattle resulting from feeding of difenoconazole at three dose levels. ■■■■■ Report No 202/99.	N	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP, Published. Syngenta File No CGA 169374/2039				
KCP 7.2.2 (KCA 6.2.1)	Madrid SO. Huber MK	1987a	The distribution and characterization of phenyl-14C vs. triazole 14C-CGA 169374 on spray treated tomatoes – a side by side comparison study in greenhouse. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-87025. Not GLP, Published. Syngenta File No CGA 169374/0043	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Madrid SO. Huber MK	1987b	The distribution and characterization of phenyl-14C vs. triazole 14C-CGA 169374 on their metabolites in field grown tomatoes. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-87033. Not GLP, Published. Syngenta File No CGA 169374/0044	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Velagaleti PR.	1990a	Metabolism of triazole-14C-CGA 169374 in spray-treated tomatoes. Novartis Crop Protection AG, Basel, Switzerland. Battelle, Columbus, United States Report No N-0964-0600. GLP, Published. Syngenta File No CGA 169374/0355	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Schweitzer MG.	1990a	Metabolism of phenyl-14C-CGA 169374 in spray-treated tomatoes. Novartis Crop Protection AG, Basel, Switzerland. Battelle, Columbus, United States Report No N-0964-0700. GLP, Published. Syngenta File No CGA 169374/0356	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Hubbard L.	1991a	Uptake and metabolism of 14C-CGA 169374 by wheat resulting from seed treatment application under field condi-	N	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			tions. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-90009. GLP, Published. Syngenta File No CGA 169374/0415				
KCP 7.2.2 (KCA 6.2.1)	Hubbard L.	1991b	Uptake and metabolism of 14C-CGA 169374 by wheat resulting from seed treatment application under greenhouse conditions. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-90010. GLP, Published. Syngenta File No CGA 169374/0416	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Hubbard L.	1991c	Uptake and metabolism of 14C-CGA 169374 by wheat resulting from foliar spray application under greenhouse environment. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-90011. GLP, Published. Syngenta File No CGA 169374/0417	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Schweitzer MG.	1990b	Metabolism of phenyl-14C-CGA 169374 in spray-treated potatoes. Novartis Crop Protection AG, Basel, Switzerland. Battelle, Columbus, United States Report No N-0964-0400. GLP, Published. Syngenta File No CGA 169374/0357	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Velagaleti PR.	1990b	Metabolism of triazole-14C-CGA 169374 in spray-treated potatoes. Novartis Crop Protection AG, Basel, Switzerland. Battelle, Columbus, United States Report No N-0964-0500.	N	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP, Published. Syngenta File No CGA 169374/0489				
KCP 7.2.2 (KCA 6.2.1)	Capps T.	1992	Uptake and metabolism of 14C-CGA 169374 by grapes from foliar spray treatment. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-92003. GLP, Published. Syngenta File No CGA 169374/0537	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Naumann Ch.	1993a	Metabolism of [Phenyl-14C] CGA-169374 in field grown spring rape. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd. Basel, Switzerland. Report No 11/93. GLP, Published. Syngenta File No CGA 169374/0809	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.2.1)	Naumann Ch.	1993b	Metabolism of [Triazole-14C] CGA-169374 in field grown spring rape. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd. Basel, Switzerland. Report No 12/93. GLP, Published. Syngenta File No CGA 169374/0810	N	N	-	Syngenta
KCP 7.2.2. (KCA 6.2.2 – 6.2.5)	■■■■	1998	Metabolism of triazole and phenyl-14C-CGA 169374 in lactating goats dosed daily for ten consecutive days. ■■■■. Report No ABR-88087. Not GLP, Published. Syngenta File No CGA 169374/0234	N	N	-	Syngenta
KCP 7.2.2. (KCA 6.2.2 – 6.2.5)	■■■■	1990a	[14C]CGA-169374 phenyl and triazole label distribution, elimination and metabolism in goats. ■■■■. Report No ABR-89100. GLP, Published.	N	N	-	Syngenta

