

# 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: SAP50SCF

Product name(s): FOLPEC

Chemical active substance:

Folpet, 500 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: May 2024 (initial Core Assessment)

August 2024 (final Core Assessment)

### Version history

When	What
December 2023	V0 - Initial version submitted by the Selectis Productos 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)
May 2024	Initial assessment by the zRMS  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 <del>struck through</del> and shaded for transparency.
August 2024	Final report (Core Assessment updated following the commenting period)  No additional information or assessments after the commenting period.

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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 Folpet**

Folpet	min. 940 g/kg according to Reg. (EU) 540/2011 min. 960 g/kg (ASCENZA Agro, S.A. minimum purity)
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##### **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: SAP50SCF

## 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)
Folpet	500	475 – 525 g/L	520.8	42

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

\*\* Based on the density of the formulation = 1.24 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)
SAP50SCF does not contain safeners or synergists				

**Table 1.4-3: Relevant impurities**

Relevant impurity	Maximum content (g/kg)
Perchloromethylmercaptan	1.75
Carbon tetrachloride	2

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

**Table 1.4-4: 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 cream liquid suspension concentrate, with a characteristic odour. It is not explosive, has no oxidising properties. No flash point was observed. It did not self-ignite at temperature of up to 400 °C. In aqueous solution, it has a pH value around 6.0 at 20.1 °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 2 years at ambient temperature when stored in *HDPE*, Coex PA and Coex EVOH. Its technical characteristics are acceptable for a *suspension concentrate* formulation.

The intended concentration of use is 0.3% ~~0.225%~~ to 0.8%.

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 SAP50SCF complies with FAO specifications.

