

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: CA3642

Product name(s): JOUST PRO

Chemical active substance:

Prothioconazole, 150 g/L

Azoxystrobin, 150 g/L

Central Zone

Zonal Rapporteur Member State: PL

CORE ASSESSMENT

New Authorisation (Art.33)

Sponsor: Nufarm Crop Products UK Limited

Applicant: Nufarm Polska Sp. z o. o.

Submission date: 23/02/2023, updated March 2024,
September 2024

MS Finalisation date: May 2024 (initial Core Assessment), updated
October 2024

December 2024, update June 2025 (final Core Assessment)

Version history

When	What
February 2023	First submission – applicant version
October 2023	<p>Initial assessment by the zRMS</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>
March 2024	Correction of the packaging material - all changes are highlighted in green – version updated by the applicant.
May 2024	<p>Initial assessment by the zRMS - version updated</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> <p>Following the evaluation and before sending the document for commenting, all coloured highlighting was removed, from the parts updated by the Applicant, for better legibility.</p>
October 2024	<p>Core Assessment updated following the commenting period and new data received from Applicant</p> <p>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.</p>
December 2024	<p>Final report (Core Assessment updated following the second commenting period)</p> <p>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.</p>
June 2025	Information about “data gap” has been removed from the page 4 of the registration report. Not agreed or not relevant information are struck through and shaded for transparency.

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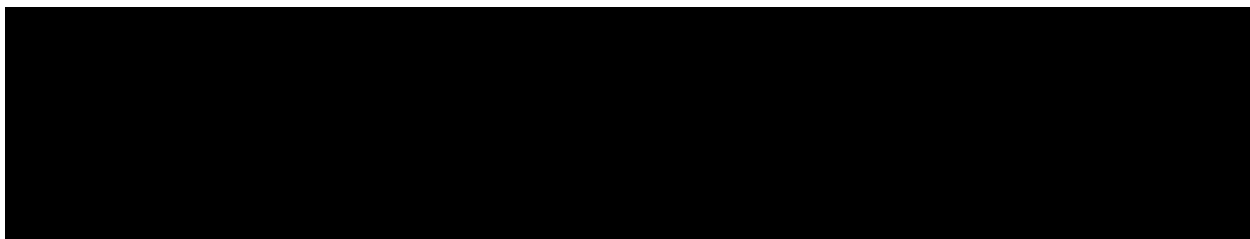
Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substance(s).

~~Noticed data gaps are:~~

~~— Ambient temperature study is currently ongoing, and should be provided upon completion.~~

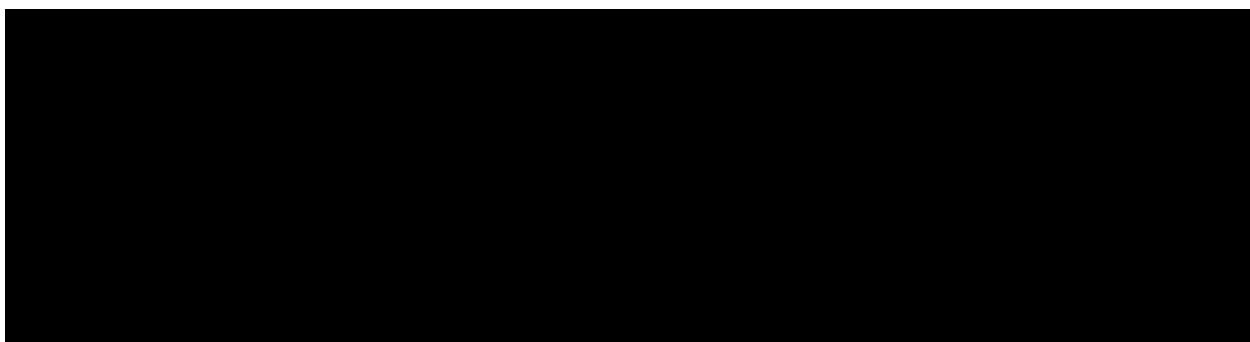
1 Section 1: Identity of the plant protection product

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



1.2.2 Producers of the active substances

1.2.2.1 Producers of the active substance prothioconazole

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

1.2.2.2 Producers of the active substance azoxystrobin

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

According to Commission Implementing Regulation (EU) No 540/2011, the minimum purity for prothioconazole and maximum impurity level of toluene and prothioconazole-desthio is:

Prothioconazole	min. 970 g/kg
Toluene	max. 5 g/kg in the technical material
Prothioconazole-desthio	max. 0.5 g/kg in the technical material

For the Nufarm source (source 1), the min purity of the active substance is 97.0 % w/w (970 g/kg).

For the Hailir Pesticides and Chemicals Group Co. source (source 2), Ciech Sarzyna S.A. source (source 3) and Anhui JiuYi Agriculture Co., Ltd. source (source 4) the min purity of the active substance is 98.0% w/w (980 g/kg).

1.2.3.2 Azoxystrobin

According to Commission Implementing Regulation (EU) No 540/2011, the minimum purity for azoxystrobin and maximum impurity level of toluene and Z-isomer is:

Azoxystrobin	min. 930 g/kg
Toluene	max. 2 g/kg in the technical material
Z-Isomer	max. 25 g/kg in the technical material

For the Nufarm source (source 1), the min purity of the active substance is 97.8 % w/w (978 g/kg).

For the CAC Nantong Chemical Co., Ltd source (source 2), the min purity of the active substance is 97.5% w/w (975 g/kg).

