

REGISTRATION REPORT

Part A

Risk Management

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

NATIONAL ASSESSMENT Poland

(New product authorization)

Applicant: XXXX

Submission date: July 2022

Evaluation date: March 2023

MS Finalisation date: December 2023

Version history

When	What
23 rd January 2023	Following comments from evaluators, update of Appendix 4 for Data Protection claims and studies already evaluated. In addition removal (strikethrough) of efficacy studies which were by mistake listed in Appendix 4 while not relied upon for central zone. All new information is highlighted in yellow and removal is strikethrough
March 2023	Version evaluated by zRMS PL
October 2023	Applicant update – 2y. storage stability study: - Section 3.1 - Appendix 4 All new information is highlighted in blue and removal is strikethrough
December 2023	Updated after the reporting stage.

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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application was submitted by XXXX was the zRMS for the evaluation.

The application was for approval of Kayak Era (A23282A), an Emulsifiable Concentrate (EC) containing 225 g/L cyprodinil and 75 g/L prothioconazole for use as a fungicide in Northern, Central and Southern Zone on cereals (see details of intended uses in paragraph 2.6 of this document).

To obtain authorization the product A23282A, must (where appropriate) meet the conditions of a.s. EU inclusion and be supported by a dossier satisfying the requirements of Commission Regulation (EU) No. 284/2013, and the associated Annex, which repeals Commission Regulation (EU) No 545/2011 which, under Regulation (EC) 1107/2009, replaced the requirements of Annex III to Directive 91/414/EEC.

The application was submitted in order to allow the authorization of this product in the concerned Member State Poland in accordance with the above.

1.2 Letters of Access

Where XXXX relies on data belonging to a third party that are included in the dossier, then the ownership of the data is indicated in Appendix 4 of this document and also in the corresponding reference lists in Appendix 1 of the Registration Report, Part B Sections 1-10 and a letter of access to that data or reference to such is provided in Appendix 3 of this document.

1.3 Justification for submission of tests and studies

Art. 33 (3) c Justification of steps taken to avoid animal testing and duplication of such testing:

This is a new plant protection product, which is intended to be authorized in Member States for the first time. There is no duplication of vertebrate studies and extrapolation to data of similar formulations is not possible. The testing strategy takes into account methods compliant with the 3R concept for refinement, reduction and replacement of animal testing where applicable and acceptable.

Art. 33 (3) d Reasons for submission of tests and study reports:

This a new plant protection product and there is no EU derogation allowing for these data points to be addressed by extrapolation from existing data; therefore in order to obtain approval new tests were required and the study reports are provided.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of A23282A in accordance with Article 59 of Regulation (EC) No. 1107/2009, it is indicated in Appendix 4 of this document.

2 Details of the authorization decision

2.1 Product identity

Product code	A2382A
Product name in MS	KAYAK ERA
Authorization number	New registration
Function	fungicide
Applicant	XXXX
Active substance(s) (incl. content)	225 g/L cyprodinil and 75 g/L prothioconazole
Formulation type	Emulsifiable Concentrate (EC)
Packaging	HDPE 250 mL canister – professional HDPE 500 mL canister – professional HDPE 1L canister – professional HDPE 5L canister – professional HDPE 10 L canister – professional HDPE 20 L canister – professional
Coformulants of concern for national authorizations	Not applicable
Restrictions related to identity	Not applicable
Mandatory tank mixtures	Not applicable
Recommended tank mixtures	Not applicable

2.2 Conclusion

The evaluation of the application for A23282A / KAYAK ERA resulted in the decision to grant the authorization.

2.3 Substances of concern for national monitoring

Not applicable.


2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Skin irritation, Category 2 Serious eye damage, Category 1 Skin sensitisation, Category 1 Specific target organ toxicity – single exposure, Category 3, Respiratory system Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 1
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The following **labelling information** is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label** is **formatted bold**:

Hazard pictograms:	
Signal word:	Danger
Hazard statement(s):	H315 Causes skin irritation. H317 May cause an allergic skin reaction. H318 Causes serious eye damage. H335 May cause respiratory irritation. H410 Very toxic to aquatic life with long lasting effects.
Precautionary statement(s):	<p>Prevention:</p> <p>P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray. P264 Wash skin thoroughly after handling P280 Wear protective gloves/ eye protection/ face protection P271 Use only outdoors or in a well-ventilated area P272 Contaminated work clothing should not be allowed out of the workplace.</p> <p>Response</p> <p>P302 + P352 IF ON SKIN: Wash with plenty of soap and water. P304 + P340 + P312 IF INHALED: remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor. P332 + P313 If skin irritation occurs: Get medical advice/attention. P362 + P364 Take off contaminated clothing and wash before reuse</p> <p>Storage</p> <p>P403 + P233 Store in a well-ventilated place. Keep container tightly closed. P405 Store locked up.</p> <p>Disposal</p> <p>P391 Collect spillage. P501 Dispose of contents/container in accordance with local regulation.</p>
Additional labelling phrases:	To avoid risks to human health and the environment, comply with the instructions for use. [EUH401]

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
	mixture of octanoic acid- decanoic acid- N,N-dimethylamide cyprodinil (ISO)
	benzenesulfonic acid, C10-13-alkyl derivs., calcium salts 2-ethylhexan-1-ol

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application
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	equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	To protect aquatic organisms respect an unsprayed buffer zone of : Winter cereals (considering the ETO-RAC – R3, R4 scenarios not relevant to PL) 20 m SD + 20 m RO 5 m SD + 50 % DR ø 10 m SD Spring cereals (considering the ETO-RAC – R3, R4 scenarios not relevant to PL) 20 m SD + 20 m RO 5 m SD + 50 % DR ø 10 m SD
SPe3	To protect aquatic organisms respect an unsprayed buffer zone of : Winter and spring cereals (considering the ETO-RAC – scenarios relevant to PL) 10 m SD + 10 m RO

SD = spray drift buffer
DR = drift reducing techniques
RO = run-off mitigation

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

	Refer to national product label
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2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
	None Protective gloves, eye protection/face protection during mixing/loading operations or when directly contacting surface of equipment contaminated with concentrated product.
Worker protection:	
	None
Integrated pest management (IPM)/sustainable use:	
None	n/a
Environmental protection	
SPe3	Protection of aquatic organisms: Winter cereals (considering the ETO-RAC – R3, R4 scenarios not relevant to PL) 20 m SD + 20 m RO 5 m SD + 50 % DR ø 10 m SD Spring cereals (considering the ETO-RAC – R3, R4 scenarios not relevant to PL) 20 m SD + 20 m RO 5 m SD + 50 % DR ø 10 m SD

	Winter cereals (considering the ETO-RAC) 20 m SD + 20 m RO 10 m SD + 10-12 m RO Spring cereals (considering the ETO-RAC) 20 m SD + 20 m RO 10 m SD
Other specific restrictions	
None	n/a

SD = spray drift buffer

DR = drift reducing techniques

RO = run-off mitigation

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
None	n/a

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
None	n/a	n/a
Environmental protection:		Relevant for use no.
n/a	n/a	n/a

2.6 Intended uses (only NATIONAL GAP)

GAP rev. 1.0, date: 2022-July-10

PPP (product name/code): Kayak Era / A23282A
Active substance 1: cyprodinil
Active substance 2: prothioconazole
Safener: n/a
Synergist: n/a
Applicant: XXXX
Zone(s): Central zone
Verified by MS: yes/no

Formulation type: EC^(a, b)
Conc. of as 1: 225 g/L^(c)
Conc. of as 2: 75g/L^(c)
Conc. of safener: n/a
Conc. of synergist: n/a
Professional use: ☒
Non professional use: ☐

Field of use: Fungicide

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destina- tion / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate				PHI (days)	Remarks: e.g. g saf- ener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val be- tween ap- plications (days)	L product / ha a) max. rate per appl. b) max. to- tal rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)														
PL1	Poland	spring wheat; TRZAS	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL2	Poland	spring wheat; TRZAS	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	-
PL3	Poland	spring wheat; TRZAS	F	Blumeria graminis; ER- YSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL4	Poland	spring wheat;	F	Oculimacula yallundae;	foliar	BBCH30-69	a) 1	NA	a) 1.5-2	a) 338-450	a) 113-150	100	N/A*	-

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destina- tion / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate				PHI (days)	Remarks: e.g. g saf- ener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val be- tween ap- plications (days)	L product / ha a) max. rate per appl. b) max. to- tal rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max		
		TRZAS		PSDCHE	spray		b) 1		b) 1.5-2	b) 338-450	b) 113-150	400		
PL5	Poland	winter wheat; TRZAW	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL6	Poland	winter wheat; TRZAW	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL7	Poland	winter wheat; TRZAW	F	Blumeria graminis; ER- YSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL8	Poland	winter wheat; TRZAW	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL13	Poland	spring barley; HORVS	F	Pyrenophora teres; PYRNTE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL14	Poland	spring barley; HORVS	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	-
PL15	Poland	spring barley; HORVS	F	Blumeria graminis; ER- YSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL16	Poland	spring barley; HORVS	F	Puccinia hordei; PUC- CHD	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL17	Poland	spring barley; HORVS	F	Ramularia collo-cygni; RAMUCC	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL18	Poland	spring barley; HORVS	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	-
PL19	Poland	winter barley; HORVW	F	Pyrenophora teres; PYRNTE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL20	Poland	winter barley; HORVW	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL21	Poland	winter barley; HORVW	F	Blumeria graminis; ER- YSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destina- tion / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate				PHI (days)	Remarks: e.g. g saf- ener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val be- tween ap- plications (days)	L product / ha a) max. rate per appl. b) max. to- tal rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
PL22	Poland	winter barley; HORVW	F	Puccinia hordei; PUC- CHD	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL23	Poland	winter barley; HORVW	F	Ramularia collo-cygni; RAMUCC	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL24	Poland	winter barley; HORVW	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL25	Poland	spring rye; SECCS	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	Minor use under art. 33
PL26	Poland	winter rye; SECCW	F	Rhynchosporium secalis; RHYNSE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL27	Poland	Oat, spring; AVESP	F	Blumeria graminis; ER- YSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL28	Poland	Oat, winter; AVESW	F	Blumeria graminis; ER- YSGR	foliar spray	BBCH30-59	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	-
PL29	Poland	spring tritcale; TTLSO	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL30	Poland	winter tritcale; TTLWI	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL44	Poland	spring wheat; TRZAS	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL45	Poland	winter wheat; TRZAW	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
Minor uses according to Article 51 (zonal uses)														
PL9	Poland	durum wheat; TRZDU	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL10	Poland	durum wheat; TRZDU	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destina- tion / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate				PHI (days)	Remarks: e.g. g saf- ener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val be- tween ap- plications (days)	L product / ha a) max. rate per appl. b) max. to- tal rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max		
PL11	Poland	durum wheat; TRZDU	F	Blumeria graminis; ER- YSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL12	Poland	durum wheat; TRZDU	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL31	Poland	spring rye; SECCS	F	Blumeria graminis; ER- YSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL32	Poland	spring rye; SECCS	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL33	Poland	spring rye; SECCS	F	Fusarium culmorum; FUSACU	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL34	Poland	durum wheat; TRZDU	F	Puccinia recondita; PUCCRE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL35	Poland	durum wheat; TRZDU	F	Fusarium sp.; FUSASP	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL36	Poland	spring triticale; TTLSO	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL37	Poland	spring rye; SECCS	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL38	Poland	spelt; TRZSP	F	Zymoseptoria tritici; SEPTTR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL39	Poland	spelt; TRZSP	F	Puccinia striiformis; PUCCST	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL40	Poland	spelt; TRZSP	F	Blumeria graminis; ER- YSGR	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL41	Poland	spelt; TRZSP	F	Oculimacula yallundae; PSDCHE	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
PL42	Poland	spelt;	F	Puccinia recondita;	foliar	BBCH30-69	a) 1	NA	a) 1.5-2	a) 338-450	a) 113-150	100-	N/A*	