### **Formulation used for tests**

The formulation used for 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)	Visual and organoleptic, OPPTS 830.6302 OPPTS 830.6303 OPPTS 830.6304	SAP50SCF Batch V-FSA	<u>Initial and after 14 days at 54 °C:</u> Cream liquid suspension concentrate with characteristic odour;  <u>After 24 months:</u> Cream liquid suspension concentrate with characteristic odour.	Y	KCP 2.1/01 Boas, P. (2011), Study EF/88/11  KCP 2.1/02 Vieira, R. (2013), Study EF/88/11-T24	Accepted.
Explosive properties (KCP 2.2.1)	Theoretical certificate by expert	SAP50SCF	No explosive hazards in the formulation.	N	KCP 2.2.1/01 Correia, C., 2022, Doc. no. TR/22/04	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)	Theoretical certificate by expert	SAP50SCF	No oxidant hazards in the formulation.	N	KCP 2.2.2/01 Correia, C., 2022, Doc. no. TR/22/04 <b>(Submitted in KCP 2.2.1/01)</b>	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 A9	SAP50SCF Batch V-FSA	No flash observed.	Y	KCP 2.3.1/01 Campbell, N. (2011), Doc. no. OA02062	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.
Flammability (KCP 2.3.2)	-	-	Not applicable for SC formulations.	-	-	-
Self-heating	EEC A15	SAP50SCF		Y	KCP 2.3.3/01	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																		
(KCP 2.3.3)		Batch V-FSA	Sample did not self-ignite at temperature of up to 400 °C.		Campbell, N. (2011), Doc. no. OA02062 <b>(Submitted in KCP 2.3.1/01)</b>	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	SAP50SCF Batch 20J0785B	Acidity or alkalinity are not required since pH between 4 and 10. <b>pH in neat preparation:</b> <u>Initial:</u> 5.1 (19.5 °C)  <u>After 14 days at 54 °C:</u> 5.1 (19.8 °C)	Y	KCP 2.4.1/01 Morais, F. (2022), Study EF/375/21	Accepted.																		
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	MT065	SAP50SCF Batch V-FSA	<u>Initial:</u> 7.6 (25.4 °C) <u>After 14 days at 54 °C:</u> 7.2 (25.3 °C)  <u>After 24 months:</u> 7.7 (24.5 °C)	Y	KCP 2.4.2/01 Boas, P. (2011), Study EF/88/11 <b>(Submitted in KCP 2.1/01)</b>	Accepted.																		
	AM063				KCP 2.4.2/02 Vieira, R. (2013), Study EF/88/11-T24 <b>(Submitted in KCP 2.1/02)</b>																			
	AM063	Batch 20J0785B	<u>Initial:</u> 6.0 (20.1 °C) <u>After 14 days at 54 °C:</u> 6.0 (20.1 °C)		KCP 2.4.2/03 Morais, F. (2022), Study EF/375/21 <b>(Submitted in KCP 2.4.1/01)</b>																			
Viscosity (KCP 2.5.1)	CIPAC MT 192	SAP50SCF Batch V-FSA    Batch	<table><tr><th colspan="3">Viscosity (cP) (20 °C)</th></tr><tr><th></th><th>Initial</th><th>After 14 days at 54°C</th></tr><tr><td>10 rpm</td><td>1344.0/1308.0</td><td>1140.0/1140.0</td></tr><tr><td>20 rpm</td><td>786.0/792.0</td><td>702.0/702.0</td></tr><tr><td>50 rpm</td><td>403.8/410.4</td><td>376.8/376.8</td></tr><tr><td>100 rpm</td><td>256.8</td><td>240</td></tr></table>	Viscosity (cP) (20 °C)				Initial	After 14 days at 54°C	10 rpm	1344.0/1308.0	1140.0/1140.0	20 rpm	786.0/792.0	702.0/702.0	50 rpm	403.8/410.4	376.8/376.8	100 rpm	256.8	240	Y	KCP 2.5.1/01 Boas, P. (2011), Study EF/88/11 <b>(Submitted in KCP 2.1/01)</b>  KCP 2.5.1/02	Accepted.
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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																		
		20J0785B	<table><tr><th colspan="3">Viscosity (cP)</th></tr><tr><td></td><td>20 °C</td><td>40 °C</td></tr><tr><td>0.5 rpm</td><td>18120/18600</td><td>16860/15600</td></tr><tr><td>5 rpm</td><td>3120/3072</td><td>3024/2772</td></tr><tr><td>10 rpm</td><td>1830/1806</td><td>1728/1638</td></tr><tr><td>30 rpm</td><td>807.0</td><td>724.0</td></tr></table>	Viscosity (cP)				20 °C	40 °C	0.5 rpm	18120/18600	16860/15600	5 rpm	3120/3072	3024/2772	10 rpm	1830/1806	1728/1638	30 rpm	807.0	724.0		Morais, F. (2022), Study EF/375/21 <b>(Submitted in KCP 2.4.1/01)</b>	
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30 rpm	807.0	724.0																						
Surface tension (KCP 2.5.2)	EEC A5  AM243	SAP50SCF Batch V-FSA  Batch 20J0785B	<u>Initial:</u> 36.3 mN/m (20 °C)  <u>Initial:</u> 31.2 mN/m (20 °C)  Since the surface tension is below 60 mN/m, the formulation tested should be regarded as being a surface-active material.	Y	KCP 2.5.2/01 Boas, P. (2011), Study EF/88/11 <b>(Submitted in KCP 2.1/01)</b>  KCP 2.5.2/02 Morais, F. (2022), Study EF/375/21 <b>(Submitted in KCP 2.4.1/01)</b>	Accepted.  The formulation should be considered as being a surface-active.																		
Relative density (KCP 2.6.1)	CIPAC MT 3.3.2  AM262	SAP50SCF Batch V-FSA  Batch 20J0785B	<u>Initial and after 14 days at 54 °C:</u> 1.24  <u>After 24 months:</u> 1.24  <table><tr><td></td><th>Density (g/cm³)</th><th>Relative density</th></tr><tr><td>Initial</td><td>1.23</td><td>1.23</td></tr><tr><td>After 14 days at 54 °C</td><td>1.22</td><td>1.22</td></tr></table> Measuring Temperature: 20 °C ± 0.5 °C		Density (g/cm³)	Relative density	Initial	1.23	1.23	After 14 days at 54 °C	1.22	1.22	Y	KCP 2.6.1/01 Boas, P. (2011), Study EF/88/11 <b>(Submitted in KCP 2.1/01)</b> KCP 2.6.1/02 Vieira, R. (2013), Study EF/88/11-T24 <b>(Submitted in KCP 2.1/02)</b>  KCP 2.6.1/03 Morais, F. (2022), Study EF/375/21 <b>(Submitted in KCP 2.4.1/01)</b>	Accepted.									
	Density (g/cm³)	Relative density																						
Initial	1.23	1.23																						
After 14 days at 54 °C	1.22	1.22																						
Bulk density (KCP 2.6.2)	-	-	Not applicable for SC formulations.	-	-	-																		
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.4 HPLC – UV –	SAP50SCF Batch V-FSA and	The sample is considered to be stable at 54 °C for 14 days. The physical-chemical properties are similar between samples before and after storage.	Y	KCP 2.7.1/01 Boas, P. (2011), Study EF/88/11	The product showed no significant physical changes after accelerated																		

