

FINAL REGISTRATION REPORT

Part B

Section 1: Identity

Section 2: Physical and chemical properties

Section 4: Further information

Detailed summary of the risk assessment

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: 07/2024

MS Finalisation date: 06/2024, 08/2024, 10/2024; 11/2024

Version history

When	What
01/2024	Initial dRR
06/2024	zRMS first evaluation
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

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zRMS comment: noticed data gap – 2 years ambient shelf life study, the study is ongoing. Expected date of completion of the study and the final report - approx. July 2025.
Provisional authorisation for 2 years is possible and proposed.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Synthos Agro sp. z o.o.
Address: ul. Chemików 1
32-600 Oświęcim
Poland

1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

1.2.1 Producer(s) of the preparation

Confidential information or data are provided separately (Part C).

1.2.2 Producer(s) of the active substance(s)

Confidential information or data are provided separately (Part C).

1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

1.2.3.1 Difenoconazole

Difenoconazole min. 940 g/kg (SANCO/830/08 – rev. 3, 18 May 2020)

min 960 g/kg (Synthos source)

Toluene

Max. 5 g/kg

1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name: Please refer to Registration Report Part A for the relevant country (or)

Trade name: DISFERA 90 EC
LIPOSTAR 90 EC

Company code number: SNS-F-11

1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

Table 1.4-1: Active substance and variant of the active substance

Active substance / variant	Declared content of the pure active substance / variant (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L)	Technical content** (%w/w)
Difenoconazole	90 g/L	81 – 99 g/L	94.8 93.8	8.55 8.45

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers

** Based on the density of the formulation = 1.110 g/mL

Table 1.4-2: Safener and synergists

Neither safener nor synergists were used in the formulation.

Table 1.4-3: Relevant impurities

Confidential information or data are provided separately (Part C).

Relevant impurity	Maximum content in the formulation (g/L)
Toluene	0.45

1.4.2 Information on the active substance (KCP 1.4.2)

Table 1.4-4: Information on Difenoconazole

Type	Name/Code Number
ISO common name	Difenoconazole
CAS No.	119446-68-3
EC No.	601-613-1
CIPAC No.	Not allocated

1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

Table 1.4-5: Information on safeners/ synergists / co-formulant

Confidential information or data are provided separately (Part C).

1.5 Type and code of the plant protection product (KCP 1.5)

Type: EC (Emulsifiable concentrate)

[Code: EC]

1.6 Function (KCP 1.6)

Fungicide

2 Section 2: Physical, chemical and technical properties of the plant protection product

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 content 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. Its technical characteristics are acceptable for a EC formulation.

The intended concentration of use is 1 L/ha to 1.3 1.15 L/ha (0.33-0.58% v/v).

Not intended for use in tank mixes.

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

Neither classification nor labelling are relevant for the physical chemical section.

Classification

~~Acute Tox. 4 — H302: Harmful if swallowed.~~

~~Acute Tox. 4 — H332: Harmful if inhaled.~~

~~Eye Dam. 1 — H318: Causes serious eye damage.~~

~~Skin Irrit. 2 — H315: Causes skin irritation.~~

~~Aquatic Chronic 1 — H410: Very toxic to aquatic life with long lasting effects.~~

Labelling

~~Pictograms:~~

~~GHS 05 — Corrosion~~

~~GHS 07 — Harmful~~

~~GHS 09 — Environment~~

~~Signal words:~~

~~Danger~~

Notifier Proposals for Risk and Safety Phrases (KCP 12)

No risk and safety phrases are relevant for the physical chemical section.

Hazard Statements

~~Acute Tox. 4 — H302: Harmful if swallowed.~~

~~Acute Tox 4 — H332: Harmful if inhaled.~~

~~Eye Dam. 1 — H318: Causes serious eye damage.~~

~~Skin Irrit. 2 — H315: Causes skin irritation.~~

~~Aquatic Chronic 1 — H410: Very toxic to aquatic life with long lasting effects.~~

Precautionary Statements

~~P301 + P312 IF SWALLOWED: Call a POISON CENTRE/doctor if you feel unwell.~~

~~P330 — Rinse mouth.~~

P280 - Wear protective gloves/protective clothing/eye protection/face protection

~~P302 + P352 IF ON SKIN: Wash with plenty of water with soap~~

~~P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.~~

~~P332 + P313 If skin irritation occurs: Get medical advice/attention.~~

~~P273 — Avoid release to the environment~~

~~The product was classified in accordance with additivity formula rules (H302, H332, H315) and on the basis of formulation studies (H318, H410).~~

Compliance with FAO specifications:

No FAO specification exist for difenoconazole.