1	2	3	4	5	6	7	8	9	10	11a	11b	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destina- tion / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate				PHI (days)	Remarks: e.g. g saf- ener/synergist per ha ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val be- tween ap- plications (days)	L product / ha a) max. rate per appl. b) max. to- tal rate per crop/season	g cyprodinil/ha a) max. rate per appl. b) max. total rate per crop/season	g prothioconazole/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max		
		TRZSP		PUCCRE	spray		b) 1		b) 1.5-2	b) 338-450	b) 113-150	400		
PL43	Poland	spelt; TRZSP	F	Fusarium sp.; FUSASP	foliar spray	BBCH30-69	a) 1 b) 1	NA	a) 1.5-2 b) 1.5-2	a) 338-450 b) 338-450	a) 113-150 b) 113-150	100- 400	N/A*	
Minor uses according to Article 33 (zonal uses)														
none														

* N/A stands for 'Not Applicable'; The PHI is covered by the conditions of use and/or the vegetation period remaining between the application of the plant protection product and the use of the commodity (e.g. harvest) and/or the setting of a PHI in days is not required

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l

(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

Kayak Era (A23282a) is a Emulsifiable Concentrate (EC) formulation. 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**.

3.2 Efficacy (Part B, Section 3)

A23282A is an emulsifiable concentrate (EC) formulation containing 225 g/L cyprodinil and 75 g/L prothioconazole. It is a foliar fungicide treatment proposed for disease control in winter and spring wheat, durum wheat, winter and spring barley, winter and spring rye, winter and spring triticale and winter and spring oats.

3.3 Efficacy data

Data are presented from specific crop safety trials and trials where assessable levels of disease did not develop in cereals. The trials were undertaken in Denmark, France, Germany, Ireland, the Netherlands and the United Kingdom (Maritime EPPO zone), France, Italy and Spain (Mediterranean EPPO zone), Bulgaria, Hungary and Romania (South-East EPPO zone) and Finland, Latvia, Lithuania and Poland (North East EPPO zone) between 2020 and 2021 on a wide range of commercially grown varieties. Selectivity assessments, from efficacy and crop safety trials conducted in the vast majority of the experiments, did not reveal any adverse effects on crop emergence or significant phytotoxicity symptoms on cereals. A23282A demonstrated excellent selectivity on a wide range of commercially grown cereal varieties at 2.0 LPR/ha (450 gai/ha cyprodinil and 150 gai/ha prothioconazole).

All the data presented in biological dossier are supporting the proposed registration for A23282A for the following uses:

Intended uses

Crop	Target (s)	Max. number of applications	Max. Individual Dose
Winter wheat	<i>Blumeria graminis</i> <i>Zymoseptoria tritici</i> <i>Puccinia striiformis</i> <i>Oculimacula yallundae</i>	1	2 L/ha
Winter barley	<i>Blumeria graminis</i> <i>Puccinia hordei</i> <i>Oculimacula yallundae</i> <i>Pyrenophora teres</i> <i>Ramularia collo-cygni</i> <i>Rhynchosporium secalis</i>	1	2 L/ha
Winter rye	<i>Rhynchosporium secalis</i>	1	2 L/ha
Winter triticale	<i>Zymoseptoria tritici</i>	1	2 L/ha
Spring wheat	<i>Blumeria graminis</i> <i>Zymoseptoria tritici</i> <i>Puccinia striiformis</i> <i>Oculimacula yallundae</i>	1	2 L/ha
Spring barley	<i>Blumeria graminis</i> <i>Puccinia hordei</i> <i>Oculimacula yallundae</i> <i>Pyrenophora teres</i> <i>Ramularia collo-cygni</i> <i>Rhynchosporium secalis</i>	1	2 L/ha
Spring rye	<i>Rhynchosporium secalis</i> <i>Blumeria graminis</i> <i>Fusarium culmorum</i> <i>Puccinia recondita</i>	1	2 L/ha
Spring triticale	<i>Zymoseptoria tritici</i> <i>Puccinia striiformis</i>	1	2 L/ha
Oat (winter)	<i>Blumeria graminis</i>	1	2 L/ha
Oat (spring)	<i>Blumeria graminis</i>	1	2 L/ha
Durum	<i>Blumeria graminis</i> <i>Zymoseptoria tritici</i> <i>Puccinia striiformis</i> <i>Puccinia recondita</i> <i>Oculimacula yallundae</i> <i>Fusarium sp.</i>	1	2 L/ha

No preliminary laboratory or field testing was required due to previous knowledge about the efficacy and dose response of cyprodinil and prothioconazole.

In order to determine the minimum effective dose for the use of A23282A for foliar disease control in cereals, several efficacy trials were conducted at a range of rates, in accordance with EPPO standard PP 1/225 '*Minimum effective dose*'. Efficacy was tested under a range of environmental conditions to fully challenge the product. Data are presented across Europe to fully reflect the range of climatic and agronomic conditions. Trials were conducted in EPPO zones Maritime, Mediterranean, South-East and North-East.

Minimum effective dose in wheat

Based on presented data, 2.0 LPR/ha is considered to be fully justified as the minimum effective dose rate for A23282A as that required to deliver consistently effective control of diseases on wheat, under different disease pressures, development patterns and wide-ranging environmental conditions.

In commercial practice foliar diseases on the leaves often occur as a complex of several pathogen species and the choice of a fungicide dose is driven by the need to control the less manageable pathogen. As a result, the proposed rate of 2.0 LPR/ha should be considered as the minimum effective dose to deliver control of foliar disease of winter, spring and Durum wheat, under a wide range of environmental conditions.

The presented data also demonstrated that under certain conditions A23282A provided acceptable efficacy of foliar diseases down to the 1.5 LPR/ha dose rate. To be able to give good recommendations taking the local conditions into account, it may therefore be appropriate in some countries to consider including a dose range of 1.5 – 2.0 LPR/ha on the proposed label. This proposed range of use rates would allow the grower flexibility to adapt the applied dose rate according to disease pressure and climatic conditions. Instructions on when to use full or reduced dose rates would be included on individual country labels as appropriate.

Minimum effective dose in barley

Based on presented data, 2.0 LPR/ha is considered to be fully justified as the minimum effective dose rate for A23282A as that required to deliver consistently effective control of diseases on barley, under different disease pressures, development patterns and wide-ranging environmental conditions.

In commercial practice foliar diseases on the leaves often occur as a complex of several pathogen species and the choice of a fungicide dose is driven by the need to control the less manageable pathogen. As a result, the proposed rate of 2.0 LPR/ha should be considered as the minimum effective dose to deliver control of foliar disease of winter and spring barley, under a wide range of environmental conditions.

The presented data also demonstrated that under certain conditions A23282A provided acceptable efficacy of foliar diseases down to the 1.5 LPR/ha dose rate. To be able to give good recommendations taking the local conditions into account, it may therefore be appropriate in some countries to consider including a dose range of 1.5 – 2.0 LPR/ha on the proposed label. This proposed range of use rates would allow the grower flexibility to adapt the applied dose rate according to disease pressure and climatic conditions. Instructions on when to use full or reduced dose rates would be included on individual country labels as appropriate.

Minimum effective dose in rye

Based on presented data, 2.0 LPR/ha is considered to be fully justified as the minimum effective dose rate for A23282A as that required to deliver consistently effective control of *Rhynchosporium secalis* on rye, under different disease pressures, development patterns and wide-ranging environmental conditions.

The presented data also demonstrated that under certain conditions A23282A provided acceptable efficacy of foliar diseases down to the 1.5 LPR/ha dose rate. To be able to give good recommendations taking the local conditions into account, it may therefore be appropriate in some countries to consider including a dose range of 1.5 – 2.0 LPR/ha on the proposed label. This proposed range of use rates would allow the grower

flexibility to adapt the applied dose rate according to disease pressure and climatic conditions. Instructions on when to use full or reduced dose rates would be included on individual country labels as appropriate.

Minimum effective dose in triticale

Based on presented data, 2.0 LPR/ha is considered to be fully justified as the minimum effective dose rate for A23282A as that required to deliver consistently effective control of *Zymoseptoria tritici* on triticale, under different disease pressures, development patterns and wide-ranging environmental conditions.

The presented data also demonstrated that under certain conditions A23282A provided acceptable efficacy of foliar diseases down to the 1.5 LPR/ha dose rate. To be able to give good recommendations taking the local conditions into account, it may therefore be appropriate in some countries to consider including a dose range of 1.5 – 2.0 LPR/ha on the proposed label. This proposed range of use rates would allow the grower flexibility to adapt the applied dose rate according to disease pressure and climatic conditions. Instructions on when to use full or reduced dose rates would be included on individual country labels as appropriate.

Minimum effective dose in oats

Based on presented data, 2.0 LPR/ha is considered to be fully justified as the minimum effective dose rate for A23282A as that required to deliver consistently effective control of *Erysiphe graminis* on oats, under different disease pressures, development patterns and wide-ranging environmental conditions.

The presented data also demonstrated that under certain conditions A23282A provided acceptable efficacy of foliar diseases down to the 1.5 LPR/ha dose rate. To be able to give good recommendations taking the local conditions into account, it may therefore be appropriate in some countries to consider including a dose range of 1.5 – 2.0 LPR/ha on the proposed label. This proposed range of use rates would allow the grower flexibility to adapt the applied dose rate according to disease pressure and climatic conditions. Instructions on when to use full or reduced dose rates would be included on individual country labels as appropriate.