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			Syngenta File No CGA 169374/1232				
KCP 7.2.2. (KCA 6.2.2 – 6.2.5)	██████	1996	Metabolism of phenyl-14C CGA 169374 in lactating goats. ██████. Report No ABR-89051 GLP, Published. Syngenta File No CGA 169374/0364	N	N	-	Syngenta
KCP 7.2.2. (KCA 6.2.2 – 6.2.5)	██████	1989	Metabolism of triazole and phenyl-14C-CGA 169374 in laying hens dosed daily for fourteen consecutive days. ██████. Report No ABR-89051. GLP, Published. Syngenta File No CGA 169374/0270	N	N	-	Syngenta
KCP 7.2.2. (KCA 6.2.2 – 6.2.5)	██████	1990b	[ <sup>14</sup> C]CGA-169374 phenyl and triazole label distribution, elimination and metabolism in goats. ██████. Report No ABR-89101. GLP, Published. Syngenta File No CGA 169374/0364	N	N	-	Syngenta
KCP 7.2.2. (KCA 6.2.2 – 6.2.5)	██████	2004	[Triazole-14C] CGA-169374-nature of the residue in laying hens. ██████. Report No 786-02 GLP, Published. Syngenta File No CGA 169374/2441	N	N	-	Syngenta
KCP 7.2.2 (KCA 6.5.1)	Muir GT.	2003	Difenoconazole: Aqueous hydrolysis at 90, 100 and 120°C. Syngenta Crop Protection AG, Basel, Switzerland. Syngenta – Jealott's Hill International, Bracknell, Berkshire, UK. Report No RJ3360B GLP, Published. Syngenta File No CGA 169374/2312	N	N	-	Syngenta
KCP 7.2.6. (KCA 6.6.2)	Walser M.	1994a	Outdoor confined accumulation study on rotational crops after bare ground soil application of [14C-phenyl]-CGA-169374. Novartis Crop Protection AG, Basel, Switzerland. Ciba-	N	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Geigy Ltd., Basel, Switzerland. Report No 8/94. GLP, Published. Syngenta File No CGA 169374/0924				
KCP 7.2.6. (KCA 6.6.2)	Walser M.	1994b	Outdoor confined accumulation study on rotational crops after bare ground soil application of [14C-triazole]-CGA-169374. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland. Report No 4/94. GLP, Published. Syngenta File No CGA 169374/2395	N	N	-	Syngenta
KCP 7.2.6. (KCA 6.6.2)	Close C.	1995	14C-CGA-169374: Uptake and distribution of residues in confined rotational crops. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-95057. GLP, Published. Syngenta File No CGA 169374/1118	N	N	-	Syngenta
KCP 7.2.6. (KCA 6.6.2)	Heyer R.	1995a	CGA-169374 (metabolite CGA 131013), 250 EC, A-7402 G, rotational crop: carrot, soil, Germany. Novartis Crop Protection AG, Basel, Switzerland. RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany. Report No 488002. GLP, Published. Syngenta File No CGA 169374/1215	N	N	-	Syngenta
KCP 7.2.6. (KCA 6.6.2)	Heyer R.	1995b	CGA-169374 (metabolite CGA 131013), 250 EC, A-7402 G, rotational crop: spinach, soil, Germany. Novartis Crop Protection AG, Basel, Switzerland. RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany. Report No 488001. GLP, Published. Syngenta File No CGA 169374/1216	N	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 9.1	Atkins, R.H.	1991a	CGA 169374, Soil adsorption/desorption of 14C-CGA-169374 by the batch equilibrium method. Novartis Crop Protection AG, Basel, Switzerland. PTRL East, Inc., Richmond, United States, Report No 495, Syngenta File N° CGA169374/0477 GLP; Not Published	N	N	-	Syngenta
KCP 9.1	Atkins, R.H.	1991b	Hydrolysis of 14C CGA169374 at pH 5, 7 and 9. Novartis Crop Protection AG, Basel, Switzerland. PTRL East, Inc., Richmond, United States, Report No 494. GLP; Not Published Syngenta File N° CGA169374/0488	N	N	-	Syngenta
KCP 9.1	Atkins, R.H.	1994	CGA 169374, Soil surface photolysis of Phenyl-14C-CGA-169374 under artificial sunlight. Novartis Crop Protection AG, Basel, Switzerland. PTRL East, Inc., Richmond, United States, Report No 791. GLP; Not Published Syngenta File N° CGA169374/1184	N	N	-	Syngenta
KCP 9.1	Beidler, W.T.	1991	Stability of CGA 169374 residues in soil under freezer storage conditions for 2 years. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States, Report No ABR-90068. GLP; Not Published Syngenta File N° CGA169374/0451	N	N	-	Syngenta
KCP 9.1	Baumann, W.	1993	Report on the test for ready biodegradability of CGA 169374 tech. in the carbon dioxide evolution test. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Basel, Oekotoxikologie, Basel, Switzerland, Report No 933652. GLP; Not Published Syngenta File N° CGA169374/0813	N	N	-	Syngenta
KCP 9.1	Gonzalez-	1992a	CGA 169374 Degradation in soil under aerobic conditions at	N	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
	Valero, J.		20°C. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Basel, Oekotoxikologie, Basel, Switzerland, Report No 91-GJ-05. GLP; Not Published Syngenta File N° CGA169374/0606				
KCP 9.1	Gonzalez-Valero, J.	1992b	Rate of degradation of 14C-CGA 169374 in aerobic soil at various conditions. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No 12-92. GLP; Not Published Syngenta File N° CGA169374/0713	N	N	-	Syngenta
KCP 9.1	Gonzalez-Valero, J.	1993	Metabolism of CGA 169374 Under Aerobic Conditions in Aquatic Systems. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No 34/92 91GJ04. GLP; Not Published Syngenta File N° CGA169374/0746	N	N	-	Syngenta
KCP 9.1	Harvey, B. R.	2004	Difenoconazole (CGA169374) Summary of degradation rates in European field dissipation and residue trials. Syngenta Crop Protection AG, Basel, Switzerland. Syngenta, Jealott's Hill, United Kingdom, Report No RAJ0208B. Not GLP; Not Published Syngenta File N° CGA169374/2429	N	N	-	Syngenta
KCP 9.1	Hawkins, D.R.	1988	Soil adsorption and desorption of 1,2,4- Triazole. Novartis Crop Protection AG, Basel, Switzerland. Rohm and Haas, Philadelphia, United States, Report No 34S-88-27. GLP; Not Published Syngenta File N° CGA71019/0014	N	N	-	Triazole derivative metabolite group
KCP 9.1	Hennecke, D.	2002a	Quantum Yield of the photochemical degradation of CGA169374 in aqueous solution.	N	N	-	Syngenta

