

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

Product code: GF-3307 (S7K-3-3)

Product name(s): QUEEN

Chemical active substances:

Fenpicoxamid (XDE-777), 50 g/L

Prothioconazole, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

**CORE ASSESSMENT**  
(extension of use)

Applicant: Corteva Agriscience

Submission date: March 2025, updates: June 2025, July 2025

MS Finalisation date: July 2025 (initial Core Assessment),

November 2025 (final Core Assessment)

### Version history

When	What
March 2025	Initial dRR - Corteva Agriscience Submission of GF-3307 (S7K-3-3) Sugar beet/Fodder beet Extension of Use in the Central Zone.
June 2025	Updated dRR (GAP table expanded to detail individual countries on separate lines) - Corteva Agriscience GAP table updated and additional information provided to address zRMS request
July 2025	GAP update – change in the number of applications per use - change indicated by the applicant in response to the email – E-V-A
July 2025	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 <b>highlighted in grey</b> . Not agreed or not relevant information are <del>struck through</del> and <del>shaded</del> for transparency.  Following the evaluation and before sending the document for commenting, all coloured highlighting was removed, from the parts updated by the Applicant, for better legibility.
November 2025	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 <b>highlighted in yellow</b> . Not agreed or not relevant information are <del>struck through</del> and <del>shaded</del> for transparency.

## Table of Contents

<b>3</b>	<b>Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)</b> .....	<b>5</b>
3.1	Summary and conclusions on Section 3: Efficacy (KCP 6) .....	5
3.2	Efficacy data (KCP 6) .....	10
3.2.1	Preliminary tests (KCP 6.1) .....	22
3.2.1.1	Preventive and curative properties of GF-3307 (S7K-3-3) in a glasshouse test for the control of <i>Cercospora beticola</i> in sugar beet .....	22
3.2.1.2	Mix partner justification for fenpicoxamid + prothioconazole in the final formulation GF-3307 (S7K-3-3) .....	26
(a)	Results for the justification against <i>Cercospora beticola</i> in sugar beet. ....	26
(b)	Results for the justification against <i>Uromyces betae</i> in sugar beet .....	34
(c)	Summary and conclusions on the preliminary trials .....	38
3.2.2	Minimum effective dose tests (KCP 6.2) .....	39
3.2.2.1	Minimum effective dose of GF-3307 (S7K-3-3) for the control of <i>Cercospora beticola</i> in sugar beet .....	39
3.2.2.2	Minimum effective dose of GF-3307 (S7K-3-3) for the control of <i>Uromyces betae</i> in sugar beet .....	49
3.2.2.3	Minimum effective dose of GF-3307 (S7K-3-3) for the control of <i>Erysiphe betae</i> in sugar beet .....	53
3.2.2.4	Minimum effective dose of GF-3307 (S7K-3-3) for the control of <i>Ramularia beticola</i> in sugar beet .....	58
3.2.2.5	Summary and conclusions on the minimum effective dose (MED) .....	64
3.2.3	Efficacy tests (KCP 6.2) .....	65
3.2.3.1	Efficacy of GF-3307 (S7K-3-3) for the control of <i>Cercospora beticola</i> in sugar beet .....	66
3.2.3.2	Efficacy of GF-3307 (S7K-3-3) for the control of <i>Uromyces betae</i> in sugar beet ..	86
3.2.3.3	Efficacy of GF-3307 (S7K-3-3) for the control of <i>Erysiphe betae</i> in sugar beet ....	95
3.2.3.4	Efficacy of GF-3307 (S7K-3-3) for the control of <i>Ramularia beticola</i> in sugar beet .....	104
3.2.3.5	Yield (and relevant quality indicators), from efficacy trials (in the presence of challenging pest populations) .....	116
3.2.3.6	Summary and conclusions on effectiveness .....	120
3.3	Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3) .....	126
3.3.1	Mode of Action .....	127
3.3.2	Mechanism of Resistance and Evidence of Resistance .....	128
3.3.3	Cross Resistance .....	128
3.3.4	Sensitivity data – Sensitivity baseline for European <i>Cercospora beticola</i> population versus fenpicoxamid (DE-777) and prothioconazole .....	129
3.3.5	Use pattern .....	133
3.3.6	Resistance risk associated with unrestricted use pattern .....	133
3.3.7	Test methods .....	135
3.3.8	Acceptability of the resistance risk .....	135
3.3.9	Management Strategy for GF-3307 (S7K-3-3) .....	135
3.3.10	Implementation of the Management Strategy .....	136
3.3.11	Monitoring, reporting and reaction to the changes in performance .....	137
3.4	Adverse effects on treated crops (KCP 6.4) .....	138
3.4.1	Phytotoxicity to host crop (KCP 6.4.1) .....	139
3.4.1.1	Phytotoxicity in efficacy trials to sugar beet (BEAVA) .....	139
3.4.2	Effect on the yield of treated plants or plant product (KCP 6.4.2) .....	140
3.4.3	Effects on the quality of plants or plant products (KCP 6.4.3) .....	140
3.4.4	Effects on transformation processes (KCP 6.4.4) .....	145

---

3.4.5	Impact on treated plants or plant products to be used for propagation (KCP 6.4.5).....	145
3.5	Observations on other undesirable or unintended side-effects (KCP 6.5).....	146
3.5.1	Impact on succeeding crops (KCP 6.5.1) .....	146
3.5.2	Impact on other plants including adjacent crops (KCP 6.5.2).....	146
3.5.3	Effects on beneficial and other non-target organisms (KCP 6.5.3).....	146
3.6	Other/special studies.....	147
3.7	List of test facilities including the corresponding certificates .....	147
<b>Appendix 1</b>	<b>Lists of data considered in support of the evaluation.....</b>	<b>197</b>
<b>Appendix 2</b>	<b>Draft label.....</b>	<b>208</b>



### 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 on Section 3: Efficacy (KCP 6)

##### Abstract by zRMS

This application has been submitted for the extension of use the fungicide GF-3307 (S7K-3-3) (trade name Queen), containing 50 g/L fenpicoxamid (Qil-fungicide; FRAC group 21) and 100 g/L prothioconazole (DMI fungicide; FRAC group 3).

GF-3307 (S7K-3-3) is intended for the control of *Cercospora beticola* (CERCBE), *Uromyces betae* (UROMBE), *Erysiphe betae* (ERYSBE), *Ramularia beticola* (RAMUBE) on sugar beet and fodder beet. This application concerns authorization in the following Member States: Austria, Belgium, Czech Republic, and the Netherlands (Maritime EPPO zone); Poland (North-East EPPO zone); as well as Hungary, Romania, and Slovakia (South-East EPPO zone). GF-3307 (S7K-3-3) is intended to be applied two times per growing season, within the crop growth stage BBCH 39 to 49. The recommended application rate is 1.5 L/ha in the Maritime EPPO zone, and 1.2–1.5 L/ha in the North-East and South-East EPPO zones.

##### Preliminary tests

The co-formulation justification for GF-3307 (S7K-3-3), containing 50 g/L fenpicoxamid and 100 g/L prothioconazole, has been demonstrated based on efficacy data obtained from a series of preliminary field trials conducted in 2020, 2022, and 2023, as well as from glasshouse tests performed in 2023, conducted also to assess the preventive and curative properties of GF-3307 (S7K-3-3).

Based on the submitted preliminary efficacy trial results, it can be concluded, that the benefits of using the co-formulation of fenpicoxamid with prothioconazole in the control of CERCBE and UROMBE on sugar beet have been justified.

##### Minimum effective dose

The dose rate of 1.5 L/ha can be considered as the minimum effective dose to provide sufficient efficacy in the control of CERCBE, UROMBE, ERYSBE and RAMUBE on sugar beet across a broad range of disease pressure. Lower dose rate of 1.2 L/ha requested for North-East EPPO zone (PL) and South-East EPPO zone (HU, RO, SK) can be also recommended under low disease pressure conditions.

##### Efficacy

The submission contains 56 valid efficacy trials carried out between 2020 and 2023 in 3 EPPO zones: Maritime (Austria, Czech Republic, Germany, Denmark, France, the United Kingdom), North-East (Lithuania, Poland) and South-East (Hungary, Romania). Efficacy trials were carried out on sugar beet. No trials were conducted on fodder beet. Based on the efficacy trial results, it can be concluded, that the fungicide GF-3307 (S7K-3-3), when applied at the recommended dose rates, is effective or moderately effective in control of the target pathogens, for which the efficacy data has been submitted. Moderate efficacy was demonstrated for dose rate of 1.2-1.25 L/ha in the control of CERCBE and for dose rate 1.5 L/ha in the control of RAMUBE. Efficacy <60% was demonstrated for dose rate 1.2-1.25 L/ha in the control of RAMUBE. The national labels of the fungicide GF-3307 (S7K-3-3) should include appropriate notes, informing about the levels of effectiveness of the product, depending on the application rate and target pathogen and a recommendation to use a lower dose rate in cases of low disease pressure. Some of the claimed uses have not been accepted by the zRMS, due to no or limited efficacy data, and for some of the others the zRMS kindly advises the respective cMSs to make a decision on acceptance on the national level, according to these Member States' national requirements. See also the zRMS commenting box following the GAP table.

Summarizing the evaluation, the following uses have been accepted by the zRMS:

**Maritime EPPO zone (AT, BE, CZ, NL)**

BEAVA: CERCBE, UROMBE, ERYSB, RAMUBE

**North-East EPPO zone (PL)**

BEAVA: CERCBE, RAMUBE

BEAVA: ERYSB (possible authorization with further restrictions)

**South-East EPPO zone (HU, RO, SK)**

BEAVA: CERCBE

The following uses are have not been accepted by the zRMS:

**North-East EPPO zone (PL)**

~~BEAVA: ERYSB~~

BEAVA: UROMBE (possible authorization on the grounds of article 51)

BEAVC: CERCBE, UROMBE, ERYSB, RAMUBE (possible authorization on the grounds of article 51)

The following uses should be confirmed by cMSs:

**Maritime EPPO zone (AT, BE, CZ, NL)**

BEAVC: CERCBE, UROMBE, ERYSB, RAMUBE

**South-East EPPO zone (HU, RO, SK)**

BEAVA: UROMBE, ERYSB, RAMUBE

BEAVC: CERCBE, UROMBE, ERYSB, RAMUBE

The zRMS is kindly asking the cMS to not only take their decisions, but also to share the underlying information with the zRMS PL, within the commenting period framework.

After the commenting period, and taking into account the decision of cMS AT and NL regarding the extrapolation of data from BEAVA to BEAVC, the use on BEAVC has been accepted for AT and NL.

**Phytotoxicity, yield, propagation material**

No phytotoxicity and no adverse effect on the yield as well as its quality parameters and propagation material is expected after application of GF-3307 (S7K-3-3), when used according to GAP recommendations.

**Resistance management strategy** (concerning both cereals and the currently claimed sugar beet and fodder beet)

- The product GF-3307 (S7K-3-3) should be used in accordance with the principles of Good Plant Protection Practice and Integrated Pest Management (IPM), including the alternation use of fungicides containing active substances from different FRAC groups, i.e. with various modes of action (MoA), applied at recommended dose rates, that ensure effective control of the target pathogens,
- Whenever possible, the fungicide GF-3307 (S7K-3-3) should be applied in tank mixtures with fungicides containing active substances with different modes of action, than prothioconazole and fenpicoxamid (INATREQ™). In such cases, the instructions for use provided on the labels of all components of the tank mixture must be strictly followed,
- Apply the product mainly preventively, in accordance with the recommended dose rates and timing of application as specified on the product label,
- GF-3307 (S7K-3-3) shall be used exclusively for the control of the fungal diseases specified on the product label,
- Do not exceed the maximum number of GF-3307 (S7K-3-3) applications permitted per growing season, as specified on the product label,
- Use non-chemical control measures for the management of fungal diseases in cereals, sugar beet, and fodder beet, in accordance with the principles of, including the cultivation of disease-resistant or less susceptible varieties,
- Regular check the most recent FRAC resistance management recommendations for fungicides intended for use cereals, sugar beet, and fodder beet.

The cMSs are kindly encouraged to adopt or adjust the wording, according to their local circumstances and requirements.

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. * <sup>(c)</sup>	Me- mber stat- e(s)	Crop and/ or situation  (crop destina- tion / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests con- trolled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g saf- ener/syner- gist per ha ( <sup>(i)</sup> )	zRMS Conclusion (efficacy)
					Meth- od / Kind	Timing / Growth stage of crop & sea- son	Max. number a) per use b) per crop/ sea- son	Min. in- terval between applica- tions (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min/ max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL, HU, RO, SK	Sugar Beet (BEAVA) Fodder Beet (BEAVC)	F	<i>Cercospora beticola</i> (CER- CBE) <i>Uromyces betae</i> (UROMBE) <i>Erysiphe betae</i> (ERYSBE) <i>Ramularia beticola</i> (RAMUBE)	Trac- tor moun- ted spray	BBCH 39-49	a) 2 <sup>+</sup> b) 2	21	a) 1.5 L/ha b) 3 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 150 Fenpicoxamid + 300 Prothioconazole	150- 300	21	Range 1.2- 1.5 L/ha	<div>A BEAVA: CERCBE, RAMUBE</div> <div>N BEAVA: UROMBE BEAVC: CERCBE, UROMBE, ERYSBE, RAMUBE Possible authorization on the grounds of article 51</div> <div>R BEAVA: ERYSBE ***</div>
2	HU	Sugar Beet (BEAVA) Fodder Beet (BEAVC)	F	<i>Cercospora beticola</i> (CER- CBE) <i>Uromyces betae</i> (UROMBE) <i>Erysiphe betae</i> (ERYSBE) <i>Ramularia beticola</i> (RAMUBE)	Trac- tor moun- ted spray	BBCH 39-49	a) 2 <sup>+</sup> b) 2	21	a) 1.5 L/ha b) 3 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 150 Fenpicoxamid + 300 Prothioconazole	150- 300	21	Range 1.2- 1.5 L/ha	<div>A BEAVA: CERCBE</div> <div>C BEAVA: UROMBE, ERSYBE, RAMUBE BEAVC: CERCBE, UROMBE, ERYSBE, RAMUBE</div>
3	RO	Sugar Beet (BEAVA) Fodder Beet (BEAVC)	F	<i>Cercospora beticola</i> (CER- CBE) <i>Uromyces betae</i> (UROMBE) <i>Erysiphe betae</i> (ERYSBE) <i>Ramularia beticola</i> (RAMUBE)	Trac- tor moun- ted spray	BBCH 39-49	a) 2 <sup>+</sup> b) 2	21	a) 1.5 L/ha b) 3 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 150 Fenpicoxamid + 300 Prothioconazole	150- 300	21	Range 1.2- 1.5 L/ha	<div>A BEAVA: CERCBE</div> <div>C BEAVA: UROMBE, ERSYBE, RAMUBE BEAVC:</div>

														CERCBE, UROMBE, ERYSB, RAMUBE
4	SK	Sugar Beet (BEAVA) Fodder Beet (BEAVC)	F	<i>Cercospora beticola</i> (CER-CBE) <i>Uromyces betae</i> (UROMBE) <i>Erysiphe betae</i> (ERYSB) <i>Ramularia beticola</i> (RAMUBE)	Tractor mounted spray	BBCH 39-49	a) 2+ b) 2	21	a) 1.5 L/ha b) 3 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 150 Fenpicoxamid + 300 Prothioconazole	150-300	21	Range 1.2-1.5 L/ha	<div>A BEAVA: CERCBE</div> <div>C BEAVA: UROMBE, ERYSB, RAMUBE BEAVC: CERCBE, UROMBE, ERYSB, RAMUBE</div>
25	BE, CZ, AT, NL	Sugar Beet (BEAVA) Fodder Beet (BEAVC)	F	<i>Cercospora beticola</i> (CER-CBE) <i>Uromyces betae</i> (UROMBE) <i>Erysiphe betae</i> (ERYSB) <i>Ramularia beticola</i> (RAMUBE)	Tractor mounted spray	BBCH 39-49	a) 2+ b) 2	21	a) 1.5 L/ha b) 3 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 150 Fenpicoxamid + 300 Prothioconazole	150-300	21	-	<div>A BEAVA: CERCBE, UROMBE, ERYSB, RAMUBE</div> <div>C BEAVC: CERCBE, UROMBE, ERYSB, RAMUBE</div>
6	CZ	Sugar Beet (BEAVA) Fodder Beet (BEAVC)	F	<i>Cercospora beticola</i> (CER-CBE) <i>Uromyces betae</i> (UROMBE) <i>Erysiphe betae</i> (ERYSB) <i>Ramularia beticola</i> (RAMUBE)	Tractor mounted spray	BBCH 39-49	a) 2+ b) 2	21	a) 1.5 L/ha b) 3 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 150 Fenpicoxamid + 300 Prothioconazole	150-300	21	-	<div>A BEAVA: CERCBE, UROMBE, ERYSB, RAMUBE</div> <div>C BEAVC: CERCBE, UROMBE, ERYSB, RAMUBE</div>
7	AT	Sugar Beet (BEAVA) Fodder Beet (BEAVC)	F	<i>Cercospora beticola</i> (CER-CBE) <i>Uromyces betae</i> (UROMBE) <i>Erysiphe betae</i> (ERYSB) <i>Ramularia beticola</i> (RAMUBE)	Tractor mounted spray	BBCH 39-49	a) 2+ b) 2	21	a) 1.5 L/ha b) 3 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 150 Fenpicoxamid + 300 Prothioconazole	150-300	21	-	<div>A BEAVA, BEAVC: CERCBE, UROMBE, ERYSB, RAMUBE</div>
8	NL	Sugar Beet (BEAVA) Fodder Beet (BEAVC)	F	<i>Cercospora beticola</i> (CER-CBE) <i>Uromyces betae</i> (UROMBE) <i>Erysiphe betae</i> (ERYSB) <i>Ramularia beticola</i> (RAMUBE)	Tractor mounted spray	BBCH 39-49	a) 2+ b) 2	21	a) 1.5 L/ha b) 3 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 150 Fenpicoxamid + 300 Prothioconazole	150-300	21	-	<div>A BEAVA, BEAVC: CERCBE, UROMBE, ERYSB, RAMUBE</div>

\* 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

\*\*\* Final decision is left at the Authority discretion – for details, see point 5 part A

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

#### Comments of zRMS – to the GAP table:

##### Additional note on blue markings in GAP table

Please note, that where a particular use is marked blue in the GAP table, it means that taking individual decision on that use by the respective cMS is welcome. It should not be meant as an off-loading, of the decision-taking, by the zRMS onto the cMS. Instead, it aims at allowing the cMSs to take decisions different from that taken by zRMS for their own country, in recognition of the cMSs` different national requirements or preferences. Bearing that in mind, zRMS has discussed, in the commenting boxes, any doubtful issues, highlighting positive efficacy results where relevant, while also sharing with cMSs the reasons for which taking different decisions may be justified in different EPPO zones.

In case of the **draft** Registration Report there is still time for any of the cMS to express their view, and argue in favour or against the authorization in their country. That is why the zRMS is kindly asking the cMSs to not only take their decisions, but also to **share** the underlying information with the zRMS PL, within the commenting period framework. Only then will the zRMS be able to complete the GAP table unambiguously, in the **final Registration Report**, for all the EPPO zones and for all the concerned Member States, for which the present dossier has been submitted.

## 3.2 Efficacy data (KCP 6)

### Introduction

This document summarises the information related to the efficacy data of the plant protection product GF-3307 (S7K-3-3) containing the active substances fenpicoxamid + prothioconazole for the control of foliar diseases *Cercospora beticola*, *Uromyces betae*, *Erysiphe betae* and *Ramularia beticola* in sugar beet/fodder beet crops at a maximal dose rate of 1.5 L/ha.

GF-3307 (S7K-3-3) is as an emulsifiable concentrate (EC) containing 50 grams per litre (g/L) fenpicoxamid and 100 grams per litre (g/L) prothioconazole. The dossier for approval of fenpicoxamid under Regulation EC 1007/2009 was submitted in December 2014 to the RMS (UK), the coRMS (France) and then to all EU Member States; GF-2925 (130 g/L DE-777, SC) was the representative formulation. Active substance approval for fenpicoxamid was given in October 2018. Active substance approval for prothioconazole was given in August 2008.

Dossiers for the control of a range of diseases in wheat, triticale and rye at a dose rate range of 1.2 and up to 2.0 L/ha has been submitted previously to Central registration zone countries for this formulation and authorisation granted under the tradename Univoq or Queen. Member states where Univoq are currently registered for use in wheat, triticale and rye are Austria, Belgium and The Netherlands where extension of use is sought in sugar beet. Queen is registered for use in wheat, triticale and rye in Czech Republic, Hungary, Slovakia and is currently under registration process in Romania where extension of use is sought in sugar beet. Queen is registered in Poland for use in winter and spring wheat, triticale and rye under registration number R-140/2023.

This document supports submission for use extension of the formulation GF-3307 (S7K-3-3) on sugar beet/fodder beet in Central registration zone. zRMS in charge of this request is Poland with Austria, Belgium, Czech Republic, Hungary, The Netherlands, Romania and Slovakia being concerned MS by this request. Corteva wish to register a maximum of two applications of this dual active product as part of a robust resistance management strategy which will offer the highest levels of broad spectrum control of sugar beet/fodder beet diseases as part of a spray program integrated with other products along side good cultural control strategies and IPM.

The concise summary is located in the following report: Part B, Section 3 (Efficacy Data and Information) of the draft registration report (dRR) for GF-3307 (S7K-3-3). The data presented in this BAD fully support label claims for the use of GF-3307 (S7K-3-3) for the control of foliar diseases *Cercospora beticola*, *Uromyces betae*, *Erysiphe betae* and *Ramularia beticola* in sugar beet/fodder beet crops.

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-3307 (S7K-3-3)

GF-3307 (S7K-3-3) contains fenpicoxamid (XDE-777) which is a potent naturally derived novel fungicide active with translaminar properties and prothioconazole which is a broad-spectrum synthetic fungicide produced by Bayer CropScience of the triazolinthione family of compounds with curative, preventative with translaminar and systemic action. Fenpicoxamid is a new active substance for use on sugar beet. No product containing prothioconazole is currently registered against foliar diseases of sugar beet in Poland, Belgium, Hungary, The Netherlands and Romania, except in Czech Republic where Prothioconazole is in mixture with Fluopyram (Propulse #4912-1). However, prothioconazole is a component of many products registered for several years on other crops including cereals for use for control of a wide range of diseases in the Central regulatory zone.

Fenpicoxamid will be a novel target site fungicide in the sugar beet crops segment (assigned to FRAC group C4 #21) and does not show target site based cross resistance to any of the current commercial fungicides. 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 available in the future for control of foliar diseases in sugar beet, especially *Cercospora beticola*.

Fenpicoxamid is derived from a natural product, UK-2A, produced by a soil dwelling *Streptomyces* species belonging to the phylum Actinobacteria. The original strain was isolated from a soil sample collected at Osaka University in Japan. In the manufacturing of fenpicoxamid, UK-2A is first produced

through a conventional fermentation process within a contained bioreactor. Afterward, a single (and reversible) chemical modification step is added to enhance molecule stability and performance in the field, without changing the active function of the natural substance. The fact that fenpicoxamid converts exactly back to the natural product UK-2A in the presence of carboxylase enzymes released by fungi and in plants makes the product a potential bio-control/bio-stimulant partner solution for growers going forwards.

Fenpicoxamid will bring a significant benefit for sugar beet growers as it is a new active substance of natural origin offering a novel target site with no cross resistance to current chemistries that will complement prothioconazole as another new addition for sugar beet growers for control of diseases.

