

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: CA3301

Product name(s): JOUST 250 EC

Chemical active substance:

Prothioconazole, 250 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

New Authorisation (Art.33)

Applicant: Nufarm Polska Sp. z o. o.

Submission date: 23/12/2021

MS Finalisation date: September 2022 (initial National Assessment)

January 2023 (final Core Assessment)

Version history

When	What
December 2021	First submission
September 2022	Addition of informatio under 4.2
September 2022	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 .
January 2023	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 . Information no longer relevant is struck through and shaded .

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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.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Nufarm Polska Sp. z o. o.
Address: Grójecka 1/3, 02-019 Warszawa
Email:

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

1.2.1 Producer(s) of the preparation

Producer : Nufarm Crop Products UK
Wyke Lane,
Wyke,
Bradford,
BD12 9EJ,
United Kingdom

Contact person : xxxxxxxxxxxxxxxx
E-mail : xxxxxxxxxxxxxxxx

Production Sites :

Site 1

Company: Nufarm SAS
Address: Notre Dame de la Garenne
27600 Gaillon
France

Contact person: xxxxxxxxxxxxxxxx
E-mail : xxxxxxxxxxxxxxxx

Site 2

Company: Chemark Zrt.
Address: H-8182 Berhida
Peremarton gyártelep 06/75 hrsz.
P.O.Box 31.
Hungary

Contact person: xxxxxxxxxxxxxxxx
E-mail : xxxxxxxxxxxxxxxx

Site 3

Company: Phyteurop
Address: Zone Industrielle de Grande Champagne
49260 Montreuil-Bellay
France

Contact person: xxxxxxxxxxxxxxxx
E-mail : xxxxxxxxxxxxxxxx

Site 4

Company: Autopak-Vetlab Group
Address: 39 Harris Street
St Marys

New South Wales 2760
Australia

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

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

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

1.2.3.1 Prothioconazole

Confidential information or data are provided separately (Part C)
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

Confidential information is provided separately (Part C).

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

Trade name: JOUST
Company code number: CA3301
NUL 3390

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	250 g/L	235-265 g/L	257.7 g/L	25.91

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

** Based on the nominal density of the formulation = 0.9948 g/mL

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content	
	g/kg	%w/w
Toluene	1.295	0.129
Prothioconazole-desthio	0.129	0.013

*Based on the official maximum impurity content as stated in Commission Implementing Regulation (EU) No 540/2011

For detailed composition, refer to confidential part C.

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

Table 1.4-2: Information on active substance

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
CAS No.	178928-70-6
EC No.	605-841-2
CIPAC No.	745

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

The product does not contain any safener nor synergist.
CONFIDENTIAL information is provided separately (Part C) for co-formulants.

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

Type: Emulsifiable concentrate

Code: EC

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 yellow, odourless liquid. Based on the constituents of the formulation, it has no explosive or oxidising properties. The product is not flammable and has no flash point. It has a self-ignition temperature of over 400 °C. It has a pH value around 6 in a 1 % aqueous solution. There is no effect of low or high temperature on the stability of the formulation, since after 7 days at °C and 14 days at 54 °C. The stability data indicate a shelf life of at least 2 years at ambient temperature in HDPE packaging. Its technical characteristics are acceptable for an emulsifiable concentrate formulation. It is recommended to mix product before use and to mix/agitate the product during use. Triple rinsing procedure is recommended.

The intended concentration of use is 0.15% v/v to 0.8% v/v.

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

CLP Hazard category	Data - Justification	Classification
Explosive properties	Based on experimental results, 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 (EC).	No
Aerosol	Not applicable as the product is a liquid not conditioned as aerosol (EC).	No
Oxidising gases	Not applicable as the product is a liquid (EC).	No
Gases under pressure	Not applicable as the product is a liquid (EC).	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 (EC).	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 (EC).	No
Self-heating substance	During experimental test (EC A.16, DSC), 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. 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	Based on experimental results, the product is not classified for oxidising properties. Refer to KCP 2.2 for further details. Further to KCP 2.2, considering the absence of substances presenting oxidising properties oxidising properties test should not be considered	No

	necessary. Refer to KCP 2.2 for further details.	
Oxidising solid	Not applicable as the product is a liquid (EC).	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.

Labelling:

As the product is a plant protection product, the specific statement EUH401 must appear on the label:

EUH401: To avoid risks to human health and the environment, comply with the instructions for use.

SP1: Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).