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

Prothioconazole (PTZ) is a demethylation inhibitor (DMI) fungicide and is classified in group G1 of FRAC. The DMI's are a group of fungicides highly active against a broad range of fungi. There are a large number of DMI's commercially available for use in a broad range of crops, e.g. mefentrifluconazole, difenoconazole and tebuconazole. The mode of action is inhibition of ergosterol biosynthesis, which has been classified as a medium resistance risk.

Cyprodinil (CDL) belongs to the anilinopyrimidine fungicides. The anilinopyrimidines (APs) are a group of fungicides highly active against a broad range of pathogens. The mode of action includes inhibition of methionine biosynthesis and secretion of hydrolytic enzymes. The mode of action is most probably monogenetic, but not fully elucidated. The resistance mechanisms for APs are disruptive.

AP products, applied following the FRAC-AP guidelines, continue to show good performance in the field, after many years of use, although resistant isolates can be found in recent field populations of some pathogens (e.g. *Botrytis cinerea* and *Venturia inaequalis*).

The intrinsic resistance risks for the active substances in A23282A are estimated as moderate. According to latest available FRAC Pathogen Risk List©2019, the risk of resistance developing to fungicides relating to the proposed target diseases can be considered as low for *Puccinia* sp. and *Rhynchosporium* sp., medium for *Oculimacula yallundae*, *Septoria tritici*, *Pyrenophora teres* and *Pyrenophora tritici repentis* and high for *Blumeria* sp. and *Ramularia collo-cygni*. Whilst the overall risk of resistance from the application of A23282A with an unrestricted use pattern ranges from low to high, depending on risk associated with the

individual target foliar disease, the overall resistance risk for all proposed uses of A23282A, applied according to label recommendations, is considered to be acceptable based on the combination of the two active substances and when FRAC guidelines are followed.

Current resistance management strategies below should be considered (www.frac.info):

- The avoidance of repetitive and sole use of a particular fungicide or those with the same mode of action
- The mixing or alternating sequences of fungicides with different modes of action
- Do not reduce rates of fungicides in tank mixtures
- Integrate fungicide use with cultural control methods
- Limiting the number of treatments per season
- Avoid unnecessary prophylactic treatments, ensure preventative treatments are applied in accordance with recommendations for disease control

3.3.2 Adverse effects on treated crops

Phytotoxicity symptoms in wheat caused by a single application of A23282A, applied at BBCH 30-69 at 2.0 LPR/ha (450 g/ha cyprodinil and 150 g/ha prothioconazole), were only observed in 17 of the 120 efficacy trials and in 3 of the 18 disease free or low disease trials reported within this dossier. In all trials phytotoxicity was <15%. In most of the trials where phytotoxicity occurred, symptoms were either transient or considered acceptable by the trialist. The symptoms varied between trials, but took the form of either chlorosis, necrosis, burning or general discoloration. No adverse impact on wheat yield or quality were observed. Trials were conducted in both the presence and absence of disease and were located across four EPPO zones, in 16 countries over two seasons (2020–2021) on a range of commercially grown varieties. Therefore, it can be concluded that A23282A applied at 2.0 LPR/ha can be considered safe to all varieties of winter, spring and durum wheat.

Phytotoxicity symptoms in barley caused by a single application of A23282A, applied at BBCH 30-59 at 2.0 LPR/ha (450 g/ha cyprodinil and 150 g/ha prothioconazole), were only observed in 7 of the 131 efficacy trials and in 1 of the 29 disease free or low disease trials reported within this dossier. The most frequent symptoms were chlorosis or necrosis/burning. In the majority of these trials the symptoms were transient and had no negative impact on the barley yield. Trials were conducted in both the presence and absence of disease and were located across four EPPO zones, in 18 countries over two seasons (2020–2021) on a range of commercially grown varieties. Therefore, it can be concluded that A23282A applied at 2.0 LPR/ha can be considered safe to all varieties of winter and spring barley.

Phytotoxicity symptoms in rye caused by a single application of A23282A, applied at BBCH 30-69 at 2.0 LPR/ha (450 g/ha cyprodinil and 150 g/ha prothioconazole), were not observed in any of the 20 efficacy trials reported within this dossier. No impact on yield or quality was observed. Trials were conducted in both the presence and absence of disease and were located across two EPPO zones, in 5 countries over two seasons (2020–2021) on a range of commercially grown varieties. Therefore, it can be concluded that A23282A applied at 2.0 LPR/ha can be considered safe to all varieties of winter and spring rye.

Phytotoxicity symptoms in triticale caused by a single application of A23282A, applied at BBCH 30-69 at 2.0 LPR/ha (450 g/ha cyprodinil and 150 g/ha prothioconazole), were only observed in 1 of the 10 efficacy trials and in none of the two disease free or low disease trials reported within this dossier. No impact on yield or quality was observed. Trials were conducted in both the presence and absence of disease and were located across two EPPO zones, in 4 countries over two seasons (2020–2021) on a range of commercially grown varieties. Therefore, it can be concluded that A23282A applied at 2.0 LPR/ha can be considered safe to all varieties of winter and spring triticale.

Phytotoxicity symptoms in oats caused by a single application of A23282A, applied at BBCH 30-59 at 2.0 LPR/ha (450 g/ha cyprodinil and 150 g/ha prothioconazole), were not observed neither in the 6 efficacy

trials nor in the two disease free or low disease trials reported within this dossier. No impact on yield or quality was observed. Trials were conducted in both the presence and absence of disease and were located across two EPPO zones, in 5 countries over two seasons (2020–2021) on a range of commercially grown varieties. Therefore, it can be concluded that A23282A applied at 2.0 LPR/ha can be considered safe to all varieties of winter and spring oats.

Regarding quality and yield in absence of disease, the presented data demonstrated that A23282A, applied at the proposed label rate of 2.0 LPR/ha (450 g/ha cyprodinil and 150 g/ha prothioconazole), had no adverse effect on the yield, hectolitre weight, thousand grain weight and percentage protein content of wheat, barley, rye, triticale and oats in the absence of significant levels of disease.

A23282A applied at the proposed maximum label rate of 2.0 LPR/ha (450 g/ha cyprodinil and 150 g/ha prothioconazole) and according to other label recommendations would not be expected to have any adverse impact on treated plants or plant products to be used for propagation.

A23282A applied at a rate of 2.0 LPR/ha (450 g/ha cyprodinil and 150 g/ha prothioconazole) and applied according to label recommendations on cereals would not be expected to have an adverse effect on relevant transformation processes.

3.3.3 Observations on other undesirable or unintended side-effects

When applied in accordance with the uses supported in this submission, A23282A would not be expected to have an adverse effect to succeeding crops, adjacent crops and beneficial organisms and non-target arthropods.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

An analytical method has been developed for the determination of Cyprodinil and Prothioconazole in A23282A. Full validation of the method SF-1115/1 has been conducted. The method is suitable for the specific and accurate determination of Cyprodinil and Prothioconazole in the formulation A23282A. Analytical method SD-1540/1 has been previously developed for the determination of toluene in formulated products and validated for formulation A16283D. The method is suitable for the specific, accurate and precise determination of toluene in product A23282A.

Analytical method SD-2433/1 has been developed and fully validated for the determination of the relevant impurity EXC5578 in A23282A. The method is suitable for the specific, accurate and precise determination of EXC5578 in product A23282A.

There is no CIPAC method available for the determination of Cyprodinil and Prothioconazole in a EC formulation.

3.4.2 Analytical methods for residues

Cyprodinil

Pre-authorization data;

- Methods for soil, water and air (environmental fate studies): No specific analytical methods were used to support environmental fate studies the on this product.

- Methods for soil, water (efficacy studies): No specific analytical methods were used to support the efficacy data generated on this product.
- Methods for feed, body fluids and tissues and air (toxicology studies): No specific analytical methods were used to support the toxicology data generated on this product.
- Methods for body fluids, air and any additional matrices used (operator, worker, resident and bystander exposure studies): No specific operator, worker, resident or bystander exposure studies were conducted to support this product. Consequently no analytical methods were required.
- Methods for plant and animal products (residues studies): Analytical methods for Cyprodinil REM 141.01 was evaluated during the EU review and considered acceptable, for the high oil content matrix type new data are validated and considered acceptable.
New methods REM 141.10 and GRM010.02A and validation were submitted and considered acceptable.
Method REM 141.06 for determination of cyprodinil and CGA304075 was evaluated during the EU review and considered acceptable.
- Methods for soil, water (ecotoxicity studies): New methods ECO_019_01B and ECO_019_03B for water, bee adult oral feeding solution, bee larval diet, Elendt M4 media, Saltwater, Pond water/sediment and validation were submitted and considered acceptable.
- Methods for water, buffer solutions (physical and chemical properties tests): New method for determination of CGA321915 Reconstituted test water, Elendt M7 medium, OECD test medium and validation were submitted and considered acceptable.

Post-authorization control and monitoring data;

- Methods for the determination of residues in plant matrices: Method DFG S19 for determination of cyprodinil was evaluated during the EU review and considered acceptable, for the high acid content matrix type new data are validated and consider acceptable. New methods GRM010.02A and QuEChERs and validation were submitted and considered acceptable.
- Methods for the determination of residues in animal matrices: REM141.06 and GRM010.06B methods and validation for cyprodinil and CGA304075 in animal matrices were submitted and considered acceptable.
- Methods for the determination of residues in body fluids and tissues: Methods REM141.06 and GRM010.06B and validation for cyprodinil were submitted and considered acceptable.
- Methods for the determination of residues in soil: Methods REM 141.03 and REM 141.08 for determination of cyprodinil was evaluated during the EU review and considered acceptable. Analytical method GRM010.08B and validation were submitted and considered acceptable.
- Methods for the determination of residues in water: Methods REM 141.02, REM 141.07 and REM 141.08 for determination of cyprodinil in water were evaluated during the EU review and considered acceptable. Analytical method GRM010.07A and validation was submitted and considered acceptable.
- Methods for the determination of residues in air: Method REM 141.05 for determination of cyprodinil in air was evaluated during the EU review and considered acceptable. Analytical method GRM010.09A and validation was submitted and considered acceptable.

