

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: FGF11

Product name(s): Telaron Alpha / Patton Alpha
Azoxystrobin 160 g/L + Prothioconazole 200 g/L SC

Chemical active substance(s):

Azoxystrobin, 160 g/L
Prothioconazole, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(new authorization)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: November 2024

MS Finalisation date: April 2025 (initial Core Assessment)

August 2025, update September 2025 (final Core Assessment)

Version history

When	What
November 2024	Initial version
April 2025	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.
July 2025	Applicant update is highlighted in green.
August 2025	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments received from the CMS and the Applicant are highlighted in yellow. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.
September 2025	Final report (Core Assessment updated after the correction of Appendix 4 in Part A prepared by the Applicant) In order to facilitate tracking of changes in the Lists of data considered in support of the evaluation (Appendix 1), amendments are highlighted in turquoise.

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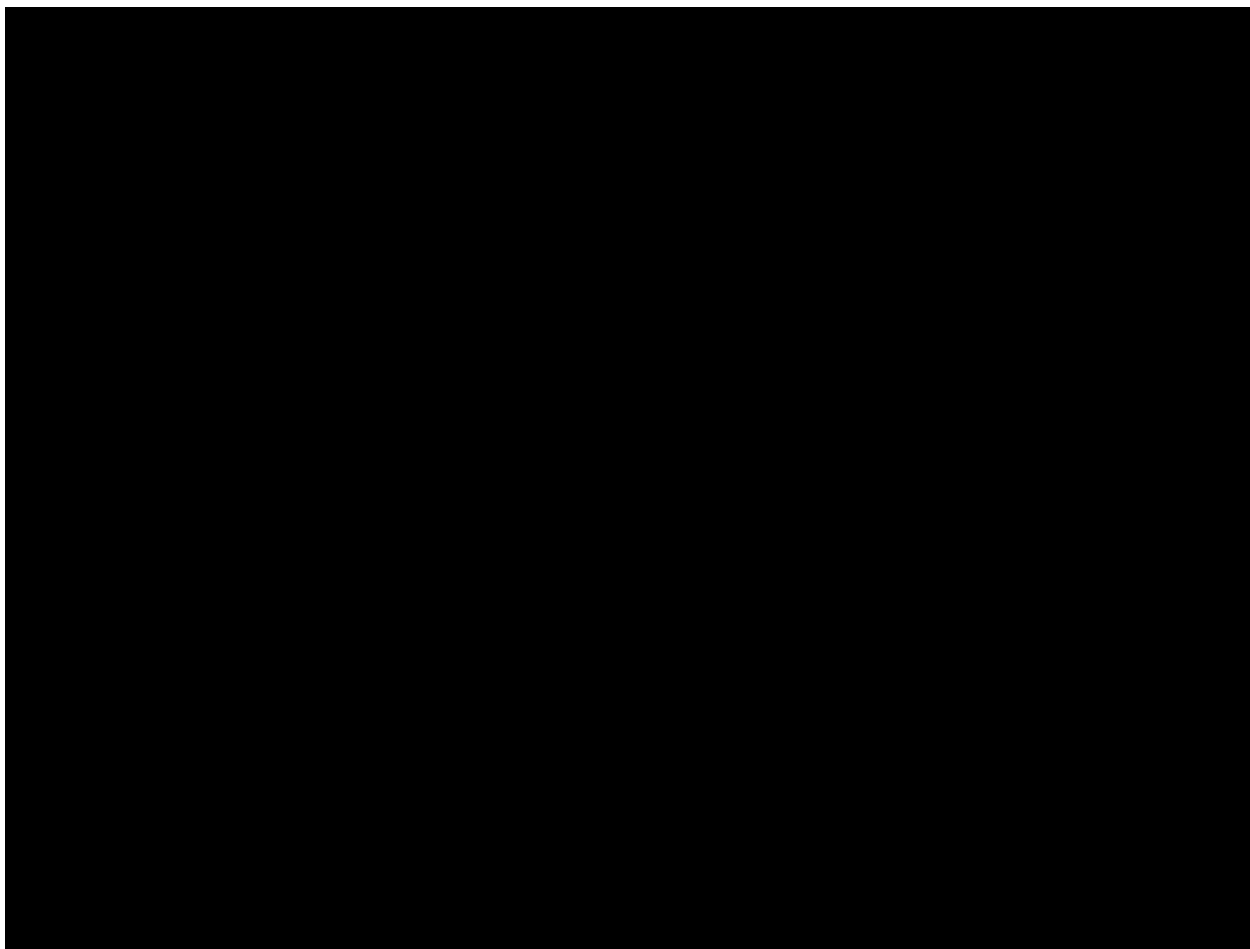
Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are:

- The 2 years storage stability is still ongoing upon submission of the dossier, which is a formal data GAP. Sufficient data however is available from the accelerated storage testing.

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 Active substance 1: Azoxystrobin

Azoxystrobin	min. 930 g/kg (Regulation (EU) No 703/2011)
Toluene	max. 2 g/kg (Regulation (EU) No 703/2011)
Azoxystrobin Z-isomer	max. 25 g/kg (Regulation (EU) No 703/2011)

1.2.3.2 Active substance 2: Prothioconazole

Prothioconazole	min. 970 g/kg (Regulation (EU) No 540/2011)
Toluene	max. 5 g/kg (Regulation (EU) No 540/2011)
Prothioconazole-desthio	max. 0.5 g/kg (Regulation (EU) No 540/2011)

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

Trade name: Patton Alpha
Please refer to Registration Report Part A for the relevant country.