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

Trade name: JOUST PRO
Company code number: CA3642

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)
Prothioconazole	150 g/L	141-159 g/L	154.6 g/L	14.05
Azoxystrobin	150 g/L	141-159 g/L	161.3 g/L	14.66

* Based on the official minimum purity, 970 g/kg for Prothioconazole and 930 g/kg for Azoxystrobin, as stated in Commission Implementing Regulation (EU) No 540/2011

** Based on the nominal density of the formulation = 1.1004 g/mL (see details in Section B2 below)

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content*		
	g/L	g/Kg	%w/w
Toluene**	1.096	1.00	0.10
Prothioconazole-desthio	0.077	0.07	0.007
Azoxystrobin-Z-isomer	4.033	3.67	0.367

* Based on the maximum permitted content according to Reg. (EU) No 540/2011

** Based on the maximum permitted content of toluene considering both actives, according to Reg. (EU) No 540/2011

For detailed composition, refer to confidential part C.

1.4.2 Information on the active substances (KCP 1.4.2)

Table 1.4-2: Information on active substance: Prothioconazole

Type	Name/Code Number
ISO common name	prothioconazole
IUPAC name	(RS)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)- 2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3- thione

Type	Name/Code Number
CAS No.	178928-70-6
EC No.	605-841-2
CIPAC No.	745

Table 1.4-3: Information on active substance: Azoxystrobin

Type	Name/Code Number
ISO common name	azoxystrobin
IUPAC name	methyl (E)-2-{2[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate
CAS No.	131860-33-8
EC No.	603-524-3
CIPAC No.	571

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

The product does not contain any safener nor synergist.

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

Type: Suspension concentrates

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 off-white, weak pungent liquid. Based on the constituents of the formulation, it has no explosive or oxidising properties. The product is not flammable and has a self-ignition temperature of over 400 °C. It has a pH value approximately 6.2 in a 1 % aqueous solution. 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 in HDPE containers, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature (determined from accelerated storage). Data from an on-going GLP ambient stability study will be used to support the 2 years minimum shelf life. Its technical characteristics are acceptable for a suspension concentrate formulation. The intended concentration of use is 0.24% v/v to 1.4% v/v. The product is not intended to be used in tank mixtures.

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

CLP Hazard category	Data - Justification	Classification
Explosive properties	Based on the constituents of the formulation, the product is not classified for explosive properties. Refer to KCP 2.2 for further details.	No
Flammable gases	Not applicable as the product is a liquid (SC).	No
Aerosol	Not applicable as the product is a liquid not conditioned as aerosol (SC).	No
Oxidising gases	Not applicable as the product is a liquid (SC).	No
Gases under pressure	Not applicable as the product is a liquid (SC).	No
Flammable liquids (Flash point)	Based on experimental results, the product is not classified for flammability. Refer to KCP 2.2 for further details.	No
Flammable solid	Not applicable as the product is a liquid (SC).	No
Self-reactive mixture	The classification procedure for self-reactive mixtures need not be applied to the product as there are no chemical groups present in the substances contained in the product associated with explosive or self-reactive properties (given in Tables A6.1 and A6.3 in Appendix 6 of the UN RTDG, Manual of Tests and Criteria). Refer to part CP 1.4.3 in this document for details on substances contained in the product.	No
Pyrophoric liquid	Experience with the product in manufacturing, handling and tests shows that the product does not ignite spontaneously on coming into contact with air at normal temperatures (the product is stable at room temperature for prolonged periods of time (days)),	No
Pyrophoric solid	Not applicable as the product is a liquid (SC).	No
Self-heating substance	During experimental test (EC A.15), no self-heating properties were observed. Thus, the product is not classified for self-heating. Refer to KCP 2.3 for further details.	No
Substances and mixtures which in contact with water emit flammable gases	Testing can be waived based on a consideration of the structure (the chemical structures of the substances contained in the product do not contain metals or metalloids). Additionally, experience in production or handling shows that the mixture does not react with water (presence of water in the formulation). Therefore, the product is not classified for this hazard. Refer to part CP 1.4.3 for details on substances contained in the product.	No
Oxidising liquid	Considering the absence of substances presenting oxidising properties, oxidising properties test should not be considered necessary. Refer to KCP 2.2 for further details.	No
Oxidising solid	Not applicable as the product is a liquid (SC).	No
Organic peroxide	The product does not contain any substances with peroxide chemical group. Therefore, the product is not classified for this hazard. Refer to part C for details on substances contained in the product.	No
Corrosive to metal	The product is not packaged into metal containers. Therefore, this hazard category is not relevant for the product.	No

Refer to confidential part C (KCP 12) for further details on classification using conventional calculation method.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

According to Regulation (EC) No. 1272/2008 no specific labelling or classification is proposed based on the measured physico-chemical properties of product JOUST PRO (CA3642)..

Compliance with FAO specifications:

There is no FAO specification for Prothioconazole.

FAO specifications exist for Azoxystrobin technical: in SC formulations FAO 571/SC (January 2022).
FAO specifications are only applicable to single active substances, consequently, as CA3642 contains a mixture of active substances, there is no directly applicable FAO specification, according to the Manual on development and use of FAO and WHO specifications for pesticides (Second edition, 2022).

Formulation used for tests

The product on which the physicochemical testing has been performed has the same composition as that declared in Part C.

