REGISTRATION REPORT

Part B
Section 3
Efficacy Data and Information

Concise summary

Product code: GF-3308

Product name(s): Questar

Chemical active substance(s):

Fenpicoxamid (XDE-777), 50 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Corteva AgriScience

Submission date: August 2021

MS Finalisation date: January 2022 (initial Core Assessment)

August 2022 (final Core Assessment)

Version history

When	What
August 2021	Initial dRR – Corteva Agriscience
January 2022	Initial zRMS assessment. The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through and shaded for transparency~~.
August 2022	Final report (Core Assessment updated following the commenting period). Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Information no longer relevant ~~is struck through and shaded~~.

Table of Contents

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

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

Comments of zRMS:

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

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

Abstract

Comments of zRMS:

This application has been submitted for authorization of the fungicide GF-3308 (Questar) containing 50 g/L fenpicoxamid (Qil fungicide, FRAC code C4 # 21). GF-3308 is intended to be used in wheat to the control of: *Zymoseptoria tritici* (SEPTTR), *Puccinia recondita* (PUCCRT), *Puccinia striiformis* (PUCCST); in rye to the control of: *Rhynchosporium secalis* (RHYNSE), *Puccinia recondit*a (PUCCRE) and in triticale to the control of: *Septoria* spp. (SEPTSP), *Puccinia striiformis* (PUCCST).

Efficacy

The Applicant has submitted 118 efficacy trials from the years 2014-2020, carried out in winter wheat (81 trials), spring wheat (1 trial), winter rye (18 trials) and winter triticale (18 trials). The trials were conducted in 3 EPPO zones: Maritime (AT, CZ, DE, DK, FR, UK), North-East (LV, PL) and South-East (BG, HU, RO).
Based on the submitted efficacy trial results it can be concluded that the fungicide GF-3308 at the highest recommended dose rate of 2,0 L/ha is effective in the control of target pathogens, which are the subject of evaluation. Lower dose rates: 1,2 and 1,5 L/ha due to high level of control of target pathogens can be also recommended in South-East EPPO zone. Dose rate of 1,5 L/ha is claimed for North-East EPPO zone, and can be recommended for the control of *Rhynchosporium secalis* in winter rye and *Zymoseptoria tritici* in wheat and winter triticale in this zone due to high level of control achieved in the presented trials. As no trials have been submitted for spring wheat for PUCCRT control; for durum wheat, spelt, spring rye, spring triticale for the control of all target pathogens in any of the concerned EPPO zones and only one Polish trial has been submitted for spring wheat for the control of SEPPTR and PUCCST, the decision of acceptance of these uses is to be made on the national level by cMSs.
Based on the comments received from cMS, the following crops have been finally accepted:

- TRZDU, TRZSP (CZ)

Phytotoxicity, yield, transformation processes, germination, succeeding crops and adjacent crops

No phytotoxicity and no negative impact on the yield and its quality parameters was observed after application of GF-3308 at dose rate of 2,0 L/ha in the course of the efficacy trials presented in support of the submission. No phytotoxicity symptoms have been detected in 5 of 6 selectivity trials. In one French selectivity trial, 4,3% chlorosis at the 1,5 L/ha (1N) and 7,5% at the 3,0 L/ha (2N) dose rate have been observed. These symptoms had temprorary character and decreased over time. 5% necrosis was also observed after application of reference product Proline. No negative impact on the yield and its quality parameters was observed after application of GF-3308 in 6 selectivity trials. No phytotoxicity on 8 varieties of winter wheat and 1 variety of spring wheat was also noted in 1 additional screening trial. It can be concluded that GF-3308 can be safely used in all target crops.
Based on the submitted trial results or other data it can be also concluded that no adverse effect on transformation processes, seed germination, succeeding crops, adjacent crops is to be expected after application of GF-3308. Nevertheless, in order to avoid the risk of adverse effects on adjacent crops, being in accordance with the rules of good agricultural practice it is recommended to include, in the product label, the following remark: "*When using GF-3308 do not allow spray drift to the neighbouring crop plantations*".

Resistance management strategy

To avoid development of resistance the following resistance management strategy is proposed to be included in the label of GF-3308:
"The fungicide GF-3308 contains active substance: fenpicoxamid from picolinamides chemical group – inhibitor of respiration processes, belonging to Qil fungicides (FRAC group C4, # 21). As a part of anti-resistance strategy GF-3308 is recommended to be used:

– mainly preventatively in the control of target diseases, in appropriate growth stages of crops and only at the recommended dose rate - specified in the product label,
– only once per growth season,
– in the tank mixtures with other fungicides containing active substances of different mode of action recommended for control of the same target pathogens, at recommended dose rates ensuring full protection against diseaes and in the plant protection programs with other fungicides (alternating use of fungicides with different modes of action).

Additionally it is advisable to follow current recommendations of resistance management strategy for cereal fungicides".

This strategy is to be considered by the cMSs.

GF-3308 is a new agricultural fungicide for the control of a range of important foliar diseases in wheat, rye and triticale. The product is formulated as an emulsifiable concentrate (EC) containing 50 g/L fenpicoxamid.
This dossier is supported by ~~111~~ 118 effectiveness trials from across the EPPO Maritime, North-East and South-East climatic zone. It is considered that the proposed disease claims and dose rates are fully supported by these data and authorisation across the Central EU Authorisation zone can be recommended.
GF-3308 is a non-cross resistant fungicide (fenpicoxamid). The resistance risk is considered low to high, depending on the target pathogen, and a number of modifiers have been proposed to restrict use. The applicant is conducting a resistance monitoring programme on a regular basis in order to detect the potential development of fungicide resistance in fungi in Europe. If this should occur, they provide recommendations in terms of chemical control and agronomic practices.
It considered that the use of GF-3308 as proposed will have no adverse effects on winter and spring wheat (including spelt and durum wheat), rye and triticale crops treated between growth stage BBCH 30 (beginning of stem elongation) and up to and including the end of flowering (BBCH 69).
It considered that the use of GF-3308 as proposed will have no undesirable or unintended side-effects on succeeding crops, adjacent crops or on beneficial and other non-target organism.
This assessment is fully compliant with Uniform Principles.

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

	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 ai/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	Winter wheat (TRZAW), Durum wheat (TRZDU), Spelt (TRZSP)	F	*Zymoseptoria tritici* (SEPTTR) *Puccinia recondita* (PUCCRT), *Puccinia striiformis* (PUCCST	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	~~14~~	a) 2.0 L/ha b) 2.0 L/ha	a) 100 fenpicoxamid b) 100 fenpicoxamid	100-300	PHI F	Range 1.5-2.0 L/ha proposed	A TRZAW Range 1.5-2.0 L/ha accepted for SEPTTR. Lower dose rate of 1,5 L/ha recommended under low disease pressure. Dose rate of 2,0 L/ha recommended for PUCCST and PUCCRT. N TRZDU, TRZSP (possible registration under art. 51)
2	PL,	Winter triticale (TTLWI)	F	~~*Septoria* spp. (SEPTSP)~~ *Zymoseptoria tritici* (SEPTTR) *Puccinia striiformis* (PUCCST)	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	~~14~~	a) 2.0 L/ha b) 2.0 L/ha	a) 100 fenpicoxamid b) 100 fenpicoxamid	100-300	PHI F	Range 1,5-2,0 L/ha proposed	A Range 1.5-2.0 L/ha accepted for SEPTTR. Lower dose rate of 1,5 L/ha recommended under low disease pressure. Dose rate of 2,0 L/ha recommended for PUCCST.
3	PL	Winter rye (SECCW)	F	*Rhynchosporium secalis* (RHYNSE) *Puccinia recondita* (PUCCRE)	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	~~14~~	a) 2.0 L/ha b) 2.0 L/ha	a) 100 fenpicoxamid b) 100 fenpicoxamid	100-300	PHI F	Range 1.5-2.0 L/ha proposed	A Range 1.5-2.0 L/ha accepted for RHYNSE. Lower dose rate of 1,5 L/ha recommended under

														low disease pressure. Dose rate of 2,0 L/ha recommended for PUCCRE.
4	PL	Spring wheat (TRZAS)	F	*Zymoseptoria tritici* (SEPTTR) *Puccinia recondita* (PUCCRT), *Puccinia striiformis* (PUCCST)	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	~~14~~	a) 2.0 L/ha b) 2.0 L/ha	a) 100 fenpicoxamid b) 100 fenpicoxamid	100-300	PHI F	Range 1.5-2.0 L/ha proposed	A SEPTTR, PUCCST Range 1.5-2.0 L/ha accepted for SEPTTR. Lower dose rate of 1,5 L/ha recommended under low disease pressure. Dose rate of 2,0 L/ha recommended for PUCCST. N PUCCRT
5	PL	Spring triticale (TTLSO)	F	*Septoria* spp. (SEPTSP) *Puccinia striiformis* (PUCCST)	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	~~14~~	a) 2.0 L/ha b) 2.0 L/ha	a) 100 fenpicoxamid b) 100 fenpicoxamid	100-300	PHI F	Range 1,5-2,0 L/ha proposed	N (possible registration of PUCCST under art. 51)
6	PL	Spring rye (SECCS)	F	*Rhynchosporium secalis* (RHYNSE) *Puccinia recondita* (PUCCRE)	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	~~14~~	a) 2.0 L/ha b) 2.0 L/ha	a) 100 fenpicoxamid b) 100 fenpicoxamid	100-300	PHI F	Range 1.5-2.0 L/ha proposed	N (possible registration under art. 51)
7	AT, CZ	Winter wheat (TRZAW), Durum wheat (TRZDU), Spelt (TRZSP)	F	*Zymoseptoria tritici* (SEPTTR), *Puccinia recondita* (PUCCRT), *Puccinia striiformis* (PUCCST)	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	~~14~~	a) 2.0 L/ha b) 2.0 L/ha	a) 100 fenpicoxamid b) 100 fenpicoxamid	100-300	PHI F		A TRZAW (AT, CZ) TRZDU (CZ), TRZSP (CZ) C TRZDU (AT), TRZSP (AT)
8	AT, CZ	Winter triticale (TTLWI)	F	*Septoria* spp. (SEPTSP) *Puccinia striiformis* (PUCCST)	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	~~14~~	a) 2.0 L/ha b) 2.0 L/ha	a) 100 fenpicoxamid b) 100 fenpicoxamid	100-300	PHI F		A
9	AT, CZ	Winter rye (SECCW)	F	*Puccinia recondita* (PUCCRE) *Rhynchosporium*	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	~~14~~	a) 2.0 L/ha b) 2.0 L/ha	a) 100 fenpicoxamid b) 100 fenpicoxamid	100-300	PHI F		A

				secalis (RHYNSE)										
10	AT, CZ	Spring wheat (TRZAS)	F	*Zymoseptoria tritici* (SEPTTR), *Puccinia recondita* (PUCCRT), *Puccinia striiformis* (PUCCST)	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	~~14~~	a) 2.0 L/ha b) 2.0 L/ha	a) 100 fenpicoxamid b) 100 fenpicoxamid	100-300	PHI F		C
11	AT, CZ	Spring triticale (TTLSO)	F	*Septoria* spp. (SEPTSP) *Puccinia striiformis* (PUCCST)	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	~~14~~	a) 2.0 L/ha b) 2.0 L/ha	a) 100 fenpicoxamid b) 100 fenpicoxamid	100-300	PHI F		C
12	AT, CZ	Spring rye (SECCS)	F	*Puccinia recondita* (PUCCRE) *Rhynchosporium secalis* (RHYNSE)	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	~~14~~	a) 2.0 L/ha b) 2.0 L/ha	a) 100 fenpicoxamid b) 100 fenpicoxamid	100-300	PHI F		C
13	SK, RO	Winter wheat (TRZAW), Durum wheat (TRZDU), Spelt (TRZSP)	F	*Zymoseptoria tritici* (SEPTTR), *Puccinia recondita* (PUCCRT), *Puccinia striiformis* (PUCCST)	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	~~14~~	a) 2.0 L/ha b) 2.0 L/ha	a) 100 fenpicoxamid b) 100 fenpicoxamid	100-300	PHI F	Dose range proposed from 1.2-2.0 L/ha for SEPTTR. 1.5-2.0 L/ha for PUCCST and PUCCRT. Lower doses to be used when lower disease pressure	A TRZAW C TRZDU, TRZSP
14	SK, RO	Spring wheat (TRZAS)	F	*Zymoseptoria tritici* (SEPTTR), *Puccinia recondita* (PUCCRT), *Puccinia striiformis* (PUCCST)	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	~~14~~	a) 2.0 L/ha b) 2.0 L/ha	a) 100 fenpicoxamid b) 100 fenpicoxamid	100-300	PHI F	Dose range proposed from 1.2-2.0 L/ha for SEPTTR. 1.5-2.0 L/ha for PUCCST and PUCCRT. Lower doses to be used when lower disease pressure	C

* 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 summarizes the information related to the efficacy data of the plant protection product GF-3308 containing the active substance fenpicoxamid (XDE-777). The Dossier for approval of Fenpicoxamid under Regulation EC 1007/2009 was submitted in December 2014 to the then RMS United Kingdom, the coRMS France and to all member states with GF-2925 (130 g/L XDE-777, SC) as the representative formulation. Fenpicoxamid active substance approval was in October 2018.
GF-3308 is a new agricultural fungicide for the control of important foliar diseases of wheat, spelt, triticale and rye which is formulated as an emulsifiable concentrate (EC) containing 50 grams per litre Fenpicoxamid.
Fenpicoxamid (XDE-777) was discovered by Dow AgroSciences (Any reference in this docment to Dow AgroSciences is now Corteva Agriscience) and is being co-developed by Meji Seika Kaisha, Japan.
GF-3308 is a new product which has not yet been submitted for a registration in countries of the European Union.
This document supports the registration of GF-3308 in Poland (PL) as the zRMS, Austria (AT), the Czech Republic (CZ), Romania (RO) and Slovakia (SK).
The Biological Assessment dossier (BAD) is located in the following report: Part B, Section 3 (Efficacy Data and Information) of the draft registration report (dRR) for GF-3308. The data presented in this dossier support label claims for the use of GF-3308 for the control of *Mycosphaerella* (*Septoria*) spp. (SEPTSP, SEPTTR) in wheat, spelt and triticale, *Puccinia recondita* (PUCCRT, PUCCRE) in wheat and rye, *Puccinia striiformis* (PUCCST) in wheat and triticale as well as *Rhynchosporium secalis* (RHYNSE) on rye.
For further physical-chemical properties reference should be made to Registration Report Part B Section 1: Identity, physical and chemical properties, other information.

Benefit statement for GF-3308

GF-3308 contains fenpicoxamid (XDE-777) which is a potent naturally derived novel fungicide active with locally systemic and translaminar properties. GF-3308 binds very strongly to the cuticular layers of leaves and provides reliable long term protectant control of SEPTTR and other diseases such as *Puccinia* spp. or *Rhynchosporium*. It has also excellent curativity (reach back) on SEPTTR which allows the flexible use of GF-3308 for disease control based on integrated pest control principles. GF-3308 builds stable deposits on the treated foliage very quickly and therefore it is rain fast as soon as the spray cover has dried.
GF-3308 can be used over a wide window of application from crop growth stage BBCH 30 up to BBCH 69 with a high level of crop safety to all wheat, rye and triticale varieties. GF-3308 has a very positive effect on yield amount and quality of the grain.
Cereal pathogens such as SEPTTR have developed resistance to many fungicides from different chemical groups such as the Methyl Benzimidazole Carbamates (MBCs), Triazoles (DMIs) and strobilurin fungicides (QoIs). There are also first indications (Rehfus *et al.*, 2016) towards adaptation to SDHI fungicides. GF-3308 will be a novel target site fungicide in the cereal crop segment (will be assigned to FRAC group C4 #21) and does not show target site based cross resistance to any of the current commercial fungicides used in cereals. As a consequence it will be an important additional tool for farmers in aiding the management of resistance risk to the limited number of effective fungicide options currently available for control of SEPTTR.

Description of active substances

The active substance, fenpicoxamid'(XDE-777) belongs to a proposed new family of Picolinamide type fungicides. Fenpicoxamid is a fungicide derived from the natural-product UK-2A. UK-2A is produced through fermentation of *Streptomyces* sp. 517-02. In early stage testing, UV instability was found to be inherent in UK-2A and was clearly an issue for field performance of the natural product. In the period between 1997 and 2002, Dow AgroSciences committed considerable synthesis and biology resources to improve UV stability. At manufacturing, through a single synthetic step UK-2A is converted to Fenpicoxamid (XDE-777). When Fenpicoxamid is applied to the plant it is converted in both fungi and plants to UK-2A which is a potent inhibitor of mitochondrial electron transport and consequently fungal respiration.

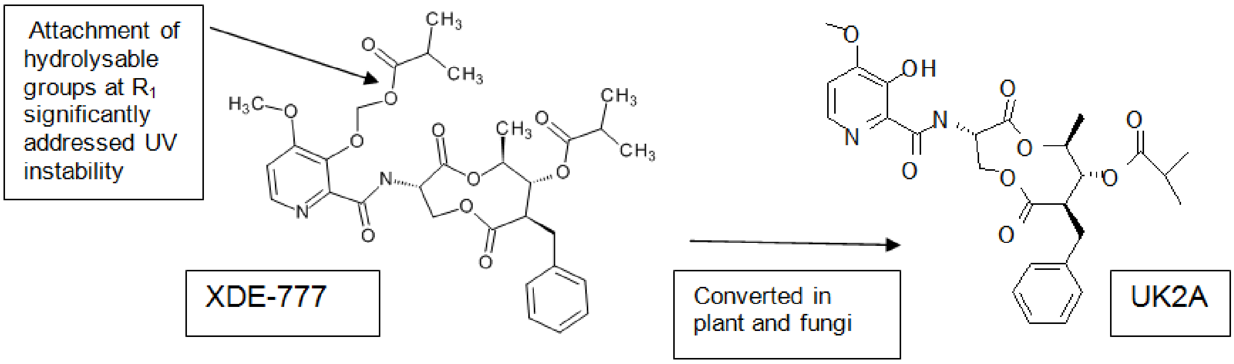
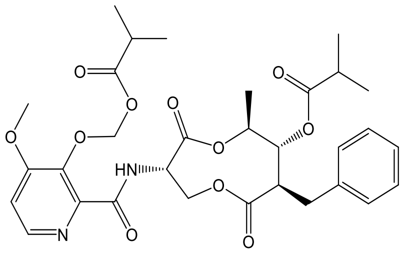


Figure 3.2-1: Sites of structural modification to UK-2A to make fenpicoxamid (XDE-777)

Fenpicoxamid (XDE-777) formulated as GF-3308 is a curative and protectant fungicide for control of foliar diseases in cereal crops. UK-2A, which is derived from Fenpicoxamid, inhibits mitochondrial electron transport (MET) binding to the Qi site of the cytochrome *bc*1 (ubiquinone reductase) complex III in the electron transport chain. The mode of action of fenpicoxamid will be novel to the European cereal fungicide market and will be assigned to FRAC group C4#21. The MET lll Q_i site is distinct from the MET lll Q_o site, with which the strobilurins interact, so that no cross-resistance of field isolates of SEPTTR resistant to strobilurin fungicides has been observed or would be anticipated.

Table 3.2-1: Details of the active substance in GF-3308

	Active substance Fenpicoxamid (XDE-777)
Formulation concentration	50 g Fenpicoxamid per litre
Chemical group (proposed)	Picolinamide
IUPAC name (if applicable):	(3S,6S,7R,8R)-8-benzyl-3-{[(4-methoxy-3-{[(2-methylpropanoyl)oxy]methoxy} pyridin-2-yl)carbonyl]amino}-6-methyl-4,9-dioxo-1,5-dioxonan-7-yl-2-methylpropanoate
Active brand name	Inatreq™ active
ISO common name (approved)	Fenpicoxamid
CAS number	517875-34-2
Molar weight	614.64
Structural formula	 $C_{31}H_{38}N_2O_{11}$
Mode of action (proposed)	FRAC group C4#21 Inhibition of respiration at complex III (QiI fungicides)
Biological action	Curative and protectant fungicide with locally systemic and translaminar properties for use on wheat, triticale and rye. When sprayed onto foliage it provides long lasting protection against SEPTSP, PUCCRE, PUCCST and RHYNSE. Best results are obtained by treatment at the first symptoms of the disease.

Description of the plant protection product

GF-3308 is an emulsifiable concentrate (EC) containing 50 g/L fenpicoxamid (XDE-777). The data presented in this dossier are intended to support the label claim for GF-3308 for the control of foliar diseases in wheat, rye and triticale as shown in Part B – Section 0.

Table 3.2-2: Simplified table of requested uses for GF-3308.

Uses		**Member State**	**Requested individual rate**	**Comments / Other relevant details on GAPs**
Crop(s)	**Target(s)**			
TRZAW TRZAS TRZDU TRZSP	SEPTTR PUCCRT PUCCST	PL	1,5-2,0 L/ha	One application between BBCH 30-69
	SEPTTR PUCCRT PUCCST	AT, CZ	2,0 L/ha	
	SEPTTR PUCCRT PUCCST	RO, SK	1,2-2,0 L/ha SEPTTR 1,5-2,0 L/ha PUCCST, PUCCRT	
TTLWI TTLSO	SEPTSP* PUCCST	PL	1,5-2,0 L/ha	One application between BBCH 30-69
	SEPTSP* PUCCST	AT, CZ	2,0 L/ha	
SECCW SECCS	PUCCRE RHYNSE	PL	1,5-2,0 L/ha	One application between BBCH 30-69

Uses		Member State	Requested individual rate	Comments / Other relevant details on GAPs
Crop(s)	Target(s)			
	PUCCRE RHYNSE	AT, CZ	2,0 L/ha	

*in triticale different *Septoria* species (SEPTSP) are frequently present in mixture. The infection levels visually assessed in the efficacy trials was addressed as SEPTTR as the prevailing symptom.

Description of the target pests

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

EPPO code	Scientific name	Common name
SEPTTR	*Zymoseptoria tritici*	*Septoria* leaf blotch on wheat
PUCCRT	*Puccinia recondita tritici*	Brown rust on wheat
PUCCRE	*Puccinia recondita*	Brown rust on rye
PUCCST	*Puccinia striiformis*	Yellow rust or Stripe rust on wheat
PUCCST	*Puccinia striiformis*	Yellow rust or Stripe rust on triticale
RHYNSE	*Rhynchosporium secalis*	*Rhynchosporium* on rye, rye scald
SEPTSP	*Septoria* spp.	*Septoria* species on triticale

SEPTTR

Septoria leaf blotch (SEPTTR) is caused by the fungus *Zymoseptoria tritici* which is a species of filamentous fungus, an ascomycete in the family *Mycosphaerellaceae*. It is a major wheat plant pathogen in Europe that is difficult to control due to resistance to multiple fungicides. *Mycosphaerella graminicola* is the name of the sexual stage (teleomorph) of the pathogen. The disease is more commonly referred to as *Septoria tritici* which is the name of its asexual stage (anamorph). The disease is widely distributed across the main wheat growing regions of the world. Yield losses in badly infected susceptible varieties can be major with reductions of up to 50% reported in the UK.

The disease is most damaging in regions where periods of rainfall and leaf wetness are common. Within the EU Central authorization zone the disease is more frequently damaging in the EPPO Maritime regions where it usually occurs first during the winter months. The initial infection arises from wind borne ascospores released from debris. Once a spore has landed on a new leaf, it is reported to take 12 hours for the spore to germinate; infection of the new leaf usually takes place within 24 hours of the spore being released. Wet conditions are required during this infection process. Leaf wetness can be caused by either rain or dew, so spore dispersal and infection can still take place even during dry weather spells. Symptoms do not appear immediately on a new leaf. The fungus grows undetected inside the leaf for a period of 2-4 weeks which is referred to as the latent phase. The speed of visible symptom development is linked to temperature so during the winter it can take a long time for symptoms to appear, while in the summer, symptoms can develop more rapidly. The existence of such a relatively long latent phase can make interpretation of results difficult as, for example, the effectiveness of fungicides with curative activity can be greatly reduced if applied during this phase.

The disease is most severe where these conditions are prevalent during the stem elongation phase of crop development. Further spread of the disease up the growing plant and onto the main yield producing higher leaf levels is primarily the result of the splash borne release of asexual pycniospores. Frequent cycles of infection can occur throughout the lifetime of the crop.

In triticale different *Septoria* species (SEPTSP) are frequently present in mixture including *Septoria nodorum* and *Septoria tritici*.

PUCCRT/PUCCRE

Brown (leaf) rust caused by *Puccinia recondita* is a fungal disease that affects cereals leaves and grains. In temperate zones it is destructive on winter wheat and other cereals because the pathogen overwinters. Infections can lead up to 5-20% yield loss exacerbated by dying leaves which fertilise the fungus but this can increase to 50% yield loss in severe infestations. It is the most prevalent of all the rust diseases,

occurring in most wheat, barley and rye growing regions. Brown rust spreads via airborne spores. Five types of spores are formed in the life cycle. Uredospores, teleutospores, and basidiospores develop on cereal plants, whereas pycnidiospores and aeciospores develop on alternate hosts. The germination process requires moisture, and works best at 100% humidity. Optimum temperature for spore germination is between 15–20°C. Before sporulation, the cereal plants appear completely asymptomatic. Wheat, barley and rye brown rust pathogen is biotrophic and requires living plant cells to survive.
Symptoms are small, orange-brown pustules randomly scattered over leaves. It is common to see a yellowing of the leaf around the rust pustules. During autumn and winter symptoms are usually confined to older leaves. These winter symptoms are sometimes difficult to distinguish from those of yellow rust. Late in the season brown rust can become very severe and result in leaf death. Leaf sheaths and ears sometimes become affected. Tiny black spore cases may be seen on diseased plant tissue, indicating a second developmental stage of the fungus (the teliospore stage). In high-risk situations typically, brown rust develops later in the summer than yellow rust, during warm, humid spells of weather. However, with higher than normal spring temperatures, the disease can develop much earlier in the season. Within the EU Central authorisation zone the disease is very damaging in the EPPO North-East, South-East as well as the Maritime regions which experience hot dry summers. Early-sown crops are at greater risk as they are more likely to become infected by wind-blown spores from infected wheat volunteers

PUCCST
Yellow rust *(Puccinia striiformis*) is a primarily a disease on wheat and triticale occurring throughout Europe. It can cause severe infections in maritime climates such as Western Europe, and right across Europe to the Middle East. Yellow rust can occur on all aerial parts of the plant, but is most frequently seen on the leaves. The pathogen spreads by means of airborne uredospores. When spores land on wheat plants they germinate in high humidity, usually at temperatures of less than 15°C, and the germ tubes enter the leaves or other parts of the plant via the stomata. Once inside the leaf, haustoria are inserted into the mesophyll cells and the mycelium spreads along the leaf. In mature leaves it spreads longitudinally between the veins of the leaf. Lines of bright yellow new uredospores are produced and give the typical striped appearance on the leaves. The pustules are often arranged into conspicuous stripes and their linear orientation between vascular bundles can progress the length of the leaf blade. Damage is caused to the plant by extraction of nutrients via the haustoria of the pathogen and by disruption of the epidermis, which reduces the water retention capacity of the leaves. The major grain-producing parts of the wheat plant are the flag leaf and the ear, and severe infections on these parts of the plant may cause large reductions in yield. Greater reductions occurred with earlier infections, yields of susceptible cultivars could be reduced by 50% or more under severe and prolonged infection in the field.
The major method of control is the use of resistant cultivars. The development of systemic fungicides has led to the use of chemical control, particularly in areas where yields are high, as in Western Europe, where the cost of fungicide application is low in comparison with the value of the crop. Epidemics of yellow rust require appropriate weather conditions and the presence of susceptible cultivars. However, the repeated appearance of new yellow rust races continues to challenge varietal resistance, emphasising the importance of the balance between varieties and fungicides in managing the disease.

RHYNSE
Rhynchosporium secalis is one of the most important economical diseases of barley, rye and triticale which emerges particularly during wet seasons. The disease is referred to as 'Rhynchosporium' or 'scald' and is one of the most destructive pathogens which can greatly impact the yield and quality of grain. *Rhynchosporium* is polycyclic with the primary inoculum including conidia produced on crop debris and infected seeds. No teleomorph has been associated with *R. secalis*. Secondary disease spread is primarily by splash dispersal of conidia produced on infected leaves, which may be symptomless early in the growing season. Symptoms first appear as chlorotic, irregular or diamond-shaped lesions. Later symptoms are typically blue-grey water-soaked lesions on leaves and leaf sheaths. Mature lesions become pale brown with a dark purple margin. As they grow, they merge forming large areas of dead tissue, even destroying the whole plant leaf.

Information on wheat production in the Central Zone

Wheat is the most widely-grown crop in the world. Global harvests reached 765 million metric tonnes in 2019-2020. Within the EU, wheat advances from its world position of second most important food crop (after rice) to the status of most important cereal. In 2020 the various countries which comprise the EU produced over 125 million metric tonnes of wheat, which is comparable to that produced by China, 17% more than India and 2.5 times that produced by the USA. Of the various EU member states, France and Germany are the biggest wheat producers, harvesting circa 24% and 18% respectively of the EU total, with UK gathering around 8.0%. Over the past 10 years, EU metric tonnage has increased by 23%, whilst, over the same period, US tonnages have fallen by around 8%. The EU currently exports up to 15% of its harvest and this figure is rising annually. Wheat grain grown in the EU provides calories for human foodstuffs (less than one third of harvest) and animal feed (circa two thirds of harvest). Wheat is also grown for alcohol distillation, as a raw material for biofuels and wheat straw is used for livestock bedding and fodder, roof thatching and basket-making. Such figures and statistics attest to the huge economic and social importance of wheat as an EU crop and commodity. It follows that losses to the wheat crop from attack by pests and infection by pathogens are of considerable concern. Of the various pathogens, the foliar disease of wheat, *Septoria tritici* is most problematic in our wheat fields. *S. tritici* flourishes in the humid climate that prevails in EPPO Maritime Zone. Thus, the fungus pervades the major wheat growing regions of the EU. In fact, this persistent pathogen accounts for approximately 70% of annual fungicide usage in the EU. During severe epidemics losses of up to 50% of yield have been documented in fields planted with wheat cultivars susceptible to *S. tritici* (Fones & Gurr, 2015). Wheat production occurs in the whole Central Registration Zone which encloses three different EPPO zones of comparable climates: the Maritime Zone (Austria, Belgium, Czech Republic, Germany, Ireland, Luxembourg, The Netherlands and the United Kingdom), the North-East zone (Poland) and the South-East zone (Hungary, Romania, Slovenia and Slovakia,). The main countries for wheat production in the Central Zone are Germany, UK, Poland and Romania. The highest yield amounts are usually obtained in countries of the Maritime EPPO Zone such as Ireland, Netherlands, Belgium, Germany, United Kingdom, Denmark, France (North, maritime) and Sweden. Detailed information on wheat production is available from the Eurostat website on the following Tables. The importance of cereal crops within the Central Zone is demonstrated in Table 3.2-4.

Information on triticale production in the Central Zone

Triticale (× *Triticosecale*), is a hybrid of wheat (*Triticum*) and rye (*Secale*). Commercially available triticale is almost always a second generation hybrid, i.e., a cross between two kinds of primary triticale. As a rule, triticale combines the yield potential and grain quality of wheat with the disease and environmental tolerance - including soil conditions - of rye. Depending on the cultivar, triticale can more or less resemble either of its parents. It is grown mostly for forage or fodder, although some triticale-based foods can be purchased at health food stores or are to be found in some breakfast cereals. Triticale production in the EU-28 amounted to 11.2 million tonnes in 2020. The primary producers of triticale in the EU-28 are Poland (5.1 million tonnes), Germany (2.0 million tonnes) and France (1.2 million tonnes). As a feed grain, triticale is already well established and of high economic importance. It also has received attention as a potential energy crop. Most wheat and rye diseases also occur on triticale. In comparison with wheat, some triticale varieties can have good resistance to several common wheat diseases including: rusts (*Puccinia* spp.), *Septoria* spp., scalds (*Rhynchosporium* sp.), smuts (*Ustilago* and *Urocystis* spp.), bunts (*Tilletia* sp.) or powdery mildew (*Blumeria graminis*). However, triticale has relatively greater susceptibility than wheat to diseases such as spot blotch (*Bipolaris sorokiniana*), scab (*Fusarium* spp.) and ergot (*Claviceps purpurea*).

Information on rye production in the Central Zone

Rye (*Secale cereale*) is a cereal crop grown extensively as a grain, a cover crop and as a forage crop. It is a member of the wheat tribe (Triticeae) and is closely related to barley (Hordeum) and wheat (Triticum). Rye grain is used for flour, rye bread, rye beer, crisp bread, some whiskeys, some vodkas, and animal fodder. It can also be eaten whole, either as boiled rye, or by being rolled, similar to rolled oats.

Rye grows well in much poorer soils than those necessary for most cereal grains. Thus, it is an especially valuable crop in regions where the soil has sand or peat. Rye plants withstand cold better than other small grains do. Rye will survive with snow cover that would otherwise result in winter-kill for winter wheat. Most farmers grow winter ryes, which are planted and begin to grow in autumn. In spring, the plants develop and produce their crop. Fall-planted rye shows fast growth. By the summer solstice, plants reach their maximum height of about a 120 cm while spring-planted wheat has only recently germinated. Vigorous growth suppresses even the most noxious weed competitors and rye can be grown without application of herbicides. Rye is grown primarily in Eastern, Central and Northern Europe. The main rye belt stretches from northern Germany through Poland, Ukraine, Belarus, Lithuania and Latvia into central and northern Russia. Rye is also grown in North America (Canada and the USA), in South America (Argentina, Brazil and Chile), in Oceania (Australia and New Zealand) in Turkey, in Kazakhstan and in northern China. Most rye is consumed locally or exported only to neighboring countries, rather than being shipped worldwide.

Table 3.2-4: The 30 most important field and vegetable crop species within the 3 EPPO climatic areas of the EU Central Zone[1]

Maritime Zone		**North-East Zone**		**South-East Zone**	
	1000 ha		1000 ha		1000 ha
Common winter wheat	12048.1	Common winter wheat	2462.5	Grain maize	5757.6
Temporary grasses	6208.2	Spring barley	2105.9	Common winter wheat	5408.7
Winter rape	4087.3	Temporary grasses	1570.5	Sunflower seed	2373.2
Green maize	3917.0	Winter rye	1514.3	Winter rape	857.4
Winter barley	3528.6	grain other than maslin	1423.6	Winter barley	758.1
Spring barley	3124.7	Winter triticale	1295.9	Lucerne	646.8
Grain maize	2114.2	Oats	1045.7	Spring barley	482.5
Sugar beet	1217.8	Winter rape	852.7	Potatoes	458.8
Potatoes	947.3	Winter barley	815.0	Soya bean	353.2
Winter rye	920.1	Common spring wheat	797.0	Oats	334.9
Oats	842.6	Potatoes	649.5	Green maize	305.2
Winter triticale	789.5	Green maize	414.7	Clover and mixtures	253.0
Other annual fodder	565.3	Clover and mixtures	386.2	Other annual fodder	227.3
Sunflower seed	523.1	Grain maize	296.7	Winter triticale	191.4
Clovers	363.6	Spring rape	259.1	sainfoin, sweet clover	181.9
Common spring wheat	357.1	Sugar beet	254.1	Sugar beet	167.0
Lucerne	353.1	sainfoin, sweet clover	189.4	Temporary grasses	148.8
Field peas	336.4	Buckwheat	114.9	Winter rye	86.9
Broad bean, fields beans	265.3	Turnip rape	90.5	Officinal aromatic plants	67.5
Winter durum wheat	165.5	Other annual fodder	89.8	Cabbage (white)	66.4
Other oil seeds	120.8	Maslin	73.6	Water melons	58.4
grain other than maslin	107.5	Other dried pulses	58.2	Broad bean, fields beans	56.1
sainfoin, sweet clover	98.7	Lucerne	49.1	Onion	54.6
Spring rape	88.9	Lupins	40.5	Other oil seeds	50.2
Peas	87.7	Officinal, aromatic plants	37.7	Winter durum wheat	48.1
Flax (straw)	80.7	Cabbage (white)	35.5	Tobacco raw	47.1
Buckwheat	72.3	Fodder beet	35.1	Beans	45.1
Oil flax	70.4	Carrots	34.0	Field peas	42.3
Cauliflower	63.5	Onion	33.3	Kidney beans	41.7
Soya bean	63.4	Broad bean, fields beans	32.0	Peas	38.5

[1] Pierre HUCORNE, Centre Wallon de Recherches Agronomiques, 5030 Gembloux, BE: The actual distribution of crops in Europe. http://www.eppo.int/PPPRODUCTS/zonal_efficacy/12-18159_Distribution_of_crops_in_Europe.doc

Table 3.2-5: EU wheat growing area for selected countries (Eurostat)

Wheat (incl, spelt) growing area (1000 ha)	Year 2020
European Union (2020)	(27,799,9)
France	4261,5
Germany	2833,3
Poland	2471,6
Romania	2145,6
United Kingdom	1415,1
Hungary	933,5
Lithuania	891,6
Czech Republic	798,6
Denmark	502,6
Latvia	498,0
Sweden	450,4
Slovakia	387,1
Austria	279,0
Finland	198,8
Belgium	195,0
Estonia	168,0
Netherlands	108,9
Norway	67,6
Republic of Ireland	46,4
Luxembourg	11,9

Table 3.2-6: Typical yield amounts for winter wheat in selected EU countries (Eurostat)

Winter wheat yield (t/ha) by country	Year 2020
Belgium	9,08
Netherlands	8,97
Denmark	8,20
Republic of Ireland	8,05
Germany	7,89
Sweden	7,45
United Kingdom	7,08
France	6,76
Czech Republic	6,20
Luxembourg	6,08
Austria	6,01
Latvia	5,69
Lithuania	5,65
Slovakia	5,63
Estonia	5,54
Hungary	5,40
Poland	4,81
Finland	4,51
Romania	2,99

Table 3.2-7: 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
Winter wheat TRZAW	PL, AT, CZ, SK, RO	-	SEPTTR PUCCRT PUCCST	SEPTTR, PUCCRT PUCCST	-
Spring wheat TRZAS	PL, CZ	AT, ~~CZ,~~ SK, RO	SEPTTR PUCCRT PUCCST	SEPTTR, PUCCRT PUCCST	-
Durum wheat TRZDU	-	PL, AT, CZ, SK, RO	SEPTTR PUCCRT PUCCST	SEPTTR, PUCCRT PUCCST	-
Spelt TRZSP	-	PL, AT, CZ, SK, RO	SEPTTR PUCCRT PUCCST	SEPTTR, PUCCRT PUCCST	-
Winter rye SECCW	PL, AT, CZ	~~CZ~~	PUCCRE RHYNSE	PUCCRE RHYNSE	-
Spring rye SECCS	CZ	PL, AT~~, CZ~~	PUCCRE RHYNSE	PUCCRE RHYNSE	-
Winter triticale TTLWI	PL, CZ	AT~~, CZ~~	SEPTSP PUCCST	SEPTSP PUCCST	-
Spring triticale TTLWO	PL, CZ	AT~~, CZ~~	SEPTSP PUCCST	SEPTSP PUCCST	-

Compliance with the Uniform Principles

This dossier is supplied in accordance with the requirements of the Annex to Commission Regulation (EU) No 545/2011, at the latest at the time of finalization of the evaluation for the purpose of decision-making, without prejudice, where relevant, to the provisions of Articles 33, 34 and 59 of Regulation (EC) No 1107/20. The data submitted are acceptable in terms of quantity, quality, consistency and reliability and sufficient to permit a proper evaluation of the dossier.
All field trials presented in this dossier to demonstrate the minimum effective dose, the efficacy at the proposed label rates, trials to evaluate crop selectivity and the impact on yield and yield quality were carried out by GEP certified testing organisations according to the relevant EPPO guidelines. The trials were carried out under a range of agricultural and environmental conditions across the EU, in areas or regions where the cereal crop species and varieties are commercially grown and where the diseases under investigation are prevalent. The primary guidelines used were the following:
- PP 1/26 Foliar and ear diseases on cereals (leading guideline and guidelines quoted therein)
- PP 1/225 Minimum effective dose
- PP 1/135 Phytotoxicity
- PP 1/152 Trial design
- PP 1/181 Conduct efficacy trial
- PP 1/278 Principles of Zonal Data Production and Evaluation
- PP 1/226 Number of Efficacy Trials
- PP 1/241 Guidance on Comparable Climates
- PP 1/214 Principles of Acceptable Efficacy
- PP 1/213 Resistance Risk Analysis
- PP 1/207 Effects of Succeeding Crops
- PP 1/256 Effects on Adjacent Crops

Information on trials submitted (3.1 Efficacy data)

Table 3.2-8: Presentation of MED and efficacy trials

Crops*	Target(s)*	Country	Years	Type of trial**	Number of valid trials			GEP, non-GEP, official***	Comments (any other relevant information)
					Maritime Zone	North-East Zone	South-East Zone		
TRZAW	**SEPTTR**	Czech Repbulic	2014	E	1	-	-	GEP	
			2016	MED + E	~~1~~ 2	-	-	GEP	
		Denmark	2015	MED +E	~~1~~ 2	-	-	GEP	1 MED
			2016	MED +E	2	-	-	GEP	
		Germany	2014	MED +E	~~2~~ 4	-	-	GEP	1 MED
			2015	MED +E	~~4~~ 3	-	-	GEP	~~2~~ 1 MED
			2016	E	1	-	-	GEP	
			2017	MED +E	2	-	-	GEP	~~1~~ MED
			2019	MED +E	1	-	-	GEP	
		France	2015	MED +E	4	-	-	GEP	
		UK	2015	MED +E	1	-	-	GEP	
			2016	MED +E	1	-	-	GEP	
		Latvia	2014	E	-	1	-	GEP	
			2015	E	-	1	-	GEP	
			2016	MED + E	-	2	-	GEP	
		Poland	2014	E	-	4	-	GEP	
			2015	E	-	2	-	GEP	
			2016	MED + E	-	~~2~~ 5	-	GEP	
		Bulgaria	2016	MED + E	-	-	2	GEP	
		Hungary	2014	E	-	-	2	GEP	
			2015	MED + E	-	-	4	GEP	1 MED
			2016	MED + E	-	-	1	GEP	
			2017	MED + E	-	-	1	GEP	
		Romania	2015	MED + E			1	GEP	
			2016	MED + E			1	GEP	

Crops*	Target(s)*	Country	Years	Type of trial**	Number of valid trials			GEP, non-GEP, official***	Comments (any other relevant information)
					Maritime Zone	North-East Zone	South-East Zone		
			2020	MED + E	-	-	~~7~~ 6	GEP	~~5~~ 4 MED
		Total ~~(42)~~ **(57)**	**2014-2020**	**E (MED)**	~~13 (7)~~ **24 (16)**	~~12 (4)~~ **15 (7)**	~~17 (10)~~ **18 (11)**	**GEP**	
		N-E EPPO + neighbouring countries	**2014-2017**	**E (MED)**	-	~~9-22(11)$~~ **14-29(14)$**	-	**GEP**	
TRZAS	**SEPTTR**	**Poland (1)**	**2016**	**E (MED)**	-	**1 (1)**	-	**GEP**	
TRZAW	**PUCCRT**	Austria	2015	E	1	-	-	GEP	
		Czech Repbulic	2015	E	1	-	-	GEP	
			2016	MED + E	2	-	-	GEP	
			2018	MED + E	1	-	-	GEP	
		Germany	2014	E	1	-	-	GEP	
			2015	E	3	-	-	GEP	
			2019	MED + E	1			GEP	
		UK	2015	E	2	-	-	GEP	
			2016	MED + E	1	-	-	GEP	
		Poland	2014	E	-	3	-	GEP	
			2015	E	-	3	-	GEP	
			2016	MED +E	-	2	-	GEP	
		Bulgaria	2016	MED + E	-	-	2	GEP	
		Hungary	2015	E	-	-	~~4~~ 5	GEP	
			2016	MED +E	-	-	3	GEP	
		Total ~~(29)~~ **(31)**	**2014-** ~~2018~~ **2019**	**E (MED)**	~~12 (4)~~ **13 (5)**	**8 (2)**	~~9~~ **10 (5)**	**GEP**	
		N-E EPPO + neighbouring countries	**2015-** ~~2018~~ **2019**	**E (MED)**	-	~~16 (5)~~ **17 (6)**	-	**GEP**	
TRZAW	**PUCCST**	Denmark	2016	MED + E	3	-	-	GEP	
		Germany	2014	E	1	-	-	GEP	
			2015	MED + E	1	-	-	GEP	
			2016	MED + E	2	-	-	GEP	

Crops*	Target(s)*	Country	Years	Type of trial**	Number of valid trials			GEP, non-GEP, official***	Comments (any other relevant information)
					Maritime Zone	North-East Zone	South-East Zone		
			2017	MED + E	1	-	-	GEP	
			2019	MED + E	1	-	-	GEP	
		UK	2015	~~MED +~~ E	2	-	-	GEP	
		Poland	2016	MED + E	-	~~4~~ 5	-	GEP	
		Latvia	2016	MED + E	-	1	-	GEP	
		Hungary	2014	E	-	-	2	GEP	
			2015	E	-	-	2	GEP	
			2016	MED + E	-	-	2	GEP	
		Romania	2016	MED + E	-	-	1	GEP	
			2020	~~MED +~~ E	-	-	1	GEP	
		Total ~~(20)~~ **(25)**	**2014-2020**	**E (MED)**	~~10 (7)~~ **11 (8)**	~~4 (4)~~ **6 (6)**	~~6 (4)~~ **8 (3)**	**GEP**	
		N-E EPPO + neighbouring countries	**2014-2019**	**E (MED)**	-	~~9 (8)~~ **12 (11)**	-	**GEP**	
TRZAS	**PUCCST**	**Poland (1)**	**2016**	**E (MED)**	-	**1 (1)**	-	**GEP**	
SECCW	**PUCCRE**	Germany	2015	E	8	-	-	GEP	
			2016	MED +E	~~1~~ 2	-	-	GEP	
			2017	MED +E	2	-	-	GEP	
		Poland	2016	MED + E	-	3	-	GEP	
		Total ~~(14)~~ **(15)**	**2015-2017**	**E (MED)**	~~11 (3)~~ **12 (4)**	**3 (3)**	-	**GEP**	
		N-E EPPO + neighbouring countries	**2015-2017**	**E (MED)**	-	~~14 (6)~~ **15 (7)**	-	**GEP**	
SECCW	**RHYNSE**	Germany	2015	E	~~5~~ 7	-	-	GEP	
			2016	MED + E	3	-	-	GEP	
			2017	MED + E	2	-	-	GEP	
		Poland	2016	MED + E	-	5	-	GEP	
		Total ~~(15)~~ **(17)**	**2015-2017**	**E (MED)**	~~10 (5)~~ **12 (5)**	**5 (5)**	-	**GEP**	
		N-E EPPO +	**2015-**	**E**	-	~~10 15 (8)$~~	-	**GEP**	

Crops*	Target(s)*	Country	Years	Type of trial**	Number of valid trials			GEP, non-GEP, official***	Comments (any other relevant information)
					Maritime Zone	North-East Zone	South-East Zone		
		neighbouring countries	**2017**	**(MED)**		**10-17 (10)[$]**			
TTLWI	**SEPTSP**	Germany	2015	E	3	-	-	GEP	
			2016	MED + E	1	-	-	GEP	
			2017	MED + E	1	-	-	GEP	
			2020	E	1	-	-	GEP	
		Poland	2016	MED + E	-	3	-	GEP	
		Total (9)	**2015-2020**	**E (MED)**	**6 (2)**	**3 (3)**	-	**GEP**	
		N-E EPPO + neighbouring countries	**2015-2020**	**E (MED)**	**-**	**5-9** ~~(4)~~ **(5)[$]**	-	**GEP**	
TTLWI	**PUCCST**	Germany	2015	E	~~1~~ 2		-	GEP	
			2020	MED + E	6		-	GEP	5 MED
		Poland	2016~~, 2020~~	MED +E		~~3~~ 1	-	GEP	
			2020	MED +E		2	-	GEP	
		Total ~~(10)~~ **(11)**	**2015-2020**	**E (MED)**	~~7~~ **8 (5)**	**3 (3)**	-	**GEP**	
		N-E EPPO + neighbouring countries	**2015-2020**	**E (MED)**		~~10 (8)~~ **8-11 (8)[$]**	-	**GEP**	
Grand Total (~~141~~ **167#)**			**2014-2020**	**E (MED)**	~~69 (33)~~ **86 (45)**	~~33 (26)~~ **33 (31)**	~~32 (19)~~ **36 (19)**	**GEP**	

*According to the GAP table. Timing of the application(s) can be added if relevant.
**P = preliminary trial, MED = minimum effective dose, E = efficacy trial.
***GEP: Good Experimental Practices. Official: carried out by a national official organisation
#Dossier includes a total of ~~111~~ 118 individual effectiveness trials (~~74~~ 81 TRZAW, one 1 TRZAS, 18 SECCW and 18 TTLWI). Total of ~~141~~ 167 trials includes ~~30~~ 44 trials that are used to support two or three disease each: Four SEPTTR/TRZAW trials are also used for PUCCRT, PUCCST/TRZAW, ~~Seven~~ nine SEPTTR/TRZAW trials are also used for PUCCRT/TRZAW, ~~six~~ twelve SEPTTR/TRZAW trials are also used for PUCCST/TRZAW, ~~four~~ two PUCCRT/TRZAW trials are also used for PUCCST/TRZAW, one SEPTTR/TRZAS trial is also used for PUCCST/TRZAS, ~~11~~ Fourteen PUCCRE/SECCW trials are also used for RHYNSE/SECCW and ~~one~~ two SEPTSP/TTLWI trials ~~is~~ are used to support PUCCST/TTLWI.
[$] Number of trials differ for supporting 1,5 L/ha or 2,0 l/ha in North-East EPPO climatic zone + neighbouring countries

Table 3.2-9 Presentation of 43 58 trials - Efficacy trials - Wheat - SEPTTR

Crop(s)(1)	Target(s) (1)	Type of trial(2)	Registration zone	EPPO climatic zone(3)	Country	Year	Trial code	Testing facilities / Organisation	Leading EPPO Guideline	Trial Status(4)
TRZAW	SEPTTR	E	Central	Maritime	Czech Republic	2014	CZ14E7B028PV01C*	Zemedelsky vyzkumny ustav Kromeriz, s.r.o.	PP 1/26	GEP
TRZAW	SEPTTR	MED+ E	Central	Maritime	Czech Republic	2016	CZ16E7B038PV02C	Zemedelsky vyzkumny ustav Kromeriz, s.r.o.	PP 1/26	GEP
TRZAW	SEPTTR	MED + E	Central	Maritime	Czech Republic	2016	CZ16E7B038PV01C	Ditana s.r.o.	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	Maritime	Germany	2014	DE14E7B014FS01*	Dow Agroscience GmbH	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	Maritime	Germany	2014	DE14E7B026UB01C*	Biochem Agrar GmbH	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	Maritime	Germany	2014	DE14E7B028TS01*	Dow Agroscience GmbH	PP 1/26	GEP
TRZAW	SEPTTR	MED+ E	Central	Maritime	Germany	2015	DE14E7B027UB01C*	Agrartest GmbH	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	Maritime	Germany	2015	DE15E7B014AS01	Dow Agroscience GmbH	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	Maritime	Germany	2015	DE15E7B014UB02C	Agrartest GmbH	PP 1/26	GEP
TRZAW	SEPTTR	MED+ E	Central	Maritime	Germany	2015	DE15E7B025AS01	Dow Agroscience GmbH	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	Maritime	Germany	2016	DE16E7B037DD02	Dow Agroscience GmbH	PP 1/26	GEP
TRZAW	SEPTTR	MED + E	Central	Maritime	Germany	2017	DE17G1C012ASO1	Dow Agroscience GmbH	PP 1/26	GEP
TRZAW	SEPTTR	MED +E	Central	Maritime	Germany	2017	DE17G1C012UB02C	Eurofins Agroscience Services GmbH	PP 1/26	GEP
TRZAW	SEPTTR	MED + E	Central	Maritime	Germany	2019	EA19F9B017F-DPE01	Dow Agroscience GmbH	PP 1/26	GEP
TRZAW	SEPTTR	MED+ E	Northern	Maritime	Denmark	2015	DK15E7B019MN02C	Aarhus University Flakkebjerg	PP 1/26	GEP
TRZAW	SEPTTR	E	Northern	Maritime	Denmark	2015	DK15E7B018MN01C	Aarhus University Flakkebjerg	PP 1/26	GEP
TRZAW	SEPTTR	MED+ E	Northern	Maritime	Denmark	2016	DK16E7B002KF02C	Aarhus University Flakkebjerg	PP 1/26	GEP
TRZAW	SEPTTR	MED+ E	Northern	Maritime	Denmark	2016	DK16E7B002KF03C	Aarhus University Flakkebjerg	PP 1/26	GEP
TRZAW	SEPTTR	MED + E	Central	Maritime	France	2015	FR15E7B025YC02	Dow Agroscience, France	PP 1/26	GEP
TRZAW	SEPTTR	MED + E	Central	Maritime	France	2015	FR15E7B025MC04C	SARL PHYLIAE	PP 1/26	GEP
TRZAW	SEPTTR	MED + E	Central	Maritime	France	2015	FR15E7B025FO01	Dow Agroscience, France	PP 1/26	GEP
TRZAW	SEPTTR	MED + E	Central	Maritime	France	2015	FR15E7B025MC03C	Staphyt	PP 1/26	GEP
TRZAW	SEPTTR	MED + E	Central	Maritime	United Kingdom	2015	GB15E7B025EB01C	EUROFINS AGROSCIENCE SERVICES LTD, UK	PP 1/26	GEP
TRZAW	SEPTTR	MED + E	Central	Maritime	United Kingdom	2016	GB16E7B038EB01C	BIOTEK Agriculture Ltd.	PP 1/26	GEP
TRZAW	SEPTTR	E	Northern	North East	Latvia	2014	LV14E7B028MN02C*	Latvian Plant Protection Research Centre, LAAPC	PP 1/26	GEP
TRZAW	SEPTTR	E	Northern	North-East	Latvia	2015	LV15E7B019MN03C	Latvian Plant Protection Research Centre, LAAPC	PP 1/26	GEP
TRZAW	SEPTTR	MED+ E	Northern	North-East	Latvia	2016	LV16E7B031KF01C	Latvian Plant Protection Research Centre, LAAPC	LV-1039	GEP
TRZAW	SEPTTR	MED+ E	Northern	North-East	Latvia	2016	LV16E7B031KF03C	Latvian Plant Protection Research Centre, LAAPC	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	North East	Poland	2014	PL14E7B014AS01C*	Poznan University of Life Sciences	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	North East	Poland	2014	PL14E7B014AS03C*	Staphyt Sp. z.o.o.	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	North East	Poland	2014	PL14E7B028AS01C*	IOR Sosnicowice	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	North East	Poland	2014	PL14E7B028AS02C*	Poznan University of Life Sciences	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	North East	Poland	2015	PL15E7B041AS01C	Poznan University of Life Sciences	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	North East	Poland	2015	PL15E7B041AS02C	IOR Sosnicowice	PP 1/26	GEP
TRZAW	SEPTTR	MED+ E	Central	North-East	Poland	2016	PL16E7B031AS02C	Staphyt Sp. z.o.o.	PP 1/26	GEP
TRZAW	SEPTTR	MED+ E	Central	North-East	Poland	2016	PL16E7B031AS03C	IOR Sosnicowice	PP 1/26	GEP
TRZAW	SEPTTR	MED+ E	Central	North-East	Poland	2016	PL16E7B038AS01C	Poznan University of Life Sciences	PP 1/26	GEP

Crop(s)[(1)]	Target(s) [(1)]	Type of trial[(2)]	Registration zone	EPPO climatic zone[(3)]	Country	Year	Trial code	Testing facilities / Organisation	Leading EPPO Guideline	Trial Status[(4)]
TRZAW	SEPTTR	MED+ E	Central	North-East	Poland	2016	PL16E7B031AS01C	IOR Sosnicowice	PP 1/26	GEP
TRZAW	SEPTTR	MED+ E	Central	North-East	Poland	2016	PL16E7B046AS02C	Poznan University of Life Sciences	PP 1/26	GEP
TRZAS	SEPTTR	MED+ E	Central	North-East	Poland	2016	PL16E7B031AS04C	Staphyt Sp. z.o.o.	PP 1/26	GEP
TRZAW	SEPTTR	MED+ E	Southern	South-East	Bulgaria	2016	BG16E7B030VA01C	ANADIAG Bulgaria Ltd	PP 1/26	GEP
TRZAW	SEPTTR	MED+ E	Southern	South-East	Bulgaria	2016	BG16E7B030VA02C	ANADIAG Bulgaria Ltd	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	South East	Hungary	2014	HU14E7B014AB01C*	Agrofil Szaktanacsado Mernoki Iroda Kft.	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	South-East	Hungary	2014	EA14E7B028AB01C*	SynTech Research Hungary Kft.	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	South East	Hungary	2015	HU15E7B011AB01C	Agrofil Szaktanacsado Mernoki Iroda Kft.	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	South East	Hungary	2015	HU15E7B011AB02C	Agrofil Szaktanacsado Mernoki Iroda Kft.	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	South East	Hungary	2015	HU15E7B011LM01	Dow Agrosciences Hungary Kft	PP 1/26	GEP
TRZAW	SEPTTR	MED+ E	Central	South-East	Hungary	2015	HU15E7B025AB01C	Agrofil Szaktanacsado Mernoki Iroda Kft.	PP 1/26	GEP
TRZAW	SEPTTR	MED+ E	Central	South East	Hungary	2016	HU16E7B030LM03	Dow Agrosciences Hungary Kft	PP 1/26	GEP
TRZAW	SEPTTR	MED+ E	Central	South-East	Hungary	2017	HU17G1C012AB01	Dow Agrosciences Hungary Kft	PP 1/26	GEP
TRZAW	SEPTTR	MED+ E	Central	South-East	Romania	2015	RO15E7B025AP01C	NARDI Fundulea	PP 1/26	GEP
TRZAW	SEPTTR	MED+ E	Central	South East	Romania	2016	RO16E7B046AP01C	NARDI Fundulea	PP 1/26	GEP
TRZAW	SEPTTR	MED+ E	Central	South-East	Romania	2020	EA20E7B020F-DHT047	NARDI Fundulea	PP 1/26	GEP
TRZAW	SEPTTR	MED+ E	Central	South-East	Romania	2020	EA20E7B020F-DHT048	SC AgroProspect SRL	PP 1/26	GEP
TRZAW	SEPTTR	MED+ E	Central	South-East	Romania	2020	EA20E7B020F-DHT084	Eurofins Agricultural Services SRL	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	South-East	Romania	2020	EA20E7B035F-DHT074	SC AgroProspect SRL	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	South-East	Romania	2020	EA20E7B035F-DHT075	NARDI Fundulea	PP 1/26	GEP
TRZAW	SEPTTR	MED+ E	Central	South-East	Romania	2020	EA20E7B065F-DHT071	Eurofins Agricultural Services SRL	PP 1/26	GEP

(1) According to the GAP table.
(2) P= Efficacy trials used in preliminary part - MED: Efficacy trials used in Minimum effective dose - E = Efficacy trial
(3) According to EPPO guideline PP 1/241(1) "Guidance on comparable climates”.
(4) GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Table 3.2-10 Presentation of 29 31 trials - Efficacy trials - Wheat - PUCCRT

Crop(s)[(1)]	Target(s) [(1)]	Type of trial[(2)]	Registration zone	EPPO climatic zone[(3)]	Country	Year	Trial code	Testing facilities / Organisation	Leading EPPO Guideline	Trial Status[(4)]
TRZAW	PUCCRT	E	Central	Maritime	Austria	2015	DE15E7B014UB06C	Agro Trial Center GmbH	PP 1/26	GEP
TRZAW	PUCCRT	E	Central	Maritime	Czech Republic	2015	CZ15E7B014PV01C	OSEVA PRO s.r.o.	PP 1/26	GEP
TRZAW	PUCCRT	MED+ E	Central	Maritime	Czech Republic	2016	CZ16E7B038PV01C	Ditana Spol. s.r.o.	PP 1/26	GEP
TRZAW	PUCCRT	MED+ E	Central	Maritime	Czech Republic	2016	CZ16E7B038PV02C	Zemedelsky vyzkumny ustav Kromeriz, s.r.o.	PP 1/26	GEP
TRZAW	PUCCRT	MED+ E	Central	Maritime	Czech Republic	2018	CZ18E7B017PV01C	Zemedelska zkusebni stanice Kujavy, s.r.o.	PP 1/26	GEP
TRZAW	PUCCRT	E	Central	Maritime	Germany	2014	DE14E7B026UB01C*	Biochem Agrar GmbH	PP 1/26	GEP
TRZAW	PUCCRT	E	Central	Maritime	Germany	2015	DE15E7B014AS01	Dow Agroscience GmbH	PP 1/26	GEP
TRZAW	PUCCRT	E	Central	Maritime	Germany	2015	DE15E7B014UB02C	Agrartest GmbH	PP 1/26	GEP
TRZAW	PUCCRT	E	Central	Maritime	Germany	2015	DE15E7B014UB04C	Eurofins Agroscience Services GmbH	PP 1/26	GEP
TRZAW	PUCCRT	MED + E	Central	Maritime	Germany	2019	EA19F9B017F-DPE01	Dow Agroscience GmbH	PP 1/26	GEP
TRZAW	PUCCRT	E	Central	Maritime	UK	2015	GB15E7B014EB01C	FieldArm Limited	PP 1/26	GEP
TRZAW	PUCCRT	E	Central	Maritime	UK	2015	GB15E7B014EB03C	FieldArm Limited	PP 1/26	GEP
TRZAW	PUCCRT	MED+ E	Central	Maritime	UK	2016	GB16E7B038EB01C	BIOTEK Agriculture Ltd	PP 1/26	GEP
TRZAW	PUCCRT	E	Central	North-East	Poland	2014	PL14E7B010AS01C*	Poznan University of Life Sciences	PP 1/26	GEP
TRZAW	PUCCRT	E	Central	North-East	Poland	2014	PL14E7B010AS02C*	IOR Sosnicowice	PP 1/26	GEP
TRZAW	PUCCRT	E	Central	North-East	Poland	2014	PL14E7B028AS01C*	IOR Sosnicowice	PP 1/26	GEP
TRZAW	PUCCRT	E	Central	North-East	Poland	2015	PL15E7B022AS01C	Poznan University of Life Sciences	PP 1/26	GEP
TRZAW	PUCCRT	E	Central	North-East	Poland	2015	PL15E7B022AS02C	Poznan University of Life Sciences	PP 1/26	GEP
TRZAW	PUCCRT	E	Central	North-East	Poland	2015	PL15E7B022AS03C	Staphyt Sp. z.o.o.	PP 1/26	GEP
TRZAW	PUCCRT	MED+ E	Central	North-East	Poland	2016	PL16E7B038AS01C	Poznan University of Life Sciences	PP 1/26	GEP
TRZAW	PUCCRT	MED+ E	Central	North East	Poland	2016	PL16E7B046AS02C	Poznan University of Life Sciences	PP 1/26	GEP
TRZAW	PUCCRT	MED+ E	Southern	South-East	Bulgaria	2016	BG16E7B030VA01C	ANADIAG Bulgaria Ltd	PP 1/26	GEP
TRZAW	PUCCRT	MED+ E	Southern	South-East	Bulgaria	2016	BG16E7B030VA02C	ANADIAG Bulgaria Ltd	PP 1/26	GEP
TRZAW	PUCCRT	E	Central	South-East	Hungary	2015	HU15E7B012AB01C	Agrofil Szaktanacsado Mernoki Iroda Kft.	PP 1/26	GEP
TRZAW	PUCCRT	E	Central	South-East	Hungary	2015	HU15E7B012AB02	Dow Agrosciences Hungary Kft	PP 1/26	GEP
TRZAW	PUCCRT	E	Central	South-East	Hungary	2015	HU15E7B012AB02C	Agrofil Szaktanacsado Mernoki Iroda Kft.	PP 1/26	GEP
TRZAW	PUCCRT	E	Central	South-East	Hungary	2015	HU15E7B040AB02C	Agrofil Szaktanacsado Mernoki Iroda Kft.	PP 1/26	GEP
TRZAW	PUCCRT	E	Central	South-East	Hungary	2015	HU15E7B011LM01	Dow Agrosciences Hungary Kft	PP 1/26	GEP
TRZAW	PUCCRT	MED+ E	Central	South-East	Hungary	2016	HU16E7B029AB04	Dow Agrosciences Hungary Kft	PP 1/26	GEP
TRZAW	PUCCRT	MED+ E	Central	South-East	Hungary	2016	HU16E7B029LM03	Dow Agrosciences Hungary Kft	PP 1/26	GEP
TRZAW	PUCCRT	MED+ E	Central	South-East	Hungary	2016	HU16E7B046AB01C	BIOTEK Agriculture Hungary Kft.	PP 1/26	GEP

(1) According to the GAP table.
(2) P= Efficacy trials used in preliminary part - MED: Efficacy trials used in Minimum effective dose - E = Efficacy trial
(3) According to EPPO guideline PP 1/241(1) "Guidance on comparable climates".
(4) GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Table 3.2-11 Presentation of ~~21~~ 26 trials - Efficacy trials - Wheat - PUCCST

Crop(s)(1)	Target(s) (1)	Type of trial(2)	Registration zone	EPPO climatic zone(3)	Country	Year	Trial code	Testing facilities / Organisation	Leading EPPO Guideline	Trial Status(4)
TRZAW	PUCCST	E	Central	Maritime	Germany	2014	DE14E7B028TS01*	Dow Agrosciences GmbH	PP 1/26	GEP
TRZAW	PUCCST	MED + E	Central	Maritime	Germany	2015	DE15E7B025AS01	Dow Agrosciences GmbH	PP 1/26	GEP
TRZAW	PUCCST	MED+ E	Central	Maritime	Germany	2016	DE16E7B027DD01	Dow Agrosciences GmbH	PP 1/26	GEP
TRZAW	PUCCST	MED+ E	Central	Maritime	Germany	2016	DE16E7B037DD02	Dow Agrosciences GmbH	PP 1/26	GEP
TRZAW	PUCCST	MED+ E	Central	Maritime	Germany	2017	DE17G1C012UB02C	Eurofins Agroscience Services GmbH	PP 1/26	GEP
TRZAW	PUCCST	MED+ E	Central	Maritime	Germany	2019	EA19F9B017F-DPE01	Dow Agrosciences GmbH	PP 1/26	GEP
TRZAW	PUCCST	MED+ E	Northern	Maritime	Denmark	2016	DK16E7B002KF01C	Aarhus University Flakkebjerg	PP 1/26	GEP
TRZAW	PUCCST	MED+ E	Northern	Maritime	Denmark	2016	DK16E7B002KF02C	Aarhus University Flakkebjerg	PP 1/26	GEP
TRZAW	PUCCST	MED+ E	Northern	Maritime	Denmark	2016	DK16E7B002KF03C	Aarhus University Flakkebjerg	PP 1/26	GEP
TRZAW	PUCCST	E	Central	Maritime	UK	2015	GB15E7B015EB01C	Armstrong Fisher Ltd	PP 1/26	GEP
TRZAW	PUCCST	E	Central	Maritime	UK	2015	GB15E7B015EB04C	Suffolk and Cambridge Crop Station Ltd	PP 1/26	GEP
TRZAW	PUCCST	MED + E	Central	North-East	Latvia	2016	LV16E7B031KF01C	Latvian Plant Protection Research Centre, LAAPC	PP 1/26	GEP
TRZAW	PUCCST	MED+ E	Central	North-East	Poland	2016	PL16E7B031AS01C	IOR Sosnicowice	PP 1/26	GEP
TRZAW	PUCCST	MED+ E	Central	North-East	Poland	2016	PL16E7B031AS02C	Staphyt Sp. z.o.o.	PP 1/26	GEP
TRZAS	PUCCST	MED+ E	Central	North-East	Poland	2016	PL16E7B031AS04C	Staphyt Sp. z.o.o.	PP 1/26	GEP
TRZAW	PUCCST	MED+ E	Central	North-East	Poland	2016	PL16E7B038AS01C	Poznan University of Life Sciences	PP 1/26	GEP
TRZAW	PUCCST	MED+ E	Central	North East	Poland	2016	PL16E7B046AS02C	Poznan University of Life Sciences	PP 1/26	GEP
TRZAW	PUCCST	MED+ E	Central	North East	Poland	2016	PL16E7B031AS03C	IOR Sosnicowice	PP 1/26	GEP
TRZAW	PUCCST	E	Central	South East	Hungary	2014	HU14E7B010AB01*	SynTech Research Hungary Kft.	PP 1/26	GEP
TRZAW	PUCCST	E	Central	South East	Hungary	2014	HU14E7B026LM01*	Dow Agrosciences Hungary Kft	PP 1/26	GEP
TRZAW	PUCCST	E	Central	South East	Hungary	2015	HU15E7B011LM01	Dow Agrosciences Hungary Kft	PP 1/26	GEP
TRZAW	PUCCST	E	Central	South East	Hungary	2015	HU15E7B012AB02	Dow Agrosciences Hungary Kft	PP 1/26	GEP
TRZAW	PUCCST	MED+ E	Central	South-East	Hungary	2016	HU16E7B029AB04	Dow Agrosciences Hungary Kft	PP 1/26	GEP
TRZAW	PUCCST	MED+ E	Central	South-East	Hungary	2016	HU16E7B029LM03	Dow Agrosciences Hungary Kft	PP 1/26	GEP
TRZAW	PUCCST	MED+ E	Central	South East	Romania	2016	RO16E7B046AP01C	NARDI Fundulea	PP1/26	GEP
TRZAW	PUCCST	~~MED+~~ E	Central	South East	Romania	2020	EA20E7B035F-DHT075	NARDI Fundulea	PP1/26	GEP

(1) According to the GAP table.
(2) P= Efficacy trials used in preliminary part - MED: Efficacy trials used in Minimum effective dose - E = Efficacy trial
(3) According to EPPO guideline PP 1/241(1) "Guidance on comparable climates".
(4) GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Table 3.2-12 Presentation of ~~14~~ 15 trials - Efficacy trials - Rye - PUCCRE

Crop(s)[1]	Target(s) [1]	Type of trial[2]	Registration zone	EPPO climatic zone[3]	Country	Year	Trial code	Testing facilities / Organisation	Leading EPPO Guideline	Trial Status[4]
SECCW	PUCCRE	E	Central	Maritime	Germany	2015	DE15E7B002TS01	Dow Agrosciences GmbH	PP 1/26	GEP
SECCW	PUCCRE	E	Central	Maritime	Germany	2015	DE15E7B002UB02C	Agrartest GmbH	PP 1/26	GEP
SECCW	PUCCRE	E	Central	Maritime	Germany	2015	DE15E7B002UB03C	Agrartest GmbH	PP 1/26	GEP
SECCW	PUCCRE	E	Central	Maritime	Germany	2015	DE15E7B033UB01C	Agrartest GmbH	PP 1/26	GEP
SECCW	PUCCRE	E	Central	Maritime	Germany	2015	DE15E7B033UB02C	Agrartest GmbH	PP 1/26	GEP
SECCW	PUCCRE	E	Central	Maritime	Germany	2015	DE15E7B033UB03C	Agrartest GmbH	PP 1/26	GEP
SECCW	PUCCRE	E	Central	Maritime	Germany	2015	DE15E7B033UB04C	Agrartest GmbH	PP 1/26	GEP
SECCW	PUCCRE	E	Central	Maritime	Germany	2015	DE15E7B033UB05C	Agrartest GmbH	PP 1/26	GEP
SECCW	PUCCRE	MED+ E	Central	Maritime	Germany	2016	DE16E7B019UB01C	Agrartest GmbH	PP 1/26	GEP
SECCW	PUCCRE	MED+ E	Central	Maritime	Germany	2016	DE16E7B044DW01C	Agrartest GmbH	PP 1/26	GEP
SECCW	PUCCRE	MED+ E	Central	Maritime	Germany	2017	DE17G1C012TS01	Dow Agrosciences GmbH	PP 1/26	GEP
SECCW	PUCCRE	MED+ E	Central	Maritime	Germany	2017	DE17G1C012UB03C	Eurofins Agroscience Services GmbH	PP 1/26	GEP
SECCW	PUCCRE	MED+ E	Central	North-East	Poland	2016	PL16E7B019AS03C	Poznan University of Life Sciences	PP 1/26	GEP
SECCW	PUCCRE	MED+ E	Central	North-East	Poland	2016	PL16E7B019AS04C	Staphyt Sp. z.o.o.	PP 1/26	GEP
SECCW	PUCCRE	MED+ E	Central	North-East	Poland	2016	PL16E7B019AS05C	Staphyt Sp. z.o.o.	PP 1/26	GEP

(1) According to the GAP table.
(2) P= Efficacy trials used in preliminary part - MED: Efficacy trials used in Minimum effective dose - E = Efficacy trial
(3) According to EPPO guideline PP 1/241(1) "Guidance on comparable climates".
(4) GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Table 3.2-13 Presentation of ~~15~~ 17 trials - Efficacy trials - Rye - RHYNSE

Crop(s)[1]	Target(s) [1]	Type of trial[2]	Registration zone	EPPO climatic zone[3]	Country	Year	Trial code	Testing facilities / Organisation	Leading EPPO Guideline	Trial Status[4]
SECCW	RHYNSE	E	Central	Maritime	Germany	2015	DE15E7B002UB02C	Agrartest GmbH	PP 1/26	GEP
SECCW	RHYNSE	E	Central	Maritime	Germany	2015	DE15E7B033UB01C	Agrartest GmbH	PP 1/26	GEP
SECCW	RHYNSE	E	Central	Maritime	Germany	2015	DE15E7B033UB02C	Agrartest GmbH	PP 1/26	GEP
SECCW	RHYNSE	E	Central	Maritime	Germany	2015	DE15E7B033UB03C	Agrartest GmbH	PP 1/26	GEP
SECCW	RHYNSE	E	Central	Maritime	Germany	2015	DE15E7B033UB05C	Agrartest GmbH	PP 1/26	GEP
SECCW	RHYNSE	E	Central	Maritime	Germany	2015	DE15E7B002UB03C	Agrartest GmbH	PP 1/26	GEP
SECCW	RHYNSE	E	Central	Maritime	Germany	2015	DE15E7B033UB04C	Agrartest GmbH	PP 1/26	GEP
SECCW	RHYNSE	MED+ E	Central	Maritime	Germany	2016	DE16E7B019UB01C	Agrartest GmbH	PP 1/26	GEP
SECCW	RHYNSE	MED+ E	Central	Maritime	Germany	2016	DE16E7B019WD01	Dow Agrosciences GmbH	PP 1/26	GEP
SECCW	RHYNSE	MED+ E	Central	Maritime	Germany	2016	DE16E7B044DW01C	Agrartest GmbH	PP 1/26	GEP
SECCW	RHYNSE	MED+ E	Central	Maritime	Germany	2017	DE17G1C012TS01	Dow Agrosciences GmbH	PP 1/26	GEP
SECCW	RHYNSE	MED+ E	Central	Maritime	Germany	2017	DE17G1C012UB03C	Eurofins Agroscience Services GmbH	PP 1/26	GEP
SECCW	RHYNSE	MED+ E	Central	North-East	Poland	2016	PL16E7B019AS01C	IOR Sosnicowice	PP 1/26	GEP
SECCW	RHYNSE	MED+ E	Central	North-East	Poland	2016	PL16E7B019AS02C	IOR Sosnicowice	PP 1/26	GEP
SECCW	RHYNSE	MED+ E	Central	North-East	Poland	2016	PL16E7B019AS03C	Poznan University of Life Sciences	PP 1/26	GEP
SECCW	RHYNSE	MED+ E	Central	North-East	Poland	2016	PL16E7B019AS04C	Staphyt Sp. z.o.o.	PP 1/26	GEP
SECCW	RHYNSE	MED+ E	Central	North-East	Poland	2016	PL16E7B019AS05C	Staphyt Sp. z.o.o.	PP 1/26	GEP

* Trials that support both the one and two application regimes.
(1) According to the GAP table.
(2) P= Efficacy trials used in preliminary part - MED: Efficacy trials used in Minimum effective dose - E = Efficacy trial
(3) According to EPPO guideline PP 1/241(1) "Guidance on comparable climates".
(4) GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Table 3.2-14 Presentation of 9 trials - Efficacy trials - Triticale - SEPTSP

Crop(s)(1)	Target(s) (1)	Type of trial(2)	Registration zone	EPPO climatic zone(3)	Country	Year	Trial code	Testing facilities / Organisation	Leading EPPO Guideline	Trial Status(4)
TTLWI	SEPTSP	E	Central	Maritime	Germany	2015	DE15E7B003UB01C	Agrartest GmbH	PP 1/26	GEP
TTLWI	SEPTSP	E	Central	Maritime	Germany	2015	DE15E7B034UB02C	Agrartest GmbH	PP 1/26	GEP
TTLWI	SEPTSP	E	Central	Maritime	Germany	2015	DE15E7B034UB04C	Agrartest GmbH	PP 1/26	GEP
TTLWI	SEPTSP	MED+ E	Central	Maritime	Germany	2016	DE16X02002FS01C	Eurofins Agroscience Services GmbH	PP 1/26	GEP
TTLWI	SEPTSP	MED+ E	Central	Maritime	Germany	2017	DE17G1C012UB01C	Agrartest GmbH	PP 1/26	GEP
TTLWI	SEPTSP	E	Central	Maritime	Germany	2020	EA20F9B007F-DPE014	Agrartest GmbH	PP 1/26	GEP
TTLWI	SEPTSP	MED+ E	Central	North-East	Poland	2016	PL16E7B020AS03C	Poznan University of Life Sciences	PP 1/26	GEP
TTLWI	SEPTSP	MED+ E	Central	North-East	Poland	2016	PL16E7B020AS04C	Staphyt Sp. z.o.o.	PP 1/26	GEP
TTLWI	SEPTSP	MED+ E	Central	North-East	Poland	2016	PL16E7B020AS05C	Staphyt Sp. z.o.o.	PP 1/26	GEP

(1) According to the GAP table.
(2) P= Efficacy trials used in preliminary part - MED: Efficacy trials used in Minimum effective dose - E = Efficacy trial
(3) According to EPPO guideline PP 1/241(1) "Guidance on comparable climates”.
(4) GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Table 3.2-15 Presentation of ~~10~~ 11 trials - Efficacy trials - Triticale - PUCCST

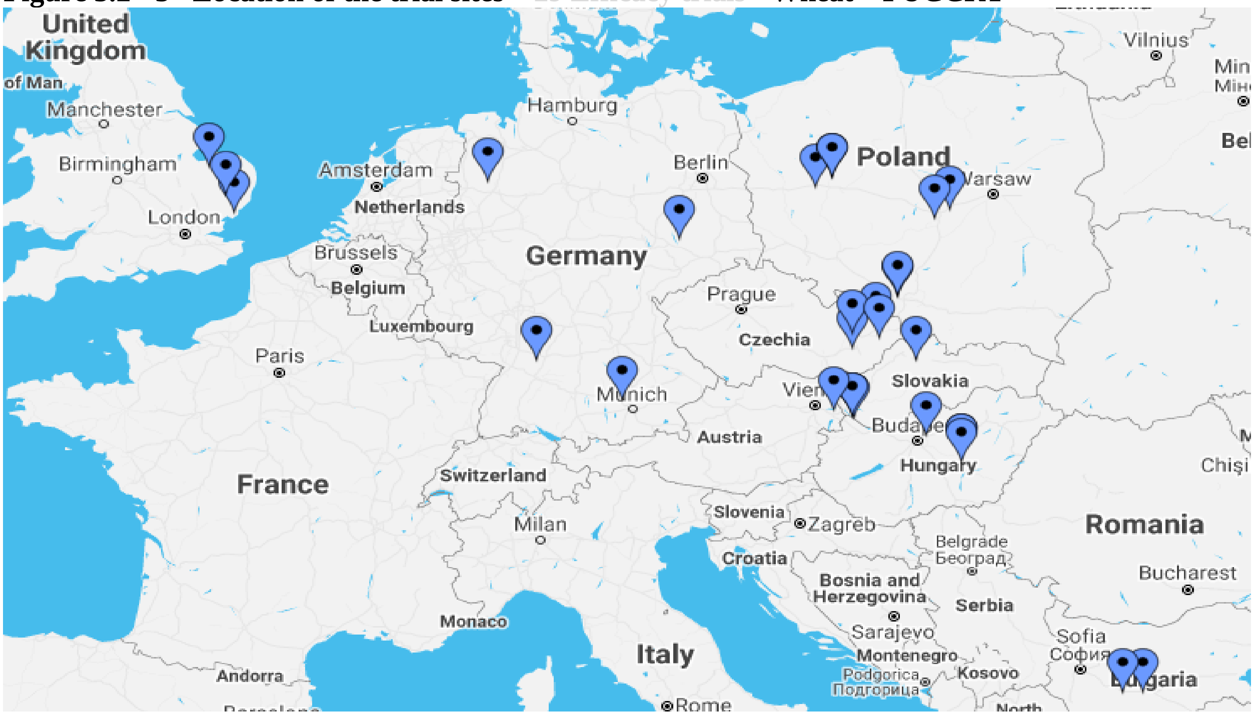
Crop(s)(1)	Target(s) (1)	Type of trial(2)	Registration zone	EPPO climatic zone(3)	Country	Year	Trial code	Testing facilities / Organisation	Leading EPPO Guideline	Trial Status(4)
TTLWI	PUCCST	E	Central	Maritime	Germany	2015	DE15E7B034UB03C	Agrartest GmbH	PP 1/26	GEP
TTLWI	PUCCST	E	Central	Maritime	Germany	2015	DE15E7B034UB02C	Agrartest GmbH	PP 1/26	GEP
TTLWI	PUCCST	MED+ E	Central	Maritime	Germany	2020	EA20E7B018F-DNZ056	Trial-tec GmbH	PP 1/26	GEP
TTLWI	PUCCST	MED+ E	Central	Maritime	Germany	2020	EA20E7B018F-DNZ057	Trial-tec GmbH	PP 1/26	GEP
TTLWI	PUCCST	MED+ E	Central	Maritime	Germany	2020	EA20E7B018F-DNZ058	Trial-tec GmbH	PP 1/26	GEP
TTLWI	PUCCST	MED+ E	Central	Maritime	Germany	2020	EA20E7B068F-DNZ074	Trial-tec GmbH	PP 1/26	GEP
TTLWI	PUCCST	MED+ E	Central	Maritime	Germany	2020	EA20E7B068F-DNZ075	Trial-tec GmbH	PP 1/26	GEP
TTLWI	PUCCST	E	Central	Maritime	Germany	2020	EA20F9B007F-DPE013	Trial-tec GmbH	PP 1/26	GEP
TTLWI	PUCCST	MED+ E	Central	North-East	Poland	2016	PL16E7B020AS03C	Poznan University of Life Sciences	PP 1/26	GEP
TTLWI	PUCCST	MED+ E	Central	North-East	Poland	2020	EA20E7B018F-DPF026	Poznan University of Life Sciences	PP 1/26	GEP
TTLWI	PUCCST	MED+ E	Central	North-East	Poland	2020	EA20E7B018F-DPF027	Staphyt Sp. z.o.o.	PP 1/26	GEP

* Trials that support both the one and two application regimes.
(1) According to the GAP table.
(2) P= Efficacy trials used in preliminary part - MED: Efficacy trials used in Minimum effective dose - E = Efficacy trial
(3) According to EPPO guideline PP 1/241(1) "Guidance on comparable climates”.
(4) GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Figure 3.2 - 2 Location of the trial sites ~~43 Efficacy trials~~ **Wheat - SEPTTR**

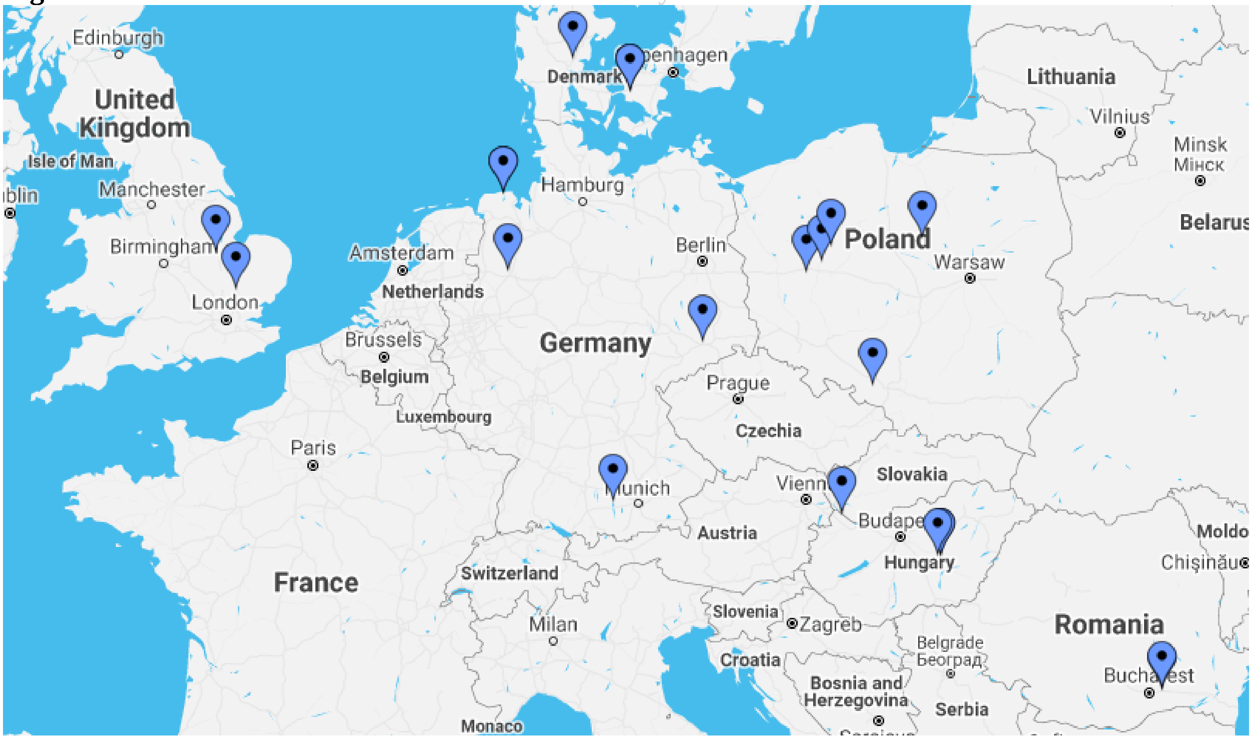
Note: Some markers may be for multiple sites in close proximity

Figure 3.2 - 3 Location of the trial sites ~~29 Efficacy trials~~ **Wheat – PUCCRT**



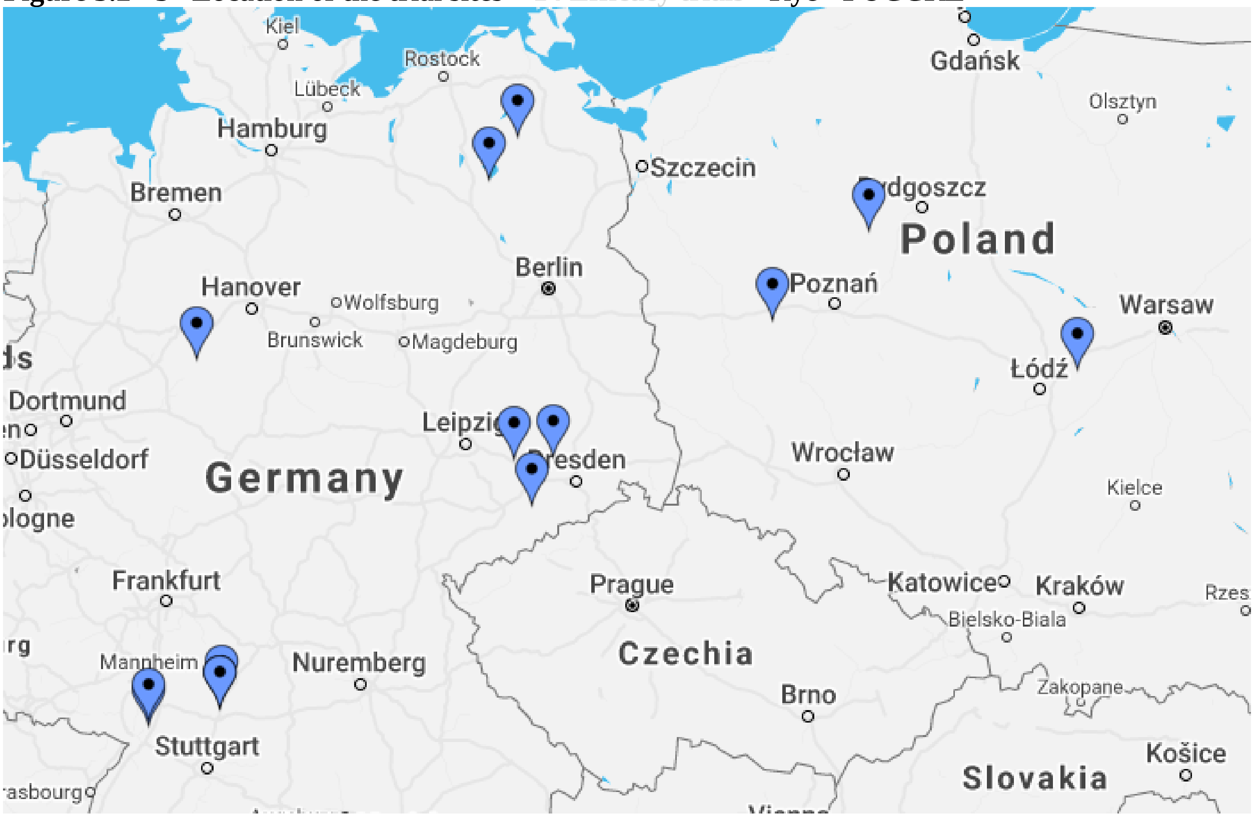
Note: Some markers may be for multiple sites in close proximity

Figure 3.2 - 4 Location of the trial sites ~~– 21 Efficacy trials –~~ **Wheat - PUCCST**



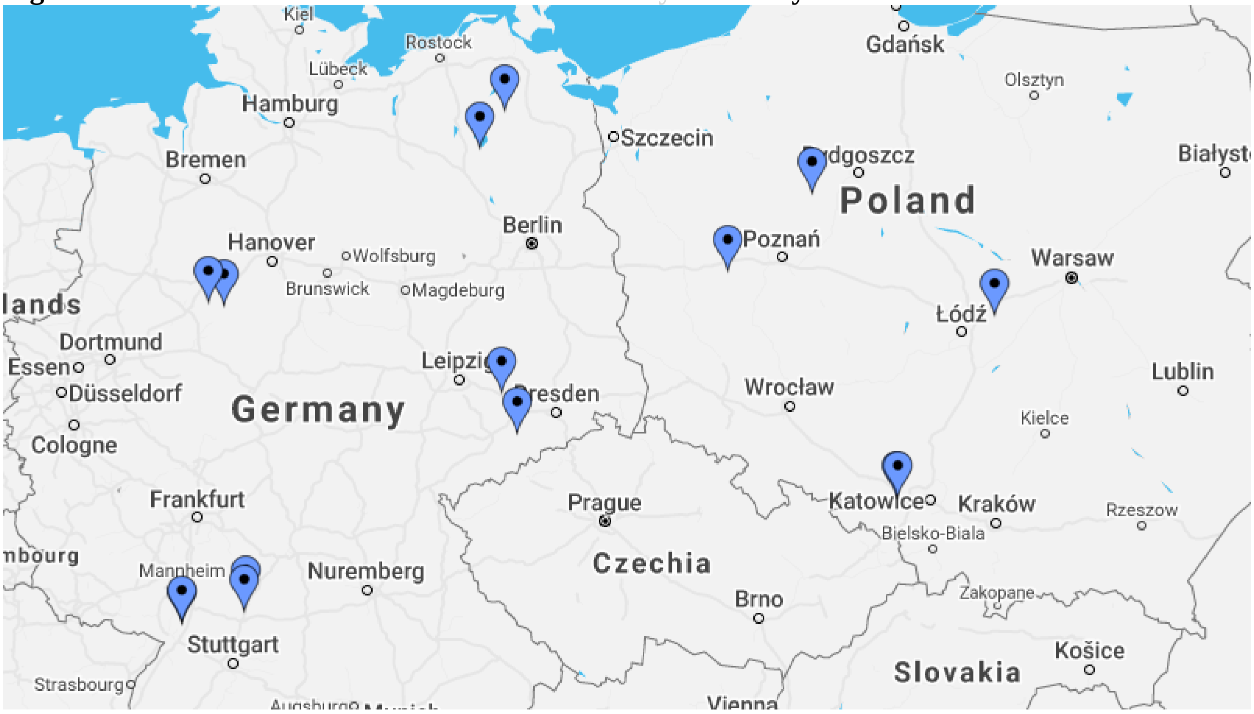
Note: Some markers may be for multiple sites in close proximity

Figure 3.2 - 5 Location of the trial sites ~~– 14 Efficacy trials –~~ **Rye - PUCCRE**



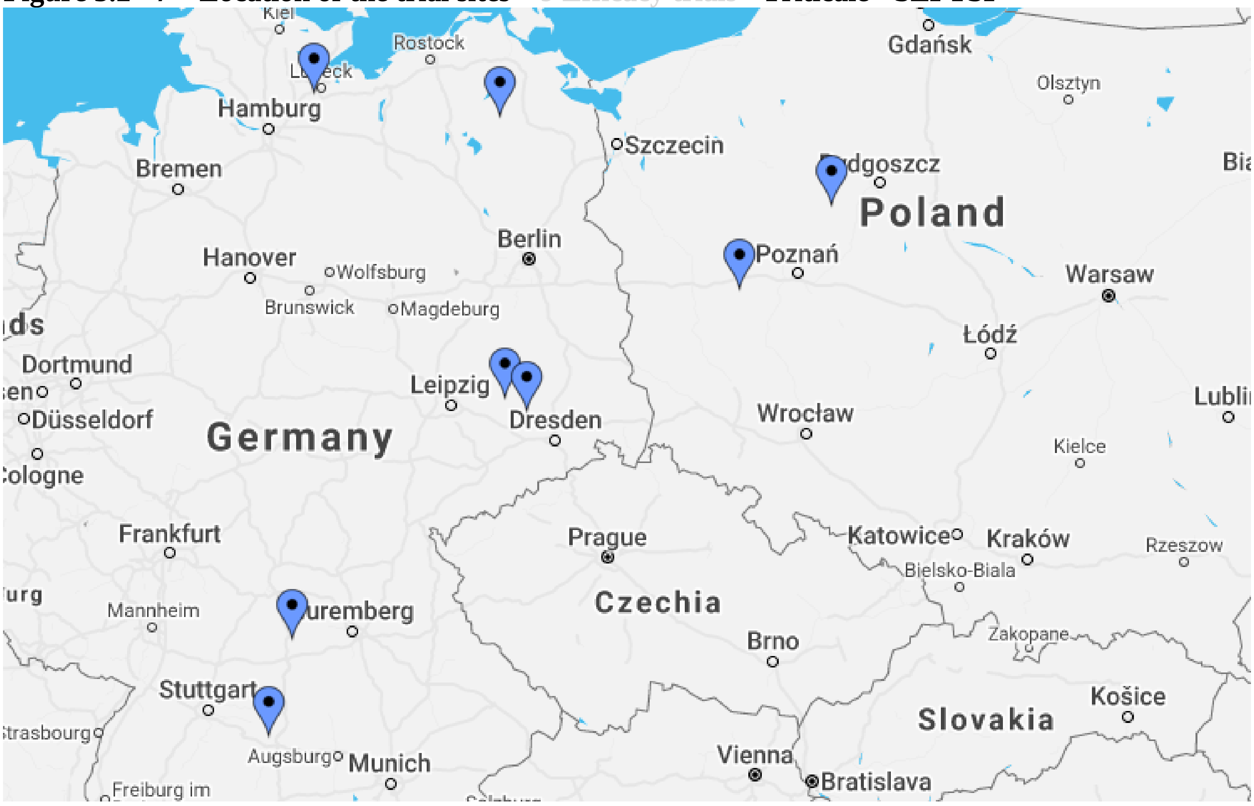
Note: Some markers may be for multiple sites in close proximity

Figure 3.2 - 6 Location of the trial sites ~~– 15 Efficacy trials –~~ Rye – RHYNSE



Note: Some markers may be for multiple sites in close proximity

Figure 3.2 - 7 Location of the trial sites ~~– 9 Efficacy trials –~~ Triticale - SEPTSP



Note: Some markers may be for multiple sites in close proximity

Figure 3.2 - 8 Location of the trial sites ~~– 10 Efficacy trials –~~ Triticale – PUCCST

Note: Some markers may be for multiple sites in close proximity

Remark: These maps show locations of trials presented by the applicant. Under evaluation, additional trials have been considered with locations of trial sites in close proximity to these existing on maps or other locations of trial sites.

To facilitate comparison of data produced in different conditions the same reference products have been used in the majority of trials (see Table 3.2-16), in line with EPPO PP 1/278 *Principles of Zonal Data Production and Evaluation*. Both the prothioconazole product Proline (275 g/L prothioconazole) and bixafen + prothioconazole product Aviator Xpro (75 g/L bixafen + 150 g/L prothioconazole) have been chosen as the representative standards across the countries, as at least one of these products (or a related product, e.g. Proline/250 g/L prothioconazole) is authorised in all countries. In some trials other standards have been used (Vertisan/200 g/l penthiopyrad, Librax/45 g/l fluxapyroxad + 62.5 g/l metconazole or Input/160 g/l prothioconazole + 300 g/L spiroxamine) and where these have been used is detailed in the relevant section. Some trials included other standards, but these have not been listed as they are not referenced in this dossier.

Table 3.2-16: Presentation of reference standards used in MED and efficacy trials

Crop(s)	Reference standard	Country(ies) where the product is registered (1)	Authorization number	Active substance(s)	Formulation		Registered application rate(3)	Application rate in trials (per treatment)	Remark(4)
					Type(2)	Content of a,s,			
TRZAW	Proline 275	UK	MAPP 14790	prothioconazole	EC	275 g/ L	0,72 L/ha	0,72 L/ha	
	Proline 275	FR	n/a	prothioconazole	EC	275 g/ L	n/a	0,72 L/ha	
	Proline 275	DK	n/a	prothioconazole	EC	275 g/ L	n/a	0,72 L/ha	250 g/l product registered
	Proline 275	CZ	n/a	prothioconazole	EC	275 g/ L	n/a	0,72 L/ha	250 g/l product registered
	Proline 275 or Proline 250	DE	n/a	prothioconazole	EC	275 g/ L or 250 g/L	n/a	0,72 L/ha or 0,8 L/ha	250 g/l product registered
	Proline 275	LV	n/a	prothioconazole	EC	275 g/ L	n/a	0,72 L/ha	250 g/l product registered
	Proline 275	PL	n/a	prothioconazole	EC	275 g/ L	n/a	0,72 L/ha	250-300 g/l products registered
	Proline 275	HU	n/a	prothioconazole	EC	275 g/ L	n/a	0,72 L/ha	250 g/l product registered
	Proline 275	RO	n/a	prothioconazole	EC	275 g/ L	n/a	0,72 L/ha	250 g/l product registered
	Proline 275	BG	n/a	prothioconazole	EC	275 g/ L	n/a	0,72 L/ha	250 g/l product registered
	Aviator XPRO 225 EC	AT	3053	bixafen + prothioconazole	EC	75+150 g/L	1,25 L/ha	1,25 L/ha	
	Aviator XPRO 225 EC	DE	006764-00	bixafen + prothioconazole	EC	75+150 g/L	1,25 L/ha	1,25 L/ha	
	Aviator XPRO 225 EC	CZ	5635-0	bixafen + prothioconazole	EC	75+150 g/L	0,8-1,0 L/ha	1,25 L/ha	
	Aviator XPRO 225 EC	PL	R-11/2013	bixafen + prothioconazole	EC	75+150 g/L	0,8-1,0 L/ha	1,25 L/ha	
	Aviator XPRO 225 EC	RO	352PC/29,11,2017	bixafen + prothioconazole	EC	75+150 g/L	0,8-1,0 L/ha	~~1,25 L/ha~~ 1,0 L/ha	
	Aviator XPRO 225 EC	HU	n/a	bixafen + prothioconazole	EC	75+150 g/L	n/a	1,25 L/ha	60 + 200 g/l product registered
	Aviator XPRO	UK	MAPP 15026	bixafen + prothioconazole	EC	75+160 g/L	1,25 L/ha	1,25 L/ha	
	Librax	DE	007969-00	fluxapyroxad + metconazole	EC	45 + 62,5 g/l	2,0 L/ha	2,0 L/ha	
	Vertisan	PL	n/a	penthiopyrad	EC	200 g/l	n/a	1,0 L/ha	Other 200 g/l product registered
	Vertisan	HU	n/a	penthiopyrad	EC	200 g/l	n/a	1,0 L/ha	Other 200 g/l product

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)	Content of a,s,			
									registered
	Vertisan	RO	n/a	penthiopyrad	EC	200 g/l	n/a	1,0 L/ha	Other 200 g/l product registered
	Input	RO	n/a	prothioconazole + spiroxamine	EC	160 g/l + 300 g/l	n/a	1,0 L/ha	
TRZAS	Proline 275	PL	n/a	prothioconazole	EC	275 g/ L	n/a	0,72 L/ha	250-300 g/l products registered
TTLWI	Proline 275 or Proline 250	DE	n/a	prothioconazole	EC	275 g/L or 250 g/L	n/a	0,72 L/ha or 0,65 L/ha	250 g/l product registered
	Proline 275 or Proline 250	PL	n/a	prothioconazole	EC	275 g/ L or 250 g/L	n/a	0,72 L/ha or 0,8 L/ha	
	Prosaro	DE	025662-00	tebuconazole + prothioconazole	EC	125+125 g/L	1,0 L/ha	1,0 L/ha	
SECCW	Proline 275	DE	n/a	prothioconazole	EC	275 g/ L	n/a	0,72 L/ha	250 g/l product registered
	Aviator XPRO 225 EC	DE	006764-00	bixafen + prothioconazole	EC	75+150 g/L	1,25 L/ha	1,25 L/ha	
	Proline 275	PL	n/a	prothioconazole	EC	275 g/ L	n/a	0,72 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.)
n/a = not currently authorised/registered in 2021

3.2.1 Preliminary tests (KCP 6.1)

Introduction

From this point on in this dossier fenpicoxamid may also be referred to as XDE-777 (and early stage coded X772777 or XR-777). Fenpicoxamid has been tested extensively in preliminary laboratory and field tests which demonstrated efficacious activity and appropriate crop safety of this novel fungicide active. Fenpicoxamid is a protectant and curative foliar applied fungicide for the control of a range of diseases frequently damaging cereal crops in countries of the European Union. It has especially strong curative and lasting protectant activity against SEPTSP, PUCCRE, PUCCST and RHYNSE in cereal crops.

Formulation Development History of fenpicoxamid

The straight fenpicoxamid formulation has been improved over years of development and optimised to finally register GF-3308. The active substance dossier was submitted in 2014 for the SC formulation GF-2925 containing 130 g as/ha fenpicoxamid. Between 2013 and 2015 preliminary studies concentrated on optimising performance of fenpicoxamid in cereals with a view to obtain higher levels of control, broader spectrum, improved leaf spreading and mobility, enhanced curative activity and a lower target dose. The move from the SC formulation to the new EC formulations enhanced many characteristics of fenpicoxamid and enabled a step change in performance against cereal diseases when compared to the SC formulation GF-2925. The preliminary studies presented in the section explain the improved characteristics and performance of fenpicoxamid through formulation development. The table below is a brief description of formulation development history of Fenpicoxamid. See Part C for further details on formulations.

Formulation development timeline

Years	Fenpicoxamid Formulation No.	Formulation type	Formulation concentration g as/l
2012	GF-2925	SC	130
2013	GF-3135	EC	50
2014	GF-3311	EC	~~67.5~~ 66,7
2015	GF-3308	EC	50

3.2.1.1 Early Stage Screening

The non-GEP/GLP early stage screening tests were carried out in the laboratories and glasshouses on the premises of Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268, USA.

In vitro fungi toxicity

Early stage biological evaluation of Fenpicoxamid included *in vitro* fungi toxicity testing across five pathogens and using eight dose rates expressed in ppm. Fungi toxicity assays were carried out in 96-well plates, each well containing a total assay volume of 200 µl. The growth media employed were yeast extract-malt extract-peptone agar for *Septoria nodorum* (LEPTNO), *S. tritici* (SEPTTR), *Pyricularia oryzae* (PYRIOR) & *Ustilago maydis* (USTIMA), a synthetic growth medium was used for *Phytophthora infestans* (PHYTIN).

Serial dilutions of picolinamides UK-2A and Fenpicoxamid were prepared using stock solutions in DMSO and 2 µl aliquots added to the wells to give the required 8 rate dose response (8.3 to 0.003 ppm) and a consistent final DMSO concentration of 1%. After addition of spore suspensions, initial readings of cell density were determined using a BMG NepheloStar nephelometer. Plates were subsequently placed in a shake incubator set at 90 rpm. SEPTTR was incubated at 22 °C for 72 hours, LEPTNO and PYRIOR at 22 °C for 48 hours, PHYTIN at 20 °C for 48 hours, and USTIMA at 24 °C for 48 hours respectively, and then read in the NepheloStar a second time to assess growth.

Growth inhibition in percent (%) was calculated by reference to control wells containing only growth media and inoculum. Data presented in Table 3.2-17 below show the compelling *in vitro* potency of this chemistry across the Ascomycetes (LEPTNO, SEPTTR & PYRIOR) and, to a lesser extent the Basidiomycete (USTIMA), as well as inactivity against Oomycete pathogens represented by PHYTIN. With the possible exception of USTIMA, the data also indicate relatively modest differences in growth

inhibition between Fenpicoxamid and UK-2A. The implication is that the fungal pathogens are able to rapidly 'activate' Fenpicoxamid by blocking group removal to form UK-2A.
Reference report: Owen, W. J; Yao, C: Myung, K; Young, D; Meyer, S; Correa, O, XR-777 Discovery Advancement Report, Dow AgroSciences, unpublished report number 2009830; 2011

Table 3.2-17: Dose response of UK-2A and Fenpicoxamid (XDE-777) for *in vitro* fungal growth inhibition

Test conc. ppm a.s.	Test pathogen, % control									
	LEPTNO		PHYTIN		PYRIOR		SEPTTR		USTIMA	
	UK-2A	Fenpicoxamid	UK-2A	Fenpicoxamid	UK-2A	Fenpicoxamid	UK-2A	Fenpicoxamid	UK-2A	Fenpicoxamid
8.3	100	100	20	0	90	90	100	100	90	50
2.8	100	100	20	10	90	90	100	100	100	50
0.93	100	100	10	0	90	90	100	100	100	50
0.31	100	100	0	0	90	90	100	100	80	40
0.1	100	90	0	0	90	90	100	100	40	10
0.033	100	70	0	0	90	80	100	90	20	0
0.01	90	50	0	0	80	70	90	60	10	0
0.003	70	30	0	0	60	50	70	30	0	0

Insecticide activity
Fenpicoxamid was evaluated for insecticidal activity in high throughput insecticide screens against beet armyworm (*Spodoptera exigua*, LAPHEG), corn earworm (*Helicoverpa zeae*, HELIZE), the green peach aphid (*Myzus persicae*, MYZUPE) and the yellow fever mosquito (*Aedes aegypti*, AEDSAE). The level 1 assays are designed to give the test compound the best chance of causing insect mortality. The high concentration of compound, combined with prolonged insect exposure to the test compound and the possibility of ingestion, increase the likelihood of observing insecticidal activity if it exists at all.
In addition to the high throughput screens, Fenpicoxamid was evaluated in more stringent single-dose screens against LAPHEG, MYZUPE and the cabbage looper (*Trichoplusia ni*, TRIPNI). Fenpicoxamid was either inactive or had limited activity against the species tested and is not considered to have significant insecticidal activity at practical use rates proposed.
Reference report: Wessels, F., Owen, J. Insecticidal Activity of XDE-777. Dow AgroSciences, unpublished report # DAI 1101, January 2013.

Herbicide activity
Fenpicoxamid was evaluated for herbicidal activity in level 2 herbicide screens. The screen included the two broadleaf species *Ipomea hederaceae* (morning-glory) & *Helianthus annuus* (sunflower) and the four grasses *Avena fatua* (wild oat), *Echinochloa crus-galli* (barnyard grass), *Setaria faberii* (giant foxtail) & *Alopecurus myosuroides* (black grass). The data indicate that Fenpicoxamid applied at 4000 g as/ha was inactive as an herbicide regardless of whether the treatment was made pre- or post-emergence.
Reference report: Parker C. L; Owen, J. Herbicide Activity of XDE-777. Dow AgroSciences, unpublished report # DAI 1177, January 2013.

3.2.1.2 Uptake and foliar movement

Foliar uptake and mobility was evaluated in a drop line test in a glasshouse bioassay. At this stage of development of Fenpicoxamid various formulations existed which were tested for their performance.
The following formulations of XDE-777 were used in the experiment:

Test product	Formulation type	Active substance	Active g as/L
GF-2925	SC	Fenpicoxamid	130
GF-3308	EC	Fenpicoxamid	50
GF-3311	EC	Fenpicoxamid	67,5 66,7

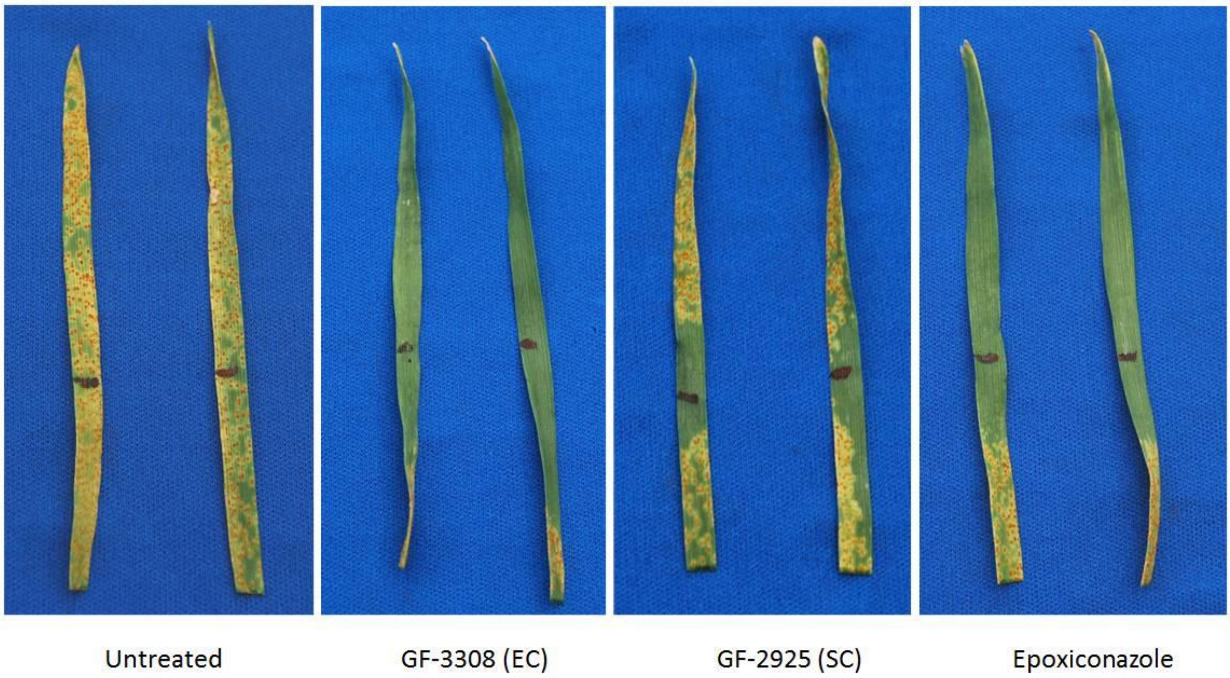
Seedlings of wheat cv. Yuma at growth stage BBCH 12 were all marked 5 centimetres from the tip of the primary leaf with a pen to designate the point of fungicide application. Fungicides were applied to the leaf tissue in a 2 µl droplet containing commercial hectare rates of the test fungicides diluted in 150 litres of water. The droplet was applied 5 cm below the tip of the leaf. At the time of fungicide application the leaf was maintained in a horizontal position to allow for optimum contact and absorption of the compounds. Products included in the bioassay were GF-3308, GF-2925 (130 g/L Fenpicoxamid, SC) and commercial formulations of chlorothalonil (Bravo) and epoxiconazole (Ignite). Also included in the test was GF-3311 which is a formulation with a composition similar to GF-3308 but with slightly higher loading (67.5 66,7 g/L Fenpicoxamid). For more details on formulations GF-3308 and GF-3311 see also Chapter 0.
The wheat seedlings were inoculated with PUCCRT 24 hours after application with a suspension containing Tween 20 and $1x10^6$ uredospores/ml. After inoculation, seedlings were placed in a dew room for 24 hours with no light, 22 °C, and 99% relative humidity and then moved to a greenhouse for the remainder of the experiment. Wheat seedlings were evaluated 8 to 9 days after inoculation. Each leaf dosed with a fungicide was evaluated to determine the disease free distance from the point of application to the area containing the first signs of disease caused by PUCCRT. The percent disease-free area was calculated by determining the distance in centimetres from the point of fungicide application to the first pustules and multiplying by 20. The distance from the point of application to the leaf tip was 5 centimetres. A score of 5 cm would indicate 100% disease free zone from the application point to the tip of the leaf. If the leaf was disease free on the ad axial surface the fungicide was considered to be translaminar.
Both chlorothalonil and GF-2925 were less mobile than GF-3308 and epoxiconazole. GF-3308 as EC formulation at corresponding rates demonstrated improved uptake and superior fungicide performance compared to GF-2925.
All fungicides were translaminar. However, chlorothalonil had a disease-free area only directly below the point of application. No upward disease-free zone was observed with chlorothalonil. GF-3308, GF-2925 and Ignite were found to be disease free on the upper side and lower side of the leaf at similar proportions. The results are summarized in Table 3.2-18 The improved performance of EC formulation GF-3308 over the SC formulation GF-2925 is also demonstrated in Figure 3.2-9.

Table 3.2-18: Foliar movement and translaminar activity of Fenpicoxamid (XDE-777) formulations

Treatment (active)	Use rate of g active diluted in 150 L water	Average distance moved (cm)	Disease free area (%)	Translaminar activity
Untreated	0	0.0 c	0	no
GF-2925 (Fenpicoxamid)	130 g as	3.0 b	60	yes
GF-3308 (Fenpicoxamid)	130 g as	5.0 a	100	yes
GF-3311 (Fenpicoxamid)	130 g as	4.3 a	86	yes
Chlorothalonil (Bravo)	1250 g as	0.3 c	3	yes
Epoxiconazole (Ignite)	125 g as	4.9 a	98	yes

Means not followed by the same letter are significantly different at $P<0.05$.

Figure 3.2-9: Acropetal systemicity and translaminar behaviour of GF-3308 compared to GF-2925 in a 1 day protectant test using PUCCRT in the bioassay.



Reference report: Mathieson, T, Kemmit, G. Comparative mobility of three XDE-777 formulations and select commercial standards as measured by glasshouse bioassay with Puccinia recondita on wheat. Dow AgroSciences internal report # 2024367, October 2014.

3.2.1.3. Uptake and dispersion of Fenpicoxamid in wheat plants

Materials and Methods

To evaluate the distribution of Fenpicoxamid in wheat plants four different formulations of radiolabeled material were prepared from $_{14}$C-labeled Fenpicoxamid:

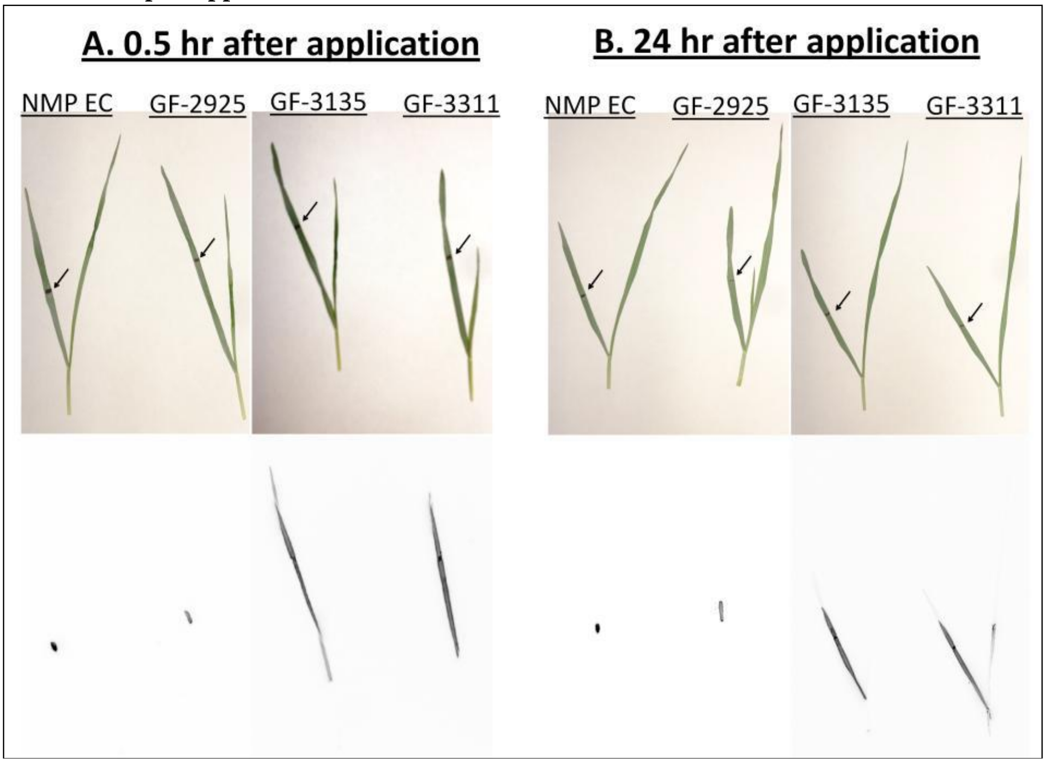
Test product	Formulation type	Active substance	Active g as/L	
NMP-based	EC	Fenpicoxamid	65	Lab formulation based on *N*-methyl pyrrolidone (NMP)
GF-2925	SC	Fenpicoxamid	130	
GF-3311	EC	Fenpicoxamid	~~67.5~~ 66,7	
GF-3135	EC	Fenpicoxamid	50	

Solutions of formulations GF-2925, GF-3311 and GF-3135 each with $_{14}$C-labeled Fenpicoxamid were prepared at the concentration of 650 ppm, equivalent to target field rate of 130 g/ha. One 2 µL drop of the solutions was applied to a line, marked at 4 cm from the leaf tip, on the ad axial surface of the primary leaf. The droplets were allowed to dry for 30 min prior to sampling. At each sampling time (0.5 or 24 h after application), two plants per treatment were harvested. The plants were freeze-dried for 2 days and then exposed to phosphor screens (Molecular Dynamics) for a week. Images of plant samples were produced using a Storm 860 scanner and ImageQuant software (Molecular Dynamics).

Results

When NMP-based EC formulation and SC based GF-2925 were applied to wheat leaves, most of the Fenpicoxamid signal was detected at the application site without any noticeable movement out of the application zone up to 24 h after application.
In contrast, Fenpicoxamid EC based formulations GF-3135 or GF-3311 became dispersed some 4-5 cm from the application site in both acropetal and basipetal directions within seconds (data not shown), giving rise to the significant dispersion shown on plants sampled 0.5 h after application. The recovery of radioactive Fenpicoxamid in the EC matrix formulations GF-3311 and GF-3135 was four times greater than recovered from the NMP and GF-2925 SC formulations 48 h after application which provided evidence of increased uptake of Fenpicoxamid in GF-3311 and GF-3135 formulations.
Noticeably, the phosphor images of 24 h samples, specifically for GF-3311, showed the presence of Fenpicoxamid -derived radioactivity in the second leaf implying Fenpicoxamid dispersal down to the leaf axil area, and subsequent xylem movement into the untreated second leaf (see Figure 3.2-10).
It was difficult to detect acropetal movement of Fenpicoxamid in GF-2925, likely due to low foliar uptake of the active in this formulation. On the contrary, when GF-3135 and GF-3311 EC matrix formulations were applied, radioactivity of Fenpicoxamid was clearly seen throughout the treated leaves, showing that surface dispersion of Fenpicoxamid was mirrored by a parallel distribution of Fenpicoxamid within the leaf tissue. These results further suggest that by using the EC matrix formulations, improved redistribution of compounds into the leaf tissue can be attained through increased surface spreading and penetration through the cuticle.

Figure 3.2-10: Distribution of $_{14}$C-labelled Fenpicoxamid in four different formulations, 0,5 h and 24 h after droplet application



Mounted plants (above) and phosphor images (below). Arrows indicate the application sites.

3.2.1.4 Mode of action of the active substance

Fenpicoxamid is a curative and protectant fungicide for control of foliar diseases in cereal crops. Fenpicoxamid is rapidly activated in both fungi and plants to UK-2A which is a potent inhibitor of mitochondrial electron transport (MET). Previous biochemical studies on the mode of action of UK-2A have demonstrated binding to the Qi site of the cytochrome *bc*1 (ubiquinone reductase) complex (complex III) in the electron transport chain, similar to the mechanism of the structurally related natural

product antimycin A. UK-2A inhibits respiration at complex III which likely represents the primary biochemical mode of action for this chemistry. The mode of action of Fenpicoxamid will be novel to the European cereal fungicide market and will be assigned to FRAC group C4#21.
The cytochrome *bc*1 complex (complex III) of the mitochondrial electron transport (MET) chain has two quinone binding sites known as the Qo and Qi sites. The Qo site is the target site of the strobilurin fungicides, which include many commercial products. Inhibitors of the Qi site are also known, although to date only the Oomycete-specific fungicides cyazofamid and ambisulbrom (FRAC group 21) have been commercialized. Although the target site of activity is the same, Fenpicoxamid has no activity against Oomycete diseases but has strong activity against cereal diseases such as *Septoria* and *Puccinia spp*.
The MET lll Q_i site is distinct from the MET lll Q_o site with which the strobilurins interact, so that no cross-resistance of field isolates of *Septoria* resistant to strobilurin fungicides has been observed or would be anticipated.

3.2.1.5 First field testing

With trial IT13E7B012DC01 the first field test of the new EC probe formulation GF-3135 was carried out in Italy against SEPTTR in durum wheat in 2013 in an especially curative situation. The trial comprised a single application at BBCH 35-37 and then a sequential application sprayed at BBCH 31-32 and then BBCH 45. The reference products included were Bravo (chlorothalonil) applied at 750 g as/ha in the single application or 500 g as/ha followed by 750 g as/ha as a sequential application and Proline (prothioconazole) applied at 200 g as/ha in a corresponding single or two spray programme.
Both SC (GF-2925) and EC (GF-3135) formulations were evaluated with a clear benefit observed between the two formulation types. Table 3.2-19 shows the trial results where an assessment was made on leaf 1 (Flag) at 26 days after the single application and 19 days after the repeat application schedule and the corresponding yield relative to the untreated. This trial provided clear evidence of the very much improved efficacy level of the EC matrix formulation (GF-3135) compared to the SC formulated material (GF-2925) as well as the improved yield benefit.

Table 3.2-19: Early field testing with SC formulation GF-2925 compared to EC formulation GF-3135 against SEPTTR in durum wheat in Italy in 2013

Evaluation	Untreated % infection	% control of SEPTTR							
		GF-2925 Fenpicoxamid g as/ha		GF-3135 Fenpicoxamid g as/ha		Bravo chlorothalonil g as/ha		Proline prothioconazole g as/ha	
		1x 130	2x 130	1x 130	2x 130	1x 750	500 + 750	1x 200	2x 200
Leaf 1 (Flag)	59,1	50,6	62,4	77,5	89	54,7	52,7	64,9	88,6
% Relative yield (Untreated t/ha)	4,0 t/ha	124 def*	133 cd	144 b	160 a	117 f	128 c-f	121 def	161 a

*Tukey's HSD P=.05

3.2.1.6 Protectant and curative properties of different Fenpicoxamid formulation types in a glasshouse test - SC compared to EC

Three different formulations of Fenpicoxamid, GF-2925 (130 g as/L SC), GF-3135 (50 g as/L EC), and GF-3311 (66.7 g as/L EC) were compared in a glasshouse test to evaluate their efficacy profile. The formulation GF-3311 is very similar to GF-3308 as detailed in in chapter 0 of this document.

Methods and Materials

The test was carried out using wheat plant seedlings cv. Yuma. Aliquots of three formulation GF-2925, GF-3135, and GF-3311were applied to the plants using a water volume of 200 L/ha. The track sprayer was equipped with a Tee Jet 8003E spray nozzle operating at 2.2 bar.

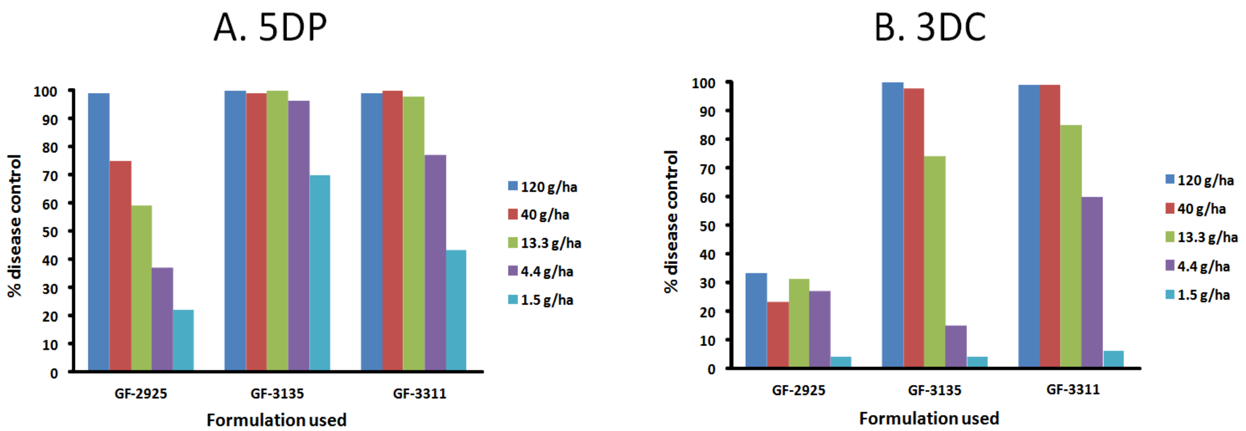
Test plants were inoculated with a suspension of micro conidia of SEPTTR either 3 days prior to (3-day curative test, 3DC) or 5 days after (5-day protectant test, 5DP) the application formulations. After inoculation, the plants were kept at 100% relative humidity to permit spores to germinate and infect host leaves. The plants in 5DP tests were directly moved to a greenhouse after inoculation, while plants in curative tests were sprayed with formulations prior to moving to the greenhouse. Test plants were kept in a greenhouse set at 20 °C until disease was fully expressed on untreated plants. Infection levels on the primary leaves were visually assessed on a scale of 0 to 100 percent disease severity. Percent disease control was calculated using the ratio of disease severity on treated plants relative to untreated plants.

Results and Conclusions

SEPTTR wheat leaf blotch control of GF-2925, GF-3135 and GF-3311 in the 5 days protectant and 3 days curative test are shown in Figure 3.2-11. For the 5DP timing, GF-2925 completely controlled SEPTTR at a rate of 120 g/ha, but SEPTTR control was reduced as application rate decreased. In contrast, both GF-3135 and GF-3311 EC formulations provided excellent SEPTTR disease control (70-100% disease control) at rates as low as 4.4 g/ha, and delivered 40-70% disease control even at a rate of 1.5 g/ha. As 3DC treatments, GF-2925 failed to control SEPTTR at the highest rate used in this study, while both GF-3135 and GF-3311 provided more than 70% disease control at rates above 13.3 g/ha. At 4.4 g/ha, the 3DC activity by GF-3311 was better than that by GF-3135.

Overall, the glasshouse test results correlate with the enhancement of efficacy of Fenpicoxamid seen in the field with EC formulations GF-3135 and GF-3311 compared to the SC formulation GF-2925 and the ability to reduce the dose of Fenpicoxamid when applied in this EC matrix formulation. However, it is commonly accepted that the rates tested and efficacy levels found in glasshouse studies do not translate 1:1 to results found under field conditions.

Figure 3.2-11: 5-day protectant (A) and 3-day curative (B) control of SEPTTR wheat leaf blotch by formulations GF-2925, GF-3135, and GF-3311.



Reference report: Myung, K *et al*. Effects of different formulations on retention, surface coverage, and uptake of XDE-777 in wheat plants. Dow AgroSciences, SAGE report # 2026067, February 2015.

3.2.1.7 Protectant and curative properties of GF-3308 in a glasshouse test for the control of SEPTTR and PUCCRT

Introduction

As demonstrated in the previous chapter 3.2.1.6, EC formulation matrices of Fenpicoxamid proved to be more efficacious in controlling SEPTTR than SC based formulation types. In order to obtain a better understanding of how GF-3308 as optimized formulation of Fenpicoxamid compares to leading cereal reference products, a series of tests were completed to evaluate the protectant and curative properties of GF-3308 for the control of PUCCRT and SEPTTR of wheat.

Materials and Methods

Testing facilities involved
This study (non GEP/non GLP) was carried out in the laboratories and glasshouses of Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN., 46268, USA in 2018.

Experimental details
The experiment used a randomized complete block design with 3 replications per treatment. The test with both SEPTTR and PUCCRT was carried out using wheat plant seedlings cv. Yuma which were raised in pots grown up to BBCH 12. GF-3308 and the reference products were applied to the plants prior (protectant) or after (curative) inoculation of the disease under investigation using a water volume of 150 L/ha. The track sprayer was equipped with a Tee Jet 8003E spray nozzle operating at 2.2 bar (32 psi). After inoculation and application of products the wheat plants were transferred to a greenhouse kept at 24 °C.
For the evaluation against PUCCRT the wheat seedlings were inoculated with a suspension of uredospores either 1 day prior to (1-day curative test, 1DC) or 1 day after (1-day protectant test, 1DP) the application of test products. For SEPTTR the wheat plants were inoculated with a suspension of micro conidia either 3 days prior to (3-day curative test, 3DC) or 1 days after (1-day protectant test, 1DP) the application of products. The SEPTTR isolate used in the study was a wild type unselected strain with original sensitivity collected from the state of Indiana.

Formulations and rates used in the 1 day curative and 1 day protectant test against PUCCRT

Test product	Formulation type	Active substance	Rates g as/ha
GF-3308	50 g/L EC	Fenpicoxamid	25, 50, 75, 100
Comet	200 g/L EC	Pyraclostrobin	50, 100, 125, 200
Proline 275	275 g/L EC	Prothioconazole	50, 100, 150, 200

Formulations and rates used in the 3 day curative and 1 day protectant test against SEPTTR

Test product	Formulation type	Active substance	Rates g as/ha
GF-3308	50 g/L EC	Fenpicoxamid	50, 75, 100
Imtrex	62,5 g/L EC	Fluxapyroxad	62,5, 93,8, 125
Proline 275	275 g/L EC	Prothioconazole	100, 150, 200

Assessments
The visual assessments for % infected leaf area were made 8 days after inoculation for PUCCRT and 16 days after inoculation for SEPTTR using a scale of 0 to 100% (where 0 was no disease and 100 complete coverage with disease). Numbers were then converted to percent disease control relative to the untreated check (% Abbott).

Results

In both the 1 day curative and 1 day protectant test with PUCCRT all treatments with Proline 275, Comet and GF-3308 provided equivalent at the corresponding rates of compounds used in these test (see Table 3.2-20 and Table 3.2-21).
In the curative test for the control of SEPTTR, GF-3308 and Imtrex gave equivalent control of the fungus with Proline 275 being slightly inferior to GF-3308 (see Table 3.2-22).
In the 1-day protectant test with SEPTTR, GF-3308 and Imtrex were equivalent, whereby Proline was less efficacious against SEPTTR (see Table 3.2-23).

Table 3.2-20: 1-day curative efficacy of GF-3308 against PUCCRT

Formulation	Rate g ai/ha	% control of PUCCRT			
		rep 1*	rep 2	rep 3	Average
GF-3308	100	100	100	100	100
GF-3308	75	100	100	100	100
GF-3308	50	100	100	100	100
GF-3308	25	99	99	100	99
Comet	200	100	100	100	100
Comet	125	100	100	100	100
Comet	100	100	100	100	100
Comet	50	99	99	100	99
Proline 275	200	100	100	100	100
Proline 275	150	100	100	100	100
Proline 275	100	100	100	100	100
Proline 275	50	100	100	100	100

* rep = replicate

Table 3.2-21: 1-day protectant efficacy of GF-3308 against PUCCRT

Formulation	Rate g ai/ha	% control of PUCCRT			
		rep 1	rep 2	rep 3	Average
GF-3308	100	94	69	81	81
GF-3308	75	100	75	81	85
GF-3308	50	100	75	81	85
GF-3308	25	75	50	75	67
Comet	200	96	75	94	88
Comet	125	94	74	99	89
Comet	100	88	75	44	69
Comet	50	25	50	50	42
Proline 275	200	94	88	50	77
Proline 275	150	96	94	75	88
Proline 275	100	98	98	38	78
Proline 275	50	69	25	25	40

Table 3.2-22: 3 day curative efficacy of GF-3308 against SEPTTR

Formulation	Rate g ai/ha	% control of SEPTTR			
		rep 1	rep 2	rep 3	Average
GF-3308	100	100	100	100	100
GF-3308	75	100	100	100	100
GF-3308	50	96	100	100	99
Imtrex	125	100	98	100	99
Imtrex	93,8	100	100	96	99
Imtrex	62,5	100	100	100	100
Proline 275	200	98	96	100	98
Proline 275	150	90	90	42	74
Proline 275	100	81	98	4	61

Table 3.2-23: 1-day protectant efficacy of GF-3308 against SEPTTR

Formulation	Rate g ai/ha	% control of PUCCRT			
		rep 1	rep 2	rep 3	Average
GF-3308	100	100	99	95	98
GF-3308	75	99	98	97	98
GF-3308	50	98	97	99	98
Imtrex	125	98	97	98	97
Imtrex	93,75	89	94	86	90
Imtrex	62,5	94	83	86	88
Proline 275	200	66	86	77	77
Proline 275	150	55	72	77	68
Proline 275	100	66	43	55	55

Conclusions

This glasshouse study clearly demonstrated that Fenpicoxamid formulation GF-3308 does provide both, curative and protectant control of important cereal diseases such as SEPTTR and PUCCRT at levels that compare well to the efficacies shown by leading reference products Proline 275 (DMI), Imtrex (SDHI) or Comet (QoI).
Reference Report: Mathieson, T, Leader, A, 2018; How does the efficacy of Inatreq formulation GF-3307 (a combination) and GF-3308 (solo) compare to market references when tested against Septoria tritici (SEPTTR) and Puccinia recondita (PUCCRT) in greenhouse conditions? Dow AgroSciences internal report # 2051736, June 2018

3.2.1.8 Protectant and curative properties of GF-3308 under field conditions

Introduction

Initial infections with SEPTTR arise from wind borne ascospores released from debris or from conidia released from secondary infections on lower leaves of the cereal plant. Once a spore has landed on a new leaf, it is reported it can take 12 hours for the spore to germinate; infection of the new leaf usually takes place within 24 hours of the spore being released. Wet conditions are required during this critical infection period. Symptoms do not appear immediately on a new leaf. The fungus grows undetected inside the leaf for a period of 2-4 weeks which is referred to as the latent phase.
The existence of such a relatively long latent phase of SEPTTR can cause a problem for farmers as the level of infection taken place days or even weeks ago is not known in its extent and thus might be under estimated with the possible consequence that chemical plant protection measures to control SEPTTR might be sprayed too late to stop the disease.
However, this risk can be greatly reduced if a given fungicide also controls the fungus during its latent period. Fungicides which have both, curative and protectant properties are of advantage because they provide a higher flexibility of use through widening the window of application to control this important disease. In the United Kingdom a trial coded GB15E7B052JF01 was carried out to explore the efficacy profile of GF-3308 for the control of SEPTTR on wheat.

Materials and Methods

The GEP trial was conducted by DOW AgroSciences UK at Wellesbourne, Warwickshire. GF-3308 and the reference product Proline were applied at BBCH 39-41 of winter wheat cv. Conqueror. The trial was of a RCB design comprising 4 replicates. Products were applied using a precision small plot sprayer equipped with flat fan nozzles delivering a water volume of 200 L/ha.

Testing facilities or organisations
The trial was carried out by the testing facility listed in the following Table.

Table 3.2-24: Testing facilities involved by EPPO Zone

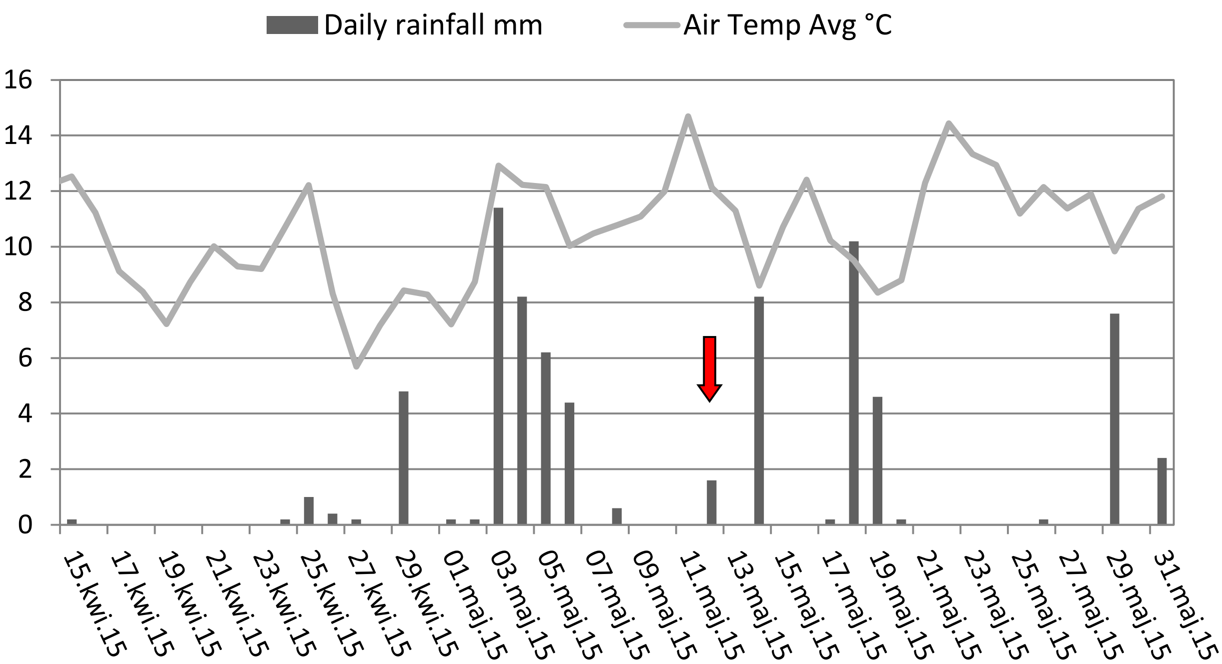
Admin.Zone	EPPO Zone	Country	Year	Trial number	Testing organisation	EPPO Guideline	Trial status
Central	Maritime	United Kingdom	2015	GB15E7B052JF01	DOW AGROSCIENCES UK	PP 1/26	GEP

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3308	EC	Fenpicoxamid	2,0	100
Proline 275	EC	Prothioconazole	0,72	198

Weather data and wet periods for infections with SEPTTR (critical events)
Figure 3.2-12 details the daily values for rainfall and average temperatures during the trial period. The application of GF-3308 was carried out on the 13th of May 2015. As the Graph shows critical wet periods for infections with SEPTTR took place 1 week before the application from 3rd-6th of May (Event 1) and after application possibly on the 14th of May (Event 2) and on 18th -19th of May (Event 3). Later critical events took place during the trial period but are not detailed here as these are not considered relevant in the context discussed.

Figure 3.2-12: Weather data for trial GB15E7B052JF01
Arrow in red indicates the date of application on the 13th of May



Results

The efficacy of GF-3308 against SEPTTR by leaf level was assessed 5 weeks after application. The results are summarized in Table 3.2-25 below.
Leaf 1 assessment:
The level of control shown on Leaf 1 is considered primarily protectant. Leaf 1 (Flag leaf) was only a spike or less when infection Event 1 took place 7 days prior to application. At the time of application Leaf 1 was fully developed. GF-3308 showed 85% control which was superior to the included reference Proline which gave 72% control of SEPTTR.
Leaf 2 assessment:
At infection Event 1, i.e. 7 days before application, the top fully expanded leaf was Leaf 2. At the time of application Leaf 2 did not show any visual symptoms of SEPTTR. As Event 1 was a strong push

lasting for 4 days it can be assumed that Leaf 2 was in the latent period of infection when GF-3308 was applied. Any efficacy of test products exhibited on Leaf 2 can be characterized primarily as curative effect but also as protectant because Event 2 and Event 3 took place after application. GF-3308 showed excellent curative and protectant control of SEPTTR (78%) which was superior to Proline (50% control), Leaf 3 assessment:
Leaf 3 at the time of application did already show lesions of SEPTTR. The level of efficacy found on this leaf level would show eradicant, late curative and protectant properties of products under severe disease conditions. Even under strong infection pressure on Leaf 3 GF-3308 provided 50% control of SEPTTR which was superior to Proline which gave 33% control. However, due to the complex disease infection pattern found on Leaf 3 the data for this leaf level does not allow to differentiate between the proportion of the eradicant, the curative or the protectant effect of GF-3308. However, what is clearly evident on the disease pattern present on Leaf 3 is that GF-3308 does provide efficacious control of SEPTTR even when the disease has already established on the plant at the time of application.

Table 3.2-25: Curative and protectant efficacy of GF-3308 for the control of SEPTTR on winter wheat

TRZAW leaf level	SEPTTR visual % Infection at application	% infection with SEPTTR 34 days after application (% control)		
	Untreated	Untreated	GF-3308 100 g as/ha	Proline 198 g as/ha
Leaf 1 (Flag)	0	21,3	3,0 (85,2)	5,5 (74,2)
Leaf 2 (F-1)	0	45	9,8 (78,2)	23,0 (48,9)
Leaf 3 (F-2)	3	100	50,0 (50,0)	67,5 (32,5)
Leaf 4 (F-3)	15	-	-	-
Leaf 5 (F-4)	40	-	-	-

3.2.1.9 Equivalence of formulations GF-3308 and GF-3311 for the control of SEPTTR in winter wheat

Introduction

This dossier is for the submission of GF-3308 to control of a range of foliar diseases on wheat, rye and triticale. GF-3308 contains 50 g/L fenpicoxamid, at 2.0 L/ha delivering 100 g/ha fenpicoxamid.
However, in 2014 the first year of registration the wheat trials have been carried out with formulation GF-3311 which contains 66,7 g/L fenpicoxamid delivering 100 g/ha fenpicoxamid at 1,5 L product per hectare. In terms of formulation contents GF-3308 and GF-3311 are very similar formulations (see Part C for comparison of both formulation). To prove comparability of both formulations and support the use of data generated with GF-3311 for the registration of GF-3308, bridging trials were carried out in 2015 and 2016 on winter wheat.
Data from 11 field trials are summarized in this chapter that demonstrate the comparability of formulations in terms of disease control of SEPTTR in wheat and selectivity to the crop. In the trials both formulations were tested side by side at a rate of 100 g as/ha which reflects the proposed label rate of GF-3308 for countries in the EPPO Maritime, North-East and South-East climatic zones.
GF-3308 and GF-3311 were evaluated in accordance with the EPPO Standard PP 1/26 '*Foliar and ear diseases on cereals*'. The trials were carried out by Dow AgroSciences, contractor companies and Official Research institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in the Czech Republic (1), Denmark (1),

France (4), Germany (1), the United Kingdom (1), Poland (1), Hungary (1) and Romania (1) in 2015 and 2016 whereby the French trials were all located in the Maritime Zone part of the country.
In line with the guidance in EPPO PP1/307/2: '*Efficacy considerations and data generation when making changes to the chemical composition or formulation type of plant protection products'*, it is not required to generate formulation bridging data on all targets, so SEPTTR has been chosen as the representative target disease for GF-3308 on wheat. EPPO PP1/307/2 recommends a minimum of 5 bridging trials for a single crop on a small number of targets. As the proposed use on wheat is for only three target diseases it is considered that the 11 trials submitted meets this requirement. The trials are spread across all EPPO zones that make up the Central EU Authorisation zone (Maritime, North-East and South-East) to confirm comparability of the formulation across a range of climatic conditions. The majority of trials are in the EPPO Maritime zone, as this is the most challenging climatic regions for this disease.

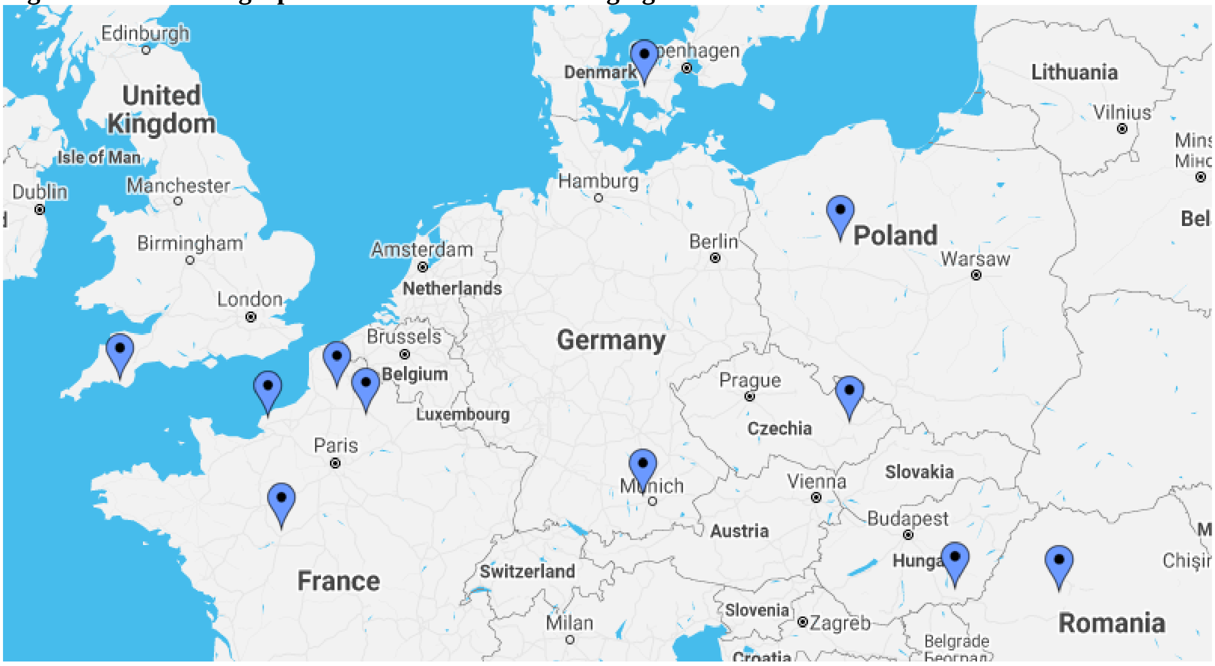
Materials and Methods

Testing facilities or organisations
The bridging trials were carried out by the testing facilities in the countries listed in the following Table.

Table 3.2-26: Testing facilities involved by EPPO Zone

Admin. Zone	EPPO Zone	Country	Year	Trial number	Testing organisation	EPPO Guideline	Trial status
Central	Maritime	Czech Republic	2016	CZ16E7B038PV01C	Ditana Spol. s.r.o.	PP 1/26	GEP
North	Maritime	Denmark	2015	DK15E7B018MN01C	Aarhus University Flakkebjerg	PP 1/26	GEP
South	Maritime	France	2015	FR15E7B025FO01	Dow Agrosciences S.A.S.	PP 1/26	GEP
South	Maritime	France	2015	FR15E7B025MC03C	Staphyt	PP 1/26	GEP
South	Maritime	France	2015	FR15E7B025MC04C	Phyliae	PP 1/26	GEP
South	Maritime	France	2015	FR15E7B025YC02	Dow Agrosciences S.A.S.	PP 1/26	GEP
Central	Maritime	Germany	2015	DE15E7B025AS01	Dow Agrosciences GmbH	PP 1/26	GEP
Central	Maritime	UK	2015	GB15E7B025EB01C	Eurofins Agroscience Services Ltd	PP 1/26	GEP
Central	North-East	Poland	2016	PL16E7B031AS02C	Staphyt Sp. z.o.o.	PP 1/26	GEP
Central	South-East	Hungary	2015	HU15E7B025AB01C	Agrofil Szaktanacsado Mernoki Iroda Kft..	PP 1/26	GEP
Central	South-East	Romania	2015	RO15E7B025AP01C	NARDI Fundulea	PP 1/26	GEP

Figure 3.2-13: Geographical distribution of 11 bridging trials



<u>Formulations applied and rates</u>

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3308	EC	Fenpicoxamid	2,0	100
GF-3311	EC	Fenpicoxamid	1,5	100
Proline 275	EC	Prothioconazole	0,72	198

In terms of formulation contents GF-3308 and GF-3311 are very similar formulations (see Part C for comparison of both formulation).

<u>Experimental details</u>
All 11 bridging trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organisations. The trials were of a randomized complete block design with 4 replicates and a plot size ranging between 20 m² and ~~36~~ 30 m². The treatments in all trials were applied using self-propelled, bicycle or knapsack precision plot sprayers equipped with conventional or low drift flat fan nozzles delivering water volumes between 150 and ~~300~~ 220 L/ha.
GF-3308, GF-3311 and the reference product Proline 275 were applied as a single application timing sprayed between BBCH 31 and BBCH 65 of winter wheat. The treatments were typically applied when SEPTTR started to develop on the lower leaves. For further site and application details see Appendix 3 and Appendix 4 in the BAD.
Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. The final assessments for efficacy summarized in this chapter of the documents were made approx. 3-8 weeks after application when differences between treatments and the untreated control were most obvious. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with SEPTTR or leaves which were fully senesced in treated and untreated plots were excluded from summarization.
<u>Statistical analysis</u>
The tabulated efficacy data presented in this section ~~of the biological dossier are~~ is showing the treatment means of the percentage control relative to the untreated. Instead of statistical tests across trials the minimum and maximum means of percentage infection or control of the individual trial means are presented in the summary tables.

Results

Data is presented from 11 trials across the EPPO Maritime, North-East and South-East climatic zones comparing GF-3308 and GF-3311 at 100 g as/ha applied as a single application for the control of SEPTTR on winter wheat. The data clearly show comparable efficacy of the formulations with GF-3308 obtaining 82.4% 82,6% and GF-3311 obtaining 82.5% 82,7% control when assessed 23-56 days after application and the range of control being similar for both formulations. The range of results is also identical, at 64.5 65-100% for GF-3308 and 66,4-100% for GF-3311. In comparison, the reference product Proline at 0,72 L/ha obtained 73.6% 73,9% control. In each trials there was no statistical difference between control achieved by GF-3308 and GF-3311.
GF-3308, GF-3311 and Proline did not cause any phytotoxic effects to the wheat varieties tested. The comparable performance of GF-3311 and GF-3308 against SEPTTR confirms the justifiable use of GF-3311 data from 2014 trials in the MED and Efficacy SEPTTR sections of this dossier to support the registration of GF-3308.

Table 3.2-27: Comparative efficacy of formulations GF-3308 and GF-3311 applied at corresponding rates for the control of SEPTTR in winter wheat. Single application assessed 23-56 days later (mean 5-6 weeks)

	Untreated SEPTTR % infection	% control of SEPTTR		
		GF-3308 2,0 L/ha (100 g as/ha)	GF-3311 1,5 L/ha (100 g as/ha)	Proline 275 0,72 L/ha (198 g as/ha)
Mean	**18,2**	82,4 **82,6**	82,5 **82,7**	73,6 **73,9**
Min	6,0	64,5 65	66,4	35,6
Max	41,6	100	100	100
n trials	11	11	11	11

The individual trials results for efficacy are presented in the BAD.

Table 3.2-28: Crop tolerance of GF-3308 and GF-3311 in bridging trials

Trial number	Crop	Crop variety	Crop BBCH at appl,	Maximum recorded phytotoxicity for the duration of the trials (%)		
				GF-3308 2,0 L/ha (100 g as/ha)	GF-3311 1,5 L/ha (100 g as/ha)	Proline 0,72 L/ha (198 g as/ha)
CZ16E7B038PV01C	TRZAW	Tobak	49-51	0	0	0
DE15E7B025AS01	TRZAW	JB Asano	31	0	0	0
DK15E7B018MN01C	TRZAW	Mariboss	65	0	0	0
FR15E7B025FO01	TRZAW	Dinosor	32	0	0	0
FR15E7B025MC03C	TRZAW	Trapez	32	0	0	0
FR15E7B025MC04C	TRZAW	Bermude	32	0	0	0
FR15E7B025YC02	TRZAW	Pakito	32-33	0	0	0
GB15E7B025EB01C	TRZAW	Relay	31	0	0	0
PL16E7B031AS02C	TRZAW	Muszelka	39-43	0	0	0
HU15E7B025AB01C	TRZAW	GK Körös	31	0	0	0
RO15E7B025AP01C	TRZAW	Andrada	31-32	0	0	0

Summary and conclusions on the preliminary trials

Fenpicoxamid is a foliar systemic fungicide with translaminar properties. GF-3308 has strong curative and protectant activity against cereal diseases such as *Septoria* spp. and *Puccinia* spp.
XDE-777 is rapidly activated in both fungi and plants to UK-2A which is a potent inhibitor of mitochondrial electron transport (MET) binding to the Qi site of the cytochrome *bc*1 complex in the electron transport chain. The MET lll Q_i site is distinct from the MET lll Q_o site with which the strobilurins interact, so that no cross-resistance of field isolates of SEPTSP resistant to strobilurin fungicides, but also to DMI and SDHI fungicides is anticipated.
Fenpicoxamid in glasshouse screening tests even at extremely high dose rates up to 4 kg as/ha did not show herbicidal and insecticidal activities which indicate that fenpicoxamid has a favourable crop tolerance and beneficials safety profile.

Early stage field characterisation trials provided the first evidence that a dose of fenpicoxamid above 130 g as/ha formulated using an EC-matrix might not be required for high level control of SEPTTR in winter wheat.
The comparable performance of GF-3311 and GF-3308 against SEPTTR confirms the justifiable use of GF-3311 data from 2014 trials in the MED and Efficacy sections of this dossier to support the registration of GF-3308.

Comments of zRMS on:

Preliminary tests (3.2.1)
GF-3308 is a new fungicide containing a novel active substance fenpicoxamid (XDE-777). Fenpicoxamid is rapidly activated in both fungi and plants to UK-2A which is a potent inhibitor of mitochondrial electron transport (MET). UK-2A inhibits respiration at complex III. The mode of action of Fenpicoxamid is assigned by FRAC as group C4 # 21.
Formulation development covers 4 years of research (2012-2015) on optimising the performance of fenpicoxamid in cereals. At this time four fenpicoxamid formulations were tested in preliminary tests: GF-2925 (SC), GF-3135 (EC), GF-3311 (EC) and the final formulation GF-3308 (EC).
Based on the early stage screening tests, fenpicoxamid is not considered to have significant insecticidal activity and has no herbicidal activity regardless of whether the treatment is made made pre or post-emergence. Fungicidal actividy was tested for five pathogens: LEPTNO, SEPTTR, PYRIOR, USTIMA and PHYTIN. The presented study results indicate the activity od GF-3308 towards Ascomycetes (LEPTNO, SEPTTR, PYRIOR), less activity towards Basidiomycete (USTIMA) and inactivity towards Oomycete (PHYTIN).
Results from preliminary tests show also that:
- GF-3308 and its previous formulations have translaminar properties.
- XDE-777 shows better performance and better uptake, distribution on the leaf surface and in the tissue, when formulated as an EC.
- GF 3308 has protectant and curative properties against SEPTTR and PUCCRT.

Bridging trials
In 16 out of 118 efficacy trials the previous formulation GF-3311 was tested in wheat. These trials were carried out in 2014. In the following years 2015-2016, 11 bridging trials were conducted to compare efficacy between GF-3311 and GF-3308 in the control of SEPTTR in wheat. Both formulation differ in the amount of a.s. (GF-3311 contains 66,7 g fenpicoxamid /l product, GF-3308 contains 50 g fenpicoxamid/ l product) but the dose rate of products in terms of amount of a.s. per ha is the same - 100 g a.s/ha. Summarizing bridging trial results, GF-3311 performed comparably as GF-3308. The average efficacy of both formulations was better than efficacy of reference product Proline in bridging trials. Additionally GF-3311 and GF-3308 cause no phytotoxicity effects on wheat. **It can be concluded that trials with GF-3311 F can be used in the efficacy evaluation of the target fungicide GF-3308. For simplicity, only the code name GF-3308 F will be used in the evaluation.**

3.2.2 Minimum effective dose tests (KCP 6.2)

This chapter covers the minimum effective dose tests of GF-3308 for the control of foliar diseases in wheat, rye and triticale. Data are presented across a range of diseases in wheat, rye and triticale based on a single application of GF-3308 applied between BBCH 31-59.
The data in this section relate to the proposed claims for use of GF-3308 in wheat, rye and triticale, using;

- a dose of 2,0 L/ha in the EPPO Maritime countries of the Central EU Authorisation zone across all crops and targets,
- a dose of 1,5-2,0 L/ha in the EPPO North-East countries of the Central EU Authorisation zone across all crops (rate target specific),
- a dose rate range of 1,2-2,0 L/ha in the EPPO South-East countries of the Central EU Authorisation zone on wheat.

Efficacy data presented within the tables in this section are from one key leaf layer, where differences were apparent at the time of assessment and which satisfy the minimum level of disease on the untreated leaves ($\geq$5% infection). Where results on more than one leaf were available, the chosen leaf is the highest assessed leaf with >5% infection in the untreated, at assessment. In the majority of cases this is Leaf 1 or Leaf 2. It is considered that in wheat, rye and triticale, Leaf 1 and Leaf 2 will have the most significant

impact on yield of the crop, from disease control on that leaf. Where lower leaves have been used, this due to higher levels of disease infection (>10%) representing a more robust test of the product.
Assessment timings chosen in the following summary tables are for effectiveness at approximately 4-7 weeks after application (28-49 DAA), to reflect the disease protection delivered by a single dose of GF-3308. The longer assessment timings have only been used where disease levels were less than 5% at the earlier assessment timings. Early assessment timings (11-21 days) have been used when no appropriate later timings were available. **Note:** Throughout this section. DAA = days after first/one application, DAB = days after second/two applications. 'DAA' is also used for trials where the single application treatment was applied as timing B and 'DAB' for the two-application regime applied at timings A and C.
Where a trials report includes calculated percentage control values, those figures have been used. If the percentage control was not calculated in the trials report, (i.e. only percentage infection (severity) was recorded), the percentage control has been calculated using an Abbott's formula.
To determine the minimum effective dose, GF-3308 was tested at 1,0, 1,2, 1,3, 1,5, 1,6 and 2,0 L/ha, corresponding to 50, 60, 65, 75, 80 and 100 g fenpicoxamid /ha. These rates reflect 50%, 60%, 65%, 75%, 80% and 100% of the proposed label rate. GF-3308 was evaluated in accordance with the EPPO Standard PP 1/225 (*Minimum effective dose*) and the specific EPPO Standard PP 1/26 (*Foliar and ear diseases on cereals*). For the EPPO Maritime dataset, the 1,0 L/ha dose rate was included in all summary tables for completeness, however as it is outside the dose range recommended by EPPO for comparison of lower doses (60-80% recommended in EPPO Standard PP 1/225), it is not discussed in the final conclusions for the minimum effective dose of each crop/disease recommendation.

Statistical analysis
The tabulated efficacy data presented in this section of the biological dossier include the treatment means of the percentage control, relative to the untreated. Across trials, the minimum and maximum means of percentage infection or control are also presented in the summary tables.

3.2.2.1 MED of GF-3308 for the control of SEPTTR in winter wheat

This section addresses the minimum effective dose (MED) of GF-3308, for the control of SEPTTR on winter wheat, when applied at the proposed label rate of 2,0 L/ha for the EPPO Maritime climatic zone countries of the Central EU Authorisation zone, the proposed dose range of 1,5-2,0 L/ha in Poland (EPPO North-East climatic zone) and the proposed dose range of 1,2-2,0 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone.

Table 3.2-29 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 13,5-30 m² EPPO North-East: 20-30 m² EPPO South-East: 20-36 m²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: ~~7~~ 16 TRZAW EPPO North-East: ~~4~~ 7 TRZAW EPPO North-East: 1 TRZAS EPPO South-East: ~~10~~ 11 TRZAW
	Varieties per crop (number of trials)	EPPO Maritime: Akteur (2), Ambition, Bohemia, JB Asano (2), Hereford, Substance, Crusoe, Patras, Pakito, Bermude, Dinosor, Relay, Trapez, Tobak EPPO North-East (TRZAW): Arkadia, Fredis, Muszelka, Zentos, Bogatka (2), Zyta. EPPO North-East (TRZAS): Tybalt EPPO South-East: Ariesan, Buzogány, Enova, GK Körös, Glossa (2), Miranda (2), MV Suba, Sadovo 772, Andrada
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 31-~~39~~ 51 EPPO North-East: BBCH 37-~~43~~ 56 EPPO South-East: BBCH ~~31~~ 30-41
	Timing Pest stage at application	GF-3308 has both protectant and curative properties. For the control of SEPTTR, applications were timed to cover both these situations, commencing when there was a risk of infection with SEPTTR or when the disease started to develop on the lower leaf levels, to applications against established infections.
	Number of applications	1
	Spray volumes	200-~~300~~ 250 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were conducted at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were conducted approximately aimed at the timing of application, 2-3 weeks after appplication, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field. Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where SEPTTR is a prevalent and challenging disease.

Introduction

In total, data from ~~21~~ 34 field trials are presented in this section to demonstrate the minimum effective dose of GF-3308, for the control of SEPTTR in winter wheat (TRZAW) and one ~~on~~ in spring wheat (TRZAS). GF-3308 was tested at 2,0, 1,5, 1,2 and 1,0 L/ha. The trials were performed in accordance with the EPPO Standard PP 1/225 '*Minimum effective dose*'. The reference standard products include Proline 275 applied at 0,72 L/ha, Aviator Xpro applied at 1,0 L/ha or 1,25 l/ha, Input applied at 1,0 L/ha, Librax applied at 2,0 L/ha and Vertisan applied at 1,0 L/ha. Proline 275 was applied in the majority of trials. Results for all standards have been combined in the following summary tables, however, individual results for each standard are presented in the individual trial tables and are compared orthogonally with GF-3308 in section 3.2.3.
The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes,

all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in the Czech Republic ~~(1)~~ (2), Denmark (3) and Germany ~~(3)~~ (5), France (4), United Kingdom (2) in the EPPO Maritime climatic zone, Latvia (2) and Poland ~~(3)~~ (6) in the EPPO North-East climatic zone, and Bulgaria (2), Hungary (3) and Romania ~~(5)~~ (6) in the EPPO South-East climatic zone, between 2014 and 2020.

On the basis of the EPPO Standard PP 1/241 '*Guidance on comparable climates'*, the trials included in the dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime, North-East and South-East EPPO climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from each of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The minimum effective dose (MED) efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-9.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where SEPTTR is a prevalent disease. For trial site and application details see Appendix 3 and Appendix 4 in the BAD. Figure 3.2 - 2 provides an overview of the geographical distribution of the MED trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3308#	EC	100 g/L fenpicoxamid	1,0, 1,2, 1,5, 2,0	50, 60, 75, 100
Proline 275	EC	275 g/L prothioconazole	0,72	198
Aviator Xpro 225EC	EC	75 g/L bixafen + 150 g/L prothioconazole	1,0-1,25	225-281
Input	EC	160 g/L prothioconazole + 300 g/L spiroxamine	1,0	460
Vertisan 200 EC	EC	200 g /L penthiopyrad	1,0	200
Librax	EC	62,5 g/L fluxapyroxad + 45 g/L metconaozole	2,0	215

#The minimum effective dose data includes one trial (DE14E7B027UB01C) from 2014 where an earlier formulation GF-3311 (~~67.5~~ 66,7 g a.s./L) was used. The same quantities of active substance (50, 75 and 100 g as/ha) were applied with each formulation in either 2014 using GF-3311 or in later trials using GF-3308, so these treatments are considered comparable. As stated previously in the Preliminary data section 3.2.1.9, due to the similarity of the composition of formulations, data generated using GF-3311 is considered comparable to GF3308, to support the evaluation of GF-3308. Trials established in 2015-2016 for bridging of GF-3311 and GF-3308 formulations against SEPTTR, confirm equivalent performance. For ease of summarisation, the 2014 trials applied with GF-3311 are referred to as GF-3308 in this section.

Experimental details

The ~~22~~ 35 MED trials were conducted to GEP by officially recognized testing organisations and followed the appropriate EPPO standards. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 13,5 m² and 36 m². The treatments in all trials, were applied using self-propelled, bicycle or knapsack precision small plot sprayers, equipped with conventional or low drift flat fan nozzles, delivering water volumes of 200-~~300~~ 250 L/ha.

GF-3308 was applied as a single application at BBCH ~~31-43~~ 30-56 of winter wheat. The treatments were typically sprayed when SEPTTR had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials, see Appendix 3 and Appendix 4 in the BAD.

Assessments for efficacy (% infection) were made at approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level, relative to the infection level present in the untreated control. Leaves showing less than 5% infection with SEPTTR or leaves which were already senesced to a high degree in both treated and untreated plots were excluded from summarization. Assessments were generally conducted on Leaf 1 and Leaf 2, with a few on Leaf 3 or Leaf 4.

Results

Proposed dose of 2,0 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

~~Seven~~ Sixteen GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3308, for the control of SEPTTR in wheat, following a single application, applied at BBCH 31-~~39~~ 51 of the crop. The MED trials were conducted in the Czech Republic ~~(1)~~ (2), Denmark (3), France (4), United Kingdom (2) and Germany ~~(3)~~ (5) in the EPPO Maritime climatic zone. Assessments across all trials were on Leaf 1, ~~or~~ Leaf 2 or Leaf 4, as these leaves had high levels of SEPTTR infection (mean of ~~31.1%~~ 28,6% in the untreated, range 6,1-75%) so was considered to be a robust test of the product.
A single application of GF-3308 applied at 2,0 L/ha achieved mean control of ~~91.2%~~ 84,5% (range ~~80.6~~ 65,0-100%) for SEPTTR, ~~33-45~~ 29-56 days after application. Applied in the same trials, the 1,5 L/ha (75% rate/0,75N) dose of GF-3308 achieved a lower mean level of control of ~~83.7%~~ 79,8%, with more variable results (range ~~70.7~~ 59,1-96,9%). ~~Five~~ Twelve trials compared the proposed dose (2,0 L/ha), with a dose of 1,0 L/ha (50% rate/0,5N). In these trials GF-3308 achieved mean control of ~~91.3%~~ 85,0% using the proposed dose (range ~~80.6~~ 65,0-100%) compared to a lower level of control of ~~83.2%~~ 77,7% using the 0,5N dose, with more variable results (range ~~72.2~~ 59,0-97,2%).
Across almost all trials, control of SEPTTR demonstrated by the proposed dose rate of 2,0 L/ha was considerably higher than the prothioconazole standard Proline (~~61.3%~~ 70,7% across ~~6~~ 14 trials) and fluxapyroxad + metconazole standard, Librax (72,7% in one trial) and lower than ~~comparable to~~ the bixafen + prothioconazole standard, Aviator Xpro (~~96.7%~~ 96,9% in one trial).
The results are summarised in Table and individual trial results are detailed in the BAD and in the single trial reports.

~~**Table 3.2-30 Minimum effective dose testing of GF-3308 at the proposed label rate of 2.0 L/ha, at 75% and 50% dose rates against SEPTTR in winter wheat (TRZAW). Results from 7 trials conducted in the EPPO Maritime climatic zone in 2014-2017. Assessment at 33-49 days after one application.**~~

~~EPPO Zone~~	~~Number of trials~~	~~Untreated control % infection SEPTTR~~		~~% control of SEPTTR~~							
				~~GF-3308 1,0 L/ha (50% rate)~~		~~GF-3308 1,5 L/ha (75 % rate)~~		~~GF-3308 2,0 L/ha (100 % rate)~~		~~Reference (Proline 275 at 0,72 L/ha) or other standards~~	
		~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~
~~Maritime*~~	~~7~~	~~31,1~~	~~6,1-75,0~~	~~-~~	~~-~~	~~**83,7**~~	~~70,7-96,9~~	~~**91,2**~~	~~80,6-100~~	~~**66,4#**~~	~~20,0-96,7~~
~~Maritime**~~	~~5~~	~~27,3~~	~~6,3-57,5~~	~~**83,2**~~	~~72,2-97,2~~	~~**85,5**~~	~~75,3-96,9~~	~~**91,3**~~	~~80,6-100~~	~~**59,3**~~	~~20,0-96,7~~

~~*Direct comparison of 2.0 L/ha and 1.5 L/ha doses.~~
~~**Direct comparison of 2.0 L/ha and 1.0 L/ha doses.~~
~~#Reference standard results include one trial where Aviator Xpro at 1.25 L/ha was included as reference standard, as Proline was not included in the trial.~~

Table 3.2-30 Minimum effective dose testing of GF-3308 at the proposed label rate of 2,0 L/ha, at 75% and 50% dose rates against SEPTTR in winter wheat (TRZAW). Results from 16 trials conducted in the EPPO Maritime climatic zone in 2014-2019. Assessment at 29-56 days after one application.

EPPO Zone	Number of trials	Untreated control % infection SEPTTR		% control of SEPTTR							
				GF-3308 1,0 L/ha (50% rate)		GF-3308 1,5 L/ha (75 % rate)		GF-3308 2,0 L/ha (100 % rate)		Reference (Proline 275 at 0,72 L/ha) or other standards	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Maritime*	16	28,6	6,1-75,0	-	-	**79,8**	59,1-96,9	**84,5**	65,0-100	**72,4#**	29,3-96,9
Maritime**	12	25,8	6,3-57,5	**77,7**	59,0-97,2	**80,4**	63,1-96,9	**85,0**	65,0-100	**68,8**	29,3-96,7

* Direct comparison of 2,0 L/ha and 1,5 L/ha doses.
**Direct comparison of 2,0 L/ha and 1,0 L/ha doses.
#Reference products results include 1 trial where Aviator Xpro at 1,25 L/ha was included as standard and 1 trial where Librax at 2,0 L/ha was included as standard, as Proline was not included in these trials.

Summary and conclusions on the minimum effective dose (MED) for control of SEPTTR in winter wheat (EPPO Maritime climatic zone)

SEPTTR is a foliar disease which under favourable conditions builds up very rapidly and is important disease in wheat. Therefore, high levels of efficacy are required to successfully control this disease. SEPTTR is therefore an important target disease for GF-3308 and the data reported demonstrate that it provides excellent control of SEPTTR at the proposed dose rate of 2,0 L/ha. The proposed dose of 2,0 L/ha consistently achieved over 80% control, across all the trials, compared to the 0,75N dose of 1,5 L/ha which achieved over 80% control in only ~~4~~ 8 of the ~~7~~ 16 trials. In almost all the trials, the proposed dose achieved levels of control higher than the 0,75N dose.
It is considered that the proposed dose rate of 2,0 L/ha is the minimum effective dose of GF-3308 to deliver robust control of this disease, as both a protectant and curative fungicide, under the challenging environmental conditions most suitable for SEPTTR infections found within the EPPO Maritime climatic zone.

Proposed dose range of 1,5-2,0 L/ha for Poland (EPPO North-East climatic zone)

~~Five~~ Eight GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3308, for the control of the SEPTTR in winter wheat and spring wheat, following a single application applied at BBCH 37-~~43~~ 56 of the crop. The MED trials were conducted in Latvia (2) and Poland ~~(3)~~ (6) in the EPPO North-East climatic zone. Assessments across all trials were mainly on Leaf 1 or Leaf 2 (mean of ~~13.3%~~ 12,2% in the untreated - range 7,2-18,9% for TRZAW and 5,0% for TRZAS) so was considered to be a robust test of the product.
For winter wheat, a single application of GF-3308 applied at 1,5 L/ha achieved mean control of ~~79.7%~~ 82,2% (range ~~66.1~~ 41,4-100%) for SEPTTR, ~~33-45~~ 14-39 days after application. Applied in the same trials at 2,0 L/ha, GF-3308 achieved control of ~~81.9%~~ 85,0% (range ~~71.0~~ 49,4-100%). A dose of 1,0 L/ha achieved a lower mean level of control of ~~69.6%~~ 70,2%, with more variable control (range ~~52.3-94%~~ 24,1-100%). ~~Across all trials,~~ The average control of SEPTTR demonstrated by the proposed dose rate range of 1,5-2,0 L/ha was comparable to the prothioconazole standard Proline (~~85.7%~~ 87,5%).
In addition to these trials, data from neighbouring countries in the EPPO Maritime climatic zone are available and can also be considered supportive of the proposed dose. These ~~three~~ four trials were conducted in CZ + DE and GF-3308 at 1,5 L/ha demonstrated a comparable dose response to the EPPO North-East data with the 1,5 L/ha achieving control of ~~86.6%~~ 81,0%, ~~the~~ at 2,0 L/ha dose ~~93.0%~~ 86,0% control and ~~the~~ at 1,0 L/ha dose lower control of ~~83.1%~~ 77,1%. Combined with the ~~four~~ seven EPPO North-East trials, these give overall control of SEPTTR across ~~7~~ 11 trials of ~~82.6-86.7%~~ 81,8-85,4% for the proposed dose range of 1,5-2,0 L/ha, and ~~75.4%~~ 72,9% for the lower 1,0 L/ha dose. Details for the Czech and German trials are in the EPPO Maritime climatic zone section, above.

A larger data set of 9 15 trials from North East, CZ and DE directly comparing the 1,5 l/ha and 2,0 L/ha is presented in the Efficacy section 3.2.3.1. Some of these trials did not have the lowest dose of 1,0 L/ha and so are not presented in this MED section. This data shows comparable efficacy of the two doses in these trials and further support range of 1,5-2,0 L/ha for use in wheat.
The results are summarised in Table 3.2-31 and individual trial results are detailed in the BAD and in the single trial reports.

Table 3.2-31 Minimum effective dose testing of GF-3308 at the proposed label rate range of 1.5-2.0 L/ha against SEPTTR in winter wheat (TRZAW). Results from 4 trials conducted in the EPPO North-East climatic zone in 2016 plus three CZ+ DE trials conducted between 2014-2016. Assessment at 33-43 days after one application.

EPPO Zone	Number of trials	Untreated control % infection SEPTTR		% control of SEPTTR							
				GF-3308 1.0 L/ha		GF-3308 1.5 L/ha		GF-3308 2.0 L/ha		Proline 0.72 L/ha	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East	4	13.3	7.2-18.9	**69.6**	52.3-94.8	**79.7**	66.1-100	**81.9**	71.0-100	**83.5**	69.4-97.1
CZ + DE	3	27.2	6.1-57.5	**83.1**	72.2-97.2	**86.6**	78.9-96.9	**93.0**	80.6-100	**82.3**	58.3-96.7
North-East + CZ + DE	7	19.3	6.3-57.5	**75.4**	52.3-97.2	**82.6**	66.1-100	**86.7**	71.0-100	**73.0**	58.3-97.1

Table 3.2-31 Minimum effective dose testing of GF-3308 at the proposed label rate range of 1,5-2,0 L/ha against SEPTTR in winter wheat (TRZAW). Results from 7 trials conducted in the EPPO North-East climatic zone in 2016 plus 4 CZ+ DE trials conducted between 2014-2016. Assessment at 14-43 days after one application.

EPPO Zone	Number of trials	Untreated control % infection SEPTTR		% control of SEPTTR							
				GF-3308 1,0 L/ha		GF-3308 1,5 L/ha		GF-3308 2,0 L/ha		Proline 0,72 L/ha or other stndards	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East	7	12,2	7,2-18,9	**70,2***	24,1-100	**82,2**	41,4-100	**85,0**	49,4-100	**87,5#**	69,4-100
CZ + DE	4	25,9	6,3-57,5	**77,1**	59,0-97,2	**81,0**	63,6-96,9	**86,0**	65,0-100	**76,7**	59,0-96,7
North-East + CZ + DE	11	17,1	6,3-57,5	**72,9**	24,1-100	**81,8**	41,4-100	**85,4**	49,4-100	**83,6**	59,0-100

*Results from 6 trials. In one trial dose rate of 1,0 L/ga was not tested
#Reference standard results include 1 trial where Vertisan at 1,0 L/ha was included as reference standard, as Proline was not included in the trial.

In addition to data on winter wheat, one trial was conducted on spring wheat (TRZAS). This trial demonstrated a similar visible dose response to the winter wheat data with the 1,5 L/ha achieving 78,3% control, the 2,0 L/ha dose 92,5% control and the 1,0 L/ha dose lower control of 67,8%. The results are summarised in Table 3.2 and the results of the individual trials are detailed in the BAD.

Table 3.2-32 Minimum effective dose testing of GF-3308 at the proposed label rate range of 1,5-2,0 L/ha against SEPTTR in spring wheat (TRZAS). Results from one trial conducted in the EPPO North-East climatic zone in 2016. Assessment at 14 days after one application.

EPPO Zone	Number of trials	Untreated control % infection SEPTTR		% control of SEPTTR							
				GF-3308 1,0 L/ha		GF-3308 1,5 L/ha		GF-3308 2,0 L/ha		Proline 0,72 L/ha	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East	1	5,0	-	**67,8**	-	**78,3**	-	**92,5**	-	**88,3**	-

Summary and conclusions on the minimum effective dose (MED) for control of SEPTTR in winter wheat (EPPO North-East climatic zone)

SEPTTR is an important target disease for GF-3308 and the data reported demonstrate that it provides ~~excellent~~ high level of efficacy in the control of SEPTTR on winter wheat at the proposed dose rate range of 1,5-2,0 L/ha based on MED trials. The proposed lower dose rate of 1,5 L/ha achieved overall control of ~~82.6%~~ 81,8%, compared to ~~75.4%~~ 72,9% for the 1,0 L/ha dose (across ~~four~~ seven EPPO North-East trials and ~~three~~ four CZ + DE trials). The proposed dose rate range demonstrated control greater than the 1,0 L/ha dose across the majority of trials. In one trial on spring wheat a similar dose response was demonstrated. The results for the higher dose rate of 2,0 L/ha (required for other diseases) demonstrate that high levels of control of SEPTTR will be achieved in mixed disease situations as PUCCST was also present in this trial.
It is considered that the proposed dose rate of 1,5 L/ha is the minimum effective dose of GF-3308 to deliver robust control of this disease on winter and spring wheat under a wide range of environmental conditions in Poland (EPPO North-East climatic zone). However, as cereal diseases may occur together, For higher disease pressure disease situations in wheat where *Septoria* and rusts occur, the higher dose of 2,0 L/ha may be recommended for broad spectrum disease control.
A dose range of 1,5-2,0 L/ha will be proposed for diseases of wheat to offer growers flexibility so they can adjust dose according to the conditions.
Data in the efficacy section 3.2.3.1 will present the 1,5 L/ha from ~~9~~ 15 trials and also the 2,0 L/ha dose that will be advised in the more severe disease situations from a larger data set of ~~22~~ 29 trials from North East EPPO, the Czech Republic and Germany.

Proposed dose range of 1,2-2,0 L/ha for EPPO South-East climatic zone countries of the Central EU Authorisation zone

~~Ten~~ Eleven GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3308, for the control of the SEPTTR in winter wheat, following a single application applied at BBCH ~~31~~ 30-41 of the crop. The MED trials were conducted in Bulgaria (2), Hungary (3) and Romania ~~(5)~~ (6) in the EPPO South-East climatic zone. Assessments across all trials were on Leaf 1 or Leaf 2 (mean of ~~19.6%~~ 17,8% in the untreated - range 6,0-32,2% in trials comparing the 1,5 and 2,0 L/ha doses and a mean of 10,9% in the untreated - range 5,1-17,5% in trials comparing the 1,0, 1,2 and 1,5 L/ha doses) so was considered to be a robust test of the product.
~~Six~~ Seven trials compared the maximum dose rate of 2,0 L/ha with a dose of 1,5 L/ha. GF-3308 at 2,0 L/ha achieved mean control of ~~89.8%~~ 88,2% (range 76,0-100%), 36-49 days after application. Applied in the same trials, the 1,5 L/ha dose of GF-3308 achieved mean control of ~~88.3%~~ 86,2% (range ~~74.5~~ 74,1-100%). In two trials with low disease pressures of 6,0% and ~~8.4%~~ 8,5%, respectively, in the untreated, 100% control was demonstrated by all treatments including the standard~~s~~ (prothioconazole/Proline).
Four trials compared a dose rate of 1,5 L/ha with doses of 1,2 L/ha and 1,0 L/ha. In these trials, a single application of GF-3308 applied at 1,5 L/ha achieved mean control of 91,0% (range 81,2-98,5%), 28-35 days after application, compared to 80,8% control for the 1,2 L/ha dose and 72,5% control for the 1,0 L/ha.
Across all trials, control of SEPTTR demonstrated by the proposed dose rate range of 1,2-2,0 L/ha was comparable to the standards. The results are summarised in Table 3.2-33 and individual trial results are detailed in the BAD and in the single trial reports.

Table: 3.2-33 Minimum effective dose testing of GF-3308 at the proposed label rate range of 1,2-2,0 L/ha and at 50-83% of the dose range, against SEPTTR in winter wheat (TRZAW). Results from ~~10~~ 11 trials conducted in the EPPO South-East climatic zone in 2015-2020. Assessment at 28-49 days after one application.

EPPO Zone	Number of trials	Untreated control % infection SEPTTR		% control of SEPTTR									
				GF-3308 1,0 L/ha (50-83% rate)		GF-3308 1,2 L/ha		GF-3308 1,5 L/ha		GF-3308 2,0 L/ha		Reference (Proline 275 at 0,72 L/ha) or other standards	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
South-East*	~~6~~ 7	~~19,6~~ 17,8	6,0-32,2	-	-	-	-	~~**88,3**~~ **86,2**	~~74,5~~ 74,1-100	~~**89,8**~~ **88,2**	76,0-100	~~**90,0**~~ **89,2#**	75,1-100
South-East**	4	10,9	5,1-17,5	**72,5**	65,9-79,0	**80,8**	73,1-89,0	**91,0**	81,2-98,5	-	-	~~**86,6**~~ **86,5**^	~~78,2~~ 77,6-98,6

*Direct comparison of 2,0 L/ha and 1,5 L/ha doses.
**Direct comparison of 1,5 L/ha, 1,2 L/ha and 1,0 L/ha doses.
#~~Four~~ Five trials used Proline as the ~~reference~~ standard, ~~one~~ 1 trial used Aviator Xpro at 1,25 L/ha and ~~one~~ 1 trial used Vertisan at 1,0 L/ha
^Standard used in ~~three~~ 3 trials was Input at 1,0 L/ha and in ~~one~~ 1 trial was Aviator Xpro at 1,0 L/ha

Summary and conclusions on the minimum effective dose (MED) range of 1,2-2,0 L/ha for control of SEPTTR in winter wheat (EPPO South-East climatic zone)

SEPTTR is an important target disease for GF-3308 and the data reported demonstrate that it provides effective control of SEPTTR at the proposed dose rate range (1,2-2,0 L/ha). The maximum dose of 2,0 L/ha will give excellent control (~~89.8%~~ 88,2%) in all situations, including where varietal resistance to SEPTTR is low and fungicide resistance is a concern or in geographical locations which have a history of severe SEPTTR infections. In other situations, which may be more typical for SEPTTR in the South East EPPO zone, where disease pressure is lower than Maritime conditions and if PUCCRT is not present in the crop (or expected to be a concern, see PUCRRT section), a dose of 1,5 L/ha will give sufficient control of SEPTTR in the EPPO South-East climatic zone (~~88.3%~~ 86,2% control across all ~~6~~ 7 trials). For situations with low disease pressure such as earlier in the season, a dose of 1,2 L/ha will also give sufficient control of SEPTTR in EPPO South-East conditions (mean control of 80,8% across four trials). A dose of 1,0 L/ha dose (50% of the upper dose rate and 83% of the lower dose rate) ~~does not generally~~ give sufficient moderate control of SEPTTR (mean control of 72,5% across four trials).
It is considered that the proposed dose rate range of 1,2-2,0 L/ha is the minimum effective dose to deliver robust control of this disease under a wide range of environmental conditions in the EPPO South-East climatic zone (dependent on disease pressure).

3.2.2.2 MED of GF-3308 for the control of PUCCRT in winter wheat

This section addresses the minimum effective dose (MED) of GF-3308, for the control of PUCCRT on winter wheat, when applied at the proposed label rate of 2,0 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone and Poland (EPPO North-East climatic zone) and the proposed dose range of 1,5-2,0 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone.

Table 3.2.-34 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 20-30 m² EPPO North-East: 25-30 m² EPPO South-East: 20-30 m²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: ~~4~~ 5 TRZAW EPPO North-East: 2 TRZAW EPPO South-East: 5 TRZAW
	Varieties per crop (number of trials)	EPPO Maritime: Bohemia, Crusoe, Tobak (2), Patras EPPO North-East: Bogatka (2) EPPO South-East: Enova, GK Élet, Iridium, Lupus, Sadovo 772
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 32-51 EPPO North-East: BBCH 45-56 EPPO South-East: BBCH 37-55
	Timing Pest stage at application	GF-3308 has both protectant and curative properties. For the control of PUCCRT applications were timed to cover these situations from commencing when there was a risk of infection with PUCCRT or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	1
	Spray volumes	200~~-300~~ L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were approximately 2-3 weeks after application, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where PUCCRT is a prevalent disease.

Introduction

In total, data from ~~11~~ 12 field trials are presented in this section to demonstrate the minimum effective dose of GF-3308, for the control of PUCCRT in winter wheat (TRZAW). GF-3308 was tested at 2,0, 1,5 and 1,0 L/ha. The trials were performed in accordance with the EPPO Standard PP 1/225 '*Minimum effective dose*'. The reference products include Proline 275 applied at 0,72 L/ha, Proline 250 applied at

0,8 L/ha, Librax at 2,0 L/ha and Vertisan applied at 1,0 L/ha. Proline 275 was applied in the majority of trials. Results for all standards have been combined in the following summary tables, however, individual results for each standard are presented in the individual trial tables and are compared orthogonally with GF-3308 in section 3.2.3.
The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which follow the EPPO Standards and are officially recognized by the competent authorities to carry out registration field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in the Czech Republic (3), Germany (1) and the UK (1) in the EPPO Maritime climatic zone, Poland (2) in the EPPO North-East climatic zone, also Bulgaria (2) and Hungary (3) in the EPPO South-East climatic zone, between 2014 and 2020 2016 and 2019.
In line with EPPO Standard PP 1/241 '*Guidance on comparable climates'*, the trials included in the dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone includes countries in the Maritime, North-East and South-East EPPO climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from each of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations
The minimum effective dose (MED) efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-10.

Sites
Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where PUCCRT is a prevalent disease. For trial site and application details see Appendix 3 and Appendix 4 in the BAD.
Figure 3.2 - 3 provides an overview of the geographical distribution of the MED trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3308	EC	100 g/L fenpicoxamid	1,0, 1,5, 2,0	50, 75, 100
Proline 275	EC	275 g/L prothioconazole	0,72	198
Proline 250	EC	250 g/L prothioconazole	0,8	200
Librax	EC	62,5 g/L fluxapyroxad + 45 g/L metconaozole	2,0	215
Vertisan 200 EC	EC	200 g /L penthiopyrad	1,0	200

Experimental details
The 11 12 MED trials were conducted to GEP, by officially recognized testing organisations and followed the appropriate EPPO Standards. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 20 m² and 30 m². The treatments in all trials, were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles, delivering water volumes of 200-300 L/ha.
GF-3308 was applied as a single application at BBCH 33 32-56 of winter wheat. The treatments were typically sprayed when PUCCRT had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials see Appendix 3 and Appendix 4 in the BAD.
Assessments for efficacy (% infection) were made at approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level, relative to the infection

level present in the untreated control. Leaves showing less than 5% infection with PUCCRT or leaves which were already senesced to a high degree in both treated and untreated plots, were excluded from summarization. Assessments were generally conducted on Leaf 1 and Leaf 2, with one on Leaf 3.

Results

Proposed dose of 2,0 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

~~Four~~ Five GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3308, for the control of PUCCRT in wheat, following a single application, applied at BBCH 32-51 of the crop. The MED trials were conducted in the Czech Republic (3), Germany (1) and the UK (1) in the EPPO Maritime climatic zone. Assessments across all trials were on the highest leaf (Leaf 1, Leaf 2 or Leaf 3), as this leaf had high levels of PUCCRT infection (mean of ~~17.9%~~ 15,9% in the untreated - range 6,6-27,9%) and was considered to be a robust test of the product.
A single application of GF-3308 applied at 2,0 L/ha achieved mean control of ~~89.9%~~ 83,8% (range ~~71.7~~ 59,4-100%) for PUCCRT, 11-~~37~~ 40 days after application. Applied in the same trials, at 1,5 L/ha (75% rate/0,75N), GF-3308 achieved a lower mean level of control of ~~71.6%~~ 66,3%, with more variable results (range ~~31.1~~ 32,6-98,9%). ~~All~~ Four trials also compared the proposed dose (2,0 L/ha), with a dose of 1,0 L/ha (50% rate/0.5N), which demonstrated ~~71.2%~~ 71,3% overall control (range ~~17.8~~ 18,3-98,9%).
Note: In trial CZ18E7B017PV01C, the latest assessment timing after a single application was 11 days. Later assessments followed a second application and are not considered valid to support the proposed GAP.
Across all trials, control of PUCCRT demonstrated by the proposed dose rate of 2,0 L/ha was comparable with the prothioconazole standard Proline (~~88.5%~~ 87,1%).
The results are summarised in Table 3.2- and individual trial results are detailed in the BAD and in the sinle trial reports.

~~**Table 3.2-35 Minimum effective dose testing of GF-3308 at the proposed label rate of 2,0 L/ha, at 75% and 50% dose rates against PUCCRT in winter wheat (TRZAW). Results from 4 trials conducted in the EPPO Maritime climatic zone in 2016 and 2018. Assessment at 11-37 days after one application.**~~

~~EPPO Zone~~	~~Number of trials~~	~~Untreated control % infection PUCCRT~~		~~% control of PUCCRT~~							
				~~GF-3308 1.0 L/ha (50% rate)~~		~~GF-3308 1.5 L/ha (75 % rate)~~		~~GF-3308 2.0 L/ha (100 % rate)~~		~~Proline 0.72 L/ha~~	
		~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~
~~Maritime~~	~~4~~	~~17.9~~	~~6.6-27.9~~	~~**71.2**~~	~~17.8-98.9~~	~~**71.6**~~	~~31.1-98.9~~	~~**89.9**~~	~~71.7-100~~	~~**88.5**~~	~~73.3-99.4~~

Table 3.2-35 Minimum effective dose testing of GF-3308 at the proposed label rate of 2,0 L/ha, at 75% and 50% dose rates against PUCCRT in winter wheat (TRZAW). Results from 5 trials conducted in the EPPO Maritime climatic zone in 2016 and 2019. Assessment at 11-40 days after one application.

EPPO Zone	Number of trials	Untreated control % infection PUCCRT		% control of PUCCRT							
				GF-3308 1,0 L/ha (50% rate)		GF-3308 1,5 L/ha (75 % rate)		GF-3308 2,0 L/ha (100 % rate)		Proline 0,72 L/ha or other standards	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Maritime*	4	17,9	6,6-27,9	**71,3**	18,3-98,9	**72,0**	32,6-98,9	**89,9**	71,7-100	**88,6#**	73,8-99,4
Maritime**	5	15,9	6,6-27,9	-	-	**66,3**	32,6-98,9	**83,8**	59,4-100	**87,1#**	73,8-99,4

*Direct comparison of 2,0 L/ha and 1,0 L/ha doses.
**Direct comparison of 2,0 L/ha and 1,5 L/ha doses.
#Reference products results include 1 trial where Librax at 2,0 L/ha was included as standard and 1 trial where Proline 250 at 0,8 L/ha ha was included as standard, as Proline 275 was not included in these trials.

Summary and conclusions on the minimum effective dose (MED) for control of PUCCRT in winter wheat (EPPO Maritime climatic zone)

PUCCRT is an important target disease for GF-3308 and the data reported demonstrate that it provides excellent control of PUCCRT at the proposed dose rate of 2,0 L/ha. The proposed dose of 2,0 L/ha was the only dose to achieve a mean control >80%. The proposed dose achieved levels of control higher than the 0,75N dose, in ~~3~~ 4 of the ~~4~~ 5 trials (with results being identical in the fourth trial).
It is considered that the proposed dose rate of 2,0 L/ha is the minimum effective dose of GF-3308, required for the control of PUCCRT in winter wheat, in the EPPO Maritime climatic zone.

Proposed maximum dose of 2,0 L/ha for Poland (EPPO North-East climatic zone)

Two GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3308, for the control of the PUCCRT in winter wheat, following a single application applied at BBCH 45-56 of the crop. The MED trials were conducted in Poland (2) in the EPPO North-East climatic zone. Assessments across both trials were on Leaf 1 (mean of 20,4% in the untreated - range 18,8-22,0%) so was considered to be a robust test of the product.
A single application of GF-3308 applied at 2,0 L/ha achieved mean control of 81,7% (range 80,9-82,4%) for PUCCRT, 41-42 days after application. Applied in the same trials at 1,5 L/ha (75% rate/0,75N), GF-3308 achieved a good mean level of control of 79,4% (range 77,3-81,4%). One trial compared the proposed 2,0 L/ha dose with a dose of 1,0 L/ha (50% rate/0,5N). In this trial GF-3308 achieved 82,4% control using the 2,0 L/ha dose, compared to 76,1% for the 1,0 L/ha dose.
In the 2 North-East EPPO Zone trials, control of PUCCRT demonstrated by the proposed maximum dose rate of 2,0 L/ha (81,7% control) was comparable to, or higher than, the standards (68,6% for prothioconazole/Proline and 82,7% for penthiopyrad/Vertisan) and the 1,5 l/ha dose achieved 79,4% control which was at least comparable to the refences in the North East EPPO Zone trials.
In addition to these 2 North East EPPO Zone trials, data from neighbouring countries in the EPPO Maritime climatic zone are available and can also be considered supportive of the proposed maximum dose. ~~These~~ Three trials were conducted in the Czech Republic and demonstrate a comparable dose response to the Polish data with the 2,0 L/ha achieving the highest level of control of 90,6% and compared to ~~66.2%~~ 66,7% for the 1,5 L/ha dose and ~~67.9%~~ 68,1% for the 1,0 L/ha. One trial was conducted in Germany, where lower efficacy was achieved at 1,5 and 2,0 L/ha dose rate of GF-3308, but visible dose response was noted between these two doses: 43,8% for 1,5 L/ha and 59,4% for 2,0 L/ha.Combined with the two PL trials, these give overall control of PUCCRT across ~~5~~ 6 trials of ~~87.0%~~ 82,4% for the proposed dose of 2,0 L/ha and ~~71.5%~~ 67,1% for the 1,5 L/ha dose based on ~~5~~ 6 trials. The impact on the mean control from the 1,5 L/ha dose may be from one Czech trial (CZ16E7B038PV01C) where poor control of ~~31,1%~~ 32,6% was achieved with this dose in a very high disease pressure situation of 27,9 % infection on L1, The assessment point in this trial was 37 DAA and can be considered a long protection period after application, as even the 2,0 L/ha dose achieved moderate control of 71,7% and Proline ~~73.3%~~ 73,8% control. If the Czech trial (CZ16E7B038PV01C) is removed as an outlier, then control with 1,5 L/ha dose would be ~~81.6%~~ 83,0% and 2,0 L/ha would achieve ~~90.8%~~ 94,1% control based on ~~4~~ 3 trials with the reference at ~~85.4%~~ 86,3%. This could mean that a dose range of 1,5-2,0 L/ha is possible in wheat and where SEPTTR is the main target. Where rust pressure is lower, then the 1,5 l/ha dose would be acceptable, though 2,0 L/ha is the most effective dose when rust pressure is higher. Details for the Czech trials and for Germany trial are in the EPPO Maritime climatic zone section, above.
The results are summarised in

~~Table 3.2~~ Table 3.2-36 and individual trial results are detailed in the BAD and in the single trial reports.

~~Table 3.2-36 Minimum effective dose testing of GF-3308 at the proposed maximum label rate of 2.0 L/ha, at 75% and 50% dose rates against PUCCRT in winter wheat (TRZAW). Results from 2 trials conducted in the EPPO North-East climatic zone and 3 trials conducted in CZ in 2016 and 2018. Assessment at 11-42 days after one application.~~

~~EPPO Zone~~	~~Number of trials~~	~~Untreated control % infection PUCCRT~~		~~% control of PUCCRT~~							
				~~GF-3308 1.0 L/ha (50% rate)~~		~~GF-3308 1.5 L/ha (75 % rate)~~		~~GF-3308 2.0 L/ha (100 % rate)~~		~~Reference (Proline 275 at 0.72 L/ha) or other standards~~	
		~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~
~~North-East*~~	~~2~~	~~20.4~~	~~18.8-22.0~~	-	-	~~**79.4**~~	~~77.3-81.4~~	~~**81.7**~~	~~80.9-82.4~~	~~**75.7^**~~	~~68.6-82.7~~
~~North-East**~~	~~1~~	~~18.8~~	-	~~**76.1**~~	-	~~**81.4**~~	-	~~**82.4**~~	-	~~**68.6**~~	-
~~CZ~~	~~3~~	~~17.3~~	~~6.6-27.9~~	~~**67.9**~~	~~17.8-98.9~~	~~**66.2**~~	~~31.1-98.9~~	~~**90.6**~~	~~71.7-100~~	~~**87.8**~~	~~73.3-99.4~~
~~North-East + CZ*~~	~~5~~	~~18.6~~	~~6.6-27.9~~	~~**70.0#**~~	~~17.8-98.9~~	~~**71.5**~~	~~31.1-98.9~~	~~**87.0**~~	~~71.7-100~~	~~**83.0^**~~	~~68.6-99.4~~
~~North-East + CZ***~~	~~4~~	~~16.2~~	~~6.6-22.0~~	-	-	~~**81.6**~~	~~68.7-98.9~~	~~**90.8**~~	~~80.9-100~~	~~**85.4**~~	~~68.6-99.4~~

~~*Direct comparison of 2.0 L/ha and 1.5 L/ha doses.~~
~~**Direct comparison of 2.0 L/ha and 1.0 L/ha doses.~~
~~^Standard used in one trial was Vertisan at 1.0 L/ha.~~
~~#Results from 4 trials only. *** trial CZ16E7B038PV01C removed~~

Table 3.2-36 Minimum effective dose testing of GF-3308 at the proposed maximum label rate of 2,0 L/ha, at 75% and 50% dose rates against PUCCRT in winter wheat (TRZAW). Results from 2 trials conducted in the EPPO North-East climatic zone, 3 trials conducted in CZ in 2016 and 2018 and 1 trial conducted in Germany in 2019. Assessment at 11-42 days after one application.

EPPO Zone	Number of trials	Untreated control % infection PUCCRT		% control of PUCCRT							
				GF-3308 1,0 L/ha (50% rate)		GF-3308 1,5 L/ha (75 % rate)		GF-3308 2,0 L/ha (100 % rate)		Reference (Proline 275 at 0,72 L/ha) or other standards	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East*	2	20,4	18,8-22,0	-	-	**79,4**	77,3-81,4	**81,7**	80,9-82,4	**75,7^**	68,6-82,7
North-East**	1	18,8	-	**76,1**	-	**81,4**	-	**82,4**	-	**68,6**	-
CZ	3	17,3	6,6-27,9	**68,1**	18,3-98,9	**66,7**	32,6-98,9	**90,6**	71,7-100	**88,0**	73,8-99,4
DE	1	8,0	-	-	-	**43,8**	-	**59,4**	-	**81,3**	-
North-East + CZ +DE *	6	16,8	6,6-27,9	-	-	**67,1**	32,6-98,9	**82,4**	59,4-100	**82,8**	68,6-99,4
North-East + CZ +DE **	4	17,7	6,6-27,9	**70,1**	18,3-98,9	**70,4**	32,6-98,9	**88,5**	71,7-100	**83,2**	68,6-99,4
North-East + CZ + DE ***	3	14,3	6,6-18,8	**87,3**	76,1-98,9	**83,0**	68,7-98,9	**94,1**	82,4-100	**86,3**	68,6-99,4

*Direct comparison of 2,0 L/ha and 1,5 L/ha doses.
**Direct comparison of 2,0 L/ha and 1,0 L/ha doses.
^Standard used in 1 trial was Vertisan at 1,0 L/ha.
*** Trial CZ16E7B038PV01C removed

Summary and conclusions on the minimum effective dose (MED) for control of PUCCRT in winter wheat (EPPO North-East climatic zone)

PUCCRT is an important target disease for GF-3308 and the data reported demonstrate that it provides excellent control of PUCCRT at the proposed maximum dose rate of 2,0 L/ha under a wide range of environmental conditions in Poland. ~~high disease pressure.~~ The proposed dose of GF-3308 achieved the highest level of overall control and ~~was the only dose to~~ demonstrated overall control >80% in most of the trials (81,7% in two PL trials and 90,6% in three CZ trials). In almost all trials, it achieved levels of control higher than the 0,75N dose.~~, however, the 1,5 L/ha dose also offered good levels of control and may be appropriate in lower disease pressure situations.~~

It is considered that the proposed maximum dose rate of 2,0 L/ha is the most effective dose of GF-3308 to deliver robust control of this disease under ~~the~~ low and high~~est~~ disease pressure conditions in Poland (EPPO North-East climatic zone~~). A dose range of 1,5-2,0 L/ha will be proposed for diseases of wheat to offer growers flexibility so they can adjust dose according to the conditions.~~ Data in the efficacy section 3.2.3.2 will present the 2,0 L/ha dose that will be recommended ~~advised in high risk situations~~ for PUCCRT and also ~~the~~ results for 1,5 L/ha dose will be presented, that can be used in the less severe disease situations.

Proposed dose range of 1,5-2,0 L/ha for EPPO South-East climatic zone countries of the Central EU Authorisation zone

Five GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3308, for the control of the PUCCRT in winter wheat, following a single application applied at BBCH 37-55 of the crop. The MED trials were conducted in Bulgaria (2) and Hungary (3) in the EPPO South-East climatic zone. Assessments across all trials were on either Leaf 1 or Leaf 2 (mean of 23,9% in the untreated - range 8,4-39,4%) and was considered to be a robust test of the product.

All five trials compared the maximum dose rate of 2,0 L/ha with a dose of 1,5 L/ha. No trials included the lower dose of the dose range (1,2 L/ha) or the 1,0 L/ha dose. GF-3308 at 2,0 L/ha achieved mean control of ~~89,0%~~ 87,9% (range 76,0-100%), 28-37 days after application, compared to 86,0% for the reference standards. Applied in the same trials, the 1,5 L/ha dose of GF-3308 achieved lower mean control of ~~80,1%~~ 81,8% (range 64,2-100%). In one trial with low disease pressure of 8,4% in the untreated, 100% control was demonstrated by all treatments including the standard (penthiopyrad/Vertisan).

Across all trials, control of PUCCRT demonstrated by the proposed dose rate of 2,0 L/ha was comparable to the standards (82,5% for prothioconazole/Proline in 5 trials and 100% for penthiopyrad/Vertisan in 1 trial).

The results are summarised in Table 3.2 and individual trial results are detailed in the BAD and in the single trial reports.

Table 3.2-37 Minimum effective dose testing of GF-3308 at the proposed label rates of 1,5 and 2,0 L/ha against PUCCRT in winter wheat (TRZAW). Results from 5 trials conducted in the EPPO South-East climatic zone in 2016. Assessment at 28-37 days after one application.

EPPO Zone	Number of trials	Untreated control % infection PUCCRT		% control of PUCCRT					
				GF-3308 1,5 L/ha		GF-3308 2,0 L/ha		Reference (Proline 275 at 0,72 L/ha) or other standards	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
South-East	5	23,9	8,4-39,4	~~80,1~~ **81,8**	64,2-100	~~89,0~~ **87,9**	76,0-100	**86,0**^	63,9-100
Low disease	1	8,4	-	**100**	-	**100**	-	**100**^	-

^Standard used in one trial was Vertisan at 1,0 L/ha.

Summary and conclusions on the minimum effective dose (MED) range of 1,5-2,0 L/ha for control of PUCCRT in winter wheat (EPPO South-East climatic zone)

PUCCRT is an important target disease for GF-3308 and the data reported demonstrate that it provides excellent control of PUCCRT at the proposed maximum dose rate date of 2,0 L/ha. The maximum dose of 2,0 L/ha will give excellent control in all situations. Where disease pressure is low, a dose of 1,5 L/ha will provide effective control of PUCCRT.
It is considered that the proposed dose rate range of 1,5-2,0 L/ha is the minimum effective dose to deliver robust control of this disease under a wide range of environmental conditions in the EPPO South-East climatic zone (dependent on disease pressure).

3.2.2.3 MED of GF-3308 for the control of PUCCST in wheat

This section addresses the minimum effective dose (MED) of GF-3308, for the control of PUCCST on winter wheat, when applied at the proposed label rate of 2,0 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone and Poland (EPPO North-East climatic zone of the Central EU Authorisation zone) and the proposed dose range of 1,5-2,0 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone

Table 3.2-38 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 13,5-30 m² EPPO North-East: 20-30 m² EPPO South-East: 20 m²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: ~~7~~ 8 TRZAW EPPO North-East: ~~4~~ 6 TRZAW EPPO North-East: 1 TRZAS EPPO South-East: 3 TRZAW
	Varieties per crop (number of trials)	EPPO Maritime: Ambition, JB Asano ~~(3)~~ (4), Patras, Substance (2) EPPO North-East (TRZAW): Bogatka (2), Muszelka, Zyta, Arkadia, Fredis EPPO North-East (TRZAS): Tybalt EPPO South-East: Enova, GK Élet, Iridium, Miranda
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH ~~32~~ 31-43 EPPO North-East: BBCH ~~39~~ 37-56 EPPO South-East: BBCH 39-41
	Timing Pest stage at application	GF-3308 has both protectant and curative properties. For the control of PUCCST applications were timed to cover these situations from commencing when there was a risk of infection with PUCCST or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	1
	Spray volumes	200-~~300~~ 250 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were approximately 2-3 weeks after application, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where PUCCST is a prevalent disease.

Introduction

In total, data from ~~14~~ 17 field trials are presented in this section to demonstrate the minimum effective dose of GF-3308, for the control of PUCCST in winter wheat (TRZAW) and one ~~on~~ in spring wheat (TRZAS). GF-3308 was tested at 2,0, 1,5 and 1,0 L/ha. The trials were performed in accordance with the EPPO Standard PP 1/225 '*Minimum effective dose*'. The reference products include Proline 275 applied at 0,72 L/ha, Aviator Xpro applied at 1,25 L/ha, Librax applied at 2,0 L/ha and Vertisan applied at 1,0 L/ha. Proline 275 was applied in the majority of trials. Results for all standards have been combined in the following summary tables, however, individual results for each standard are presented in the individual trial tables and are compared orthogonally with GF-3308 in section 3.2.3.
The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Denmark (3) and Germany ~~(4)~~ (5) in the EPPO Maritime climatic zone, Poland ~~(5)~~ (6), Latvia (1) in the EPPO North-East climatic zone, as well as Hungary (2) and Romania (1) in the EPPO South-East climatic zone, between ~~2014 and 2020~~ 2015 and 2019.
On the basis of the EPPO Standard PP 1/241 '*Guidance on comparable climates'*, the trials included in the dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime, North-East and South-East EPPO climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from each of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations
The minimum effective dose (MED) efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-11.

Sites
Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where PUCCST is a prevalent disease. For trial site and application details see Appendix 3 and Appendix 4 in the BAD. Figure 3.2-4 provides an overview of the geographical distribution of the MED trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3308	EC	100 g/L fenpicoxamid	1,0, 1,5, 2,0	50, 75, 100
Proline 275	EC	275 g/L prothioconazole	0,72	198
Aviator Xpro 225EC	EC	75 g /L bixafen + 150 g /L prothioconazole	1,0-1,25	225-281
Librax	EC	62,5 g/L fluxapyroxad + 45 g/L metconazole	2,0	215
Vertisan 200 EC	EC	200 g /L penthiopyrad	1,0	200

Experimental details
The ~~12~~ 18 MED trials were conducted to GEP, by officially recognized testing organisations and followed the appropriate EPPO Standards. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 13,5 m² and 30 m². The treatments in all trials, were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles, delivering water volumes of 200-~~300~~ 250 L/ha.

GF-3308 was applied as a single application at BBCH ~~32~~ 31-56 of ~~winter~~ wheat. The treatments were typically sprayed when PUCCST had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials, see Appendix 3 and Appendix 4 in the BAD.
Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level, relative to the infection level present in the untreated control. Leaves showing less than 5% infection with PUCCST or leaves which were already senesced to a high degree in both treated and untreated plots were excluded from summarization. Assessments were generally conducted on Leaf 1, with only ~~one~~ three trial~~s~~ results on Leaf 2.

Results

Proposed dose of 2,0 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

~~Seven~~ Eight GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3308, for the control of PUCCST in wheat, following a single application, applied at BBCH ~~32~~ 31-43 of the crop. The MED trials were conducted in Denmark (3) and Germany ~~(4)~~ (5) in the EPPO Maritime climatic zone. Assessments across all trials were mainly on the highest leaf (Leaf 1), as this leaf had high levels of PUCCST infection (mean of ~~26.6%~~ 26,0% in the untreated across all trials - range 6,1-65,0%), so was considered to be a robust test of the product.
A single application of GF-3308 applied at 2,0 L/ha achieved mean control of ~~84.2%~~ 81,7% (range ~~71.7~~ 62,0-95,8%) for PUCCST, ~~35~~ 33-41 days after application. Applied in the same trials, at 1,5 L/ha (75% rate/0,75N), GF-3308 achieved a lower mean level of control of ~~71.9%~~ 69,2%, with more variable results (range 38,3-~~87.8%~~82,7%). ~~Four~~ Five trials also compared the proposed dose (2,0 L/ha), with a dose of 1,0 L/ha (50% rate/0,5N), which demonstrated ~~63.5%~~ 59,7% overall control (range ~~50.0~~44,3-73,6%) compared to ~~86.3%~~ 81,4% for the 2,0 L/ha dose.
Across all trials, control of PUCCST demonstrated by the proposed dose rate of 2,0 L/ha was comparable with the prothioconazole standard Proline (~~93.9%~~ 87,9% across ~~five~~ six trials), the bixafen + prothioconazole standard Aviator Xpro (~~95.1%~~ 94,9% in one trial) and the fluxapyroxad + metconazole standard Librax (71,7% in one trial).
The results are summarised in Table 3.2-39 and individual trial results are in the BAD and in the single trial reports.

~~**Table 3.2-39 Minimum effective dose testing of GF-3308 at the proposed label rate of 2.0 L/ha, at 75% and 50% dose rates against PUCCST in winter wheat (TRZAW). Results from 7 trials conducted in the EPPO Maritime climatic zone between 2016 - 2019. Assessment at 35-41 days after one application.**~~

~~EPPO Zone~~	~~Number of trials~~	~~Untreated control % infection PUCCST~~		~~% control of PUCCST~~							
				~~GF-3308 1,0 L/ha (50% rate)~~		~~GF-3308 1,5 L/ha (75% rate)~~		~~GF-3308 2,0 L/ha (100% rate)~~		~~Reference (Proline 275 at 0,72 L/ha) or other standards~~	
		~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~
~~Maritime*~~	~~7~~	~~26,6~~	~~6,1-65,0~~	-	-	~~**71,9**~~	~~38,3-87,8~~	~~**84,2**~~	~~71,7-95,8~~	~~**90,9^**~~	~~71,7-98,0~~
~~Maritime*~~	~~4~~	~~36,2~~	~~10,6-65,0~~	~~**63,5**~~	~~50,0-73,6~~	~~**74,9**~~	~~71,2-78,3~~	~~**86,3**~~	~~74,9-95,8~~	~~**92,9**~~	~~91,4-94,6~~

~~*Direct comparison of 2,0 L/ha and 1,5 L/ha doses.~~
~~**Direct comparison of 2,0 L/ha and 1,0 L/ha doses.~~
~~^Standard used in 5 trials was Proline, in one trial each Aviator Xpro at 1,25 L/ha and Librax at 2,0 L/ha were used.~~

Table 3.2-39 Minimum effective dose testing of GF-3308 at the proposed label rate of 2,0 L/ha, at 75% and 50% dose rates against PUCCST in winter wheat (TRZAW). Results from 8 trials conducted in the EPPO Maritime climatic zone between 2015 - 2019. Assessment at 30-41 days after one application.

EPPO Zone	Number of trials	Untreated control % infection PUCCST		% control of PUCCST							
				GF-3308 1,0 L/ha (50% rate)		GF-3308 1,5 L/ha (75% rate)		GF-3308 2,0 L/ha (100% rate)		Reference (Proline 275 at 0,72 L/ha) or other standards	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Maritime*	8	26,0	6,1-65,0	-	-	**69,2**	38,3-82,7	**81,7**	62,0-95,8	**86,7^**	57,5-98,0
Maritime**	5	33,4	10,6-65,0	**59,7**	44,3-73,6	**70,9**	54,8-78,3	**81,4**	62,0-95,8	**85,8**	57,5-94,6

*Direct comparison of 2,0 L/ha and 1,5 L/ha doses.
**Direct comparison of 2,0 L/ha and 1,0 L/ha doses.
^Standard used in 5 trials was Proline, in 1 trial was Aviator Xpro at 1,25 L/ha and in 1 trial was Librax at 2,0 L/ha.

Summary and conclusions on the minimum effective dose (MED) for control of PUCCST in winter wheat (EPPO Maritime climatic zone)

PUCCST is an important target disease for GF-3308 and the data reported demonstrate that it provides excellent control of PUCCST at the proposed dose rate of 2,0 L/ha. The proposed dose of 2,0 L/ha was the only dose to achieve mean control >80%. The proposed dose achieved levels of control higher than the 0,75N dose, in all trials. The 0,75N dose demonstrated below 80% in ~~6~~ 7 of the ~~7~~ 8 trials.
It is considered that the proposed dose rate of 2,0 L/ha is the minimum effective dose of GF-3308, required to deliver robust control of this disease, under a wide range of environmental conditions in the EPPO Maritime climatic zone.

Proposed maximum dose of 2,0 L/ha for Poland (EPPO North-East climatic zone)

~~Five~~ Seven GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3308, for the control of the PUCCST in winter wheat and spring wheat, following a single application applied at BBCH ~~39~~ 37-56 of the crop. The MED trials were conducted in Poland ~~(5)~~ (6) and Latvia (1) in the EPPO North-East climatic zone. Assessments across all trials were on Leaf 1 or Leaf 2 (mean of ~~10.4%~~ 25,4% in the untreated - range 5,7-~~23.3~~83,1% for TRZAW and 8,7% for TRZAS), so was considered to be a robust test of the product.
For winter wheat, a single application of GF-3308 applied at 2,0 L/ha achieved mean control of ~~81.8%~~ 71,1% (range ~~67.5-100%~~ 44,4-85,7%) for PUCCST, ~~28-41~~31-42 days after application compared to ~~79.6%~~ 68,5% for the 1,5 L/ha dose (75% rate/0,75N). ~~Three~~ Five trials also compared the proposed dose (2,0 L/ha), with a dose of 1,0 L/ha (50% rate/0,5N), which demonstrated ~~67.4%~~60,1% overall control (range ~~49.1-100%~~ 40,6-81,2%) compared to ~~82.9%~~ 69,6% for the 2,0 L/ha dose.
Across all trials, ~~81.8%~~ 71,1% control of PUCCST demonstrated by the proposed maximum dose rate of 2,0 L/ha was ~~comparable to~~ lower than the standards; ~~87.8%~~ 81,3% for prothioconazole (Proline) across ~~three~~ five trials and 78,5% for penthiopyrad (Vertisan) in one trial, with the 1,5 L/ha dose of GF-3308 delivering ~~an acceptable~~ ~~79.6%~~ 68,5% moderate level of control.
In addition to these trials, data from neighbouring countries in the EPPO Maritime climatic zone are available and can also be considered supportive of the proposed dose. These ~~four~~ five trials were conducted in Germany and demonstrate a comparable dose response to the EPPO North-East data with the 2,0 L/ha achieving the highest level of control of ~~82.6%~~ 78,9% compared to ~~70.6%~~ 66,4% for the 1,5 L/ha dose. Combined with the ~~four~~ six EPPO North-East trials, these give overall control of PUCCST across ~~8~~ 11 trials of ~~82.2%~~ 74,6% for the proposed dose and ~~75.1%~~ 67,5% for the 1,5 L/ha dose. Details for the German trials are in the EPPO Maritime climatic zone section, above.

The results are summarised in Table 3.2-40 and individual trial results are detailed in the BAD and in the single trial reports.

~~**Table 3.2-40 Minimum effective dose testing of GF-3308 at the proposed maximum label rate of 2.0 L/ha, at 75% and 50% dose rates against PUCCST in winter wheat (TRZAW). Results from 5 trials conducted in the EPPO North-East climatic zone in 2016 plus 5 DE trials conducted between 2016-2019. Assessment at 28-41 days after one application.**~~

~~EPPO Zone~~	~~Number of trials~~	~~Untreated control % infection PUCCST~~		~~% control of PUCCST~~							
				~~GF-3308 1.0 L/ha (50% rate)~~		~~GF-3308 1.5 L/ha (75 % rate)~~		~~GF-3308 2.0 L/ha (100 % rate)~~		~~Reference (Proline 275 at 0.72 L/ha) or other standards~~	
		~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~
~~North-East*~~	~~4~~	~~10.4~~	~~5.7-23.3~~	-	-	~~**79.6**~~	~~59.2-100~~	~~**81.8**~~	~~67.5-100~~	~~**85.5^**~~	~~69.6-100~~
~~North-East**~~	~~3~~	~~6.1~~	~~5.7-6.4~~	~~**67.4**~~	~~49.1-100~~	~~**80.7**~~	~~59.2-100~~	~~**82.9**~~	~~67.5-100~~	~~**87.8**~~	~~69.6-100~~
~~DE*~~	~~4~~	~~12.9~~	~~6.1-40.0~~	~~**73.6#**~~	-	~~**70.6**~~	~~38.3-87.8~~	~~**82.6**~~	~~71.7-89.7~~	~~**89.1**~~	~~71.7-98.0~~
~~North-East + DE*~~	~~8~~	~~11.7~~	~~5.7-23.3~~	~~**69.0##**~~	~~49.1-100~~	~~**75.1**~~	~~38.3-100~~	~~**82.2**~~	~~67.5-100~~	~~**87.3**~~	~~69.6-100~~
~~North-East + DE***~~	~~7~~	~~11.2~~	~~5.7-23.3~~			~~**80.4**~~	~~59.2-100~~	~~**83.7**~~	~~67.5-100~~	~~**89.5**~~	~~69.6-100~~

~~*Direct comparison of 2.0 L/ha and 1.5 L/ha doses.~~
~~**Direct comparison of 2.0 L/ha and 1.0 L/ha doses.~~
~~^Standard used in 3 trials was Proline and in one trial Vertisan at 1.0 L/ha was used.~~
~~#Result from one trial only. ##Results from four trials only. ***EA19F9B017F-DPE01 removed~~

Table 3.2-40 Minimum effective dose testing of GF-3308 at the proposed maximum label rate of 2,0 L/ha, at 75% and 50% dose rates against PUCCST in winter wheat (TRZAW). Results from 6 trials conducted in the EPPO North-East climatic zone in 2016 plus 5 DE trials conducted between 2015-2019. Assessment at 30-42 days after one application.

EPPO Zone	Number of trials	Untreated control % infection PUCCST		% control of PUCCST							
				GF-3308 1,0 L/ha (50% rate)		GF-3308 1,5 L/ha (75 % rate)		GF-3308 2,0 L/ha (100 % rate)		Reference (Proline 275 at 0,72 L/ha) or other standards	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East*	6	25,4	5,7-83,1	-	-	**68,5**	45,9-86,8	**71,1**	44,4-85,7	**80,9^**	69,2-100
North-East**	5	25,8	5,7-83,1	**60,1**	40,6-81,2	**66,9**	45,9-86,8	**69,6**	44,4-85,7	**81,3**	69,2-100
DE*	5	14,8	6,1-22,1	**59,0#**	44,3-73,6	**66,4**	38,3-82,7	**78,9**	62,0-91,8	**82,7**	57,5-98,0
North-East + DE*	11	20,6	5,7-83,1	**-**	-	**67,5**	38,3-86,8	**74,6**	44,4-91,8	**81,7**	57,5-100
North-East + DE***	9	14,2	5,7-26,6	**-**	-	**73,2**	59,2-86,8	**75,6**	44,4-91,8	**84,2**	57,5-100
North-East + DE**	7	23,1	5,7-83,1	**59,8**	40,6-81,2	**66,8**	45,9-86,8	**70,8**	44,4-85,8	**79,4**	57,5-100

*Direct comparison of 2,0 L/ha and 1,5 L/ha doses.
**Direct comparison of 2,0 L/ha and 1,0 L/ha doses.
^Standard used in 5 trials was Proline and in 1 trial Vertisan at 1,0 L/ha was used.
#Results from 2 trials, ***EA19F9B017F-DPE01 and LV16E7B031KF01C removed

In addition to data on winter wheat, one trial was conducted on spring wheat (TRZAS). This trial demonstrated ~~a similar~~ visible dose response ~~to the winter wheat data~~, with the proposed 2,0 L/ha dose

achieving the highest level of control (96,9%) which was comparable to the 1,5 L/ha dose that achieved 94,3% and 90,1% for the 1,0 L/ha dose.
The results are summarised in Tabl and the results of the individual trials are detailed in the BAD and in the single trial report.

Table 3.2-41 Minimum effective dose testing of GF-3308 at the proposed label rate of 2,0 L/ha, at 75% and 50% dose rates against PUCCST in spring wheat (TRZAS). Results from one trial conducted in the EPPO North-East climatic zone in 2016. Assessment at 32 days after one application.

EPPO Zone	Number of trials	Untreated control % infection PUCCST		% control of PUCCST							
				GF-3308 1,0 L/ha (50% rate)		GF-3308 1,5 L/ha (75 % rate)		GF-3308 2,0 L/ha (100 % rate)		Proline 0,72 L/ha	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East	1	8,7	-	**90,1**	-	**94,3**	-	**96,9**	-	**95,8**	-

Summary and conclusions on the minimum effective dose (MED) for control of PUCCST in winter wheat (EPPO North-East climatic zone)

PUCCST is an important target disease for GF-3308 and the data reported from MED trials demonstrate that it provides ~~excellent~~ moderate control of PUCCST on winter wheat at the proposed maximum dose rate of 2,0 L/ha. The 2,0 L/ha of GF-3308 achieved ~~the highest~~ higher level of overall control as compared to lower dose rate of 1,5 L/ha. ~~and was the only dose to demonstrate overall control >80% (81.8% in four PL trials and 82.6% in four DE trials)~~ In one trial on spring wheat a ~~similar~~ visible dose response was also demonstrated. However, the 1,5 L/ha dose delivered ~~79.6%~~ 68,5% control in the ~~four~~ six Polish trials and ~~70.6 %~~ 66,4% in the ~~four~~ five German trials. In one German trial (EA19F9B017F-DPE01) the 1,5 L/ha dose only achieved 38,3% control compared to 71,7% from the 2,0 L/ha dose and ~~71.1%~~ 71,7% from the reference Librax . In other Latvian trial under high disease pressure (83,1% of infection in the untreated) the 1,5 L/ha dose only achieved 45,9% control compared to 69,2% from the 2,0 L/ha dose and the same result 69,2% from the reference Proline. These trials ~~which~~ show~~s~~ the benefits of the higher dose in exteme rusts conditions. If ~~this~~ these trials ~~is~~ are removed from the summary across trials, the mean control from the three Germany trials would increase to ~~81.4%~~ 73,5% for 1,5 L/ha GF-3308 compared to ~~86.2%~~ 80,7% for the 2,0 L/ha dose, the mean control from the five Polish trials would increase to 73,0% for 1,5 L/ha GF-3308 compared to 72,0% for the 2,0 L/ha dose and the overall control from ~~7~~ 9 trials would be raised to ~~80.4%~~ 73,2% for the 1,5 L/ha dose and ~~83.7%~~ 75,6% from the 2,0 L/ha dose from ~~7~~ 9 trials. ~~This data would support a dose range in wheat of 1,5-2,0 L/ha. with the lower dose being acceptable where SEPTTR is the main target and rust pressure is lower.~~
It is considered that the proposed maximum dose rate of 2,0 L/ha is the most effective dose of GF-3308 to deliver robust control of this PUCCST on winter and spring wheat under a wide range of environmental conditions in Poland (EPPO North-East climatic zone)~~, although the 1,5 L/ha dose rate also offers good, moderate control. and would be appropriate in lower disease pressure situations.~~
A dose ~~range of 1,5~~ 2,0 L/ha will be proposed for ~~diseases~~ the control of PUCCST in ~~of~~ wheat. ~~to offer growers flexibility so they can adjust dose according to the conditions.~~ Data in the efficacy section 3.2.3.3 will present the 2,0 L/ha dose that will be ~~advised in high risk situations~~ recommended for PUCCST and ~~also the~~ results for 1,5 L/ha dose will be also presented, that can be used in the severe disease situations where SEPTTR is the main target disease.

Proposed dose range of 1,5-2,0 L/ha for EPPO South-East climatic zone countries of the Central EU Authorisation zone

Three GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3308, for the control of the PUCCST in winter wheat, following a single application

applied at BBCH 39-41 of the crop. The MED trials were conducted in Hungary (2) and Romania (1) in the EPPO South-East climatic zone. Assessments across ~~all~~ two trials were on Leaf 1 and in one trial the assessment was on leaf 2 (mean of 23,4% in the untreated - range 16,4-28,8%), so is considered to be a robust test of the product.
All three trials compared the maximum dose rate of 2,0 L/ha with a dose of 1,5 L/ha. No trials on this disease included results using a dose lower than the proposed dose range (1,0 L/ha or 1,2 L/ha). GF-3308 at 2,0 L/ha achieved mean control of 96,0% (range ~~83,3~~88,8-100%), 28-44 days after application. Applied in the same trials, the 1,5 L/ha dose of GF-3308 achieved mean control of ~~95,6%~~ 95,1% (range 86,1-100%).
Across all trials, control of PUCCST demonstrated by the proposed dose rate range of 1,5-2,0 L/ha was comparable to the standards (100% for prothioconazole/Proline in two trials and 85,7% for penthiopyrad/Vertisan in one trial).
The results are summarised in Table 3.2-42 and individual trial results are detailed in in the BAD and in the single trial reports.

Table 3.2-42 Minimum effective dose testing of GF-3308 at the proposed label rates of 1,5 and 2,0 L/ha against PUCCST in winter wheat (TRZAW). Results from 3 trials conducted in the EPPO South-East climatic zone in 2016. Assessment at 28-44 days after one application.

EPPO Zone	Number of trials	Untreated control % infection PUCCST		% control of PUCCST					
				GF-3308 1,5 L/ha		GF-3308 2,0 L/ha		Reference (Proline 275 at 0,72 L/ha) or other standards	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
South-East*	3	23,4	16,4-28,8	**95,1**	86,1-100	**96,0**	88,8-100	**95,2^**	85,7-100

^Standard used in ~~two~~ 2 trials was Proline and Vertisan at 1,0 L/ha in ~~one~~ 1 trial.

Summary and conclusions on the minimum effective dose (MED) range of 1,5-2,0 L/ha for control of PUCCST in winter wheat (EPPO South-East climatic zone)

PUCCST is an important target disease for GF-3308 and the data reported demonstrate that it provides excellent control of PUCCST at the proposed maximum dose rate of 2,0 L/ha. The maximum dose of 2,0 L/ha will give excellent control in all situations. Where disease pressure is lower, a dose of 1,5 L/ha will still provide sufficient control of PUCCST.
It is considered that the proposed dose rate range of 1,5-2,0 L/ha is the minimum effective dose to deliver effective control of this disease across a wide range of environmental conditions, in the EPPO South-East climatic zone (dependent on disease pressure).

3.2.2.4 MED of GF-3308 for the control of PUCCRE in winter rye

This section addresses the minimum effective dose (MED) of GF-3308, for the control of PUCCRE on winter rye, when applied at the proposed label rate of 2,0 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone and in Poland (EPPO North-East climatic zone).

Table 3.2-43 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: ~~25~~ 20-30 m² EPPO North-East: 20-30 m²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: ~~3~~ 4 SECCW EPPO North-East: 3 SECCW
	Varieties per crop (number of trials)	EPPO Maritime: Minello, Palazzo ~~(2)~~ (3) EPPO North-East: Bono, Dankowskie Diament, Kier
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 39-59 EPPO North-East: BBCH 37-52
	Timing Pest stage at application	GF-3308 has both protectant and curative properties. For the control of PUCCRE applications were timed to cover these situations from commencing when there was a risk of infection with PUCCRE or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	1
	Spray volumes	200-230 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were approximately 2-3 weeks after application, 5-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where PUCCRE is a prevalent disease.

Introduction

In total, data from ~~six~~ seven field trials are presented in this section to demonstrate the minimum effective dose of GF-3308, for the control of PUCCRE in winter rye (SECCW). GF-3308 was tested at 2,0, 1,5, 1,6, 1,3, 1,2 and 1,0 L/ha. The trials were performed in accordance with the EPPO Standard PP 1/225 '*Minimum effective dose*'. The reference products include Proline 275 applied at 0,72 L/ha and Aviator Xpro applied at 1,25 L/ha. Proline 275 was applied in the majority of trials. Results for all standards have been combined in the following summary tables. However, individual results for each standard are presented in the individual trial tables and are compared orthogonally with GF-3308, in section 3.2.3.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out registration efficacy field trials, in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in the Germany ~~(3)~~ (4) in the EPPO Maritime climatic zone and Poland (3) in the EPPO North-East climatic zone in 2016 and 2017.

On the basis of EPPO Standard PP 1/241 '*Guidance on comparable climates'*, the trials included in the dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime and North-East climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from both of these zones, which are representative of the proposed GAP.

Materials and Methods

<u>Testing facilities or organisations</u>
The minimum effective dose (MED) efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-12.

<u>Sites</u>
Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where PUCCRE is a prevalent disease. For trial site and application details, see Appendix 3 and Appendix 4 in the BAD.

Figure 3.2-5 provides an overview of the geographical distribution of the MED trials across the EU countries involved.

<u>Formulations applied and rates</u>

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3308	EC	100 g/L fenpicoxamid	1,0, 1,2, 1,3, 1,5, 1,6, 2,0	50, 60, 65, 75, 80, 100
Proline 275	EC	275 g/L prothioconazole	0,72	198
Aviator Xpro 225EC	EC	75 g /L bixafen + 150 g /L prothioconazole	1,25	281

<u>Experimental details</u>
The ~~six~~ seven MED trials were conducted by officially recognized testing organisations to GEP and followed the appropriate EPPO Standards. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between ~~25~~ 20 m² and 30 m². In all trials, the treatments were applied using self-propelled, bicycle or knapsack precision small plot sprayers, equipped with conventional or low drift flat fan nozzles, delivering water volumes of 200-230 L/ha.
GF-3308 was applied as a single application at BBCH 37-59 of winter rye. The treatments were typically sprayed when PUCCRE had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials, see Appendix 3 and Appendix 4 in the BAD.
Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level, relative to the infection level present in the untreated control. Leaves showing less than 5% infection with PUCCRE or leaves which were already senesced to a high degree in both treated and untreated plots were excluded from summarization. Assessments were all conducted on Leaf 1.

<u>Results</u>

Proposed dose of 2,0 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

~~Three~~ Four GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3308, for the control of PUCCRE in winter rye, following a single application, applied at BBCH 39-59 of the crop. The MED trials were conducted in Germany ~~(3)~~ (4) in the EPPO Maritime climatic zone. For all ~~three~~ four trials, assessments were conducted on the highest leaf (Leaf 1), as this leaf had high levels of PUCCRE infection (mean of ~~30.1%~~ 24,3% in the untreated - range ~~7.0~~ 6,8-74,0%), so was considered to be a robust test of the product.
A single application of GF-3308 applied at 2,0 L/ha achieved mean control of ~~84.9%~~ 83,6% (range ~~81.0~~ 79,6-87,8%) for PUCCRE, 34-56 days after application. Applied in the same trials, the 1,5 L/ha (75%

rate/0,75N) dose of GF-3308 achieved a lower mean level of control of ~~79.9%~~ 77,5%, ~~with more variable results~~ (range ~~31.1-98.9%~~ 70,4-85,7%). A dose of 1,0 or 1,3 L/ha (50 or 65% rate/0,5 or 0,65N) GF-3308 was included in ~~one trial~~ two trials, and demonstrated ~~69.9%~~ 68,9% and 63% control compared to 87,8% and 79,6% for the proposed (2,0 L/ha) dose. Across all trials, control of PUCCRE demonstrated by the proposed dose rate of 2,0 L/ha was comparable with the prothioconazole standard Proline (86,5% in one trial) and Aviator Xpro standard (~~90.2%~~ 92,2% across ~~2~~ 3 trials).
In addition to these trials, data from neighbouring Poland, in the EPPO North-East climatic zone, are available and can also be considered supportive of the proposed dose. The three trials conducted in Poland demonstrate a comparable dose response to the EPPO Maritime data with the 2,0 L/ha achieving the highest level of control of 84,0% compared to 80,7% for the 1,5 L/ha dose and ~~72.0%~~ 72,1% for the ~~1,0~~ 1,2 L/ha. Combined with the ~~three~~ four EPPO Maritime trials, these provide overall control of PUCCRE, across ~~6~~ 7 trials, of ~~84.5%~~ 83,8% for the proposed (2,0 L/ha) dose and ~~80.3%~~ 78,9% for the 1,5 L/ha (0,75N) dose. Details of these EPPO North-East climatic zone (Polish) trials are shown in the section below.
The results are summarised in Table 3.2-44 and individual trial results are detailed in the BAD and in the single trial reports.

~~**Table 3.2-44 Minimum effective dose testing of GF-3308 at the proposed label rate of 2.0 L/ha, at 75% and 50% dose rates against PUCCRE in winter rye (SECCW). Results from 3 trials conducted in the EPPO Maritime climatic zone and 3 trials conducted in PL in 2016 and 2017. Assessment at 34-56 days after one application.**~~

EPPO Zone	Number of trials	Untreated control % infection PUCCRE		% control of PUCCRE							
				GF-3308 1,0 L/ha (50% rate)		GF-3308 1,5 L/ha (75 % rate)		GF-3308 2,0 L/ha (100 % rate)		Reference (Proline 275 at 0,72 L/ha) or other standards	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Maritime*	3	30,1	7,0-74,0	-	-	**79,9**	74,3-85,7	**84,9**	81,1-87,8	**88,9#**	85,7-94,6
Maritime**	1	9,3	-	**69,9**	-	**79,7**	-	**87,8**	-	**86,5**	-
PL**	3	28,8	18,1-36,9	**72,0**	61,8-83,9	**80,7**	76,1-86,4	**84,0**	81,4-87,8	**76,0**	68,9-94,6
Maritime + PL*	6	29,4	7,0-74,0	-	-	**80,3**	74,3-86,4	**84,5**	81,1-87,8	**82,5#**	68,9-86,5
Maritime + PL**	4	23,9	9,3-36,9	**71,3**	61,8-83,9	**80,5**	76,1-86,4	**85,0**	81,4-87,8	**78,7**	68,9-86,5

~~*Direct comparison of 2.0 L/ha and 1.5 L/ha doses. **Direct comparison of 2.0 L/ha, 1.5 L/ha and 1.0 L/ha doses.~~
~~#Standard used in two trials was Aviator Xpro at 1.25 L/ha.~~

Table 3.2-44 Minimum effective dose testing of GF-3308 at the proposed label rate of 2,0 L/ha, at 75-80% and 50-65% dose rates against PUCCRE in winter rye (SECCW). Results from 4 trials conducted in the EPPO Maritime climatic zone and 3 trials conducted in PL in 2016 and 2017. Assessment at 34-56 days after one application.

EPPO Zone	Number of trials	Untreated control % infection PUCCRE		% control of PUCCRE: GF-3308 1,0-1,3 L/ha (50-65% rate)***		GF-3308 1,5-1,6 L/ha (75-80% rate)****		GF-3308 2,0 L/ha (100 % rate)		Reference (Proline 275 at 0,72 L/ha) or other standards	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Maritime*	4	24,3	6,8-74,0	-	-	**77,5**	70,4-85,7	**83,6**	79,6-87,8	**90,8#**	85,7-96,3
Maritime**	2	8,1	6,8-9,3	**66,0**	63-69,9	**75,1**	70,4-79,7	**83,7**	79,6-87,8	**91,4#**	86,5-96,3
PL**	3	28,8	18,1-36,9	**72,1**	61,8-84,0	**80,7**	76,1-86,4	**84,0**	81,4-87,8	**76,0**	68,9-86,3
Maritime + PL*	7	26,2	6,8-74,0	-	-	**78,9**	70,4-86,4	**83,8**	79,6-87,8	**84,5#**	68,9-96,3
Maritime + PL**	5	20,5	6,8-36,9	**69,6**	61,8-84,0	**78,5**	70,4-86,4	**83,9**	79,6-87,8	**82,2#**	68,9-96,3

*Direct comparison of 2,0 L/ha and 1,5 L/ha doses.
**Direct comparison of 2,0 L/ha, 1,5 L/ha and 1,0-1,3 L/ha doses.
***Dose rate 1,3 L/ha tested in 1 German trial, dose rate 1,2 L/ha tested in 3 Polish trials. Dose rate 1,0 L/ha tested in 1 German trial.
****Dose rate 1,6 L/ha tested in 1 German trial, dose rate 1,5 l/ha tested in 3 Polich and 3 German trials.
#Standard used in 3 trials was Aviator Xpro at 1,25 L/ha.

Summary and conclusions on the minimum effective dose (MED) for control of PUCCRE in winter rye (EPPO Maritime climatic zone)

PUCCRE is an important target disease for GF-3308 on winter rye and the data reported demonstrate that it provides excellent control of PUCCRE at the proposed dose rate of 2,0 L/ha. The proposed dose of GF-3308 achieved the highest level of overall control and was the ~~only~~ dose to consistently demonstrate control >80% across ~~all~~ 3 of 4 trials (overall control of ~~84,9 %~~ 83,6% in the EPPO Maritime climate zone trials and 84,0% in the three PL trials). In ~~5~~ 6 of the ~~6~~ 7 trials, the proposed (2,0 L/ha) dose achieved levels of control higher than the 0,75N dose (in the remaining trial, results were identical).
It is considered that the proposed dose rate of 2,0 L/ha is the most effective dose of GF-3308, required to deliver robust control of this disease, under a wide range of environmental conditions, in the EPPO Maritime climatic zone.

Proposed maximum dose of 2,0 L/ha for Poland (EPPO North-East climatic zone)

Three GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3308, for the control of the PUCCRE in winter rye, following a single application applied at BBCH 37-52 of the crop. The MED trials were conducted in Poland (3) in the EPPO North-East climatic zone. Assessments for all three trials were on Leaf 1 (mean of 28,8% in the untreated - range 18,1-36,9%), so is considered to be a robust test of the product.
A single application of GF-3308 applied at 2,0 L/ha achieved mean control of 84,0% (range 81,4-87,8%) against PUCCRE, 41-49 days after application. Applied in the same trials at 1,5 L/ha (75% rate/0,75N), GF-3308 achieved a good mean level of control of 80,7% (range 76,1-86,4%) and lowest control of ~~72,0%~~ 72,1% (range 61,8-~~83,9%~~84,0%) for a dose of ~~1,0~~ 1,2 L/ha (~~50%~~ 60% rate/~~0,5~~ 0,6N). Across all three trials, control of PUCCRE demonstrated by the proposed maximum dose rate of 2,0 L/ha and the lower dose range of 1,5 L/ha was higher than the prothioconazole/Proline standard, at 76,0% overall control.

In addition to these trials, data from neighbouring countries in the EPPO Maritime climatic zone are available and can also be considered supportive of the proposed dose. These ~~three~~ four trials were conducted in Germany and demonstrate a comparable dose response to the EPPO North-East climatic zone data, with the 2,0 L/ha achieving the highest level of control at ~~84.9%~~ 83,6%, compared to ~~79.9%~~ 77,5% for the 1,5 L/ha dose. Combined with the three EPPO North-East climatic zone trials, these give overall control of PUCCRE across the ~~six~~ seven trials of ~~84.5%~~ 83,8% for the proposed dose, and ~~80.3%~~ 78,9% for the 1,5 L/ha dose. Details for these German trials are included in the EPPO Maritime climatic zone section, above.
The results are summarised in Table 3.2-45 individual trial results are detailed in the BAD and in the single trial reports.

~~**Table 3.2-45 Minimum effective dose testing of GF-3308 at the proposed maximum label rate of 2.0 L/ha, at 75% and 50% dose rates against PUCCRE in winter rye (SECCW). Results from 3 trials conducted in the EPPO North-East climatic zone and 3 trials conducted in DE in 2016 and 2017. Assessment at 34-56 days after one application.**~~

~~EPPO Zone~~	~~Number of trials~~	~~Untreated control % infection PUCCRE~~		~~% control of PUCCRE~~							
				~~GF-3308 1,0 L/ha (50% rate)~~		~~GF-3308 1,5 L/ha (75 % rate)~~		~~GF-3308 2,0 L/ha (100 % rate)~~		~~Reference (Proline 275 at 0,72 L/ha) or other standards~~	
		~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~
~~North-East**~~	~~3~~	~~28,8~~	~~18,1-36,9~~	~~**72,0**~~	~~61,8-83,9~~	~~**80,7**~~	~~76,1-86,4~~	~~**84,0**~~	~~81,4-87,8~~	~~**76,0**~~	~~68,9-94,6~~
~~DE*~~	~~3~~	~~30,1~~	~~7,0-74,0~~	~~**68,9‡**~~	-	~~**79,9**~~	~~74,3-85,7~~	~~**84,9**~~	~~81,1-87,8~~	~~**88,9#**~~	~~85,7-94,6~~
~~North-East + DE*~~	~~6~~	~~29,4~~	~~7,0-74,0~~	-	-	~~**80,3**~~	~~74,3-86,4~~	~~**84,5**~~	~~81,1-87,8~~	~~**82,5#**~~	~~68,9-86,5~~
~~North-East + DE**~~	~~4~~	~~23,9~~	~~9,3-36,9~~	~~**71,3**~~	~~61,8-83,9~~	~~**80,5**~~	~~76,1-86,4~~	~~**85,0**~~	~~81,4-87,8~~	~~**78,7**~~	~~68,9-86,5~~

~~*Direct comparison of 2,0 L/ha and 1,5 L/ha doses. **Direct comparison of 2,0 L/ha and 1,0 L/ha doses.~~
~~#Standard used in two trials was Aviator Xpro at 1,25 L/ha, ‡Result from one trial only~~

Table 3.2-45 Minimum effective dose testing of GF-3308 at the proposed maximum label rate of 2,0 L/ha, at 75-80% and 50-65% dose rates against PUCCRE in winter rye (SECCW). Results from 3 trials conducted in the EPPO North-East climatic zone and 4 trials conducted in DE in 2016 and 2017. Assessment at 34-56 days after one application.

EPPO Zone	**Number of trials**	**Untreated control % infection PUCCRE**		**% control of PUCCRE**							
				GF-3308 1,0-1,3 L/ha (50-65% rate)* **		**GF-3308 1,5-1,6 L/ha (75-80 % rate)********		**GF-3308 2,0 L/ha (100 % rate)**		**Reference (Proline 275 at 0,72 L/ha) or other standards**	
		Mean	**min-max**	**Mean**	**min-max**	**Mean**	**min-max**	**Mean**	**min-max**	**Mean**	**min-max**
North-East**	3	28,8	18,1-36,9	**72,1**	61,8-84,0	**80,7**	76,1-86,4	**84,0**	81,4-87,8	**76,0**	68,9-86,3
DE*	4	24,3	6,8-74,0	**66,0‡**	63-69,9	**77,5**	70,4-85,7	**83,6**	79,6-87,8	**90,8#**	85,7-96,3
North-East + DE*	7	26,2	6,8-74,0	-	-	**78,9**	70,4-86,4	**83,8**	79,6-87,8	**84,5#**	68,9-96,3
North-East + DE**	5	20,5	6,8-36,9	**69,6**	61,8-84,0	**78,5**	70,4-86,4	**83,9**	79,6-87,8	**82,2#**	68,9-96,3

*Direct comparison of 2,0 L/ha and 1,5 L/ha doses.
**Direct comparison of 2,0 L/ha and 1,0 L/ha doses.
***Dose rate 1,3 L/ha tested in 1 German trial, dose rate 1,2 L/ha was tested in 3 Polish trials and dose rate 1,0 L/ha was tested in 1 German trial.
****Dose rate 1,6 L/ha tested in 1 German trial, dose rate 1,5 l/ha tested in 3 Polish and 3 German trials.

#Standard used in 3 trials was Aviator Xpro at 1,25 L/ha.
‡Result from 2 trials.

Summary and conclusions on the minimum effective dose (MED) for control of PUCCRE in winter rye (EPPO North-East climatic zone)

PUCCRE is an important target disease for GF-3308 on winter rye and the data reported demonstrate that it provides excellent control of PUCCRE at the proposed maximum dose rate of 2,0 L/ha. The proposed dose of GF-3308 achieved the highest overall level of control and was the only dose to consistently demonstrate control >80% across all 6 of 7 trials (overall control of 84,0% in three EEPO North-East climatic zone trials and 84.9 % 83,6% in the three four German trials). In 5 6 of the 6 7 trials, the proposed 2,0 L/ha dose achieved slightly higher levels of control than the 1,5 L/ha dose (in the remaining trial, results were identical). However, as The 1,5 L/ha dose achieved 80.3% moderate efficacy - 78,9% control from 6 7 trials. and this supports a dose range of 1,5-2,0 L/ha in rye. Where RHYNSE is the main target and when rust pressure is lower, then the 1,5 L/ha dose would be acceptable, though 2,0 L/ha is the most effective dose when rust pressure is higher or for PUCCRE control and when a longer period of protection is required.
It is considered that the proposed maximum dose rate of 2,0 L/ha is the most effective dose of GF-3308 to provide robust control of this disease under a wide range of environmental conditions in Poland (EPPO North-East climatic zone)., though The 1,5 L/ha dose achieved good moderate levels of control. After evaluation a dose range rate of 1,5 2,0 L/ha will be proposed for diseases of rye to offer growers flexibility so they can adjust dose according to the conditions. the control of PUCCRE in rye, Data in the efficacy section 3.2.3.4 will present the 2,0 L/ha dose that will be advised in high risk situations recommended for the control of PUCCRE and also results for the 1,5 L/ha dose that can be used in the less severe disease situations. will be presented.

3.2.2.5 MED of GF-3308 for the control of RHYNSE in winter rye

This section addresses the minimum effective dose (MED) of GF-3308, for the control of RHYNSE on winter rye, when applied at the proposed label rate of 2,0 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone and 1,5-2,0 L/ha in Poland (EPPO North-East climatic zone).

Table 3.2-46 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 21,3-30 m² EPPO North-East: 19,6-30 m²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: 5 SECCW EPPO North-East: 5 SECCW
	Varieties per crop (number of trials)	EPPO Maritime: Minello, Palazzo (3), SU Performer EPPO North-East: Bono, Dankowskie Diament (2), Kier, Palazzo
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 39-59 EPPO North-East: BBCH 37-59 52
	Timing Pest stage at application	GF-3308 has both protectant and curative properties. For the control of RHYNSE applications were timed to cover these situations from commencing when there was a risk of infection with RHYNSE or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	1
	Spray volumes	200-230 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury

		(phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were approximately 2-3 weeks after application, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where RHYNSE is a prevalent disease.

Introduction

In total, data from 10 field trials are presented in this section to demonstrate the minimum effective dose of GF-3308, for the control of RHYNSE in winter rye (SECCW). GF-3308 was tested at 2,0, 1,6, 1,5, ~~and~~ 1,0, 1,2 and 1,3 L/ha. The trials were performed in accordance with the EPPO Standard PP 1/225 '*Minimum effective dose*'. The reference products include Proline 275 applied at 0,72 L/ha and Aviator Xpro applied at 1,25 L/ha. Proline 275 was applied in the majority of trials. Results for all standards have been combined in the following summary tables. However, individual results for each standard are presented in the individual trial tables and are compared orthogonally with GF-3308 in section 3.2.3.
The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in the Germany (5) in the EPPO Maritime climatic zone and Poland (5) in the EPPO North-East climatic zone, in 2016 and 2017.
On the basis of the EPPO Standard PP 1/241 '*Guidance on comparable climates'*, the trials included in this dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime and North-East climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from both of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations
The minimum effective dose (MED) efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-13.

Sites
Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where RHYNSE is a prevalent disease. For trial site and application details see Appendix 3 and Appendix 4 in the BAD. Figure 3.2 - 6 provides an overview of the geographical distribution of the MED trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3308	EC	100 g/L fenpicoxamid	1,0, 1,2, 1,3, 1,5, 1,6, 2,0	50, 60, 65, 75, 80, 100
Proline 275	EC	275 g/L prothioconazole	0,72	198
Aviator Xpro 225EC	EC	75 g /L bixafen + 150 g /L prothioconazole	1,25	281

Experimental details

The 10 MED trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organisations. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 19,6 m² and 30 m². The treatments in all trials, were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles, delivering water volumes of 200-230 L/ha.
GF-3308 was applied as a single application at BBCH 37-59 of winter rye. The treatments were typically sprayed when RHYNSE had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials see Appendix 3 and Appendix 4 in the BAD.
Assessments for efficacy (% infection) were conducted approximately, 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with RHYNSE or leaves which were already senesced to a high degree in both the treated and untreated plots, were excluded from summarization. Assessments were conducted on Leaf 1 or Leaf 2.

Results

Proposed dose of 2,0 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Five GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3308, for the control of RHYNSE in winter rye, following a single application, applied at BBCH 39-59 of the crop. The MED trials were conducted in Germany (5) in the EPPO Maritime climatic zone. Assessments across all trials were on the highest leaf (Leaf 1 or Leaf 2), as this leaf had high levels of RHYNSE infection (mean of 18,8% in the untreated - range 12,0-25,5%), so was considered to be a robust test of the product.
A single application of GF-3308 applied at 2,0 L/ha achieved mean control of 87,2% (range 77,8-94,1%) for RHYNSE, 30-56 days after application. Applied in the same trials, at 1,5 L/ha or 1,6 L/ha (75-80% rate/0,75-0,8N), GF-3308 achieved a lower mean level of control of ~~83.0%~~ 83,5%, with more variable results (range 75,0-90,0%). A dose of 1,0-1,3 L/ha (50-65% rate/0,5-0,65N) was included in three trials and demonstrated overall mean control of ~~54.5%~~ 54,0% compared to 84,4% for the proposed dose.
Across all trials, control of RHYNSE demonstrated by the proposed dose rate of 2,0 L/ha was comparable with the prothioconazole standard Proline (82,7% across two trials) and Aviator Xpro standard (97,6% across three trials).
The results are summarised in Table and individual trial results are detailed in the BAD and in the single trial reports.

Table 3.2-47 Minimum effective dose testing of GF-3308 at the proposed label rate of 2,0 L/ha, at 75-80% and 50-65% dose rates against RHYNSE in winter rye (SECCW). Results from 5 trials conducted in the EPPO Maritime climatic zone in 2016 and 2017. Assessment at 30-56 days after one application.

EPPO Zone	Number of trials	Untreated control % infection RHYNSE		% control of RHYNSE: GF-3308 1,0-1,3 L/ha (50-65% rate)***		GF-3308 1,5-1,6 L/ha (75-80% rate)****		GF-3308 2,0 L/ha (100 % rate)		Reference (Proline 275 at 0,72 L/ha) or other standards	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Maritime*	5	18,8	12,0-25,5	-	-	~~83,0~~ **83,5**	75,0-90,0	**87,2**	77,8-94,1	**91,6#**	77,8-100
Maritime**	3	20,0	12,0-25,5	~~54,5~~ **54,0**	~~12,5~~ 11,1-86,3	~~79,7~~ **80,7**	75,0-89,2	**84,4**	77,8-94,1	**88,4##**	77,8-100

*Direct comparison of 2,0 L/ha and 1,5 L/ha doses.
**Direct comparison of 2,0 L/ha, 1,5-1,6 L/ha and 1,0-1,3 L/ha doses.
***Dose rate 1,3 L/ha tested in 1 German trial, dose rate 1,0 L/ha tested in 2 German trials
****Dose rate 1,6 L/ha tested in 1 German trial, dose rate 1,5 L/ha tested in 4 German trials.
#Standard used in ~~three~~ 3 trials was Aviator Xpro at 1,25 L/ha.
##Standard used in ~~one~~ 1 trial was Aviator Xpro at 1,25 L/ha.

Summary and conclusions on the minimum effective dose (MED) for control of RHYNSE in winter rye (EPPO Maritime climatic zone)

RHYNSE is an important target disease for GF-3308 on winter rye, and the data reported demonstrate that it provides excellent control of RHYNSE at the proposed dose rate of 2,0 L/ha. The proposed dose of GF-3308 achieved the highest level of overall control at ~~87,7%~~ 87,2%. In ~~4~~ 3 of the 5 trials, the proposed (2,0 L/ha) dose achieved levels of control higher than the 0,75-0,8N dose (in the remaining two trials, results were identical).
It is considered that the proposed dose rate of 2,0 L/ha is the minimum effective dose of GF-3308, required for the control of RHYNSE in winter rye, in the EPPO Maritime climatic zone.

Proposed dose rate range of 1,5-2,0 L/ha for Poland (EPPO North-East climatic zone)

Five GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3308, for the control of the RHYNSE in winter rye, following a single application applied at BBCH 37-59 of the crop. The MED trials were conducted in Poland (5) in the EPPO North-East climatic zone. Assessments across all trials were on Leaf 2 (mean of 30,2% in the untreated - range 11,1-60,0%), so was considered to be a robust test of the product.
A single application of GF-3308 applied at 1,5 L/ha achieved mean control of 83,0% (range 69,4-99,0%) for RHYNSE, 35-42 days after application. Applied in the same trials at 2,0 L/ha, GF-3308 achieved control of ~~87,9%~~ 85,9% (range 73,3-100%). A dose of ~~1,0~~ 1,2 L/ha achieved a lower mean level of control of 69,5% (range 63,7-76,7%). Across all trials, control of RHYNSE demonstrated by the proposed dose rate range of 1,5-2,0 L/ha was comparable to or higher than, the prothioconazole/Proline standard at 71,9% overall control.
In addition to these trials, data from three trials in neighbouring countries in the EPPO Maritime climatic zone are available, and can also be considered supportive of the proposed dose. These three trials were conducted in Germany and demonstrate a comparable dose response to that seen for the EPPO North-East climatic zone data, with the 1,5-1,6 L/ha dose of GF-3308 achieving mean control of ~~79,7%~~ 80,7%, the 2,0 L/ha dose achieved a mean of 84,4% control and the 1,0-1,3 L/ha dose provided lower control of ~~54,5%~~ 54,0%. Combined with the five EPPO North-East climatic zone trials, these gave overall control of RHYNSE across the eight trials of ~~81,8-86,6%~~ 82,2-85,4%, for the proposed dose range of 1,5-2,0

L/ha and ~~63.9%~~ 63,7% for the lower 1,0-1,3 L/ha dose rates. Details for the German trials are in the EPPO Maritime climatic zone section above.
The results are summarised in Table 3.2-48 and individual trial results are detailed in the BAD and in the single trial reports.

Table 3.2-48 Minimum effective dose testing of GF-3308 at the proposed label rate range of 1,5-2,0 L/ha against RHYNSE in winter rye (SECCW). Results from 5 trials conducted in the EPPO North-East climatic zone in 2016 and three trials conducted in DE in 2016. Assessment at 35-42 days after one application.

EPPO Zone	Number of trials	Untreated control % infection RHYNSE		% control of RHYNSE							
				GF-3308 1,0-1,3 L/ha*		GF-3308 1,5-1,6 L/ha**		GF-3308 2,0 L/ha		Reference (Proline 275 at 0,72 L/ha) or other standards	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East	5	30,2	11,1-60,0	**69,5**	63,7-76,7	**83,0**	69,4-99,0	~~87,9~~ **85,9**	73,3-100	**71,9**	56,9-90,0
DE	3	20,0	12,0-25,5	~~54,5~~ **54,0**	~~12,5~~ 11,1-86,3	~~79,7~~ **80,7**	75,0-89,2	**84,4**	77,8-94,1	**88,4#**	77,8-100
North-East + DE	8	26,4	11,1-60,0	~~63,9~~ **63,7**	~~12,5~~ 11,1-86,3	~~81,8~~ **82,2**	69,4-~~99,0~~ 99,1	~~86,6~~ **85,4**	73,3-100	**78,1#**	56,9-100

#Standard used in ~~one~~ 1 trial was Aviator Xpro at 1,25 L/ha.
*Dose rate 1,3 L/ha tested in 1 German trial, dose rate 1,2 L/ha tested in 5 Polish trials, dose rate 1,0 L/ha tested in 2 German trials.
**Dose rate 1,6 L/ha tested in 1 German trial, dose rate 1,5 L/ha tested in 5 Polish trials and 2 German trials.

Summary and conclusions on the minimum effective dose (MED) for control of RHYNSE in winter rye (EPPO North-East climatic zone)

RHYNSE is an important target disease for GF-3308 on winter rye and the data reported demonstrate that it provides excellent control of RHYNSE at the proposed dose rate range of 1,5-2,0 L/ha. The ~~proposed~~ lower dose rate of 1,5-1,6 L/ha achieved mean control of ~~81.8%~~ 82,2% compared to ~~63.9%~~ 63,7% for the 1,0-1,3 L/ha dose (across five EEPO North-East trials and three German trials). In all eight trials, the proposed rate range achieved levels of control higher than the 1,0-1,3 L/ha dose range. The results for the higher dose rate of 2,0 L/ha (required for high ~~rust~~ pressure disease situations) demonstrated that high levels of control of RHYNSE will be achieved in these mixed disease situations. It is considered that the proposed dose rate of 1,5 L/ha is the minimum effective dose of GF-3308 to deliver robust control of this disease on rye under a wide range of environmental conditions in Poland (EPPO North-East climatic zone). As cereal diseases may occur together, for disease situations in rye where RHYNSE and other diseases such as rust (PUCCRE) may occur, the higher dose of 2,0 L/ha would be recommended for broad spectrum disease control and especially when rust pressure is high.
A dose range of 1,5-2,0 L/ha will be proposed for diseases of rye to offer growers flexibility so they can adjust dose according to the conditions. Data in the efficacy section 3.2.3.5 will be presented at 1,5 and 2,0 L/ha dose to enable a larger data set to be viewed at both dose rates.

3.2.2.6 MED of GF-3308 for the control of SEPTSP in winter triticale

This section addresses the minimum effective dose (MED) of GF-3308, for the control of SEPTSP on winter triticale, when applied at the proposed label rate of 2,0 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone and 1,5-2,0 L/ha in Poland (EPPO North-East climatic zone).

Table 3.2-49 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 21-25 m² EPPO North-East: 30 m²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: 2 TTLWI EPPO North-East: 3 TTLWI
	Varieties per crop (number of trials)	EPPO Maritime: Grenado, KWS Aveo EPPO North-East: Grenado, Magnat, Tulus
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 39-49 EPPO North-East: BBCH 33-52
	Timing Pest stage at application	GF-3308 has both protectant and curative properties. For the control of SEPTSP applications were timed to cover these situations from commencing when there was a risk of infection with SEPTSP or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	1
	Spray volumes	200-230 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were approximately 2-3 weeks after application, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where SEPTSP is a prevalent disease.

Introduction

In total, data from five field trials are presented in this section to demonstrate the minimum effective dose of GF-3308, for the control of SEPTSP in winter triticale (TTLWI). GF-3308 was tested at 2,0, 1,5, 1,6, 1,3 and 1,2 L/ha. ~~and 1.0 L/ha~~. The trials were performed in accordance with the EPPO Standard PP 1/225 '*Minimum effective dose*'. The reference products include Proline 275 applied at 0,72 L/ha, Proline 250 at 0,65 L/ha and Prosaro applied at 1,0 L/ha. Proline 275 was applied in the majority of trials. Results for all standards have been combined in the following summary tables. However, individual results for each standard are presented in the individual trial tables and are compared orthogonally with GF-3308 in section 3.2.3.
The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to

carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in the Germany (2) in the EPPO Maritime climatic zone and Poland (3) in the EPPO North-East climatic zone, in 2016 and 2017.
On the basis of the EPPO Standard PP 1/241 '*Guidance on comparable climates'*, the trials included in the dossier have been grouped and summarised by EPPO zone. EPPO zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the EPPO Maritime and North-East climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from both of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations
The minimum effective dose (MED) efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-14.

Sites
Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where SEPTSP is a prevalent disease. For trial site and application details see Appendix 3 and Appendix 4 in the BAD.

Figure 3.2 **- 7** provides an overview of the geographical distribution of the MED trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3308	EC	100 g/L fenpicoxamid	~~1,0,~~ 1,2, 1,3 1,5, 1,6, 2,0	~~50,~~ 60, 65, 75, 80, 100
Proline 275	EC	275 g/L prothioconazole	0,72	198
Proline 250	EC	250 g/L prothioconazole	0,65	163
Prosaro	EC	125 g /L tebuconazole + 125 g /L prothioconazole	1,0	250

Experimental details
The five MED trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organisations. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 21 m² and 30 m². The treatments in all trials, were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles, delivering water volumes of 200-230 L/ha.
GF-3308 was applied as a single application at BBCH 33-52 of winter triticale. The treatments were typically sprayed when SEPTSP had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials see Appendix 3 and Appendix 4 in the BAD.
Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with SEPTSP or leaves which were already senesced to a high degree in both treated and untreated plots, were excluded from summarization. Assessments were on Leaf 1, Leaf 2 or Leaf 3.

Results

Proposed dose of 2,0 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Two GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3308, for the control of SEPTSP in winter triticale, following a single application, applied at BBCH 39-49 of the crop. The MED trials were conducted in Germany (2) in the EPPO Maritime climatic zone. Assessments across all trials were on the highest leaf (Leaf 1 or Leaf 2), as this leaf had high levels of SEPTSP infection (mean of 10,7% in the untreated - range 7,0-14,3%) so was considered to be a robust test of the product.
A single application of GF-3308 applied at 2,0 L/ha achieved mean control of 78,3% (range 75,4-81,1%) for SEPTSP, 27-48 days after application. Applied in the same trials, at 1,5-1,6 L/ha (75-80% rate/0.75-0,8N), GF-3308 achieved a lower mean level of control of 65,1%, with more variable results (range 63,5-66,7%). A dose of ~~1,0~~ 1,3 L/ha (~~50~~ 65% rate/~~0.5~~ 0,65N) was included in one trial and demonstrated 48,8% control compared to 81,1% for the proposed dose. Across all trials, control of SEPTSP demonstrated by the proposed dose rate of 2,0 L/ha was comparable with the prothioconazole standard Proline (63,3%) and Prosaro standard (86,0%).
In addition to these trials, data from three trials in neighbouring countries of the EPPO North-East climatic zone are available and can also be considered supportive of the proposed dose. These three trials were conducted in Poland and demonstrate a comparable dose response to the EPPO Maritime climatic zone trials, with the 2,0 L/ha achieving the highest level of control of 87,6% compared to 84,4% for the 1,5 L/ha dose and 80,0% for the ~~1.0~~ 1,2 L/ha. Combined with the two EPPO Maritime trials, these give mean control of SEPTSP across 5 trials of 83,9% for the proposed dose, and 76,7% for the 0,75-0,8N dose. Details for these Polish trials are included in the EPPO North-East climatic zone section, below.
The results are summarised in Table 3.2-50 and individual trial results are detailed in the BAD and in the single trial reports.

Table 3.2-50 Minimum effective dose testing of GF-3308 at the proposed label rate of 2,0 L/ha, at 75-80% and ~~50~~ 60-65% dose rates against SEPTSP in winter triticale (TTLWI). Results from 2 trials conducted in the EPPO Maritime climatic zone and 3 trials conducted in PL in 2016 and 2017. Assessment at 21-48 days after one application.

EPPO Zone	Number of trials	Untreated control % infection SEPTSP		% control of SEPTSP: GF-3308 ~~1,0~~ 1,2-1,3 L/ha (~~50%~~ 60-65% rate)***		GF-3308 1,5-1,6 L/ha (75-80% rate)****		GF-3308 2,0 L/ha (100 % rate)		Reference (Proline 275 at 0,72 L/ha) or other standards	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Maritime*	2	10,7	7,0-14,3	-	-	**65,1**	63,5-66,7	**78,3**	75,4-81,1	**74,7#**	63,3-86,0
Maritime**	1	7,0	-	**48,8**	-	**63,5**	-	**81,1**	-	**63,3**	-
PL**	3	13,6	8,9-20,9	**80,0**	70,0-100	**84,4**	75,9-100	**87,6**	79,2-100	**88,2**	78,2-100
Maritime + PL*	5	12,4	7,0-20,9	-	-	**76,7**	63,5-100	**83,9**	75,4-100	**82,8#**	63,3-100
Maritime + PL**	4	12,0	7,0-20,9	**72,2**	48,8-100	**79,2**	63,5-100	**86,0**	79,2-100	**82,0**	63,3-100

*Direct comparison of 2,0 L/ha and 1,5-1,6 L/ha doses.
**Direct comparison of 2,0 L/ha, 1,5-1,6 L/ha and ~~1,0~~ 1,2-1,3 L/ha doses.
*** Dose rate 1,2 L/ha tested in 1 German trial and in 3 Polish trials, dose rate 1,3 L/ha tested in 1 German trial.
**** Dose rate 1,5 L/ha tested in 3 Polish trials and 1 German trial. Dose rate 1,6 L/ha tested in 1 German trial.
#Standard used in one trial was Prosaro at 1,0 L/ha.

Summary and conclusions on the minimum effective dose (MED) for control of SEPTSP in winter triticale (EPPO Maritime climatic zone)

SEPTSP is an important target disease for GF-3308 on winter triticale and the data reported demonstrate that it provides effective control of SEPTSP at the proposed dose rate of 2,0 L/ha. The proposed dose of GF-3308 achieved the highest level of overall control (mean control of 78,3% from the EPPO Maritime climatic zone trials and 87,6% from the three Polish trials). In 4 of the 5 trials, the proposed (2,0 L/ha) dose achieved levels of control higher than the 0,75-0,8N dose (in the remaining trial, results were identical) and demonstrated overall mean control of >80% ~~across the five trials~~ in 3 of the 5 trials. It is considered that the proposed dose rate of 2,0 L/ha is the minimum effective dose of GF-3308, required to deliver robust control of this disease under a wide range of environmental conditions, in the EPPO Maritime climatic zone.

Proposed dose rate range of 1,5-2,0 L/ha for Poland (EPPO North-East climatic zone)

Three GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3308, for the control of the SEPTSP in winter triticale, following a single application applied at BBCH 33-52 of the crop. The MED trials were conducted in Poland (3) in the EPPO North-East climatic zone. Assessments across all trials were on Leaf 3 (mean of 13,6% in the untreated - range 8,9-20,9%) so was considered to be a robust test of the product.
A single application of GF-3308 applied at 1,5 L/ha achieved mean control of 84,4% (range 75,9-100%) for SEPTSP, 21 days after application. Applied in the same trials at 2,0 L/ha, GF-3308 achieved control of 87,6% (range 79,2-100%). A dose of ~~1,0~~ 1,2 L/ha achieved a lower mean level of control of 80,0% (range 70,0-100%). Across all trials, control of SEPTSP demonstrated by the proposed dose rate range of 1,5-2,0 L/ha was comparable to the prothioconazole/Proline standard at 88,2% overall control.
In addition to these trials, data from neighbouring Germany, in the EPPO Maritime climatic zone, are available and can also be considered supportive of the proposed dose. One trial was conducted in Germany and demonstrates a comparable dose response to the EPPO North-East data with the ~~1.5~~ 1,6 L/ha dose achieving control of 63,5%, the 2,0 L/ha dose 81,1% control and the ~~1.0~~ 1,3 L/ha dose lower control of ~~54.5~~ 48,8%. Combined with the three Polish trials, these give overall control of SEPTSP across four trials of 79,2-86,0% for the proposed dose range of 1,5-2,0 L/ha and 72,2% for the lower ~~1.0~~ 1,2-1,3 L/ha dose range. Details for ~~these~~ this German trial~~s are~~ is provided in the EPPO Maritime climatic zone section, above.
The results are summarised in Table 3.2-51 and individual trial results are detailed in the BAD and in the single trial reports.

Table 3.2-51 Minimum effective dose testing of GF-3308 at the proposed label rate range of 1,5-2,0 L/ha against SEPTSP in winter triticale (TTLWI). Results from 3 trials conducted in the EPPO North-East climatic zone and one trial conducted in DE in 2016. Assessment at 21-48 days after one application.

EPPO Zone	Number of trials	Untreated control % infection SEPTSP		% control of SEPTSP							
				GF-3308 ~~1,0 L/ha~~ 1,2-1,3 L/ha*		GF-3308 1,5-1,6 L/ha**		GF-3308 2,0 L/ha		Proline 0,72 L/ha or other standards	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East	3	13,6	8,9-20,9	**80,0**	70,0-100	**84,4**	75,9-100	**87,6**	79,2-100	**88,2**	78,2-100
DE	1	7,0	-	**48,8**	-	**63,5**	-	**81,1**	-	**63,3#**	-
North-East + DE	4	12,0	7,0-20,9	**72,2**	48,8-100	**79,2**	63,5-100	**86,0**	79,2-100	**82,0**	63,3-100

* Dose rate 1,2 L/ha tested in 3 Polish trials, dose rate 1,3 L/ha tested in 1 German trial.
** Dose rate 1,5 L/ha tested in 3 Polish trials. Dose rate 1,6 L/ha tested in 1 German trial.
# Standard Proline 250 at 0,65 L/ha tested in 1 trial

Summary and conclusions on the minimum effective dose (MED) for control of SEPTSP in winter triticale (EPPO North-East climatic zone)

SEPTSP is an important target disease for GF-3308 on winter triticale and the data reported demonstrate that it provides excellent control of SEPTSP at ~~the proposed~~ dose rate ~~range~~ of ~~1,5~~ 2,0 L/ha. The ~~proposed~~ lower dose rate of 1,5-1,6 L/ha achieved control of 79,2% compared to 72,2% for the ~~0.75~~ 0,6-0,65N dose (across three EPPO North-East trials and one German trial). This dose rate can also be considered to be supported by the data on winter wheat, which demonstrated ~~82.6%~~ 82,6% control of SEPTTR for the 1,5 L/ha dose and ~~86.7%~~ 86,7% for the 2,0 L/ha dose across seven winter wheat trials. The results for the higher dose rate of 2,0 L/ha (required for other diseases) demonstrate that high levels of control of SEPTSP will be achieved in mixed disease situations.
It is considered that the proposed dose rate of 1,5 L/ha is the minimum effective dose of GF-3308 to deliver robust control of this disease under a wide range of environmental conditions, in Poland (EPPO North-East climatic zone). As cereal diseases may occur together, for disease situations in triticale where SEPTSP and other diseases such as rust (PUCCST) occur, the higher dose of 2,0 L/ha would be recommended for broad spectrum disease control and especially where rust is the main target disease.
A dose range of 1,5-2,0 L/ha will be proposed for diseases of triticale to offer growers flexibility so they can adjust dose according to the conditions. Data in the efficacy section 3.2.3.6 will be presented at 1,5 and 2,0 L/ha dose to enable a larger data set to be viewed at both dose rates.

3.2.2.7 MED of GF-3308 for the control of PUCCST in winter triticale

This section addresses the minimum effective dose (MED) of GF-3308, for the control of PUCCST on winter triticale, when applied at the proposed label rate of 2,0 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone and Poland (EPPO North-East climatic zone of the Central EU Authorisation zone).

Table 3.2-52 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 22,5-23,8 m² EPPO North-East: 25-30 m²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: 5 TTLWI EPPO North-East: 3 TTLWI
	Varieties per crop (number of trials)	EPPO Maritime:KWS Aveo, Tender (4) EPPO North-East: Magnat, Trismart, Twingo
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 37-51 EPPO North-East: BBCH 35-52
	Timing Pest stage at application	GF-3308 has both protectant and curative properties. For the control of PUCCST applications were timed to cover these situations from commencing when there was a risk of infection with PUCCST or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	1
	Spray volumes	200-230 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were approximately 2-3 weeks after application, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where PUCCST is a prevalent disease.

Introduction

In total, data from eight trials are presented in this section to demonstrate the minimum effective dose of GF-3308, for the control of PUCCST in winter triticale (TTLWI). GF-3308 was tested at 2,0, 1,5 and ~~1,0~~ 1,2 L/ha. The trials were performed in accordance with the EPPO Standard PP 1/225 '*Minimum effective dose*'. The reference product was Proline 275, applied at 0,72 L/ha and Proline 250 applied at 0,8 L/ha in ~~all~~ the trials.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out registration efficacy field trials, in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in the Germany (5) in the EPPO Maritime climatic zone and Poland (3) in the EPPO North-East climatic zone in 2016 and 2020.

On the basis of the EPPO Standard PP 1/241 '*Guidance on comparable climates'*, the trials included in the dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime and North-East climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from both of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The minimum effective dose (MED) efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-15.

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Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where PUCCST is a prevalent disease. For trial site and application details see Appendix 3 and Appendix 4 in the BAD. Figure 3.2 - 8 provides an overview of the geographical distribution of the MED trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3308	EC	100 g/L fenpicoxamid	~~1,0~~ 1,2, 1,5, 2,0	~~50~~ 60, 75, 100
Proline 275	EC	275 g/L prothioconazole	0,72	198
Proline 250	EC	250 g/L prothioconazole	0,8	200

Experimental details

The eight MED trials were conducted to GEP by officially recognized testing organisations and followed the appropriate EPPO Standards. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 22,5 m² and 30 m². The treatments in all trials, were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles, delivering water volumes of 200-230 L/ha.

GF-3308 was applied as a single application at BBCH 35-52 of winter triticale. The treatments were typically sprayed when PUCCST had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials see Appendix 3 and Appendix 4 in the BAD.

Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with PUCCST or leaves which were already senesced to a high degree in both treated and untreated plots, were excluded from summarization. Assessments were either on Leaf 1 or Leaf 2.

Results

Proposed dose of 2,0 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Five GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3308, for the control of PUCCST in winter triticale, following a single application, applied at BBCH 37-51 of the crop. The MED trials were conducted in Germany (5) in the EPPO Maritime climatic zone. Assessments across all trials were on the highest leaf (Leaf 1 or Leaf 2), as this leaf had high levels of PUCCST infection (mean of 53,7% in the untreated - range 13,5-96,5%) so was considered to be a robust test of the product.

A single application of GF-3308 applied at 2,0 L/ha achieved mean control of 84,1% (range 63,0-~~95.8~~ 95,9%) for PUCCST, 28-44 days after application. Applied in the same trials, at 1,5 L/ha (75% rate/0,75N), GF-3308 achieved a lower mean level of control of 75,6%, with more variable results (range 40,7-~~93.9~~ 94%). A dose of ~~1,0~~ 1,2 L/ha (~~50~~ 60% rate/~~0.5~~ 0,6N) was included in three trials and demonstrated 64,2% mean control compared to 77,4% for the proposed dose.

Across all trials, control of PUCCST demonstrated by the proposed dose rate of 2,0 L/ha was ~~comparable with~~ higher than the prothioconazole standard Proline (~~83.9%~~ 76,7%)

The results are summarised in Table 3.2- and individual trial results are detailed in the BAD and in the single trial reports.

Table 3.2-53 Minimum effective dose testing of GF-3308 at the proposed label rate of 2,0 L/ha, at 75% and ~~50~~ 60% dose rates against PUCCST in winter triticale (TTLWI). Results from 5 trials conducted in the EPPO Maritime climatic zone in 2020. Assessment at 28-44 days after one application.

EPPO Zone	Number of trials	Untreated control % infection PUCCST		% control of PUCCST							
				GF-3308 ~~1,0~~ 1,2 L/ha (~~50~~ 60% rate)		GF-3308 1,5 L/ha (75 % rate)		GF-3308 2,0 L/ha (100 % rate)		Proline 0,72 L/ha or Proline 0,8 L/ha	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Maritime*	5	53,7	13,5-96,5	-	-	**75,6**	40,7-~~93,9~~ 94,0	**84,1**	63,0-~~95,8~~ 95,9	~~83,9~~ **76,7#**	~~54,5~~ 18,5-100
Maritime**	3	35,4	13,5-78,8	**64,2**	33,3-81,8	**66,4**	40,7-80,0	**77,4**	63,0-87,3	~~76,0~~ **64#**	~~54,5~~ 18,5-89,8

*Direct comparison of 2,0 L/ha and 1,5 L/ha doses.
**Direct comparison of 2,0 L/ha, 1,5 L/ha and ~~1.0~~ 1,2 L/ha doses.
Proline 250 at 0,8 L/ha tested as standard in 3 trials.

Summary and conclusions on the minimum effective dose (MED) for control of PUCCST in winter triticale (EPPO Maritime climatic zone)

PUCCST is an important target disease for GF-3308 on winter triticale and the data reported demonstrate that it provides excellent control of PUCCST at the proposed dose rate of 2,0 L/ha. The proposed dose of GF-3308 achieved the highest level of overall control (84,1%), compared to 75,6% for the 0,75N dose. In all five trials, the proposed (2,0 L/ha) dose achieved control higher than the 0,75N dose.
It is considered that the proposed dose rate of 2,0 L/ha is the minimum effective dose of GF-3308, required for the control of PUCCST in winter triticale, in the EPPO Maritime climatic zone.

Proposed maximum dose of 2,0 L/ha for Poland (EPPO North-East climatic zone)

Three GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3308, for the control of the PUCCST in winter triticale, following a single application applied at BBCH 35-52 of the crop. The MED trials were conducted in Poland (3) in the EPPO North-East climatic zone. Assessments across the trials were on Leaf 1 or Leaf 2 (mean of 19,6% in the untreated - range 7,1-37,8%) so was considered to be a robust test of the product.
A single application of GF-3308 applied at 2,0 L/ha achieved mean control of 88,4% (range 83,5-94,9%) for PUCCST, 35-43 days after application. Applied in the same trials at 1,5 L/ha (75% rate/0,75N), GF-3308 achieved a lower mean level of control of 83,8% (range 73,5-93,6%) and 75,0% (range 58,9-85,2%) for a dose of ~~1.0~~ 1,2 L/ha (~~50~~ 60% rate/~~0.5~~ 0,6N).
Across all trials, control of PUCCST demonstrated by the proposed dose rate of 2,0 L/ha GF-3308 was higher than that achieved by the prothioconazole/Proline standard, at 66,0% overall control.
In addition to these trials, data from neighbouring Germany in the EPPO Maritime climatic zone are available and can also be considered supportive of the proposed dose. These five trials conducted in Germany demonstrate a comparable dose response to the Polish trials data, with the 2,0 L/ha achieving the highest level of control of 84,1% compared to 75,6% for the 1,5 L/ha dose. Combined with the three Polish trials, these give overall control of PUCCST across 8 trials of 85,7% for the proposed dose and 78,7% for the 0,75N dose. Details for the German trials are in the EPPO Maritime climatic zone section, above.
The results are summarised in Table 3.2- and individual trial results are detailed in the BAD and in the single trial reports.

Table 3.2-54 Minimum effective dose testing of GF-3308 at the proposed maximum label rate of 2,0 L/ha, at 75% and ~~50~~ 60% dose rates against PUCCST in winter triticale (TTLWI). Results from 3 trials conducted in the EPPO North-East climatic zone and 5 trials conducted in DE in 2016 and 2020. Assessment at 28-44 days after one application.

EPPO Zone	Number of trials	Untreated control % infection PUCCST		% control of PUCCST							
				GF-3308 ~~1,0~~ 1,2 L/ha (~~50~~ 60% rate)		GF-3308 1,5 L/ha (75 % rate)		GF-3308 2,0 L/ha (100 % rate)		Proline 0,72 L/ha or Proline 0,8 L/ha	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East**	3	19,6	7,1-37,8	**75,0**	58,9-85,2	**83,8**	73,5-93,6	**88,4**	83,5-94,9	**66,0#**	54,1-73,7
DE*	5	53,7	13,5-96,5	-	-	**75,6**	40,7-~~93,9~~ 94,0	**84,1**	63,0-~~95,8~~ 95,9	~~**83,9**~~ **76,7#**	~~54,5~~ 18,5-100
DE**	3	35,4	13,5-78,8	**64,2**	33,3-81,8	**66,4**	40,7-80,0	**77,4**	63,0-87,3	~~**76,0**~~ **64,0#**	~~54,5~~ 18,5-89,8
North-East + DE*	8	40,9	7,1-96,5	-	-	**78,7**	40,7-~~93,9~~ 94,0	**85,7**	63,0-~~95,8~~ 95,9	~~**77,2**~~ **72,7#**	~~54,1~~ 18,5-100
North-East + DE**	6	27,5	7,1-78,8	**69,6**	33,3-85,2	**75,1**	40,7-93,6	**82,9**	63,0-94,9	~~**71,0**~~ **65,0#**	~~54,1~~ 18,5-89,8
North-East + DE***	7	44,8	7,1-96,5			**84,1**	73,5-~~93,9~~ 94,0	**89,0**	81,9-~~95,8~~ 95,9	**80,4#**	~~54,1~~ 18,5-100

*Direct comparison of 2,0 L/ha and 1,5 L/ha doses.
**Direct comparison of 2,0 L/ha, 1,5 L/ha and ~~1,0~~ 1,2 L/ha doses.
***One German trial: EA20E7B018F-DNZ056 removed
Proline 250 at 0,8 L/ha tested as standard in three German trials and two Polish trials.

Summary and conclusions on the effective dose (MED) for control of PUCCST in winter triticale (EPPO North-East climatic zone)

PUCCST is an important target disease for GF-3308 on winter triticale and the data reported demonstrate that it provides effective control of PUCCST, at the proposed dose rate of 2,0 L/ha. The proposed dose of GF-3308 achieved the highest level of overall control (88,4% in three EPPO North-East climatic zone trials and 84,1% in the five EPPO Maritime climatic zone trials). Across the eight trials, the proposed (2,0 L/ha) dose of GF-3308 achieved levels of control higher than the 0,75N dose in every trial, with only one result below 80% using the 2,0 L/ha dose, compared to three results below 80% for the 1,5 L/ha dose. However, the 1,5 L/ha dose achieved 78,7% control from 8 trials and in one of these trials (EA20E7B018F-DNZ056) relatively poor control was achieved by all treatments (40,7% at 1,5 L/ha, 63,0% at 2,0 L/ha and ~~54.5%~~ 18,5% for Proline at 0,72 L/ha). If this trial is removed as an outlier then mean control for the 1,5 L/ha dose would increase to 84,1% over 7 trials compared to 89,0% for the 2,0 L/ha and 80,4% for Proline. ~~This supports a dose range of 1,5-2,0 L/ha in triticale. Where SEPTSP is the main target and when rust pressure is lower than the 1,5 l/ha dose would be acceptable, though 2,0 L/ha is the most effective dose when rust pressure is higher, which is similar to the proposal in wheat.~~
It is considered that the proposed dose rate of 2,0 L/ha is the minimum effective dose of GF-3308 to deliver robust control of this disease under a wide range of environmental conditions, in Poland (EPPO North-East climatic zone). Lower dose rate 1,5 L/ha was moderately effective.
After evaluation, a dose ~~range~~ rate of ~~1,5-~~ 2,0 L/ha will be ~~proposed for diseases of triticale to offer growers flexibility so they can adjust dose according to the conditions.~~ recommended for the control of PUCCST in triticale to provide sufficient control under wide range of environmental conditions Data in the efficacy section 3.2.3.4 will present the 2,0 L/ha ~~dose that will be advised in high risk situations for PUCCST~~ and also the 1,5 L/ha to enable a larger data set to be viewed at both dose rates. ~~dose that can be used in the less severe disease situations.~~

Summary and conclusions on the minimum effective dose (all crops and disease claims)

Data have been presented across a range of diseases (*Septoria*, rusts and *Rhynchosporium*) in wheat, rye and triticale.

The majority of data were generated on winter crops. However, as spring varieties of these crops are a less challenging situation for disease control and are generally minor crops in the majority of countries of the Central EU Authorisation zone, it is considered that the conclusions on minimum effective dose for winter crops are equally applicable to spring crops. For spelt wheat and durum wheat it is considered that disease control in winter wheat is a more challenging situation and the winter wheat data can be used to support the proposed dose on all wheat crops (see the ‘Conclusions’ in section 3.2.3 for a more detailed case to support extrapolation between winter crops and spring crops, spelt wheat and durum wheat).
The summary tables below are split by EPPO climatic zone. and the following colour coding has been used to illustrate the differences in effectiveness between the dose rates.

Level of Effectiveness
>79% control
70-78.9% control
<69.9% control

EPPO Maritime zone

The proposed use is for a single application at 2,0 L/ha applied at BBCH 30-69 to winter and spring wheat (TRZAW and TRZAS), spelt wheat (TRZSP) and durum wheat (TRZDU) for the control of SEPTTR, PUCCRT and PUCCST; winter and spring rye (SECCW and SECCS) for the control of PUCCRE and RHYNSE and winter and spring triticale (TTLWI and TTLSO) for the control of SEPTSP and PUCCST.

Summary of minimum effective dose testing of GF-3308 for EPPO Maritime zone

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control					
							GF-3308 1.0 L/ha (50% rate)*		GF-3308 1.5 L/ha (75 % rate)		GF-3308 2.0 L/ha (Full rate)	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
SEPTTR	TRZAW	MAR	7	31-39	31.1	6.1-75.0	83.2*	72.2-97.2	83.7	70.7-96.9	91.2	80.6-100
PUCCRT	TRZAW	MAR	4	32-51	17.9	6.6-27.9	71.2	17.8-98.9	71.6	31.1-98.9	89.9	71.7-100
PUCCST	TRZAW	MAR	7	32-43	26.6	6.1-65.0	63.5*	50.0-73.6	71.9	38.3-87.8	84.2	71.7-95.8
PUCCRE	SECCW	MAR	3	39-59	30.1	7.0-74.0	69.9*	-	79.9	74.3-85.7	84.9	81.1-87.8
		PL + DE	6	37-59	29.4	7.0-74.0	71.3*	61.8-83.9	80.3	74.3-86.4	84.5	81.1-87.8
RHYNSE	SECCW	MAR	5	39-59	18.8	12.0-25.5	54.5*	12.5-86.3	83.0	75.0-90.0	87.2	77.8-94.1
SEPTSP	TTLWI	MAR	2	39-49	10.7	7.0-14.3	48.8*	-	65.1	63.5-66.7	78.3	75.4-81.1
		PL + DE	5	33-52	12.4	7.0-20.9	72.2*	48.8-100	76.7	63.5-100	83.9	75.4-100
PUCCST	TTLWI	MAR	5	37-51	53.7	13.5-96.5	64.2*	33.3-81.8	75.6	40.7-93.9	84.1	63.0-95.8

*Results for the 50% doses are for a lower number of trials

Summary of minimum effective dose testing of GF-3308 for EPPO Maritime zone (2,0 L/ha recommendations

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control					
							GF-3308 1,0-1,3 L/ha (50-65% rate)*		GF-3308 1,5-1,6 L/ha** (75-80 % rate)		GF-3308 2,0 L/ha (100% rate)	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
SEPTTR	TRZAW	MAR	16	31-51	28,6	6,1-75,0	**77,7***	59,0-97,2	**79,8**	59,1-96,9	**84,5**	65,0-100
PUCCRT	TRZAW	MAR	5	32-51	15,9	6,6-27,9	**71,3***	18,3-98,9	**66,3**	32,6-98,9	**83,8**	59,4-100
PUCCST	TRZAW	MAR	8	31-43	26,0	6,1-65,0	**59,7***	44,3-73,6	**69,2**	38,3-82,7	**81,7**	62,0-95,8
PUCCRE	SECCW	MAR	4	39-59	24,3	6,8-74,0	**66,0***	63,0-69,9	**77,5**	70,4-85,7	**83,6**	79,6-87,8
		PL + DE	7	37-59	26,2	6,8-74,0	**69,6***	61,8-84,0	**78,9**	70,4-86,4	**83,8**	79,6-87,8
RHYNSE	SECCW	MAR	5	39-59	18,8	12,0-25,5	**54,0***	11,1-86,3	**83,5**	75,0-90,0	**87,2**	77,8-94,1
SEPTSP	TTLWI	MAR	2	39-49	10,7	7,0-14,3	**48,8***	-	**65,1**	63,5-66,7	**78,3**	75,4-81,1
		PL + DE	5	33-52	12,4	7,0-20,9	**72,2***	48,8-100	**76,7**	63,5-100	**83,9**	75,4-100
PUCCST	TTLWI	MAR	5	37-51	53,7	13,5-96,5	**64,2***	33,3-81,8	**75,6**	40,7-94,0	**84,1**	63,0-95,9

*Results for the 50% doses are for a lower number of trials
** Dose rate 1,6 L/ha tested in only 1 German trial

The results from the EPPO Maritime climatic zone trials (supported by data from Poland) demonstrate that the proposed dose of 2,0 L/ha of GF-3308 is the minimum effective dose required to achieve a claim of 'very good control' across all the proposed diseases, across all the proposed cereal crops. The 0,75N dose was effective in delivering good control in the ~~70~~ 65-80% range for most target pathogens, but did not always provide consistent control of SEPTTR, PUCCRT and PUCCST on wheat, PUCCRE, RHYNSE on rye or SEPTSP and PUCCST on triticale when compared to the 2,0 l/ha dose.

EPPO North-East zone

The proposed use is for a single application at 1,5 or 2,0 L/ha applied at BBCH 30-69 to winter and spring wheat (TRZAW and TRZAS), spelt wheat (TRZSP) and durum wheat (TRZDU) for the control of SEPTTR, PUCCRT and PUCCST; winter and spring rye (SECCW and SECCS) for the control of PUCCRE and RHYNSE and winter and spring triticale (TTLWI and TTLSO) for the control of SEPTSP and PUCCST. The lower dose of 1,5 L/ha is recommended for application where SEPTTR in wheat, SEPTSP in triticale or RHYNSE in rye is the major disease requiring control. ~~and where there is lower pressure from rusts.~~ Where *Puccinia* species are also present and expected to be a concern because of high disease pressure, a higher dose rate of 2,0 L/ha is recommended, hence a label dose range of 1,5-2,0 l/ha is proposed, to offer growers the greatest flexibility.

~~**Summary of minimum effective dose testing of GF-3308 for EPPO North-East zone (2.0 L/ha recommendations)**~~

~~Target (EPPO code)~~	~~Crop (EPPO)~~	~~EPPO Zone/ Country~~	~~Number of trials~~	~~Application timing (BBCH)~~	~~Untreated % infection~~		~~% control~~					
							~~GF-3308 1.0 L/ha (50% rate)*~~		~~GF-3308 1.5 L/ha (75 % rate)~~		~~GF-3308 2.0 L/ha (Full rate)~~	
					~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~
~~PUCCRT~~	~~TRZAW~~	~~NE~~	~~2~~	~~45-56~~	~~20.4~~	~~18.8-22.0~~	~~**76.1***~~	-	~~**79.4**~~	~~77.3-81.4~~	~~**81.7**~~	~~80.9-82.4~~
		~~CZ~~	~~3~~	~~32-51~~	~~17.3~~	~~6.6-27.9~~	~~**67.9**~~	~~17.8-98.9~~	~~**66.2**~~	~~31.1-98.9~~	~~**90.6**~~	~~71.7-100~~

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control					
							GF-3308 1.0 L/ha (50% rate)*		GF-3308 1.5 L/ha (75 % rate)		GF-3308 2.0 L/ha (Full rate)	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
		All	5	32-56	18.6	6.6-27.9	70.0*	17.8-98.9	71.5	31.1-98.9	87.0	71.7-100
PUCCST	TRZAW	NE	4	39-56	10.4	5.7-23.3	67.4*	49.1-100	79.6	59.2-100	81.8	67.5-100
		DE	4	32-43	12.9	6.1-40.0	73.6*	-	70.6	38.3-100	82.6	71.7-89.7
		All	8	32-56	11.7	5.7-23.3	69.0*	49.1-100	75.1	38.3-100	82.2	67.5-100
PUCCST	TRZAS	NE	1	39-41	8.7	-	90.1	-	94.3	-	96.9	-
PUCCRE	SECCW	NE	3	37-52	28.8	18.1-36.9	72.0	61.8-83.9	80.7	76.1-86.4	84.0	81.4-87.8
		DE	3	39-59	30.1	7.0-74.0	68.9*	-	79.9	74.3-85.7	84.9	81.1-87.8
		All	6	37-59	29.4	7.0-74.0	71.3*	61.8-83.9	80.3	74.3-86.4	84.5	81.1-87.8
PUCCST	TTLWI	NE	3	35-52	19.6	7.1-37.8	75.0	58.9-85.2	83.8	73.5-93.6	88.4	83.5-94.9
		DE	5	37-51	53.7	13.5-96.5	64.2*	33.3-81.8	75.6	40.7-93.9	84.1	63.0-95.8
		All	8	35-52	40.9	7.1-96.5	69.6*	33.3-85.2	78.7	40.7-93.9	85.7	63.0-95.8

*Results for 50% doses are for a lower number of trials

Summary of minimum effective dose testing of GF-3308 for North-East EPPO zone (2,0 L/ha recommendations)

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control					
							GF-3308 1,0-1,3L/ha (50-65% rate)*		GF-3308 1,5-1,6 L/ha** (75-80 % rate)		GF-3308 2,0 L/ha (100% rate)	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
PUCCRT	TRZAW	NE	2	45-56	20,4	18,8-22,0	**76,1***	-	**79,4**	77,3-81,4	**81,7**	80,9-82,4
		CZ	3	32-51	17,3	6,6-27,9	**68,1**	18,3-98,9	**66,7**	32,6-98,9	**90,6**	71,7-100
		DE	1	39	8,0	-	-	-	**43,8**	-	**59,4**	-
		All	**6**	**32-56**	16,8	6,6-27,9	**70,1***	18,3-98,9	**67,1**	32,6-98,9	**82,4**	59,4-100
PUCCST	TRZAW	NE	6	37-56	25,4	5,7-83,1	**60,1***	40,6-81,2	**68,5**	45,9-86,8	**71,1**	44,4-85,7
		DE	5	31-43	14,8	6,1-22,1	**59,0***	44,3-73,6-	**66,4**	38,3-82,7	**78,9**	62,0-91,8
		All	**11**	**31-56**	20,6	5,7-83,1	**59,8***	40,6-81,2	**67,5**	38,3-86,8	**74,6**	44,4-91,8
PUCCST	TRZAS	NE	1	39-41	8,7	-	**90,1**	-	**94,3**	-	**96,9**	-
PUCCRE	SECCW	NE	3	37-52	28,8	18,1-36,9	**72,1**	61,8-84,0	**80,7**	76,1-86,4	**84,0**	81,4-87,8

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control					
							GF-3308 1,0-1,3L/ha (50-65% rate)*		GF-3308 1,5-1,6 L/ha** (75-80 % rate)		GF-3308 2,0 L/ha (100% rate)	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
		DE	4	39-59	24,3	6,8-74,0	**66,0***	63,0-69,9	**77,5**	70,4-85,7	**83,6**	79,6-87,8
		All	**7**	**37-59**	26,2	6,8-74,0	**69,6***	61,8-84,0	**78,9**	70,4-86,4	**83,8**	79,6-87,8
PUCCST	TTLWI	NE	3	35-52	19,6	7,1-37,8	**75,0**	58,9-85,2	**83,8**	73,5-93,6	**88,4**	83,5-94,9
		DE	5	37-51	53,7	13,5-96,5	**64,2***	33,3-81,8	**75,6**	40,7-94,0	**84,1**	63,0-95,9
		All	**8**	**35-52**	40,9	7,1-96,5	**69,6***	33,3-85,2	**78,7**	40,7-94,0	**85,7**	63,0-95,9

*Results for 50% doses are for a lower number of trials
** Dose rate 1,6 L/ha tested in only 1 German trial

The results from the EPPO North-East climatic zone trials (supported by data from CZ and DE) demonstrate that the proposed maximum dose of 2,0 L/ha GF-3308 is the most effective dose required to ~~achieve a claim of 'very good~~ control~~[2]~~ of *Puccinia* species across all crops (PUCCRT and PUCCST on wheat, PUCCRE on rye and PUCCST on triticale) ~~with minimum control levels of 80+%.~~ The 1,5 L/ha dose offered ~~good~~ control of ~~70~~ 44-80% (and ~~79.4~~ 68,5-94,3% in EPPO North-East trials), but did not always provide consistently high levels of control, as control was more variable in some trials, although this was most impacted with trials from trials carried out in neighbouring countries of the Maritime EPPO Zone. ~~In rust trials from the North East EPPO Zone the levels of disease control at 1,5 L/ha were close to that achieved by the 2,0 L/ha dose.~~ Data from neighbouring countries were also used, giving the overall efficacy for dose rate of 1,5 L/ha lower than for higher dose rate of 2,0 L/ha.

It is considered that to support these claims, the maximum proposed 2,0 L/ha dose of GF-3308 is required to be fully effective in all situations, although the 1,5 L/ha dose would provide good control of SEPTTR in wheat, SEPTSP in triticale and RHYNSE in rye. ~~most disease situations in the EPPO North East zone.~~ Hence a dose range of 1,5– 2,0 L/ha is proposed and data is presented for both doses in the Efficacy section of this document.

~~**Summary of minimum effective dose testing of GF-3308 for EPPO North-East zone (1.5-2.0 L/ha recommendations)**~~

~~Target (EPPO code)~~	~~Crop (EPPO)~~	~~EPPO Zone/ Country~~	~~Number of trials~~	~~Application timing (BBCH)~~	~~Untreated % infection~~		~~% control~~					
							~~GF-3308 1.0 L/ha~~		~~GF-3308 1.5 L/ha~~		~~GF-3308 2.0 L/ha~~	
					~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~
		~~NE~~	~~4~~	~~37-43~~	~~13.3~~	~~7.2-18.9~~	~~**69.6***~~	~~52.3-94.8~~	~~**79.7**~~	~~66.1-100~~	~~**81.9-**~~	~~71.0-100~~
~~SEPTTR~~	~~TRZAW~~	~~CZ + DE~~	~~3~~	~~32-39~~	~~27.2~~	~~6.3-57.5~~	~~**83.1**~~	~~72.2-97.2~~	~~**86.6**~~	~~78.9-96.9~~	~~**93.0**~~	~~80.6-100~~
		~~**All**~~	~~7~~	~~**32-43**~~	~~19.3~~	~~6.3-57.5~~	~~**75.4**~~	~~52.3-97.2~~	~~**82.6**~~	~~66.1-100~~	~~**86.7**~~	~~71.0-100~~
~~SEPTTR~~	~~TRZAS~~	~~NE~~	~~1~~	~~39-41~~	~~5.0~~	-	~~**67.8**~~	-	~~**78.3**~~	-	~~**92.5**~~	-
~~RHYNSE~~	~~SECCW~~	~~NE~~	~~5~~	~~37-59~~	~~30.2~~	~~11.1-60.0~~	~~**69.5**~~	~~63.7-76.7~~	~~**83.0**~~	~~69.4-99.0~~	~~**87.9**~~	~~73.3-100~~
		~~DE~~	~~3~~	~~39-55~~	~~20.0~~	~~12.0-25.5~~	~~**54.5**~~	~~12.5-86.3~~	~~**79.7**~~	~~75.0-89.2~~	~~**84.4**~~	~~77.8-94.1~~

~~Target (EPPO code)~~	~~Crop (EPPO)~~	~~EPPO Zone/ Country~~	~~Number of trials~~	~~Application timing (BBCH)~~	~~Untreated % infection~~		~~% control~~					
							~~GF-3308 1.0 L/ha~~		~~GF-3308 1.5 L/ha~~		~~GF-3308 2.0 L/ha~~	
					~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~
		~~All~~	~~8~~	~~37-59~~	~~26.4~~	~~11.1-60.0~~	~~63.9~~	~~12.5-86.3~~	~~81.8~~	~~69.4-99.0~~	~~86.6~~	~~73.3-100~~
~~SEPTSP~~	~~TTLWI~~	~~NE~~	~~3~~	~~33-52~~	~~13.6~~	~~8.9-20.9~~	~~80.0~~	~~70.0-100~~	~~84.4~~	~~75.9-100~~	~~87.6~~	~~79.2-100~~
		~~DE~~	~~1~~	~~45~~	~~7.0~~	~~-~~	~~48.8~~	~~-~~	~~63.5~~	~~-~~	~~81.1~~	
		~~All~~	~~4~~	~~33-52~~	~~12.0~~	~~7.0-20.9~~	~~72.2~~	~~48.8-100~~	~~79.2~~	~~63.5-100~~	~~86.0~~	~~79.2-100~~

Summary of minimum effective dose testing of GF-3308 for EPPO North-East zone (1,5-2,0 L/ha recommendations)

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control					
							GF-3308 1,0-1,3L/ha (50-65% rate)*		GF-3308 1,5-1,6 L/ha** (75-80% rate)		GF-3308 2,0 L/ha (100% rate)	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
RHYNSE	SECCW	NE	5	37-59	30,2	11,1-60,0	**69,5**	63,7-76,7	**83,0**	69,4-99,0	**85,9**	73,3-100
		DE	3	39-59	20,0	12,0-25,5	**54,0**	11,1-86,3	**80,7**	75,0-89,2	**84,4**	77,8-94,1
		All	**8**	**37-59**	26,4	11,1-60,0	**63,7**	11,1-86,3	**82,2**	69,4-99,1	**85,4**	73,3-100
SEPTSP	TTLWI	NE	3	33-52	13,6	8,9-20,9	**80,0**	70,0-100	**84,4**	75,9-100	**87,6**	79,2-100
		DE	1	45	7,0	-	**48,8**	-	**63,5**	-	**81,1**	
		All	**4**	**33-52**	12,0	7,0-20,9	**72,2**	48,8-100	**79,2**	63,5-100	**86,0**	79,2-100
SEPTTR	TRZAW	NE	7	31-42	12,2	7,2-18,9	**70,2***	24,1-100	**82,2**	41,4-100	**85,0**	49,4-100
		CZ + DE	4	31-51	25,9	6,3-57,5	**77,1**	59,0-97,2	**81,0**	63,6-96,9	**86,0**	65,0-100
		All	**11**	**31-51**	17,1	6,3-57,5	**72,9***	24,1-100	**81,8**	41,4-100	**85,4**	49,4-100
SEPTTR	TRZAS	NE	1	39-41	5,0	-	**67,8**	-	**78,3**	-	**92,5**	-

*Results for 50% doses are for a lower number of trials
** Dose rate 1,6 L/ha tested in only one German trial

The results from the EPPO North-East climatic zone trials (supported by data from CZ and DE) demonstrate that the proposed minimum dose of 1,5 L/ha of GF-3308 is required to achieve a claim of 'very good control' of SEPTTR in wheat, SEPTSP in triticale and RHYNSE in rye. The 1,0-1,3 L/ha dose provided insufficient control and was more variable. The data-set for SEPTSP in triticale is more limited, however it is considered that this use can be supported by the data on winter wheat which demonstrated ~~82.6%~~ 81,8% control of SEPTTR for the 1,5 L/ha dose, across ~~7~~ 11 winter wheat trials.
In high pressure mixed disease situations (*Puccinia* species also present or expected at high pressure) the higher dose of 2,0 L/ha of GF-3308 is considered to be the minimum effective dose to achieve high levels of control of both *Puccinia* species and SEPTTR in wheat, RHYNSE and PUCCRE in rye, also SEPTSP and PUCCST in triticale. Hence a dose range of 1,5–2,0 L/ha is proposed and data is presented for both doses in the Efficacy section of this document.

EPPO South-East zone

The proposed use of GF-3308 is for a single application at 1,2-2,0 L/ha, applied at BBCH 30-69 to winter and spring wheat (TRZAW and TRZAS), spelt wheat (TRZSP) and durum wheat (TRZDU) for the control of SEPTTR, PUCCRT and PUCCST. The lower dose of 1,2 L/ha GF-3308 is recommended for application where disease pressure is low and only SEPTTR ~~or PUCSST~~ is present or forecast to be a concern. In moderate disease situations a dose of 1,5 L/ha GF-3308 is recommended. Where disease pressure is very high, particularly for PUCCRT, the highest dose rate of 2,0 L/ha GF-3308 is recommended.

~~**Summary of minimum effective dose testing of GF-3308 for EPPO South-East zone (TRZAW)**~~

~~Target (EPPO code)~~	~~Number of trials~~	~~Application timing (BBCH)~~	~~Untreated % infection~~		~~% control~~									
					~~GF-3308 1.0# L/ha (60 % rate~~		~~GF-3308 1.2# L/ha~~		~~GF-3308 1.5 L/ha~~		~~GF-3308 2.0 L/ha~~		~~Reference standards~~	
			~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~
~~SEPTTR~~	~~6~~	~~31-41~~	~~17.1~~	~~6.0-24.4~~	~~**72.5**#~~	~~65.9-79.0~~	~~**80.8**#~~	~~73.1-89.0~~	~~**88.3**~~	~~74.5-100~~	~~**89.8**~~	~~76.0-100~~	~~**90.0**~~	~~75.1-100~~
~~PUCCRT~~	~~5~~	~~37-55~~	~~23.9~~	~~8.4-39.4~~	-	-	-	-	~~**80.1**~~	~~64.2-100~~	~~**89.0**~~	~~76.0-100~~	~~**86.0**~~	~~63.9-100~~
~~PUCCST~~	~~3~~	~~39-41~~	~~23.4~~	~~16.4-28.8~~	-	-	-	-	~~**95.1**~~	~~86.1-100~~	~~**96.0**~~	~~88.8-100~~	~~**95.2**~~	~~85.7-100~~

~~#Results from 4 trials~~

Summary of minimum effective dose testing of GF-3308 for EPPO South-East zone (TRZAW) (1,2-2,0 L/ha recommendations for SEPTTR and 1,5-2,0 recommendations for PUCCRT and PUCCST)

Target (EPPO code)	**Number of trials**	**Application timing (BBCH)**	**Untreated % infection**		**% control**							
					GF-3308 1,0# L/ha (50% rate)		**GF-3308 1,2# L/ha (60% rate)**		**GF-3308 1,5 L/ha (75% rate)**		**GF-3308 2,0 L/ha (100% rate)**	
			Mean	**min-max**	**Mean**	**min-max**	**Mean**	**min-max**	**Mean**	**min-max**	**Mean**	**min-max**
SEPTTR	7	31-41	17,8	6,0-32,2	**72,5**#	65,9-79,0	**80,8**#	73,1-89,0	**86,2**	74,1-100	**88,2**	76,0-100
PUCCRT	5	37-55	23,9	8,4-39,4	-	-	-	-	**81,8**	64,2-100	**87,9**	76,0-100
PUCCST	3	39-41	23,4	16,4-28,8	-	-	-	-	**95,1**	86,1-100	**96,0**	88,8-100

#Results from 4 trials

The results from the EPPO South-East climatic zone trials demonstrate that the proposed dose range of 1,2-2,0 L/ha GF-3308, is the minimum effective dose range, depending on the target disease. The 1,5 L/ha and 2,0 L/ha doses of GF-3308 will give effective control in most situations. However, depending on the disease pressure, the 2,0 L/ha dose of GF-3308 would be the minimum effective dose, where broad spectrum control across a range of target disease is required or where disease pressure from PUCCRT is high. The lower dose of 1,2 L/ha can be expected to provide effective control of SEPTTR in low disease pressure situations. The 1,0 L/ha dose (50-83% of the dose range) did not provide sufficient control of SEPTTR.

Comments of zRMS on:

Minimum effective dose tests (3.2.2)

64 efficacy trials carried out between 2014 and 2020 in 3 EPPO zones: Maritime (MAR), North-East (NE) and South-East (SE) have been submitted to determine the Minimum Effective Dose (MED) of GF-3308. All claimed pathogens: *Zymoseptoria tritici* (SEPTTR), *Puccinia recondita* (PUCCRT), *Puccina striiformis* (PUCCST) in wheat, *Rhynchosporium secalis* (RHYNSE), *Puccinia recondita* (PUCCRE) in rye, *Septoria* spp. (SEPTSP), *Puccinia striiformis* (PUCCST) in triticale were tested for MED evaluation. 53 trials were conducted with the GF-3308, 1 German trial (DE14E7B027UB01C) was carried out in 2014 with the earlier version GF-3311 of tested fungicide. The similarity between GF-3308 and GF-3311 has been demonstrated in 11 bridging trials presented in a separate chapter (Preliminary tests (3.2.1)). As dose range 1,0 – 2,0 L/ha was tested in 10 of 11 bridging trials, data for GF-3308 from these trials have been also considered for MED evaluation. For simplification, only the code name GF-3308 will be used in the assessment.
GF-3308 F was tested at the recommended dose rate of 2,0 L/ha and at lower dose rates: 1,0 L/ha (50% of of the target dose rate) in wheat, rye and triticale; 1,2 L/ha (60% of the target dose rate) in rye and triticale; 1,5 L/ha (75% of the target dose rate) in wheat, rye and triticale. In 2 German trials caried out in rye and triticale GF-3308 was also tested at dose rate of 1,3 L/ha (65% of the target dose rate) and 1,6 L/ha (80% of the target dose rate).

Percentage of difference in efficacy between tested dose rates is presented below:

Target (EPPO code)	Crop (EPPO code)	EPPO zone	Difference in efficacy between tested dose rates (%)					
			1,0 L/ha/ 2,0 L/ha	1,5 L/ha/ 2,0 L/ha	1,0 L/ha/ 1,5 L/ha	1,0 L/ha/ 1,2 L/ha	1,2 L/ha/ 1,5 L/ha	1,2 L/ha/ 2,0 L/ha
TRZAW	SEPTTR	MAR	7,3	4,6	2,7	-	-	
TRZAW	SEPTTR	NE	14,8	2,8	12	-	-	
TRZAW	SEPTTR	NE + MAR*	12,5	3,6	8,9	-	-	
TRZAW	SEPTTR	SE	-	2	18,5	8,3	10,2	
TRZAS	SEPTTR	NE	24,7	14,2	10,5	-	-	
TRZAW	PUCCRT	MAR	18,6	17,5	0,7	-	-	
TRZAW	PUCCRT	NE	6,3	2,3	5,3	-	-	
TRZAW	PUCCRT	NE + MAR*	18,4	15,3	0,3	-	-	
TRZAW	PUCCRT	SE	-	6,1	-	-	-	
TRZAW	PUCCST	MAR	21,7	12,5	11,2	-	-	
TRZAW	PUCCST	NE	9,5	2,6	6,8	-	-	
TRZAW	PUCCST	NE + MAR*	11	7,1	7	-	-	
TRZAW	PUCCST	SE	-	0,9	-	-	-	
TRZAS	PUCCST	NE	6,8	2,6	4,2			
SECCW	PUCCRE	MAR		6,1			9,1	17,7
SECCW	PUCCRE	NE		3,3			8,6	11,9
SECCW	PUCCRE	NE + MAR*		4,9			8,9	14,3
SECCW	RHYNSE	MAR		3,7			26,7	30,4
SECCW	RHYNSE	NE		2,9			13,5	16,4
SECCW	RHYNSE	NE + MAR*		3,2			18,5	21,7
TTLWI	SEPTSP	MAR	-	13,2	-	-	14,7	32,3
TTLWI	SEPTSP	NE		3,2			4,4	7,6
TTLWI	SEPTSP	NE + MAR*		7,2			7	13,8
TTLWI	PUCCST	MAR	-	8,5	-	-	2,2	13,2
TTLWI	PUCCST	NE		4,6			8,8	13,4
TTLWI	PUCCST	NE + MAR*		7			5,5	13,3

* Only countries neighbouring with Poland considered

The dose response was observed for increasing dose rate in MAR, NE, NE+MAR and SE EPPO zone for all target pathogens. Much clearer dose response was visible between the dose rate of 1,0 L/ha or 1,2 L/ha and the target dose rate of 2,0 L/ha. The highest increase of efficacy in favor of the recommended dose rate is visible in the control of SEPTSP in triticale in MAR zone (32,3%) and in the control of RHYNSE in rye in MAR zone (30,4%), as compared dose rate of 1,2 L/ha with target dose rate of 2,0 L/ha. Difference > 10% between dose

rates 1,2 and 2,0 L/ha is visible in the control of PUCCRE, RHYNSE in winter rye, PUCCST in winter triticale in NE, MAR and NE + MAR EPPO zone and in the control of SEPTSP in MAR zone and NE + MAR zone. Difference > 10% between dose rates 1,0 and 2,0 L/ha is visible in the control of: SEPTTR in winter wheat in NE and NE+MAR zone, SEPTTR in spring wheat in NE zone, PUCCRT and PUCCST in winter wheat in MAR and MAR+NE zone. Comparing dose rate 1,2 with 1,5 L/ha the highest increase in efficacy in favor of dose rate of 1,5 L/ha can be noted in the control of RHYNSE in MAR zone (difference about 27%). High increase of efficacy: 18,5% in favor of higher dose rate was noted in the control of SEPTTR in SE zone comparing dose rates 1,0 and 1,5 L/ha. Comparing dose rate 1,5 L/ha with 2,0 L/ha the differences are presented for all claimed uses with difference >10% in favor of higher dose rate of 2,0 L/ha in the control of SEPTTR in spring wheat in NE zone, PUCCRT in winter wheat in MAR zone, and NE + MAR zone, PUCCST in winter wheat in MAR zone and SEPTSP in winter triticale in MAR zone.
When considering the values of efficacy presented in the tables 3.2-30-3.2-54, dose rate of 2,0 L/ha is the most effective dose in the control of all target pathogens in all zones. This is the only dose giving >80% efficacy for the majority of claimed uses (SEPTTR/winter wheat/MAR, NE, SE zone; PUCCST/winter wheat/MAR, SE zone; SEPTTR, PUCCST/spring wheat/NE zone; PUCCRT/winter wheat/ MAR, NE, SE zone; PUCCRE, RHYNSE/winter rye/MAR, NE zone; PUCCST/winter triticale/MAR, NE zone; SEPTSP/winter triticale/NE zone), based on the only MED trials. Dose rate of 2,0 L/ha is fully supported by efficacy trial results and can be regarded as the most effective dose of GF-3308 in the control of all target pathogens.
Dose rate of 1,0 L/ha or 1,2 L/ha is visibly less effective in the control of most of the concerned pathogens: SEPTTR in wheat in MAR and NE zone, PUCCRT, PUCCST in winter wheat in MAR and NE zone, PUCCRE, RHYNSE in rye in MAR and NE zone and SEPTSP, PUCCST in triticale in MAR and NE zone. High level of efficacy (about 90%) in PUCCST control after application of GF-3308 at 1,0 L/ha was achieved in 1 trial carrried out in spring wheat under low disease pressure (8,7% infection in the untreated plot).
The average efficacy of GF-3308 at 1,2 L/ha in the control of SEPTTR on wheat in SE zone was >80% based on the 4 available trials. For this zone range of dose rates 1,2-2,0 L/ha is proposed for SEPTTR in wheat. Range of dose rates 1,5-2,0 L/ha is claimed for the control of PUCCRT and PUCCST based on the trial results showing high level of control of both pathogens after application of GF-3308 at 1,5 and 2,0 L/ha, with a slight better results for higher dose rate. For South-East zone the dose rate of 1,2 L/ha can be considered ad the minimum effective dose in the control of SEPTTR in wheat, and a dose rate of 1,5 L/ha can be considered as the minimum effective dose in the control of PUCCRT and PUCCST in wheat.
The range of dose rates 1,5-2,0 L/ha is also proposed for the control of SEPTTR in wheat and for the control of RHYNSE in rye and SEPTSP in triticale in NE EPPO zone. Based on the submitted trial results dose rate of 1,5 L/ha show high level of efficacy in the control of RHYNSE in winter rye and SEPTTR in winter wheat but moderate efficacy in the control of PUCCRT and PUCCST in winter wheat and high level of efficacy above 80% in the control of PUCCRE in winter rye and PUCCST, SEPTSP in winter triticale, but moderate control when combining data from NE and Maritime zone altogether. Dose rate 1,5 L/ha can be considered as the minimum effective dose in the control of RHYNSE in rye and SEPTTR in wheat and triticale in NE EPPO zone. For other claimed uses: PUCCRT, PUCCST in wheat, PUCCRE in rye, PUCCST in triticale, dose rate of 2,0 L/ha can be considered as the minimum effective dose in this zone.
For Maritime zone only dose rate 2,0 L/ha is proposed for all concerned uses. Lower dose rate 1,5 L/ha was less effective than a recommended dose rate 2,0 L/ha for all claimed uses.

Based on the submitted trial results the Minimum Effective Dose rate of the GF-3308 F 1,2 in the control of SEPTTR in wheat in SE EPPO zone, 1,5 L/ha in the control of RHYNSE in rye, SEPTTR in wheat SEPTSP in triticale in NE EPPO and in the control of PUCCRT, PUCCST in wheat in SE EPPO zone and 2,0 L/ha in the control of PUCCRT, PUCCST in wheat, PUCCRE in rye, PUCCST in triticale in NE EPPO zone can be considered justified. Dose rate of 2,0 L/ha can be considered justified as the minimum effective dose rate and can be recommended in MAR zone for all target pathogens. Range of dose rates 1,5-2,0 L/ha can be recommended in NE zone for the control of RHYNSE in rye and SEPTTR in wheat and SEPTSP in triticale with remark of using lower dose rates under low disease pressure. For other claimed uses dose rate of 2,0 L/ha can be recommended in this zone. Dose range 1,2-2,0 L/ha can be recommended in in the control of SEPTTR in wheat, and dose range 1,5-2,0 L/ha can be recommended in the control of PUCCRT and PUCCST in wheat in SE zone with remark of using lower dose rates under low disease pressure.

3.2.3 Efficacy tests (KCP 6.2)

This chapter covers the effectiveness of GF-3308 for the control of foliar diseases in wheat, rye and triticale. Data are presented across a range of diseases in wheat, rye and triticale. The effectiveness of GF-3308 is based on a single application between BBCH 31-61; at a dose of 2.0 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone (across all crops), at a dose range of 1.5-2.0 L/ha in the EPPO North-East climatic zone countries of the Central EU Authorisation zone (across all crops), and dose rate range of 1.2-2.0 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone (only on wheat).
Efficacy data presented in the tables within this section are from one key leaf layer, where differences were apparent at the time of assessment and which satisfy the minimum level of disease on the untreated leaves (≥5% infection). Where results on more than one leaf were available, the chosen leaf is the highest assessed leaf with >5% infection at assessment. In the majority of cases this was Leaf 1 or Leaf 2. It is considered that in wheat, rye and triticale, disease control on Leaf 1 and Leaf 2 will have the greatest positive impact on crop yield. Where lower leaves have been used, this is due to insufficient disease on Leaf 1 or Leaf 2 (in the untreated) at assessment, whilst higher levels of disease infection (>10%) were present on those lower leaves, representing a more robust test of the product.
Assessment timings chosen in the following summary tables are for effectiveness at approximately 3-6 weeks after application (21-42 DAA), to reflect the disease protection delivered by a single dose of GF-3308. The longer assessment timings have only been used where disease levels were less than 5% at the earlier assessment timings. Early assessment timings (11-21 days) have been used when no appropriate later timings were available. **Note:** Throughout this section. DAA = days after first/one application, DAB = days after second/two applications. 'DAA' is also used for trials where the single application treatment is applied as timing B and 'DAB' for the two-application regime applied at timing A and C.
Where a trials report includes calculated percentage control values, those figures have been used. If the percentage control was not calculated in the trials report, (i.e. only percentage infection (severity) was recorded), the percentage control has been calculated using an Abbott's formula.

Statistical analysis
The tabulated efficacy data presented in this section of the biological dossier are showing the treatment means of the percentage control relative to the untreated. Across trials the minimum and maximum means of percentage infection or control are presented in the summary tables.

3.2.3.1 GF-3308 for the control of SEPTTR in wheat

This section addresses the efficacy of GF-3308, for the control of SEPTTR on wheat, when applied at the proposed label rate of 2,0 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone, 1,5-2,0 L/ha in Poland (EPPO North-East climatic zone) and the proposed dose range of 1,2-2,0 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone.

Table 3.2-55 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 13,5-30 m² EPPO North-East: ~~15-36~~ 20-30 m² EPPO South-East: 12-36 m²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: ~~13~~ 24 TRZAW EPPO North-East: 12 15 TRZAW EPPO North-East: 1 TRZAS EPPO South-East: ~~17~~ 18 TRZAW
	Varieties per crop (number of trials)	EPPO Maritime: Akteur ~~(2)~~ (3), Ambition, Bohemia, Etana, JB Asano ~~(3)~~ (4), Hereford, Pionier, Socrates, Substance, Toras, Crusoe, Patras, Pakito, Bermude, Mariboss, Dinosor, Relay, Trapez, Tobak EPPO North-East (TRZAS): Arkadia (2), Artis, Fidelius, Fredis, Muszelka, Sailor, Wydma, Zentos ~~(2)~~ (3), Zyta (2), Bogatka (2) EPPO North-East (TRZAS): Tybalt EPPO South-East: Antonius, Ariesan (2), Buzogány, Enova, Genius, GK Élet, GK Körös, Glossa (2), Iridium, Miranda (3), MV Suba, MV-Toldi, Sadovo 772, Andrada
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 31-~~51~~ 65 EPPO North-East: ~~31-49~~ 30-56 EPPO South-East: BBCH ~~31~~30-47
	Timing Pest stage at application	GF-3308 has both protectant and curative properties. For the control of SEPTTR applications were timed to cover these situations from commencing when there was a risk of infection with SEPTTR or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	1
	Spray volumes	~~200~~ 150-~~300~~ 250 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were approximately 2-3 weeks after application, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where SEPTTR is a prevalent disease.

Introduction

In total ~~43~~ 58 field trials were conducted to demonstrate the efficacy of GF-3308 for the control of SEPTTR in winter wheat (TRZAW ~~42~~ 57 trials) and spring wheat (TRZAS 1 trial). To support the label claims, GF-3308 was tested at the proposed label rate of 2,0 L/ha (EPPO Maritime zone), 1,5-2,0 L/ha (EPPO North-East) and a range from 1,2 to 2,0 L/ha in EPPO South-East trials, in accordance with the EPPO Standard PP 1/26, '*Foliar and ear diseases on cereals*'.
The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which followed the EPPO standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted the Czech Republic ~~(2)~~ (3), Denmark ~~(3)~~ (4), France (4), United Kingdom (2) and Germany ~~(8)~~ (11) in the EPPO Maritime climatic zone, Latvia (4) and Poland ~~(9)~~ (12) in the EPPO North-East climatic zone and Bulgaria (2), Hungary (8) and Romania ~~(7)~~ (8) in the EPPO South-East climatic zone, between 2014 and 2020.
On the basis of the EPPO Standard PP 1/241 '*Guidance on comparable climates'*, the trials included in this dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime, North-East and South-East EPPO climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from each of these zones, so are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations
The efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-9.

Sites
Trial sites were selected on the basis of known pest pressure, favourable agronomic and environmental factors, in areas representative of those where the crop is grown commercially and where SEPTTR is a prevalent disease. SEPTTR is a disease which multiplies rapidly at short cycles, under warm climatic conditions, such as are found in the Maritime, North-East and South-East EPPO climatic zones. For trial site and application details, see Appendix 3 and Appendix 4 in the BAD. Figure 3.2 - 2 provides an overview of the geographical distribution of the efficacy trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3308#	EC	100 g/L fenpicoxamid	1,2, 1,5, 2,0	60, 75, 100
Proline 275	EC	275 g/L prothioconazole	0,72	198
Aviator Xpro 225EC	EC	75 g/L bixafen + 150 g/L prothioconazole	1,0-1,25	225-281
Input	EC	160 g/L prothioconazole + 300 g/L spiroxamine	1,0	460
Vertisan 200 EC	EC	200 g /L penthiopyrad	1,0	200
Librax	EC	62,5 g/L fluxapyroxad + 45 g/L metconaozole	2,0	215

#The data includes results from ~~ten trials~~ eleven (CZ14E7B028PV01C, DE14E7B014FS01, DE14E7B026UB01C, DE14E7B027UB01C, DE14E7B028TS01, LV14E7B028MN02C, PL14E7B014AS01C, PL14E7B014AS03C, PL14E7B028AS01C, PL14E7B028AS02C and HU14E7B014AB01C) conducted in 2014, where an earlier formulation, GF-3311 (67.5 g as/l) was used. The same quantities of active substance were applied with each formulation (in 2014 using GF-3311 or in later trials using GF-3308) so both treatments are comparable. As stated previously in the Preliminary data section 3.2.1.9, due to the similarity of the composition of formulations, data generated with GF-3311 is considered comparable, so supports the evaluation of GF-3308. Bridging trials established in 2015 and 2016 comparing GF-3311 and GF-3308 against SEPTTR, confirm the equivalent performance of these two formulations. For ease of summarisation, the 2014 trials applied with GF-3311 are referred to as GF-3308 within this section.

Experimental details

The ~~43~~ 58 efficacy trials were conducted to GEP by officially recognized efficacy testing organisations and followed the appropriate EPPO Standards. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 13,5 m² and 36 m². The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers, equipped with conventional or low drift flat fan nozzles, delivering water volumes between ~~200 and 300~~ 150-250 L/ha. GF-3308 was applied as a single application at BBCH ~~31-51~~ 30-65 of winter wheat and at BBCH 39-41 of spring wheat. The treatments were typically sprayed when SEPTTR had established on the lower leaves, to stop further disease development. For further site and application details of individual trials, see Appendix 3 and Appendix 4 in the BAD.

Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with SEPTTR or leaves which were already senesced to a high degree in both treated and untreated plots, were excluded from summarization. Assessments were generally on Leaf 1 or Leaf 2, with a few assessments on Leaf 3 or Leaf 4.

Results

Proposed dose of 2,0 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

In total ~~13~~ 24 small plot GEP efficacy field trials were conducted to demonstrate the effectiveness of GF-3308 for the control of SEPTTR in winter wheat, at the proposed label rate of 2,0 L/ha, following a single application applied at BBCH 31-~~51~~ 65 of the crop. The trials were conducted in the Czech Republic ~~(2)~~ (3), Denmark ~~(3)~~ (4), France (4), United Kingdom (2) and Germany ~~(8)~~ (11) in the EPPO Maritime climatic zone, between 2014-~~2017~~2019. The data includes trials where SEPTTR was established before application (including on the leaves assessed for control in some trials) and trials where SEPTTR did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3308. Assessments across ~~12~~ 20 of the ~~13~~ 24 trials were on either Leaf 1 or Leaf 2 (~~one~~ four trials on Leaf 4), as these leaves had high levels of SEPTTR infection (mean of ~~25.5%~~ 24,8% in the untreated - range 5,0-75%), so was considered to be a robust test of the product.

Across these ~~13~~ 24 EPPO Maritime climatic zone trials, GF-3308 achieved mean control of SEPTTR of ~~92.5%~~ 86,0% (range ~~78.7~~ 52-100%), 21-~~49~~ 56 days after application, compared to ~~78.6%~~ 76,9% for the reference standards. In nineteen trials, GF-3308 was compared directly to the prothioconazole standard, Proline, and achieved mean control of ~~93.9%~~ 86,5% compared to mean control of ~~73.2%~~ 74,2% using Proline. In four trials, GF-3308 was compared directly to the bixafen + prothioconazole standard, Aviator Xpro, and GF-3308 achieved mean control of ~~89.2%~~ 89,1% compared to mean control of 90,7% using Aviator Xpro. In one trial, GF-3308 was compared directly to the fluxapyroxad + metconazole standard, Librax, and achieved control of 65,0% compared to mean control of 72,7% using Librax. Across all trials, control of SEPTTR achieved by GF-3308 was either statistically higher or not statistically different from the standards.

The results are summarised in Table 3.2-56, with the results of the individual trials detailed in the BAD and in the single trial reports. Results in Table 3.2-56 are shown across all trials first ~~(shaded grey)~~, before being shown orthogonally against the various standards.

~~**Table 3.2-56: Efficacy of GF-3308 applied at 2.0 L/ha for the control of SEPTTR in winter wheat (TRZAW) between 2014 and 2017. Assessment at 21-49 days after a single application.**~~

~~EPPO Zone~~	~~Number of trials~~	~~Untreated: SEPTTR % infection~~		~~% control of SEPTTR~~					~~Significantly >, =, < Standards~~
				~~GF-3308 2.0 L/ha~~		~~Reference standard~~			
		~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Product/dose~~	
~~Maritime~~	~~13~~	~~25.5~~	~~5.0-75.0~~	~~**92.5**~~	~~78.7-100~~	~~**78.6**~~	~~20.0-100~~	~~All~~	~~2 >, 7 = P, 4 = A~~
~~Maritime*~~	~~9~~	~~32.2~~	~~5.0-75.0~~	~~**93.9**~~	~~80.6-100~~	~~**73.2**~~	~~20.0-100~~	~~Proline/0.72 L/ha~~	~~2 > P, 7 = P~~
~~Maritime**~~	~~4~~	~~10.5~~	~~6.1-15.0~~	~~**89.2**~~	~~78.7-100~~	~~**90.7**~~	~~74.0-100~~	~~Aviator Xpro/1.25 L/ha~~	~~4 = A~~

~~*Direct comparison to Proline (P)~~
~~**Direct comparison to Aviator Xpro (A)~~

Table 3.2-56: Efficacy of GF-3308 applied at 2,0 L/ha for the control of SEPTTR in winter wheat (TRZAW) between 2014 and 2019. Assessment at 21-56 days after a single application.

EPPO Zone	Number of trials	Untreated: SEPTTR % infection		% control of SEPTTR					Significantly >, =, < Standards
				GF-3308 2,0 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
Maritime	24	24,8	5,0-75,0	**86,0**	52,0-100	**76,9**	29,3-100	All	4 >, 15 = P, 4 = A, 1 = L
Maritime*	19	26,2	5,0-75,0	**86,5**	52,0-100	**74,2**	29,3-100	Proline/0,72 L/ha	4 > P, 15 = P
Maritime**	4	10,5	6,1-15,0	**89,1**	78,7-100	**90,7**	74,0-100	Aviator Xpro/1,25 L/ha	4 = A
Maritime***	1	55,0	-	**65,0**	-	**72,7**	-	Librax/ 2,0 L/ha	1 = L

*Direct comparison to Proline (P)
**Direct comparison to Aviator Xpro (A)
*** Direct comparison to Librax (L)

Summary and conclusions for the proposed dose of 2,0 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Based on results from the ~~13~~ 24 EPPO Maritime climatic zone trials, demonstrating mean overall control of SEPTTR in winter wheat of ~~92.5%~~ 86,0% from a single application of GF-3308 at 2,0 L/ha, it is considered that the proposed label claim for control of SEPTTR is fully supported.

Proposed dose range of 1,5-2,0 L/ha for Poland (EPPO North-East climatic zone)

In total, ~~12~~ 16 small plot GEP efficacy field trials were conducted to demonstrate the effectiveness of GF-3308 for the control of SEPTTR in winter and spring wheat at the proposed label rates of 1,5 and 2,0 L/ha, following a single application applied at BBCH ~~31-49~~ 30-56 of the crop. The 1,5 L/ha dose was present in ~~5~~ 9 of the ~~12~~ 16 trials. The trials were conducted in Latvia (4) and Poland ~~(8)~~ (12) in the EPPO North-East climatic zone. The data included trials where SEPTTR was established before application (including on the leaves assessed for control in some trials) and trials where SEPTTR did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3308. Assessments across ~~10~~ 11 of the ~~12~~ 16 trials were on Leaf 1 or Leaf 2 (with two trials on Leaf 4 and three trials on Leaf 3), as these leaves had high levels of SEPTTR infection (mean of ~~16.0%~~ 14,5% in the untreated - range 5,8-~~49.1%~~ 49,1% for TRZAW and 5,0% for TRZAS) so was considered to be a robust test of the product.
Note: Four trials (PL14E7B014AS01C, PL14E7B014AS03C, PL15E7B041AS01C and PL15E7B041AS02C) were based on a two-dose regime. However, the results used in this dossier are based on assessments after the first application, but before the second application (hence the assessment timings of for these trials are somewhat shorter, at 16-27 days after application). These trials are considered to be valid to support the GAP of one application.

Across the ~~12~~ 15 EPPO North-East climatic zone trials on winter wheat, GF-3308 at 2,0 L/ha achieved mean control of SEPTTR of ~~89.5%~~ 89,5% (range ~~71.0~~49,4-100%), ~~16-45~~ 14-42 days after one application. This is comparable to the level of control achieved by the reference products, at 88,5% (range 69,4-100%). For prothioconazole standard Proline, ~~at~~ the efficacy was ~~86.9%~~ 87,7% (range ~~69.4 -98,9%~~ 69,4-100%), across 14 trials. Across the majority of trials, control of SEPTTR achieved by GF-3308 was statistically higher than or not statistically different to the standards, ~~Proline.~~
Across ~~five~~ eight EPPO North-East climatic zone trials on winter wheat, GF-3308 at 1,5 L/ha achieved mean control of SEPTTR of ~~83.0%~~ 84,2% (range ~~66.1~~ 41,4-100%), ~~33-45~~ 14-39 days after one application, which is comparable to control achieved by the standards, at 89,1% (range 69,4-100%). For prothioconazole standard Proline, ~~at~~ the efficacy was ~~85.7%~~ 87,5% (range ~~69.4-97.1%~~ 69,4-100%) across 7 rials. Across the majority of trials, control of SEPTTR achieved by GF-3308 was not statistically different to the standards. ~~Proline.~~
In addition to these trials, data from neighbouring countries in the EPPO Maritime climatic zone are available and can also be considered supportive of the proposed use. At the 2,0 L/ha dose rate, ~~10~~ 14 trials were conducted in the Czech Republic and Germany, demonstrating comparable control to that seen in the EPPO North-East climatic zone trials, at ~~93.3%~~ 86,1% (range ~~78.7~~ 52,0-100%). Combined with the ~~12~~ 15 EPPO North-East climatic zone trials, these gave mean control of SEPTTR of ~~91.2%~~ 87,9%, across the ~~22~~ 29 trials. In ~~18~~ 23 trials, 2,0 L/ha GF-3308 was compared directly to the prothioconazole standard Proline, and achieved mean control of ~~91.7%~~ 88,2%, compared to mean control of ~~87.8%~~ 85,1% using Proline. At the 1,5 L/ha dose rate, ~~four~~ seven trials were conducted in the Czech Republic and Germany, demonstrating comparable control to that seen in the EPPO North-East climatic zone trials, at ~~86.9%~~ 78,3% (range ~~78.9~~ 59,1%-96,9%). Combined with the ~~five~~ eight EPPO North-East climatic zone trials results, these gave mean control of SEPTTR of ~~84.7%~~ 81,4%, across the ~~nine~~ fifteen trials. In ~~eight~~ twelve trials, 1,5 L/ha GF-3308 was compared directly to the prothioconazole standard Proline, and ~~both treatments achieved~~ the mean ~~control~~ efficacy ~~as of~~ was ~~84.4%~~ 81,2% for GF-3308 and 84,3% for standard Proline. Details for the German and Czech trials are in the EPPO Maritime climatic zone section, above.
The results are summarised in The results are summarised in Table 3.2-57 are the results of the individual trials are detailed in the BAD and in the single trial reports. Results in Table 3.2-57 are shown across all trials ~~first (shaded grey~~), before being and are shown orthogonally against the various standards.

~~**Table 3.2-57: Efficacy of GF-3308 applied at the dose rate range of 1.5-2.0 L/ha for the control of SEPTTR in winter wheat (TRZAW) between 2014 and 2017. Assessment at 16-45 days after a single application**~~

EPPO Zone/ Country	Number of trials	Untreated: SEPTTR % infection		% control of SEPTTR							Significantly >, =, < Standards
				GF-3308 1.5 L/ha		GF-3308 2.0 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
North-East* (1.5 L/ha)	5	14.2	7.2-18.9	**83.0**	66.1-100	**85.4**	71-100	**85.7**	69.4-97.1	Proline/0.72 L/ha	4 =, 1< P
North-East* (2.0 L/ha)	12	16.0	5.8-49.1	-	-	**89.5**	71.0-100	**86.9**	69.4-98.9	Proline/0.72 L/ha	1 >, 10 =, 1< P
CZ + DE (1.5 L/ha)	4	21.9	6.1-57.5	**86.9**	78.9-96.9	**92.3**	80.6-100	**85.9**	58.3-96.7	All	3 = P, 1 = A
CZ + DE (2.0 L/ha)	10	20.2	5.0-61.0	-	-	**93.3**	78.7-100	**90.1**	58.3-100	All	1 >, 5 = P, 4 = A
North-East + CZ + DE (1.5 L/ha)	9	17.6	6.1-57.5	**84.7**	66.1-100	**88.5**	71-100	**85.8**	58.3-97.1	All	7 =, 1 < P 1 = A
North-East + CZ + DE (2.0 L/ha)	22	17.9	5.0-61.0	-	-	**91.2**	71.0-100	**88.4**	58.3-100	All	2 >, 15=, 1< P, 4= A
North-East + CZ + DE* (1.5 L/ha)	8	19.1	6.3-57.5	**84.4**	66.1-100	**88.2**	71-100	**84.4**	58.3-97.1	Proline/0.72 L/ha	7 =, 1 < P
North-East + CZ + DE* (2.0 L/ha)	18	19.6	5.0-61.0	-	-	**91.7**	71.0-100	**87.8**	58.3-100	Proline/0.72 L/ha	2 >, 15=, 1< P

~~*Direct comparison to Proline (P), A = Aviator Xpro~~

Table 3.2-57: Efficacy of GF-3308 applied at the dose rate range of 1,5-2,0 L/ha for the control of SEPTTR in winter wheat (TRZAW) between 2014 and 2019. Assessment at 14-56 days after a single application

EPPO Zone/ Country	Number of trials	Untreated: SEPTTR % infection		% control of SEPTTR							Significantly >, =, < Standards
				GF-3308 1,5 L/ha		GF-3308 2,0 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
North-East* (1,5 L/ha)	7	11,6	7,2-18,9	**81,9**	41,4-100	**85,0**	49,4-100	**87,5**	69,4-100	Proline/0,72 L/ha	5 =, 2 < P
North-East* (2,0 L/ha)	14	14,5	5,8-49,1	-	-	**88,7**	49,4-100	**87,7**	69,4-100	Proline/0,72 L/ha	1 >, 11 =, 2< P
North-East (1,5 L/ha)	8	12,0	7,2-18,9	**84,2**	41,4-100	**86,9**	49,4-100	**89,1**	69,4-100	All	5 =, 2 < P, 1 =V
North-East (2,0 L/ha)	15	14,5	5,8-49,1	-	-	**89,5**	49,4-100	**88,5**	69,4-100	All	1 >, 11 =, 2< P, 1 =V
North-East (1,5 and 2,0 L/ha)**	1	14,8	-	**100**	-	**100**	-	**100**	-	Vertisan/1,0 L/ha	1,5 = V, 2 =V
CZ + DE (1,5 L/ha)	7	25,3	6,1-57,5	**78,3**	59,1-96,9	**83,8**	65,0-100	**81,2**	59,0-96,9	All	5 = P, 1 = A, 1 =L
CZ + DE (2,0 L/ha)	14	21,3	5,0-61,0	-	-	**86,1**	52,0-100	**83,3**	58,5-100	All	2 >, 7 = P, 4 = A. 1 = L
North-East + CZ + DE (1,5 L/ha)	15	18,2	6,1-57,5	**81,4**	41,4-100	**85,4**	49,4-100	**85,4**	59,0-100	All	10=, 2 < P, 1 = A, 1 = V, 1 = L
North-East + CZ + DE (2,0 L/ha)	29	17,8	5,0-61,0	-	-	**87,9**	49,4-100	**86,0**	59,0-100	All	3>, 2 <,, 18 = P, 4 = A. 1 = L, 1 =V
North-East + CZ + DE* (1,5 L/ha)	12	16,4	6,3-57,5	**81,2**	41,4-100	**85,5**	49,4-100	**84,3**	59,2-100	Proline/0,72 L/ha	10 =, 2 < P
North-East + CZ + DE* (2,0 L/ha)	23	17,6	5,0-61,0	**-**	-	**88,2**	49,4-100	**85,1**	59,0-100	Proline/0,72 L/ha	3 >, 2 <, 18 = P,

*Direct comparison to Proline (P),
** Direct comparison to Vertisan (V),
A = Aviator Xpro

In addition to data on winter wheat, one trial was conducted on spring wheat (TRZAS). This trial demonstrated broadly comparable levels of control of SEPTTR to those seen on winter wheat (78,3% using the 1,5 L/ha dose rate, 92,5% using the 2,0 L/ha dose rate, and 88,3% using Proline) at 14 days after application - the latest timing for assessment of control of SEPTTR in this trial. The results are summarised in Table 3.2-58 and the results of the individual trials are detailed in the BAD and in the single trial report.

Table 3.2-58: Efficacy of GF-3308 applied at the dose rate range of 1,5-2,0 L/ha for the control of SEPTTR in spring wheat (TRZAS) in 2016. Assessment at 14 days after a single application

EPPO Zone	Number of trials	Untreated: SEPTTR % infection		% control of SEPTTR							Significantly >, =, < Standards
				GF-3308 1,5 L/ha		GF-3308 2,0 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
North-East	1	5,0	-	**78,3**	-	**92,5**	-	**88,3**	-	Proline/0,72 L/ha	1,5 = P, 2,0 = P

P = Proline

Summary and conclusions for the proposed dose rate range of 1,5-2,0 L/ha in the EPPO North-East climatic zone

Where disease pressure is low and only SEPTTR requires control, dose rate of 1,5 L/ha is recommended. Based on data from ~~nine~~ fifteen trials on winter wheat using the 1,5 L/ha dose rate of GF-3308, demonstrating mean overall control of SEPTTR of ~~84.7%~~ 81,4% (~~5~~ 8 EPPO North-East climatic zone trials at ~~83.0%~~ 84,2% control and ~~4~~ 7 Czech Republic and German trials at ~~86.9%~~ 78,3% control) plus one EPPO North-East climatic zone trial on spring wheat, demonstrating 78,3% control of SEPTTR, it is considered that the proposed claim for control of SEPTTR using GF-3308 at a dose rate of 1,5 L/ha on winter and spring wheat is fully supported.
In high pressure mixed disease situations (*Puccinia* species also present or expected), the higher dose of 2,0 L/ha is recommended. Based on data from ~~22~~ 29 trials on winter wheat using the 2,0 L/ha dose rate, demonstrating mean overall control of SEPTTR of ~~91.2%~~ 87,9% (~~12~~ 15 EPPO North-East trials at ~~89.5%~~89,5% control and ~~10~~ 14 Czech Republic and German trials at ~~93.3%~~ 86,1% control) plus one EPPO North-East climatic zone trial on spring wheat demonstrating 92,5% control of SEPTTR, it is considered that the proposed claim for control of SEPTTR using GF-3308 at a maximum dose rate of 2,0 L/ha on winter and spring wheat is fully supported, as is the lower dose rate of 1,5 L/ha for situations where SEPTTR is the main target disease or there is lower disease pressure. ~~from a complex of diseases.~~
A dose range of 1,5-2,0 L/ha will be proposed for diseases of wheat to offer growers flexibility so they can adjust dose according to the conditions.

Proposed dose of 1,2-2,0 L/ha for South-East climatic zone countries of the Central EU Authorisation zone

In total, ~~17~~ 18 GEP small plot efficacy field trials were conducted to demonstrate the effectiveness of GF-3308 for the control of SEPTTR in winter wheat, across the range of proposed label rates, following a single application at BBCH ~~31-47~~ 30-41 of the crop. The trials were conducted in Bulgaria (2), Hungary (8) and Romania ~~(7)~~ (8) in the EPPO South-East climatic zone. The data included trials where SEPTTR was established before application (including on the leaves assessed for control in some trials) and trials where SEPTTR did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3308. Assessments in ~~16~~ 17 of the ~~17~~ 18 trials were on Leaf 1 or Leaf 2 (with one trial on Leaf 4), as these leaves had high levels of SEPTTR infection (mean of ~~17.7%~~ 17,2% in the untreated - range 6,0-51,3%) so was considered to be a robust test of the product.
A single application of GF-3308 at 2,0 L/ha achieved mean control of ~~91.1%~~ 89,9% (range 76,0-100%) against SEPTTR across the ~~11~~ 12 trials where this dose was applied, compared to ~~87.4%~~ 87,3% using the reference standards. When compared directly to the various standards used, GF-3308 at 2,0 L/ha achieved mean control of ~~90.6%~~ 89,3%, compared to 85,8% using the prothioconazole standard Proline (~~9~~ 10 trials), ~~98.5%~~ 95,5% compared to 100% using the bixafen + prothioconazole standard Aviator Xpro (one trial) and ~~90.5%~~ 90,6% compared to 89,4% using the penthiopyrad standard Vertisan (one trial). The 1,5 L/ha dose rate achieved mean control of SEPTTR of ~~89.3%~~ 88,0% (range ~~74.5~~74,1-100%) across the ~~10~~ 11 trials where this dose was applied, compared to ~~88.6%~~ 88,2% using the reference standards. When compared directly to the various standards used, GF-3308 at 1,5 L/ha achieved mean control of ~~87.4%~~ 84,7%, compared to ~~87.6%~~ 87,0% using the prothioconazole standard Proline (~~4~~ 5 trials), 85,5% control compared to 88,8% using the bixafen + prothioconazole standard Aviator Xpro (two trials), 94,2% control compared to 89,4% using the prothioconazole + spiroxamine standard Input (three trials) and 90,4% compared to 89,4% using the penthiopyrad standard Vertisan (one trial).
The 1,2 L/ha dose rate achieved mean control of SEPTTR of 81,1% (range 73,1-89,0%) across the 6 trials where this dose was applied, which was comparable to the reference standards at ~~85.5%~~ 88,2%. When compared directly to the various standards used, GF-3308 at 1,2 L/ha achieved mean control of 81,9%, compared to ~~83.6%~~ 91,6% using the prothioconazole standard, Proline (2 trials), 80,5% control, compared to 77,6% using the bixafen + prothioconazole standard, Aviator Xpro (one trial) and ~~80.8%~~ 80,9% control, compared to 89,4% using the prothioconazole + spiroxamine standard, Input (three trials).

The results are summarised in Table 3.2-59 and the results of the individual trials are detailed in the BAD and in the single trial reports. Results in Table 3.2-59 are shown across all trials for each dose first (shaded grey), before being shown orthogonally against the various standards.

Table 3.2-59: Efficacy of GF-3308 applied at 1.2, 1.5 and 2.0 L/ha for the control of SEPTTR in winter wheat (TRZAW) between 2014 and 2020. Assessment at 22-49 days after a single application.

EPPO Zone	Number of trials	Untreated: SEPTTR % infection		% control of SEPTTR								Significantly >, =, < Standards
				GF-3308 1.2 L/ha		GF-3308 1.5 L/ha		GF-3308 2.0 L/ha		Reference standard		
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	
South-East (2.0 L/ha dose)	11	21.6	6.0-51.3	-	-	-	-	**91.1**	76.0-100	**87.4**	75.1-100	9= P, 1 = A, 1 =V
South-East#	9	20.4	6.0-51.3	-	-	-	-	**90.6**	76.0-100	**85.8**	75.1-100	9 = P
South-East##	1	22.5	-	-	-	-	-	**95.5**	-	**100**	-	1 = A
South-East+	1	32.2	-	-	-	-	-	**90.5**	-	**89.4**	-	1 = V
South-East (1.5 L/ha dose)	10	16.1	5.1-32.2	-	-	**89.3**	74.5-100			**88.6**	75.1-100	4 = P, 2 = A, 3 = I, 1 = V
South-East#	4	15.8	6.0-24.4	-	-	**87.4**	74.5-100	**88.2**	76.0-100	**87.6**	75.1-100	4 = P
South-East##	2	13.8	5.1-22.5	-	-	**85.5**	81.2-89.8	-	-	**88.8**	77.6-100	2 = A
South-East+	1	32.2	-	-	-	**90.3**	-	-	-	**89.4**	-	1 = V
South-East^	3	12.9	8.7-17.5	-	-	**94.2**	81.2-89.8	-	-	**89.4**	83.0-98.6	3 = I
South-East (1.2 L/ha dose)	6	10.6	5.1-17.5	**81.1**	73.1-89.0	-	-	-	-	**85.5**	77.6-98.6	2 = P, 1 = A, 2 =, 1 < I
South-East#	2	10.0	6.1-13.8	**81.9**	79.8-84.0	-	-	-	-	**83.6**	81.5-85.7	2 = P
South-East##	1	5.1	-	**80.5**	-	-	-	-	-	**77.6**	-	1 = A
South-East^	3	12.9	8.7-17.5	**80.8**	73.1-89.0	-	-	-	-	**89.4**	83.0-98.6	2 =, 1 < I

#Direct comparison with Proline (P) , ##Direct comparison with Aviator Xpro (A), +Direct comparison with Vertisan (V), ^Direct comparison with Input (I)

Table 3.2-59: Efficacy of GF-3308 applied at 1,2, 1,5 and 2,0 L/ha for the control of SEPTTR in winter wheat (TRZAW) between 2014 and 2020. Assessment at 22-49 days after a single application.

EPPO Zone	**Number of trials**	**Untreated: SEPTTR % infection**		**% control of SEPTTR**								**Significantly >, =, < Standards**
				GF-3308 1,2 L/ha		**GF-3308 1,5 L/ha**		**GF-3308 2,0 L/ha**		**Reference standard**		
		Mean	**min-max**	**Mean**	**min-max**	**Mean**	**min-max**	**Mean**	**min-max**	**Mean**	**min-max**	
South-East (2,0 L/ha dose)	12	20,4	6,0-51,3	-	-	-	-	**89,9**	76,0-100	**87,3**	75,1-100	10 = P, 1 = A, 1 =V
South-East#	10	19,1	6,0-51,3	-	-	-	-	**89,3**	76,0-100	**85,8**	75,1-100	10 = P
South-East##	1	22,5	-	-	-	-	-	**95,5**	-	**100**	-	1 = A
South-East+	1	32,2	-	-	-	-	-	**90,6**	-	**89,4**	-	1 = V
South-East (1,5 L/ha dose)	11	15,3	5,1-32,2	-	-	**88,0**	74,1-100	-	-	**88,2**	75,1-100	5 = P, 2 = A, 3 = I, 1 = V
South-East#	5	14,0	6,0-24,4	-	-	**84,7**	74,1-100	**88,2**	76,0-100	**87,0**	75,1-100	5 = P
South-East##	2	13,8	5,1-22,5	-	-	**85,5**	81,2-89,8	-	-	**88,8**	77,6-100	2 = A
South-East+	1	32,2	-	-	-	**90,4**	-	-	-	**89,4**	-	1 = V
South-East^	3	12,9	8,7-17,5	-	-	**94,2**	90,2-98,5	-	-	**89,4**	83,0-98,6	3 = I
South-East (1,2 L/ha dose)	6	10,6	5,1-17,5	**81,1**	73,1-89,0	-	-	-	-	**88,2**	77,6-98,6	2 = P, 1 = A, 2 =, 1 < I
South-East#	2	10,0	6,1-13,8	**81,9**	79,8-84,0	-	-	-	-	**91,6**	85,7-97,5	2 = P
South-East##	1	5,1	-	**80,5**	-	-	-	-	-	**77,6**	-	1 = A
South-East^	3	12,9	8,7-17,5	**80,9**	73,1-89,0	-	-	-	-	**89,4**	83,0-98,6	2 =, 1 < I

#Direct comparison with Proline (P)
##Direct comparison with Aviator Xpro (A),
+Direct comparison with Vertisan (V)
^Direct comparison with Input (I)

Summary and conclusions for the proposed dose range of 1,2-2,0 L/ha for EPPO South-East climatic zone countries of the Central EU Authorisation zone

Based on ~~11~~ 12 EPPO South-East climatic zone trials results, demonstrating mean overall control of SEPTTR in winter wheat of ~~91.1%~~ 89,9% from a single application of GF-3308 at 2,0 L/ha, it is considered that the proposed claim for control of SEPTTR is fully supported. The 2,0 L/ha dose is considered to be appropriate for situations where the wheat variety has low resistance to SEPTTR or where fungicide resistance to SEPTTR may be a concern and season long control is required. In situations where fungicide resistance is not a concern, a lower dose of 1,5 L/ha is considered appropriate, as this has demonstrated ~~89.3%~~ 88,0% control across a total of ~~10~~ 11 trials.
For situations where the wheat variety has inherent resistance to SEPTTR and fungicide resistance is not a concern, the lowest dose in the proposed range of 1,2 L/ha is considered appropriate, as this demonstrated 81,1% control across a total of six trials.
Across the majority of trials, the level of control of SEPTTR achieved by GF-3308, at all three dose rates tested, was not statistically different from the standards.
Note: Many EU Member State regulatory authorities in the EPPO South-East climatic zone, prefer to see dose ranges for Plant Protection Products, as this allows some level of flexibility for the user, which would otherwise not be permitted by law.

3.2.3.2 GF-3308 for the control of PUCCRT in winter wheat

This section addresses the efficacy of GF-3308, for the control of PUCCRT on winter wheat, when applied at the proposed label rate of 2,0 L/ha, in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone and Poland (EPPO North-East climatic zone of the Central EU Authorisation zone), and the proposed dose range of 1,5-2,0 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone.

Table 3.2-60 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 20-36 m² EPPO North-East: 20-30 m² EPPO South-East: 20-30 m²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: ~~12~~ 13 TRZAW EPPO North-East: 8 TRZAW EPPO South-East: ~~9~~ 10 TRZAW
	Varieties per crop (number of trials)	EPPO Maritime: Artist, Bohemia, Cordiale, Crusoe (2), Hermann, Muza, Pionier, Socrates, Tobak (2), Toras, Patras EPPO North-East: Bogatka (3), Sailor (2), Sukces, Turnia, Zyta EPPO South-East: Antonius, Enova, GK Élet ~~(2)~~ (3), Iridium (2), Lupus, Marshall, Sadovo 772
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 32-61 EPPO North-East: BBCH 39-61 EPPO South-East: BBCH 37-55
	Timing Pest stage at application	GF-3308 has both protectant and curative properties. For the control of PUCCRT applications were timed to cover these situations from commencing when there was a risk of infection with PUCCRT or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	EPPO Maritime: 1 application EPPO North-East: 1 application EPPO South-East: 1 application (~~5~~ 6 trials), 2 applications (4 trials)
	Spray volumes	200-300 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were aimed at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were aimed at the timing of application, 2-3, 5-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where PUCCRT is a prevalent disease.

Introduction

In total, ~~29~~ 31 field trials were conducted to demonstrate the efficacy of GF-3308 for the control of PUCCRT in winter wheat (TRZAW). To support the label claims, GF-3308 was tested at the proposed label rate of 2,0 L/ha in EPPO Maritime and North-East trials and a range from 1,5 to 2,0 L/ha in EPPO South-East trials, in accordance with the EPPO Standard PP 1/26, '*Foliar and ear diseases on cereals*'. The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which followed the EPPO Standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Austria (1), the Czech Republic (4), Germany ~~(4)~~ (5) and the UK (3) in the EPPO Maritime climatic zone, Poland (8) in the EPPO North-East climatic zone and Bulgaria (2) and Hungary ~~(7)~~ (8) in the EPPO South-East climatic zone, between 2014 and ~~2020~~ 2019. On the basis of the EPPO Standard PP 1/241 '*Guidance on comparable climates'*, the trials included in this dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime, North-East and South-East EPPO climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from each of these zones, so are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations
The efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-10.

Sites
Trial sites were selected on the basis of known pest pressure, favourable agronomic and environmental factors, in areas representative of those where the crop is grown commercially and where PUCCRT is a prevalent disease. PUCCRT is a disease which multiplies rapidly, at short cycles, under warm climatic conditions, such as are found in the Maritime, North-East and South-East EPPO climatic zones. For trial site and application details, see Appendix 3 and Appendix 4 in the BAD.
Figure 3.2 - 3 provides an overview of the geographical distribution of the efficacy trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3308#	EC	100 g/L fenpicoxamid	1,5, 2,0	75, 100
Proline 275	EC	275 g/L prothioconazole	0,72	198
Proline 250	EC	250 g/L prothioconazole	0,8	200
Librax	EC	62,5 g/L fluxapyroxad + 45 g/L metconaozole	2,0	215
Aviator Xpro 225EC	EC	75 g/L bixafen + 150 g/L prothioconazole	1,25	281
Vertisan 200 EC	EC	200 g /L penthiopyrad	1,0	200

#The data includes results from four trials (DE14E7B026UB01C, PL14E7B010AS01C, PL14E7B010AS02C, and PL14E7B028AS01C) conducted in 2014, where an earlier formulation GF-3311 (67,5 g a.s./L) was used. The same quantities of active substance were applied with each formulation (in 2014 using GF-3311 or in later trials using GF-3308) so both treatments are comparable. As stated previously in the Preliminary data section 3.2.1.9, due to the similarity of the composition of formulations, data generated with GF-3311 is considered comparable, so supports the evaluation of GF-3308. Bridging trials established in 2015 and 2016 comparing GF-3311 and GF-3308 against ~~PUCCRT~~ SEPTTR, confirm the equivalent performance of these two formulations. For ease of summarisation, the 2014 trials applied with GF-3311 are referred to as GF-3308 within this section.

Experimental details

The ~~29~~ 31 efficacy trials were conducted to GEP and followed the appropriate EPPO standards, by officially recognized efficacy testing organisations. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 20 m² and 36 m². The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles delivering water volumes between 200 and 300 L/ha.
In the EPPO Maritime and North-East climatic zone trials, GF-3308 was applied as a single application at BBCH ~~33~~32-61 of winter wheat. The treatments were typically sprayed when PUCCRT had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials see Appendix 3 and Appendix 4 in the BAD.
The EPPO South-East climatic zone trials were set up to support both a single and two-dose regime and in many trials included both regimes. PUCCRT is generally a late season disease, that spreads quickly onto the upper leaves of crops from BBCH 37-49, during periods of hot weather. Some of the trials were targeted specifically at PUCCRT and were based on a single application from BBCH 37-39 onwards, to provide mainly protective control of the disease. However, other trials were designed as general disease trials, with the first applications applied from BBCH 32, which is potentially too early for effective control of PUCCRT, followed by a second application at BBCH 37-49. In four EPPO South-East climatic zone trials which were based on a two-dose regime (HU15E7B012AB01C, HU15E7B012AB02, HU15E7B012AB02C and HU15E7B040AB02C), PUCCRT did not develop until 13-14 days after the second application. In these trials, the first applications were made at BBCH 32-34 of the crop and the second applications were made at BBCH 37-49. PUCCRT did not develop in these trials until 25-35 days after the first application, demonstrating how the disease can infect crops late in their development, and this is considered to be beyond the expected protection period for the first application of GF-3308 (see summary of disease levels at application for these trials below). In addition, the assessed leaf (Leaf 1) had not emerged at the time of the first application (BBCH 32-34) and would not have been protected by that spray. For these trials, results after two applications have been used, as it is considered that the second application is comparable to a single dose regime. For full site and application details of individual trials see Appendix 3 and Appendix 4 in the BAD.

Summary of disease levels at application in two-dose trials

Trial number	1st Application timing (BBCH)	PUCCRT % infection at 1st application	2nd Application timing (BBCH)	PUCCRT % infection at 2nd application	Days after 2nd application PUCCRT found in trial (days after 1st application)
HU15E7B012AB01C	32-33	0% all leaves	37-39	0% all leaves	15 days (26 days)
HU15E7B012AB02	32	0% all leaves	39~~-41~~	0% all leaves	14 days (35 days)
HU15E7B012AB02C	32-33	0% all leaves	39-41	0% all leaves	14 days (25 days)
HU15E7B040AB02C	33-34	0% all leaves	39-49	0% all leaves	13 days (28 days)

Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with PUCCRT or leaves which were already senesced to a high degree in both treated and untreated plots were excluded from summarization. Assessments were generally on Leaf 1, with three trials on Leaf 2 and one trial on Leaf 3.

Results

Proposed dose of 2,0 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

In total, ~~12~~ 13 small plot GEP trials were conducted to demonstrate the efficacy of GF-3308 for the control of PUCCRT in winter wheat at the proposed label rate of 2,0 L/ha, following a single application applied at BBCH ~~33~~32-61 of the crop. The trials were conducted in Austria (1), the Czech Republic (4), Germany ~~(4)~~ (5) and the UK (3) in the EPPO Maritime climatic zone, between 2014 and ~~2016~~ 2019. The data included trials where PUCCRT was established before application (including on the leaves assessed for control in some trials) and trials where PUCCRT did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3308. Assessments in ~~9~~ 10 of the ~~12~~ 13 trials were on Leaf 1 (two trials on Leaf 2 and one trial on Leaf 3), as these leaves had high levels of PUCCRT infection (mean of ~~26.4%~~ 25,0% in the untreated - range 5,6-97,5%) so was considered to be a robust test of the product.

Across these ~~12~~ 13 EPPO Maritime climatic zone trials, GF-3308 achieved mean control of PUCCRT of ~~89.0%~~ 86,7% (range ~~71.7~~59,4-100%), 11-48 days after application, compared to ~~93.9%~~ 93,0% for the reference ~~standards~~ products. In five trials, GF-3308 was compared directly to the prothioconazole standard Proline, and achieved mean control of 91,9% compared to mean control of ~~90.8%~~ 90,9% using Proline. In seven trials, GF-3308 was compared directly to the bixafen + prothioconazole standard, Aviator Xpro, and GF-3308 achieved mean control of 87,0% compared to mean control of 96,1% using Aviator Xpro. Across the majority of trials, control of PUCCRT achieved by GF-3308 was ~~statistically higher or~~ not statistically different, compared to the standards. **Note:** In trial CZ18E7B017PV01C, the latest assessment timing after a single application was 11 days. Later assessments followed a second application and are not considered valid to support the proposed GAP.

The results are summarised in Table 3.2-61 and the results of the individual trials are detailed in the BAD and in the single trial reports. Results in Table 3.2-61 are shown across all trials first ~~(shaded grey)~~, before being shown orthogonally against the various standards.

~~**Table 3.2-61: Efficacy of GF-3308 applied at 2.0 L/ha for the control of PUCCRT in winter wheat (TRZAW) between 2014 - 2018. Assessment at 11-48 days after a single application.**~~

EPPO Zone	Number of trials	Untreated: PUCCRT % infection		% control of PUCCRT					Significantly >, =, < Standards
				GF-3308 2,0 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
~~Maritime~~	~~12~~	~~26,4~~	~~5,6-97,5~~	~~**89,0**~~	~~71,7-100~~	~~**93,9**~~	~~73,3-100~~	~~All~~	~~1 > P, 4 = P 6 =, 1 < A~~
~~Maritime*~~	~~5~~	~~16,3~~	~~6,6-27,9~~	~~**91,9**~~	~~71,7-100~~	~~**90,8**~~	~~73,3-100~~	~~Proline/0,72 L/ha~~	~~1 > P, 4 = P~~
~~Maritime**~~	~~7~~	~~33,7~~	~~5,6-97,5~~	~~**87,0**~~	~~72,3-94,5~~	~~**96,1**~~	~~92,4-98,5~~	~~Aviator Xpro/1,25 L/ha~~	~~6 =, 1 < A~~

~~*Direct comparison to Proline (P)~~
~~**Direct comparison to Aviator Xpro (A)~~

Table 3.2-61: Efficacy of GF-3308 applied at 2,0 L/ha for the control of PUCCRT in winter wheat (TRZAW) between 2014 - 2019. Assessment at 11-48 days after a single application.

EPPO Zone	Number of trials	Untreated: PUCCRT % infection		% control of PUCCRT					Significantly >, =, < Standards
				GF-3308 2,0 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
Maritime	13	25,0	5,6-97,5	**86,7**	59,4-100	**93,0**	73,8-100	All	5 = P 6 =, 1 < A 1 = L
Maritime*	5	16,3	6,6-27,9	**91,9**	71,7-100	**90,9**	73,8-100	Proline/0,72 L/ha or Proline/0,8 L/ha	5 = P
Maritime**	7	33,7	5,6-97,5	**87,0**	72,3-94,5	**96,1**	92,4-98,5	Aviator Xpro/1,25 L/ha	6 =, 1 < A
Maritime***	1	8,0	-	**59,4**	-	**81,3**	-	Librax/2,0 L/ha	1 = L

*Direct comparison to Proline (P)
**Direct comparison to Aviator Xpro (A)
*** Direct comparison to Librax (L)

Summary and conclusions for the proposed dose of 2,0 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Based on ~~12~~ 13 EPPO Maritime climatic zone trials demonstrating mean overall control of PUCCRT in winter wheat of ~~89.0%~~ 86,7% from a single application of GF-3308 at 2,0 L/ha, it is considered that the proposed label claims for control of PUCCRT is fully supported.

Proposed maximum dose of 2,0 L/ha ~~and dose range of 1,5–2,0 L/ha~~ for Poland (EPPO North-East climatic zone)

In total, eight small plot GEP efficacy field trials were conducted to demonstrate the effectiveness of GF-3308 against PUCCRT in winter wheat, at the proposed label rate (2,0 L/ha), following a single application applied at BBCH 39-61 of the crop. The trials were conducted in Poland (8) in the EPPO North-East climatic zone. The data include trials where PUCCRT was established before application (including on the leaves assessed for control in some trials) and trials where PUCCRT did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3308. Assessments across all trials were on Leaf 1, as this leaf had high levels of PUCCRT infection (mean of 24,4% in the untreated - range 6,0-43,1%) so was considered to be a robust test of the product.
Across all 8 EPPO North-East climatic zone trials, GF-3308 achieved mean control of PUCCRT of 88,1% (range 80,9-96,0%), 23-49 days after one application, compared to 85,5% using the reference standards. In four trials, GF-3308 was compared directly to the prothioconazole standard Proline, and achieved mean control of 85,8% compared to mean control of 79,9% using Proline. In three trials GF-3308 was compared directly to the bixafen + prothioconazole standard, Aviator Xpro, and GF-3308 achieved mean control of 93,5% compared to mean control of ~~93.8%~~ 93,9% using Aviator Xpro. In one trial, GF-3308 was compared directly to the penthiopyrad standard, Vertisan, and GF-3308 achieved 80,9% control, compared to 82,7% using Vertisan. Across all trials, control of PUCCRT achieved by GF-3308 was statistically higher or not statistically different, compared to the standards.
In addition to these trials, data from ~~eight~~ nine trials conducted in neighbouring countries in the EPPO Maritime climatic zone are available and can also be considered supportive of the proposed use. These ~~8~~ 9 trials were conducted in the Czech Republic and Germany, demonstrating comparable control to that seen in the EPPO North-East climatic zone trials, at ~~89.9%~~ 86,5% (range ~~71.7~~59,4-100%). Combined with the eight EPPO North-East trials, these ~~16~~ 17 trials gave mean control of PUCCRT of ~~89%~~ 87,2%, compared to ~~94.0%~~ 89,3% using the reference standards. In 8 trials, GF-3308 was compared directly to the prothioconazole standard Proline, and achieved mean control of 89,4% compared to mean control of 85,4% for Proline. Details for the German and Czech Republic trials are in the EPPO Maritime climatic zone section, above.
The results are summarised in Table 3.2-62 and the results of the individual trials are detailed in the BAD and in the single trial reports. Results in Table 3.2-62 are shown across all trials first ~~(shaded grey)~~, before being shown orthogonally against the various standards.

~~Table 3.2-62 Efficacy of GF-3308 applied at 1.5 and 2.0 L/ha for the control of PUCCRT in winter wheat (TRZAW) between 2014 and 2016. Assessment at 23-49 days after a single application~~

EPPO Zone	Number of trials	Untreated: PUCCRT % infection		% control of PUCCRT							Significantly >, =, < Standards
				GF-3308 1.5 L/ha		GF-3308 2.0 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
North-East (2.0 L/ha)	8	24.4	6.0-43.1	-	-	**88.1**	80.9-96.0	**85.5**	68.6-95.0	All	1 >, 3 = P 3 = A, 1 = V
North-East* (2.0 L/ha)	4	28.5	18.8-43.1	-	-	**85.8**	82.2-96.0	**79.9**	68.6-95.0	Proline/0.72 L/ha	1 >, 3 = P
North-East** (2.0 L/ha)	3	19.7	6.0-27.8	-	-	**93.5**	92.9-94.2	**93.8**	92.8-94.6	Aviator Xpro/1.25 L/ha	3 = A

~~North-East^ (2.0 L/ha)~~	~~1~~	~~22.0~~	~~-~~	~~-~~	~~-~~	~~**80.9**~~	~~-~~	~~**82.7**~~	~~-~~	~~Vertisan/1.0 L/ha~~	~~1 = V~~
~~CZ + DE (2.0 L/ha)~~	~~8~~	~~23.0~~	~~5.6-97.5~~	~~-~~	~~-~~	~~**89.9**~~	~~71.7-100~~	~~**94.0**~~	~~73.3-100~~	~~All~~	~~1 >, 3 = P 3 =, 1 < A~~
~~North-East + CZ + DE (2.0 L/ha)~~	~~16~~	~~23.7~~	~~5.6-97.5~~	~~-~~	~~-~~	~~**89.0**~~	~~71.7-100~~	~~**89.7**~~	~~68.6-100~~	~~All~~	~~1 >, 3 = P 3 =, 1 < A~~
~~North-East + CZ + DE* (2.0 L/ha)~~	~~8~~	~~22.0~~	~~6.6-43.1~~	~~-~~	~~-~~	~~**89.4**~~	~~71.7-100~~	~~**85.4**~~	~~68.6-100~~	~~All~~	~~2 >, 6 = P, 6 =, 1 < A, 1= V~~
~~North-East (1.5 L/ha)~~	~~2~~	~~20.4~~	~~18.8-22.0~~	~~**79.4**~~	~~77.3-81.4~~	~~**81.7**~~	~~80.9-82.4~~	~~**75.7**~~	~~68.6-82.7~~	~~All~~	~~1 > P 1 < V~~
~~CZ (1.5 L/ha)~~	~~2~~	~~12.1~~	~~6.6-17.5~~	~~**83.8**~~	~~68.7-98.9~~	~~**100**~~	~~100-100~~	~~**95.1**~~	~~90.8-99.4~~	~~Proline/0.72 L/ha~~	~~2 = P~~
~~North-East + CZ (1.5 L/ha)~~	~~4~~	~~16.2~~	~~6.6-22.0~~	~~**81.6**~~	~~68.7-98.9~~	~~**90.8**~~	~~80.9-100~~	~~**85.4**~~	~~68.6-99.4~~	~~All~~	~~1 >, 2 = P 1 < V~~

~~*Direct comparison to Proline (P)~~
~~**Direct comparison to Aviator Xpro (A)~~
~~^Direct comparison to Vertisan (V)~~

Table 3.2-62: Efficacy of GF-3308 applied at 1,5 and 2,0 L/ha for the control of PUCCRT in winter wheat (TRZAW) between 2014 and 2019. Assessment at 23-49 days after a single application

EPPO Zone	Number of trials	Untreated: PUCCRT % infection		% control of PUCCRT							Significantly >, =, < Standards
				GF-3308 1,5 L/ha		GF-3308 2,0 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
North-East (2,0 L/ha)	8	24,4	6,0-43,1	-	-	**88,1**	80,9-96,0	**85,5**	68,6-95,0	All	1 >, 3 = P 3 = A, 1 = V
North-East* (2,0 L/ha)	4	28,5	18,8-43,1	-	-	**85,8**	82,2-96,0	**79,9**	68,6-95,0	Proline/0,72 L/ha	1 >, 3 = P
North-East** (2,0 L/ha)	3	19,7	6,0-27,8	-	-	**93,5**	92,9-94,2	**93,9**	92,9-94,6	Aviator Xpro/1,25 L/ha	3 = A
North-East^ (2,0 L/ha)	1	22,0	-	-	-	**80,9**	-	**82,7**	-	Vertisan/1,0 L/ha	1 = V
CZ + DE (2,0 L/ha)	9	21,3	5,6-97,5	-	-	**86,5**	59,4-100	**92,7**	73,8-100	All	4 = P 3 =, 1 < A 1 = L
North-East + CZ + DE (2,0 L/ha)	17	22,8	5,6-97,5	-	-	**87,2**	59,4-100	**89,3**	68,6-100	All	1 >, 7 = P 6 =, 1 < A 1 = L, 1 = V
North-East + CZ + DE* (2,0 L/ha)	8	22,0	6,6-43,1	-	-	**89,4**	71,7-100	**85,4**	68,6-100	Proline/0,72 L/ha or Proline/0,8 L/ha	1 >, 7 = P
North-East (1,5 L/ha)	2	20,4	18,8-22,0	**79,4**	77,3-81,4	**81,7**	80,9-82,4	**75,7**	68,6-82,7	All	1 > P 1 < V
CZ + DE (1,5 L/ha)	4	15,0	6,6-17,5	**61,0**	32,6-98,9	**82,8**	59,4-100	**86,3**	73,8-99,4	All	1 = P, 2 < P 1 < L
North-East + CZ + DE (1,5 L/ha)	6	16,8	6,6-27,9	**67,1**	32,6-98,9	**82,4**	59,4-100	**82,8**	68,6-99,4	All	1 =P, 1 >, 2 < P 1 < L, 1 < V

*Direct comparison to Proline (P)
**Direct comparison to Aviator Xpro (A)
^Direct comparison to Vertisan (V)

Summary and conclusions

Summary and conclusions for the proposed maximum dose of 2,0 L/ha ~~and dose range of 1,5–2,0 L/ha~~ in the EPPO North-East climatic zone

The data presented in this section is based on a large data set that confirms the 2,0 L/ha dose is highly effective on PUCCRT. Based on ~~16~~ 17 trials on winter wheat demonstrating mean overall control of PUCCRT of ~~89.0%~~ 87,2% (8 EPPO North-East trials at 88,1% control and conducted in the Czech

Republic and Germany at 89.9% 86,5% control), it is considered that the proposed claim for control of PUCCRT on wheat is fully supported.

Data from two Polish trials, and two three Czech trials and one German trial demonstrate that the 1,5 L/ha dose achieved 81.6% 67,1% control of PUCCRT, showing a moderate efficacy of GF-3308 at lower dose rate of 1,5 L/ha. Although this is a more limited dataset, it does confirm that the 1.5 L/ha dose recommended for control of SEPTTR on wheat should deliver around 80% control of PUCCRT, where PUCCRT is not the main target. The performance of GF-3308 at 1,5 L/ha on PUCCRT is further supported by 5 trials from the SE EPPO and the efficacy against the disease in rye.

After evaluation of all submitted efficacy trials, a dose range rate of 2,0 L/ha is proposed on the Polish label of 1,5-2,0 L/ha for control of diseases for the control of PUCCRT in wheat to provide high efficacy under a wide range of environmental conditions. offer growers flexibility to adjust to the disease conditions. The lower dose may be used where pressure from PUCCRT is lower and SEPTTR is the the main target disease, and the 2,0 L/ha dose should be used in high pressure rust situations.

Proposed dose of 1,5-2,0 L/ha for South-East climatic zone countries of the Central EU Authorisation zone

Nine Ten GEP small plot field trials were conducted to demonstrate the efficacy of GF-3308 for the control of PUCCRT in winter wheat at the proposed label rate following a single application at BBCH 37-55 of the crop. Results for four trials supporting the maximum dose of 2,0 L/ha are based on a two-dose regime. In these trials PUCCRT did not develop until 13-15 days after the second application, 25-35 days after the first application, which is beyond the protection period the first application of GF-3308 could be expected to deliver. It is also considered that as the first application was at BBCH 32-34 of the crop, the assessed leaf (Leaf 1) had not emerged at this timing. For these trials, results after two applications have been used, as it is considered that the second application is comparable to a single dose regime. In Table 3.2- the results from single dose and two-dose trials are shown separately and demonstrate comparable levels of control (87.7% 82,6% control of PUCCRT from one application across 6 trials and 84,8% control of PUCCRT from a two dose regime across four trials), confirming the conclusion that in these situations, the second application is comparable to a single dose regime.

The trials were conducted in Bulgaria (2) and Hungary (7) (8) in the EPPO South-East climatic zone. The data include trials where PUCCRT was established before application (including on the leaves assessed for control in some trials) and trials where PUCCRT did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3308. Assessments across all trials were generally on Leaf 1 (plus one trial on Leaf 2), as this leaf had high levels of PUCCRT infection (mean of 34.3% 35,0% in the untreated - range 8,4-62,5%) so was considered to be a robust test of the product.

A single Application of GF-3308 at 2,0 L/ha achieved mean control of 87.1% 83,4% (range 76.0 55,6-100%) against PUCCRT across 9 10 trials. Compared directly to the various standards used, GF-3308 at 2,0 L/ha achieved identical similar control to the prothioconazole standard, Proline (85.5% 81,6% using GF-3308 and 85.3% 82,9% using Proline mean of 8 9 trials) and the penthiopyrad standard Vertisan (100% control for both products, in one trial). The 1,5 L/ha dose rate achieved mean control of PUCCRT of 80.1% 81,8% (range 64,2-100%) across 5 trials. Compared directly to the various standards used, GF-3308 at 1,5 L/ha achieved mean control of 75.1% 77,3% compared to 82,5% control for the prothioconazole standard Proline (4 trials) and identical control to the penthiopyrad standard, Vertisan, (100% control for both products in one trial).

As shown in Table 3.2-, where disease levels were low (8,4% in the untreated), the 1,5 L/ha dose achieved a high level of control of PUCCRT (100%). Therefore, it is considered that the 1,5 L/ha dose of GF-3308 will provide effective control, where disease levels are lower.

The results are summarised in Table 3.2-63 and the results of the individual trials are detailed in the BAD and in the single trial reports. Results in Table 3.2-63 are shown across all trials for each dose first (shaded grey), before being shown orthogonally against the various standards

~~Table 3.2-63 Efficacy of GF-3308 applied at 1.5 and 2.0 L/ha for the control of PUCCRT in winter wheat (TRZAW) between 2014 and 2016. Assessment at 28-42 days after application.~~

EPPO Zone	Number of trials	Untreated: PUCCRT % infection		% control of PUCCRT							Significantly >, =, < Standards
				GF-3308 1.5 L/ha		GF-3308 2.0 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
South-East (2.0 L/ha)	9	34.3	8.4-62.5	-	-	**87.1**	76.0-100	**87.0**	63.9-100	All	8 = P, 1 = V
South-East# (2.0 L/ha)	8	37.5	18.0-96.5	-	-	**85.5**	76.0-96.9	**85.3**	63.9-97.6	Proline/0.72 L/ha	9 = P
South-East^ (1.5 and 2.0 L/ha)	1	8.4	-	**100**	-	**100**	-	**100**	-	Vertisan/1.0 L/ha	1 = V
South-East# (One application at 2.0 L/ha)	5	23.9	8.4-39.4	-	-	**89.0**	76.0-100	**86.0**	63.9-100	All	7 = P, 1 = V
South-East# (Two applications at 2.0 L/ha)	4	47.2	27.5-62.5	-	-	**84.8**	82.4-90	**88.2**	84.4-92.0	Proline/0.72 L/ha	4 = P
South-East (1.5 L/ha)	5	23.9	8.4-39.4	**80.1**	64.2-100	**89.0**	76.0-100	**86.0**	63.9-100	All	3 =, 1< P, 1 = V
South-East# (1.5 L/ha)	4	27.8	18.0-39.4	**75.1**	64.2-89.9	**86.3**	76.0-96.9	**82.5**	63.9-97.6	Proline/0.72 L/ha	3 =, 1 < P
South-East (Low disease)	1	8.4	-	**100**	-	**100**	-	**100**	-	Vertisan/1.0 L/ha	1.5 = V, 2.0 = V

~~#Direct comparison with Proline (P)~~
~~^Direct comparison with Vertisan (V)~~

Table 3.2-63: Efficacy of GF-3308 applied at 1,5 and 2,0 L/ha for the control of PUCCRT in winter wheat (TRZAW) between 2015 and 2016. Assessment at 28-42 days after application.

EPPO Zone	Number of trials	Untreated: PUCCRT % infection		% control of PUCCRT							Significantly >, =, < Standards
				GF-3308 1,5 L/ha		GF-3308 2,0 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
South-East (2,0 L/ha)	10	35,0	8,4-62,5	-	-	**83,4**	55,6-100	**84,6**	63,5-100	All	9 = P, 1 = V
South-East# (2,0 L/ha)	9	37,9	18,0-96,5	-	-	**81,6**	55,6-95,3	**82,9**	63,5-97,6	Proline/0,72 L/ha	9 = P
South-East^ (1,5 and 2,0 L/ha)	1	8,4	-	**100**	-	**100**	-	**100**	-	Vertisan/1,0 L/ha	1 = V
South-East# (One application at 2,0 L/ha)	6	26,8	8,4-41,3	-	-	**82,6**	55,6-100	**82,2**	63,5-100	All	5 = P, 1 = V
South-East# (Two applications at 2,0 L/ha)	4	47,2	27,5-62,5	-	-	**84,8**	82,4-90	**88,2**	84,4-92,0	Proline/0,72 L/ha	4 = P
South-East (1,5 L/ha)	5	23,9	8,4-39,4	**81,8**	64,2-100	**87,9**	76,0-100	**86,0**	63,9-100	All	3 =, 1< P, 1 = V
South-East# (1,5 L/ha)	4	27,8	18,0-39,4	**77,3**	64,2-89,9	**84,9**	76,0-91,4	**82,5**	63,9-97,6	Proline/0,72 L/ha	3 =, 1 < P
South-East (Low disease)	1	8,4	-	**100**	-	**100**	-	**100**	-	Vertisan/1,0 L/ha	1,5 = V, 2,0 = V

#Direct comparison with Proline (P)
^Direct comparison with Vertisan (V)

Summary and conclusions for the proposed dose range of 1,5-2,0 L/ha for EPPO South-East climatic zone countries of the Central EU Authorisation zone

Based on the ~~nine~~ ten EPPO South-East climatic zone trials demonstrating mean overall control of PUCCRT in winter wheat of ~~87.1%~~ 83,4% from a single (in 6 trials) or double (in 4 trials) application of GF-3308 at 2,0 L/ha, it is considered that the claim for control of PUCCRT is fully supported. Where disease levels are low, the 1,5 L/ha dose could be used, as this provided effective control of PUCCRT in this situation.
Note: Many EU Member State regulatory authorities in the EPPO South-East climatic zone, prefer to see dose ranges for Plant Protection Products, as this allows some level of flexibility for the user, which would otherwise not be permitted by law.

3.2.3.3 GF-3308 for the control of PUCCST in wheat

This section addresses the efficacy of GF-3308, for the control of PUCCST on wheat, when applied at the proposed label rate of 2,0 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone and Poland (EPPO North-East climatic zone of the Central EU Authorisation zone), and the proposed dose range of ~~1,2~~ 1,5-2,0 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone.

Table 3.2-64 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 13,5-37,5 m² EPPO North-East: 20-30 m² EPPO South-East: 20-30 m²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: ~~10~~ 11 TRZAW EPPO North-East: ~~4~~ 6 TRZAW EPPO North-East: 1 TRZAS EPPO South-East: ~~6~~ 8 TRZAW
	Varieties per crop (number of trials)	EPPO Maritime: Akteur, Ambition, JB Asano ~~(3)~~ (4), Patras, Santiago, Solstice, Substance (2) EPPO North-East (TRZAW): Bogatka (2), Muszelka, Zyta, Arkadia, Fredis EPPO North-East (TRZAS): Tybalt EPPO South-East: ~~Enova, Genius,~~ GK Élet ~~(2)~~ (5), Iridium, Miranda (2)
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH ~~32~~ 31-45 EPPO North-East: BBCH 39-56 EPPO South-East: BBCH 39-47
	Timing Pest stage at application	GF-3308 has both protectant and curative properties. For the control of PUCCST applications were timed to cover these situations from commencing when there was a risk of infection with PUCCST or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	EPPO Maritime: 1 application EPPO North-East: 1 application EPPO South-East: 1 application (7 trials), 2 applications (1 trial)
	Spray volumes	200-300 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected

	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were aimed at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were aimed at the timing of application, 2-3, 5-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where PUCCST is a prevalent disease.

Introduction

In total, ~~21~~ 26 field trials were conducted to demonstrate the efficacy of GF-3308 for the control of PUCCST in winter wheat (TRZAW) and one on spring wheat (TRZAS). To support the label claims, GF-3308 was tested at the proposed label rate of 2,0 L/ha in the EPPO Maritime and North-East climatic zone trials and a range from 1,2 L/ha to 2,0 L/ha in the EPPO South-East climatic zone trials, in accordance with the EPPO Standard PP 1/26, '*Foliar and ear diseases on cereals*'.
The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which followed the EPPO standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Denmark (3), Germany ~~(5)~~ (6) and the UK (2) in the EPPO Maritime climatic zone, Poland ~~(5)~~ (6) and Latvia (1) in the EPPO North-East climatic zone and Hungary ~~(4)~~ (6) and Romania (2) in the EPPO South-East climatic zone, between 2014 and 2020.
On the basis of the EPPO Standard PP 1/241 '*Guidance on comparable climates'*, the trials included in this dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime, North-East and South-East EPPO climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from each of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations
The efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-11.

Sites
Trial sites were selected on the basis of known pest pressure, favourable agronomic and environmental factors, in areas representative of those where the crop is grown commercially and where PUCCST is a prevalent disease. PUCCST is a disease which multiplies rapidly, at short cycles, under warm climatic conditions, such as are found in the Maritime, North-East and South-East EPPO climatic zones. For trial site and application details see Appendix 3 and Appendix 4 in the BAD. Figure 3.2 - 4 provides an overview of the geographical distribution of the efficacy trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3308#	EC	100 g/L fenpicoxamid	1,2, 1,5, 2,0	60, 75, 100
Proline 275	EC	275 g/L prothioconazole	0,72	198
Aviator Xpro 225EC	EC	75 g/L bixafen + 150 g/L prothioconazole	1,25	281
Librax	EC	62.5 g/L fluxapyroxad + 45 g/L metconazole	2,0	215
Vertisan 200 EC	EC	200 g /L penthiopyrad	1,0	200

#The data includes results from three trials (DE14E7B028TS01, HU14E7B010AB01 and HU14E7B026LM01) conducted in 2014, where an earlier formulation GF-3311 (~~67.5~~ 66,7 g as/l) was used. The same quantities of active substance were applied with each formulation in either 2014 with GF-3311 or later trials with GF-3308 and so treatments at compatible. The same quantities of active substance were applied with each formulation (in 2014 using GF-3311 or in later trials using GF-3308) so both treatments are comparable. As stated previously in the Preliminary data section 3.2.1.9, due to the similarity of the composition of formulations, data generated with GF-3311 is considered comparable, so supports the evaluation of GF-3308. Bridging trials established in 2015 and 2016 comparing GF-3311 and GF-3308 against ~~PUCCST~~ SEPTTR, confirm the equivalent performance of these two formulations. For ease of summarisation, the 2014 trials applied with GF-3311 are referred to as GF-3308 within this section.

Experimental details

The ~~21~~ 26 efficacy trials were conducted to GEP, by officially recognized efficacy testing organisations and followed the appropriate EPPO Standards. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 13,5 m² and 37,5 m². In all trials, the treatments were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles delivering water volumes between 200 and 300 L/ha.
In almost all trials, GF-3308 was applied as a single application at BBCH ~~32~~ 31-56 of winter wheat and 39-41 of spring wheat. In one Hungarian trial GF-3308 was applied twice, and result from this trial has been compiled together with results from single-dose regime trials.The treatments were typically sprayed when PUCCST had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials, see Appendix 3 and Appendix 4 in the BAD. Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with PUCCST or leaves which were already senesced to a high degree in both treated and untreated plots were excluded from summarization. Assessments were made on Leaf 1 in ~~19~~ 21 of the ~~21~~ 26 trials, with Leaf 2 assessed in ~~just two~~ five trials.

Results

Proposed dose of 2,0 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

In total, ~~10~~ 11 small plot GEP trials were conducted to demonstrate the efficacy of GF-3308 for the control of PUCCST in winter wheat at the proposed label rate of 2,0 L/ha, following a single application applied at BBCH ~~32~~ 31-45 of the crop. The trials were conducted in Denmark (3), Germany ~~(5)~~ (6) and the UK (2) in the EPPO Maritime climatic zone between 2014 -2019. The data included trials where PUCCST was established before application (including on the leaves assessed for control in some trials) and trials where PUCCST did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3308. Assessments across 9 of the ~~10~~ 11 trials were on Leaf 1 (plus ~~one~~ two trials on Leaf 2), as these leaves had high levels of PUCCST infection (mean of ~~23.4%~~ 22,8% in the untreated - range 6,1-65,0%) so were considered to be a robust test of the product.
Across these ~~10~~ 11 EPPO Maritime climatic zone trials, GF-3308 achieved mean control of PUCCST of ~~86.5%~~ 83,5% (range ~~71.7~~ 62,0-98,6%), 25-41 days after one application, compared to ~~91.5%~~ 88,9% for the reference standards. In ~~eight~~ nine trials, GF-3308 was compared directly to the prothioconazole standard Proline and achieved mean control of ~~87.9%~~ 83,9% compared to mean control of ~~93.6%~~ 90,2% using Proline. In one trial, GF-3308 was compared directly to the bixafen + prothioconazole standard Aviator Xpro, and GF-3308 achieved ~~89.7%~~ 91,8% control, compared to ~~95.1%~~ 94,9% control using Aviator Xpro. In one other trial, GF-3308 was compared directly to the fluxapyroxad + metconazole standard Librax, and GF-3308 achieved 71,7% control, compared to 71,7% control using Librax. Across ~~all~~ the majority of trials, control of PUCCST achieved by GF-3308 was not statistically different from the standards.
The results are summarised in Table 3.2-65 and the the results of the individual trials are detailed in the BAD and in the single trial reports. Results in Table 3.2-65 are shown across all trials first ~~(shaded grey)~~, before being shown orthogonally against the various standards.

~~**Table 3.2-65: Efficacy of GF-3308 applied at 2.0 L/ha for the control of PUCCST in winter wheat (TRZAW) between 2014 - 2019. Assessment at 25-41 days after a single application.**~~

~~EPPO Zone~~			~~% control of PUCCST~~	~~Significantly~~

	~~Number of trials~~	~~Untreated: PUCCST % infection~~		~~GF-3308 2.0 L/ha~~		~~Reference standard~~			~~>, =, < Standards~~
		~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Product/dose~~	
~~Maritime~~	~~10~~	~~23.4~~	~~6.1-65.0~~	~~**86.5**~~	~~71.7-98.6~~	~~**91.5**~~	~~71.7-100~~	~~All~~	~~8= P, 1 =A, 1 = L~~
~~Maritime*~~	~~8~~	~~26.6~~	~~7.4-65.0~~	~~**87.9**~~	~~74.9-98.6~~	~~**93.6**~~	~~83.0-100~~	~~Proline/0.72 L/ha~~	~~8 = P~~
~~Maritime**~~	~~1~~	~~6.1~~	~~-~~	~~**89.7**~~	~~-~~	~~**95.1**~~	~~-~~	~~Aviator Xpro/1.25 L/ha~~	~~1 = A~~
~~Maritime***~~	~~1~~	~~15.0~~	~~-~~	~~**71.7**~~	~~-~~	~~**71.7**~~	~~-~~	~~Librax at 2.0 L/ha~~	~~1 = L~~

~~*Direct comparison to Proline (P), **Direct comparison to Aviator Xpro (A), ***Direct comparison to Librax (L)~~

Table 3.2-65: Efficacy of GF-3308 applied at 2.0 L/ha for the control of PUCCST in winter wheat (TRZAW) between 2014 - 2019. Assessment at 25-41 days after a single application.

EPPO Zone	Number of trials	Untreated: PUCCST % infection		% control of PUCCST					Significantly >, =, < Standards
				GF-3308 2,0 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
Maritime	11	22,8	6,1-65,0	**83,5**	62,0-98,6	**88,9**	57,5-100	All	1 <, 8= P, 1 =A, 1 = L
Maritime*	9	25,5	7,4-65,0	**83,9**	62,0-98,6	**90,2**	57,5-100	Proline/0,72 L/ha	1 <, 8 = P
Maritime**	1	6,1	-	**91,8**	-	**94,9**	-	Aviator Xpro/1,25 L/ha	1 = A
Maritime***	1	15,0	-	**71,7**	-	**71,7**	-	Librax at 2,0 L/ha	1 = L

*Direct comparison to Proline (P),
**Direct comparison to Aviator Xpro (A),
***Direct comparison to Librax (L)

Summary and conclusions for the proposed dose of 2,0 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Based on the ~~10~~ 11 EPPO Maritime climatic zone trials, demonstrating mean overall control of PUCCST in winter wheat of ~~86.5%~~ 83,5% from a single application of GF-3308 at 2,0 L/ha, it is considered that the proposed label claims for control of PUCCST is fully supported.

Proposed maximum dose of 2,0 L/ha ~~and dose range of 1,5–2,0 L/ha~~ for Poland (EPPO North-East climatic zone)

In total ~~5~~ 7 small plot GEP trials were conducted to demonstrate the efficacy of GF-3308 for the control of PUCCST in winter and spring wheat at the proposed maximum label rate (2,0 L/ha), following a single application applied at BBCH ~~39~~ 37-56 of the crop. The trials were conducted in Poland ~~(5)~~ (6) and Latvia (1) in the EPPO North-East climatic zone. The data included trials where PUCCST was established before application (including on the leaves assessed for control in some trials) and trials where PUCCST did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3308. Assessments in 4 5 of the ~~5~~ 7 trials were on Leaf 1 (with ~~one~~ two trials on Leaf 2), as these leaves had high levels of PUCCST infection (mean of ~~10.4%~~ 25,2% in the untreated - range 5,7-~~23.3%~~ 83,1% for TRZAW and 8,7% for TRZAS) so was considered to be a robust test of the product.

Across ~~four~~ six EPPO North-East climatic zone trials on winter wheat, GF-3308 achieved mean control of PUCCST of ~~81.8%~~ 70,9% (range ~~67.5~~ 44,4-100%), 28-41 days after one application, compared to ~~85.5%~~ 85,2% control from the reference standards. In ~~three~~ five trials, GF-3308 was compared directly to the prothioconazole standard Proline, and achieved mean control of ~~82.9%~~ 69,4%, compared to mean control of ~~87.8%~~ 86,5% using Proline. In one trial, GF-3308 was compared directly to the penthiopyrad standard Vertisan, and GF-3308 achieved control of 78,5% compared to 78,5% using Vertisan.

In addition, data from ~~5~~ 6 trials in neighbouring countries within the EPPO Maritime climatic zone are also considered supportive of the proposed use. These ~~five~~ six trials on winter wheat (all conducted in

Germany) demonstrated comparable control to that seen in the EPPO North-East climatic zone trials, at ~~82.4%~~ 77,7% (range ~~71.7-89.7~~ 62,0-91,8%) at 2,0 L/ha compared to ~~81.4%~~ 66,4% (~~3~~ 5 trials) where the 1,5 l/ha dose was included . Combined with the ~~four~~ six EPPO North-East climatic zone trials, these provide mean control of PUCCST of ~~82.2%~~ 74,3% for 2,0 l/ha dose, across ~~9~~ 12 trials, compared to ~~86.8%~~ 84,4% control from the reference standards. In ~~7~~ 11 of these trials where the 1,5 L/ha was applied this achieved ~~80,4%~~ 68,7% control compared to ~~83.7%~~ 74,5% from the 2,0 L/ha dose, which supports the proposed dose range of 1,5–2,0 L/ha in wheat. Details for the German trials are in the EPPO Maritime climatic zone section, above.

The results are summarised in The results are summarised in Table 3.2-66 and the results of the individual trials are detailed in the BAD and in the single trial reports. Results in Table 3.2-66 are shown across all trials first ~~(shaded grey)~~, before being shown orthogonally against the various standards.

~~**Table 3.2-66: Efficacy of GF-3308 applied at 1.5 and 2.0 L/ha for the control of PUCCST in winter wheat (TRZAW) between 2014 and 2019. Assessment at 28-41 days after a single application**~~

EPPO Zone	Number of trials	Untreated: PUCCST % infection		% control of PUCCST							Significantly >, =, < Standards
				GF-3308 1.5 L/ha		GF-3308 2.0 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
North-East (1.5 and 2.0 L/ha)	4	10.4	5.7-23.3	**79.6**	59.2-100	**81.8**	67.5-100	**85.5**	69.6-100	All	3 = P, 1 = V
North-East (1.5 and 2.0 L/ha)	3	6.1	5.7-6.4	**80.7**	59.2-100	**82.9**	67.5-100	**87.8**	69.6-100	Proline/0.72 L/ha	3 = P
North-East (2.0 L/ha)	1	23.3	-	-	-	**78.5**	-	**78.5**	-	Vertisan/1.0 L/ha	1 = V
DE (2.0 L/ha)	5	16.0	6.1-28.3	-	-	**82.4**	71.7-89.7	**87.9**	71.7-100	All	3= P, 1 = A, 1 = L
North-East + DE (2.0 L/ha)	9	13.5	5.7-28.3	-	-	**82.2**	67.5-100	**86.8**	69.6-100	All	6= P, 1 = A, 1 = L, 1 = V
DE (1.5 L/ha)	3	12.2	6.1-20.0	**81.4**	78.0-87.8	**86.2**	83.0-89.7	**94.9**	91.5-98.0	All	2 = P, 1 =A
North-East + DE (1.5 L/ha)	7	11.2	5.7-23.3	**80.4**	59.2-100	**83.7**	67.5-100	**89.5**	69.9-100	All	1 <, 4 = P 1 = V, 1 =A

~~P = Proline, A = Aviator Xpro, L = Librax, V = Vertisan~~

Table 3.2-66: Efficacy of GF-3308 applied at 1,5 and 2,0 L/ha for the control of PUCCST in winter wheat (TRZAW) between 2014 and 2019. Assessment at 28-41 days after a single application

EPPO Zone	Number of trials	Untreated: PUCCST % infection		% control of PUCCST							Significantly >, =, < Standards
				GF-3308 1,5 L/ha		GF-3308 2,0 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
North-East (1,5 and 2,0 L/ha)	6	25,2	5,7-83,1	**70,7**	45,9-100	**70,9**	44,4-100	**85,2**	69,2-100	All	1.5: 2 <, 3 = P, 1 = V 2.0: 1 <, 4 = P, 1 = V
North-East (1,5 and 2,0 L/ha)	5	25,5	5,7-83,1	**69,5**	45,9-100	**69,4**	44,4-100	**86,5**	69,2-100	Proline/0,72 L/ha	1.5: 2 <, 3 = P 2.0: 1<, 4 = P
North-East (2,0 L/ha)	1	23,3	-	-	-	**78,5**	-	**78,5**	-	Vertisan/1,0 L/ha	1 = V
DE (2,0 L/ha)	6	16,1	6,1-22,6	-	-	**77,7**	62,0-91,8	**83,7**	57,5-98,0	All	1<, 3= P, 1 = A, 1 = L
North-East + DE (2,0 L/ha)	12	20,6	5,7-83,1	-	-	**74,3**	44,4-100	**84,4**	57,5-100	All	2<, 7= P, 1 = A, 1 = L, 1 = V
DE (1,5 L/ha)	5	14,8	6,1-22,1	**66,4**	38,3-82,7	**78,9**	62,0-91,8	**82,7**	57,5-98,0	All	3 = P, 1 =A, 1 < L
North-East + DE (1,5 L/ha)	11	20,4	5,7-83,1	**68,7**	38,3-100	**74,5**	44,4-100	**84,1**	57,5-100	All	2 <,6 = P 1 = V, 1 =A, 1 < L

P = Proline
A = Aviator Xpro

L = Librax, V = Vertisan

In addition to data on winter wheat, one trial was conducted on spring wheat (TRZAS). In this trial, the 2,0 L/ha dose of GF-3308 achieved 96,9% control of PUCCST, compared to 94,3% for the 1,5 L/ha dose and 95,8% control using Proline.
The results are summarised in
Table 3.2- and results of the individual trials are detailed in the BAD and in the single trial report.

Table 3.2-67: Efficacy of GF-3308 applied at 1,5 and 2,0 L/ha for the control of PUCCST in spring wheat (TRZAS) in 2016. Assessment at 32 days after a single application

EPPO Zone	Number of trials	Untreated: PUCCST % infection		% control of PUCCST							Significantly >, =, < Standards
				GF-3308 1,5 L/ha		GF-3308 2,0 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
North-East	1	8,7	-	**94,3**	-	**96,9**	-	**95,8**	-	Proline/0,72 L/ha	1,5 = P, 2,0 = P

P = Proline

Summary and conclusions for the proposed maximum dose of 2,0 L/ha ~~and proposed range of 1,5–2,0 L/ha~~ in the EPPO North-East climatic zone

Based on the ~~9~~ 12 trials on winter wheat demonstrating mean overall control of PUCCST of ~~82.8%~~ 74,3% (~~4~~ 6 EPPO North-East trials at ~~81.8%~~ 70,9% control and ~~5~~ 6 DE trials at ~~82.4%~~ 77,7% control) from 2,0 L/ha and one EPPO North-East climatic zone trial on spring wheat demonstrating 96,9% control of PUCCST, it is considered that the proposed claim for control of PUCCST on winter and spring wheat is fully supported, indicating that moderate control has been demonstrated in the trials carried out in winter wheat.
Data from ~~four~~ six Polish and ~~three~~ five German trials on winter wheat demonstrate that the 1,5 L/ha dose achieved ~~good~~ moderate control of PUCCST at ~~80.4%~~ 68,7%. A single Polish trial on spring wheat demonstrated 94,3% control for the 1,5 L/ha dose. ~~Athough this is a more limited dataset, it does confirm that the 1,5 L/ha dose recommended for control of SEPTTR on wheat should deliver around 80% control of PUCCST, where PUCCST is not the main target or in high disease pressure situations~~.
After evaluation of all submitted efficacy trials, a dose ~~range~~ rate of 2,0 L/ha as the most effective is proposed on the Polish label ~~of 1,5-2,0 L/ha~~ for the control of ~~diseases~~ PUCCST in wheat, indicating, that moderate level of control is achieved at the recommended dose rate. ~~offer grower flexibility to adjust to the disease conditions. The lower dose may be used earlier in the season or where pressure from PUCCST is lower and SEPTTR is the main target disease. The 2,0 L/ha dose should be used in higher pressure rust situations.~~

Proposed dose of 1,5-2,0 L/ha for South-East climatic zone countries of the Central EU Authorisation zone

~~Six~~ Eight GEP small plot field trials were conducted to demonstrate the efficacy of GF-3308, for the control of PUCCST in winter wheat, following a single application at BBCH 39-47 of the crop in seven trials and following a double application at BBCH 39 at the time of second application in one trial. The trials were conducted in Hungary ~~(4)~~ (6) and Romania (2) in the EPPO South-East climatic zone. The data included trials where PUCCST was established before application (including on the leaves assessed for control in some trials) and trials where PUCCST did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3308. Assessments across all trials were on either Leaf 1 (in 7 trials) or Leaf 2 (in one trial), as this leaf had high levels of PUCCST infection (mean of ~~24.6%~~ 35,3% in the untreated - range 16,4-~~31.3%~~77,5%) so was considered to be a robust test of the product. Results for one trial supporting the maximum dose of 2,0 L/ha is based on a two-dose regime. In this trial PUCCST developed slowly (first symptoms of disease and low disease pressure – 2-2,8% infection in untreated control – 21 days after the first application). For this trial, result after two applications has been used, as it is considered that the second application is comparable to a single dose regime. (83,1% efficacy from one trial based on double-dose regime, compared to 86,2% from six trial based on single-dose regime). ~~A single~~ Application of GF-3308 at 2,0 L/ha achieved mean control of ~~92.3%~~ 85,7% (range ~~83.0~~ 55,6-100%) against PUCCST across ~~five~~ seven trials, compared to ~~96.0%~~ 94,3% for the reference standards. Compared directly to the various standards used, GF-3308 at 2,0 L/ha achieved ~~93.2%~~ 85,2% control, compared to ~~98.6 %~~ 95,8% for the prothioconazole standard Proline (mean of ~~four~~ six trials) and 88,8% compared to 85,7% for the penthiopyrad standard Vertisan (one trial). The 1,5 L/ha dose rate achieved 95,1% control of PUCCST (range ~~58.8~~ 86,1-100%) across 3 trials. Compared directly to the various standards used, GF-3308 at 1,5 L/ha achieved mean control of 99,6% control compared to 100% for the prothioconazole standard Proline (mean of 2 trials) and 86,1% control, compared to 85,7% for the penthiopyrad standard, Vertisan (one trial). One trial applied only the lowest dose ~~in the proposed range~~ (1,2 L/ha GF-3308) and this trial demonstrated good levels of control of PUCCST at 91,5%, which was comparable to the prothioconazole standard Proline at 99,5%.

The results are summarised in The results are summarised in Table 3.2-68 and the results of the individual trials are detailed in the BAD and in the single trial reports. Results in Table 3.2-68 are shown across all trials for each dose first ~~(shaded grey)~~, before being shown orthogonally against the various standards.

~~**Table 3.2-68 Efficacy of GF-3308 applied at 1.2, 1.5 and 2.0 L/ha for the control of PUCCST in winter wheat (TRZAW) between 2014 and 2020. Assessment at 28-44 days after one application.**~~

EPPO Zone	Number of trials	Untreated: PUCCST % infection		% control of PUCCST								Significantly >, =, < Standards
				GF-3308 1.2 L/ha		GF-3308 1.5 L/ha		GF-3308 2.0 L/ha		Proline 0.72 L/ha		
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	
South-East# (2.0 L/ha)	5	23.3	16.4-28.8	-	-	-	-	**92.3**	83.0-100	**96.0#**	85.7-100	4 = P, 1 = V
South-East* (2.0 L/ha)	4	25.0	17.9-28.8	-	-	-	-	**93.2**	83.0-100	**98.6**	95.6-100	4 = P
South-East^ (2.0 L/ha)	1	16.4	-	-	-	-	-	**88.8**	-	**85.7^**	-	1 = V
South-East# (1.5 L/ha)	3	23.4	16.4-28.8	-	-	**95.1**	86.1-100	**96.0**	88.8-100	**95.2#**	85.7-100	2 = P, 1 = V
South-East* (1.5 L/ha)	2	26.9	25.0-28.8	-	-	**99.6**	99.2-100	**99.6**	99.2-100	**100**	100-100	2 = P
South-East^ (1.5 L/ha)	1	16.4	-	-	-	**86.1**	-	-	-	**85.7^**	-	1 = V
South-East* (1.2 L/ha)	1	31.3	-	**91.5**	-	-	-	-	-	**99.5**	-	1 = P

~~#Comparison with all reference standards~~
~~*Direct comparison with Proline (P)~~
~~^Direct comparison with Vertisan (V)~~

Table 3.2-68: Efficacy of GF-3308 applied at 1,2, 1,5 and 2,0 L/ha for the control of PUCCST in winter wheat (TRZAW) between 2014 and 2020. Assessment at 28-44 days after one application.

EPPO Zone	**Number of trials**	**Untreated: PUCCST % infection**		**% control of PUCCST**								**Significantly >, =, < Standards**
				GF-3308 1,2 L/ha		**GF-3308 1,5 L/ha**		**GF-3308 2,0 L/ha**		**Proline 0,72 L/ha or other standards**		
		Mean	**min-max**	**Mean**	**min-max**	**Mean**	**min-max**	**Mean**	**min-max**	**Mean**	**min-max**	
South-East# (2,0 L/ha)	7	35,9	16,4-77,5	-	-	-	-	**85,7**	55,6-100	**94,3#**	84,2-100	1 <, 5 = P, 1 = V
South-East* (2,0 L/ha)	6	39,2	17,9-77,5	-	-	-	-	**85,2**	55,6-100	**95,8**	84,2-100	1 <, 5 = P
South-East^ (2,0 L/ha)	1	16,4	-	-	-	-	-	**88,8**	-	**85,7^**	-	1 = V
South-East# (one application at 2,0 L/ha)	6	29,0	16,4-57,5	-	-	-	-	**86,2**	55,6-100	**94,0**	84,2-100	1 < ,4 = P, 1 = V
South-East* (two applications at 2,0 L/ha)	1	77,5	-	-	-	-	-	**83,1**	-	**96,1**	-	1 = P
South-East# (1,5 L/ha)	3	23,4	16,4-28,8	-	-	**95,1**	86,1-100	**96,0**	88,8-100	**95,2#**	85,7-100	2 = P, 1 = V
South-East* (1,5 L/ha)	2	26,9	25,0-28,8	-	-	**99,6**	99,2-100	**99,6**	99,2-100	**100**	100-100	2 = P
South-East^ (1,5 L/ha)	1	16,4	-	-	-	**86,1**	-	-	-	**85,7^**	-	1 = V
South-East* (1,2 L/ha)	1	31,3	-	**91,5**	-	-	-	-	-	**99,5**	-	1 = P

#Comparison with all reference standards
*Direct comparison with Proline (P)
^Direct comparison with Vertisan (V)

Summary and conclusions for the proposed dose range of 1,5-2,0 L/ha for EPPO South-East climatic zone countries of the Central EU Authorisation zone

Based on the ~~five~~ seven EPPO South-East climatic zone trials demonstrating mean overall control of PUCCST in winter wheat of ~~92.3%~~ 85,7%, from a single or double (in only 1 trial) application of GF-3308 at 2,0 L/ha, it is considered that the proposed claim for control of PUCCST is fully supported. Where disease levels are low, a 1,5 L/ha dose of GF-3308 could be used, as this provided effective control of PUCCST.
Note: Many EU Member State regulatory authorities in the EPPO South-East climatic zone, prefer to see dose ranges for Plant Protection Products, as this allows some level of flexibility for the user, which would otherwise not be permitted by law.

3.2.3.4 GF-3308 for the control of PUCCRE in winter rye

This section addresses the efficacy of GF-3308, for the control of PUCCRE on winter rye, when applied at the proposed label rate of 2,0 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone and Poland (EPPO North-East climatic zone).

Table 3.2-69 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 20-30 m² EPPO North-East: 30 m²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: ~~11~~ 12 SECCW EPPO North-East: 3 SECCW
	Varieties per crop (number of trials)	EPPO Maritime: Minello, Palazzo ~~(7)~~ (8), Recrut, Visello (2) EPPO North-East: Bono, Dankowskie Diament, Kier
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 37-59 EPPO North-East: BBCH 37-52
	Timing Pest stage at application	GF-3308 has both protectant and curative properties. For the control of PUCCRE applications were timed to cover these situations from commencing when there was a risk of infection with PUCCRE or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	1
	Spray volumes	200-230 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were approximately 2-3 and 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where PUCCRE is a prevalent disease.

Introduction

In total, ~~14~~ 15 field trials were conducted to demonstrate the efficacy of GF-3308 for the control of PUCCRE in winter rye (SECCW). To support the label claims, GF-3308 was tested at the proposed label rate of 2,0 L/ha, in accordance with the EPPO Standard PP 1/26, '*Foliar and ear diseases on cereals*'.
The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which followed the EPPO standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Germany ~~(11)~~ (12) in the EPPO Maritime climatic zone and Poland (3) in the EPPO North-East climatic zone, between 2015 and 2017.
On the basis of the EPPO Standard PP 1/241 '*Guidance on comparable climates'*, the trials included in this dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime and North-East EPPO climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from both of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The efficacy trials were carried out by the testing facilities in the countries listed in countries listed in Table 3.2-12.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomic and environmental factors, in areas representative of those where the crop is grown commercially and where PUCCRE is a prevalent disease. PUCCRE is a disease which multiplies rapidly at short cycles under warm climatic conditions, such as are found in the Maritime and North-East EPPO climatic zones. For trial site and application details see Appendix 3 and Appendix 4 in the BAD.

Figure 3.2 **- 5** provides an overview of the geographical distribution of the efficacy trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3308	EC	100 g/L fenpicoxamid	1,5, 2,0	75, 100
Proline 275	EC	275 g/L prothioconazole	0,72	198
Aviator Xpro 225EC	EC	75 g/L bixafen + 150 g/L prothioconazole	1,25	281

Experimental details

The ~~14~~ 15 efficacy trials were conducted to GEP by officially recognized efficacy testing organisations and followed the appropriate EPPO Standards. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 20 m² and 30 m². The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers, equipped with conventional or low drift flat fan nozzles, delivering water volumes between 200 and 230 L/ha.

In all the trials, GF-3308 was applied as a single application at BBCH 37-59 of winter rye. The treatments were typically sprayed when PUCCRE had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials, see Appendix 3 and Appendix 4 in the BAD.

Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with PUCCRE or leaves which were already senesced to a high degree in both treated and untreated plots were excluded from summarization. Assessments were on Leaf 1 or Leaf 2.

Results

Proposed dose of 2,0 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

In total ~~11~~ 12 small plot GEP trials were conducted to demonstrate the efficacy of GF-3308 for the control of PUCCRE in winter rye at the proposed label rate of 2,0 L/ha, following a single application applied at BBCH 37-59 of the crop. The trials were conducted in Germany ~~(11)~~ (12) in the EPPO Maritime climatic zone between 2015 -2017. The data includes trials where PUCCRE was established before application and trials where PUCCRE did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3308. Assessments in ~~10~~ 11 of the ~~11~~ 12 trials were on Leaf 1 (plus one trial on Leaf 2), as these leaves had

high levels of PUCCRE infection (mean of ~~18.1%~~ 17,2% in the untreated - range 5,0-74,0%) so was considered to be a robust test of the product.
Across these ~~11~~ 12 EPPO Maritime climatic zone trials, GF-3308 achieved mean control of PUCCRE of ~~84.7%~~ 84,2% (range 75,5-92,6%), 33-56 days after one application, compared to ~~90.6%~~ 91,0% control using the reference standards. In 9 trials, GF-3308 was compared directly to the prothioconazole standard Proline, and achieved mean control of 84,9%, compared to mean control of 90,6% using Proline. In ~~two~~ three trials, GF-3308 was compared directly to the bixafen + prothioconazole standard, Aviator Xpro, and GF-3308 achieved mean control of ~~83.4%~~ 82,1%, compared to mean control of ~~90.2%~~ 92,2% using Aviator Xpro. Across the majority of trials there were no statistically significant difference between the levels of control of PUCCRE achieved by GF-3308 and the reference standards.
The results are summarised in The results are summarised in Table 3.2-70 and the results of the individual trials are detailed in the BAD and in the single trial reports. Results in Table 3.2-70 are shown across all trials first ~~(shaded grey)~~, before being shown orthogonally against the various standards.

~~**Table 3.2-70: Efficacy of GF-3308 applied at 2.0 L/ha for the control of PUCCRE in winter rye (SECCW) between 2015 - 2017. Assessment at 33-56 days after a single application.**~~

~~EPPO Zone~~	~~Number of trials~~	~~Untreated: PUCCRE % infection~~		~~% control of PUCCRE~~					~~Significantly >, =, < Standards~~
				~~GF-3308 2.0 L/ha~~		~~Reference standard~~			
		~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Product/dose~~	
~~Maritime~~	~~11~~	~~18.1~~	~~5.0-74.0~~	~~**84.7**~~	~~75.5-92.6~~	~~**90.6**~~	~~81.6-100~~	~~All~~	~~9 = P; 1 =, 1< A~~
~~Maritime*~~	~~9~~	~~13.1~~	~~5.0-41.2~~	~~**84.9**~~	~~75.5-92.6~~	~~**90.6**~~	~~81.6-100~~	~~Proline/0.72 L/ha~~	~~9 = P~~
~~Maritime**~~	~~2~~	~~40.5~~	~~7.0-74.0~~	~~**83.4**~~	~~81.1-85.7~~	~~**90.2**~~	~~85.7-94.6~~	~~Aviator Xpro/1.25 L/ha~~	~~1 =, 1< A~~

~~*Direct comparison to Proline (P)~~
~~**Direct comparison to Aviator Xpro (A)~~

Table 3.2-70: Efficacy of GF-3308 applied at 2,0 L/ha for the control of PUCCRE in winter rye (SECCW) between 2015 - 2017. Assessment at 33-56 days after a single application.

EPPO Zone	Number of trials	Untreated: PUCCRE % infection		% control of PUCCRE					Significantly >, =, < Standards
				GF-3308 2,0 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
Maritime	12	17,2	5,0-74,0	**84,2**	75,5-92,6	**91,0**	81,6-100	All	9 = P; 2 =, 1< A
Maritime*	9	13,1	5,0-41,4	**84,9**	75,5-92,6	**90,6**	81,6-100	Proline/0,72 L/ha	9 = P
Maritime**	3	29,3	6,8-74,0	**82,1**	79,6-85,7	**92,2**	85,7-96,3	Aviator Xpro/1,25 L/ha	2 =, 1< A

*Direct comparison to Proline (P)
**Direct comparison to Aviator Xpro (A)

Summary and conclusions for the proposed dose of 2,0 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Based on the ~~11~~ 12 EPPO Maritime climatic zone trials, demonstrating mean overall control of PUCCRE in winter rye of ~~84.6%~~ 84,2% from a single application of GF-3308 at 2,0 L/ha, it is considered that the proposed label claim for control of PUCCRE is fully supported.

Proposed maximum dose of 2,0 L/ha ~~and proposed range of 1,5–2,0 L/ha~~ for Poland (EPPO North-East climatic zone)

In total, 3 small plot GEP trials were conducted to demonstrate the efficacy of GF-3308 for the control of PUCCRE in winter rye, at the proposed label rate (2,0 L/ha), following a single application applied at BBCH 37-52 of the crop. The trials were conducted in Poland (3) in the EPPO North-East climatic zone. The data were from trials where PUCCRE did not develop until after application. These trials can therefore be considered to be a robust test of both the protectant properties of GF-3308. Assessments across all trials were on Leaf 1, as this leaf had high levels of PUCCRE infection (mean of 28,8% in the untreated - range 18,1-36,9%) so was considered to be a robust test of the product.

Across all three EPPO North-East climatic zone trials, GF-3308 applied at dose rate of 2,0 L/ha achieved mean control of PUCCRE of 84,0% (range 81,4-87,8%), 41-49 days after one application, compared to the prothioconazole standard Proline at 76,0% (range 68,9-86,3%). GF-3308 applied at dose rate of 1,5 L/ha achieved mean control of PUCCRE of 80,7% (range 76,1-86,4%), in these three trials. Across all trials, control of PUCCRE achieved by GF-3308 at dose rate of 2,0 L/ha was statistically higher or not statistically different from the standards.

In addition to these trials, data from neighbouring countries in the EPPO Maritime climatic zone are available and can also be considered supportive of the proposed use. ~~Eleven~~ Tvelve trials were conducted in Germany and demonstrated comparable control to that seen in the EPPO North-East climatic zone trials, at ~~84.7%~~ 84,2% (range 75,5-92,6%). Combined with the three EPPO North-East climatic zone trials, these gave overall control of PUCCRE of ~~84.5%~~ 84,2%, across ~~14~~ 15 trials. In 12 trials, GF-3308 was compared directly to the prothioconazole standard Proline and achieved mean control of 84,7%, compared to mean control of 87,0% using Proline. Details for the German trials are in the EPPO Maritime climatic zone section, above.

The results are summarised in The results are summarised in Table 3.2-71 and the results of the individual trials are detailed in the BAD and in the single trial reports. Results in Table 3.2-71 are shown across all trials first ~~(shaded grey)~~, before being shown orthogonally against the various standards.

~~**Table 3.2-71: Efficacy of GF-3308 applied at 1.5 and 2.0 L/ha for the control of PUCCRE in winter rye (SECCW) in 2015-2017. Assessment at 33-56 days after a single application**~~

EPPO Zone	Number of trials	Untreated: PUCCRE % infection		% control of PUCCRE							Significantly >, =, < Standards
				GF-3308 1.5 L/ha		GF-3308 2.0 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
North-East* (1.5 and 2.0 L/ha)	3	28.8	18.1-36.9	**72.0**	61.8-83.9	**84.0**	81.4-87.8	**76.0**	68.9-86.3	Proline/0.72 L/ha	1.5:1 >,1<,1 = P 2.0: 2 >, 1 = P
DE (2.0 L/ha)	11	18.1	5.0-74.0			**84.7**	75.5-92.6	**90.6**	81.6-100	All	9 = P, 1 =, 1< A
North-East + DE (2.0 L/ha)	14	20.4	5.0-74.0			**84.5**	75.5-92.6	**87.4**	68.9-100	All	2 >, 10 = P 1 =, 1< A
North-East + DE* (2.0 L/ha)	12	17.0	5.0-41.2			**84.7**	75.5-92.6	**90.6**	81.6-100	Proline/0.72 L/ha	2 >, 10 = P
DE (1.5 L/ha)	3	30.1	7.0-74.0	**79.9**	74.3-85.7	**84.9**	81.1-87.8	**88.9**	85.7-94.6	All	1 = P 1 =, 1< A
North-East + DE (1.5 L/ha)	6	29.4	7.0-74.0	**80.3**	74.3-86.4	**84.5**	81.1-87.8	**82.5**	68.9-94.6	All	1 >, 1<, 2 = P 1 =, 1< A

~~*Direct comparison to Proline (P)~~
~~A = Aviator Xpro~~

Table 3.2-71 Efficacy of GF-3308 applied at 1,5 and 2,0 L/ha for the control of PUCCRE in winter rye (SECCW) in 2015-2017. Assessment at 33-56 days after a single application

EPPO Zone	Number of trials	Untreated: PUCCRE % infection		% control of PUCCRE							Significantly >, =, < Standards
				GF-3308 1,5 L/ha**		GF-3308 2,0 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
North-East* (1,5 and 2,0 L/ha)	3	28,8	18,1-36,9	**80,7**	76,1-86,4	**84,0**	81,4-87,8	**76,0**	68,9-86,3	Proline/0,72 L/ha	1,5:1 >,1<,1 = P 2,0: 2 >, 1 = P
DE (2,0 L/ha)	12	17,2	5,0-74,0	-	-	**84,2**	75,5-92,6	**91,0**	81,6-100	All	9 = P, 2 =, 1< A
North-East + DE (2,0 L/ha)	15	19,5	5,0-74,0	-	-	**84,2**	75,5-92,6	**88,0**	68,9-100	All	2 >, 10 = P 2 =, 1< A
North-East + DE* (2,0 L/ha)	12	17,0	5,0-41,4	-	-	**84,7**	75,5-92,6	**87,0**	68,9-100	Proline/0,72 L/ha	2 >, 10 = P
DE (1,5 L/ha)	4	24,3	6,8-74,0	**77,5**	70,4-85,7	**83,6**	79,6-87,8	**90,8**	85,7-96,3	All	1 = P 1 =, 2< A
North-East + DE (1,5 L/ha)	7	26,2	6,8-74,0	**78,9**	70,4-86,4	**83,8**	79,6-87,8	**84,5**	68,9-96,3	All	1 >, 1<, 2 = P 1 =, 2< A

*Direct comparison to Proline (P)
A = Aviator Xpro
** Dose rate of 1,6 L/ha used in only 1 German trial

Summary and conclusions for the proposed maximum dose of 2,0 L/ha and proposed range of 1,5–2,0 L/ha in the EPPO North-East climatic zone

Based on the three EPPO North-East climatic zone trials results (84,0% control) and ~~11~~ 12 trial~~s~~ results from Germany (~~84.7%~~ 84,2% control), demonstrating mean overall control of PUCCRE in winter rye of ~~84.5%~~ 84,2%, from a single application of GF-3308 at 2,0 L/ha, it is considered that the proposed claim for control of PUCCRE in winter rye is fully supported.
Data from three Polish and ~~three~~ four German trials demonstrate that the 1,5 L/ha dose achieved ~~80.3%~~ 78,9% control of PUCCRE. Although this is a more limited dataset, it does confirm that the 1,5 L/ha dose recommended for control of RHYNSE on rye should deliver around ~~80%~~ 79% control of PUCCRE, where PUCCRE is not the main target.
After evaluation of all trial results, a dose ~~range~~ rate of 2,0 L/ha is proposed on the Polish label ~~of 1,5-2,0 L/ha~~ for the control of ~~diseases~~ PUCCRE in rye to provide high efficacy under a wide range of environmental conditions. ~~offer growers flexibility to adjust to the disease conditions~~.

3.2.3.5 GF-3308 for the control of RHYNSE in winter rye

This section addresses the efficacy of GF-3308, for the control of RHYNSE on winter rye, when applied at the proposed label rate of 2,0 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone and 1,5-2,0 L/ha Poland (EPPO North-East climatic zone).

Table 3.2-72 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 20-30 m² EPPO North-East: 19,6-30 m²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: ~~10~~ 12 SECCW EPPO North-East: 5 SECCW
	Varieties per crop (number of trials)	EPPO Maritime: Minello, Palazzo ~~(5)~~ (7), Recrut, Visello (2), SU Performer EPPO North-East: Bono, Dankowskie Diament (2), Kier, Palazzo
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 39-59 EPPO North-East: BBCH 37-~~59~~ 51
	Timing Pest stage at application	GF-3308 has both protectant and curative properties. For the control of RHYNSE applications were timed to cover these situations from commencing when there was a risk of infection with RHYNSE or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	1
	Spray volumes	200-230 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were conducted 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where RHYNSE is a prevalent disease.

Introduction

In total ~~15~~ 17 field trials were conducted to demonstrate the efficacy of GF-3308 for the control of RHYNSE in winter rye (SECCW). To support the label claims, GF-3308 was tested at the proposed label rate of 2,0 L/ha (EPPO Maritime climatic zone) and 1,5-2,0 L/ha (EPPO North-East climatic zone), in accordance with the EPPO Standard PP 1/26, '*Foliar and ear diseases on cereals*'.
The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which followed the EPPO Standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Germany ~~(10)~~ (12) in the EPPO Maritime climatic zone and Poland (5) in the EPPO North-East climatic zone, between 2015 and 2017.

On the basis of the EPPO Standard PP 1/241 '*Guidance on comparable climates'*, the trials included in this dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime and North-East EPPO climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from each of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations
The efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-13.

Sites
Trial sites were selected on the basis of known pest pressure, favourable agronomic and environmental factors, in areas representative of those where the crop is grown commercially and where RHYNSE is a prevalent disease. RHYNSE is a disease which multiplies rapidly, at short cycles, under warm climatic conditions, such as are found in the Maritime and North-East EPPO climatic zones. For trial site and application details see Appendix 3 and Appendix 4 in the BAD. Figure 3.2 - 6 provides an overview of the geographical distribution of the efficacy trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3308	EC	100 g/L fenpicoxamid	1,5, 2,0	75, 100
Proline 275	EC	275 g/L prothioconazole	0,72	198
Aviator Xpro 225EC	EC	75 g/L bixafen + 150 g/L prothioconazole	1,25	281

Experimental details
The ~~15~~ 17 efficacy trials were conducted to GEP, by officially recognized efficacy testing organisations and followed the appropriate EPPO Standards. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 19,6 m² and 30 m². The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers, equipped with conventional or low drift flat fan nozzles, delivering water volumes between 200 and 230 L/ha.
In the all trials, GF-3308 was applied as a single application at BBCH 37-59 of winter rye. The treatments were typically sprayed when RHYNSE had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials, see Appendix 3 and Appendix 4 in the BAD.
Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level, relative to the infection level present in the untreated control. Leaves showing less than 5% infection with RHYNSE or leaves which were already senesced to a high degree in both treated and untreated plots, were excluded from summarization. Assessments in 14 of the ~~15~~ 17 trials were on either Leaf 1 or Leaf 2 (plus ~~one~~ three trials on Leaf 3).

Results

Proposed dose of 2,0 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

In total, ~~10~~ 12 small plot GEP trials were conducted to demonstrate the efficacy of GF-3308 for the control of RHYNSE in winter rye, at the proposed label rate of 2,0 L/ha, following a single application

applied at BBCH 39-59 of the crop. The trials were conducted in Germany ~~(10)~~ (12) in the EPPO Maritime climatic zone, between 2015-2017. The data included trials where RHYNSE was established before application and trials where RHYNSE did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3308. Assessments in 7 of the ~~10~~ 12 trials were on Leaf 1 (plus two trials on Leaf 2 and ~~one~~ three trials on Leaf 3), as these leaves had high levels of RHYNSE infection (mean of ~~16.5%~~ 18,3% in the untreated - range 9,8-~~25.5%~~ 27,0%) so was considered to be a robust test of the product.
Across these ~~10~~ 12 EPPO Maritime climatic zone trials, GF-3308 achieved mean control of RHYNSE of ~~88.2%~~ 85,0% (range ~~76.2~~ 66,7-100%), 30-56 days after one application, compared to ~~92.5%~~ 91,7% control by the reference standards. In ~~7~~ 9 trials, GF-3308 was compared directly to the prothioconazole standard Proline, and achieved mean control of ~~86.5%~~ 82,5%, compared to mean control of ~~90.3%~~ 89,7% using Proline. In three trials, GF-3308 was compared directly to the bixafen + prothioconazole standard, Aviator Xpro, and GF-3308 achieved mean control of 92,3%, compared to mean control of 97,6% using Aviator Xpro. Across ~~all~~ 9 trials there were no statistical differences between control of RHYNSE achieved by GF-3308 and the standards. In 3 trials statistically significant decrease in efficacy was noted for GF-3308 at dose rate of 2,0 L/ha as compared to standard Proline.
The results are summarised in Table 3.2-73 and the results of the individual trials are in the BAD and in the single trial reports. Results in Table 3.2-73 are shown across all trials first ~~(shaded grey)~~, before being shown orthogonally against the various standards.

~~**Table 3.2-73: Efficacy of GF-3308 applied at 2.0 L/ha for the control of RHYNSE in winter rye (SECCW) between 2015 - 2017. Assessment at 30-56 days after a single application.**~~

~~EPPO Zone~~	~~Number of trials~~	~~Untreated: RHYNSE % infection~~		~~% control of RHYNSE~~					~~Significantly >, =, < Standards~~
				~~GF-3308 2.0 L/ha~~		~~Reference standard~~			
		~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Product/dose~~	
~~Maritime~~	~~10~~	~~16.5~~	~~9.8-25.5~~	~~**88.2**~~	~~76.2-100~~	~~**92.5**~~	~~77.8-100~~	~~All~~	~~7 = P, 3 = A~~
~~Maritime*~~	~~7~~	~~15.1~~	~~9.8-22.5~~	~~**86.5**~~	~~76.2-100~~	~~**90.3**~~	~~77.8-100~~	~~Proline/0.72 L/ha~~	~~7 = P~~
~~Maritime**~~	~~3~~	~~19.8~~	~~14.0-25.5~~	~~**92.3**~~	~~90.0-94.1~~	~~**97.6**~~	~~92.9-100~~	~~Aviator Xpro/1.25 L/ha~~	~~3 = A~~

~~*Direct comparison to Proline (P)~~
~~**Direct comparison to Aviator Xpro (A)~~

Table 3.2-73: Efficacy of GF-3308 applied at 2,0 L/ha for the control of RHYNSE in winter rye (SECCW) between 2015 - 2017. Assessment at 30-56 days after a single application.

EPPO Zone	Number of trials	Untreated: RHYNSE % infection		% control of RHYNSE					Significantly >, =, < Standards
				GF-3308 2,0 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
Maritime	12	18,3	9,8-27,0	**85,0**	66,7-100	**91,7**	76,9-100	All	3 <, 6 = P, 3 = A
Maritime*	9	17,8	9,8-27,0	**82,5**	66,7-100	**89,7**	76,9-100	Proline/0,72 L/ha	3 <, 6 = P
Maritime**	3	19,8	14,0-25,5	**92,3**	90,0-94,1	**97,6**	92,9-100	Aviator Xpro/1,25 L/ha	3 = A

*Direct comparison to Proline (P)
**Direct comparison to Aviator Xpro (A)

Summary and conclusions for the proposed dose of 2,0 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Based on the ~~10~~ 12 EPPO Maritime climatic zone trials, demonstrating mean overall control of RHYNSE in winter rye of ~~88.2%~~ 85,0%, from a single application of GF-3308 at 2,0 L/ha, it is considered that the proposed label claim for control of RHYNSE is fully supported.

Proposed dose rate range of 1,5-2,0 L/ha for Poland (EPPO North-East climatic zone)

In total, five small plot GEP trials were conducted to demonstrate the efficacy of GF-3308 for the control of RHYNSE in winter rye at the proposed label rates of 1,5 L/ha and 2,0 L/ha, following a single application applied at BBCH 37-~~59~~ 52 of the crop. The trials were conducted in Poland (5) in the EPPO North-East climatic zone. The data included trials where RHYNSE was established before application (including on the leaves assessed for control in some trials) and trials where RHYNSE did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3308. Assessments across all trials were on Leaf 2, as this leaf had high levels of RHYNSE infection (mean of 30,2% in the untreated - range 11,1-60,0%) so was considered to be a robust test of the product.

Across the five EPPO North-East climatic zone trials, GF-3308 at 1,5 L/ha achieved mean control of RHYNSE of 83,0% (range 69,4-99,1%) and ~~87.9%~~ 85,9% (range 73,3-100%) using the 2,0 L/ha dose, 35-42 days after one application. Control by both dose rates exceeded that achieved by the prothioconazole standard Proline at 71,9% (range 56,9-90,0%). Across all trials, control of RHYNSE achieved by GF-3308, at both dose rates, was statistically higher or not statistically different from the standards.

In addition to these trials, data from neighbouring countries in the EPPO Maritime climatic zone are available and can also be considered supportive of the proposed use. At the 2,0 L/ha dose rate of GF-3308, ~~10~~ 12 trials were conducted in Germany, demonstrating comparable control to that seen in the EPPO North-East climatic zone trials, at ~~88.2%~~ 85,0% (range ~~76.2~~ 66,7-100%). Combined with the five EPPO North-East climatic zone trials, these gave overall control of RHYNSE of ~~88.1%~~ 85,2%, across ~~15~~ 17 trials, at the 2,0 L/ha dose rate. In ~~12~~ 14 trials, GF-3308 at 2,0 L/ha achieved mean control of ~~87.1%~~ 83,7% when compared directly to Proline which achieved mean control of ~~82.6%~~ 83,4%. At the 1,5 L/ha dose rate, five trials were conducted in Germany and demonstrated comparable control to that seen in the EPPO North-East climatic zone trials, at ~~83.0%~~ 83,5% (range 75,0-~~90.0%~~ 99,1%). Combined with the five EPPO North-East climatic zone trials, these gave overall control of RHYNSE of ~~83.0%~~ 83,3%, across 10 trials using the 1,5 L/ha dose rate of GF-3308. In 7 trials, GF-3308 was compared directly to the prothioconazole standard Proline, and achieved mean control of ~~80.7%~~ 81,1% compared to mean control of 75,0% for Proline. Details for the German trials are in the EPPO Maritime climatic zone section, above.

The results are summarised in The results are summarised in Table 3.2-74 and the results of the individual trials are detailed in the BAD and in the single trial reports. Results in Table 3.2-74 are shown across all trials first ~~(shaded grey)~~, before being shown orthogonally against the various standards.

~~**Table 3.2-74: Efficacy of GF-3308 applied at the dose rate range of 1.5-2.0 L/ha for the control of RHYNSE in winter rye (SECCW) in 2015-2017. Assessment at 30-56 days after a single application**~~

EPPO Zone	Number of trials	Untreated: RHYNSE % infection		% control of RHYNSE							Significantly >, =, < Standards
				GF-3308 1.5 L/ha		GF-3308 2.0 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
North-East (1.5 and 2.0 L/ha)	5	30.2	11.1-60.0	**83.0**	69.4-99.0	**87.9**	**73.3-100**	**71.9**	56.9-90.0	Proline/0.72 L/ha	3 >, 2 = P 4 >, 1 = P
DE (1.5 and 2.0 L/ha)	5	18.8	12.0-25.5	**83.0**	75.0-90.0	**87.2**	**77.8-94.1**	**91.6**	77.8-100	All	2 = P 2 =, 1< A
DE (2.0 L/ha)	10	16.5	9.8-25.5	-	-	**88.2**	76.2-100	**92.5**	77.8-100	All	7 = P, 3 = A
North-East + DE (1.5 and 2.0 L/ha)	10	24.5	11.1-60.0	**83.0**	69.4-99.0	**87.5**	**73.3-100**	**81.8**	56.9-100	All	3 >, 4 = P 2 =, 1< A
North-East + DE (2.0 L/ha)	15	21.1	9.8-60.0	-	-	**88.1**	73.3-100	**85.6**	56.9-100	All	4 >, 8 = P 3 = A

~~North-East + DE* (1.5 and 2.0 L/ha)~~	~~7~~	~~26.5~~	~~11.1-60.0~~	~~**80.7**~~	~~69.4-99.0~~	~~**85.5**~~	~~73.3-100~~	~~**75.0**~~	~~56.9-90.0~~	~~Proline/0.72 L/ha~~	~~3 >, 4 = P~~
~~North-East + DE* (2.0 L/ha)~~	~~12~~	~~21.4~~	~~9.8-60.0~~	~~-~~	~~-~~	~~**87.1**~~	~~73.3-100~~	~~**82.6**~~	~~56.9-100~~	~~Proline/0.72 L/ha~~	~~4 >, 8 = P~~

~~*Direct comparison to Proline (P)~~
~~A = Aviator Xpro~~

Table 3.2-74: Efficacy of GF-3308 applied at the dose rate range of 1,5-2,0 L/ha for the control of RHYNSE in winter rye (SECCW) in 2015-2017. Assessment at 30-59 days after a single application

EPPO Zone	Number of trials	Untreated: RHYNSE % infection		% control of RHYNSE							Significantly >, =, < Standards
				GF-3308 1,5 L/ha**		GF-3308 2,0 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
North-East (1,5 and 2,0 L/ha)	5	30,2	11,1-60,0	**83,0**	69,4-99,1	**85,9**	73,3-100	**71,9**	56,9-90,0	Proline/0,72 L/ha	3 >, 2 = P 4 >, 1 = P
DE (1,5 and 2,0 L/ha)	5	18,8	12,0-25,5	**83,5**	75,0-90,1	**87,2**	77,8-94,1	**91,6**	77,8-100	All	2 = P 2 =, 1< A
DE (2,0 L/ha)	12	18,3	9,8-27,0	-	-	**85,0**	66,7-100	**91,7**	76,9-100	All	3 <, 6 = P, 3 = A
North-East + DE (1,5 and 2,0 L/ha)	10	24,5	11,1-60,0	**83,3**	69,4-99,1	**86,6**	73,3-100	**81,8**	56,9-100	All	3 >, 4 = P 2 =, 1< A
North-East + DE (2,0 L/ha)	17	21,8	9,8-60,0	-	-	**85,2**	66,7-100	**85,9**	56,9-100	All	3 <, 4 >, 7 = P 3 = A
North-East + DE* (1,5 and 2,0 L/ha)	7	26,5	11,1-60,0	**81,1**	69,4-99,1	**84,1**	73,3-100	**75,0**	56,9-90,0	Proline/0,72 L/ha	3 >, 4 = P
North-East + DE* (2,0 L/ha)	14	22,2	9,8-60,0	-	-	**83,7**	66,7-100	**83,4**	56,9-100	Proline/0,72 L/ha	3 <, 4 >, 7 = P

*Direct comparison to Proline (P)
A = Aviator Xpro
** Dose rate of 1,6 L/ha used in only 1 German trial

Summary and conclusions for the proposed dose rate range of 1,5-2,0 L/ha in the EPPO North-East climatic zone

Where disease pressure is low and the only disease requiring control is RHYNSE, the lower dose of 1,5 L/ha provides effective control. Based on five EPPO North-East climatic zone trials (83,0% mean control) and five trials from Germany (~~83.0%~~ 83,5% mean control) at the 1,5 L/ha dose rate, demonstrating mean overall control of RHYNSE in winter rye of ~~83.0%~~ 83,3% (mean of 10 trials) from a single application of GF-3308, it is considered that the proposed claim for control of RHYNSE at the lower dose rate of 1,5 L/ha, in winter rye, is fully supported.
In mixed disease situations (PUCCRE also present or expected) the higher dose of 2,0 L/ha is recommended. Based on five EPPO North-East climatic zone trials (mean control of ~~87.9%~~ 85,9%) and ~~10~~ 12 trials from Germany (mean control of ~~88.2%~~ 85,0%) at the 2,0 L/ha dose rate, demonstrating mean overall control of RHYNSE in winter rye of ~~88.1%~~ 85,2%, from a single application of GF-3308 (mean of ~~15~~ 17 trials), it is considered that the proposed claim for control of RHYNSE at a maximum dose rate of 2,0 L/ha, in winter rye, is also fully supported.
A dose range is proposed on the Polish label of 1,5-2,0 L/ha for control of ~~diseases~~ RHYNSE in rye to offer growers flexibility to adjust to the disease conditions.

3.2.3.6 GF-3308 for the control of SEPTSP in winter triticale

This section addresses the efficacy of GF-3308, for the control of SEPTTR and SEPTSP (often mixed populations present in triticale) on winter triticale, when applied at the proposed label rate of 2,0 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone and 1,5-2,0 L/ha for Poland (EPPO North-East climatic zone).

Table 3.2-75 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 21-30 m² EPPO North-East: 30 m²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: 6 TTLWI EPPO North-East: 3 TTLWI
	Varieties per crop (number of trials)	EPPO Maritime: Adverda, Agostino, Grenado, KWS Aveo, ~~Talendro~~ Talentro (2) EPPO North-East: Grenado, Magnat, Tulus
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 39-51 EPPO North-East: BBCH 33-52
	Timing Pest stage at application	GF-3308 has both protectant and curative properties. For the control of SEPTSP applications were timed to cover these situations from commencing when there was a risk of infection with SEPTSP or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	1
	Spray volumes	200-230 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were made at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where SEPTSP is a prevalent disease.

Introduction

In total, 9 field trials were conducted to demonstrate the efficacy of GF-3308 for the control of SEPTSP in winter triticale (TTLWI). To support the label claims, GF-3308 was tested at the proposed label rate of 2,0 L/ha (EPPO Maritime climatic zone) and 1,5-2,0 L/ha (EPPO North-East climatic zone), in accordance with the EPPO Standard PP 1/26, '*Foliar and ear diseases on cereals*'.
The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which followed the EPPO Standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Germany (6) in the EPPO Maritime climatic zone and

Poland (3) in the EPPO North-East climatic zone, between 2015 and 2020.
On the basis of the EPPO Standard PP 1/241 '*Guidance on comparable climates'*, the trials included in this dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime and North-East EPPO climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from each of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations
The efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-14.

Sites
Trial sites were selected on the basis of known pest pressure, favourable agronomic and environmental factors, in areas representative of those where the crop is grown commercially and where SEPTSP is a prevalent disease. SEPTSP is a disease which multiplies rapidly, at short cycles, under warm climatic conditions, such as are found in the Maritime and North-East EPPO climatic zones. For trial site and application details see Appendix 3 and Appendix 4 in the BAD.

Figure 3.2 **- 7** provides an overview of the geographical distribution of the efficacy trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3308	EC	100 g/L fenpicoxamid	1,5, 2,0	75, 100
Proline 275	EC	275 g/L prothioconazole	0,72	198
Proline 250	EC	250 g/L prothioconazole	0,65	163
Prosaro	EC	125 g /L tebuconazole + 125 g prothioconazole	1,0	250

Experimental details
The nine efficacy trials were conducted to GEP by officially recognized efficacy testing organisations and followed the appropriate EPPO Standards. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between ~~20~~ 21 m² and 30 m². The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers, equipped with conventional or low drift flat fan nozzles, delivering water volumes between 200 and 230 L/ha.
In all the trials, GF-3308 was applied as a single application, at BBCH 33-52 of winter triticale. The treatments were typically sprayed when SEPTSP had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials see Appendix 3 and Appendix 4 in the BAD.
Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level, relative to the infection level present in the untreated control. Leaves showing less than 5% infection with SEPTSP or leaves which were already senesced to a high degree in both treated and untreated plots were excluded from summarization. Assessments were on Leaf 1, Leaf 2 or Leaf 3.

Results

Proposed dose of 2,0 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

In total, 6 small plot GEP trials were conducted to demonstrate the efficacy of GF-3308 for the control of SEPTSP in winter triticale at the proposed label rate of 2,0 L/ha, following a single application applied at BBCH 39-51 of the crop. The trials were conducted in Germany (6) in the EPPO Maritime climatic zone, between 2015-2020. The data included trials where SEPTSP was established before application (including on the leaves assessed for control in some trials) and trials where SEPTSP did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3308. Assessments across all trials were on either Leaf 1 or Leaf 2, as these leaves had high levels of SEPTSP infection (mean of 13,3% in the untreated - range 5,8-32,5%) so was considered to be a robust test of the product.

Across these 6 EPPO Maritime climatic zone trials, GF-3308 achieved mean control of SEPTSP of 84,8% (range 73,1-100%), 27-48 days after one application, compared to mean control of 79,3% from the reference standards. In four trials, GF-3308 was compared directly to the prothioconazole standard Proline, and achieved mean control of 83,4%, compared to mean control of 72,4% using Proline. In two trials, GF-3308 was compared directly to the tebuconazole + prothioconazole standard, Prosaro, where GF-3308 achieved mean control of 87,7%, compared to mean control of 93,0% using Prosaro. Across all trials there were no statistical differences between the levels of control of SEPTSP achieved by GF-3308 and the standards.

In addition to these trials, data from neighbouring countries in the EPPO North-East climatic zone are available and can also be considered supportive of the proposed use. The three trials conducted in Poland demonstrated comparable control to that seen in the EPPO Maritime climatic zone trials, at 87,6% (range 79,2-100%). Combined with the six EPPO Maritime trials results, these gave overall control of SEPTSP of 85,7%, across 9 trials, compared to mean control of 82,3%, using the reference standards. Details for the Polish trials are in the EPPO North-East climatic zone section, below.

The results are summarised in The results are summarised in 3.2-76 and the results of the individual trials are detailed in the BAD and in the single trial reports. Results in 3.2-76 are shown across all trials first ~~(shaded grey)~~, before being shown orthogonally against the various standards.

Table 3.2-76: Efficacy of GF-3308 applied at 2,0 L/ha for the control of SEPTSP in winter triticale (TTLWI) between 2015 - 2020. Assessment at 21-48 days after a single application.

EPPO Zone/ Country	Number of trials	Untreated: SEPTSP % infection		% control of SEPTSP					Significantly >, =, < Standards
				GF-3308 2,0 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
Maritime	6	13,3	5,8-32,5	**84,8**	73,1-100	**79,3**	63,3-100	All	4 = P, 2 = PO
Maritime*	4	14,9	7,0-32,5	**83,4**	73,1-93,5	**72,4**	63,3-87,0	Proline/0,72 L/ha or Proline/0,65 L/ha	4 = P
Maritime**	2	10,1	5,8-14,3	**87,7**	75,4-100	**93,0**	86,0-100	Prosaro/1,0 L/ha	2 = PO
PL*	3	13,6	8,9-20,9	**87,6**	79,2-100	**88,2**	78,2-100	Proline/0,72 L/ha	3 = P
Maritime + PL	9	13,4	5,8-32,5	**85,7**	73,1-100	**82,3**	63,3-100	All	7= P, 2 =PO

*Direct comparison to Proline (P)
**Direct comparison to Prosaro (PO)

Summary and conclusions for the proposed dose of 2,0 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Based on the six EPPO Maritime climatic zone trials (mean control of 84,8%) and three trials from Poland (mean control of 87,6%), demonstrating mean overall control of SEPTSP in winter triticale of 85,7% (9 trials), from a single application of GF-3308 at 2,0 L/ha, it is considered that the proposed claim for control of SEPTSP is fully supported.

Proposed dose rate range of 1,5-2,0 L/ha for Poland (EPPO North-East climatic zone)

In total, 3 small plot GEP trials were conducted to demonstrate the efficacy of GF-3308 for the control of SEPTSP in winter triticale, at the proposed label rates of 1,5 L/ha and 2,0 L/ha, following a single application applied at BBCH 33-52 of the crop. The trials were conducted in Poland (3) in the EPPO North-East climatic zone. The data included trials where SEPTSP was established before application and trials where SEPTSP did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3308. Assessments across all trials were on Leaf 3, as this leaf had high levels of SEPTSP infection (mean of 13,6% in the untreated - range 8,9-20,9%) so was considered to be a robust test of the product.
Across all three EPPO North-East climatic zone trials, GF-3308 at 1,5 L/ha achieved mean control of SEPTSP of 84,4% (range 75,9-100%) and mean control of 87,6% (range 79,2-100%) using the 2,0 L/ha dose, 21 days after one application. Control by both dose rates was comparable to that achieved by the prothioconazole standard Proline at 88,2% (range 78,2-100%).
In addition to these trials, data from neighbouring countries in the EPPO Maritime climatic zone are available and can also be considered supportive of the proposed use. At the 2,0 L/ha dose rate of GF-3308, six trials were conducted in Germany and demonstrated comparable control to that seen in the EPPO North-East climatic zone trials, at 84,8% (range 73,1-100%). Combined with the three EPPO North-East climatic zone trials, these gave overall control of SEPTSP of 85,7%, across 9 trials, using the 2,0 L/ha dose rate of GF-3308, compared to 82,3% using the reference standards. At the 1,5 L/ha dose rate of GF-3308, two trials were conducted in Germany, achieving mean control of 65,1% (range 63,5-66,7%). Combined with the three EPPO North-East climatic zone trials, these gave overall control of SEPTSP of 76,7%, across five trials, at the 1,5 L/ha dose rate, compared to ~~82,0%~~ 82,8% control using the reference standards. Details for the German trials are in the EPPO Maritime climatic zone section, above.
The results are summarised in The results are summarised in 3.2-77 and the results of the individual trials are detailed in the BAD and in the single trial reports. Results in 3.2-77 are shown across all trials first ~~(shaded grey)~~, before being shown orthogonally against the various standards.

Table 3.2-77: Efficacy of GF-3308 applied at the dose rate range of 1,5-2,0 L/ha for the control of SEPTSP in winter triticale (TTLWI) between 2015 - 2020. Assessment at 21-48 days after a single application.

EPPO Zone/ Country	Number of trials	Untreated: SEPTSP % infection		% control of SEPTSP							Significantly >, =, < Standards
				GF-3308 1,5 L/ha***		GF-3308 2,0 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
North-East*	3	13,6	8,9-20,9	**84,4**	75,9-100	**87,6**	79,2-100	**88,2**	78,2-100	Proline/0,72 L/ha	1,5 L/ha: 2 =, 1< P 2,0 L/ha: 3 = P
DE (1,5 and 2,0 L/ha)	2	10,7	7,0-14,3	**65,1**	63,5-66,7	**78,3**	75,4-81,1	**74,7**	63,3-86,0	All	1,5 and 2,0 L/ha: 1 = P, 1= PO
DE	1	7,0	-	**63,5**	-	**81,1**	-	**63,3**	-	Proline/~~0,72~~ 0,65 L/ha	1,5 L/ha: 1 = P 2,0 L/ha: 1 = P
DE**	1	14,3	-	**66,7**	-	~~75,1~~ **75,4**	-	~~75,4~~ **86,0**	-	Prosaro/1,0 L/ha	1,5 L/ha: 1 = PO 2,0 L/ha: 1 = PO

North-East + DE (1,5 and 2,0 L/ha)	5	12,4	7,0-20,9	**76,7**	63,5-100	**83,9**	75,4-100	~~82,0~~ **82,8**	63,3-100	All	~~3 =, 1 < P 1 = PO~~ 1,5 L/ha: 3 =, 1< P, 1= PO 2,0 L/ha: 4 = P, 1= PO
DE (2,0 L/ha)	6	13,3	5,8-32,5	-	-	**84,8**	73,1-100	**79,3**	63,3-100	All	4 = P, 2 = PO
North-East + DE (2,0 L/ha)	9	13,4	5,8-32,5	-	-	**85,7**	73,1-100	**82,3**	63,3-100	All	7= P, 2 =PO

*Direct comparison to Proline (P)
** Direct comparison to Prosaro (PO)
*** Dose rate of 1,6 L/ha used in only 1 German trial

Summary and conclusions for the proposed rate range of 1,5-2,0 L/ha in the EPPO North-East climatic zone

Where disease pressure is low and only control of SEPTSP is required, the lower dose of 1,5 L/ha is acceptable. Three EPPO North-East climatic zone trials (mean control of 84,4%) and two trials from Germany (mean control of 65,1%) at this dose rate, demonstrated mean overall control of SEPTSP in winter triticale of 76,7% from a single application of GF-3308. Based on these triticale data and supported by data from ~~nine~~ fifteen trials on winter wheat, which achieved mean control of ~~84.7%~~ 81,4% of SEPTTR using the 1,5 L/ha dose, it is considered that the proposed claim for control of SEPTSP, at a dose rate of 1,5 L/ha in winter triticale, is supported.
In mixed disease situations (where PUCCST is also present or expected) or where SEPTSP pressure is higher, as experienced in the trials from neighbouring countries, the higher dose of 2,0 L/ha is recommended. Based on three EPPO North-East climatic zone trials (mean control of 87,6%) and six trials from Germany (mean control of 84,8%) GF-3308 at ~~this~~ dose rate of 2,0 L/ha, demonstrated mean overall control of SEPTSP in winter triticale of 85,7%, from a single application of GF-3308, it is considered that the proposed claim for control of SEPTSP, at a dose rate of 2,0 L/ha in winter triticale, is fully supported.
A dose range is proposed on the Polish label of 1,5-2,0 L/ha for control of diseases in triticale to offer growers flexibility to adjust to the disease conditions.

3.2.3.7 GF-3308 for the control of PUCCST in winter triticale

This section addresses the efficacy of GF-3308, for the control of PUCCST on winter triticale, when applied at the proposed label rate of 2,0 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone and Poland (EPPO North-East climatic zone).

Table 3.2-78 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 22,5-25 m² EPPO North-East: 25-30 m²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: ~~7~~ 8 TTLWI EPPO North-East: 3 TTLWI
	Varieties per crop (number of trials)	EPPO Maritime:KWS Aveo, SU Agendus, Tender (5), Talentro EPPO North-East: Magnat, Trismart, Twingo
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH ~~39~~ 35-51 EPPO North-East: BBCH 35-52
	Timing Pest stage at application	GF-3308 has both protectant and curative properties. For the control of PUCCST applications were timed to cover these situations from commencing when there was a risk of infection with PUCCST or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	1
	Spray volumes	200-230 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were made at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where PUCCST is a prevalent disease.

Introduction

In total, ~~10~~ 11 field trials were conducted to demonstrate the efficacy of GF-3308 for the control of PUCCST in winter triticale (TTLWI). To support the label claims, GF-3308 was tested at the proposed label rate of 2,0 L/ha, in accordance with the EPPO Standard PP 1/26, '*Foliar and ear diseases on cereals*'.
The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which followed the EPPO standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Germany ~~(7)~~ (8) in the EPPO Maritime climatic zone and Poland (3) in the EPPO North-East climatic zone, between 2015 and 2020.

On the basis of the EPPO Standard PP 1/241 '*Guidance on comparable climates'*, the trials included in this dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime and North-East EPPO climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from both of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations
The efficacy trials were carried out by the testing facilities in the countries listed in

Table 3**.2-15**.

Sites
Trial sites were selected on the basis of known pest pressure, favourable agronomic and environmental factors, in areas representative of those where the crop is grown commercially and where PUCCST is a prevalent disease. PUCCST is a disease which multiplies rapidly, at short cycles, under warm climatic conditions, such as are found in the Maritime and North-East EPPO climatic zones. For trial site and application details, see Appendix 3 and Appendix 4 in the BAD. Figure 3.2 - 8 provides an overview of the geographical distribution of the efficacy trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3308	EC	100 g/L fenpicoxamid	1,5, 2,0	75, 100
Proline 275	EC	275 g/L prothioconazole	0,72	198
Proline 250	EC	250 g/L prothioconazole	0,8	200
Prosaro	EC	125 g /L tebuconazole + 125 g /L prothioconazole	1,0	250

Experimental details
The ~~10~~ 11 efficacy trials were conducted to GEP and followed the appropriate EPPO standards, by officially recognized efficacy testing organisations. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 22,5 m² and 30 m². The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers, equipped with conventional or low drift flat fan nozzles, delivering water volumes between 200 and 230 L/ha.
In all the trials, GF-3308 was applied as a single application at BBCH 35-52 of winter triticale. The treatments were typically sprayed when PUCCST had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials, see Appendix 3 and Appendix 4 in the BAD.
Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level, relative to the infection level present in the untreated control. Leaves showing less than 5% infection with PUCCST or leaves which were already senesced to a high degree in both treated and untreated plots were excluded from summarization. Assessments were on either Leaf 1 or Leaf 2.

Results

Proposed dose of 2,0 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

In total, ~~7~~ 8 small plot GEP trials were conducted to demonstrate the efficacy of GF-3308 for the control of PUCCST in winter triticale at the proposed label rate of 2,0 L/ha, following a single application applied at BBCH ~~39~~ 35-51 of the crop. The trials were conducted in Germany ~~(7)~~ (8) in the EPPO Maritime climatic zone between 2015-2020. The data included trials where PUCCST was established before application (including on the leaves assessed for control in some trials) and trials where PUCCST did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3308. Assessments across all trials were on either Leaf 1 or Leaf 2, as these leaves had high levels of PUCCST infection (mean of ~~46.9%~~ 43,2% in the untreated - range 6,0-96,5%) so was considered to be a robust test of the product.

Across these ~~7~~ 8 EPPO Maritime climatic zone trials, GF-3308 achieved mean control of PUCCST of ~~86.0%~~ 83,5% (range 63,0-98,1%), 21-~~44~~ 46 days after one application, compared to mean control of ~~88.2%~~ 83,0% from the reference standards. In ~~six~~ seven trials, GF-3308 was compared directly to the prothioconazole standard Proline, and achieved mean control of ~~84.0%~~ 81,4% compared to mean control of ~~86.6%~~ 80,9% using Proline. In one trial, GF-3308 was compared directly to the tebuconazole + prothioconazole standard, Prosaro, where GF-3308 achieved control of 98,1%, compared to 98,1% from Prosaro. Across ~~all~~ 7 trials, control of PUCCST achieved by GF-3308 was statistically higher or not statistically different from the standards.

In addition to these trials, data from neighbouring countries in the EPPO North-East climatic zone are available and can also be considered supportive of the proposed use. Three trials were conducted in Poland and demonstrated comparable control to that seen in the EPPO Maritime climatic zone trial, at 88,4% (range 83,5-94,9%). Combined with the ~~seven~~ eight EPPO Maritime climatic zone trials, these gave overall control of PUCCST of ~~86.7%~~ 84,9%, across ~~10~~ 11 trials, using the 2,0 L/ha dose of GF-3308, compared to mean control of ~~81.6%~~ 78,4% from the reference standards. Details for the Polish trials are in the EPPO North-East climatic zone section, below.

The results are summarised in The results are summarised in Table 3.2-79 and the results of the individual trials are detailed in the BAD and in the single trial reports. Results in Table 3.2-79 are shown across all trials first ~~(shaded grey)~~, before being shown orthogonally against the various standards.

~~**Table 3.2-79: Efficacy of GF-3308 applied at 2.0 L/ha for the control of PUCCST in winter triticale (TTLWI) between 2015 - 2020. Assessment at 21-44 days after a single application.**~~

~~EPPO Zone/ Country~~	~~Number of trials~~	~~Untreated: PUCCST % infection~~		~~% control of PUCCST~~					~~Significantly >, =, < Standards~~
				~~GF-3308 2.0 L/ha~~		~~Reference standard~~			
		~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Product/dose~~	
~~Maritime~~	~~7~~	~~46.9~~	~~6.0-96.5~~	~~**86.0**~~	~~63.0-98.1~~	~~**88.2**~~	~~54.5-100~~	~~All~~	~~1 >, 5 = P, 1 = PO~~
~~Maritime*~~	~~6~~	~~45.8~~	~~6.0-96.5~~	~~**84.0**~~	~~63.0-95.8~~	~~**86.6**~~	~~54.5-100~~	~~Proline/0.72 L/ha~~	~~1 >, 5 = P~~
~~Maritime**~~	~~1~~	~~53.8~~	-	~~**98.1**~~	-	~~**98.1**~~	-	~~Prosaro/1.0 L/ha~~	~~1 = PO~~
~~PL*~~	~~3~~	~~19.6~~	~~7.1-37.8~~	~~**88.4**~~	~~83.5-94.9~~	~~**66.0**~~	~~54.1-73.7~~	~~Proline/0.72 L/ha~~	~~2 >, 1= P~~
~~DE + PL~~	~~10~~	~~38.7~~	~~6.0-96.5~~	~~**86.7**~~	~~63.0-98.1~~	~~**81.6**~~	~~54.1-100~~	~~All~~	~~3 >, 6 = P, 1 = PO~~

~~**Direct comparison to Proline (P)~~
~~**Direct comparison to Prosaro (PO)~~

Table 3.2-79: Efficacy of GF-3308 applied at 2,0 L/ha for the control of PUCCST in winter triticale (TTLWI) between 2015 - 2020. Assessment at 21-46 days after a single application.

EPPO Zone/ Country	Number of trials	Untreated: PUCCST % infection		% control of PUCCST					Significantly >, =, < Standards
				GF-3308 2,0 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
Maritime	8	43,2	6,0-96,5	**83,5**	63,0-98,1	**83,0**	18,5-100	All	1 >, 1 <, 5 = P, 1 = PO
Maritime*	7	41,7	6,0-96,5	**81,4**	63,0-95,9	**80,9**	18,5-100	Proline/0,72 L/ha or Proline/0,8 L/ha	1 >, 1 < P, 5 = P
Maritime**	1	53,8	-	**98,1**	-	**98,1**	-	Prosaro/1,0 L/ha	1 = PO
PL*	3	19,6	7,1-37,8	**88,4**	83,5-94,9	**66,0**	54,1-73,7	Proline/0,72 L/ha or Proline/0,8 L/ha	2 >, 1= P
DE + PL	11	36,7	6,0-96,5	**84,9**	63,0-98,1	**78,4**	18,5-100	All	3 >, 1 <, 6 = P, 1 = PO

**Direct comparison to Proline (P)
**Direct comparison to Prosaro (PO)

Summary and conclusions for the proposed dose of 2,0 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Based on ~~seven~~ eight EPPO Maritime climatic zone trials (mean control of ~~86.0%~~ 83,5%) and three trials from Poland (mean control of 88,4%), demonstrating mean overall control of PUCCST in winter triticale of ~~86.7%~~ 84,9% from a single application of GF-3308 at 2,0 L/ha, it is considered that the proposed claim for control of PUCCST in winter triticale is fully supported.

Proposed maximum dose of 2,0 L/ha ~~and proposed range of 1,5–2, 0 L/ha~~ for Poland (EPPO North-East climatic zone)

In total, 3 small plot GEP trials were conducted to demonstrate the efficacy of GF-3308 for the control of PUCCST in winter triticale at the proposed label rate (2,0 L/ha), following a single application applied at BBCH 35-52 of the crop. The trials were conducted in Poland (3) in the EPPO North-East climatic zone. The data includes trials where PUCCST was established before application and trials where PUCCST did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3308. Assessments across all trials were on either Leaf 1 or Leaf 2, as these leaves had high levels of PUCCST infection (mean of 19,6% in the untreated - range 7,1-37,8%) so was considered to be a robust test of the product.
Across the three EPPO North-East climatic zone trials, GF-3308 achieved mean control of PUCCST of 88,4% (range 83,5-94,9%), 35-43 days after one application, compared control from the prothioconazole standard Proline at 66,0% (range 54,1-73,7%). Across all three trials, control of PUCCST achieved by GF-3308 was statistically higher or not statistically different from the standards.
In addition to these trials, data from neighbouring countries in the EPPO Maritime climatic zone are available and can also be considered supportive of the proposed use. ~~Seven~~ Eight trials were conducted in Germany and demonstrated comparable control to that seen in the EPPO North-East climatic zone trials, with the 2,0 L/ha dose providing mean control of PUCCST of ~~86.0%~~ 83,5%. Combined with the three EPPO North-East climatic zone trials, these gave overall control of PUCCST of ~~86.7%~~ 84,9%, across ~~10~~ 11 trials, compared to ~~81.6%~~78,4% control using the reference standards. Details for the German trials are in the EPPO Maritime climatic zone section, above.
The results are summarised in Table 3.2-80 and the results of the individual trials are detailed in the BAD and in the single trial reports. Results in 3.2-80 are shown across all trials first ~~(shaded grey)~~, before being shown orthogonally against the various standards.

~~**Table 3.2-80: Efficacy of GF-3308 applied at 1.5 and 2.0 L/ha t 2.0 L/ha for the control of PUCCST in winter triticale (TTLWI) between 2015 - 2020. Assessment at 21-44 days after a single application.**~~

EPPO Zone	Number of trials	Untreated: PUCCST % infection		% control of PUCCST							Significantly >, =, < Standards
				GF-3308 1.5 L/ha		GF-3308 2.0 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
North-East* (1.5 and 2.0 L/ha)	3	19.6	7.1-37.8	**83.8**	73.5-93.6	**88.4**	83.5-94.9	**66.0**	54.1-73.7	Proline/0.72 L/ha	1.5: 2 >, 1= P 2.0: 2 >, 1= P
DE (2.0 L/ha)	7	46.9	6.0-96.5	-	-	**86.0**	63.0-98.1	**88.2**	54.5-100	All	1 >, 5 = P, 1 = PO
DE* (2.0 L/ha)	6	45.8	6.0-96.5	-	-	**84.0**	63.0-95.8	**86.6**	54.5-100	Proline/0.72 L/ha	1 >, 5 = P
DE** (2.0 L/ha)	1	53.8	-	-	-	**98.1**	-	**98.1**	-	Prosaro/1.0 L/ha	1 = PO
North-East + DE (2.0 L/ha)	10	38.7	6.0-96.5			**86.7**	63.0-98.1	**81.6**	54.1-100	All	3 >, 6 = P, 1 = PO
DE (1.5 L/ha)	4	63.8	13.8-96.5	**84.3**	78.4-93.9	**89.4**	81.9-95.8	**91.3**	83.6-100	Proline/0.72 L/ha	1 <, 3 = P
North-East + DE (1.5 L/ha)	7	44.8	7.1-96.5	**84.1**	73.5-93.9	**89.0**	81.9-95.8	**80.4**	54.1-100	Proline/0.72 L/ha	2 >, 1 <, 4 = P

~~**Direct comparison to Proline (P)~~
~~**Direct comparison to Prosaro (PO)~~

Table 3.2-80: Efficacy of GF-3308 applied at 1,5 and 2,0 L/ha for the control of PUCCST in winter triticale (TTLWI) between 2015 - 2020. Assessment at 21-46 days after a single application.

EPPO Zone	Number of trials	Untreated: PUCCST % infection		% control of PUCCST							Significantly >, =, < Standards
				GF-3308 1,5 L/ha		GF-3308 2,0 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
North-East* (1,5 and 2,0 L/ha)	3	19,6	7,1-37,8	**83,8**	73,5-93,6	**88,4**	83,5-94,9	**66,0**	54,1-73,7	Proline/0,72 L/ha or Proline/0,8 L/ha	1,5: 2 >, 1= P 2,0: 2 >, 1= P
DE (2,0 L/ha)	8	43,2	6,0-96,5	-	-	**83,5**	63,0-98,1	**83,0**	18,5-100	All	1 >, 1 <, 5 = P, 1 = PO
DE* (2,0 L/ha)	7	41,7	6,0-96,5	-	-	**81,4**	63,0-95,9	**80,9**	18,5-100	Proline/0,72 L/ha or Proline/0,8 L/ha	1 >, 1 <, 5 = P
DE** (2,0 L/ha)	1	53,8	-	-	-	**98,1**	-	**98,1**	-	Prosaro/1,0 L/ha	1 = PO
North-East + DE (2,0 L/ha)	11	36,7	6,0-96,5	-	-	**84,9**	63,0-98,1	**78,4**	18,5-100	All	3 >, 1 <, 6 = P, 1 = PO
DE (1,5 L/ha)	5	53,7	13,5-96,5	**75,6**	40,7-94,0	**84,1**	63,0-95,9	**76,7**	18,5-100	Proline/0,72 L/ha or Pro-line/0,8 L/ha	1 <, 4 = P
North-East + DE (1,5 L/ha)	8	40,9	7,1-96,5	**78,7**	73,5-94,0	**85,7**	63,0-95,9	**72,7**	18,5-100	Proline/0,72 L/ha or Pro-line/0,8 L/ha	2 >, 1 <, 5 = P

**Direct comparison to Proline (P)
**Direct comparison to Prosaro (PO)

Summary and conclusions for the proposed maximum dose of 2,0 L/ha and proposed range of 1,5–2,0 L/ha in the EPPO North-East climatic zone

Based on the three EPPO North-East climatic zone trials (mean control of 88,4%) and ~~seven~~ eight trials from Germany (mean control of ~~86.0%~~ 83,5%), demonstrating mean overall control of PUCCST in winter triticale of ~~86.7%~~ 84,9%, from a single application of GF-3308 at 2,0 L/ha, it is considered that the proposed claim for control of PUCCST in winter triticale is fully supported.
Data from three Polish and ~~four~~ five German trials demonstrate that the 1,5 L/ha dose achieved ~~84.1%~~ 78,7% of PUCCST (moderate level of control). The efficacy of GF-3308 at 1,5 L/ha was higher and achieved 83,8% based on the results from the three available Polish trials. ~~Although this is a more limited dataset, it does confirm indicates that the 1,5 L/ha dose recommended for control of SEPTSP on triticale should deliver around 80% control of PUCCST, where PUCCST is not the main target.~~
After evaluation of all submitted trial results, a dose ~~range~~ rate of 2,0 L/ha is proposed on the Polish label ~~of 1,5-2,0 L/ha~~ for control of ~~diseases~~ PUCCST in triticale to provide high efficacy under a wide range of environmental conditions. ~~offer growers flexibility to adjust to the disease conditions.~~

3.2.3.8 Yield in effectiveness trials

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

In total ~~111~~ 118 effectiveness trials are included in this dossier; ~~75~~ 81 trials on winter wheat (TRZAW), 1 trial on spring wheat, 18 trials on winter rye (SECCW) and 18 trials on winter triticale (TTLWI). The majority of trials were harvested and yield and quality assessed (Thousand grain weight/TGW and Specific weight/hectolitre weight/HLW). **Note**: TGW and particularly HLW, were not assessed in all harvested trials. The results from these trials split by crop and EPPO zone are summarised in the following tables. Trials supporting the various target diseases have been combined for each crop, as many trials included more than one disease, even at levels below the threshold for assessment (5%). These results therefore reflect the benefits of the use of GF-3308 for general disease control in each crop. Results for GF-3308 are shown against the reference standards used in each disease section.
A number of EPPO Maritime and North-East trials trials were based on a two-dose regime, with results for effectiveness assessed before the second dose. The results from these trials have not been included, however, for completeness they can be found in Appendix 5 in the BAD. Similarly, results from two-dose regime EPPO South-East trials are not included but can be found in Appendix 5 in the BAD.

<u>Winter wheat (TRZAW)</u>

Results – EPPO Maritime climatic zone

Of the ~~28~~ 34 EPPO Maritime climatic zone effectiveness trials on winter wheat generated between 2014-2019, the impact on grain yield after a single dose of GF-3308 was assessed in ~~22~~ 27 trials. ~~Two~~ Three trials (DE15E7B014UB02C, FR15E7B025YC02 and DE15E7B025AS01) were not harvested. Four trials (CZ18E7B017PV01C, DE14E7B014FS01, GB15E7B015EB01C, GB15E7B015EB04C) only have results after two applications. (although the results used for effectiveness were based on assessment after the first application). The results from these trials have not been included, however, for completeness they can be found in Appendix 5 in the BAD.
In these ~~22~~ 27 trials there were no significant negative effects noted in any trial. A single application of GF-3308 at 2,0 L/ha, in the presence of disease, had a positive impact on grain yield across all trials, with a mean yield increase of ~~16.4%~~ 14,7%, relative to the untreated. These trials also achieved an ~~8.4%~~ 8,0% increase in thousand grain weight (TGWT), relative to the untreated and a ~~2.3%~~ 1,8% increase in hectolitre weight (HLW). Results for the standards were comparable.
A summary of the yield and quality data from efficacy trials is presented in Table 3.2-81 to Table 3.2-83. The individual trial results are detailed in Appendix 5 in the BAD.

~~Table 3.2-81 Impact of GF-3308 on grain yield when applied at 2.0 L/ha on winter wheat (TRZAW) in EPPO Maritime climatic zone efficacy trials~~

Crop	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
				GF-3308 100 g as/ha 2.0 L/ha		Reference standard		
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	22	**7.7**	4.7-10.6	**116.4**	101.7-140.8	**116.1**	99.5-153.1	All
TRZAW*	12	**7.9**	4.7-10.2	**116.6**	106.0-131.9	**114.1**	101.0-129.8	Proline/0.72 L/ha
TRZAW**	9	**7.3**	5.0-10.6	**116.3**	101.7-140.8	**118.7**	99.5-153.1	Aviator Xpro/1.25 L/ha
TRZAW***	1	**8.0**	-	**114.4**	-	**117.4**	-	Librax/2.0 L/ha

~~*Direct comparison to Proline~~
~~**Direct comparison to Aviator Xpro~~
~~***Direct comparison to Librax~~

Table 3.2-81: Impact of GF-3308 on grain yield when applied at 2,0 L/ha on winter wheat (TRZAW) in EPPO Maritime climatic zone efficacy trials

Crop	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
				GF-3308 100 g as/ha 2,0 L/ha		Reference standard		
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	27	**8,0**	4,7-11,0	**114,7**	101,7-140,8	**114,5**	99,5-153,1	All
TRZAW*	18	**8,3**	4,7-11,0	**114,7**	105,0-131,9	**113,0**	101,0-129,8	Proline/0,72 L/ha
TRZAW**	9	**7,2**	5,0-10,6	**114,7**	101,7-140,8	**117,5**	99,5-153,1	Aviator Xpro/1,25 L/ha
TRZAW***	1	**8,0**	-	**114,4**	-	**117,4**	-	Librax/2,0 L/ha

*Direct comparison to Proline
**Direct comparison to Aviator Xpro
***Direct comparison to Librax

~~Table 3.2-31: Impact of GF-3308 on grain quality (TGWT) when applied at 2.0 L/ha on winter wheat (TRZAW) in EPPO Maritime climatic zone efficacy trials~~

Crop	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)				
				GF-3308 100 g as/ha 2.0 L/ha		Reference standard		
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	21	**41.3**	28.3-50.5	**108.4**	99.8-126.3	**106.8**	98.3-139.1	All
TRZAW*	12	**42.4**	28.3-50.5	**108.4**	99.8-118.9	**105.6**	98.3-117.1	Proline/0.72 L/ha
TRZAW**	9	**39.7**	32.9-45.5	**108.3**	100.3-126.3	**108.4**	99.0-139.1	Aviator Xpro/1.25 L/ha

~~*Direct comparison to Proline~~
~~**Direct comparison to Aviator Xpro~~

Table 3.2-82: Impact of GF-3308 on grain quality (TGWT) when applied at 2,0 L/ha on winter wheat (TRZAW) in EPPO Maritime climatic zone efficacy trials

Crop	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)				
				GF-3308 100 g as/ha 2,0 L/ha		Reference standard		
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	26	**41,1**	28,3-50,5	**108,0**	99,8-126,3	**106,6**	98,3-139,1	All
TRZAW*	18	**41,4**	28,3-50,2	**108,1**	100,3-118,9	**105,7**	98,3-117,1	Proline/0,72 L/ha
TRZAW**	8	**40,3**	32,9-45,5	**107,8**	100,3-126,3	**108,5**	99,0-139,1	Aviator Xpro/1,25 L/ha

*Direct comparison to Proline
**Direct comparison to Aviator Xpro

~~Table 3.2-83: Impact of GF-3308 on grain quality (HLW when applied at 2.0 L/ha on winter wheat (TRZAW) in EPPO Maritime climatic zone efficacy trials~~

Crop		HLW (kg)	Relative HLW (Untreated = 100%)

	Number of trials	untreated control		GF-3308 100 g as/ha 2.0 L/ha		Reference standard		
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	15	**71.6**	63.6-79.3	**102.3**	99.1-107.7	**101.8**	93.0-110.5	All
TRZAW*	7	**71.3**	68.9-76.0	**101.8**	100.3-103.8	**99.8**	93.0-103.6	Proline/0.72 L/ha
TRZAW**	7	**72.2**	63.6-79.3	**102.7**	99.1-107.7	**103.4**	99.7-110.5	Aviator Xpro/1.25 L/ha
TRZAW***	1	**68.8**	-	**102.1**	-	**104.3**	-	Librax/2.0 L/ha

*Direct comparison to Proline
**Direct comparison to Aviator Xpro
***Direct comparison to Librax

Table 3.2-83: Impact of GF-3308 on grain quality (HLW when applied at 2,0 L/ha on winter wheat (TRZAW) in EPPO Maritime climatic zone efficacy trials

Crop	Number of trials	HLW (kg) untreated control		Relative HLW (Untreated = 100%)				
				GF-3308 100 g as/ha 2,0 L/ha		Reference standard		
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	21	**72,5**	59,1-82,0	**101,8**	99,1-107,7	**102,1**	98,8-110,5	All
TRZAW*	14	**72,3**	59,1-82,0	**101,8**	100,3-103,8	**101,5**	98,8-105,0	Proline/0,72 L/ha
TRZAW**	6	**73,6**	66,1-79,3	**102,4**	99,1-107,7	**103,2**	99,7-110,5	Aviator Xpro/1,25 L/ha
TRZAW***	1	**68,8**	-	**102,1**	-	**104,3**	-	Librax/2,0 L/ha

*Direct comparison to Proline
**Direct comparison to Aviator Xpro
***Direct comparison to Librax

Results – EPPO North-East climatic zone

Of the 20 EPPO North-East climatic zone effectiveness trials on winter wheat (TRZAW) and one trial on spring wheat (TRZAS) generated between 2014-2016, the impact on grain yield after a single dose of GF-3308 was assessed in 17 trials. Four trials (PL14E7B014AS01C, PL14E7B014AS03C, PL15E7B041AS01C and PL15E7B041AS02C) only have results after two applications (although the results used for effectiveness were based on assessment after the first application). The results from these trials have not been included, however, for completeness they can be found in Appendix 5 in the BAD.
All 17 trials included the maximum dose rate of 2,0 L/ha and there were no significant negative effects noted in any trial. A single application of GF-3308 at 2,0 L/ha, in the presence of disease, had a positive impact on grain yield across all trials, with a mean yield increase of 14.1% 13,1%, relative to the untreated across 16 winter wheat trials and 30,8% increase in one spring wheat trial. These trials also achieved a 3,9% increase in thousand grain weight (TGWT) for winter wheat and 4,2% increase for spring wheat. No trials were assessed for hectolitre weight (HLW). Results for the standards were comparable.
A summary of the yield and quality data from efficacy trials is presented in Table 3.2-84 to Table 3.2-85. The individual trial results are detailed in Appendix 5 in the BAD.

Table 3.2-84: Impact of GF-3308 on grain yield when applied at 2.0 L/ha on wheat in EPPO North-East climatic zone efficacy trials

Crop	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
				GF-3308 100 g as/ha 2.0 L/ha		Reference standard		
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	16	**6.5**	4.3-9.2	**114.1**	103.5-126.9	**114.6**	105.7-128.1	All
TRZAW*	11	**6.3**	4.9-7.8	**113.5**	103.5-126.9	**113.5**	105.7-123.7	Proline/0.72 L/ha
TRZAW**	4	**7.7**	5.3-9.2	**112.7**	110.1-115.3	**114.4**	110.9-119.4	Aviator Xpro/1.25 L/ha
TRZAW***	1	**4.3**	-	**126.4**	-	**128.1**	-	Vertisan/1.0 L/ha
TRZAS	1	**3.8**	-	**130.8**	-	**126.8**	-	Proline/0.72 L/ha

*Direct comparison to Proline. **Direct comparison to Aviator Xpro, ***Direct comparison to Vertisan

Table 3.2-84: Impact of GF-3308 on grain yield when applied at 2,0 L/ha on wheat in EPPO North-East climatic zone efficacy trials

Crop	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
				GF-3308 100 g as/ha 2,0 L/ha		Reference standard		
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	16	**6,9**	4,3-12,2	**113,1**	99,8-126,9	**105,9**	100,2-123,7	All
TRZAW*	11	**6,8**	4,9-12,2	**112,1**	99,8-126,9	**112,5**	100,2-123,7	Proline/0,72 L/ha
TRZAW**	4	**7,7**	5,3-9,2	**112,7**	110,1-115,3	**114,4**	110,9-119,4	Aviator Xpro/1,25 L/ha
TRZAW***	1	**4,3**	-	**126,4**	-	**128,1**	-	Vertisan/1,0 L/ha
TRZAS	1	**3,8**	-	**130,8**	-	**126,8**	-	Proline/0,72 L/ha

*Direct comparison to Proline
**Direct comparison to Aviator Xpro
***Direct comparison to Vertisan

Table 3.2-85: Impact of GF-3308 on grain quality (TGWT) when applied at 2,0 L/ha on wheat in EPPO North-East climatic zone efficacy trials

Crop	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)				
				GF-3308 100 g as/ha 2,0 L/ha		Reference standard		
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	15	**44,3**	36,0-54,5	**103,9**	100,1-108,1	~~104,2~~ **104,1**	100,6-114,8	All
TRZAW*	11	**43,1**	36,0-48,9	**104,5**	100,7-108,1	~~104,7~~ **104,5**	100,6-114,8	Proline/0,72 L/ha
TRZAW**	3	**47,4**	41,3-~~51,3~~ 54,5	**101,7**	100,1-104,1	**102,9**	101,8-103,7	Aviator Xpro/1,25 L/ha
TRZAW***	1	**48,7**	-	**104,2**	-	**103,5**	-	Vertisan/1,0 L/ha
TRZAS	1	**34,1**	-	**104,2**	-	**103,5**	-	Proline/0,72 L/ha

*Direct comparison to Proline
**Direct comparison to Aviator Xpro
***Direct comparison to Vertisan

Use on wheat in the EPPO North-East zone includes a lower dose of 1,5 L/ha. This dose rate is supported by ~~15~~ 17 winter wheat trials (8 EPPO North-East zone trials and ~~7~~ 9 trials from the EPPO Maritime zone: CZ and DE) and one spring wheat trial (EPPO North-East zone). A summary of the yield and quality data from ~~14~~ 17 of these efficacy trials at the 1,5 L/ha dose rate is presented in Table 3.2- and Table 3.2-. One DE trial (DE15E7B025AS01) ~~and one CZ trial (CZ18E7B017PV01C) were~~ was not harvested.

A single application of GF-3308 at 1,5 L/ha, in the presence of disease, had a positive impact on grain yield across all trials. The increases found were similar to the 2,0 L/ha dose rate, with a mean yield increase of ~~11,6-14,6%~~ 10,1-14,5%, relative to the untreated across ~~13~~ 16 winter wheat trials and 22,9% increase in one spring wheat trial. These trials also achieved a 3,4-~~8,5%~~7,4% mean increase in thousand grain weight (TGWT) for winter wheat and 3,7% increase for spring wheat. Results for the standards were comparable.

~~**Table 3.2-86: Impact of GF-3308 on grain yield when applied at 1,5 L/ha on wheat in EPPO North-East climatic zone and DE and CZ efficacy trials**~~

Crop	EPPO zone	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
					GF-3308 75 g as/ha 1,5 L/ha		Reference standard		
			Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	NE	8	**6,3**	4,3-7,8	**111,6**	100,4-125,9	**114,0**	105,7-128,1	All
TRZAW*	NE	7	**6,6**	4,9-7,8	**109,5**	100,4-119,8	**112,0**	105,7-122,4	Proline/0,72 L/ha
TRZAW***	NE	1	**4,3**	-	**125,9**	-	**128,1**	-	Vertisan/1,0 L/ha

TRZAW	MAR	5	**7.6**	6.1-9.5	**114.6**	111.0-116.5	**115.8**	106.1-122.6	All
TRZAW*	MAR	4	**8.0**	6.7-9.5	**114.2**	111.0-116.5	**114.1**	106.1-121.1	Proline/0.72 L/ha
TRZAW**	MAR	1	**6.1**	-	**116.4**	-	**122.6**	-	Aviator Xpro/1.25 L/ha
TRZAS	NE	1	**3.8**	-	**122.9**	-	**126.8**	-	Proline/0.72 L/ha

*Direct comparison to Proline. **Direct comparison to Aviator Xpro, ***Direct comparison to Vertisan.

Table 3.2-86: Impact of GF-3308 on grain yield when applied at 1,5 L/ha on wheat in EPPO North-East climatic zone and DE and CZ efficacy trials

Crop	EPPO zone	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
					GF-3308 75 g as/ha 1,5 L/ha		Reference standard		
			Mean	**min-max**	**Mean**	**min-max**	**Mean**	**min-max**	**Product/dose**
TRZAW	NE	8	**7,0**	4,3-12,2	**110,1**	100,4-125,9	**112,7**	100,2-128,1	All
TRZAW*	NE	7	**7,3**	4,9-12,2	**107,9**	100,4-119,8	**110,4**	100,2-122,4	Proline/0,72 L/ha
TRZAW***	NE	1	**4,3**	-	**125,9**	-	**128,1**	-	Vertisan/1,0 L/ha
TRZAW	MAR	8	**7,6**	6,1-9,5	**114,5**	105,0-128,0	**118,1**	106,1-127,8	All
TRZAW*	MAR	5	**7,9**	6,7-9,5	**116,9**	111,0-128,0	**116,8**	106,1-127,8	Proline/0,72 L/ha
TRZAW**	MAR	2	**6,4**	6,1-6,7	**113,3**	110,2-116,4	**121,5**	120,3-122,6	Aviator Xpro/1,25 L/ha
TRZAW****	MAR	1	**8,0**	-	**105,0**	-	**117,4**	-	Librax/2,0 L/ha
TRZAS	NE	1	**3,8**	-	**122,9**	-	**126,8**	-	Proline/0,72 L/ha

*Direct comparison to Proline
**Direct comparison to Aviator Xpro
***Direct comparison to Vertisan
****Direct comparison to Librax

Table 3.2-87: Impact of GF-3308 on grain quality (TGWT) when applied at 1.5 L/ha on wheat in EPPO North-East climatic zone and DE and CZ efficacy trials

Crop	EPPO Zone	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)				
					GF-3308 75 g as/ha 1.5 L/ha		Reference standard		
			Mean	**min-max**	**Mean**	**min-max**	**Mean**	**min-max**	**Product/dose**
TRZAW	NE	8	**44.0**	37.6-48.9	**103.4**	100.7-109.0	**104.6**	100.6-114.8	All
TRZAW*	NE	7	**43.4**	37.6-48.9	**103.3**	100.7-109.0	**104.7**	100.6-114.8	Proline/0.72 L/ha
TRZAW***	NE	1	**48.7**	-	**103.9**	-	**103.5**	-	Vertisan/1.0 L/ha
TRZAW	MAR	5	**43.7**	38.9-47.7	**108.5**	102.4-115.5	**106.3**	103.4-112.6	All
TRZAW*	MAR	4	**44.9**	40.5-47.7	**109.5**	102.4-115.5	**107.1**	103.6-112.6	Proline/0.72 L/ha
TRZAW**	MAR	1	**38.9**	-	**104.6**	-	**103.4**	-	Aviator Xpro/1.25 L/ha
TRZAS	NE	1	**34.1**	-	**103.7**	-	**103.5**	-	Proline/0.72 L/ha

*Direct comparison to Proline. **Direct comparison to Aviator Xpro, ***Direct comparison to Vertisan.

Table 3.2-87: Impact of GF-3308 on grain quality (TGWT) when applied at 1,5 L/ha on wheat in EPPO North-East climatic zone and DE and CZ efficacy trials

Crop	EPPO Zone	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)				
					GF-3308 75 g as/ha 1,5 L/ha		Reference standard		
			Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	NE	8	**44,0**	37,6-48,9	**103,4**	100,7-109,0	**104,4**	100,6-114,8	All
TRZAW*	NE	7	**43,4**	37,6-48,9	**103,3**	100,7-109,0	**104,5**	100,6-114,8	Proline/0,72 L/ha
TRZAW***	NE	1	**48,7**	-	**103,9**	-	**103,5**	-	Vertisan/1,0 L/ha
TRZAW	MAR	7	**41,3**	34,9-47,7	**107,4**	97,9-115,5	**105,4**	99,0-112,6	All
TRZAW*	MAR	5	**42,9**	34,9-47,7	**109,9**	102,4-115,5	**107,1**	103,6-112,6	Proline/0,72 L/ha
TRZAW**	MAR	2	**37,2**	35,4-38,9	**101,3**	97,9-104,6	**101,2**	99,0-103,4	Aviator Xpro/1,25 L/ha
TRZAS	NE	1	**34,1**	-	**103,7**	-	**103,5**	-	Proline/0,72 L/ha

*Direct comparison to Proline
**Direct comparison to Aviator Xpro
***Direct comparison to Vertisan

Results – EPPO South-East climatic zone

Of the ~~26~~ 27 EPPO South-East climatic zone effectiveness trials on winter wheat generated between 2014-2020, the impact on grain yield after a single dose of GF-3308 was assessed in ~~19~~ 20 trials. Two trials (HU14E7B026LM01 and HU16E7B029AB04) were not harvested. Five trials (HU14E7B014AB01C, HU15E7B012AB02, HU15E7B012AB01C, HU15E7B012AB02C, HU15E7B040AB02C). The results from these trials have not been included, however, for completeness they can be found in Appendix 5 in the BAD.

In these ~~19~~ 20 trials there were no significant negative effects noted in any trial. ~~Thirteen~~ Fourteen trials were based on the maximum dose rate of 2,0 L/ha. A single application of GF-3308 at 2,0 L/ha, in the presence of disease had a positive impact on grain yield across the majority of trials, with a mean yield increase of ~~19.0%,~~ 19,4% relative to the untreated. These trials also achieved a ~~6.5%~~ 6,6% mean increase in thousand grain weight (TGWT), relative to the untreated and a 0,9% mean increase in hectolitre weight (HLW). The 1,5 L/ha dose rate was included in 13 trials. In these trials, a single application of GF-3308 at 1,5 L/ha, in the presence of disease, had a positive impact on grain yield, with a mean yield increase of ~~9.1%~~ 9,5%, relative to the untreated. These trials also achieved a ~~5.1%~~ 5,5% mean increase in thousand grain weight (TGWT) and a ~~0.8%~~ 1,2% mean increase in hectolitre weight (HLW). In ~~one~~ six trials, the ~~maximum~~ dose rate ~~was~~ 1.2 L/ha of GF-3308 was also tested and ~~this~~ these trials demonstrated a yield increase of ~~3.2%~~ 6,8%, a ~~7.0%~~ 2,9% increase in thousand grain weight (TGWT) and a ~~4.7%~~ 1,6% increase in hectolitre weight (HLW). Results for the standards across all trials and dose rates were comparable to GF-3308.

A summary of the yield and quality data from efficacy trials is presented in Table 3.2-88 to Table 3.2-90. The individual trial results are detailed in Appendix 5 in the BAD.

~~**Table 3.2-88: Impact of GF-3308 on grain yield when applied at 1,2-2,0 L/ha on winter wheat (TRZAW) in EPPO South-East climatic zone efficacy trials**~~

~~Crop~~	~~Number of trials~~	~~Yield (t/ha) untreated control~~		~~Relative yield (Untreated = 100%)~~						
				~~GF-3308 75 g as/ha 1.5 L/ha~~		~~GF-3308 100 g as/ha 2.0 L/ha~~		~~Reference standard~~		
		~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Product/dose~~
~~TRZAW~~	~~13~~	~~**4.5**~~	~~2.6-6.6~~	-	-	~~**119.0**~~	~~95.3-142.4~~	~~**118.2**~~	~~100.0-140.5~~	~~All~~
~~TRZAW*~~	~~10~~	~~**4.5**~~	~~2.6-6.6~~	-	-	~~**121.1**~~	~~95.3-142.4~~	~~**119.4**~~	~~102.0-140.5~~	~~Proline/0.72 L/ha~~
~~TRZAW**~~	~~2~~	~~**3.7**~~	~~2.9-4.5~~	-	-	~~**112.7**~~	~~106.9-118.4~~	~~**106.8**~~	~~100.0-113.5~~	~~Vertisan/1.0 L/ha~~

~~TRZAW#~~	~~1~~	~~**6.0**~~	-	-	-	~~**111.1**~~	-	~~**129.0**~~	-	~~Aviator Xpro/1.25 L/ha~~
~~TRZAW~~	~~13~~	~~**4.7**~~	~~2.9-6.8~~	~~**109.1**~~	~~98.9-117.0~~	-	-	~~**111.7**~~	~~100.0-129.0~~	~~All~~
~~TRZAW*~~	~~7~~	~~**4.8**~~	~~3.5-6.8~~	~~**110.3**~~	~~98.9-117.0~~	-	-	~~**112.7**~~	~~102.0-120.8~~	~~Proline/0.72 L/ha~~
~~TRZAW**~~	~~2~~	~~**3.7**~~	~~2.9-4.5~~	~~**110.1**~~	~~106.9-113.2~~	-	-	~~**106.8**~~	~~100.0-113.5~~	~~Vertisan/1.0 L/ha~~
~~TRZAW***~~	~~3~~	~~**4.7**~~	~~3.0-6.7~~	~~**107.3**~~	~~103.9-109.0~~	-	-	~~**107.1**~~	~~104.2-110.4~~	~~Input/1.0 L/ha~~
~~TRZAW##~~	~~1~~	~~**5.3**~~	-	~~**103.2##**~~	-	-	-	~~**104.2**~~	-	~~Aviator Xpro/1.0 L/ha~~

~~*Direct comparison to Proline~~
~~**Direct comparison to Vertisan~~
~~***Direct comparison to Input~~
~~#Direct comparison to Aviator Xpro.~~
~~##Direct comparison to Aviator Xpro. GF-3308 applied at 1.2 L/ha~~

Table 3.2-88: Impact of GF-3308 on grain yield when applied at 1,2-2,0 L/ha on winter wheat (TRZAW) in EPPO South-East climatic zone efficacy trials

Crop	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)						
				GF-3308 75 g as/ha 1,5 L/ha		GF-3308 100 g as/ha 2,0 L/ha		Reference standard		
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	14	**4,8**	2,6-7,6	-	-	**119,4**	95,3-142,4	**118,4**	102,0-140,5	All
TRZAW*	11	**4,8**	2,6-7,6	-	-	**121,4**	95,3-142,4	**119,6**	102,0-140,5	Proline/0,72 L/ha
TRZAW**	2	**3,7**	2,9-4,5	-	-	**112,7**	106,9-118,4	**106,8**	100,0-113,5	Vertisan/1,0 L/ha
TRZAW***	1	**6,0**	-	-	-	**111,1**	-	**129,0**	-	Aviator Xpro/1,25 L/ha
TRZAW	13	**4,9**	2,9-7,6	**109,5**	102,7-117,0	-	-	**112,5**	100,0-129,0	All
TRZAW*	6	**5,2**	3,5-7,6	**112,2**	102,7-117,0	-	-	**115,7**	102,0-121,9	Proline/0,72 L/ha
TRZAW**	2	**3,7**	2,9-4,5	**110,1**	106,9-113,2	-	-	**106,8**	100,0-113,5	Vertisan/1,0 L/ha
TRZAW***	3	**4,7**	3,0-6,7	**107,3**	103,9-109,0	-	-	**107,1**	104,2-110,4	Input/1,0 L/ha
TRZAW****	2	**5,7**	5,3-6,0	**104,0**	103,2-104,8	-	-	**116,6**	104,1-129	Aviator Xpro/1,0 L/ha or 1,25 L/ha
TRZAW^	6	**4,9**	3,0-6,8	**106,8**	103,1-109,0	-	-	**107,1**	104,2-110,4	All
TRZAW#	1	**5,3**	-	**103,1**	-	-	-	**104,2**	-	Aviator Xpro/1,0 L/ha
TRZAW##	2	**5,2**	3,5-6,8	**108,4**	107,9-108,8	-	-	**108,4**	108,0-108,8	Proline/0,72 L/ha
TRZAW###	3	**4,7**	3,0-6,7	**106,9**	103,3-109,0			**107,1**	104,2-110,4	Input/ 1,0 L/ha

*Direct comparison to Proline
**Direct comparison to Vertisan
***Direct comparison to Input
**** Direct comparison to Aviator Xpro
#Direct comparison to Aviator Xpro. GF-3308 applied at 1,2 L/ha
Direct comparison to Input. GF-3308 applied at 1,2 L/ha
Direct comparison to Proline. GF-3308 applied at 1,2 L/ha
^ GF-3308 applied at 1,2 L/ha

~~**Table 3.2-89: Impact of GF-3308 on grain quality (TGWT) when applied at 1.2-2.0 L/ha on winter wheat (TRZAW) in EPPO South-East climatic zone efficacy trials**~~

~~Crop~~	~~Number of trials~~	~~TGW (g) untreated control~~		~~Relative TGW (Untreated = 100%)~~						
				~~GF-3308 75 g as/ha 1.5 L/ha~~		~~GF-3308 100 g as/ha 2.0 L/ha~~		~~Reference standard~~		
		~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Product/dose~~
~~TRZAW~~	~~13~~	~~**43.6**~~	~~37.2-56.8~~	-	-	~~**106.5**~~	~~97.7-123.2~~	~~**104.7**~~	~~97.3-114.2~~	~~All~~

TRZAW*	10	**44.6**	39.7-56.8	-	-	**105.6**	97.7-123.2	**104.5**	97.3-114.2	Proline/0.72 L/ha
TRZAW**	2	**39.5**	37.2-41.7	-	-	**104.8**	102.4-107.3	**100.9**	98.9-102.9	Vertisan/1.0 L/ha
TRZAW#	1	**42.9**	-	-	-	**119.2**	-	**114.2**	-	Aviator Xpro/1.25 L/ha
TRZAW	13	**43.2**	36.4-48.1	**105.1**	99.6-117.1	-	-	**104.2**	97.3-114.2	All
TRZAW*	7	**44.9**	40.9-47.7	**105.4**	99.6-113.9	-	-	**104.4**	97.3-114.1	Proline/0.72 L/ha
TRZAW**	2	**39.5**	37.2-41.7	**103.2**	102.1-104.3	-	-	**100.9**	98.9-102.9	Vertisan/1.0 L/ha
TRZAW***	3	**41.7**	36.4-48.1	**101.9**	99.9-104.0	-	-	**102.6**	100.2-104.4	Input/1.0 L/ha
TRZAW##	1	**29.8**	-	**107.0##**	-	-	-	**107.9**	-	Aviator Xpro/1.0 L/ha

*Direct comparison to Proline
**Direct comparison to Vertisan
***Direct comparison to Input
#Direct comparison to Aviator Xpro.
##Direct comparison to Aviator Xpro. GF-3308 applied at 1.2 L/ha

Table 3.2-89: Impact of GF-3308 on grain quality (TGWT) when applied at 1,2-2,0 L/ha on winter wheat (TRZAW) in EPPO South-East climatic zone efficacy trials

Crop	Number of trials	Yield (t/ha) untreated control		Relative TGW (Untreated = 100%)						
				GF-3308 75 g as/ha 1,5 L/ha		GF-3308 100 g as/ha 2,0 L/ha		Reference standard		
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	14	**43,8**	37,2-56,8	-	-	**106,6**	97,7-123,2	**105,0**	97,3-114,2	All
TRZAW*	11	**44,6**	39,7-56,8	-	-	**105,8**	97,7-123,2	**104,9**	97,3-114,1	Proline/0,72 L/ha
TRZAW**	2	**39,5**	37,2-41,7	-	-	**104,8**	102,4-107,3	**100,9**	98,9-102,9	Vertisan/1,0 L/ha
TRZAW***	1	**42,9**	-	-	-	**119,2**	-	**114,2**	-	Aviator Xpro/1,25 L/ha
TRZAW	13	**42,9**	36,4-48,1	**105,5**	99,6-117,1	-	-	**105,0**	97,3-114,2	All
TRZAW*	6	**45,2**	42,8-46,7	**105,9**	99,6-113,9	-	-	**105,6**	97,3-114,1	Proline/0,72 L/ha
TRZAW**	2	**39,5**	37,2-41,7	**103,2**	102,1-104,3	-	-	**100,9**	98,9-102,9	Vertisan/1,0 L/ha
TRZAW***	3	**41,7**	36,4-48,1	**101,9**	99,9-104,0	-	-	**102,6**	100,2-104,4	Input/1,0 L/ha
TRZAW****	2	**41,4**	39,8-42,9	**112,0**	106,9-117,1	-	-	**111,0**	107,8-114,2	Aviator Xpro/1,0 L/ha or 1,25 L/ha
TRZAW^	6	**42,3**	36,4-48,1	**102,9**	99,4-107,0			**103,6**	100,2-107,9	All
TRZAW#	1	**39,8**	-	**107,0**	-	-	-	**107,9**	-	Aviator Xpro/1,0 L/ha
TRZAW##	2	**44,3**	40,9-47,7	**103,6**	102,8-104,4	-	-	**102,8**	102,5-103,1	Proline/0,72 L/ha
TRZAW###	3	**41,7**	36,4-48,1	**101,1**	99,4-102,1			**102,6**	100,2-104,4	Input/ 1,0 L/ha

*Direct comparison to Proline
**Direct comparison to Vertisan
***Direct comparison to Input
**** Direct comparison to Aviator Xpro
#Direct comparison to Aviator Xpro. GF-3308 applied at 1,2 L/ha
Direct comparison to Input. GF-3308 applied at 1,2 L/ha
Direct comparison to Proline. GF-3308 applied at 1,2 L/ha
^ GF-3308 applied at 1,2 L/ha

Table 3.2-90: Impact of GF-3308 on grain quality (HLW when applied at 1.2-2.0 L/ha on winter wheat (TRZAW) in EPPO South-East climatic zone efficacy trials

Crop	Number of trials	HLW (kg) untreated control	Relative HLW (Untreated = 100%)		
			GF-3308 75 g as/ha 1.5 L/ha	GF-3308 100 g as/ha 2.0 L/ha	Reference standard

~~		~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Product/dose~~
~~TRZAW*~~	~~3~~	~~**76.0**~~	~~75.1-76.8~~	~~-~~	~~-~~	~~**100.9**~~	~~100.1-101.7~~	~~**101.1**~~	~~100.3-102.0~~	~~Proline/0.72 L/ha~~
~~TRZAW~~	~~7~~	~~**74.6**~~	~~70.6-80.4~~	~~**100.8**~~	~~99.6-101.6~~	~~-~~	~~-~~	~~**101.1**~~	~~100.0-102.7~~	~~All~~
~~TRZAW*~~	~~4~~	~~**74.2**~~	~~70.6-76.1~~	~~**100.7**~~	~~100.1-101.4~~	~~-~~	~~-~~	~~**101.3**~~	~~100.3-102.7~~	~~Proline/0.72 L/ha~~
~~TRZAW**~~	~~3~~	~~**75.3**~~	~~71.0-80.4~~	~~**100.9**~~	~~99.6-101.6~~	~~-~~	~~-~~	~~**100.9**~~	~~100.0-101.8~~	~~Input/1.0 L/ha~~
~~TRZAW#~~	~~1~~	~~**75.3**~~	~~-~~	~~**104.7#**~~	~~-~~	~~-~~	~~-~~	~~**105.5**~~	~~-~~	~~Aviator Xpro/1.0 L/ha~~

~~*Direct comparison to Proline~~
~~**Direct comparison to Input~~
~~#Direct comparison to Aviator Xpro. GF-3308 applied at 1.2 L/ha~~

Table 3.2-90: Impact of GF-3308 on grain quality (HLW when applied at 1,2-2,0 L/ha on winter wheat (TRZAW) in EPPO South-East climatic zone efficacy trials

Crop	**Number of trials**	**HLW (kg) untreated control**		**Relative HLW (Untreated = 100%)**						
				GF-3308 75 g as/ha 1,5 L/ha		**GF-3308 100 g as/ha 2,0 L/ha**		**Reference standard**		
		Mean	**min-max**	**Mean**	**min-max**	**Mean**	**min-max**	**Mean**	**min-max**	**Product/dose**
TRZAW*	3	**76,0**	75,1-76,8	**-**	-	**100,9**	100,1-101,7	**101,1**	100,3-102,0	Proline/0,72 L/ha
TRZAW	6	**75,4**	71,0-80,4	**101,2**	99,6-104,5	-	-	**101,6**	100,0-105,4	All
TRZAW*	2	**75,6**	75,1-76,1	**100,1**	100,1-100,1	-	-	**100,7**	100,3-101,1	Proline/0,72 L/ha
TRZAW**	3	**75,3**	71,0-80,4	**100,9**	99,6-101,6	-	-	**100,9**	100,0-101,8	Input/1,0 L/ha
TRZAW***	1	**75,3**	-	**104,5**	-			**105,4**	-	Aviator Xpro/1,0 L/ha
TRZAW^	6	**74,4**	70,6-80,4	**101,6**	99,7-104,7			**102,0**	100,0-105,5	All
TRZAW#	1	**75,3**	-	**104,7**	-	-	-	**105,5**	-	Aviator Xpro/1,0 L/ha
TRZAW##	2	**72,8**	70,6-74,9	**101,3**	101,2-101,4			**102,0**	101,2-102,7	Proline/0,72 L/ha
TRZAW###	3	**75,7**	72,0-79,7	**100,8**	99,7-101,3			**100,9**	100,0-101,8	Input/ 1,0 L/ha

*Direct comparison to Proline
**Direct comparison to Input
*** Direct comparison to Aviator Xpro
#Direct comparison to Aviator Xpro. GF-3308 applied at 1,2 L/ha
Direct comparison to Input. GF-3308 applied at 1,2 L/ha
Direct comparison to Proline. GF-3308 applied at 1,2 L/ha
^ GF-3308 applied at 1,2 L/ha

Summary and conclusion

GF-3308 at the proposed label rate~~s~~ of 2,0 L/ha in the EPPO Maritime climatic zone~~, 1.5-2.0 L/ha~~ and in the EPPO North-East climatic zone or 1,2-2, L/ha in the EPPO South-East climatic zone had an overall positive effect on grain yield and quality of wheat crops treated in the presence of disease. GF-3308 at 1,5 L/ha had also no negative effect on grain yield and yield quality in North-East EPPO zone.

Winter rye (SECCW)

Results – EPPO Maritime climatic zone

Of the 13 EPPO Maritime climatic zone effectiveness trials on winter rye generated between 2015-2017, the impact on grain yield after a single dose of GF-3308 was assessed in 12 trials. One trial (DE17G1C012UB03C) was not harvested.
In these 12 trials there were no significant negative effects noted in any trial. A single application of GF-3308 at 2,0 L/ha, in the presence of disease, had a positive impact on grain yield across all trials, with a mean yield increase of ~~16.4%~~ 14,9%, relative to the untreated. These trials also achieved a ~~4.2%~~ 4,3% increase in thousand grain weight (TGWT), relative to the untreated. No trials were assessed for hectolitre weight (HLW). Results for the standards were comparable.
A summary of the yield and quality data from efficacy trials is presented in Table 3.2-91 and Table 3.2-92. The individual trial results are detailed in Appendix 5 in the BAD.

Table 3.2-91: Impact of GF-3308 on grain yield when applied at 2,0 L/ha on winter rye (SECCW) in EPPO Maritime climatic zone efficacy trials

Crop	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
				GF-3308 100 g as/ha 2,0 L/ha		Reference standard		
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
SECCW	12	**6,8**	3,9-9,8	**114,9**	102,0-148,9	**116,6**	100,0-158,5	All
SECCW*	10	**7,0**	5,2-9,8	**112,0**	102,0-128,0	**114,1**	105,0-125,9	Proline/0,72 L/ha
SECCW**	2	**6,1**	3,9-8,4	**129,0**	109,0-148,9	**129,3**	100,0-158,5	Aviator Xpro/1,25 L/ha

*Direct comparison to Proline
**Direct comparison to Aviator Xpro

Table 3.2-92: Impact of GF-3308 on grain quality (TGWT) when applied at 2,0 L/ha on winter rye (SECCW) in EPPO Maritime climatic zone efficacy trials

Crop	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)				
				GF-3308 100 g as/ha 2,0 L/ha		Reference standard		
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
SECCW	11	**29,5**	22,3-40,0	**104,3**	100,9-119,1	**105,9**	100,7-119,3	All
SECCW*	10	**28,5**	22,3-34,1	**104,4**	100,9-119,1	**106,2**	100,7-119,3	Proline/0,72 L/ha
SECCW**	1	**40,0**	-	**102,5**	-	**102,5**	-	Aviator Xpro/1,25 L/ha

*Direct comparison to Proline
**Direct comparison to Aviator Xpro

Results – EPPO North-East climatic zone

All five EPPO North-East climatic zone effectiveness trials on winter rye generated in 2016 were assessed for the impact on grain yield after a single dose of GF-3308 at the 2,0 L/ha dose rate.
In these five trials there were no significant negative effects noted in any trial. A single application of GF-3308 at 2,0 L/ha, in the presence of disease, had a positive impact on grain yield across all trials,

with a mean yield increase of 14,2%, relative to the untreated. There was no impact on thousand grain weight (TGWT). No trials were assessed for hectolitre weight (HLW). Results for the standards were comparable.
A summary of the yield and quality data from efficacy trials is presented in Table 3.2-93 to Table 3.2-94. The individual trial results are detailed in Appendix 5 in the BAD.

Table 3.2-93: Impact of GF-3308 on grain yield when applied at 2,0 L/ha on winter rye (SECCW) in EPPO North-East climatic zone efficacy trials

Crop	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
				GF-3308 100 g as/ha 2,0 L/ha		Reference standard		
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
SECCW*	5	**5,1**	3,6-7,3	**114,2**	102,1-131,8	**115,7**	107,1-138,3	Proline/0,72 L/ha

*Direct comparison to Proline

Table 3.2-94: Impact of GF-3308 on grain quality (TGWT) when applied at 2,0 L/ha on winter rye (SECCW) in EPPO North-East climatic zone efficacy trials

Crop	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)				
				GF-3308 100 g as/ha 2,0 L/ha		Reference standard		
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
SECCW*	5	~~31,2~~ **31,3**	28,7-35,8	**99,9**	95,6-103,2	**103,7**	100,1-107,5	Proline/0,72 L/ha

*Direct comparison to Proline

Use on rye in the EPPO North-East zone includes a lower dose of 1,5 L/ha. This dose rate is supported by 10 winter ~~wheat~~ rye trials (5 EPPO North-East zone trials and 5 trials from the EPPO Maritime zone/DE). A summary of the yield and quality data from 9 of these efficacy trials at the 1,5 L/ha dose rate is presented in Table 3.2-95 and Table 3.2-96. One DE trial (DE17G1C012UB03C) was not harvested.
A single application of GF-3308 at 1,5 L/ha, in the presence of disease, had a positive impact on grain yield across all trials. The increases found were similar to the 2,0 L/ha dose rate, with a mean yield increase of 9,7-23,8%, relative to the untreated. These trials also achieved a ~~0,5~~ 0,1-7,7% mean increase in thousand grain weight (TGWT). Results for the standards were comparable.

Table 3.2-95: Impact of GF-3308 on grain yield when applied at 1,5 L/ha on winter rye (SECCW) in EPPO North-East climatic zone and DE efficacy trials

Crop	EPPO zone	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
					GF-3308 75 g as/ha 1,5 L/ha		Reference standard		
			Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
SECCW	NE	5	**5,1**	3,6-7,3	**109,7**	104,1-119,8	**115,7**	107,1-138,3	Proline/0,72 L/ha
SECCW	MAR	4	**6,1**	3,9-8,4	**123,8**	110,0-148,6	**124,1**	100,0-158,5	All
SECCW*	MAR	2	**6,1**	5,2-7,0	**118,3**	112,0-124,6	**118,9**	112,0-125,9	Proline/0,72 L/ha
SECCW**	MAR	2	**6,1**	3,9-8,4	**129,3**	110,0-148,6	**129,3**	100,0-158,5	Aviator Xpro/1,25 L/ha

*Direct comparison to Proline
**Direct comparison to Aviator Xpro

Table 3.2-96: Impact of GF-3308 on grain quality (TGWT) when applied at 1,5 L/ha on winter rye (SECCW) in EPPO North-East climatic zone and DE efficacy trials

Crop	EPPO Zone	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)				
					GF-3308 75 g as/ha 1,5 L/ha		Reference standard		
			Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
SECCW	NE	5	31,2 **31,3**	28,7-28,7 35,8	100,5 **100,1**	97,2-103,0	**103,7**	100,1-107,5	Proline/0,72 L/ha
SECCW	MAR	3	**32,9**	27,8-40,0	**107,7**	100,0-117,9	**111,0**	102,5-119,3	All
SECCW*	MAR	2	**29,4**	27,8-30,9	**111,6**	105,3-117,9	**115,3**	111,2-119,3	Proline/0,72 L/ha
SECCW**	MAR	1	**40,0**	-	**100,0**	-	**102,5**	-	Aviator Xpro/1,25 L/ha

*Direct comparison to Proline
**Direct comparison to Aviator Xpro

Summary and conclusion

GF-3308 at the proposed label rates of 2,0 L/ha in the EPPO Maritime climatic zone and 1,5-2,0 L/ha in the EPPO North-East climatic zone had an overall positive effect on grain yield and quality of winter rye crops treated in the presence of disease.

Winter triticale (TTLWI)

Results – EPPO Maritime climatic zone

Of the 13 EPPO Maritime climatic zone effectiveness trials on winter triticale generated between 2015-2020, the impact on grain yield after a single dose of GF-3308 was assessed in 11 trials. Two trials (DE15E7B034UB03C and EA20E7B018F-DNZ057) were not harvested.
In these 11 trials there were no significant negative effects noted in any trial. A single application of GF-3308 at 2,0 L/ha, in the presence of disease, had a positive impact on grain yield across all trials, with a mean yield increase of 15.3%, 15,4% relative to the untreated. These trials also achieved a 7,4% increase in thousand grain weight (TGWT), relative to the untreated and a 3,7% increase in hectolitre weight (HLW). Results for the standards were comparable.
A summary of the yield and quality data from efficacy trials is presented in Table 3.2-97 to Table 3.2-99. The individual trial results are detailed in Appendix 5 in the BAD.

Table 3.2-97: Impact of GF-3308 on grain yield when applied at 2,0 L/ha on winter triticale (TTLWI) in EPPO Maritime climatic zone efficacy trials

Crop	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
				GF-3308 100 g as/ha 2,0 L/ha		Reference standard		
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TTLWI	11	**7,6**	5,2-11,4	115,3 **115,4**	103,1-166,7	117,2 **117,3**	102,2-169,7	All
TTLWI*	8	**7,7**	5,2-11,4	110,4 **110,5**	103,1-116,9	113,3 **113,5**	102,2-135,7 136,9	Proline/0,65; 0,72 and 0,8 L/ha
TTLWI**	3	**7,3**	6,4-8,6	**128,3**	104,3-166,7	**127,6**	103,4-169,7	Prosaro/1,0 L/ha

*Direct comparison to Proline
**Direct comparison to Prosaro

Table 3.2-98: Impact of GF-3308 on grain quality (TGWT) when applied at 2,0 L/ha on winter triticale (TTLWI) in EPPO Maritime climatic zone efficacy trials

Crop	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)				
				GF-3308 100 g as/ha 2,0 L/ha		Reference standard		
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TTLWI	6	~~41,3~~ **41,4**	34,1-54,6	**107,4**	101,3-117,9	~~104,9~~ **105,7**	~~100,0~~ 101,4-110,7	All
TTLWI*	3	**45,2**	40,3-54,6	**103,9**	101,3-106,6	~~102,5~~ **104,1**	~~100,0~~ 101,4-106,1	Proline/0,72 L/ha
TTLWI**	3	~~37,5~~ **37,6**	34,1-40,7	**110,8**	105,4-117,9	**107,3**	103,9-110,7	Prosaro/1,0 L/ha

*Direct comparison to Proline
**Direct comparison to Prosaro

Table 3.2-99: Impact of GF-3308 on grain quality (HLW when applied at 2,0 L/ha on winter triticale (TTLWI) in EPPO Maritime climatic zone efficacy trials

Crop	Number of trials	HLW (kg) untreated control		Relative HLW (Untreated = 100%)				
				GF-3308 100 g as/ha 2,0 L/ha		Reference standard		
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TTLWI	5	**74,6**	73,3-77,2	**103,7**	102,0-105,4	**103,9**	101,5-105,9	All
TTLWI*	4	**73,9**	73,3-74,8	**103,3**	102,0-105,3	**103,4**	101,5-105,9	Proline/0,72 L/ha or 0,8
TTLWI**	1	**77,2**	-	**105,4**	-	**105,7**	-	Prosaro/1,0 L/ha

*Direct comparison to Proline
**Direct comparison to Prosaro

Results – EPPO North-East climatic zone

All five EPPO North-East climatic zone effectiveness trials on winter triticale generated in 2016 and 2020 were assessed for the impact on grain yield after a single dose of GF-3308 at the 2,0 L/ha dose rate. In these five trials there were no significant negative effects noted in any trial. A single application of GF-3308 at 2,0 L/ha, in the presence of disease, had a positive impact on grain yield across all trials, with a mean yield increase of 15,8%, relative to the untreated. These trials also achieved a 4,0% mean increase in thousand grain weight (TGWT), relative to the untreated and a 1,7% increase in hectolitre weight (HLW). Results for the standards were comparable.
A summary of the yield and quality data from efficacy trials is presented in Table 3.2-100 to Table 3.2-102. The individual trial results are detailed in Appendix 5 in the BAD.

Table 3.2-100: Impact of GF-3308 on grain yield when applied at 2,0 L/ha on winter triticale (TTLWI) in EPPO North-East climatic zone efficacy trials

Crop	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
				GF-3308 100 g as/ha 2,0 L/ha		Reference standard		
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TTLWI*	5	**6,1**	4,5-7,5	**115,8**	107,6-127,0	**115,6**	110,3-127,5	Proline/0,72 L/ha or 0,8 L/ha

*Direct comparison to Proline

Table 3.2-101: Impact of GF-3308 on grain quality (TGWT) when applied at 2,0 L/ha on winter triticale (TTLWI) in EPPO North-East climatic zone efficacy trials

Crop	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)				
				GF-3308 100 g as/ha 2,0 L/ha		Reference standard		
		Mean	**min-max**	**Mean**	**min-max**	**Mean**	**min-max**	**Product/dose**
TTLWI*	4	**43,8**	33,8-53,7	**104,0**	100,9-111,3	**104,3**	100,0-111,6	Proline/0,72 L/ha or 0,8 L/ha

*Direct comparison to Proline

Table 3.2-102: Impact of GF-3308 on grain quality (HLW when applied at 2,0 L/ha on winter triticale (TTLWI) in EPPO North-East climatic zone efficacy trials

Crop	Number of trials	HLW (kg) untreated control		Relative HLW (Untreated = 100%)				
				GF-3308 100 g as/ha 2,0 L/ha		Reference standard		
		Mean	**min-max**	**Mean**	**min-max**	**Mean**	**min-max**	**Product/dose**
TTLWI*	1	**59,9**	-	**101,7**	-	**104,6**	-	Proline/~~0,72~~ 0,8 L/ha

*Direct comparison to Proline

~~Use on triticale in the EPPO North-East zone includes a~~ Data for lower dose of 1,5 L/ha have been also presented. This dose rate is supported by ~~9~~ 11 winter ~~wheat~~ triticale trials (~~three~~ five EPPO North-East zone trials and six trials from the EPPO Maritime zone/DE). A summary of the yield and quality data from ~~8~~ 11 of these efficacy trials at the 1,5 L/ha dose rate is presented in Table 3.2-103 to Table 3.2-105. One DE trial (EA20E7B018F-DNZ057) was not harvested.
A single application of GF-3308 at 1,5 L/ha, in the presence of disease, had a positive impact on grain yield across all trials. The increases found were similar to the 2,0 L/ha dose rate, with a mean yield increase of ~~10,2-12,5%~~ 9,2-15,4%, relative to the untreated. These trials also achieved a ~~0,6-~~ 2,9-8,0% mean increase in thousand grain weight (TGWT) and ~~a~~ 1,5-2,6% mean increase in hectolitre weight (HLW). Results for the standards were comparable.

Table 3.2-103: Impact of GF-3308 on grain yield when applied at 1,5 L/ha on on winter triticale (TTLWI) in EPPO North-East climatic zone and DE efficacy trials

Crop	EPPO zone	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
					GF-3308 75 g as/ha 1,5 L/ha		Reference standard		
			Mean	**min-max**	**Mean**	**min-max**	**Mean**	**min-max**	**Product/dose**
TTLWI	NE	~~3~~ 5	~~6,4~~ **6,1**	~~4,7~~ 4,5-7,5	~~112,5~~ **115,4**	110,3-~~116,0~~ 127,5	~~112,6~~ **115,6**	110,3-~~115,2~~ 127,5	Proline/0,72 L/ha or 0,8 L/ha
TTLWI	MAR	~~5~~ 6	~~6,7~~ **7,5**	5,2-~~8,8~~ 11,4	~~110,2~~ **109,2**	102,8-~~117,8~~ 117,3	~~116,5~~ **114,3**	~~106,0-135,7~~ 102,2-136,9	All
TTLWI*	MAR	~~4~~ 5	~~6,8~~ **7,7**	5,2-~~8,8~~ 11,4	~~110,4~~ **109,0**	102,8-117,3	~~118,2~~ **115,3**	~~106,0-135,7~~ 102,2-136,9	Proline/0,72 L/ha
TTLWI**	MAR	1	**6,4**	-	**109,7**	-	**109,6**	-	Prosaro/1,0 L/ha

*Direct comparison to Proline
**Direct comparison to Prosaro

Table 3.2-104: Impact of GF-3308 on grain quality (TGWT) when applied at 1,5 L/ha on winter triticale (TTLWI) in EPPO North-East climatic zone and DE efficacy trials

Crop	EPPO Zone	Number of trials	TGW (g) untreated control	Relative TGW (Untreated = 100%)	
				GF-3308	Reference standard

					75 g as/ha 1,5 L/ha				
			Mean	**min-max**	**Mean**	**min-max**	**Mean**	**min-max**	**Product/dose**
TTLWI	NE	~~3~~ 4	~~47,1~~ **43,8**	~~37,4~~33,8-53,7	~~100,6~~ **102,9**	98,1-102,4	~~101,8~~ **104,3**	100,0-~~102,8~~ 111,6	Proline/0,72 L/ha or 0,8 L/ha
TTLWI	MAR	1	**37,9**	-	**108,0**	-	**107,4**	-	Prosaro/1,0 L/ha

Table 3.2-105: Impact of GF-3308 on grain quality (HLW when applied at 1,5 L/ha on winter triticale (TTLWI) ~~in EPPO Maritime climatic zone efficacy trials~~ in EPPO North-East climatic zone and DE efficacy trials

Crop	**EPPO Zone**	**Number of trials**	**TGW (g) untreated control**		**Relative HLW (Untreated = 100%)**				
					GF-3308 75 g as/ha 1,5 L/ha		**Reference standard**		
			Mean	**min-max**	**Mean**	**min-max**	**Mean**	**min-max**	**Product/dose**
TTLWI	NE	1	**59,9**	-	**101,5**	-	**104,6**	-	Proline/0,8 L/ha
TTLWI	MAR	~~3~~ 4	**74,0**	73,3-74,8	**102,6**	~~101,1~~ 101,8-104,1	~~104,1~~ **103,4**	101,5-105,9	Proline/0,72 L/ha or 0,8 L/ha

~~*Direct comparison to Proline~~
~~**Direct comparison to Prosaro~~

Summary and conclusion

GF-3308 at the proposed label rates of 2,0 L/ha in the EPPO Maritime climatic zone and and also in dose rate range: 1,5-2,0 L/ha in the EPPO North-East climatic zone had an overall positive effect on grain yield and quality of winter triticale crops treated in the presence of disease

Summary and conclusions on effectiveness (all crops and disease claims)

Data have been presented across a range of disease in wheat, rye and triticale. Disease levels across the trials ranged from 5,0-~~96.5%~~ 43,2% infection (severity) at assessment. GF-3308 was applied between BBCH ~~31-61~~ 30-65 and achieved at dose rate of 2,0 L/ha over 80% control of most target pathogens and supports the proposed claims of ‘Control’ for the proposed target diseases.
The summary tables below are split by EPPO climatic zone. ~~and the following colour coding has been used to illustrate both the effectiveness of GF-3308 and the comparability between GF-3308 and the reference standards used.~~

~~Level of Effectiveness~~
~~>79% control~~
~~70-78.9% control~~
~~<69.9% control~~

EPPO Maritime zone

The proposed use is for a single application at 2,0 L/ha applied at BBCH 30-69 to winter and spring wheat (TRZAW and TRZAS), spelt wheat (TRZSP) and durum wheat (TRZDU) for control of SEPTTR, PUCCRT and PUCCST; winter and spring rye (SECCW and SECCS) for control of PUCCRE and RHYNSE and winter and spring triticale (TTLWI and TTLSO) for control of SEPTSP and PUCCST.

~~**Summary of effectiveness data for GF-3308 for EPPO Maritime zone**~~

~~Target (EPPO code)~~	~~Crop (EPPO)~~	~~EPPO Zone/ Country~~	~~Number of trials~~	~~Application timing (BBCH)~~	~~Untreated % infection~~		~~% control~~			
							~~GF-3308 2.0 L/ha~~		~~Reference standard~~	
					~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~
~~SEPTTR~~	~~TRZAW~~	~~MAR~~	~~13~~	~~31-51~~	~~25.5~~	~~5.0-75.0~~	~~**92.5**~~	~~78.7-100~~	~~**78.6***~~	~~20.0-100~~
~~PUCCRT~~	~~TRZAW~~	~~MAR~~	~~12~~	~~33-61~~	~~26.4~~	~~5.6-97.5~~	~~**89.0**~~	~~71.7-100~~	~~**93.9**~~$^{+}$	~~73.3-100~~
~~PUCCST~~	~~TRZAW~~	~~MAR~~	~~10~~	~~32-45~~	~~23.4~~	~~6.1-65.0~~	~~**86.5**~~	~~71.7-98.6~~	~~**91.5**~~$^{\$}$	~~71.7-100~~

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control			
							GF-3308 2.0 L/ha		Reference standard	
					Mean	min-max	Mean	min-max	Mean	min-max
~~PUCCRE~~	~~SECCW~~	~~MAR~~	~~11~~	~~37-59~~	~~18.1~~	~~5.0-74.0~~	~~**84.7**~~	~~75.5-92.6~~	~~**90.6**^~~	~~81.6-100~~
~~RHYNSE~~	~~SECCW~~	~~MAR~~	~~10~~	~~39-59~~	~~16.5~~	~~9.8-25.5~~	~~**88.2**~~	~~76.2-100~~	~~**92.5**#~~	~~77.8-100~~
~~SEPTSP~~	~~TTLWI~~	~~MAR~~	~~6~~	~~39-51~~	~~13.3~~	~~5.8-32.5~~	~~**84.8**~~	~~73.1-100~~	~~**79.3**$~~	~~63.3-100~~
		~~PL~~	~~3~~	~~33-52~~	~~13.6~~	~~8.9-20.9~~	~~**87.6**~~	~~79.2-100~~	~~**88.2**$$~~	~~78.2-100~~
		~~**All**~~	~~**9**~~	~~**33-52**~~	~~13.4~~	~~5.8-32.5~~	~~**85.7**~~	~~73.1-100~~	~~**82.3**$$$~~	~~63.3-100~~
~~PUCCST~~	~~TTLWI~~	~~MAR~~	~~7~~	~~39-51~~	~~46.9~~	~~6.0-96.5~~	~~**86.0**~~	~~63.0-98.1~~	~~**88.2**±~~	~~54.5-100~~
		~~PL~~	~~3~~	~~35-52~~	~~19.6~~	~~7.1-37.8~~	~~**88.4**~~	~~83.5-94.9~~	~~**66.0**±±~~	~~54.1-73.7~~
		~~**All**~~	~~**10**~~	~~**35-52**~~	~~38.7~~	~~6.0-96.5~~	~~**86.7**~~	~~93.0-98.1~~	~~**81.6**±±±~~	~~54.1-100~~

~~*Mean of 9 trials using Proline at 0.72 L/ha and 4 trials using Aviator Xpro at 1.25 L/ha.~~
~~+Mean of 5 trials using Proline at 0.72 L/ha and 7 trials using Aviator Xpro at 1.25 L/ha.~~
~~§Mean of 8 trials using Proline at 0.72 L/ha, one trial using Aviator Xpro at 1.25 L/ha and one trial using Librax at 2.0 L/ha.~~
~~^Mean of 9 trials using Proline at 0.72 L/ha and two trials using Aviator Xpro at 1.25 L/ha.~~
~~#Mean of 7 trials using Proline at 0.72 L/ha and 3 trials using Aviator Xpro at 1.25 L/ha.~~
~~$Mean of 4 trials using Proline at 0.72 L/ha and two trials using Prosaro at 1.0 L/ha.~~
~~$$Mean of 3 trials using Proline at 0.72 L/ha.~~
~~$$$Mean of 7 trials using Proline at 0.72 L/ha and two trials using Prosaro at 1.0 L/ha.~~
~~±Mean of 6 trials using Proline at 0.72 L/ha and one trial using Prosaro at 1.0 L/ha.~~
~~±±Mean of 3 trials using Proline at 0.72 L/ha.~~
~~±±±Mean of 9 trials using Proline at 0.72 L/ha and one trial using Prosaro at 1.0 L/ha~~

Summary of effectiveness data for GF-3308 for EPPO Maritime zone (1,5-2,0 L/ha dose recommendations)

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control			
							GF-3308 2,0 L/ha		Reference standard	
					Mean	min-max	Mean	min-max	Mean	min-max
SEPTTR	TRZAW	MAR	24	31-65	24,8	5,0-75,0	**86,0**	52,0-100	**76,9***	29,3-100
PUCCRT	TRZAW	MAR	13	32-61	25,0	5,6-97,5	**86,7**	59,4-100	**93,0**+	73,8-100
PUCCST	TRZAW	MAR	11	31-45	22,8	6,1-65,0	**83,5**	62,0-98,6	**88,9**§	57,5-100
PUCCRE	SECCW	MAR	12	37-59	17,2	5,0-74,0	**84,2**	75,5-92,6	**91,0**^	81,6-100
RHYNSE	SECCW	MAR	12	39-59	18,3	9,8-27,0	**85,0**	66,7-100	**91,7**#	76,9-100
SEPTSP	TTLWI	MAR	6	39-51	13,3	5,8-32,5	**84,8**	73,1-100	**79,3**$	63,3-100
		PL	3	33-52	13,6	8,9-20,9	**87,6**	79,2-100	**88,2**$$	78,2-100
		All	**9**	**33-52**	13,4	5,8-32,5	**85,7**	73,1-100	**82,3**$$$	63,3-100
PUCCST	TTLWI	MAR	8	35-51	43,2	6,0-96,5	**83,5**	63,0-98,1	**83,0**±	18,5-100
		PL	3	35-52	19,6	7,1-37,8	**88,4**	83,5-94,9	**66,0**±±	54,1-73,7
		All	**11**	**35-52**	36,7	6,0-96,5	**84,9**	63,0-98,1	**78,4**±±±	18,5-100

*Mean of 19 trials using Proline at 0,72 L/ha, 4 trials using Aviator Xpro at 1,25 L/ha and 1 trial using Librax at 2,0 L/ha
+Mean of 5 trials using Proline at 0,72 L/ha or Proline at 0,8 L/ha, 7 trials using Aviator Xpro at 1,25 L/ha and 1 trial using Librax at 2,0 L/ha
§Mean of 9 trials using Proline at 0,72 L/ha, 1 trial using Aviator Xpro at 1,25 L/ha and 1 trial using Librax at 2,0 L/ha.
^Mean of 9 trials using Proline at 0,72 L/ha and 3 trials using Aviator Xpro at 1,25 L/ha.
#Mean of 9 trials using Proline at 0,72 L/ha and 3 trials using Aviator Xpro at 1,25 L/ha.
$Mean of 4 trials using Proline at 0,72 L/ha or Proline at 0,65 L/ha and 2 trials using Prosaro at 1,0 L/ha.
$$Mean of 3 trials using Proline at 0,72 L/ha.
$$$Mean of 7 trials using Proline at 0,72 L/ha or Proline at 0,65 L/ha and 2 trials using Prosaro at 1,0 L/ha.
±Mean of 7 trials using Proline at 0,72 L/ha or Proline at 0,8 L/ha and 1 trial using Prosaro at 1,0 L/ha.
±±Mean of 3 trials using Proline at 0,72 L/ha or Proline at 0,8 L/ha.

+++Mean of 10 trials using Proline at 0,72 L/ha or Proline at 0,8 L/ha and 1 trial using Prosaro at 1,0 L/ha

On winter wheat (TRZAW) a single dose of 2,0 L/ha of GF-3308 applied between BBCH 31-61 65 achieved over 80% control of SEPTTR (92.5% 86,0%), PUCCRT (89.0% 86,7%) and PUCCST (86.5% 83,5%) from 10-12 11-24 trials.
On winter rye (SECCW) a single dose of 2,0 L/ha of GF-3308 applied between BBCH 37-59 achieved over 80% control of PUCCRE (84.7% 84,2%) and RHYNSE (88.2% 85,0%) from 10-11 12 trials.
On winter triticale (TTLWI) a single dose of 2,0 L/ha of GF-3308 applied between BBCH 33-52 achieved over 80% control of SEPTSP (85,7% mean of 9 trials) and PUCCST (86.7% 84,9% mean of 10 11 trials) from a combination of EPPO Maritime climatic zone trials (DE) and trials in neighbouring countries (PL).
Across almost all data-sets the control achieved by the GF-3308 was comparable to the reference standards and not statistically different in the majority of cases.
Data are only available on winter crops. However, spring varieties of these crops are generally minor crops in the EPPO Maritime climatic zone. Spring rye (SECCS) and spring triticale (TTLSO) are listed as minor crops in AT and the area of spring wheat (TRZAS) in 2020 was minor at 2,650 ha (Eurostats). It is also considered that spring rye (SECCS) and spring triticale (TTLSO) are minor crops in CZ. For spring wheat (TRZAS), 46,000 ha were grown in CZ in 2020 compared to 774,000 ha of winter wheat (Eurostats), indicating that the area of spring wheat in CZ is relatively minor, at just 6% of the winter crop area.
Winter crops are a more challenging situation for control of these diseases, as the disease has time to establish in the crop over winter before GF-3308 is applied from BBCH 30. All target diseases equally infect both winter and spring crops and it is considered that the conclusions on effectiveness for winter crops are equally applicable to spring crops.
Similarly, it is considered that uses on spelt wheat (TRZSP) and durum wheat (TRZDU) can be extrapolated from the data on winter wheat as these crops are very similar wheat crops, the disease pressures are more challenging in winter wheat and the areas of durum wheat in these countries are relatively minor (Eurostat (2020): AT 16,500 ha, CZ: no significant area).
GF-3308 at the proposed label rate of 2,0 L/ha had an overall positive effect on grain yield and quality of crops treated in the presence of disease.
It is considered that the proposed GAP for countries of the EPPO Maritime climatic zone of the Central EU Authorisation zone is fully supported.

EPPO North-East zone

The proposed use is for a single application at 1,5 or 2,0 L/ha applied at BBCH 30-69 to winter and spring wheat (TRZAW and TRZAS), spelt wheat (TRZSP) and durum wheat (TRZDU) for control of SEPTTR, PUCCRT and PUCCST; winter and spring rye (SECCW and SECCS) for control of PUCCRE and RHYNSE and winter and spring triticale (TTLWI and TTLSO) for control of SEPTSP and PUCCST. The lower dose of 1,5 L/ha is recommended for application where SEPTTR in wheat, SEPTSP in triticale or RHYNSE in rye is the only disease requiring control or and where rust disease pressure is low. Where *Puccinia* species are also present at high pressure or expected to be a concern, a higher dose rate of 2,0 L/ha is recommended. The 2,0 L/ha dose is fully supported with over 8 trial from the North East and neibouring countries. Although there are less than 8 trials for each rust disease at the 1,5 L/ha dose, the applicant believes that the data set is reliable and supports the lower dose in the label range will offer around 80% control in low to modereate rust pressure situations.

Summary of effectiveness data for GF-3308 for EPPO North-East Zone (2.0 L/ha dose recommendations plus results for the 1.5 L/ha dose)

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control					
							GF-3308 1.5 L/ha#		GF-3308 2.0 L/ha		Reference standard	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
PUCCRT	TRZAW	NE	8	39-61	24.4	6.0-43.1	-	-	**88.1**	80.9-96.0	**85.5**+	68.6-95.0

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control					
							GF-3308 1.5 L/ha#		GF-3308 2.0 L/ha		Reference standard	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
		CZ + DE	8	32-55	23.0	5.6-97.5	-	-	**89.9**	71.7-100	**94.0**++	73.3-100
		All	**16**	**32-61**	23.7	5.6-97.5	-	-	**89.0**	71.7-100	**89.7**+++	68.6-100
		All	**4**	**32-61**	16.2	6.6-22.0	**81.6#**	68.7-98.9	**90.8**	80.9-100	**85.4**	68.6-99.4
PUCCST	TRZAW	NE	4	39-56	10.4	5.7-23.3	**79.6**	59.2-100	**81.8**	67.5-100	**85.5**$	69.6-100
		DE	5	32-45	16.0	6.1-28.3	-	-	**82.4**	71.7-89.7	**87.9**$$	71.7-100
		All	**9**	**32-56**	13.5	5.7-28.3	-	-	**82.2**	67.5-100	**86.8**	69.6-100
		All	**7**	**32-56**	11.2	5.7-23.3	**80.4#**	59.2-100	**83.7**	67.5-100	**89.5**	69.9-100
PUCCST	TRZAS	**NE**	**1**	**39-41**	38.7	-	**94.3**	-	**96.9**	-	**95.8***	-
PUCCRE	SECCW	NE	3	37-52	28.8	18.1-36.9	**72.0**	61.8-83.9	**84.0**	81.4-87.8	**76.0**^	68.9-86.3
		DE	11	37-59	18.1	5.0-74.0	-	-	**84.7**	75.5-92.6	**90.6**^^	81.6-100
		All	**14**	**37-59**	20.4	5.0-74.0	-	-	**84.5**	75.5-92.6	**87.4**^^	68.9-100
		All	**6**	**37-59**	29.4	7.0-74.0	**80.3#**	74.3-86.4	**84.5**	81.1-87.8	**82.5**	68.9-94.6
PUCCST	TTLWI	NE	3	35-52	19.6	7.1-37.8	**83.8**	73.5-93.6	**88.4**	83.5-94.9	**66.0**‡	54.1-73.7
		DE	7	39-51	46.9	6.0-96.5	-	-	**86.0**	63.0-98.1	**88.2**‡‡	54.5-100
		All	**10**	**35-52**	38.7	6.0-96.5	-	-	**86.7**	93.0-98.1	**81.6**‡‡‡	54.1-100
		All	**7**	**35-52**	44.8	7.1-96.5	**84.1#**	73.5-93.9	**89.0**	81.9-95.8	**80.4**	54.1-100

#Results for the 1.5 L/ha dose rate are from a smaller datasets of 4-7 trials (PUCCRT 4 trials (90.8% from 2.0 L/ha) , PUCCST 7 trials (83.7% 2.0 L/ha), PUCCRE 6 trials (85.4% 2.0 L/ha), PUCCST triticale 7 trials (89.0% 2.0 L/ha)

*All trials used Proline at 0.72 L/ha.

+Mean of 4 trials using Proline at 0.72 L/ha and 3 trials using Aviator Xpro at 1.25 L/ha and one using Vertisan at 1.0 L/ha.

++Mean of 4 trials using Proline at 0.72 L/ha and 4 trials using Aviator Xpro at 1.25 L/ha.

+++Mean of 8 trials using Proline at 0.72 L/ha and 7 trials using Aviator Xpro at 1.25 L/ha and one using Vertisan at 1.0 L/ha.

$Mean of 3 trials using Proline at 0.72 L/ha and one using Vertisan at 1.0 L/ha.

$$Mean of 3 trials using Proline at 0.72 L/ha, one trial using Aviator Xpro at 1.25 L/ha and one trial using Librax at 2.0 L/ha.

$$$ Mean of 6 trials using Proline at 0.72 L/ha, one trial using Aviator Xpro at 1.25 L/ha, one trial using Librax at 2.0 L/ha and one using Vertisan at 1.0 L/ha.

^Mean of 3 trials using Proline at 0.72 L/ha.

^^Mean of 9 trials using Proline at 0.72 L/ha and two trials using Aviator Xpro at 1.25 L/ha.

^^^Mean of 12 trials using Proline at 0.72 L/ha and two trials using Aviator Xpro at 1.25 L/ha.

‡Mean of 3 trials using Proline at 0.72 L/ha.

‡‡Mean of 6 trials using Proline at 0.72 L/ha and one trial using Prosaro at 1.0 L/ha.

‡‡‡Mean of 9 trials using Proline at 0.72 L/ha and one trial using Prosaro at 1.0 L/ha

Summary of effectiveness data for GF-3308 for EPPO North-East zone (2,0 L/ha recommendations plus results for the 1,5 L/ha dose)

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control					
							GF-3308 1,5 L/ha#		GF-3308 2,0 L/ha		Reference standard	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
PUCCRT	TRZAW	NE	8	39-61	24,4	6,0-43,1	-	-	**88,1**	80,9-96,0	**85,5**[+]	68,6-95,0
		CZ + DE	9	32-55	21,3	5,6-97,5	-	-	**86,5**	59,4-100	**92,7**[++]	73,8-100
		All	**17**	**32-61**	22,8	5,6-97,5	-	-	**87,2**	59,4-100	**89,3**[+++]	68,6-100
		All	**6**	**32-56**	16,8	6,6-27,9	**67,1#**	32,6-98,9	**82,4**	59,4-100	**82,8**	68,6-99,4
PUCCST	TRZAW	NE	6	37-56	25,2	5,7-83,1	**70,7**	45,9-100	**70,9**	44,4-100	**85,2**[§]	69,2-100
		DE	6	31-45	16,1	6,1-22,6	-	-	**77,7**	62,0-91,8	**83,7**[§§]	57,5-98,0
		All	**12**	**31-56**	20,6	5,7-83,1	-	-	**74,3**	44,4-100	**84,4**	57,5-100
		All	**11**	**31-56**	20,4	5,7-83,1	**68,7#**	38,3-100	**74,5**	44,4-100	**84,1**	57,5-100
PUCCST	TRZAS	**NE**	**1**	**39-41**	38,7	-	**94,3**	-	**96,9**	-	**95,8***	-
PUCCRE	SECCW	NE	3	37-52	28,8	18,1-36,9	**80,7**	76,1-86,4	**84,0**	81,4-87,8	**76,0**^	68,9-86,3
		DE	12	37-59	17,2	5,0-74,0	-	-	**84,2**	75,5-92,6	**91,0**^^	81,6-100
		All	**15**	**37-59**	19,5	5,0-74,0	-	-	**84,2**	75,5-92,6	**88,0**^^	68,9-100
		All	**7**	**37-59**	26,2	6,8-74,0	**78,9#**	70,4-86,4	**83,8**	79,6-87,8	**84,5**	68,9-96,3
PUCCST	TTLWI	NE	3	35-52	19,6	7,1-37,8	**83,8**	73,5-93,6	**88,4**	83,5-94,9	**66,0**[±]	54,1-73,7
		DE	8	35-51	43,2	6,0-96,5	-	-	**83,5**	63,0-98,1	**83,0**[±±]	18,5-100
		All	**11**	**35-52**	36,7	6,0-96,5	-	-	**84,9**	63,0-98,1	**78,4**[±±±]	18,5-100
		All	**8**	**35-52**	40,9	7,1-96,5	**78,7#**	73,5-94,0	**85,7**	63,0-95,9	**72,7**	18,5-100

#Results for the 1,5 L/ha dose rate are from a smaller datasets of 4-7 trials (PUCCRT 4 trials (82,4% from 2,0 L/ha) , PUCCST 11 trials (74,5% from 2,0 L/ha), PUCCRE 7 trials (83,8% from 2,0 L/ha), PUCCST triticale 8 trials (85,7% from 2,0 L/ha)
*One trial using Proline at 0,72 L/ha.
[+]Mean of 4 trials using Proline at 0,72 L/ha, 3 trials using Aviator Xpro at 1,25 L/ha and 1 trial using Vertisan at 1,0 L/ha.
[++]Mean of 4 trials using Proline at 0,72 L/ha, 4 trials using Aviator Xpro at 1,25 L/ha and 1 trial using Librax at 2,0 L/ha
[+++]Mean of 8 trials using Proline at 0,72 L/ha, 7 trials using Aviator Xpro at 1,25 L/ha, 1 trial using Vertisan at 1,0 L/ha and 1 trial using Librax at 2,0 L/ha.
[§]Mean of 5 trials using Proline at 0,72 L/ha and 1 trial using Vertisan at 1,0 L/ha.
[§§]Mean of 4 trials using Proline at 0,72 L/ha, 1 trial using Aviator Xpro at 1,25 L/ha and 1 trial using Librax at 2,0 L/ha.
[§§§] Mean of 9 trials using Proline at 0,72 L/ha, 1 trial using Aviator Xpro at 1,25 L/ha, 1 trial using Librax at 2,0 L/ha and 1 trial using Vertisan at 1,0 L/ha.
^Mean of 3 trials using Proline at 0,72 L/ha.
^^Mean of 9 trials using Proline at 0,72 L/ha and 3 trials using Aviator Xpro at 1,25 L/ha.
^^^Mean of 12 trials using Proline at 0,72 L/ha and 3 trials using Aviator Xpro at 1,25 L/ha.
[±]Mean of 3 trials using Proline at 0,72 L/ha.

++Mean of 7 trials using Proline at 0,72 L/ha and 1 trial using Prosaro at 1,0 L/ha.
+++Mean of 10 trials using Proline at 0,72 L/ha and 1 trial using Prosaro at 1,0 L/ha

On winter wheat (TRZAW) a single dose of 2,0 L/ha of GF-3308 applied between BBCH 32-61 achieved ~~89.0%~~ 87,2% control of PUCCRT (~~16~~ 17 trials) and ~~82.2%~~ 74,3% control of PUCCST (~~9~~ 12 trials) from a combination of EPPO North-East trials and trials in neighbouring countries (CZ and DE). One trial on spring wheat (TRZAS) showed good control of PUCCST at 96,9%. Data from two Polish, ~~and two~~ three Czech and one German trial ~~trials~~ demonstrate that the 1,5 L/ha dose achieved ~~81.6%~~ 67,1% control of PUCCRT. Data from ~~four~~ six Polish and ~~three~~ five German trials on winter wheat demonstrate that the 1,5 L/ha dose achieved ~~80.4%~~ 68,7% control of PUCCST. A single Polish trial on spring wheat demonstrated 94,3% control for the 1,5 L/ha dose. ~~Although these are more limited datasets, they confirm that the recommended for control of SEPTTR on wheat should deliver around 80% control of PUCCRT and PUCCST, where rusts are not the main target.~~ Based on the trial results it can be concluded that 1,5 L/ha dose is less effective in the control of PUCCRT and PUCCST in winter wheat, showing a moderate level of control.

On winter rye (SECCW) a single dose of 2,0 L/ha of GF-3308 applied between BBCH 37-59 achieved ~~84.5%~~ 84,2% control of PUCCRE (mean of ~~14~~ 15 trials) from a combination of EPPO North-East trials and trials in neighbouring countries (DE). Data from three Polish and ~~three~~ four German trials demonstrate that the 1,5 L/ha dose achieved ~~80.3%~~ 78,9% control of PUCCRE. ~~Although this is a more limited dataset, It does confirm that the 1,5 L/ha dose recommended for control of RHYNSE on rye should deliver around 80% control of PUCCRE. where PUCCRE is not the main target.~~ Based on the trial results it can be concluded that 1,5 L/ha dose is less effective in the control of PUCCRE in rye, showing a moderate level of control.

On winter triticale (TTLWI) a single dose of 2,0 L/ha of GF-3308 applied between BBCH 35-52 achieved ~~86.7%~~ 84,9% control of PUCCST (mean of ~~10~~ 11 trials) from a combination of EPPO North-East trials and trials in neighbouring countries (DE). Data from three Polish and ~~four~~ five German trials demonstrate that the 1,5 L/ha dose achieved ~~84.1%~~ 78,7% control of PUCCST. ~~Although this is a more limited dataset, It does confirm that the 1,5 L/ha dose recommended for control of SEPTSP on triticale should deliver around 80% control of PUCCST., where PUCCST is not the main target.~~ Based on the trial results it can be concluded that 1,5 L/ha dose is less effective in the control of PUCCST in triticale, showing a moderate level of control.

~~**Summary of effectiveness data for GF-3308 for EPPO North-East Zone zone (1.5-2.0 L/ha dose recommendations)**~~

~~Target (EPPO code)~~	~~Crop (EPPO)~~	~~EPPO Zone/ Country~~	~~Number of trials~~	~~Application timing (BBCH)~~	~~Untreated % infection~~		~~% control~~					
							~~GF-3308 1.5 L/ha~~		~~GF-3308 2.0 L/ha~~		~~Reference standard~~	
					~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~
~~SEPTTR~~	~~TRZAW~~	~~NE~~	~~5~~	~~37-43~~	~~14.2~~	~~7.2-18.9~~	~~**83.0**~~	~~66.1-100~~	~~**85.4**~~	~~71-100~~	~~**85.7***~~	~~69.4-97.1~~
			~~12~~	~~31-49~~	~~16.0~~	~~5.8-49.1~~	-	-	~~**89.5**~~	~~71.0-100~~	~~**86.9***~~	~~86.9-69.4~~
		~~CZ + DE~~	~~4~~	~~32-39~~	~~21.9~~	~~6.1-57.5~~	~~**86.9**~~	~~78.9-96.9~~	~~**92.3**~~	~~80.6-100~~	~~**85.9**~~	~~58.3-96.7~~
			~~10~~	~~32-51~~	~~20.2~~	~~5.0-61.0~~	-	-	~~**93.3**~~	~~78.7-100~~	~~**90.1**~~	~~58.3-100~~
		~~**All**~~	~~**9**~~	~~**32-43**~~	~~17.6~~	~~6.1-57.5~~	~~**84.7**~~	~~66.1-100~~	~~**88.5**~~	~~71-100~~	~~**85.8**+~~	~~58.3-97.1~~
			~~**22**~~	~~**31-51**~~	~~17.9~~	~~5.0-61.0~~	-	-	~~**91.2**~~	~~71.0-100~~	~~**88.4**++~~	~~58.3-100~~
~~SEPTTR~~	~~TRZAS~~	~~**NE**~~	~~**1**~~	~~**39-41**~~	~~5.0~~	-	~~**78.3**~~	-	~~**92.5**~~	-	~~**88.3***~~	-
~~RHYNSE~~	~~SECCW~~	~~NE~~	~~5~~	~~37-59~~	~~30.2~~	~~11.1-60.0~~	~~**83.0**~~	~~69.4-99.0~~	~~**87.9**~~	~~73.3-100~~	~~**71.9***~~	~~56.9-90.0~~
		~~DE~~	~~5~~	~~39-55~~	~~18.8~~	~~12.0-25.5~~	~~**83.0**~~	~~75.0-90.0~~	~~**87.2**~~	~~**77.8-94.1**~~	~~**91.6**~~	~~77.8-100~~
			~~10~~	~~39-59~~	~~16.5~~	~~9.8-25.5~~	-	-	~~**88.2**~~	~~76.2-100~~	~~**92.5**~~	~~77.8-100~~
		~~**All**~~	~~**10**~~	~~**37-59**~~	~~26.5~~	~~11.0-60.0~~	~~**83.0**~~	~~69.4-99.0~~	~~**87.5**~~	~~**73.3-100**~~	~~**81.8**#~~	~~56.9-100~~

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control					
							GF-3308 1.5 L/ha		GF-3308 2.0 L/ha		Reference standard	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
			15	**37-59**	21.1	9.8-60.0	-	-	**88.1**	73.3-100	**85.6[##]**	56.9-100
SEPTSP	TTLWI	NE	3	33-52	13.6	8.9-20.9	**84.4**	75.9-100	**87.6**	79.2-100	**88.2***	78.2-100
		DE	2	39-45	10.7	7.0-14.3	**65.1**	63.5-66.7	**78.3**	75.4-81.1	**74.7**	63.3-86.0
			6	39-51	13.3	5.8-32.5	-	-	**84.8**	73.1-100	**79.3**	63.3-100
		All	**5**	**33-52**	12.4	7.0-20.9	**76.7**	63.5-100	**83.9**	75.4-100	**82.0[$]**	63.3-100
			9	**33-52**	13.4	5.8-32.5	-	-	**85.7**	73.1-100	**82.3[$$]**	63.3-100

*All trials used Proline at 0.72 L/ha.
[+]Mean of 8 trials using Proline at 0.72 L/ha and one trial using Aviator Xpro at 1.25 L/ha.
[++]Mean of 18 trials using Proline at 0.72 L/ha and 4 trials using Aviator Xpro at 1.25 L/ha.
[#]Mean of 7 trials using Proline at 0.72 L/ha and three trials using Aviator Xpro at 1.25 L/ha.
[##]Mean of 12 trials using Proline at 0.72 L/ha and three trials using Aviator Xpro at 1.25 L/ha.
[$]Mean of 4 trials using Proline at 0.72 L/ha and one trial using Prosaro at 1.0 L/ha.
[$$]Mean of 7 trials using Proline at 0.72 L/ha and two trials using Prosaro at 1.0 L/ha.

Summary of effectiveness data for GF-3308 for EPPO North-East zone (1,5-2,0 L/ha dose recommendations)

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control					
							GF-3308 1,5 L/ha		GF-3308 2,0 L/ha		Reference standard	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
SEPTTR	TRZAW	NE	8	37-56	12,0	7,2-18,9	**84,2**	41,4-100	**86,9**	49,4-100	**89,1***	69,4-100
			15	31-56	14,5	5,8-49,1	-	-	**89,5**	49,4-100	**88,5****	69,4-100
		CZ + DE	7	31-51	25,3	6,1-57,5	**78,3**	59,1-96,9	**83,8**	65,0-100	**81,2**	59,0-96,9
			14	31-51	21,3	5,0-61,0	-	-	**86,1**	52,0-100	**83,3**	58,5-100
		All	**15**	**31-56**	18,2	6,1-57,5	**81,4**	41,4-100	**85,4**	49,4-100	**85,4[+]**	59,0-100
			29	**31-56**	17,8	5,0-61,0	-	-	**87,9**	49,4-100	**86,0[++]**	59,0-100
SEPTTR	TRZAS	**NE**	**1**	**39-41**	5,0	-	**78,3**	-	**92,5**	-	**88,3*****	-
RHYNSE	SECCW	NE	5	37-52	30,2	11,1-60,0	**83,0**	69,4-99,1	**85,9**	73,3-100	**71,9*****	56,9-90,0
		DE	5	39-59	18,8	12,0-25,5	**83,5**	75,0-90,1	**87,2**	**77,8-94,1**	**91,6**	77,8-100
			12	39-59	18,3	9,8-27,0	-	-	**85,0**	66,7-100	**91,7**	76,9-100
		All	**10**	**37-59**	24,5	11,0-60,0	**83,3**	69,4-99,1	**86,6**	**73,3-100**	**81,8[#]**	56,9-100
			17	**37-59**	21,8	9,8-60,0	-	-	**85,2**	66,7-100	**85,9[##]**	56,9-100
SEPTSP	TTLWI	NE	3	33-52	13,6	8,9-20,9	**84,4**	75,9-100	**87,6**	79,2-100	**88,2*****	78,2-100
		DE	2	39-49	10,7	7,0-14,3	**65,1**	63,5-66,7	**78,3**	75,4-81,1	**74,7**	63,3-86,0
			6	39-51	13,3	5,8-32,5	-	-	**84,8**	73,1-100	**79,3**	63,3-100
		All	**5**	**33-52**	12,4	7,0-20,9	**76,7**	63,5-100	**83,9**	75,4-100	**82,8[$]**	63,3-100
			9	**33-52**	13,4	5,8-32,5	-	-	**85,7**	73,1-100	**82,3[$$]**	63,3-100

* Mean of 7 trials using Proline at 0,72 L/ha and 1 trial using Vertisan at 1,0 L/ha
** Mean of 14 trials using Proline at 0,72 L/ha and 1 trial using Vertisan at 1,0 L/ha
[+]Mean of 12 trials using Proline at 0,72 L/ha, 1 trial using Aviator Xpro at 1,25 L/ha, 1 trial using Librax at 2,0 L/ha and 1 trial using Vertisan at 1,0 L/ha.

[++]Mean of 23 trials using Proline at 0,72 L/ha, 4 trials using Aviator Xpro at 1,25 L/ha, 1 trial using Librax at 2,0 L/ha and 1 trial using Vertisan at 1,0 L/ha.
*** Trial/s with Proline at 0,72 L/ha.
[#]Mean of 7 trials using Proline at 0,72 L/ha and 3 trials using Aviator Xpro at 1,25 L/ha.
[##]Mean of 14 trials using Proline at 0,72 L/ha and 3 trials using Aviator Xpro at 1,25 L/ha.
[$]Mean of 4 trials using Proline at 0,72 L/ha and 1 trial using Prosaro at 1,0 L/ha.
[$$]Mean of 7 trials using Proline at 0,72 L/ha and 2 trials using Prosaro at 1,0 L/ha.

On winter wheat (TRZAW) a single dose of 1,5 L/ha of GF-3308 applied between BBCH ~~32-43~~ 31-56 achieved ~~84.7%~~ 81,4% control of SEPTTR (over ~~9~~ 15 trials) from a combination of EPPO North-East trials and trials in neighbouring countries (CZ and DE). Comparable control of 78,3% was demonstrated from one trial on spring wheat (TRZAS). Where rusts also need to be controlled (PUCCRT and/or PUCCST) a dose of 2,0 L/ha is recommended and GF-3308 applied between BBCH 31-~~51~~ 56 at 2,0 L/ha achieved ~~91.2%~~ 87,9% control of SEPTTR (over ~~22~~ 29 trials) from a combination of EPPO North-East trials and trials in neighbouring countries (CZ and DE). Comparable control of 92,5% was demonstrated from one trial on spring wheat (TRZAS) at this higher dose.
On winter rye (SECCW) a single dose of 1,5 L/ha of GF-3308 applied between BBCH 37-59 achieved ~~83.0%~~ 83,3% control of RHYNSE (over 10 trials) from a combination of EPPO North-East trials and trials in neighbouring countries (DE). Where PUCCRE also needs to be controlled, a dose of 2,0 L/ha is recommended and GF-3308 applied between BBCH 37-59 at 2,0 L/ha achieved ~~88.1%~~ 85,2% control of RHYNSE (over ~~15~~ 17 trials) from a combination of EPPO North-East trials and trials in neighbouring countries (DE).
On winter triticale (TTLWI) a single dose of 1,5 L/ha of GF-3308 applied between BBCH 33-52 achieved ~~76.6%~~ 76,7% control of SEPTSP (over 5 trials) from a combination of EPPO North-East trials and trials in neighbouring countries (DE). In the 3 Noth East EPPO trials 84,4% was achieved by the 1,5 L/ha dose. It is considered that this use/claim can also be supported by the data on winter wheat which demonstrated ~~84.7%~~ 81,4% control of SEPTTR for the 1,5 L/ha dose across ~~9~~ 15 winter wheat trials. Where PUCCST also needs to be controlled, a dose of 2,0 L/ha is recommended and-GF-3308 applied between BBCH 33-52 at 2,0 L/ha achieved 85,7% control of SEPTSP (over 9 trials) from a combination of EPPO North-East trials and trials in neighbouring countries (DE).
Across almost all data-sets the control achieved by both the 1,5 L/ha and 2,0 L/ha doses of GF-3308 was comparable to the reference standards and not statistically different in the majority of cases.
The majority of data are only available on winter crops, however spring varieties of most of these crops are generally minor crops in PL. Spring rye (SECCS) is listed as a minor crop in PL. For spring triticale (TTLSO), 100,000 ha grown in PL in 2020, compared to 1,200,000 ha of winter triticale (Main Statistical Office), indicating that the area of spring triticale in PL is 8.3% of the winter crop area. Spring wheat (TRZAS) is major crop in PL (400,000 ha were grown in PL in 2020). One trial has been included and demonstrated comparable control to that achieved on winter wheat on both SEPTTR and PUCCST. Winter crops are a more challenging situation for control of these diseases, as the disease has time to establish in the crop over winter before GF-3308 is applied from BBCH 30. All target diseases equally infect both winter and spring crops and it is considered that the conclusions on effectiveness for winter crops are equally applicable to spring crops.
Similarly it is considered that uses on spelt wheat (TRZSP) and durum wheat (TRZDU) can be extrapolated from the data on winter wheat as these crops are very similar wheat crops, the disease pressures are more challenging in winter wheat and the area of durum wheat is minor (Eurostat (2020): PL: no significant area).
GF-3308 at the proposed label rate of 1,5-2,0 L/ha had an overall positive effect on grain yield and quality of crops treated in the presence of disease.
It is considered that the proposed GAP for Poland (EPPO North-East climatic zone of the Central EU Authorisation zone) is fully supported.

EPPO South-East zone

The proposed use is for a single application at 1,2-2,0 L/ha applied at BBCH 30-69 to winter and spring wheat (TRZAW and TRZAS), spelt wheat (TRZSP) and durum wheat (TRZDU) for control of SEPTTR and the range of dose rates 1,5-2,0 L/ha is proposed in winter and spring wheat for control of PUCCRT and PUCCST according to GAP. The lower dose of 1,2 L/ha is recommended for application where disease pressure is low and only SEPTTR ~~or PUCSST~~ is present or forecast to be a concern. In moderate disease situations a dose of 1,5 L/ha is recommended. Where disease pressure is high, particularly for PUCCRT, a higher dose rate of 2,0 L/ha is recommended.

~~**Summary of effectiveness data for GF-3308 for EPPO South-East Zone zone (1.2-2.0 L/ha dose range)**~~

~~Target (EPPO code)~~	~~Crop (EPPO)~~	~~Dose rate~~	~~Number of trials~~	~~Application timing (BBCH)~~	~~Untreated % infection~~		~~% control~~			
							~~GF-3308~~		~~Reference standard~~	
					~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~	~~Mean~~	~~min-max~~
~~SEPTTR~~	~~TRZAW~~	~~2.0 L/ha~~	~~11~~	~~31-41~~	~~21.6~~	~~6.0-51.3~~	~~**91.1**~~	~~76.0-100~~	~~**87.4***~~	~~75.1-100~~
		~~1.5 L/ha~~	~~10~~	~~31-41~~	~~16.1~~	~~5.1-31.3~~	~~**89.3**~~	~~74.5-100~~	~~**88.6****~~	~~75.1-100~~
		~~1.2 L/ha~~	~~6~~	~~30-47~~	~~10.6~~	~~5.1-17.5~~	~~**81.1**~~	~~73.1-100~~	~~**85.5*****~~	~~77.6-98.6~~
~~PUCCRT~~	~~TRZAW~~	~~2.0 L/ha~~	~~9~~	~~37-39~~	~~34.3~~	~~8.4-72.5~~	~~**87.1**~~	~~76.0-100~~	~~**87.0**+~~	~~63.9-100~~
		~~1.5 L/ha~~	~~5~~	~~37-39~~	~~23.9~~	~~8.4-39.4~~	~~**80.1**~~	~~64.2-100~~	~~**86.0**++~~	~~63.9-100~~
~~PUCCST~~	~~TRZAW~~	~~2.0 L/ha~~	~~5~~	~~39-43~~	~~23.3~~	~~16.4-28.8~~	~~**92.3**~~	~~83.0-100~~	~~**96.0**$~~	~~85.7-100~~
		~~1.5 L/ha~~	~~3~~	~~39-41~~	~~23.4~~	~~16.4-28.8~~	~~**95.1**~~	~~86.1-100~~	~~**95.2**$$~~	~~85.7-100~~
		~~1.2 L/ha~~	~~1~~	~~45-47~~	~~31.3~~	-	~~**91.5**~~	-	~~**99.5**$$$~~	-

~~*Mean of 9 trials using Proline at 0.72 L/ha, one trial using Aviator Xpro at 1.25 L/ha and one trial using Vertisan at 1.0 L/ha.~~
~~**Mean of 4 trials using Proline at 0.72 L/ha, two trials using Aviator Xpro at 1.0-1.25 L/ha, one trial using Vertisan at 1.0 L/ha and three trials using Input at 1.0 L/ha.~~
~~*** Mean of 2 trials using Proline at 0.72 L/ha, one trial using Aviator Xpro at 1.0 L/ha and three trials using Input at 1.0 L/ha.~~
~~+Mean of 8 trials using Proline at 0.72 L/ha and one trial using Vertisan at 1.0 L/ha.~~
~~++Mean of 4 trials using Proline at 0.72 L/ha and one trial using Vertisan at 1.0 L/ha.~~
~~$Mean of 4 trials using Proline at 0.72 L/ha and one trial using Vertisan at 1.0 L/ha~~
~~$$Mean of 2 trials using Proline at 0.72 L/ha and one trial using Vertisan at 1.0 L/ha~~
~~$$$One trial using Proline at 0.72 L/ha~~

Summary of effectiveness data for GF-3308 for EPPO South-East zone (1,2-2,0 L/ha dose range recommended for SEPTTR and 1,5-2,0 L/ha dose range recommended for PUCCRT and PUCCST)

Target (EPPO code)	Crop (EPPO)	Dose rate	Number of trials	Application timing (BBCH)	Untreated % infection		% control			
							GF-3308		Reference standard	
					Mean	min-max	Mean	min-max	Mean	min-max
SEPTTR	TRZAW	2,0 L/ha	12	31-41	20,4	6,0-51,3	**89,9**	76,0-100	**87,3***	75,1-100
		1,5 L/ha	11	31-41	15,3	5,1-32,2	**88,0**	74,1-100	**88,2****	75,1-100
		1,2 L/ha	6	30-47	10,6	5,1-17,5	**81,1**	73,1-100	**88,2*****	77,6-98,6
PUCCRT	TRZAW	2,0 L/ha	10	37-55	35,0	8,4-62,5	**83,4**	55,6-100	**84,6**[+]	63,5-100
		1,5 L/ha	5	37-55	23,9	8,4-39,4	**81,8**	64,2-100	**86,0**[++]	63,9-100
PUCCST	TRZAW	2,0 L/ha	7	39-43	35,9	16,4-77,5	**85,7**	55,6-100	**94,3**[§]	84,2-100
		1,5 L/ha	3	39-41	23,4	16,4-28,8	**95,1**	86,1-100	**95,2**[§§]	85,7-100
		1,2 L/ha	1	45-47	31,3	-	**91,5**	-	**99,5**[§§§]	-

*Mean of 10 trials using Proline at 0,72 L/ha, 1 trial using Aviator Xpro at 1,25 L/ha and 1 trial using Vertisan at 1,0 L/ha.
**Mean of 5 trials using Proline at 0,72 L/ha, 2 trials using Aviator Xpro at 1,0-1,25 L/ha, 1 trial using Vertisan at 1,0 L/ha and 3 trials using Input at 1,0 L/ha.
*** Mean of 2 trials using Proline at 0,72 L/ha, 1 trial using Aviator Xpro at 1,0 L/ha and 3 trials using Input at 1,0 L/ha.
[+]Mean of 9 trials using Proline at 0,72 L/ha and 1 trial using Vertisan at 1,0 L/ha.
[++]Mean of 4 trials using Proline at 0,72 L/ha and 1 trial using Vertisan at 1,0 L/ha.
[§]Mean of 6 trials using Proline at 0,72 L/ha and 1 trial using Vertisan at 1,0 L/ha
[§§]Mean of 2 trials using Proline at 0,72 L/ha and 1 trial using Vertisan at 1,0 L/ha
[§§§]One trial using Proline at 0,72 L/ha

Based on ~~11~~ 12 EPPO South-East climatic zone trials, demonstrating mean overall control of SEPTTR in winter wheat of ~~91.1%~~ 89,9% from a single application of GF-3308 at 2,0 L/ha, it is considered that the proposed claim for control of SEPTTR is fully supported. The 2,0 L/ha is considered to be appropriate for situation, where the wheat variety has low resistance to SEPTTR or fungicide resistance for SEPTTR is a concern and season long control is required. In situation where fungicide resistance is not a concern, the lower dose of 1,5 L/ha is considered appropriate, as this has demonstrated ~~89.3%~~ 88,0% control across ~~10~~ 11 trials. For situations where the wheat variety has inherent resistance to SEPTTR and fungicide resistance is not a concern, the lowest dose in the proposed range of 1,2 L/ha is considered appropriate, as this has demonstrated 81,1% control across 6 trials.

Based on ~~9~~ 10 EPPO South-East climatic zone trials demonstrating mean overall control of PUCCRT in winter wheat of ~~87.1%~~ 83,4% from a single application of GF-3308 at 2,0 L/ha, it is considered that the proposed claim for control of PUCCRT is fully supported. Where disease levels are low, the 1,5 L/ha dose could be used, as this provided adequate control of PUCCRT.

Based on ~~five~~ seven EPPO South-East climatic zone trials demonstrating mean overall control of PUCCST in winter wheat of ~~92.3%~~ 85,7% from a single application of GF-3308 at 2,0 L/ha, it is considered that the proposed claim for control of PUCCST is fully supported. Where disease levels are low, ~~1.2 and~~ 1,5 L/ha dose~~s~~ could be used, as ~~these~~ this provided good control of PUCCST.

Across almost all data-sets the control achieved by the GF-3308 at the various doses was comparable to the reference standards and not statistically different in the majority of cases.

Data are only available on winter wheat, however spring wheat (TRZAS) is a minor crop in the EPPO South-East zone (Eurostats (2020): HU: 9,000 ha, RO: 7,000 ha, SI: no significant area, SK: 13,000 ha). Winter wheat is a more challenging situation for control of these diseases, as the disease has time to establish in the crop over winter before GF-3308 is applied from BBCH 30. All target diseases equally infect both winter and spring crops and it is considered that the conclusions on effectiveness for winter wheat are equally applicable to spring wheat. Similarly it is considered that uses on spelt wheat (TRZSP) and durum wheat (TRZDU) can be extrapolated from the data on winter wheat as these crops are very similar and the disease pressures are more challenging in winter wheat.

Note: Many EU Member State regulatory authorities in the EPPO South-East climatic zone, prefer to see dose ranges for Plant Protection Products, as this allows some level of flexibility for the user, which would otherwise not be permitted by law.

GF-3308 at the proposed label rates of 1,2-2,0 L/ha had an overall positive effect on grain yield and quality of crops treated in the presence of disease.
It is considered that the proposed GAP for countries of the EPPO South-East climatic zone of the Central EU Authorisation zone is fully supported.

Comments of zRMS on:

Efficacy (3.2.3)
A total of 118 efficacy trials carried out between 2014 and 2020 have been submitted for the evaluation of new fungicide GF-3308 containing active substance fenpicoxamid (XDE-777). The trials were carried out in 3 EPPO zones: Maritime (AT, CZ, DE, DK, FR, UK), North-East (LV, PL) and South-East (BG, HU, RO). A range of trial locations allows to evaluate the performance of GF-3308 in all the Member States (PL, AT, CZ, SK, RO) for which the authorisation is sought. All the efficacy trials were carried out by the officially GEP-recognized testing units. A part of the trials, carried in 2014 in winter wheat presents efficacy data for GF-3308 or its earlier version GF-3311, for which similarity has been proved in a range of bridging trials presented in a separate chapter (Preliminary tests (3.2.1)). For simplification, only the code name GF-3308 will be used in the assessment. GF-3308 is intended to be used for the control of *Zymoseptoria tritici* (SEPTTR), *Puccinia recondita*. (PUCCRT), *Puccina striiformis* (PUCCST) in wheat (TRZAW, TRZAS, TRZDU, TRZSP) in Maritime (MAR), North-East (NE) and South-East (SE) EPPO zone; *Septoria* spp. (SEPTSP), *Puccinia striiformis* (PUCCST) in triticale (TTLWI, TTLSO), *Puccinia recondita* (PUCCRE), *Rhynchosporium secalis* (RHYNSE) in rye (SECCW, SECCS) in MAR and NE EPPO zone. GF-3308 is intended to be used within the crop stage ranging from 30-69 in all target crops.
Conclusions from the evaluation have been summarized separately for individual claimed uses listed in the GAP table.

WHEAT/ SEPTTR – 58 trials [24 MAR (CZ, DE, DK, FR, UK) + 16 NE (LV, PL) + 18 SE (BG, HU, RO); Tables: 3.2-55-3.2-59
Efficacy datapackage for the control of SEPTTR includes 57 trials carried out in winter wheat in MAR, NE and SE EPPO zone and only 1 trial conducted in spring wheat in NE (PL) EPPO zone. The trials were conducted in the years 2014-2020 and the BBCH growth stage of the crop ranging from 30 to 65 in winter wheat and from 39 to 41 in spring wheat at the time of application. Range of dose rates is proposed for SE EPPO zone (1,2 – 2,0 L/ha) and for NE EPPO zone (1,5 – 2,0 L/ha). For MAR EPPO zone only one dose rate of 2,0 L/ha is proposed. The average efficacy of GF-3308 was high and exceeded 80% at the lowest tested dose rate of 1,2 L/ha. The average efficacy achieved the level about 90% and 88% for the dose rate of 2,0 L/ha and 1,5 L/ha respectively in SE EPPO zone. No significant differences in efficacy have been noted between GF-3308 and reference products in the majority of trials. Significantly lower efficacy for GF-3308 at dose rate of 1,2 L/ha as compared with standard Input was noted in only 1 trial.
Efficacy above 80% in the control of SEPTTR in winter wheat for GF-3308 at dose rate of 1,5 L/ha was noted in NE EPPO zone and summing up trials results from NE EPPO zone with the results from neighbouring countries (CZ, DE) in winter wheat, achieving about 84% and 81,4% respectively. GF-3308 at higher dose rate of 2,0 l/ha was about 89% and 86% effective, based on NE zone trials, and NE + MAR zone (CZ, DE) trials. Similar efficacy was demonstrated in the single trial carried out in spring wheat (about 78% efficacy at dose rate of 1,5 L/ha and about 93,0% efficacy at dose rate of 2,0 L/ha). Based on the trial results, a range of dose rates 1,5-2,0 L/ha can be recommended for SEPTTR control in wheat with remark of using lower dose rate under low disease presssure. The average efficacy of GF-3308 was comparable or higher than efficacy of standards in the majority of trials. Significantly lower efficacy for GF-3308 at dose rate of 1,5 L/ha was noted in 2 Polish trials as compared with standard Proline. Statistically lower efficacy for GF-3308 at dose rate of 2,0 L/ha was noted in 2 Polish trials as compared with standard Proline. Statistically higher efficacy for GF-3308 at dose rate of 2,0 L/ha as compared with standard Proline was noted in 1 Polish trial.
The dose rate of 2,0 l/ha was sufficiently effective in MAR zone, achieving the average value of efficacy 86%. No significant differences in efficacy have been noted between GF-3308 and reference products in the majority of trials. Statistically higher efficacy for GF-3308 at dose rate of 2,0 L/ha as compared with standard Proline was noted in 4 trials.
As the only 1 trial was carried out in spring wheat in NE EPPO zone (PL) and no trials have been submitted for durum wheat and spelt in any of EPPO zones, the concerned MSs are kindly advised to consider individually possible extrapolation of efficacy trial results from winter wheat to spring wheat, durum wheat and spelt, according to the national requirements and make a decision concerning acceptance of this use on the national level

WHEAT/ PUCCRT – 31 trials [13 MAR (AT, CZ, DE UK) + 8 NE (PL) + 10 SE (BG, HU); Tables: 3.2-

60-3.2-63
Efficacy trials were carried out only in winter wheat in the years 2014-2019. GF-3308 was applied at BBCH growth stage of the crop ranging from 32 to 61. Range of dose rates 1,5 – 2,0 L/ha is proposed for SE EPPO zone. For MAR and NE EPPO zone only one dose rate of 2,0 L/ha is proposed for this use. GF-3308 was highly effective at dose rate of 1,5 L/ha as well as at the maximum dose rate of 2,0 L/ha achieving the efficacy about 83% across 10 trials and about 82% efficacy across 5 trials respectively in SE EPPO zone. The efficacy of tested fungicide was comparable to the efficacy of standards in the majority of trials. The performance of GF-3308 at dose rate of 1,5 L/ha was significantly worse than performance of reference product Proline in only 1 Hungarian trial. In 4 of 10 SE zone trials GF-3308 at dose rate of 2,0 L/ha was applied twice without possibility to assess efficacy after first application, due to late development of disease – 13-15 DAB/ 25-35 DAA. Results from these trials have been compiled together with trials, in which the tested fungicide was applied once and also separately to demonstrate eventual differences in efficacy. Comparable efficacy was seen between single dose regime trials (about 83% efficacy) and two-dose regime trials (about 85% efficacy).
Efficacy about 87% was noted for GF-3308 at dose rate of 2,0 L/ha in MAR EPPO zone, which allows to accept the GAP claim for PUCCRT in winter wheat in this EPPO zone. The efficacy of GF-3308 was comparable to the efficacy of standards in the majority of trials. The efficacy of GF-3308 at dose rate of 2,0 L/ha was significantly lower than efficacy of reference product Aviator Xpro in only 1 German trial.
High efficacy about 88% and about 87% was also demonstrated for GF-3308 at dose rate of 2,0 L/ha across 8 NE zone trials and across 17 trials from PL, DE and CZ respectively. For lower dose rate 1,5 L/ha a moderate control was achieved (about 79% efficacy across 2 Polish trials and about 67% across 6 trials after summing up trials from Poland with trial results from CZ and DE). Based on the trial results, a dose rate of 2,0 L/ha can be recommended for PUCCRT control in wheat, to provide high level of efficacy. No significant differences in efficacy have been noted between GF-3308 and reference products in the majority of trials. GF-3308 at both dose rates: 1,5 and 2,0 L/ha performed significantly better than standard Proline in 1 Polish trial. Statistically lower efficacy of GF-3308 at dose rate of 1,5 L/ha was noted in 4 Polish trials as compared with standards: Proline, Librax or Vertisan. The efficacy of GF-3308 at dose rate of 2,0 L/ha was significantly lower than efficacy of reference product Aviator Xpro in 1 German trial.
As no trials have been submitted for spring wheat, durum wheat and spelt in any of EPPO zones, the concerned MSs are kindly advised to consider individually possible extrapolation of efficacy trial results from winter wheat to spring wheat, durum wheat and spelt, according to the national requirements and make a decision concerning acceptance of this use on the national level

WHEAT/ PUCCST – 26 trials [11 MAR (DE, DK, UK) + 7 NE (LV, PL) + 8 SE (HU, RO); Tables: 3.2-64-3.2-68
Efficacy datapackage for the control of PUCCST includes 25 trials carried out in winter wheat in MAR, NE and SE EPPO zone and only single trial conducted in spring wheat in North-East (NE) EPPO zone. The trials were conducted in the years 2014-2020 and the BBCH growth stage of the crop ranging from 31 to 56 in winter wheat and from 39 to 41 in spring wheat at the time of application. Range of dose rates 1,5-2,0 L/ha is proposed for SE EPPO zone. For MAR and NE EPPO zone only one dose rate of 2,0 L/ha is proposed.
High efficacy of GF-3308 at dose rate of 1,5 L/ha as well as at the maximum dose rate of 2,0 L/ha has been demonstrated, showing the average efficacy about 95% across 3 trials and about 86% across 7 trials respectively in SE EPPO zone. The efficacy of tested fungicide was comparable to the efficacy of standards in the majority of trials. The performance of GF-3308 at dose rate of 2,0 L/ha was significantly worse than performance of reference product Proline in only 1 Hungarian trial. In 6 of 7 SE zone trials GF-3308 at dose rate of 2,0 L/ha was applied twice without possibility to assess efficacy after first application, due to slow disease development. Result from this trials has been compiled together with trials, in which the tested fungicide was applied once and also separately to demonstrate eventual differences in efficacy. Comparable efficacy was seen between single dose regime trials (about 86% efficacy) and two-dose regime trial (about 83% efficacy).
Based on the results from 11 MAR EPPO zone trials, high average value of efficacy has been achieved – about 84% efficacy. The efficacy of GF-3308 at dose rate of 2,0 L/ha was comparable to the efficacy of reference products in 10 trials and significantly lower than efficacy of standard Proline in only 1 German trial.
Moderate control of GF-3308 at dose rate of 1,5 and 2,0 L/ha has been demonstrated in the trials carried out in winter wheat in NE EPPO zone showing about 71% efficacy across 6 trials. Summing up data from NE zone trials with trial results from Germany, the effect was: about 69% efficacy for GF-3308 at 1,5 L/ha, across 11 trials and about 74% efficacy for GF-3308 at 2,0 L/ha, across 12 trials. High efficacy was demonstrated in the only 1 trial carried out in spring wheat (about 94% efficacy at dose rate of 1,5 L/ha and about 97,0% efficacy at dose rate of 2,0 L/ha). Based on the results from all trials, a dose rate of 2,0 L/ha can be recommended for PUCCST control in wheat in NE EPPO zone with remark of moderate level of efficacy. The average efficacy of GF-3308 was comparable to efficacy of standards in the majority of trials. Significantly lower efficacy for GF-3308 at dose rate of 1,5 L/ha was noted in 2 Polish trials as compared with standard Proline and in 1 German

trial as compared with reference product Librax. Statistically lower efficacy for GF-3308 at dose rate of 2,0 L/ha was noted in 1 Polish trial and in 1 German trial as compared with standard Proline.
As the only single trial was carried out in spring wheat in NE EPPO zone (PL) and no trials have been submitted for durum wheat and spelt in any of EPPO zones, the concerned MSs are kindly advised to consider individually possible extrapolation of efficacy trial results from winter wheat to spring wheat, durum wheat and spelt, according to the national requirements and make a decision concerning acceptance of this use on the national level

RYE/ PUCCRE – 15 trials [12 MAR (DE) + 3 NE (PL)] Tables: 3.2-69-3.2-71
Trials were conducted only in winter rye cultivars in the years 2015-2017. At the time of application the growth stage of the crop ranged from BBCH 37-59. Dose rate of 2,0 is proposed for MAR zone and for NE zone. High level of average efficacy above 80% was achieved across 12 German trials and 3 Polish trials and across total of 15 trials (about 84% efficacy) for GF-3308 at the recommended dose rate of 2,0 L/ha. For lower dose rate of 1,5 L/ha the efficacy was about 81% based on 3 NE zone trials. Summing up data from 4 German trials with the results from 3 Polish trials the efficacy about 79% was achieved (moderate level of control) for lower dose rate of 1,5 L/ha. Based on the trials conducted in winter rye and also trials carried out in winter wheat (67% efficacy in the control of PUCCRT for lower dose rate, across 6 trials), dose rate of 2,0 can be recommended to provide high level of efficacy in the control of PUCCRE in winter rye.
The efficacy of GF-3308 at dose rate of 1,5 L/ha or 2,0 L/ha was comparable or higher than the efficacy of reference products Proline or Aviator Xpro in almost all trials. Significantly lower efficacy was noted in 1 German trial for dose rate of 1,5 L/ha and 2,0 L/ha, as compared with standard Aviator Xpro, and in other 2 trials conducted in Poland and Germany for dose rate of 1,5 L/ha as compared with reference product Proline and Aviator Xpro respectively.
As no efficacy trials were carried out in spring rye, the concerned MSs are kindly advised to consider individually possible extrapolation of efficacy trial results from winter rye to the spring rye, according to the national requirements and make a decision concerning acceptance of this use on the national level

RYE/ RHYNSE – 17 trials [12 MAR (DE) + 5 NE (PL); Tables: 3.2-72-3.2-74
Efficacy datapackage includes a total of 17 trials carried out in the years 2015-2017 only in winter rye cultivars. At the time of application the growth stage of the crop ranged from BBCH 37-59. Dose rate of 2,0 is proposed for MAR zone and range of dose rates 1,5-2,0 L/ha is proposed for NE zone. Based on 12 trials from Germany and 5 trials from Poland, GF-3308 at dose rate of 2,0 L/ha was highly effective, achieving about 85% of the control (about 86% efficacy across 5 Polish trials and 85% efficacy across 12 German trials). High level of average efficacy above 80% was also achieved for dose rate of 1,5 L/ha of tested fungicide (about 83% efficacy for NE zone and for NE and MAR zone altogether, based on 10 available trials). Based on the trial results, a range of dose rate 1,5-2,0 L/ha can be recommended for RHYNSE control in winter rye in NE EPPO zone with remark of using lower dose rate under low disease pressure.
The efficacy of GF-3308 at dose rate of 1,5 L/ha or 2,0 L/ha was comparable or higher than the efficacy of reference products Proline or Aviator Xpro in almost all trials. Significantly lower efficacy was noted in 3 German trials for dose rate of 2,0 L/ha, as compared with standard Proline, and in other trial conducted in Germany for dose rate of 1,5 L/ha as compared with reference product Aviator Xpro.
As no efficacy trials were carried out in spring rye, the concerned MSs are kindly advised to consider individually possible extrapolation of efficacy trial results from winter rye to the spring rye, according to the national requirements and make a decision concerning acceptance of this use on the national level

TRITICALE/ SEPTSP – 9 trials [6 MAR (DE) including 4 trials for SEPTTR control, 1 trial for LEPTNO control and 1 trial for SEPTSP control + 3 NE (PL) all for SEPTTR control; Tables: 3.2-75-3.2-77
All the trials were carried out in winter triticale cultivars across 2 EPPO zones. No trials were conducted in spring triticale. Trials were conducted in the years 2015-2020. At the time of application the BBCH growth stage of the crop ranged from 33-52. For Maritime zone dose rate of 2,0 L/ha is proposed. Based on the results from 6 German trials the average efficacy was about 85%. Summing up results from MAR zone trials with NE zone trials the average efficacy of GF-3308 at 2,0 Lha was also high and achieved level of high disease control (about 86% efficacy). For NE zone a range of dose rates 1,5-2,0 L/ha is proposed. GF-3308 at maximum dose rate of 2,0 L/ha achieved high level of control - about 88% efficacy based on the results from 3 Polish trials. For lower dose rate of 1,5 L/ha the efficacy was about 84% in NE zone trials. When data from 6 German trials are compiled together with data from 3 Polish trials the result is about 77% efficacy (moderate level of control) for lower dose rate of 1,5 L/ha across 5 trials available for this dose rate. Efficacy of 86% for recommended dose rate of 2,0 L/ha was noted across 9 trials from NE and MAR zone altogether. Based on the trials conducted in winter triticale and also supportive trials carried out in winter wheat (about 81% efficacy in SEPTTR control for dose rate of 1,5 L/ha, across 15 trials), a range of dose rates 1,5-2,0 L/ha can be recommended for SEPTTR control in winter triticale in NE EPPO zone, with remark of using of lower dose rate under low disease pressure.

The efficacy of GF-3308 at dose rate of 1,5-2,0 L/ha was comparable with the efficacy of reference product Proline in almost all trials. Significantly lower efficacy was noted in only 1 Polish trial for dose rate of 1,5 L/ha as compared with standard Proline. No significant difference in efficacy was also noted in 1 German trial between GF-3308 at both dose rates and standard Prosaro, and the same value of efficacy was noted in other German trial for GF-3308 at 2,0 L/ha and for reference product Prosaro.
As no efficacy trials were carried out in spring triticale, the concerned MSs are kindly advised to consider individually possible extrapolation of efficacy trial results from winter triticale to the spring triticale, according to the national requirements and make a decision concerning acceptance of this use on the national level.

TRITICALE/ PUCCST – 11 trials [8 MAR (DE) + 3 NE (PL); Tables: 3.2-78-3.2-80
Trials were conducted only in winter triticale cultivars in the years 2015-2020. At the time of application the growth stage of the crop ranged from BBCH 35-52. Dose rate of 2,0 is proposed for MAR and NE EPPO zone. High level of average efficacy above 80% was achieved across 8 German trials (about 84% control), 3 Polish trials (about 88% control) and across a total of 11 trials (about 85% control) for GF-3308 at the maximum dose rate of 2,0 L/ha. For lower dose rate of 1,5 L/ha the efficacy was about 84% in NE zone based on 3 trials. Summing up data from 5 German trials with the results from 3 Polish trials the efficacy about 79% was achieved (moderate level of control) for lower dose rate of 1,5 L/ha. Based on the trials conducted in winter triticale and also trials carried out in winter wheat (69% efficacy in the control of PUCCST for lower dose rate, across 11 trials), dose rate of 2,0 can be recommended to provide high level of efficacy in the control of PUCCST in winter triticale.
The efficacy of GF-3308 at dose rate of 1,5 L/ha or 2,0 L/ha was comparable or higher than the efficacy of reference product Proline in almost all trials. Significantly lower efficacy was noted in 2 German trials for dose rate of 1,5 L/ha in 1 trial and 2,0 L/ha in other trial, as compared with standard Proline. The same value of efficacy was noted in 1 German trial for GF-3308 at dose rate of 2,0 L/ha and for standard Prosaro.
As no efficacy trials were carried out in spring triticale, the concerned MSs are kindly advised to consider individually possible extrapolation of efficacy trial results from winter triticale to the spring triticale, according to the national requirements and make a decision concerning acceptance of this use on the national level

Based on the submitted efficacy trial results it can be concluded that the fungicide GF-3308 is effective in the control of target pathogens which are the subject of the evaluation. For some uses for which the authorization is sought (PUCCRT/winter wheat/NE/NE+MAR (CZ, DE), PUCCST/winter wheat/ NE/NE+MAR (DE), PUCCRE/winter rye/NE+MAR (DE), SEPTSP/winter triticale/NE+MAR (DE), PUCCST/winter triticale/NE+MAR (DE)) moderate level of efficacy has been demonstrated for GF-3308 at dose rate of 1,5 L/ha. Moderate performance of GF-3308 at dose rate of 2,0 L/ha was also noted in the control of PUCCST in winter wheat in NE EPPO zone and when combining trials from NE EPPO zone with the trials from the MAR zone (DE).
No trials results are available for spring wheat for PUCCRT control; for durum wheat, spelt, spring rye, spring triticale for the control of all target pathogens in any of the concerned EPPO zones and only 1 Polish trial has been submitted for spring wheat for the control of SEPPTR and PUCCST. The decision of acceptance of these uses is to be made on the national level by cMSs.

Yield (and relevant quality indicators), from efficacy trials (in the presence of challenging pest populations) (3.2.3.8); Tables: 3.2-81 - 3.2-105

<u>YIELD</u>

WHEAT
Yield was recorded in a total of 61 efficacy trials carried out in winter wheat in three EPPO zones (MAR – 27 trials, NE – 16 trials and SE – 18 trials) and 1 trial conducted in spring wheat in NE EPPO zone. For winter wheat, the average increase of the yield was: 13,1% in NE EPPO zone, 14,7% in MAR zone and 19,4% in SE zone, after single application of GF-3308 at the highest recommened dose rate of 2,0 L/ha. In 9 of 16 trials (NE zone), 12 of 27 trials (MAR zone) and in 3 of 14 trials (SE zone) statistically significant increase of the yield was noted for GF-3308 at the highest dose rate of 2,0 L/ha as compared to the control. For GF-3308 applied at 1,5 L/ha the increase of the yield was: 10,1-14,5% for NE zone and MAR (DE, CZ) and 9,5% in SE zone. In 5 of 13 trials (SE zone), 2 of 8 trials (NE zone) and in 4 of 8 trials (MAR: DE, CZ)) statistically significant increase of the yield was noted for GF-3308 at dose rate of 1,5 L/ha. For SE EPPO zone the lowest recommended dose rate is 1,2 L/ha. The average increase of the yield achieved 6,8% across 6 SE zone trials, and in 4 of 6 trials yield for GF-3308 was statistically higher as compared to the control. In a single trial conducted in spring wheat in PL, the increase of the yield was statistically significant and achieved 22,9-30,8% for GF-3308 at dose rate of 1,5 and 2,0 L/ha respectively. No negative effect on the yield was noted for any of tested dose rate of GF-

3308 in any of trials carried out. Comparing GF-3308 with standards, no statistically significant differences were noted for the yield in the majority of trials.

RYE

Seventeen efficacy trials including 12 trials from MAR EPPO zone and 5 trials from NE zone presents data on the yield of winter rye. The average increase of the yield was: 14,9% in MAR EPPO zone, and 14,2% in NE EPPO zone, after single application of GF-3308 at the recommened dose rate of 2,0 L/ha. In 2 of 5 trials (NE zone) and 7 of 12 trials (MAR zone) statistically significant increase of the yield was noted for GF-3308 at the highest dose rate of 2,0 L/ha as compared to the control. For NE EPPO zone the lowest recommended dose rate in rye is 1,5 L/ha. The average increase of the yield achieved 9,7% across 5 NE zone trials and 23,8% across 4 MAR zone (DE) trials. In 1 of 5 trials (NE zone) and in 2 of 4 trials (MAR zone), yield for GF-3308 was statistically higher as compared to the control. No negative effect on the yield was noted for any of tested dose rate of GF-3308 in any of trials carried out. Comparing GF-3308 with standards, no statistically significant differences were noted for the yield in the majority of trials.

TRITICALE

Sixteen efficacy trials including 11 trials from MAR EPPO zone and 5 trials from NE zone presents data on the yield of winter triticale. The increase of 15,4% and 15,8% was noted across MAR zone trials and NE zone trials respectively, after application of GF-3308 at dose rate of 2,0 L/ha. In 4 of 5 trials (NE zone) and 3 of 11 trials (MAR zone) statistically significant increase of the yield was noted for GF-3308 at the highest dose rate of 2,0 L/ha as compared to the control. For GF-3308 applied at 1,5 L/ha the increase of the yield was 15,4% for NE zone and 9,2% for MAR (DE). In 4 of 5 trials (NE zone) statistically significant increase of the yield was noted for GF-3308 at dose rate of 1,5 L/ha. No negative effect on the yield was noted for any of tested dose rate of GF-3308 in any of trials carried out. Comparing GF-3308 with standards, no statistically significant differences were noted for the yield in the majority of trials.

TGW

WHEAT

Data on TGW is presented in 59 efficacy trials carried out in three EPPO zones (MAR – 26 trials, NE – 15 trials and SE – 18 trials) in winter wheat and in 1 trial conducted in spring wheat in NE EPPO zone. For winter wheat, the average increase of TGW was: 3,9% in NE EPPO zone, 8,0% in MAR zone and 6,6% in SE zone, after single application of GF-3308 at the highest recommened dose rate of 2,0 L/ha. In 3 of 15 trials (NE zone), 13 of 26 trials (MAR zone) and in 1 of 14 trials (SE zone) statistically significant increase of TGW was noted for GF-3308 at the highest dose rate of 2,0 L/ha as compared to the control. For GF-3308 applied at 1,5 L/ha the increase of TGW was: 3,4-7,4% for NE zone and MAR (DE, CZ) zone and 5,5% for SE EPPO zone. In 4 of 13 trials (SE zone), 1 of 8 trials (NE zone) and in 4 of 8 trials (MAR: DE, CZ)) statistically significant increase of TGW was noted for GF-3308 at dose rate of 1,5 L/ha. In SE EPPO zone, for the lowest recommended dose rate 1,2 L/ha, the average increase of TGW achieved 2,9% across 6 SE zone trials, and in 1 of 6 trials TGW for GF-3308 was statistically higher as compared to the control. In a single trial conducted in spring wheat in PL, the increase of TGW was statistically significant and achieved 3,7-4,2% for GF-3308 at dose rate of 1,5 and 2,0 L/ha respectively. No negative effect on TGW was noted for any of tested dose rate of GF-3308 in any of trials carried out. Comparing GF-3308 with standards, no statistically significant differences were noted for TGW in the majority of trials.

RYE

Sixteen efficacy trials including 11 trials from MAR EPPO zone and 5 trials from NE zone presents data on TGW of winter rye. The average increase of TGW was: 4,3% in MAR EPPO zone, after single application of GF-3308 at the recommened dose rate of 2,0 L/ha. In 2 of 11 trials (MAR zone) statistically significant increase of TGW was noted for GF-3308 at the highest dose rate of 2,0 L/ha as compared to the control. For NE EPPO zone comparable results for TGW were noted between GF-3308 at dose rates: 1,5-2,0 L/ha and control. Increase of TGW of 7,7% was noted across 3 MAR (DE) trials for GF-3308 at dose rate of 1,5 L/ha and staitistically significant increase of TGW was in 1 of 3 trials. No negative effect on TGW was demonstrated for any of tested dose rate of GF-3308 in any of trials carried out. Comparing GF-3308 with standards, no statistically significant differences were noted for TGW in the majority of trials.

TRITICALE

Ten efficacy trials including 6 trials from MAR EPPO zone and 4 trials from NE zone presents data on the yield of winter triticale. The increase of 7,4% and 4,0% was noted across MAR and NE zone trials respectively, after application of GF-3308 at dose rate of 2,0 L/ha. In 1 of 4 trials (NE zone) and 3 of 6 trials (MAR zone) statistically significant increase of TGW was noted for GF-3308 at the highest dose rate of 2,0 L/ha as compared to the control. For GF-3308 applied at 1,5 L/ha the increase of TGW was 2,9% for NE zone and 8,0% for MAR (DE). In 2 of 5 trials (NE +MAR (DE) zone) statistically significant increase of TGW was noted for GF-3308 at dose rate of 1,5 L/ha. No negative effect on TGW was noted for any of tested dose rate of GF-3308 in any of trials carried out. Comparing GF-3308 with standards, no statistically significant differences were noted for TGW in the majority of trials.

<u>HLW</u>

WHEAT
HLW was recorded in a total of 30 efficacy trials carried out in two EPPO zones (MAR – 21 trials, and SE – 9 trials) in winter wheat. The average increase of HLW was: 1,8% in MAR EPPO zone, after single application of GF-3308 at the highest recommened dose rate of 2,0 L/ha and in 5 of 21 trials statistically significant increase of HLW was demonstrated as compared to untreated control. For SE EPPO zone comparable results for HLW were noted between GF-3308 at dose rate of 2,0 L/ha and control. For lower dose rates: 1,2 l/ha and 1,5 L/ha the increase of HLW achieved 1,6% and 1,2% respectively in SE EPPO zone. In 3 of 6 trials and in 2 of 6 trials statistically significant increase of HLW was demonstrated after application of GF-3308 at 1,2 and 1,5 L/ha. No negative effect on HLW was noted for any of tested dose rate of GF-3308 in any of trials carried out. Comparing GF-3308 with standards, no statistically significant differences were noted for HLW in the majority of trials.
RYE
HLW was not recorded in any of trials conducted in winter rye.
TRITICALE
Six efficacy trials including 5 trials from MAR EPPO zone and 1 trial from NE zone presents data on HLW of winter triticale. The increase of 3,7% and 1,7% was noted across MAR and NE zone trials respectively, after application of GF-3308 at dose rate of 2,0 L/ha. In 3 of 5 trials (MAR zone) statistically significant increase of HLW was noted for GF-3308 at the highest dose rate of 2,0 L/ha as compared to the control. For NE EPPO zone comparable results for HLW were noted between GF-3308 at dose rates: 1,5-2,0 L/ha and control. Increase of HLW of 2,6% was noted across 4 MAR (DE) trials for GF-3308 at dose rate of 1,5 L/ha and staitistically significant increase was in 1 of 4 trials. No negative effect on HLW was noted for any of tested dose rate of GF-3308 in any of trials carried out. Comparing GF-3308 with standards, no statistically significant differences were noted for HLW in the majority of trials.

Summarizing data on yield and yield quality from the efficacy trials, it can be concluded that the tested fungicide GF-3308 applied at the maximum dose rate of 2,0 L/ha and at lower dose rates 1,2 and 1,5 L/ha has no adverse effects on the yield and its quality parameters of target crops.

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

Introduction

GF-3308 will be registered for use against SEPTTR/SEPTSP in wheat and triticale, PUCCSP in wheat, ~~and~~ rye, triticale and RHYNSE on rye. The analysis of resistance risk is primarily focusing on SEPTSP and PUCCSP crop/pathogen combinations.
EPPO guidelines followed during the resistance or cross resistance testing carried out by Dow Agrosciences were as follows assessment can be found in the BAD.

EPPO guideline number	Title
PP 1/213(2)	Resistance Risk Analysis

Proposed label text

When fungicides with the same mode of action are used repeatedly over several years in the same field, naturally occurring strains with decreased sensitivity may be selected, survive, propagate and become dominant in the field. A pathogen is considered resistant to a fungicide if it survives a correctly applied treatment at the recommended dose and timing under normal environmental conditions.
Development of resistance can be avoided or delayed by alternating or mixing products having different modes of action.
Fenpicoxamid (XDE-777) is not cross resistant with other classes of fungicide chemistry used against key cereal pathogens including the succinate dehydrogenase inhibitors (SDHIs), QoIs, benzimidazoles and sterol biosynthesis inhibitors (SBIs). To reduce the risk of resistance developing, fenpicoxamid should be used in a program based approach based on products with different modes of action. In addition fenpicoxamid must always be used in mixture with another product, recommended for control of the same target disease that contains a fungicide from a different cross resistance group applied at a dose that will give robust disease control. It is also important not to exceed the maximum number of application given on this label.

3.3.1 Mode of Action

GF-3308 50g/L EC contains fenpicoxamid (XDE-777) the first and to date only member of a new picolinamides class of fungicides representing a novel mode of action within the cereal fungicide segment. Its target site has been identified as the Quinone Inside (Qi) site of the cytochrome *bc*1 (ubiquinone reductase) complex (complex III) in the electron transport chain.

This target site was confirmed by a combination of previously published literature references, biochemical and molecular genetics studies. Biochemical binding assays where performed on a range of fungi including *Zymoseptoria tritici* (SEPTTR) whilst molecular genetic studies were performed using chemically induced resistant mutants of *Saccharomyces cerevisiae* (SACCCE).

Summary

Aside from the literature publications around UK-2A MOA additional evidence generated by DAS in support of the likely biological and biochemical (target site) MOA of Fenpicoxamid following its conversion to UK-2A include the following .
Fenpicoxamid / UK-2A were both active in inhibiting mitochondrial respiration in cell-free mitochondrial preparations from a wide range of fungi, as well as wheat and bovine heart. Fungal species could be categorized in two groups based on target site sensitivity: a highly sensitive group comprising SEPTTR, LEPTNO, PYRIOR and BOTRCI, and a less sensitive group which included GIBBZE, USTIMA and PLASVI.

At the cellular level, Fenpicoxamid and UK-2A caused a rapid partial depolarization of mitochondria, which is characteristic of complex III inhibition.
Further evidence for the target site of UK-2A was demonstrated in the model organism SACCCE by isolation of cytochrome *b* mutants with 3 distinct mutations involving amino acids which are highly conserved between species. Clustering of these mutations at the Qi site, and cross-resistance to antimycin A, confirmed binding of UK-2A to the Qi site.

3.3.2 Mechanism of resistance

3.3.3 Evidence of resistance

All artificially generated SACCCE mutants resistant to fenpicoxamid have mutations in the cytochrome bc1 domain that affect the fenpicoxamid binding pocket. Attempts to generate similar mutations in *Zymoseptoria tritici* in the laboratory were not successful.
Laboratory studies in yeast and on isolates of SEPTTR have found no evidence of target site cross resistance between fenpicoxamid and other key cereal fungicide classes i.e. QoI, triazoles, benzimidazoles, SDHIs. The baseline sensitivity of 1875 isolates of SEPTTR collected across 14 EU countries during 2011- 2014 and 260 isolates of PUCCRT from 9 countries collected in 2015 have been determined. For both pathogens there was little variation in sensitivity between isolates or across Europe. It should therefore be easy to identify isolates showing reduced sensitivity by the use of future post launch monitoring bioassays.

3.3.4 Cross Resistance

Since XDE-777 does not have activity against oomycete pathogens whilst amisulbrom and cyazofamid are not active on SEPTTR any potential cross resistance within the Qi inhibitor group is not considered relevant at this stage. Dow AgroSciences has however conducted laboratory testing to look for evidence of cross resistance between Fenpicoxamid and other key commercially important MOAs used in the control of SEPTTR e.g. QoIs, DMIs, SDHIs, MBCs.
In vitro susceptibility testing of SEPTTR field strains showed no cross-resistance between Fenpicoxamid (XDE-777)(X772777) and the five other compounds tested, representing MBC, QoI, azole, SDHI and multi-site fungicides, previously or currently being used to control *Septoria* leaf blotch. Fenpicoxamid controlled azole-insensitive, MBC-resistant and QoI-resistant SEPTTR field strains as well as a selection of SDHI-resistant lab mutants of SEPTTR. These results indicate that Fenpicoxamid has a different mode of action to fungicides currently used to control SEPTTR and will be a good potential resistance management partner for combinations with these other MOAs. Full details can be found in the BAD.

3.3.5 Sensitivity data –baseline information on Fenpicoxamid

Full details of baseline sensitivity data can be found in the BAD.

3.3.6 Use pattern and resistance risk associated with unrestricted use pattern

The actual risk of evolution of resistance to Fenpicoxamid depends on three main parameters.

Mechanism of resistance against the compound (intrinsic fungicide risk)
Fenpicoxamid is a single site inhibitor at the QiI site. FRAC classifies the current commercial QiI inhibitors (cyazofamid and amisulbrom in FRAC group 21) as having unknown resistance risk but assumed to be medium to high due to mutations at target site in model organisms. (FRAC Code List 2015 version http://www.frac.info/docs/default-source/publications/frac-code-list/frac-code-list-2015-finalC2AD7AA36764.pdf?sfvrsn=4). There are to date no reports of field resistance to QiI inhibitors in SEPTTR, PUCCRT or PUCCST as would be expected since this MOA is not currently commercialised in this segment and no other current MOA used in cereals would be expected to have target site based cross resistance to Fenpicoxamid. It is not known if the mutations generated in yeast *in vitro* which confer reduced sensitivity to QiI inhibitors will also occur in SEPTTR, PUCCRT or PUCCST and furthermore if they would appear and persist in the field population. Another theoretical mechanism of resistance to Fenpicoxamid might be lack of conversion to the active UK-2A by the fungus particular if this conversion is enzyme mediated as previously postulated (section 3.3.1). To date we have not conducted any experiments to identify which if any enzymes are involved in converting Fenpicoxamid to UK-2A and hence the risk of the possibility this mechanism operating is unknown. Based on our knowledge today we must assume that the intrinsic fungicide risk for fenpicoxamid's biochemical MOA at the QiI target site is medium to high.

Biology of the pathogen (pathogen risk)
SEPTTR has a high potential to cause serious epidemics and an ability to produce large numbers of spores both asexual and sexual. More importantly the degree of sexual recombination in SEPTTR is significant. Septoria leaf blotch is currently, in the absence of host resistance, controlled by programmed application of azoles (triazoles and imidazoles), succinate dehydrogenase inhibitors (SDHIs) and multi-site inhibitors. Methyl benzimidazole carbamates (MBC) (e.g. carbendazim) and quinone outside inhibitors (QoIs) (e.g. azoxystrobin) no longer control the disease in some major cereal producing regions of Western Europe due to development of mutations resulting in amino acid substitutions in the target proteins β-tubulin (E198A) and cytochrome *b* (F129L and G143A), respectively (Fraaije *et al*., 2005; Lucas and Fraaije, 2008). SEPTTR is classified by FRAC as a medium risk pathogen in regards to potential to develop fungicide resistance. (FRAC Pathogen Risk List, 2013 version http://www.frac.info/docs/default-source/publications/pathogen-risk/pathogen-risk-list.pdf?sfvrsn=8).
Reports of resistance development to both PUCCRT and PUCCST are very infrequent in the literature. A review (Fungicide Resistance Action Committee (FRAC) List of Pathogenic Organisms resistant to Disease Control Agents - 2013 revision) references only one publication reporting a sensitivity shift with PUCCST to DMI fungicides as measured in the laboratory (Bayles et al, 2000). Interestingly the G143A mutation has never been detected in rusts. This is believed due to the presence of an intron positioned exactly after codon GCT which affects the splicing process leading to a deficient cytochrome b. Thus it is postulated that QoI resistance based on G143A will not evolve in such species (Gisi and Sierotzki, 2008). To date no QoI resistance has developed to either PUCCRT or PUCCST. FRAC designate both PUCCRT and PUCCST as pathogens with a low risk of developing resistance to fungicides. (FRAC Pathogen Risk List, 2013 version). PUCCRT and PUCCST are also not amongst the pathogens listed in EPPO guidance document PP1/213(2) as an example of pathogens considered being at high risk of developing resistance and requiring that sensitivity baseline data be generated.

Agronomical factors (agronomic risk)
Use of cultural practices such as stubble burial, crop rotation, and varietal resistance can play a role in lowering primary inoculum pressure and slowing rate of epidemic development with SEPTTR however fungicides remain the key component of strategies to manage this disease effectively. In the most intensive cereal growing regions of Europe and particularly in seasons where weather conditions are favourable for buildup of high pressure of SEPTTR up to 4 foliar sprays per crop may be applied.
Considering the above parameters the overall resistance risk for Fenpicoxamid within an unrestricted use pattern scenario should be considered as medium to high in relation to the SEPTTR wheat pathosystem. Out of the target pathogens applied for on the GF-3308 label SEPTTR is considered likely to be the pathogen at most risk of potential resistance development. As such a risk management strategy will be necessary and driven by SEPTTR although the risk modifiers which will be proposed in section in 3.3.7 will also directly help to manage risk in PUCCRT, PUCCRE and PUCCST.

3.3.7 Management strategy for GF-3308

Annual monitoring of the sensitivity of the EU SEPTTR and PUCCRT populations to fenpicoxamid will continue post launch in order to detect any signs of a shift away from the pre-launch baseline which has been presented in this dossier section. This will be supplemented by continuous observation of field performance. Any significant change in sensitivity will be reported through FRAC and the relevant country resistance management and regulatory agencies. This will allow DAS to rapidly adapt the resistance management strategy should the need arise.
The following risk modifiers are proposed:
In order to reduce the risk of potential resistance development FRAC would recommend that GF-3308 (Fenpicoxamid) is applied in mixtures with an appropriate partner (i.e. fungicide of a different MOA group that is active against SEPTTR). (group-21-(c4)---fenpicoxamid-(qii)-recommendations-17th-of-april-2019.pdf (frac.info)).
Maintenance of recommended rates of GF-3308 is essential. GF-3308 (Fenpicoxamid) should not be used in repeated applications at reduced rates as there is some general evidence from the literature that this may increase the potential risk of selection of resistance to single site inhibitors.
In line with FRAC recommendations for a medium to high risk fungicide DAS will recommend restricting the number of applications of GF-3308 (Fenpicoxamid) in wheat, rye and triticale to no more than one per crop in areas where at least two sprays per season are typical.
The applicant is an active member of FRAC and would anticipate joining the FRAC QiI working group once Fenpicoxamid is commercialized.
Corteva Agriscience will undertake training of its sales and development representatives and produce educational material and commercial advisory literature promoting good plant protection practice and advising on the use and importance of appropriate resistance management strategies.
Bioassay techniques to detect resistance will be refined where relevant, molecular methods of precisely monitoring the spread of any future mutations will be developed. Routine annual monitoring for resistant strains will commence once the product is placed on the market and reports of any possible resistance systematically investigated.
Updates on any change in the resistance status of fenpicoxamid will be communicated through technical or scientific publications and/or through FRAC and via the relevant registration authorities according to Art. 56 of the regulation 1107/2009 EU. The GF-3308 use recommendations will be adjusted as needed depending on the success of the above strategy

Comments of zRMS on:

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

GF-3308 is a novel fungicide containing active substance: fenpicoxamid (chemical group: picolinamides; group name: QiI-fungicides (Quinone inside Inhibitors); FRAC target site and code: C4 # 21). Fenpicoxamid derived from antifungal natural product UK-2, which is a structural relative of antimycin, isolated from antifungal antibiotis that demonstrated inhibition of respiratory activity in yeast cells. Fenpicoxamid belongs to the fungicides acting as inhibitors of respiration processes. Its target site has been identified as the Quinone Inside (Qi) site of the cytochrome *bc*1 (ubiquinone reductase) complex (complex III) in the electron transport chain. This site of the cytochrome bc1 is the subject of many studies on mutations and possible resistance to chemical agents as a consequence. Due to literature data numerous *Saccharomyces cerevisiae* (used as a model to detect mutation in cytochrome b found in fungal and oomycete plant pathogens resistant to chemical agents) mutants (mutations in bc1 complex) resistant to antimycin, funiculosin, diuron, myxothiazol, strobilurin, stigmatellin or ilicicolin have been isolated and described. It has been also presented in literature that in the QoI site of the cytochrome bc1 mutations resulting in the replacement of glycine by an alanine (G143A mutation) have led to resistance of strains of *Septoria tritici* to QoI fungicides. The resistance risk of QiI fungicides is unknown but is assumed to be medium to high due to mutations at target site known in model organisms. Based on literature data existence of cyazofamid (other substance from QiI fungicides group) insensitive *Phytophthora capsici* isolates have been detected and described. Hence, the resistance management is required.

FRAC List of first confirmed cases of plant pathogenic organisms resistant to disease control agents (revised in May 2020), does not include cases of cereal pathogens resistance to QiI fungicides. However, it should be noted that, according to the FRAC Pathogen Risk List (revised in September 2019), *Zymoseptoria tritici* (one of the main target pathogen) on wheat is classified as pathogen of medium risk of resistance to fungicides. Whereas *Puccinia sp.* on various cereal crops is listed among low-risk pathogens. According to data submitted by the applicant and baseline sensitivity of 1875 isolates of SEPTTR collected across 14 EU countries during 2011- 2014 and 260 isolates of PUCCRT from 9 countries collected in 2015, for both pathogens there was little variation in sensitivity between isolates or across Europe. It can be explained that lack of a shift is because fenpicoxamid has not yet been launched commercially and hence exerted no significant selection pressure on the field population. No evidence of target site cross resistance between fenpicoxamid and other key cereal fungicide classes i.e. QoI, triazoles, benzimidazoles, SDHIs have been found based in laboratory studies in yeast and on isolates of SEPTTR.
Due to literature data, cases of resistance or shift in sensitivity of *Septoria triti* to other groups of cereal fungicides (e.g. DMI fungicides, SDHI fungicides, QoI fungicides) or *Puccinia striiformis* to DMI fungicides have been described. This shows, that the new modes of action are needed to ensure sustainable disease control. If fungicides with the same mode of action are used repeatedly over in the same field, resistant strains may be selected and become dominant in the field. To avoid development of resistance the following resistance management strategy is proposed to be included in the label of GF-3308:
"The fungicide GF-3308 contains active substance: fenpicoxamid from picolinamides chemical group – inhibitor of respiration processes, belonging to QiI fungicides (FRAC group C4, # 21). As a part of anti-resistance strategy GF-3308 is recommended to be used:
- mainly preventatively in the control of target diseases, in appropriate growth stages of crops and only at the recommended dose rate - specified in the product label,
- only once per growth season,
- in the tank mixtures with other fungicides containing active substances of different mode of action recommended for control of the same target pathogens, at recommended dose rates ensuring full protection against diseaes and in the plant protection programs with other fungicides (alternating use of fungicides with different modes of action).

Additionally it is advisable to follow current recommendations of resistance management strategy for cereal fungicides".
The zRMS considers the proposed resistance management strategy to be sufficient but all cMS may wish to consider these recommendations in line with the resistance situation in individual countries or their own specific requirements.

3.4 Adverse effects on treated crops (KCP 6.4)

Information on trials submitted (3.4: Adverse effects on treated crops)
The efficacy trials reported no phytotoxicity or adverse effects to treated crops at dose rates of GF 3308 up to 2,0 L/ha, on all crops (see section 3.4.1.) and yield results from these trials demonstrated no adverse effects in the presence of disease (see section 3.2.3).
EPPO PP 1/135(4) '*Phytotoxicity Assessment*' states that no specific crop safety/selectivity trials to assess adverse effects on treated crops (yield and quality) are required, where no adverse effects have been reported in the effectiveness trials. However, some selectivity data are available and these have been included in this dossier for completeness and are detailed in Table 3.4-1.

Table 3.4-1: Presentation of selectivity and transformation trials

Crop*	Country	Type of trial**	Number of trials				Years	GEP, non-GEP, official***	Comments (any other relevant information)
			Maritime zone	North-East zone	South-East zone	Mediterranean zone			
TRZAW	France	S + Y + Q + P	1				2014	GEP	
	France	TF	3			1	2015	GEP	Bread baking with grain collected from 4 field trials
	Germany	TF	2				2015	GEP	Beer brewing study with grain from 2 field trials
	Hungary	S + Y + Q + P			1		2014	GEP	
	UK	S + Y + Q + P	~~2~~ 1				2014	GEP	
	UK	S	1				2016	GEP	8 varieties screening trial
TRZAS	Germany	S + Y + Q + P	1				2014	GEP	
	Poland	S + Y + Q + P		1			2014	GEP	
	UK	S	1				2016	GEP	variety screening trial
TOTAL	-	-	~~11~~ **10**	**1**	**1**	**1**	-	-	

* 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 (germination test)
*** Official: carried out by a national official organisation, 2014 trials used GF-3311

Table 3.4-2: Presentation of reference standards used in selectivity and transformation trials

Crop(s)	Reference standards	Country(ies) where the product is registered(1)	Authorization number	Active substance(s) (a.s)	Formulation		Registered application rate(3)	Application rate in trials (per treatment)	Remark(4)
					Type(2)	Concentration of a.s.			
TRZAW	Proline 275	(see Table 3.2-16)		Prothioconazole	EC	275 g/L	0.72 L/ha	0.72 L/ha	
TRZAS	Proline 275	(see Table 3.2-16)		Prothioconazole	EC	275 g/L	0.72 L/ha	0.72 L/ha	
TRZAW	Ignite	As the active substance is generic, many products and brands are registered across the EU countries.		Epoxiconazole	EC	83 g/L	1.5 L/ha	1.5 L/ha	Only used in bread baking study as azole reference

(1) only on use(s) applied for (with the test product)
(2) e.g.WP (wettable powder), EC (emulsifiable concentrate), etc.
(3) Dose / dose range authorized in the country
(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application…)

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

Introduction

Data presented in this section cover phytotoxicity data from ~~111~~ 118 efficacy trials and from specific trials conducted to evaluate potential phytotoxicity of GF-3308 at up to 2,0 L/ha (100 g as/ha) and also ~~six~~ seven selectivity trials at dose rates up to 4 L/ha (200 g as/ha) as the 2 N dose rates. The crops involved in the testing were winter wheat, winter rye and winter triticale. An overview of the evaluation of the crop tolerance of GF-3308 is presented in Table 3.4-3. Trials from 2014 used the earlier formulation GF-3311 (66,7 g as/l fenpicoxamid) where bridging efficacy to GF-3308 has been proven in section 3.2.1.9 and where no selectivity issues were observed with this formulation which is very similar to GF-3308.

Table 3.4-3: Overview on the cereal crop tolerance of GF-3308 observed in the efficacy and selectivity trials

Trial type	Crop	GF-3308 (GF-3311) 1N/2N rate	Number of GEP trials	Maximum phytotoxicity (%) recorded during the trials
Efficacy	TRZAW	1N	~~74~~ 81	0
Efficacy	TRZAS	1N	1	0
Efficacy	SECCW	1N	18	0
Efficacy	TTLWI	1N	18	0
Selectivity	TRZAW	1N/2N	4	4,4/7,5*
Selectivity	TRZAS	1N/2N	2	0
Selectivity variety screening**	TRZAW 8 varieties TRZAS 1 variety	1N/2N	1	0

* transient chlorosis with some necrosis in 1 FR trial, a similar response (5% injury) was also observed in treatments with Proline 275 at 0,72 L/ha.
**trial with only 2 replicates where crops or varieties are drilled in large stripes with treatments applied perpendicularly to the drilling direction.

3.4.1.1 Phytotoxicity in efficacy trials

Introduction

In total, ~~74~~ 81 effectiveness trials were carried out on winter wheat (TRZAW), one on spring wheat (TRZAS), 18 trials in winter rye (SECCW) and 18 trials on winter triticale (TTLWI) to evaluate the

efficacy of GF-3308, applied at a dose rate of up to 2,0 L/ha against various diseases. All ~~111~~ 118 trials included assessments of crop phytotoxicity and the majority were taken to harvest. All trials were conducted according to GEP and were of an RCB plot design with 4 replicates on a wide range of commercially grown varieties, across a range of climatic and agronomic conditions. Crops were treated between growth stages BBCH 31-~~61~~ 65.
The trials were conducted in Austria, Czech Republic, Denmark, France, Germany, UK, Latvia, Poland, Bulgaria, Hungary and Romania between 2014 and 2020. The trials covering countries in the Maritime, North-East and South-East EPPO climatic zones, as described in EPPO Standard PP 1/241, and are representative of the proposed GAP.

Material and methods

For information on testing organisations used, as well as for trials site and experimental details refer to sections 3.2.3.1 through 3.2.3.7 and Appendix 3 and Appendix 4 in the BAD.
A summary of the varieties used is as follows:

Table 3.4-4: Phytotoxicity assessments of GF-3308 - Varieties tested in efficacy trials

Crop (EPPO)	No of trials	No of varieties	Variety names (No of trials)
Winter wheat (TRZAW)	**Total: ~~74~~ 81** EPPO Maritime: ~~28~~ 34 EPPO North-East: 20 EPPO South-East ~~26~~ 27	**Total: 44** EPPO Maritime: ~~18~~ 25 EPPO North-East: 12 EPPO South-East ~~14~~ 16	**EPPO Maritime:** Artist, Akteur (3), Ambition, Bermude, Bohemia, Cordiale, Crusoe (2), Dinosor, Etana, JB ~~Hereford~~ Asano (5), Hereford, Hermann, Mariboss, Muza, Pakito, Patras, Pionier, Relay, Santiago, Socrates, Solstice, Substance (2), Tobak (2), Toras, Trapez. **EPPO North-East:** Arkadia (2), Artis, Bogatka (3), Fidelius, Fredis, Muszelka ~~(2)~~, Sailor (3), Sukces, Turnia, Wydma, Zentos ~~(2)~~ (3), Zyta (2). **EPPO South-East:** Andrada, Antonius (2), Ariesan (2), Buzogány, Enova ~~(2)~~, Genius ~~(2)~~, GK Élet ~~(4)~~ (5), GK Körös, Glossa (2), Iridium (3), Lupus, Marshall, Miranda ~~(5)~~ (3), MV Suba, MV-Toldi, Sadovo 772.
Spring wheat (TRZAS)	**Total: 1** EPPO North-East: 1	**Total: 1** EPPO North-East: 1	**EPPO North-East:** Tybalt.
Winter rye (SECCW)	**Total: 18** EPPO Maritime: 13 EPPO North-East: 5	**Total: 8** EPPO Maritime: 5 EPPO North-East: 4	**EPPO Maritime**: Minello, Palazzo (8), Recrut, Visello (2), SU Performer. **EPPO North-East**: Bono, Dankowskie Diament (2), Kier, Palazzo.
Winter triticale (TTLWI)	**Total: 18** EPPO Maritime: 13 EPPO North-East: 5	**Total: 11** EPPO Maritime: 7 EPPO North-East: 5	**EPPO Maritime**: Adverda, Agostino, Grenado, KWS Aveo (2), SU Agendus, Talendro (2), Tender (5). **EPPO North-East:** Grenado, Magnat, Trismart, Tulus, Twingo.

Results

No phytotoxicity symptoms were seen at any point in the season, using GF-3308 at dose rates up to 2,0 L/ha or using the commercial standards, in any of the ~~74~~ 81 trials were carried out on winter wheat (TRZAW), one on spring wheat (TRZAS), 18 trials in winter rye (SECCW) and 18 trials on winter triticale (TTLWI), across a wide range of varieties ~~(64)~~ (75). The individual results from the trials are detailed in Appendix 6 in the BAD.

3.4.1.2 Phytotoxicity to wheat in selectivity trials

Introduction

In total 6 phytotoxicity trials were established to demonstrate the selectivity of GF-3308 applied in winter wheat (4) and spring wheat (2). The trials were carried out by contractor companies and Official

Research institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP).
The trials were placed in France (1), Germany ~~(2)~~ (1), Hungary (1), Poland (1) and the United Kingdom (2), in 2014 in areas where wheat is commercially grown. The trial from France was within the Maritime EPPO zone part of the country.
On the basis of the EPPO Standard 1/241 (*Guidance on comparable climates*) the trials included in the BAD have been grouped and summarized by EPPO zone. EPPO zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region. The EU Central Regulatory Zone covers countries in EPPO climatic zones Maritime, North-East and South-East as described in EPPO Standard PP 1/241. This chapter comprises data from the Maritime, North-East and South-East EPPO zones which are representative of the proposed GAP.
In 2014, the first year of registration trials were been carried out with formulation GF-3311 which contains 66,7 g/L fenpicoxamid, delivering 100 g fenpicoxamid at 1,5 L product per hectare. In terms of formulation contents GF-3308 and GF-3311 are very similar formulations (see Part C for comparison of both formulation) and no phytotoxicity was observed with this formulation in 2014 or in 2015 when used in bridging trials. As the formulations are very similar then we would propose that fungicide selectivity trials with GF-3311 are acceptable to support the selectivity of GF-3308 as the label dose of 100 g as/ha was applied.
On the basis of the EPPO Standard 1/135 (3) '*Phytotoxicity Assessment'* there is no requirement for specific selectivity trials with fungicides (as there is for herbicides) if selectivity issues are not observed in efficacy trials. However, Dow AgroSciences established some confirmatory trials for our own benefit and these are presented in this section.

Material and methods

Testing facilities or organisations

The selectivity trials were carried out by the testing facilities in the countries listed in the following Table:

Table 3.4-5: Testing facilities involved by EPPO Zone

Admin. Zome	EPPO Zone	Country	Year	Trial#	Testing Organisation	EPPO Guideline	Trial Status
Central	Maritime	GERMANY	2014	DE14E7B016UB01C	BioChem agrar GmbH	PP1/135(3)	GEP
Central	Maritime	UK	2014	GB14E7B016EB01C	ARMSTRONG FISHER LTD, UK	PP1/135(3)	GEP
Central	Maritime	UK	2014	GB14E7B016EB02C	OXFORD AG. TRIALS, UK	PP1/135(3)	GEP
South	Maritime	FRANCE	2014	FR14E7B016MC02C	BIOTEK AGRICULTURE, FR	PP1/135(3)	GEP
Central	North-East	POLAND	2014	PL14E7B016AS01C	IOR SOSNICOWICE, PL	PP1/135(3)	GEP
Central	South-East	HUNGARY	2014	HU14E7B016AB01C	AGROFIL, HU	PP1/135(3)	GEP

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3311	EC	Fenpicoxamid	1,5 and 3,0	100 and 200
Proline 275	EC	Prothioconazole	0,72	198

Experimental details

The trials were of a randomized complete block design with 4 replicates and a plot size ranging between ~~15~~ 20 and 36 m². The treatments in all trials were applied using precision small plot sprayers equipped with conventional or low drift flat fan nozzles delivering water volumes between 100 and 300 L/ha. To support the label claims for GF-3308, GF-3311 was applied at of 100 gas/h and at 200 g as/ha as the double rate in accordance with the EPPO Standard PP 1/135 (*Phytotoxicity assessment*) as leading guideline. The reference product included was Proline 275 applied at 0,72 L/ha (198 gas/ha prothioconazole). To support the suggested GAP GF-3308 and Proline each were applied at 2 timings between crop BBCH 33-43 and BBCH 65-69, respectively. Further Site and Application Details are summarized in the BAD.

Assessments for crop selectivity were aimed at 1 and 2 weeks after each application. Crop injury was assessed as % crop injury; phytotoxic effects such as chloroses, necrosis, stunting or thinning were specified if present.

Statistical analysis

The tabulated selectivity data presented in this section of the biological dossier are showing the treatment means of the percentage of crop injury found relative to the untreated. Instead of statistical tests across trials the minimum and maximum means of the individual trial means are presented in the summary tables.

Results

GF-3311 at 100 g as/ha (1,5 L/ha) applied at 2 timings proved to be fully selective to the crop in 4 out of 5 trials. Only in 1 trial from France (see Table 3.4-6 below) 4,3% chlorosis at the 1,5 L/ha and 7,5% at the 3,0 L/ha rate (2 N) was observed.

The chlorotic effect was transient with a maximum of expression 22 days after the second application timing. A similar level of 5% chlorosis was found in the same trial in treatments with reference Proline 275 applied at the 1 N rate. The chlorotic effect was accompanied by some necrotic spotting. However, the level of chlorosis observed in commercial terms is considered not relevant. As outlined in the following chapters it did not negatively impact yield or yield quality parameters.

Table 3.4-6: Maximum phytotoxicity on wheat recorded for the duration of the selectivity trials in treatments with GF-3311 and the reference Proline.

EPPO Zone	Trial number	Wheat crop and variety	1st Application		2nd Application		Max, phytotoxicity %		
							GF-3311		Proline
			Crop BBCH	Date	Crop BBCH	Date	100 g as/ha (1,5L/ha)	200 g as/ha (3,0 L/ha)	200 g as/ha (0,72 L/ha)
Maritime	DE14E7B016UB01C	TRZAS TRISO	39-41	31-May-14	65	12-Jun-14	0	0	0
Maritime	FR14E7B016MC02C	TRZAW ALIXAN	33-39	28-Apr-14	65 ~~65~~	30-May-14	4,3*	7,5*	5,0*
Maritime	GB14E7B016EB01C	TRZAW REVELATION	39 ~~39~~	14-May-14	65-69	03-Jun-14	0	0	0
Maritime	GB14E7B016EB02C	TRZAW CLAIRE	43 ~~43~~	30-May-14	69 ~~69~~	30-Jun-14	0	0	0
North-East	PL14E7B016AS01C	TRZAS ZURA	39	20-May-14	69	16-Jun-14	0	0	0
South-East	HU14E7B016AB01C	TRZAW GENIUS	37-39	07-May-14	65-69	11-Jun-14	0	0	0

* maximum expression of phytotoxicity observed 14 days after 2nd application. Prevailing symptom observed was transient chlorosis with some necrosis.

3.4.1.3 Phytotoxicity of GF-3308 to spring wheat and winter wheat in a variety screening trial

To evaluate the crop selectivity of GF-3308 at the proposed label rate and the 2 X rate commercial wheat varieties of TRZAW and TRZAS were tested in a replicated cereal crop screening trial in the UK in 2016. GF-3308 was applied at 2 timings at 2,0 L/ha as the proposed label rate and at 4,0 L/ha as the double rate to simulate a worst-case scenario as it could be found with overlapping sprays in the headland of a given field with a cereal crop. The reference product included was Proline applied at the UK approved rate of 0,72 L/ha applied at the same timings as GF-3308. Further trial details are presented below.

Table 3.4-7: Material and methods

Trial details	Trial number	GB16E7B077RH01
	EPPO Zone	Maritime
	Trial status	GEP
	Testing organisation	Dow AgroSciences UK
	Country	United Kingdom
	Trial location/Zip Code State/Region	Wellesbourne, CV35 9EF Warwickshire
Guidelines	Guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225 and guidelines refferred therein
Experimental design	Plot design	Randomized
	Plot size	2 m x 45 m
	Number of replications	2
Crop	Trials per crop	1 trial comprising TRZAW (winter wheat) and autumn sown TRZAS (spring wheat)
	Varieties per crop	TRZAW cv Skyfall, Revelation, Trinity, Lilli, Conversion, Britannia, Reflection, Cordiale. TRZAS cv Paragon
	Drilling date	30-Sep-16
Application	Application timings, at crop BBCH	1st Appliation 3-Jun-16 , Crop BBCH 55-59 2nd Application 21-Jun-16, Crop BBCH 69
	Spray interval days	18
	Spray volume L/ha	200 L/ha
	Nozzle	Flat fan, Hypro 110-03
	Air temperatute °C	11/23
	Relative humidity	82/60
Assessment	Assessment types	Phytotoxic effects as % injury to crop
	Assessment dates*	6 DAAA, 13 DAAA, 21 DAAA, 6 DAAB 10 DAAB and 20 DAAB*

* DAAA=days after timing A
DAAB=days after timing B

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3308	EC	Fenpicoxamid	2,0 and 4,0	100 and 200
Proline 275	EC	Prothioconazole	0,72	198

Results

Applied at 2,0 and 4,0 L/ha GF-3308 and the reference Proline at 0,72 L/ha proved to be fully selective to 8 TRZAW and 1 TRZAS varieties. For the duration of the trial no phytotoxic effects such as chlorosis, necrosis, growth inhibition, lodging or other adverse effects were observed at the 1 N or 2 N of the proposed label rate of GF-3308 (see
Table 3.4-8).

Table 3.4-8: Maximum phytotoxicity of GF-3308 applied at 2x 2,0 L/ha (1N rate) and 2x 4,0 L/ha to 8 winter and 1 spring wheat varieties in a crop screen.

Crop	Varieties	Maximum level of crop injury (%) observed for the duration of the trial		
		GF-3308		Proline
		2 x 2,0 L/ha	2 x 4,0 L/ha	2x 0-72 L/ha
TRZAW	Skyfall, Revelation, Trinity, Lilli, Conversion, Britannia, Reflection, Cordiale	0	0	0
TRZAS	Paragon	0	0	0

Comments of zRMS on:

Phytotoxicity to host crop (3.4.1)
Phytotoxicity was assessed in 118 efficacy trials (in th presence of disease or under low disease pressure) carried out in winter wheat (81 trials), spring wheat (1 trial), winter rye (18) and winter triticale (18) in three EPPO zones: Maritime, North-East and South-East. No symptoms of phytotoxicity have been observed after application of GF-3308 or its previous version GF-3311 across all trials carried out. Phytotoxicity was also assessed in additional 6 selectivity trials (in the absence of disease), conducted in winter wheat (4 trials) and spring wheat (2 trials) in 2014 with the formulation GF-3311 applied twice at single (1N) and double dose rate (2N). The selectivity trials were carried out in Hungary (1), Germany (1), Poland (1), UK (2) and France (1). No phytotoxicity symptoms have been detected in 5 of 6 trials. In one French trial, 4,3% chlorosis at the 1,5 L/ha (1N) and 7,5% at the 3,0 L/ha (2N) dose rate have been observed. These symptoms had temporary character and decreased over time. 5% necrosis was also observed after application of reference product Proline. Additionally 1 screening trial was conducted in UK in 2016 to evaluate phytotoxicity after double application of GF-3308 at dose rate of 2,0 and 4,0 L/ha (worst case scenario) on 8 varieties of winter wheat and 1 variety of spring wheat. No phytotoxicity symptoms have been demonstrated in this trial.
Based on the submitted trial results it can be concluded that GF-3308 can be safely used in all target crops.

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

Introduction

All ~~111~~ 118 efficacy trials reported no phytotoxicity or adverse effects to treated crops at dose rates up to 2,0 L/ha of GF-3308 (see section 3.4.1.1) and yield results from these trials demonstrated no adverse effects on grain yields, in the presence of disease (see section 3.2.3).
In total 6 phytotoxicity trials were established to demonstrate the selectivity and yield effect of GF-3308 (GF-3311 was used in these trial) applied in winter wheat (4) and spring wheat (2). The trials were carried out by contractor companies and Official Research institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP).
The trials were placed in France (1), Germany ~~(2)~~ (1), Hungary (1), Poland (1) and the United Kingdom (2), in 2014 in areas where wheat is commercially grown. The trial from France was within the Maritime EPPO zone part of the country.

On the basis of the EPPO Standard 1/241 (*Guidance on comparable climates*) the trials included in the BAD have been grouped and summarized by EPPO zone. EPPO zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region. The EU Central Regulatory Zone covers countries in EPPO climatic zones Maritime, North-East and South-East as described in EPPO Standard PP 1/241. This chapter comprises data from the Maritime, North-East and South-East EPPO zones which are representative of the proposed GAP.
In 2014, the first year of registration trials were been carried out with formulation GF-3311 which contains 66,7 g/L Fenpicoxamid, delivering 100 g Fenpicoxamid at 1,5 L product per hectare. In terms of formulation contents GF-3308 and GF-3311 are very similar formulations (see Part C for comparison of both formulation) and no phytotoxicity was observed with this formulation in 2014 or in 2015 when used in bridging trials. As the formulations are very similar then we would propose that fungicide selectivity trials with GF-3311 are acceptable to support the selectivity of GF-3308 as the label dose of 100 g as/ha was applied.
On the basis of the EPPO Standard 1/135 (3) '*Phytotoxicity Assessment'* there is no requirement for specific selectivity trials with fungicides (as there is for herbicides) if selectivity issues are not observed in efficacy trials. However, Dow AgroSciences established some confirmatory trials for our own benefit and these are presented in this section.

Material and methods

For information on testing organisations involved, for trials site and experimental details refer to chapters 3.4.1.2 (*Phytotoxicity to wheat in selectivity trials*)

Results

A summary of the yield data from 4 selectivity trials in winter wheat is presented in Table 3.4-9. GF-3311 (GF-3308) averaged across 4 trials at the 2,0 L/ha rate yielded ~~104,3%~~ 104,0% and applied at 4,0 L/ha (2 N) ~~104,6%~~ 104,3% over untreated which yielded 9,57 t/ha. The reference Proline applied at 0,72 L/ha yielded ~~104,1%~~ 103,5% relative to untreated.
The yield data obtained from 2 selectivity trials in spring wheat are presented in Means followed **by the same letter in the same row do not significantly differ (Tukey HSD, p=0,05)**

Table 3.4-10.
In average of 2 trials GF-3311 (GF-3308) applied in sequence at 2,0 L/ha yielded ~~108,4%~~ 109,6% and at 4,0 L/ha (2N) ~~106,7%~~ 107,7% relative to the control plots which yielded 4,88 t/ha. Proline with 2 applications at 0,72 L/ha yielded ~~112,8%~~ 115,1% over untreated.
The yield increase observed in treatments with GF-3311 (GF-3308) and Proline 275 can be ascribed to a certain level of diseases which were present in the trials and which cannot be fully eliminated using other fungicides for trial maintenance measures.

Table 3.4-9: Impact of GF-3311 (GF-3308) on the yield amount (t/ha) when applied twice at the proposed label rate and at double rate. Summary of data from 4 phytotoxicity trials conducted in winter wheat in the absence of disease or at low disease pressure

EPPO Zone	**Trial number**	**Crop**	**Yield (corrected)**										
					GF-3311 (GF-3308)						**Proline**		
			Untr,		**100 g as/ha**			**200 g as/ha**			**200 g as/ha (0,72 L/ha)**		
			t/ha		**t/ha**		**rel%**	**t/ha**		**rel%**	**t/ha**		**rel%**
Maritime	**Mean**	**TRZAW**	**9,98**		**10,55**		~~105,7~~ **105,5**	**10,52**		~~105,4~~ **105,2**	**10,61**		~~106,3~~ **106,1**
	min		9,3		9,1		98,0	9,1		97,7	9,2		98,6
	max		10,3		11,5		111,4	11,5		111,5	11,5		111,5
	n trials		3		3		3	3		3	3		3
South-East		TRZAW	8,34	a	8,28	a	99,3	8,48	a	101,7	7,99	a	95,8
All trials	**Mean**	**TRZAW**	**9,57**		**9,98**		~~104,3~~ **104,0**	**10,01**		~~104,6~~ **104,3**	**9,96**		~~104,1~~ **103,5**
	min		8,3		8,3		98,0	8,5		97,7	8,0		95,8
	max		10,3		11,5		111,4	11,5		111,5	11,5		111,5

	n trials		4		4		4	4		4	4		4

Means followed by the same letter in the same row do not significantly differ (Tukey HSD, p=0,05)

Table 3.4-10: Impact of GF-3311 (GF-3308) on the yield amount (t/ha) when applied twice at the proposed label rate and at double rate. Summary of data from 2 phytotoxicity trials conducted in spring wheat in the absence of disease or at low disease pressure

EPPO Zone	**Trial number**	**Crop**	**Yield (corrected)**										
					GF-3311 (GF-3308)						**Proline**		
			Untr,		**100 g as/ha**			**200 g as/ha**			**200 g as/ha (0,72 L/ha)**		
			t/ha		**t/ha**		**rel%**	**t/ha**		**rel%**	**t/ha**		**rel%**
Maritime		TRZAS	5,623	a	5,71	a	101,6	5,71	a	101,6	5,66	a	100,6
North-East		TRZAS	4,14	a	4,86	a	117,6	4,70	a	113,7	5,353	a	129,5
All trials	**Mean**		**4,88**		**5,29**		~~108,4~~ **109,6**	**5,21**		~~106,7~~ **107,7**	**5,50**		~~112,8~~ **115,1**
	min		4,1		4,9		101,6	4,7		101,6	5,4		100,6
	max		5,6		5,7		117,6	5,7		113,7	5,7		129,5

Means followed by the same letter in the same row do not significantly differ (Tukey HSD, p=0,05)

Comments of zRMS on:

Effect on the yield of treated plants or plant product (3.4.2)
Based on the submitted additional 6 selectivity trials it can be concluded that GF-3308 has no adverse effect on the yield of wheat.

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

All ~~111~~ 118 efficacy trials reported no phytotoxicity or adverse effects to treated crops at dose rates up to 2,0 L/ha of GF-3308 (see section 3.4.1.1) and quality results (TGW and HLW) from these trials demonstrated no adverse effects on grain quality, in the presence of disease (see section 3.2.3).
The following chapters demonstrate the effect of GF-3308 yield quality parameters such as protein content, thousand grain weight, hectolitre weight, Hagberg falling number or the viability of seeds harvested selectivity trials.

3.4.3.1 Effect on yield quality in phytotoxicity trials – winter wheat and spring wheat

Introduction

As detailed already in section 3.4.1.2 (*Phytotoxicity to wheat in selectivity trials*) 6 phytotoxicity trials were established to demonstrate the selectivity and the impact of GF-3308 (GF-3311 was used in these trials) on yield quality parameters when applied in winter wheat (4) and spring wheat (2). The trials were carried out by contractor companies and Official Research institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were placed in France (1), Germany ~~(2)~~ (1), Hungary (1), Poland (1) and the United Kingdom (2), in 2014 in areas where wheat is commercially grown. The trial from France was within the Maritime EPPO zone part of the country.

Material and methods

For information on testing organisations involved, for trials site and experimental details refer to chapters 3.4.1.2 (*Phytotoxicity to wheat in selectivity trials*)

Results

In 6 phytotoxicity trials conducted in France (1), Germany ~~(2)~~ (1), Hungary (1), Poland (1) and the

United Kingdom (2) in 2014 GF-3311 (GF-3308) applied at the proposed label rate of 100 g as/ha and 200 g as/ha as the double rate no negative impact on yield quality parameters grain moisture at the timing of harvest, the thousand grain weight, the protein content of the grain, the Hagberg falling number or the viability of seeds of the winter and spring wheat. Results are summarized in Table 3.4-11 to Table 3.4-15.
At this point reference is also made to 3.4.4.3 (*Effect of GF-3308 on bread baking*) where no negative impact was found in 4 French field trials on a range of grain quality parameter of wheat treated according to the suggested GAP.

Table 3.4-11: Impact of GF-3311 (GF-3308) on the grain moisture of wheat in phytotoxicity trials at harvest.

EPPO Zone	Country	Trial number	Crop	Grain Moisture content %							
						GF-3311 (GF-3308)				Proline	
				Untr,		100 g as/ha		200 g as/ha		200 g as/ha (0,72 L/ha)	
				%		%		%		%	
Maritime	**Maritime**	**Mean**		**13,6**		**13,7**		**13,6**		**13,5**	
		min		11,8		11,8		11,6		11,3	
		max		16,8		16,9		16,9		16,8	
		n trials		3		3		3		3	
North-East			TRZAS	15,1	a	15,7	a	15,6	a	15,3	a
South-East			TRZAW	11,8	a	12	a	11,7	a	11,9	a
All trials		**Mean**		**13,5**		**13,7**		**13,6**		**13,5**	
		min		11,8		11,8		11,6		11,3	
		max		16,8		16,9		16,9		16,8	
		n trials		5		5		5		5	

Means followed by the same letter in the same row do not significantly differ (Tukey HSD, p=0,05)

Table 3.4-12: Impact of GF-3311 (GF-3308) on 1000 grain weight of wheat in phytotoxicity trials

EPPO Zone	Country	Trial number	Crop	Thousand grain weight (g)							
						GF-3311 (GF-3308)				Proline	
				Untr,		100 g as/ha		200 g as/ha		200 g as/ha (0,72 L/ha)	
				g		g		g		g	
Maritime		**Mean**		**44,1**		**46,1**		**46,1**		**45,9**	
		min		34,7		34,1		34,4		34,3	
		max		50,8		53,2		52,7		53,4	
		n trials		3		3		3		3	
North-East			TRZAS	36,7	b	39,6	ab	37,8	ab	41,7	ab
South-East			TRZAW	45,9	a	45,5	a	46,2	a	46,0	a
All trials		**Mean**		**42,94**		**44,67**		**44,45**		**45,06**	
		min		34,7		34,1		34,4		34,3	
		max		50,8		53,2		52,7		53,4	
		n trials		5		5		5		5	

Means followed by the same letter in the same row do not significantly differ (Tukey HSD, p=0,05)

Table 3.4-13: Impact of GF-3311 (GF-3308) on the protein content of wheat in phytotoxicity trials

EPPO Zone	Country	Trial number	Crop	Protein content %							
						GF-3311 (GF-3308)				Proline	
				Untr,		100 g as/ha		200 g as/ha		200 g as/ha (0,72 L/ha)	
				%		%		%		%	
Maritime		**Mean**		**10,7**		**10,8**		**10,7**		**10,6**	
		min		9,7		9,8		9,7		9,6	
		max		12,7		13,1		12,9		12,7	
		n trials		4		4		4		4	
North-East			TRZAS	13,7	ab	14	ab	13,4	ab	13,4	ab
South-East			TRZAW	12,3	a	12,3	a	12,3	a	12,1	a
All trials		**Mean**		**11,5**		**11,6**		**11,4**		**11,3**	
		min		9,7		9,8		9,7		9,6	
		max		13,7		14,0		13,4		13,4	
		n trials		6		6		6		6	

Means followed by the same letter in the same row do not significantly differ (Tukey HSD, p=0,05)

Table 3.4-14: Impact of GF-3311 (GF-3308) on the of wheat in phytotoxicity trials

EPPO Zone	Country	Trial number	Crop	Hagberg (seconds)							
						GF-3311 (GF-3308)				Proline	
				Untr,		100 g as/ha		200 g as/ha		200 g as/ha (0,72 L/ha)	
				s		s		s		s	
Maritime		**Mean**		**286,1**		**258,9**		**265,2**		**269,4**	
		min		213,0		158,5		155,8		181,0	
		max		324,8		309,3		332,3		318,3	
		n trials		3		3		3		3	
South-East			TRZAW	322	a	328	a	325		326,8	a
All trials		**Mean**		**295,1**		**276,2**		**280,2**		**283,7**	
		min		213,0		158,5		155,8		181,0	
		max		324,8		328,0		332,3		326,8	
		n trials		4		4		4		4	

Means followed by the same letter in the same row do not significantly differ (Tukey HSD, p=0,05)

Table 3.4-15: Impact of GF-3311 (GF-3308) on the viability of seeds of wheat in phytotoxicity trials

EPPO Zone	Country	Trial number	Crop	Germination of seeds (%)							
						GF-3311 (GF-3308)				Proline	
				Untr,		100 g as/ha		200 g as/ha		200 g as/ha (0,72 L/ha)	
				%		%		%		%	
Maritime	FRANCE	FR14E7B016MC02C	TRZAW	97,3	a	95,8	a	-		98,4	a
Maritime	GERMANY	DE14E7B016UB01C	TRZAS	98	m/s*	99	m/s	-		98	m/s
Maritime	UK	GB14E7B016EB01C	TRZAW	99	m/s	99	m/s	-		99	m/s
Maritime	UK	GB14E7B016EB02C	TRZAW	90	a	91	a	-		92	a
	Maritime	**Mean**		**96,1**		**96,2**				**96,9**	
		min		90,0		91,0				92,0	
		max		99,0		99,0				99,0	
		n trials		4		4				4	
North-East	POLAND	PL14E7B016AS01C	TRZAS	89	a	89	a	85,5	a	85,5	a
South-East	HUNGARY	HU14E7B016AB01C	TRZAW	89	m/s	90	m/s	m/s		90	m/s
	All trials	**Mean**		**93,7**		**94,0**		**85,5**		**93,8**	
		min		89,0		89,0		-		85,5	
		max		99,0		99,0		-		99,0	
		n trials		6		6		1		6	

Means followed by the same letter in the same row do not significantly differ (Tukey HSD, p=0,05)
* m/s = germination test was conducted with seeds from a mixed sample obtained from 4 reps

Comments of zRMS on:

Effects on the quality of plants or plant products (3.4.3)
Based on the submitted additional 6 selectivity trials, in which the impact of GF-3311 on grain moisture content, TGW, protein content, Hagberg falling number and germination of seeds were assessed, it can be concluded that GF-3308 has no adverse effect on the yield quality of wheat.

Summary and conclusions for chapters 3.4.1 - 3.4.3 (phytotoxicity, yield and yield quality)

A range of efficacy and selectivity field trials was carried out to evaluate the impact of GF-3308 (GF-3311) on the crop tolerance and on the yield quantity and quality, both, in the presence or in the absence of disease. The trial locations involved were covering countries in EPPO climatic zones Maritime, North-East and South-East as described in EPPO Standard PP 1/241.
Tested within the proposed GAP GF-3308 (and GF-3311) in GEP efficacy field trials on winter wheat, spring wheat, winter rye and winter triticale at the proposed label rate of 1,5 (75 g as/ha) or 2,0 L/ha (100 g as/ha) did not cause any negative effects that were due to the treatment. In the presence of disease, relative to the untreated check, treatments with GF-3308 showed significant levels of yield increase as it can be expected from a fungicide products that reliably controls *Septoria* spp., *Puccinia* spp. and *Rhynchosporium* on cereal crops.
Tested in the absence of diseases or at low disease levels in specific phytotoxicity trials GF-3308 (GF-3311) applied in sequence at the proposed label rate of 100 g as/ha or at the double rate of 200 g as/ha did not cause any major phytotoxic effects on a range of varieties of winter wheat, spring wheat, triticale

or winter rye nor did it negatively affect the yield quantity and quality parameters such as grain moisture at harvest, the 1000 grain weight, the specific weight, the Hagberg number or the protein content.
It can be concluded that GF-3308 (and GF-3311) applied within the proposed GAP will not cause phytotoxic damage to commercial cereal varieties grown nor will it induce any negative effects on the growth, the maturation and yield of cereal crops. No warnings for negative effects are required on the label.

Comments of zRMS on: **Adverse effects on treated crops (3.4.1, 3.4.2, 3.4.3), Yield in effectiveness trials (3.2.3.8)** GF-3308 at the maximum recommended dose rate of 2,0 L/ha can be safely used in target crops without risk of serious phytotoxicity symptoms. GF-3308 has no adverse effect on yield and yield quality parameters on target crops.

3.4.4 Effects on transformation processes (KCP 6.4.4)

Plant protection products such as fungicides might affect processes performed for the transformation of harvested crops. For the use of GF-3308 the crops concerned in this dossier is wheat or rye which may be subjected to transformation processes such as brewing or baking. The following chapters report on the impact of fenpicoxamid on the growth of yeast (*Saccharomyces cerevisiae*) cultures under laboratory conditions and the effect of GF-3308 on brewing wheat beer (Weißbier) and on bread baking.
For the brewing study data are presented that have been generated using the EC formulation coded GF-3307. GF-3307 is a fungicide formulation that contains fenpicoxamid and prothioconazole which applied at 2.0 L/ha delivers 100 g as/ha fenpicoxamid and 200 g as/ha prothioconazole. However, apart from the prothioconazole content, formulations GF-3307 and GF-3308 have a similar composition using the same co-formulants. Therefore the data generated with GF-3307 for beer brewing is considered representative for the evaluation of GF-3308.
In terms of formulation contents GF-3308 and GF-3307 are very similar formulations (see Part C for comparison of both formulation).

3.4.4.1 Effect of Fenpicoxamid and UK-2A on the growth of yeast

Introduction

Preliminary biological spectrum characterization with UK-2A and Fenpicoxamid *in-vitro* indicated strong growth inhibition of fungi such as SEPTTR, LEPTNO, USTIMA, PYRIOR and a wild type strain of the yeast *S. cerevisiae* growing on a medium with glycerol as sole carbon source. However, since yeasts such as *S. cerevisiae* are capable of fermentative growth, which bypasses terminal mitochondrial respiration involving the *bc*1 complex, it would be expected that growth under conditions supporting fermentation, i.e. media containing a fermentable carbon source, would not be inhibited by either UK-2A or Fenpicoxamid.

<u>Testing facilities involved</u>
A non GEP/non GLP laboratory study (report # DAI 1399) was carried out by Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN., 46268, USA to evaluate Fenpicoxamid and UK-2A for antifungal activity against *S. cerevisiae*.

Material and methods

The yeast culture with yeast strain X2180-1A was initiated by transfer onto petri dishes containing YPD agar and maintained in the dark for 24h in an incubator set at 30°C. Assay inoculums were subsequently prepared by spore transfer into two separate broths, YPD broth (1% yeast extract, 2% peptone and 2%

dextrose) and YPG broth (1% yeast extract, 2% peptone and 3% glycerol) and spore densities adjusted to 1.0 x 10 spores/mL. Assays conducted with yeast growing in each of the two media were initiated by addition of 200 µl inoculum into wells of 96-well plates containing 2 µL of a 5-fold dilution series of Fenpicoxamid or UK-2A prepared using stock solutions in DMSO, to deliver a total of 7 test concentrations ranging from 0.000128 ppm to 2 ppm. Test plates were placed on a tray with moistened paper towels, covered to reduce evaporation, and incubated in the dark without shaking for 96 h at 30 °C. Initial and final cell density readings were determined using a NepheloStar nephelometer (BMG LABTECH GmbH, D-77799 Ortenberg, Germany). Six replicates were assayed and percentage growth inhibition was calculated by reference to control wells containing only growth media, amended with 2 µL DMSO, and inoculum.

Results

Table 3.4-16 below presents the data obtained on the effect of both UK-2A and Fenpicoxamid on *S. cerevisiae* when growing on either a fermentable (dextrose, medium YPD) or non-fermentable (glycerol, medium YPG) carbon source. The data clearly demonstrates very strong growth inhibition of *S. cerevisiae* by Fenpicoxamid and UK-2A when grown aerobically on the non-fermentable glycerol as sole carbon source. However, neither compound is inhibitory to growth when *S. cerevisiae* is presented with a fermentable sugar (dextrose) which supports anaerobic fermentation.

Table 3.4-16: Effects of UK-2A & Fenpicoxamid on growth of *S. cerevisiae* on a fermentable *vs.* non-fermentable carbon source

Rate (as, mg/L)	**Growth inhibition [%]**			
	YPG Medium (glycerol, non-fermentable)		**YPD Medium** (dextrose, fermentable)	
	Fenpicoxamid	**UK-2A**	**Fenpicoxamid**	**UK-2A**
2,0	100	91	3	0
0,4	87	93	3	0
0,08	81	85	1	0
0,016	100	94	2	1
0,0032	89	85	0	0
0,00064	98	94	0	0
0,000128	61	68	0	0

Summary and conclusions

When growing on a fermentable carbon source such as dextrose the growth of *S. cerevisiae is* not inhibited by either UK-2A or Fenpicoxamid. From this data it can be concluded that it is unlikely that Fenpicoxamid or UK-2A residues in the grain have a negative effect on the growth of *S. cerevisiae* during fermentation in the beer production process.
Reference report: Owen, W. J; Slanec, T; Impact of Carbon Source on Growth Inhibition of Saccharomyces cerevisiae by XDE-777 and UK-2A. Dow AgroSciences, unpublished report number DAI 1399, 12. February 2015.

3.4.4.2 Effect of GF-3308 on brewing

Wheat beer or in German Weizenbier, in the southern parts of Germany is called Weißbier (literally 'white beer'). Weißbier is a beer in which a significant proportion of malted barley is replaced with malted wheat. By law Weißbier brewed in Germany must be top-fermented. Specialized strains of yeast are used which produce certain overtones and clove as by-products of fermentation. Weißbier is so called because at the time of its inception it was paler in colour than Munich brown beer. The terms 'Hefeweizen' or 'Hefeweißbier' refer to wheat beer in its traditional, unfiltered form which has a cloudy appearance due to the yeast content. The term 'Kristallweizen' refers to a wheat beer that is filtered to remove the yeast from suspension and has a 'crystal clear' appearance. Weißbier is available in a number of other forms including Dunkelweizen (dark wheat) and Weizenstarkbier (strong wheat beer), commonly referred to as Weizenbock. The dark wheat varieties are made with darker, more highly kilned malts, of both, wheat and barley. The Weizenbock typically have a much higher alcohol content than their lighter cousins.
Two processing studies DE15E7B005UB01C and DE15E7B005UB01C each comprising grain samples collected from field sites were initiated in Germany in 2015. The studies fell into a field part to provide the grain for malting and a laboratory part to evaluate possible effects on the processing phase. The study was carried out using formulation GF-3307. As stated previously due to the similarity of the composition of formulations data generated with GF-3307 is considered representative for the evaluation of GF-3308 for brewing purposes. The reference product included was Proline 275.
The trials were carried out on behalf of Dow AgroSciences by BioChem located in Kupferstraße 6 in 04827 Gerichshain, Germany which is a qualified contractor following the EPPO standards and is officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The leading EPPO standards followed were PP 1/242 ('*Taint Tests*') and PP 1/243 ('*Effects of plant protection products on transformation processes*'). For the laboratory processing parts of the studies GLP compliance is not claimed but procedural GLP aspects were included within the QA programme of both studies.

Material and methods

Testing facilities or organisations
The trials were carried out as detailed in the subsequent Table.

Table 3.4-17: Testing facilities involved

Admin. Zome	EPPO Zone	Country	Year	BioChem Study Code	Trial number	Testing Organisation	EPPO Guideline	Trial Status
Central	Maritime	GERMANY	2015	15 1047 2114	DE15E7B005UB01C	BioChem agrar	PP 1/242 PP 1/243	GEP
					DE15E7B005UB02C	BioChem agrar	PP 1/242 PP 1/243	GEP

Field trial sites
Trial sites were selected on the basis of favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially. For further trial site details (field phase) see the BAD. The following map provides an overview of the geographical distribution of the field trials in Germany.

Figure 3.4-1: Distribution of 2 field trials sites conducted to obtain the wheat grain samples for the beer processing (field phase

Formulations applied and rates

Test products	Formulation type	Active substance	Rate product L/ha	Rate gas/ha
GF-3307	EC	Fenpicoxamid + prothioconazole (50 +100 g/L)	2,0	300
Proline 275	EC	Prothioconazole	0,72	198

Treatment and application timings

Treatment	Appl. timing	Formulation	Rate L/ha	Appl. crop growth stage aimed at in protocol
1	AB	GF-3307	2,0	Timing A at BBCH 39/45 and timing B at BBCH 65/69
2	AB	Proline 275	0,72	Timing A at BBCH 39/45 and timing B at BBCH 65/69

All treatments were applied in accordance with the requirements of the test protocol EA15E7B005.

Experimental details

To obtain the grain for malting 2 field trials were carried out in Germany in 2015. The trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organisations. The trials were of a randomized complete block design with 4 replicates and a plot size of 30 m² in either trial. The treatments in both trials were applied using precision small plot sprayers equipped with flat fan nozzles delivering water volumes of 200 and 250 L/ha.

GF-3307 and the reference product Proline in both field trials were applied in sequence at wheat growth stage BBCH 39-41 and BBCH 65. The late application timing of the test products is considered worst case in terms of testing the impact on brewing beer. Further application details are shown in the BAD.

The 2 field trials were conducted under almost pest free conditions through the use of appropriate plant protection products such as herbicides, insecticides and fungicides. Before malting seed viability test was conducted. The grain specimens were cleaned and sieved prior to malting. After sieving, wet steeping was conducted. After steeping a germination procedure followed. Kiln-drying was conducted in a dry chamber or drying oven. After drying the germs were removed mechanically using a trimmer. Until brewing the malt was stored at room temperature (malt rest).

The processing phase was performed between January and March 2016 at laboratory scale which fully compared to the industrial beer brewing process. After fermentation and maturation all specimens were filled into suitable glass bottles which were clearly and uniquely identified. The specimens were then stored at cooled conditions until the triangle taint test was carried out.

Results

To evaluate the effect of GF-3307 on beer making and the gustatory qualities of the resulting Weißbier a processing study comprising grain samples collected from 2 field sites was initiated in Germany in 2015. The studies fell into a field part to provide the grain for malting and a laboratory part to evaluate possible effects of GF-3307 on the processing phase. The reference product included was Proline 275 (275 g /L prothioconazole).
GF-3307 and Proline in both field trials were applied in sequence at wheat growth stage BBCH 39-41 and BBCH 65. The late application timing of the test products is considered worst case in terms of testing the impact on brewing beer.
No adverse effects due to the application of GF-3307 on fermentation were apparent in both studies. Quality parameters such as seed viability, protein, alcohol, carbon dioxide, oxygen and extract contents, colour or foam stability were all in normal range and presented no distinct differences.
No significant (α=0.05) differences were found in the taint test between GF-3307 and Proline and none of the testers attributed a bad or negative taste profile to either GF-3307 or Proline treated specimen samples.

Summary and conclusions

GF-3307 applied at the proposed maximum label rate of 2,0 L/ha does not have a negative impact on the course of fermentation nor does the product negatively affect the quality parameters and gustatory qualities of the resulting Weißbier. Due to the similarity of formulations it is concluded that GF-3308 applied according to the proposed GAP will have no negative impact on the grain quality of treated wheat crops and the consecutive brewing process. Although there were two applications in these trials, this represents the worst case scenario and it can be concluded that GF-3308 at 2,0 L/ha applied at the latest timing according to the proposed GAP will have no negative effect on the quality of the yielded grain and the consecutive steps of the brewing process.
<u>Reference report:</u> Kästner, K; Processing phase report. Field study to generate specimen of beer from RAC wheat treated with GF-3307 or GF-3309 for subsequent triangle taint testing and determination of quality parameters, 2 Sites in Germany 2015. BioChem agrar, unpublished report number 15 1047 2114.

Table 3.4-18: Impact of GF-3307 on grain quality and quality parameters of the produced Weißbier

Trial number	Treatment	Appli-cation timing	Seed viability germination [%]	Protein grain [%]	Original extract [°P]	Real extract [°P]	Alcohol v/v [%]	Protein beer [%]	Carbon dioxide g/L	Oxygen mg/L	Colour [EBC]	Density g/mL	Foam stability [s]
DE15E7B005UB01C	GF-3307 at 2,0 L/ha	AB	95,3	12,4	12,7	4,37	4,42	0,73	6,61	n,d,	7,8	1,0075	188
	Proline at 0,72 L/ha	AB	95,5	12,3	12,7	4,31	4,43	0,67	6,58	n,d,	7,9	1,0073	193
DE15E7B005UB02C	GF-3307 at 2,0 L/ha	AB	92,5	10,1	12,5	4,35	4,31	0,48	6,97	n,d,	6,4	1,0076	188
	Proline at 0,72 L/ha	AB	91,8	10,5	12,8	4,74	4,30	0,52	6,48	n,d,	7,2	1,0092	208

n.d. = not detectable

Table 3.4-19: Results of the triangle taint test

Trial number	Treatment/specimen	Number of testers	Number of correctly determined differences	Percent of correctly determined differences	Significance (α = 0,05)
DE15E7B005 UB01C	GF-3307	18	9	50	no
	Proline				
DE15E7B005 UB02C	GF-3307	18	7	39	no
	Proline				

No difference in taste could be observed between treatment GF-3307 vs Proline in both trials.

Table 3.4-20: Results of preferences within the triangle taint test

Trial number	Treatment/ specimen	Number of tests with correct determined differences	Preferred specimen GF-3307	Preferred specimen Proline	Significance (α = 0.05)
DE15E7B005UB01C	GF-3307	9	5	3	no
	Proline				
DE15E7B005UB02C	GF-3307	7	2	4	no
	Proline				

Table 3.4-21: Description of taste descriptors attributed to the specimen beer

Specimen source trial	Treatment/ specimen	Description of the preferred specimen
DE15E7B005UB01C	GF-3307	long lasting taste, sweeter, more distinct banana tone, fresh, fruity, pleasant
	Proline	clove* tone, dryer, fruity
DE15E7B005UB02C	GF-3307	clove tone, malty, fresh, fruity
	Proline	sweeter, quaffable, clove tone, intensive, aromatic

* Cloves (English) = Gewürznelke (German) = *Syzygium aromaticum*

3.4.4.3 Effect of GF-3308 on bread baking

Introduction

Four studies were carried out in France in 2015 to show that GF-3308 does not affect the quality of wheat and the baking process. All trials were carried out by officially recognized organizations according to Good Experimental Practice. The studies included a field phase and a laboratory phase whereby both were carried out by the same contractor.

Material and methods

Testing facilities or organisations

The trials were carried out in France by the officially recognized testing facility BIOTEK Agriculture according to the EPPO and CEB guidelines indicated in Table 3.4-22 below.

Table 3.4-22: Testing facilities involved

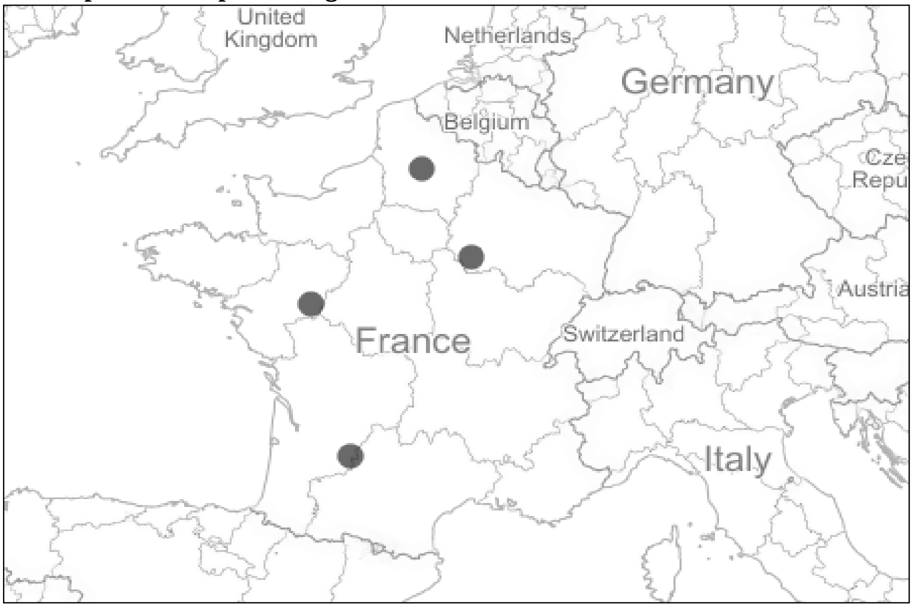
Admin. Zome	EPPO Zone	Country	Year	Trial number	Testing Organisation	Guidelines	Trial Status
South	Maritime	FRANCE	2015	FR15E7B006MC01C	Biotek agriculture	EPPO PP 1/243 CEB n° 218	GEP
South	Mediterranean	FRANCE	2015	FR15E7B006MC02C	Biotek agriculture	EPPO PP 1/243 CEB n° 218	GEP
South	Maritime	FRANCE	2015	FR15E7B006MC03C	Biotek agriculture	EPPO PP 1/243 CEB n° 218	GEP
South	Maritime	FRANCE	2015	FR15E7B006MC04C	Biotek agriculture	EPPO PP 1/243 CEB n° 218	GEP

Sites and experimental details

The trials were conducted in Central, North and South-West of France which correspond to areas with favourable conditions for the production of milling wheat. The trials were conducted in almost pest- and disease-free situations with maintenance sprays carried out as per normal farming practice using only fungicides different to GF-3308 and the reference product.

The experimental design was a randomized complete block with 3 replicates and a minimum plot size of 24 m². The applications were performed with precision small plot sprayers equipped with flat fan nozzles delivering water volumes of 200-250 L/ha. The trials were yielded using a small plot combined harvester. The following map provides an overview of the geographical distribution of the field trials across France.

Figure 3.4-2: Geographical distribution of the 4 field trials sites conducted to obtain the wheat grain samples for the processing



Formulations applied and rates

Test products	Formulation type	Active substance	Rate product L/ha	Rate g ai/ha	Appl. crop growth stage aimed at in the test protocol
GF-3308	EC	Fenpicoxamid	2,0	100	BBCH 39/45 & 65/69
IGNITE	EC	epoxiconazole	1,5	124,5	BBCH 39/45 & 65/69

Treatments and application timings

GF-3308 was applied twice at 2 L/ha at BBCH 39-45 followed by BBCH 65-69. IGNITE was applied twice at 1,5 L/ha at the same application timings.

Results

The data generated from these bread-making studies are presented below step by step.

Yield amount field trials

The following table presents yield measured in metric tons/ha.

Table 3.4-23: Impact of GF-3308 on yield amount

Trial	Corrected yield, t/ha					
	GF-3308		IGNITE		Untreated	
FR15E7B006MC01C	10,3	a	10,1	a	10,2	a
FR15E7B006MC02C	7,6	a	7,4	a	7,5	a
FR15E7B006MC03C	10,5	a	10,9	a	10,8	a
FR15E7B006MC04C	9,4	a	9,4	a	9,3	a

No significant yield differences were observed between GF-3308, the untreated and the reference product. Therefore, the bread-making tests could be performed. The results of the qualitative and bread-making tests are summarized in the next tables.

Grain protein content and Hagberg test

According to CEB method n°218, treatments tested should not show any statistical difference to the reference product for protein content and show a Hagberg falling number superior to the minimum threshold of 180. The results presented in the Table below show no statistical difference between GF-3308 at 2 L/ha and the reference product.

Table 3.4-24: Impact of GF-3308 on grain protein content

Trial	Protein content %					
	GF-3308		IGNITE		Untreated	
FR15E7B006MC01C	8,5	a	8,7	a	8,6	a
FR15E7B006MC02C	13	a	13	a	13,1	a
FR15E7B006MC03C	11,9	a	12	a	12	a
FR15E7B006MC04C	9,7	a	9,8	a	10	a

Table 3.4-25: Impact of GF-3308 on Hagberg falling number

Trial	Hagberg falling number (seconds)			
	GF-3308		IGNITE	
FR15E7B006MC01C	338,0	a	348,8	a
FR15E7B006MC02C	352,8	a	344,7	a
FR15E7B006MC03C	345,7	a	346,2	a
FR15E7B006MC04C	360,3	a	355,7	a

The Hagberg falling number was always higher than 180 and no significant differences were evident between the treatments. When applied twice at 2,0 L/ha to winter wheat, GF-3308 had no impact on the protein content and the amylases activity.

Zeleny test and Chopin alveograph

The Zeleny test and Chopin alveograph were performed on the bulk sample. The Zeleny rating is expressed as a volume in ml. The test checks the capability of flour protein to inflate. Values are considered to differ significantly if the difference is superior to 10%. In these four trials, the difference between GF-3308 and the reference product never exceeded 10%. It can be concluded that GF-3308 applied twice at 2 L/ha on winter has no negative impact on the Zeleny index.

Table 3.4-26: Impact of GF-3308 on Zeleny volume

Trial	Zeleny volume (mL)	
	GF-3308	IGNITE
FR15E7B006MC01C	25	24
FR15E7B006MC02C	33	32
FR15E7B006MC03C	31	31
FR15E7B006MC04C	20	24

The results of the Chopin alveograph parameters are presented in the following table. According to the CEB method n°218, values are considered to differ significantly if the difference is 8 % for W, 8 % for P and 5 % for G. The results of the Chopin test revealed equivalent or higher G values for GF-3308 compared to the reference standard IGNITE thus causing no negative effect. The W value was lower than that of IGNITE in one trial and the P value for tenacity was lower in two trials. Nevertheless, in the other studies the values were equivalent or higher than those of IGNITE. Since no clear trend was evident in the four studies, it can therefore be considered that the differences were due to experimental variability. The results of the Chopin test indicate that two applications of GF-3308 at 2 L/ha on winter wheat have no negative impact on the various parameters (W, G, P and P/L) measured.

Table 3.4-27: Impact of GF-3308 on Chopin alveograph

Trial	Chopin Type	GF-3308	IGNITE
FR15E7B006MC01C	CHOPIN W	137	119
	CHOPIN G (Swelling)	15,4	13,5
	CHOPIN P (Tenacity)	77	79
	CHOPIN P/L	1,6	2,1
FR15E7B006MC02C	CHOPIN W	221	204
	CHOPIN G (Swelling)	20	17,8
	CHOPIN P (Tenacity)	78	86
	CHOPIN P/L	1	1,3
FR15E7B006MC03C	CHOPIN W	205	177
	CHOPIN G (Swelling)	16,7	17,1
	CHOPIN P (Tenacity)	101	85
	CHOPIN P/L	1,8	1,4
FR15E7B006MC04C	CHOPIN W	101	113
	CHOPIN G (Swelling)	13,2	12,2
	CHOPIN P (Tenacity)	70	86
	CHOPIN P/L	2	2,9

Bread-making test

Finally, the studies were completed by a bread-making test followed by a sensory test. The observations were performed on the dough, the bread and on the soft part of the bread using a scale from 0 - 100 leading to an overall score ranging between 0 and 300.

According to the acceptable difference limits governed by the method AFNOR NF V 03-716, no significant difference was evident between GF-3308 and the reference product considering dough, soft part of bread, bread and total bread results, except in one trial where GF-3308 reached a higher bread score than IGNITE. In three trials out of the four, GF-3308 reached a numerically higher overall score than IGNITE. GF-3308 applied twice at 2 L/ha on winter wheat at BBCH 39-45 followed by BBCH 65-69 had no impact on the bread-making measures on bread and dough. The results of the bread-making test are presented on the following table.

Table 3.4-28: Impact of GF-3308 on baking process – bread quality assessment

Trial	Evaluation Type	Scale	GF-3308	IGNITE	Acceptable difference limit
FR15E7B006MC01C	DOUGH	(0-100)	99	97	24
	BREAD	(0-100)	58	60	16
	SOFT PART/CRUMB	(0-100)	97	94	26
	TOTAL BREAD	(0-300)	254	251	43
FR15E7B006MC02C	DOUGH	(0-100)	81	96	24
	BREAD	(0-100)	43	43	16
	SOFT PART/CRUMB	(0-100)	94	94	26
	TOTAL BREAD	(0-300)	218	233	43
FR15E7B006MC03C	DOUGH	(0-100)	87	81	24
	BREAD	(0-100)	30	30	16
	SOFT PART/CRUMB	(0-100)	94	94	26
	TOTAL BREAD	(0-300)	211	205	43
FR15E7B006MC04C	DOUGH	(0-100)	84	93	24
	BREAD	(0-100)	42	22	16
	SOFT PART/CRUMB	(0-100)	100	97	26
	TOTAL BREAD	(0-300)	226	212	43

According to the acceptable difference limits governed by the method AFNOR NF V 03-716, no significant difference was evident between GF-3308 and the reference product considering dough, soft part of bread, bread and total bread results, except in one trial where GF-3308 reached a higher bread score than IGNITE. In three trials out of the four, GF-3308 reached a numerically higher overall score than IGNITE. GF-3308 applied twice at 2 L/ha on winter wheat at BBCH 39-45 followed by BBCH 65-69 had no impact on the bread-making measures on bread and dough.

Summary and conclusion

~~In total~~ Four bread-making studies were performed in 2015 in France within the Maritime (3) and Mediterranean (1) EPPO Zone. GF-3308 was applied at 2,0 L/ha compared to the untreated control and the reference product IGNITE. The results demonstrated that when applied twice at 2,0 L/ha even at a late application timing (BBCH 39-45 followed by BBCH 65-69) GF-3308 had no negative impact on the quality of the grain and the baking process. There was no significant difference in yield, protein content, Zeleny index, the Hagberg falling number, the Chopin alveograph and the bread-making quality parameters measured. Although there were two applications in these trials, this represents the worst case scenario and it can be concluded that GF-3308 at 2,0 L/ha applied at the latest timing according to the proposed GAP will have no negative effect on the quality of the yielded grain and the consecutive steps of the baking process.

Comments of zRMS on:

Effects on transformation processes (3.4.4)
Six trials have been submitted by the applicant to assess whether GF-3308 has any impact on transformation processes including: 1 laboratory study carried out in USA in 2015 to evaluate the effect of fenpicoxamid and UK-2A for the growth of yeast (*S. cerevisiae),* 2 trials carried out in Germany in 2015 to evaluate the effect of GF-3308 on brewing and 4 studies conducted in France in 2015 to assess whether GF-3308 affect the quality of wheat and the baking process. Result from the first trial shows that the growth of *S. cerevisiae* growing on a fermentable carbon source such as dextrose is not inhibited by either UK-2A or fenpicoxamid. It can be concluded that a negative effect of fenpicoxamid or UK-2A residues on the growth of *S.* cerevisiae during fermentation in beer production process is not expected. Results from two German trials show that GF-3307 (a fungicide containing fenpicoxamid and prothioconazole) applied at dose rate of 2,0 L/ha (delivering 100 g as/ha fenpicoxamid and 200 g as/ha prothioconazole) has no negative impact on the grain quality of treated wheat crops, quality parameters and gustatory qualities of the resulting wheat beer. Based on the four French studies it can be concluded that a negative impact on the quality of the grain and the baking process is not expected after application of GF-3308 at dose rate of 2,0 L/ha (no significant difference between GF-3308 and standard Ignite (containing epoxiconazole) in yield, protein content, Zeleny index, the Hagberg falling number, the Chopin alveograph and the bread-making quality parameters measured).
Based on the results from submitted studies it can be concluded that a negative effect of GF-3308 applied at the maximum dose rate of 2,0 L/ha on transformation processes (brewing, baking) is not expected.

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

Introduction

The only part of the plant used for propagating small grain cereals such as wheat, triticale or rye is the seeds that are stored after the harvest to be used for drilling in the next growing season. To evaluate a possible impact of treatments with GF-3308 on the germination ability of wheat, grain samples from 6 selectivity trials were collected and tested according to ISTA[2] testing rules. As detailed already in section 3.4.1.2 (*Phytotoxicity to wheat in selectivity trials*) the 6 phytotoxicity trials were established to demonstrate the selectivity of GF-3308 to wheat. In these trials the impact of GF-3308 on the germination of seeds collected was evaluated.
The trials were carried out by contractor companies and Official Research institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were placed in France (1), Germany (1), Hungary (1), Poland (1) and the United Kingdom (2), in 2014

[2] The International Seed Testing Association, International rules for seed testing.

in areas where wheat is commercially grown. The trial from France was within the Maritime EPPO zone part of the country.

Material and methods

For information on testing organisations involved, for trials site and experimental details refer to chapters 3.4.1.2 (*Phytotoxicity to wheat in selectivity trials*)

Results

In 6 phytotoxicity trials conducted in France (1), Germany (1), Hungary (1), Poland (1) and the United Kingdom (2) in 2014, GF-3308 applied at the proposed label rate of 2,0 L/ha had no negative impact on the germination of seeds collected from the respective trial areas (see Table 3.4-29). At this point reference is also made to chapter 3.4.4.2 (*Effect of GF-3308 on brewing*) which well demonstrates the fact that GF-3308 applied in line with the proposed GAP will not negatively affect the viability of seeds of wheat.

Table 3.4-29: Impact of GF-3308 on the viability of seeds of wheat in phytotoxicity trials

EPPO Zone	Country	Trial number	Crop	Germination of seeds (%)					
						GF-3308		Proline	
				Untr,		2,0 L/ha		0,72 L/ha	
				%		%		%	
Maritime		**Mean**		**96,1**		**96,2**		**96,9**	
		min		90,0		91,0		92,0	
		max		99,0		99,0		99,0	
		n trials		4		4		4	
North-East			TRZAS	89	a	89	a	85,5	a
South-East			TRZAW	89	m/s	90	m/s	90	m/s
All trials		**Mean**		**93,7**		**94,0**		**93,8**	
		min		89,0		89,0		85,5	
		max		99,0		99,0		99,0	
		n trials		6		6		6	

Means followed by the same letter in the same row do not significantly differ (Tukey HSD, p=0.05)
* m/s = germination test was conducted with seeds from a mixed sample obtained from 4 reps

Summary and conclusions

In 6 selectivity trials GF-3308 applied in sequence at the proposed label rate of 2,0 L/ha to spring wheat (2) and winter wheat (4) did not negatively affect the germination ability of seeds obtained from the trials.

Comments of zRMS on:

Impact on treated plants or plant products to be used for propagation (3.4.4)
Based on the results from six selectivity trials it can be concluded that GF-3308 applied at the maximum dose rate of 2,0 L/ha has no adverse effect on germination of wheat seeds.

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

3.5.1 Impact on succeeding crops (KCP 6.5.1)

Introduction

Cereals such as wheat, triticale or rye are arable crops that are typically part of intensive crop rotations. In this chapter a risk assessment is made according to EPPO guideline PP 1/207 whether fenpicoxamid causes a negative effect on crops grown as rotational or replacement crops after a preceding crop was treated with GF-3308.
Winter or spring cereals such as wheat, triticale or rye in the Central Zone are typically harvested at the end of July and August. Crops following within rotations are cereals such as barley or wheat, oilseed rape, legumes such as winter field beans (*Vicia* spp.) or break crops such as mustard (*Sinapis* spp.) or legume or legume grass mixtures. To evaluate whether GF-3308 affects the emergence or growth of plants through soil activity a NTP seedling emergence study following OECD Guideline 208 (July 19, 2006) was carried out in the laboratory and glasshouses of *Agro-check*, Dr. Teresiak & Erdmann GbR in Lentzke, Germany. The study coded AC/DOW/16/01 was conducted in compliance with the principles of GLP.

Material and methods

GF-3308 containing 50 g/L fenpicoxamid was applied at rates between 0,25 L/ha (12,5g as/ha) and 4,0 L/ha (200g as/ha) to the soil pre-emergence shortly after seeding of the 10 representative test species. Test products were sprayed using a laboratory application chamber 'Spraylab 210/110–SPS', from Schachtner, Ludwigsburg, Germany. The nozzle type used was flat fan EVS 8001 used at 2,7 bar pressure with water volumes ranging between 183-192 L/ha.
The 10 representative plant test species included were oats (*Avena sativa*), ryegrass (*Lolium perenne*), onion (*Allium cepa*), oilseed rape *(Brassica napus),* soybean (*Glycine max),* carrot (*Daucus carota),* cucumber *(Cucumis sativa*), sugar beet *(Beta vulgaris)*, sunflower *(Helianthus annuus)* and tomato (*Lycopersicon esculentum*). The test species were sown in pots containing a natural loamy sand soil taken from the field, sieved to 2 mm with a pH of 7,4 and an organic matter content of 1,31%.
After application of GF-3308 the test species were cultivated in the glasshouse for 21 days (28 days for onion and carrot) at a daily average temperature ranging between 21,6 °C and 27,1 °C and a daily mean relative humidity between 46,4% and 65,6%. The day length was set to ≥ 16 hours.
Assessments for plant injury (phytotoxicity) and plant stand (emergence and mortality) were done 7, 14 and 21 days after treatment (onion and carrot 14, 21 and 28 days). The shoot fresh weight was determined at study termination 21 DAT (28 DAT for onion and carrot).

Results

The detailed results for each test species are summarized in Table 3.5-1 below.

Plant emergence and survival
All plant species had reached the 50% emergence rate after 7 days except onion and carrot (14 days). None of the tested plant species was affected with regard to seedling emergence and plant survival by the application of any rate of GF-3308.

Phytotoxicity
None of the tested plant species showed phytotoxic symptoms after pre-emergence applications of GF-3308.

Biomass (fresh weight)
The plant biomass (shoot fresh weight) was determined 21 DAA (28 DAA for onion and carrot). No significant influence of GF-3308 on plant weight was observed for any of the tested plant species. No dose response effect was apparent and hence it was not possible to calculate ER_{50} values. Therefore, ER_{50} values are estimated to be > 200 g as/ha, the 2 N rate of GF-3308 tested.

Summary and conclusions

Based on the results of the NTP seedling emergence study it can be concluded that the fungicide GF-3308 did not cause any adverse effects to the seedling emergence, survival and biomass of the tested plant species even at the highest rate tested. The ER_{50} values are considered to be ≥ 200 g as/ha which was the highest rate of GF-3308 tested and which is the 2 N rate of the proposed label rate. GF-3308 applied at practical field rates has no herbicidal potential through residues in the soil and hence does not pose a risk to succeeding crops within a normal rotation or to replacements crops in case of a crop failure.
Label restrictions or risk phrases with regard to following crops after application of GF-3308 are not required.

Table 3.5-1: NTP seedling emergence test. NOER (g as/ha) of different test plants to GF-3308

Test species				GF-3308 – NOER (g as/ha)		
				Plant emergence	**Plant survival**	**Biomass reduction**
Oat	*Avena sativa*	Poaceae		≥ 200*	≥ 200	≥ 200
Ryegrass	*Lolium perenne*	Poaceae		≥ 200	≥ 200	≥ 200
Onion	*Allium cepa*	Liliaceae		≥ 200	≥ 200	≥ 200
Oilseed rape	*Brassica*	Brassicaceae		≥ 200	≥ 200	≥ 200
Soybean	*Glycine max*	Fabaceae		≥ 200	≥ 200	≥ 200
Carrot	*Daucus carota*	Apiaceae		≥ 200	≥ 200	≥ 200
Cucumber	*Cucumis sativus*	Cucurbitaceae		≥ 200	≥ 200	≥ 200
Sugar beet	*Beta vulgaris*	Chenopodiaceae		≥ 200	≥ 200	≥ 200
Sunflower	*Helianthus annuus*	Asteraceae		≥ 200	≥ 200	≥ 200
Tomato	*Lycopersicon esculentum*	Solanaceae		≥ 200	≥ 200	≥ 200

* ≥ 200 g as/ha equals ≥ 4 L/ha of GF-3308 as formulated product, i.e. the 2 N rate of the proposed label rate

Comments of zRMS on:

Impact on succeeding crops (3.5.1)
Results from Seedling emergence study, carried out in glasshouse in Lentzke, Germany in 2017 have been presented to determine, whether GF-3308 cause any adverse effects on 10 representative plant species: oat, ryegrass, onion, oilseed rape, soybean, carrot, cucumber, sugar beet, and tomato. GF-3308 was applied at dose rate of 0,25; 0,5; 1,0; 2,0 and 4,0 L/ha to the soil pre-emergence shortly after seeding of the 10 test species. Results from this study showed that GF-3308 at tested dose rates including double recommended dose rate of 4,0 L/ha (2N), applied pre-emergence had no negative influence on seedling emergence, plant survival, biomass and cause no phytotoxicity symptoms on 10 representative plant species. Based on the trial results, it can be concluded that no negative impact on following crops is to be expected after application of GF-3308 at dose rate of 2,0 L/ha.

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

3.5.2.1 Impact on adjacent crops

For GF-3308 a risk assessment was performed based on NTP seedling emergence study AC/DOW/16/01 already quoted in chapter 3.5.1 (*impact on succeeding crops*) and a vegetative vigour study which is described below. With both studies a risk assessment according to EPPO Standard PP 1/256 '*Effects on adjacent crops'* was carried out for crops grown adjacent to a field treated with GF-3308. For adjacent crops the TER-value is calculated by comparing the biological activity of the test product (ER_{50}-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. If the TER-value of the most sensitive crop is greater than 1, according to EPPO PP1/256 no higher tier testing is required.

Material and methods: (vegetative vigour study AC/DOW/16/02)

To evaluate whether Fenpicoxamid affects the growth of plants through foliar contact a NTP vegetative vigour study on a range of representative crops was carried in the glasshouses of *agro-check*, Dr. Teresiak & Erdmann GbR in Lentzke, Germany. The study was conducted following OECD Guideline 227, July 19, 2006 and compliance to GLP principles.
The 10 representative plant species included were oats (*Avena sativa*), ryegrass (*Lolium perenne*), onion (*Allium cepa*), oilseed rape *(Brassica napus)*, soybean (*Glycine max)*, carrot (*Daucus carota)*, cucumber *(Cucumis sativa*), sugar beet *(Beta vulgaris)*, sunflower *(Helianthus annuus)* and tomato (*Lycopersicon esculentum*).
Applications were made using a laboratory application chamber 'Spraylab 210/110–SPS', from Schachtner, Ludwigsburg, Germany. The nozzle type used was flat fan EVS 8001 used at 2.7 bar pressure with water volumes of 192 L/ha. GF-3308 was applied at BBCH 12 – 14 of the representative plants species included in the bioassay.
After the application of GF-3308 the test plants were cultivated further for 21 days. The test rates of GF-3308 ranged between 0.25 L/ha and (12.5 g as/ha) and 4.0 L/ha (200 g as/ha). The factor between two consecutive rates was 2. During the test period the glasshouse was kept at a daily average temperature between 18.3 °C and 27.4 °C, a daily mean relative humidity between 47.4% and 72.4% and a day length of ≥ 16 hours.
Assessments for plant injury (phytotoxicity) and plant survival were done 7, 14 and 21 days after application of GF-3308, shoot fresh weight was determined at study termination 21 days after application.

Results

<u>Plant survival</u>
No plant mortality was observed for all tested plant species after application of GF-3308 up to the highest tested rate of 4.0 L/ha (200 g as/ha)

<u>Phytotoxicity</u>
Oat, ryegrass and onion showed no phytotoxic symptoms after application of the test item up to the highest tested rate. Very slight injury was observed for oilseed rape, soybean, carrot, cucumber and tomato with light chlorosis and necrosis. Very slight deformations were observed for oilseed rape, soybean and cucumber. Notable phytotoxic symptoms were observed for sugar beet and sunflower. These species Fenpicoxamid suffering especially from necrosis, deformations and stunting at rates ≥ 2.0 L GF-3308/ha (≥ 100 g Fenpicoxamid /ha)

<u>Biomass (fresh weight)</u>
The plant biomass (shoot fresh weight) was determined 21 DAT. No influence of GF-3308 on plant fresh weight was observed for all tested species except sugar beet and sunflower. Sunflower and sugar beet showed significant fresh weight reduction of around 21 % after application of 4.00 L GF-3308/ha (200.0 g as/ha). For sugar beet fresh biomass reduction was already significant by 6 % after application of 2.00 L GF-3308/ha (100.0 g as/ha) applied at BBCH 12-14 of the representative crops.

Table 3.5-2: NOER and ER50 values (g as/ha) of different test plants to GF-3308

Test plant		EPPO Code	NOER	ER_{50}
Common name	**Scientific name (lat.)**			
Oat	*Avena sativa*	AVESA	≥ 200*	> 200
Ryegrass	*Lolium perenne*	LOLPE	≥ 200	> 200
Onion	*Allium cepa*	ALLCE	≥ 200	> 200
Oilseed rape	*Brassica*	BRSNW	≥ 200	> 200
Soybean	*Glycine max*	GLXMA	≥ 200	> 200
Carrot	*Daucus carota*	DAUCA	≥ 200	> 200
Cucumber	*Cucumis sativus*	CUMSA	≥ 200	> 200
Sugar beet	*Beta vulgaris*	BEAVA	50	> 200
Sunflower	*Helianthus annuus*	HELAN	100	> 200
Tomato	*Lycopersicon esculentum*	LYPES	≥ 200	> 200

* Estimated ≥ 200 g as/ha equals ≥ 4 L/ha of GF-3308 as double rate of the formulated product

The corresponding TER-values for arable crops are presented in
Table 3.5-3 below.

Table 3.5-3: PEC and estimated TER-values (gas/ha) for drift to arable crops in a pre- and post-emergence situation

Distance to adjacent crop (m)	**% drift values for arable crops**	**PEC GF-3308 (g as/ha)***	**TER seedling emergence test**** AC/DOW/16/01 (ER_{50}/PEC)	**TER vegetative vigour test** AC/DOW/16/02 (ER_{50}/PEC)
1	2,77	2,77	> 72,2	> 72,2
3	0,95	0,95	> 210,5	> 210,5
5	0,57	0,57	> 350,8	> 350,8

* based on max single rate of 2,0 L/ha of GF-3308 = 100 g as/ha Fenpicoxamid
** see chapter 3.5.1

Summary and conclusions

In both NTP studies AC/DOW/16/01 (seedlings emergence test, see chapter 3.5.1) and study AC/DOW/16/02 (vegetative vigour test) the ER_{50} values were estimated as ≥200 g/ha Fenpicoxamid which was the highest rate of GF-3308 tested. This rate corresponds to the 2 N rate of the proposed label rate of GF-3308. In both NTP studies GF-3308 demonstrated a high margin of safety to a range of representative crops. Based on that data it is concluded that fungicide GF-3308 applied at the proposed label rate does not pose a risk of damage to crops growing adjacent to a field treated with GF-3308. Even for a short distance of 1 m the estimated TER values are greater than 72. This indicates a very high safety margin to the adjacent crop being in a pre-emergence or post emergence situation.
GF-3308 as fungicide applied at the proposed label rate does not pose a risk of damage to crops growing adjacent to a field treated with GF-3308 and therefore no higher tier (field trials) studies are required. Label restrictions or risk phrases with regard to damage to adjacent crops are not required.

Comments of zRMS on:

Impact on adjacent crops (3.5.2)
Results from seedling emergence study (presented in chapter 3.5.1 and commented by zRMS) and a a vegetative vigour study have been presented by the applicant to assess impact on adjacent crops. Vegetative vigour test was conducted in glasshouse in Lentzke, Germany in 2016. Ten representative plant species: oats, ryegrass, onion, oilseed rape, soybean, carrot, cucumber, sugar beet, sunflower and tomato at growth stage of BBCH 12-14 were treated with GF-3308 at dose rate of 0,25; 0,5; 1,0; 2,0 and 4,0 L/ha and then cultivated for 21 days. Results from this study showed that GF-3308 at tested dose rates including double recommended dose rate of 4,0 L/ha (2N), applied post-emergence had no negative influence on plant survival of 10 representative plant species. No phytotoxic symptoms were observed on oat, ryegrass and onion. Phytotoxicity was observed on other crops manifested by: very slight injury on oilseed rape, soybean, carrot, cucumber and tomato with light chlorosis and necrosis. Very slight deformations were observed for oilseed rape, soybean and cucumber. Remarkable phytotoxic symptoms were observed for sugar beet and sunflower. For these crops, symptoms especially necrosis, deformations and stunting were noted at rates ≥ 2,0 L GF-3308/ha (≥ 100 g fenpicoxamid/ha). GF-3308 has not affected on plant fresh weight in all tested species except sugar beet and sunflower. Reduction of around 21% was noted for sunflower and sugar beet after application of GF-3308 at dose rate of 4,0 L/ha (200 g fenpicoxamid/ha) and a significant reduction of around 6% was noted for sugar beet after application of Gf-3308 at dose rate of 2,0 L/ha (100 g fenpicoxamid/ha). In both pre-emergence and post-emergence study the ER_{50} values were estimated as ≥200 g/ha fenpicoxamid – double recommended dose rate of GF-3308 (2N). Estimated TER value for drift to arable crops in pre and post-emergence situation for a short distance of 1 m was at least >72,2 indicating high safety margin to the adjacent crops. Based on the trial results, it can be concluded that no serious risk to adjacent crops is to be expected after application of GF-3308 at recommended dose rate of 2,0 L/ha. Being in be in line with the rules of good agricultural practice it would be beneficial to include, in the product label, the following remark: "*When using GF-3308 do not allow spray drift to the neighbouring crop plantations*", in order to avoid the risk of adverse effects on adjacent crops.

3.5.2.2 Tank cleaning procedure for GF-3308

Introduction

As insufficient tank cleaning can cause adverse effects on non-target plants such as rotational crops or crops that are sprayed using the same tank that could contain residues of a phytotoxic product that has been applied previously to a different crop. GF-3308, at practical use rates, has no herbicidal properties that would cause phytotoxic effects to succeeding (see chapter 3.5.1) or to adjacent crops (see chapter 3.5.2.1). To estimate the risk of damage to non-target plants the following calculation example is made: Assuming a wheat field is sprayed with GF-3308 at the proposed label rate of 2,0 L/ha in 200 L/ha water volume using a 1000 litre spray tank. The spray tank would contain 10 litres of GF-3308. Further assuming that after an application of GF-3308 a quantity of 10% of the spray solution remains in the tank. Without washing, i.e. assuming a *worst-case-scenario*, to spray another field with another product, the tank would be topped up to 1000 litres again. The resulting quantity of GF-3308 remaining in the tank would be 1,0 litre diluted in 1000 litres spray solution. Assuming the farmer would spray the contaminated spray mixture using water volumes of 100 L/ha and 200 L/ha, under the described scenario the following quantities of GF-3308 would be applied as 'pollutant':

Assumed water volume used to spray the next field L/ha	Assumed residue of GF-3308 applied L/ha	PEC Fenpicoxamid g as/ha	ER_{50}* Fenpicoxamid g as/ha	TER (ER_{50}/PEC)
100	0,1	5	> 200	> 40
200	0,2	10	> 200	> 20

* see NTP seedling emergence and vegetative vigour studies according to OECD Guideline 208 and 227 presented in chapters 3.5.1 (following crops) and 3.5.2.1 (adjacent crops).

Study LES 101 26

Traces of active substance have the potential to adhere to the internal surface of a sprayer. To demonstrate that residues of the plant protection product do not remain in the application equipment after cleaning, a laboratory study coded LES 10126 was conducted by Amega Sciences in the United Kingdom in 2016. The study was carried out to evaluate whether GF-3308 can be adequately washed off from the inside tank surfaces after being rinsed with water.

Materials and methods

Testing facilities or organisations

The non GLP/GEP study was performed by Amega Sciences Ltd, 17 Lanchester Way, Royal Oak Industrial Estate, Daventry, Northamptonshire. NN11 5PH, which have developed specific methodologies for studying tank sprayer cleaning and analysis of residues. They are certified according to ISO 9001 and ISO 14001 standards.

Formulations applied and rates (field trials)

Test product	Formulation type	Active substance	Concentration of GF-3308 in the 'spray tank' %
GF-3308	EC	50 g/L Fenpicoxamid	1,0*

*1,0% equals GF-3308 at 2,0 L/ha applied using a typical water volume of 200 L/ha

Experimental details

GF-3308 as aqueous preparation containing 1,0% v/v was added to 150 mL bottles that were of similar material to that used for farm-scale application machinery, i.e. high density polyethylene (HDPE). The bottles with the GF-3308 solution were agitated and stored for 16 hours prior to the solution being discarded and rinsed with water. A cleaning regime of using 10% of tank volume of water was applied. Potential residues in the bottles were extracted using Acetyl nitrite solution which was retained for HPLC analysis to quantify the residues of GF-3308 that adhered to the surface of the test bottles.

Results

The data demonstrates that after a single rinse with water GF-3308 can be adequately removed from sprayer surfaces. Table 3.5-4 shows the reduction in contamination from the bottles following a water only washout regime with 10% of spray tank volume. Cleaning GF-3308 with 10% water sprayer volume the cleanout was over 99,9% which is considered an excellent result.

Table 3.5-4: Reduction in contamination from the bottles following a single water only washout regime with 10% of simulated spray tank volume

Test product	Initial amount of Fenpicoxamid in test tank (mg)	Fenpicoxamid retained after washing with 10% tank volume water (mg)	Fenpicoxamid % removed with single rinse
GF-3308	75	0,0277	99,96

Summary and conclusions

The study results clearly demonstrate that there is generally low adhesion of GF-3308 fungicide formulation to the tank wall. The amount of residues identified in the study will not cause any crop injury or other adverse effects to crops treated subsequently using the same sprayer. The following tank-cleaning measures are recommended for GF-3308:

'*Thoroughly rinse inside of tank with clean water using at least 1/10th of spray tank capacity. Flush pump, filters and boom after removing in-line strainers, nozzle tips and screens. Drain the remainder of the rinsate from the tank and dispose washings safely. It is recommended to spray washings onto the previously treated field. Repeat the rinse, flush and drain*.'

Reference Report: Topham, D, 2016, Dow AgroSciences Clean Out Report for Fungicides: GF-2925, GF-3307, GF-3308, GF-3309, GF-3312; LES 101 26, AmegA Sciences.

Comments of zRMS on:

Tank cleaning procedure for GF-3308 (3.5.2.2)
Results from presented trial demonstrate that there is low adhesion of GF-3308 fungicide to the tank wall, and single rinse with water (with 10% water sprayer volume) is enough to remove GF-3308 from sprayer surfaces. The amount of residues identified in the study is very slight and it is unlikely to cause any crop injury or other adverse effects to crops treated subsequently using the same sprayer. The proposed tank cleniang procedure: '*Thoroughly rinse inside of tank with clean water using at least 1/10th of spray tank capacity. Flush pump, filters and boom after removing in-line strainers, nozzle tips and screens. Drain the remainder of the rinsate from the tank and dispose washings safely. It is recommended to spray washings onto the previously treated field. Repeat the rinse, flush and drain*.' is acceptable.

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

No observations on adverse effects to beneficials or other non-target organisms have been reported in the efficacy and selectivity trials presented in this document. 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 have not been observed in a part of efficacy and selectivity 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

3.6.1 Rain fastness of GF-3308

Introduction

Application of agricultural pesticides often takes places under marginal conditions. One problem which may impact performance is rainfall. Loss of fungicide from plant surfaces due to exposure to dew or rain can impact fungicide performance. Rain fastness of foliar applied fungicides is influenced by a range of factors including the physiochemical properties of the active ingredient influencing uptake into plant tissue, cuticular waxes and fungicide formulation being used. GF-3308 was developed as a fungicide to control SEPTSP and PUCCSP in cereal crops. The objective of the experiment was to determine the rain fast intervals of GF-3308 in comparison to Aviator Xpro which is considered in the market as a rain fast cereal fungicide as well as compared to Bravo 500 which is a surface acting contact fungicide.

Materials and methods

Testing facilities involved

The rain fastness study (non GEP/non GLP) was carried out in the laboratories and glasshouses of Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN., 46268, USA

Formulations applied and rates

Test product	Formulation type	Active substance	Rates product L/ha	Rates g as/ha
GF-3308	EC	Fenpicoxamid	2,0/1,0	100/50
Bravo 500	SC	Chlorothalonil	1,5/0,75	750/375
Aviator Xpro 225	EC	Prothioconazole + bixafen (150 g/L + 75 g/L)	1,25/0,625	281,3/140,6

Experimental details
Wheat seedlings cv. Yuma (TRZAW) were used to evaluate the rain fastness of GF-3308 for the control of PUCCRT and SEPTTR.
The wheat seeds were planted in small plastic pots (6,5 cm x 6,5 cm) containing artificial potting soil and then placed in a greenhouse. Seedlings were thinned to 10 to 12 per pot and watered as needed to sustain plant growth and kept at 21 to 25 °C and sub-irrigated with a 200 ppm solution of liquid fertilizer (5N-5P-15K-4 Ca and 2 Mg) three times per week. The experiments used a randomized complete block design with 4 replicates for each treatment. Treatments consisted of factorial arrangement of the treatments and two rates placed in four blocks.

Fungicide application
All materials were applied with the use of a DeVries research sprayer. Each fungicide was sprayed at the label rate or proposed label rate (1X) and 1/2X rate using a water volume of 150 litres/ha. Before spraying, activated charcoal was placed on the surface of the soil to prevent compound which was washed off during the application of the rain from being translocated from the roots back up into the plants. A flat fan nozzle was used (8003), and the speed of the applicator was 3,9 km/h with a pressure of 220 kPa.

Rain simulation
The rain was applied with the same sprayer used for the application of the fungicides applying a total of 10 mm of rain within a period of 25 minutes with the use of an 8002 nozzle. The speed of the rain applicator was 2,9 km/h and the pressure used was 220 kPa. Each compound was subdivided into four groups. Each group received rain at a different interval after application. The timings were 1) no rain, 2) 5 minutes 3) 60 minutes 4) 120 minutes after application of the fungicide.

Artificial inoculation
Plants were dried for 24 hours after the rain application and the pathogens applied through artificial inoculation by spraying adjusted spore suspensions to represent a one day protection situation.

Assessments and statistical analysis
To accommodate different latent periods PUCCRT was evaluated 8 days after inoculation and seedlings inoculated with SEPTTR were evaluated for disease 21 days after inoculation. Percent disease control was calculated by comparing the amount of disease on the treated plants to the untreated diseased plants which were considered to have zero control, [Percent control=(1-disease in treated plants/disease in untreated plants)*100]. A Tukey's means comparison using an alpha level of 0,05 was used to assess treatment differences.

Results

The results are summarized in Table 3.6-1 and Table 3.6-2. GF-3308 for the control of SEPTTR and PUCCRT was rain fast already 5 minutes after application at 1,0 L/ha or 2,0 L/ha. The reference product Bravo 500 overall showed a lower level of efficacy against SEPTTR or PUCCRT and was significantly less rain fast than GF-3308. The reference Aviator Xpro at 1N and 0,5N dose rate maintained high levels of control against SEPTTR and PUCCRT after rainfall and with that the efficacy of GF-3308 at 1 N and 0.5 N rates was comparable to Aviator Xpro.

Table 3.6-1: Rain fastness of GF-3308 in a glasshouse bioassay when applied as protectant for the control of SEPTTR

Application - rain interval**	% control of SEPTTR					
	GF-3308 1,0 L/ha	GF-3308 2,0 L/ha	Bravo 500 0,75 L/ha	Bravo 500 1,5 L/ha	Aviator Xpro 235 0,625 L/ha	Aviator Xpro 235 1,25 L/ha
No rain	99 ab*	100 a	24 a	59 a	100 a	98 a
5 minutes	99 ab	97 b	0 a	17 a	97 b	98 a
60 minutes	98 b	99 a	9 a	20 a	98 b	99 a
120 minutes	100 a	100 a	17 a	24 a	97 b	96 a
Prob, >F	0,006	0,001	0,3	0,23	0,0001	0,4

* Tukey HSD test, p=0.05, means in the same column followed by the same letter are not significantly different
** Rainfall amount, 10 mm of simulated rainfall within a period of 25 minutes.

Table 3.6-2: Rain fastness of GF-3308 in a glasshouse bioassay when applied as protectant for the control of PUCCRT

Application - rain interval**	% control of PUCCRT					
	GF-3308 1,0 L/ha	GF-3308 2,0 L/ha	Bravo 500 0,75 L/ha	Bravo 500 1,5 L/ha	Aviator Xpro 235 0,625 L/ha	Aviator Xpro 235 1,25 L/ha
No rain	100 a*	100 a	45 a	85 a	100 a	99 a
5 minutes	100 a	100 a	57 a	88 a	99 a	100 a
60 minutes	100 a	100 a	10 b	29 b	99 a	100 a
120 minutes	100 a	100 a	10 b	24 b	100 a	100 a
Prob, >F	n/a	n/a	0,0027	0,0001	0,5	n/a

* Tukey HSD test, p=0.05, means in the same column followed by the same letter are not significantly different
** Rainfall amount: 10 mm of simulated rainfall within a period of 25 minutes.

Summary and Conclusions

Exposed to simulated rainfall of 10 mm rain within 25 minutes for the control of SEPTTR and PUCCRT on wheat GF-3308 was rain fast when applied immediately (5 minutes) or 2 hours after application even when applied at the 50% rate of the proposed label rate. The following statement for rain fastness is proposed for the label:
'*Once the spray cover has dried GF-3308 is rain fast'*

Comments of zRMS on:

Rain fastness of GF-3308 (3.6.1)
Based on the submitted trial results it can be concluded that GF-3308 applied at the maximum dose rate of 2,0 L/ha is rain fast after 5 minutes as well as after 60 and 120 minutes.

3.6.2 Efficacy of GF-3308 applied in tank-mix with partner fungicides

Introduction

In order to reduce the risk of potential resistance development DAS will recommend that GF-3308 is only applied in mixture with an appropriate partner fungicide of a different MOA group that is active against SEPTTR. In this section data from 10 trials are presented that demonstrate the benefit of mixing GF-3308 with commercially available partner fungicides to control SEPTTR, PUCCRT and PUCCST. As frequently practiced in commercial spray programmes in cereal crops, GF-3308 as well as the mixing partner fungicides were tested at reduced label rates. The trials were performed by Dow AgroSciences or contractor companies all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in France (4), Germany (2) and the United Kingdom (4).

Materials and Methods

Testing facilities or organisations

The trials were carried out by the testing facility listed in the following Table.

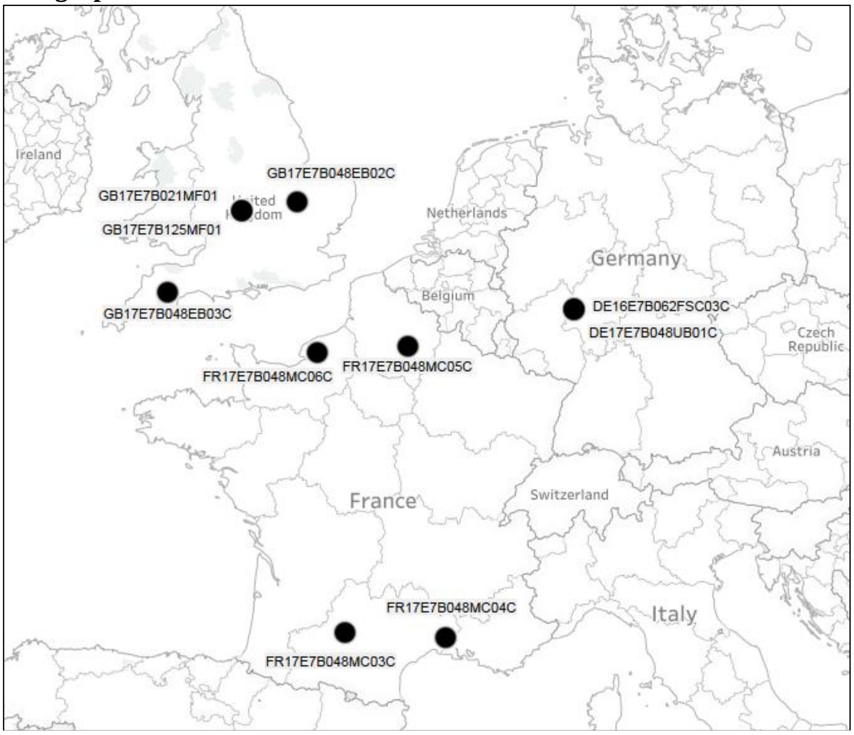
Table 3.6-3: Testing facilities involved by EPPO Zone

Admin. Zone	EPPO Zone	Country	Year	Trial number	Testing organisation	EPPO Guideline	Trial status
Central	Maritime	GERMANY	2016	DE16E7B062FSC03C	AGRARTEST, DE	PP 1/26	GEP
Central	Maritime	GERMANY	2017	DE17E7B048UB01C	AGRARTEST, DE	PP 1/26	GEP
Central	Maritime	UK	2017	GB17E7B048EB02C	FIELD ARM LIMITED	PP 1/26	GEP
Central	Maritime	UK	2017	GB17E7B048EB03C	OXFORD AG TRIALS, UK	PP 1/26	GEP
Central	Maritime	UK	2017	GB17E7B125MF01	DOW AGROSCIENCES LTD, UK	PP 1/26	GEP
Central	Maritime	UK	2017	GB17E7B021MF01	DOW AGROSCIENCES LTD, UK	PP 1/26	GEP
South	Maritime	FRANCE	2017	FR17E7B048MC05C	STAPHYT. FR	PP 1/26	GEP
South	Maritime	FRANCE	2017	FR17E7B048MC06C	PHYLIAE, FR	PP 1/26	GEP
South	Mediterranean	FRANCE	2017	FR17E7B048MC03C	AGROLIS CONSULTING	PP 1/26	GEP
South	Mediterranean	FRANCE	2017	FR17E7B048MC04C	SYNTECH RESEARCH FR S.A.S. FR	PP 1/26	GEP

Sites

The following map provides an overview of the geographical distribution of the tank-mix trials. Trials conducted on close sites or on the same sites but different years might appear as a single dot on the map. Apart from 2 PUCCRT trials in the Mediterranean Zone of France the trials were conducted in the Maritime EPPO Zone.

Figure 3.6-1: Geographical distribution of tank-mix trials



<u>Experimental details</u>

The trials were of a randomized complete block design with 4 replicates. The treatments were applied using precision small plot sprayers equipped with conventional or low drift flat fan nozzles delivering water volumes between 170 and 200 L/ha. All data presented are from single applications only. For further application details of individual trials see the following Table 3.6-4.

<u>Formulations used in trials as tank-mix partner or reference product</u>

Test product	**Formulation type**	**Active substance**	**Formulation content g/L**
GF-3308	EC	Fenpicoxamid (XDE-777)	50
Adexar	EC	Fluxapyroxad + epoxiconazole	62,5 + 62,5
Ascra Xpro	EC	Bixafen + fluopyram + prothioconazole,	65+65+130
Aviator 235 Xpro	EC	Bixafen + prothioconazole,	75 + 160
Bravo 500	SC	Chlorothalonil	500
Credo	SC	Chlorothalonil + picoxystrobin	500+100
Imtrex	EC	Fluxapyroxad	62,5
Proline 250	EC	Prothioconazole	250
Vertisan	EC	Penthiopyrad	200

Results

Across 10 trials GF-3308 at 1,5-1,6 L/ha tank-mixed with the different partner fungicides provided reliable control of wheat foliar diseases SEPTTR, PUCCRT and PUCCST. As demonstrated in Tables ~~3.6-5 to 3.6-7~~ 3.6-4 to 3.6-6 below the addition of the mixing partner products resulted in clearly improved levels of disease control compared to GF-3308 applied alone. No phytotoxic effects or other adverse or antagonistic effects were apparent for the duration of these trials.

Table 3.6-4: Efficacy of GF-3308 in tank mix with Vertisan or Credo applied for the control of SEPTTR, PUCCRT and PUCCST of winter and durum wheat. Data from 7 trials conducted in France, Germany and the United Kingdom in 2017.

~~Trial number~~	~~Target~~	~~DAA~~	~~Plant part assess~~	~~Untr, %infect~~	% disease control			
					GF-3308	GF-3308 +Vertisan	GF-3308 + Credo	Ascra Xpro
					1,5 L/ha	1,5+1,5 L/ha	1,5+1,0 L/ha	1,5 L/ha
Mean SEPTTR control (2 trials)					79,5	90,2	84,6	93,3
Mean PUCCRT control (2 trials)					~~72,5~~ 72,4	96,9	~~91,7~~ 91,5	99,3
Mean PUCCST control (3 trials)					~~86,6~~ 82,8	~~90,9~~ 88,9	~~87,3~~ 84,3	~~86,8~~ 90,8

Table 3.6-5: Efficacy of GF-3308 in tank-mix with Bravo 500 for the control of SEPTTR on winter wheat. 2 trials from the United Kingdom conducted in 2017.

	% disease control			
	GF-3308	GF-3308 + Bravo 500	Ascra Xpro	Aviator 235 Xpro
	1,5 L/ha	1,5+1,5 L/ha	1,2 L/ha	1,0 L/ha
Mean SEPTTR control (2 trials)	79,5	89,5	85,2*	74,5*

*Result from 1 trial

Table 3.6-6: Efficacy of GF-3308 in tank-mix with Imtrex or Proline 250 applied for the control of SEPTTR in winter wheat. Trial from Germany conducted 2016.

	% disease control			
	GF-3308	GF-3308 +Imtrex	GF-3308 + Proline 250	Adexar
	1,6 L/ha	1,6+1,2 L/ha	1,6+0,65 L/ha	1,6 L/ha
SEPTTR control (1 trial)	75,7	86,6	84,5	76,6

Conclusions

In order to reduce the risk of potential resistance development DAS will recommend to apply GF-3308 only in mixture with an appropriate partner fungicide of a different MOA group that is active against SEPTTR. Data from the 10 trials presented clearly demonstrate the benefit of mixing GF-3308 with fungicides containing a multisite product (chlorothalonil), DMIs (prothioconazole) or SDHIs (fluxapyroxad, penthiopyrad) to optimize the efficacy of GF-3308 against SEPTTR, PUCCRT and PUCCST.

Comments of zRMS on:

Efficacy of GF-3308 applied in tank-mix with partner fungicides (3.6.2)
As a part of resistance management strategy GF-3308 is recommended to be applied in mixtures with other fungicides containing active substances of different MoA intended for the control of the same target pathogens. Results from presented trials show higher efficacy results for mixtures of GF-3308 (fenpicoxamid, Qil fungicide, FRAC group C4, # 21) with the fungicides: Vertisan (penthiopyrad, SDHI fungicide, FRAC group C2, # 7), Credo (chlorothalonil, FRAC group M05 + picoxystrobin, Qol fungicide, FRAC group C3, # 11) in the control of SEPTTR, PUCCRT and PUCCST; Bravo (chlorothalonil, FRAC group M05), Imtrex (fluxapyroxad, SDHI fungicide, FRAC group C2, # 7) and Proline (prothioconazole, DMI fungicide FRAC group G1, # 3), in the control of SEPTTR, as compared with GF-3308 applied solo at dose rate of 1,5 or 1,6 L/ha. Presented trials provide additional information on benefits of use GF-3308 at dose rate 1,5 L/ha in mixtures with partner fungicides containing penthiopyrad, fluxapyroxad, prothioconazole, chlorothalonil or chlorothalonil + picoxystrobin).

3.6.3 Characterisation of GF-3308 and visualisation of foliar spray deposits

Introduction

It is accepted that the application of GF-3308 will be necessary through drift reducing technology such as 75% (3*) nozzles. In order to evaluate the effect on the coverage of a leaf surface a series of studies were undertaken in 2016 by Silsoe Spray Applications Unit Ltd, UK to quantify the effect of formulation on the characteristics of sprays produced by agricultural nozzles and to provide qualitative information through photographic images on the characteristics of deposits on both real and artificial surfaces.
Two nozzles were used; (i) a conventional flat fan nozzle, FF110 03 (Hypro EU Ltd) at 3,0 bar; (ii) an air-induction nozzle, AIXR 03 (Spraying Systems Ltd) at 3,0 bar. GF-3308 was included as part of a wider screen and was compared to water and a common standard, Aviator Xpro which was used as it is widely accepted that the formulation matrix of Aviator Xpro has desirable characteristics. Elatus Era was included as a standard that must be applied through drift reducing nozzles.

Materials and Methods

<u>Products and formulations</u>

Test product	Formulation type	Active substance	Formulation as content g/L
GF-3308	EC	Fenpicoxamid (XDE-777)	50
Aviator 235 Xpro	EC	Bixafen + prothioconazole.	75 + 160
Elatus Era	EC	benzovindiflupyr + prothioconazole	75 + 150

Results and conclusions

The images of droplets containing GF-3308 show very little differences between the different application types, because (a) all nozzle types produce very large droplets with any size differences being relatively small, and (b) most importantly, the degree of spreading achieved by the droplets was sufficient to reach close to 100% coverage of the leaf surface, potentially overcoming any deficiencies in coverage that could be encountered with large droplet application techniques.
Based on observation from these photographs, it was concluded that the area of the leaf that is covered by spray liquids containing GF-3308 was independent of the nozzle design, level of drift reduction,

forward speed or application volume and is close to 100%.
The two other products tested, Elatus Era and Aviator Xpro 235, do not demonstrate the same level of spreading, and therefore the area of the leaf that is covered by spray liquid containing either of these products is likely to be lower. It was interesting to note that the 'poorer' coverage by Aviator Xpro in the 2017 experiment compared to the 2016 experiment could be attributed to the increased forward speed of 12 km/h in the 2017 test compared to 8 km/h in the 2016 test.

Comments of zRMS on:

Characterisation of GF-3308 and visualisation of foliar spary deposits (3.6.3)
Results from presented trials provide additional information on no impact of nozzle design, level of drift reduction, forward speed or application volume on covering the area of leaf by spray liquids wit GF-3308 (covered area close to 100% each time).

3.6.4 Impact of water volumes and nozzle type on the efficacy of GF-3308

A series of studies were conducted in 2014 and 2015 using mixture formulations of fenpicoxamid (namely GF-3307 and GF-3309). The same formulation matrix used to deliver fenpicoxamid in GF-3308 has been used in the GF-3307 and GF-3309 formulations and so these water volume and nozzle studies are considered representative of the performance of GF-3308 when applied through a simulated growers application.
A field study coded DE14E7B017UB01C was conducted in Germany in 2014 to evaluate the impact of water volume and nozzle type on the efficacy of GF-3307 (50 g as/L DE-777 + 100 g as/L prothioconazole) against SEPTTR and the resulting yield response. For the experiment standard flat fan nozzles (SFF) and low drift nozzles (LDN) were compared using water volumes of 100 l/ha or 200 L/ha with each nozzle type.
GF-3307 was applied at 2 timings at 2,0 L/ha at the proposed label rate. The reference products included were Proline applied at 0,72 L/ha and Bravo 500 applied at 1,5 L/ha at the same timings as GF-3307. Further trial details are presented in Table 3.6-7 below.

Table 3.6-7: Material and methods

Trial details	Trial number	DE14E7B017UB01C
	EPPO Zone	Maritime
	Trial status	GEP
	Testing organisation	Agrartest, DE
	Country	Germany
	Trial location/Zip Code State/Region	65326 Panrod Hessen
Guidelines	Specific guidelines General guidelines	EPPO PP 1/26 EPPO PP 1/135, 1/152, 1/181, 1/225, 1/214, 1/213
Experimental design	Plot design	Split-Plot
	Plot size	2,5 m x 8 m
	Number of replications	4
Crop	Trials per crop	Winter wheat (1)
	Varieties per crop	JB Asano
	Drilling date	19-Oct-13
Application	Application timings, at crop BBCH	Timing A:23-Apr-2014 , BBCH 32-33 Timing B: 16-May-2014, BBCH 39-49 Application interval 23 days
	Spray volume L/ha	100 or 200
	Nozzle	XR11002VP (standard)* or air induction nozzle AI11002VP (low drift)*
	Air temperatute °C	19.2/18.2
	Relative humidity	46/53
Assessment	Assessment types	Efficacy of SEPTTR as % foliar infection (severity), calculation of control according to Abbott, Phytotoxic effects as % injury to crop Yield, t/ha corrected to 86% dry matter, 1000 grain weight
	Assessment dates	% infection at both application timings, 23DAAA, 35 DAAA/12DAAB, 53DAAA/30DAAB Injury 1 and 2 weeks after application and at every efficacy assessment Yield 108 DAAA/85 DAAB

Formulations applied and rates

Test product	**Formulation type**	**Active substance**	**Rate product L/ha**	**Rate g as/ha**
GF-3307	EC	DE-777 + prothioconazole	2,0	300
Proline 275	EC	Prothioconazole	0,72	200
Bravo 500	SC	Chlorothalonil	1,5	750

Results

A field study was conducted in Germany in 2014 to evaluate the efficacy of GF-3307 against SEPTTR when sprayed using standard flat fan nozzles (XR11002VP) or low drift nozzles (AI11002VP) each applied at a spray volume of 100 l/ha or of 200 L/ha. GF-3307 was applied at 2 timings at 2,0 L/ha at BBCH 32/33 and 39/49 of winter wheat to control SEPTTR. The treatments with GF-3307 did not significantly affect the efficacy against SEPTTR and the resulting yield response of the winter wheat crop irrespective of the nozzle type and water volumes used. For the duration of the trial no phytotoxic effects on the winter wheat crop cv. JB Asano were observed in any of the treatments with GF-3307.

Studies conducted in the United Kingdom in 2015

Two further studies were conducted the UK in 2015 to evaluate the impact of water volume and nozzle type on the efficacy of GF-3307 and GF-3309 (50 g as/L fenpicoxamid + 62,5 g as/L pyraclostrobin) against SEPTTR and the resulting yield response.
It is considered that the efficacy against SEPTTR brought by the pyraclostrobin within the formulation of GF-3309 based upon QoI resistance would be minimal so the key activity will be brought by fenpicoxamid and so can be representative of the activity of GF-3308.
For the experiment standard flat fan nozzles (SFF) and low drift nozzles (LDN) were compared using water volumes of 100 l/ha or 200 L/ha with each nozzle type.
GF-3307 and GF-3309 were applied at 2 timings at 2,0 L/ha at the proposed label rate. The reference product included was Proline applied at 0,72 L/ha at the same timings as GF-3307. Further trial details are presented in Table 3.6.8 below.

Table 3.6-8: Materials and Methods

Trial details	Trial number	GB15E7B030MF01	GB15E7B030SD01
	EPPO Zone	Maritime	
	Trial status	GEP	
	Testing organisation	Dow AgroSciences Ltd, UK	
	Country	United Kingdom	
	Trial location/Zip Code State/Region	Wellesbourne, Warwickshire CV35 9EF	South Runcton, Norfolk, PE33 0EX
Guidelines	Specific guidelines General guidelines	EPPO PP 1/26 EPPO PP 1/135, 1/152, 1/181, 1/225, 1/214, 1/213	
Experimental design	Plot design	Split-Plot	
	Plot size	3 m x 12 m	2,5 m x 12 m
	Number of replications	4	
Crop	Trials per crop	Winter wheat (2)	
	Varieties per crop	Consort	Conqueror
	Drilling date	24-Sep-14	16-Oct-14
Application	Application timings, at crop BBCH	Timing A:16-Apr-2015, BBCH 31 Timing B: 15-May-2015, BBCH 39-45	Timing A:3-May-2015, BBCH 32 Timing B: 21-May-2015, BBCH 39
	Spray volume L/ha	100 or 200	
	Nozzle	XR11002VP (standard)* or air induction nozzle AI11002VP (low drift)*	
	Air temperatute °C	17,5/18,9	18/18
	Relative humidity	54,2/61,4	56/68
Assessment	Assessment types	Efficacy of SEPTTR as % foliar infection (severity), calculation of control according to Abbott, Phytotoxic effects as % injury to crop Yield, t/ha corrected to 86% dry matter, 1000 grain weight	

***** The XR11002VP flat fan nozzle was selected as a flat fan nozzle that is commonly mounted on conventional hydraulic spray booms. Operated at 2 bars the output of this nozzle is classified as FINE. The selection of a '02' type nozzle was driven by the possibility to spray 200 and 100 L/ha at a pressure of 2 bars with the experimental spray equipment just changing the speed (7,2 km/ha and 3,6 km/h) and in a velocity range still feasible for spraying randomized plot trials and thus maintaining identical spray patterns. The drift reduced flat fan low drift nozzle AI11002VP was selected because at 2 bar it is accredited by LERAP of a 3 Stars low drift rating (< 25% drift). At 2 bar its output is classified as ULTRA COARSE (BCPT specs in accordance with ASABE Stand. S572.1). For further technical details and parameters see the BAD.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	DE-777 + prothioconazole (50 + 100 g as/L)	2,0	300
GF-3309	EC	DE-777 + ~~prothioconazole~~ pyraclostronin (50 + 62,5 g as/L)	2,0	225
Proline 275	EC	Prothioconazole (275 g as/L)	0,72	~~200~~ 198

Results

Two field studies were conducted in the United Kingdom in 2015 to evaluate the efficacy of GF-3307 and GF-3309 against SEPTTR when sprayed using standard flat fan nozzles (XR11002VP) or low drift nozzles (AI11002VP) each applied at a spray volume of 100 l/ha or of 200 L/ha. GF-3307 was applied at 2 timings at 2,0 L/ha at BBCH 31/32 and 39/45 of winter wheat to control SEPTTR. The treatments with GF-3307 and GF-3309 did not significantly affect the efficacy against SEPTTR and the resulting yield response of the winter wheat crop irrespective of the nozzle type and water volumes used. For the duration of the trial no phytotoxic effects on the winter wheat crops cv. Consort and Conqueror were observed in any of the treatments with GF-3307 or GF-3309.

Conclusions

GF-3307 and GF-3309 provide consistent and comparable levels of control of SEPTTR in wheat when applied at spray volumes between 100 and 200 L/ha using conventional or low drift nozzles. In these efficacy trials no pattern was apparent when water volumes reduced down to 100 L/ha or that use of drift reduced nozzle types would negatively affect the efficacy of GF-3307 or GF-3309. As GF-3307 and GF-3309 have the same formulation system as GF-3308 then we can assume the performance of GF-3308 would also not be impacted by being applied at 100 L/ha water volume or through low drift nozzles. Further evidence for this is supported in section 3.6.3.

Comments of zRMS on:

Impact of water volumes and nozzle type on the efficacy of GF-3308 (3.6.4**)**
Results from three field studies provide additional data on no significant influence of nozzle type (conventional or low drift nozzle) and water volume (100 L/ha or 200 L/ha) on efficacy of GF-3307 and GF-3309 – EC formulations containing fenpicoxamid with prothioconazole (GF-3307) or fenpicoxamid with pyraclostrobin (GF-3309) in the control of SEPTTR. As explained by the applicant, the same formulation matrix was used to deliver fenpicoxamid in GF-3308 used also in the GF-3307 and GF-3309 formulations. It is expected that the performance of GF-3308 would also no be affected by using low drift nozzle or the lowest recommended water volume 100 L/ha.

3.6.5. Efficacy of XDE-777 metabolites to *Septoria tritici* on wheat

Reference:	KCP 10.2.3/4
Report:	Mathieson, T. 2018; Efficacy of XDE-777 metabolites to Septoria tritici on wheat; Dow AgroSciences LLC, Zionsville, Indiana, USA; 30 July 2018; Unpublished
Acceptability:	Yes
Duplication (if vertebrate study)	NA

SUMMARY

XDE-777, a pro-fungicide of the natural picolinamide UK-2A, is a fungicide of Dow AgroSciences. Seven metabolites of XDE-777 identified in soil metabolism, soil photolysis, or aqueous hydrolysis studies were evaluated for their biological activity vs. wheat leaf blotch caused by *Septoria tritici* (SEPTTR), the key driver disease in the European cereal fungicide market. In the current study, XDE-777 was highly potent vs. SEPTTR when used as both protectant and curative treatments. UK-2A, from which XDE-777 was derived, showed high level of protectant activity but significantly weaker curative activity. None of the seven metabolites of XDE-777 showed any meaningful fungicidal activity vs. SEPTTR.

MATERIALS AND METHODS

Chemicals

XDE-777, UK-2A, and the seven metabolites of XDE-777, plus one formulated material were used in the studies Table 1. Their structures and lot information are listed in Figure 1. X696476, X2313581, X12019520, X12335723, X12314005, are soil metabolites (Hastings and Jackson, 2013), X12255349 is a soil photolysis metabolite (Cooke, 2013), and X12393285 is a hydrolysis metabolite (Yoder and Jackson, 2013).

Table 1. Compounds tested for the control of SEPTTR.

Compound	X number	Lot number	Use rate (ppm)
XDE-777	X772777	TSN303160	100, 25, 6.25, 1.56, 0.39 , 0.10
UK-2A	X642188	TSN303567	100, 25, 6.25, 1.56, 0.39 , 0.10
	X696476	TSN307152	100, 25, 6.25, 1.56, 0.39 , 0.10
	X2313581	TSN306004	100, 25, 6.25, 1.56, 0.39 , 0.10
	X12019520	TSN307264	100, 25, 6.25, 1.56, 0.39 , 0.10
	X12255349	TSN306954	100, 25, 6.25, 1.56, 0.39 , 0.10
	X12314005	TSN306252	100, 25, 6.25, 1.56, 0.39 , 0.10
	X12335723	TSN304462	100, 25, 6.25, 1.56, 0.39 , 0.10
	X12393285	TSN304332	100, 25, 6.25, 1.56, 0.39 , 0.10
XDE-777	GF-3308		100, 25, 6.25, 1.56, 0.39 , 0.10

Table 2. Source of metabolites.

Metabolite	Source
X12019520	hydrolysis, surface water mineralization, water/sediment
X12255349	soil photolysis
X12313581	aerobic soil, surface water mineralization, water/sediment
X12314005	hydrolysis, surface water mineralization, water/sediment
X12335723	hydrolysis, water/sediment
X12393285	hydrolysis
X696476	aerobic and anaerobic soil, surface water mineralization, water/sediment

Plant Material

Wheat plants (variety 'Yuma') were grown from seeds in a greenhouse in plastic pots of surface area 27,5 cm2 containing a mixture of 90% artificial soil and 10% field soil. The resulting seedlings (8-12 per pot) were used for testing when the primary or first leaves were fully emerged typically 8 to 9 days after planting.

Compound application and evaluation of disease development.

Two mg of each compound were dissolved in 2 mL acetone, and 0,5 mL of the solution was sequentially mixed with 1,5 mL of acetone to make 4-fold dilutions. The acetone dilutions were mixed with 9 volumes of water containing 110 ppm Triton X-100 to obtain formulated high volume (HV) spray solutions. The solutions were applied to the plants at 15 mL per tray using an automated booth sprayer, which utilized two 6218-1/4 JAUPM spray nozzles operating at 20 psi and set at opposing angles to cover both sides of leaf surfaces. After application, the plants were allowed to air dry prior to further handling.

Wheat plants were inoculated with an aqueous spore suspension of *Septoria tritici* either three days prior to (3-DC) or one day after (1-DP) fungicide treatments. After inoculation the plants were maintained at 100% relative humidity (one day in a dark dew chamber followed by two days in a lighted dew chamber at 20 C) to permit spores to germinate and infect the leaf. The plants were then transferred to a green-house set at 20 C for disease to develop. When disease symptoms were fully expressed on the 1st leaves of the untreated plants, infection levels were assessed on a scale of 0 to 100 percent disease severity. Percent disease control was calculated using the ratio of disease severity on treated plants relative to untreated controls.

RESULTS AND DISCUSSION

Activity of UK-2A, XDE-777 and its seven metabolites vs. SEPTTR

High volume one day protectant (1-DP) and three day curative (3-DC) SEPTTR activity of XDE- 777, UK-2A, and the seven metabolites of XDE-777 were evaluated using compound rates ranging from 100 to 0.1 ppm. The test results indicated: 1) XDE-777 was highly active vs. SEPTTR in both curative and protectant treatments; 2) UK-2A showed very strong protectant SEPTTR activity but curative efficacy was much weaker; 3) none of the seven metabolites showed any meaningful biological activity vs. SEPTTR. One compound X772777 did show an anomaly in the curative test at the second rate, cause unknown. This result did not appear in the repeat test.

CONCLUSION

In these studies, we evaluated the biological activity of XDE-777, UK-2A, the formulated product GF-3308 as well as seven metabolites of XDE-777, vs. SEPTTR, the causal agent of wheat leaf blotch. The compound XDE-777 was highly potent as both protectant and curative treatments vs. SEPTTR the key driver disease. The natural product UK-2A, from which XDE-777 was derived, showed a high level of protectant activity but curative activity was weaker. With the metabolites tested none showed any meaningful fungicidal activity vs. SEPTTR. The formulated product was also highly active in both curative and protectant test.

Comments of zRMS on:
Efficacy of XDE-777 metabolites to *Septoria tritici* on wheat (3.6.5)

Results from the presented trial confirm curative and protectant activity of XDE-777 and formulated product GF-3308 against the target pathogen - *Zymoseptoria tritici*. The natural product UK-2A, from which XDE-777 was derived shows high protectant activity, but weaker curative activity. Seven metabolites of XDE-777: X696476, X2313581, X12019520, X12335723, X12314005, X12255349, X12393285 show no significant activity against *Zymoseptoria tritici*, based on the trial results.

3.6.6. *Septoria tritici* Biological screening report for five mteabolites of XDE-777

Reference:	KCP 10.2.3/5
Report:	Yao, C.; 2014; *Septoria tritici* Biological Screening Report for Five Metabolites of XDE-777; Dow AgroSciences LLC, Zionsville, Indiana, USA; Lab Study No. DAI 1370; 04 November 2014; Unpublished
Acceptability:	Yes
Duplication (if vertebrate study)	NA

SUMMARY

XDE-777, a pro-fungicide of the natural picolinamide UK-2A, is a pre-development fungicide of Dow AgroSciences. Five metabolites of XDE-777 identified in soil metabolism, soil photolysis, or aqueous hydrolysis studies were evaluated for their biological activity vs. wheat leaf blotch caused by *Septoria tritici* (SEPTTR), the key driver disease in the European cereal fungicide market. In the current studies, XDE-777 was highly potent vs. SEPTTR when used as both protectant and curative treatments. UK-2A, from which XDE-777 was derived, showed high level of protectant activity but significantly weaker curative activity. However, none of the five metabolites of XDE-777 showed any meaningful fungicidal activity vs. SEPTTR.

MATERIALS AND METHODS

Chemicals
XDE-777, UK-2A, and the five metabolites of XDE-777 were used in the studies. Their structures and lot information are listed in Figure 1. X763024, X11963422 and X12264475 are soil metabolites (Hastings and Jackson, 2013), X12255349 is a soil photolysis metabolite (Cooke, 2013), and X12393285 is a hydrolysis metabolite (Yoder and Jackson, 2013).

Plant Material
Wheat plants (variety 'Yuma') were grown from seeds in a greenhouse in plastic pots of surface area 27.5 cm2 containing 50% mineral soil and 50% soil-less Metro mix. The resulting seedlings (8-12 per pot) were used for testing when the primary or first leaves were fully emerged, typically 7 to 8 days after planting.

Compound applications and evaluation of disease development
Two mg of each compound were dissolved in 2 mL acetone, and 0.5 mL of the solution was sequentially mixed with 1.5 mL of acetone to make 4-fold dilutions. The acetone dilutions were mixed with 9 volumes of water containing 110 ppm Triton X-100 to obtain formulated high volume (HV) spray solutions. The solutions were applied to the plants at 15 mL per tray using an automated booth sprayer, which

utilized two 6218-1/4 JAUPM spray nozzles operating at 20 psi and set at opposing angles to cover both sides of leaf surfaces. After application, the plants were allowed to air dry prior to further handling.

Wheat plants were inoculated with an aqueous spore suspension of *Septoria tritici* either three days prior to (3-DC) or one day after (1-DP) fungicide treatments. After inoculation the plants were maintained at 100% relative humidity (one day in a dark dew chamber followed by two days in a lighted dew chamber at 20 oC) to permit spores to germinate and infect the leaf. The plants were then transferred to a green-house set at 20 oC for disease to develop. When disease symptoms were fully expressed on the 1st leaves of untreated plants, infection levels were assessed on a scale of 0 to 100 percent disease severity. Percent disease control was calculated using the ratio of disease severity on treated plants relative to untreated controls.

RESULTS AND DISCUSSION

Activity of UK-2A, XDE-777 and its three soil metabolites vs. SEPTTR

High volume one day protectant (1-DP) and three day curative (3-DC) SEPTTR activity of XDE-777, UK-2A, and the three soil metabolites of XDE-777 were evaluated using compound rates ranging from 100 to 0.1 ppm (Table 1). The test results indicated that: 1) XDE-777 was highly active vs. SEPTTR in both curative and protectant treatments; 2) UK-2A showed very strong protectant SEPTTR activity but curative efficacy was much weaker; 3) none of the three metabolites showed any meaningful biological activity vs. SEPTTR (activity levels of metabolites were < 1/1000 the activity levels observed for XDE-777).

Activity of UK-2A, and XDE-777 soil photolysis and aqueous hydrolysis metabolites vs. SEPTTR

UK-2A, the soil photolytic product X12255349 and the hydrolysis metabolite X12393285 of XDE-777 were tested vs. SEPTTR in both protectant and curative treatments (Table 2). The test rates ranged from 100 to 6.25 ppm. The test results indicated that the two metabolites of XDE-777 were inactive against SEPTTR as curative and protectant treatments, while UK-2A was highly active as a protectant treatment.

CONCLUSIONS

In this study, we evaluated the biological activity of XDE-777 and UK-2A, as well as that of five metabolites of XDE-777, vs. SEPTTR, the causal agent of wheat leaf blotch. XDE-777 was highly potent as both protectant and curative treatments vs. this key driver disease. UK-2A, the natural product from which XDE-777 was derived, showed a high level of protectant activity but curative activity was weaker. However, none of the five metabolites showed any meaningful fungicidal activity vs. SEPTTR.

Comments of zRMS on:
Septoria tritici. Biological screening report for five metabolites of XDE-777 (3.6.6)

Results from the presented trial confirm curative and protectant activity of XDE-777 against the target pathogen - *Zymoseptoria tritici*. The natural product UK-2A, from which XDE-777 was derived shows high protectant activity, but weaker curative activity. Five metabolites of XDE-777: X763024, X11963422, X12264475, X12255349, X12393285 show no significant activity against *Zymoseptoria tritici*, based on the trial results.

3.7 List of test facilities including the corresponding certificates

The following facilities were involved in the trials and studies presented in this dossier:

Table 3.7-1: List of test facilities

TEST FACILITY	ADDRESS	GEP Certificate in trial reports (Yes or No)
AARHUS UNIVERSITY FLAKKEBJERG, DK	RESEARCH CENTRE FLAKKEBJERG, 4200 SLAGELSE, DENMARK	Yes
AGRARTEST, DE	HANS-WERNER SCHERF, PALMBACH-STR.37, 65326 AARBERGEN-PANROD, GERMANY	Yes
AGRO-CHECK	DORFSTRASSE 15, 16833 LENTZKE, GERMANY	Yes
SC AGROPROSPECT SRL	COMUNA HOGHIZ, SATUL FANTANA, NR, 1, JUDETUL BRASCOV, COD 507099, ROMANIA	Yes
AGROFIL SZAKTANACSADO MERNOKI IRODA KFT.	PETOFI SANDOR U. 7. PUSKI H-9235 HUNGARY	Yes
AGROLIS CONSULTING	Z.A. LA GRANDE MARINE-185, AVENUE ANDRÉ AMPÈRE-84800 L'ISLE-SUR-LA-SORGUE-FRANCE	Yes
AMEGA SCIENCES LIMITED	17 LANCHESTER WAY, ROYAL OAK INDUSTRIAL ESTATE, DAVENTRY, NORTHAMPTONSHIRE. NN11 5PH, ENGLAND	No (non GEP)
ANADIAG BULGARIA LTD	244 4000 PLOVDIV, BULGARIA	Yes
ARMSTRONG FISHER LTD, UK	8 BARN OWL CLOSE, LANGTOFT PETERBOROUGH, LINCOLNSHIRE PE6 9RG, UK	Yes
ATC - AGRO TRIAL CENTER GMBH, AT	VERSUCHSSTATION GERHAUS, 2471 ROHRAU, AUSTRIA	Yes
BIOCHEM AGRAR. DE	KUPFERSTR. 6, 04827 MACHERN OT GERICHSHAIN, GERMANY	Yes
BIOTEK AGRICULTURE LTD.	UNIT 5 WINTERBECK INDUSTRIAL ESTATE,ORSTON LANE, BOTTESFORD, NG13 0AU, UK	Yes
BIOTEK AGRICULTURE. FR	ROUTE DE VIELAINES - 10120 SAINT-POUANGE, FRANCE	Yes
BIOTEK AGRICULTURE HUNGARY KFT	H12013 POMAZ, MARTIROK UTJA 1-3, HUNGARY	Yes
DITANA SPOL. S.R.O.	CSA 92, 78353 VELKA BYSTRICE, CZECH REPUBLIC	Yes
DOW AGROSCIENCES DEVELOPMENT STATION. HU	SZOLNOK STATION, VIZPART KORUT 32, H-5000 SZOLNOK, HUNGARY	Yes
DOW AGROSCIENCES GMBH. DE	TRUDERINGER STRASSE 15, 81677 MUNICH, GERMANY	Yes
DOW AGROSCIENCES LTD, UK	WARWICK ENTERPRISE PARK, WELLESBOURNE, WARWICK, CV35 9EF, UK	Yes
DOW AGROSCIENCES LTD., KINGS LYNN. UK	CROSSBANK ROAD, KING'S LYNN, NORFOLK PE30 2JD, UNITED KINGDOM	Yes
DOW AGROSCIENCES SAS. FR	MARCO POLO B, 790 AV. DU DR. DONAT, 06250 MOUGINS, FRANCE	Yes
DOW AGROSCIENCES LLC	9330 ZIONSVILLE ROAD, INDIANAPOLIS, IN. 46268, USA	No (non GEP)
EUROFINS AGROSCIENCE SERVICES LTD, UK	SLADE LANE, WILSON, MELBOURNE, DERBYSHIRE, DE73 8AG. UNITED KINGDOM	Yes
EUROFINS AGROSCIENCE SERVICES GMBH, DE	CARL-GOERDELER-WEG 5, 21684 STADE, GERMANY	Yes

SC EUROFINS AGRICULTURAL SERVICES SRL	STR. MUNTELE MIC, NR. 20, GIARMAYA, JUD TIMIS, ROMANIA	Yes
FIELD ARM LIMITED	7 WYCKE LANE, TOLLESBURY, MALDON, ESSEX, CM9 8ST, UK	Yes
IOR SOSNICOWICE, PL	GLIWICKA STR. 29, 44-153 SOSNICOWICE, POLAND	Yes
LATVIAN PLANT PROTECTION RESEARCH CENTRE, (LAAPC)	STRUCKTORU IELA 14A, RIGA LV1039, LATVIA	Yes
NARDI FUNDULEA, RO	N. TITULESCU STREET NO 1, FUNDULEA, CALARASI, 915200 ROMANIA	Yes
OSEVA PRO S.R.O. ODSTEPNY ZAVOD VYZKUMNY USTAV TRAVINARSKY ZUBRI. CZ	ZUBRI 698 756 54, CZECH REPUBLIC	Yes
OXFORD AG TRIALS, UK	WEST FARM BARNS, STRATTON AUDLEY, BICESTER, OXON, OX27 9AS. UNITED KINGDOM	Yes
PHYLIAE, FR	3 IMPASSE DE LA VOIE ROMAINE, F76190 VEAUVILLE LES BAONS	Yes
SILSOE SPRAY APPLICATIONS UNIT LIMITED	BUILDING 42, WREST PARK, SILSOE, BEDFORD, MK45 4HP, UK	No (non GEP)
STAPHYT SP. Z.O.O.	UL. ZIEBICKA 2, 60-164 POZNAN, POLAND	Yes
STAPHYT, FR	23, ROUTE DE MOEUVRES, 62860 INCHY EN ARTOIS, FRANCE	Yes
SUFFOLK AND CAMBRIDGE CROP STATION LTD	LOWER LEY BARN, WOODITTON ROAD, SETCHWORTH, NEWMARKET, CB8 9TX, UK	Yes
SYNTECH RESEARCH FR S.A.S. FR	LE BOIS DE LOYSE 71570 LA CHAPELLE DE GUINCHAY, FRANCE	Yes
SYNTECH RESEARCH HUNGARY KFT.	9761, TAPLANSZENTKERESZT, RAKOCZI U. 4. HUNGARY	Yes
TRIAL-TEC GMBH	KAMPENREDDER5, 24363 HABY, GERMANY	Yes
UNIWERSYTET PRZYRODNICZY POZNAN, PL (Poznan University of Life Sciences)	MAZOWIECKA STR, 45/46, 60-623 POZNAN, POLAND	Yes
ZEMEDELSKA ZKUSEBNI STANICE KUJAVY, S.R.O	KUJAVY 48, 742 44 KUJAVY, CZECH REPUBLIC	Yes
ZEMEDELSKY VYZKUMNY USTAV KROMERIZ, S.R.O. CZ	HAVLICKOVA 2787 767 01 KROMERIZ, CZECH REPUBLIC	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 6.1/01 6.2/108	Cana, L.	2015	Comparative efficacy of XDE-777 formulations against SEPTTR in wheat. EU 2015. NARDI FUNDULEA RO15E7B025AP01C GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.1/02 6.2/109	Charlot, Y.	2015	Comparative efficacy of XDE-777 formulations against SEPTTR in wheat. EU 2015. FR15E7B025YC02 DOW AGROSCIENCES S.A.S. GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.1/03	Crestani, D.	2013	Evaluation of XDE-777 (GF-2925 & GF-3135) applied for the control of SEPTTR in wheat in Southern Europe. 2013 IT13E7B012DC01 DOW AGROSCIENCES GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.1/04	Fraser, J.	2015	What is the length of residual protection GF-3307 and GF-3309 provide when applied at a typical T2 timing against SEPTTR, UK 2015? GB15E7B052JF01 DOW AGROSCIENCES LTD, UK GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.1/05 6.2/110	Levasseur, T.	2015	Comparative efficacy of XDE-777 formulations against SEPTTR in wheat. EU PHYLIAE, FR GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.1/06	Mathieson, T, Kemmit, G	2014	Comparative mobility of three XDE-777 formulations and select commercial standards as measured by glasshouse bioassay with *Puccinia recondita* on wheat. DOW AGROSCIENCES internal report # 2024367 Non GEP/non GLP Unpublished	N	DAS/Corteva AgriScience

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 6.1/07	Mathieson, T, Leader, A	2018	How does the efficacy of Inatreq formulation GF-3307 (a combination) and GF-3308 (solo) compare to market references when tested against *Septoria tritici* (SEPTTR) and *Puccinia recondita* (PUCCRT) in greenhouse conditions? DOW AGROSCIENCES internal report # 2051736, June 2018 Non GEP/non GLP Unpublished	N	DAS/Corteva AgriScience
KCP 6.1/08	Myung K, Madary MW, Kemmit G, Annangudi SP, Yao C	2015	Effects of different formulations on retention, surface coverage, and uptake of XDE-777 in wheat plants. DOW AGROSCIENCES internal report # 2026067, February 2015. Non GEP/non GLP Unpublished	N	DAS/Corteva AgriScience
KCP 6.1/09 6.2/111	Nistrup Jørgensen, L.	2015	XDE-777 straight and in combination with prothioconazole or pyraclostrobin for the control Fusarium head blight in wheat. EU 2015. DK15E7B018MN01C AARHUS UNIVERSITY FLAKKEBJERG, DK GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.1/10 6.2/112	Olivier, F.	2015	Comparative efficacy of XDE-777 formulations against SEPTTR in wheat. EU 2015. FR15E7B025FO01 DOW AGROSCIENCES S.A.S. GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.1/11	Owen, W.J. *et al.*	2011	XR-777 Discovery Advancement Report DOW AGROSCIENCES internal report # 2009830 Non GEP/non GLP Unpublished	N	DAS/Corteva AgriScience
KCP 6.1/12 6.2/113	Packwood, J.	2015	Comparative efficacy of XDE-777 formulations against SEPTTR in wheat. EU 2015. GB15E7B025EB01C EUROFINS AGROSCIENCE SERVICES LTD, UK GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.1/13	Parker C.L.; Owen, J.	2013	Herbicide Activity of XDE-777 DOW AGROSCIENCES internal report # DAI 1177 Non GEP/non GLP Unpublished	N	DAS/Corteva AgriScience

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 6.1/14 6.2/114	Varret, F.	2015	Comparative efficacy of XDE-777 formulations against SEPTTR in wheat. EU 2015. FR15E7B025MC03C STAPHYT. FR GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.1/15	Wessels, F., Owen, J.	2013	Insecticidal Activity of XDE-777 DOW AGROSCIENCES internal report # DAI 1101 Non GEP/non GLP Unpublished	N	DAS/Corteva AgriScience
KCP 6.1/16 6.2/115 ~~and KCP 6.2/01~~	Bezdickova, A.	2016	The efficacy GF-3308 straight and mixture with partner fungicides for the control of foliar diseases of wheat. EU 2016 CZ16E7B038PV01C DITANA SPOL. S.R.O. GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.1/17 6.2/116 ~~and KCP 6.2/02~~	Kasztner, G.	2015	Comparative efficacy of XDE-777 formulations against SEPTTR in wheat. EU 2015. HU15E7B025AB01C AGROFIL Szaktanacsado Mernoki Iroda Kft. GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.1/18 6.2/117 ~~and KCP 6.2/03~~	Pawlak, A.	2016	What is the efficacy of Inatreq formulations under North East Europe conditions PL16E7B031AS02C STAPHYT, PL GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.1/19 6.2/118 ~~and KCP 6.2/04~~	Stephan, A.	2015	Comparative efficacy of XDE-777 formulations against SEPTTR in wheat. EU 2015. DE15E7B025AS01 DOW AGROSCIENCES GMBH. DE GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/01	Babrik, Z.	2015	Efficacy and dose response of different XDE-777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ, . 2014. HU14E7B014AB01C AGROFIL, HU	N	DAS/Corteva AgriScience

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
			GEP Unpublished		
KCP 6.2/02	Babrik, Z.	2015	What is the efficacy of DE-777 formulations against SEPTTR in wheat in South East Europe EPPO HU15E7B012AB01C DOW AGROSCIENCES Hungary GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/03	Babrik, Z.	2015	What is the efficacy of DE-777 formulations against SEPTTR in wheat in South East Europe EPPO HU15E7B012AB02C DOW AGROSCIENCES Hungary GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/04	Babrik, Z.	2015	Efficacy and dose response of different DE-777 + Prothioconazole/pyraclostrobin EC formulations for control of SEPTTR in wheat. EU CZ SE EPPO, 2015. HU15E7B040AB02C DOW AGROSCIENCES Hungary GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/05	Banachowska, J	2014	Efficacy of XDE-777 + prothioconazole and XDE-777 + pyraclostrobin formulations for control of PUCCRT in wheat: EU CZ, 2014. PL14E7B010AS02C IOR SOSNICOWICE, PL GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/06	Banachowska, J.	2016	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin and DE-777 straight for the control of foliar diseases in rye. Europe 2016. PL16E7B019AS01C IOR SOSNICOWICE, PL GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/07	Banachowska, J.	2016	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin and DE-777 straight for the control of foliar diseases in rye. Europe 2016. PL16E7B019AS02C IOR SOSNICOWICE, PL	N	DAS/Corteva AgriScience

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
			GEP Unpublished		
KCP 6.2/08	Beyreiss, S	2017	Evaluation of the minimum effective dose of XR-659 for the control of *Septoria tritici* in wheat and triticale and RHYNSE in rye. EU 2017. DE17G1C012UB03C EUROFINS AGROSCIENCE SERVICES GMBH, DE GEP GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/09	Beyreiss, S	2018	Evaluation of the minimum effective dose of XR-659 for the control of *Septoria tritici* in wheat and triticale and RHYNSE in rye, EU 2017 DE17G1C012UB02C EUROFINS AGROSCIENCE SERVICES GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/10	Biro, A.	2014	Efficacy of XDE-777 + prothioconazole and XDE-777 + pyraclostrobin formulations for control of PUCCRT in wheat: EU CZ, 2014 HU14E7B010AB01 DOW AGROSCIENCES Hungary GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/11	Biro, A.	2015	What is the efficacy of XDE-777 formulations against SEPTTR in wheat in South East Europe EPPO when applied as a single application. HU15E7B011AB01C DOW AGROSCIENCES Hungary GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/12	Biro, A.	2015	What is the efficacy of XDE-777 formulations against SEPTTR in wheat in South East Europe EPPO when applied as a single application. HU15E7B011AB02C DOW AGROSCIENCES Hungary GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/13	Biro, A.	2015	What is the efficacy of DE-777 formulations against SEPTTR in wheat in South East Europe EPPO HU15E7B012AB02 DOW AGROSCIENCES Hungary	N	DAS/Corteva AgriScience

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
			GEP Unpublished		
KCP 6.2/14	Biro, A.	2016	Efficacy of Inatreq formulations against rusts and another various diseases in wheat. SE EPPO zone, 2016 HU16E7B029AB04 DOW AGROSCIENCES Hungary GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/15	Biro, A.	2017	Evaluation of the minimum effective dose of XR-659 for the control of *Septoria tritici* in wheat and triticale and RHYNSE in rye. EU 2017. HU17G1C012AB01 DOW AGROSCIENCES Hungary GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/16	Botoman, C.	2020	Benchmark local programs for GF-3308 / GF-3307. T1 to support low doses CORTEVA AGRISCIENCE EA20E7B020F-DHT048 GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/17	Botoman, C..	2020	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+80 g ai/l) against key diseases in wheat. CORTEVA AGRISCIENCE EA20E7B035F-DHT074 GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/18	Bouffandeau, P-A.	2017	The efficacy of GF-3308 straight and in mixture with partner fungicides for the control of foliar diseases of wheat. GB16E7B038EB01C BIOTEK AGRICULTURE LTD GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/19	Bounds, P.	2015	To evaluate the efficacy of XDE-777+Pyraclostrobin (GF-3309) mixtures against key cereal diseases. EU CZ, 2015 GB15E7B032EB01C ADAS, UK	N	DAS/Corteva AgriScience

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
			GEP Unpublished		
KCP 6.2/20	Burton, N.D..	2015	What is the efficacy of XDE-777 formulations against PUCCSTcompared to reference standards? GB15E7B015EB04C SUFFOLK & CAMBRIDGE CROP STATION LTD GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/21	Cana, L.	2016	Efficacy of Inatreq formulations compare DuPont cereal fungicide when applied against various diseases in wheat EU, 2016 RO16E7B046AP01C NARDI FUNDULEA GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/22	Cana, L.	2020	Benchmark local programs for GF-3308 / GF-3307. T1 to support low doses CORTEVA AGRISCIENCE EA20E7B020F-DHT047 GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/23	Cana, L.	2020	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+80 g ai/l) against key diseases in wheat. CORTEVA AGRISCIENCE EA20E7B035F-DHT075 GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/24	Dietrich, W.	2016	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin and DE-777 straight for the control of foliar diseases in rye. Europe 2016. DE16E7B019WD01 DOW AGROSCIENCES GMBH. DE GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/25	Donner, M.	2016	What is the efficacy of XDE-777 formulations against PUCCST compared to reference standards, EU 2016? DE16E7B027DD01 DOW AGROSCIENCES GEP	N	DAS/Corteva AgriScience

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 6.2/26	Donner, M.	2016	Evaluation of the MED of GF-3308 for the control of Septoria tritici. EU 2016 DE16E7B037DD02 DOW AGROSCIENCES GMBH GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/27	Fisher, S.	2015	The efficacy of XDE-777 formulations compared to reference standards for control of PUCCST in Europe? GB15E7B015EB01C ARMSTRONG FISHER LTD, UK GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/28	Frydrych, J.	2015	XDE-777 formulations GF-3308, GF-3307, GF-3309, GF-3312A for the control of PUCCRT. EU 2015. CZ15E7B014PV01C OSEVA PRO S.R.O. ODSTEPNY ZAVOD VYZKUMNY USTAV TRAVINARSKY ZUBRI. CZ GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/29	Good, R.	2015	XDE-777 formulations GF-3308, GF-3307, GF-3309, GF-3312A for the control of PUCCRT. EU 2015. GB15E7B014EB01C FIELD ARM LIMITED GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/30	Good, R.	2015	XDE-777 formulations GF-3308, GF-3307, GF-3309, GF-3312A for the control of PUCCRT. EU 2015. GB15E7B014EB03C FIELD ARM LIMITED GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/31	Hrabovsky, J.	2019	Evaluation of new formulation of Inatreq and Inatreq + Prothioconazole against foliar diseases in wheat. CZ Zone - 2018 CZ18E7B017PV01C ZEMĚDĚLSKÁ ZKUŠEBNÍ STANICE KUJAVY, S.R.O. GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/32	Kiraly, B.	2016	Efficacy of Inatreq formulations compare DuPont cereal fungicide when applied against various diseases in wheat - EU, 2016	N	DAS/Corteva AgriScience

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
			HU16E7B046AB01C BIOTEK AGRICULTURE HUNGARY KFT. GEP Unpublished		
KCP 6.2/33	Maczynska, A.	2014	Efficacy and dose response of different XDE-777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ. 2014. PL14E7B028AS01C Dow AgroSciences, Poland IOR SOSNICOWICE GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/34	Menyhart, L.	2014	Efficacy and dose response of different DE-777 + Prothioconazole/fenbuconazole EC formulations for control of foliar diseases in wheat. EU CZ, 2014. HU14E7B026LM01 DOW AGROSCIENCES, Hungary GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/35	Maczynska, A.	2015	What is the efficacy of DE-777 formulations against SEPTTR in wheat in Poland and Baltics when applied as a repeat application PL15E7B041AS02C ~~Dow Agrosciences~~ IOR SOSNICOWICE GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/36	Menyhart, L.	2015	What is the efficacy of DE-777 formulations against SEPTTR in wheat in South East Europe EPPO when applied as a single application. HU15E7B011LM01 DOW AGROSCIENCES Hungary GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/37	Menyhart, L.	2016	Efficacy of Inatreq formulations against rusts and another various diseases in wheat. SE EPPO zone, 2016 HU16E7B029LM03 DOW AGROSCIENCES Hungary GEP Unpublished	N	DAS/Corteva AgriScience

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 6.2/38	Menyhart, L.	2016	Efficacy of Inatreq formulations when applied against various diseases in wheat in SE EPPO Zone HU16E7B030LM03 DOW AGROSCIENCES Hungary GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/39	Nistrup Jørgensen, L.	2015	What is the efficacy of XDE-777 products against SEPTTR at B33-69, when applied as a single application in northern European conditions? DK15E7B019MN02C AARHUS UNIVERSITY FLAKKEBJERG, DK GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/40	Nistrup Jørgensen, L.	2016	What is the minimum effective dose of GF-3307, GF-3309 and GF-3308 against PUCCST, NZ, 2016 DK16E7B002KF01C AARHUS UNIVERSITY FLAKKEBJERG, DK GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/41	Nistrup Jørgensen, L.	2016	What is the minimum effective dose of GF-3307, GF-3309 and GF-3308 against PUCCST, NZ, 2016 DK16E7B002KF02C AARHUS UNIVERSITY FLAKKEBJERG, DK GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/42	Nistrup Jørgensen, L.	2016	What is the minimum effective dose of GF-3307, GF-3309 and GF-3308 against PUCCST, NZ, 2016 DK16E7B002KF03C AARHUS UNIVERSITY FLAKKEBJERG, DK GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/43	Pawlak, A.	2014	Efficacy and dose response of different XDE-777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ, . 2014. PL14E7B014AS03C STAPHYT GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/44	Pawlak, A.	2015	XDE-777 formulations GF3308, GF-3307, GF-3309, GF-3312A for the control of PUCCRT and other cereal diseases. Poland 2015. PL15E7B022AS03C	N	DAS/Corteva AgriScience

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
			STAPHYT, PL GEP Unpublished		
KCP 6.2/45	Pawlak, A.	2016	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin and DE-777 straight for the control of foliar diseases in rye. Europe 2016. PL16E7B019AS04C STAPHYT, PL GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/46	Pawlak, A.	2016	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin and DE-777 straight for the control of foliar diseases in rye. Europe 2016. PL16E7B019AS05C STAPHYT, PL GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/47	Pawlak, A.	2016	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin and DE-777 straight for the control of foliar diseases in triticale. Europe 2016. PL16E7B020AS04C STAPHYT, PL GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/48	Pawlak, A.	2016	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin and DE-777 straight for the control of foliar diseases in triticale. Europe 2016. PL16E7B020AS05C STAPHYT, PL GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/49	Pawlak, A	2017	What Is The Efficacy Of Inatreq Formulations Under North East Europe Conditions PL16E7B031AS04C STAPHYT, PL GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/50	Pszczolkowski, M.	2020	Efficacy of Inatreq on PUCCST in Triticale - Benchmark program, Europe, 2020. EA20E7B018F-DPF027 STAPHYT, PL	N	DAS/Corteva AgriScience

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
			GEP Unpublished		
KCP 6.2/51	Reisenhofer, A.	2015	XDE-777 formulations GF-3308, GF-3307, GF-3309, GF-3312A for the control of PUCCRT. EU 2015. DE15E7B014UB06C ATC - AGRO TRIAL CENTER GMBH, AT GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/52	Rohr, J.	2014	What is the comparative efficacy of XDE-777 formulations GF-3311 (EC) and GF-2925 (SC) against SEPTTR in wheat? DE14E7B027UB01C AGRARTEST, DE GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/53	Rohr, J.	2015	Dose response of XDE-777+prothioconazole and XDE-777+pyraclostrobin for the control of foliar diseases in rye. EU 2015. DE15E7B002UB02C AGRARTEST, DE GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/54	Rohr, J.	2015	Dose response of XDE-777+prothioconazole and XDE-777+pyraclostrobin for the control of foliar diseases in triticale. EU 2015. DE15E7B003UB01C AGRARTEST, DE GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/55	Rohr, J.	2015	XDE-777 formulations GF-3308, GF-3307, GF-3309, GF-3312A for the control of PUCCRT. EU 2015. DE15E7B014UB02C AGRARTEST, DE GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/56	Rohr, J.	2015	Dose response of XDE-777+prothioconazole and XDE-777+pyraclostrobin for the control of foliar diseases in rye. Germany 2015. DE15E7B033UB03C AGRARTEST, DE	N	DAS/Corteva AgriScience

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
			GEP Unpublished		
KCP 6.2/57	Rohr, J.	2015	Dose response of XDE-777+prothioconazole and XDE-777+pyraclostrobin for the control of foliar diseases in rye. Germany 2015. DE15E7B033UB04C AGRARTEST, DE GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/58	Rohr, J.	2015	Dose response of XDE-777+prothioconazole and XDE-777+pyraclostrobin for the control of foliar diseases in triticale. Germany 2015. DE15E7B034UB02C AGRARTEST, DE GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/59	Rohr, J.	2015	Dose response of XDE-777+prothioconazole and XDE-777+pyraclostrobin for the control of foliar diseases in triticale. Germany 2015. DE15E7B034UB04C AGRARTEST, DE GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/60	Rohr, J.	2016	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin and DE-777 straight for the control of foliar diseases in rye. Europe 2016. DE16E7B019UB01C AGRARTEST, DE GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/61	Rohr, J.	2015	Dose response of XDE-777+prothioconazole and XDE-777+pyraclostrobin for the control of foliar diseases in rye. Germany 2015. DE15E7B033UB02C AGRARTEST, DE GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/62	Rohr, J.	2015	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin for the control of foliar diseases in rye. Germany 2015. DE15E7B033UB01C	N	DAS/Corteva AgriScience

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
			AGRARTEST, DE GEP Unpublished		
KCP 6.2/63	Rohr, J.	2015	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin for the control of foliar diseases in rye. EU 2015. DE15E7B002UB03C AGRARTEST, DE GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/64	Rohr, J.	2015	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin for the control of foliar diseases in rye. Germany 2015. DE15E7B033UB05C AGRARTEST, DE GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/65	Rohr, J	2016	Internal Inatreq review in rye DE16E7B044DW01C AGRARTEST, DE GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/66	Rohr, J	2016	How does the efficacy dose response of GF-3307 and GF-3309 against foliar diseases in triticale compare to the included reference product Proline? DE15E7B034UB03C AGRARTEST, DE GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/67	Rohr, J.	2017	Evaluation of the minimum effective dose of XR-659 for the control of Septoria tritici in wheat and triticale and RHYNSE in rye. EU 2017.. DE17G1C012UB01C AGRITEST, DE GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/68	Rohr, J.	2020	Efficacy and dose response of XDE-481 EC (GF-4480) and SC (GF-4505 + GF-4493) on *Puccinia striiformis* and other keydiseases in triticale. EU 2020 EA20F9B007F-DPE013	N	DAS/Corteva AgriScience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			TRIAL-TEC GMBH GEP Unpublished		
KCP 6.2/69	Rohr, J.	2020	Efficacy of Inatreq on PUCCST in Triticale - Benchmark program, Europe, 2020. EA20E7B018F-DNZ056 TRIAL-TEC GMBH GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/70	Rohr, J.	2020	Efficacy of Inatreq on PUCCST in Triticale - Benchmark program, Europe, 2020. EA20E7B018F-DNZ057 TRIAL-TEC GMBH GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/71	Rohr, J.	2020	Efficacy of Inatreq on PUCCST in Triticale - Benchmark program, Europe, 2020. EA20E7B018F-DNZ058 TRIAL-TEC GMBH GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/72	Rohr, J.	2020	Efficacy of Inatreq on PUCCST in Triticale - Benchmark program, Europe, 2020. EA20E7B068F-DNZ074 TRIAL-TEC GMBH GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/73	Rohr, J.	2020	Efficacy of Inatreq on PUCCST in Triticale - Benchmark program, Europe, 2020. EA20E7B068F-DNZ075 TRIAL-TEC GMBH GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/74	Roj, J.	2016	What Is The Efficacy Of Inatreq Formulations Under North East Europe Conditions PL16E7B031AS01C DOW AGROSCIENCES GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/75	Roj, J.	2016	What is the efficacy of Inatreq formulations under North East Europe conditions PL16E7B031AS03C	N	DAS/Corteva AgriScience

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
			DOW AGROSCIENCES, Poland GEP Unpublished		
KCP 6.2/76	Sawinska, Z.	2016	The efficacy GF-3308 straight and in mixture with partner fungicides for the control of foliar diseases of wheat. EU 2016. PL16E7B038AS01C ~~UNIWERSYTET PRZYRODNICZY POZNAN, PL~~ POZNAN UNIVERSITY OF LIFE SCIENCES, PL GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/77	Sawinska, Z.	2014	Efficacy of XDE-777 + prothioconazole and XDE-777 + pyraclostrobin formulations for control of PUCCRT in wheat: EU CZ, 2014. PL14E7B010AS01C ~~UNIWERSYTET PRZYRODNICZY POZNAN, PL~~ POZNAN UNIVERSITY OF LIFE SCIENCES, PL GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/78	Sawinska, Z.	2015	XDE-777 formulations GF-3308, GF-3307, GF-3309, GF-3312 for the control of PUCCRT and other cereal diseases. Poland 2015. PL15E7B022AS01C ~~UNIWERSYTET PRZYRODNICZY POZNAN, PL~~ POZNAN UNIVERSITY OF LIFE SCIENCES, PL GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/79	Sawinska, Z.	2015	XDE-777 formulations GF-3308, GF-3307, GF-3309, GF-3312A for the control of PUCCRT and other cereal diseases. Poland 2015. PL15E7B022AS02C ~~UNIWERSYTET PRZYRODNICZY POZNAN, PL~~ POZNAN UNIVERSITY OF LIFE SCIENCES, PL GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/80	Sawinska, Z.	2016	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin and DE-777 straight for the control of foliar diseases in rye. Europe 2016. PL16E7B019AS03C ~~UNIWERSYTET PRZYRODNICZY POZNAN, PL~~	N	DAS/Corteva AgriScience

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
			POZNAN UNIVERSITY OF LIFE SCIENCES, PL GEP Unpublished		
KCP 6.2/81	Sawinska, Z.	2016	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin and DE-777 straight for the control of foliar diseases in triticale. Europe 2016. PL16E7B020AS03C UNIWERSYTET PRZYRODNICZY POZNAN, PL POZNAN UNIVERSITY OF LIFE SCIENCES, PL GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/82	Sawinska, Z.	2020	Efficacy of Inatreq on PUCCST in Triticale - Benchmark program, Europe, 2020. EA20E7B018F-DPF026 UNIWERSYTET PRZYRODNICZY POZNAN, PL POZNAN UNIVERSITY OF LIFE SCIENCES, PL GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/83	Schnieder, F.	2014	Efficacy and dose response of different XDE-777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ, . 2014. DE14E7B014FS01 DOW AGROSCIENCES GMBH. DE GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/84	Schulz, T.	2014	Efficacy and dose response of different XDE-777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ. 2014. DE14E7B028TS01 DOW AGROSCIENCES GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/85	Schulz, T.	2015	Dose response of XDE-777+prothioconazole and XDE-777+pyraclostrobin for the control of foliar diseases in rye. EU 2015. DE15E7B002TS01 DOW AGROSCIENCES GMBH. DE GEP Unpublished	N	DAS/Corteva AgriScience

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 6.2/86	Schultz, T	2017	Evaluation of the minimum effective dose of XR-659 for the control of Septoria tritici in wheat and triticale and RHYNSE in rye. EU 2017.. DE17G1C012TS01 DOW AGROSCIENCES GMBH. DE GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/87	Stephan, A.	2015	XDE-777 formulations GF-3308, GF-3307, GF-3309, GF-3312a for the control of PUCCRT. EU 2015 DE15E7B014AS01 DOW AGROSCIENCES GMBH GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/88	Stephan, A	2017	Evaluation of the minimum effective dose of XR-659 for the control of *Septoria tritici* in wheat and triticale and RHYNSE in rye. EU 2017. DE17G1C012ASO1 DOW AGROSCIENCES GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/89	Stephan, A.	2020	What is the optimum dose of XDE-481 EC and fenpicoxamid EC in mixtures for *Septoria tritici* control in wheat? EA19F9B017F-DPE01 DOW AGROSCIENCES GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/90	Stepien, A.	2014	Efficacy and dose response of different DE-777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ. 2014. PL14E7B028AS02C POZNAN UNIVERSITY OF LIFE SCIENCES GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/91	Stepien, A.	2015	What is the efficacy of DE-777 formulations against SEPTTR in wheat in Poland and Baltics when applied as a repeat application PL15E7B041AS01C POZNAN UNIVERSITY OF LIFE SCIENCES GEP Unpublished	N	DAS/Corteva AgriScience

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 6.2/92	Sawinska, Z.	2014	Efficacy and dose response of different DE-777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ, . 2014. PL14E7B014AS01C POZNAN UNIVERSITY OF LIFE SCIENCES GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/93	Sawinska, Z.	2016	Efficacy of Inatreq formulations compare DuPont cereal fungicide when applied against various diseases in wheat – EU, 2016. PL16E7B046AS02C POZNAN UNIVERSITY OF LIFE SCIENCES GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/94	Treikale, O.	2014	Efficacy and dose response of different DE-777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ. 2014. LV14E7B028MN02C LATVIAN PLANT PROTECTION RESEARCH CENTRE LTD. GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/95	Treikale, O.	2015	What is the efficacy of XDE-777 products against SEPTTR at B33-69, when applied as a single application in northern European conditions? LV15E7B019MN03C LATVIAN PLANT PROTECTION RESEARCH CENTRE, LPPRC GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/96	Treikale, O.	2016	What is the efficacy of Inatreq formulations against diseases of wheat under North East Europe conditions? LV16E7B031KF03C LATVIAN PLANT PROTECTION RESEARCH CENTRE, LPPRC GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/97	Tuna, V.	2021	Benchmark local programs for GF-3308 / GF-3307. T1 to support low doses EA20E7B020F-DHT084 CORTEVA AGRISCIENCE GEP Unpublished	N	DAS/Corteva AgriScience

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 6.2/98	Tuna, V.	2021	Benefit trials local programs for GF-3308. T2 to support low doses, Romania 2020. EA20E7B065F-DHT071 CORTEVA AGRISCIENCE GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/99	Tvaruzek, L.	2014	Efficacy and dose response of different XDE-777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ. 2014. CZ14E7B028PV01C ZEMEDELSKY VYZKUMNY USTAV KROMERIZ, S.R.O. CZ GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/100	Tvaruzek, L.	2016	The efficacy GF-3308 straight and in mixture with partner fungicides for the control of foliar diseases of wheat. EU 2016. CZ16E7B038PV02C ZEMEDELSKY VYZKUMNY USTAV KROMERIZ, S.R.O. CZ GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/101	Von Appen, A	2016	Top 20, Triticale. EU 2016. DE16X02002FS01C EUROFINS AGROSCIENCE SERVICES GMBH, DE GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/102	Vourkos, F.	2016	Efficacy of Inatreq formulations when applied against various diseases in wheat in SE EPPO Zone BG16E7B030VA01C ANADIAG Bulgaria Ltd GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/103	Vourkos, F.	2016	Efficacy of Inatreq formulations when applied against various diseases in wheat in SE EPPO Zone BG16E7B030VA02C ANADIAG Bulgaria Ltd GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/104	Wagner, G.	2014	Efficacy and dose response of different DE-777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ. 2014. EA14E7B028AB01C	N	DAS/Corteva AgriScience

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
			SYNTECH RESEARCH HUNGARY KFT. GEP Unpublished		
KCP 6.2/105	Wonckhaus, S	2020	Efficacy and dose response of XDE-481 EC (GF-4480) and SC (GF-4505 + GF-4493) on *Puccinia striiformis* and other key diseases in triticale. EU 2020 EA20F9B007F-DPE014 AGRARTEST, DE GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/106	Zickart, U.	2014	Efficacy and dose response of different XDE-777 + Prothioconazole/fenbuconazole EC formulations for control of foliar diseases in wheat. EU CZ, 2014. DE14E7B026UB01C BIOCHEM AGRAR. DE GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.2/107	Zoller, P.	2015	XDE-777 formulations GF-3308, GF-3307, GF-3309, GF-3312A for the control of PUCCRT. EU 2015. DE15E7B014UB04C EUROFINS AGROSCIENCE SERVICES GMBH, DE GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.3/01	Kemmit, G.	2012	XDE-777 *Septoria tritici* (*Mycosphaerella graminicola*) sensitivity baseline generation Year 1 2011 season. DAS internal report # 2011920. non GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.3/02	Kemmit, G.	2013	XDE-777 *Septoria tritici* (*Mycosphaerella graminicola*) sensitivity baseline generation Year 2 2012 season Europe. DAS internal report # 2020427. non GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.3/03	Kemmit, G.	2014	XDE-777 *Septoria tritici* (*Mycosphaerella graminicola*) sensitivity baseline generation Year 3 2013 season Europe. DAS internal report # 2021524 non GEP Unpublished	N	DAS/Corteva AgriScience

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 6.3/04	Kemmit, G.	2015	XDE-777 *Septoria tritici* (*Mycosphaerella graminicola*) sensitivity baseline generation Year 4 2014 season Europe. DAS internal report # 2025137. non GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.3/05	Kemmit, G.	2015	Inatreq (DE-777) *Puccinia triticina* (Wheat Brown Rust) sensitivity baseline generation. Year 1 2015 season, Europe. DAS internal research report no. DAI 2032179 Non GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.3/06	Myung K., Yao C., Owen, W., Meyer, K.G. and Nugent B.M.,	2011	Uptake, redistribution and metabolism of picolinamides (XR-777 and UK-2A) and neo-picolinamides (X12072033 and X12070381) in wheat and *Septoria tritici*. DAS internal research report no. DAI 1074 Non GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.3/07	Myung, K.,Young, D., Meyer, S.T., Kemmitt, G., Owen, W.J.	2016	Metabolism of InatreqTM active to UK-2A by *Zymoseptoria tritici* DAS internal research report no. DAI 1517 Non GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.3/08	Owen, W.J. et al.	2011	XR-777 Discovery Advancement Report DOW AGROSCIENCES internal report DAI 1040 Non GEP/non GLP Unpublished	N	DAS/Corteva AgriScience
KCP 6.3/09	Young D.H, and Wang N.	2005	Insights into the binding of UK-2A to cytochrome bc1 from cross-resistance analyses using antimycin-resistant *Saccharomyces cerevisiae* mutants and molecular docking studies. DAI 1077 non GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.3/10	Anonymous	2013	FRAC Pathogen Risk List, 2013 version. Online - http://www.frac.info/docs/default-source/publications/pathogen-risk/pathogen-risk-list.pdf?sfvrsn=8	N	Public
KCP 6.3/11	Anonymous	2015	FRAC Code List, 2015 version . Online - http://www.frac.info/docs/default-source/publications/frac-code-list/frac-code-list-2015-finalC2AD7AA36764.pdf?sfvrsn=4)	N	Public

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KCP 6.3/12	Bayles RA, Stigwood PL, Clarkson JDS	2000	Shifts in sensitivity of *Puccinia striiformis* to DMI fungicides in the UK. Acta Phytop. Entom. Hungarica 35, 381-382	N	Public
KCP 6.3/13	Brasseur G, Saribas AS and Daldal F	1996	A compilation of mutations located in the cytochrome b subunit of the bacterial and mitochondrial bc1 complex. Biochim. Biophys. Acta 1275: 61-69	N	Public
KCP 6.3/14	Clark, W.	2005	QoI resistance in *Mycosphaerella graminicola* in the UK. Implications for future use of QoI fungicides. Proceedings of the BCPC International Congress, Crop Science and Technology 383-290	N	Public
KCP 6.3/15	Cools HJ, Bayon C, Atkins S, Lucas JA and Fraaije BA	2012	Over-expression of the sterol 14α-demethylase gene (MgCYP51) in *Mycosphaerella graminicola* isolates confers a novel azole fungicide sensitivity phenotype. Pest Management Science 68, 1034-1040	N	Public
KCP 6.3/16	Cools HJ, Fraaije BA	2013	Update on mechanisms of azole resistance in *Mycosphaerellla graminicola* and implications for future control . Pesticide Management Science 69, 150-155	N	Public
KCP 6.3/17	Cools HJ, Mullins JGL, Fraaije BA, Parker JE, Kelly DE, Lucas JA and Kelly SL	2011	Impact of recently emerged sterol 14α-demethylase (CYP51) variants of *Mycosphaerella graminicola* on azole fungicide sensitivity. Applied and Environmental Microbiology 77, 3830-3837	N	Public
KCP 6.3/18	Di Rago JP and Colson A-M	1988	Molecular basis for resistance to antimycin and diuron, Q-cycle inhibitors acting at the Qi site in the mitochondrial ubiquinol-cytochrome c reductase in *Saccharomyces cerevisiae*. J. Biol. Chem. 263: 12564-12570	N	Public
KCP 6.3/19	Ding MG, Di Rago JP and Trumpower BL	2006	Investigating the Qn site of the cytochrome bc1 complex in *Saccharomyces cerevisiae* with mutants resistant to Ilicicolin H, a novel Qn site inhibitor. J. Biol. Chem. 281 (47): 36036-36043	N	Public
KCP 6.3/20	Fehr et al.	2015	Binding of the respiratory chain inhibitor Ametoctradin to the mitochondrial bc1 complex. Pesticide Management Science	N	Public
KCP 6.3/21	Fisher N, Brown AC, Sexton G, Cook A, Windass J and Meunier B	2004	Modeling the Qo site of crop pathogens in *Saccharomyces cerevisiae* cytochrome b. Eur. J. Biochem. 271: 2264-2271	N	Public
KCP 6.3/22	Fraaije BA, Bayon C, Atkins	2012	Risk assessment studies on Succinate Dehydrogenase Inhibitors, the new weapons in the battle to control Septoria leaf blotch in wheat. Molecular Plant Pathology 13, 263-275	N	Public

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	S, Cools HJ, Lucas JA and Fraaije MW				
KCP 6.3/23	Fraaije BA, Cools HJ, Fountaine J, Lovell DJ, Motteram J, West JS and Lucas JA	2005	The role of ascospores in further spread of QoI-resistant cytochrome b alleles (G143A) in field populations of *Mycosphaerella graminicola*. Phytopathology 95, 933-941	N	Public
KCP 6.3/24	Fraaije BA, Lovell DJ, Rohel EA and Hollomon DW	1999	Rapid detection and diagnosis of Septoria tritici epidemics in wheat using a polymerase chain reaction/PicoGreen assay. Journal of Applied Microbiology 86, 701-708	N	Public
KCP 6.3/25	Gisi U, Sierotzki H	2008	Modern fungicides and antifungal compouns: 53. Deutsche Phytom. Ges. Braunschweig, Germany, 2008	N	Public
KCP 6.3/26	Hill P, Kessl K, Fisher N, Meshnick S, Trumpower BL and Meunier B.	2003	Recapitulation in *Saccharomyces cerevisiae* of cytochrome b mutations conferring resistance to atovaquone in Pneumocystis jiroveci. Antimicrob. Agents Chemother. 47: 2725-2731	N	Public
KCP 6.3/27	Huang L, Cobessi D, Tung EY and Berry EA	2005	Binding of the respiratory chain inhibitor antimycin to the mitochondrial bc1 complex: a new crystal structure reveals an altered intramolecular hydrogen-bonding pattern. J. Mol. Biol. 351: 573-597	N	Public
KCP 6.3/28	Kousik C.S. and Keinath, A P	2008	First report of insensitivity to cyazofamid among isolates of Phytophthora capsici from the South Eastern United States. Plant Disease 92. 979	N	Public
KCP 6.3/29	Lucas JA and Fraaije BA	2008	QoI resistance in *Mycosphaerella graminicola*: what have we learned so far? In: Modern Fungicides and Antifungal Compounds V (Dehne, H.W., Deising, H.B., Gisi, U., Kuck, K-H., Russell, P.E. and Lyr, H., eds), pp. 71-77. Braunschweig, Germany: DPG	N	Public
KCP 6.3/30	Putrament A, Baranowska H, Ejchart A and Prazmo W	1975	Manganese mutagenesis in yeast. A practical application of manganese for the induction of mitochondrial antibiotic-resistant mutations. J. Gen. Microbiol. 90 :265-270	N	Public
KCP 6.3/31	Ueki M and Taniguchi M.	1997	The mode of action of UK-2A and UK-3A, novel antifungal antibiotics from Streptomyces sp. 517-02. J. Antibiotics 50: 1052-1057	N	Public

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KCP 6.4/01	Babrik, Z.	2014	Selectivity of XDE-777 + Prothioconazole EC and XDE-777+pyraclostrobin EC in cereals, 2014. EU HU14E7B016AB01C AGROFIL SZAKTANACSADO MERNOKI IRODA KFT. GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.4/02	Banachowska, J.	2014	Selectivity of XDE-777 + Prothioconazole EC and XDE-777+pyraclostrobin EC in cereals, 2014. EU PL14E7B016AS01C IOR SOSNICOWICE, PL GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.4/03	Cunningham, A.	2014	Selectivity of XDE-777 + Prothioconazole EC and XDE-777+pyraclostrobin EC in cereals, 2014. EU GB14E7B016EB02C OXFORD AG TRIALS, UK GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.4/04	Fisher, S.	2014	Selectivity of XDE-777 + Prothioconazole EC and XDE-777+pyraclostrobin EC in cereals, 2014. EU GB14E7B016EB01C ARMSTRONG FISHER LTD, UK GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.4/05	Hilton, R.	2016	Inatreq selectivity on cereal varieties GB16E7B077RH01 DOW AGROSCIENCES LTD, UK GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.4/06	Tartier, J.	2014	Selectivity of XDE-777 + Prothioconazole EC and XDE-777+pyraclostrobin EC in cereals, 2014. EU FR14E7B016MC02C BIOTEK AGRICULTURE. FR GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.4/07	Zickart, U.	2014	Selectivity of XDE-777 + Prothioconazole EC and XDE-777+pyraclostrobin EC in cereals, 2014. EU DE14E7B016UB01C BIOCHEM AGRAR. DE GEP Unpublished	N	DAS/Corteva AgriScience

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KCP 6.4.4/01	Kästner, K.	2016	Field study to generate specimen of Beer from RAC Wheat treated with GF-3307 or GF-3309 for subsequent triangle taint testing and determination of quality parameters, 2 Sites in Germany 2015 BIOCHEM PROJECT No 15 1047 2114 GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.4.4/02	Owen J, Slanec T	2015	Impact of carbon source on growth inhibition of *Saccharomyces cervisiae* by XDE-777 and UK-2A Report DAI1399 DOW AGROSCIENCES INDIANAPOLIS Non GLP/non GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.4.4/03	Tartier, J.	2015	Evaluation of XDE-777 formulations in wheat with grain used for bread making. EU 2015. FR15E7B006MC01C BIOTEK AGRICULTURE, FR GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.4.4/04	Tartier, J.	2015	Evaluation of XDE-777 formulations in wheat with grain used for bread making. EU 2015. FR15E7B006MC02C BIOTEK AGRICULTURE, FR GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.4.4/05	Tartier, J.	2015	Evaluation of XDE-777 formulations in wheat with grain used for bread making. EU 2015. FR15E7B006MC03C BIOTEK AGRICULTURE, FR GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.4.4/06	Tartier, J.	2015	Evaluation of XDE-777 formulations in wheat with grain used for bread making. EU 2015. FR15E7B006MC04C BIOTEK AGRICULTURE, FR GEP Unpublished	N	DAS/Corteva AgriScience
KCP 6.5/01	Strömel, C; Friedemann, A.	2016	GF-3308 (DE-777 50 g a.s/L, EC): A seedling emergence and seedling growth test with ten non target plant species, GLP Terrestrial Non Target Plants (based on OECD Guideline 208) – Europe 2016 AC/DOW/16/01 AGRO-CHECK	N	DAS/Corteva AgriScience

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
			GLP Unpublished report		
KCP 6.5/02	Strömel, C; Friedemann, A.	2017	GF-3308 (DE-777 50 g a.s/L, EC): A vegetative vigour test with ten non target plant species, GLP Terrestrial Non Target Plants (based on OECD Guideline 227) – Europe 2016 AC/DOW/16/02 AGRO-CHECK GLP Unpublished report	N	DAS/Corteva AgriScience
KCP 6.5/03	Topham, D.	2017	Dow AgroSciences Clean Out Report for Fungicides: GF-2925, GF-3307, GF-3308, GF-3309, GF-3312 LES 101 26 AMEGA SCIENCES Non GEP Unpublished	N	DAS/Corteva AgriScience
~~3.6~~ KCP 6 Other/ special studies	Beaucamp, M.	2017	What is the best Dupont fungicide partner with Inatreq formulations for broad spectrum disease control. EU 2017 FR17E7B048MC06C PHYLIAE, FR GEP Unpublished	N	DAS/Corteva AgriScience
~~3.6~~ KCP 6 Other/ special studies	Butler Ellis C, Lane A, Tuck C	2016	Characterisation of sprays and visualisation of deposits on surfaces Report S0140/1 SILSOE SPRAY APPLICATIONS UNIT LIMITED Non GEP Unpublished	N	DAS/Corteva AgriScience
~~3.6~~ KCP 6 Other/ special studies	Downey, S.	2015	EU 2015: Efficacy of GF-3307 and GF-3309 for the control of cereal diseases using LD Nozzles compared to std. Flat Fan nozzles at different water volumes GB15E7B030SD01 DOW AGROSCIENCES LTD, UK GEP Unpublished	N	DAS/Corteva AgriScience
~~3.6~~ KCP 6 Other/ special studies	Fairfax, M.	2015	EU 2015: Efficacy of GF-3307 and GF-3309 for the control of cereal diseases using LD Nozzles compared to std. Flat Fan nozzles at different water volumes GB15E7B030MF01 DOW AGROSCIENCES LTD, UK	N	DAS/Corteva AgriScience

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
			GEP Unpublished		
3.6 KCP 6 Other/ special studies	Fairfax, M.	2017	What is the length of kickback of Inatreq products compared to market references, UK 2017 GB17E7B021MF01 DOW AGROSCIENCES LTD, UK GEP Unpublished	N	DAS/Corteva AgriScience
3.6 KCP 6 Other/ special studies	Fairfax, M.	2017	To identify in antagonism occurs when Inatreq formulations are applied with multi-site fungicides for curative control of SEPTTR GB17E7B125MF01 DOW AGROSCIENCES LTD, UK GEP Unpublished	N	DAS/Corteva AgriScience
3.6 KCP 6 Other/ special studies	Haigh, I.	2017	What is the best Dupont fungicide partner with Inatreq formulations for broad spectrum disease control. EU 2017 GB17E7B048EB02C FIELD ARM LIMITED GEP Unpublished	N	DAS/Corteva AgriScience
3.6 KCP 6 Other/ special studies	Lane A, O'Sullivan C, Butler Ellis C	2017	Characterising deposits on plants for a range of formulations and application conditions Report S0181 SILSOE SPRAY APPLICATIONS UNIT LIMITED Non GEP Unpublished	N	DAS/Corteva AgriScience
3.6 KCP 6 Other/ special studies	Mathieson, T. et all.	2016	Rainfast studies to compare the rainfast ability of new Dow AgroSciences fungicide formulations of DE-777(Inatreq) to current market fungicides DOW AGROSCIENCES LLC Non GEP/non GLP Unpublished	N	DAS/Corteva AgriScience
3.6 KCP 6 Other/ special studies	Quillet, M.	2017	What is the best Dupont fungicide partner with Inatreq formulations for broad spectrum disease control. EU 2017 FR17E7B048MC03C AGROLIS CONSULTING GEP Unpublished	N	DAS/Corteva AgriScience

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
3.6 KCP 6 Other/ special studies	Rohr, H.	2014	Efficacy of GF-3307 and GF-2925 for the control of cereal diseases using LD Nozzles compared to Flat Fan nozzles at different water volumes. EU 2014 DE14E7B017UB01C AGRARTEST, DE GEP Unpublished	N	DAS/Corteva AgriScience
3.6 KCP 6 Other/ special studies	Rohr, J.	2016	Inatreq 063 internal use DE16E7B062FSC03C AGRATEST, DE GEP Unpublished	N	DAS/Corteva AgriScience
3.6 KCP 6 Other/ special studies	Rohr, J.	2017	What is the best Dupont fungicide partner with Inatreq formulations for broad spectrum disease control. EU 2017 DE17E7B048UB01C AGRARTEST, DE GEP Unpublished	N	DAS/Corteva AgriScience
3.6 KCP 6 Other/ special studies	Thibault, A.	2017	What is the best Dupont fungicide partner with Inatreq formulations for broad spectrum disease control. EU 2017 FR17E7B048MC04C SYNTECH RESEARCH FR S.A.S. FR GEP Unpublished	N	DAS/Corteva AgriScience
3.6 KCP 6 Other/ special studies	Thorpe, A.	2017	What is the best Dupont fungicide partner with Inatreq formulations for broad spectrum disease control. EU 2017 GB17E7B048EB03C OXFORD AG TRIALS, UK GEP Unpublished	N	DAS/Corteva AgriScience
3.6 KCP 6 Other/ special studies	Touche, C.	2017	What is the best Dupont fungicide partner with Inatreq formulations for broad spectrum disease control. EU 2017 FR17E7B048MC05C STAPHYT. FR GEP Unpublished	N	DAS/Corteva AgriScience

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KCP 6	Fones, H.; Gurr, S.	2015	The impact of *Septoria tritici* Blotch disease on wheat:An EU perspective. Fungal Genetics and Biology 79 (2015) 3-7	N	Public
KCP 6	Rehfus A, Prochnow J, Strobel D, Bryson R, Stammler G	2016	Sensitivitätssituation von Getreidepathogenen in Europa gegenüber Succinat-Dehydrogenase Inhibitoren (Sensitivity situation of cereal pathogens in Europe to succinate dehydrogenase inhibitors) 60. Deutsche Pflanzenschutztagung, Julius-Kühn-Archiv 454, Präsentation 32-3	N	Public
KCP 6	Ashby		Clarification of efficacy data requirements for the authorization of a fungicide for the control of Septoria leaf blotch (Mycosphaerella graminicola, SEPTTR) on winter wheat (Triticum aestivum, TRZAX) in the European Central authorization zone	N	Public
KCP 10.2.3/4	Mathieson, T.	2018	Efficacy of XDE-777 metabolites to *Septoria tritici* on wheat DAS# NA DOW AGROSCIENCES, LLC, ZIONSVILLE, INDIANA, USA Non GEP/non GLP Unpublished	N	DAS/Corteva AgriScience
KCP 10.2.3/5	Yao, C.	2014	*Septoria tritici* Biological Screening Report for Five Metabolites of XDE-777 DAS# DAI 1370 DOW AGROSCIENCES, LLC, ZIONSVILLE, INDIANA, USA Non GEP/non GLP Unpublished	N	DAS/Corteva AgriScience

List of data submitted by the applicant and not relied on

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

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-	-	-	-	-	-