

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: A23282A

Product name: **KAYAK ERA**

Chemical active substances:

Cyprodinil, 225 g/L

Prothioconazole, 75 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(New product authorization)

Applicant: XXXX

Submission date: July 2022

Evaluation date: March 2023

MS Finalisation date: December 2023

Version history

When	What
March 2023	Version evaluated by PL zRMS
October 2023	Version amended by Applicant (XXXX) by adding storage stability data (2 years at at 20°C) - Section 2, Table 2-1, Appendix 1, Appendix 4 by deleting an erroneously reported table in section 1.2.3 by correcting the intended concentration of use under section 2 All changes are highlighted in yellow and deletion are strikethrough
December 2023	Version taking into account comments of cMSs and the applicant

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1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: XXXX

Contact: XXXX

Telephone no.: XXXX

E-mail: XXXX

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

1.2.1 Producer(s) of the preparation

Name: XXXX

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

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

Cyprodinil

Name: XXXX

Prothioconazole

Name: XXXX

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 Cyprodinil

Test Substance	EU agreed minimum purity Reference: IMPLEMENTING REGULATION (EU) 540/2011
Cyprodinil	≥ 980 g/kg

Test Substance	MINISTERE DE L'AGRICULTURE ET DE L'ALIMENTATION, 21 OCT 2009 *
Cyprodinil	≥ 990 g/kg

* considering the equivalence evaluation by AFSSA 2009-0389 spe (06/07/2009)

Pure Cyprodinil in A23282A

content of pure active substance:	225 g/L	22.7 % w/w*
limits:**	211.5 – 238.5 g/L	21.3 - 24.0 % w/w*

Technical Cyprodinil in A23282A

at a minimum purity of the technical active substance of 98.0 % w/w.		
content of technical active substance:	229.6 g/L	23.1 % w/w*
limits:**	215.8 – 243.4 g/L	21.7 – 24.5 % w/w*

* Based on the density of the formulation = 0.993 g/cm³

** FAO limits calculated based on the ±6% of the declared content, according to the Manual on development and use of FAO and WHO specifications for pesticides (First edition-third revision March 2016)

1.2.3.2 Prothioconazole

Test Substance	EU agreed minimum purity Reference: IMPLEMENTING REGULATION (EU) 540/2011
Prothioconazole	≥ 970 g/kg
Toluene	< 5 g/kg (< 0.4 g/kg in A23282A)
Prothioconazole-desthio (2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1,2,4-triazol-1-yl)-propan-2-ol)	< 0.5 g/kg (LOD) (< 0.4 g/kg in A23282A)

Pure Prothioconazole in A23282A

content of pure active substance:	75.0 g/L	7.6 % w/w*
limits:**	67.5 – 82.5 g/L	6.8 – 8.3 % w/w*

Technical Prothioconazole in A23282A

at a minimum purity of the technical active substance of 97.0 % w/w.		
content of technical active substance:	77.3 g/L	7.8 % w/w*
limits:**	69.6 – 85.0	7.0 – 8.6 % w/w*

* Based on the density of the formulation = 0.993 g/cm³

** FAO limits calculated based on the ±10% of the declared content, according to the Manual on development and use of FAO and WHO specifications for pesticides (First edition-third revision March 2016)

Table 1.2-1: Relevant impurities

Relevant impurity	Maximum content in formulation A23109A
2,6 dimethylphenylamine	≤ 0.09 g/kg
4 methoxy 5 methyl 5H [1,2]oxathiole 2,2 dioxide	≤ 0.18 g/kg
2-[(2,6 dimethyl phenyl) (2 methoxyacetyl) amino] propionic acid 1 methoxycarbonyl ethyl ester [†]	≤ 0.03 g/kg

An assessment of equivalence is not required since sources for the active substances have been approved previously.

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

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

Trade name: KAYAK ERA

Company code number: A23282A

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)

The product A23282A was not evaluated previously as a representative formulation (same uses and same GAPs) during the EU review of the active substances Cyprodinil and Prothioconazole.

The content of Cyprodinil and Prothioconazole is given under point 1.2.3

The maximum amount of relevant impurities has been addressed in point 1.2.3

Information on the variants is addressed under point 1.4.2

Information on the formulants including safeners and synergists is confidential and is included in **Part C (Confidential information)**.

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

Table 1.4-1: Information on Cyprodinil

Type	Name/Code Number	
ISO common name	Cyprodinil	Variant: not relevant
CAS No.	121522-61-2	
EC No.	601-785-8	
CIPAC No.	511	

Table 1.4-2: Information on Prothioconazole

Type	Name/Code Number	
ISO common name	Prothioconazole	Variant: not relevant
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)

CONFIDENTIAL information is provided separately (Part C).

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 a yellow, clear liquid, with a slight chemical odour. It is not explosive, has no oxidising properties. The product has a flash point of $128 \pm 6^{\circ}\text{C}$. It has an auto ignition temperature of $365 \pm 11^{\circ}\text{C}$. In aqueous solution, it has a pH value around 6.6 at 23°C . There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C , 14 and 28 days at 54°C , neither the active ingredient content nor the technical properties were changed. The stability data derived from accelerated storage stability studies and the storage stability study over 2 years at 20°C indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE packaging. Its technical characteristics are acceptable for an EC formulation. ~~A storage stability study at ambient temperature over 2 years has been however started, and a final report will be available by end of October 2023.~~ The content of the relevant impurity Prothioconazole-desthio (2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1,2,4-triazol-1-yl)-propan-2-ol) was not exceeding the allowed limit after storage over 2 years at ambient temperature.