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			Syngenta Crop Protection AG, Basel, Switzerland. Fraunhofer Institut für Umweltchemie und Oekotoxikologie, Schmallenberg, Germany, Report No SYN-001/7-05. GLP; Not Published Syngenta File N° CGA169374/2208				
KCP 9.1	Hennecke, D.	2002b	Quantum yield of the photochemical degradation of CGA205375 in aqueous solution. Syngenta Crop Protection AG, Basel, Switzerland. Fraunhofer Institut für Umweltchemie und Oekotoxikologie, Schmallenberg, Germany, Report No SYN-001/7-05. GLP Not Published Syngenta File N° CGA205375/0017	N	N	-	Syngenta
KCP 9.1	Mamouni, A.	2000a	Degradation and metabolism of CGA169374 (14C-Triazole) in one soil incubated under aerobic conditions. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 738606. GLP; Not Published Syngenta File N° CGA169374/2101	N	N	-	Syngenta
KCP 9.1	Mamouni, A.	2000b	Degradation and metabolism of CGA 169374 (14C-Chlorophenyl) in one soil incubated under aerobic conditions. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 738617. GLP; Not Published Syngenta File N° CGA169374/2102	N	N	-	Syngenta
KCP 9.1	Mamouni, A.	2002	Degradation of CGA169374 [14C-Chlorophenyl] in three Soils incubated under Aerobic Conditions. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 775438. GLP;Not Published Syngenta File N° CGA169374/2223	N	N	-	Syngenta
KCP 9.1	Mamouni, A	2003	[14C]-CGA71019: Anaerobic soil degradation.	N	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 798660. GLP; Not Published Syngenta File N° CGA71019/0062				
KCP 9.1	Mani, J.	1991a	Leaching mobil study with 14C-CGA 169374 in four soil under laboratory conditions. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No 23-91. GLP; Not Published Syngenta File N° CGA169374/0467	N	N	-	Syngenta
KCP 9.1	Shadrick, BA, Bloomberg, AM, Helfrich, KK	1999	Freezer Storage Stability of 1H-1,2,4- Triazole[3,5-14C] in Soil. Syngenta Crop Protection AG, Basel, Switzerland. Bayer Corporation, Kansas City, United States, Report No 108303. GLP; Not Published Syngenta File N° CGA71019/0068	N	N	-	Syngenta
KCP 9.1	Slangen, P.J.	2000	Degradation of 1,2,4-triazole in Three Soils under Aerobic Conditions. Novartis Crop Protection AG, Basel, Switzerland. NOTOX B.V., 'S Hertogenbosch, Netherlands, Report No NOTOX 278336. GLP; Not Published Syngenta File N° CGA64250/4345	N	N	-	Triazole derivative metabolite group
KCP 9.1	Spare, W.C.	1983	Determination of the hydrolysis rate constants of 1,2,4-H-Triazole (CGA 71019). Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States, Report No 83-E-074. Not GLP; Not Published Syngenta File N° CGA71019/0033	N	N	-	Triazole derivative metabolite group
KCP 9.1	Spare, W.C.	1988	CGA 169374, Adsorption/Desorption of 14C-CGA-169374.	N	N	-	Syngenta