Prothioconazole

Pre-authorization data;

- Methods for soil, water and air (environmental fate studies): Methods 00610, 00086/M038, 00684, 00724, 00731 for determination prothioconazole and prothioconazole-desthio were evaluated during the EU review and considered acceptable. New methods 00610/M001, 00684/M00, 00731/M001 and validation were submitted and considered acceptable.
- Methods for soil, water (efficacy studies): No specific analytical methods were used to support the efficacy data generated on this product.
- Methods for feed, body fluids and tissues and air (toxicology studies): No specific analytical methods were used to support the toxicology data generated on this product.

- Methods for body fluids, air and any additional matrices used (operator, worker, resident and bystander exposure studies): No specific operator, worker, resident or bystander exposure studies were conducted
- Methods for plant and animal products (residues studies): Methods for determination of prothioconazole-desthio and all metabolites (00598^(a), 00598/M001^(a), 00647^(b), 00647/E001^(b), 00979^(c), 00979/M001^(d), 01013^(a), 00655^(e), 00655/M001^(e), JA-009-A08-01^(f)) were evaluated during the EU review and considered acceptable.
- Methods for determination Triazole Alanine, Triazole Acetic Acid, Triazole Lactic Acid, 1,2,4-Triazole, GRM053.01A^(g), 01062/M002, 01062/M003, 01062/M004, 001132, Method 01062, 01062/M001, 2280, 2281, ARAM 217, D0905, 2175, 2199 were evaluated during the EU review and considered acceptable.
- Methods for soil, water (ecotoxicity studies): No specific analytical methods were used to support the ecotoxicity data generated on this product.

Post-authorization control and monitoring data;

- Methods for the determination of residues in plant matrices: QuEChERS method and validation for prothioconazole in plant matrices were evaluated during the EU review and are considered acceptable.
- Methods for the determination of residues in animal matrices: Methods 00655/M002 and 01009 were evaluated during the EU review and are considered acceptable.
- Methods for the determination of residues in body fluids and tissues: Method 01471 and validation was submitted and considered acceptable.
- Methods for the determination of residues in soil: Methods 00610 and 00086/M038 were evaluated during the EU review and are considered acceptable. New method 00610/M001 and validation was submitted and considered acceptable.
- Methods for the determination of residues in water: Method 00684 was evaluated during the EU review and is considered acceptable. New methods 00684/M001, 01387/M002 (Primary/confirmatory) and 01387/M002 (ILV) and validation were submitted and considered acceptable.
- Methods for the determination of residues in air: Methods 00724 and 00731 were evaluated during the EU review and are considered acceptable. New method 00731/M001 and validation was submitted and considered acceptable.

zRMS comment:

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions. For cyprodinil the applicant provided a set of acceptable fully validated methods for post-authorization control and monitoring purposes: LC-MS/MS method DFG S 19 applicable in high acid matrices (ILV for strawberry), and dry matrices (ILV for barley grain); QuEChERS/LC-MS/MS method applicable in high water matrices (ILV for lettuce), high oil matrices (ILV for oilseed rape), and high starch (ILV for barley grain). For animal matrices (ILV for milk, whole egg and liver) the fully validated LC-MS/MS method GRM010.06A was provided. For blood matrix the QuEChERS/LC-MS/MS method was validated with no ILV. For honey the provided QuEChERS/LC-MS/MS was fully validated. Moreover, fully validated LC-MS/MS GRM010.07A method for determination of cyprodinil, CGA249287, and CGA275535 in water was provided as well as the validated LC-MS/MS method for cyprodinil, CGA249287, CGA275535 and CGA321915 in soil (method GRM010.08B) and cyprodinil in air (method GRM010.09A). For prothioconazole residues in soil, water, and air the applicant did not provide the original studies on method modifications which were presented in Appendix 2 of section B5 for completion as new data (method 00610/ M001, 00684/M001, 00731/M001, 01387/M002). Therefore, the assessment of these data has been omitted. The data, as mostly confirmatory for already agreed validated prothioconazole methods were not necessary in the context of the approval.

3.5 Mammalian toxicology (Part B, Section 6)

3.5.1 Acute toxicity

A summary of the toxicological evaluation for A23282A is given in the following table:

Table 3.5-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for A23282A/KAYAK ERA

Type of test, species, model system (Guideline)	Result	ATE & Additivity Calculation Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)
LD ₅₀ oral	n/a	>2000 mg/kg Not Classified	Yes	None
LD ₅₀ dermal	n/a	>2000 mg/kg Not Classified	Yes	None
LC ₅₀ inhalation	n/a	>5 mg/L Not Classified	Yes	None
Skin irritation	n/a	Cat. 2	Yes	H315
Eye irritation	n/a	Cat. 1	Yes	H318
Skin sensitisation)	n/a	Cat. 1	Yes	H317
Supplementary studies for combinations of plant protection products	No data – not required			

3.5.2 Operator exposure

Operator exposure for use of A23282A was modelled using EFSA Guidance on the assessment of exposure of operators, workers, resident and bystanders in risk assessment for plant protection product [EFSA Journal 2014;12(10):3874 (55pp.)].

According to the exposure calculations, it can be concluded that the risk for the operator using A23282A on cereals (winter wheat is used as a critical - one application of 2 L product/ha) is acceptable without the use of personal protective equipment.

zRMS:

The exposure to Cyprodinil of operator wearing a work clothing (long sleeved shirt, long trousers) but no PPE and applying Kayak Era (A23282A) on cereals at maximal dose of 2.0 L product/ha (0.450 kg a.s./ha) using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM amounted to 71.66% of AOEL. In case the operator is using protective gloves during mixing and loading the exposure to Cyprodinil is reduced to 27.41% of AOEL.

The exposure to Prothioconazole of operator wearing a work clothing (long sleeved shirt, long trousers) but

no PPE and applying Kayak Era (A23282A) on cereals at maximal dose of 2.0 L product/ha (0.150 kg a.s./ha) using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM amounted to 7.09 % of AOEL. In case the operator is using protective gloves during mixing and loading the exposure to Prothioconazole is reduced to 1.78 % of AOEL.

The maximal exposure during application of the Kayak Era to Prothioconazole-desthio (assuming total conversion of Prothioconazole to Prothioconazole-desthio during drying) of operator wearing a work clothing (long sleeved shirt, long trousers) but no PPE and applying Kayak Era (A23282A) on cereals at maximal dose of 2.0 L product/ha (0.150 kg Prothioconazole/ha) using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM amounted to 28.47% of AOEL.

The sum of exposures of operator wearing a work clothing (long sleeved shirt, long trousers) during mixing/loading and application to Cyprodinil and Prothioconazole-desthio (assuming total conversion of Prothioconazole to Prothioconazole-desthio during drying) expressed as percentage of their AOELs is 100.13% of AOEL (71.66% + 28.47%), therefore the application of product Kayak Era (A23282A) according to its intended use within good agricultural practice pose an unacceptable risk to the health of operator.

The sum of exposures of operator wearing a work clothing (long sleeved shirt, long trousers) during mixing/loading and application and protective gloves during mixing and loading to Cyprodinil and Prothioconazole-desthio (assuming total conversion of Prothioconazole to Prothioconazole-desthio during drying) expressed as percentage of their AOELs is 55.88 % of AOEL (27.41% + 28.47%), therefore the application of product Kayak Era (A23282A) according to its intended use within good agricultural practice does not pose an unacceptable risk to the health of operator.

Summing up, the application of product Kayak Era (A23282A) does not pose an unacceptable risk to the health of operator during its intended use within good agricultural practice providing that operator is wearing work wear covering arms, body and legs during mixing/loading and application and protective gloves during mixing/loading. Since the product classified as Eye Dam. 1, Skin Irrit.2 and Skin Sens. 1 the operator should wear protective gloves, eye protection/face protection during mixing/loading operations or when directly contacting surface of equipment contaminated with concentrated product.

~~The sum of exposures of operator wearing a work clothing (long sleeved shirt, long trousers) during mixing/loading and application to both active substances or to Cyprodinil and Prothioconazole-desthio (assuming total conversion of Prothioconazole to Prothioconazole-desthio during drying) expressed as percentage of their AOELs is also below 100%, therefore the application of product Kayak Era (A23282A) according to its intended use within good agricultural practice does not pose an unacceptable risk to the health of operator.~~

~~Summing up, the application of product Kayak Era (A23282A) does not pose an unacceptable risk to the health of operator during its intended use within good agricultural practice providing that operator is wearing work wear covering arms, body and legs during mixing/loading and application. Since the product classified as Eye Dam. 1, Skin Irrit.2 and Skin Sens. 1 the operator should wear protective gloves, eye protection/face protection during mixing/loading operations or when directly contacting surface of equipment contaminated with concentrated product.~~

3.5.3 Worker exposure

Worker exposure for A23282A was modelled using EFSA Guidance on the assessment of exposure of operators, workers, resident and bystanders in risk assessment for plant protection product [EFSA Journal 2014;12(10):3874 (55pp.)].

According to the exposure calculations, it can be concluded that the risk for the worker using A23282A on cereals (winter wheat is used as a critical - one application of 2 L product/ha) is acceptable without the use

of personal protective equipment.

zRMS evaluation of worker exposure

The exposure to Cyprodinil, an active substance of a product Kayak Era (A23282A) of worker not wearing PPE (gloves) but wearing a work clothing (long sleeved shirt, long trousers) and entering for 2 hours for inspection a field of cereals treated with a product Kayak Era (A23282A) at maximal dose of 2.0 L product/ha (0.450 kg a.s./ha) as foreseen in GAP, calculated with the EFSA AOEM amounted 21 - 27.30% of respective AOEL depending upon a volume of water used (100-400L/ha) .

The exposure to Prothioconazole, an active substance of a product Kayak Era (A23282A), of worker not wearing PPE (gloves) but wearing a work clothing (long sleeved shirt, long trousers) and entering for 2 hours for inspection a field of cereals treated with a product Kayak Era (A23282A) at maximal dose of 2.0 L product/ha (0.150 kg a.s./ha) as foreseen in GAP, calculated with the EFSA AOEM amounted 1.68 % - 1.16 % of respective AOEL depending upon a volume of water used (100-400L/ha) .

The exposure to Prothioconazole-desthio (assuming total conversion of Prothioconazole to Prothioconazole-desthio during drying) of worker not wearing PPE (gloves) but wearing a work clothing (long sleeved shirt, long trousers) and entering for 2 hours for inspection a field of cereals treated with a product Kayak Era (A23282A) at maximal dose of 2.0 L product/ha (0.150 kg Prothioconazole /ha) as foreseen in GAP, calculated with the EFSA AOEM amounted 26.66 % - 30.46 % of respective AOEL depending upon a volume of water used (100-400L/ha) .