Notifier Proposals for Risk and Safety Phrases (KCP 12)

None for physical hazards.

Compliance with FAO specifications:

No FAO specifications for prothioconazole.

The product CA3301 complies with FAO specifications for EC formulations.

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)	Visual Inspection	Prothioconazole 250 EC (batch A19045, purity 250.9 g/L)	Initial measurements/Before storage: Yellow, odorless liquid. After 14 days' storage at 54°C: Deep yellow, odorless liquid.	Y	KCP 2.1/01 Ge, H., 2019a Report no.: ABC-2019-024 KCP 2.1/02 Ge, H., 2019b Report no.: ABC-2019-027	Accepted.
Explosive properties (KCP 2.2.1)	OPPTS 830.6316 Differential Scanning Calorimetry	Prothioconazole 250 EC, (batch A19045, purity 250.9 g/L)	The enthalpy of reaction of the test item is zero. It is not exothermic. The test item can be considered as having no explosive properties.	Y	KCP 2.1/01 Ge, H., 2019a Report no.: ABC-2019-024	Accepted. Considered as not explosive.
Oxidizing properties (KCP 2.2.2)	OCSPP 830.6314 Statement	Prothioconazole 250 EC, (batch A19045, purity 250.9 g/L)-	The test item was considered to be non-reactive towards water, n-hexane, NH ₄ H ₂ PO ₄ , iron powder and KMnO ₄ . In all mixtures tested the temperature change was less than 5°C. Further more, considering the absence of substances presenting oxidising properties, an oxidising properties test should not be considered as necessary.	Y/N	KCP 2.1/01 Ge, H., 2019a Report no.: ABC-2019-024 J-KCP 2.2/01, Hoque A. & Michelet D., 2021, Report 21/133	Statement accepted.
Flash point (KCP 2.3.1)	CIPAC MT 12 Equivalent to EEC A.9	Prothioconazole 250 EC, (batch A19045, purity 250.9 g/L)	The flash point of the test item at Standard Air Pressure is 149.7°C.	Y	KCP 2.1/01 Ge, H., 2019a Report no.: ABC-2019-024	Accepted.
Flammability (KCP 2.3.2)	Not required – CA3301 is not a solid preparation or a gas. CA 3301 is not flammable based on flash point obtained (KCP 2.3.1).					-
Self-heating (KCP 2.3.3)	EEC A.16. Differential Scanning Calorimetry	Prothioconazole 250 EC, (batch A19045, purity 250.9 g/L)	Based on DSC scan, no self-ignition was observed up to a temperature of 400°C.	Y	KCP 2.1/01 Ge, H., 2019a Report no.: ABC-2019-024	Accepted. No self-ignition.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Acidity or alkalinity and pH (KCP 2.4.1)	EPA OCSPP 830.7000, CIPAC MT 191	Prothioconazole 250 EC, (batch A19045, purity 250.9 g/L)	Initial measurements/Before storage: Average acidity calculated as H ₂ SO ₄ : 0.0075% After 14 days' storage at 54°C: Average acidity calculated as H ₂ SO ₄ : 0.001% After 7 days' storage at 0°C: Average acidity calculated as H ₂ SO ₄ : 0.0042% After 2 years' storage at 25°C: Average acidity calculated as H ₂ SO ₄ : 0.0071%	Y	KCP 2.1/01 Ge, H., 2019a Report no.: ABC-2019-024 KCP 2.1/02 Ge, H., 2019b Report no.: ABC-2019-027 KCP 2.7.4/01 Ge, H., 2019c Report no.: ABC-2019-028 KCP 2.7.5/01 Wang, Q., 2021 Report no.: ABC-2019-020	Accepted.
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	EPA OCSPP 830.7000, Equivalent to CIPAC MT 75.3	Prothioconazole 250 EC, (batch A19045, purity 250.9 g/L) 1% w/v Test Item	Initial measurements/Before storage: The average pH is 6.18 at room temperature. After 14 days' storage at 54°C: The average pH after 14 days at 54 °C is 6.90 at room temperature. After 7 days' storage at 0°C: The average pH after 7 days at 0°C is 6.66 at room temperature. After 2 years' storage at 25°C: The average pH after 2 years at 25°C is 6.19 at room temperature.	Y	KCP 2.1/01 Ge, H., 2019a Report no.: ABC-2019-024 KCP 2.1/02 Ge, H., 2019b Report no.: ABC-2019-027 KCP 2.7.4/01 Ge, H., 2019c Report no.: ABC-2019-028 KCP 2.7.5/01 Wang, Q., 2021 Report no.: ABC-2019-	Accepted.