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			Novartis Crop Protection AG, Basel, Switzerland. Agriseach Inc., Frederick, United States, Report No 12115. GLP; Not Published Syngenta File N° CGA169374/0476				
KCP 9.1	Ulbrich, R.	1997	Metabolism of 14C labeled CGA 169374 in aquatic systems under aerobic conditions at 8°C. Novartis Crop Protection AG, Basel, Switzerland. Novartis Crop Protection AG, Basel, Switzerland, Report No 94UL03. GLP; Not Published Syngenta File N° CGA169374/1357	N	N	-	Syngenta
KCP 9.1	Van, Der Gaauw A.	2001	CGA 205375 [14C-Triazole]: Hydrolysis at three different pH Values. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 798658. GLP; Not Published Syngenta File N° CGA205375/0010	N	N	-	Syngenta
KCP 9.1	Van, der Gaauw A.	2002a	Aqueous Photolysis of CGA169374 [14C- Triazole] under Laboratory Conditions. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 815635. GLP; Not Published Syngenta File N° CGA169374/2209	N	N	-	Syngenta
KCP 9.1	Van, der Gaauw A.	2002b	Aqueous Photolysis of CGA205375 [14C- Triazole] under Laboratory Conditions. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 815657. GLP; Not Published Syngenta File N° CGA205375/0018	N	N	-	Syngenta
KCP 9.1	Völkel, W.	2000a	Degradation and metabolism of CGA 169374 (14C-Triazole) in one soil incubated under anaerobic conditions. Syngenta Crop Protection AG, Basel, Switzerland.	N	N	-	Syngenta

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			RCC Ltd., Itingen, Switzerland, Report No 738630. GLP; Not Published Syngenta File N° CGA169374/2099				
KCP 9.1	Völkel, W.	2000b	Degradation of CGA 169374 (14C-Triazole) in one soil incubated under various conditions. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No738628. GLP; Not Published Syngenta File N° CGA169374/2100	N	N	-	Syngenta
KCP 9.1	Völkel, W	2002a	Degradation of CGA205375 [14C-triazole] in three soils incubated under aerobic and anaerobic conditions. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 775451. GLP; Not Published Syngenta File N° CGA169374/2240	N	N	-	Syngenta
KCP 9.1	Volkel, W.	2002b	Adsorption/Desorption of CGA205375 [14C-Triazole] on Soils. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 798647. GLP; Not Published Syngenta File N° CGA205375/0013	N	N	-	Syngenta
KCP 9.1	Völkl, S.	2002c	CGA205375 [14C-Triazole]: Route and Rate of Degradation in Aerobic Aquatic Systems. Syngenta Crop Protection AG, Basel, Switzerland, Report No 798636. GLP; Not Published Syngenta File N° CGA205375/0016	N	N	-	Syngenta
KCP 9.1.1.2	Kühne-Thu, H.	1990a	Determination of residues of parent compound in soil after treatment with 'Difenaconazole EC 250' - field experiment. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No RR-2097-89. GLP (analytical phase); Not Published Syngenta File N° CGA169374/0335	N	N	-	Syngenta