Formulation used for tests

The product used in the tests has the same composition as the one cited in Part C.

Table 2-1: Physical, chemical and technical properties of the plant protection product

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	OPPTS 830.6302-04	SNS-F-11, batch no. S/1/090323	Cloudy, homogenous light brown liquid of characteristic odour.	Y	Jarosław Kupiec, M.Sc., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-13/23; Warsaw; June 2023	Accepted
Explosive properties (KCP 2.2.1)	EC A.14	SNS-F-11, batch no. S/1/090323	SNS-F-11 does not have explosive properties. In the impact sensitivity test, no explosion occurred. In the thermal sensitivity test, no explosion occurred.	Y	Grzegorz Ołowski, M.Sc. Eng., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BW-02/23; Warsaw; June 2023	Accepted Considered non-explosive
Oxidizing properties (KCP 2.2.2)	Test UN O.2.	SNS-F-11, batch no. S/1/090323	SNS-F-11 has not got the oxidizing properties. During the test no spontaneous ignition was noted; the pressure did not reach the critical value of 2070 kPa. The formulation is not oxidising.	Y	Piotr Pachnicki, M.Sc., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BC-24/23; Warsaw; July 2023	Accepted No oxidising properties
Flash point (KCP 2.3.1)	PN-EN ISO 2719:2016	SNS-F-11, batch no. S/1/090323	71.0°C	Y	Piotr Pachnicki, M.Sc., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; Bc-24/23; Warsaw; July 2023	Accepted Performed with the Pensky-Martens apparatus. Considered as non-flammable
Flammability (KCP 2.3.2)	Not applicable. It is not a solid or gas plant protection product.					
Self-heating	PN-EN ISO/IEC 80079-	SNS-F-11,	SNS-F-11 has not got the auto-ignition temperature	Y	Piotr Pachnicki, M.Sc.,	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.3.3)	20-1:2020	batch no. S/1/090323	up to 359°C.		Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; Bc-24/23; Warsaw; July 2023	Considered as non-flammable
Acidity or alkalinity and pH (KCP 2.4.1)	Not applicable. It is not a plant protection product which is acidic (pH < 4) or alkaline (pH > 10).					
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	SNS-F-11, batch no. S/1/090323	pH undiluted: 5.29 pH 1 % solution: 6.65	Y	Jarosław Kupiec, M.Sc., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-13/23; Warsaw; June 2023	Accepted
Viscosity (KCP 2.5.1)	CIPAC MT 192		Non-Newtonian liquid: shear 20°C shear 40°C rate: [mPa·s] rate: [mPa·s] 1.0 s ⁻¹ 1375 2.5 s ⁻¹ 417 2.5 s ⁻¹ 1331 5.0 s ⁻¹ 392 5.0 s ⁻¹ 1293 10.0 s ⁻¹ 378 10.0 s ⁻¹ 1257 25.0 s ⁻¹ 357 The viscosity was determined by using of Brookfield Test Method. The formulation is a non-Newtonian liquid. The formulation does not pose an aspiration hazard			Accepted A non-Newtonian liquid which does not pose an aspiration hazard
Surface tension (KCP 2.5.2)	OECD 115		1L/300L: 43.09 mN/m (at 20°C) 1.3L/200L: 42.38 mN/m (at 20°C) The surface tension of the formulation was tested using the ring method. The product is surface active.			Accepted Surface active
Relative density (KCP 2.6.1)	OECD 109		At 20°C At 40°C Absolute 1.110 g/mL 1.097 g/mL Relative 1.110 1.097			Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Bulk density (KCP 2.6.2)	Not applicable. It is not a plant protection product in the form of powder or granules.					
Storage Stability after 14 days at 54° C (KCP 2.7.1)	OPPTS 830.6302-04	SNS-F-11, batch no. S/1/090323	Cloudy, homogenous light brown liquid of characteristic odour.	Y	Jarosław Kupiec, M.Sc., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-13/23; Warsaw; June 2023	<p>Stored in a commercial packaging (HDPE bottle 1L).</p> <p>After storage:</p> <ul style="list-style-type: none"> - a.s. content: +1.22%, compared to the initial content 81.16 g/kg (8.116%). - no significant changes in the physical, chemical or technical properties of the formulation after storage. <p>Regarding the packaging – no perforation, leakage etc. was observed and the weight change was insignificant (-0.05%).</p> <p>Accepted</p>
	CIPAC MT 75.3		pH undiluted: 5.15 pH 1 % solution: 6.34			
	CIPAC MT 36.3		Emulsion stability (1L/300L and 1.3L/200L): <ol style="list-style-type: none"> 1) After one rotation and 30 s <ul style="list-style-type: none"> – sediment trace 2) After ten rotations and 30 min <ul style="list-style-type: none"> – homogenous 3) After ten rotations and 2 h <ul style="list-style-type: none"> – homogenous 4) After ten rotations and 24 <ul style="list-style-type: none"> – homogenous 5) Re-emulsification <ul style="list-style-type: none"> • after ten rotations and 30 s – homogenous • after ten rotations and 30 min – homogenous 			