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments									
			Mean dynamic viscosity: 42.63 mPa s Mean kinematic viscosity: 0.4320 cm2/s The test item is a Newtonian liquid.												
Surface tension (KCP 2.5.2)	OECD 115, EEC A.5 Ring method	Prothioconazole 250 EC, (batch A19045, purity 250.9 g/L)	The result of surface tension value for 0.9 g/L Test Item solution is 30.65 mN/m at 20.1°C The diluted test item is surface active (< 60 mN/m)	Y	KCP 2.1/01 Ge, H., 2019a Report no.: ABC-2019-024	Accepted.									
Relative density (KCP 2.6.1)	EPA OCSPP 830.7300, OECD 109, EEC A.3 Pycnometer method	Prothioconazole 250 EC, (batch A19045, purity 250.9 g/L)	The density of the test item at 20 ± 0.5°C is 0.9948 g/mL.	Y	KCP 2.1/01 Ge, H., 2019a Report no.: ABC-2019-024	Accepted.									
Bulk density (KCP 2.6.2)	This data requirement does not apply to this formulation type.					-									
Storage Stability after 14 days at 54° C (KCP 2.7.1)	EPA OCSPP 830.6317, OECD 113 Analytical method: Active Ingredient content: ABCTM-2019-020-02 Impurity I and II content: ABCTM-2019-020-03 and ABCTM-2019-020-04	Prothioconazole 250 EC, (batch A19045, purity 250.9 g/L)	Sample is stable after storage at 54 °C for 14 days. The test item was considered to be stable after storage for 14 days at 54°C in HDPE bottles with regards to: - packaging weight - active substance content - impurities content - packaging stability/corrosion - pH/acidity (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 storage</td></tr><tr><td>Appearance of HDPE bottle</td><td colspan="2">No visual change was observed after 14 days</td></tr><tr><td>Weight of HDPE bottle</td><td>59.29 g</td><td>59.28 g</td></tr></table>		Before storage	After storage	Appearance of HDPE bottle	No visual change was observed after 14 days		Weight of HDPE bottle	59.29 g	59.28 g	Y	KCP 2.1/01 Ge, H., 2019a Report no.: ABC-2019-024	Accepted. The product showed no significant physical changes after accelerated storage. No significant changes were observed in the HDPE 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 HDPE.
	Before storage	After storage													
Appearance of HDPE bottle	No visual change was observed after 14 days														
Weight of HDPE bottle	59.29 g	59.28 g													

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
			Appearance of test item	Yellow, odorless, liquid	Deep yellow, odorless, liquid			
			Prothioconazole content	25.57 % w/w	25.52 % w/w			
			Prothioconazole-desthio content	0.0063 % w/w	< LOQ (< 0.0044 % w/w)			
			Toluene content	0.028 % w/w	0.030 % w/w			
			Conclusion: No significant change in appearance or weight of the packaging material for CA3301 was observed. The analysis of the product composition indicates no decomposition. Therefore CA3301 can be packaged in the supplier’s packaging without corrosion or stability concerns.					
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	Not required – CA3301 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 – CA3301 was found to be stable after storage for 14 days at 54 °C							-
Effect of low temperatures on stability (KCP 2.7.4)	Equivalent to MT 39.3	Prothioconazole 250 EC, (batch A19045)	Sample is stable after storage at 0 ± 2°C for 7 days. The acidity, pH and emulsion stability remained stable; refer to KCP 2.4.1, 2.4.2, KCP 2.8.2 and KCP 2.8.6.			Y	KCP 2.7.4/01 Ge, H., 2019c Report no.: ABC-2019-028	Accepted.
Ambient temperature shelf life (KCP 2.7.5)	EPA OCSPP 830.6317, EPA OCSPP 830.6320, OECD 113 Determination of Active Ingredient in Test Item:	Prothioconazole 250 EC (batch A19045, purity 250.9 g/L)	Sample is stable after storage at 25 °C for 24 months (2 years). The test item was considered to be stable after storage for 2 years at 25°C in HDPE bottles with regards to: - packaging weight			Y	KCP 2.7.5/01 Wang, Q., 2021 Report no.: ABC-2019-020	Study accepted. The HDPE container showed no indications of significant weight loss or physical deterioration

