

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: FHO04

Product name(s): Prothioconazole/Sulphur (50+625) SC,
/ Patton Supra

Chemical active substance(s): Prothioconazole 50 g/L,
Sulphur 625 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: 31/05/2024

MS Finalisation date: November 2024 (initial Core Assessment)

February 2025 (final Core Assessment)

Version history

When	What
31 May 2024	Applicant version
November 2024	<p>Initial zRMS assessment.</p> <p>The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency.</p>
February 2025	<p>Final report (Core Assessment updated following the commenting period)</p> <p>No additional information or assessments after the commenting period.</p>

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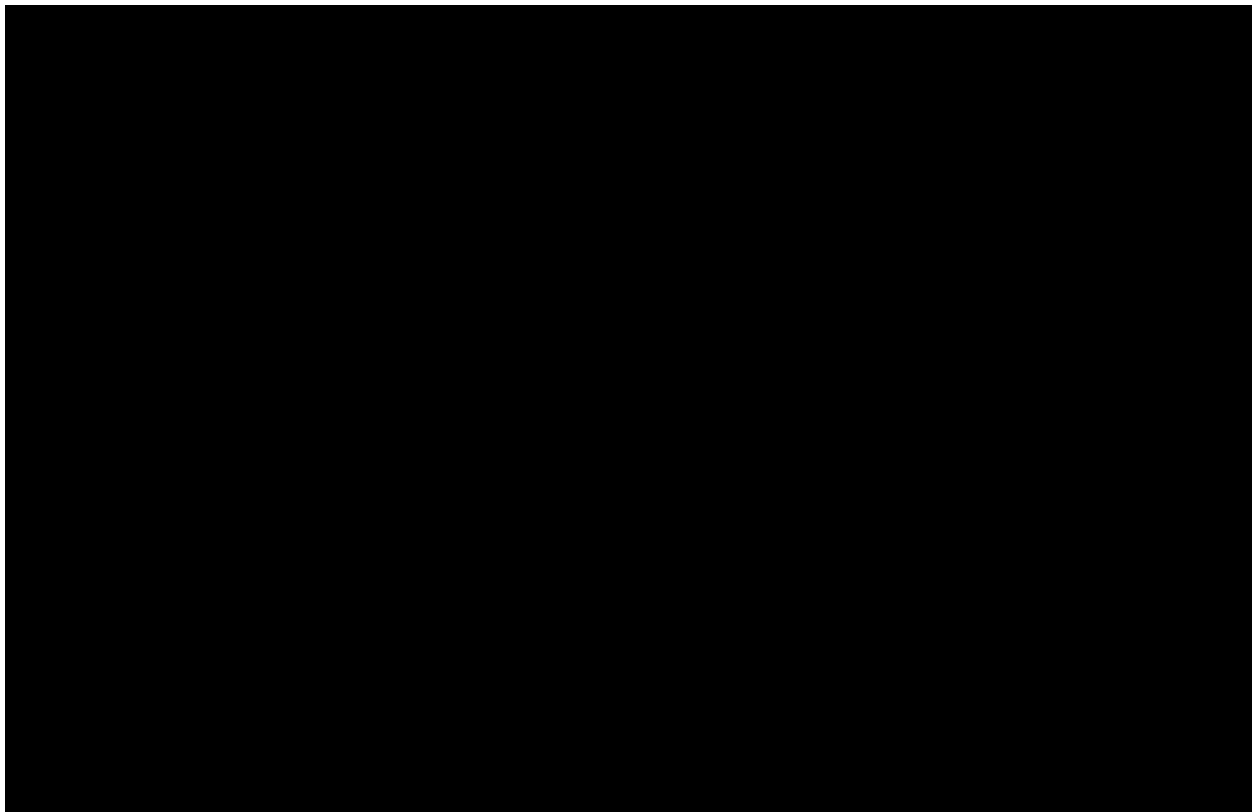
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Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substances.

Noticed data gaps are: none.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)



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

1.2.1 Producer(s) of the preparation

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

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

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

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

1.2.3.1 Prothioconazole

Prothioconazole

min. 970 g/kg
Reg. (EU) No 540/2011

Relevant impurities of toxicological concern:

Toluene	max. 5 g/kg
Prothioconazole-desthio	max. 0.5 g/kg (LOD)

1.2.3.2 Sulphur

Sulphur	min. 990 g/kg Reg. (EU) No 540/2011
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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: FHO04

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 1-1: Active substance(s) and variant(s) of the active substance(s)

Active substance / variant	Declared content of the pure active substance / variant (g/L)	FAO Limits (min – max)	Technical content* (g/L)	Technical content** (%w/w)
Prothioconazole	50	45-55	51.55	3.80
Sulphur	625	600-650	631.31	46.59

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers (prothioconazole 970 g/kg, sulphur 990 g/kg)

** Based on the density of the formulation = 1.355 g/cm³

FHO04 does not contain any safeners or synergists. For further information on the formulation details please refer to the Part C.