	CIPAC MT 180		Dispersion stability (1L/300L and 1.3L/200L): <p>Cylinder 1</p> <ul style="list-style-type: none"> – after 30 inverts and 30 min: <p>Emulsion tube – homogenous</p> <p>Centrifuge tube – homogenous</p> <p>Cylinder 2</p> <ul style="list-style-type: none"> – after 24 hours at room temp.: <p>At the beginning: homogenous</p> <p>Re-dispersion</p> <ul style="list-style-type: none"> – after 30 inverts and 30 min: <p>Emulsion tube – homogenous</p> <p>Centrifuge tube – homogenous</p>			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	CropLife International Technical Monograph No. 17		Package stability: The shape and colour of the 1 litre HDPE package were stable, negligible mass change			
	HPLC-DAD MT/BA-05/23		Difenoconazole content: 8.215% (82.15 g/kg)			
	HS-GC-FID MT/BA-04/23		Impurities content – Toluene: 0.0048% (0.0480 g/kg)			
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	Not applicable. The product is chemically and physically stable after storage for 14 days at 54° C.					Not required
Minimum content after heat stability testing (KCP 2.7.3)	HPLC-DAD MT/BA-05/23	SNS-F-11, batch no. S/1/090323	Difenoconazole content: 8.215% (82.15 g/kg)	Y	Jarosław Kupiec, M.Sc., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-13/23; Warsaw; June 2023	Accepted
Effect of low temperatures on stability (KCP 2.7.4)	OPPTS 830.6302-04	SNS-F-11, batch no. S/1/090323	Cloudy, homogenous light brown liquid of characteristic odour.	Y	Jarosław Kupiec, M.Sc., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-13/23; Warsaw; June 2023	Accepted No significant changes in the physical, chemical, and technical properties of the formulation after the freeze-thaw stability procedure
	CIPAC MT 36.3		Emulsion stability (1L/300L and 1.3L/200L): 1) After one rotation and 30 s – sediment trace 2) After ten rotations and 30 min – homogenous 3) After ten rotations and 2 h – homogenous 4) After ten rotations and 24 – homogenous 5) Re-emulsification • after ten rotations and 30 s – homogenous after ten rotations and 30 min – homogenous			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	CIPAC MT 180		Dispersion stability (1L/300L and 1.3L/200L): Cylinder 1 – after 30 inverts and 30 min: Emulsion tube – homogenous Centrifuge tube – homogenous Cylinder 2 – after 24 hours at room temp.: At the beginning: homogenous Re-dispersion – after 30 inverts and 30 min: Emulsion tube – homogenous Centrifuge tube – homogenous			
Ambient temperature shelf life (KCP 2.7.5)	OPPTS 830.6302-04	SNS-F-11, batch no. S/1/090323	Physical state color and odour: Initial: Cloudy, homogenous light brown liquid of characteristic odour. After 1 year: Cloudy, homogenous light brown liquid of characteristic odour. After 2 years: the study is ongoing	Y	Jarosław Kupiec, M.Sc., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-13/23; Warsaw; June 2023	After 1-year storage at 20±2°C: - a.s. content: +0.65%. - no significant changes in the physical, chemical or technical properties of the formulation after storage. Information included on the label: - prepare spray solution and spray with agitator on; - agitation should be repeated before each application. Stored in a commercial packaging (HDPE bottle
	CIPAC MT 75.3		Initial: pH undiluted: 5.29 pH 1 % solution: 6.65 After 1 year: pH undiluted: 5.29 pH 1 % solution: 6.65 After 2 years: the study is ongoing			
	CIPAC MT 36.3		Emulsion stability (1L/300L and 1.3L/200L): Initial: 1) After one rotation and 30 s – sediment trace 2) After ten rotations and 30 min			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			<ul style="list-style-type: none"> – homogenous 3) After ten rotations and 2 h <ul style="list-style-type: none"> – homogenous 4) After ten rotations and 24 <ul style="list-style-type: none"> – homogenous 5) Re-emulsification <ul style="list-style-type: none"> • after ten rotations and 30 s – homogenous • after ten rotations and 30 min – homogenous After 1 year: 1) After one rotation and 30 s <ul style="list-style-type: none"> – homogenous 2) After ten rotations and 30 min <ul style="list-style-type: none"> – homogenous 3) After ten rotations and 2 h <ul style="list-style-type: none"> – homogenous 4) After ten rotations and 24 <ul style="list-style-type: none"> – sediment trace 5) Re-emulsification <ul style="list-style-type: none"> • after ten rotations and 30 s – sediment trace • after ten rotations and 30 min – sediment trace After 2 years: the study is ongoing			1L). Regarding the packaging – no perforation, leakage etc. was observed and the weight change was insignificant (-0.05%). Deformation was reported – the package was concave on one side. After 2 years of storage details of any deformation should be reported for evaluator's consideration. Accepted 2 years shelf life – data gap. Expected date of completion of the study and the final report - approx. July 2025. Based on the formulation composition and accelerated storage results, A provisional authorisation for 2 years is possible and proposed.