The intended concentration of use is 0.38 4.5% to 2 8% v/v.

The product A23282A is not recommended as tank mix.

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

According to Regulation (EC) No. 1272/2008 no specific labelling or classification is proposed based on the measured physico-chemical properties of A23282A.

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 A23282A.

Compliance with FAO specifications:

There is no FAO specification for A23282A.

Formulation used for tests

Physico-chemical studies have been conducted with the A23282A (batch LCR001-021-001)

The detailed composition of A23282A is shown in the **Confidential Part C**

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

All tests have been performed under GLP, except where mentioned.

All tests were conducted using material from batches:

Batch LCR001-021-001 (A23282A) containing a mean of 22.1 % w/w (corresponding to 219 g/L) Cyprodinil and 7.40 % w/w (corresponding to 73.5 g/L) Prothioconazole (*Mink C., 2021, VV-928679, Cyprodinil/Prothioconazole A23282A – Chemical Characterization of Batch LCR001-021-001*)

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Visual and organoleptic assessment	Batch: LCR001-021-001 Cyprodinil: 22.1 % w/w Prothioconazole: 7.40 % w/w	Colour: Yellow Physical State: Liquid Appearance: Clear Odor: Slight chemical	Y	<i>Fumeaux J. 2021</i> <i>VV-928681</i>	Accepted
Explosive properties (KCP 2.2.1)	ASTM E537 (Differential Scanning Calorimetry)	Batch: LCR001-021-001 Cyprodinil: 22.1 % w/w Prothioconazole: 7.40 % w/w	Heat of Decomposition: 140 J/g The heat of decomposition is less than 500 J/g, in which case no further testing is necessary. Not classified as an explosive substance.	Y	<i>Jackson W. 2021</i> <i>VV-928682</i>	Accepted
Oxidizing properties (KCP 2.2.2)	Theoretical assessment	-	An examination of the structures of the active ingredients, cyprodinil and prothioconazole, shows that they do not contain bond groupings associated with oxidizing properties. Although prothio-conazole contains oxygen and chlorine atoms, these are bonde only to carbon or hydrogen. The rest of the formulation consists of common chemicals or commercially available products which are known not to possess oxidizing properties. Not classified as an oxidizing substance	Y	<i>Jackson W. 2021</i> <i>VV-928682</i>	Accepted
Flash point (KCP 2.3.1)	ASTM D3828 (Setaflash) closed cup testing	Batch: LCR001-021-001 Cyprodinil: 22.1 % w/w Prothioconazole: 7.40 % w/w	128 ± 6°C The test substance is not classified as a flammable liquid in terms of its flash point.	Y	<i>Jackson W. 2021</i> <i>VV-928682</i>	Accepted
Flammability (KCP 2.3.2)	ASTM D3828 (Setaflash) closed cup testing	Batch: LCR001-021-001 Cyprodinil: 22.1 % w/w Prothioconazole: 7.40 % w/w	The test substance is not classified as a flammable liquid in terms of its flash point.	Y	<i>Jackson W. 2021</i> <i>VV-928682</i>	Accepted
Self-heating (KCP 2.3.3)	ISO/IEC 80079-20-1	Batch: LCR001-021-001 Cyprodinil: 22.1 % w/w Prothioconazole: 7.40 % w/w	Auto-Ignition Temperature: 365 ± 11°C	Y	<i>Jackson W. 2021</i> <i>VV-928682</i>	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 191	Batch: LCR001-021-001 Cyprodinil: 22.1 % w/w Prothioconazole: 7.40 % w/w	0.01 % w/w (calculated as H ₂ SO ₄)	Y	<i>Fumeaux J</i> <i>2021</i> <i>VV-928678</i>	Accepted
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Batch: LCR001-021-001 Cyprodinil: 22.1 % w/w Prothioconazole: 7.40 % w/w	1 % w/v in deionized water at 23°C: pH = 6.6	Y	<i>Fumeaux J.</i> <i>2021</i> <i>VV-928681</i>	Accepted
Viscosity (KCP 2.5.1)	OECD 114	Batch: LCR001-021-001 Cyprodinil: 22.1 % w/w Prothioconazole: 7.40 % w/w	Shear rate: Ramped down from 100 s ⁻¹ to 20 s ⁻¹ : Mean η = 71.8 mPa.s (at 20°C) Mean η = 25.0 mPa.s (at 40°C) The viscosity is not significantly depending on the shear rate The test item can be considered as a Newtonian liquid. Kinematic viscosity The kinematic viscosity was calculated (d=0.993 g/cm ³) At 20°C with shear rate 100-200 s ⁻¹ : 72.3 mm ² /s At 40°C with shear rate 100-200 s ⁻¹ : 25.2 mm ² /s Equipment The test was performed using the “Brookfield Engineering Labs” Viscometer (Model: DV-II+ Pro) with the “Small Sample Adapter” DIN-82. The shear rate was ramped down from 200 to 100 s ⁻¹	Y	<i>Fumeaux J</i> <i>2021</i> <i>VV-928678</i>	Accepted
Surface tension (KCP 2.5.2)	EEC A.5	Batch: LCR001-021-001 Cyprodinil: 22.1 % w/w Prothioconazole: 7.40 % w/w	30.20 mN/m (0.25 % w/v in pure water at 20°C) 28.91 mN/m (2.00% w/v in pure water at 20°C) 27.56 mN/m (undiluted at 25°C) According to EEC guideline A.5 the preparation should be classified as a surface active material.	Y	<i>Fumeaux J</i> <i>2021</i> <i>VV-928678</i>	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Relative density (KCP 2.6.1)	OECD 109 (Oscillating density meter)	Batch: LCR001-021-001 Cyprodinil: 22.1 % w/w Prothioconazole: 7.40 % w/w	0.993 g/cm ³ at 20°C	Y	<i>Mink C. 2021 VV-928679</i>	Accepted
Bulk density (KCP 2.6.2)	Not applicable as this is only required for a liquid formulation.					
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.4	Batch: LCR001-021-001 Cyprodinil: 22.1 % w/w Prothioconazole: 7.40 % w/w	The formulation undergoes no significant physical or chemical change in the packaging material HDPE with regards to content of the active substances and relevant impurity prothioconazole-desthio, colour, odour, physical state, appearance, pH value, density and emulsion characteristics. For detailed results see Appendix 3.	Y	<i>Fumeaux J. 2021 VV-928681</i>	Accepted The analytical method SF-1115/1 used for analysing Cyprodinil and Prothioconazole content in this PPP was assessed and accepted in Part B Section 5.
