

FINAL REGISTRATION REPORT

Part B

Section 1: Identity

Section 2: Physical and chemical properties

Section 4: Further information

Detailed summary of the risk assessment

Product code: SAP09I

Product name: VOLKETE MAX

Chemical active substance:

Spinosad, 480 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(New product authorization according to article 34 of Regulation (EC) 1107/2009)

Applicant(s): Albaugh TKI d.o.o.

Submission date: January 2025

MS Finalisation date: 12/2025

Version history

When	What
January 2025	V0 – Original dRR version from applicant Albaugh TKI d.o.o. for submission to zRMS Poland in the frame of a new authorization according to Article 33/34 of Regulation (EC) No. 1107/2009.
April 2025	Dossier sent for evaluation
October 2025	zRMS evaluation of dRR
December 2025	Final RR

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zRMS comments:

The text highlighted in grey was provided by the zRMS.

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.

- ~~data gap 1~~
- ~~data gap 2~~
- ~~data gap 3~~

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Trade name: **VOLKETE MAX**
Company: **Albaugh TKI d.o.o.**
Address: Grajski trg 21
SI-2327 RAČE
SLOVENIA

Contact: xxxxxxxx
Telephone number: xxxxxxxxxxxx
E-mail: xxxxxxxxxxxxxxxxx

1.2 Producer of the plant protection product and of the active substances (KCP1.2)

1.2.1 Producer(s) of the preparation

Name: Albaugh Europe Sàrl
Address: World Trade Center Lausanne
Avenue Gratta-Paille 2
1018 Lausanne
Switzerland

Contact: xxxxxxxx
Telephone number: xxxxxxxxxxxx
E-mail: xxxxxxxxxxxxxxxxx

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

Confidential information, please see dRR_PART C

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

1.2.3.1 Spinosad

Confidential information, please see dRR_PART C

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

Trade name: Volkete Max

Company code number: SAP09I

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)

SAP09I is a chemically comparable formulation to the reference product SPINTOR 480 SC registered in Poland since 2003 (No. R-18/2003 of 12 September 2003), and currently with registration No. R-47/2018wu of 19 October 2018. The composition of SAP09I and information of co-formulants is provided in order to assess the comparability to the reference product SPINTOR 480 SC.

Information on the co-formulants is provided in Part C (Confidential Information).

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)
Spinosad	480	456 – 504 g/L	500	45.87

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

** Based on the density of the formulation = 1.09 g/mL

Table 1.4-1: 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)
None. The formulation does not contain toxicologically, ecotoxicologically or environmentally relevant impurities.				

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content (g/L)
None	

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

Table 1.4-3: Information on Spinosad

Type	Name/Code Number
ISO common name	Spinosad, a mixture of 50-95% spinosyn A and 5-50% spinosyn D
CAS No.	168316-95-8 (Spinosyn A: 131929-60-7; Spinosyn D: 131929-63-0)
EC No.	434-300-1 (mixture of Spinosyn A and D)
CIPAC No.	636

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

SAP09I does not contain a safener or a synergist.

Information on the co-formulants is provided in Part C (Confidential Information).

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

Type: Suspension concentrate

[Code: SC]

1.6 Function (KCP 1.6)

Insecticide

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

Due to comparable behaviour of SPINTOR 480 SC and SAP09I (please see Part C for details), comparable physical-chemical properties are also expected for SAP09I.

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 off-white liquid, with a characteristic odour. It is not explosive and has no oxidising properties. The product has no flash point. It has a self-ignition temperature of 400 °C. In aqueous solution, it has a pH value around 7.0 at 20.0 °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 2-3 years at ambient temperature when stored in HDPE. Its technical characteristics are acceptable for a *suspension concentrate* formulation.

Please refer to the reference product Dossier of SPINTOR 480 SC in Poland registered since 2003 (No. R-18/2003 of 12 September 2003), and currently the permit of the Ministry of Agriculture and Rural Development No. R-47/2018wu of 19 October 2018.

RMS conclusion on the use of article 34 of Regulation (EC) 1107/2009 in Poland

Volkete Max cannot be considered equivalent/ comparable to already registered SpinTor 480 SC in physicochemical area under Composition's comparison in accordance with Article 34 of Regulation 1107/2009. In summary, unprotected physicochemical data taken SpinTor 480 SC cannot be used to support Volkete Max registration in Poland. In the case of unprotected data taken from the other than the physicochemical section, the final decision belongs to the experts evaluating these sections during the registration in Poland.

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

Not classified as dangerous.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

Not classified as dangerous.

Compliance with FAO specifications:

The product SAP09I complies with FAO specifications.