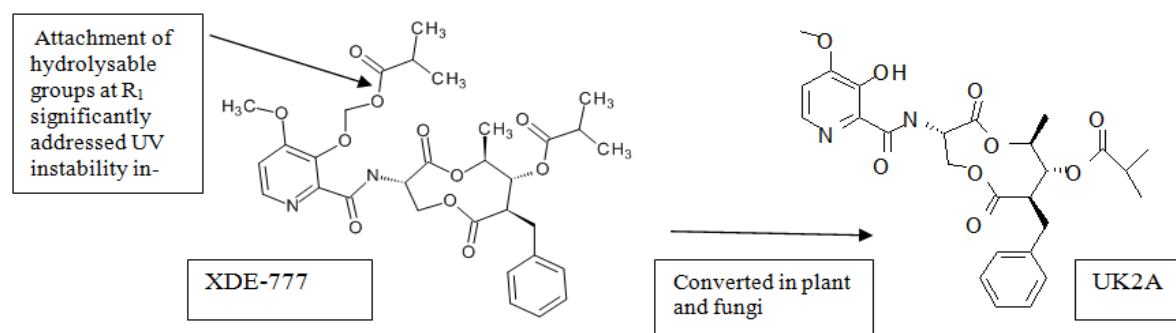
Prothioconazole is a new active ingredient for controlling sugar beet diseases in Poland, Belgium, Hungary, The Netherlands and Romania and will also offer a new triazole option for growers combined with Fenpicoxamid for control of sugar beet diseases. After absorption, prothioconazole moves into cells of the target organisms, affecting sterol biosynthesis and thereby disrupting membrane structure. This ultimately affects hyphal growth and germ tube elongation. Prothioconazole is sold in combination with numerous other fungicides, including bixafen, spiroxamine, tebuconazole, fluoxastrobin, trifloxystrobin and fluopyram. Prothioconazole is one of the most effective triazole fungicides used in crop protection. GF-3307 (S7K-3-3) will be a vital tool for growers to manage foliar diseases complex in sugar beet crops in the next decade and especially at a period where there is limited grower choice as a result of existing fungicide solutions exiting the market as a result of regulatory restrictions and when resistance to some existing solutions may be an issue for some diseases. The maximum single dose is 1.5 L/ha though for benefit of growers where they may not be able to legally reduce the label dose under lower disease pressure situations such as in the South East EPPO Zone then a dose range of 1.2-1.5 L/ha is proposed. The proposed dose range of 1.2-1.5 in Poland, Hungary, Romania and Slovakia is proposed for continuity of understanding for the grower as it matches the already registered doses (proposed in Romania) for use in wheat, rye and triticale.

### **Description of active substances**

The active substance fenpicoxamid (early stage coded X772777, XDE-777 and DE-777) belongs to a proposed new family of Picolinamide type fungicides. Fenpicoxamid is based on the natural-product UK-2A which 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 pursue both synthetic and semi-synthetic approaches for introducing structural variation in the UK-2A molecule. Finally, the semi synthetic approach was found to be most stable and successful approach to improve UV stability.

At manufacturing, through a single synthetic step, UK-2A is converted to fenpicoxamid. When fenpicoxamid is applied to the plant it is photostable on the leaf surface. Only in the presence of fungi on the outside of the plant is fenpicoxamid rapidly activated to UK-2A (see Figure 3.2-1) and becomes a potent inhibitor of mitochondrial electron transport and consequently fungal respiration. Conversely, when fenpicoxamid disperses inside the leaf it is also rapidly converted to UK-2A and so becomes a potent fungicide inside the leaf. It is thought that carboxylase enzymes released by the fungus and inside the plant, promote conversion of fenpicoxamid to UK-2A, though further detailed studies are ongoing.

**Figure 3.2-1: Sites of structural modification to UK-2A to make fenpicoxamid**



## Mode of action

### Fenpicoxamid

Fenpicoxamid when formulated as an EC formulation (as in GF-3307) (S7K-3-3) is a protectant and curative fungicide for control of a range of diseases. Fenpicoxamid is rapidly activated in the presence of fungi and inside 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 Q<sub>i</sub> 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 sugar beet 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 Q<sub>o</sub> and Q<sub>i</sub> sites. The Q<sub>o</sub> site is the target site of the strobilurin fungicides, which include many commercial products. Inhibitors of the Q<sub>i</sub> 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.

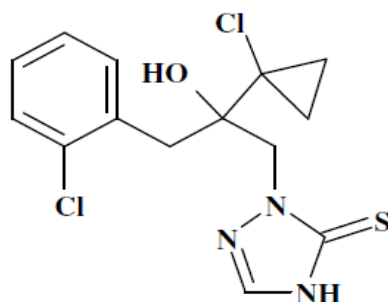
The MET III Q<sub>i</sub> site is quite distinct from the MET III Q<sub>o</sub> site with which the strobilurins interact, so that no cross-resistance of field isolates of *Cercospora beticola* resistant to strobilurin fungicides has been observed or would be anticipated.

### Prothioconazole

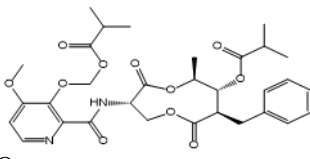
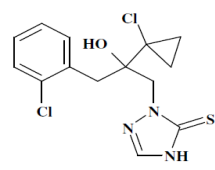
Prothioconazole is a broad-spectrum synthetic fungicide produced by Bayer CropScience of the triazolinthione family of compounds with curative, preventative and eradicated action. The mode of action of prothioconazole is as a Sterol Biosynthesis Inhibitor (SBI) class 1 DeMethylation Inhibitors (DMI) and it is classified in FRAC group G1. It can be used as both a seed treatment and a foliar treatment. After absorption it moves into cells of the target organisms, effecting sterol biosynthesis and thereby disrupting membrane structure. This ultimately effects hyphal growth and germ tube elongation. Fungi susceptible to prothioconazole include diseases caused by ascomycetes, basidiomycetes and deuteromycetes. Prothioconazole is currently authorised across the EU for use on a range of cereal crops and in sugar beet in some countries. Prothioconazole is sold in combination with numerous other fungicides, including bixafen, spiroxamine, tebuconazole, fluoxastrobin, trifloxystrobin and fluopyram. Prothioconazole is one of the strongest triazole fungicides used in crop protection. Although there have been some shifts in triazole sensitivity to a number of diseases in the last decade, prothioconazole is still highly effective against these diseases in many countries. Prothioconazole is especially beneficial in mixture with strong partners and brings as a mix partner, robust activity against a wide range of diseases where reduced sensitivity is not an issue for triazole fungicides. It will be a new azole active ingredient for sugar beet diseases in Central registration zone and will fully complement fenpicoxamid which is also a new active ingredient for use in sugar beet crops.



**Figure 3.2-2: Structural formula of prothioconazole**



**Table 3.2-1: Details of the active substances**

Active substance	Fenpicoxamid	Prothioconazole
Concentration (Unit: g/kg or g/L....)	50 g/L	100 g/L
Chemical group	Picolinamide	Triazolinthione
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	2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1H-1,2,4-triazole-3-thione
Active brand name	Inatreq™ active	Proline
ISO common name	Fenpicoxamid	Prothioconazole
CAS number	517875-34-2	178928-70-6
Molar weight g/mol	614.64	344.2594
Structural formula	 $C_{31}H_{38}N_2O_{11}$	
Mode of action	FRAC group C4#21 Inhibition of respiration at complex III (Qil fungicides)	FRAC group G1 Sterol Biosynthesis Inhibitor (SBI) class 1 DeMethylation Inhibitors (DMI)
Biological action	Curative and Protectant foliar fungicide, contact/residual with translaminar properties for use on sugar beet. When sprayed onto foliage/flowers it provides long lasting protection against disease.	

### Description of the plant protection product

GF-3307 (S7K-3-3) is an emulsifiable concentrate (EC) containing 50 g/L fenpicoxamid + 100 g/L prothioconazole. The data presented in this dossier are intended to support the label claim for GF-3307 (S7K-3-3) for the control of *Cercospora beticola* (CERCBE), *Uromyces betae* (UROMBE), *Erysiphe betae* (ERYSBE) and *Ramularia beticola* (RAMUBE) in sugar beet crops. For the control of CERCBE, UROMBE, ERYsBE and RAMUBE GF-3307 (S7K-3-3) acts as a protectant and is applied during BBCH 39-49, which is the main infection period and can last over 2-3 months.

**Table 3.2-2: Simplified table of requested uses for the product GF-3307 (S7K-3-3).**

Uses		Member State/Country	Requested individual dose rate	Comments / Other relevant details on GAPs
Crop(s)	Target(s)			
Sugar beet (BEAVA)	CERCBE	AT, BE, CZ, NL	1.5 L/ha	Two applications between BBCH 39-49
	UROMBE ERYSBE RAMUBE	PL, HU, RO, SK	1.2-1.5 L/ha	

Uses		Member State/Country	Requested individual dose rate	Comments / Other relevant details on GAPs
Crop(s)	Target(s)			
Fodder beet (BEAVC)	CERCBE	AT, BE, CZ, NL	1.5 L/ha	Two applications between BBCH 39-49
	UROMBE ERYSBE RAMUBE	PL, HU, RO, SK	1.2-1.5 L/ha	

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

### Description of the target pests

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

EPPO code	Scientific name	Common name (English)
CERCBE	<i>Cercospora beticola</i>	Leaf spot of beet (UK)
UROMBE	<i>Uromyces betae</i>	Rust of beet (UK)
ERYSBE	<i>Erysiphe betae</i>	Powdery mildew of beet (UK)
RAMUBE	<i>Ramularia beticola</i>	Ramularia leaf spot (UK)

#### **Cercospora beticola - CERCBE**

Leaf spot disease caused by *Cercospora beticola* (ascomycete fungus) is the most destructive foliar pathogen of sugar beet worldwide.

The disease appears as small round grey spots with reddish margins. Under humid conditions black spots can appear through the stomata, which help to distinguish the disease from *Ramularia*. It usually appears early in the season and can spread if temperature and humidity are both high. Although *Cercospora beticola* develops above 17°C, it requires daytime temperatures of 25°C or greater and high humidity (superior to 60%) for rapid spread.

In hot areas of the world where there are frequent storms or irrigation is used, *Cercospora beticola* can cause severe damage resulting in 50% loss of yield or more. *Cercospora beticola* usually over - winters as spores on old leaves and debris but, unlike powdery mildew, survival is not reduced by cold winters.

#### **Uromyces betae - UROMBE**

*Uromyces betae* (basidiomycete fungus) infection appears on both sides of the leaves as small - circa 1 to 2 mm diameter - raised pustules that are red - orange or brown in colour. When infection is severe, spores will brush off onto animals, machinery and the clothing of people passing through the crop. Disease spread occurs during periods of moist weather when temperatures are between 15 and 20°C and is most intense when dew persists for long periods. Development of the disease is halted by warm, dry weather leaving yellow sunken spots on the leaves. Rust over - winters on dead leaf tissue, crowns or wild relatives of sugar beet. The disease is most prevalent under the optimal conditions in more temperate areas of Maritime Europe (UK, Denmark, Germany). Rust over - winters on dead leaf tissue, crowns or wild relatives of sugar beet.

Heavy infections in mid to late August have been shown to reduce yields by 10% or more. Recent experiences suggest that frost is likely to cause greater damage when foliage is infected with rust than with powdery mildew.

#### **Erysiphe betae - ERYSB**

Infection is characterised by the white powdery covering of leaves by mycelia and spores. Older leaves tend to be infected first and symptoms are more prevalent on the upper rather than lower leaf surfaces. After a while the leaves turn yellow and die.

Yield reductions from *Erysiphe betae* (ascomycete fungus) can be 20% or more as a result of reduced photosynthesis and early leaf senescence. Growth of the fungus is favoured by high temperatures - around 25°C - with dew at night. The disease overwinters on host plants such as beet crowns and wild beet species such as sea beet, but the level of survival is very much dependent on the severity of the winter. Depending upon the weather, powdery mildew usually appears in late July or early August but can develop in early to mid July after a mild winter and with favourable summer conditions.

### **Ramularia beticola - RAMUBE**

*Ramularia beticola* (ascomycete fungus) appears first on older leaves as brownish grey spots with dark edges. Under a microscope or powerful lens, small white spots can be seen emerging through the stomata. Under humid conditions, similar looking spots occur on *Cercospora* infected leaves but are distinguished from *Ramularia* by their black colour. *Ramularia beticola* prefers cooler conditions than powdery mildew - around 17°C - and infection only occurs when relative humidity exceeds 95% so it is mainly observed from September onwards.

It seldom causes significant yield losses unless it is so severe that leaves are lost and new ones grow using up accumulated energy from the root. It is thought to overwinter on crop debris.

### **Description of the crops**

Table 3.2-4 present the details of the production area used in concerned members states.

**Table 3.2-4: Production area used for sugar beet and beetroot crop in Central registration zone 2023 (Eurostat)**

Country	Sugar beet (excluding seed)	
	Production area (1000 ha)	Production (1000 t)
Austria	35.68	2 675.69
Belgium	55.34	4 812.87
Czech Republic	58.80	3 833.87
Hungary	14.38	833.70
Netherlands	80.44	6 942.51
Poland	260.76	15 972.78
Romania	12.90	427.09
Slovakia	21.89	1 326.05

**Table 3.2-5: Major/minor status of intended uses**

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	Minor		Major	Minor
Sugar beet (BEAVA)	AT - BE - CZ - HU - PL - RO - SK - NL	-	CERCBE	AT - BE - CZ - HU - PL - RO - SK - NL	-
			UROMBE	AT - BE - CZ - RO - NL	HU - PL - SK
			ERYSBE	AT - BE - CZ - <del>PL</del> - RO - SL - NL	HU - <del>PL</del>
			RAMUBE	AT - BE - SK - NL - <del>PL</del>	CZ - HU - <del>PL</del> - RO
Fodder beet (BEAVC)	BE	AT - CZ - HU - PL - RO - SK - NL	CERCBE	BE - CZ - SK - PL	AT - HU - RO - NL
			UROMBE	BE - CZ	AT - HU - PL - RO - SK - NL
			ERYSBE	BE - CZ - <del>PL</del>	AT - HU - <del>PL</del> - RO - SK - NL
			RAMUBE	BE - CZ - <del>PL</del>	AT - HU - <del>PL</del> - RO - SK - NL

### **Compliance with the Uniform Principles**

This dossier supplied is 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 1107/2009. 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 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 sugar beet is commercially grown and where the diseases under investigation are abundant. The primary guidelines used were the following:

- PP 1/1 Foliar diseases on sugar beet
- 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 1/223 Introduction to the efficacy evaluation of plant protection products

#### **Justification for the use of data from other countries/zones**

Data for GF-3307 (S7K-3-3) Biological Assessment Dossier is summarised by EPPO PP 1/241(1) defined zones. The zones have been defined on the basis of comparable climates in the form of a 'Climatic Justification' paper as approved by EPPO and found within the standard PP 1/241(1), thus the issue of climatic differences need not be addressed within this dossier. According to EPPO PP 1/241(1) zones, the Central registration zone is composed of 3 EPPO climatic zones: Maritime, North-East and South-East zones.

Data from the Northern registration zone (Lithuania and Poland) was used in this dossier to support Poland (Northeast EPPO zone) where sugar beet is predominantly grown. Data from neighbouring countries including Germany and Czech Republic are also provided as acceptable supportive data for Poland.

Trials were performed in Denmark and Lithuania, belonging to the Maritime and Northeast EPPO climatic zones according to EPPO PP 1/241(1) 'Guidance on comparable climates'. As well, data from the United-Kingdom belonging to the Maritime EPPO climatic zone are also used. Data from Maritime EPPO climatic zone from France in sugar beet (representation from Southern registration zone) have been also used in this BAD for GF-3307 (S7K-3-3) as they represent high disease pressure situations.

This use has been considered possible by the division of biological data into three regions i.e. North, Central and South Europe based on data comparability between Member states as it is indicated in the Annex III of Directive 93/71/EEC. The following justifications are presented:

Disease presented are common throughout Europe. Although trials were performed in different countries, sites were selected with known pest populations in order to exert maximum control pressure and to exacerbate treatment differences. No difference in disease susceptibility is apparent from the control levels achieved between the efficacy data presented for each country within the zonal regions presented.

Similar trial methodologies were used in all countries. All trials are in compliance with GEP and were undertaken by official or officially recognised testing facilities in accordance with the relevant EPPO guidelines. Furthermore, identical methods of assessment for efficacy and crop tolerance were employed.

Agronomic practices for the growing of sugar beet are similar between countries. Levels of inorganic fertilisers and other crop inputs are also similar. Trials were performed in the major sugar beet growing areas in each respective country. These areas have been found to be particularly suitable for sugar beets production due to their innate similarity in terms of soil type and climate.

In recent years, *Cercospora beticola* (CERCBE) has become more prevalent in Europe and has become the most destructive foliar pathogen of sugar beet. It is widely present in most beet-growing regions and can cause major yield losses if not properly controlled. This disease usually appears early in the season and is most severe in wet and warm areas in case of very early attack. Data are presented from all climatic zones for this disease and reflect the full range of climatic conditions across the Central registration zone.

Data presented on *Uromyces betae* (UROMBE) is from Maritime zone from France, Germany, UK and Denmark and fully support the registration of Univoq/Queen for control of UROMBE in Central registration zone. In fact, the United-Kingdom and Denmark present high risk situations for UROMBE as *Cercospora beticola* is less prevalent. It is proposed that data on UROMBE from Maritime countries would support countries in the North East and South East where this disease is less prevalent as a result of warmer summer climate. Additional data is presented from Maritime countries for control of *Ramularia beticola* (RAMUBE) and *Erysiphe betae* (ERYSBE) which fully support Central registration zone where these are major diseases.

### Information on trials submitted (3.1 Efficacy data)

Data to confirm efficacy claims for applications of GF-3307 (S7K-3-3) were taken from a set of 33 efficacy trials carried out from 2020 to 2023 including 1 trial in Austria, 1 trial in Czech Republic, 15 trials in Germany, 6 trials in Poland, 6 trials in Hungary and 4 trials in Romania for the Central registration zone.

In addition, to complete the data package, 23 efficacy trials performed from 2020 to 2023 in the Maritime and Northeast EPPO climatic zones (as defined by EPPO standard PP 1/241(2)) from Southern and Northern registration zone (Denmark (6), France (8), The United-Kingdom (7) and Lithuania (2)) are also provided, as the United-Kingdom and Denmark present high risk situations for UROMBE as *Cercospora* is less prevalent.

The trials were undertaken by contractors' test facilities, all of which follow the EPPO guidelines and have Official Recognition status for undertaking efficacy trials in accordance with the principles of Good Experimental Practice (GEP). Some trials had more than one disease present.

The following table provides an overview of submitted trials to evaluate the efficacy of GF-3307 (S7K-3-3). The number of trials is summarised in

Table 3.2-6 and detailed in Table 3.2-7. The locations of trials is detailed in Figure 3.2 - 3.

All trials were carried out by Dow AgroSciences/Corteva Agriscience or officially recognised contract research organisations in accordance with the principles of Good Experimental Practice (Table 3.7-1).

**Table 3.2-6: Presentation of Preliminary, MED and efficacy trials**

Crop(s) <sup>(1)</sup>	Target(s) <sup>(1)</sup>	Country	Years	Type of trial <sup>(2)</sup>	Number of valid trials			GEP, non-GEP, official <sup>(4)</sup>
					Maritime Zone <sup>(3)</sup>	Northeast zone <sup>(3)</sup>	Southeast zone <sup>(3)</sup>	
Sugar beet (BEAVA)	CERCBE	Czech Republic	2023	P + MED + E + Y + Q + S	1	-	-	GEP
		France	2020	E + S	2	-	-	GEP
			2021	E + S	1	-	-	GEP
			2022	P + MED + E + S	3	-	-	GEP
				P + MED + E + Y + Q + S	1	-	-	GEP
		Germany	2020	E + S	1			GEP
				P + MED + E + S	3	-		GEP
			2021	E + S	1			GEP
				MED + E + S	2			GEP
			2022	P + MED + E + S	3	-		GEP
				P + MED + E + Y + Q + S	1	-		GEP
			2023	MED + E + S	1			GEP
				P + MED + E + S	2	-		GEP
			P + MED + E + Y + Q + S	1	-		GEP	
			Hungary	2020	E + S	-	-	2
		2023		P + MED + E + S	-	-	1	GEP
				P + MED + E + Y + Q + S	-	-	3	GEP
		Lithuania	2023	P + MED + E + S	-	1	-	GEP
				P + MED + E + Y + Q + S	-	1	-	GEP
		Poland	2020	E + S	-	1	-	GEP
				E + Y + Q + S	-	1	-	GEP
			2021	E + S	-	1	-	GEP
				P + MED + E + S	-	1	-	GEP
		Romania	2020	P + MED + E + Y + Q + S	-	2	-	GEP
				E + Y + S	-	-	1	GEP
			2023	E + Y + Q + S	-	-	1	GEP
				P + MED + E + Y + S	-	-	2	GEP
		United-Kingdom	2023	P + MED + E + S	1	-	-	GEP
		TOTAL	-	2020-2023	-	24	8	10
	UROMBE	France	2020	E + S	1	-	-	GEP
			2022	P + MED + E + S	2	-	-	GEP
		Germany	2022	MED + E + S	1	-	-	GEP
		Denmark	2020	E + Y + Q + S	2	-	-	GEP
			2022	P + MED + E + S	1	-	-	GEP
				P + MED + E + Y + Q + S	1	-	-	GEP

Crop(s) <sup>(1)</sup>	Target(s) (1)	Country	Years	Type of trial <sup>(2)</sup>	Number of valid trials			GEP, non-GEP, official <sup>(4)</sup>
					Maritime Zone <sup>(3)</sup>	Northeast zone <sup>(3)</sup>	Southeast zone <sup>(3)</sup>	
		United-Kingdom	2023	P + MED + E + Y + Q + S	2	-	-	GEP
			2020	E + Y + S	2	-	-	GEP
			2023	P + MED + E + S	4	-	-	GEP
		<b>TOTAL</b>	<b>2020-2023</b>	<b>-</b>	<b>16</b>	<b>-</b>		<b>GEP</b>
	ERYSBE	Austria	2023	MED + E + S	1	-	-	GEP
			2020	E + S	1			GEP
		France	2021	E + S	1			GEP
			2020	E + S	1	-		GEP
		Germany	2022	P + MED + E + S	1	-		GEP
			2023	MED + E + S	1	-		GEP
			2020	P + MED + E + Y + Q + S	1	-		GEP
			2022	P + MED + E + S	1	-		GEP
		Denmark	2020	E + Y + Q + S	2	-		GEP
			2022	P + MED + E + Y + Q + S	1	-		GEP
		United-Kingdom	2022	MED + E + S	1	-		GEP
	<b>TOTAL</b>	<b>-</b>	<b>2020-2023</b>	<b>-</b>	<b>12</b>	<b>-</b>		<b>GEP</b>
	RAMUBE	Germany	2020	E + S	1	-	-	GEP
			2021	P + MED + E + S	3	-	-	GEP
			2021	E + S	1	-	-	GEP
		Denmark	2022	P + MED + E + S	1	-		GEP
		Poland	2023	P + MED + E + Y + Q + S	-	1	-	GEP
	<b>TOTAL</b>	<b>-</b>	<b>2020-2023</b>	<b>-</b>	<b>8</b>	<b>1</b>		<b>GEP</b>

<sup>(1)</sup> According to the GAP table.

<sup>(2)</sup> P = Efficacy trials used in preliminary part - MED = Efficacy trials used in Minimum effective dose - E = Efficacy trial - S = Phytotoxicity assessments - Y = Harvested trial - Q = Quality parameters measures (Sodium content, potassium content, amino nitrogen content and sugar content in%).

<sup>(3)</sup> According to EPPO guideline PP 1/241(1) "Guidance on comparable climates".