Table 1-2: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)*
Toluene	0.26 g/L
Prothioconazole-desthio	0.03 g/L

* Based on the declared concentration of the active substances in the formulation (51.5 g/L for prothioconazole).

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

Table 1-3: Information on prothioconazole

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

Table 1-4: Information on sulphur

Type	Name/Code Number
ISO common name	Sulfur
CAS No.	7704-34-9
EC No.	231-722-6
CIPAC No.	18

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

Not relevant, the product does not contain any safeners or synergists. Information on the co-formulants is CONFIDENTIAL and 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 a light yellow opaque viscous liquid without characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. Self ignition was not observed at temperatures below 600 °C. In aqueous solution, it has a pH value around 6.3 at 20.7 °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 substance content nor the technical properties were changed. The stability data of the product when stored in HDPE/EVOH indicates a shelf life of at least 2 years. Its technical characteristics are acceptable for a suspension concentrate formulation. The intended concentration of use, covering all crops, is 1 % (4 L in 400 L water) to 4 % (4 L in 100 L water).

Physical compatibility studies regarding combinations of the product with a limited number of other plant protection products were submitted and the application as tank mixture is acceptable with labelling to first establish the physical compatibility of each mixture by preparing a small amount separately before use. For a full details please refer point 2.9.1.

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

Not required.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

Not required.

Compliance with FAO specifications:

The product FHO04 complies with FAO specifications.

Formulation used for tests

The formulation used to determine the physical, chemical, and technical properties is the same as the formulation described in the 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 inspection	FHO04 Batch No. 028421	A light yellow, opaque, viscous liquid with no characteristic odour.	N	V. Buchholz, 2022, Report No. R C1254	Accepted.
Explosive properties (KCP 2.2.1)	EC A.14	FHO04 Batch No. 028421	The test item has no explosive properties. A positive result was not produced and therefore, in line with SANCO/10473/2003 –rev.5, the EC method is acceptable and the UN method is not required.	Y	V. Buchholz, 2022, Report No. R C1254	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)	EC A.21	FHO04 Batch No. 028421	The test item has no oxidising properties. A positive result was not produced and therefore, in line with SANCO/10473/2003 –rev.5, the EC method is acceptable and the UN method is not required.	Y	V. Buchholz, 2022, Report No. R C1254	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)	EC A.9	FHO04 Batch No. 028421	No flash point was observed.	Y	V. Buchholz, 2022, Report No. R C1254	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)	-	-	Please refer to KCP 2.3.3.	-	-	Please refer to KCP 2.3.3.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Self-heating (KCP 2.3.3)	EC A.15	FHO04 Batch No. 028421	No auto-ignition up to 600 °C.	Y	V. Buchholz, 2022, Report No. R C1254	Accepted. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.
Acidity or alkalinity and pH (KCP 2.4.1)	MT 75.3	FHO04 Batch No. 028421	6.3	Y	V. Buchholz, 2022, Report No. R C1254	Accepted.
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	MT 75.3	FHO04 Batch No. 028421	6.3 (Temperature 20.3°C)	Y	V. Buchholz, 2022, Report No. R C1254	Accepted.
Viscosity (KCP 2.5.1)	OECD 114	FHO04 Batch No. 028421	At 20 °C ± 0.2 °C: from 142938 to 316 mPa.s for shear rates from 0.03 to 50.00 s ⁻¹ At 40 °C ± 0.2 °C: from 131222 to 289 mPa.s. for shear rates from 0.03 to 50.00 s ⁻¹	Y	V. Buchholz, 2022, Report No. R C1254	Accepted.
Surface tension (KCP 2.5.2)	EC A.5	FHO04 Batch No. 028421	The mean surface tension of the test item at 4% v/v in distilled water was 24.5 mN/m ± 0.1 mN/m	Y	V. Buchholz, 2022, Report No. R C1254	Accepted. Product is surface active. 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.
Relative density (KCP 2.6.1)	EC A.3	FHO04 Batch No. 028421	1.355 g/mL	Y	V. Buchholz, 2022, Report No. R C1255	Accepted.