Table 2-1.6-1: 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)	OCSPP 830.6302 (Color) OCSPP 830.6303 (Physical state) OCSPP 830.6304 (Odor)	Prothioconazole 150 g/L + Azoxystrobin 150 g/L SC, CA3642 (batch A20026, purity 154.83 g/L for Azoxystrobin, 152.30 g/L for prothioconazole)	Initial measurements/Before storage: Off-white liquid with weak pungent odor After 14 days of storage at 54°C ± 2°C: Off-white liquid with weak pungent odor After 7 days of storage at 0°C ± 2°C: Off-white liquid with weak pungent odor	Y	KCP 2.1/01 Wang, Q., 2022 Report no.: ABC-2021-019	Accepted.
Explosive properties (KCP 2.2.1)	Statement based on UNRTDG Manual of Tests and Criteria	-	Considering the absence of substances presenting explosive properties in the product, an explosive properties test should not be considered as necessary.	Y	KCP 2.2.1/01 Fitzmaurice T, 2022, Report no. DNA6888	Accepted. JOUST PRO is not explosive. 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)	Statement based on UNRTDG Manual of Tests and Criteria	-	Considering the absence of substances presenting oxidising properties in the product, an oxidising properties test should not be considered as necessary.	Y	KCP 2.2.1/01 Fitzmaurice T, 2022, Report no. DNA6888	Accepted. JOUST PRO has no oxidizing properties. 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; EEC A.9 (Pensky-Martens closed cup)	Prothioconazole 150 g/L + Azoxystrobin 150 g/L SC, CA3642	The flash point of the test item at Standard Air Pressure is > 103.5°C	Y	KCP 2.1/01 Wang, Q., 2022 Report no.: ABC-	Accepted. The formulation is not flammable.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		(batch A20026, purity 154.83 g/L for Azoxystrobin, 152.30 g/L for prothioconazole)			2021-019	The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.
Flammability (KCP 2.3.2)	Not required – CA3642 is not a solid preparation or a gas.					-
Self-heating (KCP 2.3.3)	EEC A.15	Prothioconazole 150 g/L + Azoxystrobin 150 g/L SC, CA3642 (batch A20026, purity 154.83 g/L for Azoxystrobin, 152.30 g/L for prothioconazole)	Test item did not ignite below 400°C.	Y	KCP 2.2.1/01 Fitzmaurice T, 2022, Report no. DNA6888	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)	EPA OCSPP 830.7000, OECD 122	Prothioconazole 150 g/L + Azoxystrobin 150 g/L SC, CA3642 (batch A20026, purity 154.83 g/L for Azoxystrobin, 152.30 g/L for prothioconazole)	Initial measurements/Before storage: pH = 6.23 at 20.1°C (1% aqueous dilution). The pH value is in the range from 4 to 10, therefore the acidity or alkalinity test is not necessary. After 14 days of storage at 54°C ± 2°C: pH = 6.19 at 20.1°C (1% aqueous dilution). The pH value is in the range from 4 to 10, therefore the acidity or alkalinity test is not necessary.	Y	KCP 2.1/01 Wang, Q., 2022 Report no.: ABC-2021-019	Accepted.
	EPA OCSPP 830.7000, CIPAC MT 75.3	Prothioconazole 150 g/L + Azoxystrobin 150 g/L SC, CA3642 (batch FRAI008392, purity 148 g/L for Azoxystrobin, 151 g/L for prothioconazole)	Initial measurements/Before storage: pH = 6.56 (undiluted) at 25.2°C After 14 days of storage at 54°C ± 2°C: pH = 6.22 (undiluted) at 25.8°C	Y	KCP 2.4.2/01 Wang, Q., 2023, Report n° ABC-2023-007	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	EPA OCSPP 830.7000, OECD 122; CIPAC MT 75.3	Prothioconazole 150 g/L + Azoxystrobin 150 g/L SC, CA3642 (batch A20026, purity 154.83 g/L for Azoxystrobin, 152.30 g/L for prothioconazole)	Initial measurements/Before storage: pH = 6.23 at 20.1°C (1% w/v in water) After 14 days of storage at 54°C ± 2°C: pH = 6.19 at 20.1°C (1% w/v in water)	Y	KCP 2.1/01 Wang, Q., 2022 Report no.: ABC-2021-019	Accepted.
	EPA OCSPP 830.7000, OECD 122; CIPAC MT 75.3	Prothioconazole 150 g/L + Azoxystrobin 150 g/L SC, CA3642 (batch A20026, purity 154.83 g/L for Azoxystrobin, 152.30 g/L for prothioconazole)	Initial measurements/Before storage: pH = 6.23 at 20.1°C (1% w/v in water) After 12 months of storage at 20°C ± 2°C: pH = 5.86 at 25.2°C (1% w/v in water) After 18 months of storage at 20°C ± 2°C: pH = 6.20 at 25.0°C (1% w/v in water) After 24 months of storage at 20°C ± 2°C: pH = 5.81 at 25.1°C (1% w/v in water)	Y	KCP 2.7.5/01 Wang, Q., 2024 Report no.: ABC-2021-020	Accepted.
Viscosity (KCP 2.5.1)	EPA OCSPP 830.7100, OECD 114 Rotational viscometer	Prothioconazole 150 g/L + Azoxystrobin 150 g/L SC, CA3642 (batch A20026, purity 154.83 g/L for Azoxystrobin, 152.30 g/L for prothioconazole)	<u>Dynamic viscosity</u> At 20.0 ± 0.2°C: Rotor speed, 3 r/min: 21.21 Pa.s Rotor speed, 1.5 r/min: 29.46 Pa.s At 40.0 ± 0.5°C: Rotor speed, 3 r/min: 18.99 Pa.s Rotor speed, 1.5 r/min: 23.44 Pa.s <u>Kinematic viscosity</u> At 20.0 ± 0.2°C: Rotor speed, 3 r/min: v = 0.0193 m²/s Rotor speed, 1.5 r/min: v = 0.0268 m²/s At 40.0 ± 0.5°C: Rotor speed, 3 r/min: v = 0.0173 m²/s Rotor speed, 1.5 r/min: v = 0.0213 m²/s The test item is a non-Newtonian liquid.	Y	KCP 2.1/01 Wang, Q., 2022 Report no.: ABC-2021-019	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments												
Surface tension (KCP 2.5.2)	OECD 115, EEC A.5 Ring method	Prothioconazole 150 g/L + Azoxystrobin 150 g/L SC, CA3642 (batch A20026, purity 154.83 g/L for Azoxystrobin, 152.30 g/L for prothioconazole)	The result of surface tension value for a 1.4% v/v (2.1 g/L) test item solution is 37.158 mN/m at 20.0°C ± 0.5°C. The diluted test item is surface active (< 60 mN/m).	Y	KCP 2.1/01 Wang, Q., 2022 Report no.: ABC-2021-019	Accepted.												
Relative density (KCP 2.6.1)	EPA OCSPP 830.7300, OECD 109, EEC A.3 Pycnometer method	Prothioconazole 150 g/L + Azoxystrobin 150 g/L SC, CA3642 (batch A20026, purity 154.83 g/L for Azoxystrobin, 152.30 g/L for prothioconazole)	Initial measurements/Before storage: The density of the test item at 20 ± 0.5°C is 1.1004 g/mL.	Y	KCP 2.1/01 Wang, Q., 2022 Report no.: ABC-2021-019	Accepted.												
Bulk density (KCP 2.6.2)	Not applicable, the test item is a suspension concentrate (SC).					-												
Storage Stability after 14 days at 54° C (KCP 2.7.1)	EPA OCSPP 830.6317, 830.6320 OECD 113, CIPAC MT 46.3 Analytical method ABCTM-2021-018-02 validated in study reference KCP 5.1.1/01	Prothioconazole 150 g/L + Azoxystrobin 150 g/L SC, CA3642 (batch A20026, purity 154.83 g/L for Azoxystrobin, 152.30 g/L for prothioconazole) HDPE bottles	Sample is stable after storage at 54°C ± 2°C for 14 days. The test item was considered to be stable after storage for 14 days at 54°C in polyethylene plastic bottle with regards to: - packaging weight - active substance content - impurities content - packaging stability/corrosion - pH (refer to KCP 2.4.1 and 2.4.2) - foam persistence (refer to KCP 2.8.2) - viscosity (refer to KCP 2.5.1) - emulsion stability (refer to KCP 2.8.6) <table><tr><td></td><td>Before storage</td><td>After 14 days at 54°C</td></tr><tr><td>Appearance of polyethylene plastic bottle</td><td colspan="2">No visual change was observed. No corrosion of the bottle occurred.</td></tr><tr><td>Weight of polyethylene plastic bottle</td><td>84.31 g</td><td>84.30 g</td></tr><tr><td>Appearance of test item</td><td>Off-white liquid, weak pungent odor</td><td>Off-white liquid, weak pungent odor</td></tr></table>		Before storage	After 14 days at 54°C	Appearance of polyethylene plastic bottle	No visual change was observed. No corrosion of the bottle occurred.		Weight of polyethylene plastic bottle	84.31 g	84.30 g	Appearance of test item	Off-white liquid, weak pungent odor	Off-white liquid, weak pungent odor	Y	KCP 2.1/01 Wang, Q., 2022 Report no.: ABC-2021-019	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).
	Before storage	After 14 days at 54°C																
Appearance of polyethylene plastic bottle	No visual change was observed. No corrosion of the bottle occurred.																	
Weight of polyethylene plastic bottle	84.31 g	84.30 g																
Appearance of test item	Off-white liquid, weak pungent odor	Off-white liquid, weak pungent odor																