Company code number: FGF11

1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)

Active substance / variant	Declared content of the pure active substance / variant (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
Azoxystrobin	160 g/L	160 g/L ± 9.6 g/L = 150.4 – 169.6 g/L pure azoxystrobin	172.0 g/L (161.7 – 182.3 g/L)	15.3
Prothioconazole	200 g/L	200 g/L ± 12 g/L = 188 – 212 g/L pure prothioconazole	206.2 g/L (193.8 – 218.6 g/L)	18.3

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers (see section 1.2.3.1 and section 1.2.3.2).

** Based on the density of the formulation = 1.1228 g/mL

Batch No. ARD/AP/360/SC/36 of the formulated product (FGF11) was used to generate the physical-chemical properties data (Table 2-1). According to the GLP certificate of analysis, this product batch contains 162.20 g/L (14.45 %w/w) Azoxystrobin and 200.54 g/L (17.86 %w/w) Prothioconazole. These active substance levels comply with the standard FAO tolerances (Table 1.4-1).

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
Toluene	2 g/kg ^a / 5 g/kg ^b
Z-isomer of Azoxystrobin	25 g/kg ^c
Prothioconazole-desthio	0.5 g/kg ^d

- a The stated maximum relevant impurity level for toluene in the azoxystrobin technical material (according to the Commission Implementing Regulation (EU) No 540/2011). This is equivalent to 0.0285% w/w of toluene within the formulated product, FGF11, based on the nominal pure content of azoxystrobin (160 g/L) in the product and the density of the formulation (1.1228 g/mL).
- b The stated maximum relevant impurity level for toluene in the prothioconazole technical material (according to the Commission Implementing Regulation (EU) No 540/2011). This is equivalent to 0.089% w/w of toluene within the formulated product, FGF11, based on the nominal pure content of prothioconazole (200 g/L) in the product and the density of the formulation (1.1228 g/mL).
- c The stated maximum relevant impurity level for the azoxystrobin Z-isomer in the azoxystrobin technical material (according to the Commission Implementing Regulation (EU) No 540/2011). This is equivalent to 0.356% w/w of the azoxystrobin Z-isomer within the formulated product, FGF11, based on the pure nominal content of azoxystrobin (160 g/L) in the product and the density of the formulation (1.1228 g/mL).
- d The stated maximum relevant impurity level for prothioconazole-desthio in the prothioconazole technical material (according to the Commission Implementing Regulation (EU) No 540/2011). This is equivalent to 0.0089% w/w of prothioconazole-desthio within the formulated product, FGF11, based on the nominal pure content of prothioconazole (200 g/L) in the product and the density of the formulation (1.1228 g/mL).

With reference to the results provided in Table 2-1 (KCP 2.7.2), the content of the respective relevant impurities present within the tested formulation (FGF11, Batch No. ARD/AP/360/SC/36) comply with the maximum permitted levels (as described within Table 1.4-2).

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

Table 1.4-3: Information on Azoxystrobin

Type	Name/Code Number
ISO common name	Azoxystrobin
CAS No.	131860-33-8
EC No.	Not allocated
CIPAC No.	571

Table 1.4-4: Information on Prothioconazole

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

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)

Function: 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 light brown liquid (suspension), with a characteristic odour. It is not explosive, has no oxidising properties. The product has a flash point of >102 °C. It has a self-ignition temperature of >600 °C. In aqueous solution, it has a pH value around 6.73 at 20.1 °C. FGF11 is considered to be “Surface active”. There is no effect of low and high temperature on the stability of the formulation, since after 42 days at 45 °C, neither the active ingredient content nor the technical properties were changed. A shelf life of at least 2 years at ambient temperature is expected when the product is stored in the COEX/EVOH, COEX/PA and COEX/F packaging material (based on results of accelerated and after one year of storage stability study); an ambient temperature shelf-life study is currently underway to confirm this expected shelf-life. Its technical characteristics are acceptable for a suspension concentrate formulation.

The intended concentration of use is 0.25%v/v (1 L/ha product, with 400 L water per ha) to 1%v/v (1 L/ha product, with 100 L water per ha).

The product will not be mixed in the tank together with other plant protection products.

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

Neither classification nor labelling are relevant for this section.

Hazard class(es), categories:	-
Hazard pictograms or Code(s) for hazard pictogram(s):	-
Signal word:	-
Hazard statement(s):	-
Precautionary statement(s):	-
Additional labelling phrases:	-

Notifier Proposals for Risk and Safety Phrases (KCP 12)

No risk and safety phrases are relevant for this section. See above.

Compliance with FAO specifications:

The product FGF11 complies with the FAO specifications (see section 1.4.1).

Formulation used for tests

The product (Batch No. ARD/AP/360/SC/36), which has been used to generate the physical-chemical properties data and ecotoxicological data, matches the composition stated within Part C. This batch of the product complies with the standard tolerances set within the FAO specifications (see section 1.4.1 and Table 2-1).