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	CIPAC MT 46.4	Batch: LCR001-021-001 Cyprodinil: 22.1 % w/w Prothioconazole: 7.40 % w/w	The formulation undergoes no significant physical or chemical change during storage at 54°C for 4 weeks in the packaging material HDPE with regards to content of the active substances and relevant impurity prothioconazole-desthio, colour, odor, physical state, appearance, pH value, density and emulsion characteristics. For detailed results see Appendix 3.	Y	<i>Fumeaux J. 2021 VV-928681</i>	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Minimum content after heat stability testing (KCP 2.7.3)	Analytical method SF-1115/1	Batch: LCR001-021-001 Cyprodinil: 22.1 % w/w Prothioconazole: 7.40 % w/w	The active substance content did not decline to less than 95 % of the initial content. Packaging material: HDPE For detailed results see Appendix 3.	Y	<i>Fumeaux J. 2021 VV-928681</i>	Accepted The analytical method SF-1115/1 used for analysing Cyprodinil and Prothioconazole content in this PPP was assessed and accepted in Part B Section 5.
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC 39.3	Batch: LCR001-021-001 Cyprodinil: 22.1 % w/w Prothioconazole: 7.40 % w/w	After storage of 7 days at 0°C ± 2°C no separation was observed. After allowing the test item to reach room temperature over a period of 24 h and inverting once no separation was observed.	Y	<i>Fumeaux J. 2021 VV-928678</i>	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Ambient temperature shelf life (KCP 2.7.5)	-	-	<p>In accordance with international guidelines, extrapolation of the chemical, physico-chemicals and packaging properties after storage for 2 weeks at 54°C indicate that for a period of at least two years the product remains suitable for use and continues to comply with the specification.</p> <p>Extrapolation of the chemical, physico-chemical and packaging properties after storage for 4 weeks at 54°C further confirms, that for a period of at least two years the product remains suitable for use and continues to comply with the specification, if stored in an unopened original container, away from direct sunlight and following the product instructions during transport and storage.</p> <p>A storage stability study at ambient temperature has been initiated, and the respective report will be available by end of October 2023.</p>	Y	Fumeaux J. 2021 VV-928681	<p>On-going</p> <p>This study has to be assessed when available in post registration.</p> <p>Accepted</p> <p>All the physicochemical parameters tested before and after storage were accepted. The HDPE packaging remained intact after storage. In summary, the two-year shelf life can be granted for the PPP</p> <p>The analytical methods SF-1115/1 and SD-2433/1 are accepted in Part B Section 5.</p> <p>Nevertheless, the relevant impurities cannot be forming under the storage conditions. They are coming from the technical materials.</p>
		<p>Batch: LCR001-021-001 Cyprodinil: 22.1 % w/w Prothioconazole: 7.40 % w/w</p>	<p>Storage over 2 years at 20°C: The formulation is physically and chemically stable after storage for two years at 20°C in the following packaging material: -High density polyethylene pack (HDPE)</p> <p>The content of the relevant impurity Prothioconazole-desthio (2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1,2,4-triazol-1-yl)-propan-2-ol) was not exceeding the allowed limit after storage over 2 years at ambient</p> <p>For full details, please see Appendix 4</p> <p>Findings of the present ambient study confirms a shelf life of at least 2 years.</p>	Y	Fumeaux J. 2023 VV-1010627	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Shelf life in months (if less than 2 years) (KCP 2.7.6)	Please refer to KCP 2.7.5.					
Wettability (KCP 2.8.1)	Not required, formulation is a liquid.					
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	Batch: LCR001-021-001 Cyprodinil: 22.1 % w/w Prothioconazole: 7.40 % w/w	0.25 % w/v in CIPAC water D: After 1 minute: 4 mL After 12 minutes: 2 mL 2.00 % w/v in CIPAC water D: After 1 minute: 2 mL After 12 minutes: 0mL	Y	<i>Fumeaux J. 2021 VV-928681</i>	Accepted
Suspensibility (KCP 2.8.3.1)	Not applicable as this is not required for EC formulation.					
Spontaneity of dispersion (KCP 2.8.3.2)	Not applicable as this is not required for EC formulation.					
Dispersion stability (KCP 2.8.3.3)	Not applicable as this is not required for EC formulation.					
Degree of dissolution and dilution stability (KCP 2.8.4)	Not applicable as this is only required for water soluble formulations.					
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	Not applicable as this is not required for EC formulation.					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Wet sieve test (KCP 2.8.5.1.2)	Not applicable as this is not required for EC formulation.					
Dust content (KCP 2.8.5.2.1)	Not required, formulation is not a powder or granule.					
Particle size of dust (KCP 2.8.5.2.2)	Not required, formulation is not a powder or granule.					
Attrition (KCP 2.8.5.3)	Not required, formulation is not a powder or granule.					
Hardness and integrity (KCP 2.8.5.4)	Not applicable as this is only required for tablet formulations.					