	CIPAC MT 180		Dispersion stability (1L/300L and 1.3L/200L): Initial: Cylinder 1 – after 30 inverts and 30 min: Emulsion tube – homogenous Centrifuge tube – homogenous Cylinder 2 – after 24 hours at room temp.: At the beginning: homogenous Re-dispersion			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			– after 30 inverts and 30 min: Emulsion tube – homogenous Centrifuge tube – homogenous After 1 year: Cylinder 1 – after 30 inverts and 30 min: Emulsion tube – homogenous Centrifuge tube – homogenous Cylinder 2 – after 24 hours at room temp.: At the beginning: homogenous Re-dispersion – after 30 inverts and 30 min: Emulsion tube – homogenous Centrifuge tube – homogenous After 2 years: the study is ongoing			
	CropLife International Technical Monograph No. 17		Package stability: Initial: White, cylindrical 1 litre HDPE package. After 1 year: The colour of the 1 litre HDPE package was stable. The package was concave on one side, no leaks. After 2 years: the study is ongoing			
	HPLC-DAD MT/BA-05/23		Difenoconazole content: Initial: 8.116% (81.16 g/kg) After 1 year: 8.169% (81.69 g/kg) After 2 years: the study is ongoing			
	HS-GC-FID MT/BA-04/23		Impurities content – Toluene: Initial:			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			0.005% (0.0496 g/kg) After 1 year: 0.005% (0.0527 g/kg) After 2 years: the study is ongoing			
Shelf life in months (if less than 2 years) (KCP 2.7.6)	Not applicable. Proposed shelf life is not less than 2 years.					See KCP 2.7.5
Wettability (KCP 2.8.1)	Not applicable. It is not a solid plant protection product, which is diluted for use.					
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	SNS-F-11, batch no. S/1/090323	1L/300L: 9 mL after 1 min 8 mL after 12 min 1.3L/200L: 12 mL after 1 min 10 mL after 12 min	Y	Jarosław Kupiec, M.Sc., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-13/23; Warsaw; June 2023	Accepted Conc. tested – the lowest recommended and higher than the highest in use concentration (1.15L/200L)
Suspensibility (KCP 2.8.3.1)	No applicable. The test shall be carried out for formulations which create suspensions of solid particles or emulsify suspensions. Product is an EC formulation and consequently perform test is not necessary.					
Spontaneity of dispersion (KCP 2.8.3.2)	Not applicable. It is not a water dispersible plant protection product.					
Dispersion stability (KCP 2.8.3.3)	Not applicable. It is not a water dispersible plant protection product.					
Degree of dissolution and dilution stability (KCP 2.8.4)	Not applicable. It is not a water soluble plant protection product.					
Particle size distribution / nominal size range of	Not applicable. It is not a solid plant protection product.					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
granules (KCP 2.8.5.1.1)						
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	SNS-F-11, batch no. S/1/090323	Residue in 75 µm sieve: 0.00%	Y	Jarosław Kupiec, M.Sc., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-13/23; Warsaw; June 2023	Accepted Additional study
Dust content (KCP 2.8.5.2.1)	Not applicable. It is not a granular plant protection product.					
Particle size of dust (KCP 2.8.5.2.2)	Not applicable. It is not a granular plant protection product.					
Attrition (KCP 2.8.5.3)	Not applicable. It is not a plant protection product in the form of granules or tablets which are loose packed.					
Hardness and integrity (KCP 2.8.5.4)	Not applicable. It is not a plant protection product in the form of tablets.					
Emulsifiability (KCP 2.8.6.1)	CIPAC MT 36.3	SNS-F-11, batch no. S/1/090323	Emulsion stability (1L/300L and 1.3L/200L): 1) After one rotation and 30 s – sediment trace 2) After ten rotations and 30 min – homogenous 3) After ten rotations and 2 h – homogenous 4) After ten rotations and 24 – homogenous 5) Re-emulsification • after ten rotations and 30 s – homogenous after ten rotations and 30 min – homogenous	Y	Jarosław Kupiec, M.Sc., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-13/23; Warsaw; June 2023	Accepted Conc. tested – the lowest recommended and higher than the highest in use concentration (1.15L/200L)
Emulsion stability (KCP 2.8.6.2)	See point KCP 2.8.6.1 (Emulsifiability).					See KCP 2.8.6.1
Re-emulsifiability	See point KCP 2.8.6.1 (Emulsifiability).					See KCP 2.8.6.1

