

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: SAP2101F

Product name(s): ZELORA START

Chemical active substances:

Prothioconazole, 120 g/L

Folpet, 300 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Selectis Produtos para a Agricultura, S.A.

Submission date: December 2023

MS Finalisation date: June 2024 (initial Core Assessment)

August 2024 (final Core Assessment)

Version history

When	What
December 2023	V0 - Initial version submitted by the Selectis Produtos para a Agricultura, S.A. for submission to Poland in the frame of new PPP registration (According Art. 33 of Regulation EC No 1107/2009).
June 2024	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency.
August 2024	Final report (Core Assessment updated following the commenting period) No additional information or assessments after the commenting period.

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)	4
1.2.3.1	Prothioconazole	4
1.2.3.2	Folpet.....	4
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).....	5
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.....	19
4	Section 4: Further information on the plant protection product	20
4.1	Packaging and Compatibility with the Preparation (KCP 4.4).....	20
Appendix 1	Lists of data considered in support of the evaluation.....	27
Appendix 2	Additional data on the physical, chemical and technical properties of the active substance	32
A 2.1	Prothioconazole	32
A 2.2	Folpet.....	32

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 gaps are:

- None.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name:
Address:



Contact Person:
Telephone:
E-mail:



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 Prothioconazole

Prothioconazole

min. 970 g/kg according to Reg. (EU) 540/2011
min. 980 g/kg (ASCENZA Agro, S. A. minimum purity)

Impurities:

Toluene
Prothioconazole-desthio

max. 5 g/kg according to Reg. (EU) 540/2011
max. 0.5 g/kg according to Reg. (EU) 540/2011

1.2.3.2 Folpet

Folpet

min. 940 g/kg according to Reg. (EU) 540/2011
min. 960 g/kg (ASCENZA Agro, S. A. minimum purity)

Impurities:

Perchloromethylmercaptan

max. 3.5 g/kg according to Reg. (EU) 540/2011

Carbon tetrachloride

max. 4 g/kg according to Reg. (EU) 540/2011

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

Company code number: SAP2101F

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)	FAO Limits (min – max)	Technical content* (g/L)	Technical content** (%w/w)
Prothioconazole	120	112.8 – 127.2 g/L	122.4	10.7
Folpet	300	285 – 315 g/L	312.5	27.4

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

** Based on the density of the formulation = 1.14 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)
SAP2101F does not contain safeners nor synergists.				

Table 1.4-3: Relevant impurities

Relevant impurity	Maximum content (g/kg)
Toluene	0.6
Prothioconazole-desthio	0.06
Perchloromethylmercaptan	1.05
Carbon tetrachloride	1.2

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

Table 1.4-4: Information on prothioconazole

Type	Name/Code Number
ISO common name	Prothioconazole
CAS No.	178928-70-6
EC No.	Not allocated
CIPAC No.	745

Table 1.4-5: Information on folpet

Type	Name/Code Number
ISO common name	Folpet
CAS No.	133-07-3
EC No.	205-088-6
CIPAC No.	75

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

CONFIDENTIAL information is provided separately (Part C).

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

Type: Suspension concentrate

[Code: SC]

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 liquid beige to brown liquid concentrated suspension, with a characteristic odour. It is not explosive, has no oxidising properties. The product has a flash point of 102 °C. It didn't ignite until 570 °C. In aqueous solution, it has a pH value around 5.5 at 19.5 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 8 weeks at 40 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE and Coex (HDPE/PA and HDPE/EVOH). Its technical characteristics are acceptable for a *suspension concentrate* formulation.

The intended concentration of use is 0.375% to 1%.

No tank mixes are recommended.

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

No classification or labelling for physical chemical properties is proposed.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

No risk or safety phrases for physical chemical properties are proposed.

Compliance with FAO specifications:

The product SAP2101F complies with FAO specifications.

Formulation used for tests

The formulation used for 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)	AM190	SAP2101F Batch I-IEA	<u>Initial and after 8 weeks at 40 °C:</u> Liquid beige to brown liquid concentrated suspension with characteristic odour.	Y	KCP 2.1/01 Morais, F., 2022, Study EF-371-21 – Interim Report (T0)	Accepted.
Explosive properties (KCP 2.2.1)	EEC A.14	SAP2101F Batch I-IEA	No explosive hazards in the formulation.	Y	KCP 2.2.1/01 Nichetti, S., 2022, Report No.: CH – 0508/2021	Accepted. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.
Oxidizing properties (KCP 2.2.2)	EEC A.21	SAP2101F Batch I-IEA	Not oxidizing liquid.	Y	KCP 2.2.2/01 Nichetti, S., 2022, Report No.: CH – 0508/2021 Submitted in KCP 2.2.1/01	Accepted. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.
Flash point (KCP 2.3.1)	EEC A.9	SAP2101F Batch I-IEA	Not flammable liquid; Flash point: 102 °C.	Y	KCP 2.3.1/01 Nichetti, S., 2022, Report No.: CH – 0508/2021 Submitted	Accepted. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
					in KCP 2.2.1/01	tests/requirements in the UN-RTDG manual.
Flammability (KCP 2.3.2)	-	-	Not applicable for SC formulations.	-	-	-
Self-heating (KCP 2.3.3)	EEC A.15	SAP2101F Batch I-IEA	No auto-ignition until 570 °C (maximum test temperature).	Y	KCP 2.3.3/01 Nichetti, S., 2022, Report No.: CH – 0508/2021 Submitted in KCP 2.2.1/01	Accepted. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.
Acidity or alkalinity and pH (KCP 2.4.1)	AM063	SAP2101F Batch I-IEA	Acidity or alkalinity are not required since pH between 4 and 10. pH in neat preparation: <u>Initial:</u> 4.5 (19.5 °C) <u>After 8 weeks at 40 °C:</u> 4.5 (19.5 °C)	Y	KCP 2.4.1/01 Morais, F., 2022, Study EF-371-21 – Interim Report (T0) Submitted in KCP 2.1/01	Accepted.
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	AM063	SAP2101F Batch I-IEA	<u>Initial:</u> 5.5 (19.5 °C) <u>After 8 weeks at 40 °C:</u> 5.5 (19.9 °C)	Y	KCP 2.4.2/01 Morais, F., 2022, Study EF-371-21 – Interim Report (T0) Submitted in KCP 2.1/01	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																				
Viscosity (KCP 2.5.1)	CIPAC MT 192	SAP2101F Batch I-IEA	<div>Viscosity results at 20 °C</div> <table><tr><td>Speed (rpm)</td><td>0.5</td><td>5</td><td>10</td><td>30</td></tr><tr><td>Viscosity cP (mPa.s)</td><td>18120/18600</td><td>3120/3066</td><td>1830/1806</td><td>809.0</td></tr></table> <div>Viscosity results at 40 °C</div> <table><tr><td>Speed (rpm)</td><td>0.5</td><td>5</td><td>10</td><td>30</td></tr><tr><td>Viscosity cP (mPa.s)</td><td>16860/15600</td><td>3024/2772</td><td>1728/1638</td><td>724.0</td></tr></table>	Speed (rpm)	0.5	5	10	30	Viscosity cP (mPa.s)	18120/18600	3120/3066	1830/1806	809.0	Speed (rpm)	0.5	5	10	30	Viscosity cP (mPa.s)	16860/15600	3024/2772	1728/1638	724.0	Y	KCP 2.5.1/01 Morais, F., 2022, Study EF-371-21 – Interim Report (T0) Submitted in KCP 2.1/01	Accepted.
Speed (rpm)	0.5	5	10	30																						
Viscosity cP (mPa.s)	18120/18600	3120/3066	1830/1806	809.0																						
Speed (rpm)	0.5	5	10	30																						
Viscosity cP (mPa.s)	16860/15600	3024/2772	1728/1638	724.0																						
Surface tension (KCP 2.5.2)	AM243	SAP2101F Batch I-IEA	<div>43.7 mN/m (20 °C ± 0.5)</div> <div>Since the surface tension is below 60 mN/m, the preparation should be regarded as being a surface-active material.</div>	Y	KCP 2.5.2/01 Morais, F., 2022, Study EF-371-21 – Interim Report (T0) Submitted in KCP 2.1/01	Accepted. The formulation should be considered as being a surface-active.																				
Relative density (KCP 2.6.1)	AM262	SAP2101F Batch I-IEA	<table><tr><td></td><td>Density (g/cm³)</td><td>Relative density</td></tr><tr><td>Initial</td><td>1.18</td><td>1.18</td></tr><tr><td>After 8 weeks at 40 °C</td><td>1.18</td><td>1.18</td></tr></table> <div>Measuring Temperature: 20 °C ± 0.5 °C</div>		Density (g/cm³)	Relative density	Initial	1.18	1.18	After 8 weeks at 40 °C	1.18	1.18	Y	KCP 2.6.1/01 Morais, F., 2022, Study EF-371-21 – Interim Report (T0) Submitted in KCP 2.1/01	Accepted.											
	Density (g/cm³)	Relative density																								
Initial	1.18	1.18																								
After 8 weeks at 40 °C	1.18	1.18																								
Bulk density (KCP 2.6.2)	-	-	Not required for SC formulations.	-	-	-																				
Storage Stability after 14 days at 54 °C (KCP 2.7.1)	-	-	Please refer to point KCP 2.7.2.	-	-	-																				