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 / olefactory inspection	FGF11, Batch No. ARD/AP/360/SC/36 ^a	Pre-storage and Post storage: Colour: Light brown State: Liquid (suspension) Odour: Characteristic	Yes	Patil, B., 2024 Study no. 234-2-11-35150	Accepted.
Explosive properties (KCP 2.2.1)	-	FGF11	Explosive properties are not expected for the product. Waiver: As indicated within SANCO/10473/2003 Revision 5 (Section 2.2a), data to address this point are not needed where the individual co-formulants are not classified as 'explosive'. Please refer to Part C for details of the formulation FGF11.	No	-	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	FGF11, Batch No. ARD/AP/360/SC/36 ^a	As there was no spontaneous ignition observed when the test item was mixed with cellulose and even the mean pressure-rise time of the test mixture was significantly more than the reference mixture, it is concluded that FGF11 is "Non-Oxidising in Nature".	Yes	Patil, B., 2024 Study no. 230-2-11-35140	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)	CIPAC MT 12.3 OCSPP 830.6315	FGF11, Batch No. ARD/AP/360/SC/36 ^a	Flash point > 102 °C.	Yes	Patil, B., 2024 Study no. 221-2-11-35148	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)	-	-	Waiver: Not applicable for SC (suspension concentrate) formulations according to SANCO/10473/2003 Revision 5.	-	-	-
Self-heating (KCP 2.3.3)	EC A.15	FGF11, Batch No. ARD/AP/360/SC/36 ^a	The auto-flammability of FGF11 was not observed up to 600 °C (maximum temperature) at 760 mm Hg atmospheric pressure and there was no flame observed after a time-lag of 10 minutes.	Yes	Patil, B., 2024 Study no. 241-2-11-35141	Accepted. The formulation does not need to be classified