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																																																																					
	validated according to SANCO/3030/99 rev.4;  COEX bottles	20J0785B	<div>Please see points KCP 2.1, KCP 2.4.1, KCP 2.4.2, KCP 2.5.1, 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.</div> <table><tr><th colspan="2">Determinations</th><th>EF/88/11/T0</th><th>EF/88/11/HT after 14 days at 54° C</th></tr><tr><td rowspan="2">Active ingredient contents</td><td>(%)</td><td>40.43</td><td>39.47</td></tr><tr><td>g/L</td><td>501.3</td><td>489.4</td></tr><tr><td>Relative density</td><td>g/ml</td><td>1.24</td><td>1.24</td></tr><tr><td>Appearance</td><td>Physical state/ Colour/Odour</td><td>Liquid (suspension concentrate)/ Cream/Characteristic Odour</td><td>Liquid (suspension concentrate)/ Cream/Characteristic Odour</td></tr><tr><td colspan="2">Determination of pH</td><td>7.6</td><td>7.2</td></tr><tr><td rowspan="2">Suspensibility (%)</td><td>Maximum dosage: 1.0 kg a.i/hL</td><td>101</td><td>95</td></tr><tr><td>Minimum dosage 0.1 kg a.i/hL</td><td>99</td><td>102</td></tr><tr><td colspan="2">Spontaneity of dispersion (%)</td><td>102/101</td><td>97/99</td></tr><tr><td>Pourability (%)</td><td>Residue</td><td>2.1</td><td>2.3</td></tr><tr><td>Wet sieve test</td><td>(%) &lt; 75 µm</td><td>0.02</td><td>0.03</td></tr><tr><td rowspan="4">Particle size distribution</td><td>10.0% &lt; (µm)</td><td>0.64</td><td>0.72</td></tr><tr><td>50.0% &lt; (µm)</td><td>1.59</td><td>1.73</td></tr><tr><td>90.0% &lt; (µm)</td><td>3.52</td><td>3.69</td></tr><tr><td>95.0% &lt; (µm)</td><td>4.30</td><td>4.45</td></tr><tr><td colspan="2">Surface tension (mN/m)</td><td>36.3</td><td>NR</td></tr><tr><td rowspan="4">Viscosity (cP)</td><td>10rpm</td><td>1344.0/1308.0</td><td>1140.0/1140.0</td></tr><tr><td>20rpm</td><td>786.0/792.0</td><td>702.0/702.0</td></tr><tr><td>50rpm</td><td>403.8/410.4</td><td>376.8/376.8</td></tr><tr><td>100rpm</td><td>256.8</td><td>240.0</td></tr><tr><td rowspan="4">Persistent foaming (mL)</td><td>10''</td><td>30.0</td><td>30.0</td></tr><tr><td>1'</td><td>0.0</td><td>0.0</td></tr><tr><td>3'</td><td>0.0</td><td>0.0</td></tr><tr><td>12'</td><td>0.0</td><td>0.0</td></tr></table>	Determinations		EF/88/11/T0	EF/88/11/HT after 14 days at 54° C	Active ingredient contents	(%)	40.43	39.47	g/L	501.3	489.4	Relative density	g/ml	1.24	1.24	Appearance	Physical state/ Colour/Odour	Liquid (suspension concentrate)/ Cream/Characteristic Odour	Liquid (suspension concentrate)/ Cream/Characteristic Odour	Determination of pH		7.6	7.2	Suspensibility (%)	Maximum dosage: 1.0 kg a.i/hL	101	95	Minimum dosage 0.1 kg a.i/hL	99	102	Spontaneity of dispersion (%)		102/101	97/99	Pourability (%)	Residue	2.1	2.3	Wet sieve test	(%) < 75 µm	0.02	0.03	Particle size distribution	10.0% < (µm)	0.64	0.72	50.0% < (µm)	1.59	1.73	90.0% < (µm)	3.52	3.69	95.0% < (µm)	4.30	4.45	Surface tension (mN/m)		36.3	NR	Viscosity (cP)	10rpm	1344.0/1308.0	1140.0/1140.0	20rpm	786.0/792.0	702.0/702.0	50rpm	403.8/410.4	376.8/376.8	100rpm	256.8	240.0	Persistent foaming (mL)	10''	30.0	30.0	1'	0.0	0.0	3'	0.0	0.0	12'	0.0	0.0		(Submitted in KCP 2.1/01)	storage. However, there is no detailed information about the type of packages tested during storage.
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	<div>CIPAC MT 46.4</div> <div>HDPE bottles</div> <div>Folpet was quantified using a method developed and validated internally AM071, refer RR Part B5.</div>	SAP50SCF Batch V-FSA and 20J0785B	<table><tr><td colspan="2">Determinations</td><td>EF/375/21/T0</td><td>EF/375/21/HT</td></tr><tr><td rowspan="2">Folpet content</td><td>% w/w</td><td>39.64</td><td>40.48</td></tr><tr><td>g/L</td><td>487.5</td><td>493.9</td></tr><tr><td>PMM content</td><td>% w/w</td><td>&lt;LOQ (0.144)</td><td>&lt;LOQ (0.144)</td></tr><tr><td>CCl<sub>4</sub> content</td><td>% w/w</td><td>&lt;LOQ (0.081)</td><td>&lt;LOQ (0.081)</td></tr><tr><td rowspan="2">Determination of pH</td><td>1 % concentration</td><td>6.0</td><td>6.0</td></tr><tr><td>Neat preparation</td><td>5.1</td><td>5.1</td></tr><tr><td rowspan="2">Density</td><td>g/mL</td><td>1.23</td><td>1.22</td></tr><tr><td>Relative density</td><td>1.23</td><td>1.22</td></tr><tr><td rowspan="2">Suspensibility (%)</td><td>Lowest application conc.</td><td>99</td><td>99</td></tr><tr><td>Highest application conc.</td><td>100</td><td>98</td></tr><tr><td rowspan="3">Particle size distribution</td><td>&lt; 10.0 % µm</td><td>0.62</td><td>0.66</td></tr><tr><td>&lt; 50.0 % µm</td><td>1.62</td><td>1.77</td></tr><tr><td>&lt; 90.0 % µm</td><td>4.79</td><td>5.05</td></tr><tr><td>Surface tension (mN/m)</td><td>Highest application conc. (20 °C)</td><td>31.2</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></tr><tr><td>5 rpm</td><td>3120 / 3072</td></tr><tr><td>10 rpm</td><td>1830 / 1806</td></tr><tr><td>30 rpm</td><td>807.0</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>Persistent foam (mL.) [Lowest   Highest]</td><td>1 minute</td><td>[14   0]</td><td>[18   0]</td></tr><tr><td></td><td>12 minutes</td><td>[10   0]</td><td>[12   0]</td></tr><tr><td>Package stability</td><td colspan="2">No visual degradation</td><td>No visual degradation</td></tr><tr><td colspan="4">Low temperature stability (EF/375/21/L/T)</td></tr><tr><td colspan="4">It was not noticed any separated material.</td></tr><tr><td>Folpet content</td><td>% w/w</td><td colspan="2">39.51</td></tr><tr><td rowspan="2">Suspensibility (%)</td><td>Highest application conc.</td><td colspan="2">99</td></tr><tr><td>Lowest application conc.</td><td colspan="2">99</td></tr><tr><td>Wet sieve test</td><td>% w/w</td><td colspan="2">0.19</td></tr></table> <div>Where test-item solutions need to be prepared take into account that: Lowest application concentration: 2.5 mL/L (0.25 %) Highest application concentration: 8.0 mL/L (0.80 %)</div>	Determinations		EF/375/21/T0	EF/375/21/HT	Folpet content	% w/w	39.64	40.48	g/L	487.5	493.9	PMM content	% w/w	<LOQ (0.144)	<LOQ (0.144)	CCl <sub>4</sub> content	% w/w	<LOQ (0.081)	<LOQ (0.081)	Determination of pH	1 % concentration	6.0	6.0	Neat preparation	5.1	5.1	Density	g/mL	1.23	1.22	Relative density	1.23	1.22	Suspensibility (%)	Lowest application conc.	99	99	Highest application conc.	100	98	Particle size distribution	< 10.0 % µm	0.62	0.66	< 50.0 % µm	1.62	1.77	< 90.0 % µm	4.79	5.05	Surface tension (mN/m)	Highest application conc. (20 °C)	31.2	---	Viscosity (mPa.s)	20 °C	0.5 rpm	18120 / 18600	5 rpm	3120 / 3072	10 rpm	1830 / 1806	30 rpm	807.0	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	[14   0]	[18   0]		12 minutes	[10   0]	[12   0]	Package stability	No visual degradation		No visual degradation	Low temperature stability (EF/375/21/L/T)				It was not noticed any separated material.				Folpet content	% w/w	39.51		Suspensibility (%)	Highest application conc.	99		Lowest application conc.	99		Wet sieve test	% w/w	0.19		Y	KCP 2.7.1/02 Morais, F. (2022), Study EF/375/21 (Submitted in KCP 2.4.1/01)	<div>Accepted.</div> <div>The product showed no significant physical changes after accelerated storage.</div> <div>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.</div> <div>The accelerated stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging (HDPE).</div>
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Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	No other storage periods or temperatures tested.	-	-	-																																																																																																												
Minimum content after heat stability testing (KCP 2.7.3)	-	-	Not required, since the a.s. is not heat-sensitive.	-	-	-																																																																																																												
Effect of low temperatures	CIPAC MT 39.3	SAP50SCF	Visual observation: No phase separation or solid deposition.	Y	KCP 2.7.4/01	Accepted.																																																																																																												

