

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: Diflufenikan 500 SC

Product name(s): -

Chemical active substance:

diflufenican, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Pestila Sp. z o.o. / ProAgri International Sp. z o.o.

Submission date: January 2023

MS Finalisation date: July 2023, January 2024

Version history

When	What
July 2023	ZRMS assessment of dRR
January 2024	The final Registration Report

Table of Contents

1	Section 1: Identity of the plant protection product.....	4
1.1	Applicant (KCP 1.1)	4
1.2	Producer of the plant protection product and of the active substances (KCP 1.2)	4
1.2.1	Producer(s) of the preparation	4
1.2.2	Producer(s) of the active substance(s)	4
1.2.3	Statement of purity (and detailed information on impurities) of the active substance(s)	5
1.2.3.1	Diflufenican	5
1.3	Trade names and producer's development code numbers for the preparation (KCP 1.3)	5
1.4	Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)	5
1.4.1	Composition of the plant protection product (KCP 1.4.1)	5
1.4.2	Information on the active substance(s) (KCP 1.4.2)	6
1.4.3	Information on safeners, synergists and co-formulants (KCP 1.4.3)	6
1.5	Type and code of the plant protection product (KCP 1.5)	6
1.6	Function (KCP 1.6)	6
2	Section 2: Physical, chemical and technical properties of the plant protection product	7
3	Section 3 is presented as a separate document	17
4	Section 4: Further information on the plant protection product	18
4.1	Packaging and Compatibility with the Preparation (KCP 4.4)	18
Appendix 1	Lists of data considered in support of the evaluation	21
Appendix 2	Additional data on the physical, chemical and technical properties of the active substance.....	24
A 2.1	Diflufenican	24

Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substance(s).

Noticed data gap:

- 2 years ambient shelf life study (it is proposed to grant authorisation for 2 years)

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Pestila Spółka z ograniczoną odpowiedzialnością
Address: Studzianki 24a
97-320 Wolbórz
Poland

and

Name: ProAgri International Spółka z ograniczoną odpowiedzialnością
Address: ul. Józefa Piusa Dziekońskiego 1
00-728 Warszawa
Poland

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

Name: Pestila Spółka z ograniczoną odpowiedzialnością
Address: Studzianki 24a
97-320 Wolbórz
Poland

and

Name: ProAgri International Spółka z ograniczoną odpowiedzialnością
Address: ul. Józefa Piusa Dziekońskiego 1
00-728 Warszawa
Poland

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 Diflufenican

Diflufenican min. 970 g/kg (on a dry weight basis)

Relevant impurity	Maximum content (g/L or g/kg)
Not applicable	Not applicable

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

Trade name: Please refer to cover letter

Company code number: Diflufenikan 500 SC

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(s) and variant(s) of the active substance(s)

Active substance / variant	Declared content of the pure active substance / variant (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
Diflufenican	500 g/L	470 – 530 g/L 475 – 525 g/L	484.5 – 546.4 g/L 489.7 – 541.2 g/L	40.6 – 45.8 41.01 – 45.3

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

** Based on the density of the formulation = 1.194 g/mL

Table 1.4-2: Safener and synergists

Safener / synergist	Declared content of the safener / synergist (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

* Based on the minimum purity of the safener/synergist declared for registration

** Based on the density of the formulation = X.XX (Note: only applies if a liquid formulation – delete this comment if not needed)

Table 1.4-3: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
Not applicable	Not applicable

1.4.2 Information on the active substance(s) (KCP 1.4.2)

Table 1.4-4: Information on diflufenican

Type	Name/Code Number	
ISO common name	diflufenican	Variant
CAS No.	83164-33-4	not relevant
EC No.	not available	not relevant
CIPAC No.	462	not relevant

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

Not relevant. Product does not contain safeners and synergists.

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

Type: Suspension concentrate

[Code: SC]

1.6 Function (KCP 1.6)

Herbicide.