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments															
			<table><tr><td>Prothioconazole content</td><td>13.84 % w/w</td><td>13.82 % w/w</td></tr><tr><td>Azoxystrobin content</td><td>14.07 % w/w</td><td>14.06 % w/w</td></tr><tr><td>Prothioconazole-desthio content</td><td>0.0037 % w/w</td><td>0.0030 % w/w</td></tr><tr><td>Z-azoxystrobin content</td><td>0.0038 % w/w</td><td>0.0038 % w/w</td></tr><tr><td>Toluene content</td><td>0.0067 % w/w</td><td>0.0015 % w/w</td></tr></table> <p>Conclusion: No significant change in appearance or weight of the packaging material for CA3642 was observed. The analysis of the product composition indicates no decomposition. Therefore CA3642 can be packaged in the supplier's packaging without corrosion or stability concerns.</p>	Prothioconazole content	13.84 % w/w	13.82 % w/w	Azoxystrobin content	14.07 % w/w	14.06 % w/w	Prothioconazole-desthio content	0.0037 % w/w	0.0030 % w/w	Z-azoxystrobin content	0.0038 % w/w	0.0038 % w/w	Toluene content	0.0067 % w/w	0.0015 % w/w			
Prothioconazole content	13.84 % w/w	13.82 % w/w																			
Azoxystrobin content	14.07 % w/w	14.06 % w/w																			
Prothioconazole-desthio content	0.0037 % w/w	0.0030 % w/w																			
Z-azoxystrobin content	0.0038 % w/w	0.0038 % w/w																			
Toluene content	0.0067 % w/w	0.0015 % w/w																			
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	Not required – CA3642 was found to be stable after storage for 14 days at 54 °C					-															
Minimum content after heat stability testing (KCP 2.7.3)	Not required – CA3642 was found to be stable after storage for 14 days at 54 °C																				
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	Prothioconazole 150 g/L + Azoxystrobin 150 g/L SC, CA3642 (batch A20026, purity 154.83 g/L for Azoxystrobin, 152.30 g/L for prothioconazole)	Sample is stable after storage at 0 ± 2°C for 7 days. The test item was considered to be stable after storage for 7 days at 0°C in polyethylene plastic bottle with regards to: - Appearance (Refer to KCP 2.1) - Wet sieve (Refer to KCP 2.8.5.1.2) - Suspensibility (Refer to KCP 2.8.3.1)	Y	KCP 2.1/01 Wang, Q., 2022 Report no.: ABC-2021-019	Accepted.															
Ambient temperature shelf life (KCP 2.7.5)	EPA OCSPP 830.6317, EPA OCSPP 830.6320 HDPE bottle Analytical method ABCTM-2021-018-02 validated in study	Prothioconazole 150 g/L + Azoxystrobin 150 g/L SC, CA3642 (batch A20026, purity 154.83 g/L for Azoxystrobin, 152.30 g/L for prothioconazole)	<p>A long term stability for 24 and 36 months at 20°C is currently on-going and final results will be provided when available.</p> <p>Sample is stable after storage at 20°C ± 2°C for 2 years.</p> <p>The test item was considered to be stable after storage for 2 years at 20°C in polyethylene plastic bottle with regards to:</p> <ul style="list-style-type: none">- packaging weight- active substance content (refer to Table 2-1.6-2 below)- impurities content (refer to Table 2-1.6-2 below)	Y	KCP 2.7.5/01 Wang, Q., 2021-2024 Study plan no.: ABC-2021-020 Report KCP 2.7.5/02 Wang, Q., 2022 Study plan no.: ABC-2021-056	<p>Ambient temperature study is currently ongoing, and should be provided upon completion.</p> <p>Accepted. The product showed no significant physical</p>															