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																					
	Analytical method ABCTM-2019-020-02 (In Study ABC-2019-020) Determination of Impurities content in Test Item: Duplicate aliquots in Test Item were assayed for the content of impurities, employing validated test method ABCTM-2019-020-03 (Verified in Study ABC-2019-020) and ABCTM-2019-020-04 (Verified in Study ABC-2019-020)		<div>- active substance content</div> <div>- impurities content</div> <div>- packaging stability/corrosion</div> <div>- pH/acidity (refer to KCP 2.4.1 and 2.4.2)</div> <div>- foam persistence (refer to KCP 2.8.2)</div> <div>- viscosity (refer to KCP 2.5.1)</div> <div>- emulsion stability (refer to KCP 2.8.6)</div> <table><tr><td></td><td>Before storage</td><td>After storage</td></tr><tr><td>Appearance of HDPE bottle</td><td colspan="2">No visual change was observed after 2 years</td></tr><tr><td>Weight of HDPE bottle</td><td>66.65 g</td><td>66.54 g</td></tr><tr><td>Appearance of test item</td><td>Yellow, odorless, liquid</td><td>Yellow, odorless, liquid</td></tr><tr><td>Prothioconazole content</td><td>25.57 % w/w</td><td>25.51 % w/w</td></tr><tr><td>Prothioconazole-desthio content</td><td>0.0063 % w/w</td><td>0.0088 % w/w</td></tr><tr><td>Toluene content</td><td>0.028 % w/w</td><td><LOQ</td></tr></table> <div>Conclusion: No significant change in appearance or weight of the packaging material for CA3301 was observed. The analysis of the product composition indicates no decomposition. Therefore CA3301 can be packaged in the supplier’s packaging without corrosion or stability concerns.</div>		Before storage	After storage	Appearance of HDPE bottle	No visual change was observed after 2 years		Weight of HDPE bottle	66.65 g	66.54 g	Appearance of test item	Yellow, odorless, liquid	Yellow, odorless, liquid	Prothioconazole content	25.57 % w/w	25.51 % w/w	Prothioconazole-desthio content	0.0063 % w/w	0.0088 % w/w	Toluene content	0.028 % w/w	<LOQ			that would interfere with the safe handling of the product. Period of validity: 2 years.
	Before storage	After storage																									
Appearance of HDPE bottle	No visual change was observed after 2 years																										
Weight of HDPE bottle	66.65 g	66.54 g																									
Appearance of test item	Yellow, odorless, liquid	Yellow, odorless, liquid																									
Prothioconazole content	25.57 % w/w	25.51 % w/w																									
Prothioconazole-desthio content	0.0063 % w/w	0.0088 % w/w																									
Toluene content	0.028 % w/w	<LOQ																									
Shelf life in months (if less than 2 years) (KCP 2.7.6)	CA3301 is expected to be stable for two years. Please refer to KCP 2.7.1 and 2.7.5.					-																					
Wettability (KCP 2.8.1)	This data requirement does not apply to this formulation type.					-																					
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.2.	Prothioconazole 250 EC, (batch A19045, purity	Initial measurements/Before storage:	Y	KCP 2.1/01 Ge, H., 2019a	Accepted.																					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		250.9 g/L)	<p>Concentration 0.893 %w/v in CIPAC Water C</p> <p>Average volume of foam after: 10 seconds: 35 mL 1 minute: 35 mL 3 minutes: 35 mL 12 minutes: 34 mL</p> <p>After 14 days' storage at 54°C: Concentration 0.893 %w/v in CIPAC Water C</p> <p>Average volume of foam after: 10 seconds: 23 mL 1 minute: 23 mL 3 minutes: 23 mL 12 minutes: 22 mL</p> <p>After 2 years' storage at 25°C: Concentration 0.1 %v/v in CIPAC Water C</p> <p>Average volume of foam after: 10 seconds: 5 mL 1 minute: 5 mL 3 minutes: 5 mL 12 minutes: 4 mL</p> <p>Concentration 0.9 %w/v in CIPAC Water C</p> <p>Average volume of foam after: 10 seconds: 35 mL 1 minute: 35 mL 3 minutes: 35 mL 12 minutes: 34 mL</p>		<p>Report no.: ABC-2019-024</p> <p>KCP 2.1/02 Ge, H., 2019b Report no.: ABC-2019-027</p> <p>KCP 2.7.5/01 Wang, Q., 2021 Report no.: ABC-2019-020</p>	
Suspensibility (KCP 2.8.3.1)	This data requirement does not apply to this formulation type.					-
Spontaneity of dispersion	This data requirement does not apply to this formulation type.					-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.3.2)						
Dispersion stability (KCP 2.8.3.3)	This data requirement does not apply to this formulation type.					-
Degree of dissolution and dilution stability (KCP 2.8.4)	This data requirement does not apply to this formulation type.					-
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	This data requirement does not apply to this formulation type.					-
Wet sieve test (KCP 2.8.5.1.2)	This data requirement does not apply to this formulation type.					-