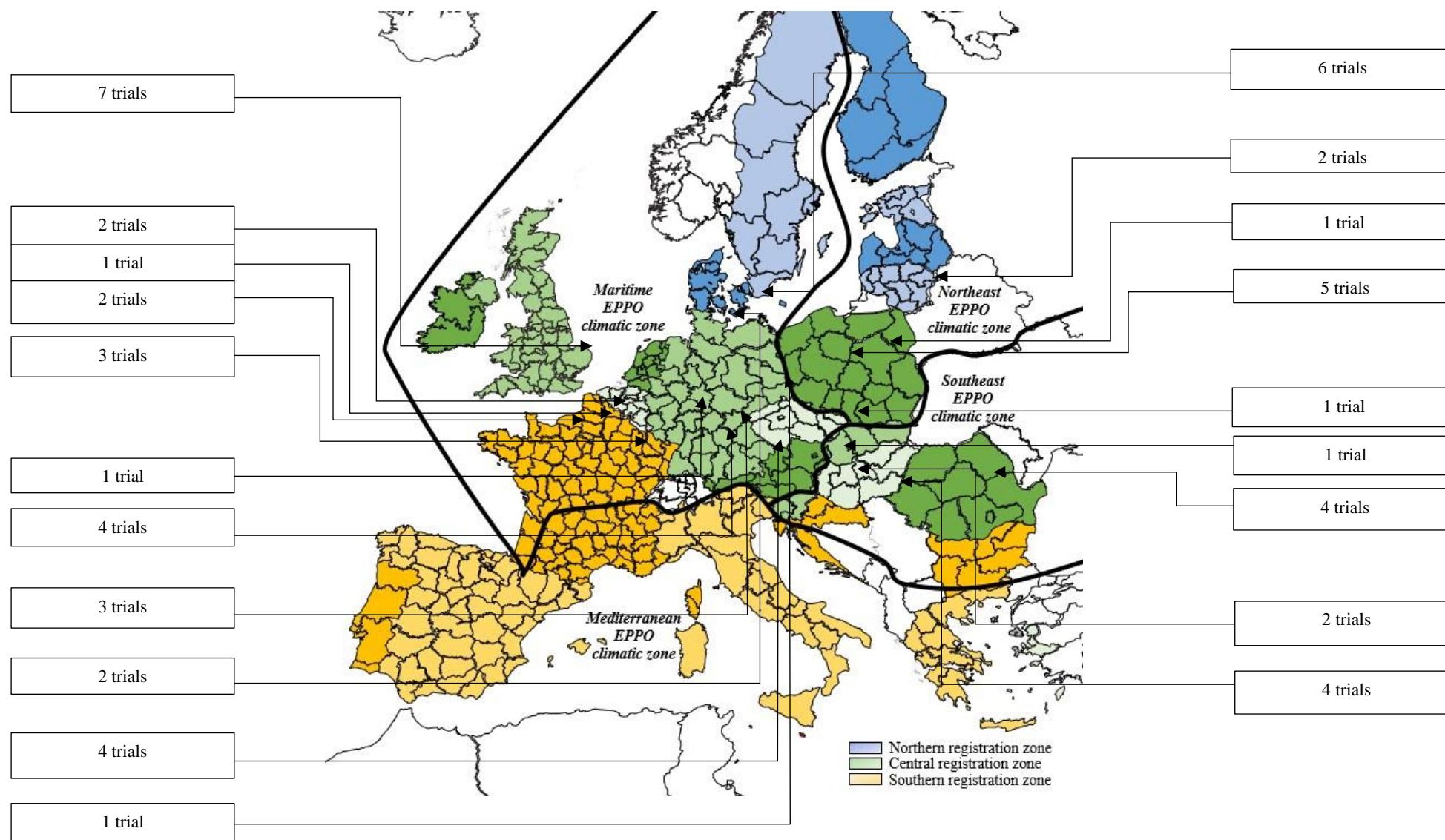
<sup>(4)</sup> GEP: Good Experimental Practices. Official: carried out by a national official organisation.

**Table 3.2-7 Presentation of trials - 56 Efficacy trials - Sugar beet**

Crop(s) <sup>(1)</sup>	Target(s) <sup>(1)</sup>	Type of trial <sup>(2)</sup>	Registration zone	EPPO climatic zone <sup>(3)</sup>	Year	Number of trials	GEP, non-GEP, official <sup>(4)</sup>
BEAVA	CERCBE + UROMBE + ERYSB E + S	E + S	Central	Maritime	2020-2021	2 trials	-
				Northeast	2020-2021	2 trials	-
				Southeast	2020	2 trials	-
			Southern	Maritime	2020-2021	4 trials	-
			All	All	2020-2021	10 trials	-
		E + Y + S	Central	Southeast	2020	1 trial	-
			-	Maritime	2020	2 trials	-
			All	All	2020	3 trials	-
		E + Y + Q + S	Northern	Maritime	2020	2 trials	-
			Central	Northeast	2020	1 trial	-
				Southeast	2020	1 trial	-
			All	All	2020	4 trials	-
		MED + E + S	Central	Maritime	2022-2023	4 trials	-
			-	Maritime	2022	1 trial	-
			All	Maritime	2022	5 trials	-
		P + MED + E + S	Central	Maritime	2020-2022-2023	8 trials	-
				Northeast	2023	1 trial	-
				Southeast	2023	1 trial	-
			Northern	Maritime	2022	1 trial	-
				Northeast	2023	1 trial	-
			Southern	Maritime	2022	3 trials	-
			-	Maritime	2023	4 trials	-
			All	Maritime	2020-2023	19 trials	-
		P + MED + E + Y + S	Central	Northeast	2023	1 trial	-
				Southeast	2023	2 trials	-
			All	All	2023	3 trials	-
		P + MED + E + Y + Q + S	Central	Maritime	2022-2023	2 trials	-
				Northeast	2023	2 trials	-
				Southeast	2023	3 trials	-
			Northern	Maritime	2022-2023	3 trials	-
			Southern	Maritime	2022	1 trial	-
			All	All	2022-2023	12 trials	-

<sup>(1)</sup> According to the GAP table. <sup>(2)</sup> P: Efficacy trials used in Preliminary par - MED: Efficacy trials used in Minimum effective dose – E: Efficacy trial Y: Yield - Q: Quality assessment - S: Phytotoxicity assessments. <sup>(3)</sup> According to EPPO guideline PP 1/241(1) "Guidance on comparable climates". / <sup>(4)</sup> GEP: Good Experimental Practices. Official: carried out by a national official organisation.

**Figure 3.2 - 3 Location of the trial sites - Efficacy trials - Sugar beet - All diseases**





**Table 3.2-8: Presentation of reference standards used in Preliminary, MED and efficacy trials - Sugar beet**

Crop(s)	Reference standard	Country(ies) where the product is registered <sup>(1)</sup>	Authorization number	Active substance(s)	Formulation		Registered application rate <sup>(3)</sup>	Application rate in trials (per treatment)	Remark <sup>(4)</sup>
					Type <sup>(2)</sup>	Content of a.s.			
BEAVA	SCORE	AT	3255-0	difenoconazole	EC	250 g/L	0.4	0.4 L/ha	-
	SCORE	CZ	Not registered on this crop	difenoconazole	EC	250 g/L	0.4	0.4 L/ha	DAFNE 250EC similar product registered under 5274-0
	SCORE	FR	Not registered on this crop	difenoconazole	EC	250 g/L	0.5	0.4-0.5 L/ha	DIFCOR similar product registered under AMM 2060002
	SCORE	DE	Not registered on this crop	difenoconazole	EC	250 g/L	0.4	0.4-0.5 L/ha	DITTO 25EC similar product registered under 00A317-00/00-001
	SCORE	LT	Not registered on this crop	difenoconazole	EC	250 g/L	0.5	0.4 L/ha	DIFCOR similar product registered under AS2-43F(2016)
	SCORE	PL	Not registered on this crop	difenoconazole	EC	250 g/L	0.4	0.4 L/ha	DIFCOR similar product registered under R-40/2015 z dn. 23.02.2015
	SCORE	RO	Not registered on this crop	difenoconazole	EC	250 g/L	0.4	0.4 L/ha	DAFNE 250EC similar product registered under 87PC/28.02.2017
	SCORE	DK	Not registered on this crop						
	SCORE	HU	Not registered on this crop						
	SCORE	UK	Not registered on this crop						
	AMISTAR GOLD	AT	4107-0	azoxystrobin + difenoconazole	SC	125+125 g/L	1.0	1.0 L/ha	2 applications
	AMISTAR GOLD	CZ	5230-0	azoxystrobin + difenoconazole	SC	125+125 g/L	1.0	1.0 L/ha	1 application
	AMISTAR GOLD	FR	2160724	azoxystrobin + difenoconazole	SC	125+125 g/L	1.0	1.0 L/ha	2 applications
	AMISTAR GOLD	DE	008267-00	azoxystrobin + difenoconazole	SC	125+125 g/L	1.0	1.0 L/ha	2 applications
	AMISTAR GOLD	DK	1-233	azoxystrobin + difenoconazole	SC	125+125 g/L	0.5-1.0	1.0 L/ha	Max 1.0 L/ha / season
	AMISTAR GOLD	HU	6300/336-1/2021	azoxystrobin + difenoconazole	SC	125+125 g/L	1.0	1.0 L/ha	2 applications
	AMISTAR GOLD	LT	AS2-88F(2017)	azoxystrobin + difenoconazole	SC	125+125 g/L	0.75-1.0	0.5-1.0 L/ha	1 application
	AMISTAR GOLD	PL	R-13/2019wu z dn. 18.03.2019	azoxystrobin + difenoconazole	SC	125+125 g/L	1.0	1.0 L/ha	2 applications
	AMISTAR GOLD	RO	4214PC din 05.06.2018	azoxystrobin + difenoconazole	SC	125+125 g/L	1.0	1.0 L/ha	2 applications
	AMISTAR GOLD	UK	=ANGLE: 19119	azoxystrobin + difenoconazole	SC	125+125 g/L	1.0	1.0 L/ha	2 applications
	SPYRALE	FR	9300487	difenoconazole+fenpropidin	EC	100+375 g/L	1.0	1.0 L/ha	2 applications
	SPYRALE	CZ	5861-0	difenoconazole+fenpropidin	EC	100+375 g/L	1.0	1.0 L/ha	2 applications
	SPYRALE	DK	Not registered on this crop						
	SPYRALE	PL	R-230/2016 z dn. 08.12. 2016	difenoconazole+fenpropidin	EC	100+375 g/L	1.0	1.0 L/ha	2 applications
	SPYRALE	RO	611PC/30.06.2020	difenoconazole+fenpropidin	EC	100+375 g/L	0.75	1.0 L/ha	2 applications
	SPYRALE	UK	Used to be registered on sugar beet under MAPP12566 until 31/05/2016	difenoconazole+fenpropidin	EC	100+375 g/L	0.75	1.0 L/ha	2 applications

- (1) only on use(s) applied for (with the test product).  
(2) e.g. SC (suspension concentrate), EC (emulsifiable concentrate).  
(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.)

In sugar beet trials, the efficacy of GF-3307 (S7K-3-3) was compared to the efficacy of different reference standards (see Table 3.2-8). To facilitate comparison of data produced in different conditions, SCORE at 0.4 L/ha (250 g ai/L difenoconazole) has been chosen as the representative reference standard among European countries, as it was included in almost all trials and similar product and/or active substance is authorised for foliar diseases control in sugar beet in all countries (except HU, UK and DK where Amistar Gold is registered which also contains difenoconazole). In contrast, other references at its local registered rate, except for 4 trials performed in UK and DK included for minor diseases only, with different mode of action (azoxystrobin in mixture with difenoconazole in AMISTAR GOLD, fenpropidin in mixture with difenoconazole SPYRALE) were also used in efficacy trials and presented and discussed.

Some trials included other standards, but these have not been listed as they are not referenced in this dossier. This is in line with EPPO PP 1/278 *Principles of Zonal Data Production and Evaluation*.

The straight prothioconazole product Proline (250 g/L prothioconazole) has been used in the Preliminary section.

### 3.2.1 Preliminary tests (KCP 6.1)

As this is an existing fungicide formulation, containing two established fungicides in wheat, it is considered that preliminary data are not typically considered necessary. However, as this is the first use of fenpicoxamid (GF-3308) on sugar beet and prothioconazole is a new use in sugar beet in Austria, Hungary, Poland, Romania, Slovakia, Belgium and the Netherlands, except in Czech Republic, some preliminary data on the protectant and curative activity of fenpicoxamid and prothioconazole and the mixture is included. In addition, the supporting trials include both component active substance and justification for the mixture of these two active substances for control of CERCBE and UROMBE in sugar beet is also discussed in this section.

#### 3.2.1.1 Preventive and curative properties of GF-3307 (S7K-3-3) in a glasshouse test for the control of *Cercospora beticola* in sugar beet

##### Introduction

In order to obtain a better understanding of how GF-3307 (S7K-3-3) as optimized formulation of fenpicoxamid + prothioconazole compared to sugar beet (BEAVA) reference products, a series of tests were completed to evaluate the preventive (a 1-day protectant) and curative (after 2-day curative application) properties of GF-3307 (S7K-3-3) for the control of CERCBE of sugar beet.

##### Materials and Methods

A greenhouse bioassay<sup>1</sup> was conducted to characterize the efficacy of GF-3307 (S7K-3-3) for controlling *Cercospora beticola* (CERCBE) following a 1-day protectant (1 DP) application and 2 days prior (2 DC) on 21-day-old sugar beet plants. The efficacy of GF-3307 (S7K-3-3) was compared to GF-3308 (fenpicoxamid), Proline (prothioconazole), Propulse (fluopyram+prothioconazole) and Score (difenoconazole).

##### - Host Plant Cultivation:

Sugar beets (*Beta vulgaris*), variety SV333 were used to test the efficacy of Inatreq (GF-3308; fenpicoxamid) alone or co-formulated with prothioconazole against competitors for control of *Cercospora beticola* (CERCBE). Sugar beet seeds were planted in plastic pots containing artificial potting soil.

##### - Inoculation of plants:

CERCBE spores were harvested from CERCBE cultures grown on potato dextrose agar ~~in~~ PDA. One day after (1 DP) and two days prior (2 DC) to compound application, BEAVA plants were sprayed to run-off with a CERCBE spore suspension using a compressed air spray gun. The spore suspension was filtered through two layers of cheesecloth and adjusted to 20,000 spores per ml. To the final suspension, 3 drops of Tween 20/100 ml of inoculum. Inoculated plants were placed ~~in~~ ~~in~~ a dew room (100% RH,

<sup>1</sup> Karaïskou, G, Kaehler, E., 2023; Performance of Corteva™ products GF-3308 and GF-3307 (S7K-3-3) for control of *Cercospora beticola* following protectant and curative applications - Dow agrosiences internal report - October, 2023.

24°C) cycled for 48 hours. Inoculated plants were then transferred to a greenhouse with a suitable environment for disease development with hoods and plug carts into sub system for 14-16 days. Plants were evaluated for disease three weeks after inoculation (21 DAI). Percent disease severity was assessed per pot on a 0-100% scale. The percent disease control was then made relative to the untreated check. Pots were arranged in a randomized complete block design with four replications. Each application timing (1 DP and 2 DC) was treated as individual experiments. The experiments were repeated once (1 DP, 2 DC).

- Experiment design:

Each application timing consisted of 2 trials. Each trial included 26 treatments included the untreated and 4 replicates.

- Compound application:

Fungicides were applied to 3-week-old plants trimmed down to 2 newer leaves using a Generation III Research Track Sprayer (DeVries Manufacturing) using a 8003E single jet flat fan nozzle with a spray arm speed of 1.81 km/h and a spray pressure of 32 PSI. Pots of sugar beet plants were placed in the spray chamber such that their mid-canopy was 50 cm below the spray nozzle. Fungicides were delivered to wheat seedlings at various rates (Table 1) simulating a spray volume of 400 L/ha.

**Table 3.2-9: Formulations, active ingredients (a.i.), a.i. loadings (g a.i./L), and rates (g a.i./ha) of fungicides used in protectant and curative studies of GF-3308 and GF-3307 (S7K-3-3) against *Cercospora beticola* (CERCBE)**

Formulation	Active substance	g a.s./L	Rates tested g a.s./ha (L/ha)				
			75+150 225 (1.5)	62.5+125 188 (1.25)	50+100 150 (1.0)	37.5+75 120 (0.75)	25+50 75 (0.5)
GF-3307	fenpicoxamid + prothioconazole	150 (50 + 100)					
GF-3308	fenpicoxamid	50	75 (1.5)	62.5 (1.25)	50 (1.0)	37.5 (0.75)	25 (0.5)
Proline 250	prothioconazole	250	150 (0.6)	125.5 (0.52)	100 (0.4)	82.5 (0.33)	50 (0.2)
Propulse	fluopyram+prothioconazole	250 (125 +125)	150+150 300 (1.2)	125+125 250 (1.0)	100+100 200 (0.8)	82.5+82.5 165 (0.66)	50+50 100 (0.4)
Score	difenoconazole	250	125 (0.5)	62.5 (0.25)	31.3 (0.125)	15.6 (0.0625)	7.8 (0.03125)

## Results

The percentage control of *Cercospora beticola* (CERCBE) after 1-day preventive application and 2-curative days application is presented in Table 3.2-10.

**Table 3.2-10: Percentage control of *Cercospora beticola* after 1-day protectant (1 DP), and 2-curative (2 DC) application of GF-3308 and GF-3307 (S7K-3-3) at 0.5, 0.75, 1, 1.25 and 1.25 L/ha compared to competitor products. Results of two trials (n=8) for each application timing**

Products	Rate (L/ha)	Rate (g a.i./ha)	Percent (%) CERCBE control				Percent (%) CERCBE severity			
			1 DP		2 DC		1 DP		2 DC	
GF-3308 (Inatreq)	1.5	75	72	abc	75.5	bcd	20.1	abc	17.2	aAb
	1.25	62.5	66.6	abc	74.7	bcd	23.9	abc	19.7	aAb
	1	50	53.1	abc	70.6	bcd	33.5	abc	20.1	aAb
	0.75	37.5	56	abc	81.5	bcd	31.4	abc	14.9	aAb
	0.5	25	50.1	abc	57	abcd	35.6	abc	32.2	aAb
GF-3307 (S7K-3-3) (Inatreq + prothioconazole)	1.5	75+150	90.8	c	88	cd	6.6	a	9.6	aA
	1.25	62.5+125.5	89.2	c	90.2	d	7.6	a	7.4	aA
	1	50+100	85.9	bc	83.6	cd	9.9	ab	14	aAb
	0.75	37.5+82.5	82.8	bc	77.1	bcd	12.1	ab	19.5	aAb
	0.5	25+50	79.1	bc	79.2	bcd	14.9	ab	18.8	aAb
Proline 250 (prothioconazole)	0.6	150	72.4	abc	84.6	cd	19.4	abc	14.4	aAb
	0.502	125.5	66.5	abc	83.5	cd	23.7	abc	13.9	aAb
	0.4	100	63.5	abc	67.8	abcd	25.6	abc	23.5	aAb
	0.33	82.5	65.4	abc	61.4	abcd	24.5	abc	28.4	aAb
	0.2	50	53.8	abc	63.9	abcd	32.6	abc	29	aAb
Propulse (fluopyram + prothioconazole)	1.2	150+150 300	69.1	abc	82	bcd	25	abc	15.9	aAb
	1	125+125 250	73.9	abc	74.4	bcd	18.4	abc	17.1	aAb
	0.8	100+100 200	72	abc	75.8	bcd	19.8	abc	16.9	aAb
	0.66	82.5+82.5 165	63.4	abc	72.4	bcd	25.9	abc	17.8	aAb

	0.4	50+50 100	68.9	abc	63	abcd	22	abc	29.4	aAb
Score 250 (difenoconazole)	0.5	125	54.2	abc	73.9	bcd	32.5	abc	19.9	aAb
	0.25	62.5	38.2	ab	64.1	abcd	43.8	bc	27	aAb
	0.125	31.3	28	a	51.6	abc	51.2	c	40.1	aAb
	0.0625	15.6	28.6	a	31.6	a	51	c	48.8	bB
	0.03125	7.8	26.4	c	45.2	ab	53.1	c	42.4	aAb
Untreated							71.9%		74.4%	
P value			<0.0001		<0.0001		<0.0001		<0.0001	

Percentage control values were calculated for each treatment within a rep according to the formula:  $[(SC - ST)/SC] \times 100$  where SC is the severity on the untreated inoculated control and ST is the severity on the treatment.

Values are the means of two independent trials with four replications each; means followed by the same letter within a column are not significantly different at P value <0.05. Means were separated using Tukey's mean comparison test (internal R based software).

GF-3307 (S7K-3-3) applied at the maximum registerable rate (1.5 L/ha) presented a 90.8% control of CERCBE after 1 DP and 88.0% control of CERCBE after 2 DC. GF-3307 (S7K-3-3) was numerical superior compared to GF-3308, Proline, Propulse and Score in CERCBE control at 21 DAI (Figure 3.2

- 4 and

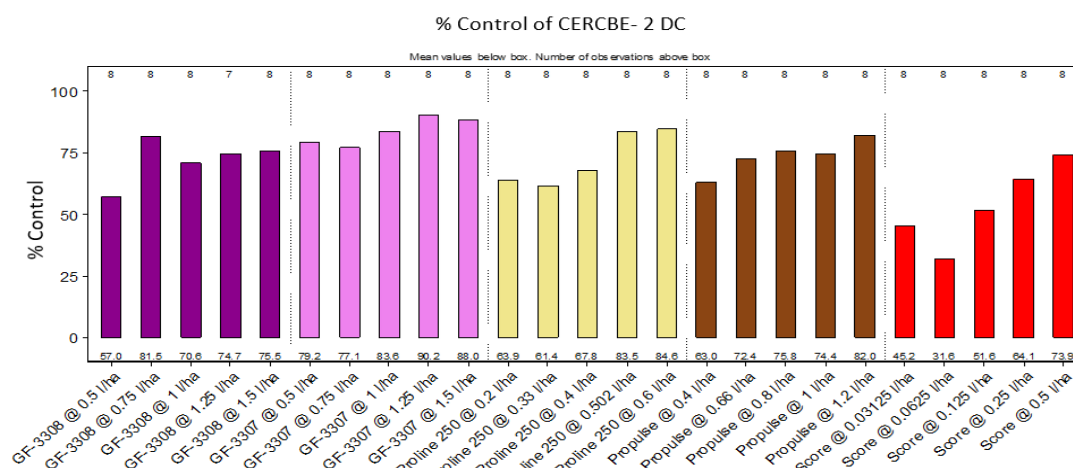


Figure 3.2 - 5). There was a clear benefit of GF-3307 (S7K-3-3) formulating Inatreq (GF-3308) at 1.5 L/ha (75 g ai/ha) which delivered 72% and 72.5% control in 1DP and 2DC, respectively, while with Proline at 0.6 L/ha (150 gai/ha) which achieved 72.4% and 84.6% control in at 1DP and 2 DC, respectively.

GF-3307 (S7K-3-3) at lower doses of 1.25 L/ha, 1.0 L/ha, 0.75 L/ha and 0.5 L/ha was in most cases were mostly numerically superior to Inatreq (GF-3308) and Proline applied alone at the equivalent dose rate of that component in GF-3307 (S7K-3-3). GF-3307 (S7K-3-3) applied at the lowest dose of 0.5 L/ha achieved 79.1% control of CERCBE after 1 DP and 79.2% control of CERCBE after 2 DC. Numerical differences with GF-3308, Proline and Propulse in CERCBE control at 21 DAI were observed between all treatments tested after 1 DP and 2DC. There was a clear benefit of GF-3307 (S7K-3-3) formulating Inatreq (GF-3308) at 0.5 L/ha (25 gai/ha) which delivered 50.1% and 57% control in 1DP and 2DC with Proline 0.4 L/ha (150 gai/ha) which achieved 68.9% and 63% control at 1DP and 2 DC

(Figure

3.2

-

4

and

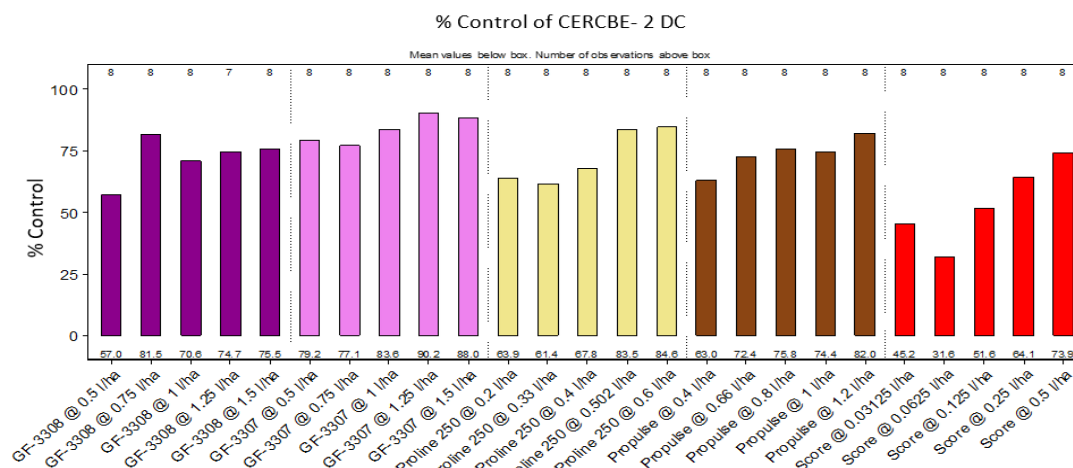


Figure 3.2 - 5) when compared to the equivalent doses in GF-3307 (S7K-3-3) at 0.5 L/ha.