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments		
(KCP 2.8.6.3)								
Flowability (KCP 2.8.7.1)	Not applicable. It is not a granular plant protection product.							
Pourability (KCP 2.8.7.2)	No applicable. The test shall be carried out for suspension concentrates, capsule suspensions, oil in water emulsions, oil dispersions and suspo-emulsions. Product is an EC formulation and consequently perform test is not necessary.							
Dustability following accelerated storage (KCP 2.8.7.3)	Not applicable. It is not a plant protection product in the form of dustable powder.							
Physical compatibility of tank mixes (KCP 2.9.1)	Not applicable. Tank mixes are not recommended.							
Chemical compatibility of tank mixes (KCP 2.9.2)	Not applicable. Tank mixes are not recommended.							
Adhesion to seeds (KCP 2.10.1)	No applicable. The test shall be carried out for products applied as seed treatment.							
Distribution to seed (KCP 2.10.2)	No applicable. The test shall be carried out for products applied as seed treatment.							
Other/special studies (KCP 2.11.1)	“Dobra praktyka postępowania przy stosowaniu środków ochrony roślin” issued by Research Institute of Horticulture (ISBN 978-83-89800-63-3)	SNS-F-11, batch no. S/1/090323	Effecttveness of the equipment cleaning procedure:			N	Paleń P., Synthos Agro Sp. z o.o.; AGRO/19/23; Oświęcim, April 2023	Accepted
			1.0 L with 200 L of water	1.3 L with 200 L of water				
Tested item			Concentration of difenoconazole, ppm	Concentration of difenoconazole, ppm				
Spray liquid			418	529				
1st washing liquid			6	7				
2nd washing liquid			0.5	0.9				
Other/special studies	CropLife International	SNS-F-11,	Package stability:		Y	Jarosław Kupiec, M.Sc.,	Accepted	