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on stability (KCP 2.7.4)	CIPAC MT 184 and MT074 CIPAC MT 185       CIPAC MT 39.3 CIPAC MT 184.1	Batch V-FSA       Batch 20J0785B	<u>Suspensability:</u> <table><tr><td>Application conc.:</td><td>Lowest</td><td>Highest</td></tr><tr><td>After 7 days at 0 °C</td><td>98%</td><td>102%</td></tr></table> <u>Wet sieve test:</u> 0.03% (sieve > 75µm)  Visual observation: It was not noticed any separated material. <u>Suspensability:</u> <table><tr><td>Application conc.:</td><td>Lowest</td><td>Highest</td></tr><tr><td>After 7 days at 0 °C</td><td>99%</td><td>99%</td></tr></table> <u>Wet sieve test:</u> 0.19% (sieve > 75µm)  The product was stable for one week at 0 °C. The physical-chemical properties are similar between samples before and after storage.	Application conc.:	Lowest	Highest	After 7 days at 0 °C	98%	102%	Application conc.:	Lowest	Highest	After 7 days at 0 °C	99%	99%		Boas, P. (2011), Study EF/88/11 <b>(Submitted in KCP 2.1/01)</b>     KCP 2.7.4/02 Morais, F. (2022), Study EF/375/21 <b>(Submitted in KCP 2.4.1/01)</b>	
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Ambient temperature shelf life (KCP 2.7.5)	GIFAP Technical Monograph 17  Folpet was quantified using a HPLC-UV method validated in this study (T0) in SAPEC Agro laboratory (internal method AM071)  COEX bottle	SAP50SCF Batch V-FSA	The physical-chemical properties are similar between samples before and after being stored for 24 months at ambient temperature in Coex packages. Please refer to points KCP 2.1, 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.  Since the product presents similar and acceptable results before and after being stored for 14 days at 54 °C in <del>HDPE</del> COEX bottle, it is considered that the product is also stable after twenty-four months at ambient temperature. Please see KCP 2.7.1.  Maximum dosage: 1.0 kg a.i/hL Minimum dosage: 0.1 kg a.i/hL	Y	KCP 2.7.5/01 Vieira, R. (2013), Study EF/88/11-T24 <b>(Submitted in KCP 2.1/01)</b>	The product showed no significant physical changes after storage. However, there is no detailed information about the type of packages tested during storage.												