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																								
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	CIPAC MT 46.4 HDPE bottles Analytical method AM290	SAP2101F Batch I-IEA	The sample is considered to be stable at 40 °C for 8 weeks. The physical-chemical properties are similar between samples before and after storage. Please see points KCP 2.1, KCP 2.4.1, KCP 2.4.2, KCP 2.6.1, 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 of the present Table 2.1 for detailed results.	Y	KCP 2.7.2/01 Morais, F., 2022, Study EF-371-21 – Interim Report (T0) Submitted in KCP 2.1/01	Accepted. The product showed no significant physical changes after accelerated storage. No significant changes were observed in the packaging and therefore it can be concluded that the test item was not corrosive to the container material. The accelerated stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging (HDPE).																								
			<table><tr><th colspan="3">Active substance content</th></tr><tr><td colspan="3">T0</td></tr><tr><td></td><td>g/L</td><td>% w/w</td></tr><tr><td>Prothioconazole</td><td>114.0</td><td>9.66</td></tr><tr><td>Folpet</td><td>297.2</td><td>25.19</td></tr><tr><td colspan="3">HT</td></tr><tr><td>Prothioconazole</td><td>114.6</td><td>9.71</td></tr><tr><td>Folpet</td><td>296.7</td><td>25.14</td></tr></table>				Active substance content			T0				g/L	% w/w	Prothioconazole	114.0	9.66	Folpet	297.2	25.19	HT			Prothioconazole	114.6	9.71	Folpet	296.7	25.14
			Active substance content																											
			T0																											
							g/L	% w/w																						
			Prothioconazole				114.0	9.66																						
			Folpet				297.2	25.19																						
			HT																											
			Prothioconazole				114.6	9.71																						
			Folpet				296.7	25.14																						
			<table><tr><th colspan="2">Prothioconazole isomers ratio (% w/w)</th></tr><tr><td colspan="2">T0</td></tr><tr><td>Peak 1:Peak 2</td><td>50.0 : 50.0</td></tr><tr><td colspan="2">HT</td></tr><tr><td>Peak 1:Peak 2</td><td>49.7 : 50.3</td></tr></table>				Prothioconazole isomers ratio (% w/w)		T0		Peak 1:Peak 2	50.0 : 50.0	HT		Peak 1:Peak 2	49.7 : 50.3														
			Prothioconazole isomers ratio (% w/w)																											
			T0																											
			Peak 1:Peak 2				50.0 : 50.0																							
			HT																											
Peak 1:Peak 2	49.7 : 50.3																													
<table><tr><th colspan="3">Impurities content (% w/w)</th></tr><tr><td></td><td>T0</td><td>HT</td></tr><tr><td>Toluene</td><td>< LOQ (0.006)</td><td>< LOQ (0.006)</td></tr><tr><td>Prothioconazole-desthio</td><td>< LOQ (0.006)</td><td>< LOQ (0.006)</td></tr><tr><td>PMM</td><td>< LOQ (0.080)</td><td>< LOQ (0.080)</td></tr><tr><td>CCl4</td><td>< LOQ (0.050)</td><td>< LOQ (0.050)</td></tr></table>	Impurities content (% w/w)				T0	HT	Toluene	< LOQ (0.006)	< LOQ (0.006)	Prothioconazole-desthio	< LOQ (0.006)	< LOQ (0.006)	PMM	< LOQ (0.080)	< LOQ (0.080)	CCl4	< LOQ (0.050)	< LOQ (0.050)												
Impurities content (% w/w)																														
	T0	HT																												
Toluene	< LOQ (0.006)	< LOQ (0.006)																												
Prothioconazole-desthio	< LOQ (0.006)	< LOQ (0.006)																												
PMM	< LOQ (0.080)	< LOQ (0.080)																												
CCl4	< LOQ (0.050)	< LOQ (0.050)																												
Lowest application concentration: 2.5 mL/L (0.25 %)																														
Highest application concentration: 10.0 mL/L (1.00 %)																														