Annex point	Method used / deviations	Test ma- terial	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.11.2)	Technical Monograph no. 17	batch no. S/1/090323	White, cylindrical 1 litre HDPE package,		Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-13/23; Warsaw; June 2023	

3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

4 Section 4: Further information on the plant protection product

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

zRMS comment: The accelerated stability study was conducted in a commercial 1L HDPE bottle and the packaging remained stable. As PPP SNS-F-11 is an EC formulation, extrapolation to other type of plastic packaging – HDPE/PA is acceptable under the current SAN-CO/10473/2003–rev.5. Ministry of Agriculture and Rural Development guidelines. All proposed commercial packaging is acceptable.

Packagings proposed for SNS-F-11 are as follows:

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

Table 4.1-1: Packaging information for 0.25 litre bottle

Type	Description
Material:	HDPE
Shape/size:	Bottle / 60 - 65 mm x 125 – 135 mm
Opening and closure:	polyethylene screw cap, 40 – 50 mm
Seal:	With liner or induction sealing
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-2: Packaging information for 0.25 litre bottle

Type	Description
Material:	PE/PA
Shape/size:	cylindrical / approx. 60 - 70 mm diameter x 120- 140 mm
Opening:	40 - 60 mm diameter
Closure:	polyethylene screw cap

Table 4.1-3: Packaging information for 0.5 litre bottle

Type	Description
Material:	HDPE
Shape/size:	Bottle / 65 - 75 mm x 170 – 190 mm
Opening and closure:	polyethylene screw cap, 40 – 60 mm
Seal:	With liner or induction sealing
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-4: Packaging information for 0.5 litre bottle

Type	Description
Material:	PE/PA
Shape/size:	cylindrical / approx. 60 - 80 mm diameter x 180 - 200 mm
Opening:	40 - 60 mm diameter
Closure:	screw cap

Table 4.1-5: Packaging information for 1 litre bottle

Type	Description
Material:	HDPE
Shape/size:	Bottle / 85 - 95 mm x 230 – 250 mm
Opening and closure:	polyethylene screw cap, 40 – 60 mm
Seal:	With liner or induction sealing
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-6: Packaging information for 1 litre bottle

Type	Description
Material:	PE/PA
Shape/size:	cylindrical / approx. 80 - 95 mm diameter x 230 - 250 mm
Opening:	40 - 60 mm diameter
Closure:	polyethylene screw cap

Table 4.1-7: Packaging information for 5 litre canister

Type	Description
Material:	HDPE
Shape/size:	125 - 145 mm x 190 – 200 mm x 295 – 320 mm
Opening and closure:	polyethylene screw cap, 50 – 65 mm
Seal:	With liner or induction sealing
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-8: Packaging information for 5 litre canister

Type	Description
Material:	PE/PA
Shape/size:	canister 295 - 315 mm x 185 – 205 mm x 125 – 145 mm
Opening:	40 - 60 mm diameter
Closure:	polyethylene screw cap

Table 4.1-9: Packaging information for 10 litre canister

Type	Description
Material:	HDPE
Shape/size:	160 - 185 mm x 220 – 250 mm x 370 – 390 mm
Opening and closure:	polyethylene screw cap, 50 – 65 mm
Seal:	With liner or induction sealing
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-10: Packaging information for 10 litre canister

Type	Description
Material:	PE/PA
Shape/size:	canister 370 - 390 mm x 225 – 245 mm x 160– 180 mm
Opening:	40 - 60 mm diameter
Closure:	polyethylene screw cap

Table 4.1-11: Packaging information for 20 litre canister

Type	Description
Material:	HDPE
Shape/size:	230 - 265 mm x 280 – 300 mm x 365 – 405 mm
Opening and closure:	polyethylene screw cap, 50 – 65 mm
Seal:	With liner or induction sealing
Manner of construction	extruded
UN/ADR	compliant

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 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	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	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	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 Study code number: BC-24/23	N	Synthos Agro Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Łukasiewicz – 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	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	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	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 and low temperature storage	N	Synthos Agro Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			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	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	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	Synthos Agro Sp. z o.o.
KCP 2.7.4	Kupiec J.	2023	SNS-F-11	N	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	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		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	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	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	Synthos Agro Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 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	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	Synthos Agro Sp. z o.o.
KCP 2.11.1	Paleń P.	2023	SNS-F-11 Effectiveness of equipment celaning procedure Study code number: AGRO/19/23 Synthos Agro Sp.z o.o. Oświęcim, 2023 Non – GLP Unpublished	N	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	Synthos Agro Sp. z o.o.

Appendix 2 Additional data on the physical, chemical and technical properties of the active substance

A 2.1 Difenoconazole

No new or additional data.