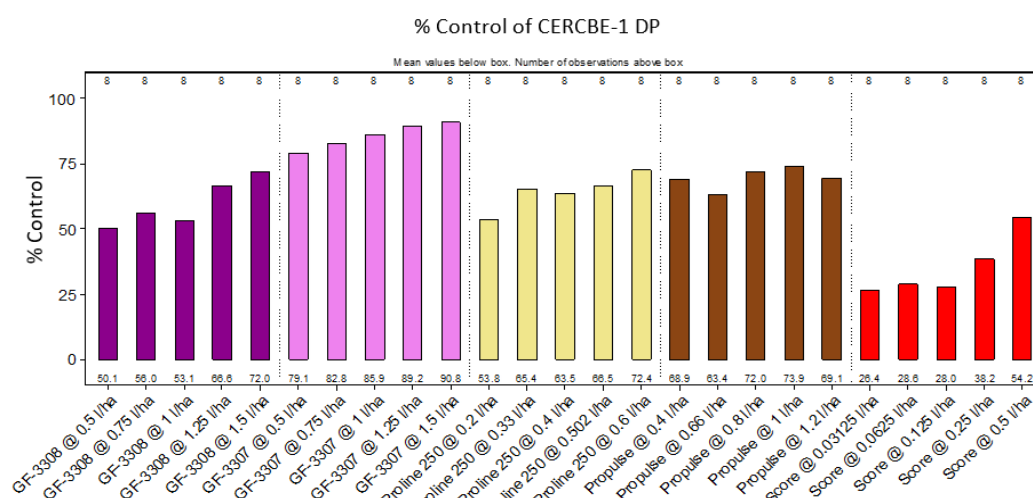
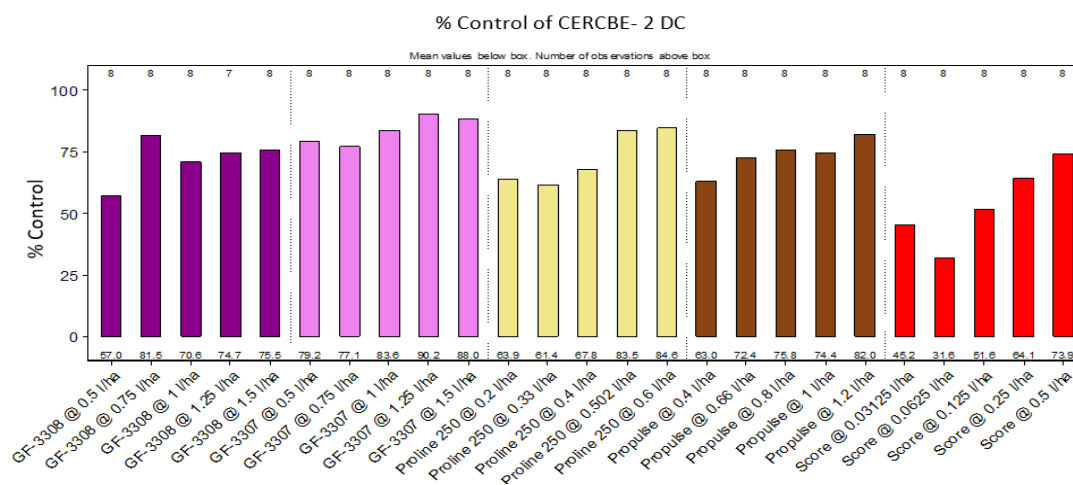


Figure 3.2 - 4 Percentage control of *Cercospora beticola* (CERCBE) after 1-day protectant application of GF-3308 and GF-3307 (S7K-3-3) at 0.5, 0.75, 1.0, 1.25 and 1.5 L/ha. Results of two trials (n=8) assessed 21 DAI (71.9% average infection in untreated)



**Figure 3.2 - 5 Percentage control of *Cercospora beticola* (CERCBE) after 2-day curative application of GF-3308 and GF-3307 (S7K-3-3) at 0.5, 0.75, 1, 1.25 and 1.5 L/ha. Results of two trials (n=8) assessed 21 DAI (74.4% average infection in untreated)**

### Conclusions

1DP: GF-3307 (S7K-3-3) at all rates was superior to GF-3308, Proline 250, Propulse and Score. There is a clear benefit in disease control from applying GF-3307 (S7K-3-3) (Inatreq+prothioconazole) compared to Inatreq (GF-3308) and prothioconazole straight at all rates.

2DC: GF-3307 (S7K-3-3) at all rates was superior to GF-3308, Proline 250, Propulse and Score. There is a clear benefit in disease control from applying GF-3307 (S7K-3-3) (Inatreq+prothioconazole) compared to Inatreq (GF-3308) and prothioconazole straight at all rates.

This glasshouse study clearly demonstrated that GF-3307 (S7K-3-3) provide a preventive and curative control of CERCBE even at lower doses tested and at levels that are superior to the efficacies shown by the individual compenets of Inatreq (GF-3308) and Proline 250, and superior to reference products Propulse and Score.

### 3.2.1.2 Mix partner justification for fenpicoxamid + prothioconazole in the final formulation GF-3307 (S7K-3-3)

GF-3307 (S7K-3-3) has been developed in line with the guidance in EPPO standard PP1/306 (1) '*General principles for the development of co-formulated mixtures of plant protection products*'. The proposed combination of fenpicoxamid and prothioconazole in GF-3307 (S7K-3-3) is intended to improve effectiveness of foliar diseases in sugar beet crop control over products containing the single active substances and to assist with resistance management. FRAC resistance management recommendations for both active substances (SBI (DMI) fungicides<sup>2</sup> and fenpicoxamid<sup>3</sup>) recommend applying both active substances in mixture (co-formulation) with a partner from a different cross-resistance group as a modifier to reduce the risk of resistance developing. This is discussed further in section 3.3.

The 1:2 ratio of fenpicoxamid and prothioconazole is already determined as the formulation GF-3307 (S7K-3-3) is authorised for use on wheat, rye and triticale with other additional crops planned in the future. We believe this is a favourable ratio for the formulated product to be used in a range of combinable crops. In addition to the above benefits of combining these two active substances in GF-3307 (S7K-3-3), this co-formulation ratio also allows the dose rate of each active substance to be reduced when compare to products applied alone, while still maintaining effective control. This complies with the advantages of a combined product detailed in EPPO PP1/306 (1), which states that when using active substances in combination, whether against a single pest or a pest complex, lower rates may sometimes be used compared with when using solo products. The maximum proposed dose rate of 1.5 L/ha (75 g of fenpicoxamid/ha + 150 g of prothioconazole/ha) delivers lower doses of both active substances.

#### (a) Results for the justification against *Cercospora beticola* in sugar beet.

To demonstrate the benefit of combining the active substances and to justify the co-formulation, field trial data are presented in this section. These trials are those used in section 3.2.3.1 (Effectiveness section) in which the formulated product GF-3307 (S7K-3-3) (50 g/L fenpicoxamid + 100 g/L prothioconazole) was tested at a comparable dose rate to both component active substances - fenpicoxamid (as the product GF-3308) and prothioconazole (as the product Proline). GF-3308 (50 g/L fenpicoxamid, early stage coded X772777, XDE-777 and DE-777) was applied at 75.0 g of fenpicoxamid/ha (1.5 L/ha of GF-3308). Proline (250 g/L prothioconazole) was applied at 150 g of prothioconazole/ha (0.6 L/ha of Proline).

---

<sup>2</sup> <https://www.frac.info/frac-teams/working-groups/sbi-fungicides/recommendations-for-sbi>

<sup>3</sup> [https://www.frac.info/docs/default-source/modes-of-action-without-recommendations-by-frac/group-21-\(c4\)---fenpicoxamid-\(qii\)-recommendations-17th-of-april-2019.pdf?sfvrsn=20bd489a\\_2](https://www.frac.info/docs/default-source/modes-of-action-without-recommendations-by-frac/group-21-(c4)---fenpicoxamid-(qii)-recommendations-17th-of-april-2019.pdf?sfvrsn=20bd489a_2)

Only trials that included all three products at these dose rates are included. The 27 trials used in this section were conducted in Czech Republic (1), France (4), Germany (10) and The United-Kingdom (1) in the EPPO Maritime, in Lithuania (2) and Poland (3) in the EPPO Northeast and in Hungary (4) and Romania (2) in the EPPO Southeast climatic zones between 2020 and 2023.

**Table 3.2-11: Details on trial methodology - Preliminary part - CERCBE**

<b>Guidelines</b>	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/1
<b>Experimental design</b>	Plot design	RCB
	Plot size	18-36 m <sup>2</sup>
	Number of replications	4
<b>Crop</b>	Trials per crop	Sugar beet (27)
	Varieties per crop	Annabella (1), Annarosa (2), Asketa (2), Belamia (1), Briga (1), BTS1140 (1), Calledia (2), Camelia (2), Danicia (1), Darvas (1), Florentina (1), Lunella (1), Marley (1), Marynia RH (1), Pavo (1), Racoon (1), Rossada (1), Smart Latoria KWS (1), Smart Mondeo (1), Smart Sanya (1), Stingray (1), Surf (1), Traper (1)
	Sowing period	Sugar beet: March – April
<b>Application</b>	Crop stage (BBCH) at application	Sugar beet: two applications between BBCH 35-49*
	Timing Pest stage at application	1 <sup>st</sup> application: At the appearance of the disease to control the foliar diseases with an interval. The application was timed to cover the main infection period to protect the crop from disease development.
	Number of applications	2 applications : 27 trials with intervals of 14 to 29 days*
	Spray volumes	200-400 L/ha
<b>Assessment</b>	Assessment types	% infection (severity) % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting)
	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) at each application and then 15-20 days, 30-40 days and 50-60 days after the last application. Yield (12 trials) and quality parameters (Sodium content (9 trials), Potassium content (9 trials), Amino nitrogen content (9 trials) and Sugar content in % (9 trials)).
<b>Other relevant information</b>	E.g. Natural / artificial inoculation...	Natural infection in 22 trials Artificial inoculation in 5 trials
	E.g. 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 CERCBE is an abundant disease.

\*In 2 trials, three applications were performed. However, only valid assessment after the second application were considered for the evaluation.

## Introduction

27 field trials were selected in 2020, 2022 and 2023 for testing in which the benefit of the formulated product, GF-3307 (S7K-3-3) is clearly evident over fenpicoxamid or prothioconazole applied straight for the control of *Cercospora beticola* (CERCBE).

These trials are those used in section 3.2.3.1 (Effectiveness section) in which the formulated product GF-3307 (S7K-3-3) (50 g/L fenpicoxamid + 100 g/L prothioconazole) was tested at a comparable dose rate to both component active substances - fenpicoxamid (as the product GF-3308) and prothioconazole (as the product Proline).

Twenty trials representative for the Central registration zone were selected in Czech Republic (1) and Germany (10) in the Maritime EPPO climatic zone, in Poland (3) in the Northeast EPPO climatic zone, in Hungary (4) and in Romania (2) in the Southeast EPPO climatic zone. In addition, to support the justification of mix partner, seven trials of others registration zones (Southern, Northern) of Maritime and Northeast EPPO climatic zones are added. These trials were carried out in Lithuania (2), France (4) and in the United-Kingdom (1).

In these trials, GF-3307 (S7K-3-3) was applied at the rate 1.5 L/ha (75 g a.s./ha fenpicoxamid + 150 g a.s./ha prothioconazole, EC) and compared to GF-3308 (75 g a.s./ha) and Proline (150 g a.s./ha) at equivalent active substances rates in GF-3307 (S7K-3-3) at 1.5 L/ha.

GF-3308 (50 g/L fenpicoxamid) was applied at 75 g of fenpicoxamid/ha (1.5 L/ha of GF-3308). Proline (250 g/L prothioconazole) was applied at 150 g of prothioconazole/ha (0.6 L/ha of Proline). All trials were carried out by officially recognised contract research organisations in accordance with the principles of Good Experimental Practice (Table 3.7 1).

### Materials and Methods

The justification of the association fenpicoxamid with prothioconazole was supported by the data from 27 efficacy trials. Material and Methods used in these efficacy trials are given within Section 3.2.3.1 “Efficacy tests (KCP 6.2)”. Trials were carried out by the testing facilities as listed in Table 3.2-7. For trial site and application details see Appendix 4. Figure 3.2 - 3 provides an overview on the geographical distribution of the trials across the EU countries and Table 3.2-11 details the trial methodologies.

GF-3307 (S7K-3-3) was applied at the rates of 1.5 L/ha.

GF-3307 (S7K-3-3) applied at 1.5 L/ha (75 g a.s./ha fenpicoxamid + 150 g a.s./ha prothioconazole, EC) was evaluated in the 27 trials and compared to 75 g a.s./ha of fenpicoxamid as GF-3308 (straight EC of fenpicoxamid) and to 150 g a.s./ha prothioconazole as Proline.

### Results

Twenty-seven field trials were selected in 2020, 2022 and 2023 to clearly demonstrate the additive effect of fenpicoxamid to prothioconazole for the control of *Cercospora beticola* (CERCBE) in sugar beet. For Maritime EPPO climatic zone the trials were carried out in Czech Republic (1), France (4), Germany (10) and The United-Kingdom (1), for Northeast EPPO climatic zone, in Poland (3) and Lithuania (2) and for Southeast EPPO climatic zone in Hungary (4) and Romania (2). The trials were selected representative of the Maritime, Northeast and Southeast EPPO climatic zones in which the disease target was CERCBE and presenting challenging situations for this disease.

The results are summarized by EPPO climatic zone in Table 3.2-12 (Maritime EPPO climatic zone), Table 3.2-13 (Northeast EPPO climatic zone), Table 3.2-14 (Southeast EPPO climatic zone) and Table 3.2-15 (All EPPO climatic zones). Only results for all valid efficacy trials (all EPPO climatic zones in Table 3.2-15) are discussed hereafter to justify the benefit of the association.

Across the 27 trials conducted in the EPPO Maritime, Northeast and Southeast climatic zones, the benefit of combining the active substances fenpicoxamid and prothioconazole in the product GF-3307 (S7K-3-3) is clearly evident.

#### Assessment around 15-20 DA-B:

Based on assessments of disease severity in 25 trials, the straight fenpicoxamid (GF-3308) product applied at a dose rate of 75 g a.s./ha (1.5 L/ha of GF-3308) achieved 73.0% mean overall control of CERCBE (range 25.9-100.0%) and the straight prothioconazole product applied at a dose rate of 150 g a.s./ha (0.6 L/ha of Proline) achieved 76.0% overall control of CERCBE (range 50.4-100.0%). GF-3307 (S7K-3-3) applied at 1.5 L/ha (75 g a.s./ha fenpicoxamid + 150 g a.s./ha prothioconazole) achieved control of CERCBE above the two components at 85.2% (range 60.3-100.0%).

#### Assessment around 30-40 DA-B:

Based on assessments of disease severity in 24 trials, the straight fenpicoxamid (GF-3308) product applied at a dose rate of 75 g a.s./ha (1.5 L/ha of GF-3308) achieved 67.9% mean overall control of CERCBE (range 43.2-91.6%) and the straight prothioconazole product applied at a dose rate of 150 g a.s./ha (0.6 L/ha of Proline) achieved 68.0% overall control of CERCBE (range 38.5-98.3%). GF-3307 (S7K-3-3) applied at 1.5 L/ha (75 g a.s./ha fenpicoxamid + 150 g a.s./ha prothioconazole) achieved control of CERCBE above the two components at 82.8% (range 62.3-100.0%).

#### Assessment after 40 DA-B:

Based on assessments of disease severity in 12 trials, the straight fenpicoxamid (GF-3308) product applied at a dose rate of 75 g a.s./ha (1.5 L/ha of GF-3308) achieved 71.7% mean overall control of CERCBE (64.2-89.3%) and the straight prothioconazole product applied at a dose rate of 150 g a.s./ha (0.6 L/ha of Proline) achieved 70.5% overall control of CERCBE (range 52.1-96.2%). GF-3307 (S7K-3-3) applied at 1.5 L/ha (75 g a.s./ha fenpicoxamid + 150 g a.s./ha prothioconazole) achieved control of CERCBE above the two components at 84.4% (range 71.5-100.0%).

#### Valid assessment after two applications (2 to 6 weeks after the application - all efficacy trials merged):

Based on assessments of disease severity in 27 trials, the straight fenpicoxamid (GF-3308) product applied at a dose rate of 75 g a.s./ha (1.5 L/ha of GF-3308) achieved 65.9% mean overall control of

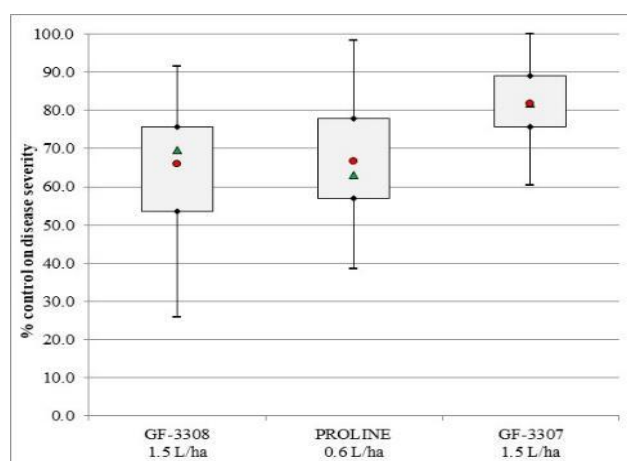


CERCBE (range 25.9-91.6%) and the straight prothioconazole product applied at a dose rate of 150 g a.s./ha (0.6 L/ha of Proline) achieved 66.8% overall control of CERCBE (range 38.5-98.3%). GF-3307 (S7K-3-3) applied at 1.5 L/ha (75 g a.s./ha fenpicoxamid + 150 g a.s./ha prothioconazole) achieved control of CERCBE above the two components at 81.7% (range 60.3-100.0%).

Across these 27 trials, control using GF-3307 (S7K-3-3) at 1.5 L/ha was higher than using straight fenpicoxamid in all trials (significantly higher in twelve trials) and also higher than using straight prothioconazole in all trials (significantly higher in height trials). In addition, as the results for the combined product are higher than the individual components, these data also demonstrate no antagonism between the two active substances.

The difference between the different products can be illustrated by box plot graphic on the disease severity on the efficacy trials in Figure 3.2 - 6.

The benefit of the formulated product GF-3307 (S7K-3-3) over fenpicoxamid or prothioconazole applied straight against key label claim disease *Cercospora beticola* (CERCBE) is clearly demonstrated.



CERCBE - Valid assessment after application B (2 to 6 weeks after the application)  
Disease severity on plants (27 trials)

♦ q1 -min ▲ median ● average -max ♦ q3

**Figure 3.2 - 6 Justification of the association - Efficacy of GF-3307 (S7K-3-3) on plants against CERCBE on sugar beet - Disease severity - All EPPO climatic zones - Box plot graphics**

**Table 3.2-12 Mix partner justification of GF-3307 (S7K-3-3) applied at 1.5 L/ha for the control of CERCBE in sugar beet in comparison to straight fenpicoxamid (GF-3308 at 1.5 L/ha) and straight prothioconazole (Proline at 0.6 L/ha). Summary of data from sixteen trials conducted in the EPPO Maritime climatic zone with direct comparison for GF-3307 (S7K-3-3) with the component active substances**

Target	Timing of assessment	EPPO climatic zone	No. of trials	Untreated			% Control of												No. of assessments significantly > , = , < GF-3307 (S7K-3-3) at 1.5 L/ha vs.	
							GF-3308 1.5 L/ha				PROLINE 0.6 L/ha				GF-3307 (S7K-3-3) 1.5 L/ha					
							Fenpicoxamid				Prothioconazole				Fenpicoxamid + Prothioconazole					
							75 g a.s./ha				150 g a.s./ha				75+150 g a.s./ha					
				Mean	Min	Max		Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	GF-3308 1.5 L/ha
Disease severity on plants	Assessment around 15-20 DA-B	Maritime	14	20.6	5.2	58.8	75.0	54.4	100.0	12.8	75.3	50.9	100.0	13.9	86.8	75.6	100.0	7.5	4> ; 10= ; 0<	1> ; 13= ; 0<
	Assessment around 30-40 DA-B	Maritime	15	30.4	5.1	63.5	70.3	43.2	89.9	14.5	70.2	38.5	98.3	14.1	84.2	66.9	100.0	9.1	4> ; 11= ; 0<	3> ; 12= ; 0<
	Assessment after 40 DA-B	Maritime	7	40.0	20.6	66.5	74.7	65.0	89.3	8.9	73.7	53.8	96.2	13.7	87.9	73.0	100.0	9.9	2> ; 5= ; 0<	3> ; 4= ; 0<
	Valid assessment after 2 applications (2 to 6 weeks after the application)	Maritime	16	30.6	5.1	63.5	69.3	43.2	89.9	14.5	69.5	38.5	98.3	14.0	83.7	66.9	100.0	9.1	5> ; 11= ; 0<	3> ; 13= ; 0<

**Table 3.2-13 Mix partner justification of GF-3307 (S7K-3-3) applied at 1.5 L/ha for the control of CERCBE in sugar beet in comparison to straight fenpicoxamid (GF-3308 at 1.5 L/ha) and straight prothioconazole (Proline at 0.6 L/ha). Summary of data from five trials conducted in the EPPO Northeast climatic zone with direct comparison for GF-3307 (S7K-3-3) with the component active substances**

Target	Timing of assessment	EPPO climatic zone	No. of trials	Untreated			% Control of												No. of assessments significantly >, =, < GF-3307 (S7K-3-3) at 1.5 L/ha vs.	
							GF-3308 1.5 L/ha				PROLINE 0.6 L/ha				GF-3307 (S7K-3-3) 1.5 L/ha					
							Fenpicoxamid				Prothioconazole				Fenpicoxamid + Prothioconazole					
							75 g a.s./ha				150 g a.s./ha				75+150 g a.s./ha					
				Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	GF-3308 1.5 L/ha	PROLINE 0.6 L/ha
Disease severity on plants	Assessment around 15-20 DA-B	Northeast	5	29.6	7.0	57.5	69.0	25.9	98.0	23.7	72.5	50.4	98.8	16.4	80.9	60.3	99.4	12.6	2> ; 3= ; 0<	1> ; 4= ; 0<
		Northeast and PL border countries (PL-CZ-DE-LT)	15	21.0	6.3	57.5	72.6	25.9	100.0	17.0	74.2	50.4	100.0	14.8	84.4	60.3	100.0	9.7	5> ; 10= ; 0<	2> ; 13= ; 0<
	Assessment around 30-40 DA-B	Northeast	3	32.9	26.7	38.3	71.9	51.3	91.6	16.5	73.1	45.6	94.0	20.3	82.4	62.3	97.2	14.7	1> ; 2= ; 0<	0> ; 3= ; 0<
		Northeast and PLborder countries (PL-CZ-DE-LT)	14	29.7	8.8	63.5	68.8	43.2	91.6	15.6	69.2	38.5	98.3	17.0	82.6	62.3	100.0	10.8	5> ; 9= ; 0<	3> ; 11= ; 0<
	Assessment after 40 DA-B	Northeast	1	69.8	-	-	74.6	-	-	-	77.8	-	-	-	87.6	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
		Northeast and PL border countries (PL-DE)	6	45.3	24.8	69.8	75.6	65.0	89.3	9.2	73.9	59.2	86.6	8.5	86.0	73.0	100.0	10.0	1> ; 4= ; 0<	2> ; 3= ; 0<
	Valid assessment after 2 applications (2 to 6 weeks after the application)	Northeast	5	38.7	26.7	57.5	62.2	25.9	91.6	22.2	66.1	45.6	94.0	18.2	78.0	60.3	97.2	14.4	3> ; 2= ; 0<	1> ; 4= ; 0<
		Northeast and PLborder countries (PL-CZ-DE-LT)	16	32.0	8.8	63.5	66.2	25.9	91.6	17.9	67.6	38.5	98.3	16.6	81.2	60.3	100.0	11.4	7> ; 9= ; 0<	4> ; 12= ; 0<