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments																					
Emulsifiability (KCP 2.8.6.1) Emulsion stability (KCP 2.8.6.2) Re-emulsifiability (KCP 2.8.6.3)	CIPAC MT 36.3	Batch: LCR001-021-001 Cyprodinil: 22.1 % w/w Prothioconazole: 7.40 % w/w	0.25 % v/v (at 30°C): <table><tr><td></td><td>CIPAC water A</td><td>CIPAC water D</td></tr><tr><td>Initial Emulsification</td><td>Spontaneous</td><td>Spontaneous</td></tr><tr><td>After 0.5 h</td><td>No cream; No oil</td><td>No cream; No oil</td></tr><tr><td>After 2 h</td><td>No cream; No oil</td><td>No cream; No oil</td></tr><tr><td>After 24 h</td><td>No cream; No oil</td><td>No cream; No oil</td></tr><tr><td>Re-emulsification after 24 h</td><td>Complete</td><td>Complete</td></tr><tr><td>0.5 h after Re-emulsification</td><td>No cream; No oil</td><td>No cream; No oil</td></tr></table>				CIPAC water A	CIPAC water D	Initial Emulsification	Spontaneous	Spontaneous	After 0.5 h	No cream; No oil	No cream; No oil	After 2 h	No cream; No oil	No cream; No oil	After 24 h	No cream; No oil	No cream; No oil	Re-emulsification after 24 h	Complete	Complete	0.5 h after Re-emulsification	No cream; No oil	No cream; No oil	Y	<i>Fumeaux J. 2021 VV-928681</i>	Accepted
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Initial Emulsification	Spontaneous	Spontaneous																											
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Re-emulsification after 24 h	Complete	Complete																											
0.5 h after Re-emulsification	No cream; No oil	No cream; No oil																											
2.00 % v/v (at 30°C): <table><tr><td></td><td>CIPAC water A</td><td>CIPAC water D</td></tr><tr><td>Initial Emulsification</td><td>Spontaneous</td><td>Spontaneous</td></tr><tr><td>After 0.5 h</td><td>No cream; No oil</td><td>No cream; No oil</td></tr><tr><td>After 2 h</td><td>< 1 mL cream at the top; No oil</td><td>No cream; No oil</td></tr><tr><td>After 24 h</td><td>1 mL cream at the top; No oil</td><td>< 1 mL cream at the top; < 1 mL oil at the top</td></tr><tr><td>Re-emulsification after 24 h</td><td>Complete</td><td>Complete</td></tr><tr><td>0.5 h after Re-emulsification</td><td>No cream; No oil</td><td>No cream; No oil</td></tr></table>				CIPAC water A	CIPAC water D	Initial Emulsification	Spontaneous	Spontaneous	After 0.5 h	No cream; No oil	No cream; No oil	After 2 h	< 1 mL cream at the top; No oil	No cream; No oil	After 24 h	1 mL cream at the top; No oil	< 1 mL cream at the top; < 1 mL oil at the top	Re-emulsification after 24 h	Complete	Complete	0.5 h after Re-emulsification	No cream; No oil	No cream; No oil						
	CIPAC water A	CIPAC water D																											
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0.5 h after Re-emulsification	No cream; No oil	No cream; No oil																											