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	<div>GIFAP Technical Monograph 17</div> <div>Folpet was quantified using a method developed and validated internally AM071, refer RR Part B5.</div>	<div>Batch 20J0785B</div>	<div>The physical-chemical properties are similar between samples before and after being stored for 24 months at ambient temperature in HDPE packages.</div> <div>Please refer to points KCP 2.1, 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.</div> <div>Since the product presents similar and acceptable results before and after being stored for 14 days at 54 °C in HDPE, it is considered that the product is also stable after twenty-four months at ambient temperature. Please see KCP 2.7.1.</div>	Y	KCP 2.7.5/02 Morais, F. (2022), Study EF/375/21 (Submitted in KCP 2.4.1/01)	<div>Accepted.</div> <div>The product showed no significant physical changes after storage.</div> <div>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.</div> <div>The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in</div>																																																																																																																																														

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			<table><tr><td colspan="2">Determinations</td><td>EF/375/21/T0</td><td>EF/375/21/HT</td></tr><tr><td rowspan="2">Folpet content</td><td>% w/w</td><td>39.64</td><td>40.48</td></tr><tr><td>g/L</td><td>487.5</td><td>493.9</td></tr><tr><td>PMM content</td><td>% w/w</td><td>&lt;LOQ (0.144)</td><td>&lt;LOQ (0.144)</td></tr><tr><td>CCl<sub>4</sub> content</td><td>% w/w</td><td>&lt;LOQ (0.081)</td><td>&lt;LOQ (0.081)</td></tr><tr><td rowspan="2">Determination of pH</td><td>1 % concentration</td><td>6.0</td><td>6.0</td></tr><tr><td>Neat preparation</td><td>5.1</td><td>5.1</td></tr><tr><td rowspan="2">Density</td><td>g/mL</td><td>1.23</td><td>1.22</td></tr><tr><td>Relative density</td><td>1.23</td><td>1.22</td></tr><tr><td rowspan="2">Suspensibility (%)</td><td>Lowest application conc.</td><td>99</td><td>99</td></tr><tr><td>Highest application conc.</td><td>100</td><td>98</td></tr><tr><td rowspan="3">Particle size distribution</td><td>&lt; 10.0 % µm</td><td>0.62</td><td>0.66</td></tr><tr><td>&lt; 50.0 % µm</td><td>1.62</td><td>1.77</td></tr><tr><td>&lt; 90.0 % µm</td><td>4.79</td><td>5.05</td></tr><tr><td>Surface tension (mN/m)</td><td>Highest application conc. (20 °C)</td><td>31.2</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></tr><tr><td>5 rpm</td><td>3120 / 3072</td></tr><tr><td>10 rpm</td><td>1830 / 1806</td></tr><tr><td>30 rpm</td><td>807.0</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>Persistent foam (mL)</td><td>1 minute</td><td>[14   0]</td><td>[18   0]</td></tr><tr><td>[Lowest   Highest]</td><td>12 minutes</td><td>[10   0]</td><td>[12   0]</td></tr><tr><td>Package stability</td><td colspan="2">No visual degradation</td><td>No visual degradation</td></tr><tr><td colspan="4">Low temperature stability (EF/375/21/LT)</td></tr><tr><td colspan="4">It was not noticed any separated material.</td></tr><tr><td>Folpet content</td><td>% w/w</td><td colspan="2">39.51</td></tr><tr><td rowspan="2">Suspensibility (%)</td><td>Highest application conc.</td><td colspan="2">99</td></tr><tr><td>Lowest application conc.</td><td colspan="2">99</td></tr><tr><td>Wet sieve test</td><td>% w/w</td><td colspan="2">0.19</td></tr></table> <div>Where test-item solutions need to be prepared take into account that: Lowest application concentration: 2.5 mL/L (0.25 %) Highest application concentration: 8.0 mL/L (0.80 %)</div>	Determinations		EF/375/21/T0	EF/375/21/HT	Folpet content	% w/w	39.64	40.48	g/L	487.5	493.9	PMM content	% w/w	<LOQ (0.144)	<LOQ (0.144)	CCl <sub>4</sub> content	% w/w	<LOQ (0.081)	<LOQ (0.081)	Determination of pH	1 % concentration	6.0	6.0	Neat preparation	5.1	5.1	Density	g/mL	1.23	1.22	Relative density	1.23	1.22	Suspensibility (%)	Lowest application conc.	99	99	Highest application conc.	100	98	Particle size distribution	< 10.0 % µm	0.62	0.66	< 50.0 % µm	1.62	1.77	< 90.0 % µm	4.79	5.05	Surface tension (mN/m)	Highest application conc. (20 °C)	31.2	---	Viscosity (mPa.s)	20 °C	0.5 rpm	18120 / 18600	5 rpm	3120 / 3072	10 rpm	1830 / 1806	30 rpm	807.0	40 °C	0.5 rpm	16860 / 15600	5 rpm	3024 / 2772	10 rpm	1728 / 1638	30 rpm	724.0	Persistent foam (mL)	1 minute	[14   0]	[18   0]	[Lowest   Highest]	12 minutes	[10   0]	[12   0]	Package stability	No visual degradation		No visual degradation	Low temperature stability (EF/375/21/LT)				It was not noticed any separated material.				Folpet content	% w/w	39.51		Suspensibility (%)	Highest application conc.	99		Lowest application conc.	99		Wet sieve test	% w/w	0.19				commercial packaging (HDPE).  Extrapolation from HDPE to HDPE co-extruded (HDPE/EVOH, HDPE/PA, HDPE-F) is acceptable.
Determinations		EF/375/21/T0	EF/375/21/HT																																																																																																															
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	Lowest application conc.	99																																																																																																																
Wet sieve test	% w/w	0.19																																																																																																																
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 a SC formulation.	-	-	-																																																																																																												
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.2	SAP50SCF Batch V-FSA	<table><tr><td colspan="4">Maximum dosage: 1.0 kg a.i/hL</td></tr><tr><td colspan="4">Minimum dosage: 0.1 kg a.i/hL</td></tr><tr><td colspan="4">Foam volume (mL)</td></tr><tr><td></td><td>Initial</td><td>After 14 days at</td><td>After 24 months</td></tr></table>	Maximum dosage: 1.0 kg a.i/hL				Minimum dosage: 0.1 kg a.i/hL				Foam volume (mL)					Initial	After 14 days at	After 24 months	Y	KCP 2.8.2/01 Boas, P. (2011), Study EF/88/11 (Submitted in KCP	Accepted.																																																																																												
Maximum dosage: 1.0 kg a.i/hL																																																																																																																		
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	Initial	After 14 days at	After 24 months																																																																																																															