Formulation used for tests

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

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

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Internal method AM190	SAP09I Batch J-BEB	Initial, after 14 days at 54 °C and after 36 months: Off-white liquid suspension concentrate with characteristic odour.	Y	KCP 2.1/01 Morais, F., 2021 Study EF/359/21 – Interim Report (T0) KCP 2.1/02 Silva, S., 2023 Study EF/359/21 – Interim Report (T24) KCP 2.1/03 Silva, S., 2024 Study EF/359/21 – Report (T36)	Accepted
Explosive properties (KCP 2.2.1)	EEC A.14.	SAP09I Batch D-CEA	No explosive hazards in the formulation.	Y	KCP 2.2.1/01 Dornhagen, J., 2021 Report No: PS20210184-2	Accepted
Oxidizing properties (KCP 2.2.2)	UN O.2	SAP09I Batch D-CEA	No oxidant hazards in the formulation.	Y	KCP 2.2.2/01 Dornhagen, J., 2021 Report No: PS20210184-4	Accepted
Flash point (KCP 2.3.1)	EEC A.9.	SAP09I Batch D-CEA	No flash point observed.	Y	KCP 2.3.1/01 Dornhagen, J., 2021 Report No: PS20210184-1	Accepted
Flammability (KCP 2.3.2)	-	-	Not applicable for SC formulations.	-	-	
Self-heating	EEC A.15.	SAP09I	Auto-ignition temperature = 400 °C	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 D-CEA			Dornhagen, J., 2021 Report No: PS20210184-3	
Acidity or alkalinity and pH (KCP 2.4.1)	Internal method AM063 (based on CIPAC method MT 75.3)	SAP09I Batch J-BEB	Acidity or alkalinity are not required since pH between 4 and 10. pH in neat preparation: <u>Initial:</u> 7.5 (20.3 °C) <u>After 14 days at 54 °C:</u> 7.5 (20.3 °C) <u>After 24 months:</u> 8.4 (19.7 °C) <u>After 36 months:</u> 8.4 (20.3 °C)	Y	KCP 2.4.1/01 Morais, F., 2021 Study EF/359/21 – Interim Report (T0) (Submitted in KCP 2.1/01) KCP 2.4.1/02 Silva, S., 2023 Study EF/359/21 – Interim Report (T24) (Submitted in KCP 2.1/02) KCP 2.1/03 Silva, S., 2024 Study EF/359/21 – Report (T36) (Submitted in KCP 2.1/03)	Accepted
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	Internal method AM063(based on CIPAC method MT 75.3)	SAP09I Batch J-BEB	<u>Initial:</u> 7.0 (20.0 °C) <u>After 14 days at 54 °C:</u> 7.0 (20.1 °C) <u>After 24 months:</u> 8.1 (20.4 °C) <u>After 36 months:</u> 8.1 (20.4 °C)	Y	KCP 2.4.2/01 Morais, F., 2021 Study EF/359/21 – Interim Report (T0) (Submitted in KCP 2.1/01) KCP 2.4.2/02 Silva, S., 2023	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																				
					Study EF/359/21 – Interim Report (T24) (Submitted in KCP 2.1/02) KCP 2.1/03 Silva, S., 2024 Study EF/359/21 – Report (T36) (Submitted in KCP 2.1/03)																					
Viscosity (KCP 2.5.1)	CIPAC MT 192	SAP09I Batch J-BEB	Viscosity results at 20 °C <table><tr><td>Speed (rpm)</td><td>0.5</td><td>10</td><td>50</td><td>60</td></tr><tr><td>Viscosity cP (mPa.s)</td><td>9780/8340</td><td>1233/1170</td><td>487.2/485.4</td><td>439.0</td></tr></table> Viscosity results at 40 °C <table><tr><td>Speed (rpm)</td><td>0.5</td><td>10</td><td>50</td><td>100</td></tr><tr><td>Viscosity cP (mPa.s)</td><td>6780/6060</td><td>954.0/927.0</td><td>376.8/379.8</td><td>276.3</td></tr></table>	Speed (rpm)	0.5	10	50	60	Viscosity cP (mPa.s)	9780/8340	1233/1170	487.2/485.4	439.0	Speed (rpm)	0.5	10	50	100	Viscosity cP (mPa.s)	6780/6060	954.0/927.0	376.8/379.8	276.3	Y	KCP 2.5.1/01 Morais, F., 2021 Study EF/359/21 – Interim Report (T0) (Submitted in KCP 2.1/01)	Accepted
Speed (rpm)	0.5	10	50	60																						
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Speed (rpm)	0.5	10	50	100																						
Viscosity cP (mPa.s)	6780/6060	954.0/927.0	376.8/379.8	276.3																						
Surface tension (KCP 2.5.2)	Internal method AM243 (based on OECD 115)	SAP09I Batch J-BEB	<u>At 0.117%:</u> 41.5 mN/m (20 °C ± 0.5) <u>At 0.250%:</u> 39.3 mN/m (20 °C ± 0.5) Since the surface tension is below 60 mN/m, the preparation should be regarded as being a surface-active material.	Y	KCP 2.5.2/01 Morais, F., 2021 Study EF/359/21 – Interim Report (T0) (Submitted in KCP 2.1/01)	Accepted																				
Relative density (KCP 2.6.1)	Internal method AM262 (based on Reg.(EC) N°440/2008, A.3 and CIPAC method MT 3.3.2)	SAP09I Batch J-BEB	<table><tr><td></td><td>Density (g/cm³)</td><td>Relative density</td></tr><tr><td>Initial</td><td>1.08</td><td>1.08</td></tr><tr><td>After 14 days at 54 °C</td><td>1.08</td><td>1.08</td></tr><tr><td>After 24 months</td><td>1.08</td><td>1.08</td></tr><tr><td>After 36 months</td><td>1.09</td><td>1.09</td></tr></table>		Density (g/cm³)	Relative density	Initial	1.08	1.08	After 14 days at 54 °C	1.08	1.08	After 24 months	1.08	1.08	After 36 months	1.09	1.09	Y	KCP 2.6.1/01 Morais, F., 2021 Study EF/359/21 – Interim Report (T0) (Submitted in KCP 2.1/01)	Accepted					
	Density (g/cm³)	Relative density																								
Initial	1.08	1.08																								
After 14 days at 54 °C	1.08	1.08																								
After 24 months	1.08	1.08																								
After 36 months	1.09	1.09																								