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KCP 9.1.1.2	Kühne-Thu, H.	1990b	Determination of residues of parent compound in soil after treatment with 'Difenaconazole EC 250' - field experiment. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No RR-2096-89. GLP (analytical phase); Not Published Syngenta File N° CGA169374/0336	N	N	-	Syngenta
KCP 9.1.1.2	Kühne-Thu, H.	1990c	Determination of residues of parent compound in soil after treatment with fungicide 'CGA169374 EC 250'. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No RR-2024-89. GLP (analytical phase); Not Published Syngenta File N° CGA169374/0341	N	N	-	Syngenta
KCP 9.1.1.2	Kühne-Thu, H.	1990d	Determination of residues of parent compound in soil after treatment with fungicide 'CGA169374 EC 250'. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No RR-2023-89. GLP (analytical phase); Not Published Syngenta File N° CGA169374/0342	N	N	-	Syngenta
KCP 9.1.1.2	Kühne-Thu, H.	1991a	Determination of residues of parent compound in soil after treatment with 'Difenaconazole EC 250' - Field experiment. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No RR-2040-89. GLP (analytical phase); Not Published Syngenta File N° CGA169374/0337	N	N	-	Syngenta
KCP 9.1.1.2	Kühne-Thu, H.	1991b	Determination of residues of parent compound in soil after treatment with 'Difenaconazole EC 250' - field experiment. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No RR-2039-89.	N	N	-	Syngenta

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			GLP (analytical phase); Not Published Syngenta File N° CGA169374/0338				
KCP 9.1.1.2	Kühne-Thu, H.	1992a	Determination of residues Difenconazole in asparagus and soil - field trial - Italy. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No 2056-90. GLP (analytical phase); Not Published Syngenta File N° CGA169374/0695	N	N	-	Syngenta
KCP 9.1.1.2	Kühne-Thu, H.	1992b	Determination of residues Difenconazole in soil of sugar beet - field trial - Italy. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No 2054-90. GLP (analytical phase); Not Published Syngenta File N° CGA169374/0696	N	N	-	Syngenta
KCP 9.1.1.2	Kühne-Thu, H.	1992c	Determination of residues Difenconazole in soil of sugar beet field - field trial - Italy. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No 2149-90. GLP (analytical phase); Not Published Syngenta File N° CGA169374/0694	N	N	-	Syngenta
KCP 9.1.1.2	Kühne-Thu, H.	2000	Long term study on fate and behaviour of Difenconazole (CGA 169374) in soil in Switzerland. Novartis Crop Protection AG, Basel, Switzerland. Novartis Crop Protection AG, Basel, Switzerland, Report No 2031/89-98. GLP; Not Published Syngenta File N° CGA169374/0652	N	N	-	Syngenta
KCP 9.1.1.2	Molinari, G.P.	2002	Soil dissipation of Difenconazole (Dissipazione nel suolo del fungicida Difenconazole). Novartis Crop Protection AG, Basel, Switzerland. Report No CIBA/96/01.	N	N	-	Syngenta

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			GLP; Not Published Syngenta File N° CGA169374/2044				
KCP 9.1.1.2	Purdy, J.	1997	Dissipation and leaching movement of CGA 169374 residues in soil after application as a seed treatment on wheat seed. Novartis Crop Protection AG, Basel, Switzerland. Novartis Crop Protection Inc., Mississauga, Canada, Report No CER 05306/94. GLP; Not Published Syngenta File N° CGA169374/1423	N	N	-	Syngenta
KCP 9.1.1.2	Ressler, H	1992a	Field Dissipation of Difenconazole. Test Report - Field Experiment. Ciba-Geigy GmbH, Frankfurt a.Main, Germany, Report No 96-88 B. Not GLP; Not Published Syngenta File N° CGA169374/2302	N	N	-	Syngenta
KCP 9.1.1.2	Ressler, H.	1992b	Field dissipation of Difenconazole. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy GmbH, Frankfurt a.Main, Germany, Report No 43-89B. Not GLP; Not Published Syngenta File N° CGA169374/0699	N	N	-	Syngenta
KCP 9.1.1.2	Ressler, H.	1992c	Field dissipation of Difenconazole. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy GmbH, Frankfurt a.Main, Germany, Report No 45-89B. Not GLP; Not Published Syngenta File N° CGA169374/0700	N	N	-	Syngenta
KCP 9.1.1.2	Ressler, H.	1992d	Field dissipation of Difenconazole. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy GmbH, Frankfurt a.Main, Germany, Report No 46-89B. Not GLP; Not Published Syngenta File N° CGA169374/0701	N	N	-	Syngenta