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						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)	CIPAC MT 191	FGF11, Batch No. ARD/AP/360/SC/36 ^a	The mean alkalinity (as NaOH) of FGF11 SC was 0.01 ± 0.00% w/w.	Yes	Patil, B., 2024 Study no. 220-2-11-35147	Accepted.
	CIPAC MT 75.3	FGF11, Batch No. ARD/AP/360/SC/36 ^a	pH of neat formulation was 6.69 ± 0.01 (at 19.6 °C ± 0.6).	Yes	Prajapati, P. N., 2025 Study no. 210-2-11-39423	Accepted.
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3 OECD 122 OCSPP 830.7000	FGF11, Batch No. ARD/AP/360/SC/36 ^a	The mean pH of 1.0% w/v aqueous solution of FGF11 was 6.73 ± 0.06 (at 20.1 °C ± 0.3).	Yes	Patil, B., 2024 Study no. 210-2-11-35142	Accepted.
Viscosity (KCP 2.5.1)	OECD 114 OCSPP 830.7100	FGF11, Batch No. ARD/AP/360/SC/36 ^a	The viscosity of FGF11 was determined by the rotational viscometer method at two temperatures. At 20 °C: - The mean viscosity of FGF11 was 24700 cP (mPa s) using spindle number SC4-31 at 0.3 rpm. - The mean viscosity of FGF11 was 269.4 cP (mPa s) using spindle number SC4-31 at 100 rpm. At 40 °C: - The mean viscosity of FGF11 was 17550 cP (mPa s) using spindle number SC4-31 at 0.3 rpm. - The mean viscosity of FGF11 was 203.3 cP (mPa s) using spindle number SC4-31 at 100 rpm. Non-Newtonian liquid.	Yes	Patil, B., 2024 Study no. 214-2-11-35135	Accepted.
Surface tension (KCP 2.5.2)	EC A.5 OECD 115	FGF11, Batch No. ARD/AP/360/SC/36 ^a	The overall mean surface tension of 1 g/L solution of FGF11 measured after 14 minutes of its preparation was 42.03 ± 0.37 mN/m, at 20.30 ± 0.04 °C. Since the measured surface tension of FGF11 was 42.03	Yes	Patil, B., 2024 Study no. 222-2-11-35139	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			± 0.37 mN/m (which is < 60 mN/m), FGF11 is considered to be “Surface active in nature”.			
Relative density (KCP 2.6.1)	CIPAC MT 3.3.2 OECD 109 OCSPP 830.7300	FGF11, Batch No. ARD/AP/360/SC/36 ^a	The mean density of FGF11 was 1.1228 ± 0.0012 g/mL, at 20.0 to 20.1 °C.	Yes	Patil, B., 2024 Study no. 204-2-11-35144	Accepted.
Bulk density (KCP 2.6.2)	-	-	Waiver: Not applicable for SC (suspension concentrate) formulations according to SANCO/10473/2003 Revision 5.	-	-	-
Storage Stability after 14 days at 54° C (KCP 2.7.1)	-	-	Please refer to section KCP 2.7.2.	-	-	-
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	CIPAC MT 46.4 Validated analytical methods were used to quantify the levels of the active substances and the relevant impurities. For further details, please refer to dRR Part B5.	FGF11, Batch No. ARD/AP/360/SC/36 ^a	The product was found to be stable following an accelerated storage period of 42 days at 45 ± 2 °C (stored in a HDPE/EVOH (COEX) container). <u>Azoxystrobin (Method = UPL/2023/1623)</u> Pre-storage content: 14.48% w/w or 162.61 g/L Post-storage content: 14.51% w/w or 162.86 g/L Difference: +0.25 g/L (<1% difference) <u>Prothioconazole (Method = UPL/2023/1623)</u> Pre-storage content: 17.80% w/w or 199.83 g/L Post-storage content: 17.95% w/w or 201.49 g/L Difference: +1.66 g/L (<1 % difference). The product appearance did not change following storage. The integrity of the product packaging was maintained over the storage period (i.e. there were no observations of distortion, perforation, or leaking, following the storage period). The technical properties did not significantly change during the storage period (please refer to the respective sections within this table for each of the tested properties: persistent foam, wet sieve test, suspensibility, pourability, spontaneity of dispersion, particle size distribution).	Yes	Patil, B., 2024 Study no. 234-2-11-35150	Accepted. The product showed no significant physical changes after accelerated storage. No significant changes were observed in the packaging and therefore it can be concluded that the test item was not corrosive to the container material. The accelerated stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging HDPE/EVOH (COEX) container.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			The levels of the relevant impurities associated with Azoxystrobin and Prothioconazole were also analysed before and after storage; no significant changes were noted. <u>Toluene (Method = UPL/2023/1629)</u> Pre-storage content: 0.02331 %w/w Post-storage content: 0.02339 %w/w <u>Azoxystrobin Z-isomer (Method = UPL/2023/11628)</u> Pre-storage content: 0.00377 %w/w Post-storage content: 0.00375 % w/w <u>Prothioconazole-desthio (Method = UPL/2023/1630)</u> Pre-storage content: 0.00354 %w/w Post-storage content: 0.00349 %w/w Full results please refer table 2-2.			
Minimum content after heat stability testing (KCP 2.7.3)	-	-	Please refer to Point KCP 2.7.2.	-	-	-
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3 (using the 'freeze-thaw cycle' method)	FGF11, Batch No. ARD/AP/360/SC/36 ^a	Azoxystrobin 160 + Prothioconazole 200 g/L SC after having kept in a cooled incubator for a freeze-thaw cycle of 18 hours freeze/6-hours melt cycles between -10 ± 2 °C and room temperature (20 ± 2 °C) for a total of 4 cycles. After this period, the test item was found to be homogeneous. No, any separated solid or oily matter and the volume was observed. Following storage, the wet sieve test showed that No residue of the test item retained on the 75 µm test sieve within 10 minutes of washing time. The Suspensibility test for azoxystrobin and prothioconazole (at the maximum and minimum in-use concentrations^b) showed acceptable results within the range 98.53 to 101.25 %w/w.	Yes	Patil, B., 2024 Study no. 211-2-11-35157	Accepted.
	CIPAC MT 39.3	FGF11, Batch No. ARD/AP/360/SC/36 ^a	Azoxystrobin 160 + Prothioconazole 200 g/L SC was stored at a low temperature 0 ± 2 °C for a period of 7	Yes	Prajapati, P.N., 2025 Study no. 252-2-11-	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			days. After storage, the test item was homogeneous without any separation of solid or oily matter in any of the centrifuge tubes. After storage of the test item at 0 ± 2 °C for 7 days, wet sieve test and suspensibility was performed, and the results are mentioned as below: - The wet sieve test showed No residue of the test item retained on the 75 µm test sieve within 10 minutes of washing time. The Suspensibility test for azoxystrobin and prothioconazole (at the maximum and minimum in-use concentrations^b) showed acceptable results within the range 98.07 to 99.86% w/w. The suspensibility was performed using standard water CIPAC D at a temperature of 26.2-27.1 °C.		39422 (UPL/2025/0048)	
Ambient temperature shelf life (KCP 2.7.5)	GIFAP Mono-graph No 17	FGF11, Batch No. ARD/AP/360/SC/36 ^a	A 3-year ambient temperature storage stability study is currently ongoing. The study report is expected to be completed by May 2027.	Y	Not available – study ongoing.	Study ongoing.
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	An ambient temperature storage stability study is underway to confirm the storage stability period (KCP 2.7.5).	-	-	-
	Yes	Patil, B. S., 2025, Study no. 237-2-11-35151 (UPL/2023/1625)	The product was found to be stable after one year storage at ambient temperature (stored in a HDPE/EVOH-COEX container) (temperature ranging from 17.8 °C to 23.3 °C for a period of 12 months). Azoxystrobin (Method = UPL/2023/1623 - please refer Section B5) Pre-storage content: 14.48% w/w or 162.61 g/L After 1 year storage content: 14.45% w/w or 162.27 g/L Difference: -0.34 g/L (<1% difference) Prothioconazole (Method = UPL/2023/1623 please refer Section B5) Pre-storage content: 17.80% w/w or 199.83 g/L After 1 year storage content: 17.74% w/w or 199.18 g/L Difference: -0.65 g/L (<1 % difference).	Yes	Patil, B. S., 2025, Study no. 237-2-11-35151 (UPL/2023/1625)	Accepted. The product showed no significant physical changes after one year of storage. No significant changes were observed in the packaging and therefore it can be concluded that the test item was not corrosive to the container material. The stability data