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
Bulk density (KCP 2.6.2)	-	-	Not relevant for SC formulations.			-	-	-
Storage Stability after 14 days at 54° C (KCP 2.7.1)	MT 75.3 MT 160 MT 184 MT 185 MT 148.1 Prothioconazole is determined by HPLC-PDA method and external standardisation. Analytical method - MA_1760_08; Sulphur determined by HPLC-PDA method and external standardization; Analytical method is MA_1781_01.	FHO04 Batch No. 028421	Test	Initial	After 14 days at 54°C	Y	V. Buchholz, 2022, Report No. R C1255	The product showed no significant physical changes after accelerated storage. No significant changes were observed in the packaging and therefore it can be concluded that the test item was not corrosive to the container material. No toxicologically, ecotoxicologically or environmentally relevant impurities are formed upon storage. The accelerated stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging (HDPE/EVOH).
			Appearance	A light yellow, opaque, viscous liquid with no characteristic odour.	A light yellow, opaque, viscous liquid with no characteristic odour.			
			Prothioconazole content	53 g/L	52.89 g/L			
			Sulphur content	639.8 g/L	640.7 g/L			
			Relevant impurity content toluene	< LOQ (0.1 g/kg)	< LOQ (0.1 g/kg)			
			Relevant impurity content prothioconazole-desthio	< LOD (2.5 mg/kg)	< LOD (2.5 mg/kg)			
			pH (undiluted)	6.3 (at 20.7°C)	5.7 (at 20.6°C)			
			pH (1 % v/v)	6.3 (at 20.3°C)	5.7 (at 20.2°C)			
			Spontaneity of dispersion 5% in Standard Water D	Prothioconazole: 90.3 % Sulphur: 95.7 %	Prothioconazole: 92.2 % Sulphur: 88.0 %			
			Suspensibility	1 % v/v in Standard Water D Prothioconazole: 100.0 % Sulphur: 97.4 % 4 % v/v in Standard Water D Prothioconazole: 98.2 % Sulphur: 94.7 %	1 % v/v in Standard Water D Prothioconazole: 97.6 % Sulphur: 93.7 % 4 % v/v in Standard Water D Prothioconazole: 96.6 % Sulphur: 94.0 %			
			Wet sieve test	0 % retained on 75 µm sieve	0 % retained on 75 µm sieve			
			Pourability	Poured residue: 5.1 % Rinsed residue: 0.2 %	Poured residue: 4.9 % Rinsed residue: 0.3 %			
			Packaging/preparation interactions	-	No alteration of the container (1L HDPE/EVOH (Coex)). No signif-			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
					icant difference in weight. 20 mL of oil was observed but was homogeneous after agitation.			
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not required			-	-	-
Minimum content after heat stability testing (KCP 2.7.3)	In house method	FHO04 Batch No. 028421	Test	Initial	After 14 days at 54°C	Y	V. Buchholz, 2022, Report No. R C1255	Accepted.
			Prothioconazole content	53 g/L	52.89 g/L			
			Sulphur content	639.8 g/L	640.7 g/L			
			Relevant impurity content toluene	< LOQ (0.1 g/kg)	< LOQ (0.1 g/kg)			
			Relevant impurity content prothioconazole-desthio	< LOD (2.5 mg/kg)	< LOD (2.5 mg/kg)			
Effect of low temperatures on stability (KCP 2.7.4)	MT 184.1	FHO04 Batch No. 028421	Test	Initial	After 7 days at 0°C	Y	V. Buchholz, 2022, Report No. R C1254	Accepted.
			Suspensibility	1 % v/v in Standard Water D Prothioconazole: 100 % Sulphur: 97.4 %	1 % v/v in Standard Water D Prothioconazole: 99.2 % Sulphur: 97.5 %			
				4 % v/v in Standard Water D Prothioconazole: 98.2 % Sulphur: 95.7 %	4 % v/v in Standard Water D Prothioconazole: 98.5 % Sulphur: 95.3 %			
				Wet sieve test	0 % retained on 75 µm sieve			
			Ambient temperature shelf life (KCP 2.7.5)	CropLife International technical monograph no. 17 2nd edition Prothioconazole is determined by HPLC-PDA method and external standardisation. Analytical method - MA_1760_08; Sulphur determined	FHO04 Batch No. 028421			
Test	Timing (years)	Result						
Stability of packaging	0	-						
	2	No alteration, seepage, or weight difference						
Prothioconazole con-	0	53.14 g/L						