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments																					
	CIPAC MT 36.3	Batch: LCR001-021-001 Cyprodinil: 22.1 % w/w Prothioconazole: 7.40 % w/w	0.25 % v/v (at 30°C): <table><tr><td></td><td>CIPAC water A</td><td>CIPAC water D</td></tr><tr><td>Initial Emulsification</td><td>Spontaneous</td><td>Spontaneous</td></tr><tr><td>After 0.5 h</td><td>No cream; No oil</td><td>No cream; No oil</td></tr><tr><td>After 2 h</td><td>No cream; No oil</td><td>No cream; No oil</td></tr><tr><td>After 24 h</td><td>No cream; No oil</td><td>No cream; No oil</td></tr><tr><td>Re-emulsification after 24 h</td><td>Complete</td><td>Complete</td></tr><tr><td>0.5 h after Re-emulsification</td><td>No cream; No oil</td><td>No cream; No oil</td></tr></table>				CIPAC water A	CIPAC water D	Initial Emulsification	Spontaneous	Spontaneous	After 0.5 h	No cream; No oil	No cream; No oil	After 2 h	No cream; No oil	No cream; No oil	After 24 h	No cream; No oil	No cream; No oil	Re-emulsification after 24 h	Complete	Complete	0.5 h after Re-emulsification	No cream; No oil	No cream; No oil	Y	<i>Fumeaux J 2021 VV-928678</i>	Accepted
	CIPAC water A	CIPAC water D																											
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After 0.5 h	No cream; No oil	No cream; No oil																											
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After 24 h	No cream; No oil	No cream; No oil																											
Re-emulsification after 24 h	Complete	Complete																											
0.5 h after Re-emulsification	No cream; No oil	No cream; No oil																											
2.00 % v/v (at 30°C): <table><tr><td></td><td>CIPAC water A</td><td>CIPAC water D</td></tr><tr><td>Initial Emulsification</td><td>Spontaneous</td><td>Spontaneous</td></tr><tr><td>After 0.5 h</td><td>No cream; No oil</td><td>No cream; No oil</td></tr><tr><td>After 2 h</td><td>< 1 mL cream at the top; No oil</td><td>No cream; No oil</td></tr><tr><td>After 24 h</td><td>< 1 mL cream at the top; No oil</td><td>< 1 mL cream at the top; < 1 mL oil at the top</td></tr><tr><td>Re-emulsification after 24 h</td><td>Complete</td><td>Complete</td></tr><tr><td>0.5 h after Re-emulsification</td><td>No cream; No oil</td><td>No cream; No oil</td></tr></table>				CIPAC water A	CIPAC water D	Initial Emulsification	Spontaneous	Spontaneous	After 0.5 h	No cream; No oil	No cream; No oil	After 2 h	< 1 mL cream at the top; No oil	No cream; No oil	After 24 h	< 1 mL cream at the top; No oil	< 1 mL cream at the top; < 1 mL oil at the top	Re-emulsification after 24 h	Complete	Complete	0.5 h after Re-emulsification	No cream; No oil	No cream; No oil						
	CIPAC water A	CIPAC water D																											
Initial Emulsification	Spontaneous	Spontaneous																											
After 0.5 h	No cream; No oil	No cream; No oil																											
After 2 h	< 1 mL cream at the top; No oil	No cream; No oil																											
After 24 h	< 1 mL cream at the top; No oil	< 1 mL cream at the top; < 1 mL oil at the top																											
Re-emulsification after 24 h	Complete	Complete																											
0.5 h after Re-emulsification	No cream; No oil	No cream; No oil																											
Flowability (KCP 2.8.7.1)	Not applicable as this is only required for granular formulations.																												

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Pourability (KCP 2.8.7.2)	Not applicable as this is not required for EC formulation.					
Dustability following accelerated storage (KCP 2.8.7.3)	Not applicable as this is only required for dustable powders.					
Physical compatibility of tank mixes (KCP 2.9.1)	Not applicable since it is not foreseen to mix the formulated product A8272C with other products.					
Chemical compatibility of tank mixes (KCP 2.9.2)	Not applicable since it is not foreseen to mix the formulated product A8272C with other products.					
Adhesion to seeds (KCP 2.10.1)	Not required, formulation is not being used for seed treatment.					
Distribution to seed (KCP 2.10.2)	Not required, formulation is not being used for seed treatment.					
Other/special studies (KCP 2.11)	CIPAC MT 30.6	Batch: LCR001-021-001 Cyprodinil: 22.1 % w/w Prothioconazole: 7.40 % w/w	<u>Water content:</u> 0.23 % w/w	Y	<i>Mink C.</i> <i>2021</i> <i>VV- 928679</i>	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	Analytical method SD-2433/1	Batch: LCR001-021-001 Cyprodinil: 22.1 % w/w Prothioconazole: 7.40 % w/w	<u>Content of the relevant impurity Prothioconazole-desthio (EXC5578):</u> < 15 mg/L, corresponding to < 0.02 g/kg in formulation Due to the sensitivity to light, all test- and spiked test solutions must be handled in dark vials.	Y	Mink C. 2021 VV-928680	Accepted The accelerated storage stability study was done using a HDPE packaging. The relevant impurities cannot be forming under the storage conditions. They are coming from the technical material
	Effectiveness Spray Tank Cleaning Procedure	Batch: LCR001-021-001 Cyprodinil: 22.1 % w/w Prothioconazole: 7.40 % w/w	Tests have been carried out to determine the effectiveness of the tank cleaning procedure for A23282A (cyprodinil/prothioconazole EC (225/ 075)). After applying the cleaning procedure, < 0.01 % residue was found in the refilled spray tank. The results show that the rinsing procedure sufficiently reduced the amount of residue in the spray tank.	Y	Fumeaux J. 2021 VV-928728	Accepted
	Procedures for Cleaning Application Equipment	-	Immediately after use, clean the spray equipment thoroughly. Drain the system competely and rinse spray tank, boom an nozzles two to three times with clean water until the foam and all traces of the formulation have been removed.	N	Fumeaux J. 2021 VV-928730	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	Procedures for Destruction or Decontamination of the Plant Protection Product and its Packaging	-	<p><u>Neutralisation procedures for use in the event of accidental spillage</u></p> <p>In the event of accidental spillage, neutralisation (with acids or bases to neutral pH) is not an effective procedure for the destruction or decontamination of A23282A. Therefore, the spilled liquid formulation should first be adsorbed onto a solid, such as sand, inert clay filler, saw dust or soil, before being swept up into a safe container to await disposal.</p> <p><u>Controlled indineration</u></p> <p>The halogen content of prothioconazole, which is an active substance in the A23282A formulation, is 20.6 %. Cyprodinil, which is the second active in the A23282A formulation, does not contain halogen. Conclusion: The halogen content of the active ingredients in the formulation is well below 60 % limit. Therefore, the product A23282A can be disposed of safely by incinerator, licensed to treat contamination waste, which fulfils the following conditions: temperature at least 800°C, minimum residence time within the incinerator of 2 seconds and equipped with a washing unit for flue gases. The ashes have to be disposed of at a suitable, approved waste disposal site. The wash water has to be disposed of by means of a suitable waste water treatment plant.</p> <p><u>Disposal of Contaminated Packaging and Wastes</u></p> <p>The recommended method to dispose of contaminated packaging and waste is the incineration. Consult the supplier where bigger quantities have to be disposed of.</p>	N	<i>Fumeaux J. 2021 VV-928729</i>	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