**Table 3.2-14 Mix partner justification of GF-3307 (S7K-3-3) applied at 1.5 L/ha for the control of CERCBE in sugar beet in comparison to straight fenpicoxamid (GF-3308 at 1.5 L/ha) and straight prothioconazole (Proline at 0.6 L/ha). Summary of data from six trials conducted in the EPPO Southeast climatic zone with direct comparison for GF-3307 (S7K-3-3) with the component active substances**

Target	Timing of assessment	EPPO climatic zone	No. of trials	Untreated			% Control of												No. of assessments significantly > , = , < GF-3307 (S7K-3-3) at 1.5 L/ha vs. PROLINE 0.6 L/ha	
							GF-3308 1.5 L/ha				PROLINE 0.6 L/ha				GF-3307 (S7K-3-3) 1.5 L/ha					
							Fenpicoxamid				Prothioconazole				Fenpicoxamid + Prothioconazole					
							75 g a.s./ha				150 g a.s./ha				75+150 g a.s./ha					
				Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	GF-3308 1.5 L/ha	PROLINE 0.6 L/ha
Disease severity on plants	Assessment around 15-20 DA-B	Southeast	6	18.8	8.0	44.5	71.7	52.0	87.2	14.1	80.5	59.0	90.7	10.5	85.1	66.8	94.4	10.4	4> ; 2= ; 0<	2> ; 4= ; 0<
	Assessment around 30-40 DA-B	Southeast	6	35.7	12.3	65.0	60.2	45.7	73.2	8.9	60.0	53.7	75.1	7.5	79.7	65.5	89.0	8.0	4> ; 2= ; 0<	4> ; 2= ; 0<
	Assessment after 40 DA-B	Southeast	4	32.0	14.0	52.5	65.7	64.2	68.3	1.6	62.9	52.1	67.6	6.4	77.5	71.5	82.7	5.1	2> ; 2= ; 0<	3> ; 1= ; 0<
	Valid assessment after 2 applications (2 to 6 weeks after the application)	Southeast	6	35.7	12.3	65.0	60.2	45.7	73.2	8.9	60.0	53.7	75.1	7.5	79.7	65.5	89.0	8.0	4> ; 2= ; 0<	4> ; 2= ; 0<

**Table 3.2-15 Mix partner justification of GF-3307 (S7K-3-3) applied at 1.5 L/ha for the control of CERCBE in sugar beet in comparison to straight fenpicoxamid (GF-3308 at 1.5 L/ha) and straight prothioconazole (Proline at 0.6 L/ha). Summary of data from twenty-seven trials conducted in All EPPO climatic zones with direct comparison for GF-3307 (S7K-3-3) with the component active substances**

Target	Timing of assessment	EPPO climatic zone	No. of trials	Untreated			% Control of												No. of assessments significantly > , = , < GF-3307 (S7K-3-3) at 1.5 L/ha vs.	
							GF-3308 1.5 L/ha				PROLINE 0.6 L/ha				GF-3307 (S7K-3-3) 1.5 L/ha					
							Fenpicoxamid				Prothioconazole				Fenpicoxamid + Prothioconazole					
							75 g a.s./ha				150 g a.s./ha				75+150 g a.s./ha					
				Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	GF-3308 1.5 L/ha
Disease severity on plants	Assessment around 15-20 DA-B	All EPPO climatic zones	25	22.0	5.2	58.8	73.0	25.9	100.0	16.0	76.0	50.4	100.0	14.0	85.2	60.3	100.0	9.7	10> ; 15= ; 0<	4> ; 21= ; 0<
	Assessment around 30-40 DA-B	All EPPO climatic zones	24	32.0	5.1	65.0	67.9	43.2	91.6	14.3	68.0	38.5	98.3	14.6	82.8	62.3	100.0	9.9	9> ; 15= ; 0<	7> ; 17= ; 0<
	Assessment after 40 DA-B	All EPPO climatic zones	12	39.8	14.0	69.8	71.7	64.2	89.3	8.1	70.5	52.1	96.2	12.4	84.4	71.5	100.0	9.5	4> ; 8= ; 0<	6> ; 6= ; 0<
	Valid assessment after 2 applications (2 to 6 weeks after the application)	All EPPO climatic zones	27	33.2	5.1	65.0	65.9	25.9	91.6	15.8	66.8	38.5	98.3	14.3	81.7	60.3	100.0	10.4	12> ; 15= ; 0<	8> ; 19= ; 0<

### (b) Results for the justification against *Uromyces betae* in sugar beet

To demonstrate the benefit of combining the active substances and to justify the co-formulation, field trial data are presented in this section. These trials are those used in section 3.2.3.1 (Effectiveness section) in which the formulated product GF-3307 (S7K-3-3) (50 g/L fenpicoxamid + 100 g/L prothioconazole) was tested at a comparable dose rate to both component active substances - fenpicoxamid (as the product GF-3308) and prothioconazole (as the product Proline). GF-3308 (50 g/L fenpicoxamid, early stage coded X772777, XDE-777 and DE-777) was applied at 75.0 g of fenpicoxamid/ha (1.5 L/ha of GF-3308). Proline (250 g/L prothioconazole) was applied at 150 g of prothioconazole/ha (0.6 L/ha of Proline).

Only trials that included all three products at these dose rates are included. The ten trials used in this section were conducted in France (2), Denmark (4) and the United-Kingdom (4) in the EPPO Maritime climatic zone in 2022 and 2023.

**Table 3.2-16: Details on trial methodology - Preliminary part - UROMBE**

<b>Guidelines</b>	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/1
<b>Experimental design</b>	Plot design	RCB
	Plot size	18-30 <del>24</del> m <sup>2</sup>
	Number of replications	4
<b>Crop</b>	Trials per crop	Sugar beet (10)
	Varieties per crop	Annabella (1), BTS1140 (1), Falster (1), Katjana (1), Morgan (1), Naskov (2), Nasser (1), Surf (1), Wren (1)
	Sowing period	Sugar beet: March – <del>May</del> April
<b>Application</b>	Crop stage (BBCH) at application	Sugar beet: two applications between BBCH 39-49
	Timing Pest stage at application	1 <sup>st</sup> application: At the appearance of the disease to control the foliar diseases with an interval. The application was timed to cover the main infection period to protect the crop from disease development.
	Number of applications	2 applications : 10 trials with intervals of 20 to 25 days
	Spray volumes	200-245 L/ha
<b>Assessment</b>	Assessment types	% infection (severity) % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting) Yield and quality parameters (Sodium content (3 trials), Potassium content (3 trials), Amino nitrogen content (3 trials) and Sugar content in % (3 trials)).
	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) at each application and then 15-20 days, 30-40 days and 50-60 days after the last application.
<b>Other relevant information</b>	E.g. Natural / artificial inoculation...	Natural infection in 10 trials
	E.g. 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 UROMBE is an abundant disease.

### Introduction

10 field trials were selected in 2022 and 2023 for testing in which the benefit of the formulated product, GF-3307 (S7K-3-3) is clearly evident over fenpicoxamid or prothioconazole applied straight for the control of *Uromyces betae* (UROMBE).

These trials are those used in section 3.2.3.1 (Effectiveness section) in which the formulated product GF-3307 (S7K-3-3) (50 g/L fenpicoxamid + 100 g/L prothioconazole) was tested at a comparable dose rate to both component active substances - fenpicoxamid (as the product GF-3308) and prothioconazole (as the product Proline).

To support the justification of mix partner, ten trials of Maritime EPPO climatic zone are selected. These trials were carried out in Denmark (4), France (2) and the United-Kingdom (4).

In these trials, GF-3307 (S7K-3-3) was applied at the rate 1.5 L/ha (75 g a.s./ha fenpicoxamid + 150 g a.s./ha prothioconazole, EC) and compared to GF-3308 (75 g a.s./ha) and Proline (150 g a.s./ha) at equivalent active substances rates in GF-3307 (S7K-3-3) at 1.5 L/ha.

GF-3308 (50 g/L fenpicoxamid) was applied at 75 g of fenpicoxamid/ha (1.5 L/ha of GF-3308). Proline (250 g/L prothioconazole) was applied at 150 g of prothioconazole/ha (0.6 L/ha of Proline). All trials were carried out by officially recognised contract research organisations in accordance with the principles of Good Experimental Practice (Table 3.7 1).

### Materials and Methods

The justification of the association fenpicoxamid with prothioconazole was supported by the data from 10 efficacy trials. Material and Methods used in these efficacy trials are given within Section 3.2.3.1 “Efficacy tests (KCP 6.2)”. Trials were carried out by the testing facilities as listed in Table 3.2-7. For trial site and application details see Appendix 4. Figure 3.2 - 3 provides an overview on the geographical distribution of the trials across the EU countries and Table 3.2-11 details the trial methodologies.

GF-3307 (S7K-3-3) was applied at the rates of 1.5 L/ha.

GF-3307 (S7K-3-3) applied at 1.5 L/ha (75 g a.s./ha fenpicoxamid + 150 g a.s./ha prothioconazole, EC) was evaluated in the 10 trials and compared to 75 g a.s./ha of fenpicoxamid as GF-3308 (straight EC of fenpicoxamid) and to 150 g a.s./ha prothioconazole as Proline.

### Results

Ten field trials were selected in 2022 and 2023 to clearly demonstrate the additive effect of fenpicoxamid to prothioconazole for the control of *Uromyces betae* (UROMBE) in sugar beet. For Maritime EPPO climatic zone the trials were carried out in France (2), Denmark (4) and the United-Kingdom (4). The trials were selected representative of the Maritime EPPO climatic zone in which the disease target was UROMBE and presenting challenging situations for this disease.

The results are summarized by EPPO climatic zone in Table 3.2-17 (GF-3307 (S7K-3-3) at 1.5 L/ha). Only results for all valid efficacy trials (Maritime EPPO climatic zone) highlighted in grey in Table 3.2-17) are discussed hereafter to justify the benefit of the association.

Across the ten trials conducted in the EPPO Maritime climatic zone, the benefit of combining the active substances fenpicoxamid and prothioconazole in the product GF-3307 (S7K-3-3) is clearly evident.

#### Assessment around 15-20 DA-B:

Based on assessments of disease severity in 10 trials, the straight fenpicoxamid product applied at a dose rate of 75 g a.s./ha (1.5 L/ha of GF-3308) achieved 85.3% mean overall control of UROMBE (range 72.1-95.1%) and the straight prothioconazole product applied at a dose rate of 150 g a.s./ha (0.6 L/ha of Proline) achieved 85.2% overall control of UROMBE (range 67.5-99.7%). GF-3307 (S7K-3-3) applied at 1.5 L/ha (75 g a.s./ha fenpicoxamid + 150 g a.s./ha prothioconazole) achieved control of UROMBE above the two components at 92.4% (range 73.8-99.7%).

#### Assessment around 30-40 DA-B:

Based on assessments of disease severity in 9 trials, the straight fenpicoxamid product applied at a dose rate of 75 g a.s./ha (1.5 L/ha of GF-3308) achieved 77.3% mean overall control of UROMBE (range 66.9-91.4%) and the straight prothioconazole product applied at a dose rate of 150 g a.s./ha (0.6 L/ha of Proline) achieved 75.4% overall control of UROMBE (range 43.9-94.8%). GF-3307 (S7K-3-3) applied at 1.5 L/ha (75 g a.s./ha fenpicoxamid + 150 g a.s./ha prothioconazole) achieved control of UROMBE above the two components at 86.5% (range 53.9-97.1%).

#### Assessment after 40 DA-B:

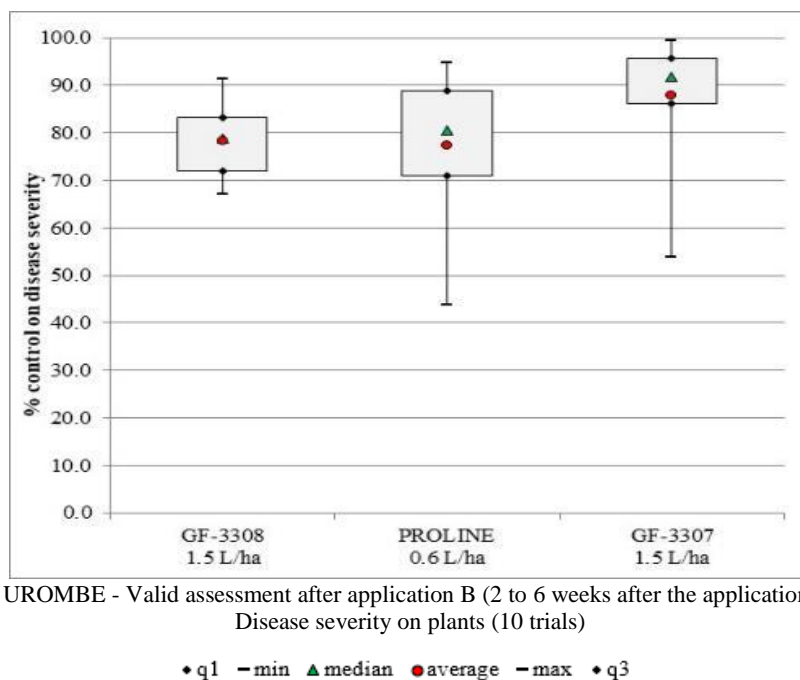
Based on assessments of disease severity in 2 trials, the straight fenpicoxamid product applied at a dose rate of 75 g a.s./ha (1.5 L/ha of GF-3308) achieved 72.4% mean overall control of UROMBE (range 63.2-81.6%) and the straight prothioconazole product applied at a dose rate of 150 g a.s./ha (0.6 L/ha of Proline) achieved 62.2% overall control of UROMBE (range 61.1-63.2%). GF-3307 (S7K-3-3) applied at 1.5 L/ha (75 g a.s./ha fenpicoxamid + 150 g a.s./ha prothioconazole) achieved control of UROMBE at 60.7% (range 52.5-68.9).

#### Valid assessment after two applications (2 to 6 weeks after the application - all efficacy trials merged):

Based on assessments of disease severity in 10 trials, the straight fenpicoxamid product applied at a dose rate of 75 g a.s./ha (1.5 L/ha of GF-3308) achieved 78.4% mean overall control of UROMBE (range 66.9-91.4%) and the straight prothioconazole product applied at a dose rate of 150 g a.s./ha (0.6 L/ha of Proline) achieved 77.3% overall control of UROMBE (range 43.9-94.8%). GF-3307 (S7K-3-3) applied at 1.5 L/ha (75 g a.s./ha fenpicoxamid + 150 g a.s./ha prothioconazole) achieved control of UROMBE above the two components at 87.8% (range 53.9-99.5%).

Across these ten trials, control using GF-3307 (S7K-3-3) at 1.5 L/ha was higher than using straight fenpicoxamid in all trials (significantly higher in two trials) and also higher than using straight prothioconazole in all trials. In addition, as the results for the combined product are higher than the individual components, these data also demonstrate no antagonism between the two active substances. The difference between the different products can be illustrated by box plot graphic on the disease severity on the efficacy trials in Figure 3.2 -.

The benefit of the formulated product GF-3307 (S7K-3-3) over fenpicoxamid or prothioconazole applied straight against the disease *Uromyces betae* (UROMBE) is clearly demonstrated.



**Figure 3.2 - Justification of the association - Efficacy of GF-3307 (S7K-3-3) on plants against UROMBE on sugar beet - Disease severity - Maritime EPPO climatic zone - Box plot graphics**



**Table 3.2-17 Mix partner justification of GF-3307 (S7K-3-3) applied at 1.5 L/ha for the control of UROMBE in sugar beet in comparison to straight fenpicoxamid (GF-3308 at 1.5 L/ha) and straight prothioconazole (Proline at 0.6 L/ha). Summary of data from ten trials conducted in the EPPO Maritime climatic zone with direct comparison for GF-3307 (S7K-3-3) with the component active substances**

Part	Timing of assessment	EPPO climatic zone	No. of trials	Untreated % INFECT UROMBE			% Control of UROMBE												No. of assessments significantly > , = , < GF-3307 (S7K-3-3) at 1.5 L/ha vs.	
							GF-3308 1.5 L/ha				PROLINE 0.6 L/ha				GF-3307 (S7K-3-3) 1.5 L/ha					
							Fenpicoxamid				Prothioconazole				Fenpicoxamid + Prothioconazole					
							75 g a.s./ha				150 g a.s./ha				75+150 g a.s./ha					
				Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	GF-3308 1.5 L/ha	PROLINE 0.6 L/ha			
Disease severity on plants	Assessment around 15-20 DA-B	Maritime	10	24.2	8.2	35	85.2	72.1	95.1	7.9	85.2	67.5	99.7	12.0	92.4	73.8	99.7	8.0	1> ; 9= ; 0<	0> ; 10= ; 0<
	Assessment around 30-40 DA-B	Maritime	9	40.4	18.6	59.1	77.3	66.9	91.4	7.5	75.4	43.9	94.8	14.9	86.5	53.9	97.1	12.7	2> ; 7= ; 0<	0> ; 9= ; 0<
	Assessment after 40 DA-B	Maritime	2	46.5	41.1	51.9	72.4	63.2	81.6	9.2	62.2	61.1	63.2	1.0	60.7	52.5	68.9	8.2	0> ; 1= ; 1<	0> ; 2= ; 0<
	Valid assessment after 2 applications (2 to 6 weeks after the application)	Maritime	10	38.4	18.6	59.1	78.4	66.9	91.4	7.8	77.3	43.9	94.8	15.3	87.8	53.9	99.5	12.6	2> ; 8= ; 0<	0> ; 10= ; 0<

### (c) Summary and conclusions on the preliminary trials

The combination of fenpicoxamid and prothioconazole in GF-3307 (S7K-3-3) has previously been demonstrated to be an effective formulation for control of a wide range of foliar diseases in cereals, with clear benefits over the component active substances when used alone.

Field and glasshouse studies demonstrate that GF-3307 (S7K-3-3) also delivers a significant benefit over products containing the component active substances on CERCBE in sugar beet. The combined product was the only product that demonstrated over 80% or 90% control across all field trials.

GF-3307 (S7K-3-3) is a formulation combining two active substances with different modes of action. Prothioconazole is a DMI fungicide, part of the SBI mode of action group, and fenpicoxamid is a picolinamide fungicides, part of the Qil mode of action group. The combined product complies with the FRAC resistance management recommendations for both SBI (DMI) fungicides<sup>4</sup> and fenpicoxamid<sup>5</sup> which recommend applying both active substances in mixture (co-formulation) with a partner from a different cross-resistance group as a modifier to reduce the risk of resistance developing.

In recent years, *Cercospora beticola* has become more prevalent in Europe, and has become the most destructive foliar pathogen of sugar beet. It is widely present in most beet-growing regions and can cause major yield losses if not properly controlled. This disease usually appears early in the season and is most severe in wet and warm areas in case of very early attacks.

The association fenpicoxamid + prothioconazole formulated in GF-3307 (S7K-3-3) allowed increasing the control of *Cercospora beticola* and *Uromyces betae* of sugar beet compared to the same rate of fenpicoxamid or prothioconazole applied straight. Indeed, the efficacy of GF-3307 (S7K-3-3) at 1.5 L/ha over fenpicoxamid or prothioconazole applied straight is clearly demonstrated in 34 valid trials.

**Based on the benefits with respect to resistance prevention and improved efficacy, the knowledge of each active substance, and technical possibilities on formulation, the combination of the active substances fenpicoxamid + prothioconazole in GF-3307 (S7K-3-3) and their rate ratio are clearly justified in sugar beet and by extrapolation in fodder beet in accordance with PP 1/257 FEET 55(1).**

#### Comments of zRMS on: Preliminary tests (3.2.1)

##### Preventive and curative properties of GF-3307 in a glasshouse

Two preliminary glasshouse trials were conducted in 2023 to assess both the preventive (1-day pre-inoculation) and curative (2-day post-inoculation) efficacy of GF-3307 (S7K-3-3) against *Cercospora beticola* (CERCBE) in sugar beet. The co-formulated product GF-3307 (S7K-3-3), containing fenpicoxamid (50 g/L) and prothioconazole (100 g/L), was compared with reference products: GF-3308 (fenpicoxamid 50 g/L), Proline 250 (prothioconazole 250 g/L), Propulse (fluopyram 125 g/L + prothioconazole 125 g/L), and Score (difenoconazole 250 g/L).

Preventive efficacy (1 DP): GF-3307 (S7K-3-3) applied at all tested dose rates (0.5 L/ha, 0.75 L/ha, 1.0 L/ha, 1.25 L/ha, 1.5 L/ha) provided superior control of CERCBE compared to GF-3308, Proline 250, Propulse, and Score. These results support the added value of the co-formulated mixture (fenpicoxamid + prothioconazole) over the individual components contained in GF-3308, Proline 250, applied alone at the same rates.

Curative efficacy (2 DC): Similarly, in the curative setting, the co-formulation GF-3307 (S7K-3-3) provided visibly better efficacy at all application rates compared to GF-3308, Proline 250, Propulse and Score.

##### Co-formulation justification

27 and 10 preliminary trials present data to justify the benefits of the co-formulated mixture of two active substances: fenpicoxamid (50 g/L) and prothioconazole (100 g/L) (GF-3307 (S7K-3-3)), for the control of *Cercospora beticola* (CERCBE) and *Uromyces betae* (UROMBE) respectively in sugar beet. The co-formulated mixture GF-3307 (S7K-3-3) was compared with the products GF-3308 and Proline, which contain the single active substances fenpicoxamid (50 g/L) and prothioconazole (250 g/L), respectively, applied at equivalent dose rates per hectare: 75.0 g fenpicoxamid/ha and 150 g prothioconazole/ha. Considering *Cercospora beticola* (CERCBE), preliminary trials were conducted in the Maritime EPPO zone (Czech Republic - 1 trial, France - 4 trials,

<sup>4</sup> <https://www.frac.info/frac-teams/working-groups/sbi-fungicides/recommendations-for-sbi>

<sup>5</sup> [https://www.frac.info/docs/default-source/modes-of-action-without-recommendations-by-frac/group-21-\(c4\)---fenpicoxamid-\(qii\)-recommendations-17th-of-april-2019.pdf?sfvrsn=20bd489a\\_2](https://www.frac.info/docs/default-source/modes-of-action-without-recommendations-by-frac/group-21-(c4)---fenpicoxamid-(qii)-recommendations-17th-of-april-2019.pdf?sfvrsn=20bd489a_2)

Germany - 10 trials, United Kingdom – 1 trial), the North-East EPPO zone (Poland - 3 trials, Lithuania - 2 trials), and the South-East EPPO zone (Hungary - 4 trials, Romania - 2 trials) in 2020, 2022 and 202. Regarding *Uromyces betae* (UROMBE), preliminary trials were conducted in the Maritime EPPO zone only (France - 2 trials, Denmark - 4 trials, United Kingdom – 4 trials) in 2022 and 2023.

Based on data from all concerned EPPO climatic zones, the trial results clearly demonstrated, that the co-formulation of fenpicoxamid and prothioconazole provided significantly higher efficacy in the control of both target pathogens CERCBE and UROMBE with 81.7% and 87.8% efficacy, respectively, compared to the solo application of fenpicoxamid (65.9% and 78.4% for CERCBE and UROMBE, respectively) and prothioconazole (66.8% and 77.3% for CERCBE and UROMBE, respectively).