The sum of exposures of worker wearing a work clothing (long sleeved shirt, long trousers) to both active substance or to Cyprodinil and Prothioconazole-desthio (assuming total conversion of Prothioconazole to Prothioconazole-desthio during drying or 50% conversion of Prothioconazole to Prothioconazole-desthio) expressed as percentage of their AOELs is below 100%, therefore the application of product Kayak Era (A23282A) according to its intended use within good agricultural practice does not pose an unacceptable risk to the health of worker.

Thus, it is concluded that the application of a product Kayak Era (A23282A) does not pose an unacceptable risk to the health of worker due to its intended use within good agricultural practice providing that the worker is wearing a work clothing (long sleeved shirt, long trousers).

3.5.4 Bystander and resident exposure

Bystander and resident exposure for A23282A was modelled using EFSA Guidance on the assessment of exposure of operators, workers, resident and bystanders in risk assessment for plant protection product [EFSA Journal 2014;12(10):3874 (55pp.)].

~~According to the exposure calculations, it can be concluded that the risk for the resident exposed to A23282A on cereals (winter wheat is used as a critical — one application of 2 L product/ha) is acceptable without the use of personal protective equipment.~~

zRMS:

Assuming 100% conversion from the parent prothioconazole to the metabolite prothioconazole-desthio as a theoretical worst case

The health risk of residents (adult and child) caused by the application of a product Kayak Era (A23282A) on a field of cereals at maximal dose of 2.0 L product/ha is acceptable when risk mitigation measures are used such as a drift reduction technology or a buffer zone of 5 m.

Assuming 50% conversion from the parent prothioconazole to the metabolite prothioconazole-desthio as requested by DE

Residents:

The application of a product Kayak Era (A23282A) in accordance with GAP does not pose an unacceptable risk to the health of residents (adult and child) due to its intended use within good agricultural practice

No additional mitigation measures used assuming 100% conversion from the parent prothioconazole to the metabolite prothioconazole-desthio as a theoretical worst case

The exposure estimation of resident (adult and child) to Cyprodinil, an active substance of a product Kayak Era (A23282A) applied on a field of cereals at maximal dose of 2.0 L product/ha (0.450 kg a.s./ha) as foreseen in GAP, using tractor-mounted/trailed boom sprayer, without any additional mitigation measures, calculated with the EFSA AOEM demonstrates that such a exposure for adult resident is in the range of 17.33 -17.81 % of AOEL and for child resident in the range of 48.63 - 40.03 % of AOEL, depending upon a volume of water used (100-400L/ha).

The exposure estimation of resident (adult and child) to Prothioconazole, an active substance of a product Kayak Era (A23282A) applied on a field of cereals at maximal dose of 2.0 L product/ha (0.150 kg a.s./ha) as foreseen in GAP, using tractor-mounted/trailed boom sprayer, without any additional mitigation measures, calculated with the EFSA AOEM demonstrates that such a exposure for adult resident is in the range of 1.44 - 0.84 % of AOEL and for child resident in the range of 4.11– 2.09 % of AOEL, depending upon a volume of water used (100-400L/ha).

The exposure estimation of resident (adult and child) to Prothioconazole-desthio (assuming total conversion of Prothioconazole to Prothioconazole-desthio during drying), after application of a product Kayak Era (A23282A) on a field of cereals at maximal dose of 2.0 L product/ha (0.150 kg Prothioconazole./ha) as foreseen in GAP, using tractor-mounted/trailed boom sprayer, without any additional mitigation measures, calculated with the EFSA AOEM demonstrates that such a exposure for adult resident is in the range of 23.31 - 21.32 % of AOEL and for child resident in the range of 67.49– 51.19 % of AOEL, depending upon a volume of water used (100-400L/ha).

The sum of exposures of residents (adult and child) to both active substance (Cyprodinil and Prothioconazole) expressed as percentage of their AOELs is below 100%, however the sum of exposures of child residents to Cyprodinil (48.63 of AOEL) and Prothioconazole-desthio (67.49 % of AOEL) expressed as percentage of their AOELs is above 100%, thus the risk is not acceptable

Additional mitigation measures used assuming 100% conversion from the parent prothioconazole to the metabolite prothioconazole-desthio as a theoretical worst case

Drift reduction technology

The exposure estimation of resident (adult and child) to Cyprodinil, an active substance of a product Kayak Era (A23282A) applied on a field of cereals at maximal dose of 2.0 L product/ha (0.450 kg a.s./ha) as foreseen in GAP, using tractor-mounted/trailed boom sprayer, with drift reduction technology, calculated with the EFSA AOEM demonstrates that such a exposure for adult resident is in the range of 14.65 -16.58% of AOEL and for child resident in the range of 36.19 - 34.92 % of AOEL, depending upon a volume of water used (100-400L/ha).

The exposure estimation of resident (adult and child) to Prothioconazole, an active substance of a product Kayak Era (A23282A) applied on a field of cereals at maximal dose of 2.0 L product/ha (0.150 kg a.s./ha) as foreseen in GAP, using tractor-mounted/trailed boom sprayer, with drift reduction technology, calculated with the EFSA AOEM demonstrates that such a exposure for adult resident is in the range of 1.23 - 0.78

% of AOEL and for child resident in the range of 3.13 - 1.87 % of AOEL, depending upon a volume of water used (100-400L/ha).

The exposure estimation of resident (adult and child) to Prothioconazole-desthio (assuming total conversion of Prothioconazole to Prothioconazole-desthio during drying), after application of a product Kayak Era (A23282A) on a field of cereals at maximal dose of 2.0 L product/ha (0.150 kg Prothioconazole./ha) as foreseen in GAP, using tractor-mounted/trailed boom sprayer, with drift reduction technology, calculated with the EFSA AOEM demonstrates that such a exposure for adult resident is in the range of 19.92 - 19.94 % of AOEL and for child resident in the range of 51.90 – 45.59 % of AOEL, depending upon a volume of water used (100-400L/ha).

The sum of exposures of residents (adult and child) to both active substance (Cyprodinil and Prothioconazole) expressed as percentage of their AOELs is below 100%, however as a result of using drift reduction technology the sum of exposures of child residents to Cyprodinil (36.19 of AOEL) and Prothioconazole-desthio (51.90 % of AOEL) expressed as percentage of their AOELs is below 100%, thus the risk is acceptable.

Use of Buffer zone: 5 (m)

The exposure estimation of resident (adult and child) to Cyprodinil, an active substance of a product Kayak Era (A23282A) applied on a field of cereals at maximal dose of 2.0 L product/ha (0.450 kg a.s./ha) as foreseen in GAP, using tractor-mounted/trailed boom sprayer with buffer zone of 5 m, calculated with the EFSA AOEM demonstrates that such a exposure for adult resident is in the range of 14.84 -16.59 % of AOEL and for child resident in the range of 39.81- 35.96 % of AOEL, depending upon a volume of water used (100-400L/ha).

The exposure estimation of resident (adult and child) to Prothioconazole, an active substance of a product Kayak Era (A23282A) applied on a field of cereals at maximal dose of 2.0 L product/ha (0.150 kg a.s./ha) as foreseen in GAP, using tractor-mounted/trailed boom sprayer, with buffer zone of 5 m, calculated with the EFSA AOEM demonstrates that such a exposure for adult resident is in the range of 1.24 - 0.78 % of AOEL and for child resident in the range of 3.42 - 1.91 % of AOEL, depending upon a volume of water used (100-400L/ha).

The exposure estimation of resident (adult and child) to Prothioconazole-desthio (assuming total conversion of Prothioconazole to Prothioconazole-desthio during drying), after application of a product Kayak Era (A23282A) on a field of cereals at maximal dose of 2.0 L product/ha (0.150 kg Prothioconazole./ha) as foreseen in GAP, using tractor-mounted/trailed boom sprayer, with buffer zone of 5 m, calculated with the EFSA AOEM demonstrates that such a exposure for adult resident is in the range of 20.16 - 19.96 % of AOEL and for child resident in the range of 56.49– 46.75 % of AOEL, depending upon a volume of water used (100-400L/ha).

The sum of exposures of residents (adult and child) to both active substance (Cyprodinil and Prothioconazole) expressed as percentage of their AOELs is below 100%, however as a result of using a buffer zone of 5 m, the sum of exposures of child residents to Cyprodinil (39.81 of AOEL) and Prothioconazole-desthio (56.49 % of AOEL) expressed as percentage of their AOELs is below 100%, thus the risk is acceptable.

Thus based on these estimations it is concluded that the health risk of residents (adult and child) caused by the application of a product Kayak Era (A23282A) on a field of cereals at maximal dose of 2.0 L product/ha is acceptable when risk mitigation measures are used such as drift reduction technology or a buffer zone of 5 m.

No bystander acute exposure estimation for Cyprodinil, Prothioconazole or Prothioconazole-desthio is required since no acute acceptable operator exposure value (AAOEL) has been set for any of these substances. Therefore, as indicated in the EU guidance (SANTE-10832-2015 rev. 1.7; 24 January 2017), no unacceptable risk is expected for bystanders due to short-term single exposure to Cyprodinil, Prothioconazole or Prothioconazole-desthio as a result of application of a product Kayak Era (A23282A) with accordance with intended use within good agricultural practice.

Summing up application of a product Kayak Era (A23282A) in line with GAP on low crops at maximal dose of 2.0 L product/ha, using tractor-mounted/trailed boom sprayer does not pose an unacceptable health risk for residents and bystanders, providing that risk mitigation measures are used, either buffer zone of 5 m or drift reduction technology.

3.6 Residues and consumer exposure (Part B, Section 7)

zRMS:

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs for prothioconazole and cyprodinil formulated as A23282A as laid down in Reg. (EU) 2019/552 and Reg. (EU) 2022/1435, respectively, is not expected. The chronic and the short-term intakes for both actives are unlikely to present a public health concern. zRMS, agrees with the authorization of the intended uses proposed for A23282A.

3.6.1 Residues

Cyprodinil

A23282A is used as a foliar treatment on field grown cereals (wheat, triticale, rye, spelt, durum wheat, barley and oat).

Wheat

Wheat is a major crop in northern Europe (SANTE/2019/12752); and therefore, generally requires eight trials in the residue region.

Data for wheat can be extrapolated to rye, triticale, spelt and durum wheat (SANTE/2019/12752). The intended cGAP is 1 x 450 g a.s./ha, BBCH 30-69, field.

The intended cGAP is less critical than the zonal cGAP (2 x 750 g a.s./ha, BBCH 30-65, interval between applications 21d, PHI 42d).