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			Measuring Temperature: 20 °C ± 0.5 °C		KCP 2.6.1/02 Silva, S., 2023 Study EF/359/21 – Interim Report (T24) (Submitted in KCP 2.1/02) Silva, S., 2024 Study EF/359/21 – Report (T36) (Submitted in KCP 2.1/03)	
Bulk density (KCP 2.6.2)	-	-	Not required for SC formulations.	-	-	
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.4	SAP09I Batch J-BEB	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. 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, after two weeks storage at 54°C.	Y	KCP 2.7.1/01 Morais, F., 2021 Study EF/359/21 – Interim Report (T0) (Submitted in KCP 2.1/01)	Accepted
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.	-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																				
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3 CIPAC MT 184.1 CIPAC MT 185	SAP09I Batch J-BEB	<u>Suspensability:</u> <table><tr><td>Application conc.:</td><td>0.1%</td><td>0.117%</td><td>0.250%</td></tr><tr><td>After 7 days at 0 °C</td><td>98%</td><td>98%</td><td>96%</td></tr></table> <u>Wet sieve test:</u> 0.01% (sieve > 75µm)	Application conc.:	0.1%	0.117%	0.250%	After 7 days at 0 °C	98%	98%	96%	Y	KCP 2.7.4/01 Morais, F., 2021 Study EF/359/21 – Interim Report (T0) (Submitted in KCP 2.1/01)	Accepted												
Application conc.:	0.1%	0.117%	0.250%																							
After 7 days at 0 °C	98%	98%	96%																							
Ambient temperature shelf life (KCP 2.7.5)	-	-	The sample is stable at ambient temperature for 36 months. 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, after 24 months at ambient temperature.	Y	KCP 2.7.5/01 Silva, S., 2023 Study EF/359/21 – Interim Report (T24) (Submitted in KCP 2.1/02) KCP 2.1/03 Silva, S., 2024 Study EF/359/21 – Report (T36) (Submitted in KCP 2.1/03)	Accepted. The HDPE bottle packaging remained intact after storage. All prhysicochemical parametersare accepted for this SC formulation In summary, a three-year shelf life is accepted for the PPP.																				
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.	-	-																					
Persistence of foaming (KCP 2.8.2)	Internal method AM078 (based on CIPAC method MT 47.3)	SAP09I Batch J-BEB	Initial: <table><tr><td colspan="5">Foam volume (mL)</td></tr><tr><td>Time</td><td colspan="4">Application conc.:</td></tr><tr><td></td><td>0.001%</td><td>0.010%</td><td>0.117%</td><td>0.250%</td></tr><tr><td>1 minute</td><td>0</td><td>12</td><td>30</td><td>30</td></tr></table>	Foam volume (mL)					Time	Application conc.:					0.001%	0.010%	0.117%	0.250%	1 minute	0	12	30	30	Y	KCP 2.8.2/01 Morais, F., 2021 Study EF/359/21 – Interim Report (T0) (Submitted in	Accepted
Foam volume (mL)																										
Time	Application conc.:																									
	0.001%	0.010%	0.117%	0.250%																						
1 minute	0	12	30	30																						

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																																																																
			<table><tr><td>12 minutes</td><td>0</td><td>4</td><td>18</td><td>20</td></tr></table> After 14 days at 54 °C: <table><tr><td colspan="5">Foam volume (mL)</td></tr><tr><td>Time</td><td colspan="4">Application conc.:</td></tr><tr><td></td><td>0.001%</td><td>0.010%</td><td>0.117%</td><td>0.250%</td></tr><tr><td>1 minute</td><td>0</td><td>10</td><td>22</td><td>28</td></tr><tr><td>12 minutes</td><td>0</td><td>2</td><td>12</td><td>14</td></tr></table> After 24 months: <table><tr><td colspan="5">Foam volume (mL)</td></tr><tr><td>Time</td><td colspan="4">Application conc.:</td></tr><tr><td></td><td>0.001%</td><td>0.010%</td><td>0.117%</td><td>0.250%</td></tr><tr><td>1 minute</td><td>0</td><td>18</td><td>34</td><td>34</td></tr><tr><td>12 minutes</td><td>0</td><td>6</td><td>20</td><td>22</td></tr></table> After 36 months: <table><tr><td colspan="5">Foam volume (mL)</td></tr><tr><td>Time</td><td colspan="4">Application conc.:</td></tr><tr><td></td><td>0.001%</td><td>0.010%</td><td>0.117%</td><td>0.250%</td></tr><tr><td>1 minute</td><td>0</td><td>18</td><td>38</td><td>36</td></tr><tr><td>12 minutes</td><td>0</td><td>6</td><td>30</td><td>34</td></tr></table>	12 minutes	0	4	18	20	Foam volume (mL)					Time	Application conc.:					0.001%	0.010%	0.117%	0.250%	1 minute	0	10	22	28	12 minutes	0	2	12	14	Foam volume (mL)					Time	Application conc.:					0.001%	0.010%	0.117%	0.250%	1 minute	0	18	34	34	12 minutes	0	6	20	22	Foam volume (mL)					Time	Application conc.:					0.001%	0.010%	0.117%	0.250%	1 minute	0	18	38	36	12 minutes	0	6	30	34		KCP 2.1/01) KCP 2.8.2/02 Silva, S., 2023 Study EF/359/21 – Interim Report (T24) (Submitted in KCP 2.1/02) KCP 2.1/03 Silva, S., 2024 Study EF/359/21 – Report (T36) (Submitted in KCP 2.1/03)	
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1 minute	0	18	38	36																																																																																		
12 minutes	0	6	30	34																																																																																		
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184.1	SAP09I Batch J-BEB	<table><tr><td>Application conc.:</td><td>0.1%</td><td>0.117%</td><td>0.25%</td></tr><tr><td>Initial</td><td>97%</td><td>98%</td><td>97%</td></tr><tr><td>After 14 days at 54 °C</td><td>97%</td><td>97%</td><td>97%</td></tr><tr><td>After 24 months</td><td>96%</td><td>100%</td><td>100%</td></tr><tr><td>After 36 months</td><td>97</td><td>98%</td><td>100%</td></tr></table>	Application conc.:	0.1%	0.117%	0.25%	Initial	97%	98%	97%	After 14 days at 54 °C	97%	97%	97%	After 24 months	96%	100%	100%	After 36 months	97	98%	100%	Y	KCP 2.8.3.1/01 Morais, F., 2021 Study EF/359/21 – Interim Report (T0) (Submitted in KCP 2.1/01) KCP 2.8.3.1/02 Silva, S., 2023	Accepted																																																												
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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments									
					Study EF/359/21 – Interim Report (T24) (Submitted in KCP 2.1/02) Silva, S., 2024 Study EF/359/21 – Report (T36) (Submitted in KCP 2.1/03)										
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	SAP09I Batch J-BEB	<table><tr><th colspan="3">Dispersibility (%)</th></tr><tr><td>Initial</td><td>After 14 days at 54 °C</td><td>After 36 months</td></tr><tr><td>98/100</td><td>100/101</td><td>100/99</td></tr></table>	Dispersibility (%)			Initial	After 14 days at 54 °C	After 36 months	98/100	100/101	100/99	Y	KCP 2.8.3.2/01 Morais, F., 2021 Study EF/359/21 – Interim Report (T0) (Submitted in KCP 2.1/01) KCP 2.8.3.1/02 Silva, S., 2023 Study EF/359/21 – Interim Report (T24) (Submitted in KCP 2.1/02) Silva, S., 2024 Study EF/359/21 – Report (T36) (Submitted in KCP 2.1/03)	Accepted
Dispersibility (%)															
Initial	After 14 days at 54 °C	After 36 months													
98/100	100/101	100/99													
Dispersion	-	-	Not required for SC formulations.	-	-										