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			The levels of the relevant impurities associated with Azoxystrobin and Prothioconazole were also analysed before and after storage; no significant changes were noted: <u>Toluene (Method = UPL/2023/1629 please refer Section B5)</u> Pre-storage content: 0.02331 %w/w After 1 year storage content: 0.02357%w/w <u>Azoxystrobin Z-isomer (Method = UPL/2023/11628 please refer Section B5)</u> Pre-storage content: 0.00377 %w/w After 1 year storage content: 0.00366% w/w <u>Prothioconazole-desthio (Method = UPL/2023/1630 please refer Section B5)</u> Pre-storage content: 0.00354 %w/w After 1 year storage content: 0.00323%w/w The product appearance did not change following storage. The integrity of the product packaging was maintained over the storage period (i.e. there were no observations of distortion, perforation, or leaking following the storage period). <u>Packaging Inspection:</u> Pre-storage: No perforation, no rusting at the seam, no leaking at the seam and no distortion of the bottle. After 1 year storage: No perforation, no rusting at the seam, no leaking at the seam and no distortion of the bottle. The technical properties did not significantly change during the storage period. <u>Appearance:</u> Pre-storage: Light brown liquid (suspension), with characteristic odour.			indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging HDPE/EVOH (COEX) container.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			After 1 year storage: Light brown liquid (suspension), with characteristic odour. <u>pH:</u> Pre-storage: 6.78 (1.0% w/v, 19.4 °C). After 1 year storage: 6.62 (1.0% w/v, 20.1 °C); 7.23 (undiluted, 20.6 °C). <u>Persistent foam:</u> Pre-storage: - Minimum in-use concentration (0.25 %v/v) After 1 Minute ± 10 Seconds (mL): 0 - Maximum in-use concentration (1 %v/v) After 1 Minute ± 10 Seconds (mL): 0 After 1 year storage: - Minimum in-use concentration (0.25 %v/v) After 1 Minute ± 10 Seconds (mL): 0 - Maximum in-use concentration (1 %v/v) After 1 Minute ± 10 Seconds (mL): 0 <u>Wet sieve test:</u> Pre-storage: No residue of test item retained on the 75 µm test sieve within 10 minutes of washing time. After 1 year storage: No residue of test item retained on the 75 µm test sieve within 10 minutes of washing time. <u>Suspensibility:</u> Pre-storage (23.9 to 24.2 °C): Minimum in-use concentration (0.25 %v/v) Azoxystrobin – suspensibility (%w/w): 97.30 Prothioconazole – suspensibility (%w/w): 96.67 Maximum in-use concentration (1%v/v) Azoxystrobin – suspensibility (%w/w): 97.48 Prothioconazole – suspensibility (%w/w): 96.90 After 1 year storage (25.2 to 26.1 °C): Minimum in-use concentration (0.25 %v/v) Azoxystrobin – suspensibility (%w/w): 97.52 Prothioconazole – suspensibility (%w/w): 96.75			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			Maximum in-use concentration (1%v/v) Azoxystrobin – suspensibility (%w/w): 98.52 Prothioconazole – suspensibility (%w/w): 98.01 <u>Pourability:</u> Pre-storage: Poured residue (%): 4.67 Rinsed residue (%): 0.20 After 1 year storage: Poured residue (%): 4.68 Rinsed residue (%): 0.22 <u>Spontaneity of dispersion:</u> Pre-storage (24.1 to 24.2 °C): Azoxystrobin – dispersion (%w/w): 94.65 Prothioconazole – dispersion (%w/w): 94.43 After 1 year storage (25.9 to 26.2 °C): Azoxystrobin – dispersion (%w/w): 97.68 Prothioconazole – dispersion (%w/w): 97.69 <u>Particle size distribution:</u> Pre-storage: d[0.1(10%)] = 0.65 d[0.5(50%)] = 2.32 d[0.9(90%)] = 6.96 After 1 year storage: d[0.1(10%)] = 0.75 d[0.5(50%)] = 2.09 d[0.9(90%)] = 6.19			
Wettability (KCP 2.8.1)	-	-	Waiver: Not applicable for SC (suspension concentrate) formulations according to SANCO/10473/2003 Revision 5.	-	-	-
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3 (using standard water D, prepared as per CIPAC MT 18.1.4)	FGF11, Batch No. ARD/AP/360/SC/36 ^a	<u>Pre-accelerated storage</u> Minimum in-use concentration (0.25 %v/v) Initial (mL): 19.2 After 1 Minute ± 10 Seconds (mL): 0 After 12 Minute ± 10 Seconds (mL): 0	Yes	Patil, B., 2024 Study no. 234-2-11-35150	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			Maximum in-use concentration (1 %v/v) Initial (mL): 30.0 After 1 Minute ± 10 Seconds (mL): 0 After 12 Minute ± 10 Seconds (mL): 0 <u>Post-accelerated storage</u> Minimum in-use concentration (0.25 %v/v) Initial (mL): 19.1 After 1 Minute ± 10 Seconds (mL): 0 After 12 Minute ± 10 Seconds (mL): 0 Maximum in-use concentration (1 %v/v) Initial (mL): 30.1 After 1 Minute ± 10 Seconds (mL): 0 After 12 Minute ± 10 Seconds (mL): 0			
