

REGISTRATION REPORT
Part B
Section 3
Efficacy Data and Information
Concise summary

Product code: ADM.03500.F.2.B/ADM.3500.F.2.B/
MCW-2075

Product name(s): Soratel 250 EC

Chemical active substance(s):

Prothioconazole, 250 g/L

Central
Zonal Rapporteur Member State: Poland

NATIONAL ADDENDUM Poland
(extension of use)

Applicant: ADAMA Polska Sp. z o.o.
Submission date: April 2024, update: May 2024, June 2024
MS Finalisation date: June 2024 (initial National Assessment)

Version history

When	What
April 2024	Initial dRR – Adama Polska Sp. z o.o.
May 2024	Update dRR (correction in the Applicant's name in Appendix 1) – Adama Polska Sp. z o.o.
June 2024	Update dRR (additional argumentation f to reduce the number of seasons to 1 for PSDCHE in winter wheat – amendments are highlighted in green) – Adama Polska Sp. z o.o.
June 2024	<p>Initial zRMS assessment</p> <p>The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency.</p> <p>Following the evaluation and before sending the document for commenting, all coloured highlighting was removed, from the parts updated by the Applicant, for better legibility.</p>

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3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

Transformation of the dRR (applicant version) into the RR (zRMS version)

Comments of zRMS:

Conclusions from the evaluation were prepared using grey commenting boxes placed at the end of each chapter. Textual changes were done using grey highlights in the text. The parts of the text amended or added by the zRMS evaluator are highlighted in grey, whereas the parts struck off are also visibly marked with the grey font.

3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

Comments of zRMS:

This application has been submitted for the extension of use of the fungicide ADM.3500.F.2.B (the trade name Soratel 250 EC), containing 250 g/L prothioconazole (DMI fungicide, FRAC code: 3), to the following additional uses: winter wheat: *Oculimacula yallundae* and spring wheat: *Puccinia striiformis*, *Puccinia recondita*, *Erysiphe graminis* and *Zymoseptoria tritici*.

Minimum effective dose

The requested dose rate of 0,8 L/ha of ADM.3500.F.2.B has been proven as the minimum effective dose (MED) in the control of target pathogens on winter and spring wheat.

Efficacy

A total of 10 valid efficacy field trials carried out in 2023 were considered for expand the use of the fungicide ADM.3500.F.2.B for the control of fungal diseases on winter and spring wheat. The trials were conducted in North-East EPPO zone (PL).

Based on the submitted trial results, it can be concluded that ADM.3500.F.2.B applied at the recommended dose rate of 0,8 L/ha is effective in the control of target pathogens: *Oculimacula yallundae* on winter wheat and *Puccinia striiformis*, *Puccinia recondita*, *Erysiphe graminis*, *Zymoseptoria tritici* on spring wheat.

Phytotoxicity, yield

Phytotoxicity and adverse effects on the yield quantity and quality are not expected after application of ADM.3500.F.2.B, when used according to the label recommendations.

Resistance management strategy

The resistance management strategy is already placed in the label of the currently registered ADM.3500.F.2.B. The strategy includes:

- Use the product mainly preventively i.e. at the beginning of primary or secondary infection periods. If preventive use is not possible, it is also permissible to use of the product at later stages of infection, but this may be associated with increased selection in the population of the pathogen toward forms with lower sensitivity to the active substance of the product,
- Use of the product at the full recommended dose, also when using the product in tank mixtures with other fungicides,
- Use the product only once per growing season,
- Include in the adopted plant protection program fungicides containing active substances from other groups according to the FRAC classification, with different modes of action, for which there is no risk of cross-resistance of pathogens to active substances from group 3 according to the FRAC classification (use the products alternately or in a tank mixture),
- Include in the adopted disease plant protection program other than chemical control methods, in accordance with the principles of integrated plant protection, e.g., cultivation of resistant varieties, proper crop rotation.

Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fnp G, Gn, Gnp 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 safener/ synergist per ha, other dose rate expression, dose range (min-max)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L prod- uct / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	TRZAW	F	<i>Oculimacula yallundae</i> (PSDCHE)	SPRAY	BBCH 30-32	a) 1 b) 1	n.a	a) 0,8 L/ha b) 0,8 L/ha	a) 200 b) 200	100-400			A
2	PL	TRZAS	F	<i>Puccinia striiformis</i> (PUCST) <i>Puccinia triticina</i> (PUCRT) <i>Blumeria graminis</i> (ERYSGR) <i>Zymoseptoria tritici</i> (SEPTTR)	SPRAY	BBCH 30-69	a) 1 b) 1	n.a	a) 0,8 L/ha b) 0,8 L/ha	a) 200 b) 200	100-400			A

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.

** F: professional field use, Fn: non-professional field use, Fnp: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gnp: professional and non-professional greenhouse use, I: indoor application

Column 15: zRMS conclusion:

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible

3.2 Efficacy data (KCP 6)

Introduction

This document summarises the information related to the efficacy data for extension of use of ADM.3500.F.2.B in control of fungal disease: *Oculimacula yallundae* on winter wheat and fungal diseases on spring wheat.

ADM.3500.F.2.B is a fungicide based on the well-known and proven fungicidal active ingredient prothioconazole.

All the trials were carried out in Poland by official testing facilities and private testing organisations.

Description of active substances/mode of action

Table 3.2-1: Details of the active substances

Active substance	Prothioconazole	
Concentration (Unit: g/kg or g/L...)	250 g/L	
Chemical group	triazoles	
Mode of action	DeMethylation Inhibitors	
Biological action	Systemic fungicide	
Degradation in soil (DT50)	Lab (DT50): 0.07 to 1.27 days median: 0.5 days (n=4) Field (DT50f): 1.3 to 2.8 days median: 1.6 days (n=8)	Based on EFSA Scientific Report (2007) 106, 1-98, Conclusion on the peer review of prothioconazole
Mobility in soil	Low mobility in soil	
Date of approval (Annex I)	01.08.2008	
Expiration of approval	31.07.2021	

Description of the plant protection product

ADM.3500.F.2.B contains the active ingredient (AI) prothioconazole and is formulated as an emulsifiable concentrate (EC). It contains 250 g/L of prothioconazole. Information on the detailed composition of ADM.3500.F.2.B can be found in the confidential dossier of this submission (Registration Report - Part C).

Table 3.2-2: Simplified table of currently registered uses and requested uses for the product code

Uses		Member State	Currently registered rate(s)	Requested rate(s)	Comments / Other relevant details on GAPS
Crop(s)	Target(s)				
Winter wheat (TRZAW)	<i>Blumeria graminis</i> <i>Puccinia triticina</i> <i>Puccinia striiformis</i> <i>Zymoseptoria tritici</i> <i>Fusarium sp.</i> <i>Oculimacula yallundae</i>	PL	0,8 L/ha	0,8 L/ha	
Spring wheat (TRZAS)	<i>Blumeria graminis</i> <i>Zymoseptoria tritici</i> <i>Puccinia striiformis</i> <i>Puccinia triticiana</i>	PL	0,8 L/ha	0,8 L/ha	
Winter barley (HORVW)	<i>Pyrenophora teres</i> <i>Puccinia hordei</i> <i>Rhynchosporium secalis</i>	PL	0,8 L/ha		
Spring barley (HORVS)	<i>Pyrenophora teres</i> <i>Puccinia hordei</i> <i>Rhynchosporium secalis</i>	PL	0,8 L/ha		
Winter triticale	<i>Puccinia triticina</i>	PL	0,8 L/ha		

Uses		Member State	Currently registered rate(s)	Requested rate(s)	Comments / Other relevant details on GAPS
Crop(s)	Target(s)				
(TTLWI)	<i>Septoria sp</i>				
Winter rye (SCCEW)	<i>Puccinia recondita</i> <i>Rhynchosporium secalis</i>	PL	0,8 L/ha		
Winter oil seed rape (BRSNW)	<i>Sclerotinia sclerotiorum</i>	PL	0,7 L/ha		

Remark: The requested uses are indicated in **bold font**.

Further details are in the table “All intended uses” in Part B - Section 0. Description of the target pests

Table 3.2-3: Glossary of pests mentioned in the dossier

EPPO code	Scientific name
ERYSGR	<i>Blumeria graminis</i>
PUCCRT	<i>Puccinia triticina</i>
PUCCST	<i>Puccinia striiformis</i>
PSDCHE	<i>Oculimacula yallundae</i>
SEPTTR	<i>Zymoseptoria tritici</i>

*—optional

Table 3.2-4: Major / minor status of intended uses

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
Winter wheat	PL		PSDCHE	PL	
Spring wheat			ERYSGH	PL	
			PUCCST		
			PUCCRT		
			SEPTTR		

Compliance with the Uniform Principles

All trials presented in this section were implemented in accordance with the GEP principles and according to relevant EPPO guidelines. All trials submitted were carried out by GEP certified test facilities. The assessments and compilation of this dossier were performed in compliance with the uniform principles for evaluation of plant protection products. These include general principles as the evaluation of data in the light of current knowledge, taking account of the particular conditions prevailing in the zone in which the product is to be used and specific principles concerning, among other things, the efficacy and the absence of unacceptable effects on target crops. The overall assessment was performed according to the Uniform Principles.

Information on trials submitted (3.1.2 Efficacy data)

The following EPPO guidelines relate to the conduct of fungicide trials for the control of foliar diseases on wheat, crop safety, and the assessment of target pathogen infestations on which data are presented in this dossier.

EPPO guidelines followed:

EPPO guideline N° PP1/181: Conduct and reporting of efficacy evaluation trials.

EPPO guideline N° PP1/152: Design and analysis of efficacy evaluation trials.

EPPO guideline N° PP1//241: Guidance on Comparable Climates.

EPPO guideline N° PP1/225: Minimum Effective Dose.

EPPO guideline N° PP1/026: Foliar and ear diseases on cereals.

EPPO guideline N° PP1/028: Eyespot of cereals

Table 3.2-5: Presentation of trials (efficacy trials, preliminary trials...)

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)	GEP, non-GEP, official***	Comments (any other relevant information)
					North East zone		
Winter wheat (post-emergence)	<i>Oculimacula yallundae</i>	Poland	2023	MED	6 (6)	GEP	
	TOTAL	-	2023	-	6 (6)	-	
Spring wheat (post-emergence)	<i>Blumeria graminis</i> <i>Zymoseptoria tritici</i> <i>Puccinia striiformis</i> <i>Puccinia triticiana</i>	Poland	2023	MED	4 (4)	GEP	
	TOTAL	-	2023	-	4 (4)	-	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Table 3.2-6: Presentation of reference standards used in trials (efficacy trials)

Crop(s)	Reference standard	Country(ies) where the product is registered ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter wheat TRZAW Spring wheat TRZAS	Input 460 EC	PL	R-134/2018b 14.03.2018 R-61/2011 05.10.2011	prothioconazole spiroxamine	EC	prothioconazole – 160 g/L spiroxamine – 300 g/L	1,0 L/ha	1,0 L/ha	
	Poleposition	PL	R - 29 /2020 - 19.03.2020	prothioconazole	EC	300 g/L	0,65 L/ha	0,65 L/ha	
	Protikon 250 EC	PL	R-127/2021 05.10.2021	prothioconazole	EC	250 g/L	0,8 L/ha	0,8 L/ha	

(1) only on use(s) applied for (with the test product).

(2) e.g. WP (wetable powder), EC (emulsifiable concentrate), etc.

(3) dose(s) / dose range authorized on that use in the country.

(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application, etc.).

3.2.1 Preliminary tests (KCP 6.1)

The active ingredient of ADM.3500.F.2.B, prothioconazole is authorised and widely used for the control of fungal pathogens in many countries inside and outside of Europe. It therefore is not deemed necessary to provide results from preliminary range finding tests. The product complies with the Uniform Principles.

Comments of zRMS on: Preliminary tests (3.2.1)

Accepted. Additional data not required.

3.2.2 Minimum effective dose tests (KCP 6.2)

A total of 10 trials were established to assess the minimum effective dose of ADM.3500.F.2.B applied on winter wheat and spring wheat. In cereal crops, for both winter and spring wheat, the target rate of ADM.3500.F.2.B is 0,8 L/ha. The reduced tested rate of ADM.3500.F.2.B is 0,6 L/ha (75%) and the target dose rate of test item is 0,8 L/ha (100%). In accordance with the EPPO guideline PP

1/225(1) “Minimum effective dose”, the rate range reflects 75% and 100% of the recommended dose rate of ADM.3500.F.2.B Efficacy is tested under a range of environmental conditions to fully challenge the product.

Table 3.2-5: Efficacy of different rates of ADM.3500.F.2.B against fungal diseases *Oculimacula yallundae* on winter wheat

Crop	Applica- tion code	Plant part	Assess- ment	Patho- gen	n	Disease index UNC		Control (%) of Test Product			
								0,6 L/ha		0,8 L/ha	
						mean	range	mean	range	mean	range
TRZAW	A	stem	62-84 DAA	PSDCHE	6	1,4	0,4- 2,4	53,4	34,2- 67,5	73,4	57,5 57,7 -85,2

Table 3.2-5a: Efficacy of different rates of ADM.3500.F.2.B against fungal diseases on spring wheat

Crop	Application code	Plant part	Assessment	Pathogen	n	PESSEV UNC (%)		Control (%) of Test Product			
								0,6 L/ha		0,8 L/ha	
						mean	range	mean	range	mean	range
TRZAS	A	Leaf 1	47 DAA	PUCCST	1	6,5	6,5	76,8	76,8	88,7	88,7
TRZAS	A	Leaf 1	41 DAA	PUCCRT	1	8,8	8,8	77,1	77,1	88,5	88,5
TRZAS	A	Leaf 2	28 DAA	ERYSGR	2	11,5	8,5- 14,5	70,4	70,1-70,7	87,3	85,1-89,5
TRZAS	A	Leaf 1	47 DAA	ERYSGR	1	8,8	8,8	74,3	74,3	85,8	85,8
TRZAS	A	Leaf 1	41 DAA	SEPTTR	1	10,8	10,8	69,4	69,4	88,1	88,1

The results demonstrate, that against fungal diseases on winter wheat and spring wheat a clear dose response effect can be observed. To reach the level of performance of the authorized reference products, the full rate of 0,8 L/ha is required. Thus, the intended target dose rate of 0,8 L/ha of ADM.3500.F.2.B is justified.

Summary and conclusions on the minimum effective dose

As a result, the proposed rate of 0,8 L/ha of ADM.3500.F.2.B in cereal crops should be considered the minimum effective dose to deliver broad spectrum control of the target pathogens under a wide range of environmental conditions.

Comments of zRMS on: Minimum effective dose (3.2.2)

Results from 10 trials conducted in 2023, in North-East EPPO zone (PL) have been presented to determine the Minimum Effective Dose (MED) of the fungicide ADM.3500.F.2.B, which was tested at recommended dose rate of 0,8 L/ha and at lower dose rate of 0,6 L/ha that corresponds to 75% of the target dose rate.

Based on the submitted trial results, a clear dose response was seen with the increasing dose rate of ADM.3500.F.2.B in the control of *Oculimacula yallundae* on winter wheat and *Puccinia striiformis*, *Puccinia recondita*, *Erysiphe graminis*, *Zymoseptoria tritici* on spring wheat.

It can be concluded, that the dose rate of 0,8 L/ha of ADM.3500.F.2.B provided better efficacy results compared to the lower dose rate of 0,6 L/ha in the trials conducted on both winter and spring wheat and therefore has been proven as the Minimum Effective Dose in the control of target pathogens.

3.2.3 Efficacy tests (KCP 6.2)

Trials in this dossier were carried out by contractor companies and official research institutes, all of which following the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

In this section results are presented for efficacy of ADM.3500.F.2.B against fungal pathogen: *Oculimacula yallundae* on winter wheat (TRZAW) and fungal diseases on spring wheat.

Control of *Oculimacula yallundae* (PSDCHE) on winter wheat

Efficacy data for the control of *Oculimacula yallundae* on winter wheat are presented from 6 efficacy trials carried out in Poland. As the relevant assessment, the rating carried out at (or close by) the preferred crop growth stage (BBCH 71-77) is used.

Materials and methods

Target dose rate of tests item; ADM.3500.F.2.B is 0,8 L/ha , clearly prove as minimum effective dose in chapter 3.2.1

ADM.3500.F.2.B is intended to be applied only once per season, at BBCH 30-32 ~~31~~.

Efficacy of test item was compared to reference products applied at registered dose rates; details are specified in Table 3.2 6.

Site

Trials were conducted in regions where winter wheat is grown commercially. The experiment was established on a set of complete randomized blocks in 4 replications.

Testing units:

Staphyt Sp z o.o..

Eurofins Agrosience Services Sp. z o.o.

The testing units ~~have~~ ~~has~~ been mandated to conduct research in the field of efficacy of plant protection products and are officially GEP recognized.

Experimental details

The trials were conducted in compliance with the principles of Good Experimental Practice (GEP) as defined by the EU law 91/414/EEC and as referred to in Regulation (EC) No 1107/ 2009 of the European Parliament and of the Council of 21 October 2009.and according to the EPPO guidelines PP 1/135(4);PP 1/152(4);PP 1/181(4);PP 1/225(2), PP 1/239(3), PP 1/26(4), PP 1/28(3).

Assessment methods

Statistical Analysis

Assessment data was analyzed using a one-way analysis of variance (ANOVA). The probability of no significant difference occurring between treatment means is calculated as the F probability value p (F). Statistical groups are indicated by letters in the treatment tables. Treatment means with no common letters are considered as significantly different at a 95% confidence level.

Assessment of efficacy

The assessment of efficacy in the treated plots was made in relation to the untreated plot on an overall plot basis (scale 0-100 %, 0 % =no efficacy). Efficacy was recorded by estimation and/or counting of severity of disease.

Scale for the assessment of attack of eyespot on cereals:

PESINC 1 - Healthy: no symptoms (I)

PESINC 2 - Slight lesions: less than 50% of tiller circumference attacked at place where infection is most severe (II)

PESINC 3 -Moderate lesions: more than 50% of tiller circumference attacked at place where infection is most severe, but tissue still firm (III)

PESINC 4 - Severe lesions: 100% of tiller circumference attacked with tissue rotted (softening) (IV)

Based on classification PESINC Index was calculated:

$$X = \frac{(n(II) \times 0.25) + (n(III) \times 0.75) + n(IV)}{n(I + II + III + IV)}$$

In trials: PL23FETRZAW055A;PL23FETRZAW055B;PL23FETRZAW055C;PL23FETRZAW055D,
% control, based on index, were calculated by author of the dossier.

Assessment of Phytotoxicity

Visual estimation of phytotoxicity according to percentage scale 0-100%, where:

- 0% –no damage
- 100% - total damage of plants

Assessment of vigour

Vigor of plants according to scale 0-100%, where:

- 0% –plant without vigour
- 100% –full vigour

Assessment of yield

- yield (kg/plot; t/ha),
- kernel moisture (%) weight of a thousand kernel (%)
- lodging (%)
- green area (%)
- weight 100 Ltr. (kg)
- protein content (%)

Table 3.2-6: Details on trial methodology

Guidelines	General guidelines	PP 1/26(4); PP 1/135(4); PP 1/152(4); PP 1/181(4); PP 1/225(2); PP1/239(3)
	Specific guidelines	PP 1/28(3)
Experimental design	Plot design	RCB
	Plot size	24-30 m ²
	Number of replications	4
Crop	Trials per crop	Winter wheat (6)
	Varieties per crop	Winter wheat: Comandor, Askaban, Kilimanjaro, Patras, Arkadia(2)
	Sowing period	Winter wheat: 30/9/2022, 01/10/2022, 08/10/2022, 28/09/2022, 27/09/2022, 01/10/2022
Application	Crop stage (BBCH)* at application	Winter wheat: BBCH 30-32 31
	Timing Pest stage at application (1)	MYCELI; 100%
	Number of applications	1
	Spray volumes	200 - 300 L/ha
Assessment	Assessment types	Efficacy was recorded by estimation and/or counting of severity of disease.
	Assessment dates	According to EPPO guideline PP 1/28(3) relevant assessments of <i>Oculimacula yallundae</i> infestations should be carried out in the area of crop growth stage BBCH 71-77 . In the trials the crop growth stage BBCH ranged from 75 to 77.
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	sandy loam, sandy clay loam, clayey sand, loamy sand pH: 5,7 – 6,6 5,8 – 6,2
	e.g. Natural / artificial inoculation...	N
	e.g. Field / Greenhouse...	F

* BBCH for weeds, pre-emergence, preventive / curative application, insect stage...

Table 3.2-7 Efficacy of ADM.3500.F.2.B against *Oculimacula yallundae* on winter wheat compared to the reference products.

Crop	Application code	Plant part	Assessment	Pathogen	n	Disease index in UNC (%)		Control (%) of Test Product		Control (%) of Ref. Prod. Input 460 EC (n=3 4)		Control (%) of Ref. Prod. Protikon 250 EC (n=3 6)	
						mean	range	0,8 L/ha		mean	range	mean	range
								mean	range				
TRZAW	A	stem	62-84 DAA	PSD-CHE	6	1,4	0,4-2,4	73,4	57,5 57,7 -85,2	65,2	52,2-73,91	67,8 66,7	56-85,2 79,2

Based on the results of 6 trials, the mean efficacy of ADM.3500.F.2.B applied at the rate of 0,8 L/ha was 73,4 % (range 57,5 57,7% to 85,2%). The results clearly demonstrate the good performance of ADM.3500.F.2.B against *Oculimacula yallundae*. The performance is comparable to the performance provided by reference products.

In 6 efficacy trials with a relevant infestation of *Oculimacula yallundae* yield was taken. The results are presented in table 3.2.-8 (quantity of yield) and table 3.2.-9 (quality of yield).

Table 3.2-8 Yield results of harvested efficacy trials

Type of assessment	UNCK			ADM.3500.F.2.B 0,8 L/ha			Protikon 250 EC 0,8 L/ha			Input 460 EC 1,0 L/ha		
	mean	min	max	mean	min	max	mean	min	max	mean	min	max
YIELD kg/plot	8,4	7,9	9,0	9,4	8,6	10,7	9,1	8,6	10,2	8,9	8,7	9,2
n	6			6			6			4		
YIELD t/ha	6,3	5,0	7,5	7,0	5,7	8,9	6,8	5,7	8,5	6,3	5,5	6,9
n	6			6			6			4		

The results clearly demonstrate the benefits provided by the control of *Oculimacula yallundae* with ADM.3500.F.2.B. Compared to the untreated control the mean yield increase was 12 %.

Table 3.2 9 Quality of yield in harvested efficacy trials

Type of assessment	UNCK			ADM.3500.F.2.B 0,8 L/ha			Protikon 250 EC 0,8 L/ha			Input 460 EC 1,0 L/ha		
	mean	min	max	mean	min	max	mean	min	max	mean	min	max
MOICON %	13,3	12,2	15,9	12,8 13,3	12,3	15,8	12,8	9,6	15,8	12,6	12,2	13,2
n	6			6			6			4		
HLW kg	78,3 77,9	74,3	80,3 81,6	78,6 78,2	74,4	81,6	78,6 78,2	74,3	81,7	78,8 78,2	76,8 75,6	81,6 80,3
n	6			6			6			4		
TKW g	42,2 42,0	39,8 39,2	45,7	42,6 42,0	40,0 39,3	46,7	42,5 42,3	42,2 39,5	46,6	41,7 41,4	41,3 40,7	42,2
n	6			6			6			4		
PROCON %	11,5 11,4	9,1 9,0	12,9 12,7	11,5 11,7	9,3 9,2	12,9	11,8 11,7	9,0 8,9	13,0	11,9 11,8	9,2 9,1	13,3
	4			4			4			4		

There are no indications that quality parameters of yield are affected adversely.

Based on national harmonization arrangements, for a product containing a known substance, it is required to submit min. 6 trials performed in 2 crop growing seasons, however it is possible to reduce the number of seasons to 1 if the substantive reasoning is presented.

The efficacy data package submitted for the ADM.3500.F.2.B application on winter wheat: *Oculimacula yallundae* contains 6 trials carried out in 1 growing season. ADM.3500.F.2.B is a fungicide based on the well-known and proven active substance prothioconazole. On the Polish market there are currently registered products containing prothioconazole in the 250 EC formulation, which are registered for cereal against PSDCHE, such as VIRID 250 EC, or Protikon 250 EC, used in trials as a standard.

Taking into account the average efficacy of the six trials that were conducted in Poland under conditions characteristic of this country, the efficacy of ADM.3500.F.2.B was higher than that of the standards included in the protocol (Protikon 250 EC - prothioconazole 250 g/a, and Input 460 EC prothioconazole - 160 g/l, spiroxamine- 300 g/l), which, given the large problem of the severity of stem base disease in Poland due to limitations in crop rotation, gives the opportunity for users to effectively reduce the disease. In addition, ADM.3500.F.2.B under trade name Soratel is already registered in Poland and the safety of its use has been confirmed for use in the range of phases from BBCH 30-69, so the requested range for use of the agent against PSDCHE (BBCH 30-32) is within the accepted range.

It can be concluded that ADM.3500.F.2.B is suitable for the control of *Oculimacula yallundae* on winter wheat.

Control of fungal diseases on spring wheat

Efficacy data for the control of fungal diseases on spring wheat are presented from 4 efficacy trials carried out in Poland. As the relevant assessment, the rating carried out at (or close by) the preferred crop growth stage (BBCH 75) is used.

Materials and methods

Target dose rate of the test item; ADM.3500.F.2.B is 0,8 L/ha , clearly proven as minimum effective dose in chapter 3.2.1

ADM.3500.F.2.B is intended to be applied only once per season, at BBCH 30-69 65.

Efficacy of the test item was compared to reference products applied at registered dose rates; details are specified in Table 3.2 6.

Site

Trials were conducted in regions where spring wheat is grown commercially. The experiment was established on a set of complete randomized blocks in 4 replications.

Testing units:

Fertico Sp z o.o.

The testing unit has been mandated to conduct research in the field of efficacy of plant protection products and are officially GEP recognized.

Experimental details

The trials were conducted in compliance with the principles of Good Experimental Practice (GEP) as defined by the EU law 91/414/EEC and as referred to in Regulation (EC) No 1107/ 2009 of the European Parliament and of the Council of 21 October 2009.and according to the EPPO guidelines PP 1/135(4), PP 1/152(4), PP 1/181(4), PP 1/225(2), PP 1/26(4) .

Assessment methods

Statistical Analysis

Statistical analysis was carried out with the use of statistic pack of ARM Research Manager 9 Software (Gylling Data Management). The trial results were statistically analyzed using analysis of variance. To assess the significance of differences between the investigated products NIR (LSD) test was used

Assessment of efficacy

The effectiveness was assessed based on the percentage of leaf surface infection

Assessment of Phytotoxicity

Visual estimation of phytotoxicity according to percentage scale 0-100%, where:

- 0% –no damage
- 100% - total damage of plants

Assessment of vigour

Vigor of plants according to scale 0-100%, where:

- 0% –plant without vigour
- 100% –full vigour

Assessment of yield

- yield (kg/plot; t/ha),
- kernel moisture (%) weight of a thousand kernel (%)

- lodging (%)
- Green area (%)
- weight 100 Ltr. (kg)

Table 3.2-10 Details on trial methodology

Guidelines	General guidelines	PP 1/135(4);PP 1/152(4);PP 1/181(4);PP 1/225(2)
	Specific guidelines	PP 1/26(4)
Experimental design	Plot design	RCBD
	Plot size	21 m ²
	Number of replications	4
Crop	Trials per crop	Spring wheat (4)
	Varieties per crop	Spring wheat: Rusalka, Goplana (2), Tybalt
	Sowing period	Spring wheat: 31/03/2023,18/03/2023,17/03/2023,27/03/2023
Application	Crop stage (BBCH)* at application	BBCH 39-45
	Timing	Foliar application at infestation and/or re-infestation
	Number of applications	1
	Spray volumes	200-250 L/ha
Assessment	Assessment types	PESSEV %
	Assessment dates	According to EPPO guideline PP 1/26(4) relevant assessments of infestations should be carried out preferably in the area of crop BBCH 75 . In the trials the crop growth stage BBCH ranged from 63-79 75 to 77.
Other relevant information	e.g. Soil type, pH	clayey sand ,sandy clay, sandy clay loam, less pH: 5,8 6 – 6,9
	e.g. Natural / artificial inoculation...	No
	e.g. Field / Greenhouse...	F

Table 3.2-11 Efficacy of ADM.3500.F.2.B against fungal diseases on spring wheat compared to the reference products

Crop	Pathogen	Plant part	Assessment	n	Disease level PESSEV in UTC (%)		Control (%) of test item 0,8 L/ha		Control (%) of Ref. Prod. (Poleposition)	
					mean	range	mean	range	mean	range
TRZAS	PUCGST	Leaf 1	47 DAA	1	6,5 4,2-7,5	2,5-6,5	88,7 94,1	88,7-100	92,3 95,3	92,3 93,8-100
	PUCCRT	Leaf 1	41 DAA	1	8,8	8,8	88,5	88,5	88,5	88,5
	ERYSGR	Leaf 2	28 DAA	2	11,5 1,3-18,5	8,5-14,5	87,3 90,3	85,1-89,5 85,76-100	84,6 88,2	81-88,2 100
	ERYSGR	Leaf 1	47 DAA	1	8,8	8,8	85,8	85,8	85,8	85,8
	SEPTTR	Leaf 1	41 DAA	1	10,8	10,8	88,1	88,1	74,4	74,4

Based on the results of 4 trials, the mean efficacy of ADM.3500.F.2.B applied at the rate of 0,8 L/ha was ranged from **85,8-88,7%** ~~94,1 % – 88,1~~. The results clearly demonstrate the good performance of ADM.3500.F.2.B against fungal diseases . The performance is comparable to the performance provided by reference product³.

In 4 efficacy trials with a relevant infestation of fungal diseases yield was taken. The results are presented in table 3.2.-12 (quantity of yield) and table 3.2.-13 (quality of yield).

Table 3.2 -12 Yield results of harvested efficacy trials

Type of assessment	UNCK			ADM.3500.F.2.B 0,8 L/ha			Poleposition 0,65 L/ha		
	mean	min	max	mean	min	max	mean	min	max
YIELD kg/plot	6,2	5,5	6,5	6,9 7,0	6,6 6,9	7,3	7,1	6,7	7,6
n	4			4			4		
YIELD t/ha	5,9	5,3	6,2	6,6	6,3	6,9	6,8	6,4	7,2
n	4			4			4		

The results clearly demonstrate the benefits provided by the control of fungal diseases with ADM.3500.F.2.B. Compared to the untreated control the mean yield increase was 12 %.

Table 3.2.13 Quality of yield in harvested efficacy trials

Type of assessment	UNCK			ADM.3500.F.2.B 0,8 L/ha			Poleposition 0,65 L/ha		
	mean	min	max	mean	min	max	mean	min	max
MOICON %	13,6	13,2	14,2	13,8	13,2	14,3	13,8	13,2	14,4
n	4			4			4		
HLW kg	76,3	71,7	81,0	77,6	72,4	81,8	77,5	72,5	81,5
n	4			4			4		
TKW g	42,7	41,3	44,3	43,1	41,7	44,6	43,1	41,7	44,5
n	4			4			4		

There are no indications that quality parameters of yield are affected adversely.

It can be concluded that ADM.3500.F.2.B is suitable for the control of fungal diseases on spring wheat.

Minor use

n.a.

Yield (and relevant quality indicators), from efficacy trials (in the presence of challenging pest populations)

As ADM.3500.F.2.B showed no herbicidal activity, no dedicated crop safety trial was necessary (in accordance with EPPO standard PP1/135(4) “Phytotoxicity assessment”).

Since this part concerns only trials in pest-free conditions, no data are presented. Yield results achieved from efficacy trials are presented in section 3.2 (efficacy data).

Summary and conclusion

10 trials were carried out in Poland to evaluate the efficacy of ADM.3500.F.2.B against the target fungal pathogen on winter wheat: *Oculimacula yallundae* and fungal diseases on spring wheat.

The results demonstrate that the intended target dose rates of ADM.3500.F.2.B (0,8 L/ha) is required for a comprehensive successful protection of the target crops. At the target dose rates, ADM.3500.F.2.B achieves **good to** very good efficiency for the control of the target fungal diseases on

winter and spring wheat.

At presence of the target diseases, applications of ADM.3500.F.2.B have a clearly positive effect on the yield of winter and spring wheat.

The product complies with the Uniform Principles.

Extrapolation

It is justifiable to extrapolate from a strong database of one crop to support registration of another crop if certain conditions are met.

According to SANCO/D3/S12.395857, proposed general principles for efficacy extrapolations between crops for the same target: fungal diseases.

- Extrapolations may only be accepted for the extension of use of a given plant protection product used in the same way and at the same rate and dose, i.e. they cannot be used to extrapolate a use to a different product.
- When considering the acceptability of an extrapolation, account must be taken of timing of disease control, times of sowing/planting, competitiveness of the crop and time/method of harvesting.

According to extrapolation table, acceptable for national registrations, the following considerations have to be regarded for extrapolation in the case of this dossier:

ERYSGR – representative crop: winter wheat – spring wheat – number of valid results: 2 (necessary ~~no~~ of valid results:1-2) extrapolation possible.

PUCGST – representative crop: winter wheat – spring wheat – number of valid results: 1 (necessary ~~no~~ of valid results:1-2) extrapolation possible.

PUCCRT - representative crop: winter wheat – spring wheat – number of valid results: 1 (necessary ~~no~~ of valid results:1-2) extrapolation possible.

SEPTTR- representative crop: winter wheat – spring wheat – number of valid results: 1 (necessary ~~no~~ of valid results:1-2) extrapolation possible.

Comments of zRMS on:

Efficacy tests (3.2.3)

A total of 10 valid efficacy field trials carried out in 2023 were considered for expand the use of fungicide ADM.3500.F.2.B for the control of fungal diseases on winter and spring wheat. The requested uses include: *Oculimacula yallundae* (PSDCHE) on winter wheat (TRZAW); application timing: BBCH 30-32 and *Puccinia striiformis* (PUCGST), *Puccinia recondita* (PUCCRT), *Erysiphe graminis* (ERYSGR), *Zymoseptoria tritici* (SEPTTR) on spring wheat (TRZAS); application timing BBCH 30-69. ADM.3500.F.2.B is intended to be applied only once per growing season, at recommended dose rate of 0,8 L/ha.

The trials were conducted in North-East EPPO zone (PL). All the trials were carried out by the officially GEP-recognized testing units.

Conclusions from the evaluation have been summarized separately for winter and spring wheat.

TRZAW: PSDCHE

As demonstrated in 6 efficacy trials carried out on winter wheat, the fungicide ADM.3500.F.2.B was moderately effective in the control of PSDCHE with the mean efficacy result of 73%. The efficacy of ADM.3500.F.2.B was comparable or higher, than the efficacy of the reference products Input 460 EC and Protikon 250 EC.

The Applicant has presented a substantive reasoning for submitting efficacy trials from only 1 growing season including the following arguments:

- ADM.3500.F.2.B is based on well-known active substance prothioconazole,
- other products with prothioconazole intended for the control of PSDCHE are available on the Polish market,
- higher efficacy of ADM.3500.F.2.B as compared with reference products containing prothioconazole was noted in the presented efficacy trials,
- the crop safety after application of ADM.3500.F.2.B (within the crop growth stage BBCH 30-69) was tested and assessed in core assessment.

It can also be added, that the efficacy of ADM.3500.F.2.B against foliar diseases and crop safety were tested in

various growing seasons and assessed in core assessment.

The justification has been accepted by the zRMS.

It can be concluded the extension of use of ADM.3500.F.2.B for the control of *Oculimacula yallundae* on winter wheat may be granted in Poland.

TRZAS: PUC CST, PUC CRT, ERYSGR, SEPTTR

As demonstrated in 4 efficacy trials (1 trial per PUC CST, PUC CRT, SEPTTR; ERYSGR occurred in 2 trials) carried out on spring wheat, the fungicide ADM.3500.F.2.B was highly effective in the control of all target pathogens with the mean efficacy result of 86-89%. The efficacy of ADM.3500.F.2.B for the control of PUC CST; PUC CRT, ERYSGR was comparable to the reference product Poleposition. For the control of SEPTTR, the tested fungicide ADM.3500.F.2.B was visibly more effective as compared to the reference product Poleposition.

Based on the national extrapolation rules (the possibility of extrapolation efficacy data from winter wheat to spring wheat), the presented efficacy data package (1-2 trials per each claimed use) is sufficient to support the authorization of ADM.3500.F.2.B for the control of PUC CST, PUC CRT, ERYSGR and SEPTTR on spring wheat.

It can be concluded the extension of use of ADM.3500.F.2.B for the control of *Puccinia striiformis*, *Puccinia recondita*, *Erysiphe graminis*, *Zymoseptoria tritici* on spring wheat may be granted in Poland.

Yield data from efficacy trials

Based on the submitted trial results, it can be concluded, that ADM.3500.F.2.B, applied at the recommended dose rate of 0,8 L/ha has no negative impact on the yield quantity and yield quality parameters (TGW, HLW, Protein content) of wheat.

The fungicide ADM.3500.F.2.B visibly increased the yield of winter and spring wheat compared to the untreated control.

Additional remark

The presented data have been submitted to support the extension of use of the product ADM.3500.F.2.B in the control *Oculimacula yallundae* on winter wheat and *Puccinia striiformis*, *Puccinia recondita*, *Erysiphe graminis*, *Zymoseptoria tritici* on spring wheat in Poland (North-East EPPO zone). All the trials submitted to cover the requested uses, were carried out only in North-East EPPO zone (PL). No trials were conducted in Maritime or South-East EPPO zone. In case of possible future applications in other Member States, the decision on acceptance data from North-East EPPO zone will be made on the national level, according to the national requirements.

3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

Please refer to core dossier.

Comments of zRMS on:

Information on the occurrence or possible occurrence of the development of resistance (3.3)

Detailed data is contained in core assessment. No additional data has been submitted by the Applicant.

The test item ADM.3500.F.2.B contains active substance prothioconazole (chemical group: triazoles, group name: DMI-fungicides, SBI: Class I; FRAC code: 3). The resistance risk for DMI-fungicides has been defined by FRAC as medium.

According to the FRAC Pathogen Risk List (revised in September 2019), *Erysiphe graminis*, *Zymoseptoria tritici* and *Puccinia* spp. are defined as high, medium and low risk of resistance pathogens respectively.

FRAC List of the first confirmed cases of plant pathogenic organisms resistant to disease control agents (revised in May 2020) includes the following cases of the cereal pathogens resistance to:

DMI-fungicides:

- *Erysiphe graminis* (on wheat, barley)
- *Fusarium spp* (on wheat)
- *Pseudocercospora herpotrichoides* = *Oculimacula yallundae* (on wheat)

- ***Puccinia striiformis* (on wheat)**
- *Pyrenophora teres* (on barley)
- *Pyrenophora tritici-repentis* (on wheat)
- *Rhynchosporium secalis* (on barley)
- ***Zymoseptoria tritici* (on wheat)**
- *Ustilago avenae* (on oat).

According to results from monitoring studies reported by FRAC Sterol Biosynthesis Inhibitor (SBI) Working Group (Minutes from WG meeting on January 19st, 2024):

- For Wheat/ *Zymoseptoria tritici*: In 2023, in general, field performance of DMI-containing fungicides was good when used according to the manufacturers and FRAC recommendation. Overall, the sensitivity of European populations monitored in 2023 stayed in the range observed in previous years. Slight shifts in sensitivity of populations have been observed depending on the individual active ingredient and regions. In 2023, monitoring was carried out in Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, France, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, Netherlands, Norway, Poland, Romania, Russia, Slovakia, Spain, Sweden, Switzerland, Ukraine, and United Kingdom,
- For Wheat/ *Erysiphe graminis*: In 2023 monitoring was carried out in France. Sensitivity data presented for 2016 to 2023 confirmed that the situation was overall stable within the range of variability detected during the last 20 years,
- For Wheat/ *Puccinia triticina*: In 2023 monitoring was carried out in France and Germany (limited number of samples). Data from 2023 for wheat brown rust showed that sensitivities were in the range of those of the last 20 years,
- For Wheat/ *Oculimacula spp.*: In 2021 monitoring was carried out in Germany, Italy, Latvia, Poland, Slovakia, and Ukraine. The same range of sensitivity as in previous years was observed in all countries,
- For Wheat/ *Puccinia striiformis*: In 2023 monitoring was carried out in France, Germany, Poland, and the United Kingdom. The first monitoring in 2015 showed high sensitivity and low diversity, and from 2016 to 2023 a stable situation was reported.

To avoid the risk of resistance development, the resistance management is necessary. The resistance management strategy is already placed in the label of the currently registered ADM.3500.F.2.B. The strategy includes:

- Use the product mainly preventively i.e. at the beginning of primary or secondary infection periods. If preventive use is not possible, it is also permissible to use of the product at later stages of infection, but this may be associated with increased selection in the population of the pathogen toward forms with lower sensitivity to the active substance of the product,
- Use of the product at the full recommended dose, also when using the product in tank mixtures with other fungicides,
- Use the product only once per growing season,
- Include in the adopted plant protection program fungicides containing active substances from other groups according to the FRAC classification, with different modes of action, for which there is no risk of cross-resistance of pathogens to active substances from group 3 according to the FRAC classification (use the products alternately or in a tank mixture),
- Include in the adopted disease plant protection program other than chemical control methods, in accordance with the principles of integrated plant protection, e.g., cultivation of resistant varieties, proper crop rotation.

3.4 Adverse effects on treated crops (KCP 6.4)

Information on trials submitted (3.4: Adverse effects on treated crops)

As ADM.3500.F.2.B showed no herbicidal activity, no dedicated crop safety trial was necessary (in accordance with EPPO standard PP1/135(4) “Phytotoxicity assessment”). No data are available from specific selectivity (pest free) trials, since the active ingredient of ADM.3500.F.2.B is already well known and used on the market of several European countries for several years, and in commercial use, no reports on negative effects of prothioconazole on crops were recorded.

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

As ADM.3500.F.2.B showed no herbicidal activity, no dedicated crop safety trial was necessary (in accordance with EPPO standard PP1/135(4) “Phytotoxicity assessment”).

Materials and Methods of efficacy trials have been covered in section 3.2.

EPPO guidelines followed:

EPPO guideline N° PP1/181: Conduct and reporting of efficacy evaluation trials.

EPPO guideline N° PP1/152: Design and analysis of efficacy evaluation trials.

EPPO guideline N° PP1//241: Guidance on Comparable Climates.

EPPO guideline N° PP1/135: Phytotoxicity.

EPPO guideline N° PP1/225: Minimum Effective Dose.

EPPO guideline N° PP1/026: Foliar and ear diseases on cereals.

EPPO guideline N° PP1/028/: Eyespot of cereals

All assessments were based on a 0-100 scale where 0 means no damage and 100 means total crop loss. Individual phytotoxicity symptoms were recorded where appropriate. Where no phytotoxicity was observed, this was generally recorded within the individual trial reports either as assessment (0) or as text in the comments. No phytotoxicity was observed also in all trials, where no specific ratings or comments were made in the detailed trial records.

Winter wheat

6 trials were carried out Poland in crop season 2023 on a wide range of commercially grown cultivars. The frequency and magnitude of the maximum observed phytotoxicity in the trials is shown in table 3.4.1-1

Table 3.4.1-1: Phytotoxicity of product

Crop	Evaluation period	# of tests	ADM.3500.F.2.B 0,8 L/ha	Reference product(s)
			Phyto*(%)	Phyto*(%)
TRZAW	across the whole test period	≤ 5%	6	6
		>5% to 10%	0	0
		>10% to 15%	0	0
		>15 %	0	0

No phytotoxicity symptom caused by ADM.3500.F.2.B at the proposed dose rate of 0,8 L/ha was recorded in any trials.

Spring wheat

4 trials were carried out Poland in crop season 2023 on a wide range of commercially grown cultivars. The frequency and magnitude of the maximum observed phytotoxicity in the trials is shown in table 3.4.1-2

Table 3.4.1-2: Phytotoxicity of product

Crop	Evaluation period	# of tests	ADM.3500.F.2.B 0,8 L/ha	Reference product(s)
			Phyto*(%)	Phyto*(%)
TRZAS	across the whole test period	≤ 5%	4	4
		>5% to 10%	0	0
		>10% to 15%	0	0
		>15 %	0	0

No phytotoxicity symptom caused by ADM.3500.F.2.B at the proposed dose rate of 0,8 L/ha was recorded in any trials.

Comments of zRMS on:

Phytotoxicity to host crop (3.4.1)

No phytotoxicity symptoms were observed after application of ADM.3500.F.2.B at recommended dose rate of 0,8 L/ha in all 10 trials conducted on winter and spring wheat.
Based on the submitted trial results it can be concluded that ADM.3500.F.2.B can be safely used on target cereal crops.

3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

As ADM.3500.F.2.B showed no herbicidal activity, no dedicated crop safety trial was necessary (in accordance with EPPO standard PP1/135(4) “Phytotoxicity assessment”).
Since this part concerns only trials in pest-free conditions, no data are presented. Yield results achieved from efficacy trials are presented in section 3.2 (efficacy data).

Comments of zRMS on:

Effects on yield of treated plants or plant products (3.4.2)

Yield results achieved from efficacy trials are presented in section 3.2.3 (Efficacy data).

Based on the submitted trial results, it can be concluded that ADM.3500.F.2.B, applied at the recommended dose rate of 0,8 L/ha has no negative impact on the yield quantity of wheat.

3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

The yield quality results separated by uses of the harvested efficacy trials of ADM.3500.F.2.B are already presented in the efficacy section (3.2.2).

For details on trial methodology, please refer to section 3.2.2.

Quality parameters like the thousand grain weight, the volume weight (hectolitre weight) of grains, protein content are presented from trials where yield was taken. Any adverse effects on the target crops have been observed.

Comments of zRMS on:

Effects on quality of plants and plant products (3.4.3)

Yield quality results achieved from efficacy trials are presented in section 3.2.3 (Efficacy data).

Based on the submitted trial results, it can be concluded that ADM.3500.F.2.B, applied at the recommended dose rate of 0,8 L/ha has no negative impact on the yield quality parameters (TGW, HLW, Protein content) of wheat.

3.4.4 Effects on transformation processes (KCP 6.4.4)

No relevant residues of prothioconazole or its metabolites are present in the target crops at harvest after a timely application of 0,8 L/ha of ADM.3500.F.2.B on small grain cereals or 0,7 L/ha on oilseed rape. If the product is used correctly and in the designated way, relevant residues in harvested plants or plant products can be excluded. Special investigations on possible effects on transformation processes are not required.

Since the market introduction of the active ingredient prothioconazole, any no cases of negative influences on parameters influencing the processing procedure of target crop plants or grains were reported, neither from practical use nor from trial experience.

Comments of zRMS on:
Effects on transformation processes (3.4.4)

Accepted.

3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

Neither from the agricultural use of prothioconazole during the past years, nor from field trials, there is any information that the application of products containing this active ingredient has any influence on the propagation behaviour of the target crops.

Comments of zRMS on:
Impact on treated plants or plant parts to be used for propagation (3.4.5)

Accepted.

Summary and conclusion

Based on the results of 10 trials on wheat it can be concluded that ADM.3500.F.2.B is very safe on the target crops. If applied at the intended target dose rate (0,8 L/ha), there is no risk for enduring crop injury, adverse effects on yield quantity, and yield quality. Since market introduction of prothioconazole containing products, the experience proves that prothioconazole has no adverse effects on transformation processes or plant parts or products used for propagation.

3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

Since ADM.3500.F.2.B shows any herbicidal activity, it can be concluded that there is any impact of the product on succeeding crops if the product is applied according to good agricultural practice.

Comments of zRMS on:
Impact on adjacent crops (3.5.2)

Accepted.

3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

Drift onto adjacent crops should be generally avoided. Since ADM.3500.F.2.B shows any herbicidal activity there is no risk for adjacent crops to become injured, even in case of improper applications.

**Comments of zRMS on:
Impact on adjacent crops (3.5.2)**

Accepted.

3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

No observations about effects of ADM.3500.F.2.B on beneficials or other non-target organisms were reported in the field trials. The results of the required standard tests are presented and discussed in Part B - Section 6, see Part A – Chemical Plant Protection Products, section 10 (Eco-toxicological Studies).

**Comments of zRMS on:
Effects on beneficial and other non-target organisms (3.5.3)**

Adverse effects on non-target organisms were not observed in a part of efficacy trials. In other trials no observations on beneficial or non-target organisms have been reported.

3.6 Other/special studies

No other/special studies are available.

3.7 List of test facilities including the corresponding certificates

Table 3.7-1: List of test facilities

Test facility	Address	Certificate (Yes or No)
Eurofins Agroscience Services Sp. z o.o.	ul. Parkowa 6; 64-530 Kaźmierz, Poland	Yes
Fertico Sp. z o.o.	Goliany 43, 05-620 Błędów, Poland	Yes
STAPHYT Sp. z o.o.	ul. Poznanska 62/53; 60-853 Poznań Poland	Yes

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2	-	2024	Biological Assessment Dossier of ADM.03500.F.2.B Unpublished	N	Adama Polska Sp. z o.o.
KCP 6.2	Krzysztof Rusek	2023	Efficacy of ADM.3500.F.2.B, ADM.03503.F.1.A, ADM.3502.F.1.A, MCW-2073 and ADM.3501.F.1.A in control of fungal diseases in spring wheat, Poland 2023 Company Report No; 137_01_F23_368 Trial ID: PL23FETRZAS064A Fertico Sp. z o.o. GEP Unpublished	N	Adama Polska Sp. z o.o.
KCP 6.2	Krzysztof Rusek	2023	Efficacy of ADM.3500.F.2.B, ADM.03503.F.1.A, ADM.3502.F.1.A, MCW-2073 and ADM.3501.F.1.A in control of fungal diseases in spring wheat, Poland 2023 Company Report No; 138_01_F23_369 Trial ID: PL23FETRZAS065A Fertico Sp. z o.o. GEP Unpublished	N	Adama Polska Sp. z o.o.
KCP 6.2	Mateusz Pszczółkowski	2023	Efficacy of Forapro 425 EC, Input 460 EC, Delaro Forte, Empartis, Flexity, Soratel 250 EC, Protikon 250 EC applied on T1 in Poland in 2023. Company Report No; MP2-23-104669-01-PL01 Trial ID: PL23FETRZAW060A Staphyt Sp. z o.o. GEP Unpublished	N	Adama Polska Sp. z o.o.
KCP 6.2	Mateusz Pszczółkowski	2023	Efficacy of Forapro 425 EC, Input 460 EC, Delaro Forte, Empartis, Flexity, Soratel 250 EC, Protikon 250 EC applied on T1 in Poland in 2023. Company Report No; MP2-23-104669-01-PL02 Trial ID: PL23FETRZAW060B Staphyt Sp. z o.o. GEP Unpublished	N	Adama Polska Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2	Grzegorz Głowacki	2023	Efficacy of various fungicides against <i>Oculimacula yallundae</i> (PSDCHE) in winter wheat in Poland, in 2023. Company Report No; S23-102326-01 Trial ID: PL23FETRZAW055A Eurofins Agrosience Services Sp. z o.o. GEP Unpublished	N	Adama Polska Sp. z o.o.
KCP 6.2	Grzegorz Głowacki	2023	Efficacy of various fungicides against <i>Oculimacula yallundae</i> (PSDCHE) in winter wheat in Poland, in 2023. Company Report No; S23-102326-02 Trial ID: PL23FETRZAW055B Eurofins Agrosience Services Sp. z o.o. GEP Unpublished	N	Adama Polska Sp. z o.o.
KCP 6.2	Grzegorz Głowacki	2023	Efficacy of various fungicides against <i>Oculimacula yallundae</i> (PSDCHE) in winter wheat in Poland, in 2023. Company Report No; S23-102326-03 Trial ID: PL23FETRZAW055C Eurofins Agrosience Services Sp. z o.o. GEP Unpublished	N	Adama Polska Sp. z o.o.
KCP 6.2	Grzegorz Głowacki	2023	Efficacy of various fungicides against <i>Oculimacula yallundae</i> (PSDCHE) in winter wheat in Poland, in 2023. Company Report No; S23-102326-04 Trial ID: PL23FETRZAW055D Eurofins Agrosience Services Sp. z o.o. GEP Unpublished	N	Adama Polska Sp. z o.o.
KCP 6.2	Krzysztof Rusek	2023	Efficacy of ADM.3500.F.2.B, ADM.03503.F.1.A, ADM.3502.F.1.A, MCW-2073 and ADM.3501.F.1.A in control of Puccinia striiformis (PUCCST) in spring wheat, Poland 2023 Company Report No; 135_PROT_F23 Trial ID: PL23FETRZAS062A Fertico Sp. z o.o. GEP Unpublished	N	Adama Polska Sp. z o.o.
KCP 6.2	Krzysztof Rusek	2023	Efficacy of ADM.3500.F.2.B, ADM.03503.F.1.A, ADM.3502.F.1.A, MCW-2073 and ADM.3501.F.1.A in control of fungal diseases in spring wheat, Poland 2023 Company Report No; 136_PROT_F23	N	Adama Polska Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Trial ID: PL23FETRZAS063A Fertico Sp. z o.o. GEP Unpublished		

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
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List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
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List of data relied on not submitted by the applicant but necessary for evaluation

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