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 homogenous whitish liquid of characteristic odour. It is not explosive, has no oxidizing properties. The product is not flammable. It has a self-ignition temperature of 600 °C. In aqueous solution, it has a pH value around 7.91 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 shelf life of at least 1 year at ambient temperature when stored in HDPE. Its technical characteristics are acceptable for a SC formulation.

The intended concentration of use is ~~0.067%~~ 0.05% to ~~0.15%~~ 0.3%.

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

Study	Result	Classification acc. to Reg. 1272/2008	Labelling acc. to Reg. 1272/2008
Explosive properties (A.14)	Product does not have explosive properties.	Not classified.	None.
Oxidizing properties (A.21)	Product does not have oxidizing properties.	Not classified.	None.
Flammability – not relevant for liquids.	Product is not flammable.	Not classified.	None.
Flash point (A.9)	up to 300 °C	Not classified.	None.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

Not relevant.

Compliance with FAO specifications:

The product Di flufenikan 500 SC complies with FAO specifications.

RMS comment	<p>The plant protection product, code: Di flufenikan 500 SC, complies with FAO specification for Di flufenikan Aqueous Suspension Concentrates (FAO Specification 462/SC/S/F (1997)) as regards declared content, pH, pourability, the spontaneity of dispersion, suspensibility, wet sieve test, and stability after storage at 0°C and 54°C. In the case of persistent foam, FAO Specification 462/SC/S/F (1997) requires the test to be conducted at conc. 1% w/v whereas the formulation was tested at the concentrations 0.067% v/v (0.08% w/v) and 0.15% v/v (0.18% w/v). The results for these concentrations were 11 and 12 mL respectively which is within the limit of FAO Specification 462/SC/S/F (1997) (max. 15 mL).</p> <p>As the maximum recommended use conc. is 0.3% and the formulation fulfils the requirement of SANCO/10473/2003 – rev.5, there is no need to repeat the testing with the conc. 1%.</p>
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Formulation used for tests

Product used in the test 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	Diflufenikan 500 SC Batch no. 1/DIF/2022	Diflufenikan 500 SC is a homogenous whitish liquid of characteristic odour.	Y	J. Kupiec, 2022; BF – 24/22	Accepted.
Explosive properties (KCP 2.2.1)	A.14	Diflufenikan 500 SC Batch no. 1/DIF/2022	Diflufenikan 500 SC does not have explosive properties.	Y	G. Ołowski, 2022; BW-15/22	In the thermal sensitivity (Koenen) test no explosion occurred. In the impact sensitivity test, no explosion occurred. Accepted.
Oxidizing properties (KCP 2.2.2)	A.21	Diflufenikan 500 SC Batch no. 1/DIF/2022	Diflufenikan 500 SC does not have the oxidizing properties.	Y	P. Flasińska, 2022; BC-44/22	During the test no spontaneous ignition was noted; the mean pressure rise time did not reach the value of 690kPa. Accepted.
Flash point (KCP 2.3.1)	A.9	Diflufenikan 500 SC Batch no. 1/DIF/2022	Diflufenikan 500 SC does not have the flash point up to 300 °C.	Y	P. Flasińska, 2022; BC-44/22	The flash point was determined using a Rapid-Tester apparatus according to standard PN-EN ISO 3679:2015