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184.1 (using standard water D, prepared as per CIPAC MT 18.1.4)	FGF11, Batch No. ARD/AP/360/SC/36 ^a	<u>Pre-accelerated storage</u> Minimum in-use concentration (0.25 %v/v) Azoxystrobin – suspensibility (%w/w): 97.30 Prothioconazole – suspensibility (%w/w): 96.67 Maximum in-use concentration (1%v/v) Azoxystrobin – suspensibility (%w/w): 97.48 Prothioconazole – suspensibility (%w/w): 96.90 <u>Post-accelerated storage</u> Minimum in-use concentration (0.25 %v/v) Azoxystrobin – suspensibility (%w/w): 97.22 Prothioconazole – suspensibility (%w/w): 96.74 Maximum in-use concentration (1 %v/v) Azoxystrobin – suspensibility (%w/w): 97.59 Prothioconazole – suspensibility (%w/w): 97.07	Yes	Patil, B., 2024 Study no. 234-2-11-35150	Accepted.
Spontaneity of dispersion	CIPAC MT 160	FGF11, Batch No.	<u>Pre-accelerated storage</u>	Yes	Patil, B., 2024	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.3.2)	(using standard water D, prepared as per CIPAC MT 18.1.4)	ARD/AP/360/SC/36 ^a	Azoxystrobin – dispersion (%w/w): 94.65 Prothioconazole – dispersion (%w/w): 94.43 <u>Post-accelerated storage</u> Azoxystrobin – dispersion (%w/w): 94.48 Prothioconazole – dispersion (%w/w): 94.36		Study no. 234-2-11-35150	
Dispersion stability (KCP 2.8.3.3)	-	-	Waiver: Not applicable for SC (suspension concentrate) formulations according to SANCO/10473/2003 Revision 5.	-	-	-
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Waiver: Not applicable for SC (suspension concentrate) formulations according to SANCO/10473/2003 Revision 5.	-	-	-
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187	FGF11, Batch No. ARD/AP/360/SC/36 ^a	<u>Pre-accelerated storage</u> d[0.1(10%)] = 0.65 d[0.5(50%)] = 2.32 d[0.9(90%)] = 6.96 <u>Post-accelerated storage</u> d[0.1(10%)] = 0.64 d[0.5(50%)] = 2.32 d[0.9(90%)] = 7.12		Patil, B., 2024 Study no. 234-2-11-35150	Accepted.
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185 (using standard water D, prepared as per CIPAC MT 18.1.4)	FGF11, Batch No. ARD/AP/360/SC/36 ^a	<u>Pre-accelerated storage</u> No residue of test item retained on the 75 µm test sieve within 10 minutes of washing time. <u>Post-accelerated storage</u> No residue of test item retained on the 75 µm test sieve within 10 minutes of washing time.	Yes	Patil, B., 2024 Study no. 234-2-11-35150	Accepted.
Dust content (KCP 2.8.5.2.1)	-	-	Waiver: Not applicable for SC (suspension concentrate) formulations according to SANCO/10473/2003 Revision 5.	-	-	-
Particle size of dust (KCP 2.8.5.2.2)	-	-	Waiver: Not applicable for SC (suspension concentrate) formulations according to SANCO/10473/2003 Revision 5.	-	-	-
Attrition (KCP 2.8.5.3)	-	-	Waiver: Not applicable for SC (suspension concentrate) formulations according to SANCO/10473/2003 Revision 5.	-	-	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			5.			
Hardness and integrity (KCP 2.8.5.4)	-	-	Waiver: Not applicable for SC (suspension concentrate) formulations according to SANCO/10473/2003 Revision 5.	-	-	-
Emulsifiability (KCP 2.8.6.1)	-	-	Waiver: Not applicable for SC (suspension concentrate) formulations according to SANCO/10473/2003 Revision 5.	-	-	-
Emulsion stability (KCP 2.8.6.2)	-	-	Waiver: Not applicable for SC (suspension concentrate) formulations according to SANCO/10473/2003 Revision 5.	-	-	-
Re-emulsifiability (KCP 2.8.6.3)	-	-	Waiver: Not applicable for SC (suspension concentrate) formulations according to SANCO/10473/2003 Revision 5.	-	-	-
Flowability (KCP 2.8.7.1)	-	-	Waiver: Not applicable for SC (suspension concentrate) formulations according to SANCO/10473/2003 Revision 5.	-	-	-
Pourability (KCP 2.8.7.2)	CIPAC MT 148	FGF11, Batch No. ARD/AP/360/SC/36 ^a	<u>Pre-accelerated storage</u> Poured residue (%): 4.67 Rinsed residue (%): 0.20 <u>Post-accelerated storage</u> Poured residue (%): 4.68 Rinsed residue (%): 0.21	Yes	Patil, B., 2024 Study no. 234-2-11-35150	Accepted.
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Waiver: Not applicable for SC (suspension concentrate) formulations according to SANCO/10473/2003 Revision 5.	-	-	-
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	No data generated. No positive tank mix claims are indicated on the product label.	-	-	No data generated.
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	No data generated. No positive tank mix claims are indicated on the product label.	-	-	No data generated.
Adhesion to seeds (KCP 2.10.1)	-	-	Waiver: Not applicable for SC (suspension concentrate) formulations according to SANCO/10473/2003 Revision	-	-	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			5.			
Distribution to seed (KCP 2.10.2)	-	-	Waiver: Not applicable for SC (suspension concentrate) formulations according to SANCO/10473/2003 Revision 5.	-	-	-
Other/special studies (KCP 2.11)	-	-	No additional studies have been generated.	-	-	-