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	reference KCP 5.1.1/01		<ul style="list-style-type: none"> - packaging stability/corrosion - pH (refer to KCP 2.4.1 and 2.4.2) - foam persistence (refer to KCP 2.8.2) - viscosity (refer to KCP 2.5.1) - suspensibility (refer to KCP 2.8.3.1) - emulsion stability (refer to KCP 2.8.6) - wet sieve test (refer KCP 2.8.5.1.2) -pourability (refer KCP 2.8.7.2) <p>A long-term stability 36 months at 20°C is currently on-going and final results will be provided when available.</p>			<p>changes after storage.</p> <p>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.</p> <p>The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging (HDPE).</p>
Shelf life in months (if less than 2 years) (KCP 2.7.6)	A long-term stability for 24 and 36 months at 20°C is currently on-going and final results will be provided when available.					-
Wettability (KCP 2.8.1)	Not applicable, the test item is a suspension concentrate (SC).					-
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	Prothioconazole 150 g/L + Azoxystrobin 150 g/L SC, CA3642 (batch A20026, purity 154.83 g/L for Azoxystrobin, 152.30 g/L for prothioconazole)	<p>Initial measurements/Before storage: Concentration 0.15 % v/v in CIPAC Water D Average volume of foam after: 10 seconds: 15 mL 1 minute: 0 mL 3 minutes: 0 mL 12 minutes: 0 mL</p> <p>Concentration 1.4 % v/v in CIPAC Water D Average volume of foam after: 10 seconds: 25 mL 1 minute: 0 mL 3 minutes: 0 mL 12 minutes: 0 mL</p>	Y	KCP 2.1/01 Wang, Q., 2022 Report no.: ABC-2021-019	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	CIPAC MT 47.3	Prothioconazole 150 g/L + Azoxystrobin 150 g/L SC, CA3642 (batch A20026, purity 154.83 g/L for Azoxystrobin, 152.30 g/L for prothioconazole)	Initial measurements/Before storage: Concentration 0.15 % v/v in CIPAC Water C Average volume of foam after: 10 seconds: 15 mL 1 minute: 0 mL 3 minutes: 0 mL 12 minutes: 0 mL Concentration 1.4 % v/v in CIPAC Water C Average volume of foam after: 10 seconds: 25 mL 1 minute: 0 mL 3 minutes: 0 mL 12 minutes: 0 mL After 12 months of storage at 20°C ± 2°C: Concentration 0.15 % v/v in CIPAC Water C Average volume of foam after: 10 seconds: 15 mL 1 minute: 0 mL 3 minutes: 0 mL 12 minutes: 0 mL Concentration 1.4 % v/v in CIPAC Water C Average volume of foam after: 10 seconds: 25 mL 1 minute: 0 mL 3 minutes: 0 mL 12 minutes: 0 mL After 18 months of storage at 20°C ± 2°C: Concentration 0.15 % v/v in CIPAC Water C Average volume of foam after: 10 seconds: 16 mL 1 minute: 0 mL 3 minutes: 0 mL 12 minutes: 0 mL	Y	KCP 2.7.5/01 Wang, Q., 2024 Report no.: ABC-2021-020	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			<p>Concentration 1.4 % v/v in CIPAC Water C Average volume of foam after:</p> <p>10 seconds: 26 mL 1 minute: 0 mL 3 minutes: 0 mL 12 minutes: 0 mL</p> <p>After 24 months of storage at 20°C ± 2°C: Concentration 0.15 % v/v in CIPAC Water D Average volume of foam after:</p> <p>10 seconds: 24 mL 1 minute: 1 mL 3 minutes: 0 mL 12 minutes: 0 mL</p> <p>Concentration 1.4 % v/v in CIPAC Water D Average volume of foam after:</p> <p>10 seconds: 33 mL 1 minute: 1 mL 3 minutes: 0 mL 12 minutes: 0 mL</p> <p>After 24 months of storage at 20°C ± 2°C: Concentration 0.15 % v/v in CIPAC Water D Average volume of foam after:</p> <p>1 minute: 1 mL 12 minutes: 0 mL</p> <p>Concentration 1.4 % v/v in CIPAC Water D Average volume of foam after:</p> <p>1 minute: 1 mL 12 minutes: 0 mL</p>			
Suspensibility (KCP 2.8.3.1)	CIPAC MT 18.1 (for CIPAC water preparation) and CIPAC MT 184.1	Prothioconazole 150 g/L + Azoxystrobin 150 g/L SC, CA3642 (batch A20026, purity	<p>Initial measurements/Before storage: Prothioconazole (at 30 ± 1°C): Dose 0.15% v/v (dilution in CIPAC water D), suspensibility = 99.29%</p>	Y	KCP 2.1/01 Wang, Q., 2022 Report no.: ABC-2021-019	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	Analytical method ABCTM-2021-018-02 validated in study reference KCP 5.1.1/01	154.83 g/L for Azoxystrobin, 152.30 g/L for prothioconazole)	<p>Dose 1.4% v/v (dilution in CIPAC water D), suspensibility = 98.36%</p> <p>Azoxystrobin (at 30 ± 1°C):</p> <p>Dose 0.15% v/v (dilution in CIPAC water D), suspensibility = 99.01%</p> <p>Dose 1.4% v/v (dilution in CIPAC water D), suspensibility = 98.75%</p> <p>After 7 days of storage at 0°C ± 2°C:</p> <p>Prothioconazole (at 30 ± 1°C):</p> <p>Dose 0.15% v/v (dilution in CIPAC water D), suspensibility = 97.99%</p> <p>Dose 1.4% v/v (dilution in CIPAC water D), suspensibility = 98.30%</p> <p>Azoxystrobin (at 30 ± 1°C):</p> <p>Dose 0.15% v/v (dilution in CIPAC water D), suspensibility = 96.75%</p> <p>Dose 1.4% v/v (dilution in CIPAC water D), suspensibility = 98.47%</p> <p>After 14 days of storage at 54°C ± 2°C:</p> <p>Prothioconazole (at 30 ± 1°C):</p> <p>Dose 0.15% v/v (dilution in CIPAC water D), suspensibility = 98.79%</p> <p>Dose 1.4% v/v (dilution in CIPAC water D), suspensibility = 98.51%</p> <p>Azoxystrobin (at 30 ± 1°C):</p> <p>Dose 0.15% v/v (dilution in CIPAC water D), suspensibility = 98.89%</p> <p>Dose 1.4% v/v (dilution in CIPAC water D), suspensibility = 99.84%</p>			
	The test method based on CIPAC MT 18.1 and MT 184.	Prothioconazole 150 g/L + Azoxystrobin 150 g/L SC, CA3642 (batch A20026, purity 154.83 g/L for Azoxystrobin, 152.30 g/L for prothioconazole)	<p>After 12 months of storage at 20°C ± 2°C:</p> <p>Suspensibility 30 ± 1 °C</p> <p>Prothioconazole (1.4% v/v) 99.77%</p> <p>Azoxystrobin (1.4% v/v) 99.18%</p> <p>Prothioconazole (0.15% v/v) 99.84%</p> <p>Azoxystrobin (0.15% v/v) 99.11%</p> <p>After 18 months of storage at 20°C ± 2°C:</p> <p>Suspensibility 30 ± 1 °C</p>	Y	KCP 2.7.5/01 Wang, Q., 2024 Report no.: ABC-2021-020	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			Prothioconazole (1.4% v/v) 95.04% Azoxystrobin (1.4% v/v) 98.24% Prothioconazole (0.15% v/v) 98.21% Azoxystrobin (0.15% v/v) 99.45% After 24 months of storage at 20°C ± 2°C: Suspensibility 30 ± 1 °C Prothioconazole (1.4% v/v) 98.33% Azoxystrobin (1.4% v/v) 99.19% Prothioconazole (0.15% v/v) 99.17% Azoxystrobin (0.15% v/v) 99.35%			