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
	by HPLC-PDA method and external standardization; Analytical method is MA_1781_01.		tent	2	51.66 g/L			<p>item was not corrosive to the container material.</p> <p>The stability data indicate a shelf life of 2 years at ambient temperature when stored in commercial packaging (HDPE/EVOH).</p>
			Sulphur content	0	638.0 g/L			
				2	644.3 g/L			
			Prothioconazole-	0	< LOD = 2.5 mg/kg			
			Desthio content	2	< LOD = 2.5 mg/kg			
			Toluene content	0	< LOQ = 0.10 g/kg			
				2	< LOQ = 0.10 g/kg			
			Appearance	0	Light yellow viscous liquid			
				2	Light yellow viscous liquid presence of oil on the surface (~ 40 mL), homogeneous after mixing			
			pH undiluted	0	6.3 (at 20.7°C)			
				2	5.5 (at 19.6°C)			
			pH of a dilution	0	6.3 (at 20.3°C)			
				2	5.8 (at 20.0°C)			
			Relative density	0	1.358			
				2	1.346			
			Persistent foaming (water standard D and at 25°C)	0	1% v/v: After 1 min: 0 mL After 12 min :0 mL 4% v/v: After 1 min: 0 mL After 12 min: 0 mL			
				2	1% v/v: After 1 min: 0 mL After 12 min :0 mL 4% v/v: After 1 min: 0 mL After 12 min: 0 mL			
			Suspensibility (water standard D and at 25°C) Prothioconazole	0	At a concentration of 1% v/v:100.0% At a concentration of 4% v/v:98.2%			
				2	At a concentration of 1% v/v:99.4% At a concentration of 4% v/v:99.9%			
			Suspensibility (water standard D and at 25°C) Sulphur	0	At a concentration of 1% v/v:97.4% At a concentration of			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
				2	4% v/v:94.7% At a concentration of 1% v/v:96.3% At a concentration of 4% v/v:93.4%			
			Spontaneity of dispersion (water standard C and at 25°C) Prothioconazole	0	At a concentration of 12.5 mL / 250 mL : 90.3 %			
				2	At a concentration of 12.5 mL / 250 mL : 98.6 %			
			Spontaneity of dispersion (water standard C and at 25°C) Sulphur	0	At a concentration of 12.5 mL / 250 mL : 95.7 %			
				2	At a concentration of 12.5 mL / 250 mL : 96.0 %			
			Wet sieve test	0	At a concentration of 10 g/100 mL : 0 %			
				2	At a concentration of 10 g/100 mL : 0 %			
			Pourability	0	Residue after pouring : 5.1 % Residue after rinsing : 0.2%			
				2	Residue after pouring :4.1 % Residue after rinsing 0.2 %			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
			Dynamic viscosity (at 20°C and 40°C)	0	Taking into account the results obtained at 20.0 °C and 40.0 °C, the test item was considered to have non-newtonian properties under the experimental conditions used. The dynamic viscosity varied as following: At 20 °C ± 0.2 °C, from η (0.03 s ⁻¹) = 142938 mPa.s to η (50.00 s ⁻¹) = 316 mPa.s. At 40 °C ± 0.2 °C, from η (0.03 s ⁻¹) = 131222 mPa.s to η (50.00 s ⁻¹) = 289 mPa.s.			
				2	Taking into account the results obtained at 20.0 °C and 40.0 °C, the test item was considered to have non-newtonian properties under the experimental conditions used. The dynamic viscosity varied as following: At 20 °C ± 0.2 °C, from η (0.03 s ⁻¹) = 149968 mPa.s to η (50.00 s ⁻¹) = 319 mPa.s. At 40 °C ± 0.2 °C, from η (0.03 s ⁻¹) = 130441 mPa.s to η (50.00 s ⁻¹) = 280 mPa.s.			
			Surface Tension in an aqueous solution at 4% v/v	0	The mean surface tension of the test item at 4% v/v in distilled water at 20.2 °C was 24.5 mN/m ± 0.1 mN/m. The test item was considered as surface-active under			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
				2	the experimental conditions used. The mean surface tension of the test item at 4% v/v in distilled water at 19.7 °C was 27.5 mN/m ± 0.2 mN/m. The test item was considered as surface-active under the experimental conditions used.			
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Not relevant.			-	-	-
Wettability (KCP 2.8.1)	-	-	Not relevant for SC formulations.			-	-	-
Persistence of foam-ing (KCP 2.8.2)	MT 47.3	FHO04 Batch No. 028421	using CIPAC water D 1 % v/v: after 1 min.: 0.0 mL after 12 min.: 0.0 mL 4 % v/v: after 1 min.: 0.0 mL after 12 min.: 0.0 mL			Y	V. Buchholz, 2022, Report No. R C1254	Accepted.
Suspensibility (KCP 2.8.3.1)	MT 184.1	FHO04 Batch No. 028421	1 % v/v in Standard Water D Prothioconazole: 100.0 % Sulphur: 97.4 % 4 % v/v in Standard Water D Prothioconazole: 98.2 % Sulphur: 94.7 %			Y	V. Buchholz, 2022, Report No. R C1254	Accepted.