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments				
stability (KCP 2.8.3.3)										
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not required for SC formulations.	-	-					
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187	SAP09I Batch J-BEB						Y	KCP 2.8.5.1.1/01 Morais, F., 2021 Study EF/359/21 – Interim Report (T0) (Submitted in KCP 2.1/01) KCP 2.8.5.1.1/02 Silva, S., 2023 Study EF/359/21 – Interim Report (T24) (Submitted in KCP 2.1/03) Silva, S., 2024 Study EF/359/21 – Report (T36) (Submitted in KCP 2.1/03)	Accepted
			Particle size analysis results (µm)							
			Sample	Initial	After 14 days at 54 °C	After 24 months	After 36 months			
			< 10%	1.23	1.26	1.21	1.26			
			< 50%	4.65	4.72	4.61	4.58			
			< 90%	13.47	13.63	13.46	12.79			
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	SAP09I Batch J-BEB						Y	KCP 2.8.5.1.2/01 Morais, F., 2021 Study EF/359/21 – Interim Report (T0) (Submitted in KCP 2.1/01) KCP 2.8.5.1.2/02 Silva, S., 2023	Accepted
			Wet sieve test (%)							
			sieve	Initial	After 14 days at 54 °C	After 24 months	After 36 months			
			> 75µm	0.02	0.01	0.00	0.00			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
					Study EF/359/21 – Interim Report (T24) (Submitted in KCP 2.1/02) Silva, S., 2024 Study EF/359/21 – Report (T36) (Submitted in KCP 2.1/03)	
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.	-	-	
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	CIPAC MT 148.1	SAP09I		Y	KCP 2.8.7.2/01	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments						
(KCP 2.8.7.2)		Batch J-BEB	<table><tr><th colspan="2">Residue (%)</th></tr><tr><td>Initial</td><td>After 14 days at 54 °C</td></tr><tr><td>2.6</td><td>2.4</td></tr></table> <u>After 24 months:</u> Residue: 2.9% Rinsed residue 1: 0.40% Rinsed residue 2: 0.25% <u>After 36 months:</u> Residue: 3% Rinsed residue: 0.25%	Residue (%)		Initial	After 14 days at 54 °C	2.6	2.4		Morais, F., 2021 Study EF/359/21 – Interim Report (T0) (Submitted in KCP 2.1/01) KCP 2.8.7.2/02 Silva, S., 2023 Study EF/359/21 – Interim Report (T24) (Submitted in KCP 2.1/02) Silva, S., 2024 Study EF/359/21 – Report (T36) (Submitted in KCP 2.1/03)	
Residue (%)												
Initial	After 14 days at 54 °C											
2.6	2.4											
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.	-	-							
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not required as tank mixtures are not recommended.	-	-							

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
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)	-	-	-	-	-	

Table of results of the Storage Stability after 14 days at 54°C (KCP 2.7.1/01 – Morais, F., 2021, Study EF/359/21 – Interim Report (T0)) below:

Determinations		EF/359/21/T0	EF/359/21/HT
Spinosyn A	% w/w	35.23	34.97
	g/L	380.5	377.7
Spinosyn D	% w/w	8.84	8.74
	g/L	95.4	94.4
Spinosad content ¹	% w/w	44.07	43.71
	g/L	475.9	472.1
Spinosad isomers ratio (A : D)		85.3 : 14.7	85.3 : 14.7
Appearance	Physical state	Liquid, suspension concentrate	Liquid, suspension concentrate
	Colour	Off-white	Off-white
	Odour	Characteristic odour	Characteristic odour
Determination of pH	1 % concentration	7.0	7.0
	Neat preparation	7.5	7.5
Density	g/mL	1.08	1.08
	Relative density	1.08	1.08
Suspendibility (%)	Europe Highest application conc.	97	97
	Mexico Highest application conc.	98	97
	0.1% application conc.	97	97
Spontaneity of dispersion (%)	Determination 1	98	100
	Determination 2	100	101
Pourability (%)	Residue	2.6	2.4
Wet sieve test (% w/w)	> 75 µm	0.02	0.01
Particle size distribution	< 10.0 %	1.23	1.26
	< 50.0 %	4.65	4.72
	< 90.0 %	13.47	13.63
Surface tension (mN/m)	Europe Highest application conc. (20 °C)	39.3	---
	Mexico Highest application conc. (20 °C)	41.5	---
Viscosity (mPa.s) [20 °C 40 °C]	0.5 rpm	[9780 / 8340] [6780 / 6060]	---
	10 rpm	[1233 / 1170] [954.0 / 927.0]	---
	50 rpm	[487.2 / 485.4] [376.8 / 379.8]	---
	60 rpm / 100 rpm	[439.0] / [276.3]	---
Persistent foam (mL) [Lowest Highest]	Europe	1 minute	[12 / 30]
		12 minutes	[4 / 20]
	Mexico	1 minute	[0 / 30]
		12 minutes	[0 / 18]

Table of results of the Storage Stability after 36 months at ambient temperature (KCP 2.7.5/01 – Silva, S., 2024, Study EF/359/21 –(T36)) below:

Determinations			EF/359/21/T0 ¹	EF/359/21/HT ¹	EF/359/21/T24 ¹	EF/359/21/T36
Spinosyn A	% w/w		35.23	34.97	35.09	37.94
	g/L		380.5	377.7	378.9	413.6
Spinosyn D	% w/w		8.84	8.74	8.64	5.90
	g/L		95.4	94.4	93.3	64.3
Spinosad content ²	% w/w		44.07	43.71	43.73	43.84
	g/L		475.9	472.1	472.2	477.9
Spinosad isomers ratio (A : D)		% w/w	85.3 : 14.7	85.3 : 14.7	---	---
Appearance	Physical state		Liquid, suspension concentrate	Liquid, suspension concentrate	Liquid, suspension concentrate	Liquid, suspension concentrate
	Colour		Off-white	Off-white	Off-white	Off-white
	Odour		Characteristic odour	Characteristic odour	Characteristic odour	Characteristic odour
Determination of pH	1% concentration		7.0	7.0	8.1	8.1
	Neat preparation		7.5	7.5	8.4	8.4
Density	g/mL		1.08	1.08	1.08	1.09
	Relative density		1.08	1.08	1.08	1.09
Suspensibility (%)	Europe Highest application conc.		97	97	100	100
	Mexico Highest application conc.		98	97	100	98
	0.1% application conc.		97	97	96	97
Determinations			EF/359/21/T0 ³	EF/359/21/HT ³	EF/359/21/T24 ³	EF/359/21/T36
Spontaneity of dispersion (%)	Determination 1		98	100	100	100
	Determination 2		100	101	100	99
Pourability (%)	Residue		2.6	2.4	2.9	3.0
	Rinsed residue 1		--	--	0.40	0.25
	Rinsed residue 2				0.25	--
Wet sieve test (% w/w)	> 75 µm		0.02	0.01	0.00	0.00
Particle size distribution (µm)	d (0.1)		1.23	1.26	1.21	1.26
	d (0.5)		4.65	4.72	4.61	4.58
	d (0.9)		13.47	13.63	13.46	12.79
Surface tension (mN/m)	Europe Highest application conc. (20 °C)		39.3	---	---	---
	Mexico Highest application conc. (20 °C)		41.5	---	---	---
Viscosity (mPa.s) [20 °C 40 °C]	0.5 rpm		[9780 / 8340] [6780 / 6060]	---	---	---
	10 rpm		[1233 / 1170] [954.0 / 927.0]	---	---	---
	50 rpm		[487.2 / 485.4] [376.8 / 379.8]	---	---	---
	60 rpm / 100 rpm		[439.0] / [276.3]	---	---	---
Persistent foam (mL) [Lowest / Highest]	Europe	1 minute	[12 / 30]	[10 / 28]	[18 / 34]	[18 / 36]
		12 minutes	[4 / 20]	[2 / 14]	[6 / 22]	[6 / 34]
	Mexico	1 minute	[0 / 30]	[0 / 22]	[0 / 34]	[0 / 38]
		12 minutes	[0 / 18]	[0 / 12]	[0 / 20]	[0 / 30]
Package stability			No visual degradation	No visual degradation	No visual degradation	No visual degradation

Low temperature stability (EF/359/21/LT) ⁴		
It was not noticed any separated material.		
Spinosyn A	% w/w	35.35
Spinosyn D	% w/w	8.65
Spinosad content ⁵	% w/w	44.00
Spinosad isomers ratio (A : D)	% w/w	85.5 : 14.5
Suspensibility (%)	Europe Highest application conc.	96
	Mexico Highest application conc.	98
	0.1% application conc.	98
Wet sieve test (% w/w)	> 75 µm	0.01

3 Section 3 is presented as a separate document

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

Section 4: Further information on the plant protection product

3.1 Packaging and Compatibility with the Preparation (KCP 4.4)

~~Please also refer to the reference product Dossier of SPINTOR 480 SC in Poland registered since 2003 (permit of the Ministry of Agriculture and Rural Development No. R-18/2003 of 12 September 2003), and currently the permit of the Ministry of Agriculture and Rural Development No. R-47/2018wu of 19 October 2018.~~

RMS comment:

The three-year storage stability study was done using HDPE packaging material bottle. So, for aqueous formulation like SC extrapolation from HDPE to other plastic packaging is accepted. Summarising, All proposed packages below (HDPE, PET, HDPE/EVOH, HDPE/PA, fluorinated HDPE) are accepted for Volkete Max.

Table 3.1-1: Packaging information for 10 mL bottle

Type	Description
Material:	PET (polyethylene terephthalate)
Shape/size:	cylindrical / approx. 42 mm diameter x 84 mm
Opening:	15 mm
Closure:	HDPE screw cap
UN/ADR	compliant

Table 3.1-2: Packaging information for 60 mL bottle

Type	Description
Material:	PET (polyethylene terephthalate)
Shape/size:	cylindrical / approx. 42 mm diameter x 84 mm
Opening:	28 mm
Closure:	HDPE screw cap
UN/ADR	compliant

Table 3.1-3: Packaging information for 100 mL bottle

Type	Description
Material:	PET (polyethylene terephthalate)
Shape/size:	cylindrical / approx. 51 mm diameter x 91.5 mm
Opening:	27 mm
Closure:	HDPE screw cap
UN/ADR	compliant

Table 3.1-4: Packaging information for 200 mL bottle

Type	Description
Material:	PET (polyethylene terephthalate)
Shape/size:	cylindrical / approx. 50 mm diameter x 142 mm

Type	Description
Opening:	26 mm
Closure:	HDPE screw cap
UN/ADR	compliant

Table 3.1-5: Packaging information for 250 mL bottle

Type	Description
Material:	PET (polyethylene terephthalate)
Shape/size:	cylindrical / approx. 63 mm diameter x 133 mm
Opening:	42 mm
Closure:	HDPE screw cap
UN/ADR	compliant