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160 Analytical method ABCTM-2021-018-02 validated in study reference KCP 5.1.1/01	Prothioconazole 150 g/L + Azoxystrobin 150 g/L SC, CA3642 (batch A20026, purity 154.83 g/L for Azoxystrobin, 152.30 g/L for prothioconazole)	Initial measurements/Before storage: Dose : 5% w/v (dilution in CIPAC water C) Prothioconazole (at 30 ± 1°C): Spontaneity of dispersion = 99.09% Azoxystrobin (at 30 ± 1°C): Spontaneity of dispersion = 99.04% After 14 days of storage at 54°C ± 2°C: Dose : 5% w/v (dilution in CIPAC water C) Prothioconazole (at 30 ± 1°C): Spontaneity of dispersion = 99.76% Azoxystrobin (at 30 ± 1°C): Spontaneity of dispersion = 98.25%	Y	KCP 2.1/01 Wang, Q., 2022 Report no.: ABC-2021-019	Accepted.
	CIPAC MT 160	Prothioconazole 150 g/L + Azoxystrobin 150 g/L SC, CA3642 (batch A20026, purity 154.83 g/L for Azoxystrobin, 152.30 g/L for prothioconazole)	Initial measurements/Before storage: Dose: 5% w/v (dilution in CIPAC water C) Prothioconazole (at 30 ± 1°C): Spontaneity of dispersion = 99.09% Azoxystrobin (at 30 ± 1°C): Spontaneity of dispersion = 99.04% After 12 months of storage at 20°C ± 2°C: Dose: 5% w/v (dilution in CIPAC water C) Prothioconazole (at 30 ± 1°C): Spontaneity of dispersion = 99.33% Azoxystrobin (at 30 ± 1°C): Spontaneity of dispersion = 99.30% After 18 months of storage at 20°C ± 2°C: Dose: 5% w/v (dilution in CIPAC water C)	Y	KCP 2.7.5/01 Wang, Q., 2024 Report no.: ABC-2021-020	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			<p>Prothioconazole (at 30 ± 1°C): Spontaneity of dispersion = 99.68% Azoxystrobin (at 30 ± 1°C): Spontaneity of dispersion = 98.16%</p> <p>After 24 months of storage at 20°C ± 2°C: Dose: 5% w/v (dilution in CIPAC water C) Prothioconazole (at 30 ± 1°C): Spontaneity of dispersion = 99.38% Azoxystrobin (at 30 ± 1°C): Spontaneity of dispersion = 99.06%</p>			
Dispersion stability (KCP 2.8.3.3)	Not applicable, the test item is a suspension concentrate (SC).					-
Degree of dissolution and dilution stability (KCP 2.8.4)	Not applicable, the test item is a suspension concentrate (SC).					-
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1) Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 59.3 and MT 167; MT 185 Wet sieve test	Prothioconazole 150 g/L + Azoxystrobin 150 g/L SC, CA3642 (batch A20026, purity 154.83 g/L for Azoxystrobin, 152.30 g/L for prothioconazole)	<p>Initial measurements/Before storage: 0.10 % on 200 mesh sieve</p> <p>After 7 days of storage at 0°C ± 2°C: 0.05 % on 200 mesh sieve</p> <p>After 14 days of storage at 54°C ± 2°C: 0.05 % on 200 mesh sieve</p>	Y	KCP 2.1/01 Wang, Q., 2022 Report no.: ABC-2021-019	Accepted.
	CIPAC MT 59.3 and MT 167; MT 185 Wet sieve test	Prothioconazole 150 g/L + Azoxystrobin 150 g/L SC, CA3642 (batch A20026, purity 154.83 g/L for Azoxystrobin, 152.30 g/L for prothioconazole)	<p>Initial measurements/Before storage: 0.10 % on 200 mesh sieve</p> <p>After 12 months of storage at 20°C ± 2°C: 0.0 % on 200 mesh sieve</p> <p>After 18 months of storage at 20°C ± 2°C: 0.0 % on 200 mesh sieve</p> <p>After 24 months of storage at 20°C ± 2°C: 0.05 % on 200 mesh sieve</p>	Y	KCP 2.7.5/01 Wang, Q., 2024 Report no.: ABC-2021-020	Accepted.
Dust content (KCP 2.8.5.2.1)	Not applicable, the test item is a suspension concentrate (SC).					-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Particle size of dust (KCP 2.8.5.2.2)	Not applicable, the test item is a suspension concentrate (SC).					-
Attrition (KCP 2.8.5.3)	Not applicable, the test item is a suspension concentrate (SC).					-
Hardness and integrity (KCP 2.8.5.4)	Not applicable, the test item is a suspension concentrate (SC).					-
Emulsifiability (KCP 2.8.6.1)	Not applicable, the test item is a suspension concentrate (SC).					-
Emulsion stability (KCP 2.8.6.2)	Not applicable, the test item is a suspension concentrate (SC).					-
Re-emulsifiability (KCP 2.8.6.3)	Not applicable, the test item is a suspension concentrate (SC).					-
Flowability (KCP 2.8.7.1)	This data requirement does not apply to this formulation type.					-
Pourability (KCP 2.8.7.2)	CIPAC MT 148	Prothioconazole 150 g/L + Azoxystrobin 150 g/L SC, CA3642 (batch A20026, purity 154.83 g/L for Azoxystrobin, 152.30 g/L for prothioconazole)	Initial measurements/Before storage: Mean residue = 2.57% After 14 days of storage at 54°C ± 2°C: Mean residue = 4.13%	Y	KCP 2.1/01 Wang, Q., 2022 Report no.: ABC-2021-019	Accepted.
	CIPAC MT 148	Prothioconazole 150 g/L + Azoxystrobin 150 g/L SC, CA3642 (batch A20026, purity 154.83 g/L for Azoxystrobin, 152.30 g/L for prothioconazole)	Initial measurements/Before storage: Mean residue = 2.57% After 12 months of storage at 20°C ± 2°C: Mean residue = 1.84% After 18 months of storage at 20°C ± 2°C: Mean residue = 2.56% After 18 months of storage at 20°C ± 2°C: Mean residue = 2.39%	Y	KCP 2.7.5/01 Wang, Q., 2024 Report no.: ABC-2021-020	Accepted.
Dustability following accelerated storage (KCP 2.8.7.3)	Not applicable, the test item is a suspension concentrate (SC).					-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Physical compatibility of tank mixes (KCP 2.9.1)	Not required – no tank mixes are recommended on the CA3642 label.					-
Chemical compatibility of tank mixes (KCP 2.9.2)	Not required – no tank mixes are recommended on the CA3642 label.					-
Adhesion to seeds (KCP 2.10.1)	Not required – CA3642 is not intended to be used for seed treatment.					-
Distribution to seed (KCP 2.10.2)	Not required – CA3642 is not intended to be used for seed treatment.					-
Other/special studies (KCP 2.11)	No other studies has been provided.					-