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments																																																																																																																																																												
			<table><tr><td colspan="2">Determinations</td><td>EF/371/21/T0</td><td>EF/371/21/HT</td></tr><tr><td rowspan="2">Prothioconazole content</td><td>% w/w</td><td>9.66</td><td>9.71</td></tr><tr><td>g/L</td><td>114.0</td><td>114.6</td></tr><tr><td rowspan="2">Folpet content</td><td>% w/w</td><td>25.19</td><td>25.14</td></tr><tr><td>g/L</td><td>297.2</td><td>296.7</td></tr><tr><td>Prothioconazole Isomers ratio (Peak 1 : Peak 2)</td><td>% w/w</td><td>50.0 : 50.0</td><td>49.7 : 50.3</td></tr><tr><td>Toluene content</td><td>% w/w</td><td>< LOQ (0.006)</td><td>< LOQ (0.006)</td></tr><tr><td>Prothioconazole-desthio content</td><td>% w/w</td><td>< LOQ (0.006)</td><td>< LOQ (0.006)</td></tr><tr><td>PMM content</td><td>% w/w</td><td>< LOQ (0.080)</td><td>< LOQ (0.080)</td></tr><tr><td>CCl4 content</td><td>% w/w</td><td>< LOQ (0.050)</td><td>< LOQ (0.050)</td></tr><tr><td rowspan="3">Appearance</td><td colspan="2">Physical state</td><td>Liquid, concentrated suspension</td><td>Liquid, concentrated suspension</td></tr><tr><td colspan="2">Colour</td><td>Beige to brown</td><td>Beige to brown</td></tr><tr><td colspan="2">Odour</td><td>Characteristic</td><td>Characteristic</td></tr><tr><td rowspan="2">Determination of pH</td><td colspan="2">1 % concentration</td><td>5.5</td><td>5.5</td></tr><tr><td colspan="2">Neat preparation</td><td>4.5</td><td>4.5</td></tr><tr><td rowspan="2">Density</td><td colspan="2">g/mL</td><td>1.18</td><td>1.18</td></tr><tr><td colspan="2">Relative density</td><td>1.18</td><td>1.18</td></tr><tr><td rowspan="4">Suspensibility (%)</td><td rowspan="2">Prothioconazole</td><td>Lowest application conc.</td><td>99</td><td>98</td></tr><tr><td>Highest application conc.</td><td>94</td><td>93</td></tr><tr><td rowspan="2">Folpet</td><td>Lowest application conc.</td><td>97</td><td>97</td></tr><tr><td>Highest application conc.</td><td>91</td><td>91</td></tr><tr><td rowspan="4">Spontaneity of dispersion (%)</td><td rowspan="2">Prothioconazole</td><td>Determination 1</td><td>96</td><td>97</td></tr><tr><td>Determination 2</td><td>97</td><td>97</td></tr><tr><td rowspan="2">Folpet</td><td>Determination 1</td><td>93</td><td>95</td></tr><tr><td>Determination 2</td><td>95</td><td>96</td></tr><tr><td>Pourability (%)</td><td colspan="2">Residue</td><td>0.8</td><td>0.8</td></tr><tr><td>Wet sieve test (% w/w)</td><td colspan="2">> 75 µm</td><td>0.05</td><td>0.05</td></tr><tr><td rowspan="3">Particle size distribution</td><td colspan="2">< 10.0 % µm</td><td>1.18</td><td>1.19</td></tr><tr><td colspan="2">< 50.0 % µm</td><td>3.11</td><td>3.15</td></tr><tr><td colspan="2">< 90.0 % µm</td><td>8.71</td><td>8.69</td></tr><tr><td>Surface tension (mN/m)</td><td colspan="2">Highest application conc. (20 °C)</td><td>43.7</td><td>---</td></tr><tr><td rowspan="8">Viscosity (mPa.s)</td><td rowspan="4">20 °C</td><td>0.5 rpm</td><td>18120 / 18600</td><td rowspan="8">---</td></tr><tr><td>5 rpm</td><td>3120 / 3066</td></tr><tr><td>10 rpm</td><td>1830 / 1806</td></tr><tr><td>30 rpm</td><td>809.0</td></tr><tr><td rowspan="4">40 °C</td><td>0.5 rpm</td><td>16860 / 15600</td></tr><tr><td>5 rpm</td><td>3024 / 2772</td></tr><tr><td>10 rpm</td><td>1728 / 1638</td></tr><tr><td>30 rpm</td><td>724.0</td></tr><tr><td rowspan="2">Persistent foam (mL.) [Lowest Highest]</td><td colspan="2">1 minute</td><td>[20 8]</td><td>[18 8]</td></tr><tr><td colspan="2">12 minutes</td><td>[12 0]</td><td>[10 0]</td></tr></table>				Determinations		EF/371/21/T0	EF/371/21/HT	Prothioconazole content	% w/w	9.66	9.71	g/L	114.0	114.6	Folpet content	% w/w	25.19	25.14	g/L	297.2	296.7	Prothioconazole Isomers ratio (Peak 1 : Peak 2)	% w/w	50.0 : 50.0	49.7 : 50.3	Toluene content	% w/w	< LOQ (0.006)	< LOQ (0.006)	Prothioconazole-desthio content	% w/w	< LOQ (0.006)	< LOQ (0.006)	PMM content	% w/w	< LOQ (0.080)	< LOQ (0.080)	CCl4 content	% w/w	< LOQ (0.050)	< LOQ (0.050)	Appearance	Physical state		Liquid, concentrated suspension	Liquid, concentrated suspension	Colour		Beige to brown	Beige to brown	Odour		Characteristic	Characteristic	Determination of pH	1 % concentration		5.5	5.5	Neat preparation		4.5	4.5	Density	g/mL		1.18	1.18	Relative density		1.18	1.18	Suspensibility (%)	Prothioconazole	Lowest application conc.	99	98	Highest application conc.	94	93	Folpet	Lowest application conc.	97	97	Highest application conc.	91	91	Spontaneity of dispersion (%)	Prothioconazole	Determination 1	96	97	Determination 2	97	97	Folpet	Determination 1	93	95	Determination 2	95	96	Pourability (%)	Residue		0.8	0.8	Wet sieve test (% w/w)	> 75 µm		0.05	0.05	Particle size distribution	< 10.0 % µm		1.18	1.19	< 50.0 % µm		3.11	3.15	< 90.0 % µm		8.71	8.69	Surface tension (mN/m)	Highest application conc. (20 °C)		43.7	---	Viscosity (mPa.s)	20 °C	0.5 rpm	18120 / 18600	---	5 rpm	3120 / 3066	10 rpm	1830 / 1806	30 rpm	809.0	40 °C	0.5 rpm	16860 / 15600	5 rpm	3024 / 2772	10 rpm	1728 / 1638	30 rpm	724.0	Persistent foam (mL.) [Lowest Highest]	1 minute		[20 8]	[18 8]	12 minutes		[12 0]	[10 0]			
Determinations		EF/371/21/T0	EF/371/21/HT																																																																																																																																																																		
Prothioconazole content	% w/w	9.66	9.71																																																																																																																																																																		
	g/L	114.0	114.6																																																																																																																																																																		
Folpet content	% w/w	25.19	25.14																																																																																																																																																																		
	g/L	297.2	296.7																																																																																																																																																																		
Prothioconazole Isomers ratio (Peak 1 : Peak 2)	% w/w	50.0 : 50.0	49.7 : 50.3																																																																																																																																																																		
Toluene content	% w/w	< LOQ (0.006)	< LOQ (0.006)																																																																																																																																																																		
Prothioconazole-desthio content	% w/w	< LOQ (0.006)	< LOQ (0.006)																																																																																																																																																																		
PMM content	% w/w	< LOQ (0.080)	< LOQ (0.080)																																																																																																																																																																		
CCl4 content	% w/w	< LOQ (0.050)	< LOQ (0.050)																																																																																																																																																																		
Appearance	Physical state		Liquid, concentrated suspension	Liquid, concentrated suspension																																																																																																																																																																	
	Colour		Beige to brown	Beige to brown																																																																																																																																																																	
	Odour		Characteristic	Characteristic																																																																																																																																																																	
Determination of pH	1 % concentration		5.5	5.5																																																																																																																																																																	
	Neat preparation		4.5	4.5																																																																																																																																																																	
Density	g/mL		1.18	1.18																																																																																																																																																																	
	Relative density		1.18	1.18																																																																																																																																																																	
Suspensibility (%)	Prothioconazole	Lowest application conc.	99	98																																																																																																																																																																	
		Highest application conc.	94	93																																																																																																																																																																	
	Folpet	Lowest application conc.	97	97																																																																																																																																																																	
		Highest application conc.	91	91																																																																																																																																																																	
Spontaneity of dispersion (%)	Prothioconazole	Determination 1	96	97																																																																																																																																																																	
		Determination 2	97	97																																																																																																																																																																	
	Folpet	Determination 1	93	95																																																																																																																																																																	
		Determination 2	95	96																																																																																																																																																																	
Pourability (%)	Residue		0.8	0.8																																																																																																																																																																	
Wet sieve test (% w/w)	> 75 µm		0.05	0.05																																																																																																																																																																	
Particle size distribution	< 10.0 % µm		1.18	1.19																																																																																																																																																																	
	< 50.0 % µm		3.11	3.15																																																																																																																																																																	
	< 90.0 % µm		8.71	8.69																																																																																																																																																																	
Surface tension (mN/m)	Highest application conc. (20 °C)		43.7	---																																																																																																																																																																	
Viscosity (mPa.s)	20 °C	0.5 rpm	18120 / 18600	---																																																																																																																																																																	
		5 rpm	3120 / 3066																																																																																																																																																																		
		10 rpm	1830 / 1806																																																																																																																																																																		
		30 rpm	809.0																																																																																																																																																																		
	40 °C	0.5 rpm	16860 / 15600																																																																																																																																																																		
		5 rpm	3024 / 2772																																																																																																																																																																		
		10 rpm	1728 / 1638																																																																																																																																																																		
		30 rpm	724.0																																																																																																																																																																		
Persistent foam (mL.) [Lowest Highest]	1 minute		[20 8]	[18 8]																																																																																																																																																																	
	12 minutes		[12 0]	[10 0]																																																																																																																																																																	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																																											
			<table><tr><td colspan="2">Determinations</td><td>EF/371/21/T0</td><td>EF/371/21/HT</td></tr><tr><td colspan="2">Package stability</td><td>No visual degradation</td><td>No visual degradation</td></tr><tr><td colspan="4">Low temperature stability (EF/371/21/LT)</td></tr><tr><td colspan="4">It was not noticed any separated material.</td></tr><tr><td>Prothioconazole content</td><td colspan="2">% w/w</td><td>9.74</td></tr><tr><td>Folpet content</td><td colspan="2">% w/w</td><td>25.20</td></tr><tr><td rowspan="4">Suspensibility (%)</td><td rowspan="2">Prothioconazole</td><td>Lowest application conc.</td><td>99</td></tr><tr><td>Highest application conc.</td><td>93</td></tr><tr><td rowspan="2">Folpet</td><td>Lowest application conc.</td><td>97</td></tr><tr><td>Highest application conc.</td><td>90</td></tr><tr><td>Wet sieve test (% w/w)</td><td colspan="2">> 75 µm</td><td>0.06</td></tr></table> <table><tr><td rowspan="2">Damage types</td><td colspan="2">Visual observations</td></tr><tr><td>EF/371/21/T0</td><td>EF/371/21/HT</td></tr><tr><td>Deformation</td><td>No</td><td>No</td></tr><tr><td>Attack by the contents</td><td>No</td><td>No</td></tr><tr><td>Leaking</td><td>No</td><td>No</td></tr><tr><td>Label damage</td><td>No</td><td>No</td></tr><tr><td>Conclusion</td><td>No visual degradation</td><td>No visual degradation</td></tr></table>	Determinations		EF/371/21/T0	EF/371/21/HT	Package stability		No visual degradation	No visual degradation	Low temperature stability (EF/371/21/LT)				It was not noticed any separated material.				Prothioconazole content	% w/w		9.74	Folpet content	% w/w		25.20	Suspensibility (%)	Prothioconazole	Lowest application conc.	99	Highest application conc.	93	Folpet	Lowest application conc.	97	Highest application conc.	90	Wet sieve test (% w/w)	> 75 µm		0.06	Damage types	Visual observations		EF/371/21/T0	EF/371/21/HT	Deformation	No	No	Attack by the contents	No	No	Leaking	No	No	Label damage	No	No	Conclusion	No visual degradation	No visual degradation			
Determinations		EF/371/21/T0	EF/371/21/HT																																																														
Package stability		No visual degradation	No visual degradation																																																														
Low temperature stability (EF/371/21/LT)																																																																	
It was not noticed any separated material.																																																																	
Prothioconazole content	% w/w		9.74																																																														
Folpet content	% w/w		25.20																																																														
Suspensibility (%)	Prothioconazole	Lowest application conc.	99																																																														
		Highest application conc.	93																																																														
	Folpet	Lowest application conc.	97																																																														
		Highest application conc.	90																																																														
Wet sieve test (% w/w)	> 75 µm		0.06																																																														
Damage types	Visual observations																																																																
	EF/371/21/T0	EF/371/21/HT																																																															
Deformation	No	No																																																															
Attack by the contents	No	No																																																															
Leaking	No	No																																																															
Label damage	No	No																																																															
Conclusion	No visual degradation	No visual degradation																																																															
Minimum content after heat stability testing (KCP 2.7.3)	-	-	Not required, since the a.s. is not heat-sensitive.	-	-	-																																																											
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 184.1 CIPAC MT 185 CIPAC MT 39.3	SAP2101F Batch I-IEA	<p><u>Suspensability:</u></p> <p>Prothioconazole:</p> <table><tr><td>Application conc.:</td><td>0.25%</td><td>1.00%</td></tr><tr><td>After 7 days at 0 °C</td><td>99%</td><td>93%</td></tr></table> <p>Folpet:</p> <table><tr><td>Application conc.:</td><td>0.25%</td><td>1.00%</td></tr><tr><td>After 7 days at 0 °C</td><td>97%</td><td>90%</td></tr></table> <p><u>Wet sieve test:</u> 0.06% (sieve > 75µm)</p>	Application conc.:	0.25%	1.00%	After 7 days at 0 °C	99%	93%	Application conc.:	0.25%	1.00%	After 7 days at 0 °C	97%	90%	Y	KCP 2.7.4/01 Morais, F., 2022, Study EF-371-21 – Interim Report (T0) Submitted in KCP 2.1/01	Accepted.																																															
Application conc.:	0.25%	1.00%																																																															
After 7 days at 0 °C	99%	93%																																																															
Application conc.:	0.25%	1.00%																																																															
After 7 days at 0 °C	97%	90%																																																															
Ambient	CIPAC MT 46.4	SAP2101F	Since the product presents similar and acceptable results before and after being stored for 8 weeks at 40 °C in	Y	KCP	Accepted.																																																											