Table 3.1-6: Packaging information for 500 mL bottle

Type	Description
Material:	PET (polyethylene terephthalate)
Shape/size:	cylindrical / approx. 63 mm diameter x 186 mm
Opening:	42 mm
Closure:	HDPE screw cap
UN/ADR	compliant

Table 3.1-7: Packaging information for 1000 mL bottle

Type	Description
Material:	PET (polyethylene terephthalate)
Shape/size:	cylindrical / approx. 89.3 mm diameter x 231 mm
Opening:	63 mm
Closure:	HDPE screw cap
UN/ADR	compliant

Table 3.1-8: Packaging information for 100 mL bottle

Type	Description
Material:	HDPE (high density polyethylene)
Shape/size:	43.5 ± 1 mm diameter x 105 ± 1 mm of total height
Opening:	32 ± 0.5 mm inner diameter
Closure:	high density polyethylene screw cap
Seal:	hot seal / aluminum / polyester
Manner of construction	extruded
UN/ADR	compliant

Table 3.1-9: Packaging information for 100 mL bottle

Type	Description
Material:	HDPE/EVOH (Coex)
Shape/size:	51 ± 1 mm diameter x 91.5 ± 0.5 mm of total height
Opening:	25 ± 0.5 mm inner diameter
Closure:	high density polyethylene screw cap
Seal:	hot seal / aluminum / polyester
Manner of construction	coextruded
UN/ADR	compliant

Table 3.1-10: Packaging information for 100 mL bottle

Type	Description
Material:	HDPE/EVOH (Coex)
Shape/size:	44 ± 1 mm diameter x 105 ± 1 mm of total height
Opening:	32 ± 0.5 mm inner diameter
Closure:	high density polyethylene screw cap
Seal:	hot seal / aluminum / polyester
Manner of construction	coextruded
UN/ADR	compliant

Table 3.1-11: Packaging information for 120 mL bottle

Type	Description
Material:	HDPE/PA (Coex)
Shape/size:	50 ± 1 mm diameter x 93 ± 1 mm of total height
Opening:	40 ± 1 mm
Closure:	screw cap
Seal:	Polypropylene copolymer
Manner of construction	coextruded
UN/ADR	compliant

Table 3.1-12: 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

Type	Description
UN/ADR	compliant

Table 3.1-13: 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 3.1-12: Packaging information for 250 mL bottle

Type	Description
Material:	Fluorinated or HDPE / Coex
Shape/size:	63,5 ± 1 mm diameter x 126 ± 1 mm of total height
Opening:	50 ± 1 mm diameter
Closure:	screw cap
Seal:	—
Manner of construction	coextruded
UN/ADR	compliant

Table 3.1-13: Packaging information for 500 mL bottle

Type	Description
Material:	HDPE (high density polyethylene)
Shape/size:	71 ± 1 mm diameter x 186 ± 0.5 mm of total height
Opening:	45.5 ± 0.5 mm inner diameter
Closure:	high density polyethylene screw cap
Seal:	hot seal / aluminum / polyester
Manner of construction	extruded
UN/ADR	compliant

Table 3.1-14: Packaging information for 500 mL bottle

Type	Description
Material:	HDPE (high density polyethylene)
Shape/size:	89 ± 1 mm diameter x 134 ± 1 mm of total height
Opening:	59 ± 0.5 mm inner diameter

Type	Description
Closure:	high density polyethylene screw cap
Seal:	hot seal / aluminum / polyester
Manner of construction	extruded
UN/ADR	compliant

Table 3.1-15: Packaging information for 500 mL bottle

Type	Description
Material:	Fluorinated or HDPE / Coex
Shape/size:	69 ± 1 mm diameter x 186 ± 1.6 mm of total height
Opening:	50 ± 1 mm diameter
Closure:	screw cap
Seal:	—
Manner of construction	coextruded
UN/ADR	compliant

Table 3.1-16: Packaging information for 500 mL bottle

Type	Description
Material:	HDPE/EVOH (Coex)
Shape/size:	72 ± 0.5 mm diameter x 186 ± 0.5 mm of total height
Opening:	45.5 ± 0.5 mm inner diameter
Closure:	high density polyethylene screw cap
Seal:	hot seal / aluminum / polyester
Manner of construction	coextruded
UN/ADR	compliant

Table 3.1-17: 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:	high density polyethylene screw cap
Seal:	hot seal / aluminum / polyester
Manner of construction	extruded
UN/ADR	compliant

Table 3.1-18: 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:	polyethylene screw cap
Seal:	PET/ALU/PEE; IHS; Tresylene
Manner of construction	extruded
UN/ADR	compliant

Table 3.1-21: 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:	high density polyethylene screw cap, model: Ø63
Seal:	<i>b-Gasket</i> : disk, duplex
Manner of construction	extruded
UN/ADR	compliant

Table 3.1-22: 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:	high density polyethylene screw cap, model: KS50
Seal:	<i>b-Gasket</i> : disk, duplex
Manner of construction	extruded
UN/ADR	compliant

Table 3.1-19: 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:	high density polyethylene screw cap
Seal:	-
Manner of construction	extruded

Type	Description
UN/ADR	compliant

Table 3.1-20: 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:	high density polyethylene screw cap
Seal:	hot seal / aluminum / polyester
Manner of construction	coextruded
UN/ADR	compliant

Table 3.1-215: 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:	high density polyethylene screw cap, model: Ø63
Seal:	<i>b-Gasket</i> : disk, duplex
Manner of construction	coextruded
UN/ADR	compliant

Table 3.1-226: 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:	high density polyethylene screw cap, model: KS50
Seal:	<i>b-Gasket</i> : disk, duplex
Manner of construction	coextruded
UN/ADR	compliant

Table 3.1-27: 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:	63 ± 1 mm diameter

Type	Description
Closure:	screw cap
Seal:	HDPE
Manner of construction	coextruded
UN/ADR	compliant

Table 3.1-28: Packaging information for 2 L jerrycan

Type	Description
Material:	HDPE (high density polyethylene)
Shape/size:	155 ± 2 mm diameter x 189 ± 2.5 mm of total height
Opening:	42 mm
Closure:	polyethylene screw cap
Seal:	PET/ALU/PEE; IHS; Tresylene
Manner of construction	extruded
UN/ADR	compliant