Table 2-2-2: Active substances and impurities content of study ABC-2021-020

	Before storage	After 12 months at 20°C	After 18 months at 20°C	After 24 months at 20°C
Appearance of polyethylene plastic bottle	No visual change was observed. No corrosion of the bottle occurred.			
Weight of polyethylene plastic bottle (+ Sample)	1059.41g (for T12m) 1059.85g (for T18m) 1060.27g (for T24m)	1059.37 g	1059.78 g	1060.19 g
Appearance of test item	Off-white liquid, weak pungent odor	Off-white liquid suspension, weak pungent odor	Off-white liquid suspension, weak pungent odor	Off-white liquid suspension, weak pungent odor
Prothioconazole content	13.84 % w/w	13.82 % w/w	13.84 % w/w	13.92 % w/w
Azoxystrobin content	14.07 % w/w	14.09 % w/w	14.00 % w/w	14.04 % w/w
Prothioconazole-desthio content	0.0037 % w/w	0.0033 % w/w	0.0037 % w/w	0.0033 % w/w
Z-azoxystrobin content	0.0038 % w/w	0.0038 % w/w	0.0036 % w/w	0.0038 % w/w
Toluene content	0.0067 % w/w	0.0065 % w/w	0.0056 % w/w	0.0064 % w/w

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:	Ambient temperature study is currently ongoing, will be provided upon completion. The accelerated and 2-years storage stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging (HDPE).
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Table 4.1-1: Packaging information for 0.5 litre bottle

Type	Description
Material:	HDPE
Shape/size:	cylindrical / approx. 69 mm diameter x 186.5 mm
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-2: Packaging information for 1L bottle

Type	Description
Material:	HDPE
Shape/size:	cylindrical / approx. 88 mm diameter x 234 mm
Opening:	39 mm inner diameter
Closure:	polyethylene screw cap
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-3: Packaging information for 5L bottle