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
temperature shelf life (KCP 2.7.5)	HDPE bottles Analytical method AM290	Batch I-IEA	HDPE, it is considered that the product is also stable after twenty four months at ambient temperature. Please refer to KCP 2.7.2.		2.7.5/01-Morais, F., 2022, Study EF-371-21 – Interim Report (T0) Submitted in KCP 2.1/01	The product showed no significant physical changes after storage.
			The sample is considered to be stable for 24 months. The physical-chemical properties are similar between samples before and after storage.			
			</			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																																																																																																																																																																
			<table><tr><th colspan="3">Determinations</th><th>EF/371/21/T0²</th><th>EF/371/21/HT²</th><th>EF/371/21/T24</th></tr><tr><td rowspan="4">Suspensibility (%)</td><td rowspan="2">Prothioconazole</td><td>Lowest application conc.</td><td>99</td><td>98</td><td>98</td></tr><tr><td>Highest application conc.</td><td>94</td><td>93</td><td>93</td></tr><tr><td rowspan="2">Folpet</td><td>Lowest application conc.</td><td>97</td><td>97</td><td>97</td></tr><tr><td>Highest application conc.</td><td>91</td><td>91</td><td>90</td></tr><tr><td rowspan="4">Spontaneity of dispersion (%)</td><td rowspan="2">Prothioconazole</td><td>Determination 1</td><td>96</td><td>97</td><td>97</td></tr><tr><td>Determination 2</td><td>97</td><td>97</td><td>97</td></tr><tr><td rowspan="2">Folpet</td><td>Determination 1</td><td>93</td><td>95</td><td>97</td></tr><tr><td>Determination 2</td><td>95</td><td>96</td><td>97</td></tr><tr><td rowspan="2">Pourability (%)</td><td colspan="2">Residue</td><td>0.8</td><td>0.8</td><td>0.8</td></tr><tr><td colspan="2">Rinsed residue 1</td><td>---</td><td>---</td><td>0.24</td></tr><tr><td>Wet sieve test (% w/w)</td><td colspan="2">> 75 µm</td><td>0.05</td><td>0.05</td><td>0.03</td></tr><tr><td rowspan="3">Particle size distribution</td><td colspan="2">d (0.1)</td><td>1.18</td><td>1.19</td><td>1.19</td></tr><tr><td colspan="2">d (0.5)</td><td>3.11</td><td>3.15</td><td>3.27</td></tr><tr><td colspan="2">d (0.9)</td><td>8.71</td><td>8.69</td><td>9.94</td></tr><tr><td>Surface tension (mN/m)</td><td colspan="2">Highest application conc. (20 °C)</td><td>43.7</td><td>---</td><td>---</td></tr><tr><td rowspan="8">Viscosity (mPa.s)</td><td rowspan="4">20 °C</td><td>0.5 rpm</td><td>18120 / 18600</td><td rowspan="8">---</td><td rowspan="8">---</td></tr><tr><td>5 rpm</td><td>3120 / 3066</td></tr><tr><td>10 rpm</td><td>1830 / 1806</td></tr><tr><td>30 rpm</td><td>809.0</td></tr><tr><td rowspan="4">40 °C</td><td>0.5 rpm</td><td>16860 / 15600</td></tr><tr><td>5 rpm</td><td>3024 / 2772</td></tr><tr><td>10 rpm</td><td>1728 / 1638</td></tr><tr><td>30 rpm</td><td>724.0</td></tr></table> <table><tr><th colspan="3">Determinations</th><th>EF/371/21/T0³</th><th>EF/371/21/HT³</th><th>EF/371/21/T24</th></tr><tr><td rowspan="2">Persistent foam (mL) [Lowest Highest]</td><td colspan="2">1 minute</td><td>[20 8]</td><td>[18 8]</td><td>[30 18]</td></tr><tr><td colspan="2">12 minutes</td><td>[12 0]</td><td>[10 0]</td><td>[12 0]</td></tr><tr><td colspan="3">Package stability</td><td>No visual degradation</td><td>No visual degradation</td><td>No visual degradation</td></tr><tr><td colspan="6">Low temperature stability (EF/371/21/LT)³</td></tr><tr><td colspan="6">It was not noticed any separated material.</td></tr><tr><td>Prothioconazole content</td><td colspan="2">% w/w</td><td colspan="3">9.74</td></tr><tr><td>Folpet content</td><td colspan="2">% w/w</td><td colspan="3">25.20</td></tr><tr><td rowspan="4">Suspensibility (%)</td><td rowspan="2">Prothioconazole</td><td>Lowest application conc.</td><td colspan="3">99</td></tr><tr><td>Highest application conc.</td><td colspan="3">93</td></tr><tr><td rowspan="2">Folpet</td><td>Lowest application conc.</td><td colspan="3">97</td></tr><tr><td>Highest application conc.</td><td colspan="3">90</td></tr><tr><td>Wet sieve test (% w/w)</td><td colspan="2">> 75 µm</td><td colspan="3">0.06</td></tr></table>	Determinations			EF/371/21/T0 ²	EF/371/21/HT ²	EF/371/21/T24	Suspensibility (%)	Prothioconazole	Lowest application conc.	99	98	98	Highest application conc.	94	93	93	Folpet	Lowest application conc.	97	97	97	Highest application conc.	91	91	90	Spontaneity of dispersion (%)	Prothioconazole	Determination 1	96	97	97	Determination 2	97	97	97	Folpet	Determination 1	93	95	97	Determination 2	95	96	97	Pourability (%)	Residue		0.8	0.8	0.8	Rinsed residue 1		---	---	0.24	Wet sieve test (% w/w)	> 75 µm		0.05	0.05	0.03	Particle size distribution	d (0.1)		1.18	1.19	1.19	d (0.5)		3.11	3.15	3.27	d (0.9)		8.71	8.69	9.94	Surface tension (mN/m)	Highest application conc. (20 °C)		43.7	---	---	Viscosity (mPa.s)	20 °C	0.5 rpm	18120 / 18600	---	---	5 rpm	3120 / 3066	10 rpm	1830 / 1806	30 rpm	809.0	40 °C	0.5 rpm	16860 / 15600	5 rpm	3024 / 2772	10 rpm	1728 / 1638	30 rpm	724.0	Determinations			EF/371/21/T0 ³	EF/371/21/HT ³	EF/371/21/T24	Persistent foam (mL) [Lowest Highest]	1 minute		[20 8]	[18 8]	[30 18]	12 minutes		[12 0]	[10 0]	[12 0]	Package stability			No visual degradation	No visual degradation	No visual degradation	Low temperature stability (EF/371/21/LT) ³						It was not noticed any separated material.						Prothioconazole content	% w/w		9.74			Folpet content	% w/w		25.20			Suspensibility (%)	Prothioconazole	Lowest application conc.	99			Highest application conc.	93			Folpet	Lowest application conc.	97			Highest application conc.	90			Wet sieve test (% w/w)	> 75 µm		0.06					
Determinations			EF/371/21/T0 ²	EF/371/21/HT ²	EF/371/21/T24																																																																																																																																																																																	
Suspensibility (%)	Prothioconazole	Lowest application conc.	99	98	98																																																																																																																																																																																	
		Highest application conc.	94	93	93																																																																																																																																																																																	
	Folpet	Lowest application conc.	97	97	97																																																																																																																																																																																	
		Highest application conc.	91	91	90																																																																																																																																																																																	
Spontaneity of dispersion (%)	Prothioconazole	Determination 1	96	97	97																																																																																																																																																																																	
		Determination 2	97	97	97																																																																																																																																																																																	
	Folpet	Determination 1	93	95	97																																																																																																																																																																																	
		Determination 2	95	96	97																																																																																																																																																																																	
Pourability (%)	Residue		0.8	0.8	0.8																																																																																																																																																																																	
	Rinsed residue 1		---	---	0.24																																																																																																																																																																																	
Wet sieve test (% w/w)	> 75 µm		0.05	0.05	0.03																																																																																																																																																																																	
Particle size distribution	d (0.1)		1.18	1.19	1.19																																																																																																																																																																																	
	d (0.5)		3.11	3.15	3.27																																																																																																																																																																																	
	d (0.9)		8.71	8.69	9.94																																																																																																																																																																																	
Surface tension (mN/m)	Highest application conc. (20 °C)		43.7	---	---																																																																																																																																																																																	
Viscosity (mPa.s)	20 °C	0.5 rpm	18120 / 18600	---	---																																																																																																																																																																																	
		5 rpm	3120 / 3066																																																																																																																																																																																			
		10 rpm	1830 / 1806																																																																																																																																																																																			
		30 rpm	809.0																																																																																																																																																																																			
	40 °C	0.5 rpm	16860 / 15600																																																																																																																																																																																			
		5 rpm	3024 / 2772																																																																																																																																																																																			
		10 rpm	1728 / 1638																																																																																																																																																																																			
		30 rpm	724.0																																																																																																																																																																																			
Determinations			EF/371/21/T0 ³	EF/371/21/HT ³	EF/371/21/T24																																																																																																																																																																																	
Persistent foam (mL) [Lowest Highest]	1 minute		[20 8]	[18 8]	[30 18]																																																																																																																																																																																	
	12 minutes		[12 0]	[10 0]	[12 0]																																																																																																																																																																																	
Package stability			No visual degradation	No visual degradation	No visual degradation																																																																																																																																																																																	
Low temperature stability (EF/371/21/LT) ³																																																																																																																																																																																						
It was not noticed any separated material.																																																																																																																																																																																						
Prothioconazole content	% w/w		9.74																																																																																																																																																																																			
Folpet content	% w/w		25.20																																																																																																																																																																																			
Suspensibility (%)	Prothioconazole	Lowest application conc.	99																																																																																																																																																																																			
		Highest application conc.	93																																																																																																																																																																																			
	Folpet	Lowest application conc.	97																																																																																																																																																																																			
		Highest application conc.	90																																																																																																																																																																																			
Wet sieve test (% w/w)	> 75 µm		0.06																																																																																																																																																																																			
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Not required, the product is stable for min. 2 years.	-	-	-																																																																																																																																																																																
Wettability (KCP 2.8.1)	-	-	Not required for SC formulations.	-	-	-																																																																																																																																																																																