- Batch No. ARD/AP/360/SC/36 of the formulated product (FGF11) was used to generate the physical-chemical properties data. According to the GLP certificate of analysis, this product batch contains 162.20 g/L (14.45 %w/w) Azoxystrobin and 200.54 g/L (17.86 %w/w) Prothioconazole. These active substance levels comply with the standard FAO tolerances (see section 1.4.1).
- a
- b According to the intended GAP for the product FGF11, the following range of in-use concentrations (per application) apply:
Minimum in-use concentration: 1 L/ha, with 400 L water per ha = 0.25 %v/v
Maximum in-use concentration: 1 L/ha, with 100 L water per ha = 1 %v/v

Table 2-2: The results of the Accelerated Storage Stability; CRD 2.7.1, SANCO/10473/2003 – rev.5, OECD 113, OCSPP 830.6317, 830.6320 and, Method: CIPAC MT 46.4

S. N°	Characteristics		Results	
			Before Storage (0 - Day)	After Storage at 45 ± 2 °C for 42 days
1	Packaging Inspection (COEX Bottle)	Perforation	No	No
		Rusting at the seam	No	No
		Leaking at the seam	No	No
		Distortion	No	No
2	Appearance of the container (visual)	Shape	Cylindrical	Cylindrical
		Colour	White bottle with green cap	White bottle with green cap
		Crack	No	No

S. N°	Characteristics		Results					
			Before Storage (0 - Day)			After Storage at 45 ± 2 °C for 42 Days		
3	Appearance	Colour	Light brown			Light brown		
		Physical State	Liquid (Suspension)			Liquid (Suspension)		
		Odour	Characteristic			Characteristic		
4	pH [1% (w/v) aqueous solution]	After 1 Minute	6.78 at 19.4 °C			6.68 at 20.0 °C		
		After 2 Minutes	6.76 at 19.4 °C			6.66 at 20.1 °C		
5	Active Ingredients Content	Azoxystrobin	14.48% w/w or 162.61 g/L			14.51% w/w or 162.86 g/L		
		The % variation of active ingredient (Azoxystrobin) content a 45 ± 2 °C after a period of 42 days is 0.21						
		Prothioconazole	17.80% w/w or 199.83 g/L			17.95% w/w or 201.49 g/L		
6	Persistent Foam	Doses	Initial Volume of Foam (mL)	Volume (mL) of Foam Recorded After		Initial Volume of Foam (mL)	Volume (mL) of Foam Recorded After	
				1 Minute ± 10 Seconds	12 Minute ± 10 Seconds		1 Minute ± 10 Seconds	12 Minute ± 10 Seconds
				Minimum Dose	19.2		0.0	0.0
		Maximum Dose	30.0	0.0	0.0	30.1	0.0	0.0
		Wet Sieve Test		No residue of test item retained on the 75 µm test sieve within 10 minutes of washing time.			No residue of test item retained on the 75 µm test sieve within 10 minutes of washing time.	
8	Suspensibility (% w/w)	Minimum Dose	Azoxystrobin	Prothioconazole	Azoxystrobin	Prothioconazole		
		Maximum Dose	97.30	96.67	97.22	96.74		
9	Pourability	Residue (%)	4.67			4.68		
		Rinsed Residue (%)	0.20			0.21		
10	Spontaneity of Dispersion (% w/w)	Azoxystrobin	94.65			94.48		
		Prothioconazole	94.43			94.36		
11	Particle Size Distribution	d[0.1(10%)]	0.65			0.64		
		d[0.5(50%)]	2.32			2.32		
		d[0.9(90%)]	6.96			7.12		
12	Impurities Content (% w/w)	Z-isomer of Azoxystrobin	0.00377			0.00375		
		Toluene	0.02331			0.02339		
		Prothioconazole-Desthio	0.00354			0.00349		

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 2 years shelf-life study is on-going. The accelerated data and after one year of storage indicate of a shelf life of at least 2 years at ambient temperature when stored in commercial packaging HDPE/EVOH (Coex). For aqueous based formulation types e.g. SL, SC, LS, CS or FS, extrapolation between any plastic material types is acceptable. Extrapolation from plastic material to metals is not acceptable. Extrapolation between HDPE/EVOH, HDPE/F and HDPE/PA is acceptable.
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The intended specifications for the product packaging are included within this section (below). The accelerated storage stability test (KCP 2.7.2) was undertaken with the product (FGF11) stored within HDPE/EVOH bottles – no observations of adverse changes to the integrity of the product packaging were noted following the storage stability test. As indicated within SANCO/10473/2003 revision.5 guideline: “For aqueous based formulation types e.g. SL, SC, LS, CS or FS, extrapolation between any plastic material types is acceptable”; therefore the following range of container types are considered to be supported by the available data.

The formulated product (SC formulation) is intended for containment in co-extruded high density polyethylene including PA layer (HDPE/PA) or ethylene vinyl alcohol layer (EVOH) bottles/cans fitted with screw caps. HDPE-F (fluorinated) bottles / cans are also intended for containment of the product.

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

Type	Description
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
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 4-2-8: 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)
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

Type	Description
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
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 4-3-15: 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

Type	Description
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:	Information on the effectiveness of the cleaning procedure below is sufficient.
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The efficacy of cleaning application equipment was estimated according to the recommendations of the PSD Efficacy Guidelines 305 and 302 (Patil, B., 2024, Study no. 284-2-11-35133).