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments															
						(rapid equilibrium closed cup method). The formulation is not flammable. Accepted.															
Flammability (KCP 2.3.2)	-	-	Not relevant. Diflufenikan 500 SC is liquid form.	-	-																
Self-heating (KCP 2.3.3)	A.15	Diflufenikan 500 SC Batch no. 1/DIF/2022	Diflufenikan 500 SC has got the auto-ignition temperature: 600 °C.	Y	P. Flasińska, 2022; BC-44/22	The auto-ignition temperature was determined according to standard DIN 51794:2003-05. Accepted.															
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 75.3	Diflufenikan 500 SC Batch no. 1/DIF/2022	Before storage: pH = 7.84; After accelerated storage: pH = 7.70.	Y	J. Kupiec, 2022; BF – 24/22	Accepted.															
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Diflufenikan 500 SC Batch no. 1/DIF/2022	Before storage: pH = 7.91; After accelerated storage: pH = 8.09.	Y	J. Kupiec, 2022; BF – 24/22	Accepted.															
Viscosity (KCP 2.5.1)	CIPAC MT 192	Diflufenikan 500 SC Batch no. 1/DIF/2022	<table><tr><td></td><td>20°C</td><td>40°C</td></tr><tr><td>5.0 s⁻¹</td><td>650 mPa·s</td><td>541 mPa·s</td></tr><tr><td>10.0 s⁻¹</td><td>393 mPa·s</td><td>330 mPa·s</td></tr><tr><td>25.0 s⁻¹</td><td>209 mPa·s</td><td>174 mPa·s</td></tr><tr><td>50.0 s⁻¹</td><td>134 mPa·s</td><td>110 mPa·s</td></tr></table>		20°C	40°C	5.0 s ⁻¹	650 mPa·s	541 mPa·s	10.0 s ⁻¹	393 mPa·s	330 mPa·s	25.0 s ⁻¹	209 mPa·s	174 mPa·s	50.0 s ⁻¹	134 mPa·s	110 mPa·s	Y	J. Kupiec, 2022; BF – 24/22	The viscosity was determined by using of Brookfield Test Method. The formulation is a non-Newtonian liquid.
	20°C	40°C																			
5.0 s ⁻¹	650 mPa·s	541 mPa·s																			
10.0 s ⁻¹	393 mPa·s	330 mPa·s																			
25.0 s ⁻¹	209 mPa·s	174 mPa·s																			
50.0 s ⁻¹	134 mPa·s	110 mPa·s																			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
								The formulation does not pose an aspiration hazard. Accepted.
Surface tension (KCP 2.5.2)	A.5	Diflufenikan 500 SC Batch no. 1/DIF/2022	<u>Concentrate</u> : 36.66 mN/m; <u>Highest concentration of usable liquid (0.15% v/v)</u> : 50.1 mN/m.			Y	J. Kupiec, 2022; BF – 24/22	The surface tension of the formulation was tested using the ring method. Surface tension was determined at a concentration lower than max. recommended use conc. (0.3% v/v). The preparation is classified as surface-active. Accepted.
Relative density (KCP 2.6.1)	A.3	Diflufenikan 500 SC Batch no. 1/DIF/2022	<u>Density</u> : 1.194 g/ml. <u>Relative density</u> : 1.194			Y	J. Kupiec, 2022; BF – 24/22	Accepted.
Bulk density (KCP 2.6.2)	-	-	Not relevant. Diflufenikan 500 SC is liquid form.			-	-	
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.4 OPPTS 830.6302-04 CIPAC MT 75.3 A.3	Diflufenikan 500 SC Batch no. 1/DIF/2022	Storage stability after 14 days at 54 °C.			Y	J. Kupiec, 2022; BF – 24/22	The formulation was stored in the commercial packaging (1L HDPE bottle). During the storage, the
			Test type	Initial preparation	After accelerated storage			
			Appearance	homogenous whitish liquid of characteristic odour	Before mixing - at the top ~ 2% v/v surfactants solution, after mixing -homogenous whitish liquid of characteris-			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