Based on the submitted preliminary efficacy trial results, it can be concluded, that the benefits of using the co-formulation of fenpicoxamid and prothioconazole have been justified. Furthermore, it can be noted, that mixture of two active substances with different modes of action - prothioconazole, belonging to the triazolinthione chemical group (DMI-fungicide; SBI: Class I; FRAC group 3), and fenpicoxamid, from the picolinamide chemical group (Qil-fungicide; FRAC group 21) - would be a valuable tool in resistance management strategies on sugar beet and fodder beet.

### 3.2.2 Minimum effective dose tests (KCP 6.2)

For the control of foliar diseases in sugar beet, a total of 39 efficacy trials were carried out from 2020 to 2023 to justify the minimum effective dose of GF-3307 (S7K-3-3) applied at a maximum dose of 1.5 L/ha for Poland, Austria, Belgium, Czech Republic, Hungary, The Netherlands, Slovakia and Romania. All trials were carried out in Austria (1), Czech Republic (1), Denmark (4), France (4), Germany (13) and The United-Kingdom (5) in the EPPO Maritime climatic zone, in Lithuania (2) and Poland (3) in EPPO Northeast climatic zone and in Hungary (4) and Romania (2) in EPPO Southeast climatic zone. A dose range 1.2-1.5 L/ha is sought in Poland, Slovakia, Hungary and Romania.

#### 3.2.2.1 Minimum effective dose of GF-3307 (S7K-3-3) for the control of *Cercospora beticola* in sugar beet

This chapter covers the minimum effective dose of GF-3307 (S7K-3-3) for the control of CERCBE on sugar beet when applied at the maximum requested label rate of 1.5 L/ha and 67 % (1.0 L/ha) and 80%-83% (1.2-1.25 L/ha) of the maximum recommended label rate of GF-3307 (S7K-3-3).

**Table 3.2-18 Details on trial methodology - Minimum effective dose - CERCBE**

<b>Guidelines</b>	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/1
<b>Experimental design</b>	Plot design	RCB (30)
	Plot size	18-36 m <sup>2</sup>
	Number of replications	4 (30)
<b>Crop</b>	Trials per crop	Sugar beet (30)
	Varieties per crop	Annabella (1), Annarosa (2), Asketa (2), Belamia (1), Briga (1), BTS1140 (1), Calledia (4), Camelia (2), Clemens (1), Danicia (1), Darvas (1), KWS Florentina (1), Lunella KWS (1), Marley (1), Marynia RH (1), Pavo (1), Racoon (1), Rossada (1), Smart Latoria KWS (1), Smart Mondeo (1), Smart Sanya KWS (1), Stingray (1), Surf (1), Traper (1)
	Sowing period	Sugar beet: March – April
<b>Application</b>	Crop stage (BBCH) at application	Sugar beet: two applications between BBCH 35-49*
	Timing Pest stage at application	1 <sup>st</sup> application: At the appearance of the disease to control the foliar diseases with an interval. The application was timed to cover the main infection period to protect the crop from disease development.
	Number of applications	2 applications: 30 trials with intervals of 14 to 29 days*
	Spray volumes	200-400 L/ha
<b>Assessment</b>	Assessment types	% infection (severity) % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting)
	Assessment dates for	Assessments for crop selectivity were aimed at 1 and 2 weeks after application

	efficacy and crop selectivity	and at every assessment timing for efficacy. Assessments for efficacy (% infection) at each application and then 15-20 days, 30-40 days and 50-60 days after the last application. Yield (12 trials) and quality parameters (Sodium content (9 trials), Potassium content (9 trials), Amino nitrogen content (9 trials) and Sugar content in % (9 trials)).
<b>Other relevant information</b>	E.g. Natural / artificial inoculation...	Natural infection in 23 trials Artificial inoculation in 7 trials
	E.g. 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 CERCBE is an abundant disease.

\*In 2 trials, three applications were performed. However, only valid assessment after the second application were considered for the evaluation.

## Introduction

In total, data from 30 field trials are presented in this section to demonstrate the minimum effective dose of GF-3307 (S7K-3-3), for the control of CERCBE in sugar beet. GF-3307 (S7K-3-3) was tested at 1.5, 1.2-1.25 and 1.0 L/ha. The trials were performed in accordance with the EPPO standard PP 1/225 ‘*Minimum effective dose*’. The European reference standards used were SCORE (250 g/L difenoconazole) applied at 0.4 L/ha, AMISTAR GOLD (125+125 g/L azoxystrobin + difenoconazole) applied at 1.0 L/ha and SPYRALE at 1.0 L/ha (100+375 g/L difenoconazole + fenpropidin). In this section results from all standards are presented and merged in one column. Orthogonal results against each standard can be found in section 3.2.3.

The trials were carried out by Dow AgroSciences/Corteva Agriscience, contractor companies and Official Research Institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

Twenty- ~~three~~ four trials representative for the Central registration zone were selected in Czech Republic (1) and Germany (13) in the Maritime EPPO climatic zone, in Poland (3) in the Northeast EPPO climatic zone, in Hungary (4) and in Romania (2) in the Southeast EPPO climatic zone. In addition, to support the minimum effective dose, seven trials of others registration zones (Southern, Northern) of Maritime and Northeast EPPO climatic zones are added. These trials were carried out in Lithuania (2), France (4) and in the United-Kingdom (1).

## Materials and Methods

The justification of the minimum effective dose of GF-3307 (S7K-3-3) for the control of CERCBE was supported by the data from 30 efficacy trials. Material and Methods used in these efficacy trials are given within Section 3.2.3 “Efficacy tests (KCP 6.2)”.

GF-3307 (S7K-3-3) at the rates tested and the reference products were applied between growth stage BBCH 35-49 when the crop conditions for CERCBE infections were favourable. Seven trials were artificially inoculated by spraying a *Cercospora beticola* spore suspension before or after the application of GF-3307 (S7K-3-3) and the reference products. Details of the natural or artificially inoculated trials are shown in Table 3.2-34 in section 3.2.3.

Inoculation of trials is detailed as acceptable practice for disease control in sugar beet trials, within EPPO Standard PP 1/1(4). Disease levels in the untreated at assessment were greater in the naturally infected trials at 5.1-65.0% severity, compared to 7.9-63.5% severity in the inoculated trials (see in Table 3.2-34). Therefore, the levels of disease in the inoculated trials were within the range of levels of disease seen in the naturally infected trials, so all trials can be considered to be fully valid to support the claims for control of this disease.

GF-3307 (S7K-3-3) was evaluated in accordance with EPPO Standard PP 1/225 ‘*Minimum effective dose*’ and specific EPPO guideline PP 1/1 ‘*Foliar diseases on sugar beet*’, to determine the minimum effective dose for control of CERCBE in sugar beet. GF-3307 (S7K-3-3) was tested at 50+100 g a.s./ha, 60-62.5+120-125 g a.s./ha and 75+150 g a.s./ha in the supporting trials, corresponding to 1.0, 1.2-1.25 and 1.5 of GF-3307 (S7K-3-3).

GF-3307 (S7K-3-3) was evaluated at 1.2-1.25 and 1.5 L/ha for the control of CERCBE in 27 MED trials included in this section. The rate of 1.0 L/ha (67 % of the proposed label rate) of GF-3307 (S7K-3-3) was evaluated in the 27 of the 30 MED trials.

## Results

In recent years, *Cercospora beticola* has become more prevalent in Europe<sup>6,7</sup> and has become the most destructive foliar pathogen of sugar beet. It is widely present in most beet-growing regions and can cause major yield losses if not properly controlled. This disease usually appears early in the season and is most severe in wet and warm areas in case of very early attacks<sup>8</sup>.

Therefore, this part was supported by 30 GEP small plot field trials conducted in order to determine the minimum effective dose of GF-3307 (S7K-3-3), for the control of the CERCBE in sugar beet, following two applications between BBCH 35-49 of the crop. The MED trials representative for the Central registration zone were carried out in 2020, 2022 and 2023 in Czech Republic (1) and Germany (13) in the Maritime EPPO climatic zone, in Poland (3) in the Northeast EPPO climatic zone, in Hungary (4) and in Romania (2) in the Southeast EPPO climatic zone. In addition, to support the minimum effective dose, seven trials of others registration zones (Southern, Northern) of Maritime and Northeast EPPO climatic zones are added. These trials were carried out in Lithuania (2), France (4) and in the United-Kingdom (1), where CERCBE can be a key problem in sugar beet and so especially the German data presents a worst case situation on sugar beet crop.

The results are summarized by EPPO climatic zone in Table 3.2-19 (Maritime EPPO climatic zone), Table 3.2-20 (Northeast EPPO climatic zone), Table 3.2-21 (Southeast EPPO climatic zone) and Table 3.2-22 (All EPPO climatic zone). Only results for all efficacy trials (all EPPO climatic zones in Table 3.2-22) are discussed hereafter to justify the minimum effective dose.

### Assessment around 15 -20 DA-B:

From 22 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha achieved mean control of CERCBE of 84.6% (range 60.3-100.0%). Applied in the same trials at 1.0 and 1.2-1.25 L/ha (67% and 80-83% of the proposed maximum label rate), GF-3307 (S7K-3-3) achieved a lower mean level of control of 72.6% at 1.0 L/ha and 78.7% at 1.2-1.25 L/ha with more variable results (range 46.9-100.0 at 1.0 L/ha and range 50.0-100.0% at 1.2-1.25 L/ha).

From 23 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha achieved mean control of CERCBE of 84.7% (range 60.3-100.0%). Applied in the same trials at 1.0 L/ha (67% of the proposed maximum label rate), GF-3307 (S7K-3-3) achieved a lower mean level of control of 72.9% with more variable results (range 46.9-100.0).

From 25 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha achieved mean control of CERCBE of 85.2% (range 60.3-100.0%). Applied in the same trials at 1.2-1.25 L/ha (80-83% of the proposed maximum label rate), GF-3307 (S7K-3-3) achieved a lower mean level of control of 78.8% with more variable results (range 50.0-100.0).

### Assessment around 30-40 DA-B:

From 21 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha achieved mean control of CERCBE of 83.1% (range 62.3-100.0%). Applied in the same trials at 1.0 and 1.2-1.25 L/ha (67% and 80-83% of the proposed maximum label rate), GF-3307 (S7K-3-3) achieved a lower mean level of control of 70.0% at 1.0 L/ha and 76.7% at 1.2-1.25 L/ha with more variable results (range 43.3-96.4 at 1.0 L/ha and range 58.5-97.1% at 1.2-1.25 L/ha).

From 24 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha achieved mean control of CERCBE of 83.5% (range 62.3-100.0%). Applied in the same trials at 1.0 L/ha (67% of the proposed maximum label rate), GF-3307 (S7K-3-3) achieved a lower mean level of control of 71.8% with more variable results (range 43.3-96.4).

From 24 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha achieved mean control of CERCBE of 82.8% (range 62.3-100.0%). Applied in the same trials at 1.2-1.25 L/ha (80-83% of the proposed maximum label rate), GF-3307 (S7K-3-3) achieved a lower mean level of control of 76.2% with more variable results (range 58.5-97.1).

### Assessment after 40 DA-B:

From 12 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha achieved mean control of CERCBE of 84.4% (range 71.5-100.0%). Applied in the same trials at 1.0 and 1.25 L/ha (67% and 83% of the proposed

---

<sup>6</sup> <http://bbro.co.uk/bbro-research/bbro-research/crop-protection/cu-integrated-disease-control-in-sugar-beet/>

<sup>7</sup> <https://www.r4p-inra.fr/fr/publication-de-la-note-commune-betterave-2022/>

<sup>8</sup> [https://www.florimond-desprez.com/es/wp-content/uploads/sites/6/2015/11/leaf-diseases\\_eng.pdf](https://www.florimond-desprez.com/es/wp-content/uploads/sites/6/2015/11/leaf-diseases_eng.pdf)

maximum label rate), GF-3307 (S7K-3-3) achieved a lower mean level of control of 70.6% at 1.0 L/ha and 77.7% at 1.25 L/ha with more variable results (range 38.1-92.0 at 1.0 L/ha and range 56.7-96.1% at 1.25 L/ha).

From 15 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha achieved mean control of CERCBE of 85.0% (range 71.5-100.0%). Applied in the same trials at 1.0 L/ha (67% of the proposed maximum label rate), GF-3307 (S7K-3-3) achieved a lower mean level of control of 72.2% with more variable results (range 38.1-92.0).

*Valid assessment after two applications (2 to 6 weeks after the application – all efficacy trials merged):*

From 24 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha achieved mean control of CERCBE of 81.9% (range 60.3-100.0%). Applied in the same trials at 1.0 and 1.2-1.25 L/ha (67% and 80-83% of the proposed maximum label rate), GF-3307 (S7K-3-3) achieved a lower mean level of control of 68.8% at 1.0 L/ha and 75.7% at 1.2-1.25 L/ha (range 43.3-96.4 at 1.0 L/ha and range 50.0-97.1% at 1.25 L/ha).

From 27 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha achieved mean control of CERCBE of 82.3% (range 60.3-100.0%). Applied in the same trials at 1.0 L/ha (67% of the proposed maximum label rate), GF-3307 (S7K-3-3) achieved a lower mean level of control of 70.5% with more variable results (range 43.3-96.4).

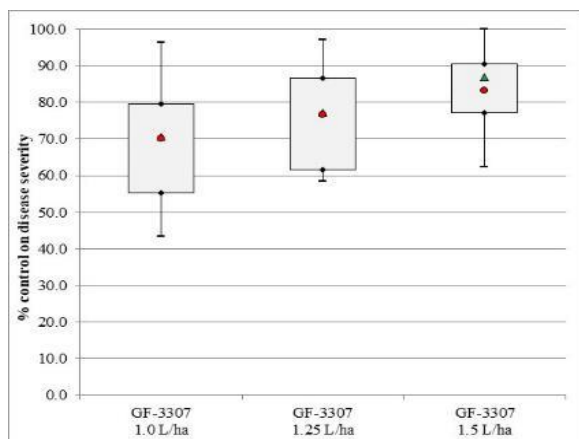
From 27 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha achieved mean control of CERCBE of 81.7% (range 60.3-100.0%). Applied in the same trials at 1.2-1.25 L/ha (80-83% of the proposed maximum label rate), GF-3307 (S7K-3-3) achieved a lower mean level of control of 75.4% with more variable results (range 50.0-97.1).

In addition, in most challenging situation, with a disease pressure superior to 40% of plants area infected, in 7 trials, GF-3307 (S7K-3-3) at 1.5 L/ha achieved mean control of CERCBE of 78.0% (range 65.5-86.8%). Applied in the same trials at 1.0 and 1.25 L/ha (67% and 83% of the proposed maximum label rate), GF-3307 (S7K-3-3) achieved a lower mean level of control at respectively 65.8% and 71.3% (range 52.8-79.3% at 1.0 L/ha and range 58.5-83.0% at 1.25 L/ha). Under lower disease pressure (<30% of plants area infected), GF-3307 (S7K-3-3) at 1.5 L/ha achieved mean control of CERCBE of 88.5% (range 77.2-100.0%). Applied in the same 9 trials at 1.0 and 1.25 L/ha (67% and 83% of the proposed maximum label rate), GF-3307 (S7K-3-3) achieved a lower mean level of control at respectively 73.6% and 81.4% (range 53.6-89.1% at 1.0 L/ha and range 61.7-97.1% at 1.25 L/ha).

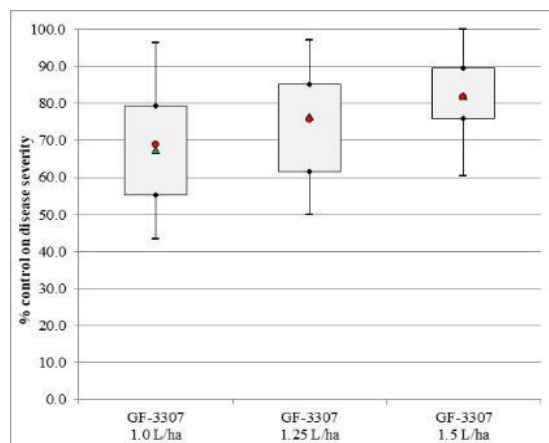
Trials results demonstrate that an increase dose rate provided an increase control and furthermore that the maximum effective dose rate of 1.5 L/ha should be applied in order to achieve highest and most consistent efficacy against *Cercospora beticola* in sugar beet. The difference between the different dose rates of GF-3307 (S7K-3-3) can be illustrated by box plot graphic on the disease severity in

Figure 3.2-7. Indeed, overall, according to the box plots graphics, the higher the dose of GF-3307 (S7K-3-3), the higher the efficacy.

The results justify also the use of a lower rate of 1.2 L/ha as requested by Poland, Hungary, Romania and Slovakia according to the local conditions and infestation pressure (e.g. under low disease pressure). Indeed, results from 6 trials conducted in EPPO Southeast climatic zone demonstrated that under lower disease pressure, the minimum rate of 1.2 L/ha provided overall good control and was equivalent or better than the reference products. However, the maximal rate of 1.5 L/ha is recommended in case of highest disease pressure to obtain a better control and in an approach of efficient management of the risk of resistance and most effective control of disease in a growers spray program. Only in Austria, Belgium, Czech Republic and The Netherlands, the recommended rate is 1.5 L/ha according with the local conditions and this dose may be legally reduced by the grower under lower disease pressure situations. Considering all factors, it is the applicants opinion that the range rate of 1.2 to 1.5 L/ha is the most balanced rate of GF-3307 (S7K-3-3) against CERCBE in sugar beet for Poland, Hungary, Romania and Slovakia which performed similar to the reference materials, while in Austria, Belgium, Czech Republic and The Netherlands the proposed rate is 1.5 L/ha for robust control of CERCBE and a broad spectrum of diseases.



CERCBE – Assessment around 4-6 (30-40 days) weeks  
after the 2<sup>nd</sup> application  
Disease severity on plants (21 trials) (Table 3.2-22)



CERCBE - Valid assessment after 2 applications (2 to 6  
weeks after the application)  
Disease severity on plants (24 trials) (Table 3.2-22)

• q1 – min ▲ median ● average – max • q3

**Figure 3.2-7 Minimum effective dose of GF-3307 (S7K-3-3) - Sugar beet - CERCBE - Box Plot graphics (all EPPO Climatic zones)**

**Table 3.2-19 Minimum effective dose of GF-3307 (S7K-3-3) at the proposed label rate of 1.5 L/ha (100%), 80-83% and 67% dose rates against CERCBE in sugar beet. Results from 19 trials conducted in the EPPO Maritime climatic zone in 2020, 2022 and 2023**

Part	Timing of assessment	EPPO climatic zone	No. of trials	Untreated % INFECT CERCBE			% Control of CERCBE																No. of assessments significantly > , = , < GF-3307 (S7K-3-3) at 1.5 L/ha vs.			
							GF-3307 (S7K-3-3) 1.0 L/ha (67%)				GF-3307 (S7K-3-3) 1.2-1.25 L/ha (80-83%)				GF-3307 (S7K-3-3) 1.5 L/ha (100%)				All reference products							
							Fenpicoxamid + Prothioconazole				Fenpicoxamid + Prothioconazole				Fenpicoxamid + Prothioconazole											
							50+100 g a.s./ha				60-62.5 + 120-125 g a.s./ha				75+150 g a.s./ha				GF-3307 (S7K-3-3)							
							Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.0 L/ha	1.25 L/ha		
Disease severity on plants	Assessment around 15 -20 DA-B	Maritime	12	19.6	5.2	58.8	75.2	56.9	100.0	12.2	-	-	-	-	86.0	75.6	100.0	7.9	56.9	34.1	84.9	15.9	3> ; 9= ; 0<	-		
			14	20.6	5.2	58.8	-	-	-	-	79.7	65.6	100.0	9.8	86.8	75.6	100.0	7.5	58.8	34.1	84.9	16.6	-	1> ; 13= ; 0<		
			11	20.7	5.2	58.8	74.8	56.9	100.0	12.6	79.9	65.6	100.0	10.4	86.1	75.6	100.0	8.2	55.1	34.1	84.9	15.4	3> ; 8= ; 0<	0> ; 11= ; 0<		
	Assessment around 30-40 DA-B	Maritime	15	29.8	5.1	63.5	76.5	54.7	89.1	12.2	-	-	-	-	85.2	66.9	100.0	8.8	55.8	30.2	86.7	17.0	2> ; 13= ; 0<	-		
			15	30.4	5.1	63.5	-	-	-	-	78.1	58.6	97.1	11.6	84.2	66.9	100.0	9.1	55.0	30.2	79.9	14.4	-	2> ; 13= ; 0<		
			12	31.1	5.1	63.5	74.6	54.7	89.1	12.9	79.4	58.6	97.1	12.4	85.0	66.9	100.0	9.7	55.0	30.2	79.9	15.9	2> ; 10= ; 0<	1> ; 11= ; 0<		
	Assessment after 40 DA-B	Maritime	10	41.3	20.6	66.5	78.2	57.5	91.5	12.9	-	-	-	-	87.7	73.0	100.0	9.0	59.1	20.8	90.5	20.0	2> ; 8= ; 0<	-		
			7	40.0	20.6	66.5	78.0	57.5	90.5	11.9	81.6	56.7	96.1	13.5	87.9	73.0	100.0	9.9	62.7	50.5	90.5	13.7	2> ; 5= ; 0<	0> ; 7= ; 0<		
	Valid assessment after 2 applications (2 to 6 weeks after the application)	Maritime	16	30.0	5.1	63.5	75.8	54.7	89.1	12.2	-	-	-	-	84.6	66.9	100.0	8.8	55.5	30.2	86.7	16.5	2> ; 14= ; 0<	-		
			16	30.6	5.1	63.5	-	-	-	-	77.9	58.6	97.1	11.3	83.7	66.9	100.0	9.1	54.7	30.2	79.9	14.0	-	2> ; 14= ; 0<		
13			31.3	5.1	63.5	73.8	54.7	89.1	12.6	79.0	58.6	97.1	12.0	84.4	66.9	100.0	9.6	54.6	30.2	79.9	15.4	2> ; 11= ; 0<	1> ; 12= ; 0<			



**Table 3.2-20 Minimum effective dose of GF-3307 (S7K-3-3) at the proposed label rate of 1.5 L/ha (100%), 80-83% and 67% dose rates against CERCBE in sugar beet. Results from 5 trials conducted in the EPPO Northeast climatic zone in 2020, 2022 and 2023**