Dust content (KCP 2.8.5.2.1)	This data requirement does not apply to this formulation type.					-
Particle size of dust (KCP 2.8.5.2.2)	This data requirement does not apply to this formulation type.					-
Attrition (KCP 2.8.5.3)	This data requirement does not apply to this formulation type.					-
Hardness and integrity (KCP 2.8.5.4)	This data requirement does not apply to this formulation type.					-
Emulsifiability (KCP 2.8.6.1) Emulsion stability (KCP 2.8.6.2) Re-emulsifiability (KCP 2.8.6.3)	CIPAC MT 36.3.	Prothioconazole 250 EC, (batch A19045, purity 250.9 g/L)	Initial measurements/Before storage: Concentration: 5% v/v, CIPAC Water D Stability after: <u>30 seconds:</u> No free oil, cream or solid formed <u>30 minutes</u> No free oil, cream or solid formed <u>2 hours:</u> 0.2 mL of cream formed <u>24 hours:</u> 1.2 mL of cream formed	Y	KCP 2.1/01 Ge, H., 2019a Report no.: ABC-2019-024 KCP 2.1/02 Ge, H., 2019b Report no.: ABC-2019-027 KCP 2.7.4/01 Ge, H., 2019c Report no.: ABC-2019-	Accepted. Based on the results obtained (the cream layer was observed after 2 hours and 24 hours for tests before and after storage), it is recommended to mix the product before use and to mix/agitate the product during use.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			<p>After the 24 hour period the cylinder was inverted 10 times; after 30 seconds no free oil, cream and solid matter formed; following 30 minutes no free oil and solid matter formed and 0.3 mL of cream was found.</p> <p>After 7 days' storage at 0°C</p> <p>Concentration: 5% v/v, CIPAC Water D</p> <p>Stability after: <u>30 seconds</u>: No free oil, cream or solid formed <u>30 minutes</u>: No free oil, cream or solid formed <u>2 hours</u>: 0.7 mL of cream formed <u>24 hours</u>: 1.4 mL of cream formed</p> <p>After the 24 hour period the cylinder was inverted 10 times; after 30 seconds no free oil, cream and solid matter formed; following 30 minutes no free oil and solid matter formed and 0.5 mL of cream was found.</p> <p>After 14 days' storage at 54°C</p> <p>Concentration: 5% v/v, CIPAC Water D</p> <p>Stability after: <u>30 seconds</u>: No free oil, cream or solid formed <u>30 minutes</u>: No free oil, cream or solid formed <u>2 hours</u>: No free oil, cream or solid formed <u>24 hours</u>: 16 mL of cream formed</p> <p>After the 24 hour period the cylinder was inverted 10</p>		<p>028</p> <p>KCP 2.7.5/01 Wang, Q., 2021 Report no.: ABC-2019-020</p>	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			<p>times; no free oil, cream and solid matter was observed after 30 seconds and 30 minutes.</p> <p>After 2 years' storage at 25°C:</p> <p>Concentration: 0.1% v/v, CIPAC Water D</p> <p>Stability after: <u>30 seconds:</u> No free oil, cream or solid formed <u>30 minutes</u> No free oil, cream or solid formed <u>2 hours:</u> No free oil, cream or solid formed <u>24 hours:</u> 16 mL of cream formed</p> <p>After the 24 hour period the cylinder was inverted 10 times; no free oil, cream and solid matter was observed after 30 seconds and 30 minutes. Concentration: 5% v/v, CIPAC Water D</p> <p>Stability after: <u>30 seconds:</u> No free oil, cream or solid formed <u>30 minutes</u> No free oil, cream or solid formed <u>2 hours:</u> 0.1 mL of cream formed <u>24 hours:</u> 1.1 mL of cream formed</p> <p>After the 24 hour period the cylinder was inverted 10 times; after 30 seconds no free oil, cream and solid matter formed; following 30 minutes no free oil and solid matter formed and 0.2 mL of cream was found.</p>			
Flowability (KCP 2.8.7.1)	This data requirement does not apply to this formulation type.					-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Pourability (KCP 2.8.7.2)	This data requirement does not apply to this formulation type.					-
Dustability following accelerated storage (KCP 2.8.7.3)	This data requirement does not apply to this formulation type.					-
Physical compatibility of tank mixes (KCP 2.9.1)	Not required – no tank mixes are recommended on the CA3301 label.					-
Chemical compatibility of tank mixes (KCP 2.9.2)	Not required – no tank mixes are recommended on the CA3301 label.					-
Adhesion to seeds (KCP 2.10.1)	Not required – CA3301 is not intended to be used for seed treatment.					-
Distribution to seed (KCP 2.10.2)	Not required – CA3301 is not intended to be used for seed treatment.					-
Other/special studies (KCP 2.11) Oxidation/reduction: chemical incompatibility	OCSPP 830.6314	Prothioconazole 250 EC, (batch A19045, purity 250.9 g/L)	The test item was considered to be non-reactive towards water, n-hexane, NH ₄ H ₂ PO ₄ , iron powder and KMnO ₄ . In all mixtures tested the temperature change was less than 5°C.	Y	KCP 2.1/01 Ge, H., 2019a Report no.: ABC-2019- 024	Accepted.