Eight new trials in northern Europe were conducted to support the intended cGAP use on wheat. In each trial one application at a nominal rate of 450 g a.s./ha at BBCH 69 was made. The actual application rate was within $\pm 25\%$ acceptance range. In these trials residues of cyprodinil in wheat grain taken at harvest were in the range of 0.03 – 0.10 mg/kg. Residues of cyprodinil in wheat straw taken at harvest were in the range of 0.07 – 0.88 mg/kg. All cyprodinil residues in grain are within the current MRL of 0.5 mg/kg.

Therefore, sufficient trials are available to support the proposed uses on wheat, rye, triticale, spelt and durum wheat, and to conduct a risk assessment. The available submitted data show that no exceedance of the MRLs is expected. The use is considered acceptable.

Barley

Barley is a major crop in northern Europe (SANTE/2019/12752); and therefore, generally requires eight trials in the residue region.

Data for barley can be extrapolated to oats (SANTE/2019/12752).

The intended cGAP is 1 x 450 g a.s./ha, BBCH 30-59, field.

The intended cGAP is less critical than the zonal cGAP (2 x 750 g a.s./ha, BBCH 30-65, interval between applications 21d, PHI 42d).

Eight new trials in northern Europe conducted with A14325E, an emulsifiable concentrate (EC) formulation containing 300 g/L cyprodinil, are available to support the use of product A23282A (EC formulation) on barley. These studies have also been submitted to France, as part of the ongoing AIR review process for cyprodinil. In each trial two applications at a nominal rate of 450 g a.s./ha at BBCH 24-75 were made. The actual application rates were within $\pm 25\%$ acceptance range. The trials GAP was more critical than the intended GAP, thus covering the intended use. In these trials residues of cyprodinil in barley grain taken at harvest were in the range of 0.26 – 0.92 mg/kg. Residues of cyprodinil in barley straw taken at harvest were in the range of 0.16 – 1.51 mg/kg. All cyprodinil residues in grain are within the current MRL of 4 mg/kg.

Therefore, sufficient trials are available to support the proposed uses on barley and oats and conduct a risk assessment. The available submitted data show that no exceedance of the MRLs is expected. The use is considered acceptable.

The use of A23282A may result in residues of cyprodinil in animal feed items, therefore the possible transfer of residues in animal commodities from the proposed uses should be considered.

The requested uses and the new mode of calculation modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

Prothioconazole

A23282A is used as a foliar treatment on field grown cereals (wheat, triticale, rye, spelt, durum wheat, barley and oat).

Wheat

Wheat is a major crop in northern Europe (SANTE/2019/12752); and therefore, generally requires eight trials in the residue region.

Data for wheat can be extrapolated to rye, triticale, spelt and durum wheat (SANTE/2019/12752).

The intended cGAP is 1 x 150 g a.s./ha, BBCH 30-69, field.

The intended cGAP is less critical than the zonal cGAP (3 x 200 g a.s./ha, BBCH 29-69, min. interval between applications 14d, PHI 35d) and also less critical than the representative cGAP for the active substance renewal (2 x 187.5 g a.s./ha, BBCH 25-69, min. interval between applications 14d).

Twenty-five northern European trials are available in the dRAR (UK/Poland, 2020) to support the intended cGAP use with product A23282A (EC formulation) on wheat. These trials were conducted either with emulsifiable concentrate (EC) formulations or suspension concentrate (SC) formulations, which have been shown to produce comparable results (SANTE/2019/12752). The GAP of these trials was more critical than the intended GAP, thus covering the intended use. In these trials residues of prothioconazole-desthio in wheat grain taken at harvest were in the range of <0.01 – 0.02 mg/kg. Residues of prothioconazole-desthio in wheat straw taken at harvest were in the range of 0.02 – 0.92 mg/kg. All prothioconazole-desthio residues in grain are within the current MRL of 0.1 mg/kg in wheat, triticale, spelt and durum wheat, and within the current MRL of 0.05 mg/kg in rye.

Therefore, sufficient trials are available to support the proposed uses on wheat, triticale, rye, spelt and durum wheat, and to conduct a risk assessment. The available submitted data show that no exceedance of the MRLs is expected. The use is considered acceptable.

Barley

Barley is a major crop in northern Europe (SANTE/2019/12752); and therefore, generally requires eight trials in the residue region.

Data for barley can be extrapolated to oats (SANTE/2019/12752).

The intended cGAP is 1 x 150 g a.s./ha, BBCH 30-59, field.

The intended cGAP is less critical than the zonal cGAP (2 x 200 g a.s./ha, BBCH 30-69, min. interval between applications 14d, PHI 35d) and also less critical than the representative cGAP for the active substance renewal (2 x 150 g a.s./ha, BBCH 25-61, min. interval between applications 14d).

Nineteen northern European trials are available in the dRAR (UK/Poland, 2020) to support the intended cGAP use with product A23282A (EC formulation) on barley. These trials were conducted either with emulsifiable concentrate (EC) formulations or suspension concentrate (SC) formulations, which have been shown to produce comparable results (SANTE/2019/12752). The GAP of these trials was more critical than the intended GAP, thus covering the intended use. In these trials residues of prothioconazole-desthio in barley grain taken at harvest were in the range of <0.01 – 0.02 mg/kg. Residues of prothioconazole-desthio in barley straw taken at harvest were in the range of 0.02 – 0.81 mg/kg. All prothioconazole-desthio residues in grain are within the current MRL of 0.2 mg/kg in barley and within the current MRL of 0.05 mg/kg in oats.

Therefore, sufficient trials are available to support the proposed uses on barley and oats, and to conduct a risk assessment. The available submitted data show that no exceedance of the MRLs is expected. The use is considered acceptable.

The use of A23282A may result in residues of prothioconazole-desthio and TDMs in animal feed items, therefore the possible transfer of residues in animal commodities from the proposed uses should be considered.

The requested uses have no impact on the dietary burdens calculated in the EFSA Reasoned Opinion for the evaluation of confirmatory data following the Article 12 review (EFSA, 2020).

TDMs

The requested uses have no impact on the dietary burdens calculated in the Addendum for the TDM Confirmatory Data (UK, 2018).

Consumer exposure

Cyprodinil

Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo 3.1	Not available
IEDI (% ADI) according to EFSA PRIMo 3.1	58% (based on NL toddler)
IESTI RAC (% ARfD) according to EFSA PRIMo 3.1*	Not applicable (no ARfD)
IESTI Processed (% ARfD) according to EFSA PRIMo 3.1*	Not applicable (no ARfD)

* include raw and processed commodities if both values are required for PRIMo 3.1

The proposed uses of cyprodinil in A23282A do not represent unacceptable chronic risks for the consumer.

Prothioconazole

Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo 3.1	Not calculated
IEDI (% ADI) according to EFSA PRIMo 3.1	14% (based on NL toddler)
IESTI RAC (% ARfD) according to EFSA PRIMo 3.1*	Bovine: Edible offals: 36% (based on children) Wheat: 6% (based on children)

	Barley: 4% (based on children) Rye: 1% (based on children) Oat: 0.2% (based on children)
IESTI Processed (% ARfD) according to EFSA PRIMo 3.1*	Wheat / milling (flour): 5% (based on children) Barley / beer: 5% (based on adults) Rye / boiled: 0.7% (based on children) Oat / boiled: 0.7% (based on children)

* include raw and processed commodities if both values are required for PRIMo 3.1

The proposed uses of prothioconazole in A23282A do not represent unacceptable acute and chronic risks for the consumer.

Combined exposure and risk assessment

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised “scientific methods accepted by the Authority to assess such effects are available.”

Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

zRMS:

The above text of the applicant is acceptable (see also B7).

3.7 Environmental fate and behaviour (Part B, Section 8)

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

PEC_S for cyprodinil

The PEC_S of cyprodinil has been assessed with the ESCAPE v2.0 model, FOCUS groundwater crop interception values and the worst-case field DT₅₀ value. Based on the recommended use rate of 450 g a.s./ha, the maximum initial Predicted Environmental Concentration in soil (PEC_{S,ini}) of cyprodinil was 0.120 mg/kg.

In addition to the seasonal PEC_{S,ini} calculations, the potential accumulation (PEC_{S,accumulation}) of cyprodinil in soil following repeated applications of A23282A to cereals was calculated. Assuming the same application regime is used year after year as a worst case, and a default DT₅₀ of 1000d, it was predicted that a plateau concentration (PEC_{S,plateau}) of 0.104 mg/kg would be reached after 10 years. The long term Predicted Environmental Concentration (PEC_{S,accumulation}) was calculated as 0.224 mg/kg.

PEC_S for CGA249287

The PEC_S of CGA249287 has been assessed with the ESCAPE v2.0 model, FOCUS groundwater crop interception values and the worst-case lab DT₅₀ value. For CGA249287, the proposed use pattern will lead to maximum PEC_{S,ini} of 0.015 mg/kg.

In addition to the seasonal PEC_{S,ini} calculations, the potential accumulation (PEC_{S,accumulation}) of CGA249287 in soil following repeated applications of A23282A to cereals was calculated. Assuming the same application regime is used year after year as a worst case, and a default DT₅₀ of 1000d, it was predicted that a plateau concentration (PEC_{S,plateau}) of 0.013 mg/kg would be reached after 10 years. The long term Predicted Environmental Concentration (PEC_{S,accumulation}) was calculated as 0.028 mg/kg.

PEC_s for CGA321915

The PEC_s of CGA321915 has been assessed with the ESCAPE v2.0 model, FOCUS groundwater crop interception values and the worst-case lab DT₅₀ value. For CGA321915, the proposed use pattern will lead to maximum PEC_{S,ini} of 0.014 mg/kg.

Given the DT₅₀ and DT₉₀ of CGA249287 are < 100d and 365d respectively, calculations estimating the potential accumulation in soil were not performed.

PEC_s for CGA275535

The PEC_s of CGA275535 has been assessed with the ESCAPE v2.0 model, FOCUS groundwater crop interception values and the worst-case lab DT₅₀ value. For CGA375535, the proposed use pattern will lead to maximum PEC_{S,ini} of 0.129 mg/kg.

Given the DT₅₀ and DT₉₀ of CGA275535 are < 100d and 365d respectively, calculations estimating the potential accumulation in soil were not performed.

PEC_s for prothioconazole

The PEC_s of prothioconazole has been assessed with the ESCAPE v2.0 model, FOCUS groundwater crop interception values and the worst-case field DT₅₀ value. Based on the recommended use rate of 150 g a.s./ha, the maximum initial Predicted Environmental Concentration in soil (PEC_{S,ini}) of cyprodinil was 0.040 mg/kg.

Given the DT₅₀ and DT₉₀ of prothioconazole are < 100d and 365d respectively, calculations estimating the potential accumulation in soil were not performed.