Part	Timing of assessment	EPPO climatic zone	No. of trials	Untreated % INFECT CERCBE			% Control of CERCBE																No. of assessments significantly > , = , < GF-3307 (S7K-3-3) at 1.5 L/ha vs.	
							GF-3307 (S7K-3-3) 1.0 L/ha (67%)				GF-3307 (S7K-3-3) 1.2-1.25 L/ha (80-83%)				GF-3307 (S7K-3-3) 1.5 L/ha (100%)				All reference products					
							Fenpicoxamid + Prothioconazole				Fenpicoxamid + Prothioconazole				Fenpicoxamid + Prothioconazole									
							50+100 g a.s./ha				60-62.5 + 120-125 g a.s./ha				75+150 g a.s./ha				GF-3307 (S7K-3-3)					
				Mean	Min	Max		Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.0 L/ha
Disease severity on plants	Assessment around 15-20 DA-B	Northeast	5	29.6	7.0	57.5	74.2	46.9	97.9	16.7	78.8	50.0	98.8	15.9	80.9	60.3	99.4	12.6	62.0	22.8	97.6	25.5	1> ; 4= ; 0<	0> ; 5= ; 0<
		Northeast and PL border countries (PL-CZ-DE-LT)	13	20.1	6.3	57.5	74.0	46.9	100.0	14.6	-	-	-	-	83.3	60.3	100.0	10.0	55.9	22.8	97.6	20.0	3> ; 10= ; 0<	-
			15	21.0	6.3	57.5	-	-	-	-	78.6	50.0	100.0	12.3	84.4	60.3	100.0	9.7	57.8	22.8	97.6	20.1	-	1> ; 14= ; 0<
			12	21.1	6.3	57.5	73.6	46.9	100.0	15.1	78.5	50.0	100.0	13.3	83.1	60.3	100.0	10.4	54.2	22.8	97.6	19.9	3> ; 9= ; 0<	0> ; 12= ; 0<
	Assessment around 30-40 DA-B	Northeast	3	32.9	26.7	38.3	72.5	43.3	96.4	22.0	79.8	60.5	96.8	14.9	82.4	62.3	97.2	14.7	65.0	46.0	90.4	18.7	0> ; 3= ; 0<	0> ; 3= ; 0<
		Northeast and PL border countries (PL-CZ-DE-LT)	14	29.1	7.9	63.5	74.8	43.3	96.4	16.0	-	-	-	-	83.7	62.3	100.0	10.7	53.7	30.2	90.4	17.9	2> ; 12= ; 0<	-
			14	29.7	8.8	63.5	-	-	-	-	76.7	58.6	97.1	13.3	82.6	62.3	100.0	10.8	52.8	30.2	90.4	15.1	-	2> ; 12= ; 0<
			11	30.3	8.8	63.5	72.2	43.3	96.4	17.1	77.7	58.6	97.1	14.6	83.1	62.3	100.0	11.8	52.3	30.2	90.4	16.9	2> ; 9= ; 0<	1> ; 10= ; 0<
	Assessment after 40 DA-B	Northeast	1	69.8	-	-	92.0	-	-	-	90.8	-	-	-	87.6	-	-	-	76.3	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
		Northeast and PL border countries (PL-DE)	9	44.9	20.8	69.8	78.3	57.5	92.0	13.8	-	-	-	-	86.4	73.0	100.0	9.0	56.2	20.8	88.7	18.5	2> ; 6= ; 0<	-
			6	45.3	24.8	69.8	78.2	57.6	92	13.1	81.5	56.7	93.9	13.7	86.0	73.0	100.0	10.0	62.7	50.5	90.5	13.7	2> ; 3= ; 0<	0> ; 5= ; 0<
	Valid assessment after 2 applications (2 to 6 weeks after the application)	Northeast	5	38.7	26.7	57.5	66.8	43.3	96.4	19.8	74.1	50.0	96.8	16.7	78.0	60.3	97.2	14.4	53.2	22.8	90.4	22.0	1> ; 4= ; 0<	0> ; 5= ; 0<
		Northeast and PL border countries (PL-CZ-DE-LT)	16	31.4	7.9	63.5	72.8	43.3	96.4	16.5	-	-	-	-	82.2	60.3	100.0	11.5	51.4	22.8	90.4	18.4	3> ; 13= ; 0<	-
			16	32.0	8.8	63.5	-	-	-	-	75.3	50.0	97.1	14.1	81.2	60.3	100.0	11.4	50.7	22.8	90.4	15.9	-	2> ; 14= ; 0<
			13	33.0	8.8	63.5	70.1	43.3	96.4	17.1	75.8	50.0	97.1	115.4	81.3	60.3	100.0	12.5	49.7	22.8	90.4	17.4	3> ; 10= ; 0<	1> ; 12= ; 0<
		Poland and border countries < 30% plants area infected in untreated control	5	18.6	8.8	26.7	81.8	65.3	89.1	9.3	84.2	61.7	97.1	12.3	89.5	77.2	100.0	7.4	54.7	36.4	74.5	12.3	0> ; 5= ; 0<	0> ; 5= ; 0<
		Poland and border countries > 40% plants area infected in untreated control	2	60.5	57.5	63.5	62.2	54.7	69.7	7.5	71.3	61.7	80.9	9.6	80.5	78.4	82.6	2.1	39.2	30.2	48.1	9.0	2> ; 0= ; 0<	1> ; 1= ; 0<

**Table 3.2-21 Minimum effective dose of GF-3307 (S7K-3-3) at the proposed label rate of 1.5 L/ha (100%), 80-83% and 67% dose rates against CERCBE in sugar beet. Results from 6 trials conducted in the EPPO Southeast climatic zone in 2020, 2022 and 2023.**

Part	Timing of assessment	EPPO climatic zone	No. of trials	Untreated % INFECT CERCBE			% Control of CERCBE																No. of assessments significantly > , = , < GF-3307 (S7K-3-3) at 1.5 L/ha vs.	
							GF-3307 (S7K-3-3) 1.0 L/ha (67%)				GF-3307 (S7K-3-3) 1.2-1.25 L/ha (80-83%)				GF-3307 (S7K-3-3) 1.5 L/ha (100%)				All reference products					
							Fenpicoxamid + Prothioconazole				Fenpicoxamid + Prothioconazole				Fenpicoxamid + Prothioconazole									
							50+100 g a.s./ha				60-62.5 + 120-125 g a.s./ha				75+150 g a.s./ha				GF-3307 (S7K-3-3)					
				Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.0 L/ha	1.25 L/ha
Disease severity on plants	Assessment around 15-20 DA-B	Southeast	6	18.8	8.0	44.5	67.3	54.7	86.8	11.9	76.6	56.9	90.4	13.0	85.1	66.8	94.4	10.4	67.5	33.2	100.0	26.3	3> ; 3= ; 0<	2> ; 4= ; 0<
	Assessment around 30-40 DA-B	Southeast	6	35.7	12.3	65.0	59.6	52.8	70.5	6.5	69.7	58.5	77.2	7.3	79.7	65.5	89.0	8.0	65.6	27.2	97.5	25.2	3> ; 3= ; 0<	3> ; 3= ; 0<
	Assessment after 40 DA-B	Southeast	4	32.0	14.0	52.5	52.1	38.1	66.7	12.3	67.7	63.5	69.4	2.4	77.5	71.5	82.7	5.1	75.3	50.6	97.0	21.8	2> ; 2= ; 0<	2> ; 2= ; 0<
	Valid assessment after 2 applications (2 to 6 weeks after the application)	Southeast	6	35.7	12.3	65.0	59.6	52.8	70.5	6.5	69.7	58.5	77.2	7.3	79.7	65.5	89.0	8.0	65.6	27.2	97.5	25.2	3> ; 3= ; 0<	3> ; 3= ; 0<
		Southeast < 30% plants area infected in untreated control	3	18.2	12.3	21.6	59.7	53.6	70.5	7.6	74.9	72.1	77.2	2.1	86.3	81.5	89.0	3.4	85.1	60.3	97.5	17.5	2> ; 1= ; 0<	2> ; 1= ; 0<
		Southeast > 40% plants area infected in untreated control	3	53.2	45.0	65.0	59.5	52.8	65.3	5.1	64.5	58.5	74.0	6.8	73.1	65.5	78.5	5.5	46.1	27.2	61.3	14.2	1> ; 2= ; 0<	1> ; 2= ; 0<

**Table 3.2-22 Minimum effective dose of GF-3307 (S7K-3-3) at the proposed label rate of 1.5 L/ha (100%), 80-83% and 67% dose rates against CERCBE in sugar beet. Results from 30 trials conducted in All EPPO climatic zones in 2020, 2022 and 2023**

Part	Timing of assessment	EPPO climatic zone	No. of trials	Untreated % INFECT CERCBE				% Control of CERCBE														No. of assessments significantly > , = , < GF-3307 (S7K-3-3) at 1.5 L/ha vs.							
								GF-3307 (S7K-3-3) 1.0 L/ha (67%)				GF-3307 (S7K-3-3) 1.2-1.25 L/ha (80-83%)				GF-3307 (S7K-3-3) 1.5 L/ha (100%)				All reference products									
								Fenpicoxamid + Prothioconazole				Fenpicoxamid + Prothioconazole				Fenpicoxamid + Prothioconazole													
								50+100 g a.s./ha				60-62.5 + 120-125 g a.s./ha				75+150 g a.s./ha													
				Mean	Min	Max		Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.0 L/ha	1.25 L/ha				
Disease severity on plants	Assessment around 15-20 DA-B	All EPPO climatic zones	23	21.6	5.2	58.8	72.9	46.9	100.0	13.6	-	-	-	-	84.7	60.3	100.0	10.0	60.8	22.8	100.0	21.8	7> ; 16= ; 0<	-					
			25	22.0	5.2	58.8	-	-	-	-	78.8	50.0	100.0	12.1	85.2	60.3	100.0	9.7	61.5	22.8	100	21.5	-	3> ; 22= ; 0<					
			22	22.2	5.2	58.8	72.6	46.9	100.0	13.9	78.7	50.0	100.0	12.6	84.6	60.3	100.0	10.2	60.1	22.8	100.0	22.0	7> ; 15= ; 0<	2> ; 20> ; 0<					
	Assessment around 30-40 DA-B	All EPPO climatic zones	24	31.7	5.1	65.0	71.8	43.3	96.4	14.7	-	-	-	-	83.5	62.3	100.0	9.9	59.4	27.2	97.5	20.1	5> ; 19= ; 0<	-					
			24	32.0	5.1	65.0	-	-	-	-	76.2	58.5	97.1	11.8	82.8	62.3	100.0	9.9	58.9	27.2	97.5	18.9	-	5> ; 19= ; 0<					
			21	32.7	5.1	65.0	70.0	43.3	96.4	14.8	76.7	58.5	97.1	12.4	83.1	62.3	100.0	10.4	59.5	27.2	97.5	20.1	5> ; 16= ; 0<	4> ; 17= ; 0<					
	Assessment after 40 DA-B	All EPPO climatic zones	15	40.7	14.0	69.8	72.2	38.1	92.0	17.6	-	-	-	-	85.0	71.5	100.0	9.0	64.6	20.8	97.0	21.3	4> ; 11= ; 0<	-					
			12	39.8	14.0	69.8	70.6	38.1	92.0	17.8	77.7	56.7	96.1	12.9	84.4	71.5	100.0	9.5	68.0	50.5	97	17.5	5> ; 7= ; 0<	2> ; 10= ; 0<					
	Valid assessment after 2 applications (2 to 6 weeks after the application)	All EPPO climatic zones	27	32.9	5.1	65.0	70.5	43.3	96.4	14.7	-	-	-	-	82.3	60.3	100.0	10.4	57.3	22.8	97.5	20.3	6> ; 21= ; 0<	-					
			27	33.2	5.1	65.0	-	-	-	-	75.4	50.0	97.1	12.3	81.7	60.3	100.0	10.4	56.8	22.8	97.5	19.0	-	5> ; 22= ; 0<					
			24	33.9	5.1	65.0	68.8	43.3	96.4	14.6	75.7	50.0	97.1	12.8	81.9	60.3	100.0	10.8	57.1	22.8	97.5	19.2	6> ; 18= ; 0<	4> ; 20= ; 0<					
		All EPPO climatic zones < 30% plants area infected in untreated control	9	16.9	5.1	26.7	73.6	53.6	89.1	13.0	81.4	61.7	97.1	10.4	88.5	77.2	100.0	6.1	67.1	36.4	97.5	19.7	2> ; 7= ; 0<	2> ; 7= ; 0<					
			All EPPO climatic zones > 40% plants area infected in untreated control	7	54.2	45.0	65.0	65.8	52.8	79.3	9.9	71.3	58.5	83.0	9.8	78.0	65.5	86.8	6.1	48.9	27.2	66.6	14.1	3> ; 4= ; 0<	2> ; 5= ; 0<				

#### Comments of zRMS on:

#### Minimum effective dose of GF-3307 (S7K-3-3) for the control of *Cercospora beticola* in sugar beet (3.2.2.1)

Thirty efficacy trials present data to determine the minimum effective dose (MED) of GF-3307 (S7K-3-3), applied twice, in the control of *Cercospora beticola* on sugar beet. The trials were carried out in 3 EPPO zones: Maritime (Czech Republic - 1 trial, France – 4 trials, Germany - 13 trials, the United Kingdom - 1 trial), North-East (Lithuania - 2 trials, Poland - 3 trials) and South-East (Hungary - 4 trials, Romania - 2 trials) in 2020, 2022 and 2023.

The maximum recommended dose rate of 1.5 L/ha was compared with lower dose rates: 1.0 L/ha and 1.2-1.25 L/ha corresponding to 67% and 80%-83% of the maximum target dose rate respectively.

Conclusions from the MED trials for individual EPPO climatic zones are presented below.

#### **Maritime EPPO zone (19 trials)**

Based on the submitted trial results, a clear dose response was seen for GF-3307 (S7K-3-3) with increase of efficacy with increasing dose rate in the control CERCBE on sugar beet. Considering numerical data, a clear differences were noted between tested dose rates. Statistically significant differences (in favor of higher dose rate) were evident in 1 to 3 trials depending on the timing of assessment and dose rates compared. The highest efficacy, under various conditions of disease pressure was noted for GF-3307 (S7K-3-3), applied at maximum recommended dose rate of 1.5 L/ha.

#### **North-East EPPO zone (5 trials)**

A clear dose response was noted comparing the efficacy of GF-3307 (S7K-3-3), applied at 1.5 L/ha with the efficacy results achieved for lower dose rates 1.0 L/ha and 1.25 L/ha. A clear differences were noted between tested dose rates considering numerical data. Statistically significant differences (in favor of higher dose rate) were evident in single trials, between dose rate 1.0 L/ha and 1.5 L/ha. The highest efficacy, under various conditions of disease pressure was noted for GF-3307 (S7K-3-3), applied at maximum recommended dose rate of 1.5 L/ha.

#### **South-East EPPO zone (6 trials)**

A clear dose response was seen for GF-3307 (S7K-3-3) with increase of efficacy with increasing dose rate in the control CERCBE on sugar beet. Considering numerical data, a clear differences were noted between tested dose rates. Statistically significant differences (in favor of higher dose rate) were evident in 1 to 3 trials, depending on the timing of assessment. The highest efficacy, under various conditions of disease pressure was noted for GF-3307 (S7K-3-3), applied at maximum recommended dose rate of 1.5 L/ha.

### 3.2.2.2 Minimum effective dose of GF-3307 (S7K-3-3) for the control of *Uromyces betae* in sugar beet

This chapter covers the minimum effective dose of GF-3307 (S7K-3-3) for the control of UROMBE on sugar beet when applied at the maximum requested label rate of 1.5 L/ha and 67 % (1.0 L/ha) and 83% (1.25 L/ha) of the maximum recommended label rate of GF-3307 (S7K-3-3).

**Table 3.2-23 Details on trial methodology - Minimum effective dose - UROMBE**

<b>Guidelines</b>	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/1
<b>Experimental design</b>	Plot design	RCB
	Plot size	18-30 m <sup>2</sup>
	Number of replications	4 (11)
<b>Crop</b>	Trials per crop	Sugar beet (11)
	Varieties per crop	Annabella (1), BTS1140 (1), Clemens (1), Falster (1), Katjana (1), Morgan (1), Nakskov (2), Nasser (1), Surf (1), Wren (1)
	Sowing period	Sugar beet: March – May
<b>Application</b>	Crop stage (BBCH) at application	Sugar beet: two applications between BBCH 39-49
	Timing Pest stage at application	1 <sup>st</sup> application: At the appearance of the disease to control the foliar diseases with an interval. The application was timed to cover the main infection period to protect the crop from disease development.
	Number of applications	2 applications: 11 trials with intervals of 20 to 25 days
	Spray volumes	200-245 L/ha
<b>Assessment</b>	Assessment types	% infection (severity) % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting) Yield and quality parameters (Sodium content (3 trials), Potassium content (3 trials), Amino nitrogen content (3 trials) and Sugar content in % (3 trials)).
	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) at each application and then 15-20 days, 30-40 days and 50-60 days after the last application.
<b>Other relevant information</b>	E.g. Natural / artificial inoculation...	Natural infection in 11 trials
	E.g. 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 UROMBE is an abundant disease.

#### Introduction

In total, data from 11 field trials are presented in this section to demonstrate the minimum effective dose of GF-3307 (S7K-3-3), for the control of UROMBE in sugar beet. GF-3307 (S7K-3-3) was tested at 1.5, 1.25 and 1.0 L/ha. The trials were performed in accordance with the EPPO standard PP 1/225 '*Minimum effective dose*'. The reference standard used was SCORE (250 g/L difenoconazole) applied at 0.4 L/ha (11 trials), AMISTAR GOLD (125+125 g/L azoxystrobin + difenoconazole) applied at 1.0 L/ha and SPYRALE at 1.0 L/ha (100+375 g/L difenoconazole + fenpropidin). In this section results from all standards are presented and merged in one column. Orthogonal results against each standard can be found in section 3.2.3.

The trials were carried out by Dow AgroSciences/Corteva Agriscience, contractor companies and Official Research Institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

To support the justification of minimum effective dose, eleven trials of Maritime EPPO climatic zone are selected. These trials were carried out in Denmark (4), France (2), Germany (1) and the United-Kingdom (4).

## Materials and Methods

The justification of the minimum effective dose of GF-3307 (S7K-3-3) for the control of UROMBE was supported by the data from 11 efficacy trials. Material and Methods used in these efficacy trials are given within Section 3.2.3 “Efficacy tests (KCP 6.2)”.

GF-3307 (S7K-3-3) at the rates tested and the reference products were applied between growth stage BBCH 39-49 when the crop conditions for UROMBE infections were favourable in natural conditions. GF-3307 (S7K-3-3) was evaluated in accordance with EPPO Standard PP 1/225 ‘*Minimum effective dose*’ and specific EPPO guideline PP 1/1 ‘*Foliar diseases on sugar beet*’, to determine the minimum effective dose for control of UROMBE in sugar beet. GF-3307 (S7K-3-3) was tested at 50+100 g a.s./ha, 62.5+125 g a.s./ha and 75+150 g a.s./ha in the supporting trials, corresponding to 1.0, 1.25 and 1.5 of GF-3307 (S7K-3-3).

GF-3307 (S7K-3-3) was evaluated at 1.25 and 1.5 L/ha for the control of UROMBE in 10 MED trials included in this section. The rate of 1.0 L/ha (67 % of the proposed label rate) of GF-3307 (S7K-3-3) was evaluated in the 11 MED trials.

## Results

This part was supported by eleven GEP small plot field trials conducted in order to determine the minimum effective dose of GF-3307 (S7K-3-3), for the control of the UROMBE in sugar beet, following two applications between BBCH 39-49 of the crop. The MED trials representative for the Central registration zone were carried out in 2022 in Germany (1) and the United-Kingdom (4). To support the minimum effective dose demonstration, six trials from 2022 to 2023 of others registration zones (Northern and Southern) of Maritime EPPO climatic zone are added. These trials were carried out in France (2) and Denmark (4) where UROMBE can be a key problem in sugar beet and so this presents a worst case situation on sugar beet crop as does the United Kingdom. Data from Maritime EPPO climatic zone presents the worst case, though fully support the whole of the Central registration zone as UROMBE is far less prevalent in the North East and South East EPPO zones where CERCBE is dominant.

The results are summarized by EPPO climatic zone in Table 3.2-24. Only results for all valid efficacy trials (Maritime EPPO climatic zone in Table 3.2-24) are discussed hereafter to justify the minimum effective dose.

### Assessment around 15-20 DA-B:

From 10 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha achieved mean control of UROMBE of 92.4% (range 73.8-99.7%). Applied in the same trials at 1.0 and 1.25 L/ha (67% and 83% of the proposed maximum label rate), GF-3307 (S7K-3-3) achieved a lower mean level of control of 82.5% at 1.0 L/ha and 89.0% at 1.25 L/ha with more variable results (range 38.5-99.1 at 1.0 L/ha and range 61.5-99.7% at 1.25 L/ha).

From 11 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha achieved mean control of UROMBE of 93.1% (range 73.8-100.0%). Applied in the same trials at 1.0 L/ha (67% of the proposed maximum label rate), GF-3307 (S7K-3-3) achieved a lower mean level of control of 83.8% with more variable results (range 38.5-99.1).

### Assessment around 30-40 DA-B:

From 9 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha achieved mean control of UROMBE of 86.5% (range 53.9-97.1%). Applied in the same trials at 1.0 and 1.25 L/ha (67% and 83% of the proposed maximum label rate), GF-3307 (S7K-3-3) achieved a lower mean level of control of 76.2% at 1.0 L/ha and 82.9% at 1.25 L/ha with more variable results (range 35.8-92.8 at 1.0 L/ha and range 43.9-95.5% at 1.25 L/ha).

From 10 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha achieved mean control of UROMBE of 87.9% (range 53.9-100.0%). Applied in the same trials at 1.0 L/ha (67% of the proposed maximum label rate), GF-3307 (S7K-3-3) achieved a lower mean level of control of 78.6% with more variable results (range 35.8-100.0).

### Assessment after 40 DA-B:

From 2 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha achieved mean control of UROMBE of 60.7% (range 52.5-68.9%). Applied in the same trials at 1.0 and 1.25 L/ha (67% and 83% of the proposed maximum label rate), GF-3307 (S7K-3-3) achieved a lower mean level of control of 41.8% at 1.0 L/ha

and a higher mean level of control of 67.6% at 1.25 L/ha (range 39.9-43.7 at 1.0 L/ha and range 43.9-99.6% at 1.25 L/ha).

From 3 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha achieved mean control of UROMBE of 68.8% (range 52.5-84.9%). Applied in the same trials at 1.0 L/ha (67% of the proposed maximum label rate), GF-3307 (S7K-3-3) achieved a lower mean level of control of 52.6% with more variable results (range 39.9-74.3).

Valid assessment after two applications (2 to 6 weeks after the application – all efficacy trials merged):

From 10 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha achieved mean control of UROMBE of 87.8% (range 53.9-99.5%). Applied in the same trials at 1.0 and 1.25 L/ha (67% and 83% of the proposed maximum label rate), GF-3307 (S7K-3-3) achieved a lower mean level of control of 78.4% at 1.0 L/ha and 84.5% at 1.25 L/ha with more variable results (range 43.9-99.6 at 1.0 L/ha and range 43.9-99.6% at 1.25 L/ha).

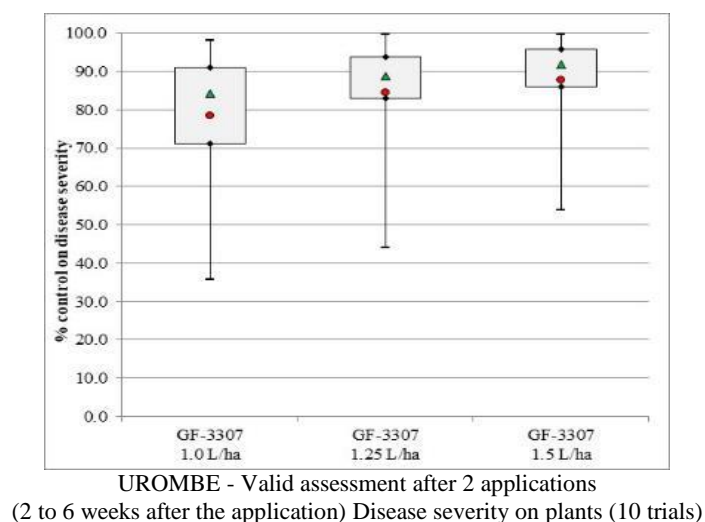
From 11 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha achieved mean control of UROMBE of 88.9% (range 53.9-100.0%). Applied in the same trials at 1.0 L/ha (67% of the proposed maximum label rate), GF-3307 (S7K-3-3) achieved a lower mean level of control of 80.3% with more variable results (range 35.8-100.0).

Trials results demonstrate that an increase dose rate provided an increase control and furthermore that the minimum effective dose rate of 1.5 L/ha should be applied in order to achieve highest and most consistent efficacy against *Uromyces betae* in sugar beet. The difference between the different dose rates of GF-3307 (S7K-3-3) can be illustrated by box plot graphic on the disease severity in

Figure 3.2-8. Indeed, in overall, according to the box plots graphics, the higher the dose of GF-3307 (S7K-3-3), the higher the efficacy.