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 packaging material HDPE tested in the 2 storage stability study has been approved and is suitable for the storage of the plant protection product.
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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
Shape/size:	rectangular / approx. 370 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	CA3301 – Effectiveness of Cleaning, Calvert A., 2022, 22/1499
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: CA3301
Batch: A21001
Purity: 258 g/L

Tank Mix Preparation

A test item solution at the maximum intended use concentration (0.80% 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 (23 h).

The initial active substance content was determined from the remaining tank mix solution, 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 100 ml in volumetric flasks with acetonitrile.

Cleaning out Procedure (Triple Rinse)

After standing overnight (~22 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 Prothioconazole removed by the triple rinse procedure was then calculated:

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

Component	Mean amount prothioconazole in initial 100 mL tank mix sample (mg)	Total Prothioconazole recovered after cleaning procedure (mg)	% Removed	Mean % Removed
Prothioconazole	191.863	0.03707	99.9807	99.9891
		0.03711	99.9807	
		0.01516	99.9921	
		0.01529	99.9920	
		0.01038	99.9946	
		0.01024	99.9947	

Conclusion

The mean % of prothioconazole removed after following the triple rinse cleaning procedure with water was 99.989% (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	Ge, H.	2019a	Physical and Chemical Characterization of Prothioconazole 250 EC, NUL 3390 (CA3301) Report no.: ABC-2019-024 Achiever Biochem Co., Ltd. GLP Unpublished	N	Nufarm
KCP 2.1/02	Ge, H.	2019b	Determination of Storage Stability and Corrosion Characteristics of Prothioconazole 250 EC, NUL 3390 (CA3301) Report no.: ABC-2019-027 Achiever Biochem Co., Ltd. GLP Unpublished	N	Nufarm
KCP 2.2/01 (submitted with confidential JK-CP)	Hoque, A. & Michelet, D.	2021	Literature review on oxidising properties of the ingredients of the product CA3301 Staphyt Regulatory Report no. 21/133 Non-GLP Unpublished	N	Nufarm
KCP 2.5.1	Sowle, J.	2022	Analysis of CA3301 (NUL 3390) containing 250 g/L Prothioconazole EC formulation, in Compliance with Good Laboratory Practice Report no.: DNA6709 DNAL David Norris Analytical Laboratories Ltd. GLP Unpublished	N	Nufarm
KCP 2.7.4/01	Ge, H.	2019c	Determination of Storage Stability at 0 °C of Prothioconazole 250 EC, NUL 3390 (CA3301) Report no.: ABC-2019-028 Achiever Biochem Co., Ltd. GLP Unpublished	N	Nufarm
KCP 2.7.5/01	Wang, Q.	2021	Determination of Storage Stability and Corrosion Characteristics of Prothioconazole 250 EC, NUL 3390 (CA3301) Report no.: ABC-2019-026 Achiever Biochem Co., Ltd. GLP Unpublished	N	Nufarm

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 4.2.2/01	Calvert A.	2022	CA3301 – Effectiveness of Cleaning Report No. 22/1499 Nufarm UK Limited 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.