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KCP 9.1.1.2	Resseler, H	2001a	Field Dissipation of Difenaconazole - Test Report - Field Experiment. Syngenta Agro GmbH, Frankfurt/Main, Germany, Report No 44-89B. Not GLP; Not Published Syngenta File N° CGA169374/2304	N	N	-	Syngenta
KCP 9.1.1.2	Resseler, H	2001b	Field Dissipation of Difenaconazole Test Report - Field Experiment. Syngenta Agro GmbH, Frankfurt/Main, Germany, Report No 40-90B. GLP; Not Published Syngenta File N° CGA169374/2306	N	N	-	Syngenta
KCP 9.1.1.2	Resseler, H	2001c	Field Dissipation of Difenaconazole Test Report - Field Experiment. Syngenta Agro GmbH, Frankfurt/Main, Germany, Report No 41-90B. GLP; Not Published Syngenta File N° CGA169374/2308	N	N	-	Syngenta
KCP 9.1.1.2	Resseler, H	2001d	Field Dissipation of Difenaconazole. test Report - Field Experiment. Syngenta Agro GmbH, Frankfurt/Main, Germany, Report No 42-90B. GLP;Not Published Syngenta File N° CGA169374/2310	N	N	-	Syngenta
KCP 9.1.1.2	Tack, T.J.	1995	The determination of Difenconazole (CGA169374) residues in soil after successive applications of A7402G 250EC containing 250 g ai CGA 169374 applied as a foliar application to winter wheat and bare soil for three years. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No CSTR 01:11. GLP; Not Published Syngenta File N° CGA169374/1205	N	N	-	Syngenta

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KCP 9.1.1.2	Walser, M.	1994	Field Dissipation of CGA 169374 after Bareground Application of [Phenyl-14C] CGA 169374 labelled Material. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No 92CN08. GLP; Not Published Syngenta File N° CGA169374/0920	N	N	-	Syngenta
KCP 9.1.1.2	Zelger, R.	2001	Ricerche sul comportamento dei residui di Difenconazolo nel frutteto. Novartis Crop Protection AG, Basel, Switzerland. Report No Final report after 4th year incl. interi. Translation to English: Research into Difenconazole Residue Behaviour in Fruit Growing. Not GLP; Not Published Syngenta File N° CGA169374/2043	N	N	-	Syngenta
KCP 9.2	Beulke, S. Brown, C.	2003	FOCUS Step 1-3 modelling to estimate predicted environmental concentrations in surface water (PEC <sub>sw</sub> ) and sediment (PEC <sub>sed</sub> ) for difenconazole and its metabolites CGA205375 and 1,2,4-triazole following use on sugar beet, apple and carrots. Syngenta Crop Protection AG Not GLP, Not Published Syngenta File No CGA169374/2418	N	N	-	Syngenta
KCP 9.2	Takacs, M.	2006	Difenconazole (CGA 169374): A European Fate Assessment using FOCUS Surface Water Scenarios at Steps 3 and 4 for Carrots and Apples Syngenta Jealotts Hill International Not GLP, Not Published Syngenta File No CGA169374/2821	N	N	-	Syngenta
KCP 9.2	Turner, N.L., Beulke, S.	2003	Estimation with FOCUS PEARL 2.2.2 of predicted concentrations of difenconazole and its metabolites CGA205375 and 1,2,4-triazole in groundwater (PECGW) following application to sugar beet, sunflower, apple and carrot crops.	N	N	-	Syngenta

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			Syngenta Crop Protection AG Not GLP, Not Published Syngenta File No CGA169374/2427				
KCP 9.3	Mani, J.	1991b	Volatilization of CGA 169374 from soil under laboratory conditions. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No 13-91. GLP; Not Published Syngenta File N° CGA169374/0468	N	N	-	Syngenta
KCP 9.3.	Rordorf, B.	1992	Report on vapour pressure curve Ciba -Geigy Ltd., Basel, Switzerland Report No. PP-92-11P-VPC, 23.09.1992 GLP, not published Syngenta File N° 173506 / 207	N	N	-	Syngenta
KCP 9.3	Sandmeier, P.	1992	Volatilization of CGA169374 from plant and soil after postemergent application of 14C-triazole) labelled material on wheat under indoor conditions. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No 8-92. GLP; Not Published Syngenta File N° CGA169374/0651	N	N	-	Syngenta
KCP 9.3	Stamm, E.	1998	Atmospheric oxidation of Difenoconazole CGA 169374 by hydroxyl radicals; rate estimation. Novartis Crop Protection AG, Basel, Switzerland. Novartis Crop Protection AG, Basel, Switzerland, Report No 98SM18. Not GLP; Not Published Syngenta File N° CGA169374/1669	N	N	-	Syngenta
KCP 10.1.1	■	1983a	A dietary LC <sub>50</sub> study in the mallard with CGA 131013 ■ non GLP, Unpublished	Y	N	-	Syngenta