Table 3.1-29: Packaging information for 2 L jerrycan

Type	Description
Material:	Fluorinated or HDPE / Coex
Shape/size:	155 ± 2 mm diameter x 189 ± 2.5 mm of total height
Opening:	42 mm diameter
Closure:	screw cap
Seal:	HDPE
Manner of construction	coextruded
UN/ADR	compliant

Table 3.1-30: Packaging information for 3 L jerrycan

Type	Description
Material:	Fluorinated or HDPE / Coex
Shape/size:	160 mm diameter x 257 mm of total height
Opening:	63 mm diameter
Closure:	screw cap
Seal:	HDPE
Manner of construction	coextruded
UN/ADR	compliant

Table 3.1-31: Packaging information for 5 L jerrycan

Type	Description
Material:	HDPE / Coex

Type	Description
Shape/size:	187 mm diameter x 306 mm of total height
Opening:	63 mm diameter
Closure:	screw cap
Seal:	HDPE
Manner of construction	coextruded
UN/ADR	compliant

Table 3.1-32: 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:	high density polyethylene screw cap
Seal:	hot seal / aluminum / polyester
Manner of construction	extruded
UN/ADR	compliant

Table 3.1-33: 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:	high density polyethylene screw cap, model: D.63
Seal:	<i>b-Gasket</i> : disk, duplex
Manner of construction	extruded
UN/ADR	compliant

Table 3.1-34: 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:	polyethylene screw cap
Seal:	-
Manner of construction	extruded
UN/ADR	compliant

Table 3.1-35: 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:	polyethylene screw cap
Seal:	expanded polyethylene
Manner of construction	extruded
UN/ADR	compliant

Table 3.1-36: 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:	polyethylene screw cap
Seal:	-
Manner of construction	coextruded
UN/ADR	compliant

Table 3.1-237: 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:	high density polyethylene screw cap
Seal:	hot seal / aluminum / polyester
Manner of construction	coextruded
UN/ADR	compliant

Table 3.1-24: 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:	high density polyethylene screw cap, model: D63
Seal:	<i>b-Gasket</i> : disk, Chromo AIKO safe foil
Manner of construction	coextruded
UN/ADR	compliant

Table 3.1-39: Packaging information for 7 L jerrycan

Type	Description
Material:	Fluorinated or HDPE / Coex
Shape/size:	240 ± 2 mm diameter x 307 ± 2.5 mm of total height
Opening:	63 mm diameter
Closure:	screw cap
Seal:	HDPE
Manner of construction	coextruded
UN/ADR	compliant

Table 3.1-40: 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:	high density polyethylene screw cap
Seal:	hot seal / aluminum / polyester
Manner of construction	extruded
UN/ADR	compliant

Table 3.1-41: 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:	polyethylene screw cap
Seal:	-
Manner of construction	extruded
UN/ADR	compliant

Table 3.1-42: 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:	high density polyethylene screw cap
Seal:	hot seal / aluminum / polyester
Manner of construction	coextruded
UN/ADR	compliant

Table 3.1-43: 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:	polyethylene screw cap
Seal:	-
Manner of construction	coextruded
UN/ADR	compliant

Table 3.1-44: Packaging information for 10L jerrycan

Type	Description
Material:	Fluorinated or HDPE / Coex
Shape/size:	245 ± 2 mm diameter x 330 ± 3 mm of total height
Opening:	60 mm diameter
Closure:	screw cap
Seal:	—
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. For aqueous based formulation type, like SC, extrapolation between any plastic material types is acceptable (according to SANCO/10473/2003 –rev.5). Therefore PET packs are supported based on data for HDPE packs (for details see findings of storage stability test (KCP 2.7.1)).

Please refer to the reference product Dossier of SPINTOR 480 SC in Poland registered since 2003 (permit of the Ministry of Agriculture and Rural Development No. R-18/2003 of 12 September 2003), and currently the permit of the Ministry of Agriculture and Rural Development No. R-47/2018wu of 19 October 2018.

The HDPE packages were examined for any visible changes before and after storage for 14 days at 54° C and they did not suffer any change. Please see point KCP 2.7.1.

Findings:

Visual observations for package stability

Damage	Visual Observations	
	Initial	After 14 days at 54° C
Deformation	No	No
Attack by the content	No	No
Leaking	No	No
Label damage	No	No
Conclusion	No visual degradation	No visual degradation

Appendix 1 Lists of data considered in support of the evaluation

Please refer to the reference product Dossier of SPINTOR 480 SC in Poland registered since 2003 (permit of the Ministry of Agriculture and Rural Development No. R-18/2003 of 12 September 2003), and currently with registration No. R-47/2018wu of 19 October 2018.

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.	2021	Spinosad 480 g/L SC (SAP09I): Physical, chemical and technical properties of the plant protection product Company Report No EF/359/21 – Interim Report ASCENZA AGRO, S.A. GLP Unpublished	N	Albaugh Europe Sàrl Ascenza Agro SA Lainco SA
KCP 2.1/02	Silva, S.	2023	Spinosad 480 g/L SC (SAP09I): Physical, chemical and technical properties of the plant protection product Company Report No EF/359/21 – Interim Report (T24) ASCENZA AGRO, S.A. GLP Unpublished	N	Albaugh Europe Sàrl Ascenza Agro SA Lainco SA
KCP 2.1/03	Silva, S.	2024	Spinosad 480 g/L SC (SAP09I): Physical, chemical and technical properties of the plant protection product Company Report No EF/359/21 – (T36) ASCENZA AGRO, S.A. GLP Unpublished	N	Albaugh Europe Sàrl Ascenza Agro SA Lainco SA
KCP 2.2.1	Dornhagen, J.	2021a	Spinosad 480 g/L SC – SAP09I: EXPLOSIVE PROPERTIES A.14. Company Report No PS20210184-2 Siemens AG GLP	N	Albaugh Europe Sàrl Ascenza Agro SA Lainco SA