PEC_s for JAU 6475-S-methyl

The PEC_s of JAU 6476-S-methyl has been assessed with the ESCAPE v2.0 model, FOCUS groundwater crop interception values and the worst-case lab DT₅₀ value. For JAU 6475-S-methyl, the proposed use pattern will lead to maximum PEC_{S,ini} of 0.006 mg/kg.

Given the DT₅₀ and DT₉₀ of JAU 6476-S-methyl are < 100d and 365d respectively, calculations estimating the potential accumulation in soil were not performed.

PEC_s for JAU 6475 6476-desthio

The PEC_s of CGA321915 has been assessed with the ESCAPE v2.0 model, FOCUS groundwater crop interception values and the worst-case lab DT₅₀ value. For JAU 6475 6476-desthio, the proposed use pattern will lead to maximum PEC_{S,ini} of 0.027 mg/kg.

Given the DT₅₀ and DT₉₀ of JAU 6476-desthio are < 100d and 365d respectively, calculations estimating the potential accumulation in soil were not performed.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

PEC_{GW} for cyprodinil and metabolites CGA249287, CGA321915 and CGA275535

Groundwater modelling on cyprodinil and its metabolites CGA249287, CGA321915 and CGA275535 has not been previously reviewed at an EU level and is provided in support of this assessment in Part B Section 8, Appendix 3.

Following FOCUS groundwater modelling with FOCUS PEARL v5.5.5 and FOCUS PELMO v6.6.4 assuming the critical use pattern of 450 g a.s./ha, BBCH window 30-69, and LoEP input parameters, all compounds resulted in PEC_{GW} values of $<0.001 \mu\text{g/L}$ across all FOCUS scenarios and models. These simulations are described further in the Part B Section 8.8.

Based on the assessment, the use of cyprodinil is not expected to lead to leaching into groundwater at levels that would be unacceptable when applied according to the recommended use pattern.

PEC_{GW} for prothioconazole and metabolites JAU-6476-S-methyl and JAU 6476-desthio

Groundwater modelling on prothioconazole and its metabolites JAU 6476-S-methyl and JAU 6476-desthio have not been previously reviewed at an EU level and is provided in support of this assessment in Part B Section 8, Appendix 3.

Following FOCUS groundwater modelling with FOCUS PEARL v5.5.5 and FOCUS PELMO v6.6.4 assuming the critical use pattern of 150 g a.s./ha, BBCH window 30-69, all compounds resulted in PEC_{GW} values of $<0.001 \mu\text{g/L}$ across all FOCUS scenarios and models. These simulations are described further in the Part B Section 8.8.

Based on the assessment, the use of prothioconazole is not expected to lead to leaching into groundwater at levels that would be unacceptable when applied according to the recommended use pattern.

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

Surface water modelling on cyprodinil and its metabolites CGA249287, CGA321915 and CGA275535 has not been previously reviewed at an EU level and is provided in support of this assessment in Part B Section 8, Appendix 3.

PEC_{SW} and PEC_{SED} for cyprodinil

FOCUS STEPS 1-4 modelling of Cyprodinil and associated major metabolites using LoEP parameters have been provided assuming the critical use pattern on cereals (450 g a.s./ha, and BBCH window 30-69) and included into the dRR B8 sections 8.9 and 8.9.2.1.

A summary of global maximum PEC_{SW} values at FOCUS STEP 4 are provided below;

Table 3.7-1: Global maximum PEC_{SW} values for cyprodinil, following single application of Kayak Era according to the Central EU zone GAP according to surface water Step 4 (Anderson, C., 2022, VV-942867)

		Mitigation options		
Vegetative strip (m)		0	10	20
No spray buffer (m)		10	10	20
Nozzle reduction (%)		0	0	0
Crop	Scenario	PEC_{SW} ($\mu\text{g/L}$)	PEC_{SW} ($\mu\text{g/L}$)	PEC_{SW} ($\mu\text{g/L}$)
Winter cereals 450 g a.s./ha BBCH 30-69	D3 ditch	0.466	0.466	0.466
	D4 pond	0.086	0.086	0.086
	D4 stream	0.507	0.507	0.507
	D5 pond	0.086	0.086	0.086
	D5 stream	0.540	0.540	0.540

Mitigation options				
Vegetative strip (m)		0	10	20
No spray buffer (m)		10	10	20
Nozzle reduction (%)		0	0	0
Crop	Scenario	PEC _{SW} (µg/L)	PEC _{SW} (µg/L)	PEC _{SW} (µg/L)
Spring cereals 450 g a.s./ha BBCH 30-69	R1 pond	0.141	0.098	0.059
	R1 stream	0.745	0.409	0.215
	D3 ditch	0.457	0.457	0.457
	D4 pond	0.086	0.086	0.086
	D4 stream	0.505	0.505	0.505
	D5 pond	0.086	0.086	0.086
	D5 stream	0.510	0.510	0.510

PEC_{SW} and PEC_{SW} for CGA249287, CGA321915 and CGA275535

The Predicted Environmental Concentration of soil, water and sediment metabolite CGA249287, as well as the soil metabolites CGA321915 and CGA275535 in surface water and sediment (PEC_{SW} and PEC_{SED}) have been assessed with the FOCUS SW 1-2 v3.2 model.

Based on the recommended use on cereals at 450 g a.s./ha and application at BBCH30 – BBCH 69, the maximum PEC_{SW} values for CGA249287 were 11.0 µg/L and 8.91 µg/L (Step 2) in NEU and SEU, respectively.

Based on the recommended use on cereals at 450 g a.s./ha and application at BBCH 30 – BBCH 69, the maximum PEC_{SW} values for CGA321915 were 1.60 µg/L and 1.28 µg/L (Step 2) in NEU and SEU, respectively.

Based on the recommended use on cereals at 450 g a.s./ha and application at BBCH 30 – BBCH 69, the maximum PEC_{SW} values for CGA275535 were 0.251 µg/L and 0.201 µg/L (Step 2) in NEU and SEU, respectively.

These simulations are described further in the Part B Section 8.

PEC_{SW} and PEC_{SED} for prothioconazole

FOCUS STEPs 1-4 modelling of prothioconazole and associated major metabolites using LoEP parameters have been provided assuming the critical use pattern on cereals (150 g a.s./ha, and BBCH window 30-69) and included into the dRR B8 sections 8.9 and 8.9.2.2.

A summary of global maximum PEC_{SW} values at FOCUS STEP 4 are provided below;

Table 3.7-2: Global maximum PEC_{SW} values for prothioconazole, following single application(s) of Kayak Era according to the Central EU zone GAP according to surface water Step 4 (Papasova, V., 2022, VV-943372)

Mitigation options				
Vegetative strip (m)		0	10	20
No spray buffer (m)		10	10	20
Nozzle reduction (%)		0	0	0
Crop	Scenario	PEC _{SW} (µg/L)	PEC _{SW} (µg/L)	PEC _{SW} (µg/L)
Winter cereals 150 g a.s./ha BBCH 30-69	D3 ditch	0.137	0.137	0.071
	D4 pond	0.020	0.020	0.014
	D4 stream	0.159	0.159	0.083
	D5 pond	0.020	0.020	0.014
	D5 stream	0.172	0.172	0.089
	R1 pond	0.037	0.024	0.015
	R1 stream	0.221	0.122	0.063
Spring cereals 150 g a.s./ha BBCH 30-69	D3 ditch	0.137	0.137	0.071
	D4 pond	0.020	0.020	0.014
	D4 stream	0.159	0.159	0.082
	D5 pond	0.020	0.020	0.014
	D5 stream	0.161	0.161	0.083

PEC_{SW} and PEC_{SW} for JAU 6476-S-methyl, JAU 6476-desthio and 1,2,4-triazole

The Predicted Environmental Concentration of soil, water and sediment formed metabolites JAU 6476-S-methyl and JAU 6476-desthio, as well as the water and sediment formed metabolite 1,2,4-triazole have been assessed with the FOCUS SW 1-2 v3.2 model. JAU 6476-desthio was also modelled further at FOCUS STEPS 3-4.

Based on the recommended use on cereals at 150 g a.s./ha and application at BBCH30 – BBCH 69, the maximum PEC_{SW} values for JAU 6476-S-methyl were 0.652 µg/L and 0.532 µg/L (Step 2) in NEU and SEU, respectively.

Based on the recommended use on cereals at 150 g a.s./ha and application at BBCH 30 – BBCH 69, the maximum PEC_{SW} values for 1,2,4-triazole were 0.180 µg/L and 0.164 µg/L (Step 2) in NEU and SEU, respectively. These simulations are described further in the Part B Section 8.

Based on the recommended use on cereals at 150 g a.s./ha and application at BBCH 30 – BBCH 69, a summary of global maximum PEC_{SW} values of JAU 6476-desthio at FOCUS STEP 4 are provided below.

Table 3.7-3: Global maximum PEC_{sw} values for JAU 6476-desthio, following single application(s) of Kayak Era according to the Central EU zone GAP according to surface water Step 4

Mitigation options				
Vegetative strip (m)		0	10	20
No spray buffer (m)		10	10	20
Nozzle reduction (%)		0	0	0
Crop	Scenario	PEC _{sw} (µg/L)	PEC _{sw} (µg/L)	PEC _{sw} (µg/L)
Winter cereals 150 g a.s/ha BBCH 30-69	D3 ditch	0.001	0.001	0.001
	D4 pond	0.005	0.005	0.003
	D4 stream	0.004	0.004	0.004
	D5 pond	0.005	0.005	0.003
	D5 stream	0.002	0.002	0.001
	R1 pond	0.026	0.013	0.007
	R1 stream	0.265	0.121	0.063
Spring cereals 150 g a.s/ha BBCH 30-69	D3 ditch	0.001	0.001	<0.001
	D4 pond	0.005	0.005	0.003
	D4 stream	0.005	0.005	0.005
	D5 pond	0.005	0.005	0.003
	D5 stream	0.002	0.002	0.001

3.7.4 Predicted environmental concentrations in air (PEC_{air})

The vapour pressure at 20 °C of the active substance cyprodinil is between 10⁻⁵ and 10⁻⁴ Pa. Hence the active substance cyprodinil is regarded as semi-volatile (volatilization only from plant surfaces). Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active cyprodinil due to volatilization with subsequent deposition was considered.

The vapour pressure at 20 °C of the active substance prothioconazole is < 10⁻⁵ Pa. Hence the active substance prothioconazole is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance prothioconazole due to volatilization with subsequent deposition should not be considered.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

Birds

The acute and long-term risks of A23282A to birds were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies with cyprodinil, prothioconazole, its major metabolite JAU 6476-desthio and maximum residues occurring on food items following applications according to the proposed use pattern.