Spontaneity of disper-sion (KCP 2.8.3.2)	MT 160	FHO04 Batch No. 028421	5 % v/v in Standard Water D Prothioconazole: 90.3 % Sulphur: 95.7 %			Y	V. Buchholz, 2022, Report No. R C1254	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Dispersion stability (KCP 2.8.3.3)	-	-	Not relevant for SC formulations.	-	-	-
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not relevant for SC formulations.	-	-	-
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	-	-	Not relevant for SC formulations.	-	-	-
Wet sieve test (KCP 2.8.5.1.2)	MT 185	FHO04 Batch No. 028421	0 % retained on 75 µm sieve.	Y	V. Buchholz, 2022, Report No. R C1254	Accepted.
Dust content (KCP 2.8.5.2.1)	-	-	Not relevant for SC formulations.	-	-	-
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not relevant for SC formulations.	-	-	-
Attrition (KCP 2.8.5.3)	-	-	Not relevant for SC formulations.	-	-	-
Hardness and integrity (KCP 2.8.5.4)	-	-	Not relevant for SC formulations.	-	-	-
Emulsifiability (KCP 2.8.6.1)	-	-	Not relevant for SC formulations.	-	-	-
Emulsion stability (KCP 2.8.6.2)	-	-	Not relevant for SC formulations.	-	-	-
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not relevant for SC formulations.	-	-	-
Flowability (KCP 2.8.7.1)	-	-	Not relevant for SC formulations.	-	-	-
Pourability (KCP 2.8.7.2)	MT 148.1	FHO04 Batch No. 028421	Poured residue: 5.1 % Rinsed residue: 0.2 %	Y	V. Buchholz, 2022, Report No. R C1254	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																																																						
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not relevant for SC formulations.	-	-	-																																																																						
Physical compatibility of tank mixes (KCP 2.9.1)	In house method	FHO04 Batch No. 0118922	<p>Physically compatible with a selection of six other pesticide formulations (with constant agitation):</p> <table><tr><th>Commercial name</th><th>Registration number in Spain</th><th>Active ingredient concentration and formulation type</th><th>Test concentration</th></tr><tr><td>Vacciplant Max</td><td>ES-00781</td><td>Laminarin 45g/L SL</td><td>2L/Ha/500L</td></tr><tr><td>Caramba EC</td><td>25781</td><td>Metconazole 90g/L EC</td><td>1L/Ha/200L</td></tr><tr><td>Chamane 25 SC</td><td>ES-00477</td><td>Azoxystrobin 250g/L SC</td><td>1L/Ha/100L</td></tr><tr><td>Comet 200 EC</td><td>25636</td><td>Pyraclostrobin 200g/L EC</td><td>1.1L/Ha/100L</td></tr><tr><td>Elatus EC</td><td>ES-00384</td><td>Prothioconazole/benzovindiflupyr 150 + 75g/L EC</td><td>1L/Ha/100L</td></tr><tr><td>Revystar (Lenvyor) EC</td><td>ES-01200</td><td>Mefentrifluconazole 100g/L EC</td><td>1.5L/Ha/100L</td></tr></table> <p>Results:</p> <table><tr><th>Product A</th><th>Product A test concentration</th><th>Product B</th><th>Product B test concentration</th><th>Compatibility A+B</th><th>Compatibility B+A</th></tr><tr><td>Prothioconazole/sulphur 50 + 625 SC</td><td>4L/Ha/100L water</td><td>Vacciplant Max SL</td><td>2L/Ha/500L water</td><td>Compatible with restrictions</td><td>Compatible with restrictions</td></tr><tr><td>Prothioconazole/sulphur 50 + 625 SC</td><td>4L/Ha/100L water</td><td>Caramba EC</td><td>1L/Ha/200L water</td><td>Compatible with restrictions</td><td>Compatible with restrictions</td></tr><tr><td>Prothioconazole/sulphur 50 + 625 SC</td><td>4L/Ha/100L water</td><td>Chamane 25 SC</td><td>1L/Ha/100L water</td><td>Compatible with restrictions</td><td>Compatible with restrictions</td></tr><tr><td>Prothioconazole/sulphur 50 + 625 SC</td><td>4L/Ha/100L water</td><td>Comet 200 EC</td><td>1.1L/Ha/100L water</td><td>Compatible with restrictions</td><td>Compatible with restrictions</td></tr><tr><td>Prothioconazole/sulphur 50 + 625 SC</td><td>4L/Ha/100L water</td><td>Elatus EC</td><td>1L/Ha/100L water</td><td>Compatible with restrictions</td><td>Compatible with restrictions</td></tr><tr><td>Prothioconazole/sulphur 50 + 625 SC</td><td>4L/Ha/100L water</td><td>Revystar EC</td><td>1.5L/Ha/100L water</td><td>Compatible with restrictions</td><td>Compatible with restrictions</td></tr></table> <p>Yellow: compatible with restrictions (keep under constant agitation while spraying).