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KCP 10.1.1	█	1988b	11 - day acute dietary LC <sub>50</sub> study with CGA 169374 technical in mallard ducklings █ GLP, Unpublished	Y	N	-	Syngenta
KCP 10.1.1	█	2000	Difenoconazole: A reproduction study with northern bobwhite. █ GLP, Unpublished	Y	N	-	Syngenta
KCP 10.1.1	█	1993	Acute oral toxicity study with CGA 169374 technical in Japanese Quail █ GLP, Unpublished	Y	N	-	Syngenta
KCP 10.1.1	█	1990	CGA169374 tech.: Toxicity and reproduction study in Mallard ducks. █ GLP, Unpublished	Y	N	-	Syngenta
KCP 10.1.2	█	1987	CGA 169374 technical: Acute oral toxicity study in rats GLP	Y	N	-	Syngenta
KCP 10.1.2	█	1983	Triazole alanine: Teratogenicity Study in the Rat GLP	Y	N	-	Syngenta
KCP 10.1.2	█	1988	CGA-169374 technical: A two generation reproductive study in albino rats GLP	Y	N	-	Syngenta
KCP 10.1.2	█	1982	Triazolylalanine (THS 2212), Acute Toxicity Studies Non GLP	Y	N	-	Syngenta
KCP 10.1.2	█	1992	A two generation reproductive toxicity study in rats █ GLP, Published	Y	N	-	Syngenta
KCP 10.2	Bell, G.	1995	1,2,4-triazole: acute toxicity to <i>Daphnia magna</i> . report no. ENVIR/95/52 Syngenta File No 169374/2620 GLP, Unpublished	N	N	-	Syngenta
KCP 10.2	█	2002	1,2,4-triazole juvenile growth test, fish ( <i>Oncorhynchus</i>	Y	N	-	Syngenta

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	Sommer, H.		mykiss) █ GLP, Unpublished				
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	N	-	Syngenta
KCP 10.2	Forbis, A.D.	1988a	Acute toxicity of CGA 169374 to Daphnia magna Syngenta File no. CGA169374/0021 GLP, Unpublished	N	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	N	-	Syngenta
KCP 10.2	Grade, R.	1993b	Report on the growth inhibition test of CGA 169374 tech. to green algae ( <i>Scenedesmus subcapitatus</i> ). report no. 938153 Syngenta File No 169374/0860 GLP, Unpublished	N	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	N	-	Syngenta
KCP 10.2	█	1993a	Report on the prolonged toxicity test of CGA169374 tech. to rainbow trout. Syngenta AG, Basel, Switzerland. Report No.: 938152;	N	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 ( <i>Slenastrum capricornutum</i> ). █ GLP, Unpublished	N	N	-	Syngenta

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KCP 10.2	Rufli H	1989	Alga Growth inhibition test of CGA 169374 to Green Algae ( <i>Scenedesmus supsicatus</i> ). Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No 881699; Syngenta File N° CGA169374/0026 GLP, Unpublished	N	N	-	Syngenta
KCP 10.2	■	2001a	CGA 205375 – Acute toxicity to rainbow trout ( <i>Oncorhynchus mykiss</i> ) GLP, Unpublished	Y	N	-	Syngenta
KCP 10.2	■	1987b	The toxicity of CGA 169374 to fathead minnow ( <i>Pimephales promelas</i> ) embryo and larva. ■ GLP, Unpublished	Y	N	-	Syngenta
KCP 10.2	■	1990a	Acute toxicity of CGA169374 to rainbow trout under flow-through conditions ■ GLP, Unpublished	Y	N	-	Syngenta
KCP 10.2	■	1990b	CGA169374 techn. Toxicity to Fathead Minnow ( <i>Pimephales promelas</i> ) embryos and larvae. ■ GLP, Unpublished	N	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	N	-	Syngenta
KCP 10.2	Swarbrick, R.H.	2001b	CGA 205375: Toxicity to the green alga <i>Selenastrum capricornutum</i> . report no. BL7203/B Syngenta File No 205375/0015 GLP, Unpublished	N	N	-	Syngenta
KCP 10.2	Swarbrick, R.H.	2002	CGA 205375: Acute toxicity to <i>Daphnia magna</i> report no. BL7202/B	N	N	-	Syngenta