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																													
	AM078	Batch 20J0785B	<table><tr><td></td><td></td><td>54 °C</td><td></td></tr><tr><td>10 seconds</td><td>30</td><td>30</td><td>30</td></tr><tr><td>1 minute</td><td>0</td><td>0</td><td>0</td></tr><tr><td>3 minutes</td><td>0</td><td>0</td><td>0</td></tr><tr><td>12 minutes</td><td>0</td><td>0</td><td>0</td></tr></table> <p>Lowest application concentration: 2.5 mL/L (0.25 %) Highest application concentration: 8.0 mL/L (0.80 %)</p> <table><tr><th colspan="5">Foam volume (mL)</th></tr><tr><td></td><th colspan="2">Initial</th><th colspan="2">After 7 days at 54 °C</th></tr><tr><td></td><th>Lowest App. conc.</th><th>Highest App. conc.</th><th>Lowest App. conc.</th><th>Highest App. conc.</th></tr><tr><td>1 minute</td><td>14</td><td>0</td><td>18</td><td>0</td></tr><tr><td>12 minutes</td><td>10</td><td>0</td><td>12</td><td>0</td></tr></table>			54 °C		10 seconds	30	30	30	1 minute	0	0	0	3 minutes	0	0	0	12 minutes	0	0	0	Foam volume (mL)						Initial		After 7 days at 54 °C			Lowest App. conc.	Highest App. conc.	Lowest App. conc.	Highest App. conc.	1 minute	14	0	18	0	12 minutes	10	0	12	0		2.1/01)  KCP 2.8.2/02 Vieira, R. (2013), Study EF/88/11-T24 <b>(Submitted in KCP 2.1/02)</b>	
		54 °C																																																	
10 seconds	30	30	30																																																
1 minute	0	0	0																																																
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12 minutes	0	0	0																																																
Foam volume (mL)																																																			
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1 minute	14	0	18	0																																															
12 minutes	10	0	12	0																																															
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184 and MT074  																																																		