	CIPAC MT 47.3 CIPAC MT 184.1 CIPAC MT 160 CIPAC MT 185 CIPAC MT 187 CIPAC MT 148.1 CropLife International Technical Monograph No. 17 MT/BA-48/22							temperature ranged from 53.3 to 54.2°C. After storage, the shape of the packaging was stable, with 0.03% weight loss. The change in a.s. content during storage was 0.14%. No significant changes in the physical, chemical, or technical properties of the formulation were observed following storage. See KCP 2.8.2 regarding the persistence of the foaming comment and KCP 2.8.3.1 regarding the suspensibility comment. Accepted.
			pH					
				undiluted	7.84		7.70	
				1% dispersion	7.91		8.09	
			Density		Absolute 1.194 g/ml Relative 1.194		Absolute 1.195 g/ml Relative 1.195	
			Persistent foam	0.067% v/v	11 ml after 1 min 8 ml after 12 min		0 ml after 1 min 0 ml after 12 min	
				0.15% v/v	12 ml after 1 min 6 ml after 12 min		0 ml after 1 min 0 ml after 12 min	
			Surface tension	0.15% v/v	50.10			
			Suspension stability	0.067% v/v	103.86%		103.77%	
				0.15% v/v	103.36%		103.64%	
			Dispersion spontaneity		101.17%		103.40%	
			Wet sieve (residue in 75 µm)		0.00%		0.00%	
			Particle size analysis		Average d ₁₀ = 0.461 µm Average d ₅₀ = 1.528 µm Average d ₉₀ = 4.437 µm Average d _{4,3} = 2.023 µm SD = 0.015 µm RSD = 0.744 %		Average d ₁₀ = 0.419 µm Average d ₅₀ = 2.233 µm Average d ₉₀ = 5.750 µm Average d _{4,3} = 2.709 µm SD = 0.010 µm RSD = 0.376 %	
			Pourability		R = 2.01%		R = 1.95%	
			Package stability		White, cylindrical 1 litre HDPE package		The shape and colour of the 1 litre HDPE package were stable, negligible mass change	
			Diflufenican content		41.98% (501.27 g/L)		41.89% (500.59 g/L)	
Stability after	-	-	Not relevant. Diflufenikan 500 SC was stable after 14 days at 54°C.			-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments			
storage for other periods and/or temperatures (KCP 2.7.2)									
Minimum content after heat stability testing (KCP 2.7.3)	MT/BA-48/22	Diflufenikan 500 SC Batch no. 1/DIF/2022	41.75 % (498.90 g/L) 41.89% (500.59 g/L)	Y	J. Kupiec, 2022; BF – 24/22	Accepted.			
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3 OPPTS 830.6302-04 CIPAC MT 75.3 A.3 CIPAC MT 47.3 CIPAC MT 184.1 CIPAC MT 160 CIPAC MT 185 CIPAC MT 187 CIPAC MT 148.1 MT/BA-48/22	Diflufenikan 500 SC Batch no. 1/DIF/2022	Storage stability after 7 days at 0°C.		Y	J. Kupiec, 2022; BF – 24/22	The formulation was stored in a glass cylinder and commercial packaging (1L HDPE bottle). During the storage, the temperature ranged from -0.9 to 0.3°C. After storage, the formulation remained homogenous. The change in a.s. content during storage was 0.6%. No significant changes in the physical, chemical, or technical properties of the formulation were		
			Test type					Initial preparation	After low temperature storage
			Appearance					homogenous whitish liquid of characteristic odour	homogenous whitish liquid of characteristic odour
			pH	undiluted				7.84	7.39
				1% dispersion				7.91	7.83
			Density					Absolute 1.194 g/ml Relative 1.194	Absolute 1.195 g/ml Relative 1.195
			Persistent foam	0.067% v/v				11 ml after 1 min 8 ml after 12 min	3 ml after 1 min 0 ml after 12 min
				0.15% v/v				12 ml after 1 min 6 ml after 12 min	2 ml after 1 min 0 ml after 12 min
			Suspension stability	0.067% v/v				103.86%	103.75%
				0.15% v/v				103.36%	99.74%
			Dispersion spontaneity					101.17%	99.14%
			Wet sieve (residue in 75 µm)					0.00%	0.00%