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments			
Persistence of foaming (KCP 2.8.2)	AM078	SAP2101F Batch I-IEA	Foam volume (mL)			Y	KCP 2.8.2/01 Morais, F., 2022, Study EF-371-21 – Interim Report (T0) Submitted in KCP 2.1/01	Accepted.	
			Time	Initial					
				0.25%	1.00%				
			1 minute	20	8				
			12 minutes	12	0				
			Foam volume (mL)						
			Time	After 8 weeks at 40 °C					
				0.25%	1.00%				
			1 minute	18	8				
			12 minutes	10	0				
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184.1	SAP2101F Batch I-IEA	Prothioconazole:			Y	KCP 2.8.3.1/01 Morais, F., 2022, Study EF-371-21 – Interim Report (T0) Submitted in KCP 2.1/01	Accepted.	
			Application conc.:		0.25%				1.00%
			Initial		99%				94%
			After 8 weeks at 40 °C		98%				93%
			Folpet:						
			Application conc.:		0.25%				1.00%
			Initial		97%				91%
			After 8 weeks at 40 °C		97%				91%
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	SAP2101F Batch I-IEA	Prothioconazole:			Y	KCP 2.8.3.2/01 Morais, F., 2022, Study EF-371-21 – Interim Report (T0) Submitted in KCP 2.1/01	Accepted.	
			Dispersibility (%)						
			Initial		After 8 weeks at 40 °C				
			96/97		97/97				
			Folpet:						
			Dispersibility (%)						
			Initial		After 8 weeks at 40 °C				
			93/95		95/96				
Dispersion stability (KCP 2.8.3.3)	-	-	Not required for SC formulations.	-	-	-			
Degree of	-	-	Not required for SC formulations.	-	-	-			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments		
dissolution and dilution stability (KCP 2.8.4)								
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187	SAP2101F Batch I-IEA		Y	KCP 2.8.5.1.1/01 Morais, F., 2022, Study EF-371-21 – Interim Report (T0) Submitted in KCP 2.1/01	Accepted.		
			Particle size analysis results (µm)					
			Sample				Initial	After 8 weeks at 40 °C
			< 10%				1.18	1.19
			< 50%				3.11	3.15
			< 90%				8.71	8.69
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	SAP2101F Batch I-IEA		Y	KCP 2.8.5.1.2/01 Morais, F., 2022, Study EF-371-21 – Interim Report (T0) Submitted in KCP 2.1/01	Accepted.		
			Wet sieve test (%)					
			sieve				Initial	After 8 weeks at 40 °C
			> 75µm				0.05	0.05
Dust content (KCP 2.8.5.2.1)	-	-	Not required for SC formulations.	-	-	-		
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not required for SC formulations.	-	-	-		
Attrition (KCP 2.8.5.3)	-	-	Not required for SC formulations.	-	-	-		
Hardness and integrity (KCP 2.8.5.4)	-	-	Not required for SC formulations.	-	-	-		
Emulsifiability (KCP 2.8.6.1)	-	-	Not required for SC formulations.	-	-	-		