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																							
			<table><tr><td>102/101</td><td>97/99</td><td>99/101</td></tr></table>	102/101	97/99	99/101		EF/88/11 <b>(Submitted in KCP 2.1/01)</b>  KCP 2.8.3.2/02 Vieira, R. (2013), Study EF/88/11-T24 <b>(Submitted in KCP 2.1/02)</b>																																					
102/101	97/99	99/101																																											
Dispersion stability (KCP 2.8.3.3)	-	-	Not required for a SC formulation.	-	-	-																																							
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not required for a SC formulation.	-	-	-																																							
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187	SAP50SCF Batch V-FSA          Batch 20J0785B	<table><tr><th colspan="4">Particle size distribution (µm)</th></tr><tr><td></td><td>Initial</td><td>After 14 days at 54 °C</td><td>After 24 months</td></tr><tr><td>&lt; 10.0%</td><td>0.64</td><td>0.72</td><td>0.67</td></tr><tr><td>&lt; 50.0%</td><td>1.59</td><td>1.73</td><td>1.64</td></tr><tr><td>&lt; 90.0%</td><td>3.52</td><td>3.69</td><td>3.81</td></tr><tr><td>&lt; 95.0%</td><td>4.30</td><td>4.45</td><td>5.08</td></tr></table> <table><tr><th colspan="3">Particle size analysis results (µm)</th></tr><tr><td>Sample</td><td>Initial</td><td>After 14 days at 54 °C</td></tr><tr><td>&lt; 10%</td><td>0.62</td><td>0.66</td></tr><tr><td>&lt; 50%</td><td>1.62</td><td>1.77</td></tr><tr><td>&lt; 90%</td><td>4.79</td><td>5.05</td></tr></table>	Particle size distribution (µm)					Initial	After 14 days at 54 °C	After 24 months	< 10.0%	0.64	0.72	0.67	< 50.0%	1.59	1.73	1.64	< 90.0%	3.52	3.69	3.81	< 95.0%	4.30	4.45	5.08	Particle size analysis results (µm)			Sample	Initial	After 14 days at 54 °C	< 10%	0.62	0.66	< 50%	1.62	1.77	< 90%	4.79	5.05	Y	KCP 2.8.5.1.1/01 Boas, P. (2011), Study EF/88/11 <b>(Submitted in KCP 2.1/01)</b>  KCP 2.8.5.1.1/02 Vieira, R. (2013), Study EF/88/11-T24 <b>(Submitted in KCP 2.1/02)</b>  KCP 2.8.5.1.1/03 Morais, F. (2022), Study EF/375/21 <b>(Submitted in KCP 2.4.1/01)</b>	Accepted.
Particle size distribution (µm)																																													
	Initial	After 14 days at 54 °C	After 24 months																																										
< 10.0%	0.64	0.72	0.67																																										
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Sample	Initial	After 14 days at 54 °C																																											
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< 50%	1.62	1.77																																											
< 90%	4.79	5.05																																											
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	SAP50SCF Batch V-FSA	<table><tr><th colspan="4">Wet sieve test (%)</th></tr><tr><td></td><td>Initial</td><td>After 14 days at 54 °C</td><td>After 24 months</td></tr><tr><td>&gt; 75µm</td><td>0.02</td><td>0.03</td><td>0</td></tr></table>	Wet sieve test (%)					Initial	After 14 days at 54 °C	After 24 months	> 75µm	0.02	0.03	0	Y	KCP 2.8.5.1.2/01 Boas, P. (2011), Study EF/88/11 <b>(Submitted in KCP</b>	Accepted.																											
Wet sieve test (%)																																													
	Initial	After 14 days at 54 °C	After 24 months																																										
> 75µm	0.02	0.03	0																																										



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments												
					2.1/01)  KCP 2.8.5.1.2/02 Vieira, R. (2013), Study EF/88/11-T24 (Submitted in KCP 2.1/02)													
Dust content (KCP 2.8.5.2.1)	-	-	Not required for a SC formulation.	-	-	-												
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not required for a SC formulation.	-	-	-												
Attrition (KCP 2.8.5.3)	-	-	Not required for a SC formulation.	-	-	-												
Hardness and integrity (KCP 2.8.5.4)	-	-	Not required for a SC formulation.	-	-	-												
Emulsifiability (KCP 2.8.6.1)	-	-	Not required for a SC formulation.	-	-	-												
Emulsion stability (KCP 2.8.6.2)	-	-	Not required for a SC formulation.	-	-	-												
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not required for a SC formulation.	-	-	-												
Flowability (KCP 2.8.7.1)	-	-	Not required for a SC formulation.	-	-	-												
Pourability (KCP 2.8.7.2)	CIPAC MT 148.1	SAP50SCF Batch V-FSA	<table><tr><th colspan="4">Pourability (%)</th></tr><tr><td></td><td>Initial</td><td>After 14 days at 54 °C</td><td>After 24 months</td></tr><tr><td>Residue</td><td>2.1</td><td>2.3</td><td>2.3</td></tr></table>	Pourability (%)					Initial	After 14 days at 54 °C	After 24 months	Residue	2.1	2.3	2.3	Y	KCP 2.8.7.2/01 Boas, P. (2011), Study EF/88/11 (Submitted in KCP 2.1/01)  KCP 2.8.7.2/02 Vieira, R. (2013), Study EF/88/11-T24 (Submitted in KCP 2.1/02)	Accepted.
Pourability (%)																		
	Initial	After 14 days at 54 °C	After 24 months															
Residue	2.1	2.3	2.3															

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not required for a SC formulation.	-	-	-
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not applicable. The product is not intended to be used in tank mixes.	-	-	The product is not intended to be used in tank mixes.
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not applicable. The product is not intended to be used in tank mixes.	-	-	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.	-	-	-
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.
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**Table 4.1-1: Packaging information for 250 mL bottle**

Type	Description
Material:	HDPE (high density polyethylene)
Shape/size:	63 ± 1 mm diameter x 133 ± 1 mm of total height
Opening:	46 ± 0.5 mm inner diameter
Closure:	high density polyethylene screw cap
Seal:	hot seal / aluminum / polyester
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-2: Packaging information for 250 mL bottle**

Type	Description
Material:	HDPE/EVOH (Coex)
Shape/size:	63 ± 1 mm diameter x 133 ± 1 mm of total height
Opening:	46 ± 0.5 mm inner diameter
Closure:	high density polyethylene screw cap
Seal:	hot seal / aluminum / polyester
Manner of construction	coextruded
UN/ADR	compliant