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments									
			<table><tr><td>Particle size analysis</td><td>Average d₁₀ = 0.461 µm Average d₅₀ = 1.528 µm Average d₉₀ = 4.437 µm Average d_{4,3} = 2.023 µm SD = 0.015 µm RSD = 0.744 %</td><td>Average d₁₀ = 0.461 µm Average d₅₀ = 1.570 µm Average d₉₀ = 4.477 µm Average d_{4,3} = 2.051 µm SD = 0.014 µm RSD = 0.692 %</td></tr><tr><td>Pourability</td><td>R = 2.01%</td><td>R = 1.86%</td></tr><tr><td>Di flufenikan content</td><td>41.98% (501.27 g/L)</td><td>41.72% (498.53 g/L)</td></tr></table>	Particle size analysis	Average d ₁₀ = 0.461 µm Average d ₅₀ = 1.528 µm Average d ₉₀ = 4.437 µm Average d _{4,3} = 2.023 µm SD = 0.015 µm RSD = 0.744 %	Average d ₁₀ = 0.461 µm Average d ₅₀ = 1.570 µm Average d ₉₀ = 4.477 µm Average d _{4,3} = 2.051 µm SD = 0.014 µm RSD = 0.692 %	Pourability	R = 2.01%	R = 1.86%	Di flufenikan content	41.98% (501.27 g/L)	41.72% (498.53 g/L)					observed following storage. Accepted.
Particle size analysis	Average d ₁₀ = 0.461 µm Average d ₅₀ = 1.528 µm Average d ₉₀ = 4.437 µm Average d _{4,3} = 2.023 µm SD = 0.015 µm RSD = 0.744 %	Average d ₁₀ = 0.461 µm Average d ₅₀ = 1.570 µm Average d ₉₀ = 4.477 µm Average d _{4,3} = 2.051 µm SD = 0.014 µm RSD = 0.692 %															
Pourability	R = 2.01%	R = 1.86%															
Di flufenikan content	41.98% (501.27 g/L)	41.72% (498.53 g/L)															
Ambient temperature shelf life (KCP 2.7.5)	-	-	Study on-going. Expected date of completing the study November 2024.			-	-										
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Study on-going. Expected date of completing the study November 2023.			-	-										
Wettability (KCP 2.8.1)	-	-	Not relevant. Diflufenikan 500 SC is liquid form.			-	-										
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	Diflufenikan 500 SC Batch no. 1/DIF/2022	At concentration 0.067% (v/v): after 1 min. 11 ml, after 12 min. 8 ml At concentration 0.15% (v/v): after 1 min. 12 ml, after 12 min. 6 ml			Y	J. Kupiec, 2022; BF – 24/22	As the formulation contains an antifoam agent, persistent foaming should also be measured at the lowest recommended conc. The test conc. at a lower level (0.067% v/v) was higher than min.									