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments						
Emulsion stability (KCP 2.8.6.2)	-	-	Not required for SC formulations.	-	-	-						
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not required for SC formulations.	-	-	-						
Flowability (KCP 2.8.7.1)	-	-	Not required for SC formulations.	-	-	-						
Pourability (KCP 2.8.7.2)	CIPAC MT 148.1	SAP2101F Batch I-IEA	<table><tr><th colspan="2">Residue (%)</th></tr><tr><th>Initial</th><th>After 8 weeks at 40 °C</th></tr><tr><td>0.8</td><td>0.8</td></tr></table>	Residue (%)		Initial	After 8 weeks at 40 °C	0.8	0.8	Y	KCP 2.8.7.2/01 Morais, F., 2022, Study EF-371-21 – Interim Report (T0) Submitted in KCP 2.1/01	Accepted.
Residue (%)												
Initial	After 8 weeks at 40 °C											
0.8	0.8											
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not required for SC formulations.	-	-	-						
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not required as tank mixtures are not recommended.	-	-	The product is not intended to be used in tank mixes.						
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not required as tank mixtures are not recommended.	-	-	The product is not intended to be used in tank mixes.						
Adhesion to seeds (KCP 2.10.1)	-	-	Not required as the preparation is not for seed treatment.	-	-	-						

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Distribution to seed (KCP 2.10.2)	-	-	Not required as the preparation is not for seed treatment.	-	-	-
Other/special studies (KCP 2.11)	-	-	-	-	-	-

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)

Comments of zRMS:	The product showed no significant physical changes after two years of storage. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging (HDPE). Extrapolation from HDPE to HDPE co-extruded (HDPE/EVOH, HDPE/PA, HDPE-F) is acceptable.
-------------------	---

Table 4.1-1: Packaging information for 1 L bottle

Type	Description
Material:	HDPE (high density polyethylene)
Shape/size:	89.3 ± 0.5 mm diameter x 230 ± 1 mm of total height
Opening:	59.5 ± 0.5 mm inner diameter
Closure:	1. high density polyethylene screw cap 2. self-ventilated screw cap
Seal:	1. hot seal / aluminum / polyester 2. screw cap system / tamper-proof cap / expanded PE seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-2: Packaging information for 1 L bottle

Type	Description
Material:	HDPE (high density polyethylene) or Coex
Shape/size:	88.5 ± 2 mm diameter x 233.2 ± 1.6 mm of total height
Opening:	63 mm
Closure:	1. polyethylene screw cap 2. self-ventilated screw cap
Seal:	1. PET/ALU/PEE; IHS; Tresylene 2. screw cap system / tamper-proof cap / expanded PE seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-3: Packaging information for 1 L bottle