</p> <p>The following recommendation is presented: “In the case of a mixture with other pesticide products, it is advisable to first establish the physical compatibility of each mixture by preparing a small amount separately before use”</p>	Commercial name	Registration number in Spain	Active ingredient concentration and formulation type	Test concentration	Vacciplant Max	ES-00781	Laminarin 45g/L SL	2L/Ha/500L	Caramba EC	25781	Metconazole 90g/L EC	1L/Ha/200L	Chamane 25 SC	ES-00477	Azoxystrobin 250g/L SC	1L/Ha/100L	Comet 200 EC	25636	Pyraclostrobin 200g/L EC	1.1L/Ha/100L	Elatus EC	ES-00384	Prothioconazole/benzovindiflupyr 150 + 75g/L EC	1L/Ha/100L	Revystar (Lenvyor) EC	ES-01200	Mefentrifluconazole 100g/L EC	1.5L/Ha/100L	Product A	Product A test concentration	Product B	Product B test concentration	Compatibility A+B	Compatibility B+A	Prothioconazole/sulphur 50 + 625 SC	4L/Ha/100L water	Vacciplant Max SL	2L/Ha/500L water	Compatible with restrictions	Compatible with restrictions	Prothioconazole/sulphur 50 + 625 SC	4L/Ha/100L water	Caramba EC	1L/Ha/200L water	Compatible with restrictions	Compatible with restrictions	Prothioconazole/sulphur 50 + 625 SC	4L/Ha/100L water	Chamane 25 SC	1L/Ha/100L water	Compatible with restrictions	Compatible with restrictions	Prothioconazole/sulphur 50 + 625 SC	4L/Ha/100L water	Comet 200 EC	1.1L/Ha/100L water	Compatible with restrictions	Compatible with restrictions	Prothioconazole/sulphur 50 + 625 SC	4L/Ha/100L water	Elatus EC	1L/Ha/100L water	Compatible with restrictions	Compatible with restrictions	Prothioconazole/sulphur 50 + 625 SC	4L/Ha/100L water	Revystar EC	1.5L/Ha/100L water	Compatible with restrictions	Compatible with restrictions	N	A. Jakubiak, 2023, Report No. UPL/2023/2018	Compatibility has been confirmed. All tested mixtures proved to be compatible with the following recommendation: “meanwhile a constant agitation must be applied while spraying”.
Commercial name	Registration number in Spain	Active ingredient concentration and formulation type	Test concentration																																																																									
Vacciplant Max	ES-00781	Laminarin 45g/L SL	2L/Ha/500L																																																																									
Caramba EC	25781	Metconazole 90g/L EC	1L/Ha/200L																																																																									
Chamane 25 SC	ES-00477	Azoxystrobin 250g/L SC	1L/Ha/100L																																																																									
Comet 200 EC	25636	Pyraclostrobin 200g/L EC	1.1L/Ha/100L																																																																									
Elatus EC	ES-00384	Prothioconazole/benzovindiflupyr 150 + 75g/L EC	1L/Ha/100L																																																																									
Revystar (Lenvyor) EC	ES-01200	Mefentrifluconazole 100g/L EC	1.5L/Ha/100L																																																																									
Product A	Product A test concentration	Product B	Product B test concentration	Compatibility A+B	Compatibility B+A																																																																							
Prothioconazole/sulphur 50 + 625 SC	4L/Ha/100L water	Vacciplant Max SL	2L/Ha/500L water	Compatible with restrictions	Compatible with restrictions																																																																							
Prothioconazole/sulphur 50 + 625 SC	4L/Ha/100L water	Caramba EC	1L/Ha/200L water	Compatible with restrictions	Compatible with restrictions																																																																							
Prothioconazole/sulphur 50 + 625 SC	4L/Ha/100L water	Chamane 25 SC	1L/Ha/100L water	Compatible with restrictions	Compatible with restrictions																																																																							
Prothioconazole/sulphur 50 + 625 SC	4L/Ha/100L water	Comet 200 EC	1.1L/Ha/100L water	Compatible with restrictions	Compatible with restrictions																																																																							
Prothioconazole/sulphur 50 + 625 SC	4L/Ha/100L water	Elatus EC	1L/Ha/100L water	Compatible with restrictions	Compatible with restrictions																																																																							
Prothioconazole/sulphur 50 + 625 SC	4L/Ha/100L water	Revystar EC	1.5L/Ha/100L water	Compatible with restrictions	Compatible with restrictions																																																																							
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not performed, please refer to the physical compatibility findings. Please refer point 2.9.1	-	-	Please refer point 2.9.1																																																																						
Adhesion to seeds (KCP 2.10.1)	-	-	Not relevant.	-	-	-																																																																						