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						recommended concentration (0.054% v/v). The test conc. at a higher level (0.15% v/v) was lower than max. recommended use conc. (0.3% v/v). However, as the results are within the limit of SANCO/ 10473/2003 – rev.5 (60 mL after 1 min) it can be accepted. Accepted.
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184.1	Di flufenikan 500 SC Batch no. 1/DIF/2022	Concentration	Y	J. Kupiec, 2022; BF – 24/22	Water D was used. The test conc. at a lower level (0.067% v/v) was higher than min. recommended concentration (0.054% v/v). The test conc. at a higher level (0.15% v/v) was lower than max. recommended use conc. (0.3% v/v). Accepted.
			Initial preparation			
			0.067%			
			0.15%			
			After accelerated storage			
			103.86%			
			103.36%			
			103.77%			
			103.64%			

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	Diflufenikan 500 SC Batch no. 1/DIF/2022	<u>Before storage:</u> 101.17 %; <u>After accelerated storage:</u> 103.40 %.		Y	J. Kupiec, 2022; BF – 24/22	Accepted.
Dispersion stability (KCP 2.8.3.3)	-	-	Not required for SC formulation.		-	-	
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not required for SC formulation.		-	-	
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187	Diflufenikan 500 SC Batch no. 1/DIF/2022	Initial preparation	After accelerated storage	Y	J. Kupiec, 2022; BF – 24/22	Accepted.
			Average d10 = 0.461 µm Average d50 = 1.528 µm Average d90 = 4.437 µm Average d4,3 = 2.023 µm SD = 0.015 µm RSD = 0.744 %	Average d10 = 0.419 µm Average d50 = 2.233 µm Average d90 = 5.750 µm Average d4,3 = 2.709 µm SD = 0.010 µm RSD = 0.376 %			
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	Diflufenikan 500 SC Batch no. 1/DIF/2022	Residue on 75 µm sieve <u>Before storage:</u> 0 %; <u>After accelerated storage:</u> 0 %.		Y	J. Kupiec, 2022; BF – 24/22	The conc. used was 10 g of formulation in 20 ml of water which was higher than the highest recommended conc. (0.3% v/v). Accepted.
Dust content (KCP 2.8.5.2.1)	-	-	Not relevant. Diflufenikan 500 SC is liquid form.		-	-	
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not relevant. Diflufenikan 500 SC is liquid form.		-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Attrition (KCP 2.8.5.3)	-	-	Not relevant. Diflufenikan 500 SC is liquid form.	-	-	
Hardness and integrity (KCP 2.8.5.4)	-	-	Not relevant. Diflufenikan 500 SC is liquid form.	-	-	
Emulsifiability (KCP 2.8.6.1)	-	-	Not required for SC formulation.	-	-	
Emulsion stability (KCP 2.8.6.2)	-	-	Not relevant. Diflufenikan 500 SC is a suspension concentrate.	-	-	
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not relevant. Diflufenikan 500 SC is a suspension concentrate.	-	-	
Flowability (KCP 2.8.7.1)	-	-	Not relevant. Diflufenikan 500 SC is a suspension concentrate.	-	-	
Pourability (KCP 2.8.7.2)	CIPAC MT 148.1	Diflufenikan 500 SC Batch no. 1/DIF/2022	<u>Before storage:</u> R = 2.01 %; <u>After accelerated storage:</u> R = 1.95 %.	Y	J. Kupiec, 2022; BF – 24/22	As the residue is within the limit of SANCO/ 10473/2003 – rev.5 (max. 5% residue), there is no need to test the rinsed residue. Accepted.
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not relevant. Diflufenikan 500 SC is liquid form.	-	-	
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not relevant. Diflufenikan 500 SC is not recommended for tank-mixes usage.	-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not relevant. Diflufenikan 500 SC is not recommended for tank-mixes usage.	-	-	
Adhesion to seeds (KCP 2.10.1)	-	-	Not relevant. Diflufenikan 500 SC is not a seedtreatment.	-	-	
Distribution to seed (KCP 2.10.2)	-	-	Not relevant. Diflufenikan 500 SC is not a seedtreatment.	-	-	
Other/special studies (KCP 2.11)	EPPO PP 1/292(1)	Diflufenikan 500 SC Batch no. 1/DIF/2022	Application equipment cleaning effectiveness – 99.77 %.	Y	J. Kupiec, 2022; BF – 24/22	The rinsing procedure consisted of rinsing 3 times with water. Accepted.

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)

Comment of zRMS:	In the accelerated stability study, the formulation has been tested in its original commercial packaging (1 litre HDPE bottle) and the packaging remained stable. Since the formulation is SC formulation (aqueous solution), it is possible, according to the guideline of the Ministry of Agriculture and Rural Development (Wytyczna w sprawie zasad zatwierdzania opakowań w środkach ochrony roślin), to extrapolate the results from HDPE packaging to another plastic packaging. Therefore, the proposed commercial packs are considered acceptable.
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Taking into account extrapolation rules of *Polish guideline on the general principles for approval of packaging of plant protection products* (actualization 18.10.2021), we are applying for additional packaging made of HDPE/PA (COEX) and fHDPE (fluorinated HDPE) for professional users. According to this guideline extrapolation from HDPE to HDPE/PA (COEX) and fHDPE (fluorinated HDPE) is possible for SC formulations.