Type	Description
Material:	HDPE (high density polyethylene)
Shape/size:	88.5 ± 0.5 mm diameter x 233 ± 1 mm of total height
Opening:	59.3 + 0.8 mm inner diameter
Closure:	1. high density polyethylene screw cap, model: Ø63 2. self-ventilated screw cap
Seal:	1. <i>b-Gasket</i> : disk, duplex 2. screw cap system / tamper-proof cap / expanded PE seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-4: Packaging information for 1 L bottle

Type	Description
Material:	HDPE (high density polyethylene)

Type	Description
Shape/size:	88.5 ± 0.5 mm diameter x 240 ± 1.5 mm of total height
Opening:	46 – 0.7 mm inner diameter
Closure:	1. high density polyethylene screw cap, model: KS50 2. self-ventilated screw cap
Seal:	1. <i>b-Gasket</i> : disk, duplex 2. screw cap system / tamper-proof cap / expanded PE seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-5: Packaging information for 1 L bottle

Type	Description
Material:	HDPE (high density polyethylene)
Shape/size:	89.3 ± 0.5 mm diameter x 228 mm of total height
Opening:	54.7 mm inner diameter
Closure:	1. high density polyethylene screw cap 2. self-ventilated screw cap
Seal:	1. - 2. screw cap system / tamper-proof cap / expanded PE seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-6: Packaging information for 1 L bottle

Type	Description
Material:	HDPE/EVOH (Coex)
Shape/size:	89.5 ± 0.5 mm diameter x 230 ± 1 mm of total height
Opening:	59.5 ± 0.5 mm inner diameter
Closure:	1. high density polyethylene screw cap 2. self-ventilated screw cap
Seal:	1. hot seal / aluminum / polyester 2. screw cap system / tamper-proof cap / expanded PE seal
Manner of construction	coextruded
UN/ADR	compliant

Table 4.1-7: Packaging information for 1 L bottle

Type	Description
Material:	HDPE/PA (Coex)
Shape/size:	88.5 ± 0.5 mm diameter x 233 ± 1 mm of total height
Opening:	59.3 + 0.8 mm inner diameter
Closure:	1. high density polyethylene screw cap, model: Ø63 2. self-ventilated screw cap
Seal:	1. <i>b-Gasket</i> : disk, duplex 2. screw cap system / tamper-proof cap / expanded PE seal
Manner of construction	coextruded
UN/ADR	compliant

Table 4.1-8: Packaging information for 1 L bottle

Type	Description
Material:	HDPE/PA (Coex)
Shape/size:	88.5 ± 0.5 mm diameter x 240 ± 1 mm of total height
Opening:	46.0 - 0.7 mm inner diameter
Closure:	1. high density polyethylene screw cap, model: KS50 2. self-ventilated screw cap
Seal:	1. <i>b-Gasket</i> : disk, duplex 2. screw cap system / tamper-proof cap / expanded PE seal
Manner of construction	coextruded
UN/ADR	compliant

Table 4.1-9: Packaging information for 5 L jerrycan

Type	Description
Material:	HDPE (high density polyethylene)
Shape/size:	188 ± 1 mm length (bottom) x 279.5 ± 1 mm of total height
Opening:	59 ± 0.5 mm inner diameter
Closure:	1. high density polyethylene screw cap 2. self-ventilated screw cap
Seal:	1. hot seal / aluminum / polyester 2. screw cap system / tamper-proof cap / expanded PE seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-10: Packaging information for 5 L jerrycan

Type	Description
Material:	HDPE (high density polyethylene)
Shape/size:	191 ± 2 mm length (bottom) x 285 ± 3 mm of total height
Opening:	59.3 + 0.8 mm inner diameter
Closure:	1. high density polyethylene screw cap, model: D.63 2. self-ventilated screw cap
Seal:	1. <i>b-Gasket</i> : disk, duplex 2. screw cap system / tamper-proof cap / expanded PE seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-11: Packaging information for 5 L jerrycan

Type	Description
Material:	HDPE (high density polyethylene)
Shape/size:	192 mm length (bottom) x 285 mm of total height
Opening:	54.7 mm
Closure:	1. polyethylene screw cap 2. self-ventilated screw cap
Seal:	1. - 2. screw cap system / tamper-proof cap / expanded PE seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-12: Packaging information for 5 L jerrycan

Type	Description
Material:	HDPE (high density polyethylene)
Shape/size:	191 ± 5.73 mm length (bottom) x 290 ± 8.7 mm of total height
Opening:	60 ± 1.8 mm inner diameter
Closure:	1. polyethylene screw cap 2. self-ventilated screw cap
Seal:	1. expanded polyethylene 2. screw cap system / tamper-proof cap / expanded PE seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-13: Packaging information for 5 L jerrycan

Type	Description
Material:	HDPE/PA (Coex)
Shape/size:	191 mm length (bottom) x 290 mm of total height
Opening:	63 mm
Closure:	1. polyethylene screw cap 2. self-ventilated screw cap
Seal:	1. - 2. screw cap system / tamper-proof cap / expanded PE seal
Manner of construction	coextruded
UN/ADR	compliant

Table 4.1-14: Packaging information for 5 L jerrycan

Type	Description
Material:	HDPE/EVOH (Coex)
Shape/size:	190 ± 1 mm length (bottom) x 282 ± 1 mm of total height
Opening:	59.5 ± 0.5 mm inner diameter
Closure:	1. high density polyethylene screw cap 2. self-ventilated screw cap
Seal:	1. hot seal / aluminum / polyester 2. screw cap system / tamper-proof cap / expanded PE seal
Manner of construction	coextruded
UN/ADR	compliant

Table 4.1-15: Packaging information for 5 L jerrycan

Type	Description
Material:	HDPE/PA (Coex)
Shape/size:	191 ± 2 mm length (bottom) x 285 ± 3 mm of total height
Opening:	59.3 + 0.8 mm inner diameter
Closure:	1. high density polyethylene screw cap, model: D63 2. self-ventilated screw cap
Seal:	1. <i>b-Gasket</i> : disk, Chromo AIKO safe foil 2. screw cap system / tamper-proof cap / expanded PE seal
Manner of construction	coextruded
UN/ADR	compliant

Table 4.1-16: Packaging information for 5 L jerrycan

Type	Description
Material:	HDPE/PA (Coex)
Shape/size:	191 ± 2 mm length (bottom) x 285 ± 3 mm of total height
Opening:	59.3 + 0.8 mm inner diameter
Closure:	1. high density polyethylene screw cap, model: D63 2. self-ventilated screw cap
Seal:	1. <i>b-Gasket</i> : disk, duplex 2. screw cap system / tamper-proof cap / expanded PE seal
Manner of construction	coextruded
UN/ADR	compliant

Table 4.1-17: Packaging information for 10 L jerrycan

Type	Description
Material:	HDPE (high density polyethylene)
Shape/size:	225.2 ± 2 mm length x 308.9 ± 1 mm of total height
Opening:	55 ± 0.5 mm inner diameter
Closure:	1. high density polyethylene screw cap 2. self-ventilated screw cap
Seal:	1. hot seal / aluminum / polyester 2. screw cap system / tamper-proof cap / expanded PE seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-18: Packaging information for 10 L jerrycan

Type	Description
Material:	HDPE (high density polyethylene)
Shape/size:	225 ± 3 mm length x 378 ± 3 mm of total height
Opening:	54.7 ± 0.3 mm inner diameter
Closure:	1. polyethylene screw cap 2. self-ventilated screw cap
Seal:	1. - 2. screw cap system / tamper-proof cap / expanded PE seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-19: Packaging information for 10 L jerrycan