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Distribution to seed (KCP 2.10.2)	-	-	Not relevant.	-	-	-

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 accelerated and ambient stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging (HDPE/EVOH). Extrapolation from HDPE/EVOH to HDPE co-extruded (HDPE/PA an HDPE-F) is acceptable.
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Table 4.1-1: Packaging information for 0.5 L bottle

Type	Description
Material:	HDPE/EVOH (Coex)
Shape/size:	Cylindrical / approx. 69 mm diameter x 186.5 mm
Opening:	50 mm neck finish
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	Extruded
UN/ADR	Compliant

Table 4.1-2: Packaging information for 1 L bottle

Type	Description
Material:	HDPE/EVOH (Coex)
Shape/size:	Cylindrical / approx. 89.5 mm diameter x 235 mm
Opening:	50 mm neck finish
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	Extruded
UN/ADR	Compliant

Table 4.1-3: Packaging information for 2 L jerrycan

Type	Description
Material:	HDPE/EVOH (Coex)
Shape/size:	Rectangular with integrated handle / approx. 94 mm x 140 mm x 173 mm
Opening:	50 mm neck finish
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	Extruded
UN/ADR	Compliant

Table 4.1-4: Packaging information for 3 L jerrycan

Type	Description
Material:	HDPE/EVOH (Coex)
Shape/size:	Rectangular with integrated handle / approx. 115 mm x 160 mm x 262 mm
Opening:	63 mm neck finish
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	Extruded

Type	Description
UN/ADR	Compliant

Table 4.1-5: Packaging information for 5 L jerrycan

Type	Description
Material:	HDPE/EVOH (Coex)
Shape/size:	Rectangular with integrated handle / approx. 142 mm x 193 mm x 305 mm
Opening:	63 mm neck finish
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	Extruded
UN/ADR	Compliant

Table 4.1-6: Packaging information for 10 L jerrycan

Type	Description
Material:	HDPE/EVOH (Coex)
Shape/size:	Rectangular with integrated handle / approx. 179 mm x 240 mm x 368 mm
Opening:	63 mm neck finish
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	Extruded
UN/ADR	Compliant

Table 4.1-7: Packaging information for 20 L jerrycan

Type	Description
Material:	HDPE/EVOH (Coex)
Shape/size:	Rectangular with integrated handle / approx. 246 mm x 290 mm x 390 mm
Opening:	63 mm neck finish
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	Extruded
UN/ADR	Compliant

Table 4.1-8: Packaging information for 0.5 L bottle

Type	Description
Material:	HDPE/PA (Coex)
Shape/size:	Cylindrical / approx. 69 mm diameter x 186.5 mm
Opening:	50 mm neck finish
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	Extruded
UN/ADR	Compliant

Table 4.1-9: Packaging information for 1 L bottle

Type	Description
Material:	HDPE/PA (Coex)

Type	Description
Shape/size:	Cylindrical / approx. 88.5 mm diameter x 238 mm
Opening:	50 mm neck finish
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	Extruded
UN/ADR	Compliant

Table 4.1-10: Packaging information for 2 L jerrycan

Type	Description
Material:	HDPE/PA (Coex)
Shape/size:	Rectangular with integrated handle / approx. 94 mm x 140 mm x 173 mm
Opening:	50 mm neck finish
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	Extruded
UN/ADR	Compliant

Table 4.1-11: Packaging information for 3 L jerrycan

Type	Description
Material:	HDPE/PA (Coex)
Shape/size:	Rectangular with integrated handle / approx. 115 mm x 160 mm x 262 mm
Opening:	63 mm neck finish
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	Extruded
UN/ADR	Compliant

Table 4.1-12: Packaging information for 5 L jerrycan

Type	Description
Material:	HDPE/PA (Coex)
Shape/size:	Rectangular with integrated handle / approx. 142 mm x 193 mm x 307 mm
Opening:	63 mm neck finish
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	Extruded
UN/ADR	Compliant

Table 4.1-13: Packaging information for 10 L jerrycan

Type	Description
Material:	HDPE/PA (Coex)
Shape/size:	Rectangular with integrated handle / approx. 179 mm x 240 mm x 368 mm
Opening:	63 mm neck finish
Closure:	HDPE screw cap
Seal:	Induction heat seal

Type	Description
Manner of construction	Extruded
UN/ADR	Compliant

Table 4.1-14: Packaging information for 20 L jerrycan

Type	Description
Material:	HDPE/PA (Coex)
Shape/size:	Rectangular with integrated handle / approx. 246 mm x 290 mm x 390 mm
Opening:	63 mm neck finish
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	Extruded
UN/ADR	Compliant

Table 4-2-15: Packaging information for 0.5 L bottle

Type	Description
Material:	HDPE/F (Coex)
Shape/size:	Cylindrical / approx. 69 mm diameter x 186.5 mm
Opening:	50 mm neck finish
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	Extruded
UN/ADR	Compliant

Table 4.1-16: Packaging information for 1 L bottle

Type	Description
Material:	HDPE/F (Coex)
Shape/size:	Cylindrical / approx. 88.5 mm diameter x 233 mm
Opening:	50 mm or 63 mm neck finish
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	Extruded
UN/ADR	Compliant

Table 4.1-17: Packaging information for 2 L jerrycan

Type	Description
Material:	HDPE/F (Coex)
Shape/size:	Rectangular with integrated handle / approx. 94 mm x 140 mm x 173 mm
Opening:	50 mm neck finish
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	Extruded
UN/ADR	Compliant