Table 4.1-1: Packaging information for 250 ml bottle

Type	Description		
Material:	HDPE	HDPE/PA (COEX)	fHDPE
Shape/size:	126mm x Ø63,5mm	126mm x Ø63,5mm	126mm x Ø63,5mm
Opening:	50mmTE	50mmBE	50mmTE
Closure:	50mmTE	50mmBE	50mmTE
Seal:	HIS or PE	IHS	IHS or PET/ALU
Manner of construction	Blow moulded extrusion	Blow moulded coextrusion	Blow moulded extrusion
UN/ADR	Y 1,5/120	Y 1,9/120	Y 1,5/120

Table 4.1-2: Packaging information for 0.5 L bottle

Type	Description		
Material:	HDPE	HDPE/PA (COEX)	fHDPE
Shape/size:	cylindrical / approx. 77,6 mm diameter x 160,6 mm	cylindrical / approx. 77,6 mm diameter x 160,6 mm	cylindrical / approx. 69 mm diameter x 186,2 mm
Opening:	31,3 mm diameter	31,3 mm diameter	45 mm inner diameter
Closure:	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)	31,3 mm inner diameter
Seal:	HF-seal	HF-seal	HF-seal
Manner of construction	blowing extrusion	blowing extrusion	blowing extrusion
UN/ADR	not relevant	not relevant	UN certified

Table 4.1-3: Packaging information for 1L bottle

Type	Description		
Material:	HDPE	HDPE/PA (COEX)	fHDPE
Shape/size:	cylindrical / approx. 84 mm diameter x 230,1 mm	cylindrical / approx. 88 mm diameter x 236,5 mm	cylindrical / approx. 88,5 mm diameter x 233,2 mm
Opening:	31,3 mm diameter	48 mm inner diameter	45 mm inner diameter
Closure:	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)
Seal:	HF-seal	HF-seal	HF-seal
Manner of construction	blowing extrusion	blowing extrusion	blowing extrusion
UN/ADR	not relevant	not relevant	UN certified

Table 4.1-4: Packaging information for 5L canister

Type	Description		
Material:	HDPE	HDPE/PA (COEX)	fHDPE
Shape/size:	cuboid / approx. 186 x 140 mm, H _{max} =300 mm	cuboid / approx. 187 x 135 mm, H _{max} =305 mm	cuboid / approx. 193 x 142 mm, H _{max} =305 mm
Opening:	54 mm diameter	53 mm inner diameter	54 mm inner diameter
Closure:	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)
Seal:	HF-seal	HF-seal	HF-seal
Manner of construction	blowing extrusion	blowing extrusion	blowing extrusion
UN/ADR	not relevant	not relevant	UN certified

Table 4.1-5: Packaging information for 10L canister

Type	Description		
Material:	HDPE	HDPE/PA (COEX)	fHDPE
Shape/size:	cuboid / approx. 228 x 192 mm, H _{max} =306,6 mm	cuboid / approx. 230 x 166 mm, H _{max} =375 mm	cuboid / approx. 240 x 179 mm, H _{max} =377,5 mm
Opening:	46,8 mm diameter	53 mm inner diameter	54 mm inner diameter
Closure:	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)
Seal:	HF-seal	HF-seal	HF-seal
Manner of construction	blowing extrusion	blowing extrusion	blowing extrusion
UN/ADR	compliant	compliant	UN certified