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			Syngenta File No 205375/0012 GLP, Unpublished				
KCP 10.2	Van der Kolk, J.	1999	CGA 169374: Chronic effects on midge larvae ( <i>Chironomus riparius</i> ) in water/sediment system report no. 97-192-1008 Syngenta File No 169374/1816 GLP, Unpublished	N	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, Unpublished	N	N	-	Syngenta
KCP 10.3.2	Grimm, C.	1999	Toxicity of CGA 169374 EC 250 (A-7402 G) to the predatory mite <i>Typhlodromus pyri</i> Scheuten (Acari: Phytoseiidae) under extended laboratory conditions. report No 983929, Syngenta No. CGA 169374/1981) GLP, Unpublished	N	N	-	Syngenta
KCP 10.3.2	Kleiner, R.	2000a	Acute dose response toxicity of CGA 169374 EC (A-7402G) to the cereal aphid [arasitoid <i>Aphidius rhapalosiphi</i> (Destefani-Perez) under laboratory conditions. report number 99 10 48 083 Syngenta File No. CGA 169374/2095 GLP, Unpublished	N	N	-	Syngenta
KCP 10.3.2	Kleiner, R.	2001	Acute dose-response toxicity of CGA 169374 EC (A-7402G) to the predatory mite, <i>Typhlodromus pyri</i> (Scheuten), under laboratory conditions. report number 99 10 48 084 Syngenta File No. CGA 169374/2131 GLP, Unpublished	N	N	-	Syngenta
KCP 10.4	Batsher, R.	2002	Acute toxicity of CGA 205375 (metabolite of CGA 169374) to the earthworm <i>Eisenia foetida</i> in a 14-day test. RCC Ltd. report no. 812092, Syngenta File No 205375/0011 GLP, Unpublished	N	N	-	Syngenta

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KCP 10.4	Ehlers, H.A.	2000	Effects of 1,2,4-triazole on reproduction and growth of earthworms <i>Eisenia foetida</i> (Savigny 1826) in artificial soil. report no. 7781022 Syngenta File No 64250/4385 GLP, Unpublished	N	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	N	-	Syngenta
KCP 10.4	Suprenant, D.C.	1987c	Fourteen-day toxicity test exposing earthworm ( <i>Eisenia foetida</i> ) to CGA 169374. report no. 87-9-2494 Syngenta File No 169374/0027 GLP, Unpublished	N	N	-	Syngenta
KCP 10.4	Friedrich, S.	2011	Difenoconazole tech. – Sublethal Toxicity to the Earthworm <i>Eisenia fetida</i> in Artificial Soil with 5 % Peat Syngenta Crop Protection AG, Basel, Switzerland BioChem Agrar, Gerichshain, Germany, 11 10 48 072 S Syngenta File No CGA169374_10511 GLP, Unpublished	N	N	-	Syngenta/ confirmatory data
KCP 10.4	Friedrich, S.	2006	CGA211391 (Difenoconazole metabolite): Sublethal toxicity to the earthworm <i>Eisenia fetida</i> Syngenta Crop Protection AG, Basel, Switzerland BioChem agrar, Gerichshain, Germany, 06 10 48 058, Syngenta File No CGA205375/0030 GLP, Unpublished	N	N	-	Syngenta/ confirmatory data
KCP 10.4	Friedrich, S.	2006	Difenoconazole (CGA169374) EC (250) (A7402T): Sublethal toxicity to the earthworm <i>Eisenia fetida</i> Syngenta Report No.: T000733-04 GLP, Unpublished	N	N	-	Syngenta/ confirmatory data
KCP 10.4	Friedrich, S.	2006	CGA211391 (difenoconazole metabolite): Effects on the reproduction of the collembolans <i>Folsomia candida</i> , Report No. 06 10 48 059, BioChem agrar GmbH, Gerichshain, Germany, 12	N	N	-	Syngenta/ confirmatory data



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			May – 09 June 2006 Syngenta File No.CGA205375/0029 GLP, Unpublished				
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	N	-	Syngenta
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