Table 4.1-18: Packaging information for 3 L jerrycan

Type	Description
Material:	HDPE/F (Coex)
Shape/size:	Rectangular with integrated handle / approx. 115 mm x 160 mm x 262 mm
Opening:	63 mm neck finish
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	Extruded
UN/ADR	Compliant

Table 4.1-19: Packaging information for 5 L jerrycan

Type	Description
Material:	HDPE/F (Coex)
Shape/size:	Rectangular with integrated handle / approx. 142 mm x 193 mm x 307 mm
Opening:	63 mm neck finish
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	Extruded
UN/ADR	Compliant

Table 4.1-20: Packaging information for 10 L jerrycan

Type	Description
Material:	HDPE/F (Coex)
Shape/size:	Rectangular with integrated handle / approx. 179 mm x 240 mm x 377.5 mm
Opening:	63 mm neck finish
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	Extruded
UN/ADR	Compliant

Table 4.1-21: Packaging information for 20 L jerrycan

Type	Description
Material:	HDPE/F (Coex)
Shape/size:	Rectangular with integrated handle / approx. 246 mm x 290 mm x 390 mm
Opening:	63 mm neck finish
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	Extruded
UN/ADR	Compliant

4.2 Procedures for cleaning application equipment (KCP 4.2)

4.2.1 Procedures for cleaning application equipment and protective clothing (KCP 4.2.1)

Wash all application equipment with water (for cleaning efficiency see Point 4.2.2 below). Suitable cleaners (commercial detergents) can be used in addition. Wash protective clothing with washing agents in commercial quality.

4.2.2 Effectiveness of the cleaning procedures (KCP 4.2.2)

Comments of zRMS:	The proposed cleaning procedure is acceptable.
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The efficacy of cleaning application equipment was estimated according to the recommendations of the PSD Efficacy Guideline 305 (V. Buchholz, 2022, Report No. R C1254).

Summary

The purpose of the study was to investigate the effectiveness of the procedures used for cleaning of application equipment in order to demonstrate that residues of FHO04 do not remain in the spray tank after cleaning. Test was run in triplicate and the results averaged.

GLP: Yes

Test item

FHO04 (Batch No. 028421)

Triple Rinse procedure

Standard water D (prepared according to CIPAC MT18), 300 mL, was placed into a 400 mL beaker and stirred. ~16.296 g of test item was added, and stirred for 2 min. After stirring, 100 mL aliquots were poured into 3 polyethylene bottles of 125 ml which were capped and allowed to stand at room temperature overnight. The bottles were then inverted twice, agitated for 1 min using vortex and the tank mix was discarded. 10 mL of tap water was added to each bottle. The bottles were inverted twice, and the rinsate was discarded. This step was repeated two more times. The residue in the bottles was then extracted with 10 ml of acetonitrile solvent and analysed for Prothioconazole and Sulphur by HPLC-PDA using validated in-house analytical methods (see Part B, Section 5, Point 5.2.1).

Results

Analyte	Mean Percentage Removed (%)
Prothioconazole	99.9
Sulphur	100.0

Based on the results of the study, active substance removed from the bottles were at least 99.9% of the initially added amount after triple rinsing.

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 KCP 2.2.1 KCP 2.2.2 KCP 2.3.1 KCP 2.3.3 KCP 2.4.2 KCP 2.5.1 KCP 2.5.2 KCP 2.7.1 KCP 2.7.4 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.3.2 KCP 2.8.5.1.2 KCP 2.8.7.2 KCP 4.2.2	V. Buchholz	2022	Physical and Chemical Properties in one batch of Prothioconazole/Sulphur (50+625) g/L SC (Formulation code FHO04). Initial tests. ANADIAG Report No. R C1254 GLP Unpublished	N	UPL
KCP 2.5.7	V. Buchholz	2024	Physical and Chemical Properties in one batch of Prothioconazole/Sulphur (50+625) g/L SC (Formulation code FHO04) after a storage period. Shelf life after ambient temperature for 2 years ANADIAG Report No. R C1256 Unpublished	N	UPL
KCP 2.6.1 KCP 2.7.3	V. Buchholz	2022	Physical and Chemical Properties in one batch of Prothioconazole/Sulphur (50+625) g/L SC (Formulation code FHO04). Tests after accelerated storage. ANADIAG Report No. R C1255 GLP Unpublished	N	UPL
KCP 2.9.1	A. Jakubiak	2023	The compatibility of Prothioconazole/Sulphur 50 + 625 SC (FHO04) with other pesticides. UPL Europe Limited Report No. UPL/2023/2018 Unpublished	N	UPL

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

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

List of data submitted by the applicant and not relied on

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

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

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

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

A 2.1 Prothioconazole

No new data submitted.

A 2.2 Sulphur

No new data submitted.