Type	Description
Material:	HDPE/EVOH (Coex)
Shape/size:	225.2 ± 2 mm length x 308.9 ± 1 mm of total height
Opening:	59 ± 0.5 mm inner diameter
Closure:	1. high density polyethylene screw cap 2. self-ventilated screw cap
Seal:	1. hot seal / aluminum / polyester 2. screw cap system / tamper-proof cap / expanded PE seal
Manner of construction	coextruded
UN/ADR	compliant

Table 4.1-20: Packaging information for 10 L jerrycan

Type	Description
Material:	HDPE/PA (Coex)
Shape/size:	229.5 ± 3 mm length x 378.0 ± 3 mm of total height
Opening:	54.7 ± 0.3 mm inner diameter
Closure:	1. polyethylene screw cap 2. self-ventilated screw cap
Seal:	1. - 2. screw cap system / tamper-proof cap / expanded PE seal
Manner of construction	coextruded
UN/ADR	compliant

Table 4.1-21: Packaging information for 20 L jerrycan

Type	Description
Material:	HDPE (high density polyethylene)
Shape/size:	270 ± 2 mm length (bottom) x 371 ± 2 mm of total height
Opening:	47.5 ± 2 mm inner diameter
Closure:	high density polyethylene screw cap
Seal:	hot seal / aluminum / polyester
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-22: Packaging information for 20 L jerrycan

Type	Description
Material:	HDPE (high density polyethylene)
Shape/size:	267.5 ± 2 mm length (bottom) x 367 ± 2 mm of total height
Opening:	59.5 ± 0.5 mm inner diameter
Closure:	high density polyethylene screw cap
Seal:	hot seal / aluminum / polyester
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-23: Packaging information for 20 L jerrycan

Type	Description
Material:	HDPE (high density polyethylene)
Shape/size:	280 ± 8.4 mm length (bottom) x 398 ± 11.94 mm of total height
Opening:	58 ± 1.74 mm
Closure:	polyethylene screw cap, ø 63 mm
Seal:	expanded polyethylene
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-24: Packaging information for 20 L jerrycan

Type	Description
Material:	HDPE (high density polyethylene)
Shape/size:	293 ± 3 mm length x 400 ± 3 mm of total height

Type	Description
Opening:	60 mm
Closure:	polyethylene screw cap
Seal:	PET/ALU/PEE; IHS; Tresylene
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-25: Packaging information for 20 L jerrycan

Type	Description
Material:	HDPE/EVOH (Coex)
Shape/size:	270 ± 2 mm length (bottom) x 371 ± 2 mm of total height
Opening:	47.5 ± 2 mm inner diameter
Closure:	high density polyethylene screw cap
Seal:	hot seal / aluminum / polyester
Manner of construction	coextruded
UN/ADR	compliant

Table 4.1-26: Packaging information for 20 L jerrycan

Type	Description
Material:	HDPE/EVOH (Coex)
Shape/size:	271 ± 2 mm length (bottom) x 370 ± 2 mm of total height
Opening:	60 ± 0.5 mm inner diameter
Closure:	high density polyethylene screw cap
Seal:	hot seal / aluminum / polyester
Manner of construction	coextruded
UN/ADR	compliant

Compatibility with the preparation

The materials proposed for use are known from experience to be very resistant to the influence of chemicals. The contents have no negative effect on the packet integrity.

The packages were examined for any visible changes, and they did not suffer any change. Please see point KCP 2.7.2.

Findings:

Visual observations for package stability

Damage types	Visual Observations		
	Initial	After 8 weeks at 40 °C	After 24 months
Deformation	No	No	No
Attack by the contents	No	No	No
Leaking	No	No	No
Label damage	No	No	No
Conclusion	No visual degradation	No visual degradation	No visual degradation

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 2.1/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product Study EF/371/21 – Interim Report (T0) ASCENZA Agro, S.A. GLP Unpublished	N	ASCENZA Agro, S.A.
KCP 2.2.1/01	Nichetti, S.	2022	Prothioconazole 120 g/L + Folpet 300 g/L SC – SAP2101F: Determination of the Physico-chemical Properties Report No.: CH – 0508/2021 ChemService GLP Unpublished	N	ASCENZA Agro, S.A.
KCP 2.2.2/01	Nichetti, S.	2022	Prothioconazole 120 g/L + Folpet 300 g/L SC – SAP2101F: Determination of the Physico-chemical Properties Report No.: CH – 0508/2021 ChemService GLP Unpublished (Submitted in KCP 2.2.1/01)	N	ASCENZA Agro, S.A.
KCP 2.3.1/01	Nichetti, S.	2022	Prothioconazole 120 g/L + Folpet 300 g/L SC – SAP2101F: Determination of the Physico-chemical Properties Report No.: CH – 0508/2021 ChemService GLP Unpublished (Submitted in KCP 2.2.1/01)	N	ASCENZA Agro, S.A.
KCP 2.3.3/01	Nichetti, S.	2022	Prothioconazole 120 g/L + Folpet 300 g/L SC – SAP2101F: Determination of the Physico-chemical Properties Report No.: CH – 0508/2021 ChemService GLP Unpublished (Submitted in KCP 2.2.1/01)	N	ASCENZA Agro, S.A.
KCP 2.4.1/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product	N	ASCENZA Agro, S.A.

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 EF/371/21 – Interim Report (T0) ASCENZA Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)		
KCP 2.4.2/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product Study EF/371/21 – Interim Report (T0) ASCENZA Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	ASCENZA Agro, S.A.
KCP 2.5.1/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product Study EF/371/21 – Interim Report (T0) ASCENZA Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	ASCENZA Agro, S.A.
KCP 2.5.2/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product Study EF/371/21 – Interim Report (T0) ASCENZA Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	ASCENZA Agro, S.A.
KCP 2.6.1/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product Study EF/371/21 – Interim Report (T0) ASCENZA Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	ASCENZA Agro, S.A.
KCP 2.7.2/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product	N	ASCENZA Agro, S.A.

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 EF/371/21 – Interim Report (T0) ASCENZA Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)		
KCP 2.7.4/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product Study EF/371/21 – Interim Report (T0) ASCENZA Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	ASCENZA Agro, S.A.
KCP 2.7.5/01	Morais, F.	2022 2024	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product Study EF/371/21 – Interim Report (T0) (T0-T24) ASCENZA Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	ASCENZA Agro, S.A.
KCP 2.8.2/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product Study EF/371/21 – Interim Report (T0) ASCENZA Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	ASCENZA Agro, S.A.
KCP 2.8.3.1/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product Study EF/371/21 – Interim Report (T0) ASCENZA Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	ASCENZA Agro, S.A.
KCP 2.8.3.2/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product	N	ASCENZA Agro, S.A.

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 EF/371/21 – Interim Report (T0) ASCENZA Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)		
KCP 2.8.5.1.1/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product Study EF/371/21 – Interim Report (T0) ASCENZA Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	ASCENZA Agro, S.A.
KCP 2.8.5.1.2/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product Study EF/371/21 – Interim Report (T0) ASCENZA Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	ASCENZA Agro, S.A.
KCP 2.8.7.2/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product Study EF/371/21 – Interim Report (T0) ASCENZA Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	ASCENZA Agro, S.A.

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
-	-	-	-	-	-

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 Prothioconazole

No additional data is submitted.

A 2.2 Folpet

No additional data is submitted.