Type	Description
Material:	HDPE
Shape/size:	rectangular / approx. 305 mm height x 142 mm depth x 193 mm width
Opening:	52.5 mm inner diameter
Closure:	polyethylene screw cap
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-4: Packaging information for 10L bottle

Type	Description
Material:	PE-PA HDPE
Shape/size:	rectangular / approx. 370 374 mm height x 179 mm depth x 240 mm width
Opening:	63 mm
Closure:	polyethylene screw cap
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-5: Packaging information for 20L bottle

Type	Description
Material:	HDPE
Shape/size:	rectangular / approx. 400 mm height x 245 mm depth x 293 mm width
Opening:	63 mm
Closure:	polyethylene screw cap
Manner of construction	extruded
UN/ADR	compliant

4.2 Procedures for Cleaning Application Equipment

4.2.1 Procedures for cleaning application equipment and protective clothing

4.2.2 Effectiveness of the cleaning procedures

Comments of zRMS:	Based on the results obtained, a triple rinsing procedure is recommended.
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Reference:	KCP 4.2.2/01
Report	CA3642 – Effectiveness of Cleaning, Calvert A., 2023, 23/1610
Guideline(s):	CRD Efficacy Guideline 305
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of this study was to demonstrate the efficiency of the tank cleaning procedure for the product as described in CRD Efficacy Guideline 305. For this study the triple rinse procedure was tested.

Test material

Test Material: CA3642
Batch: FRAI008392
Purity: 146.89 g/L for Azoxystrobin, 150.86 g/L for prothioconazole

Tank Mix Preparation

A test item solution at the maximum intended use concentration (1.4% v/v solution) was prepared by diluting the test item in CIPAC Standard Water D. 100 mL aliquots were then poured out into 3 x 100 mL HDPE bottles and allowed to stand overnight (approx. 20 h).

Approximately 100 ml of the remaining tank mix was retained for the initial active substance content analysis using a validated analytical method (full summary of the method validation is provided in the dRR Part B5, Appendix 2, KCP 5.1.2/10). Duplicate analysis solutions were prepared by dilution of 1 ml of the tank mix to a final volume of 25 ml in volumetric flasks with acetonitrile.

Cleaning out Procedure (Triple Rinse)

After standing overnight (~20 hours) the samples were shaken to re-suspend any settled matter. The solutions were then discarded.

10 ml of tap water was added to each bottle and the bottles were inverted twice. The rinsate was discarded. This process was repeated twice further with 10 ml of tap water each time. On each occasion, the rinsate was discarded.

After rinsing the sample containers with 3 x 10 ml of tap water, 10 ml of acetonitrile was added to each

bottle. The bottles were shaken to coat the entire surface of the bottles. The acetonitrile rinsates were analysed in duplicate for active ingredient content. The % of active substance (individually calculated for prothioconazole and azoxystrobin) removed by the triple rinse procedure was then calculated:

e.g. for prothioconazole:

$$\% \text{ prothioconazole removed} = 100 \times \left(1 - \frac{\text{Prothioconazole recovered after cleaning procedure (mg)}}{\text{Mean amount AI in 100 mL tank mix sample (mg)}}\right)$$

Component	Mean amount active substance in initial 100 mL tank mix sample (mg)	Total active substance recovered after cleaning procedure (mg)	% Removed	Mean % Removed
Prothioconazole	200.7457	0.00617	99.9969	99.9967
		0.00680	99.9966	
		0.00660	99.9967	
		0.00677	99.9966	
		0.00670	99.9967	
		0.00685	99.9966	
Azoxystrobin	195.6913	0.00495	99.9975	99.9975
		0.00512	99.9974	
		0.00440	99.9978	
		0.00435	99.9978	
		0.00543	99.9972	
		0.00541	99.9972	

Conclusion

The mean % of prothioconazole removed after following the triple rinse cleaning procedure with water was 99.9967% (n = 6). The mean % of azoxystrobin removed after following the triple rinse cleaning procedure with water was 99.9975% (n = 6).

Therefore, the effectiveness of the proposed cleaning procedure is considered demonstrated for the product.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1/01	Wang Q.	2022	Physical and Chemical Characterization of Prothioconazole 150 g/L + Azoxystrobin 150 g/L SC, CA3642 Report no.: ABC-2021-019 Achiever Biochem Co., Ltd. GLP Unpublished	N	Nufarm
KCP 2.2.1/01	Fitzmaurice T.	2022	Analysis of CA3642 a Suspension Concentrate Formulation containing 150 g/L Prothioconazole and 150 g/L Azoxystrobin, in Compliance with Good Laboratory Practice Report no.: DNA6888 David Norris Analytical Laboratories Limited GLP Unpublished	N	Nufarm
KCP 2.4.2/01	Wang Q.	2023	Physical and chemical caractérisation of prothioconazole 150 g/L + Azoxystrobin 150 g/L SC, CA3642 Report No.: ABC-2023-007 Achiever Biochem Co., Ltd. GLP Unpublished	N	Nufarm
KCP 2.7.5/01	Wang Q.	2024 2022 (on-going)	Determination of Storage Stability and Corrosion Characteristics of Prothioconazole 150 g/L + Azoxystrobin 150 g/L SC, CA3642 Study plan no. Report.: ABC-2021-020 Achiever Biochem Co., Ltd. GLP Unpublished	N	Nufarm
KCP 2.7.5/02	Wang Q.	2022 (on-going)	Determination of Storage Stability and Corrosion Characteristics of Prothioconazole 150 g/L + Azoxystrobin 150 g/L SC, CA3642 Study plan no.: ABC-2021-056 Achiever Biochem Co., Ltd. GLP Unpublished	N	Nufarm

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
No data submitted					

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
No data submitted					

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
No data submitted					

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

A 2.1 Prothioconazole

None.

A 2.2 Azoxystrobin

None.