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
			Unpublished		
KCP 2.2.2	Dornhagen, J.	2021b	Spinosad 480 g/L SC – SAP09I: OXIDIZING PROPERTIES (LIQUIDS) O.2 Company Report No PS20210184-4 Siemens AG GLP Unpublished	N	Albaugh Europe Sàrl Ascenza Agro SA Lainco SA
KCP 2.3.1	Dornhagen, J.	2021c	Spinosad 480 g/L SC – SAP09I: FLASH POINT A.9. Company Report No PS20210184-1 Siemens AG GLP Unpublished	N	Albaugh Europe Sàrl Ascenza Agro SA Lainco SA
KCP 2.3.3	Dornhagen, J.	2021d	Spinosad 480 g/L SC – SAP09I: AUTO-IGNITION TEMPERATURE (LIQUIDS AND GASES) A.15 Company Report No PS20210184-3 Siemens AG GLP Unpublished	N	Albaugh Europe Sàrl Ascenza Agro SA Lainco SA
KCP 2.4.1/01	Morais, F.	2021	Spinosad 480 g/L SC (SAP09I): Physical, chemical and technical properties of the plant protection product Company Report No EF/359/21 – Interim Report ASCENZA AGRO, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	Albaugh Europe Sàrl Ascenza Agro SA Lainco SA
KCP 2.4.1/02	Silva, S.	2023	Spinosad 480 g/L SC (SAP09I): Physical, chemical and technical properties of the plant protection product Company Report No EF/359/21 – Interim Report (T24) ASCENZA AGRO, S.A. GLP Unpublished	N	Albaugh Europe Sàrl Ascenza Agro SA Lainco SA

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
			(Submitted in KCP 2.1/02)		
KCP 2.4.2	Morais, F.	2021	Spinosad 480 g/L SC (SAP09I): Physical, chemical and technical properties of the plant protection product Company Report No EF/359/21 – Interim Report ASCENZA AGRO, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	Albaugh Europe Sàrl Ascenza Agro SA Lainco SA
KCP 2.5.1	Morais, F.	2021	Spinosad 480 g/L SC (SAP09I): Physical, chemical and technical properties of the plant protection product Company Report No EF/359/21 – Interim Report ASCENZA AGRO, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	Albaugh Europe Sàrl Ascenza Agro SA Lainco SA
KCP 2.5.2	Morais, F.	2021	Spinosad 480 g/L SC (SAP09I): Physical, chemical and technical properties of the plant protection product Company Report No EF/359/21 – Interim Report ASCENZA AGRO, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	Albaugh Europe Sàrl Ascenza Agro SA Lainco SA
KCP 2.6.1	Morais, F.	2021	Spinosad 480 g/L SC (SAP09I): Physical, chemical and technical properties of the plant protection product Company Report No EF/359/21 – Interim Report ASCENZA AGRO, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	Albaugh Europe Sàrl Ascenza Agro SA Lainco SA
KCP 2.7.1	Morais, F.	2021	Spinosad 480 g/L SC (SAP09I): Physical, chemical and technical properties of the plant protection	N	Albaugh Europe Sàrl

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
			product Company Report No EF/359/21 – Interim Report ASCENZA AGRO, S.A. GLP Unpublished (Submitted in KCP 2.1/01)		Ascenza Agro SA Lainco SA
KCP 2.7.4	Morais, F.	2021	Spinosad 480 g/L SC (SAP09I): Physical, chemical and technical properties of the plant protection product Company Report No EF/359/21 – Interim Report ASCENZA AGRO, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	Albaugh Europe Sàrl Ascenza Agro SA Lainco SA
KCP 2.7.5	Morais, F.	2021	Spinosad 480 g/L SC (SAP09I): Physical, chemical and technical properties of the plant protection product Company Report No EF/359/21 – Interim Report ASCENZA AGRO, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	Albaugh Europe Sàrl Ascenza Agro SA Lainco SA
KCP 2.8.2	Morais, F.	2021	Spinosad 480 g/L SC (SAP09I): Physical, chemical and technical properties of the plant protection product Company Report No EF/359/21 – Interim Report ASCENZA AGRO, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	Albaugh Europe Sàrl Ascenza Agro SA Lainco SA
KCP 2.8.3.1	Morais, F.	2021	Spinosad 480 g/L SC (SAP09I): Physical, chemical and technical properties of the plant protection product Company Report No EF/359/21 – Interim Report	N	Albaugh Europe Sàrl Ascenza Agro SA Lainco SA

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
			ASCENZA AGRO, S.A. GLP Unpublished (Submitted in KCP 2.1/01)		
KCP 2.8.3.2	Morais, F.	2021	Spinosad 480 g/L SC (SAP09I): Physical, chemical and technical properties of the plant protection product Company Report No EF/359/21 – Interim Report ASCENZA AGRO, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	Albaugh Europe Sàrl Ascenza Agro SA Lainco SA
KCP 2.8.5.1.1	Morais, F.	2021	Spinosad 480 g/L SC (SAP09I): Physical, chemical and technical properties of the plant protection product Company Report No EF/359/21 – Interim Report ASCENZA AGRO, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	Albaugh Europe Sàrl Ascenza Agro SA Lainco SA
KCP 2.8.5.1.2	Morais, F.	2021	Spinosad 480 g/L SC (SAP09I): Physical, chemical and technical properties of the plant protection product Company Report No EF/359/21 – Interim Report ASCENZA AGRO, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	Albaugh Europe Sàrl Ascenza Agro SA Lainco SA
KCP 2.8.7.2	Morais, F.	2021	Spinosad 480 g/L SC (SAP09I): Physical, chemical and technical properties of the plant protection product Company Report No EF/359/21 – Interim Report ASCENZA AGRO, S.A. GLP	N	Albaugh Europe Sàrl Ascenza Agro SA Lainco SA

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
			Unpublished (Submitted in KCP 2.1/01)		

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

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

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

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

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

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

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

None.