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 FGF11 do not remain in the spray tank after cleaning. The test was run in triplicate and the results averaged.

GLP: Yes

Test item

FGF11 (Batch No. ARD/AP/360/SC/36)

Test sample preparation

Standard water D (prepared according to CIPAC MT 18.1.4), 300 mL, was placed into a 500 mL beaker and stirred. A volume of 3 mL of test item was added and stirred for two minutes. After stirring, 100 mL aliquots were poured into 3 polyethylene bottles of 125 mL which were capped and allowed to stand at room temperature for 24 hours.

Single rinse procedure

A volume of 10 mL tap water was added, and the bottle was inverted twice. The rinsate was discarded.

Double rinse procedure

The rinse procedure as described for the ‘Single rinse procedure’ was performed twice.

Triple rinse procedure

The rinse procedure as described for the ‘Single rinse procedure’ was performed three times.

After discarding the rinsate, a volume of 10 mL diluent was added to each of the bottles and the bottles were shaken so as to coat all surfaces to extract residual pesticide from the bottle surfaces and the sample

was diluted as mentioned below and diluted samples so obtained from all the bottles were analysed by HPLC for determination of the active substance (a.s.) concentration.

Results

Test	Active substance	Rinsing	% Removed
Effectiveness of Cleaning Procedures (Rinsing / % Active Substance Removed from Bottle)	Azoxystrobin	Single	81.44 ± 0.03
		Double	96.40 ± 0.01
		Triple	99.82 ± 0.00
	Prothioconazole	Single	76.44 ± 0.08
		Double	93.71 ± 0.03
		Triple	99.69 ± 0.00

Based on the results of the study, the active substances removed from the bottles were at least 99% of the initially added amount, after triple rinsing (using only water).

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 2.2.2	Patil, B.	2024	Title – Oxidizing properties of Azoxystrobin 160 + Prothioconazole 200 g/L SC JRF, Study Report No 230-2-11-35140 GLP Unpublished	No	UPL
KCP 2.3.1	Patil, B.	2024	Title – Flash point of Azoxystrobin 160 + Prothioconazole 200 g/L SC JRF, Study Report No 221-2-11-35148 GLP Unpublished	No	UPL
KCP 2.3.3	Patil, B.	2024	Title – Autoflammability of Azoxystrobin 160 + Prothioconazole 200 g/L SC JRF, Study Report No 241-2-11-35141 GLP Unpublished	No	UPL
KCP 2.4.1	Patil, B.	2024	Title – Acidity & alkalinity of Azoxystrobin 160 + Prothioconazole 200 g/L SC JRF, Study Report No 220-2-11-35147 GLP Unpublished	No	UPL
KCP 2.4.1	Prajapati, P.N.	2025	Title – pH of Azoxystrobin 160 + Prothioconazole 200 g/L SC Study Report No 210-2-11-39423 GLP Unpublished	No	UPL
KCP 2.4.2	Patil, B.	2024	Title – pH of Azoxystrobin 160 + Prothioconazole 200 g/L SC JRF, Study Report No 210-2-11-35142 GLP Unpublished	No	UPL
KCP 2.5.1	Patil, B.	2024	Title – Viscosity of Azoxystrobin 160 + Prothioconazole 200 g/L SC JRF, Study Report No 214-2-11-35135 GLP Unpublished	No	UPL
KCP 2.5.2	Patil, B.	2024	Title – Surface tension of Azoxystrobin 160 + Prothioconazole 200 g/L SC JRF, Study Report No 222-2-11-35139	No	UPL

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
			GLP Unpublished		
KCP 2.6.1	Patil, B.	2024	Title – Density of Azoxystrobin 160 + Prothioconazole 200 g/L SC JRF, Study Report No 204-2-11-35144 GLP Unpublished	No	UPL
KCP 2.7.2 (also covers annex points KCP 2.1, 2.8.2, 2.8.3.1, 2.8.3.2, 2.8.5.1.1, 2.8.5.1.2, 2.8.7.2)	Patil, B.	2024	Title – Accelerated storage stability and corrosion characteristics of Azoxystrobin 160 + Prothioconazole 200 g/L SC JRF, Study Report No 234-2-11-35150 GLP Unpublished	No	UPL
KCP 2.7.4	Patil, B.	2024	Title - Storage stability of Azoxystrobin 160 + Prothioconazole 200 g/L SC at low temperature JRF, Study Report No 211-2-11-35157 GLP Unpublished	No	UPL
KCP 2.7.4	Prajapati, P.N.	2025	Title - Storage stability of Azoxystrobin 160 + Prothioconazole 200 g/L SC at low temperature Company Report No UPL/2025/0048 GLP Unpublished	No	UPL
KCP 2.7.6	Patil, B.	2025	Title – One year storage stability and corrosion characteristics study of Azoxystrobin 160 + Prothioconazole 200 g/L SC Company Report No UPL/2023/1625 GLP Unpublished	No	UPL
KCP 4.2.2	Patil, B.	2024	Title – Effectiveness of cleaning procedures of Azoxystrobin 160 + Prothioconazole 200 g/L SC JRF, Study Report No 284-2-11-35133 GLP Unpublished	No	UPL

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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 Active substance 1: Azoxystrobin

No additional data submitted.

A 2.2 Active substance 2: Prothioconazole

No additional data submitted.