Table 4.1-6: Packaging information for 20L canister

Type	Description		
Material:	HDPE	HDPE/PA (COEX)	fHDPE
Shape/size:	cuboid / approx. 259 x 237 mm, H _{max} =415±3 mm	cuboid / approx. 292 x 256 mm, H _{max} =345,4 mm	cuboid / approx. 294 x 245 mm, H _{max} =400 mm
Opening:	63,4 mm diameter	46,8 mm diameter	53 mm diameter
Closure:	high-density polyethylene	high-density polyethylene	high-density polyethylene

Type	Description		
	cap (screw-on type)	cap (screw-on type)	cap (screw-on type)
Seal:	HF-seal	HF-seal	HF-seal
Manner of construction	blowing extrusion	blowing extrusion	blowing extrusion
UN/ADR	compliant	compliant	compliant

Table 4.1-7: Packaging information for 220L barrel

Type	Description	
Material:	HDPE	HDPE
Shape/size:	935 (± 5)mm x Ø581 (± 5)mm	973mm x Ø590mm
Opening:	Ø581 (±5)	Ø590mm
Closure:	Cap types: 2 layer high-density polyethylene - HBCS 70x6 (Ø80 ± 0,5mm, height 23 ±1 mm) or 2 caps high-density polyethylene - BCS 56x4 (Ø71,8 ±0,3 mm, height 21,4 ±1 mm)	Lid injection moulded out of HDPE with lever action clamping ring, made from galvanised steel.
Seal:	EPDM foam rubber or PE	PUR foamed or EPDM foam rubber
Manner of construction	Blow moulded in one operation together with top and bottom out and integrated L - ring in top.	Blow moulded out of high molecular HDPE in a one-step process.
UN/ADR	UN 1H1	UN 1H2

Table 4.1-8: Packaging information for 1000 L container

Type	Description		
Material:	HDPE container in steel cage on plastic pallet	HDPE container in steel cage on wooden pallet	HDPE container in steel cage on hybrid pallet
Shape/size:	1000mm x 1200mm x 1180mm	1000mm x 1200mm x 1174 mm	1000 mm x 1200mm x 1151mm (± 5mm)
Opening:	NW150	NW150	NW150
Closure:	DN 50	DN 50	DN 50
Seal:	ETFE/PE	EPDM	ETFE/PE
Manner of construction	Blow-molded from high-density UV-stabilized PE, galvanized steel cage, plastic pallet.	Blow-molded from high-density UV-stabilized PE, galvanized steel cage, wooden pallet.	Blow-molded from high-density UV-stabilized PE, galvanized steel cage, palette made of steel corners are filled with plastic.
UN/ADR	UN 31HA1	UN 31HA1	UN 31HA1

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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 KCP 2.4.1 KCP 2.4.2 KCP 2.5.1 KCP 2.5.2 KCP 2.6.1 KCP 2.7.1 KCP 2.7.3 KCP 2.7.4 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.3.2 KCP 2.8.5.1.1 KCP 2.8.5.1.2 KCP 2.8.7.2 KCP 2.11	Kupiec J.	2022	DIFLUFENIKAN 500 SC. Stage I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Report No BF – 24/22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Not published	N	Pestila* ProAgri*
KCP 2.2.1	Ołowski G.	2022	DIFLUFENIKAN 500 SC. Determination of explosive properties. Report No BW-15/22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Not published	N	Pestila* ProAgri*

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 2.2.2 KCP 2.3.1 KCP 2.3.3	Flasińska P.	2022	Diflufenikan 500 SC. Determination of flash point, auto-ignition temperature and oxidizing properties. Report No BWC-44/22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Not published	N	Pestila* ProAgri*

*Pestila Spółka z ograniczoną odpowiedzialnością (short name: Pestila Sp. z o.o.)

**ProAgri Spółka z ograniczoną odpowiedzialnością or ProAgri International Spółka z ograniczoną odpowiedzialnością (short name: ProAgri Sp. z o.o. or ProAgri International Sp. z o.o.)

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

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

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

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

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

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

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

A 2.1 DiFlufenikan

No further data available.