**Table 4.1-3: 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 4.1-4: 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

Type	Description
	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 4.1-5: 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 4.1-6: Packaging information for 1 L bottle**

Type	Description
Material:	HDPE (high density polyethylene)
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 4.1-7: 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 4.1-8: 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

Type	Description
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 4.1-9: 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 4.1-10: 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 4.1-11: 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 4.1-12: 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

Type	Description
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 4.1-13: 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 4.1-14: 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 4.1-15: 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 4.1-16: Packaging information for 5 L jerrycan**

Type	Description
Material:	HDPE/EVOH (Coex)

Type	Description
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 4.1-17: 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 4.1-18: 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 4.1-19: 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 4.1-20: 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 4.1-21: 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 4.1-22: 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 4.1-23: 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 4.1-24: 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 4.1-25: 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 4.1-26: 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
Opening:	60 mm
Closure:	polyethylene screw cap
Seal:	PET/ALU/PEE; IHS; Tresylene
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-27: 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 4.1-28: 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

Type	Description
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 influences of chemicals. The contents have no negative effect on the packet integrity, both *HDPE* and *Coex*. These two types of packages were examined for any physical visible change, and they did not suffer any modification. Please refer to point KCP 2.7.1.

## 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	Boas, P.	2011	Folpet 50 SC: Stability Study and Physical Properties of the Formulation Study EF/88/11 Final Report – Control sample and accelerated storage stability SAPEC Agro, S.A. GLP Unpublished	N	ASCENZA Agro, S.A.
KCP 2.1/02	Vieira, R.	2013	Folpet 50 SC: Stability Study and Physical Properties of the formulation Study EF/88/11 – Final Report – T24 SAPEC Agro, S.A. GLP Unpublished	N	ASCENZA Agro, S.A.
KCP 2.2.1/01	Correia, C.	2022	Theoretical Assessment of Explosive and Oxidising properties of Folpet 50 SC (SAP50SCF) Doc. no. TR/22/04 - Explosive and Oxidising Properties of SAP50SCF ASCENZA Agro, S.A. Non GLP Unpublished	N	ASCENZA Agro, S.A.
KCP 2.2.2/01	Correia, C.	2022	Theoretical Assessment of Explosive and Oxidising properties of Folpet 50 SC (SAP50SCF) Doc. no. TR/22/04 - Explosive and Oxidising Properties of SAP50SCF ASCENZA Agro, S.A. Non GLP Unpublished (Submitted in KCP 2.2.1/01)	N	ASCENZA Agro, S.A.
KCP 2.3.1/01	Campbell, N.	2011	Determination of specified phys-chem data for 'FOLPET 50SC', a suspension concentrate formulation, in compliance with Good Laboratory Practice. Study Number: OA02062 Oxford Analytical Ltd GLP Unpublished	N	ASCENZA Agro, S.A.
KCP 2.3.3/01	Campbell, N.	2011	Determination of specified phys-chem data for 'FOLPET 50SC', a suspension concentrate formulation, in compliance with Good Laboratory Practice. Study Number: OA02062 Oxford Analytical Ltd	N	ASCENZA Agro, S.A.

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			GLP Unpublished (Submitted in KCP 2.3.1/01)		
KCP 2.4.1/01	Morais, F.	2022	FOLPET 500 g/L SC (SAP50SCF) – Physical, chemical and technical properties of the plant protection product Study EF/375/21 – Final Report ASCENZA Agro, S.A. GLP Unpublished	N	ASCENZA Agro, S.A.
KCP 2.4.2/01	Boas, P.	2011	Folpet 50 SC: Stability Study and Physical Properties of the Formulation Study EF/88/11 Final Report – Control sample and accelerated storage stability SAPEC Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	ASCENZA Agro, S.A.
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KCP 2.8.5.1.1/02	Vieira, R.	2013	Folpet 50 SC: Stability Study and Physical Properties of the formulation Study EF/88/11 – Final Report – T24 SAPEC Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/02)	N	ASCENZA Agro, S.A.
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KCP 2.8.5.1.2/01	Boas, P.	2011	Folpet 50 SC: Stability Study and Physical Properties of the Formulation Study EF/88/11 Final Report – Control sample and accelerated storage stability SAPEC Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	ASCENZA Agro, S.A.
KCP 2.8.5.1.2/02	Vieira, R.	2013	Folpet 50 SC: Stability Study and Physical Properties of the formulation	N	ASCENZA



<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
			Study EF/88/11 – Final Report – T24 SAPEC Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/02)		Agro, S.A.
KCP 2.8.7.2/01	Boas, P.	2011	Folpet 50 SC: Stability Study and Physical Properties of the Formulation Study EF/88/11 Final Report – Control sample and accelerated storage stability SAPEC Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	ASCENZA Agro, S.A.
KCP 2.8.7.2/02	Vieira, R.	2013	Folpet 50 SC: Stability Study and Physical Properties of the formulation Study EF/88/11 – Final Report – T24 SAPEC Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/02)	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**

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

**List of data submitted by the applicant and not relied on**

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

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

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-	-	-	-	-	-

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

### **A 2.1            Folpet**

No additional data is submitted.