RMS comment:

Based on the accelerated study, and the two-year study all the proposed packaging made of HDPE are accepted

Table 1.6-1: Packaging information for 250 mL canister

Type	Description
Material:	high density polyethylene (HDPE)
Shape/size:	canister / diameter 63 mm, height 130 mm
Opening , closure and seal:	Screw cap closure (45 mm diameter) with induction heat seal or compression wad and tamper evident ring.
Manner of construction	extruded
UN/ADR	compliant

Table 1.6-2: Packaging information for 500 mL canister

Type	Description
Material:	high density polyethylene (HDPE)
Shape/size:	canister / diameter 76 mm, height 170 mm
Opening , closure and seal:	Screw cap closure (45 mm diameter) with induction heat seal or compression wad and tamper evident ring.
Manner of construction	extruded
UN/ADR	compliant

Table 1.6-3: Packaging information for 1 L canister

Type	Description
Material:	high density polyethylene (HDPE)
Shape/size:	canister / diameter 89 mm, height 232 mm
Opening , closure and seal:	Screw cap closure (63 mm diameter) with induction heat seal or compression wad and tamper evident ring.
Manner of construction	extruded
UN/ADR	compliant

Table 1.6-4: Packaging information for 5 L canister

Type	Description
Material:	high density polyethylene (HDPE)
Shape/size:	canister / 189 mm x 137 mm x 324 mm (Length x Width x Height)
Opening , closure and seal:	Screw cap closure (63 mm diameter) with induction heat seal or compression wad and tamper evident ring.
Manner of construction	extruded
UN/ADR	compliant

Table 1.6-5: Packaging information for 10 L canister

Type	Description
Material:	high density polyethylene (HDPE)
Shape/size:	canister / 226 mm x 186 mm x 409 mm (Length x Width x Height)
Opening , closure and seal:	Screw cap closure (63 mm diameter) with induction heat seal or compression wad and tamper evident ring.
Manner of construction	extruded
UN/ADR	compliant

Table 1.6-6: Packaging information for 20 L canister

Type	Description
Material:	high density polyethylene (HDPE)
Shape/size:	canister / 293 mm x 245 mm x 400 mm (Length x Width x Height)
Opening , closure and seal:	Screw cap closure DIN 60 with induction heat seal or compression wad and tamper evident ring
Manner of construction	extruded
UN/ADR	compliant

The packaging for the product A23282A is in compliance with all relevant UN and ADR requirements.

Stability of the packaging material has been tested during the storage stability study done according to GIFAP monograph 17.

No significant adverse effects of the product to the stability of the packaging material have been noticed. It is concluded the packaging material will be fully resistant to the product A23282A for up to 2 years under normal storage conditions. For detailed results see Appendix 3.

A storage stability study at ambient temperature has been initiated, and the respective report will be available by end of October 2023.

Please refer to Registration Report Part A for country specific packaging.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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
XXXX	XXX	XXX	XXXX	XX	XX

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
n/a					

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

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

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

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

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

No additional data have been generated on the active substances cyprodinil and prothioconazole.