For cyprodinil, prothioconazole and the prothioconazole metabolite JAU 6476-desthio, the acute and chronic screening step or Tier 1 TER values exceed the trigger values of 10 and 5, respectively, indicating that the risk to birds is acceptable following use of A23282A according to the proposed use pattern.

Additionally, the acute and chronic TER values for the mixture exceed the relevant triggers indicating an acceptable risk to birds from A23282A.

Risk of secondary poisoning has also been assessed, as cyprodinil, prothioconazole, and prothioconazole metabolites JAU 6476-desthio and JAU 6474 S-methyl all have log P_{OW} values >3.0 . The risk to birds from exposure via drinking water has also been assessed. All assessments indicate that the risk to birds is acceptable following use of A23282A according to the proposed use pattern.

Mammals

The acute and long-term risks of A23282A to mammals were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies with cyprodinil, prothioconazole, and its metabolite JAU 6476-desthio, and maximum residues occurring on food items following applications according to the proposed use pattern.

For cyprodinil, prothioconazole and the metabolite JAU 6476-desthio, acute and long-term TER values at either screening or Tier 1, all exceed the trigger values of 10 for acute risk and 5 for long-term risk.

For the mixture toxicity assessment, the acute and long-term risk to mammals from proposed uses of A23282A is considered acceptable when consideration is given to refined crop interception values.

Risk of secondary poisoning has also been assessed, as cyprodinil, prothioconazole, and prothioconazole metabolites JAU 6476-desthio and JAU 6474 S-methyl all have log P_{OW} values >3.0 . The risk to mammals from exposure via drinking water has also been assessed. All assessments indicate that the risk to mammals is acceptable following use of A23282A according to the proposed use pattern.

Other Terrestrial Vertebrate Species

There is currently no guidance addressing terrestrial life stages of amphibians and reptiles in PPP risk assessments. Therefore, the risk assessment provided above for birds and mammals is protective of terrestrial amphibian and reptile species.

3.8.2 Effects on aquatic species

Cyprodinil

The PEC/RAC ratios, using worst-case PEC_{SW} values for fish (acute and chronic), invertebrates (acute), algae, macrophytes and sediment dwellers are less than the trigger value of 1, indicating that the risk to these groups of aquatic organisms is acceptable following use of A23282A in accordance with the proposed use pattern.

An acceptable long-term risk to invertebrates from exposure to cyprodinil is achieved if the below listed mitigation options are implemented (see Table 3.8-1 and Table 3.8-2).

Prothioconazole

The PEC/RAC ratios, using worst-case PEC_{SW} values, are less than the trigger value of 1, indicating that the risk is acceptable following use of A23282A in accordance with the proposed use pattern.

Metabolites

The PEC/RAC ratios, using worst-case PEC_{SW} values for metabolites of cyprodinil and prothioconazole, except for the prothioconazole metabolite JAU 6476-desthio, are less than the trigger value of 1, indicating that the risk to aquatic organisms for the metabolites is acceptable following use of A23282A in accordance with the proposed mitigation.

An acceptable long-term risk to fish from exposure to JAU 6476-desthio is achieved if the below listed mitigation options are implemented (see Table 3.8-1 and Table 3.8-2, mitigations options required for cyprodinil are also achieving an acceptable risk for Metabolite JAU 6476-desthio).

The mitigation required for safe use has been consolidated ~~into one table~~ for each crop:

Winter and spring cereals (considering the ETO-RAC) – 10 m SD + 10 m RO.

Table 3.8-1: Aquatic organisms: mitigation requirements / options for A23282A following use in winter cereals

FOCUS Scenario	Fish chronic	Invertebrate chronic (using Cyprodinil ETO-RAC)
D3 Ditch	-	5 m SD + 50 % DR or 10 m SD
D4 Stream	-	5 m SD + 50 % DR or 10 m SD
D5 Stream	-	5 m SD + 50 % DR or 10 m SD
R1 Stream	-	5 m SD

“mitigation measures are not required

SD = spray drift buffer

DR = drift reducing nozzles

Table 3.8-2: Aquatic organisms: mitigation requirements / options for A23282A following use in spring cereals

FOCUS Scenario	Fish chronic	Invertebrate chronic (using Cyprodinil ETO-RAC)
D3 Ditch	-	5 m SD + 50 % DR or 10 m SD
D4 Stream	-	5 m SD + 50 % DR or 10 m SD
D5 Stream	-	5 m SD + 50 % DR or 10 m SD

An empty/grey field means that the scenario is not relevant to the crop group

“mitigation measures are not required

SD = spray drift buffer

A table indicating the percentage reduction required to achieve an acceptable risk to aquatic organisms are presented below.

Table 3.8-3: Aquatic organisms: percentage reduction of entry by cyprodinil into surface water to achieve acceptable risk when considering the ETO-RAC of 0.75 µg/L

Scenario	Winter cereals		Spring cereals	
	BBCH 30	BBCH 69	BBCH 30	BBCH 69
	ETO RAC: 0.75 µg/L			
D3 Ditch	73.6	73.7	73.7	73.7
D4 Stream	64.3	69.5	67.8	69.4

D5 Stream	67.0	71.7	68.6	69.8
R1 Stream	59.9	60.1	-	-

~~These scenarios are not relevant for spring cereals~~

A23282A and Mixture Toxicity

Cyprodinil was identified as the single driver of toxicity for both the invertebrate acute and algal formulation assessments, therefore a mixture toxicity risk assessment was not required for these groups, and the single substance assessments for cyprodinil should be referred to.

For sediment dwellers, there was not sufficient data to perform a mixture toxicity assessment.

The mixture Exposure/Toxicity Ratios, using worst-case PEC_{SW} values, for fish (acute and chronic) and macrophytes are less than the relevant trigger value, indicating that the risk to aquatic organisms for the mixture of cyprodinil, prothioconazole and JAU 6476-desthio is acceptable following use of A23282A in accordance with the proposed mitigation.

The RQ_{mix}, using worst-case PEC_{SW} values, for invertebrates (chronic) are less than 1, indicating that the chronic risk to invertebrates for the mixture of cyprodinil, prothioconazole and JAU 6476-desthio is acceptable following use of A23282A in accordance with the proposed mitigation.

An acceptable long-term risk to fish and invertebrates from exposure to the mixture of cyprodinil, prothioconazole and JAU 6476-desthio is achieved if the below listed mitigation options are implemented (see Table 3.8-1 and Table 3.8-2).

3.8.3 Effects on bees

The acute risk to honeybees was assessed from hazard quotients and Exposure Toxicity Ratios (ETRs) following EFSA (2014), estimated from acute oral and contact studies with cyprodinil, prothioconazole, its metabolite JAU 6476-desthio and A23282A at the maximum single application rate. All the acute contact hazard quotients and Exposure Toxicity Ratios (ETRs) for cyprodinil, prothioconazole, its metabolite JAU 6476-desthio and A23282A are less than the relevant trigger, indicating that the acute oral and contact risk to honeybees is acceptable following use of A23282A according to the proposed use pattern.

The chronic adult and larval risk A23282A to honeybees was assessed from ETRs following EFSA (2014), estimated from chronic adult and larval studies with cyprodinil, prothioconazole, A23282A and the cyprodinil/prothioconazole mixture and potential exposure calculated from exposure via residues in pollen/nectar and the measure of consumption of foraging bees/drone larvae.

The ETR values are less than the relevant trigger values at the screening step or tier 1, indicating that the chronic risk to adult and larval honeybees is acceptable following use of A23282A according to the proposed use pattern.

The submitted risk assessment is based new EU guidance (2013) was not evaluated as this guidance is not in force.

The acute risk assessment based on actual guidance SANCO, 2002, was additionally performed.

The risk to bees is therefore acceptable following use of A23282A according to the proposed use pattern.

3.8.4 Effects on other arthropod species other than bees

The risk assessment using Tier II studies and an aged-residue extended laboratory test with *A. rhopalosiphi*, showed acceptable foliar in-field and off-field effects from foliar applications of A23282A for the worst-

case use scenario (1 x 2 L A23282A /ha in cereals). The risk to non-target arthropods is therefore acceptable following use of A23282A according to the proposed use pattern.

3.8.5 Effects on soil organisms

Soil meso- and macrofauna

The long-term risk of A23282A, cyprodinil, prothioconazole, and relevant metabolites to earthworms, *Collembola* and *Hypoaspis* was evaluated where relevant. The risk assessment demonstrated that the risk to non-target soil meso- and macrofauna is acceptable following use of A23282A according to the proposed use patterns.

Soil micro-organisms

The risk of A23282A, cyprodinil, prothioconazole and relevant metabolites to soil micro-organisms was evaluated by comparison of the maximum concentrations with effects $\leq 25\%$ derived from laboratory tests, with maximum PEC_s. All the effect levels exceeded the relevant PEC_s values, indicating that the risk to soil micro-organisms is acceptable following the use of A23282A according to the proposed use patterns.

3.8.6 Effects on non-target terrestrial plants

Less than 50% effect on seedling emergence and vegetative vigour on all six species was observed at the maximum single use rate of 2000 mL A23282A/ha at screening step. This indicates that the risk to non-target terrestrial plants in off-crop areas is acceptable following use of A23282A according to the proposed use pattern.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Tests on other non-target species are not required.

3.9 Relevance of metabolites (Part B, Section 10)

The cyprodinil metabolites CGA249287, ~~CGA321915~~ and CGA275535 and prothioconazole metabolites JAU 6476-S-methyl and JAU 6476-desthio are predicted to occur in groundwater at concentrations below 0.1 µg/L (see A23282A, dRR Part B, Section 8.8).

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Kayak Era (A23282A) contains cyprodinil which is approved as a candidate for substitution because two of PBT criteria are met.

A conclusion of the comparative assessment is provided separately.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

Physicochemical properties: The two year storage stability study is ongoing. It has to be assessed in the post registration. A temporary conditional validity period for the product may be granted. It is required that after completion of the study, this missing two year study will be submitted for evaluation in Poland.

Appendix 1 Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

Appendix 2 Copy of the product label

MS assessor to present a copy of the approved product label for MS country.

Appendix 3 Letter of Access

A Letter of Access is provided separately.

Appendix 4 Lists of data considered for national authorization

List of data submitted and updated by the applicant and relied on

Also provided separately

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
XXXX	XXXX	XXX	XXXX	XX	XX	XX	XX	XX

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

As data protection for all EU reviewed studies has expired below table has intentionally been left blank and the list as published by the RMS of the active substance is not added here.

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	Data protection claimed Y/N	Justification if data protection is claimed	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner