REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: SAP2101F

Product name(s): ZELORA START

Chemical active substances:

Prothioconazole, 120 g/L
Folpet, 300 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Selectis Produtos para a Agricultura, S.A.

Submission date: December 2023,

update: February 2024, April 2024

MS Finalisation date: May 2024 (initial Core Assessment)

August 2024 (final Core Assessment)

Version history

When	What
December 2023	V0 - Initial version submitted by the Selectis Produtos para a Agricultura, S.A. for submission to Poland in the frame of new PPP registration (Acording Art. 33 of Regulation EC No 1107/2009).
February 2024	V1 – Updated version from Applicant Selectis Produtos para a Agricultura, S.A. following aknowledge of receipt from BVL. All the changes are highlighted in yellow.
April 2024	V2 – Updated version from Applicant Selectis Produtos para a Agricultura, S.A. following data gaps identified by zRMS Poland. All the changes are highlighted in green.
April 2024	V3 – Updated version from Applicant Selectis Produtos para a Agricultura, S.A. following data gaps identified by zRMS Poland. All the changes are highlighted in blue.
May 2024	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency. 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.
August 2024	Final report (Core Assessment updated following the commenting period) No additional information or assessments after the commenting period.

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

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

Abstract

SAP2101F is a Suspension Concentrate (SC) containing 120 g of Prothioconazole/L and 300 g of Folpet/L for use as a protectant fungicide for control of *Septoria* (*Zimoseptoria tritici*) in Wheat and *Helminthosporium* (*Pyrenophora teres*) in Barley, in Poland (Central European Union zone).
Several trials have been established in order to justify the mixture of the active substances, the ratio which has been choose as well as a justification of a bridging between trials made with ready-mix and tan-mix products. Results showed are considered to be enough to justify all these parameters.

A total of 48 (~~42~~ 39) efficacy trials have been presented in wheat and barley. All trials included multiple rates of **SAP2101F** in order to justify the minimum effective dose. Data have showed that ~~minimum acceptable dose to control the diseases is~~ the dose rate of 1,5 L/ha, was the most effective dose under various conditions (high and low disease pressure) and therefore can be considered as the Minimum Effective Dose to provide sufficient efficacy in North-East EPPO zone. Lower requested dose rates 1,0 and 1,25 L/ha can be also recommended under low disease pressure. The lowest tested dose rate of 0,6 L/ha was not sufficiently effective dose. ~~being than lower doses non-effective (0.6 L/ha). The doses of 1.25 L/ha and 1.5 L/ha provide higher efficacies, being the control significantly better.~~
Furthermore, another 4 trials have been performed and are still on-going, in Maritime and Mediterranean EPPO zone, in Barley against *Helminthosporium*.
The lower dose rates of the requested range (1 and 1,25 L/ha), as well of the highest requested dose (1,5 L/ha) have been compared to reference authorized products. Average efficacy values reported of trials conducted showed a robust control of the diseases, similar to reference products which were tested.
These data are enough to confirm the effectiveness of SAP2101F against *Septoria* (*Zimoseptoria tritici*) in Wheat and *Helminthosporium* (*Pyrenophora teres*) in Barley at 1 L/ha, 1,25 L/ha and 1,5 L/ha.

Requested GAP of **SAP2101F** complies with specific recommendations of FRAC to the management DMI-fungicides group ~~and the phthalimide fungicides~~. In addition, resistance management strategy has been proposed.
In resume, **SAP2101F** is a product which complies with recommendations of FRAC to avoid occurrence of the development of resistance and has a component with a multi-site contact activity (Folpet), demonstrating to be a tool for a good resistance management.

Phytotoxicity has been evaluated in all the efficacy trials and in other two selectivity trials, as well as in 9 other transformation trials, with no phytotoxicity symptoms.
Besides, 4 bread-making trials in wheat and 5 brewing trials in barley were conducted in order to analyze other undesirable effects on transformation processes.
Field phase being finished, has showed no phytotoxicity and has proved that yield in treated plots with SAP2101F is higher than the untreated plots and similar to the ones treated with reference products.
SAP2101F at 1,5 l/ha (N dose) on barley for brewing and on wheat for bread-making, showed consistent results to demonstrate the absence of non-intentional effects, even if some French trials are still on-going.

According to data submitted, the risk of impact of **SAP2101F** on the impact on other plants including succeeding plants and adjacent crops can be considered like acceptable when it is applied following the corresponding GAP.

In conclusion, it has been proved, that **SAP2101F** provided satisfying efficacy to control *Septoria* (*Zimoseptoria tritici*) in Wheat and *Helminthosporium* (*Pyrenophora teres*) in Barley from 1 L/ha to 1,5 L/ha.

Comments of zRMS:

This application has been submitted for authorization of the fungicide SAP2101F containing 120 g/L prothioconazole (DMI fungicide, FRAC code: 3) and 300 g/L folpet (phthalimides, FRAC code: M4).
SAP2101F is intended for the control of *Zymoseptoria tritici* (SEPTTR*)* on wheat (TRZAW, TRZAS, TRZDW, TRZDS) and *Pyrenophora teres* (PYRNTE) on barley (HORVW, HORVS).
The recommended application rate range is 1,0-1,5 L/ha. SAP2101F is intended to be used within the growth stage of the crop ranging from BBCH 32-61 on wheat and BBCH 30-61 on barley.

Preliminary tests (bridging, mixture justification, ratio justification)
A total of 38 trials carried out between 2020 and 2021 have been performed in order to justify bridging between trials made with ready-mix and tan-mix products (28 trials), the mixture of the active substances (15 trials) and the ratio which has been chosen (9 trials). Based on the trial results it can be concluded:

- The equivalence between co-formulated product SAP2101F and tank-mix SAP250F+SAP50SCF has been justified,
- The co-formulation mixture SAP250F 0,48 l/ha+SAP50SCF 0,6 l/ha (equivalent to SAP2101F at 1 L/ha) (120 g Prothioconazole/ha + 300 g Folpet/ha) has been justified. The new mixture prothioconaozole with multi-site action folpet will be a valuable tool in resistance management strategy,
- The ratio 120 g prothioconazole/ha + 300 g folpet/ha has been justified as the most effective for SAP2101F.

Efficacy, MED
A total of 39 valid efficacy trials carried out between 2020 and 2021 have been submitted for the evaluation of the fungicide SAP2101F. The trials were carried out in 3 EPPO zones: Maritime (France, Germany, United Kingdom), North-East (Poland) and South-East (Bulgaria, Romania). All the efficacy trials were carried out by the officially GEP-recognized testing units. As SAP2101F is intended to be authorized in Poland, efficacy trials from North-East EPPO zone and from neighbouring country (Germany) were primarily considered for the evaluation. Trials from Maritime (France, United Kingdom) and South-East (Bulgaria, Romania) EPPO zone may be relevant for possible future applications (e.g. art 40 Mutual recognition) in other Member States.

The presented efficacy data package allow to accept the use of SAP2101F applied twice at dose rate range 1,0-1,5 L/h, in the control of SEPTTR on winter wheat at BBCH 32-59 in Poland. The dose rate of 1,5 L/ha was the most effective dose under various conditions (high and low disease pressure) and therefore can be considered as the Minimum Effective Dose to provide sufficient efficacy in the control of SEPTTR on wheat (across a broad range of disease pressure). Lower requested dose rates 1,0 and 1,25 L/ha can be recommended under low disease pressure.
As no efficacy data has been submitted for spring wheat and durum wheat (winter and spring form) these uses are not accepted to be registered on the grounds of art. 33 of Regulation (EC) No 1107/2009. Durum wheat (minor crop in PL) can be registered on the grounds of article 51 of Regulation (EC) No 1107/2009.
The presented efficacy data package is not sufficient to support the use SAP2101F in the control of PYRNTE on barley (winter and spring form), therefore this use is not accepted to be registered on the grounds of art. 33 of Regulation (EC) No 1107/2009.

Phytotoxicity, yield, transformation processes, germination, succeeding crops and adjacent crops
Based on the submitted data it can be concluded, that no phytotoxicity and no adverse effect on the yield, transformation processes, seed germination, succeeding crops, adjacent crops is expected after application of SAP2101F. Nevertheless, according to the rules of Good Agricultural Practice, to avoid any risk of adverse effects on adjacent crops, it is recommended to include, in the product label, the following remark: *When using SAP2101F do not allow spray drift to the neighbouring crop plantations*.

Resistance management strategy

- Non-chemical measures such as resistant crop varieties, plant hygiene, and good agricultural practice should be taken into consideration to reduce the infection pressure of the target pathogens,
- SAP2101F should be used at the recommended dose rate,
- SAP2101F should be used predominantly for protective fungi control at the very beginning of an infection or re-infection,

- SAP2101AF should be used alternately with other fungicides containing active substances with different mode of action,
- In case of not satisfying efficacy achieved, it is advisable to inform the authorization holder.

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: developmental 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 product / 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	Soft wheat (spring) (TRZAS); Soft wheat (winter) (TRZAW); Durum wheat (spring) (TRZDS); Durum wheat (winter) (TRZDW)	F	*Septoria* (*Zymoseptoria tritici*, SEPTTR)	Tractor mounted spray	BBCH 32-~~61~~ 59	a) 2 b) 2	14	a) 1,5 L/ha b) 3 L/ha	a) 180 g ai/ha + 450 g ai/ha b) 360 g ai/ha + 900 g ai/ha	150-400	42	Range: 1 – 1,5 L/ha	A TRZAW N TRZAS TRZDW TRZDS (possible registration on the grounds of article 51)
2	PL	Barley (spring) (HORVS); Barley (winter) (HORVW)	F	Helminthosporium (*Pyrenophora teres*, PYRNTE)	Tractor mounted spray	BBCH 30-61	a) 2 b) 2	14	a) 1,5 L/ha b) 3 L/ha	a) 180 g ai/ha + 450 g ai/ha b) 360 g ai/ha + 900 g ai/ha	150-400	42	Range: 1 – 1,5 L/ha	N

* 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, 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

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 of the plant protection product **SAP2101F** with Concentrated Suspension (SC) formulation containing 120 g/l of Prothioconazole and 300 g/l of Folpet, active ingredients are included into Regulation (EC) Nº 1107/2009.

Folpet legislation: Regulation (EU) Nº 540/2011, Regulation (EU) 2020/869).
Prothioconazole legislation: 08/44/EC, Regulation (EU) Nº 540/2011, Regulation Nº 2020/869.

The SANCO report for Folpet (SANCO/10032/2006 - rev. 5- 11 July 2008) is considered to provide the relevant review information or a reference to where such information can be found.
The SANCO report for Prothioconazole (SANCO/3923 /07 - final - 10 December 2007) is considered to provide the relevant review information or a reference to where such information can be found.

The purpose of this document is to provide data in support of an application for the registration of SAP2101F as a fungicide product to be used on wheat and barley in ~~United Kingdom, Germany, Bulgaria, Romania,~~ Poland. ~~Hungary, Slovakia, Slovenia, Belgium, Netherlands, Austria and Czech Republic.~~

Description of active substances
Prothioconazole is a systemic demethylation inhibitor (DMI) fungicide which belongs to the triazole chemical group. It acts against susceptible fungi through the inhibition of demethylation at position 14 of lanosterol or 24-methylene dihydroano-sterol, both of which are precursors of sterols in fungi; i.e., it works through disruption of ergosterol biosynthesis (Ergosterol, a precursor to Vitamin D2, is an important component of fungal cell walls).

Folpet belongs to the chemical group of the phthalimide fungicides and, according to FRAC (Fungicide Resistance Action Committee) it is included in the group M4, substances with a multi-site contact activity. This substance acts by inhibiting many oxidative enzymes, carboxylases and enzymes involved with phosphate metabolism and citrate synthesis. Folpet reacts with the sulfhydryl groups of nuclear proteins, leading to an inhibition of the cell division.

Mode of action

Table 3.2-1: Description Prothioconazole

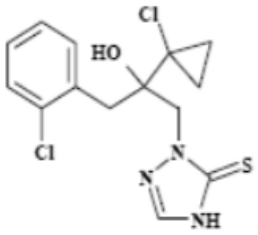
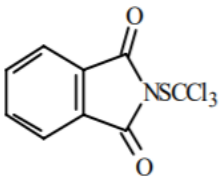
Common name (ISO)	Prothioconazole
Chemical name (IUPAC)	(*RS*)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3-thione
Chemical name (CA)	2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione
CIPAC No	745
CAS No	178928-70-6
EEC No	Not allocated
FAO SPECIFICATION	Not available
Minimum purity	≥ 970 g/kg The following manufacturing impurities are of toxicological concern and each of them must not exceed a certain amount in the technical material: - Toluene: < 5 g/kg - Prothioconazole-desthio (2-(1-chlorocycloproyl)1-(2-chlorophenyl)-3-(1,2,4-triazol-1-yl)-propan-2-ol): < 0.5 g/kg (LOD)
Molecular formula	$C_{14}H_{15}Cl_2N_3OS$
Molecular mass	344.26 g/mol
Structural formula	

Table 3.2-2: Description Folpet

Common name (ISO)	Folpet
Chemical name (IUPAC)	*N*-(trichloromethylthio) phthalimide
Chemical name (CA)	2-[(trichloromethyl)thio]-1*H*-isoindole-1,3(2H)-dione
CIPAC No	75
CAS No	133-07-3
EEC No	205-088-6
Minimum purity	940 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	Perchloromethylmercaptan (R005406) maximum level 3.5 g/kg carbon tetrachloride maximum level 4 g/kg
Molecular formula	$C_9H_4Cl_3NO_2S$
Molecular mass	296.6
Structural formula	

Description of the plant protection product

SAP2101F is a Suspension Concentrate (SC) containing 120 g of Prothioconazole/L and 300 g of Folpet/L.

Description of the target pests

Table 3.2-1: Glossary of pests mentioned in the dossier.

EPPO code	Scientific name	Common name*
PYRNTE	*Pyrenophora teres*	*Helminthosporium.* Net blotch of barley
SEPTTR	*Zymoseptoria tritici*	Septoria leaf blotch/ speckled leaf blotch

* optional

Table 3.2-2: Major / minor status of intended uses (for all cMS and zRMS)

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	Minor		Major	Minor
Wheat	PL	-	SEPTTR	PL	-
Barley	PL	-	PYRNTE	PL	-

Regarding crop status: according to the lists of major and minor crops, wheat and barley are major crops in Poland.

Regarding pest status: according to the lists of major and minor pests, the pests which are mentioned above are major crops in Poland.

Compliance with the Uniform Principles

Data to support the registration of SAP2101F has been generated by GEP companies and following EPPO/CEB guidelines. No deviations to these EPPO/CEB guidelines have been observed on the performance of the trials. Therefore, it can be concluded that the overall assessment can be performed according to the uniform principles.

Information on trials submitted (3.1 Efficacy data)

An overview of submitted trials can be consulted on the following pages on tabular form. The list of all individual trials is detailed in the table 3.2.3.-1: "List of efficacy trials carried out on SAP2101F" (see point 3.2.3 "Efficacy tests").

Table 3.2-3: Presentation of trials (efficacy trials, MED, 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)
					Maritime zone	Mediterra-nean zone	South-East zone	North-East zone		
Wheat	SEPTTR	FR	2020	P+MED+E	3(3)	2(2 0)			GEP	
			2021	P+MED+E	2(2)	2(2)			GEP	
		RO	2020	P+MED+E			3(3)		GEP	
			2021	P+MED+E			2(2)		GEP	
		BG	2020	P+MED+E			1(1)		GEP	
			2021	P+MED+E			3(3)		GEP	
		PL	2020	P+MED+E				4(4)	GEP	
			2021	P+MED+E				5(5)	GEP	
		SP	2020	P+MED+E		1(1)			GEP	
			2021	P+MED+E		2(1)			GEP	
		IT	2020	P+MED+E		1(1)			GEP	
			2021	P+MED+E		1(1)			GEP	
		HU	2021	P+MED+E			1(0)		GEP	
		DE	2020	P+MED+E	2(2)				GEP	
			2021	P+MED+E	1(1)				GEP	
		UK	2020	P+MED+E	1(1 0)				GEP	

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)
					Maritime zone	Mediterra-nean zone	South-East zone	North-East zone		
			2021	P+MED+E	1(1)				GEP	
Barley	PYRNTE	FR	2020	P+MED+E	3(~~3~~ 2)				GEP	
			2021	P+MED+E	3(3)	4(~~2~~ 1)			GEP	
			2022	P+MED+E	2				GEP	Trials on-going
		BG	2021	P+MED+E			2(2)		GEP	
		IT	2021	P~~+MED+E~~		2(2)			GEP	
			2022	P+MED+E		2			GEP	Trials on-going
		PL	2021	P+MED+E				4(4)	GEP	
		RO	2021	P+MED+E			1(1)		GEP	
		SP	2021	P+MED+E		2(~~2~~ 0)			GEP	
		HU	2021	P+MED+E			1(0)		GEP	
		DE	2020	P+MED+E	2(0)				GEP	
			2021	P+MED+E	3(~~1~~ 0)				GEP	
	~~Total~~	~~-~~	~~2020-2021~~	~~P~~	~~21(17)~~	~~17(14)~~	~~14(12)~~	~~13(13)~~	~~GEP~~	
	~~Total~~	~~-~~	~~2020-2021~~	~~MED~~	~~21(17)~~	~~17(14)~~	~~14(12)~~	~~13(13)~~	~~GEP~~	
	~~Total~~	~~-~~	~~2020-2021~~	~~E~~	~~21(17)~~	~~17(14)~~	~~14(12)~~	~~13(13)~~	~~GEP~~	
	TOTAL		2020-2021	WHEAT	10(~~10~~ 9)	9(~~8~~ 6)	10(9)	9(9)	GEP	
	TOTAL		2020-2021	BARLEY	11(~~7~~ 5)	8(~~6~~ 3)	4(3)	4(4)	GEP	
	TOTAL	**-**	**2020-2021**	**-**	**21(~~17~~ 14)**	**17(~~14~~ 9)**	**14(12)**	**13(13)**	**GEP**	

* 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. Detailed data on the number of trials for P, MED and E trials is contained in the chapters: 3.2.1, 3.2.2 and 3.2.3 (see zRMS commenting boxes).
*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

A total of 65 (48) trials on wheat and barley are submitted (21 (14) in Maritime EPPO climatic zone, 17 (9) in Mediterranean EPPO climatic zone, 14 (12) in South-East EPPO climatic zone and 13 in North-East EPPO climatic zone).
Besides, another 2 trials performed in 2022 in France in Maritime EPPO zone and 2 in Italy in Mediterranean EPPO zone, in Barley against *Helminthosporium*, are on-going and will be submitted once finished.
In two trials any disease has appeared (04B-F-2021-FR05 and 04B-F-2021-HU01), so those trials will be used as selectivity trials, and other trials just showed infestation on secondary diseases.

Table 3.2-4: Presentation of reference standards used in trials (efficacy trials, preliminary trials...)

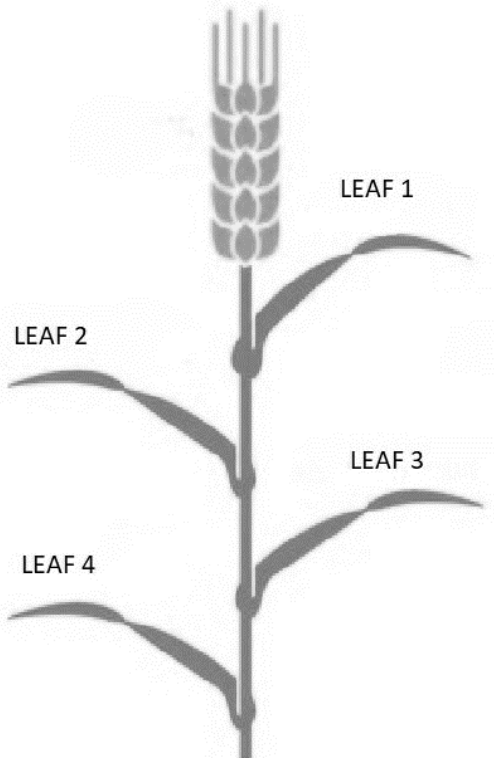
Crop(s)	Reference standard	Country(ies) where the product is registered (1)	Authorization number	Active substance(s)	Formulation		Registered application rate(3)	Application rate in trials (per treatment)	Remark(4)
					Type(2)	Concentration of a.s.			
Wheat	JOAO	France	2060116	Prothioconazole	EC	250 g/L	0,8 L/ha	0,8 L/ha	
	CURBATUR	Germany	025287-60	Prothioconazole	EC	250 g/L	0,8 L/ha	0,8 L/ha	
	PROLINE	United Kingdom	14790	Prothioconazole	EC	275 g/L	0,72 L/ha	0,72 L/ha; 0,63 L/ha	In 03B-F-2021-UK01 trial, due to a mistake, the product has been applied at a lower dose
	MANITOBA	United Kingdom	16539	Epoxiconazole + Folpet	SC	50 g/L + 375 g/L	2 L/ha	2 l/ha	
	PROSARO 250 EC	Romania	2517/22.02.2005	Prothioconazole + Epoxiconazole	EC	125 g/L + 125 g/L	0,75 L/ha	0,75 L/ha	
	PROSARO	Bulgaria	RD 11-642/19.04.2016	Prothioconazole + Epoxiconazole	EC	125 g/L + 125 g/L	1 L/ha	1 L/ha	
	PROLINE	Hungary	6300/1205-1/2020	Prothioconazole	EC	250 g/L	0,8 L/ha	0,8 L/ha	
	PROSARO 250 EC	Poland	R- 152/2014	Prothioconazole + Epoxiconazole	EC	125 g/L + 125 g/L	1 L/ha	1 L/ha	
	AsPik 250 EC	Poland	R - 157/2020	Prothioconazole + Epoxiconazole	EC	125 g/L + 125 g/L	1 L/ha	1 L/ha	
	DELARO 325 SC	Poland	R-18/2016wu	Prothioconazole + Trifloxystrobin	SC	175 g/L + 150 g/L	1 L/ha	1 L/ha	
Barley	JOAO	France	2060116	Prothioconazole	EC	250 g/L	0,8 L/ha	0,8 L/ha	
	CURBATUR	Germany	025287-60	Prothioconazole	EC	250 g/L	0,8 L/ha	0,8 L/ha	
	PROSARO 250 EC	Romania	2517	Prothioconazole + Epoxiconazole	EC	125 g/L + 125 g/L	0,75 L/ha	0,75 L/ha	

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.			
	PROSARO	Bulgaria	RD 11-642/19.04.2016	Prothioconazole + Epoxiconazole	EC	125 g/L + 125 g/L	0,75 L/ha	1 L/ha	
	PROLINE	Hungary	6300/1205-1/2020	Prothioconazole	EC	250 g/L	0,8 L/ha	0,8 L/ha	
	PROSARO 250 EC	Poland	R- 152/2014	Prothioconazole + Epoxiconazole	EC	125 g/L + 125 g/L	1 L/ha	1 L/ha	
	AsPik 250 EC	Poland	R - 157/2020)	Prothioconazole + Epoxiconazole	EC	125 g/L + 125 g/L	1 L/ha	1 L/ha	

(1) only on use(s) applied for (with the test product).
(2) e.g. WP (wettable 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)

In order to explain how the leaves levels have been evaluated, the following scheme is presented:



For the Preliminary tests, all trials have been evaluated together regardless of the EPPO Climatic zone in order to provide more data and, for instance, to make results more robust.

Bridging

In 2020 all trials were made in tank-mix SAP250F+SAP50SCF (120 g Prothioconazole/ha + 300 g Folpet/ha) and, in 2021, all trials were made in ready-mix SAP2101F (120 g Prothioconazole/ha + 300 g Folpet/ha).
Both formulations contain the same actives substances at the same concentrations. The aim of this bridging is to demonstrate the equivalence of SAP250F+SAP50SCF and SAP2101F.

For wheat, a total of 16 trials have been performed in four EPPO Climatic zones (Maritime, Mediterranean, South-East and North-East), in Italy, Romania, Bulgaria, Poland, France, Spain, Germany and United Kingdom in 2021, including both ready-mixed product and the tank-mixed products, in order to prove they are equals.
In order to properly compare both treatments, the rate of 1 L/ha is the one being compared as, the smaller is the dose, the higher are the differences.
It is also compared in two different leaves levels and at the last evaluation, which are the more representative parameters.

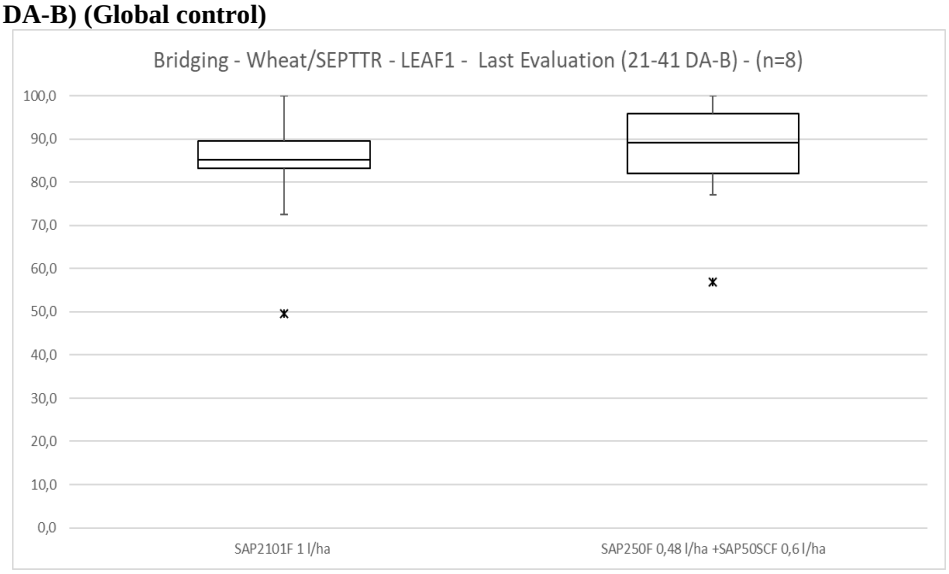
Table 3.2.1-a: Bridging. Comparison of the efficacy of SAP2101F co-formulated product with the equivalent tank-mix at 1 l/ha on wheat against *Septoria* in LEAF1. Most representative evaluation (21-41 DA-B) – Detailed table

Refer to BAD.

Table 3.2.1-b: Bridging. Comparison of the efficacy of SAP2101F co-formulated product with the equivalent tank-mix at 1 l/ha on wheat against *Septoria* in LEAF1. Most representative evaluation (21-41 DA-B)

Target	Nb of trials	Untreated plot	% control		Nb of trials where SAP2101F 1 l/ha is >, < or =
			SAP2101F 1 l/ha	SAP250F 0,48 L/ha + SAP50SCF 0,6 L/ha	
			120 g SAP250F/ha + 300 g SAP50SCF/ha	120 g SAP250F/ha + 300 g SAP50SCF/ha	
		Mean Max Min	Mean Max Min	Mean Max Min	SAP250F 0,48 L/ha + SAP50SCF 0,6 L/ha
% CONTROL (21-41 DA-B) Global average	**8 (9)**	**12,4** **25,0** **5,0**	**86,5** **100,0** **72,5**	**89,0** **100,0** **77,0**	**> 0** **= 7** **< 1**
% CONTROL (32 DA-B - 41 DA-B) Maritime EPPO zone	3	18,0 25,0 7,9	89,1 96,9 84,7	91,5 98,9 80,9	> 0 = 2 < 1
% CONTROL (23 DA-B - 33 DA-B) Mediterranean EPPO zone	2 (3)	13,9 20,4 5,0	93,6 100,0 87,2	95,7 100,0 91,3	> 0 = 2 < 0
% CONTROL (21 DA-B) North-East EPPO zone	1	6,7 6,7 6,7	72,5 72,5 72,5	77 77 77	> 0 = 1 < 0
% CONTROL (21 DA-B) South-East EPPO zone	2	6,6 7,8 5,4	82,5 83,9 81,0	84,7 87,1 82,3	> 0 = 2 < 0

Figure 3.2.1-a: Bridging. Comparison of the efficacy of SAP2101F co-formulated product with the equivalent tank-mix at 1 l/ha on wheat against *Septoria* in LEAF1. Most representative evaluation (21-41 DA-B) (Global control)



In the 8 trials where % efficacy was evaluated at the most representative evaluation, the rate of 1 L/ha of SAP2101F reached an average control of 86,5%, and the same rate of SAP250F + SAP50SCF reached an average control of 89,0%, showing just one significant difference in all the trials, in LEAF1.
Moreover, both ready-mix and tank-mix products, have shown a similar control in each trial, independently of the EPPO climatic zone where the trial has been performed.

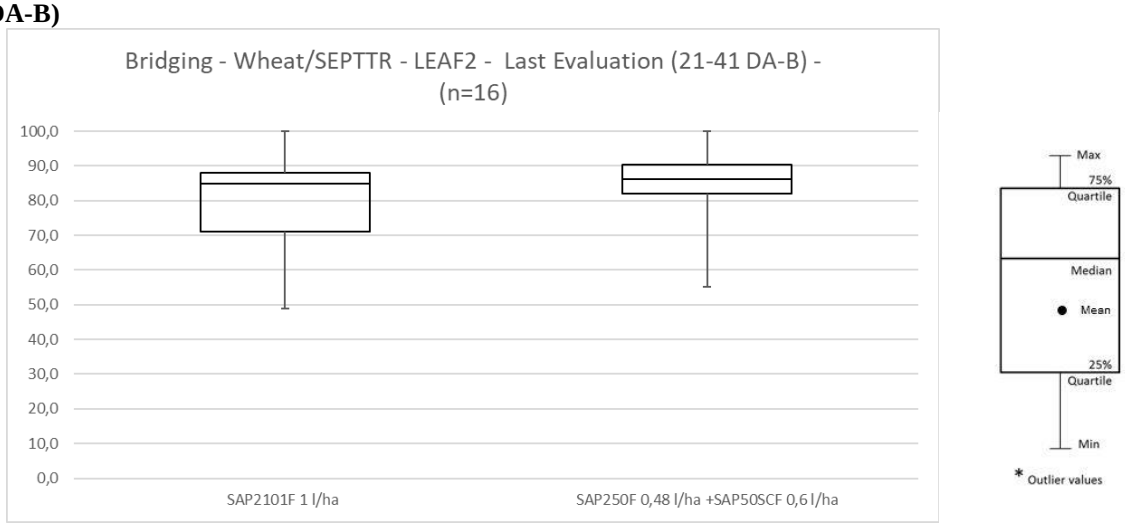
Table 3.2.1-c: Bridging. Comparison of the efficacy of SAP2101F co-formulated product with the equivalent tank-mix at 1 l/ha on wheat against *Septoria* in LEAF2. Most representative evaluation (21-41 DA-B) – Detailed table

Refer to BAD.

Table 3.2.1-d: Bridging. Comparison of the efficacy of SAP2101F co-formulated product with the equivalent tank-mix at 1 l/ha on wheat against *Septoria* in LEAF2. Most representative evaluation (21-41 DA-B)

Target	Nb of trials	Untreated plot	% control		Nb of trials where SAP2101F 1 l/ha is >, < or =
			SAP2101F 1 l/ha 120 g SAP250F/ha + 300 g SAP50SCF/ha	SAP250F 0,48 L/ha + SAP50SCF 0,6 L/ha 120 g SAP250F/ha + 300 g SAP50SCF/ha	
		Mean Max Min	Mean Max Min	Mean Max Min	SAP250F 0,48 L/ha + SAP50SCF 0,6 L/ha
% CONTROL (21-41 DA-B) Global average	**16**	**22,9** **53,3** **5,4**	**79,8** **100,0** **49,0**	**85,0** **100,0** **55,1**	**> 0** **= 14** **< 2**
% CONTROL (21 DA-B - 41 DA-B) Maritime EPPO zone	4	32,5 53,2 12,3	85,6 87,8 83,0	89,7 94,4 82,1	> 0 = 3 < 1
% CONTROL (21 DA-B - 34 DA-A) Mediterranean EPPO zone	4	31,1 53,3 11,3	74,3 100,0 49,0	79,8 100,0 55,1	> 0 = 4 < 0
% CONTROL (21 DA-B - 28 DA-B) North-East EPPO zone	3	12,5 18,4 7,5	66,2 71,6 57,2	80,4 83,9 75,3	> 0 = 2 < 1
% CONTROL (21 DA-B - 28 DA-B) South-East EPPO zone	5	15,0 24,4 5,4	87,6 91,0 85,0	88,1 91,0 85,0	> 0 = 5 < 0

Figure 3.2.1-b: Bridging. Comparison of the efficacy of SAP2101F co-formulated product with the equivalent tank-mix at 1 l/ha on wheat against *Septoria* in LEAF2. Most representative evaluation (21-41 DA-B)



In the 16 trials where % efficacy was evaluated at the most representative evaluation, the rate of 1 L/ha of SAP2101F reached an average control of 79,28%, and the same rate of SAP250F + SAP50SCF reached an average control of 85,0%, showing just two significant differences out of 16 trials, in LEAF2. Moreover, both ready-mix and tank-mix products, have shown a similar control in each trial, independently of the EPPO climatic zone where the trial has been performed.

For barley, a total of 12 trials have been performed in for EPPO Climatic zones (Maritime, Mediterranean, South-East and North-East), in Italy, Romania, Bulgaria, Poland, and France. Spain and Germany in 2021, including both ready-mixed product and the tank-mixed products, in order to prove they are equals.
In order to properly compare both treatments, the rate of 1 L/ha is the one being compared as, the smaller is the dose, the higher are the differences.
It has been compared in Leaf 2 level at last evaluation.

Table 3.2.1-e: Bridging. Comparison of the efficacy of SAP2101F co-formulated product with the equivalent tank-mix at 1 l/ha on barley against *Helminthosporium* in LEAF2. Most representative evaluation (55 DA-A - 12 35 DA-B) – Detailed table

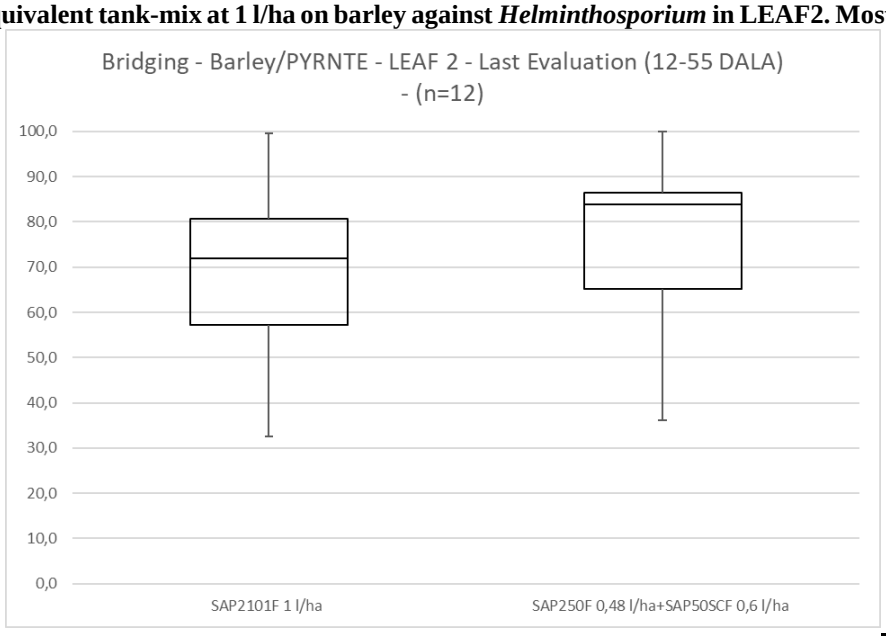
Refer to BAD.

Table 3.2.1-f: Bridging. Comparison of the efficacy of SAP2101F co-formulated product with the equivalent tank-mix at 1 l/ha on barley against *Helminthosporium* in LEAF2. Most representative evaluation (55 DA-A - 12 35 DA-B)

Target	Nb of trials	Untreated plot	% control		Nb of trials where SAP2101F 1 l/ha is >, < or =
			SAP2101F 1 l/ha	SAP250F 0,48 L/ha + SAP50SCF 0,6 L/ha	
			120 g SAP250F/ha + 300 g SAP50SCF/ha	120 g SAP250F/ha + 300 g SAP50SCF/ha	
		Mean Max Min	Mean Max Min	Mean Max Min	SAP250F 0,48 L/ha + SAP50SCF 0,6 L/ha
% CONTROL (12 DA-B – 55 DA-A) Global average	12	33,5	68,1	76,6	> 0 = 9 < 3
		96,0	99,6	100,0	
		6,2	32,6	36,1	

Target	Nb of trials	Untreated plot	% control		Nb of trials where SAP2101F 1 l/ha is >, < or =
			SAP2101F 1 l/ha	SAP250F 0,48 L/ha + SAP50SCF 0,6 L/ha	
			120 g SAP250F/ha + 300 g SAP50SCF/ha	120 g SAP250F/ha + 300 g SAP50SCF/ha	
		Mean Max Min	Mean Max Min	Mean Max Min	SAP250F 0,48 L/ha + SAP50SCF 0,6 L/ha
% CONTROL (24-34 35 DA-B) Maritime EPPO zone	3	62,6	68,6	80,7	> 0 = 3 < 0
		96,0	74,5	86,4	
		14,0	62,0	72,0	
% CONTROL (24 DA-B – 55 DA-A) Mediterranean EPPO zone	3	42,3	58,0	66,9	> 0 = 2 < 1
		60,0	99,6	100,0	
		24,3	32,6	36,1	
% CONTROL (21-23 DA-B) South-East EPPO zone	3	16,2	79,0	78,8	> 0 = 3 < 0
		35,5	87,0	87,0	
		6,2	64,7	64,7	
% CONTROL (21 - 28 DA-B) North-East EPPO zone	3	12,7	66,9	79,8	> 0 = 1 < 2
		17,3	79,1	89,9	
		7,2	43,2	65,3	

Figure 3.2.1-c: Bridging. Comparison of the efficacy of SAP2101F co-formulated product with the equivalent tank-mix at 1 l/ha on barley against *Helminthosporium* in LEAF2. Most representative evaluation



In the 12 trials where % efficacy was evaluated at the most representative evaluation, the rate of 1 L/ha of SAP2101F reached an average control of 68,1%, and the same rate of SAP250F + SAP50SCF reached an average control of 76,6%, showing three significant differences out of 12 trials, in barley in LEAF2. Moreover, both ready-mix and tank-mix products, have shown a similar control in each trial, independently of the EPPO climatic zone where the trial has been performed.

Conclusion Bridging

To conclude, it is observable that, in a total of 16 trials in wheat and 12 in barley, only a few significant differences were found (in 6 out of ~~30~~ 28 ~~evaluations~~ trials) at the lower rate of the requested range (1 L/ha), showing an equivalence of SAP2101F and SAP250F+SAP50SCF. Therefore, it is justified to use the data from trials on the tank-mix to support the use of the co-formulated SAP2101F.

Justification of the mixture (efficacy)

SAP2101F is a fungicide containing Prothioconazole and Folpet. These active ingredients are present in many authorized products for a long time ago in ~~S~~CEU.
Nevertheless, this mixture must be explained. So, to demonstrate the benefit of the association of both actives, some trials included a comparison of SAP2101F with each active ingredient straight at the equivalent rate of the mixture.

In 12 trials, SAP250F 0,48 l/ha+SAP50SCF 0,6 l/ha (equivalent to SAP2101F at 1 L/ha) (120 g Prothioconazole/ha + 300 g Folpet/ha) was compared to the straight SAP250F 0,48 l/ha (120 g Prothioconazole/ha) and the straight SAP50SCF 0,6 l/ha (300 g Folpet/ha), which are the equivalent rates of the single active substances, in wheat against Septoria (in Leaf 1 at last evaluation).

Table 3.2.1-g: Justification of the mixture. Comparison of the efficacy of SAP250F 0,48 l/ha+SAP50SCF 0,6 l/ha with the straights product at the same rate, on wheat against Septoria in LEAF1. Most representative evaluation (44 DA-A – 37 DA-B) – Detailed table

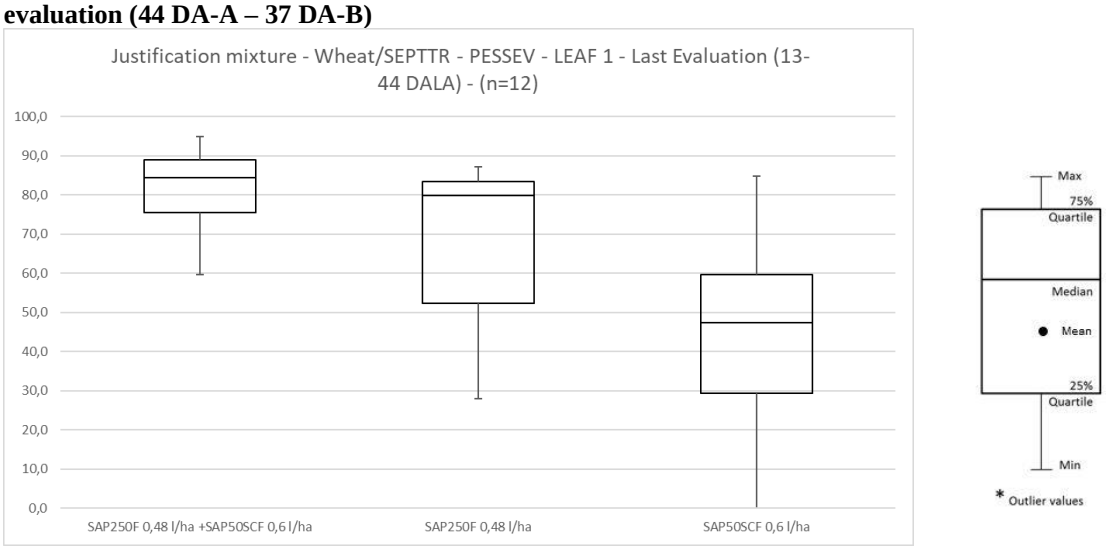
Refer to BAD.

Table 3.2.1-h: Justification of the mixture. Comparison of the efficacy of SAP250F 0,48 l/ha+SAP50SCF 0,6 l/ha with the straights product at the same rate, on wheat against Septoria in LEAF1. Most representative evaluation (44 DA-A – 37 DA-B)

Target	Nb of trials	Untreated plot	% control			Nb of trials where SAP250F 0,48 L/ha + SAP50SCF 0,6 L/ha is >, < or =	Nb of trials where SAP250F 0,48 L/ha + SAP50SCF 0,6 L/ha is >, < or =
			SAP250F 0,48 L/ha + SAP50SCF 0,6 L/ha	SAP250F 0,48 L/ha	SAP50SCF 0,6 L/ha		
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	SAP250F 0,48 L/ha	SAP50SCF 0,6 L/ha
% CONTROL (44 DA-A – 37 DA-B) Global average	**12**	**25,9** **95,4** **5,4**	**81,8** **94,8** **59,6**	**68,6** **87,1** **27,9**	**43,6** **84,8** **-4,6**	**> 4 = 8 < 0**	**> 11 = 1 < 0**
% CONTROL (44 DA-A – 37 DA-B) Maritime EPPO zone	~~3~~ 4	~~34,4~~ 49,7 ~~49,8~~ 95,4 25,0	~~82,8~~ 84,9 94,8 70,0	~~62,0~~ 68,3 ~~85,0~~ 87,1 27,9	~~53,4~~ 44,3 84,8 ~~33,3~~ 17,0	> ~~2~~ 3 = 1 < 0	> ~~3~~ 4 = 0 < 0
% CONTROL 16-30 DA-B) Mediterranean EPPO zone	~~5~~ 4	~~35,6~~ 20,7 ~~95,4~~ 32,5 13,4	~~80,2~~ 77,4 91,3 59,6	~~67,7~~ 62,8 ~~87,1~~ 82,9 35,4	~~26,0~~ 29,4 53,9 ~~-4,6~~ 0	> ~~1~~ 0 = 4 < 0	> ~~4~~ 3 = 1 < 0
% CONTROL (13-21 DA-B) South-East EPPO zone	3	7,7 8,8 5,4	85,2 87,1 83,4	82,0 85,7 77,4	58,5 72,0 36,3	> 0 = 3 < 0	> 3 = 0 < 0
% CONTROL (21 DA-B)	1	6,7 6,7	77 77	52,8 52,8	57,1 57,1	> 1 = 0	> 1 = 0

Target	Nb of trials	Untreated plot	% control			Nb of trials where SAP250F 0,48 L/ha + SAP50SCF 0,6 L/ha is >, < or =	Nb of trials where SAP250F 0,48 L/ha + SAP50SCF 0,6 L/ha is >, < or =
			SAP250F 0,48 L/ha + SAP50SCF 0,6 L/ha	SAP250F 0,48 L/ha	SAP50SCF 0,6 L/ha		
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	SAP250F 0,48 L/ha	SAP50SCF 0,6 L/ha
North-East EPPO zone		6,7	77	52,8	57,1	< 0	< 0

Figure 3.2.1-d Justification of the mixture. Comparison of the efficacy of SAP250F 0,48 l/ha+SAP50SCF 0,6 l/ha with the straights product at the same rate, on wheat against Septoria in LEAF1. Most representative evaluation (44 DA-A – 37 DA-B)



Tables and figures displayed above represent the % control of the different tested products at the lowest dose of the requested range at the most representative evaluation, which in most cases is the last evaluation, in LEAF1.

According to the results reported in the Tables and Figures shown above, the severity in the untreated plots has an average of 25,9%.

The data presented in those tables and graphics, show that SAP250F 0,48 l/ha+SAP50SCF 0,6 l/ha (equivalent to SAP2101F) presented a higher average of control (81,8%) than the straights actives substances (68,6% and 43,6%).
What is more, in 11 trials out of 12, significant differences were found between SAP2101F (Prothioconazole+Folpet) and SAP50SCF (Folpet) at an equivalent rate. And, in 4 trials out of 12, significant differences were found between SAP2101F (Prothioconazole+Folpet) and SAP250F (Prothioconazole) at an equivalent rate.
It is also remarkable that the median of SAP2101F is notably higher than the median of the two other products evaluated.

In 4 3 trials, SAP250F 0,48 l/ha+SAP50SCF 0,6 l/ha (equivalent to SAP2101F at 1 L/ha) (120 g Prothioconazole/ha + 300 g Folpet/ha) was compared to the straight SAP250F 0,48 l/ha (120 g Prothioconazole/ha) and the straight SAP50SCF 0,6 l/ha (300 g Folpet/ha), which are the equivalent rates of the single active substances, in barley against *Helminthosporium* (in Leaf 2 at last evaluation).

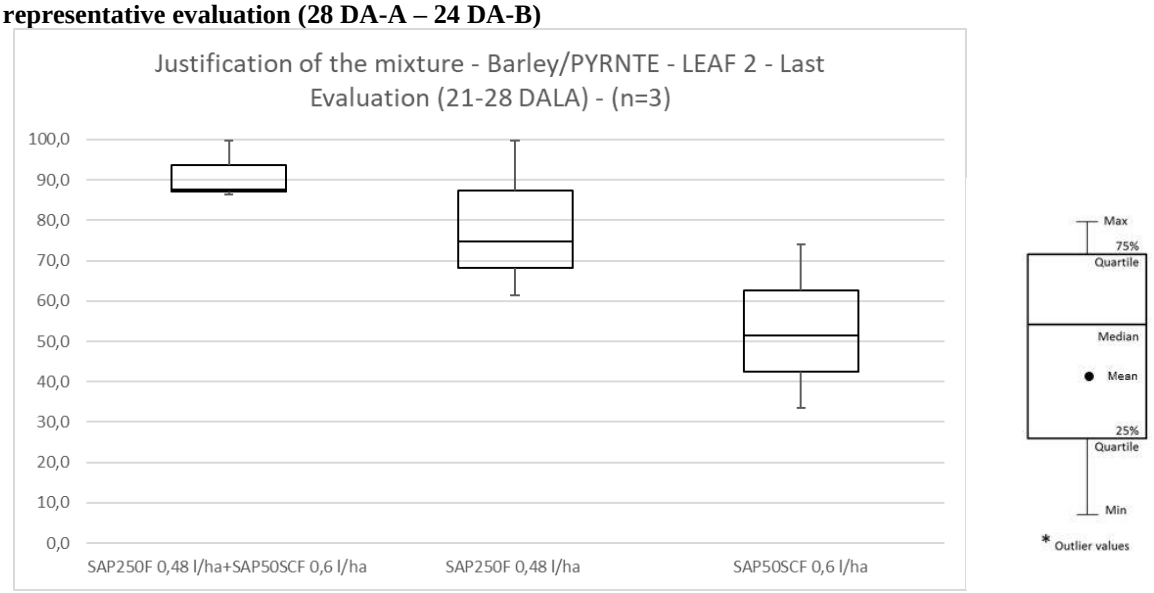
Table 3.2.1-i: Justification of the mixture. Comparison of the efficacy of SAP250F 0,48 l/ha+SAP50SCF 0,6 l/ha with the straights product at the same rate, on barley against *Helminthosporium* in LEAF2. Most representative evaluation (28 DA-A – 24 DA-B) – Detailed table

Refer to BAD.

Table 3.2.1-j: Justification of the mixture. Comparison of the efficacy of SAP250F 0,48 l/ha+SAP50SCF 0,6 l/ha with the straights product at the same rate, on barley against *Helminthosporium* in LEAF2. Most representative evaluation (28 DA-A – 24 DA-B)

Target	Nb of trials	Untreated plot	% control			Nb of trials where SAP250F 0,48 L/ha + SAP50SCF 0,6 L/ha is >, < or =	Nb of trials where SAP250F 0,48 L/ha + SAP50SCF 0,6 L/ha is >, < or =
			SAP250F 0,48 L/ha + SAP50SCF 0,6 L/ha	SAP250F 0,48 L/ha	SAP50SCF 0,6 L/ha		
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	SAP250F 0,48 L/ha	SAP50SCF 0,6 L/ha
% CONTROL (28 DA-A – 24 DA-B) Maritime EPPO zone	3	43,9	91,2	78,6	53,0	> 1 = 2 < 0	> 1 = 2 < 0
		82,8	99,7	99,7	74,0		
		14,0	86,4	61,4	33,5		

Figure 3.2.1-e: Justification of the mixture. Comparison of the efficacy of SAP250F 0,48 l/ha+SAP50SCF 0,6 l/ha with the straights product at the same rate, on barley against *Helminthosporium* in LEAF2. Most representative evaluation (28 DA-A – 24 DA-B)



Tables and figures displayed above represent the % control of the different tested products at the lowest dose of the requested range at the most representative evaluation, which in most cases is the last evaluation, in LEAF2.
According to the results reported in the Tables and Figures shown above, the severity in the untreated plots has an average of 43,9%.
The data presented in those tables and graphics, show that SAP250F 0,48 l/ha+SAP50SCF 0,6 l/ha (equivalent to SAP2101F) presented a higher average of control (91,2%) than the straights actives substances (78,6% and 53%).
In 1 trial out of 3, significant differences were found between SAP2101F (Prothioconazole+Folpet) and SAP50SCF (Folpet) at an equivalent rate. And, in 1 trial out of 3, significant differences were found between SAP2101F (Prothioconazole+Folpet) and SAP250F (Prothioconazole) at an equivalent rate.

It is also remarkable that the median of SAP2101F is notably higher than the median of the two other products evaluated.
Also, it is important to say that, even if only 3 trials have been evaluated for this use, the mixture has been as well justified in another use (Wheat-*Septoria*).

Justification of the mixture (resistance management)

Furthermore, one laboratory trial has been performed in order to demonstrate the benefit of Folpet against resistances.
Prothioconazole is a Triazole, which is one of the best solutions against *Septoria* and *Helminthosporium* in Wheat and Barley. However, lately, the more and more resistant strains to triazoles are found, what decrease or supress the efficacy of those products.
That is why Folpet, which is has multisite contact activity and for instance do not create resistance, has been mixed with Prothioconazole.
In the following trial, it was evaluated the efficacy of SAP2101F in wheat against two strains of Septoria leaf blotch (*Zemoseptoria tritici*): one resistant and one not resistant to Prothioconazole.
Results are presented hereafter:

Pest Type Pest Code Crop Type, Code Crop Name Crop Variety Rating Date Part Rated Rating Type Rating Unit/Min/Max Sample Size Collection Basis Reporting Basis Crop Stage Scale Crop Stage Majority/Min/Max Days After First/Last Applic. Trt-Eval Interval Plant-Eval Interval ARM Action Codes	D; Disease SEPTTR C; TRZAW Winter wheat Palesio 12/7/2021 LEAF; P PESSEV %; 0; 100 20 LEAF 1 PLOT 1 PLOT BBCH 14; 14; 15 14; 14 14 DA-A 35 DP-1 S05	D; Disease SEPTTR C; TRZAW Winter wheat Palesio 19/7/2021 LEAF; P PESSEV %; 0; 100 20 LEAF 1 PLOT 1 PLOT BBCH 15; 14; 16 21; 21 21 DA-A 42 DP-1 S05	D; Disease SEPTTR C; TRZAW Winter wheat Palesio 26/7/2021 LEAF; P PESSEV %; 0; 100 20 LEAF 1 PLOT 1 PLOT BBCH 15; 14; 16 28; 28 28 DA-A 49 DP-1 S05	D; Disease SEPTTR C; TRZAW Winter wheat Palesio 12/7/2021 LEAF; P PESSEV %UNCK; -; - 20 LEAF 1 PLOT 1 PLOT BBCH 14; 14; 15 14; 14 14 DA-A 35 DP-1 @UTAB[5]	D; Disease SEPTTR C; TRZAW Winter wheat Palesio 19/7/2021 LEAF; P PESSEV %UNCK; -; - 20 LEAF 1 PLOT 1 PLOT BBCH 15; 14; 16 21; 21 21 DA-A 42 DP-1 @UTAB[9]	D; Disease SEPTTR C; TRZAW Winter wheat Palesio 26/7/2021 LEAF; P PESSEV %UNCK; -; - 20 LEAF 1 PLOT 1 PLOT BBCH 15; 14; 16 28; 28 28 DA-A 49 DP-1 @UTAB[13]	Comments
Column nº	5	9	13	7	11	15	
Untreated and non inoculated	0,0 d	0,0 e	0,0 f	100,0	100,0	100,0	
Untreated Check Z1	11,0 a	20,6 a	38,2 a	9,4	12,2	9,2	Sensible to Prothioconazole
SAP2101F – 1 L/ha	4,2 bcd	7,9 bcd	13,1 bc	58,5	61,1	**66,8**	
SAP2101F – 1,25 L/ha	3,8 bcd	7,9 bcd	11,7 bcd	61,9	61,3	70,2	
SAP2101F – 1,5 L/ha	0,3 d	1,0 e	7,7 cde	97,1	94,9	80,3	
SAP250F – 0,48 L/ha	3,3 bcd	6,0 b-e	13,7 bc	66,9	70,8	**65,2**	
Untreated Check Z2	10,1 a	20,4 a	39,3 a	8,8	3,0	2,2	Resistant to Prothioconazole
SAP2101F – 1 L/ha	5,7 bc	8,4 bc	17,5 b	43,3	59,0	**55,6**	
SAP2101F – 1,25 L/ha	5,5 bc	8,5 bc	13,4 bc	45,8	58,3	65,9	
SAP2101F – 1,5 L/ha	3,8 bcd	5,7 b-e	8,2 cde	62,8	72,2	79,2	
SAP250F – 0,48 L/ha	9,6 a	18,9 a	36,2 a	6,6	7,5	**8,1**	

According to the results in the table above, where a comparation between Prothioconazole straight (SAP250F) and the mixture Prothioconazole+Folpet (SAP2101F) has been done, it can be clearly observable that there is a benefit on adding Folpet in a resistant strain:

- In all evaluations, the efficacy of Prothioconazole straight in a sensitive strain is much higher than in a resistant strain. For example, at 28 DA-A the control of SAP250F in the sensitive strain

is 65,2% while in a resistant strain is 8,1%. That proves that in a resistant strain Prothioconazole itself cannot control the disease. Besides, in the resistant strain there are no significant differences between Prothioconazole straight and the untreated plot (Z2) in any of the evaluations.

- However, if the comparative is made between SAP2101F in a resistant strain and in a sensitive strain, no significant differences are found. That proves that the product does not change its level of control regardless of the kind of strain.
- Finally, in a resistant strain, all the evaluations have shown big differences in the control of Septoria between SAP250F at 0,48 L/ha and SAP2101F at 1 L/ha, being this last product able to control the disease while Prothioconazole straight not.
  Both products contain 120 g of Prothioconazole/ha, that is why they can be compared.
  Significant differences are found in all 3 evaluations between those 2 products and, for example, at 28 DA-A the control of SAP2101F at 1 L/ha is 55,6% while the control of SAP250F at 0,48 L/ha is 8,1%.

To conclude, it has been demonstrated that SAP2101F do not lose its efficacy in resistant strains, what make it an excellent tool to fight against resistances.

Besides, according to several organisations, hereafter are some recommendations for fungicides in cereals.

FRAG (Fungicide Resistance Management in Cereals) (UK)
"*The majority of modern fungicides have single-site modes of action, acting on specific biochemical pathways in the target fungal pathogen. Once a fungicide is used on a pathogen population, individual isolates of the fungal population that have a reduced sensitivity to the fungicide will be selected by repeated use of fungicides with the same mode of action. Multi-site fungicides are less prone to the development of resistance in the target pathogen and these older fungicides still have a very important role in the resistance strategy for the more modern fungicides.*"

AHDB – "Wheat and barley disease management guide" (UK)
"*Fungicides with multisite modes of action are much less prone to resistance. The process of mutation and selection, leading to resistance, is rarely seen with multi-sites outside the laboratory.*"

"*Fungicide resistance management strategies should:*
• Exploit all practical, non-chemical control options
…
• Include a multisite fungicide, where available, in both the early and late-season sprays"

Resistance to fungicides – Cereals
Note commune 2022; INRAE, Anses, ARVALIS - Institut du Végétal (FR)

"*RECOMMANDATIONS GENERALES POUR 2022*

• Recourir lorsque cela est possible et utile aux fongicides multisites, moins susceptibles de sélectionner des populations résistantes, en particulier sur septoriose."

Translated, that would be:

GENERAL RECOMMENDATIONS IN 2022
- Apply, when possible and useful, multi-site fungicides, which are less susceptible to select resistant populations, especially in *Septoria*.

Therefore, all these organisations recommend a to include a multi-site fungicide in order to fight against resistances.

For all these reasons, SAP2101F, which contains Folpet (a multi-site fungicide), is considered to be a good tool against *Septoria* in Wheat and *Helminthosporium* in Barley, not only because of its efficacy, but to prevent resistant strains.

Conclusion Justification of the mixture

To conclude, according to the presented results, SAP2101F provided better control than the single active substance products against *Septoria* in wheat and *Helminthosporium* in barley.
Besides, the product has demonstrated to control Septoria even when applied in a resistant strain.
So, there exist a clear benefit on the association of these two active substances.

Justification of the ratio

In order to evaluate the justification of the ratio, 15 field trials (9 valid trials) were performed in wheat, in Italy, France, Germany, Romania, Bulgaria, Poland and Spain, from 2020 to 2021, where different ratios were tested to prove that the one chosen for SAP2101F is better or, at least, the same as other ratios.
Prothioconazole+Folpet was tested at 3 different ratios. The first one is the SAP2101F ratio (120 g Prothioconazole/ha + 300 g Folpet/ha), the other 2 combinations were established to compare possible options: 72 g Prothioconazole/ha + 300 g Folpet /ha and 120 g Prothioconazole /ha + 180 g Folpet /ha.
A summary of the ratio response is provided in tables and figures below. Besides, in order to make an orthogonal comparison, data has been divided in two protocols.

Table 3.2.1-k: Justification of the ratio. Comparison of the efficacy of SAP250F 0,48 l/ha+SAP50SCF 0,6 l/ha with an alternative ratio (1), on wheat against Septoria in LEAF1. Most representative evaluation (13 – 37 DA-B)

Refer to BAD.

Table 3.2.1-l: Justification of the ratio. Comparison of the efficacy of SAP250F 0,48 l/ha+SAP50SCF 0,6 l/ha with an alternative ratio (1), on wheat against *Septoria* in LEAF1. Most representative evaluation (13 – 37 DA-B)

Target	Nb of trials	Untreated plot	% control		Nb of trials where SAP250F 0,48 L/ha + SAP50SCF 0,6 L/ha is >, < or =
			SAP250F 0,48 l/ha +SAP50SCF 0,6 l/ha	SAP250F 0,288 l/ha +SAP50SCF 0,6 l/ha	
			120 g SAP250F/ha + 300 g SAP50SCF/ha	72 g SAP250F/ha + 300 g SAP50SCF/ha	
		Mean Max Min	Mean Max Min	Mean Max Min	SAP250F 0,288 l/ha +SAP50SCF 0,6 l/ha
% CONTROL (13 – 37 DA-B) Global average	**9 (11)**	**25,7** **95,4** **5,4**	**85,2** **94,8** **70,5**	**77,4** **86,0** **69,2**	**> 3** **= 6** **< 0**
% CONTROL (30 – 37 DA-B) Maritime EPPO zone	3	**56,7** 95,4 25,0	89,9 94,8 83,6	78,2 86,0 70,5	> 2 = 1 < 0
% CONTROL (16-23 DA-B) Mediterranean EPPO zone	2 (4)	20,7 32,5 13,4	83,3 91,3 70,5	77,2 85,2 69,2	> 1 = 1 < 0
% CONTROL (13-21 DA-B) South-East EPPO zone	3	7,7 8,8 5,4	85,2 87,1 83,4	78,6 83,4 75,4	> 0 = 3 < 0
% CONTROL	1	6,7	77	72,2	> 0

Target	Nb of trials	Untreated plot	% control		Nb of trials where SAP250F 0,48 L/ha + SAP50SCF 0,6 L/ha is >, < or =
			SAP250F 0,48 l/ha +SAP50SCF 0,6 l/ha	SAP250F 0,288 l/ha +SAP50SCF 0,6 l/ha	
			120 g SAP250F/ha + 300 g SAP50SCF/ha	72 g SAP250F/ha + 300 g SAP50SCF/ha	
		Mean Max Min	Mean Max Min	Mean Max Min	SAP250F 0,288 l/ha +SAP50SCF 0,6 l/ha
(21 DA-B)		6,7	77	72,2	= 1
North-East EPPO zone		6,7	77	72,2	< 0

Figure 3.2.1-f: Justification of the ratio. Comparison of the efficacy of SAP250F 0,48 l/ha+SAP50SCF 0,6 l/ha with an alternative ratio (1), on wheat against *Septoria* in LEAF1. Most representative evaluation (13 – 37 DA-B)

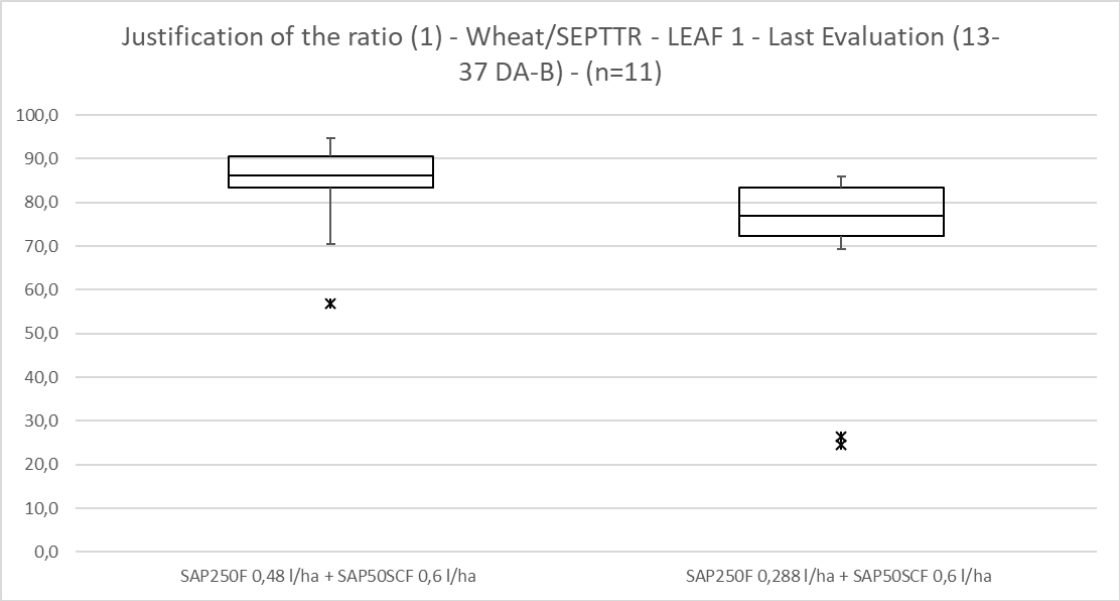


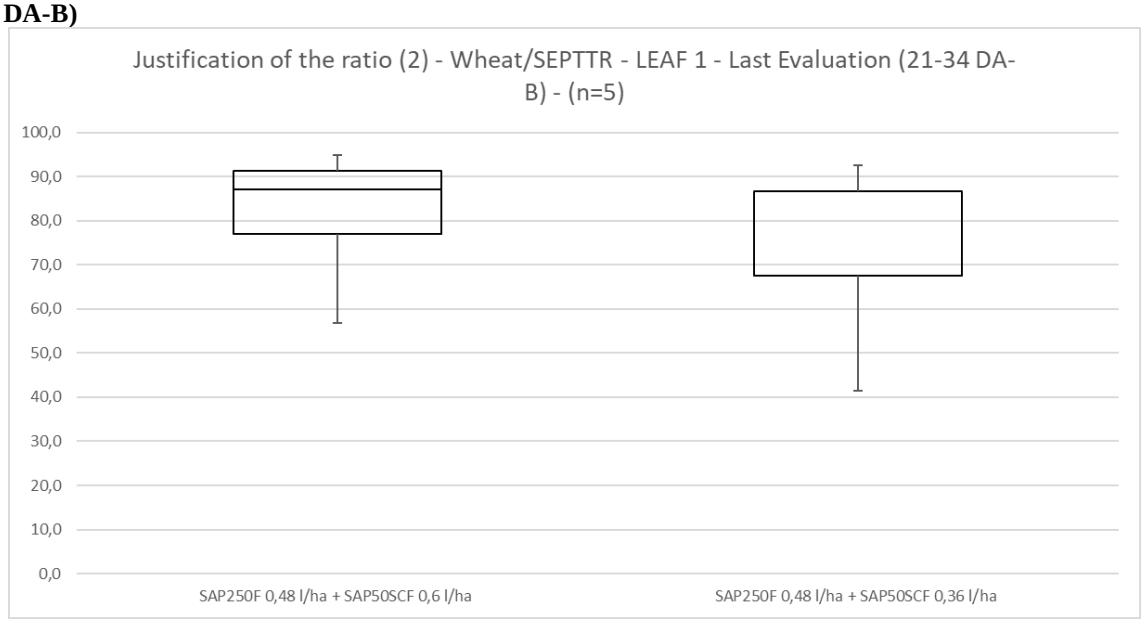
Table 3.2.1-m: Justification of the ratio. Comparison of the efficacy of SAP250F 0,48 l/ha+SAP50SCF 0,6 l/ha with an alternative ratio (2), on wheat against *Septoria* in LEAF1. Most representative evaluation (21 – 34 DA-B) - Detailed table

Refer to BAD.

Table 3.2.1-n: Justification of the ratio. Comparison of the efficacy of SAP250F 0,48 l/ha+SAP50SCF 0,6 l/ha with an alternative ratio (2), on wheat against *Septoria* in LEAF1. Most representative evaluation (21 – 34 DA-B)

Target	Nb of trials	Untreated plot	% control		Nb of trials where SAP250F 0,48 L/ha + SAP50SCF 0,6 L/ha is >, < or =
			SAP250F 0,48 L/ha + SAP50SCF 0,6 L/ha	SAP250F 0,48 l/ha +SAP50SCF 0,36 l/ha	
			120 g SAP250F/ha + 300 g SAP50SCF/ha	120 g SAP250F/ha + 180 g SAP50SCF/ha	
		Mean Max Min	Mean Max Min	Mean Max Min	SAP250F 0,48 l/ha +SAP50SCF 0,36 l/ha
% CONTROL (21– 34 DA-B) Global average	**5**	**14,8**	**81,4**	**74,9**	**> 0 = 5 < 0**
		25,0	**94,8**	**92,5**	
		5,4	**56,9**	**41,5**	
% CONTROL (34 DA-B) Maritime EPPO zone	1	25,0	94,8	92,5	> 0 = 1 < 0
		25,0	94,8	92,5	
		25,0	94,8	92,5	
% CONTROL (21-23 DA-B) Mediterranean EPPO zone	2	18,4	74,1	64,1	> 0 = 2 < 0
		20,4	91,3	86,6	
		16,3	56,9	41,5	
% CONTROL (21 DA-B) South-East EPPO zone	1	5,4	87,1	86,6	> 0 = 1 < 0
		5,4	87,1	86,6	
		5,4	87,1	86,6	
% CONTROL (21 DA-B) North-East EPPO zone	1	6,7	77	67,5	> 0 = 1 < 0
		6,7	77	67,5	
		6,7	77	67,5	

Figure 3.2.1-f: Justification of the ratio. Comparison of the efficacy of SAP250F 0,48 l/ha+SAP50SCF 0,6 l/ha with an alternative ratio (2), on wheat against *Septoria* in LEAF1. Most representative evaluation (21 – 34 DA-B)



A total of 15 trials were established to justify the ratio of SAP2101F, those trials were divided in two protocols to be compared in a correct way. Besides, due to low disease level, ~~11~~ 9 trials of the 15 have been analyzed.

- Alternative ratio 1: SAP250F 0,288 l/ha +SAP50SCF 0,6 l/ha (72 g Prothio/ha + 300 g Folpet/ha)

10-F-2020 and 03A-F-2021 protocols allowed the comparison of SAP2101F target ratio with an alternative ratio providing a lower application of Prothioconazole (72g/ha on the alternative ratio instead of 120g on the target one).

The severity average in the untreated plots was ~~27,5~~ 25,7%. Table and figure reported above prove that SAP2101F, at the lowest dose of the requested range (1 L/ha), presented a more robust control than the alternative ratio tested.
Even though just 3 significant differences were found out of 9 trials, the %control of the disease with the alternative ratio is numerically lower (77,4%) compared with the %control of SAP2101F (85,2%).

- Alternative ratio 2: SAP250F 0,48 l/ha +SAP50SCF 0,36 l/ha (120 g Prothio/ha + 180 g Folpet/ha)

03A-F-2021 protocol allowed the comparison as well of SAP2101F to another alternative ratio providing a lower application of Folpet (180 g/ha on the alternative ratio instead of 300g on the target one).
The severity average in the untreated plots was 14,8%. Table and figure reported above prove that SAP2101F, at the lowest dose of the requested range (1 L/ha), presented a more robust control than the alternative ratio tested.
Even though no significant differences were found in any of the 5 trials, the %control of the disease with the alternative ratio is numerically lower (74,9%) compared with the %control of SAP2101F (81,4%). Besides, it can be also observed on the box whisker plots figure, where target ratio has a thinner box and higher median.

Conclusion justification of the ratio

Finally, it is possible to conclude that the ratio of SAP2101F has been justified, in a total of ~~11~~ 9 trials, comparing its ratio (120:300) to two other ratios (72:300 and 120:180). Results have shown a more robust control on SAP2101F than alternative ratios targeting lower rates of one of the actives.

Comments of zRMS on:
Preliminary tests (3.2.1)

BRIDGING
Results from 28 trials:
- 16 trials conducted in wheat in four EPPO zones: Maritime (4 trials from: Germany (1), France (2), United Kingdom (1)), Mediterranean (4 trials from: Fance (2), Italy (1), Spain (1)), North-East (3 trials from Poland), South-East (5 trials from: Bulgaria (3), Romania (2)) in 2021,
- 12 trials conducted in barley in four EPPO zones: Maritime (3 trials from France), Mediterranean (3 trials from: France (1), Italy (2)), North-East (3 trials from Poland), South-East (3 trials from: Bulgaria (2), Romania (1)) in 2021,
have been presented to confirm the equivalence between the ready mix formulation SAP2101F (120 g Prothioconazole/ha + 300 g Folpet/ha) and tank-mix SAP250F+SAP50SCF (120 g Prothioconazole/ha + 300 g Folpet/ha) in the control of *Zymoseptoria tritici* on wheat and *Pyrenophora teres* on barley.
Results from bridging trials demonstrate no statistically significant differences in efficacy between SAP2101F and SAP250F+SAP50SCF applied at the same dose rate of prothioconazole (120 g/ha) and folpet (300 g/ha) in 14 of 16 trials conducted in wheat and in 9 of 12 trials performed in barley.
It can be concluded, that the equivalence between co-formulated product SAP2101F and tank-mix SAP250F+SAP50SCF has been justified. Therefore trial results with tank-mix SAP250F+SAP50SCF can be

used to support the evaluation of SAP2101F in the chapters: 3.2.2 (Minimum effective dose tests) and 3.2.3 (Efficacy tests).

MIXTURE JUSTIFICATION

Results from 15 trials carried out between 2020 and 2021 in wheat (12 trials performed in 4 EPPO zones: Maritime (4 trials from: France (3) and Germany (1)), Mediterranean (4 trials from: Italy (2), France (1), Spain (1)), North-East (1 trial from Poland), South-East (3 trials from Bulgaria (1) and Romania (2)) and in barley (3 trials carried out in Maritime EPPO zone (France) have been presented to justify the benefits of usage SAP250F 0,48 l/ha+SAP50SCF 0,6 l/ha (equivalent to SAP2101F at 1 L/ha) (120 g Prothioconazole/ha + 300 g Folpet/ha) as compared with solo SAP250F 0,48 l/ha (120 g Prothioconazole/ha) and solo SAP50SCF 0,6 l/ha (300 g Folpet/ha) at equivalent rates.

The presented trial results clearly show visibly higher efficacy of SAP250F 0,48 l/ha+SAP50SCF 0,6 l/ha (81,6%) as compared with efficacy achieved for SAP250F (68,6%) and for SAP50SCF (43,6%) in the control of *Zymoseptoria tritici* on winter wheat. Higher efficacy of tank-mixture in comparison with active substances applied solo was demonstrated in all concerned EPPO zones. Statistically significant higher efficacy of SAP250F+SAP50SCF as compared with SAP250F was noted in 4 of 12 trials conducted in Maritime (France (2), Germany (1)) and North-East (Poland) EPPO zone. Statistically significant higher efficacy of SAP250F+SAP50SCF as compared with SAP50SCF was noted in almost all trials (excluding only 1 trial performed in Italy). Similarly, the average efficacy 91,6% (achieved for SAP250F+SAP50SCF) was visibly higher efficacy, than the efficacy achieved for SAP250 F (78,6%) and for SAP50SCF (53,0%) in the control of *Pyrenophora teres* in barley in Maritime EPPO zone (France). Statistically significant higher efficacy of SAP250F+SAP50SCF) as compared with SAP250F and SAP50SCF was demonstrated in 1 out of 3 trials.

Additional 1 laboratory trial was performed to compare efficacy of SAP2101F and SAP250F in wheat in the control two strains of *Zymoseptoria tritici*: one resistant and one not resistant to prothioconazole. Results from this trial clearly show higher efficacy of SAP2101F in the control of resistant strain of *Zymoseptoria tritici* as compared with SAP250F. Statistically significant differences were demonstrated 14-28 DAA. At 28 DA-A the control for SAP2101F at 1 L/ha was 55,6% while the control for SAP250F at 0,48 L/ha was 8,1%. Comparing the efficacy of SAP250F in a sensitive and resistant strain of *Zymoseptoria tritici* (65,2% and 8,1% efficacy respectively), it was demonstrated that in a resistant strain the prothiconazole control itself is not effective. No significant differences were noted between SAP101F in a resistant and sensitive strains of *Zymoseptoria tritici*, therefore level of protection is maintained independently of the kind of pathogen strain.

It can be concluded, that the co-formulation mixture SAP250F 0,48 l/ha+SAP50SCF 0,6 l/ha (equivalent to SAP2101F at 1 L/ha) (120 g Prothioconazole/ha + 300 g Folpet/ha) has been justified. Additionally it should be highlighted, that new mixture prothioconaozole with multi-site action folpet will be a valuable tool in resistance management strategy.

RATIO JUSTIFICATION

A total of 9 valid trials carried out in winter wheat in the years 2020-2021 in 4 EPPO zones: Maritime (3 trials from: Germany (1) and France (2)), Mediterranean (2 trials from France (1), Spain (1)), North-East (1 trial from Poland), South-East (3 trials from Romania (2), Bulgaria (1)) present data for comparison of SAP250F 0,48 L/ha+SAP50SCF 0,6 L/ha (120 g Prothioconazole/ha + 300 g Folpet/ha) with different ratios:

- SAP250F 0,288 L/ha+SAP50SCF 0,6 L/ha (72 g Prothioconazole/ha + 300 g Folpet/ha) – 9 trials
- SAP250F 0,48 L/ha+SAP50SCF 0,36 L/ha (120 g Prothioconazole/ha + 180 g Folpet/ha) – 5 trials.

Considering numerical data, the efficacy of SAP250F 0,48 L/ha+SAP50SCF 0,6 L/ha was higher than efficacy of SAP250F 0,288 L/ha+SAP50SCF 0,6 L/ha and SAP250F 0,48 L/ha+SAP50SCF 0,36 L/ha in all the trials, the mean efficacy was 85,2% and 81,4% in comparison with 77,4% and 74,9% respectively. The statistically significant higher efficacy of SAP250F 0,48 L/ha+SAP50SCF 0,6 L/ha as compared with SAP250F 0,288 L/ha+SAP50SCF 0,6 L/ha was noted in 3 out of 9 nine trials conducted in EPPO zones: Maritime (France, Germany) and Mediterranean (Spain).

Based on the submitted trial results it can be concluded, that the ratio 120 g prothioconazole/ha + 300 g folpet/ha has been justified as the most effective for SAP2101F.

3.2.2 Minimum effective dose tests (KCP 6.2)

To determine the minimum effective dose of **SAP2101F** against *Septoria* in Wheat and *Helminthosporium* in Barley, different rates (0,6, 1, 1,25 and 1,5 L/ha) were tested in the performed trials (for further details, please refer to BAD).
Data is summarised numerically using tables and graphically in box whisker plots showing maximum, minimum, median, 25 and 75% quartiles.
The results have been reported separately according the different EPPO climatic zones. However, to reinforce the results they have been presented together as well.
As demonstrated on 3.2.1 "Preliminary tests", no distinctions have been done between data coming from trials applying product in tank-mix (SAP250F+SAP50SCF) and in ready-mix (SAP2101F).

3.2.2.1 Wheat - *Septoria*

29 field trials were established in order to the determine the minimum effective dose for the control of *Septoria* in Wheat, in 2020 and 2021, in countries belonging to 3 three EPPO climatic zones: Maritime, South-East and North-East. However, in two of them, due to the non-apparition of any disease, are used as Selectivity trials (04B-F-2021-FR05 and 10-F-2020-UK01) 04SAP2101F was tested from 0,6 L/ha to 1,5 L/ha (120 g Prothioconazole/L + 300 g Folpet/L). Those rates reflect the requested label rates (1-1,5 L/ha) and 60% of the minimum requested rates of SAP1240H (0,6 L/ha), in accordance with the EPPO standard PP 1/225 '*Minimum effective dose'.*
As only the most representative leaf levels (Leaf 1 , Leaf 2 and Leaf 3) and evaluations have been analyzed, a total of 23 out of 27 trials were considered to determine the minimum effective dose.

- **Wheat – *Septoria* - LEAF 1**

Table 3.2.2.1- a: Minimum effective dose – Control of Septoria in Wheat (LEAF1) achieved by SAP2101F at most representative evaluation (44 DA-A – 41 DA-B) – Detailed table

Refer to BAD.

To compare the effectiveness of the fungicide at the different doses, it is important that all trials include all the same doses. As it is not the case, trials have been divided in 2 protocols to make an orthogonal comparative.
1 L/ha has been established as the main dose, in order to compare different rates.

Table 3.2.2.1- b: Minimum effective dose – Control of *Septoria* in Wheat (LEAF1) achieved by SAP2101F at most representative evaluation (44 DAA – 41 DAB) – Protocol 1

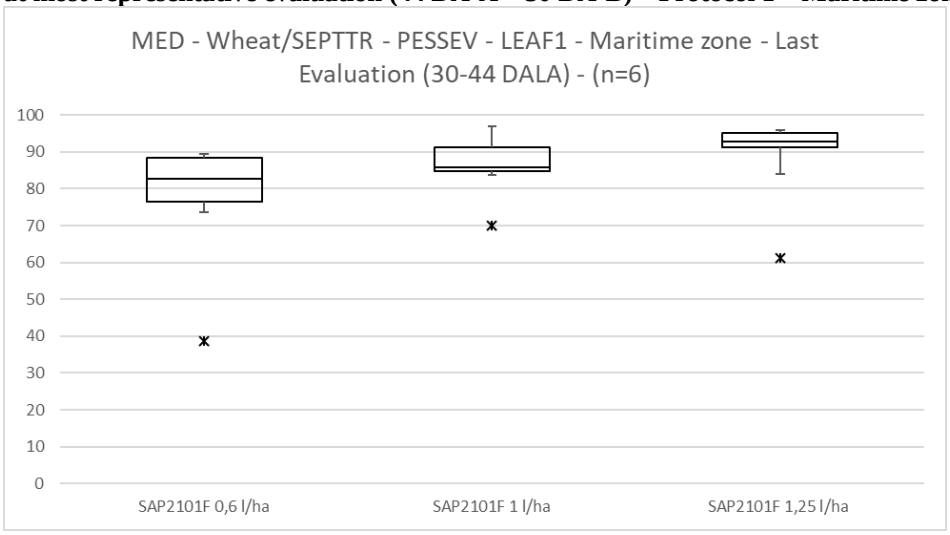
Target	Nb of trials	Untreated plot	% control			Nb of trials where SAP2101F 1 l/ha is >, < or =	Nb of trials where SAP2101F 1 l/ha is >, < or =
			SAP2101F 0,6 l/ha	SAP2101F 1 l/ha	SAP2101F 1,25 l/ha		
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	SAP2101F 0,6 L/ha	SAP2101F 1,25 L/ha
% CONTROL (44 DAA - 41 DAB) Global average	**11 (10)**	**24,1**	**78,7**	**84,8**	**88,5**	**> 0 = 10 < 0**	**> 0 = 10 < 0**
		95,4	**89,5**	**96,9**	**96,0**		
		5,4	**53,8**	**72,5**	**73,2**		
% CONTROL (44 DAA - 41 DAB)	6 (5)	38,0	82,1	88,5	91,8	> 0 = 5 < 0	> 0 = 5 < 0
		95,4	89,5	96,9	96,0		
		7,9	73,5	83,6	84,1		

Target	Nb of trials	Untreated plot	% control			Nb of trials where SAP2101F 1 l/ha is >, < or =	Nb of trials where SAP2101F 1 l/ha is >, < or =
			SAP2101F 0,6 l/ha	SAP2101F 1 l/ha	SAP2101F 1,25 l/ha		
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	SAP2101F 0,6 L/ha	SAP2101F 1,25 L/ha
Maritime EPPO zone							
% CONTROL (21 DAB) North-East EPPO zone	1	6,7	53,8	72,5	73,2	> 0 = 1 < 0	> 0 = 1 < 0
		6,7	53,8	72,5	73,2		
		6,7	53,8	72,5	73,2		
% CONTROL (13-21 DA-B) South-East EPPO zone	4	7,7	80,6	83,4	88,3	> 0 = 4 < 0	> 0 = 4 < 0
		8,8	89,1	85,1	93,1		
		5,4	74,6	81,0	84,2		

Table 3.2.2.1- c: Minimum effective dose – Control of *Septoria* in Wheat (LEAF1) achieved by SAP2101F at most representative evaluation (21 – 41 DA-B) – Protocol 2

Target	Nb of trials	Untreated plot	% control				Nb of trials where SAP2101F 1 l/ha is >, < or =	Nb of trials where SAP2101F 1 l/ha is >, < or =	Nb of trials where SAP2101F 1 l/ha is >, < or =
			SAP2101F 0,6 l/ha	SAP2101F 1 l/ha	SAP2101F 1,25 l/ha	SAP2101F 1,5 l/ha			
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	SAP2101F 0,6 L/ha	SAP2101F 1,25 L/ha	SAP2101F 1,5 L/ha
% CONTROL (21 - 41 DAB) Global average	**6**	**12,3**	**76,2**	**84,1**	**86,4**	**89,5**	**> 0 = 6 < 0**	**> 0 = 6 < 0**	**> 0 = 6 < 1**
		25,0	**88,5**	**96,9**	**96,0**	**99,8**			
		5,4	**53,8**	**72,5**	**73,2**	**81,5**			
% CONTROL (32-41 DA-B) Maritime EPPO zone	3	18,0	81,6	89,1	91,0	92,6	> 0 = 3 < 0	> 0 = 3 < 0	> 0 = 2 < 1
		25,0	88,5	96,9	96,0	99,8			
		7,9	73,5	84,7	84,1	81,5			
% CONTROL (21 DAB) North-East EPPO zone	1	6,7	53,8	72,5	73,2	82,3	> 0 = 1 < 0	> 0 = 1 < 0	> 0 = 1 < 0
		6,7	53,8	72,5	73,2	82,3			
		6,7	53,8	72,5	73,2	82,3			
% CONTROL (21 DA-B) South-East EPPO zone	2	6,6	79,4	82,5	86,1	88,5	> 0 = 2 < 0	> 0 = 2 < 0	> 0 = 2 < 0
		7,8	80,6	83,9	88,0	88,5			
		5,4	78,1	81,0	84,2	88,4			

Figure 3.2.2.1- a: Minimum effective dose – Control of *Septoria* in Wheat (LEAF1) achieved by SAP2101F at most representative evaluation (44 DA-A – 30 DA-B) – Protocol 1 – Maritime zone



For Maritime EPPO climatic zone, according to the results reported in the Table and Figure shown above, % severity of the untreated plots in Leaf 1 with *Septoria* in the 6 assessments had an average of 38%.

Tables and figures displayed above show that the lower rate of **SAP2101F** (0,6 l/ha) presented a lower average control against *Septoria* in Leaf 1 on wheat than the requested application rates 1, 1,25 and 1,5 l/ha.

To analyse data an orthogonal comparative has been done.

- Protocol 1

The lower rate of 0,6 l/ha reached an average control of 82,1%, while 1 and 1,25 l/ha rates reached 88,5% and 91,8% control.
Even if no significant differences were found between 1 L/ha and the other rates, numerical differences are observable, as well as it can be seen in the figure above, where box whisker plots of requested rates are thinner, which means more robust data.
Trial 10-F-2020-FR02 was not taken into account for those results due to outlier data

- Protocol 2

The lower rate of 0,6 l/ha reached an average control of 81,6%, while 1, 1,25 and 1,5 l/ha rates reached 89,1%, 91% and 92,6% control.
Even if no significant differences were found between 1 L/ha and lower rate, a numerical difference is observable.
Between 1 L/ha and 1,25 L/ha there is no significant difference either. However, between 1 L/ha and 1,5 L/ha 1 out 3 trials showed significant differences.

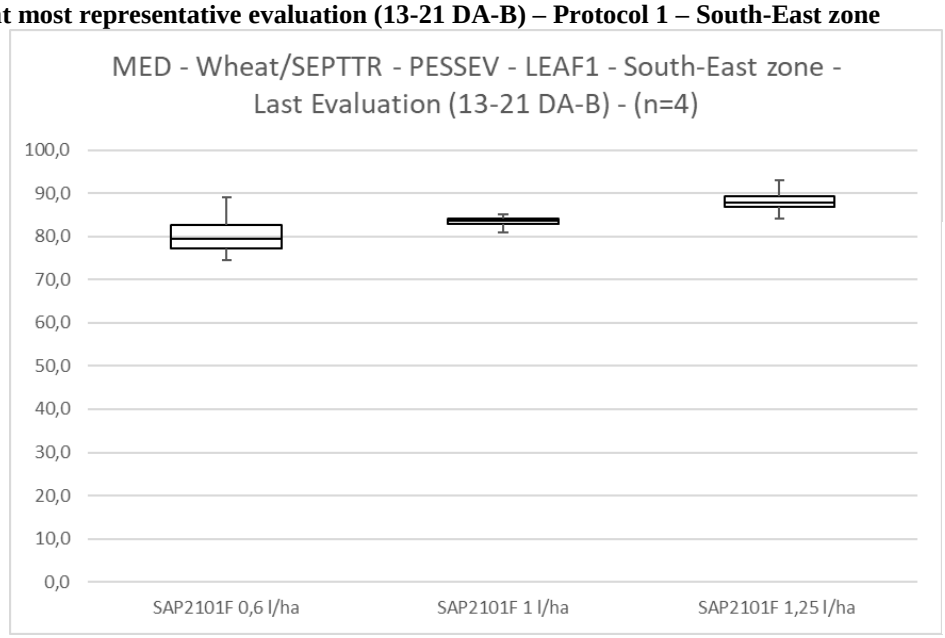
In conclusion, all the reported data have shown that the ~~non-~~ least effective dose is 0,6 L/ha of SAP2101F, being necessary a rate of 1 L/ha to control *Septoria* in wheat, for Maritime EPPO climatic zone. Besides, the doses of 1,25 and 1,5 L/ha, showing better results, are considered necessaries to achieve a higher control level.

For North-East EPPO climatic zone, according to the results reported in the Table shown above, % severity of the untreated plots in Leaf 1 with *Septoria* in 1 assessment was 6,7%.

Due to low infestation of the disease, only 1 trial has been reported at this foliar level.
However, data show that the lower rate of **SAP2101F** (0,6 l/ha) presented a lower average control (~~54.3~~ 53,8%) against *Septoria* in Leaf 1 on wheat than the requested application rates 1, 1,25 and 1,5 l/ha which showed a control of 72,5%, 73,2% and 82,~~5~~3% respectively.

Even if further data is analysed for other foliar levels, this trial prove that the ~~non-~~ least effective dose is 0,6 L/ha of SAP2101F, being necessary a rate of 1 L/ha to control *Septoria* in wheat, for North-East EPPO climatic zone. Besides, the doses of 1,25 and 1,5 L/ha, showing better results, are considered necessaries to achieve a higher control level.

Figure 3.2.2.1- b: Minimum effective dose – Control of Septoria in Wheat (LEAF1) achieved by SAP2101F at most representative evaluation (13-21 DA-B) – Protocol 1 – South-East zone



For South-East EPPO climatic zone, according to the results reported in the Table and Figure shown above, % severity of the untreated plots in Leaf 1 with *Septoria* in the 4 assessments had an average of 7,7%.

Tables and figures displayed above show that the lower rate of **SAP2101F** (0,6 l/ha) presented a lower average control against *Septoria* in Leaf 1 on wheat than the requested application rates 1, 1,5 and 1,25 l/ha.

To analyse data an orthogonal comparative has been done.

- Protocol 1

The lower rate of 0,6 l/ha reached an average control of 80,6%, while 1 and 1,25 l/ha rates reached 83,4% and 88,3% control.
Even if no significant differences between 0,6 L/ha and 1 L/ha rates have been found, numerical differences can be observable, Besides, this is represented as well in the figure above, where the box whisker plots of requested rates (1 and 1,25) are thinner and higher, which means more robust data with better control than the 0,6 l/ha rate.
Between 1 and 1,25 L/ha no significant differences have been shown, but as said before, numerical differences are observable in the table and figure.

- Protocol 2

The lower rate of 0,6 l/ha reached an average control of 79,4%, while 1, 1,25 and 1,5 l/ha rates reached 82,5%, 86,1% and 88,5% control.
Even if no significant differences were found between 1 L/ha and lower rate, a numerical difference is observable.
Between 1 L/ha and the higher rates there is no significant difference either, although, the numerical difference is clearly appreciated.

In conclusion, all the reported data have shown that the ~~non-~~ least effective dose is 0,6 L/ha of SAP2101F, being necessary a rate of 1 L/ha to control *Septoria* in wheat, for South-East EPPO climatic

zone. Besides, the doses of 1,25 and 1,5 L/ha, showing better results, are considered necessaries to achieve a higher control level.

- **Wheat – *Septoria* - LEAF 2**

Table 3.2.2.1- d: Minimum effective dose – Control of Septoria in Wheat (LEAF 2) achieved by SAP2101F at most representative evaluation (22 DAA - 43 DAB) – Detailed table

Refer to BAD.

To compare the effectiveness of the fungicide at the different doses, it is important that all trials include all the same doses. As it is not the case, trials have been divided in 2 protocols to make an orthogonal comparative.
1 L/ha has been established as the main dose, in order to compare different rates.

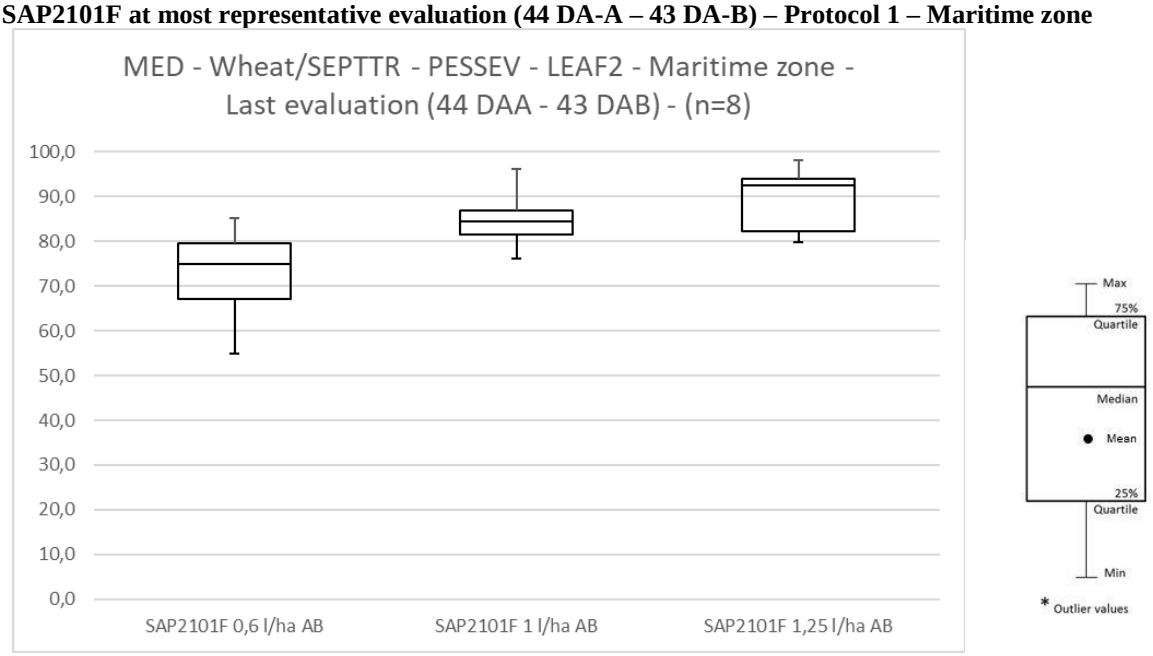
Table 3.2.2.1- e: Minimum effective dose – Control of *Septoria* in Wheat (LEAF 2) achieved by SAP2101F at most representative evaluation (22 DAA - 43 DAB) – Protocol 1

Target	Nb of trials	Untreated plot	% control			Nb of trials where SAP2101F 1 l/ha is >, < or =	Nb of trials where SAP2101F 1 l/ha is >, < or =
			SAP2101F 0,6 l/ha	SAP2101F 1 l/ha	SAP2101F 1,25 l/ha		
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	SAP2101F 0,6 L/ha	SAP2101F 1,25 L/ha
% CONTROL (22 DAA - 43 DAB) Global average	**19**	**29,8** **100,0** **5,4**	**70,9** **85,3** **45,5**	**81,1** **96,1** **57,2**	**86,8** **99,1** **67,8**	**> 6** **= 13** **< 0**	**> 0** **= 15** **< 4**
% CONTROL (44 DAA - 43 DAB) Maritime EPPO zone	8	49,8 100,0 10,0	72,6 85,3 54,8	84,5 96,1 76,1	89,4 98,1 79,8	> 3 = 5 < 0	> 0 = 6 < 2
% CONTROL (21-40 DAB) North-East EPPO zone	4	11,8 18,4 7,5	58,2 64,8 45,5	65,4 71,6 57,2	74,7 83,4 67,8	> 0 = 4 < 0	> 0 = 3 < 1
% CONTROL (22 DAA -22 DAB) South-East EPPO zone	7	17,2 28,3 5,4	76,2 84,5 67,0	86,3 91,5 74,4	90,6 99,1 84,5	> 3 = 4 < 0	> 0 = 6 < 1

Table 3.2.2.1- f: Minimum effective dose – Control of *Septoria* in Wheat (LEAF 2) achieved by SAP2101F at most representative evaluation (21-41 DA-B) – Protocol 2

Target	Nb of trials	Untreated plot	% control				Nb of trials where SAP2101F 1 l/ha is >, < or =	Nb of trials where SAP2101F 1 l/ha is >, < or =	Nb of trials where SAP2101F 1 l/ha is >, < or =
			SAP2101F 0,6 l/ha	SAP2101F 1 l/ha	SAP2101F 1,25 l/ha	SAP2101F 1,5 l/ha			
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	SAP2101F 0,6 L/ha	SAP2101F 1,25 L/ha	SAP2101F 1,5 L/ha
% CONTROL (21-41 DAB) Global average	**12**	25,7 100,0 5,4	69,9 84,5 45,5	80,7 91,0 57,2	86,6 95,1 67,8	88,8 98,0 77,6	> 3 = 9 < 0	> 0 = 9 < 3	> 0 = 8 < 4
% CONTROL (32-41 DA-B) Maritime EPPO zone	4	49,0 100,0 12,3	71,7 82,1 54,8	83,0 86,8 77,5	90,6 95,1 80,9	90,8 98,0 78,9	> 1 = 3 < 0	> 0 = 2 < 2	> 0 = 1 < 3
% CONTROL (21-28 DAB) North-East EPPO zone	3	12,5 18,4 7,5	55,9 61,4 45,5	66,2 71,6 57,2	75,5 83,4 67,8	82,3 86,5 77,6	> 0 = 3 < 0	> 0 = 2 < 1	> 0 = 2 < 1
% CONTROL (21-22 DAB) South-East EPPO zone	5	15,0 24,4 5,4	76,9 84,5 67,0	87,6 91,0 85,0	90,1 94,0 88,0	91,1 93,6 89,7	> 2 = 3 < 0	> 0 = 5 < 0	> 0 = 5 < 0

Figure 3.2.2.1- c: Minimum effective dose – Control of Septoria in Wheat (LEAF 2) achieved by SAP2101F at most representative evaluation (44 DA-A – 43 DA-B) – Protocol 1 – Maritime zone



For Maritime zone EPPO climatic zone, according to the results reported in the Table and Figure shown above, % severity of the untreated plots in Leaf 2 with *Septoria* in the 8 assessments had an average of 49,8%.

Tables and figures displayed above show that the lower rate of **SAP2101F** (0,6 l/ha) presented a lower average control against *Septoria* in Leaf 2 on wheat than the requested application rates 1, 1,25 and 1,5 l/ha.

To analyse data an orthogonal comparative has been done.

- Protocol 1

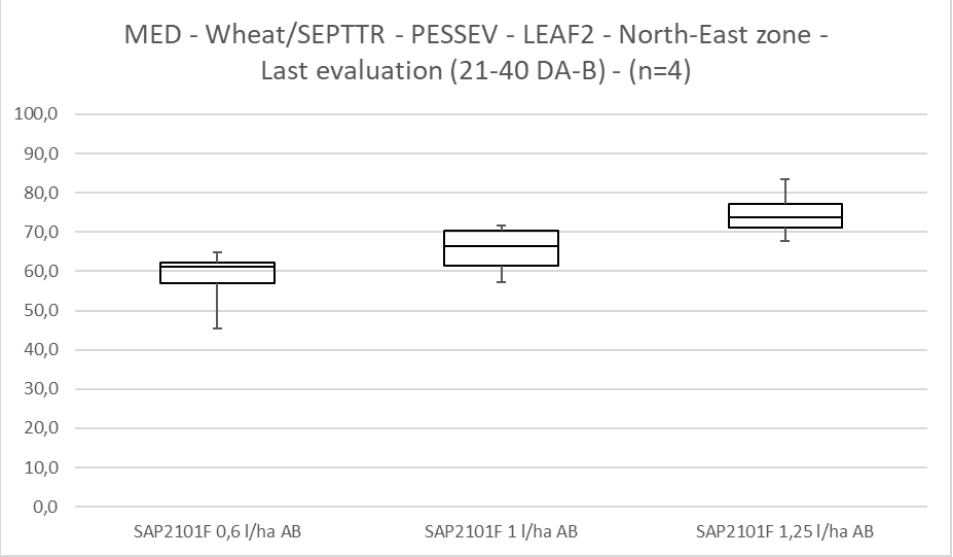
The lower rate of 0,6 l/ha reached an average control of 72,6%, while 1 and 1,25 l/ha rates reached 84,5% and 89,4% control.
Furthermore, in 3 trials out of 8 significant differences were found between 0,6 L/ha and 1 L/ha, proving a better control of the requested minimum dose. Besides, in 2 trials out of 8 significant differences were found between 1 L/ha and 1,25 L/ha, that demonstrates that the dose of 1,25 L/ha is as well necessary to achieve higher efficacies.
This situation is observable as well in the figure above.

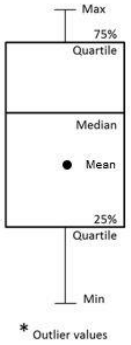
- Protocol 2

The lower rate of 0,6 l/ha reached an average control of 71,7%, while 1, 1,25 and 1,5 l/ha rates reached 83%, 90,6% and 90,8% control.
Furthermore, 1 trial out of 4 have shown significant differences between 0,6 L/ha and 1 L/ha, showing a better control of SAP2101F when applied at 1 L/ha.
Then, in 2 trials out of 4 significant differences were found between 1 L/ha and 1,25 L/ha, which demonstrates that the dose of 1,25 L/ha is as well necessary to achieve a better control.
Finally, in ~~2~~ 3 trials out of 4 significant differences were found between 1 L/ha and 1,5 L/ha, what proves that at the highest requested dose the control of the disease is better, with more robust results.

In conclusion, all the reported data have shown that the least ~~non~~ effective dose is 0,6 L/ha of SAP2101F, being necessary a rate of 1 L/ha to control *Septoria* in wheat, for Maritime EPPO climatic zone. Besides, the doses of 1,25 and 1,5 L/ha, showing better results, are considered to be necessaries to achieve a higher control level.

Figure 3.2.2.1- d: Minimum effective dose – Control of *Septoria* in Wheat (LEAF 2) achieved by SAP2101F at most representative evaluation (27 DA-A – 33 DA-B) – Protocol 1 – North-East zone





For North-East EPPO climatic zone, according to the results reported in the Table and Figure shown above, % severity of the untreated plots in Leaf 2 with *Septoria* in the 4 assessments had an average of 11,8%.

Tables and figures displayed above show that the lower rate of **SAP2101F** (0,6 l/ha) presented a lower average control against *Septoria* in Leaf 2 on wheat than the requested application rates 1, 1,25 and 1,5 l/ha.

To analyse data an orthogonal comparative has been done.

- Protocol 1

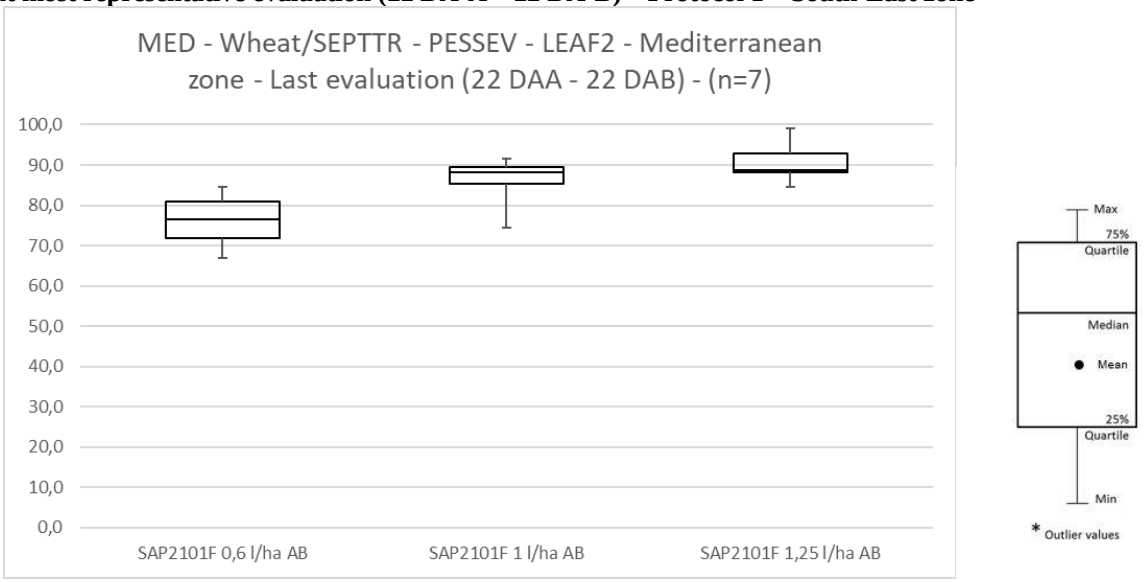
The lower rate of 0,6 l/ha reached an average control of 58,2%, while 1 and 1,25 l/ha rates reached 65,4% and 74,7% control.
Even if significant differences were not found between 0,6 L/ha and 1 L/ha in any of the 4 trials, numerically, results prove a better control with the dose of 1 L/ha.
Then, in 1 trial out of 4, significant differences were found between 1 L/ha and 1,25 L/ha, which demonstrates that the dose of 1,25 L/ha is as well necessary to obtain a better control.
This situation is as well observable in the figure above.

- Protocol 2

The lower rate of 0,6 l/ha reached an average control of 55,9%, while 1, 1,25 and 1,5 l/ha rates reached 66,2%, 75,5% and 82,3% control respectively.
Even if significant differences were not found between 0,6 L/ha and 1 L/ha, numerically, results prove a better control with the dose of 1 L/ha.
Then, in 1 trial out of 3, significant differences were found between 1 L/ha and 1,25 L/ha and 1,5 L/ha, showing a better control at higher doses.

In conclusion, all the reported data have shown that the least ~~non~~ effective dose is 0,6 L/ha of SAP2101F, being necessary a rate of 1 L/ha to control *Septoria* in wheat, for North-East EPPO climatic zone. Besides, the doses of 1,25 and 1,5 L/ha, showing better results, are considered to be necessaries to achieve a higher control level.

Figure 3.2.2.1- e: Minimum effective dose – Control of *Septoria* in Wheat (LEAF 2) achieved by SAP2101F at most representative evaluation (22 DA-A – 22 DA-B) – Protocol 1 – South-East zone



For South-East zone EPPO climatic zone, according to the results reported in the Table and Figure shown above, % severity of the untreated plots in Leaf 2 with *Septoria* in the 7 assessments had an average of 17,2%.

Tables and figures displayed above show that the lower rate of **SAP2101F** (0,6 l/ha) presented a lower average control against *Septoria* in Leaf 2 on wheat than the requested application rates 1, 1,25 and 1,5 l/ha.

To analyse data an orthogonal comparative has been done.

- Protocol 1

The lower rate of 0,6 l/ha reached an average control of 76,2%, while 1 and 1,25 l/ha rates reached 86,3% and 90,6% control.
Furthermore, 3 trials out of 7 have shown significant differences between 0,6 L/ha and 1 L/ha, showing a better control of SAP2101F when applied at 1 L/ha.
Then, in 1 trial out of 7 significant differences were found between 1 L/ha and 1,25 L/ha, which demonstrates that the dose of 1,25 L/ha is as well necessary to achieve better control.
This situation is as well observable in the figure above,

- Protocol 2

The lower rate of 0,6 l/ha reached an average control of 76,9%, while 1, 1,25 and 1,5 l/ha rates reached 87,6%, 90,1% and 91,1% control respectively.
Moreover, in 2 trials out of 5 significant differences were not found between 0,6 L/ha and 1 L/ha, which demonstrates a better control of the disease with the dose of 1 L/ha.
Then, even if no significant differences were found between 1 L/ha and 1,25 L/ha and 1,5 L/ha, a numerical difference is observable, showing better control at higher doses.

In conclusion, all the reported data have shown that the least ~~non~~ effective dose is 0,6 L/ha of SAP2101F, being necessary a rate of 1 L/ha to control *Septoria* in wheat, for South-East EPPO climatic zone, Besides, the doses of 1,25 and 1,5 L/ha, showing better results, are considered to be necessaries to achieve a higher control level.

- **Wheat – *Septoria* - LEAF 3 (North-East)**

For North-East EPPO Climatic zone, due to low infestation in this area, assessment in LEAF 3 is as well evaluated in order to evaluate more data (>5% in the untreated plots).

Table 3.2.2.1- g: Minimum effective dose – Control of Septoria in Wheat (LEAF 3) achieved by SAP2101F at most representative evaluation for North-East EPPO climatic zone (7-34 DAB) – Detailed table

Refer to BAD.

To compare the effectiveness of the fungicide at the different doses, it is important that all trials include all the same doses. As it is not the case, trials have been divided in 2 protocols to make an orthogonal comparative.

1 L/ha has been established as the main dose, in order to compare different rates.

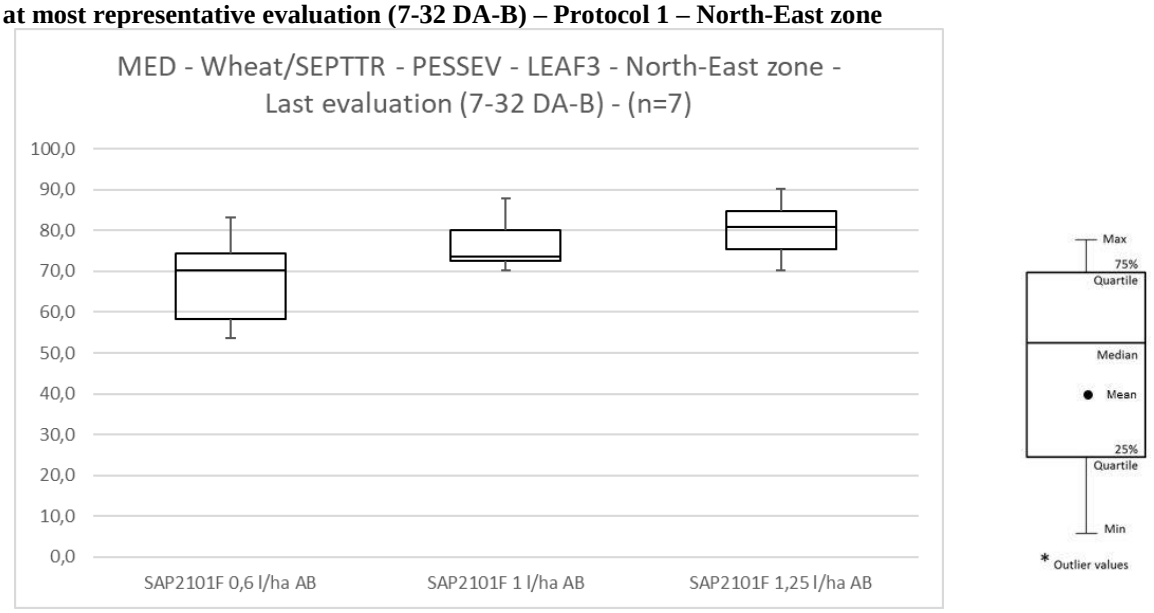
Table 3.2.2.1- h: Minimum effective dose – Control of *Septoria* in Wheat (LEAF 3) achieved by SAP2101F at most representative evaluation for North-East EPPO climatic zone (7-34 DAB) – Protocol 1

Target	Nb of trials	Untreated plot	% control			Nb of trials where SAP2101F 1 l/ha is >, < or =	Nb of trials where SAP2101F 1 l/ha is >, < or =
			SAP2101F 0,6 l/ha	SAP2101F 1 l/ha	SAP2101F 1,25 l/ha		
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	SAP2101F 0,6 L/ha	SAP2101F 1,25 L/ha
% CONTROL (7-34 DAB) North-East EPPO zone	7	12,4	67,5	76,7	80,2	> 4 = 3 < 0	> 0 = 5 < 2
		21,3	83,3	87,8	90,2		
		8,2	53,5	70,1	70,3		

Table 3.2.2.1- i: Minimum effective dose – Control of *Septoria* in Wheat (LEAF 3) achieved by SAP2101F at most representative evaluation for North-East EPPO climatic zone (7-34 DAB) – Protocol 2

Target	Nb of trials	Untreated plot	% control				Nb of trials where SAP2101F 1 l/ha is >, < or =	Nb of trials where SAP2101F 1 l/ha is >, < or =	Nb of trials where SAP2101F 1 l/ha is >, < or =
			SAP2101F 0,6 l/ha	SAP2101F 1 l/ha	SAP2101F 1,25 l/ha	SAP2101F 1,5 l/ha			
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	SAP2101F 0,6 L/ha	SAP2101F 1,25 L/ha	SAP2101F 1,5 L/ha
% CONTROL (7-34 DAB) North-East EPPO zone	5	12,9	62,4	74,6	78,1	81,4	> 4 = 1 < 0	> 0 = 3 < 2	> 0 = 4 3 < 1 2
		21,3	71,9	84,2	87,7	87,7			
		8,2	53,5	70,1	70,3	71,5			

Figure 3.2.2.1- f: Minimum effective dose – Control of *Septoria* in Wheat (LEAF 3) achieved by SAP2101F at most representative evaluation (7-32 DA-B) – Protocol 1 – North-East zone



For North-East EPPO climatic zone, according to the results reported in the Table and Figure shown above, % severity of the untreated plots in Leaf 3 with *Septoria* in the 7 assessments had an average of 12,4%.

Tables and figures displayed above show that the lower rate of **SAP2101F** (0,6 l/ha) presented a lower average control against *Septoria* in Leaf 3 on wheat than the requested application rates 1, 1,25 and 1,5 l/ha.

To analyse data an orthogonal comparative has been done.

- Protocol 1

The lower rate of 0,6 l/ha reached an average control of 67,5%, while 1 and 1,25 l/ha rates reached 76,57% and 80,2% control.

What is more, in 4 trials out of 7, significant differences were found between 0,6 L/ha and 1 L/ha demonstrating when applying at 1 L/ha.

Then, in 2 trials out of 7, significant differences were found between 1 L/ha and 1,25 L/ha, which demonstrates that the dose of 1,25 L/ha is necessary to achieve a higher control.

This situation is as well observable in the figure above.

- Protocol 2

The lower rate of 0,6 l/ha reached an average control of 62,4%, while 1, 1,25 and 1,5 l/ha rates reached 74,6%, 78,1% and 81,4% control respectively.

Furthermore, in 4 out of 5 trials, significant differences were found between 0,6 L/ha and 1 L/ha, proving a better control of the dose of 1 L/ha.

Then, in 2 trial out of 5, significant differences were found between 1 L/ha and 1,25 L/ha and ~~in 1 trial out of 5~~ between 1 L/ha and 1,5 L/ha, showing a better control at higher doses.

In conclusion, all the reported data have shown that the least ~~non~~ effective dose is 0,6 L/ha of SAP2101F, being necessary a rate of 1 L/ha to control *Septoria* in wheat, for North-East EPPO climatic zone. Besides, the doses of 1,25 and 1,5 L/ha, showing better results, are considered to be necessaries to achieve a higher control level.

Conclusion Minimum Effective Dose – Wheat/*Septoria*

According to the reported data, 0,6 l/ha showed consistently the worst efficacy results ~~than the~~ as compared with the other tested rates, ranging from 60-80% efficacy while the rest of the rates are clearly on higher figures, This rate is considered as ~~non~~ the least effective dose.
Rates from 1 to 1,5 l/ha showed good control values with a clear rate response. Higher rates showed consistently higher efficacy values, regardless of the disease pressure. Therefore, it is ASCENZA recommendation that low rate (1 l/ha) should be used under low disease pressure conditions, using the top ones when moderate/high attacks are expected, in order to minimize the impact on crop production.

3.2.2.2 Barley – *Helminthosporium*

A total of 19 trials were carried out to evaluate the efficacy of **SAP2101F** for the control of *Helminthosporium* in barley.
However, for different reasons, ~~3~~ 7 trials have not been taken into account for this section:
- In 11-F-2020-DE02 (Maritime EPPO zone) trial, the disease was present in a first time (0 DA-A), but only other diseases were present in further assessments.
- In 04B-F-2021-HU01 (South-East EPPO zone) trial, any diseases have appeared, so this trial has been used as selectivity trial.
- In 11-F-2020-DE01, 04A-F-2021-DE01, 04B-F-2021-DE02 trials, other diseases were present in the trials but not *Helminthosporium*.
- In 04B-F-2021-DE01, 11-F-2020-FR02 trials disease severity was <5%, so these trials have been used for phytotoxicity assessment.

Table 3.2.2.1- a: Minimum effective dose – Control of *Helminthosporium* in Barley (LEAF 2/3) achieved by SAP2101F at most representative evaluation (22 DAA - 35 DAB) – Detailed table

Refer to BAD.

To compare the effectiveness of the fungicide at the different doses, it is important that all trials include all the same doses. As it is not the case, trials have been divided in 2 protocols to make an orthogonal comparative.

1 L/ha has been established as the main dose, in order to compare different rates.

Table 3.2.2.1- b: Minimum effective dose – Control of *Helminthosporium* in Barley (LEAF 2/3) achieved by SAP2101F at most representative evaluation (~~22~~ 28 DAA - 35 DAB) – Protocol 1

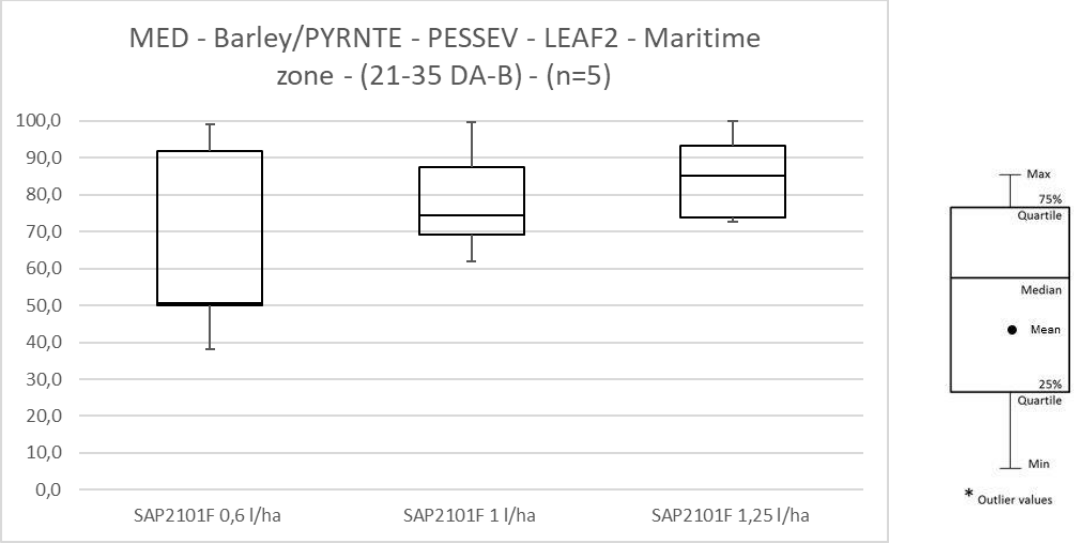
Target	Nb of trials	Untreated plot	% control			Nb of trials where SAP2101F 1 l/ha is >, < or =	Nb of trials where SAP2101F 1 l/ha is >, < or =
			SAP2101F 0,6 l/ha	SAP2101F 1 l/ha	SAP2101F 1,25 l/ha		
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	SAP2101F 0,6 L/ha	SAP2101F 1,25 L/ha
% CONTROL (22 DAA - 35 DAB) Global average	**12**	**33,5** **96,0** **6,2**	**63,9** **99,0** **38,0**	**75,4** **99,7** **43,2**	**82,2** **99,9** **66,2**	**> 5** **= 7** **< 0**	**> 0** **= 11** **< 1**
% CONTROL (~~21~~ 28 DAA - 35 DAB) Maritime EPPO zone	5	61,1 96,0 14,0	65,9 99,0 38,0	78,6 99,7 62,0	85,0 99,9 72,7	> 2 = 3 < 0	> 0 = 5 < 0
	3	16,2	58,8	79,0	82,7	> 2	> 0

Target	Nb of trials	Untreated plot	% control			Nb of trials where SAP2101F 1 l/ha is >, < or =	Nb of trials where SAP2101F 1 l/ha is >, < or =
			SAP2101F 0,6 l/ha	SAP2101F 1 l/ha	SAP2101F 1,25 l/ha		
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	SAP2101F 0,6 L/ha	SAP2101F 1,25 L/ha
% CONTROL (~~22 DAA - 22~~ 21-23 DAB) South-East EPPO zone		35,5	72,9	87,0	95,1	= 1 < 0	= 3 < 0
		6,2	43,2	64,7	66,2		
% CONTROL (12 -28 DAB) North-East EPPO zone	4	11,9	65,2	68,8	78,4	> 1 = 3 < 0	> 0 = 3 < 1
		17,3	79,1	79,1	82,6		
		7,2	40,8	43,2	69,2		

Table 3.2.2.1- c: Minimum effective dose – Control of *Helminthosporium* in Barley (LEAF 2/3) achieved by SAP2101F at most representative evaluation (~~22 DAA~~ 12 - 35 DAB) – Protocol 2

Target	Nb of trials	Untreated plot	% control				Nb of trials where SAP2101F 1 l/ha is >, < or =	Nb of trials where SAP2101F 1 l/ha is >, < or =	Nb of trials where SAP2101F 1 l/ha is >, < or =
			SAP2101F 0,6 l/ha	SAP2101F 1 l/ha	SAP2101F 1,25 l/ha	SAP2101F 1,5 l/ha			
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	SAP2101F 0,6 L/ha	SAP2101F 1,25 L/ha	SAP2101F 1,5 L/ha
% CONTROL (~~22 DAA~~ 12 - 35 DAB) Global average	**10**	**28,4** **96,0** **6,2**	**57,6** **79,1** **38,0**	**71,8** **87,0** **43,2**	**79,4** **95,1** **66,2**	**81,7** **95,1** **38,8**	**> 5 = 5 < 0**	**> 0 = 9 < 1**	**> 0 = 6 < 4**
% CONTROL (24-35 DA-B) Maritime EPPO zone	3	62,6 96,0 14,0	46,2 50,6 38,0	68,6 74,5 62,0	77,3 85,2 72,7	85,8 90,1 82,0	> 2 = 1 < 0	> 0 = 3 < 0	> 0 = 1 < 2
% CONTROL (~~22 DAA - 22~~ 21-23 DAB) South-East EPPO zone	3	16,2 35,5 6,2	58,8 72,9 43,2	79,0 87,0 64,7	82,7 95,1 66,2	74,0 95,1 38,8	> 2 = 1 < 0	> 0 = 3 < 0	> 0 = 3 < 0
% CONTROL (12 -28 DAB) North-East EPPO zone	4	11,9 17,3 7,2	65,2 79,1 40,8	68,8 79,1 43,2	78,4 82,6 69,2	84,5 89,6 72,5	> 1 = 3 < 0	> 0 = 3 < 1	> 0 = 2 < 2

Figure 3.2.2.1- a: Minimum effective dose – Control of *Helminthosporium* in Barley (LEAF 2) achieved by SAP2101F at most representative evaluation (~~21~~ 28 DAA-35 DA-B) – Protocol 1 – Maritime zone



For Maritime EPPO climatic zone, according to the results reported in the Table and Figure shown above, % severity of the untreated plots in Leaf 2 with *Helminthosporium* in the 5 assessments had an average of 61,1%.

Tables and figures displayed above show that the lower rate of **SAP2101F** (0,6 l/ha) presented a lower average control against *Helminthosporium* in Leaf 2 on barley than the requested application rates 1, 1,25 and 1,5 l/ha.

To analyse data an orthogonal comparative has been done.

– Protocol 1

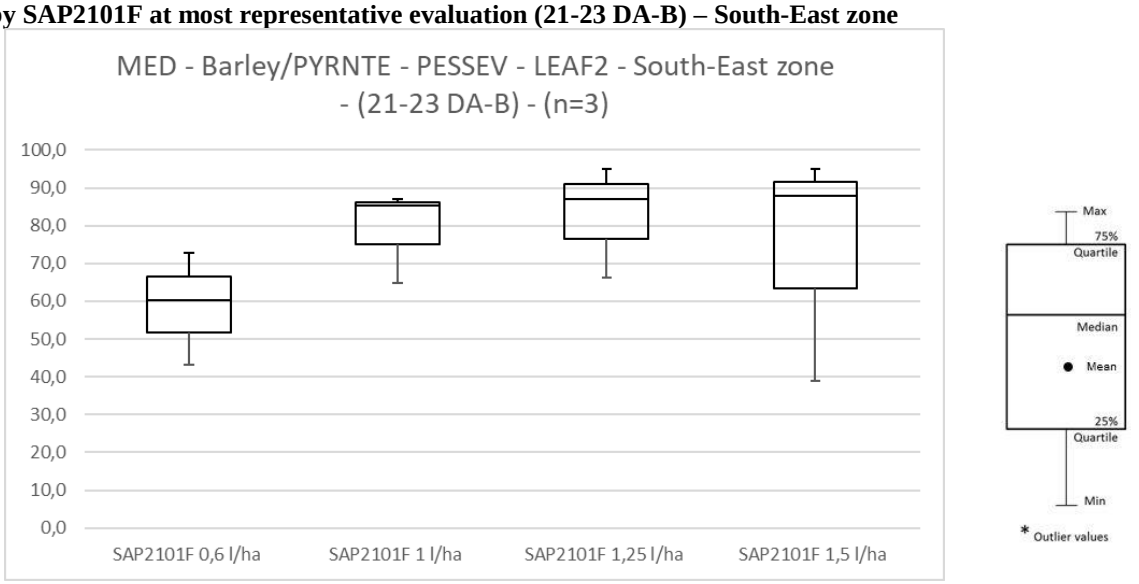
The lower rate of 0,6 l/ha reached an average control of 65,9%, while 1 and 1,25 l/ha rates reached 78,6% and 85% control.
Furthermore, in 2 trials out of 5, significant differences were found between 0,6 L/ha and 1 L/ha, proving a better control of the requested minimum dose. Besides, even if no significant differences were found between 1 L/ha and 1,25 L/ha, results show a better control with the higher dose, showing that this rate is necessary to obtain higher efficacies.
This situation is observable as well in the figure above, where the median of 0,6 L/ha dose is around 50% while the median of 1 L/ha and 1,25 L/ha is round 75% and 85% respectively.

– Protocol 2

The lower rate of 0,6 l/ha reached an average control of 46,2%, while 1, 1,25 and 1,5 l/ha rates reached 68,6%, 77,3% and 85,8% control.
Furthermore, 2 trials out of 3 have shown significant differences between 0,6 L/ha and 1 L/ha, showing a better control of SAP2101F when applied at 1 L/ha.
Besides, even if no significant differences were found between 1 L/ha and 1,25 L/ha, results show a better control with the higher dose, showing that this rate is as well necessary to achieve a better control.
Finally, in 2 trials out of 3 significant differences were found between 1 L/ha and 1,5 L/ha, what proves that at the highest requested dose the control of the disease is better, with more robust results.

In conclusion, all the reported data have shown that the least ~~non~~ effective dose is 0,6 L/ha of SAP2101F, being necessary a rate of 1 L/ha to control *Helminthosporium* in barley, for Maritime EPPO climatic zone. Besides, the doses of 1,25 and 1,5 L/ha, showing better results, are considered to be necessaries to achieve a higher control level.

Figure 3.2.2.1- b: Minimum effective dose – Control of *Helminthosporium* in Barley (LEAF 2) achieved by SAP2101F at most representative evaluation (21-23 DA-B) – South-East zone



For South-East EPPO climatic zone, according to the results reported in the Table and Figure shown above, % severity of the untreated plots in Leaf 2 with *Helminthosporium* in the 3 assessments had an average of 16,2%.

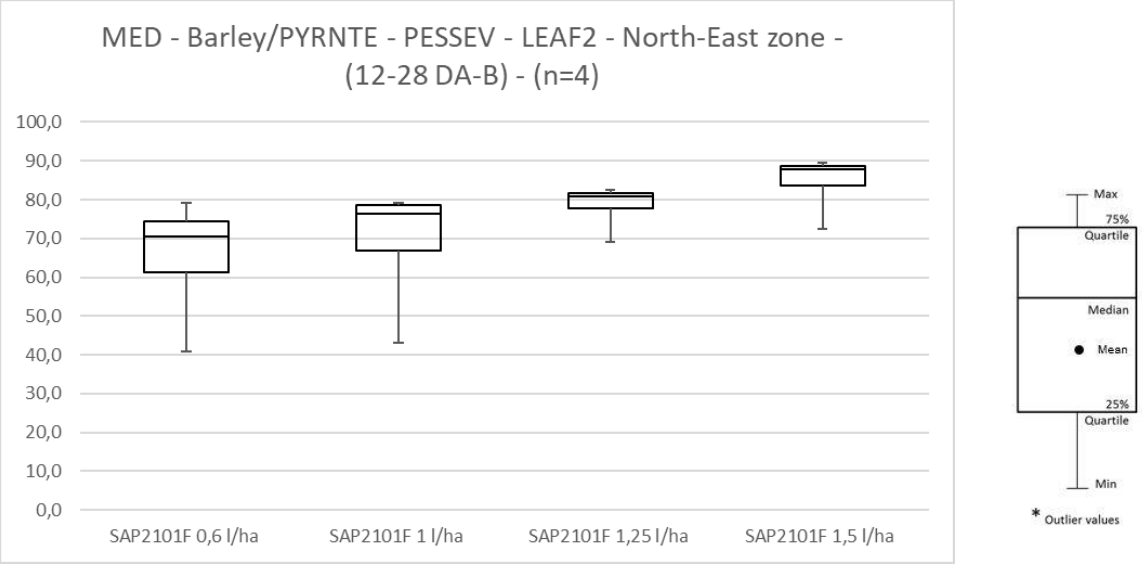
Tables and figures displayed above show that the lower rate of **SAP2101F** (0,6 l/ha) presented a lower average control against *Helminthosporium* in Leaf 2 on barley than the requested application rates 1, 1,25 and 1,5 l/ha.

The lower rate of 0,6 l/ha reached an average control of 58,8%, while 1, 1,25 and 1,5 l/ha rates reached 79%, 82,7% and 74% control.
In 2 trials out of 3, significant differences are found between 0,6 L/ha and 1 L/ha, proving a better control of the rate 1 L/ha.
Then, even if no significant differences are found between 1L/ha with 1,25 L/ha and 1,5 L/ha, a numerical difference is appreciated.
However, trials performed in this EPPO climatic zone presented low infestation and just 3 trials have been taking in consideration, that means that data is not robust and have to be taken carefully.
For that reason, it has been considered that data coming from Maritime zone can be extrapolated to this EPPO zone, according to EPPO Guideline PP1/226(3) – 'Number of efficacy trials', which states that "*In some situations there may be the opportunity to reduce the number of trials done, and a case may be made for this as follows.*
• *Where there is a large amount of supporting evidence from use of the product, or of similar products with the same active substance, on closely related pests or against the same pests on different crops, the number of trials necessary will be determined by the amount of supporting evidence and the similarity of the pests and crops sought* […] *Extrapolations from more challenging control situations to ones that pose a lower challenge to the active substance are more readily justifiable than extrapolations from less challenging to more challenging situations."*
Trials performed in Maritime EPPO climatic zone have more favourable climatic conditions to develop the disease than other zones and have as well a bigger wheat production than other climatic zones, according to EUROSTAT database.
For that, reason it has been considered that Maritime EPPO zone is a more challenging zone for the requested diseases and crops, than the other EPPO zones.
Therefore, data coming from Maritime EPPO zone can be extrapolated to the other zones.

In conclusion, all the reported data from Maritime and South-East zones have shown that the least ~~non~~ effective dose is 0,6 L/ha of SAP2101F, being necessary a rate of 1 L/ha to control *Helminthosporium*

in barley, for South-East EPPO climatic zone. Besides, the doses of 1,25 and 1,5 L/ha, showing better results, are considered to be necessaries to achieve a higher control level.

Figure 3.2.2.1- c: Minimum effective dose – Control of *Helminthosporium* in Barley (LEAF 2/3) achieved by SAP2101F at most representative evaluation (12-28 DA-B) – North-East zone



For North-East EPPO climatic zone, according to the results reported in the Table and Figure shown above, % severity of the untreated plots in Leaves 2 and 3 with *Helminthosporium* in the 4 assessments had an average of 11,9%.

Tables and figures displayed above show that the lower rate of **SAP2101F** (0,6 l/ha) presented a lower average control against *Helminthosporium* in Leaves 2 and 3 on barley than the requested application rates 1, 1,25 and 1,5 l/ha.

The lower rate of 0,6 l/ha reached an average control of ~~62,5~~ 65,2%, while 1, 1,25 and 1,5 l/ha rates reached 68,8%, 78,4% and 84,5% control.
In 1 trial out of 4, significant differences are found between 0,6 L/ha and 1 L/ha, proving a better control of the rate 1 L/ha.
Then, 1 trial out of 4, significant differences are found between 1 L/ha and 1,25 L/ha and in 2 trials out of 4 between 1 L/ha and 1,5 L/ha, what demonstrates that the disease is better controlled with higher doses.
However, just 4 trials have been taken in consideration, for that reason it has been considered that data coming from Maritime zone can be extrapolated to this EPPO zone, according to EPPO Guideline PP1/226(3) – 'Number of efficacy trials', which states that "*In some situations there may be the opportunity to reduce the number of trials done, and a case may be made for this as follows.*
- *Where there is a large amount of supporting evidence from use of the product, or of similar products with the same active substance, on closely related pests or against the same pests on different crops, the number of trials necessary will be determined by the amount of supporting evidence and the similarity of the pests and crops sought* […] *Extrapolations from more challenging control situations to ones that pose a lower challenge to the active substance are more readily justifiable than extrapolations from less challenging to more challenging situations."*

Trials performed in Maritime EPPO climatic zone have more favourable climatic conditions to develop the disease than other zones and have as well a bigger wheat production than other climatic zones, according to EUROSTAT database.
For that, reason it has been considered that Maritime EPPO zone is a more challenging zone for the requested diseases and crops, than the other EPPO zones.
Therefore, data coming from Maritime EPPO zone can be extrapolated to the other zones.

In conclusion, all the reported data from Maritime and North-East zones have shown that the least ~~non-~~ effective dose is 0,6 L/ha of SAP2101F, being necessary a rate of 1 L/ha to control *Helminthosporium* in barley, for South-East EPPO climatic zone. Besides, the doses of 1,25 and 1,5 L/ha, showing better results, are considered to be necessaries to achieve a higher control level.

Conclusion Minimum Effective Dose – Barley/*Helminthosporium*

According to the reported data, 0,6 l/ha showed consistently the worst efficacy results ~~than the~~ as compared with the other tested rates, ranging from 50-70% efficacy while the rest of the rates are clearly on higher figures. This rate is considered as the least ~~non-~~ effective dose.
Rates from 1 to 1,5 l/ha showed good control values with a clear rate response. Higher rates showed consistently higher efficacy values, regardless of the disease pressure. Therefore, it is ASCENZA recommendation that low rate (1 l/ha) should be used under low disease pressure conditions, using the top ones when moderate/high attacks are expected, in order to minimize the impact on crop production.

Comments of zRMS on:
Minimum effective dose tests (3.2.2)

Wheat: *Zymoseptoria tritici* (SEPTTR)

Results from 23 efficacy trials carried out between 2020 and 2021 have been presented to determine the Minimum Effective Dose (MED) for SAP2101F in the control of SEPTTR on wheat. The trials were carried out in 3 EPPO zones: Maritime (9 trials from: Germany (3), France (5), United Kingdom (1)), North-East (7 trials from Poland), South-East (7 trials from: Bulgaria (4) and Romania (3)). The most representative leaf levels (leaf 1, leaf 2 and leaf 3) were considered for the evaluation. As SAP2101F is intended to be authorized in Poland, and no other cMSs are listed in GAP table, efficacy data from North-East EPPO zone are primarily analysed. Trials from Maritime and South-East EPPO zone are considered as supportive data and may be also relevant for possible future applications (e.g. art 40 Mutual recognition) in other Member States. As the dose rate of 1,5 L/ha has not been tested in all efficacy trials, 2 trial protocols have been separated:

- Protocol 1 with 3 dose rates of SAP2101F (0,6; 1,0; 1,25 L/ha)
- Protocol 2 with 4 dose rates of SAP2101F (0,6; 1,0; 1,25 and 1,5 L/ha)

Based on the submitted trial results, a clear dose response was seen for SAP2101F with increase of efficacy with increasing dose rate in the control SEPTTR on wheat. Considering numerical data, a clear differences were noted between tested dose rates. Statistically significant differences (in favor of higher dose rate) were demonstrated:

- between 1,0 and 1,5 L/ha in 1 trial conducted in Maritime EPPO zone (Germany) on leaf 1 (for protocol 2),
- between 0,6 and 1,0 L/ha in 6 trials conducted in Maritime EPPO zone (Germany (2), France (1)) and South-East EPPO zone (Bulgaria (2), Romania (1)) on leaf 2 (protocol 1),
- between 1,0 and 1,25 L/ha in 4 trials conducted in EPPO zones: Maritime (Germany, France), North-East (Poland) and South-East (Bulgaria) on leaf 2 (protocol 1),
- between 0,6 and 1,0 L/ha in 3 trials conducted in Maritime EPPO zone (Germany) and South-East EPPO zone (Bulgaria, Romania) on leaf 2 (protocol 2),
- between 1,0 and 1,25 L/ha in 3 trials conducted in EPPO zones: Maritime (Germany, France), North-East (Poland) on leaf 2 (protocol 2),
- between 1,0 and 1,5 L/ha in 4 trials conducted in EPPO zones: Maritime (Germany (1), France (2)), North-East (Poland) on leaf 2 (protocol 2),
- between 0,6 and 1,0 L/ha in 4 trials conducted in North-East EPPO zone (Poland) on leaf 3 (protocol 1 and 2),
- between 1,0 and 1,25 L/ha in 2 trials conducted in North-East EPPO zone (Poland) on leaf 3 (protocol 1 and 2),
- between 1,0 and 1,5 L/ha in 2 trials conducted in North-East EPPO zone (Poland) on leaf 3 (protocol 2).

For North-East EPPO zone the highest efficacy level >80% was demonstrated at the highest recommended dose rate of 1,5 L/ha. Moderate efficacy level between 60-80% was noted for dose rates of 1,0 and 1,25 L/ha. The lowest tested dose rate of 0,6 L/ha was visibly less effective with results < 60% efficacy on leaf 1 and leaf 2 and

between 60 and 70% on leaf 3.

Based on the submitted trial results it can be concluded, that the dose rate of 1,5 L/ha was the most effective dose under various conditions (high and low disease pressure) and therefore can be considered as the Minimum Effective Dose to provide sufficient efficacy in the control of SEPTTR on wheat (across a broad range of disease pressure) in North-East EPPO zone. Lower requested dose rates 1,0 and 1,25 L/ha can be also recommended under low disease pressure.

For Maritime and South-East EPPO zone the highest efficacy level close to 90% and >90% was demonstrated at the highest recommended dose rate of 1,5 L/ha. High efficacy level >80% and >80- >90% was noted for dose rates of 1,0 and 1,25 L/ha respectively. The lowest tested dose rate of 0,6 L/ha was less effective with results >70% and >80% efficacy. For possible future applications (e.g. art 40 Mutual recognition) in other Member States, dose rate of 1,0 L/ha can be considered as Minimum Effective Dose in Maritime and South-East EPPO zone. Higher dose rates can be considered to achieve higher efficacy level especially under high disease pressure.

Barley: *Pyrenophora teres* (PYRNTE)

Twelve efficacy trials conducted between 2020 and 2021 present data to determine the Minimum Effective Dose (MED) for SAP2101F in the control of PYRNTE on barley. The trials were carried out in 3 EPPO zones: Maritime (5 trials from France), North-East (4 trials from Poland), South-East (3 trials from: Bulgaria (2) and Romania (1)). SAP2101F was tested at requested dose rates: 1,0; 1,25 and 1,5 L/ha and at lower dose rate of 0,6 L/ha corresponding to 60% of the minimum requested rate. The most representative leaf levels (leaf 1, leaf 2 and leaf 3) were considered for the evaluation. As SAP2101F is intended to be authorized in Poland, and no other cMSs are listed in GAP table, efficacy data from North-East EPPO zone are primarily analysed. Trials from Maritime and South-East EPPO zone are considered as supportive data and may be also relevant for possible future applications (e.g. art 40 Mutual recognition) in other Member States. As the dose rate of 1,5 L/ha has not been tested in all efficacy trials, 2 trial protocols have been separated:

- Protocol 1 with 3 dose rates of SAP2101F (0,6; 1,0; 1,25 L/ha)
- Protocol 2 with 4 dose rates of SAP2101F (0,6; 1,0; 1,25 and 1,5 L/ha)

Based on the submitted trial results, a clear dose response was seen for SAP2101F with increase of efficacy with increasing dose rate in the control PYRNTE on barley. Considering numerical data, a clear differences were noted between tested dose rates. Statistically significant differences (in favor of higher dose rate) were demonstrated:

- between 0,6 and 1,0 L/ha in 5 trials conducted in Maritime EPPO zone (France (2)) North-East EPPO zone (Poland) and South-East EPPO zone (Bulgaria (1), Romania (1)) (protocol 1 and 2),
- between 1,0 and 1,25 L/ha in 1 trial conducted in North-East EPPO zone (Poland) (protocol 1 and 2)
- between 1,0 and 1,5 L/ha in 4 trials conducted in Maritime EPPO zone (France (2)) and North-East EPPO zone (Poland (2)) (protocol 2).

For North-East EPPO zone the highest efficacy level >80% was demonstrated at the highest recommended dose rate of 1,5 L/ha. Efficacy >70% and >80% was noted for dose rates of 1,0 and 1,25 L/ha. The lowest tested dose rate of 0,6 L/ha was less effective with results > 60% efficacy.

Based on the submitted trial results it can be concluded, that the dose rate of 1,5 L/ha was the most effective dose under various conditions (high and low disease pressure) and therefore can be considered as the Minimum Effective Dose to provide sufficient efficacy in the control of PYRNTE on barley (across a broad range of disease pressure) in North-East EPPO zone. Lower requested dose rates 1,0 and 1,25 L/ha can be considered to be recommended under low disease pressure. Regardless of this assessment it should be highlighted, that not sufficient number of efficacy trials has been submitted to support the authorization of SAP2101F in the control of PYRNTE on barley in Poland (see zRMS commenting box under the chapter 3.2.3). Therefore, this use is not accepted in North-East EPPO zone (PL).

For Maritime EPPO zone the highest efficacy level >80% was demonstrated at the highest recommended dose rate of 1,5 L/ha. Efficacy >70% and >80% was noted for dose rate of 1,25 L/ha. Efficacy >60% and >70% was noted for dose rate of 1,0 L/ha. The lowest tested dose rate of 0,6 L/ha was less effective with results > 40% and >60% efficacy

For South-East EPPO zone the highest efficacy level >80% was demonstrated at dose rate of 1,25 L/ha. Efficacy >70% was noted for dose rate of 1,0 L/ha. The lowest tested dose rate of 0,6 L/ha was less effective with results

> 50% efficacy. As not clearly dose response was noted between 0,6; 1,0; 1,25 and the highest tested dose rate of 1,5 L/ha in South-East EPPO zone, the results from individual trials have been analysed. The dose rate of 1,5 was highly effective in 2 of 3 trials (88% and 95,1% efficacy). Low efficacy 38,8% was noted in 1 trial, while the efficacy >60% was demonstrated at lower dose rates 1,0 and 1,25 L/ha and >40% was noted at the lowest dose rate of 0,6 L/ha in this trial. Therefore, results from this trial seems to be no valid for mean average calculation of efficacy.

For possible future applications (e.g. art 40 Mutual recognition) in other Member States, dose rate of 1,5 L/ha can be considered as Minimum Effective Dose in the control of PYRNTE on barley in Maritime and South-East EPPO zone. Lower dose rates can be considered to be recommended under low disease pressure.

3.2.3 Efficacy tests (KCP 6.2)

A total of 48 field trials (39 valid trials) have been performed in France, Germany, United Kingdom, Hungary, Bulgaria, Romania and Poland under Maritime, South-East and North-East EPPO climatic zones, from 2020 to 2021, in wheat and barley to evaluate the effectiveness of **SAP2101F** (120 g Prothioconazole/ha + 300 g Folpet/ha) at the proposed range dose of 1-1,5 L/ha.

However, ~~one~~ nine trials ~~has~~ have been used ~~as selectivity trial~~ for phytotoxicity assessment and not taken into account for this section, due the non-apparition of disease (10-F-2020-UK01, 03B-F-2021-HU01, 11-F-2020-DE01, 11-F-2020-DE02, 11-F-2020-FR02, 04A-F-2021-DE01, 04B-F-2021-DE01, 04B-F-2021-DE02, 04B-F-202~~1~~0-HU01).
~~WHEAT~~

Table 3.2.3-1a: Details on trial methodology (wheat)

Guidelines	General guidelines	EPPO PP 1/152(2), PP 1/181 (2), PP 1/135(2)
	Specific guidelines	EPPO PP 1/26(4)
Experimental design	Plot design	RCBD
	Plot size	12 – 27 m²
	Number of replications	4
Crop	Trials per crop	Wheat (29)
	Varieties per crop	Avenue, Benchmark, Costello, Kilimanjaro, RGT Bilanz, Ariesan (2), Basmati, Sadovo-1 (2), Rubisko (2), Euforia, Opoka, Arkadia, Sor~~e~~ial, Barrel (2), Toras, Ozon, Fenomen, Sailor, Miranda, Apache, Patras, Némo, Oregrain, Bergamo, ~~Barrell,~~ Bernstein.
Application	Crop stage (BBCH)* at application	Application A: BBCH 31-~~58~~ 51 Application B: BBCH 37-~~71~~ 73
	Timing Pest stage at application (1)	Application at first apparition of symptoms
	Number of applications Intervals between applications	2 applications -Application A: beginning of disease on leaf 3 and if possible after BBCH32 -Application B: A1 + 3/4 weeks
	Spray volumes	160 – 300 L/ha
Assessment	Assessment types	PESINC (% incidence) PESSEV (% severity) GRNARE (% Green leaf area) YIELD (T/ha - harvest) PHYGEN (% phytotoxicity)
	Assessment dates	Pre-spray assessment: 0 (-1) DA-A Further assessments: - 0 DA-B; - 1-2 weeks after application B;

		- 3 weeks after application B.
Other relevant information	e.g. Natural / artificial innoculation…	Natural
	e.g. Field / Greenhouse...	Field

~~BARLEY~~

Table 3.2.3-1b: Details on trial methodology (barley)

Guidelines	General guidelines	EPPO PP 1/152(2), PP 1/181 (2), PP 1/135(2)
	Specific guidelines	EPPO PP 1/26(4)
Experimental design	Plot design	RCBD
	Plot size	10 – 30 m²
	Number of replications	4
Crop	Trials per crop	Barley ~~(18)~~ (19)
	Varieties per crop	Wallace(2), LG Zebra, Zanzibar, Potok, KWS Orbit, Kosmos, Etincel, KWS Dementiel, Quadriga (2), Metaxa, Sandra, Soldo, Saphira, Margaux, Cervoise, Akkord, SU Ellen.
Application	Crop stage (BBCH)* at application	Application A: BBCH 29-~~41~~ 49 Application B: BBCH ~~49~~ 39-62
	Timing Pest stage at application (1)	Application at first apparition of symptoms
	Number of applications Intervals between applications	2 applications -Application A: beginning of disease on leaf 3 -Application B: A1 + 3/4 weeks
	Spray volumes	150 – 300 L/ha
Assessment	Assessment types	PESINC (% incidence) PESSEV (% severity) GRNARE (% Green leaf area) YIELD (T/ha - harvest) PHYGEN (% phytotoxicity)
	Assessment dates	Pre-spray assessment: 0 (-1) DA-A Further assessments: - 0 DA-B; - 1-2 weeks after application B; - 3 weeks after application B.
Other relevant information	e.g. Natural / artificial innoculation…	Natural
	e.g. Field / Greenhouse...	Field

Numerical and statistical analysis

Data were subjected to analysis of variance (ANOVA) at the 95% confidence level. When significant differences were found a Student-Newman-Keuls (SNK) Post-Hoc test were applied to separate the means.

Treatment means with no letters in common are significantly different according to SNK test.
Bartlett's test was applied to study the assumption of ANOVA of homogeneity of variances. When it was necessary in order to improve the statistical analysis, raw data were transformed according to the appropriated transformation to increase homogeneity. In those cases, depending of the trial, means have

been reported as de-transformed averages, as transformed averages or as raw averages with the statistical analysis of the transformed data.

3.2.3.1 Wheat/*Septoria*

A total of 29 trials (27 valid trials) were carried out to evaluate the efficacy of **SAP2101F** for the control of *Septoria* in wheat.
Only data on SEPTTR (*Zymoseptoria tritici*) is reported. Data on other diseases appearing sporadically in some trials are not reported as being not relevant for the requested authorisations.
However, due to the apparition of another disease in the trial 03B-F-2021-HU01 or low disease severity < 5% in the trial 10-F-2020-UK01, results from these 2 trials ~~1 trial has~~ have not been taken into account for this section. ~~(03B-F-2021-HU01).~~

Table 3.2.3.1 a. Total *Septoria* of Wheat disease control (%) of PESSEV, achieved by SAP2101F and the reference products – Detailed table

Refer to BAD.

Different reference products have been applied (different active ingredients), due to the different authorized products of each country. For that reason, in order to do an orthogonal comparison, four tables are presented here below with all the results, taking as the main dose the minimum requested ~~range~~ dose rates: 1 and 1,25 L/ha of SAP2101F (120 g of Prothioconazole/ha and 300 g of Folpet/ha).

Table 3.2.3.1 b. Total *Septoria* of Wheat disease control (%) of PESSEV, achieved by SAP2101F and the reference products – Reference 1

Target	Nb of trials	Untreated plot	% control			Nb of trials where SAP2101F 1 l/ha is >, < or =	Nb of trials where SAP2101F 1,25 l/ha is >, < or =
			SAP2101F 1 l/ha	SAP2101F 1,25 l/ha	REF 1 (Prothio. + Tebu.) (0,75*) - 1 L/ha		
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	REF 1 (Prothio. + Tebu.) (0,75*) - 1 L/ha	REF 1 (Prothio. + Tebu.) (0,75*) - 1 L/ha
% CONTROL (9-~~34~~ 40 DA-B) Global average	~~13~~ **14**	~~10,1~~ **9,9** **18,4** **5,4**	~~80,3~~ **79,1** **91,0** **57,2**	**85,8** **97,8** **67,8**	~~81,6~~ **81,9** **92,6** **59,6**	**< 2** **= 9** **> 2**	< 0 = 12 > 2
% CONTROL Maritime EPPO zone	0	- - -	- - -	- - -	- - -	-	-
% CONTROL (~~13-22~~ 9-40 DA-B) North-East EPPO zone	5	11,0 18,4 6,7	71,5 84,2 57,2	78,8 87,7 67,8	72,9 86,9 59,6	< 2 = 2 > 1	< 0 = 4 > 1
% CONTROL (13-22 DA-B) South-East EPPO zone	~~8~~ 9	~~9,5~~ 9,2 17,5 5,4	~~85,9~~ 83,3 91,0 ~~81,0~~ 62,6	89,7 97,8 84,2	~~87,1~~ 86,9 92,6 70,3	< ~~0~~ 1 = 7 > 1	< 0 = 8 > 1

Note:
REF 1 (Prothioconazole 125 g/L + Tebuconazole 125 g/L): PROSARO 250 EC at 1 L/ha (except in Romania, which is applied at 0,75 L/ha); AsPik 250 EC at 1 L/ha

The table above shows a summary of the control of **SAP2101F** at 1 L/ha (120 g Prothioconazole/ha and 300 g Folpet/ha) and at 1,25 L/ha (150 g Prothioconazole/ha and 375 g Folpet/ha) against *Septoria* on wheat, compared to **Reference 1** at 1 L/ha (125 g of Prothioconazole/ha and 125 g of Tebuconazole/ha),

except in Romania, which is applied at 0,75 L/ha (94 g of Prothioconazole/ha and 94 g of Tebuconazole/ha).
The commercial names of the products belonging to Reference 1 group are the following ones: PROSARO 250 EC at 1 L/ha (except in Romania, where it is applied at 0,75 L/ha) and AsPik 250 EC at 1 L/ha.

It was considered only the most representative evaluation timing and the most representative variable as the % severity (PESSEV) in Leaf 1, Leaf 2, ~~or~~ Leaf 3 or Leaf 4 reached by the disease. According to the results, % severity in trials conducted ranged from 5,4 to 18,4 % in both North-East and South-East EPPO zones, where this reference product has been applied.

In the North-East EPPO zone, the % severity in the untreated plots in all conducted trials ranged from 6,7 to 18,4%.
The efficacy average value obtained by **SAP2101F** at 1 l/ha and 1,25 L/ha is 71,5% and 78,8% respectively according to the assessments performed, and the one obtained by the Reference 1 is 72,9%. Besides, no significant differences were found between SAP2101F at 1 L/ha and the references products belonging to Reference 1 group (PROSARO 250 EC and AsPik 250 EC), in 2 out of 5 trials. Then, for the other 3 trials, significant differences are found, where in 1 trial the control of the tested product is higher and in the other 2 trials the control of the reference products is higher. No significant differences were found between SAP2101F at 1,25 L/ha and the references products belonging to Reference 1 group in 4 out of 5 trials. In 1 trial the control of the tested product is significantly higher.
In general, all these results are showing a similar control between the tested product and the authorized products.

In the South-East EPPO zone, the % severity in the untreated plots in all conducted trials ranged from 5,4 to 17,5%.
The efficacy average value obtained by **SAP2101F** at 1 l/ha and 1,25 L/ha is ~~85,9%~~ 83,3% and 89,7% respectively, according to the assessments performed, and the one obtained by the Reference 1 is ~~87,1%~~ 86,9%.
Furthermore, no significant differences were found between SAP2101F at ~~lowest~~ requested dose rates 1,0 and 1,25 L/ha and the references products belonging to Reference 1 group (PROSARO 250 EC and AsPik 250 EC) in 7 or 8 of the ~~8~~ 9 trials, showing a similar control than the authorized products.

In resume, those facts indicate a similar behaviour in the control of *Septoria* in wheat achieved by **SAP2101F** at ~~lowest~~ requested dose rates 1,0 and 1,25 L/ha and references tested products.

Table 3.2.3.1 c. Total *Septoria* of Wheat disease control (%) of PESSEV, achieved by SAP2101F and the reference products – Reference 2

Target	Nb of trials	Untreated plot	% control			Nb of trials where SAP2101F 1 l/ha is >, < or =	Nb of trials where SAP2101F 1,25 l/ha is >, < or =
			SAP2101F 1 l/ha	SAP2101F 1,25 l/ha	REF 2 (Prothio.) (0,63/0,72*) - 0,8 L/ha		
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	REF 2 (Prothio.) (0,63/0,72*) - 0,8 L/ha	REF 2 (Prothio.) (0,63/0,72*) - 0,8 L/ha
% CONTROL (44 DAA - 43 DAB) Global average	~~8 (~~**9**~~)~~	~~**30,5** **34,0**~~ **95,4** **6,4**	~~**88,7** **87,3**~~ **96,9** ~~**83,6** **76,1**~~	**91,4** **96,1** **79,8**	~~**87,7** **84,8**~~ **95,8** ~~**78,8** **61,4**~~	**< 0** **= ~~8~~ 9** **> 0**	**< 0** **= 9** **> 0**
% CONTROL (44 DAA - 43 DAB) Maritime EPPO zone	~~8 (~~9~~)~~	~~30,5~~ 34,0 95,4 6,4	~~88,7~~ 87,3 96,9 ~~83,6~~ 76,1	91,4 96,1 79,8	~~87,7~~ 84,8 95,8 ~~78,8~~ 61,4	< 0 = ~~8~~ 9 > 0	< 0 = 9 > 0
% CONTROL	0	- -	- -		- -	-	-

Target	Nb of trials	Untreated plot	% control			Nb of trials where SAP2101F 1 l/ha is >, < or =	Nb of trials where SAP2101F 1,25 l/ha is >, < or =
			SAP2101F 1 l/ha	SAP2101F 1,25 l/ha	REF 2 (Prothio.) (0,63/0,72*) - 0,8 L/ha		
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	REF 2 (Prothio.) (0,63/0,72*) - 0,8 L/ha	REF 2 (Prothio.) (0,63/0,72*) - 0,8 L/ha
North-East EPPO zone		-	-		-		
% CONTROL South-East EPPO zone	0	-	-		-	-	-
		-	-		-		
		-	-		-		

- REF 2 (Prothioconazole 250 g/L): JOAO at 0,8 L/ha; PROLINE at 0,8 L/ha (except in United Kingdom, where PROLINE contains 275 g of Prothioconazole/L and it is applied at 0,63 L/ha and 0,72 L/ha, which correspond to 173,3 g and 198 g of Prothioconazole/ha respectively); CURBATUR at 0,8 L/ha.

The table above shows a summary of the control of **SAP2101F** at 1 L/ha (120 g Prothioconazole/ha and 300 g Folpet/ha) and at 1,25 L/ha (150 g Prothioconazole/ha and 375 g Folpet/ha) against *Septoria* in wheat, compared to **Reference 2** applied at 0,8 L/ha (equivalent to 200 g of Prothioconazole/ha), except in United Kingdom, where the authorized product contains 275 g of Prothioconazole and it is applied at 0,63 L/ha and 0,72 L/ha (which correspond to 173,3g and 198 g of Prothioconazole/ha respectively).
The commercial names of the products belonging to Reference 2 group are the following ones: JOAO at 0,8 L/ha; PROLINE at 0,8 L/ha (except in United Kingdom, where PROLINE contains 275 g of Prothioconazole and it is applied at 0,63 L/ha and 0,72 L/ha, which correspond to 173,3 g and 198 g of Prothioconazole/ha respectively); CURBATUR at 0,8 L/ha.

It was considered only the most representative evaluation timing and the most representative variable as the % severity (PESSEV) in Leaf 1, Leaf 2 or Leaf 3 reached by the disease. According to the results, % severity in trials conducted ranged from 6,4 to 95,4 % in Maritime EPPO zone, where this reference product has been applied.

In the Maritime EPPO zone, the % severity in the untreated plots in all conducted trials ranged from 6,4 to 95,4%.
The efficacy average value obtained by **SAP2101F** at 1 l/ha and 1,25 L/ha is ~~88,7%~~ 87,3% and 91,4% respectively according to the assessments performed, and the one obtained by the Reference 2 is ~~87,7%~~ 84,8%.
Furthermore, no significant differences were found between SAP2101F at ~~lowest~~ requested dose rates 1,0 and 1,25 L/ha and the references products belonging to Reference 2 group (JOAO, PROLINE and CURBATUR), in any of the ~~8~~ 9 trials, showing a similar control than the authorized products. ~~A 9th trial has been excluded from results due to outlier values (10-F-2020-FR02).~~

In resume, those facts indicate the similar behaviour in the control of *Septoria* on wheat achieved by **SAP2101F** at ~~lowest~~ requested dose rates 1,0 and 1,25 L/ha and references tested products.

Table 3.2.3.1 d. Total *Septoria* of Wheat disease control (%) of PESSEV, achieved by SAP2101F and the reference products – Reference 3

Target	Nb of trials	Untreated plot	% control			Nb of trials where SAP2101F 1 l/ha is >, < or =	Nb of trials where SAP2101F 1,25 l/ha is >, < or =
			SAP2101F 1 l/ha	SAP2101F 1,25 l/ha	REF 3 (Epoxi. + Folp.) 2 L/ha		
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	REF 3 (Epoxi. + Folp.) 2 L/ha	REF 3 (Epoxi. + Folp.) 2 L/ha
% CONTROL (20 - 43 DAB) Global average	**9**	**18,5**	**85,8**	**89,8**	**91,6**	**< 2 = 7 > 0**	< 0 = 9 > 0
		49,8	**96,9**	**96,1**	**100,0**		
		5,9	**62,9**	**72,3**	**72,3**		
% CONTROL (32- 43 DAB) Maritime EPPO zone	7	21,5	88,4	93,1	94,8	< 2 = 5 > 0	< 0 = 7 > 0
		49,8	96,9	96,1	100,0		
		6,4	83,6	84,1	85,4		
% CONTROL (20-40 DA-B) North-East EPPO zone	2	7,9	76,7	78,3	80,4	< 0 = 2 > 0	< 0 = 2 > 0
		9,9	90,5	84,2	88,4		
		5,9	62,9	72,3	72,3		
% CONTROL South-East EPPO zone	0	-	-	-	-	-	-
		-	-	-	-		
		-	-	-	-		

Note:
- REF 3 (Epoxiconazole 50 g/L + Folpet 375 g/L): MANITOBA 2 L/ha

The table above shows a summary of the control of **SAP2101F** at 1 L/ha (120 g Prothioconazole/ha and 300 g Folpet/ha) and at 1,25 L/ha (150 g Prothioconazole/ha and 375 g Folpet/ha) against *Septoria* on wheat, compared to **Reference 3** applied at 2 L/ha (100 g of Epoxiconazole/ha and 750 g of Folpet/ha). The commercial name of the product belonging to Reference 3 is MANITOBA, which is applied at 2 L/ha.

It was considered only the most representative evaluation timing and the most representative variable as the % severity (PESSEV) in Leaf 1, Leaf 2, ~~or~~ Leaf 3 or Leaf 4 reached by the disease. According to the results, % severity in trials conducted ranged from 5,9 to 49,8 % in both Maritime and North-East EPPO zones, where those reference products have been applied.

In the Maritime EPPO zone, the % severity in the untreated plots in all conducted trials ranged from 6,4 to 49,8%.
The efficacy average value obtained by **SAP2101F** at 1 l/ha and 1,25 L/ha is 88,4% and 93,1% respectively according to the assessments performed and the one obtained by the Reference 3 is 94,8%. Between SAP2101F at 1 L/ha and the Reference 3 at 2 L/ha, in 5 trials out of 7, no significant differences have been found. Besides, the reference product MANITOBA contain a higher quantity of Folpet (750 g/ha) in comparison with the tested product (300 g/ha), which are both in mixture with a Triazole. This can explain a sometimes better control of this Reference 3 group. No statistically significant differences between SAP2101F at 1,25 L/ha and the Reference 3 have been noted in all 7 trials.

In the North-East zone, the % severity in the untreated plots in all conducted trials ranged from 5,9 to 9,9%.
The efficacy average value obtained by **SAP2101F** at 1 l/ha and 1,25 L/ha is 76,7% and 78,3% respectively according to the assessments performed and the one obtained by the Reference 3 is 80,4%.

Furthermore, no significant differences were found between SAP2101F at ~~lowest~~ requested dose rates 1,0 and 1,25 L/ha and the Reference 3 (MANITOBA) in any of the 2 trials, showing a similar control ~~than~~ to the authorized products.

In resume, those facts indicate a similar behaviour in the control of *Septoria* in wheat achieved by **SAP2101F** at at ~~lowest~~ requested dose rates 1,0 and 1,25 L/ha and references tested products.

Table 3.2.3.1 e. Total *Septoria* of Wheat disease control (%) of PESSEV, achieved by SAP2101F and the reference products – Reference 4

Target	Nb of trials	Untreated plot	% control			Nb of trials where SAP2101F 1 l/ha is >, < or =	Nb of trials where SAP2101F 1,25 l/ha is >, < or =
			SAP2101F 1 l/ha	SAP2101F 1,25 l/ha	REF 4 (Prothio. + Triflo.) 1 L/ha		
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	REF 4 (Prothio. + Triflo.) 1 L/ha	REF 4 (Prothio. + Triflo.) 1 L/ha
% CONTROL (20-40 DA-B) Global average	~~3~~ **4**	~~8,3~~ **9,8**	~~80,4~~ **81,6**	**84,1**	~~83,7~~ **85,8**	**< ~~0~~ 1 = 3 > 0**	**< 0 = 4 > 0**
		~~9,9~~ **14,3**	**90,5**	**90,2**	~~88,0~~ **92,1**		
		5,9	**62,9**	**72,3**	**76,7**		
% CONTROL Maritime EPPO zone	0	-	-	-	-	-	-
		-	-	-	-		
		-	-	-	-		
% CONTROL (20-40 DA-B) North-East EPPO zone	~~3~~ 4	~~8,3~~ 9,8	~~80,4~~ 81,6	84,1	~~83,7~~ 85,8	< ~~0~~ 1 = 3 > 0	< 0 = 4 > 0
		~~9,9~~ 14,3	90,5	90,2	~~88,0~~ 92,1		
		5,9	62,9	72,3	76,7		
% CONTROL South-East EPPO zone	0	-	-	-	-	-	-
		-	-	-	-		
		-	-	-	-		

Note:
- REF 4 (Prothioconazole 175 g/L + Trifloxystrobin 150 g/L): DELARO 325 SC at 1 L/ha

The table above shows a summary of the control of **SAP2101F** at 1 L/ha (120 g Prothioconazole/ha and 300 g Folpet/ha) and at 1,25 L/ha (150 g Prothioconazole/ha and 375 g Folpet/ha) against *Septoria* on wheat, compared to **Reference 4** applied at 1 L/ha (175 g of Prothioconazole/ha and 150 g of Trifloxystrobin/ha).
The commercial name of the product belonging to Reference 4 is DELARO 325 SC, which is applied at 1 L/ha.

It was considered only the most representative evaluation timing and the most representative variable as the % severity (PESSEV) in ~~Leaf 1,~~ Leaf 2, ~~or~~ Leaf 3 or Leaf 4 reached by the disease. According to the results, % severity in trials conducted ranged from 5,9 to ~~9,9~~ 14,3 % in ~~Maritime~~ North-East EPPO zone~~s~~, where this reference product had been applied.

Then, in the ~~Maritime~~ North-East EPPO zone, the % severity in the untreated plots in all conducted trials ranged from 5,9 to ~~9,9%~~ 14,3%.
The efficacy average value obtained by **SAP2101F** at 1 l/ha and 1,25 L/ha is ~~80,4%~~ 81,6% and 84,1% respectively according to the assessments performed and the one obtained by the Reference 4 is ~~83,7%~~ 85,8%.
Furthermore, no significant differences have been found between SAP2101F at 1 L/ha and 1,25 L/ha and the Reference 4 at 1 L/ha, in ~~any of the~~ 3 out of 4 and in 4 trials respectively. ~~Besides, the reference~~

~~product DELARO 325 SC contain a higher quantity of Prothioconazole (175 g/ha) in comparison with the tested product (120 g/ha). This can explain a sometimes better control of this Reference 4 group.~~

In resume, those facts indicate a similar behaviour in the control of *Septoria* in wheat achieved by **SAP2101F** at ~~lowest~~ requested dose rates 1,0 and 1,25 L/ha and references tested product~~s~~.
Besides, in order to reinforce the efficacy of the requested range, the highest dose of 1,5 L/ha has been compared orthogonally to the reference products.

Table 3.2.3.1 f. Total *Septoria* of Wheat disease control (%) of PESSEV, achieved by SAP2101F at 1,5 L/ha and the reference products – Reference 1

Target	Nb of trials	Untreated plot	% control		Nb of trials where SAP2101F 1,5 l/ha is >, < or =
			SAP2101F 1,5 l/ha	REF 1 (Prothio. + Tebu.) (0,75*) - 1 L/ha	
		Mean Max Min	Mean Max Min	Mean Max Min	REF 1 (Prothio. + Tebu.) (0,75*) - 1 L/ha
% CONTROL (9-34 DA-B) Global average	**10**	**9,6** **18,4** **5,4**	**86,6** **93,6** **77,6**	**80,9** **91,8** **59,6**	**< 0** **= 9** **> 1**
% CONTROL Maritime EPPO zone	0	- - -	- - -	- - -	-
% CONTROL (9-34 DA-B) North-East EPPO zone	5	11 18,4 6,7	83,2 87,7 77,6	72,9 86,9 59,6	< 0 = 4 > 1
% CONTROL (13-22 DA-B) South-East EPPO zone	5	8,2 11,7 5,4	90,0 93,6 88,4	88,9 91,8 87,1	< 0 = 5 > 0

Note:
REF 1 (Prothioconazole 125 g/L + Tebuconazole 125 g/L): PROSARO 250 EC at 1 L/ha (except in Romania, which is applied at 0,75 L/ha); AsPik 250 EC at 1 L/ha

The table above shows a summary of the control of **SAP2101F** at 1,5 L/ha (180 g Prothioconazole/ha and 450 g Folpet/ha) against *Septoria* on wheat, compared to **Reference 1** at 1 L/ha (125 g of Prothioconazole/ha and 125 g of Tebuconazole/ha), except in Romania, which is applied at 0,75 L/ha (94 g of Prothioconazole/ha and 94 g of Tebuconazole/ha).
The commercial names of the products belonging to Reference 1 group are the following ones: PROSARO 250 EC at 1 L/ha (except in Romania, where it is applied at 0,75 L/ha) and AsPik 250 EC at 1 L/ha.

It was considered only the most representative evaluation timing and the most representative variable as the % severity (PESSEV) in Leaf 1, Leaf 2 or Leaf 3 reached by the disease. According to the results, % severity in trials conducted ranged from 5,4 to 18,4 % in both North-East and South-East EPPO zones, where this reference product has been applied.

In the North-East EPPO zone, the % severity in the untreated plots in all conducted trials ranged from 6,7 to 18,4%.
The efficacy average value obtained by **SAP2101F** at 1,5 l/ha is 83,2% according to the assessments performed, and the one obtained by the Reference 1 is 72,9%.
Besides, no significant differences were found between SAP2101F at 1,5 L/ha and the references products belonging to Reference 1 group (PROSARO 250 EC and AsPik 250 EC), in 4 out of 5 trials, being the efficacy of fifth trial significantly better with the tested product.
In general, all these results are showing a similar control between the tested product and the authorized products.

In the South-East EPPO zone, the % severity in the untreated plots in all conducted trials ranged from 5,4 to 11,7%.
The efficacy average value obtained by **SAP2101F** at 1,5 l/ha is 90% according to the assessments performed, and the one obtained by the Reference 1 is 88,9%.
Furthermore, no significant differences were found between SAP2101F and the references products belonging to Reference 1 group (PROSARO 250 EC and AsPik 250 EC) in any of the 5 trials, showing a similar control.

In resume, those facts indicate a similar behaviour in the control of *Septoria* in wheat achieved by **SAP2101F** at 1,5 L/ha and references tested products.

Table 3.2.3.1 g. Total *Septoria* of Wheat disease control (%) of PESSEV, achieved by SAP2101F at 1,5 L/ha and the reference products: Reference 2 and Reference 3

Target	Nb of trials	Untreated plot	% control			Nb of trials where SAP2101F 1,5 l/ha is >, < or =	
			SAP2101F 1,5 l/ha	REF 2 (Prothio.)(0,63/0,72*) - 0,8L/ha	REF 3 (Epoxi. + Folp.) 2 L/ha		
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	REF 2 (Prothio.) (0,63/0,72*) - 0,8 L/ha	REF 3 (Epoxi. + Folp.) 2 L/ha
% CONTROL (32 - 41 DAB) Global average	**4**	**21,1** 30,5 7,9	**94,0** 99,8 81,5	**88,8** 95,8 83,4	**93,5** 99,3 85,4	**< 0** **= 3** **> 1**	**< 0** **= 4** **> 0**
% CONTROL (32 - 41 DAB) Maritime EPPO zone	4	21,1 30,5 7,9	94,0 99,8 81,5	88,8 95,8 83,4	93,5 99,3 85,4	< 0 = 3 > 1	< 0 = 4 > 0
% CONTROL North-East EPPO zone	0	- - -	- - -	- - -	- - -	-	-
% CONTROL South-East EPPO zone	0	- - -	- - -	- - -	- - -	-	-

- REF 2 (Prothioconazole 250 g/L): JOAO at 0,8 L/ha; PROLINE at 0,8 L/ha (except in United Kingdom, where PROLINE contains 275 g of Prothioconazole/L and it is applied at 0,63 L/ha and 0,72 L/ha, which correspond to 173,3 g and 198 g of Prothioconazole/ha respectively); CURBATUR at 0,8 L/ha.
- REF 3 (Epoxiconazole 50 g/L + Folpet 375 g/L): MANITOBA 2 L/ha

The table above shows a summary of the control of **SAP2101F** at 1,5 L/ha (180 g Prothioconazole/ha and 450 g Folpet/ha) against *Septoria* in wheat, compared to **Reference 2** applied at 0,8 L/ha (equivalent to 200 g of Prothioconazole/ha), except in United Kingdom, where the authorized product contains 275 g of Prothioconazole and it is applied at 0,63 L/ha and 0,72 L/ha (which correspond to 173,3g and 198 g of Prothioconazole/ha respectively); and compared to **Reference 3** applied at 2 L/ha (100 g of Epoxiconazole/ha and 750 g of Folpet/ha).

The commercial names of the products belonging to Reference 2 group are the following ones: JOAO at 0,8 L/ha; PROLINE at 0,8 L/ha (except in United Kingdom, where PROLINE contains 275 g of Prothioconazole and it is applied at 0,63 L/ha and 0,72 L/ha, which correspond to 173,3 g and 198 g of Prothioconazole/ha respectively); CURBATUR at 0,8 L/ha.
The commercial name of the product belonging to Reference 3 is MANITOBA, which is applied at 2 L/ha.

It was considered only the most representative evaluation timing and the most representative variable as the % severity (PESSEV) in Leaf 1 or Leaf 2 ~~or Leaf 3~~ reached by the disease. According to the results, % severity in trials conducted ranged from 7,9 to 30,5 % in Maritime EPPO zone, where these reference products have been applied.

In the Maritime EPPO zone, the efficacy average value obtained by **SAP2101F** at 1,5 l/ha is 94% according to the assessments performed, the one obtained by the Reference 2 is 88,8% and by the Reference 3 is 93,5%.
Furthermore, no significant differences were found between SAP2101F at 1,5 L/ha and the references products belonging to Reference 2 group (JOAO, PROLINE and CURBATUR), in 3 out of 4 trials, being the efficacy of forth trial significantly better with the tested product.
Moreover, no significant differences were found between SAP2101F at 1,5 L/ha and the references products belonging to Reference 3 group in any of the 4 trials.

In resume, those facts indicate the similar behaviour in the control of *Septoria* on wheat achieved by **SAP2101F** at 1,5 L/ha and references products.

Table 3.2.3.1 h. Total *Septoria* of Wheat disease control (%) of PESSEV, achieved by SAP2101F at requested dose rates

Target	Nb of trials	Untreated plot	% control		
			SAP2101F 1 l/ha	SAP2101F 1,25 l/ha	SAP2101F 1,5 l/ha
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min
% CONTROL (44 DA-A-43 DA-B) Global average	**27 14***	**18,0**	**82,2**	**87,4**	**88,7**
		95,4	96,9	97,8	99,8
		5,4	57,2	67,8	77,6
% CONTROL (44 DA-A-43 DA-B) Maritime EPPO zone	9 4*	**34,0**	**87,3**	**91,4**	**94,0**
		95,4	96,9	96,1	99,8
		6,4	76,1	79,8	81,5
% CONTROL (9-40 DA-B) North-East EPPO zone	9 5*	**10,5**	**76,0**	**81,2**	**83,2**
		18,4	90,5	90,2	87,7
		5,9	57,2	67,8	77,6
% CONTROL (9-40 DA-B) North-East EPPO zone + Maritime EPPO zone (DE)	12 6*	**18,7**	**79,2**	**84,4**	**85,4**
		25,0	93,2	96,1	96,5
		5,9	57,2	67,8	77,6
% CONTROL (13-22 DA-B) South-East EPPO zone	9 5*	**9,2**	**83,3**	**89,7**	**90**
		17,5	91	97,8	93,6
		5,4	81,0	84,2	70,3

*Number of trials, where dose rate 1,5 L/ha was tested.

Summary and Conclusions of Efficacy of SAP2101F in wheat against *Septoria*

A total of ~~25~~ 27 reliable trials (>5% severity of the disease in the untreated plots) were run in France, United Kingdom, Bulgaria, Romania, Germany and Poland in wheat where control of severity of **SAP2101F** against *Septoria* on different leaf levels were assessed.
Average efficacy value reported of trials conducted against *Septoria* in wheat at the most representative variable and timing is ~~83,1%~~ 82,2% for SAP2101F at 1 L/ha, taking into account the different EPPO climatic zones, showing a robust control of the disease, similar to refence products used on these trials.
These data are enough to confirm the effectiveness of **SAP2101F** against the mentioned target disease in wheat at the lowest dose of the requested range (1 L/ha).

Also, the average efficacy value reported of trials conducted against *Septoria* in wheat at the most representative variable and timing is 87,4% and 88,7% for SAP2101F at 1,25 and 1,5L/ha respectively, taking into account the different EPPO climatic zones, showing a robust control of the disease, similar or higher than the refence products applied on these trials.
Therefore, the authorisation of SAP2101F at 1-1,5L/ha on Wheat to control *Septoria* is requested.

3.2.3.2 Barley/*Helminthosporium*

A total of 19 trials were carried out to evaluate the efficacy of **SAP2101F** for the control of *Helminthosporium* in barley.
However, for different reasons, ~~3~~ 7 trials have not been taken into account for this section:
- In 11-F-2020-DE02 (Maritime EPPO zone) trial, the disease was present in a first time (0 DA-A), but only other diseases were present in further assessments.
- In 04B-F-2021-HU01 (South-East EPPO zone) trial, any diseases have appeared, so this trial has been used as selectivity trial.
- In 11-F-2020-DE01, 04A-F-2021-DE01, 04B-F-2021-DE02 trials, other diseases were present in the trials but not *Helminthosporium*.
- In 04B-F-2021-DE01, 11-F-2020-FR02 trials disease severity was <5%, so these trials have been used for phytotoxicity assessment.

Table 3.2.3.2 a. Total *Helminthosporium* of Barley disease control (%) of PESSEV, achieved by SAP2101F and the reference products – Detailed table

Refer to BAD.

Different reference products have been applied (different active ingredients), due to the different authorized products of each country. For that reason, in order to do an orthogonal comparison, three tables are presented here below with all the results, taking as the main dose the minumum one of the requested range: 1 L/ha of SAP2101F (120 g of Prothioconazole/ha and 300 g of Folpet/ha).

Table 3.2.3.2 b. Total *Helminthosporium* of Barley disease control (%) of PESSEV, achieved by SAP2101F and the reference products – Reference 1

Target	Nb of trials	Untreated plot	% control			Nb of trials where SAP2101F 1 l/ha is >, < or =	Nb of trials where SAP2101F 1,25 l/ha is >, < or =
			SAP2101F 1 l/ha	SAP2101F 1,25 l/ha	REF 1 (Prothio. + Tebu.) (0,75*) - 1 L/ha		
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	REF 1 (Prothio. + Tebu.) (0,75*) - 1 L/ha	REF 1 (Prothio. + Tebu.) (0,75*) - 1 L/ha
% CONTROL (~~44 DAA-30~~ 12-28 DAB) Global average	**7**	**10,6** **17,8** **7,0**	**74,5** **97,4** **54,9**	**81,9** **97,4** **66,2**	**82,5** **97,4** **59,7**	**< 2** **= 5** **> 0**	< 1 = 6 > 0
% CONTROL Maritime EPPO zone	0	- - -	- - -	- - -	- - -	-	-
% CONTROL (12 - 28 DAB) North-East EPPO zone	4	10,3 15,0 7,2	69,7 79,1 54,9	80,8 82,6 80,0	85,2 91,7 79,7	< 2 = 2 > 0	< 1 = 3 > 0
% CONTROL (~~44 DAA-30~~ 21-27 DAB)	3	10,9 17,8 7,0	81,0 97,4 64,7	83,4 97,4 66,2	78,9 97,4 59,7	< 0 = 3 > 0	< 0 = 3 > 0

Target	Nb of trials	Untreated plot	% control			Nb of trials where SAP2101F 1 l/ha is >, < or =	Nb of trials where SAP2101F 1,25 l/ha is >, < or =
			SAP2101F 1 l/ha	SAP2101F 1,25 l/ha	REF 1 (Prothio. + Tebu.) (0,75*) - 1 L/ha		
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	REF 1 (Prothio. + Tebu.) (0,75*) - 1 L/ha	REF 1 (Prothio. + Tebu.) (0,75*) - 1 L/ha
South-East EPPO zone							

Note:
- REF 1 (Prothioconazole 125 g/L + Tebuconazole 125 g/L): PROSARO 250 EC at 1 L/ha (except in Romania, where it is applied at 0,75 L/ha); AsPik 250 EC at 1 L/ha

The table above shows a summary of the control of **SAP2101F** at 1 L/ha (120 g Prothioconazole/ha and 300 g Folpet/ha) and at 1,25 L/ha (150 g Prothioconazole/ha and 375 g Folpet/ha) against *Helminthosporium* in barley, compared to **Reference 1** at 1 L/ha (125 g of Prothioconazole/ha and 125 g of Tebuconazole/ha), except in Romania, which is applied at 0,75 L/ha (94 g of Prothioconazole/ha and 94 g of Tebuconazole/ha).
The commercial names of the products belonging to Reference 1 group are the following ones: PROSARO 250 EC at 1 L/ha (except in Romania, where it is applied at 0,75 L/ha) and AsPik 250 EC at 1 L/ha.
It was considered only the most representative evaluation timing and the most representative variable as the % severity (PESSEV) in Leaf 1, Leaf 2 or Leaf 3 reached by the disease. According to the results, % severity in trials conducted ranged from 7 to 17,8 % in both North-East and South-East EPPO zones, where this reference product has been applied.

In the North-East EPPO zone, the % severity in the untreated plots in all conducted trials ranged from 7,2 to 15%.
The efficacy average value obtained by **SAP2101F** at 1 l/ha and 1,25 L/ha is 69,7% and 80,8% respectively according to the assessments performed, and the one obtained by the Reference 1 is 85,2%. No significant differences were found between SAP2101F at 1,0 L/ha and the Reference 1 in 2 of 4 trials. No significant differences were also noted between SAP2101F at 1,25 L/ha and the Reference 1 in 3 of 4 trials.
~~However, according to the Minimum Effective Dose section (3.2.2.), SAP2101F at 1.25-1.5L/ha show a more robust control on Helminthosporium, (78.4 and 84.5% efficacy respectively) in line with the results of the reference product.~~

In the South-East EPPO zone, the % severity in the untreated plots in all conducted trials ranged from 7 to 17,8%.
The efficacy average value obtained by **SAP2101F** at 1 l/ha and 1,25 L/ha is 81% and 83,4% respectively according to the assessments performed, and the one obtained by the Reference 1 is 78,9%. Furthermore, no significant differences were found between SAP2101F at ~~lowest~~ requested dose rates 1,0 and 1,25 L/ha and the references products belonging to Reference 1 group (PROSARO 250 EC and AsPik 250 EC) in any of the 3 trials, showing a similar control than the authorized products.

In resume, those facts indicate a similar behaviour in the control of *Helminthosporium* in barley achieved by **SAP2101F** at ~~lowest~~ requested dose rates 1,0 and 1,25 L/ha and references tested products.

Table 3.2.3.2 c. Total *Helminthosporium* of Barley disease control (%) of PESSEV, achieved by SAP2101F and the reference products – Reference 2

Target	Nb of trials	Untreated plot	% control			Nb of trials where SAP2101F 1 l/ha is >, < or =	Nb of trials where SAP2101F 1,25 l/ha is >, < or =
			SAP2101F 1 l/ha	SAP2101F 1,25 L/ha	REF 2 (Prothio.) 0,8 L/ha		
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	REF 2 (Prothio.) 0,8 L/ha	REF 2 (Prothio.) 0,8 L/ha
% CONTROL (28 DAA - 35 DAB) Global average	**5**	41,5	86,3	90,9	87,0	**< 1 = 4 > 0**	**< 1 = 4 > 0**
		75,8	100,0	100	100,0		
		14,0	69,2	73,9	70,7		
% CONTROL (28 DAA - 35 DAB) Maritime EPPO zone	5	41,5	86,3	90,9	87,0	< 1 = 4 > 0	**< 1 = 4 > 0**
		75,8	100,0	100	100,0		
		14,0	69,2	73,9	70,7		
% CONTROL North-East EPPO zone	0	-	-	-	-	-	-
		-	-	-	-		
		-	-	-	-		
% CONTROL South-East EPPO zone	0	-	-	-	-	-	-
		-	-	-	-		
		-	-	-	-		

Note:
- REF 2 (Prothioconazole 250 g/L): JOAO at 0,8 L/ha; CURBATUR at 0,8 L/ha.

The table above shows a summary of the control of **SAP2101F** at 1 L/ha (120 g Prothioconazole/ha and 300 g Folpet/ha) and at 1,25 L/ha (150 g Prothioconazole/ha and 375 g Folpet/ha) against *Helminthosporium* on barley compared to **Reference 2** applied at 0,8 L/ha (equivalent to 200 g of Prothioconazole/ha).
The commercial names of the products belonging to Reference 2 group are the following ones: JOAO at 0,8 L/ha; CURBATUR at 0,8 L/ha.

It was considered only the most representative evaluation timing and the most representative variable as the % severity (PESSEV) in Leaf 1, Leaf 2 or Leaf 3 reached by the disease. According to the results, % severity in trials conducted ranged from 14 to 75,8 % in Maritime EPPO zone, where this reference product has been applied.

In the Maritime EPPO zone, the % severity in the untreated plots in all conducted trials ranged from 14 to 75,8%.
The efficacy average value obtained by **SAP2101F** at 1 l/ha and 1,25 L/ha is 86,3% and 90,9% respectively according to the assessments performed, and the one obtained by the Reference 2 is 87,0%. Furthermore, no significant differences were found between SAP2101F at ~~lowest~~ requested dose rates 1,0 and 1,25 L/ha and the references products belonging to Reference 2 group (JOAO and CURBATUR), in 4 out of 5 trials, showing a similar control than the authorized products.
Besides, the reference products contain a higher quantity of Prothioconazole (200 g/ha) in comparison with the tested product (120 and 150 g/ha), which is the active ingredient that better control this disease. This can explain a sometimes better control of this Reference 2 group.

In resume, those facts indicate the similar behaviour in the control of *Helminthosporium* in barley achieved by **SAP2101F** at ~~lowest~~ requested dose rates 1,0 and 1,25 L/ha and references tested products.

Table 3.2.3.2 d. Total *Helminthosporium* of Barley disease control (%) of PESSEV, achieved by SAP2101F and the reference products: Reference 2 and Reference 3

Target	Nb of trials	Untreated plot	% control				Nb of trials where SAP2101F 1 l/ha is >, < or =	Nb of trials where SAP2101F 1,25 l/ha is >, < or =	Nb of trials where SAP2101F 1 l/ha is >, < or =	Nb of trials where SAP2101F 1,25 l/ha is >, < or =
			SAP2101F 1 l/ha	SAP2101F 1,25 l/ha	REF 2 (Prothio.) 0,8 L/ha	REF 3 (Epoxi. + Folp.) 2 L/ha				
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min	REF 2 (Prothio.) 0,8 L/ha	REF 2 (Prothio.) 0,8 L/ha	REF 3 (Epoxi. + Folp.) 2 L/ha	REF 3 (Epoxi. + Folp.) 2 L/ha
% CONTROL (24 - 35 DAB) Global average	**3**	**48,5** **75,8** **14,0**	**79,3** **88,8** **69,2**	**85,4** **95,9** **73,9**	**86,5** **95,4** **70,7**	**74,3** **93,4** **58,5**	**< 1** **= 2** **> 0**	**< 1** **= 2** **> 0**	**< 0** **= 3** **> 0**	**< 0** **= 3** **> 0**
% CONTROL (24 - 35 DAB) Maritime EPPO zone	3	48,5 75,8 14,0	79,3 88,8 69,2	**85,4** **95,9** **73,9**	86,5 95,4 70,7	74,3 93,4 58,5	< 1 = 2 > 0	< 1 = 2 > 0	< 0 = 3 > 0	< 0 = 3 > 0
% CONTROL North-East EPPO zone	0	- - -	- - -	- - -	- - -	- - -	-	-	-	-
% CONTROL South-East EPPO zone	0	- - -	- - -	- - -	- - -	- - -	-	-	-	-

Note:
- REF 2 (Prothioconazole 250 g/L): JOAO at 0,8 L/ha; CURBATUR at 0,8 L/ha.
- REF 3 (Epoxiconazole 50 g/L + Folpet 375 g/L): MANITOBA 2 L/ha

The table above shows a summary of the control of **SAP2101F** at 1 L/ha (120 g Prothioconazole/ha and 300 g Folpet/ha)) and at 1,25 L/ha (150 g Prothioconazole/ha and 375 g Folpet/ha) against *Helminthosporium* on barley, compared to **Reference 2** applied at 0,8 L/ha (equivalent to 200 g of Prothioconazole/ha) and **Reference 3** applied at 2 L/ha (100 g of Epoxiconazole/ha and 750 g of Folpet/ha).
The commercial names of the products belonging to Reference 2 are the following ones: JOAO at 0,8 L/ha; CURBATUR at 0,8 L/ha.
The commercial name of the product belonging to Reference 3 is the following one: MANITOBA at 2 L/ha.
It was considered only the most representative evaluation timing and the most representative variable as the % severity (PESSEV) in Leaf 1, Leaf 2 or Leaf 3 reached by the disease. According to the results, % severity in trials conducted ranged from 14 to 75,8 % in Maritime EPPO zones, where those reference products have been applied.

In the Maritime EPPO zone, the % severity in the untreated plots in all conducted trials ranged from 14 to 75,8%.
The efficacy average value obtained by **SAP2101F** at 1 l/ha and 1,25 L/ha is 79,3% and 85,4% respectively according to the assessments performed, the one obtained by the Reference 2 is 86,5% and the one obtained by the Reference 3 is 74,3%.
Furthermore, no significant differences were found between SAP2101F at ~~lowest~~ requested dose rates 1,0 and 1,25 L/ha and the references products belonging to Reference 2 group (JOAO and CURBATUR), in 2 out of 3 trials, showing a similar control than the authorized products. Besides, the reference products contain a higher quantity of Prothioconazole (200 g/ha) in comparison with the tested product (120 and 150 g/ha), which is the active ingredient that better control this disease. This can explain a sometimes better control of this Reference 2 group.
Then, between SAP2101F at 1 L/ha and 1,25 L/ha and the Reference 3 at 2 L/ha, in the ~~2~~ 3 performed trials, no significant differences have been found.

In resume, those facts indicate the similar behaviour in the control of *Helminthosporium* on barley achieved by **SAP2101F** at ~~lowest~~ requested dose rates 1,0 and 1,25 L/ha and references tested products.

Besides, in order to reinforce the efficacy of the requested range, the highest dose of 1,5 L/ha has been compared orthogonally to the reference products.

Table 3.2.3.2 e. Total *Helminthosporium* of Barley disease control (%) of PESSEV, achieved by SAP2101F at 1,5 L/ha and the reference products – Reference 1

Target	Nb of trials	Untreated plot	% control		Nb of trials where SAP2101F 1,5 l/ha is >, < or =
			SAP2101F 1,5 l/ha	REF 1 (Prothio. + Tebu.) (0,75*) - 1 L/ha	
		Mean Max Min	Mean Max Min	Mean Max Min	REF 1 (Prothio. + Tebu.) (0,75*) - 1 L/ha
% CONTROL (12-28 DAB) Global average	**7**	**10,6** **17,8** **7**	**81,2** **97,4** **38,8**	**82,5** **97,4** **59,7**	**< 1** **= 4** **> 2**
% CONTROL Maritime EPPO zone	0	- - -	- - -	- - -	-
% CONTROL (12 - 28 DAB) North-East EPPO zone	4	10,3 15 7,2	86,0 89,6 81,9	85,2 91,7 79,7	< 1 = 2 > 1
% CONTROL (21-27 DAB) South-East EPPO zone	3	10,9 17,8 7	74,7 97,4 38,8	78,9 97,4 59,7	< 0 = 2 > 1

Note:
- REF 1 (Prothioconazole 125 g/L + Tebuconazole 125 g/L): PROSARO 250 EC at 1 L/ha (except in Romania, where it is applied at 0,75 L/ha); AsPik 250 EC at 1 L/ha

The table above shows a summary of the control of **SAP2101F** at 1,5 L/ha (180 g Prothioconazole/ha and 450 g Folpet/ha) against *Helminthosporium* in barley, compared to **Reference 1** at 1 L/ha (125 g of Prothioconazole/ha and 125 g of Tebuconazole/ha), except in Romania, which is applied at 0,75 L/ha (94 g of Prothioconazole/ha and 94 g of Tebuconazole/ha).
The commercial names of the products belonging to Reference 1 group are the following ones: PROSARO 250 EC at 1 L/ha (except in Romania, where it is applied at 0,75 L/ha) and AsPik 250 EC at 1 L/ha.

It was considered only the most representative evaluation timing and the most representative variable as the % severity (PESSEV) in Leaf 1, Leaf 2 or Leaf 3 reached by the disease. According to the results, % severity in trials conducted ranged from 7 to 17,8 % in both North-East and South-East EPPO zones, where this reference product has been applied.

In the North-East EPPO zone, the % severity in the untreated plots in all conducted trials ranged from 7,2 to 15%.
The efficacy average value obtained by **SAP2101F** at 1,5 l/ha is 86,0% according to the assessments performed, and the one obtained by the Reference 1 is 85,2%.
Besides, in 2 out 4 trials no significant differences have been found, being a third one significantly inferior and a forth one superior, showing a similar control.

In the South-East EPPO zone, the % severity in the untreated plots in all conducted trials ranged from 7 to 17,8%.
The efficacy average value obtained by **SAP2101F** at 1,5 l/ha is 74,7% according to the assessments performed, and the one obtained by the Reference 1 is 78,9%.
Furthermore, no significant differences were found between SAP2101F at 1,5 L/ha and the references products belonging to Reference 1 group (PROSARO 250 EC and AsPik 250 EC) in 2 out of 3 trials, showing a similar control than the authorized products, being the control of the third one significantly better.

In resume, those facts indicate a similar behaviour in the control of *Helminthosporium* in barley achieved by **SAP2101F** at 1,5 L/ha and references tested products.

Table 3.2.3.2 f. Total *Helminthosporium* of Barley disease control (%) of PESSEV, achieved by SAP2101F at 1,5 L/ha and the reference products: Reference 2 and Reference 3

Target	Nb of trials	Untreated plot	% control			Nb of trials where SAP2101F 1,5 l/ha is >, < or =	Nb of trials where SAP2101F 1,5 l/ha is >, < or =
			SAP2101F 1,5 l/ha	REF 2 (Prothio.) 0,8 L/ha	REF 3 (Epoxi. + Folp.) 2 L/ha		
						REF 2 (Prothio.) 0,8 L/ha	REF 3 (Epoxi. + Folp.) 2 L/ha
% CONTROL (24 - 35 DAB) Global average	**3**	**48,5**	**90,8**	**86,5**	**74,3**	**< 0 = 3 > 0**	**< 0 = 2 > 1**
		75,8	**98**	**95,4**	**93,4**		
		14	**82**	**70,7**	**58,5**		
% CONTROL (24 - 35 DAB) Maritime EPPO zone	3	48,5	90,8	86,5	74,3	< 0 = 3 > 0	< 0 = 2 > 1
		75,8	98	95,4	93,4		
		14	82	70,7	58,5		
% CONTROL North-East EPPO zone	0	-	-	-	-	-	-
		-	-	-	-		
		-	-	-	-		
% CONTROL South-East EPPO zone	0	-	-	-	-	-	-
		-	-	-	-		
		-	-	-	-		

Note:
- REF 2 (Prothioconazole 250 g/L): JOAO at 0,8 L/ha; CURBATUR at 0,8 L/ha.
- REF 3 (Epoxiconazole 50 g/L + Folpet 375 g/L): MANITOBA 2 L/ha

The table above shows a summary of the control of **SAP2101F** at 1,5 L/ha (180 g Prothioconazole/ha and 450 g Folpet/ha) against *Helminthosporium* on barley, compared to **Reference 2** applied at 0,8 L/ha (equivalent to 200 g of Prothioconazole/ha) and **Reference 3** applied at 2 L/ha (100 g of Epoxiconazole/ha and 750 g of Folpet/ha).
The commercial names of the products belonging to Reference 2 are the following ones: JOAO at 0,8 L/ha; CURBATUR at 0,8 L/ha.
The commercial name of the product belonging to Reference 3 is the following one: MANITOBA at 2 L/ha.

It was considered only the most representative evaluation timing and the most representative variable as the % severity (PESSEV) in Leaf 1, Leaf 2 or Leaf 3 reached by the disease. According to the results, % severity in trials conducted ranged from 14 to 75,8 % in Maritime EPPO zones, where those reference products have been applied.

In the Maritime EPPO zone, the % severity in the untreated plots in all conducted trials ranged from 14 to 75,8%.
The efficacy average value obtained by **SAP2101F** at 1,5 l/ha is 90,8% according to the assessments performed, the one obtained by the Reference 2 is 86,5% and the one obtained by the Reference 3 is 74,3%.
Furthermore, no significant differences were found between SAP2101F at 1,5 L/ha and the references products belonging to Reference 2 group (JOAO and CURBATUR), in any of the 3 trials, showing a similar control than the authorized products.
Then, between SAP2101F at 1,5 L/ha and the Reference 3 at 2 L/ha, no significant differences have been found in 2 out of 3 trials, being the efficacy of third one significantly better when applied SAP2101F.

In resume, those facts indicate the similar behaviour in the control of *Helminthosporium* on barley achieved by **SAP2101F** at 1,5 L/ha se and reference products.

Table 3.2.3.2 g. Total *Helminthosporium* of Barley disease control (%) of PESSEV, achieved by SAP2101F at recommended dose rates

Target	Nb of trials	Untreated plot	% control		
			SAP2101F 1 l/ha	SAP2101F 1,25 l/ha	SAP2101F 1,5 l/ha
		Mean Max Min	Mean Max Min	Mean Max Min	Mean Max Min
% CONTROL (24 - 35 DAB) Global average	**12 10***	**23,5**	**79,5**	**85,7**	**84,1**
		75,8	100,0	100,0	98,0
		7,0	54,9	66,2	38,8
% CONTROL (21 - 35 DAB) Maritime EPPO zone	5 3*	**41,5**	**86,3**	**90,9**	**90,8**
		75,8	100,0	100,0	98,0
		14,0	69,2	73,9	82,0
% CONTROL (12 - 28 DAB) North-East EPPO zone	4	**10,3**	**69,7**	**80,8**	**86,0**
		15,0	79,1	82,6	89,6
		7,2	54,9	80,0	81,9
% CONTROL (21 - 27 DAB) South-East EPPO zone	3	**10,9**	**81,0**	**83,4**	**74,7**
		17,8	97,4	97,4	97,4
		7,0	64,7	66,2	38,8

*Number of trials, where dose rate 1,5 L/ha was tested.

Summary and Conclusions of Efficacy of SAP2101F in barley against *Helminthosporium*

A total of 12 reliable trials (>5% severity of the disease in the untreated plots) were run in France, Poland, Bulgaria and Romania in barley where control of severity of **SAP2101F** against *Helminthosporium* on different leaf levels were assessed.
In addition, data coming from Maritime zone can be extrapolated to other EPPO zones, according to EPPO Guideline PP1/226(3) – 'Number of efficacy trials', which states that "*In some situations there may be the opportunity to reduce the number of trials done, and a case may be made for this as follows.*
- *Where there is a large amount of supporting evidence from use of the product, or of similar products with the same active substance, on closely related pests or against the same pests on different crops, the number of trials necessary will be determined by the amount of supporting evidence and the similarity of the pests and crops sought* […] *Extrapolations from more challenging control situations to ones that pose a lower challenge to the active substance are more readily justifiable than extrapolations from less challenging to more challenging situations."*

Trials performed in Maritime EPPO climatic zone have more favourable climatic conditions to develop the disease than other zones and have as well a bigger barley production than other climatic zones, according to EUROSTAT database.
For that, reason it has been considered that Maritime EPPO zone is a more challenging zone for the requested diseases and crops, than the other EPPO zones.
Therefore, data coming from Maritime EPPO zone can be extrapolated to the other zones.

Average efficacy value reported of trials conducted against *Helminthosporium* in barley at the most representative variable and timing is 79,5% for SAP2101F at 1 L/ha, 85,7% for SAP2101F at 1,25 L/ha and 84,1% for SAP2101F at 1,5 L/ha, taking into account the different EPPO climatic zones, showing a robust control of the disease, similar to reference products used on these trials.
These data are enough to confirm the effectiveness of **SAP2101F** against the mentioned target disease in barley at the requested range.

3.2.3.3 Yield from efficacy trials

- **WHEAT**

A total of ~~3~~ 6 trials were carried out in 2020-2021 in France, Spain, Italy, ~~and~~ Bulgaria and Romania. The objective was to confirm the yield response of SAP2101F in wheat in presence of challenging pest populations, in this case in presence of *Septoria* and *Puccinia*.

Table 3.2.3.3-a Yield effect of SAP2101F in efficacy trials on wheat / SEPTTR-PUCCS

Refer to BAD.

Table 3.2.3.3-b Yield effect of SAP2101F at 1 L/ha in efficacy trials on wheat / SEPTTR and PUCCS

Grouping	Nº of trials	Untreated YIELD (T/ha)		% yield relative to the untreated								No of trials where SAP2101F is >, <, = compared to UTC	No of trials where SAP2101F is >, <, = compared to REF 1	No of trials where SAP2101F is >, <, = compared to REF 2	No of trials where SAP2101F is >, <, = compared to REF 3
				SAP2101F 1 L/ha		REF 1 (Prothio. + Tebu.) 1 L/ha		REF 2 (Prothio.) 0,8 L/ha		REF 3 (Epoxi. + Folp.) 2 L/ha					
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max				
~~Wheat – SEPTT~~	~~1~~	~~5.6~~	~~5,6 – –~~	~~110,2~~	~~110,2 –~~	~~107,3~~	~~107,3 –~~	-	-	-	-	~~< 0 = 0~~	~~< 0 = 1~~	-	-

Grouping	Nº of trials	Untreated YIELD (T/ha)		% yield relative to the untreated								No of trials where SAP2101F is >, <, = compared to UTC	No of trials where SAP2101F is >, <, = compared to REF 1	No of trials where SAP2101F is >, <, = compared to REF 2	No of trials where SAP2101F is >, <, = compared to REF 3
				SAP2101F 1 L/ha		REF 1 (Prothio. + Tebu.) 1 L/ha		REF 2 (Prothio.) 0,8 L/ha		REF 3 (Epoxi. + Folp.) 2 L/ha					
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max				
~~R~~			~~5,6~~		~~110, 2~~		~~107, 3~~					~~> 1~~	~~> 0~~		
Wheat - SEPTTR	4	4,6	3,4-5,6	114, 8	103, 9-122, 9	116, 6	105, 9-126, 7	-	-	-	-	< 0 = 0 > 4	< 0 = 4 > 0	-	-
Wheat - PUCCS	1	3,7	3,7	112, 3	112, 3 - 112, 3	102, 6	102, 6 - 102, 6	-	-	-	-	< 0 = 1 > 0	< 0 = 1 > 0	-	-
Wheat - SEPTTR	1	6,3	6,3 – 6,3	109, 1	109, 1 – 109, 1	-	-	106, 2	106, 2 – 106, 2	110	110 - 110	< 0 = 0 > 1	-	< 0 = 1 > 0	< 0 = 1 > 0

Note:
- REF 1 (Prothioconazole 125 g/L + Tebuconazole 125 g/L): PROSARO 250 EC at 1 L/ha
- REF 2 (Prothioconazole 250 g/L): JOAO at 0,8 L/ha
- REF 3 (Epoxiconazole 50 g/L + Folpet 375 g/L): MANITOBA 2 L/ha

In all ~~3~~ 6 trials the average total yield of the tested product SAP2101F applied at 1 L/ha was higher than the average total yield of the untreated check, and in ~~2~~ 5 out ~~3~~ 6 trials significant difference have been found (about 10-20% more than the UTC in 4 trials).
Besides, yield obtained with SAP2101F, compared with all the standard products, was statistically identical and numerically similar or even higher.
All these facts prove a benefit of the product SAP2101F in terms of wheat production.

Table 3.2.3.3-c Yield effect of SAP2101F at 1,5 L/ha in efficacy trials on wheat / SEPTTR and PUCCS

Grouping	Nº of trials	Untreated YIELD (T/ha)		% yield relative to the untreated								No of trials where SAP2101F is >, <, = compared to UTC	No of trials where SAP2101F is >, <, = compared to REF 1	No of trials where SAP2101F is >, <, = compared to REF 2	No of trials where SAP2101F is >, <, = compared to REF 3
				SAP2101F 1,5 L/ha		REF 1 (Prothio. + Tebu.) 1 L/ha		REF 2 (Prothio.) 0,8 L/ha		REF 3 (Epoxi. + Folp.) 2 L/ha					
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max				
Wheat - SEPTTR	4	4,6	3,4-5,6	118, 9	107, 1-130, 1	115, 7	102, 3-126, 7	-	-	-	-	< 0 = 1 > 3	< 0 = 4 > 0	-	-
Wheat - PUCCS	1	3,7	3,7	107, 1	107, 1 – 107,	102, 3	102, 3 - 102,	-	-	-	-	< 0 = 1 > 0	< 0 = 1 > 0	-	-

Grouping	Nº of trials	Untreated YIELD (T/ha)		% yield relative to the untreated								No of trials where SAP2101F is >, <, = compared to UTC	No of trials where SAP2101F is >, <, = compared to REF 1	No of trials where SAP2101F is >, <, = compared to REF 2	No of trials where SAP2101F is >, <, = compared to REF 3
				SAP2101F 1,5 L/ha		REF 1 (Prothio. + Tebu.) 1 L/ha		REF 2 (Prothio.) 0,8 L/ha		REF 3 (Epoxi. + Folp.) 2 L/ha					
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max				
					1		3								
Wheat - SEPTTR	1	6,3	6,3 – 6,3	105,0	105,0 – 105,0	-	-	106,2	106,2 – 106,2	110	110 - 110	< 0 = 1 > 0	-	< 0 = 1 > 0	< 0 = 1 > 0

Note:
- REF 1 (Prothioconazole 125 g/L + Tebuconazole 125 g/L): PROSARO 250 EC at 1 L/ha
- REF 2 (Prothioconazole 250 g/L): JOAO at 0,8 L/ha
- REF 3 (Epoxiconazole 50 g/L + Folpet 375 g/L): MANITOBA 2 L/ha

In 5 trials the average total yield of the tested product SAP2101F applied at 1,5 L/ha was higher than the average total yield of the untreated check, and in 3 out 5 trials significant difference have been found (about 12-30% more than the UTC in 4 trials).
Yield obtained with SAP2101F at 1,5 L/ha, compared with all the standard products, was statistically comparable.

- **BARLEY**

A total of 7 trials were carried out in 2021 in France, Spain, Poland and Romania. The objective was to confirm the yield response of SAP2101F in barley in presence of challenging pest populations, in this case in presence of *Helminthosporium, Blumeria graminis* and *Rhynchosporium secalis*.

Table 3.2.3.3-d Yield effect of SAP2101F in efficacy trials on barley / PYRNTE-ERYSGH-RHYNSE

Refer to BAD.

Table 3.2.3.3-e Yield effect of SAP2101F at 1 L/ha in efficacy trials on barley / PYRNTE

Grouping	Nº of trials	Untreated YIELD (T/ha)		% yield relative to the untreated								No of trials where SAP2101F is >, <, = compared to UTC	No of trials where SAP2101F is >, <, = compared to REF 1	No of trials where SAP2101F is >, <, = compared to REF 2	No of trials where SAP2101F is >, <, = compared to REF 3
				SAP2101F 1 L/ha		REF 1 (Prothio. + Tebu.) 1 L/ha		REF 2 (Prothio.) 0,8 L/ha		REF 3 (Epoxi. + Folp.) 2 L/ha					
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max				
Barley / PYRNTE	4	5,1	3,6 – 6,9	112,8	106,1 – 123,7	116,1	105,1 - 132,4	-	-	-	-	< 0 = 2 > 2	< 0 = 4 > 0	-	-
Barley / PYRNTE	3	8,5	7,9 - 9	107,5	105,6 – 108,	-	-	113,2	111 – 116,	106,8	104,5 – 110,	< 0 = 2 > 1	-	< 1 = 2 > 0	< 0 = 3 > 0

Grouping	Nº of trials	Untreated YIELD (T/ha)		% yield relative to the untreated								No of trials where SAP2101F is >, <, = compared to UTC	No of trials where SAP2101F is >, <, = compared to REF 1	No of trials where SAP2101F is >, <, = compared to REF 2	No of trials where SAP2101F is >, <, = compared to REF 3
				SAP2101F 1 L/ha		REF 1 (Prothio. + Tebu.) 1 L/ha		REF 2 (Prothio.) 0,8 L/ha		REF 3 (Epoxi. + Folp.) 2 L/ha					
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max				
					7				3		2				

Note:
- REF 1 (Prothioconazole 125 g/L + Tebuconazole 125 g/L): PROSARO 250 EC at 1 L/ha (except in Romania, which is applied at 0.75 L/ha)
- REF 2 (Prothioconazole 250 g/L): JOAO at 0,8 L/ha
- REF 3 (Epoxiconazole 50 g/L + Folpet 375 g/L): MANITOBA 2 L/ha

In all 7 trials the average total yield of the tested product SAP2101F applied at 1 L/ha was higher than the average total yield of the untreated check, and in 3 out of 7 trials yield was significantly higher when applying SAP2101F (about ~~10~~ 6-24% more than the UTC).
Besides, in 6 out 7 trials, no significant differences were found in yield obtained with SAP2101F compared with all the standard products.
For instance, just in one trial the reference 2 has resulted significantly better than the tested product. Nevertheless, it has to be taken into account that Reference 2 contains 200 g of Prothioconazole/ha while SAP2101F contains 120 g Prothioconazole/ha, what can explain this sometimes-better results.
All these facts prove a benefit of the product SAP2101F in terms of barley production.

Table 3.2.3.3-f Yield effect of SAP2101F at 1,5 L/ha in efficacy trials on barley / PYRNTE

Grouping	Nº of trials	Untreated YIELD (T/ha)		% yield relative to the untreated								No of trials where SAP2101F is >, <, = compared to UTC	No of trials where SAP2101F is >, <, = compared to REF 1	No of trials where SAP2101F is >, <, = compared to REF 2	No of trials where SAP2101F is >, <, = compared to REF 3
				SAP2101F 1,5 L/ha		REF 1 (Prothio, + Tebu,) 1,0 L/ha		REF 2 (Prothio,) 0,8 L/ha		REF 3 (Epoxi, + Folp,) 2 L/ha					
		Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max				
Barley / PYRNTE	4	5,1	3,6 – 6,9	117, 6	110, 3 – 131, 7	116, 1	105, 1 - 132, 4	-	-	-	-	< 0 = 0 > 4	< 0 = 3 > 1	-	-
Barley / PYRNTE	3	8,5	7,9 - 9	110, 7	109, 0 – 112, 4	-	-	113, 2	111 – 116, 3	106, 8	104, 5 – 110, 2	< 0 = 2 > 1	-	< 0 = 3 > 0	< 0 = 3 > 0

Note:
- REF 1 (Prothioconazole 125 g/L + Tebuconazole 125 g/L): PROSARO 250 EC at 1 L/ha (except in Romania, which is applied at 0,75 L/ha)
- REF 2 (Prothioconazole 250 g/L): JOAO at 0,8 L/ha
- REF 3 (Epoxiconazole 50 g/L + Folpet 375 g/L): MANITOBA 2 L/ha

The average total yield of the tested product SAP2101F applied at maximum recommended doe rate of 1,5 L/ha was higher than the average total yield of the untreated check, and in 5 out of 7 trials yield was significantly higher when applying SAP2101F (about 10-30% more than the UTC).

In 6 out 7 trials, no significant differences were found in yield obtained with SAP2101F compared with all the standard products. Significantly higher efficacy of SAP2101F, as compared with REF 1 was noted in 1 trial.

Summary of Yield from efficacy trials

A total of ~~10~~ 13 efficacy trials on wheat and barley, performed in different EPPO climatic zones and countries in 2020-2021, in presence of challenging diseases, have harvested trials in order to analyse yield.
Results have demonstrated that SAP2101F applied at the minimum and at the maximum requested dose ~~range~~ rate (1 and 1,5 L/ha) increase the production of wheat and barley about ~~10~~ 4-30%, in comparison with the non-treated plot.
Besides, results are similar to the ones achieved by the reference products.
All these facts prove the benefit of SAP2101F in yield.

Comments of zRMS on:
Efficacy (3.2.3)

A total of 39 valid efficacy trials carried out between 2020 and 2021 have been submitted for the evaluation of the fungicide SAP2101F. The trials were carried out in 3 EPPO zones: Maritime (France, Germany, United Kingdom), North-East (Poland) and South-East (Bulgaria, Romania). All the efficacy trials were carried out by the officially GEP-recognized testing units.
As SAP2101F is intended to be authorized in Poland, and no other cMSs are listed in GAP table, efficacy trials from North-East EPPO zone and from neighbouring country (Germany) are primarily analysed. Trials from Maritime (France, United Kingdom) and South-East (Bulgaria, Romania) EPPO zone may be relevant for possible future applications (e.g. art 40 Mutual recognition) in other Member States.
SAP2101F is intended for the control of *Zymoseptoria tritici* (SEPTTR*)* on wheat and *Pyrenophora teres* (PYRNTE) on barley. The requested application dose rate range is: 1,0-1,5 L/ha according to GAP. The recommended water volumes range is 150-400 L/ha. SAP2101F is intended to be used 2 times per growth season, within the crop stage ranging from BBCH 32-61 in wheat and 30-61 in barley.

Conclusions from the evaluation

WHEAT/ SEPTTR
Results from 27 valid efficacy trials have been presented for the evaluation including:
- 9 trials from North-East EPPO zone carried out in Poland
- 9 trials from Maritime EPPO zone carried out in Germany (3), France (5) and United Kingdom (1)
- 9 trials from South-East EPPO zone carried out in Bulgaria (4), and Romania (5).

NORTH-EAST EPPO zone
SAP2101F was applied twice in all 9 trials, at BBCH growth stage range of the crop 31-59 and water volume ranging from 200 to 300 L/ha. In 3 trials carried out in Germany (supportive data for Poland), SAP2101F was applied twice, at BBCH growth stage range of the crop 32-45 and water volume 200 L/ha. All the trials were carried out in winter wheat.
Based on the submitted trials results it can be concluded, that SAP2101F, applied at maximum recommended dose rate of 1,5 L/ha was highly effective (83,2% average efficacy from 5 trials carried out in Poland and 85,4% average efficacy from 6 trials carried out in Poland and Germany altogether) against SEPPTR on wheat in North-East EPPO zone. High average efficacy (81,2% average efficacy from 9 trials carried out in Poland and 84,4% average efficacy form 12 trials carried out in Poland and Germany) was also demonstrated at dose rate of 1,25 L/ha. SAP2101F was moderately effective at the lowest recommended dose rate of 1,0 L/ha. The average efficacy was 76% from the trials carried out in Poland and 79,2% from the trials conducted in Poland and Germany. No statistically significant differences have been demonstrated between SAP2101F and reference products in the vast majority of trials.
Based on the efficacy data package from North-East and Maritime (DE) EPPO zone, the use of SAP2101F applied twice at dose rate range 1,0-1,5 L/ha in the control of SEPTTR on winter wheat at BBCH 32-59 is accepted in Poland. It is recommended to include in the product label remark to use lower dose rates under low disease pressure. As no efficacy data has been submitted for spring wheat and durum wheat (winter and spring

form) these uses are not accepted to be registered on the grounds of article 33 of Regulation (EC) No 1107/2009. Durum wheat (minor crop in PL) can be registered on the grounds of article 51 of Regulation (EC) No 1107/2009.

MARITME EPPO zone

SAP2101F was applied twice in 8 out of 9 trials and once in 1 trial, at BBCH growth stage range of the crop 32-61 and water volume ranging from 160 to 200 L/ha. All the trials were carried out in winter wheat.

Based on the submitted trials results it can be concluded, that SAP2101F, applied at maximum recommended dose rate of 1,5 L/ha was highly effective (94,0% average efficacy from 4 trials). High average efficacy (87,3% and 91,4% average efficacy from 9 trials) was also demonstrated at dose rate of 1,0 and 1,25 L/ha. No statistically significant differences have been demonstrated between SAP2101F and reference products in the vast majority of trials. The presented data may be relevant for possible future applications (e.g. art 40 Mutual recognition) in Member States from Maritime EPPO zone.

South-East EPPO zone

SAP2101F was applied twice in all 9 trials, at BBCH growth stage range of the crop 31-73 and water volume ranging from 200 to 300 L/ha. All the trials were carried out in winter wheat.

Based on the submitted trials results it can be concluded, that SAP2101F, applied at maximum recommended dose rate of 1,5 L/ha was highly effective (90,0% average efficacy from 5 trials). High average efficacy (83,3% and 89,7% average efficacy from 9 trials) was also demonstrated at dose rate of 1,0 and 1,25 L/ha. No statistically significant differences have been demonstrated between SAP2101F and reference products in the vast majority of trials. The presented data may be relevant for possible future applications (e.g. art 40 Mutual recognition) in Member States from South-East EPPO zone.

BARLEY/ PYRNTE

Results from 12 valid efficacy trials have been presented for the evaluation including:

- 4 trials from North-East EPPO zone carried out in Poland
- 5 trials from Maritime EPPO zone carried out in France
- 3 trials from South-East EPPO zone carried out in Bulgaria (2), and Romania (1).

NORTH-EAST EPPO zone

SAP2101F was applied twice in all 4 trials at BBCH growth stage range of the crop 30-62 and water volume ranging from 200 to 300 L/ha. The trials were carried out in winter barley (3) and spring barley (1).

SAP2101F, applied at maximum recommended dose rate of 1,5 L/ha was highly effective (86,0% average efficacy) against PYRNTE on barley in North-East EPPO zone. The average efficacy was 69,7% and 80,8% at lower requested dose rates 1,0 and 1,25 L/ha respectively. SAP2101F at 1,0 and 1,25 Lha was statistically similarly effective or less effective than reference products. Statistically higher or similar efficacy was noted between SAP2101F at 1,5 L/ha and reference products in 3 out of 4 trials.

The presented efficacy data package (4 trials) is not sufficient to support authorization of SAP2101F in the control of PYRNTE in winter barley and spring barley in Poland. This use is not accepted to be registered on the grounds of article 33 of Regulation (EC) No 1107/2009.

MARITIME EPPO zone

SAP2101F was applied twice in 4 out of 5 trials and once in 1 trial, at BBCH growth stage range of the crop 31-59 and water volume ranging from 150 to 250 L/ha. All the trials were carried out in winter barley.

SAP2101F was highly effective in 3 tested dose rates 1,0; 1,25 and 1,5 L/ha with average efficacy: 86,3%, 90,9% and 90,8% respectively. No statistically significant differences have been demonstrated between SAP2101F and reference products in the vast majority of trials. The presented data may be relevant for possible future applications (e.g. art 40 Mutual recognition) from Member States Maritime EPPO zone.

SOUTH-EAST EPPO zone

SAP2101F was applied twice in 3 trials, at BBCH growth stage range of the crop 29-56 and water volume ranging from 200 to 300 L/ha. All the trials were carried out in winter barley.

The average efficacy of SAP2101F was 81,0%; 83,4% and 74,7% achieved at 1,0, 1,25 and 1,5 L/ha respectively. No statistically significant differences have been demonstrated between SAP2101F and reference products in the vast majority of trials. As the efficacy achieved at the highest requested dose was visibly lower than the efficacy results achieved for lower claimed dose rates, the results from individual trials have been analysed. The dose rate of 1,5 was highly effective in 2 of 3 trials (88% and 95,1% efficacy). Low efficacy 38,8% was noted in 1 trial, while the efficacy >60% was demonstrated at lower dose rates 1,0 and 1,25 L/ha and >40% was noted

at the lowest dose rate of 0,6 L/ha in this trial. Therefore results from this trial seems to be no valid for mean average calculation of efficacy. The presented data may be relevant for possible future applications (e.g. art 40 Mutual recognition) in Member States from South-East EPPO zone.

Yield

Thirteen efficacy trials carried out in winter wheat (6 trials from: SE EPPO zone - Bulgaria (1), Romania (2) and MED EPPO zone - France (1), Spain (1) and Italy (1)) and in winter barley (7 trials from: MAR EPPO zone - France (2), NE EPPO zone - Poland (2), SE EPPO zone - Romania (1), MED EPPO zone – France (1), SP (1) presents data on the effect of SAP2101F, on the crop yield.

Results from the presented trials show that SAP2101F, applied at minimum and maximum recommended dose rate (1,0 and 1,5 L/ha), has no negative impact on the yield of winter wheat and winter barley. No significant differences in the yield have been noted comparing results achieved for SAP2101F, with reference products in most of the trials. Higher and statistically significant higher efficacy was noted as compared yield from the objects treated with SAP2101F, with untreated control.

It can be concluded, that no negative impact of SAP2101F applied at recommended dose rate range 1,0-1,5 L/ha on the yield of winter wheat and winter barley is expected.

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

Following EPPO Standard PP 1/213 ‘Resistance risk analysis’, it is reported the relevant information to the risk of resistance assessment

Mode of action

- Prothioconazole belongs to DMI-fungicides group (DeMethylation Inhibitors, SBI Class I), being Triazolinthiones its chemical group, forming part of the group 3 of FRAC (Fungicide Resistant Action Committee).
  SBI-fungicides that inhibit the C14 demethylation step within fungal sterol biosynthesis are known as demethylation inhibitors or DMIs. Chemically, DMIs belong to different chemical groups. Besides triazoles, numerous imidazoles, pyridines and pyrimidines are also demethylation inhibitors.
  All DMIs inhibit fungi by interacting with the same target site, C14-demethylase (erg11/cyp51) and are therefore considered to be cross-resistant with each other.
  Typically, DMI's have a broad spectrum of activity against a range of economically important pathogens on arable crops, top fruit, industrial crops, vines, plantation crops, etc.

- Folpet belongs to the chemical group of the phthalimide fungicides and, according to FRAC (Fungicide Resistance Action Committee) it is included in the group M4, substances with a multi-site contact activity. This substance acts by inhibiting many oxidative enzymes, carboxylases and enzymes involved with phosphate metabolism and citrate synthesis. Folpet reacts with the sulfhydryl groups of nuclear proteins, leading to an inhibition of the cell division. It is considered as a low risk group without any signs of resistance developing to the fungicides.

Importance of multisite fungicides in managing pathogen resistance

One of the key recommendations is to make use of multisite fungicides (see FRAC Group M) in spray programs, especially in crops with multiple sprays such as fruits and vegetables, or certain arable crops. Due to their mode of action, multisite fungicides are considered as a low resistance risk group. Therefore, they offer the possibility for use as mixing partners or alternating with single site and other medium to high resistance risk fungicides. Over the past decades, no cases of field resistance against multisites have been reported.

There are clear benefits to recommending multi-site fungicides in spray programs:
● Multisite fungicides display a low risk to develop resistance and are effective mixing/alternating partners for medium to high risk fungicides.
● Beyond protecting and prolonging the lifespan of highly effective medium to high resistance risk fungicides, multisite fungicides provide added levels and spectrum of disease control. With this they can also support the single sites to be even more efficient.
● Multisite fungicides are considered a valuable tool to manage resistance by preventing or delaying its development to many pathogens in many crops.
● In some crops, multisites play an increasing role in spray programs to sustain effective disease control and resistance management, e.g. for Zymoseptoria tritici in wheat, Ramularia collo-cygni in barley and for Phakopsora pachyrhizi in soybeans.
Restricting the use of multisite fungicides from use in important crops could result in faster development of resistance to single site mode of action fungicides. This in turn could lead to epidemic disease development, serious crop losses, and finally the loss of highly effective fungicides for a sustainable disease management.

Evidence of resistance and Monitoring Results 2021 (FRAC members) - (Prothioconazole)

1. WHEAT
Septoria Leaf Blotch (*Mycosphaerella graminicola / Zymoseptoria tritici*)

Presentation of monitoring data 2020: ADAMA, BASF, Bayer, Corteva, Sumitomo, Syngenta

• Disease pressure was low to moderate with very dry conditions in some countries in 2020.

• DMIs field performance was good when used according to the manufacturers and FRAC recommendations. No general field resistance has been reported.

• Monitoring 2020 was carried out in Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, France, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, Netherlands, Norway, Poland, Romania, Russia, Slovakia, Spain, Sweden, Switzerland, Turkey, Ukraine, and United Kingdom

• After the slight increase in the frequency of less sensitive isolates from 2002 to 2004, the situation had stabilised between 2005 and 2008. In 2009 a trend to slightly higher EC50 values was observed in important cereal growing areas (France, Germany, Ireland, United Kingdom), this trend has slowed down in 2010 to 2012 and was stable in 2013. 2014 sensitivity was in the same range as 2011.

• In 2015 depending on the individual active ingredient and regions slight shifts of sensitivity of populations have been observed. Highest EC50 values were observed in areas of elevated disease pressure and sub-optimal use of azoles in spray programs (e.g. reduction of rates in comparison to the manufacturer's recommended rate and inappropriate use of effective mixpartners).

• In 2016 and also in 2017 the sensitivity of the populations was overall stable on a European level with regional differences also based on different disease epidemics. In regions with lower sensitivity in 2015 the sensitivity of the populations was stable and, in some areas, even partially increased.

• In 2018 the sensitivity of the populations was overall stable on the European level.

• In 2019, the sensitivity of the populations was overall stable on European level with EC50 sensitivity values slightly higher compared to 2018 in some geographies but overall in the range of previous years.

• In 2020, the sensitivity of populations was overall stable on European level with EC50 sensitivity values in the range of previous years. www.frac.info 4

• In Z. tritici, different DMI haplotypes can lead to varying levels of sensitivity depending on the chemical structure. As DMIs are generally cross-resistant, resistance management approaches should be the same for all DMIs.

• Overall, as already reported in 2019 DMI EC50 sensitivity values were somewhat higher in the UK and Ireland than observed on the European continent where a gradient can be observed from North-West to South-East. In regions with limited options in fungicides classes and/or a common practice of significantly reduced rates DMIs are at higher risk and performance might be impacted.

2. BARLEY
Net blotch (*Pyrenophora teres* /*Drechslera teres*)

Presentation of monitoring data 2020: Bayer, Syngenta

• Disease pressure was generally low in 2019.

• Performance of SBI containing spray programmes was good.

• Monitoring was carried out in Belgium, Czech Republic, Denmark, France, Germany, Hungary, Ireland and United Kingdom.

• In 2017 in France significant shifts of sensitivity of populations have been observed. Highest EC50 values were observed in areas of elevated disease pressure, often coupled with a reported reduced variety-resistance at significant cultivation areas, and sub-optimal use of azoles in spray programs (e.g. reduction of rates in comparison to the manufacturer's recommended rate and inappropriate use of effective mix-partners).

• In general, over the past years a significant fluctuation in sensitivity levels between the years was detected. In 2017 in single locations in Germany there have been seen some shifting which needs to be observed in the next season. The monitoring in the other countries showed a stable situation in 2017 within the regular fluctuation.

• The monitoring of the last 20 years showed a certain level of fluctuations of the sensitivity level in the regions over the years. In 2018, the situation stabilized again in all countries including France and Germany, thus being comparable to the long-term monitoring results.

• In 2019, like 2017 lower sensitivities have been frequently detected in major French regions and in a single location in North-Eastern Germany. In the other European regions monitored sensitivity ranges were stable.

• In 2020, monitoring was carried out in Austria, Bulgaria, Czech Republic, Denmark, France, Germany, Hungary, Ireland, Italy, Lithuania, Poland, Romania, Russia, Slovakia, Spain, Sweden, Switzerland, Ukraine and United Kingdom.

• Overall, the sensitivity of populations monitored in 2020 stayed in the range observed in previous years, without any major geographical differences across Europe.

<u>Use Recommendations (FRAC 2021) (Prothioconazole)</u>

1. SBI – General recommendations for use

The SBI fungicides represent one of the most potent classes of fungicides available to the grower for the control of many economically important pathogens. It is in the best interest of all those involved in recommending and using these fungicides that they are utilised in such a way that their effectiveness is

maintained. The working group concentrates its resources on the major crop/pathogen targets from the point of view of resistance risk. Inevitably many, still important pathogens are omitted. To help in making recommendations for crops and pathogens not directly covered, the following general recommendations can be made:

• Repeated application of SBI fungicides alone should not be used on the same crop in one season against a high-risk pathogen in areas of high disease pressure for that particular pathogen.

• For crop/pathogen situations where repeated spray applications (e.g. orchard crops/powdery mildew) are made during the season, alternation (block sprays or in sequence) or mixtures with an effective non cross-resistant fungicide are recommended.

• Where alternation or the use of mixtures is not feasible because of a lack of effective or compatible non cross-resistant partner fungicides, then input of SBI's should be reserved for critical parts of the season or crop growth stage.

• If the performance of SBIs should decline and sensitivity testing has confirmed the presence of less sensitive isolates, SBIs should only be used in mixture or alternation with effective non cross-resistant partner fungicides.

• The introduction of new classes of chemistry offers opportunities for more effective resistance management. The use of different modes of action should be maximized for the most effective resistance management strategies.

• Users must adhere to the manufacturers' recommendations. In many cases, reports of "resistance" have, on investigation, been attributed to cutting recommended use rates, or to poorly timed applications.

• Fungicide input is only one aspect of crop management. Fungicide use does not replace the need for resistant crop varieties, good agronomic practice, plant hygiene/sanitation, etc.

• Exclusive frequency measurements of single cyp51 mutations are not sufficient to describe the sensitivity situation towards DMIs but can help to better understand the background of sensitivity shifts. www.frac.info 12 _1

2. SBI – Recommendations for cereals (DMIs and amines)

• The recommendations for the use of DMI and amine fungicides in mixture or alternation programmes with different mode of action fungicides remain unchanged. It needs to be emphasized that it is essential for resistance management purposes to follow strictly the manufacturer's and FRAC recommendations.

• Repeated application of DMI or amine fungicides alone should not be used on the same crop in one season against risky pathogens (e.g. cereal powdery mildews, barley net blotch, scald) in areas of high disease pressure for that particular pathogen.

• Reduced rates of DMIs can contribute to accelerate the shift to less sensitive populations. It is critical to use effective rates of DMIs in order to ensure robust disease control and effective resistance management. DMIs must provide effective disease control and be used at manufacturers recommended rates.

• When used in mixture recommended effective rates of the SBI must be maintained. Split and reduced rate programmes, using multiple repeated applications at dose rates below manufacturer's recommendations, provide continuous selection pressure and accelerate the development of resistant populations, and therefore must not be used.

• To ensure good performance and particularly resistance management in situations of even low disease pressure it is essential to adhere to dosages and spray timings as recommended by manufacturers. Curative applications should be avoided. Application timing has to be appropriate to all mix partners' characteristics. Mixing with a non-cross resistant fungicide at effective dose rates contributes to a more effective disease control and resistance management.

• The amine fungicides are effective non-cross-resistant partner fungicides for DMIs on cereals for the control of pathogens included in the label recommendation of each respective product.

• Ramularia leaf spot (Ramularia collo-cygni) in barley: Given that there already exist populations of Ramularia collo-cygni in Europe resistant to all main specific modes of actions it is recommended to add precautionary a multi-site to ensure robust disease control and an effective resistance management in barley

General Use Recommendations (Folpet)

According to the information provided before, considering that multisite fungicides display a low risk to develop resistance and that are effective mixing/alternating partners for medium to high risk fungicides, no use restrictions are considered to SAP2101F regarding Folpet active ingredient.

Proposed resistance management strategy (in case of registration)

The proposed resistance management strategy for this formulation remains an integrated approach to disease control on farm. The main resistance management strategies currently recommended are (generically): avoid repetitive use; alternation with fungicides having other modes of action is recommended; limit number and timing of treatments; avoid eradicant use (prefer preventive applications); maintain recommended dose rate; integrate with non-chemical methods.

Conclusions about the occurrence or possible occurrence of the development of resistance

Requested GAP of **SAP2101F** complies with specific recommendations of FRAC to the management of DMI fungicide resistance (number of applications, interval between applications etc.,). In addition, resistance management strategy has been proposed.

In resume, **SAP2101F** is a product which complies with recommendations of FRAC to avoid occurrence of the development of resistance and it has been demonstrated that achieves good control against *Septoria* and *Helminthosporium* on the different target crops. Demonstrating as a tool for a good resistance management.

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

SAP2101F is a new fungicide containing a mixture of two known active substances: prothioconazole (chemical group: triazoles, group name: DMI-fungicides, SBI: Class I; FRAC code: 3) and folpet (chemical group: phthalimides, FRAC code: M4).
The resistance risk for DMI-fungicides and for phthalimides has been defined by FRAC as medium and low respectively. A mixture of two active substances with different modes of action when one substance is of medium risk of developing resistance and the other of low risk, is an effective tool in resistance management strategy.
According to the FRAC Pathogen Risk List (revised in September 2019), *Zymoseptoria tritici* , *Pyrenophora teres* are defined as medium risk of resistance pathogens,
FRAC List of 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)

- *Pseudocercosporella herpotrichoides* (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)

No cases of cereal pathogen resistance have been described for phthalimides by FRAC.

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 Barley/ *Pyrenophora teres/:* In 2023 monitoring was carried out in Austria, Belgium, Bulgaria, Czech Republic, Denmark, France, Finland, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Netherlands, Poland, Romania, Russia, Spain, Sweden, and the United Kingdom. Overall, the sensitivity of populations monitored stayed in the range observed in previous years, without any major geographical differences across the main European barley production countries.

Based on the submitted data, to avoid the possible development of resistance, the following resistance management strategy proposed by the Applicant, and thereafter accepted in a more extended version by zRMS is recommended to be included in the label of SAP2101F:

- Non-chemical measures such as resistant crop varieties, plant hygiene, and good agricultural practice should be taken into consideration to reduce the infection pressure of the target pathogens,
- SAP2101F should be used at the recommended dose rate,
- SAP2101F should be used predominantly for protective fungi control at the very beginning of an infection or re-infection,
- SAP2101AF should be used alternately with other fungicides containing active substances with different mode of action,
- In case of not satisfying efficacy achieved, it is advisable to inform the authorization holder.

3.4 Effects on treated crops (KCP 6.4)

Prothioconazole and Folpet are tow active substances, with fungicide activity, that have been registered from more than 20 years ago in several European countries and extensively used during this period, with not known event of reducing yield in any of the authorised crops related to the use of these products.

65 efficacy trials were performed on wheat and barley in four EPPO Climatic zones. On these 65 trials, in addition to the efficacy, evaluations on any adverse phototoxicity symptoms were done. Then, another 2 efficacy trials in Maritime EPPO zone and 2 others in Mediterranean EPPO zone are still on-going and will be submitted once finished.
Moreover, 9 transformation trials were performed and exposed hereunder.

Trial	Country	Climate zone	Testing facility	Year	Crop type	Trial type
25-TT-BM- 2021-FR01	France	Maritime	STAPHYT	2021	Wheat	Bread-making
25-TT-BM- 2021-FR02	France	Maritime	STAPHYT	2021	Wheat	Bread-making
25-TT-BM- 2021-IT01	Italy	Mediterranean	SAGEA	2021	Wheat	Bread-making

25-TT-BM- 2021-IT02	Italy	Mediterranean	SAGEA	2021	Wheat	Bread-making
26-TT-BW- 2021-FR01	France	Maritime	STAPHYT + iFBM	2021	Barley	Brewing
26-TT-BW- 2021-FR02	France	Maritime	STAPHYT + iFBM	2021	Barley	Brewing
26-TT-BW- 2021-FR03	France	Maritime	STAPHYT + iFBM	2021	Barley	Brewing
26-TT-BW- 2021-IT01	Italy	Mediterranean	SAGEA	2021	Barley	Brewing
26-TT-BW- 2021-IT02	Italy	Mediterranean	SAGEA	2021	Barley	Brewing

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

Table 3.4-a Presentation of trials (selectivity trials, transformation trials...)

Crop*	Country	Type of trial**	Number of trials			Years	GEP, non-GEP, official ***	Comments (any other relevant information)
			Maritime EPPO zone	Mediterranean EPPO zone	South -East EPPO zone			
Wheat	FR	S+Y+ TF+Q	2			2021	GEP	Bread-making trials
	IT	S+Y+ TF+Q		2		2021	GEP	Bread-making trials
Barley	FR	S		1		2021	GEP	Phytotoxicity trial
	HU	S			1	2021	GEP	Phytotoxicity trial
	FR	S+Y+ TF+Q	3			2021	GEP	Brewing trials
	IT	S+Y+ TF+Q		2		2021	GEP	Brewing trials
TOTAL	-	Wheat	2	2	0	-	GEP	-
TOTAL	-	Barley	3	3	1	-	GEP	-
TOTAL	-	-	**5**	**5**	**1**	-	**GEP**	-

* According to the GAP table

** S = selectivity trial, Y = trial with yield assessment, Q = trial with quality assessment, T = trial on the basis of the study of impact on transformation process (TP: Physical transformation, TF: transformation involving microbial fermentation), P = trial with assessment of impact on propagation

*** Official: carried out by a national official organisation

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

Prothioconazole and Folpet are two active substances, with fungicide activity, that have been registered from more than 20 years ago in several European countries and extensively used during this period in several crops such as cereals, with not known event of phytotoxicity or reducing yield in any of the authorised crops related to the use of these products.

Furthermore, according to EPPO PP1 /135 (4) “Phytotoxicity assessment” specific selectivity trials (in absence of pest/weeds/disease) including 2N dose are not necessary for fungicides, insecticides and plant growth regulators, because, for these types of plant protection products, phytotoxic effects will be less frequent.

Therefore, assessment for phytotoxicity symptoms in efficacy trials are enough to support the registration of these type of products. Only, if phytotoxicity symptoms are recorded in efficacy trials, specific selectivity trials should be performed.

A total of 63 efficacy trials on wheat and barley, on a wide range of commercially grown varieties, have been conducted in France, Germany, United Kingdom, Italy, Spain, Bulgaria, Romania and Poland from 2020 to 2021.
No phytotoxicity symptom caused by SAP2101F at the proposed range of doses from 1 to 1,5 L/ha in wheat and barley was recorded in any of the trials (For SAP2101F, N=1,5 L/ha).
Furthermore, in 2 other selectivity trials (Hungary and France) no phytotoxicity was observed, neither on 9 other transformation trials (in France and Italy).

WHEAT

Number of trials with…		**Efficacy trials (38 trials)**		**Bread-making trials (4 trials)**	
		Test product	**Standards**	**Test product**	**Standards**
		N	**N**	**N**	**N**
Maximum of phytotoxicity recorded during the trials	0% to 5%	38	38	4	4
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	38	38	4	4
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0

BARLEY

Number of trials with…		**Efficacy trials (27 trials)**		**Selectivity trials (2 trials)**		**Brewing trials (5 trials)**	
		Test product	**Standards**	**Test product**	**Standards**	**Test product**	**Standards**
		N	**N**	**N**	**N**	**N**	**N**
Maximum of phytotoxicity recorded during the trials	0% to 5%	27	27	2	2	5	5
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	27	27	2	2	5	5
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0

To conclude, no phytotoxic symptoms have been caused at the proposed maximum rate of SAP2101F (1,5 L/ha) was recorded in any of the 74 ~~efficacy/selectivity~~ trials conducted.

Comments of zRMS on:
Phytotoxicity to host crop (3.4.1)

Due to no phytotoxicity symptoms observed in any of 74 submitted trials, it can be concluded that SAP2101F applied at the recommended dose rates 1,0-1,5 L/ha cause no adverse effects on the target crops and can be safely used.

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

According to EPPO PP1/135 (4) '*Phytotoxicity assessment'*, specific selectivity trials (in absence of pest/weeds/disease) including 2N dose are not necessary for fungicides, insecticides and plant growth regulators, because, for these types of plant protection phytotoxicity symptoms are less frequent.
Only if phytotoxicity symptoms appear in trials at N dose, this type of trials should be conducted.
As previously it has been noticed, phytotoxicity symptoms have not appear in any of the 74 total trials carried out, for that reason specific selectivity trials testing 2N dose have not been performed.
Nevertheless, in absence of any disease, 9 transformations trials have been performed, where yield at N dose was evaluated and SAP2101F did not had any negative effect on yield, compared with the untreated plot or the plots treated with reference products.

Summary and conclusion on effect on the yield of treated plants or plant product.

According to data submitted, the risk of impact of SAP2101F on the yield of treated plants can be considered like acceptable when it is applied following the corresponding GAP.

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

Yield data from efficacy trials is presented in the chapter 3.2.3 Efficacy tests.

Thirteen efficacy trials carried out in winter wheat (6 trials from: SE EPPO zone - Bulgaria (1), Romania (2) and MED EPPO zone - France (1), Spain (1) and Italy (1)) and in winter barley (7 trials from: MAR EPPO zone - France (2), NE EPPO zone - Poland (2), SE EPPO zone - Romania (1), MED EPPO zone – France (1), SP (1) presents data on the effect of SAP2101F on the crop yield.

Results from the presented trials show, that SAP2101F, applied at minimum and maximum recommended dose rate (1,0 and 1,5 L/ha), has no negative impact on the yield of winter wheat and winter barley. No significant differences in the yield have been noted comparing results achieved for SAP2101F with reference products in most of the trials. Higher and statistically significant higher efficacy was noted as compared yield from the objects treated with SAP2101F with untreated control.

Yield was also recorded in the trials on non-intentional effects of SAP2101F at 1,5 L/ha on transformation process on winter wheat (4 trials carried out in MED EPPO zone: Italy (2) and MAR EPPO zone: France (2)) and on winter barley (5 trials carried out in MED EPPO zone: Italy (2) and MAR EPPO zone: France (3)).
No statistically significant differences were noted between SAP2101F and reference products and untreated control in 2 out of 4 trials carried out in winter wheat and in 5 trials conducted in winter barley. Significant increase of the yield was demonstrated for SAP2101F at 1,5 L/ha as compared with reference product Sesto and untreated control in 2 trials conducted in France in winter wheat.

No yield data is available for North-East EPPO zone for wheat. As no adverse effects have been observed in the submitted trials performed in SE, MAR and MED EPPO zone in winter wheat and in the trials conducted in MAR, NE, SE and MED EPPO zone in winter barley, and due to long experience of usage folpet and prothioconazole in cereals, lack of yield data from NE EPPO zone for wheat may be acceptable.

It can be concluded, that no negative impact of SAP2101F applied at recommended dose rate range 1,0-1,5 L/ha on the yield of winter wheat and winter barley is expected.

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

A total of ~~6~~ 10 trials on wheat and 12 trials on barley allow to study the quality of plants or plants products after SA~~O~~P2101F application.
~~Two~~ Four submitted trials on Wheat and three on Barley are presented as supportive data, because being performed on a different climatic zone (Mediterranean, Italy and Spain).
Data on wheat was generated on 4 trials to study any unintentional effect on Baking and ~~2~~ 6 efficacy trials where yield and quality parameters were recorded.
Data on Barley was generated on 5 trials to study any unintentional effect on Brewing and 7 efficacy trials where yield and quality parameters were recorded.

In addition to the effect on Baking and Brewing quality parameters, other variables such as Moisture content (%), TKW (1000 grains weight) and HLW (kg/hl) were recorded.

MOICON (%) was evaluated ~~on~~ in ~~6~~ 10 trials on wheat and 12 trials on Barley; HLW ~~on~~ in ~~4~~ 7 trials on wheat and 7 trials on Barley; TKW ~~on~~ in ~~2~~ 6 trials on Wheat and 3 on Barley.

According to the summited data, just few differences were observed on quality parameters, namely:

- ~~Slightly~~ Significantly higher HLW for SAP2101F at 1,0 and/or 1,25 and/or 1,5 L/ha on wheat than the untreated in ~~1~~ 5 ~~up to~~ out of ~~4~~ 7 trials (03A-F-2021-RO01, 03B-F-2021-SP01, 03B-F-2021-RO01, 25-TT-BM-2021-FR02, 25-TT-BM-2021-FR01). Similar (4 trials) or significantly higher (1 trial) to the reference.
- ~~Slightly~~ Significantly higher TKW on wheat than the untreated in 3 out of 6 trials (03A-F-2021-RO01, 25-TT-BM-2021-IT01, 25-TT-BM-2021-FR01). ~~and the reference in 1 up to 3 trials (25-TT-BM-2021-IT01~~ No statistically significant differences with the reference products.
- No differences at all on moisture content on wheat ~~on 6~~ in 9 out of 10 trials. Statistically higher moisture content for SAP2101F at 1,25 and 1,5 L/ha as compared with untreated control in 1 out of 10 trials.
- No differences on HLW on barley in 7 trials
- ~~Slightly~~ Significantly higher TKW than the untreated in 1 ~~up to~~ out of 3 trials (04B-F-202~~0~~1-RO01). No differences with standard.
- ~~Slightly~~ Significantly higher Moisture content for SAP2101F at 1,0, 1,25 and 1,5 L/ha than the untreated ~~and reference~~ in ~~1~~ 2 ~~up to~~ out of 12 trials in Barley (04B-F-2021-PL02, 04B-F-2021-PL04) and for SAP2101F at 1,25 and 1,5 L/ha than the ~~untreated~~ reference in 1 out of 12 trials ~~on a second one~~ (04B-F-2021-PL04).

Folpet and Prothioconazole are old active ingredients used for long ago in cereals to control diseases, with no reported negative effect on quality of plants products. In fact, reported results demonstrate the absence of relevant negative effects on treated plots with SAP2101F, or even better-quality parameters on efficacy trials (higher TKW and HLW for some trials).

According to the reported data, in can be concluded that the use of SAP2101F is safe for cereals when applied according to the GAP.

Comments of zRMS on:
Effects on quality of plants and plant products (3.4.3)

Thirteen efficacy trials carried out in winter wheat (6 trials from: SE EPPO zone - Bulgaria (1), Romania (2) and MED EPPO zone - France (1), Spain (1) and Italy (1)) and in winter barley (7 trials from: MAR EPPO zone - France (2), NE EPPO zone - Poland (2), SE EPPO zone - Romania (1), MED EPPO zone – France (1), SP (1) presents data on the effect of SAP2101 F on the yield quality (moisture content, thousand grain weight and hectolitre weight).

Results from the presented trials show that SAP2101F, applied at 1,0-1,5 L/ha has no negative impact on the yield quality of winter wheat and winter barley.

Moisture content – MOICON (recorded in 13 trials)

No significant differences have been noted comparing results achieved for SAP2101F with reference products in most of the trials. Significantly higher moisture content for SAP2107F at 1,25 and 1,5 L/ha as compared with reference product was noted in 1 trial conducted in Poland in winter wheat.

No differences (5 trials in winter wheat and 5 trials in winter barley) or statistically significant higher efficacy (1 trial conducted in Romania in winter wheat and 2 trials conducted in Poland in winter barley) was noted as compared the objects treated with SAP2101F with untreated control.

Thousand grain weight – TGW (recorded in 3 trials)

Significantly higher TGW for SAP2107F at 1,0 - 1,5 L/ha as compared with untreated control was noted in 2 trials conducted in Romania in winter wheat and winter barley. No differences were noted as compared the objects treated with SAP2101F with objects treated with reference products.

Hectolitre weight – HLW (recorded in 5 trials)

Significantly higher TGW for SAP2107F at 1,0 - 1,5 L/ha as compared with untreated control was noted in 1 trials conducted in Romania in winter wheat. Statistically higher TGW for SAP2107F at 1,0 or 1,25 L/ha as compared with untreated control was also demonstrated in another trial conducted in Romania and in the trial carried out in Spain respectively in winter wheat. No differences were noted as compared the objects treated with SAP2101F with objects treated with reference products.

Yield quality was also evaluated in the trials on non-intentional effects of SAP2101F at 1,5 L/ha on transformation process on winter wheat (4 trials carried out in MED EPPO zone: Italy (2) and MAR EPPO zone: France (2)) and on winter barley (5 trials carried out in MED EPPO zone: Italy (2) and MAR EPPO zone: France (3)).

Moisture content – MOICON (recorded in 9 trials)

No statistically significant differences were noted between SAP2101F and reference products and untreated control in 9 trials carried out in winter wheat and winter barley.

Thousand grain weight – TGW (recorded in 6 trials)

No significant differences have been noted comparing results achieved for SAP2101F with reference products in 6 trials. No differences (2 trials in winter wheat and 2 trials in winter barley) or statistically significant higher efficacy (2 trials conducted in France and Italy in winter wheat) was noted as compared yield from the objects treated with SAP2101F with untreated control.

Hectolitre weight – HLW (recorded in 9 trials)

No differences (2 trials in winter wheat and 5 trials in winter barley) or statistically significant higher efficacy (2 trials conducted in France in winter wheat) was noted as compared yield from the objects treated with SAP2101F with untreated control. Statistically higher HLW for SAP2101F as compared with standard products was demonstrated in trial conducted in France in winter wheat. No differences between SAP2101F and reference products were observed in the last 8 trials conducted in winter wheat and winter barley.

No data on the effect of SAP2101F on yield quality is available for North-East EPPO zone for wheat. As no adverse effects have been observed in the submitted trials performed in SE, MAR and MED EPPO zone in winter wheat and in the trials conducted in MAR, NE, SE and MED EPPO zone in winter barley, and due to long experience of usage folpet and prothioconazole in cereals, lack of yield quality data from NE EPPO zone for wheat may be acceptable.

It can be concluded, that no negative impact of SAP2101F applied at recommended dose rate range 1,0-1,5 L/ha on the yield quality of winter wheat and winter barley is expected.

3.4.4 Effects on transformation processes (KCP 6.4.4)

According to EPPO guideline PP 1/243 (2) "*Effects of plant protection products on transformation processes":*

Effects on the processing procedure: BAKING

Four trials (25-TT-BM-2021-FR01, 25-TT-BM-2021-FR02, 25-TT-BM-2021-IT01 and 25-TT-BM-2021-IT02) were performed to study the unintentional effects of the product on quality of wheat on baking were done in France and Italy in 2021, in Maritime and Mediterranean EPPO zones.
SAP2101F at 1.5 L/ha (N) and two reference products PROSARO 250 EC (1 l/ha) and SESTO (1,5 l/ha) were tested for quality.
For detailed information on trials site and application details refer to Appendixes.

Hereafter, the conclusion of each trial is detailed.

- 25-TT-BM-2021-IT01

Considering chemical analysis results, it could be stated:
- no significant differences on most of the main qualitative parameters were assessed in wheat grain samples;
- significant difference on the parameters between Treatment 2 (SAP2101F) and
treatment 4 (PROSARO 250) noticed on Protein content and Alveogram of Chopen indexes were assessed in wheat flour samples.

After the Processing Phase, the product obtained (fresh bread) was used for the Taint test session performed on December 17th, 2021.
During this session, the assessors were not able to differentiate one sample from the other.
The comparison between processed product (bread) obtained from field specimens did not show any significant difference on the organoleptic parameters (smell, taste, odour, texture and colour).

- 25-TT-BM-2021-IT02

Considering chemical analysis results, it could be stated:
- no significant differences on most of the main qualitative parameters were assessed in wheat grain samples;
- significant difference on the parameters between Treatment 2 (SAP2101F) and
treatment 4 (PROSARO 250) noticed on Protein content and Alveogram of Chopen indexes were assessed in wheat flour samples.

After the Processing Phase, the product obtained (fresh bread) was used for the Taint test session performed on December 17th, 2021.
During this session, the assessors were not able to differentiate one sample from the other.
The comparison between processed product (bread) obtained from field specimens did not show any significant difference on the organoleptic parameters (smell, taste, odour, texture and colour).

- 25-TT-BM-2021-FR01

Considering the physicochemical analysis, significant differences were found between the grain from the experimental treatment SAP2101F and the grain from the untreated or the reference SESTO, for the Hagberg analysis, between the grains from the experimental treatment SAP2101F and the grain from the untreated for the thousand grains weight and between grains from the untreated and the other modalities (experimental and reference), for the impurities.

Regarding Zeleny index, there was no significant difference between the different modalities.

Regarding the alveogramm indexes, significant differences were found between untreated or experimental product SAP2101F and reference SESTO, between untreated or experimental product SAP2101F and reference SESTO for the dough tenacity and between untreated or experimental product SAP2101F and reference SESTO for the swelling index.
To conclude on the alveogramm indexes, experimental product SAP2101F obtained lower results than reference SESTO.

Regarding the baking test, dough, bread and crumb marks were good for all the modalities but lower for the reference SESTO.

Concerning the sensorial analysis results, no significant difference was found between breads stemming from untreated wheat and those from reference wheat treated with SESTO applied twice at 1,5 l/ha. Likewise, no significant difference was found between breads stemming from reference wheat treated with SESTO applied twice at 1,5 l/ha and those from experimental product SAP2101F applied twice at 1,5 L/ha.

However, looking into taster's comments, it was established that this difference was linked to texture or taste of bread. It seems that bread from experimental treatment SAP50SCF were preferred to the reference SESTO. Moreover, no chemical taste, odour, unpleasant taste was highlighted. Therefore, the difference did not seem to be associated with the applications of SAP50SCF applied twice at 1,5 L/ha.

Consequently, under these trial conditions and according the sensorial analysis results, we can conclude that, experimental treatment SAP2101F applied twice at 1,5 L/ha, did not lead to any significant modifications on organoleptic qualities compared with reference SESTO applied twice at 1,5 l/ha.

- 25-TT-BM-2021-FR02

Considering the physicochemical analysis, no significant differences were found between the grain from the untreated and the reference SESTO also between the experimental treatment SAP2101F and the grain from the reference SESTO.

Regarding Zeleny index, there was no significant difference between the different modalities.

Regarding the alveogramm indexes, no significant differences were found between the grain from the untreated and the reference SESTO also between the experimental treatment SAP2101F and the grain from the reference SESTO.

Regarding the baking test, dough, bread and crumb marks were good for all the modalities but lower for the reference SESTO.

Consequently, under these trial conditions and according to physicochemical results and the baking test the experimental product SAP2101F applied twice at 1,5 L/ha don't seem to have negative impact on the physicochemical.

Concerning the sensorial analysis results, no significant difference was found between breads stemming from untreated wheat and those from reference wheat treated with SESTO applied twice at 1,5 l/ha.
Likewise, no significant difference was found between breads stemming from reference wheat treated with SESTO applied twice at 1,5 l/ha and those from experimental product SAP2101F applied twice at 1,5 L/ha.

Consequently, under these trial conditions and according the sensorial analysis results, we can conclude that, experimental treatment SAP2101F applied twice at 1,5 L/ha, did not lead to any significant modifications on organoleptic qualities compared with reference SESTO applied twice at 1,5 l/ha.

Therefore, results from these 4 performed trials in Maritime and Mediterranean EPPO climatic zone, it can be concluded that SAP2101F do not have any negative impact on baking quality or bread testing.

Effects on the processing procedure: BREWING

To evaluate the effect of the formulated product SAP2101F (1,5 l/ha) when applied to barley for beer production, 5 trials were conducted in Italy and France, in Mediterranean and Maritime EPPO zones. From the 3 trials conducted in France (26-TT-BW-2021-FR01, 26-TT-BW-2021-FR02 and 26-TT-BW-2021-FR03) only 2 were selected to continue the analysis.

Hereafter, the conclusion of each trial is detailed.

- 26-TT-BW-2021-IT01

On July 5th 2021 (48 days after the last application), the harvest was performed. About 15 kg field specimens amount was obtained from each treatment to be subjected to the Processing Phases.

According to the results of the analysis on chemical parameters of barley, malt, wort and beer generally no significant differences were noticed among the treatments.

Anyway, for some parameters it was possible to notice some differences:

- significant differences among the barley samples about Protein content with the lowest value noticed on treatment T3 (PROSARO 250);
- significant differences among the barley samples about Germinative index with the highest value noticed on treatment T1 (SAP2101F) and lowest value on treatment T3 (PROSARO 250);
- significant differences among the beer samples about Apparent extract with the lowest value noticed on treatment 1 (SAP2101F);
- significant differences among the beer samples about Alcohol %v/v with the lowest value noticed on treatment 1 (SAP2101F);
- significant differences among the beer samples about Maintenance of foam with the highest values noticed on treatment 1 (SAP2101F).

Apart from the TKW differences on barley from the field, the other differences could not be a consequence of field applications but due at malting process and could be considered as a common variance. All matrix showed good qualitative characteristics typical of the commercial products.

After the Processing Phase, the product obtained (Beer) was used for the Taint test session performed on January 17th 2022. During this session, the assessors were not able to differentiate one sample from the other. The comparison between processed product (Beer) obtained from field specimens did not show any significant difference on the organoleptic parameters (smell, taste, odour and colour).

Generally, it could be stated that no undesired and unpleasant smells or tastes have been detected in all the analyzed samples.

- 26-TT-BW-2021-IT02

On June 28th 2021 (41 days after the last application), the harvest was performed. About 15 kg field specimens amount was obtained from each treatment to be subjected to the Processing Phases.

According to the results of the analysis on chemical parameters of barley, malt, wort and beer generally no significant differences were noticed among the treatments.

Anyway, for some parameters it was possible to notice some differences:
- among barley samples significant differences in germinative index were noticed, with the lowest value on treatment T1 (SAP2101F) and treatment 2 (SAP50SCF).
- among wort samples significant differences about Free aminic nitrogen (FAN) with the highest value noticed on treatment 1 (SAP2101F).
- among the beer samples significant differences about Apparent extract with the lowest value noticed on treatment 3 (PROSARO 250);

These differences could not be a consequence of field applications but due at malting process and could be considered as a common variance. All matrix showed good qualitative characteristics typical of the commercial products.

After the Processing Phases (malting and brewing), the processed product (beer) was used for the Taint test session performed on January 17th 2022. During this session, the assessors were not able to differentiate one sample from the other. The comparison between processed product (Beer) obtained from field specimens did not show any significant difference on the organoleptic parameters (smell, taste, odour and colour).

Generally, it could be stated that no undesired and unpleasant smells or tastes have been detected in all the analyzed samples.

- 26-TT-BW-FR01, 26-TT-BW-FR02 and 26-TT-BW-FR03 (field phase); RAF-1173 (processing phase)

- CONTROL OF BARLEY SPECIMENS ON RECEIPT

CEB method n° 185 dedicated to brewing barley mentions the following rules to initiate the brewing process study:

- Protein content: between 9 and 12% of dry matter
- Germination after 3 days > 95%
- Kernel size of barley (>2.5 mm) ≥ 60%
- Barley infested by mould < 2%
- Moisture content ≤ 15%.
-

The barley specimens from the trial 26B-TT-BW-2021-FR03 conform to the brewing criteria.
Most of the barley specimens from the trial 26B-TT-BW-2021-FR01 have a protein content <9%.
One barley specimen (E1173/007, plot 102 treatment SAP50SCF) from the trial 26B-TT-BW-2021-FR02 has a protein content <9%, but the fourth repetition (plot 402) for this treatment conform to the brewing criteria.
For the subsequent stages of the study were proposed the trials 26B-TT-BW-2021-FR03 and 26B-TTBW-2021-FR02.
Germinative energies ≤ 95% were redone on the specimens from the trials 26B-TT-BW-2021-FR03 and 26B-TT-BW-2021-FR02.
The specimens from the trial 26B-TT-BW-2021-FR01 were destroyed.

- MALTING STUDY

The malting experiments were carried out, according to the ISO/MPFE/001 procedure, in the IFBM micro-malting plant on 2 x 2.2 kg of calibrated barley (>2.5 mm), for each specimen.

JOAO (reference) – SAP2101F (treated 1)

	BARLEY									
>Significance reference										
> No significance reference										
= Reference	■		■		■		■		■	
< No significance reference										
< Significance reference										
■ :Winter barley	**Protein content**		**Germination index**		**Kernel size**		**DON**		**Ergosterol**	

	PHYSICO-CHEMICAL & FUNCTIONAL ANALYSES OF MALT															
>Significance reference																
> No significance reference			■													
= Reference	■				■		■		■		■		■		■	
< No significance reference																
< Significance reference																
■ :Winter barley	**Fine grind extract**		**β-glucans**		**Viscosity**		**Friability**		**Calcofluor (modification)**		**Filtration rate**		**Attenuation limit**		**Apparent gravity (8th day)**	

BREWERY												
> Significance reference												
> No significance reference												
= Reference			■		■		■		■		■	
< No significance reference	■											
< Significance reference												
■ : Winter barley	**Maïsche filtration**		**Free amino nitrogen**		**Time to ferment 5°Plato**		**Apparent attenuation**		**Head retention**		**Sensory analyses**	

IDENTITY CARD OF THE SPECIALITY

= Reference: the difference between the mean of « treated samples » and the mean of « reference samples » of 2 spots is between – ½ and + ½ of the significance difference.

< No significance reference: the difference between the mean of « treated samples » and the mean of « reference samples » of 2 spots is between – 1 and - ½ of the significance difference.

> No significance reference: the difference between the mean of « treated samples » and the mean of « reference samples » of 2 spots is between + ½ and + 1 of the significance difference.

< Significance reference: the difference between the mean of « treated samples » and the mean of « reference samples » of 2 spots is lower than the significance difference.

> Significance reference: the difference between the mean of « treated samples » and the mean of « reference samples » of 2 spots is upper than the significance difference.

These parameters are represented by their opposite: DON, ergosterol, β-glucans, viscosity, apparent gravity (8th day).

The results are similar between the reference and the treated samples.

Conclusion

To conclude, according to EPPO guideline PP 1/243 (2) "*Effects of plant protection products on transformation processes"* trials which were done to evaluate the effects of SAP2101F at 1,5 l/ha (N dose) on barley for brewing and on wheat for bread-making, showed consistent results to demonstrate the absence of non-intentional effects.

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

Results from 9 trials have been presented on non-intentional effects of SAP2101F at 1,5 L/ha on transformation processes on winter wheat (4 trials carried out in MED EPPO zone: Italy (2) and MAR EPPO zone: France (2)) and on winter barley (5 trials carried out in MED EPPO zone: Italy (2) and MAR EPPO zone: France (3)).
No negative impact of SAP2107F on baking quality or bread testing and on malting, brewing quality or beer testing was demonstrated in the presented trials.

It can be concluded, that adverse effect of SAP2101F applied at recommended dose rate range 1,0-1,5 L/ha on transformation processes: wheat bread-making and barley brewing is not expected.

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

Based on EPPO PP 1/135(4) '*Phytotoxicity assessment*' and PP 1/226(3) '*Number of efficacy trials'*, for fungicides, data on plant parts for propagation are only required when some phytotoxic effects are seen on some crops. As mentioned before, no phytotoxicity symptom were observed on any of the 74 performed trials across wheat and barley.

Therefore, additional evidence or justification for effects on parts of plants used for propagation should not be required.

Summary and conclusion on treated plants or plants products to be used for propagation

Based on EPPO PP 1/135(4) '*Phytotoxicity assessment*' the use of SAP2101F can be considered as safe for plant products to be used for propagation when applied following the corresponding GAP conditions.

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

According to the EPPO guideline PP 1/135(4) data on plants part for propagation are needed for fungicides when the plant protection product has systemic activity, is applied close to the harvest and some phytotoxic effects are seen on some crops. SAP2101F contains two active substances: folpet with contact action and prothioconazole with systemic action in plants. SAP2101F is intended to be applied up to BBCH 61. No phytotoxicity symptoms have been observed in any of 74 trials conducted in wheat and barley. Data on effect on the viability, germination capacity and development of seeds would be advisable regarding systemic action of prothioconazole. However, prothioconazole and folpet are known active substances, used in cereal crop protection for many years. No cases of adverse effects of folpet or prothioconazole on cereal crop seeds have been documented and reported yet.
It can be concluded, that adverse effect of SAP2101F on plant parts used for propagation is not expected.

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

3.5.1 Impact on succeeding crops (KCP 6.5.1)

According to EPPO guideline PP1/207(2) "*Effects on succeeding crops*": *"If the TER (Toxicity-Exposure Ratio) values are >1 (or the specific national level, if higher), then no further testing is necessary."*

$TER = EC_{10} / PEC_{soil} > 1$

A study for seedling emergence ~~and vegetative vigor~~ was performed on the Ecotox section following OECD 208.

Four dicotyledonous (oilseed rape, sugar beet, soybean, tomato) and two monocotyledonous species (ryegrass, onion) were cultivated in soil. 'Prothioconazole + Folpet 120+300 g/L SC - SAP2101F' was applied at five defined application rates ranging from 0,1781 to 2,8500 L test item/ha. In each treatment group a total of 20 seeds were applied. The test observation period was 21 day after 50 % of the seedlings in the control group had emerged. During this period, plants were assessed for mortality and phytotoxicity symptoms on day 7, 14 and 21 after 50 % of the seedlings in the control group had emerged. The effects on plant shoot height and shoot dry weight were determined for day 21. Results were compared to the water treated control.

The tested rates of SAP2101F were: 0,1781, 0,3563, 0,7125, 1,4250 and 2,8500 L test item/ha in 200 L spray solution/ha.

Seedling emergence, mortality, phytotoxicity, growth stage, shoot height and shoot dry weight; NOER (No Observed Effect Rate), LOER (Lowest Observed Effect Rate) and the ER10, 25, 50 (Effect Rate for 10 %, 25 %, 50 % effect) on seedling emergence, shoot height and shoot dry weight for day 21 after at least 50 % of the seedlings in the control had emerged; and LR10, 25, 50 (Lethal Rate for 10 %, 25 %, 50 % effect) for mortality for day 21 after at least 50 % of the seedlings in the control had emerged, where possible were assessed.

Despite no EC_{10} value was calculated, a similar value (worst case) was taken from this study (NOER value).

$TER = NOER / PEC_{soil} > 1$

EC10: dose which causes 10% of damage to the tested crop.
NOER: dose which causes none damage to the tested crop.
PEC_{soil}: concentration of the product on soil.

Tables below show that no damage is caused on the tested crops at 2,85 L/ha.

Table 3.5.1.1 NOER, LOER and $ER_{10, 25, 50}$ of 'Prothioconazole + Folpet 120+300 g/L SC - SAP2101F' for seedling emergence

Family	Species	Common Name	'Prothioconazole + Folpet 120+300 g/L SC - SAP2101F' [L test item/ha]				
			NOER	LOER	ER_{10} (95 % Confidence Limits)	ER_{25} (95 % Confidence Limits)	ER_{50} (95 % Confidence Limits)
Dicotyledonous species							
Brassicaceae	*Brassica napus*	Oilseed rape	≥2,850	>2,850	>2,850	>2,850	>2,850
Amaranthaceae	*Beta vulgaris*	Sugar beet	≥2,850	>2,850	>2,850	>2,850	>2,850
Fabaceae	*Glycine max*	Soybean	≥2,850	>2,850	>2,850	>2,850	>2,850
Solanaceae	*Lycopersicon esculentum*	Tomato	≥2,850	>2,850	>2,850	>2,850	>2,850
Monocotyledonous species							
Poaceae	*Lolium perenne*	Ryegrass	≥2,850	>2,850	>2,850	>2,850	>2,850
Amaryllidaceae	*Allium cepa*	Onion	≥2,850	>2,850	>2,850	>2,850	>2,850

Table 3.5.1.2 NOER, LOER and $LR_{10, 25, 50}$ of 'Prothioconazole + Folpet 120+300 g/L SC - SAP2101F' for mortality

Family	Species	Common Name	'Prothioconazole + Folpet 120+300 g/L SC - SAP2101F' [L test item/ha]				
			NOER	LOER	LR_{10}	LR_{25}	LR_{50}
Dicotyledonous species							
Brassicaceae	*Brassica napus*	Oilseed rape	≥2,850	>2,850	>2,850	>2,850	>2,850
Amaranthaceae	*Beta vulgaris*	Sugar beet	≥2,850	>2,850	>2,850	>2,850	>2,850
Fabaceae	*Glycine max*	Soybean	≥2,850	>2,850	>2,850	>2,850	>2,850
Solanaceae	*Lycopersicon esculentum*	Tomato	≥2,850	>2,850	>2,850	>2,850	>2,850
Monocotyledonous species							
Poaceae	*Lolium perenne*	Ryegrass	≥2,850	>2,850	>2,850	>2,850	>2,850
Amaryllidaceae	*Allium cepa*	Onion	≥2,850	>2,850	>2,850	>2,850	>2,850

Table 3.5.1.3 NOER, LOER and $ER_{25, 50}$ of 'Prothioconazole + Folpet 120+300 g/L SC - SAP2101F' for shoot height

Family	Species	Common Name	'Prothioconazole + Folpet 120+300 g/L SC - SAP2101F' [L test item/ha]				
			NOER	LOER	ER_{10}	ER_{25}	ER_{50}
Dicotyledonous species							
Brassicaceae	*Brassica napus*	Oilseed rape	≥2,850	>2,850	>2,850	>2,850	>2,850
Amaranthaceae	*Beta vulgaris*	Sugar beet	≥2,850	>2,850	>2,850	>2,850	>2,850
Fabaceae	*Glycine max*	Soybean	≥2,850	>2,850	>2,850	>2,850	>2,850
Solanaceae	*Lycopersicon esculentum*	Tomato	≥2,850	>2,850	>2,850	>2,850	>2,850
Monocotyledonous species							
Poaceae	*Lolium perenne*	Ryegrass	≥2,850	>2,850	>2,850	>2,850	>2,850
Amaryllidaceae	*Allium cepa*	Onion	≥2,850	>2,850	>2,850	>2,850	>2,850

Table 3.5.1.4 NOER, LOER and $ER_{10,25,50}$ of 'Prothioconazole + Folpet 120+300 g/L SC - SAP2101F' for shoot dry weight

Family	Species	Common Name	'Prothioconazole + Folpet 120+300 g/L SC - SAP2101F' [L test item/ha]				
			NOER	LOER	ER_{10}	ER_{25}	ER_{50}
Dicotyledonous species							
Brassicaceae	*Brassica napus*	Oilseed rape	≥2,850	>2,850	>2,850	>2,850	>2,850
Amaranthaceae	*Beta vulgaris*	Sugar beet	≥2,850	>2,850	>2,850	>2,850	>2,850
Fabaceae	*Glycine max*	Soybean	≥2,850	>2,850	>2,850	>2,850	>2,850
Solanaceae	*Lycopersicon esculentum*	Tomato	≥2,850	>2,850	>2,850	>2,850	>2,850
Monocotyledonous species							
Poaceae	*Lolium perenne*	Ryegrass	≥2,850	>2,850	>2,850	>2,850	>2,850
Amaryllidaceae	*Allium cepa*	Onion	≥2,850	>2,850	>2,850	>2,850	>2,850

Results from Seedling emergence and growth test of six non-target terrestrial plant species show that:

- **Seedling emergence**: no significant effects on emergence were observed for all the tested species,
- **Mortality**: none of the tested rates of the test item 'Prothioconazole + Folpet 120+300 g/L SC - SAP2101F' affected the survivorship of the tested species,
- **Phytotoxicity**: None of the tested rates of the test item 'Prothioconazole + Folpet 120+300 g/L SC - SAP2101F' showed phytotoxicity symptoms for any of the tested species,
- **Growth Stage**: No differences in growth stage could be detected between the test item groups and the controls for the six tested species at any of the rates tested,
- **Shoot Height:** No differences in growth stage could be detected between the test item groups and the controls for the six tested species at any of the rates tested,
- **Shoot dry weight:** No statistically significant reductions on shoot dry weight were observed for tested treatment rates of the test item 'Prothioconazole + Folpet 120+300 g/L SC - SAP2101F' for all six tested species.

Conclusion: It can be concluded that 'Prothioconazole + Folpet 120+300 g/L SC - SAP2101F' has no significant effects on mortality, on shoot height and on shoot dry weight in any of the tested species.
The overall NOER was estimated to be ≥2,850 L test item/ha (equivalent to 331,46 g prothioconazole/ha and 885,21 g folpet/ha).

No PECsoil value was determined in the test. Being 1,5 l/ha the higher dose of SAP2101F used on cereals, the worst ~~situation~~ -case scenario ~~would be~~ was assumed for calculation TER value:

TER= 2,850 L/ha / 1,5 L/ha = 1,9 (>1)

To conclude, according to the results of the Toxicity-Exposure Ratio (TER) in the worst-case scenario, no further evaluations are necessary as no negative effects on succeeding crops are likely to be observed following SAP2101F application.

Comments of zRMS on:
Impact on succeeding crops (3.5.1)

Results from Seedling emergence and growth test of six non-target terrestrial plant species: oilseed rape, sugar beet, soybean, tomato, ryegrass, onion demonstrated no negative effect of SAP2101F applied at dose rate up to 2,85 L/ha on seedling emergence, growth stage, shoot height, shoot dry weight and survivorship of tested crops. No phytotoxicity symptoms on the tested species were observed.

Based on the submitted data and regarding the calculation of the Toxicity-Exposure Ratio (TER) in the worst-case scenario assumed by the Applicant **it can be concluded, that adverse effect of SAP2101F applied at recommended dose rate range 1,0-1,5 L/ha on succeeding crops is not expected.**

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

According to EPPO Guideline PP1/256(1) – "*Effects on adjacent crops*", "*If the TER-value of the most sensitive crop is greater than 1 (or the specific national level, if higher), no further testing is necessary.*"

The TER-value is calculated by comparing the biological activity (ED50-value for each plant species) to the estimated drift values in order to predict the likelihood of effects on adjacent crops at different distances from the treated crop.

$$TER = \frac{ED_{50}}{drift\ (estimated\ )}$$

A study on the effect on the vegetative vigour of six non-target terrestrial plant species test was performed following OECD 227.

Four dicotyledonous (oilseed rape, sugar beet, soybean, tomato) and two monocotyledonous species (ryegrass, onion) were cultivated in soil. 'Prothioconazole + Folpet 120+300 g/L SC - SAP2101F' was applied at five defined application rates ranging from 0,1781 to 2,8500 L test item/ha. In each treatment group a total of 20 plants at BBCH growth stage 12 – 14 were applied. The test observation period was 21 days following application. During this period, plants were assessed for mortality and phytotoxicity symptoms on day 7, 14 and 21. The effects on plant shoot height and shoot dry weight were determined for day 21. Results were compared to the tap water treated control.

The tested rates of SAP2101F were: 0,1781, 0,3563, 0,7125, 1,4250 and 2,8500 L test item/ha in 200 L spray solution/ha.

Mortality, phytotoxicity, growth stage, shoot height and shoot dry weight; NOER (No Observed Effect Rate), LOER (Lowest Observed Effect Rate) and ER10, 25, 50 (Effect Rate for 10, 25, 50 %) for effect on shoot height and shoot dry weight on day 21, where possible, and LR10,25,50 (Lethal rate for 10, 25, 50 %) were assessed.

Results from this study are presented below:

MORTALITY

Table 3.5.2.1: Mean mortality data

Treatment		**Mean Mortality %**					
ID	**L test item/ha**	***Brassica napus***	***Beta vulgaris***	***Glycine max***	***L. esculentum***	***Lolium perenne***	***Allium cepa***
C	0,0000	0,00	0,00	0,00	0,00	0,00	0,00
T1	0,1781	0,00	0,00	0,00	0,00	0,00	0,00
T2	0,3563	0,00	0,00	0,00	0,00	0,00	0,00
T3	0,7125	0,00	0,00	0,00	0,00	0,00	0,00
T4	1,4250	0,00	0,00	0,00	0,00	0,00	0,00
T5	2,8500	0,00	0,00	0,00	0,00	0,00	0,00

Table 3.5.2.2: Effects on mortality (based on nominal rates)

Family	Species	Common Name	'Prothioconazole + Folpet 120+300 g/L SC - SAP2101F' [L test item/ha]				
			NOER	LOER	~~ER~~ LR_{10} ~~(95 % Confidence Limits)~~	~~ER~~ LR_{25} ~~(95 % Confidence Limits)~~	~~ER~~ LR_{50} ~~(95 % Confidence Limits)~~
Dicotyledonous species							
Brassicaceae	*Brassica napus*	Oilseed rape	≥2,850	>2,850	>2,850	>2,850	>2,850
Amaranthaceae	*Beta vulgaris*	Sugar beet	≥2,850	>2,850	>2,850	>2,850	>2,850
Fabaceae	*Glycine max*	Soybean	≥2,850	>2,850	>2,850	>2,850	>2,850
Solanaceae	*Lycopersicon esculentum*	Tomato	≥2,850	>2,850	>2,850	>2,850	>2,850
Monocotyledonous species							
Poaceae	*Lolium perenne*	Ryegrass	≥2,850	>2,850	>2,850	>2,850	>2,850
Amaryllidaceae	*Allium cepa*	Onion	≥2,850	>2,850	>2,850	>2,850	>2,850

None of the tested rates of the test item 'Prothioconazole + Folpet 120+300 g/L SC - SAP2101F' affected the survivorship of the tested species.

PHYTOTOXICITY

Table 3.5.2.3 NOER and LOER relative to the parameter "phytotoxicity" (based on nominal rates)

	Brassica napus	*Beta vulgaris*	*Glycine max*	*L.esculentum*	*Lolium perenne*	*Allium cepa*
Rate (L test item/ha)						
LOER	≥2,850	≥2,850	≥2,850	≥2,850	≥2,850	≥2,850
NOER	≥2,850	≥2,850	≥2,850	≥2,850	≥2,850	≥2,850

None of the tested rates of the test item 'Prothioconazole + Folpet 120+300 g/L SC - SAP2101F' showed phytotoxicity symptoms for any of the tested species.

GROWTH STAGE

No differences in growth stage could be detected between the test item groups and the control for the six tested species at any of the rates tested.

SHOOT HEIGHT

Table 3.5.2.4: NOER, LOER and ER10, 25, 50 of 'Prothioconazole + Folpet 120+300 g/L SC - SAP2101F' for shoot height after 21 days

Family	Species	Common Name	'Prothioconazole + Folpet 120+300 g/L SC - SAP2101F' [L test item/ha]				
			NOER	LOER	ER_{10}	ER_{25}	ER_{50}
Dicotyledonous species							
Brassicaceae	*Brassica napus*	Oilseed rape	≥2,850	>2,850	>2,850	>2,850	>2,850
Amaranthaceae	*Beta vulgaris*	Sugar beet	≥2,850	>2,850	>2,850	>2,850	>2,850
Fabaceae	*Glycine max*	Soybean	≥2,850	>2,850	>2,850	>2,850	>2,850
Solanaceae	*Lycopersicon esculentum*	Tomato	≥2,850	>2,850	>2,850	>2,850	>2,850

Monocotyledonous species							
Poaceae	*Lolium perenne*	Ryegrass	≥2,850	>2,850	>2,850	>2,850	>2,850
Amaryllidaceae	*Allium cepa*	Onion	≥2,850	>2,850	>2,850	>2,850	>2,850

No statistically significant reductions on shoot height were observed for tested treatment rates of the test item 'Prothioconazole + Folpet 120+300 g/L SC - SAP2101F' for all six tested species.
The species *Lolium perenne* (ryegrass) showed statistically significant reduction in final shoot height in the treatments T3 and T4, but the reduction was most probably due to a biological variability as no statistically significant reduction was observed in the treatment T5. Consequently, the NOER is reported as the highest rate tested.
The species *Allium cepa* (onion) showed statistically significant reduction in final shoot height in the treatment T3, but the reduction was most probably due to a biological variability as no statistically significant reduction was observed in the treatments T4 and T5. Consequently, the NOER is reported as the highest rate tested.

SHOOT DRY WEIGHT

Table 3.5.2.5: NOER, LOER and ER10, 25, 50 of 'Prothioconazole + Folpet 120+300 g/L SC - SAP2101F' for shoot dry weight after 21 days

Family	Species	Common Name	'Prothioconazole + Folpet 120+300 g/L SC - SAP2101F' [L test item/ha]				
			NOER	LOER	ER_{10}	ER_{25}	ER_{50}
Dicotyledonous species							
Brassicaceae	*Brassica napus*	Oilseed rape	≥2,850	>2,850	>2,850	>2,850	>2,850
Amaranthaceae	*Beta vulgaris*	Sugar beet	≥2,850	>2,850	>2,850	>2,850	>2,850
Fabaceae	*Glycine max*	Soybean	≥2,850	>2,850	>2,850	>2,850	>2,850
Solanaceae	*Lycopersicon esculentum*	Tomato	≥2,850	>2,850	>2,850	>2,850	>2,850
Monocotyledonous species							
Poaceae	*Lolium perenne*	Ryegrass	≥2,850	>2,850	>2,850	>2,850	>2,850
Amaryllidaceae	*Allium cepa*	Onion	≥2,850	>2,850	>2,850	>2,850	>2,850

No statistically significant reductions on shoot dry weight were observed for tested treatment rates of the test item 'Prothioconazole + Folpet 120+300 g/L SC - SAP2101F' for all six tested species.
The species *Allium cepa* (onion) showed statistically significant reduction in final shoot dry weight in the treatment T2, but the reduction was most probably due to a biological variability as no statistically significant reduction was observed in the treatments T3, T4 and T5. Consequently, the NOER is reported as the highest rate tested.

Conclusions:

The study was considered valid for all species; emergence recorded was ≥ 70 % (actually: 95,96 % to 99,26 %) and mean survival of the control plants was ≥ 90 % (actually: 100 %), moreover, no phytotoxic effects were detected in the control plants and the the cultivation conditions were identical for a particular species. Correct rate preparation and application was confirmed by analysis of the stock solution, with recoveries of 103 % of prothioconazole and 105 % of folpet and via calibration of the spray equipment.
It can be concluded that 'Prothioconazole + Folpet 120+300 g/L SC - SAP2101F' has no significant effects on mortality, on shoot height and on shoot dry weight in any of the tested species. The overall NOER was estimated to be ≥ 2,850 L test item/ha (equivalent to 331,46 g prothioconazole/ha and 885,21 g folpet/ha).

Table 3.5.2.3: Mean emergence data

Treatment		Mean emergence %					
ID	L test item/ha	*Brassica napus*	*Beta vulgaris*	*Glycine max*	*Lycopersicon esculentum*	*Lolium perenne*	*Allium cepa*
C	0.0000	100.00	95.00	100.00	95.00	85.00	75.00
T1	0.1781	95.00	100.00	100.00	100.00	85.00	75.00
T2	0.3563	95.00	100.00	100.00	100.00	95.00	90.00
T3	0.7125	95.00	100.00	90.00	95.00	90.00	90.00
T4	1.4250	100.00	100.00	100.00	100.00	90.00	70.00
T5	2.8500	100.00	100.00	100.00	100.00	100.00	90.00

C: control; T: Test item treatment

Table 3.5.2.4: Effects on emergence (based on nominal rates)

Family	Species	Common Name	'Prothioconazole + Folpet 120+300 g/L SC – SAP2101F' [L test item/ha]				
			NOER	LOER	ER_{10} (95 % Confidence Limits)	ER_{25} (95 % Confidence Limits)	ER_{50} (95 % Confidence Limits)
Dicotyledonous species							
Brassicaceae	*Brassica napus*	Oilseed rape	≥2.850	>2.850	>2.850	>2.850	>2.850
Amaranthaceae	*Beta vulgaris*	Sugar beet	≥2.850	>2.850	>2.850	>2.850	>2.850
Fabaceae	*Glycine max*	Soybean	≥2.850	>2.850	>2.850	>2.850	>2.850
Solanaceae	*Lycopersicon esculentum*	Tomato	≥2.850	>2.850	>2.850	>2.850	>2.850
Monocotyledonous species							
Poaceae	*Lolium perenne*	Ryegrass	≥2.850	>2.850	>2.850	>2.850	>2.850
Amaryllidaceae	*Allium cepa*	Onion	≥2.850	>2.850	>2.850	>2.850	>2.850

Table 3.5.2-1: PEC-values (kg/ha) (drift)

Distance to adjacent crop (m)	Drift (%)	Drift test product (L/ha) 1.5 L/ha of SAP2101F
1	2.77	0,042
3	0.95	0,014
5	0.57	0,009
10	0.29	0,004
15	0.20	0,003

The calculation of TER value is presented below.

Table 3.5.2-16: Lower NOER-values (L/ha) of different test plants

Test plant		NOER test product (L/ha)	
Common name	**Scientific name**	**Seedling emergence test**	**Vegetative Vigour Test**
All tested crops		2,85	
All tested crops			2,85

Table 3.5.2-17: TER-values according to the lower NOER

Distance to adjacent crop (m)	Drift (%)	Drift test product 1.5 L/ha of SAP2101F	TER for NOER, ER_{50} = 2,85 L/ha 1,5 L/ha of SAP50SCF
1	2,77	0,042	68,6
3	0,95	0,014	200,0
5	0,57	0,009	333,3
10	0,29	0,004	655,2
15	0,20	0,003	950,0

$TER = ER_{50} / Drift > 1$

The TER values are greater than 1 and consequently, the risk is acceptable to non-target higher plants when SAP2101F is applied according to the GAP with a 1 m buffer zone.

Tank cleaning

An insufficient tank cleaning can cause adverse effects on other plants (following crops treated by using the same tank). Therefore, one GLP study to determine the effectiveness of tank cleaning procedure for **SAP2101F** was conducted by ASCENZA Agro S.A.: Study EF/372/21, to demonstrate that residues of the plant protection product do not remain in the application equipment after cleaning, and that there is no risk to subsequently treated crops.

The study was conducted following PSD Efficacy Guideline 302, September 2005 and PSD Efficacy Guideline 305, December 2004.

The residue level of Prothioconazole in the effectiveness of cleaning procedure performed using water D found is 0,016%.
The residue level of Folpet in the effectiveness of cleaning procedure performed using water D found is 0,035%.

Based on these results, the main residues on SAP2101F are related to Folpet, with a 0,035%.
The risk evaluation is then performed considering this value, taking 1,5 L/ha of SAP2101F and 150 L/ha of water volume as the worst case and considering the NOER (2,85 L/ha).

The following table summarizes the remaining of SAP2101F per tank considering different tank volumes (from 1000 to 3000 L) and TER values calculated considering a 400 l/ha application (according to the example given in Appendix 4 of EPPO guideline 1/292(2) “Cleaning pesticide application equipment”.

Tank capacity (L)	Dose in tank	Residue in tank (L)	NOER (L/ha)	Application rate at (400 L/ha)	TER
1000	10	0,0035	2,85	0,0014	2035,7
2000	20	0,007	2,85	0,0028	1017,9
3000	30	0,0105	2,85	0,0042	678,6

In all cases, TER values are >1 so a safe use can be assumed.

Therefore, according to data submitted, the risk of impact of **SAP2101F** on the impact on other plants including adjacent crops can be considered like acceptable when it is applied following the corresponding GAP.
Besides, all data submitted revealed no negative impact of **SAP2101F** on crops treated after the tank cleaning.

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

Results from the study on the effect on the vegetative vigour of six non-target terrestrial plant species: oilseed rape, sugar beet, soybean, tomato, ryegrass, onion demonstrated no negative effect of SAP2101F applied at dose rate up to 2,85 L/ha on growth stage, shoot height, shoot dry weight and survivorship of tested crops. No phytotoxicity symptoms on the tested species were observed.

Based on the submitted data and according to the calculation of the Toxicity-Exposure Ratio (TER) presented by the Applicant **it can be concluded, that adverse effect of SAP2101F applied at recommended dose rate range 1,0-1,5 L/ha on adjacent crops is not expected.**
According to the rules of Good Agricultural Practice, to avoid any risk of adverse effects on adjacent crops, it is recommended to include, in the product label, the following remark: *When using SAP2101F do not allow spray drift to the neighbouring crop plantations*.

Tank cleaning
According to the decision scheme presented in Appendix 1 of the EPPO PP 1/292 (1) guidance Cleaning pesticide application equipment (PAE) – efficacy aspects: in the absence of phytotoxicity symptoms (here the Seedling emergence and Vegetative vigour tests presented in the preceding chapters) additional data should not be required. The additional TER calculation, presented by the applicant confirms the safety of any subsequent treatments with the equipment used previously for application of SAP50SCF.
The presented data highlight the importance of sufficient tank cleaning procedure as necessary to achieve a residue level of the plant protection product that poses no risk to the crops treated following tank cleaning.
It is recommended to follow the principles of Good Plant Protection Practice when tank cleaning.

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

Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in Part B, Section 9 (Ecotoxicology).

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. Detailed studies are contained in Part B, Section 9 (Ecotoxicology).

3.6 Other/special studies

No other studies are submitted.

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)
Agroensayos, Ensayos y Técnicas Agrícolas S.L.	Calle Esparragal, 4 Pol. Ind. El Esparragal, Santovenia de Pisuerga, 47155 Spain	Yes
AGROFIL	9235 Püski, Petőfi Sándor utca 7 Hungary	Yes
AgroProspect SRL	Fantana 1 Brasov 507099 Romania	Yes
ESSAIS +	1 rue du 8 mai Boyelles, 62128 France	Yes
Fertico Sp. z o.o.	Goliany 43 Błędów, 05-620 Poland	Yes
Field Research Support	Potts Kamp 8 31515 Wunstorf Germany	Yes
i2LResearch	Shotley Bridge - Consett – County Durham, DH8 6SB United Kingdom	Yes
OAT (Central)	Stratton Audley Oxfordshire OX27 9AS United Kingdom	Yes
Oxford Agricultural Trials	West Farm Barn, Launton Road, Stratton Audley Oxfordshire OX27 9AS United Kingdom	Yes
QUALIPHYT	80, chemin de Riboulin, Loriol-sur-Drôme, 26270 France	Yes
SAGEA Centro di Saggio S.r.l.	Via San Sudario, 15, Castagnito d'Alba (CN), 12050 Italy	Yes
Sagea OOD	Akchelar 522 Varna, 9000 Italy	Yes
STAPHYT	La Paluzette Route des Mas, Marsillargues, 34590 France	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 (0)	ASCENZA AGRO	2022	Biological Assessment Dossier of SAP2101F	N	ASCENZA AGRO
KCP 6 (1)	ASCENZA AGRO	2024	Erratum on Biological Assessment Dossier of SAP2101F	N	ASCENZA AGRO
KCP 6.1 (1)	Castella, G.	2020	Study the benefit of SAP50SCF in the preventions on resistances in Wheat against *Zimoseptoria tritici* under controled conditions. Italy 2021 Sagea Centro di Saggio s.r.l; 63-F-2020-FR01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (1) 6.1 6.2 6.4	Desogus, S.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against Septoria on Winter wheat. Bulgaria 2020 Sagea Centro di Saggio s.r.l; 10B-F-2020-BG01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (2) 6.4	Biaunier, M.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against Septoria on Wheat QUALIPHYT; 10B-F-2020-FR01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (3) 6.4	Herrera, D.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against Septoria on Wheat STAPHYT; 10B-F-2020-FR02 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (4) 6.2 6.4	Zöllner, H.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against Septoria on Wheat Field Research Support;	N	ASCENZA AGRO

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**
			10B-F-2020-PL01 GEP Unpublished		
KCP 6.2 (5) 6.2 6.4	Zöllner, H.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against Septoria on Wheat Field Research Support; 10B-F-2020-PL02 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (6) 6.2 6.4	Herrera, D.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against Septoria on Wheat STAPHYT; 10B-F-2020-PL03 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (7) 6.2 6.4	Herrera, D.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against Septoria on Wheat STAPHYT; 10B-F-2020-PL04 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (8) 6.2 6.4	Herrera, D.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against Septoria on Wheat STAPHYT; 10B-F-2020-RO01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (9) 6.2 6.4	Herrera, D.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against Septoria on Wheat STAPHYT; 10B-F-2020-RO02 GEP Unpublished	N	ASCENZA AGRO

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 (10) 6.1 6.2 6.4	Botoman, G.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against Septoria on Wheat AgroProspect SRL; 10B-F-2020-RO03 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (11) 6.2 6.4	Zöllner, H.	2020	Field study to evaluate the efficacy and crop selectivity of mixtures based on SAP250F and SAP50SCF against Septoria on Wheat Field Research Support; 10-F-2020-DE01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (12) 6.2 6.4	Zöllner, H.	2020	Field study to evaluate the efficacy and crop selectivity of mixtures based on SAP250F and SAP50SCF against Septoria on Wheat Field Research Support; 10-F-2020-DE02 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (13) 6.1 6.2 6.4	Biaunier, M.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against Septoria on Wheat QUALIPHYT; 10-F-2020-FR01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (14) 6.1 6.2 6.4	Biaunier, M.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against Septoria on Wheat QUALIPHYT; 10-F-2020-FR02 GEP Unpublished	N	ASCENZA AGRO

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 (15) 6.1 6.2 6.4	Rivet, J. Crepin, D.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against Septoria on Wheat ESSAIS+; 10-F-2020-FR03 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (16) 6.1 6.4	Desogus, S.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against Septoria on Wheat, Italy 2020 SAGEA Centro di Saggio s.r.l.; 10-F-2020-IT01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (17) 6.1 6.4	Hernández, J. M.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against Septoria on Wheat Agroensayos; 10-F-2020-SP01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (18) 6.4	Ord, S.	2020	Field study to evaluate the efficacy and crop selectivity of mixtures based on SAP250F and SAP50SCF against Septoria on Wheat i2LResearch; 10-F-2020-UK01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (19) 6.1 6.2 6.4	Desogus, S.	2021	Evaluate the efficacy of mixtures based on SAP2101F against Septoria tritici and Erysiphe graminis on Wheat. Bulgaria 2021 SAGEA Centro di Saggio s.r.l.; 03A-F-2021-BG01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (20) 6.1	Zöllner, H.	2021	Field study to evaluate the efficacy and crop selectivity of SAP2101F (mixtures based on SAP250F and SAP50SCF) against Septoria on Wheat	N	ASCENZA AGRO

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
6.2 6.4			FIELD RESEARCH SUPPORT; 03A-F-2021-DE01 GEP Unpublished		
KCP 6.2 (21) 6.1 6.4	Biaunier, M.	2021	Evaluate the efficacy of SAP2101F against Septoria on Wheat QUALIPHYT; 03A-F-2021-FR01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (22) 6.1 6.2 6.4	Crepin, D.	2021	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against Septoria on wheat ESSAIS+; 03A-F-2021-FR02 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (23) 6.1 6.2 6.4	Zöllner, H.	2021	Field study to evaluate the efficacy and crop selectivity of SAP2101F (mixtures based on SAP250F and SAP50SCF) against Septoria on Wheat (Poland) FIELD RESEARCH SUPPORT; 03A-F-2021-PL01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (24) 6.1 6.2 6.4	Herrera, D.	2021	Evaluate the efficacy of SAP2101F (mixtures based on SAP250F and SAP50SCF) against Septoria on Wheat, GEP Trial, POLAND, 2021 STAPHYT; 03A-F-2021-PL02 GEP Unpublished	N	ASCENZA AGRO

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 (25) 6.1 6.2 6.4	Botoman, G.	2021	Evaluate the efficacy of SAP2101F against Septoria on wheat GEP Trial, ROMANIA, 2021 Agroprospect; 03A-F-2021-RO01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (26) 6.1 6.2 6.4	Desogus, S.	2021	Evaluate the efficacy of mixtures based on SAP2101F against Zymoseptoria tritici and Blumeria graminis tritici on Wheat. Bulgaria 2021 SAGEA Centro di Saggio s.r.l.; 03B-F-2021-BG01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (27) 6.1 6.2 6.4	Desogus, S.	2021	Evaluate the efficacy of mixtures based on SAP2101F against Septoria on Wheat. Bulgaria 2021 SAGEA Centro di Saggio s.r.l.; 03B-F-2021-BG02 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (28) 6.1 6.4	Biaunier, M.	2021	Evaluate the efficacy of SAP2101F against Septoria on Wheat Qualiphyt; 03B-F-2021-FR01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (29) 6.1 6.2 6.4	Crepin, D.	2021	Evaluate the efficacy of SAP2101F against Septoria on wheat ESSAIS+; 03B-F-2021-FR02 GEP Unpublished	N	ASCENZA AGRO

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 (30) 6.4	Kasztner, G.	2021	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against Septoria on Wheat AGROFIL; 03B-F-2021-HU01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (31) 6.2 6.4	Rusek, K.	2021	Evaluate the efficacy of mixtures based on SAP2101F against Septoria on Winter Wheat, Poland 2020/2021 FERTICO Sp. z.o.o.; 03B-F-2021-PL01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (32) 6.2 6.4	Herrera, D.	2021	Evaluate the efficacy of SAP2101F (mixtures based on SAP250F and SAP50SCF) against Septoria on Wheat, GEP Trial, POLAND, 2021 STAPHYT; 03B-F-2021-PL02 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (33) 6.1 6.2 6.4	Herrera, D.	2021	Evaluate the efficacy of SAP2101F (mixtures based on SAP250F and SAP50SCF) against Septoria on Wheat, GEP Trial, POLAND, 2021 STAPHYT; 03B-F-2021-PL03 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (34) 6.1 6.2 6.4	Botoman, G.	2021	Evaluate the efficacy of SAP2101F against Septoria on wheat GEP Trial, ROMANIA, 2021 AgroProspect SRL; 03B-F-2021-RO01 GEP Unpublished	N	ASCENZA AGRO

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 (35) 6.4	Hernández, J.M.	2021	Evaluate the efficacy of mixtures based on SAP2101F against Septoria on Wheat Agroensayos; 03B-F-2021-SP01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (36) 6.1 6.4	Hernández, J.M.	2021	Evaluate the efficacy of mixtures based on SAP2101F against Septoria on Wheat Agroensayos; 03B-F-2021-SP02 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (37) 6.1 6.2 6.4	Zöllner, H.	2021	Field study to evaluate the efficacy and crop selectivity of SAP2101F (mixtures based on SAP250F and SAP50SCF) against Septoria on Wheat (United Kingdom) Field Research Support; 03B-F-2021-UK01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (38) 6.1 6.4	Desogus, S.	2021	Evaluate the efficacy of mixtures based on SAP2101F against Zymoseptoria tritici on Wheat. Italy 2021 SAGEA Centro di Saggio s.r.l.; 03A-F-2020-IT01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (39) 6.4	Zöllner, H.	2020	Field study to evaluate the efficacy and crop selectivity of mixtures based on SAP250F and SAP50SCF against Helmintosporium on Barley Field Research Support; 11-F-2020-DE01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (40) 6.4	Zöllner, H.	2020	Field study to evaluate the efficacy and crop selectivity of mixtures based on SAP250F and SAP50SCF against Helmintosporium on Barley Field Research Support;	N	ASCENZA AGRO

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
			11-F-2020-DE02 GEP Unpublished		
KCP 6.2 (41) 6.1 6.2 6.4	Biaunier, M.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against Helmintosporium on Barley QUALIPHYT; 11-F-2020-FR01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (42) 6.4	Biaunier, M.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against Helmintosporium on Barley QUALIPHYT; 11-F-2020-FR02 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (43) 6.1 6.2 6.4	Rivet, J.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against Helmintosporium on Barley ESSAIS+; 11-F-2020-FR03 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (44) 6.4	Zöllner, H.	2021	Field study to evaluate the efficacy and crop selectivity of SAP2101F (mixtures based on SAP250F and SAP50SCF) against Helmintosporium on Barley (Germany) FIELD RESEARCH SUPPORT; 04A-F-2021-DE01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (45) 6.1 6.2 6.4	Biaunier, M.	2021	Evaluate the efficacy of SAP2101F against Helmintosporium on Barley QUALIPHYT; 04A-F-2021-FR01 GEP Unpublished	N	ASCENZA AGRO

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 (46) 6.1 6.2 6.4	Desogus, S.	2021	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against Pyrenophora teres on Barley. Bulgaria 2021 (EPPOSE). SAGEA OOD; 04B-F-2021-BG01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (47) 6.1 6.2 6.4	Desogus, S.	2021	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against Pyrenophora teres on Barley. Bulgaria 2021 (EPPOSE). SAGEA OOD; 04B-F-2021-BG02 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (48) 6.4	Zöllner, H.	2021	Field study to evaluate the efficacy and crop selectivity of SAP2101F (mixtures based on SAP250F and SAP50SCF) against Helmintosporium on Barley (Germany) FIELD RESEARCH SUPPORT; 04B-F-2021-DE01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (49) 6.4	Zöllner, H.	2021	Field study to evaluate the efficacy and crop selectivity of SAP2101F (mixtures based on SAP250F and SAP50SCF) against Helmintosporium on Barley (Germany) FIELD RESEARCH SUPPORT; 04B-F-2021-DE02 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (50) 6.1 6.2 6.4	Crepin, D.	2021	Evaluate the efficacy of SAP2101F against Helmintosporium on Barley ESSAIS +; 04B-F-2021-FR01 GEP	N	ASCENZA AGRO

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
			Unpublished		
KCP 6.2 (51) 6.1 6.2 6.4	Crepin, D.	2021	Evaluate the efficacy of SAP2101F against Helmintosporium on Barley ESSAIS +; 04B-F-2021-FR02 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (52) 6.4	Biaunier, M.	2021	Evaluate the efficacy of SAP2101F against Helmintosporium on Barley QUALIPHYT; 04B-F-2021-FR03 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (53) 6.4	Biaunier, M.	2021	Evaluate the efficacy of SAP2101F against Helmintosporium on Barley QUALIPHYT; 04B-F-2021-FR04 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (54) 6.1 6.4	Herrera, D.	2021	Evaluate the efficacy of SAP2101F (mixture based on SAP250F and SAP50SCF) against Helmintosporium on Barley STAPHYT; 04B-F-2021-FR06 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (55) 6.1 6.4	Desogus, S.	2021	Evaluate the efficacy of mixtures based on SAP2101F against Pyrenophora teres on Barley. Italy 2021 SAGEA Centro di Saggio s.r.l.; 04B-F-2021-IT01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (56) 6.1 6.4	Desogus, S.	2021	Evaluate the efficacy of mixtures based on SAP2101F against Pyrenophora teres on Barley. Italy 2021 SAGEA Centro di Saggio s.r.l.;	N	ASCENZA AGRO

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**
			04B-F-2021-IT02 GEP Unpublished		
KCP 6.2 (57) 6.1 6.2 6.4	Zöllner, H.	2021	Field study to evaluate the efficacy and crop selectivity of SAP2101F against Helmintosporium on Barley (Poland) FIELD RESEARCH SUPPORT; 04B-F-2021-PL01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (58) 6.1 6.2 6.4	Rusek, K.	2021	Evaluate the efficacy of mixtures based on SAP2101F against Helminthosporium on Winter Barley, Poland 2021 FERTICO Sp. z.o.o.; 04B-F-2021-PL02 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (59) 6.2 6.4	Herrera, D.	2021	Evaluate the efficacy of SAP2101F (mixtures based on SAP250F and SAP50SCF) against Helmintosporium on Barley, GEP Trial, POLAND, 2021 STSPHYT; 04B-F-2021-PL04 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (60) 6.1 6.2 6.4	Herrera, D.	2021	Evaluate the efficacy of SAP2101F (mixtures based on SAP250F and SAP50SCF) against Helmintosporium on Barley, GEP Trial, POLAND, 2021 STSPHYT; 04B-F-2021-PL05 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (61) 6.1 6.2	Botoman, G.	2021	Evaluate the efficacy of SAP2101Fagainst Helminthosporium on Barley GEP Trial, ROMANIA, 2021 AgroProspect;	N	ASCENZA AGRO

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6.4			04B-F-2021-RO01 GEP Unpublished		
KCP 6.2 (62) 6.4	Hernández, J.M.	2021	Evaluate the efficacy of mixtures based on SAP2101F against Helmintosporium on Barley AGROENSAYOS, ENSAYOS Y TÉCNICAS AGRÍCOLAS S.L.; 04B-F-2021-SP01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.2 (63) 6.4	Hernández, J.M.	2021	Evaluate the efficacy of mixtures based on SAP2101F against Helmintosporium on Barley AGROENSAYOS, ENSAYOS Y TÉCNICAS AGRÍCOLAS S.L.; 04B-F-2021-SP02 GEP Unpublished	N	ASCENZA AGRO
KCP 6.4.1 (1) 6.4	Kasztner, G.	2021	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against Helmintosporium on Barley Agrofil-SZMI Kft; 04B-F-2020-HU01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.4.1 (2) 6.4	Herrera, D.	2021	Evaluate the efficacy of SAP2101F (mixture based on SAP250F and SAP50SCF) against Helmintosporium on Barley STAPHYT; 04B-F-2021-FR05 GEP Unpublished	N	ASCENZA AGRO
KCP 6.4.2; KCP 6.4.3 (1) 6.4.4	Gaia, U.	2021	EVALUATION OF NON-INTENTIONAL EFFECTS OF SAP2101F AND SAP50SCF ON TRANSFORMATION PROCESS (BREADMAKING) ON WHEAT– ITALY (2021) SAGEA Centro di Saggio s.r.l.; 25-TT-BM-2021-IT01	N	ASCENZA AGRO

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			GEP Unpublished		
KCP 6.4.2; KCP 6.4.3 (2) 6.4.4	Gaia, U.	2021	EVALUATION OF NON-INTENTIONAL EFFECTS OF SAP2101F AND SAP50SCF ON TRANSFORMATION PROCESS (BREADMAKING) ON WHEAT– ITALY (2021) SAGEA Centro di Saggio s.r.l.; 25-TT-BM-2021-IT02 GEP Unpublished	N	ASCENZA AGRO
KCP 6.4.2; KCP 6.4.3 (3) 6.4.4	Milhan, C.	2021	Unintentional effects of SAP2101F and SAP50SCF on transformation process (bread making) on wheat - 2021 STAPHYT; 25-TT-BM-2021-FR01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.4.2; KCP 6.4.3 (4) 6.4.4	Milhan, C.	2021	Unintentional effects of SAP2101F and SAP50SCF on transformation process (bread making) on wheat - 2021 STAPHYT; 25-TT-BM-2021-FR02 GEP Unpublished	N	ASCENZA AGRO
KCP 6.4.2; KCP 6.4.3 (5) 6.4.4	Herrera, D.	2021	Non-intentional effects of SAP2101F and SAP50SCF on transformation process (brewing) on barley, GEP Trial, FRANCE, 2021 STAPHYT; 26-TT-BW-2021-FR01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.4.2; KCP 6.4.3 (6) 6.4.4	Herrera, D.	2021	Non-intentional effects of SAP2101F and SAP50SCF on transformation process (brewing) on barley, GEP Trial, FRANCE, 2021 STAPHYT; 26-TT-BW-2021-FR02 GEP Unpublished	N	ASCENZA AGRO

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 6.4.2; KCP 6.4.3 (7) 6.4.4	Herrera, D.	2021	Non-intentional effects of SAP2101F and SAP50SCF on transformation process (brewing) on barley, GEP Trial, FRANCE, 2021 STAPHYT; 26-TT-BW-2021-FR03 GEP Unpublished	N	ASCENZA AGRO
KCP 6.4.2; KCP 6.4.3 (8) 6.4.4	Gless, A.E.	2021	STUDY OF UNINTENTIONAL EFFECTS OF SAP2101F AND SAP50SCF PRODUCTS APPLIED ON WINTER BARLEY, HARVEST 2021, ON MALT AND BEER QUALITY AND PROCESS I.F.B.M.; R-A-I-1173 GLP Unpublished	N	ASCENZA AGRO
KCP 6.4.2; KCP 6.4.3 (9) 6.4.4	Gaia, U.	2021	EVALUATION OF NON-INTENTIONAL EFFECTS OF SAP2101F AND SAP50SCF ON TRANSFORMATION PROCESS (BREWING) ON BARLEY – ITALY (2021) SAGEA Centro di Saggio s.r.l.; 26-TT-BW-2021-IT01 GEP Unpublished	N	ASCENZA AGRO
KCP 6.4.2; KCP 6.4.3 (10) 6.4.4	Gaia, U.	2021	EVALUATION OF NON-INTENTIONAL EFFECTS OF SAP2101F AND SAP50SCF ON TRANSFORMATION PROCESS (BREWING) ON BARLEY – ITALY (2021) SAGEA Centro di Saggio s.r.l.; 26-TT-BW-2021-IT02 GEP Unpublished	N	ASCENZA AGRO
KCP 6.5.2 (1) 6.5.2	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) Effectiveness of Cleaning Procedure ASCENZA Agro S.A.; Study EF/372/21 GLP Unpublished	N	ASCENZA AGRO

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 6.5.2 (2) 6.5.2	Huerta, F.	2021	'Prothioconazole + Folpet 120+300 g/L SC - SAP2101F': Effects on the Vegetative Vigour of Six Non-Target Terrestrial Plant Species under Greenhouse Conditions Eurofins Trialcamp S.L.U ; S21-05017 GLP Unpublished	N	ASCENZA AGRO
KCP 6.5.2 (3) 6.5.1	Huerta, F.	2021	'Prothioconazole + Folpet 120+300 g/L SC - SAP2101F': Effects on the Seedling Emergence and Growth of Six Non-Target Terrestrial Plant Species under Greenhouse Conditions Eurofins Trialcamp S.L.U ; S21-05016 GLP Unpublished	N	ASCENZA AGRO

List of data submitted by the applicant and not relied on

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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**
-	-	-	-	-	-