Appendix 3 Storage stability data before and after storage at 54°C in HDPE packaging

Table A 1: Content of active substances and relevant impurity before and after storage at 54°C in HDPE packaging (XXXX File No. VV-928681)

Active Substance	Initial	2 weeks		4 weeks	
		Control sample below -10°C	Test sample at 54°C	Control sample below -10°C	Test sample at 54°C
Cyprodinil	22.1 % w/w corresponding to 219 g/L	21.8 % w/w corresponding to 216 g/L	21.9 % w/w corresponding to 217 g/L	21.9 % w/w corresponding to 217 g/L	21.8 % w/w corresponding to 216 g/L
Prothioconazole	7.40 % w/w corresponding to 73.5 g/L	7.37 % w/w corresponding to 73.1 g/L	7.31 % w/w corresponding to 72.6 g/L	7.38 % w/w corresponding to 73.2 g/L	7.27 % w/w corresponding to 72.2 g/L
Relevant Impurity	Initial	Control sample below -10°C	Test sample at 54°C	Control sample below -10°C	Test sample at 54°C
Prothioconazole-desthio (EXC5578)	< 15 mg/L ¹ corresponding to < 0.02 g/kg ²	< 15 mg/L ¹ corresponding to < 0.02 g/kg ²	< 22 mg/L ¹ corresponding to < 0.03 g/kg ²	< 15 mg/L ¹ corresponding to < 0.02 g/kg ²	34 mg/L ¹ corresponding to 0.05 g/kg ²

¹ Based on the formulation

² Relative to prothioconazole content

All the values for prothioconazole-desthio are well below the limit of 0.5 g/kg relative to the prothioconazole content.

Table A 2: Physical and technical properties before and after storage at 54°C in HDPE packaging (XXXX File No VV-928681)

Test Description	Method	Initial Results	Results after 2 weeks at 54 °C	Results after 4 weeks at 54 °C
Color	Visual	Yellow	Yellow	Yellow
Odor	Organoleptic	Slight chemical	Slight chemical	Slight chemical
Physical State	Visual	Liquid	Liquid	Liquid
Appearance	Visual	Clear	Clear	Clear
pH Value Concentration: 1% Deionized Water	CIPAC MT 75.3	6.6	6.6	6.7
Relative Density Temperature: 20°C	OECD 109	0.993 g/cm ³	0.993 g/cm ³	0.993 g/cm ³

Test Description	Method	Initial Results	Results after 2 weeks at 54 °C	Results after 4 weeks at 54 °C
Emulsion Characteristics and Re-Emulsification Properties Concentration: 0.25 % CIPAC water A Temperature: 30°C Initial Emulsification Emulsion stability: After 0.5 h After 2 h After 24 h Re-emulsification after 24 h Emulsion stability 0.5 h after Re-emulsification	CIPAC MT 36.3	Spontaneous no cream, no oil no cream, no oil no cream, no oil Complete no cream, no oil	Spontaneous no cream, no oil no cream, no oil no cream, no oil Complete no cream, no oil	Spontaneous no cream, no oil no cream, no oil no cream, no oil Complete no cream, no oil
Emulsion Characteristics and Re-Emulsification Properties Concentration: 0.25 % CIPAC water D Temperature: 30°C Initial Emulsification Emulsion stability: After 0.5 h After 2 h After 24 h Re-emulsification after 24 h Emulsion stability 0.5 h after Re-emulsification	CIPAC MT 36.3	Spontaneous no cream, no oil no cream, no oil no cream, no oil Complete no cream, no oil	Spontaneous no cream, no oil no cream, no oil no cream, no oil Complete no cream, no oil	Spontaneous no cream, no oil no cream, no oil no cream, no oil Complete no cream, no oil
Emulsion Characteristics and Re-Emulsification Properties Concentration: 2.00 % CIPAC water A Temperature: 30°C Initial Emulsification Emulsion stability: After 0.5 h After 2 h After 24 h Re-emulsification after 24 h Emulsion stability 0.5 h after Re-emulsification	CIPAC MT 36.3	Spontaneous no cream, no oil < 1 mL cream at the top, no oil 1 mL cream at the top, no oil Complete no cream, no oil	Spontaneous no cream, no oil no cream, no oil < 1 mL cream at the top, no oil Complete no cream, no oil	Spontaneous no cream, no oil no cream, no oil < 1 mL cream at the top, no oil Complete no cream, no oil

Test Description	Method	Initial Results	Results after 2 weeks at 54 °C	Results after 4 weeks at 54 °C
Emulsion Characteristics and Re-Emulsification Properties Concentration: 2.00 % CIPAC water D Temperature: 30°C Initial Emulsification Emulsion stability: After 0.5 h After 2 h After 24 h Re-emulsification after 24 h Emulsion stability 0.5 h after Re-emulsification	CIPAC MT 36.3	Spontaneous no cream, no oil no cream, no oil < 1 mL cream at the top, < 1 mL oil at the top Complete no cream, no oil	Spontaneous no cream, no oil no cream, no oil < 1 mL cream at the top, no oil Complete no cream, no oil	Spontaneous no cream, no oil no cream, no oil < 1 mL cream at the top, no oil Complete no cream, no oil

Table A 3: Packaging Evaluation after storage at 54°C in HDPE packaging (XXXX File No. VV-928681)

Evaluation Criteria	Results after 2 weeks at 54 °C	Results after 4 weeks at 54 °C
Color change of the packaging	None	None
Odor (noticeable before opening the packaging)	None	None
Panelling of the test container	Weak panelling	Panelling
Ballooning of the test container	None	None
Pimples on the test container	None	None
Cracks in the test container	None	None
Tightness of the test container	Tight	Tight
Reclosability of closure	Reclosable	Reclosable
Tightness of closure	Tight	Tight
Weight change (gross weight)	0.2 % weight loss	0.05 % weight loss
Permeation through the container walls	None	None

RMS conclusion:

This accelerated study meets all the requirements and is accepted

Appendix 4 Storage stability data before and after storage over 2 years at 20°C in HDPE packaging

Table A 4: Content of active substances before and after storage over 2 years at 20°C in HDPE packaging (VV-1010627)

Active Ingredient	Initial	2 years below -10 °C (control sample)	2 years 20 °C (test sample)
cyprodinil	22.1 % w/w corresponding to 219 g/l	22.0 % w/w corresponding to 218 g/l	22.0 % w/w corresponding to 218 g/l
prothioconazole	7.40 % w/w corresponding to 73.5 g/l	7.32 % w/w corresponding to 72.7 g/l	7.26 % w/w corresponding to 72.1 g/l

Observations and Conclusion

All the values are well within the analytical error and show no decomposition.

Table A 5: Physical and technical properties before and after storage over 2 years at 20°C in HDPE packaging (VV-1010627)

Test Description	Method	Initial Results	Results after 2 years 20 °C
Color	Visual	yellow	yellow
Odor	Organoleptic	slight chemical	slight chemical
Physical State	Visual	liquid	liquid
Appearance	Visual	clear	clear
pH Value Concentration: 1 % Deionized Water	CIPAC MT 75.3	6.6	6.6
Density Temperature: 20 °C	OECD 109	0.993 g/cm ³	0.993 g/cm ³
Emulsion Characteristics and Re-Emulsification Properties Concentration: 0.25 % CIPAC Water A Temperature: 30 °C Initial emulsification Emulsion Stability after 0.5 h after 2 h after 24 h Re- emulsification after 24 h Emulsion Stability 0.5 h after Re-emulsification	CIPAC MT 36.3	spontaneous no cream, no oil no cream, no oil no cream, no oil complete no cream, no oil	spontaneous no cream, no oil no cream, no oil no cream, no oil complete no cream, no oil

Test Description	Method	Initial Results	Results after 2 years 20 °C
Emulsion Characteristics and Re-Emulsification Properties Concentration: 0.25 % CIPAC Water D Temperature: 30 °C Initial emulsification Emulsion Stability after 0.5 h after 2 h after 24 h Re- emulsification after 24 h Emulsion Stability 0.5 h after Re-emulsification	CIPAC MT 36.3	 spontaneous no cream, no oil no cream, no oil no cream, no oil complete no cream, no oil	 spontaneous no cream, no oil no cream, no oil no cream, no oil complete no cream, no oil
Emulsion Characteristics and Re-Emulsification Properties Concentration: 2 % CIPAC Water A Temperature: 30 °C Initial emulsification Emulsion Stability after 0.5 h after 2 h after 24 h Re- emulsification after 24 h Emulsion Stability 0.5 h after Re-emulsification		 spontaneous no cream, no oil < 1 ml cream at the top, no oil 1 ml cream at the top, no oil complete no cream, no oil	 spontaneous no cream, no oil trace cream at the top, no oil 1 ml cream at the top, no oil complete no cream, no oil
Emulsion Characteristics and Re-Emulsification Properties Concentration: 2 % CIPAC Water D Temperature: 30 °C Initial emulsification Emulsion Stability after 0.5 h after 2 h after 24 h Re- emulsification after 24 h Emulsion Stability 0.5 h after Re-emulsification	OECD 109	 spontaneous no cream, no oil no cream, no oil < 1 ml cream at the top, < 1 ml oil at the top complete no cream, no oil	 spontaneous no cream, no oil no cream, no oil trace oil at the top, no cream complete no cream, no oil

Observations and Conclusion

No significant changes of the physical and technical properties were found after storage.

Table A 6: Packaging Evaluation storage over 2 years at 20°C in HDPE packaging (VV-1010627)

Evaluation Criteria	Results after 2 years 20 °C
Color change of the packaging	none
Odor (noticeable before opening the packaging)	none
Panelling of the test container	none
Ballooning of the test container	none
Pimples on the test container	none
Cracks in the test container	none
Tightness of the test container	tight
Reclosability of closure	reclosable
Tightness of closure	tight
Weight change (gross weight)	0.02 % weight gain
Permeation through the container walls	none

Observations and Conclusion

The packaging material proved to be resistant to its content.

Table A 7: Content of relevant impurity after storage over 2 years at 20°C in HDPE packaging (VV-1010627)

Relevant Impurity	Initial	2 years below -10 °C (control sample)	2 years 20 °C (test sample)
EXC5578 ¹	< 15 mg/l ² corresponding to < 0.20 g/kg ³	< 15 mg/l ² corresponding to < 0.20 g/kg ³	24 mg/l ² corresponding to 0.33 g/kg ³

¹ Prothioconazole-desthio (2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1,2,4-triazol-1-yl)-propan-2-ol)

² Based on the formulation

³ Relative to the prothioconazole content

Observations and Conclusion

All the values for prothioconazole-desthio are well below the limit of 0.5 g/kg relative to the prothioconazole content.