Although no specific data is shown from the North East or South East EPPO zones, the results from Maritime justify the use of a lower rate of 1.2 L/ha as requested by Poland, Hungary, Romania and Slovakia according to the local conditions and infestation pressure (e.g. under low disease pressure). However, the maximal rate of 1.5 L/ha is recommended in case of high disease pressure to obtain a better control and in an approach of efficient management of the risk of resistance. Only in Austria, Belgium, Czech Republic and The Netherlands, the recommended rate is 1.5 L/ha according with the local conditions.

Considering all factors, it is the applicants opinion that the range rate of 1.2 to 1.5 L/ha is the most balanced rate of GF-3307 (S7K-3-3) against UROMBE in sugar beet for Poland, Hungary, Romania and Slovakia where CERCBE is dominant, while in Austria, Belgium, Czech Republic and The Netherlands the proposed rate is 1.5 L/ha for robust control of UROMBE and a broad spectrum of diseases.



**Figure 3.2-8 Minimum effective dose of GF-3307 (S7K-3-3) - Sugar beet - UROMBE - Box Plot graphics (Maritime EPPO climatic zone)**

**Table 3.2-24 Minimum effective dose of GF-3307 (S7K-3-3) at the proposed label rate of 1.5 L/ha (100%), 83% and 67% dose rates against UROMBE in sugar beet. Results from 11 trials conducted in the EPPO Maritime climatic zone in 2022 and 2023**

Part	Timing of assessment	EPPO climatic zone	No. of trials	Untreated % INFECT UROMBE			% Control of UROMBE																No. of assessments significantly > , = , < GF-3307 (S7K-3-3) at 1.5 L/ha vs.	
							GF-3307 (S7K-3-3) 1.0 L/ha (67%)				GF-3307 (S7K-3-3) 1.25 L/ha (83%)				GF-3307 (S7K-3-3) 1.5 L/ha (100%)				All reference products					
							Fenpicoxamid + Prothioconazole				Fenpicoxamid + Prothioconazole				Fenpicoxamid + Prothioconazole									
							50+100 g a.s./ha				62.5+125 g a.s./ha				75+150 g a.s./ha									
							Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min
Disease severity on plants	Assessment around 15-20 DA-B	Maritime	10	24.2	8.2	35.0	82.5	38.5	99.1	19.0	89.0	61.5	99.7	11.5	92.4	73.8	99.7	8.0	87.4	68.3	99.1	9.4	2> ; 8= ; 0<	0> ; 10= ; 0<
			11	23.5	8.5	35.0	83.8	38.5	99.1	18.6	-	-	-	-	93.1	73.8	100.0	8.0	88.6	68.3	100.0	9.7	2> ; 9= ; 0<	-
	Assessment around 30-40 DA-B	Maritime	9	40.4	18.6	59.1	76.2	35.8	92.8	17.2	82.9	43.9	95.5	15.0	86.5	53.9	97.1	12.7	82.8	59.2	93.4	12.3	1> ; 8= ; 0<	0> ; 9= ; 0<
			10	39.1	18.6	59.1	78.6	35.8	100.0	17.8	-	-	-	-	87.9	53.9	100.0	12.7	84.6	59.2	100.0	12.7	1> ; 9= ; 0<	-
	Assessment after 40 DA-B	Maritime	2	46.5	41.1	51.9	41.8	39.9	43.7	1.9	67.6	61.3	73.8	6.3	60.7	52.5	68.9	8.2	80.6	70.5	90.6	2.2	0> ; 2= ; 0<	0> ; 2= ; 0<
			3	56.8	41.1	77.5	52.6	39.9	74.3	15.4	-	-	-	-	68.8	52.5	84.9	13.2	82.4	70.5	90.6	8.6	0> ; 3= ; 0<	-
	Valid assessment after 2 applications (2 to 6 weeks after the application)	Maritime	10	38.4	18.6	59.1	78.4	35.8	98.0	17.5	84.5	43.9	99.6	15.1	87.8	53.9	99.5	12.6	84.3	59.2	97.4	12.4	1> ; 9= ; 0<	0> ; 10= ; 0<
			11	37.4	18.6	59.1	80.3	35.8	100.0	17.9	-	-	-	-	88.9	53.9	100.0	12.5	85.7	59.2	100.0	12.7	1> ; 10= ; 0<	-

**Comments of zRMS on:**

**Minimum effective dose of GF-3307 (S7K-3-3) for the control of *Uromyces betae* in sugar beet (3.2.2.2)**

Results from 11 efficacy trials, carried out between 2022 and 2023, have been presented to determine the minimum effective dose (MED) of GF-3307 (S7K-3-3), applied twice in the control of *Uromyces beate* on sugar beet. The trials were carried out only in Maritime EPPO zone (Denmark – 4 trials, France – 2 trials, Germany – 1 trial, United Kingdom – 4 trials). The maximum recommended dose rate of 1.5 L/ha was compared with lower dose rates: 1.0 L/ha and 1.25 L/ha, corresponding to 67% and 83% of the maximum target dose rate respectively.

Based on the submitted trial results, a clear dose response was seen for GF-3307 (S7K-3-3) with increase of efficacy with increasing dose rate in the control UROMBE on sugar beet. Considering numerical data, a clear differences were noted between tested dose rates. Statistically significant differences (in favor of higher dose rate) were evident in 1 to 2 trials, depending on the timing of assessment and only between dose rates 1.0 L/ha and 1.5 L/ha. The highest efficacy, under various conditions of disease pressure was noted for GF-3307 (S7K-3-3), applied at maximum recommended dose rate of 1.5 L/ha for the assessment timings up to around 40 DAB.



### 3.2.2.3 Minimum effective dose of GF-3307 (S7K-3-3) for the control of *Erysiphe betae* in sugar beet

This chapter covers the minimum effective dose of GF-3307 (S7K-3-3) for the control of ERYSB E on sugar beet when applied at the maximum requested label rate of 1.5 L/ha and 67 % (1.0 L/ha) and 80%-83% (1.2-1.25 L/ha) of the maximum recommended label rate of GF-3307 (S7K-3-3).

**Table 3.2-25 Details on trial methodology - Minimum effective dose - ERYSB E**

<b>Guidelines</b>	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/1
<b>Experimental design</b>	Plot design	RCB(7)
	Plot size	20-30 m <sup>2</sup>
	Number of replications	4 (7)
<b>Crop</b>	Trials per crop	Sugar beet (7)
	Varieties per crop	Calledia (2), Falster (1), Lunella KWS (1), Racoon (1), Sixtus (1), Wren (1)
	Sowing period	Sugar beet: March – April
<b>Application</b>	Crop stage (BBCH) at application	Sugar beet: two applications between BBCH 39-49*
	Timing Pest stage at application	1 <sup>st</sup> application: At the appearance of the disease to control the foliar diseases with an interval. The application was timed to cover the main infection period to protect the crop from disease development.
	Number of applications	1 application: 1 trial* 2 applications : 6 trials with intervals of 20 to 23 days**
	Spray volumes	200-400 L/ha
<b>Assessment</b>	Assessment types	% infection (severity) % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting) Yield (2 trials) and quality parameters (Sodium content (2 trials), Potassium content (2 trials), Amino nitrogen content (2 trials) and Sugar content in % (2 trials)).
	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) at each application and then 15-20 days, 30-40 days and 50-60 days after the last application.
<b>Other relevant information</b>	E.g. Natural / artificial inoculation...	Natural infection in 7 trials
	E.g. 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 ERYSB E is an abundant disease.

\* In one trial, only one late application was performed.

\*\* In 1 trial, three applications were performed. However, only valid assessment after the second application were considered for the evaluation.

#### Introduction

In total, data from 7 field trials are presented in this section to demonstrate the minimum effective dose of GF-3307 (S7K-3-3), for the control of ERYSB E in sugar beet. GF-3307 (S7K-3-3) was tested at 1.5, 1.2-1.25 and 1.0 L/ha. The trials were performed in accordance with the EPPO standard PP 1/225 'Minimum effective dose'. The reference standard used was SCORE (250 g/L difenoconazole) applied at 0.4 L/ha (6 trials), AMISTAR GOLD (125+125 g/L azoxystrobin + difenoconazole) applied at 1.0 L/ha and SPYRALE at 1.0 L/ha (100+375 g/L difenoconazole + fenpropidin). In this section results from all standards are presented and merged in one column. Orthogonal results against each standard can be found in section 3.2.3.

The trials were carried out by Dow AgroSciences/Corteva Agriscience, contractor companies and Official Research Institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

To support the justification of minimum effective dose, five trials representative from the Central registration zone were selected in Austria (1) and Germany (4). In addition, two trials from Maritime

EPPO climatic zone but outside Central registration zone are presented. These trials were carried out in Denmark (1) and in the United-Kingdom (1).

### Materials and Methods

The justification of the minimum effective dose of GF-3307 (S7K-3-3) for the control of ERYSB E was supported by the data from 7 efficacy trials. Material and Methods used in these efficacy trials are given within Section 3.2.3 “Efficacy tests (KCP 6.2)”.

GF-3307 (S7K-3-3) at the rates tested and the reference products were applied between growth stage BBCH 39-49 when the crop conditions for ERYSB E infections were favourable in natural conditions.

GF-3307 (S7K-3-3) was evaluated in accordance with EPPO Standard PP 1/225 ‘*Minimum effective dose*’ and specific EPPO guideline PP 1/1 ‘*Foliar diseases on sugar beet*’, to determine the minimum effective dose for control of ERYSB E in sugar beet. GF-3307 (S7K-3-3) was tested at 50+100 g a.s./ha, 60-62.5+120-125 g a.s./ha and 75+150 g a.s./ha in the supporting trials, corresponding to 1.0, 1.2-1.25 and 1.5 of GF-3307 (S7K-3-3).

GF-3307 (S7K-3-3) was evaluated at 1.2-1.25 and 1.5 L/ha for the control of ERYSB E in 6 MED trials included in this section. The rate of 1.0 L/ha (67 % of the proposed label rate) of GF-3307 (S7K-3-3) was evaluated also in other 6 MED trials.

### Results

This part was supported by seven GEP small plot field trials conducted in order to determine the minimum effective dose of GF-3307 (S7K-3-3), for the control of the ERYSB E in sugar beet, following one or two applications between BBCH 39-49 of the crop. To support the minimum effective dose demonstration, five trials representative from the Central registration zone were selected in Austria (1) and Germany (4). In addition, two trials from Maritime EPPO climatic zone but outside Central registration zone are presented. These trials were carried out in Denmark (1) and in the United-Kingdom (1), where ERYSB E can be a key problem in sugar beet and so this presents a worst case situation on sugar beet crop. Data from Maritime EPPO climatic zone presents the worst case, though fully support Central registration zone.

The results are summarized by EPPO climatic zone in Table 3.2-26. Only results at assessment performed around 15-20 days after the second application and the last valid assessment after one or two applications (all efficacy trials merged in order to estimate the intrinsic efficacy of the product) between 2 to 6 weeks are discussed hereafter to justify the minimum effective dose.

#### Assessment around 15-20 DA-B:

From 2 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha achieved mean control of ERYSB E of 88.8% (range 77.6-100.0%). Applied in the same trials at 1.0 and 1.25 L/ha (67% and 83% of the proposed maximum label rate), GF-3307 (S7K-3-3) achieved a lower mean level of control of 69.1% at 1.0 L/ha and 85.3% at 1.25 L/ha with more variable results (range 38.2-100.0 at 1.0 L/ha and range 70.6-100.0% at 1.25 L/ha).

From 3 trials conducted, GF-3307 (S7K-3-3) applied at 1.5 L/ha achieved mean control of ERYSB E of 90.5% (range 77.6-100.0%). Applied in the same trials at 1.2-1.25 L/ha (80-83% of the proposed maximum label rate), GF-3307 (S7K-3-3) achieved a lower mean level of control of 76.0% with more variable results (range 57.5-100.0).

#### Valid assessment after one or two applications (between 2 to 6 weeks after the application – all efficacy trials merged):

From 5 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha achieved mean control of ERYSB E of 95.0% (range 77.6-100.0%). Applied in the same trials at 1.0 and 1.25 L/ha (67% and 83% of the proposed maximum label rate), GF-3307 (S7K-3-3) achieved a lower mean level of control of 82.4% at 1.0 L/ha and 92.5% at 1.25 L/ha with more variable results (range 38.2-100.0 at 1.0 L/ha and range 70.6-100.0% at 1.25 L/ha).

From 6 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha achieved mean control of ERYSB E of 95.8% (range 77.6-100.0%). Applied in the same trials at 1.0 L/ha (67% of the proposed maximum label rate), GF-3307 (S7K-3-3) achieved a lower mean level of control of 85.3% with more variable results (range 38.2-100.0).

From 6 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha achieved mean control of ERYSB E of 91.3% (range 72.5-100.0%). Applied in the same trials at 1.2-1.25 L/ha (80-83% of the proposed maximum

label rate), GF-3307 (S7K-3-3) achieved a lower mean level of control of 84.5% with more variable results (range 44.6-100.0).

Trials results demonstrate that an increase dose rate provided an increase control and furthermore that the minimum effective dose rate of 1.5 L/ha should be applied in order to achieve highest and most consistent efficacy against *Erysiphe betae* in sugar beet and where broad spectrum control of a number of diseases is considered.

Although no specific data is shown from the North East or South East EPPO zones, the results from Maritime justify the use of a lower rate of 1.2 L/ha as requested by Poland, Hungary, Romania and Slovakia according to the local conditions and infestation pressure (e.g. under low disease pressure) and CERCBE is the driver disease. However, the maximal rate of 1.5 L/ha is recommended in case of high disease pressure to obtain broad spectrum control and in an approach of efficient management of the risk of resistance. Only in Austria, Belgium, Czech Republic and The Netherlands, the recommended rate is 1.5 L/ha according with the local conditions and where in some years and varieties ERYSB is a higher risk.

Considering all factors, it is the applicants opinion that the range rate of 1.2 to 1.5 L/ha is the most balanced rate of GF-3307 (S7K-3-3) against ERYSB in sugar beet for Poland, Hungary, Romania and Slovakia, while in Austria, Belgium, Czech Republic and The Netherlands the proposed rate is 1.5 L/ha for robust control of ERYSB and a broad spectrum of diseases.

**Table 3.2-26 Minimum effective dose of GF-3307 (S7K-3-3) at the proposed label rate of 1.5 L/ha (100%), 80-83% and 67% dose rates against ERY5BE in sugar beet. Results from 7 trials conducted in the EPPO Maritime climatic zone in 2020, 2022 and 2023.**

Part	Timing of assessment	EPPO climatic zone	No. of trials	Untreated % INFECT ERY5BE			% Control of ERY5BE																No. of assessments significantly > , = , < GF-3307 (S7K-3-3)at 1.5 L/ha vs.	
							GF-3307 (S7K-3-3) 1.0 L/ha (67%)				GF-3307 (S7K-3-3) 1.2-1.25 L/ha (80-83%)				GF-3307 (S7K-3-3) 1.5 L/ha (100%)				All reference products					
							Fenpicoxamid + Prothioconazole				Fenpicoxamid + Prothioconazole				Fenpicoxamid + Prothioconazole									
							50+100 g a.s./ha				60-62.5 + 120-125 g a.s./ha				75+150 g a.s./ha									
							Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.0 L/ha	1.25 L/ha
Disease severity on plants	Last valid assessment after application A	Maritime	2	31.1	18.0	44.1	97.3	94.6	100.0	2.7	99.6	99.2	100.0	0.4	99.7	99.5	100.0	0.3	-	-	-	-	0> ; 2= ; 0<	0> ; 2= ; 0<
			3	27.2	18.0	44.1	98.2	94.6	100.0	2.5	-	-	-	-	99.8	99.5	100.0	0.3	99.1	97.4	100.0	1.3	0> ; 3= ; 0<	-
	Assessment around 15-20 DA-B	Maritime	2	13.7	4.7	22.8	69.1	38.2	100.0	30.9	85.3	70.6	100.0	14.7	88.8	77.6	100.0	11.2	90.5	80.9	100.0	9.6	1> ; 1= ; 0<	0> ; 2= ; 0<
			3	11.3	4.7	22.8	-	-	-	-	76.0	57.5	100.0	17.8	90.5	77.6	100.0	9.5	93.6	80.9	100.0	9.0	-	1> ; 2= ; 0<
	Assessment around 30-40 DA-B	Maritime	1	11.0	-	-	-	-	-	-	44.6	-	-	-	72.5	-	-	-	77.5	-	-	-	-	1> ; 0= ; 0<
	Assessment after 40 DA-B	Maritime	1	60.0	-	-	79.2	-	-	-	92.9	-	-	-	97.9	-	-	-	100.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
	Valid assessment after 1 or 2 applications	Maritime	6	28.2	4.7	60.0	85.3	38.2	100	22.3	-	-	-	-	95.8	77.6	100.0	8.2	96.4	80.9	100.0	7.0	1> ; 5= ; 0<	-
			6	26.8	4.7	60.0	-	-	-	-	84.5	44.6	100	20.6	91.3	72.5	100.0	11.6	92.6	77.5	100.0	9.6	-	1> ; 5= ; 0<
			5	29.9	4.7	60.0	82.4	38.2	100	23.4	92.5	70.6	100	11.3	95.0	77.6	100.0	8.7	95.7	80.9	100.0	7.5	1> ; 4= ; 0<	1> ; 3= ; 0<

**Comments of zRMS on:**

**Minimum effective dose of GF-3307 (S7K-3-3) for the control of *Erysiphe betae* in sugar beet (3.2.2.3)**

Seven efficacy trials present data to determine the minimum effective dose (MED) of GF-3307 (S7K-3-3) applied once or twice in the control of *Erysiphe betae* on sugar beet. The trials were carried only in Maritime EPPO zone (Austria - 1 trial, Denmark - 1 trial, Germany - 4 trials, the United Kingdom - 1 trial), in 2020, 2022 and 2023. The maximum recommended dose rate of 1.5 L/ha was compared with lower dose rates: 1.0 L/ha and 1.2-1.25 L/ha corresponding to 67% and 80%-83% of the maximum target dose rate respectively.

Based on the submitted trial results, a clear dose response was noted for the assessments performed after second application, comparing the efficacy of GF-3307 (S7K-3-3) applied at 1.5 L/ha with the efficacy results achieved for lower dose rates 1.0 L/ha and 1.2-1.25 L/ha. Considering numerical data, a clear differences were noted between tested dose rates. Statistically significant differences (in favor of higher dose rate) were evident in single trials. The highest efficacy, under various conditions of disease pressure was noted for GF-3307 (S7K-3-3) applied at maximum recommended dose rate of 1.5 L/ha.

### 3.2.2.4 Minimum effective dose of GF-3307 (S7K-3-3) for the control of *Ramularia beticola* in sugar beet

This chapter covers the minimum effective dose of GF-3307 (S7K-3-3) for the control of RAMUBE on sugar beet when applied at the maximum requested label rate of 1.5 L/ha and 67 % (1.0 L/ha) and 80%-83% (1.2-1.25 L/ha) of the maximum recommended label rate of GF-3307 (S7K-3-3).

**Table 3.2-27 Details on trial methodology - Minimum effective dose - RAMUBE**

<b>Guidelines</b>	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/1
<b>Experimental design</b>	Plot design	RCB
	Plot size	21-23 m <sup>2</sup>
	Number of replications	4
<b>Crop</b>	Trials per crop	Sugar beet (5)
	Varieties per crop	Annarosa (1), Marley (1), Marynia RH (1), Nasser (1), Racoon (1)
	Sowing period	Sugar beet: March – April
<b>Application</b>	Crop stage (BBCH) at application	Sugar beet: two applications between BBCH 39-39*
	Timing Pest stage at application	1 <sup>st</sup> application: At the appearance of the disease to control the foliar diseases with an interval. The application was timed to cover the main infection period to protect the crop from disease development.
	Number of applications	2 applications : 5 trials with intervals of 21 to 24 days*
	Spray volumes	200 L/ha
<b>Assessment</b>	Assessment types	% infection (severity) % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting) Yield (1 trial) and quality parameters (Sodium content (1 trial), Potassium content (1 trial), Amino nitrogen content (1 trial) and Sugar content in % (1 trial)).
	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) at each application and then 15-20 days, 30-40 days and 50-60 days after the last application.
<b>Other relevant information</b>	E.g. Natural / artificial inoculation...	Natural infection in 5 trials
	E.g. 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 RAMUBE is an abundant disease.

\*In 2 trials, three applications were performed. However, only valid assessment after the second application were considered for the evaluation.

#### Introduction

In total, data from 5 field trials are presented in this section to demonstrate the minimum effective dose of GF-3307 (S7K-3-3), for the control of RAMUBE in sugar beet. GF-3307 (S7K-3-3) was tested at 1.5, 1.2-1.25 and 1.0 L/ha. The trials were performed in accordance with the EPPO standard PP 1/225 'Minimum effective dose'. The reference standard used was SCORE (250 g/L difenoconazole) applied at 0.4 L/ha (5 trials), AMISTAR GOLD (125+125 g/L azoxystrobin + difenoconazole) applied at 1.0 L/ha and SPYRALE at 1.0 L/ha (100+375 g/L difenoconazole + fenpropidin). In this section results from all standards are presented and merged in one column. Orthogonal results against each standard can be found in section 3.2.3.

The trials were carried out by Dow AgroSciences/Corteva Agriscience, contractor companies and Official Research Institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

RAMUBE is an incidental disease that was captured from trials aimed at other major diseases in beet such as CERCBE and UROMBE. To support the justification of minimum effective dose, five trials representative from the Central registration zone were selected in Germany (3) and Poland (1). In

addition, one trial from Maritime EPPO climatic zone but outside Central registration zone is presented. This trial was carried out in Denmark (1).

### Materials and Methods

The justification of the minimum effective dose of GF-3307 (S7K-3-3) for the control of RAMUBE was supported by the data from 5 efficacy trials. Material and Methods used in these efficacy trials are given within Section 3.2.3 “Efficacy tests (KCP 6.2)”.

GF-3307 (S7K-3-3) at the rates tested and the reference products were applied between growth stage BBCH 39-39 when the crop conditions for RAMUBE infections were favourable in natural conditions. GF-3307 (S7K-3-3) was evaluated in accordance with EPPO Standard PP 1/225 ‘*Minimum effective dose*’ and specific EPPO guideline PP 1/1 ‘*Foliar diseases on sugar beet*’, to determine the minimum effective dose for control of RAMUBE in sugar beet. GF-3307 (S7K-3-3) was tested at 50+100 g a.s./ha, 60-62.5+120-125 g a.s./ha and 75+150 g a.s./ha in the supporting trials, corresponding to 1.0, 1.2-1.25 and 1.5 of GF-3307 (S7K-3-3).

GF-3307 (S7K-3-3) was evaluated at 1.2-1.25 and 1.5 L/ha for the control of RAMUBE in 5 MED trials included in this section. The rate of 1.0 L/ha (67 % of the proposed label rate) of GF-3307 (S7K-3-3) was evaluated only in 2 MED trials.

### Results

This part was supported by a limited data set of five GEP small plot field trials conducted in order to determine the minimum effective dose of GF-3307 (S7K-3-3), for the control of the RAMUBE in sugar beet, following two applications between BBCH 39-49 of the crop. To support the minimum effective dose demonstration, four trials from the Central registration zone were selected in Germany (3) and Poland (1). In addition, one trial from Maritime EPPO climatic zone but outside Central registration zone is presented. This trial was carried out in Denmark (1).

The results are summarized by EPPO climatic zone in Table 3.2-28 (Maritime EPPO climatic zone), Table 3.2-29 (Northeast EPPO climatic zone) and Table 3.2-30 (All EPPO climatic zones). Only results from all EPPO climatic zones (Table 3.2-30) at assessment performed around 15-20 days and 30-40 days after the second application are discussed hereafter to justify the minimum effective dose.

#### Assessment around 15-20 DA-B:

From 4 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha achieved mean control of RAMUBE of 69.4% (range 60.0-93.8%). Applied in the same trials at 1.2-1.25 L/ha (80-83% of the proposed maximum label rate), GF-3307 (S7K-3-3) achieved a lower mean level of control of 53.1% at 1.2-1.25 L/ha (range 37.5-79.2% at 1.2-1.25 L/ha).

#### Assessment around 30-40 DA-B:

From 2 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha achieved mean control of RAMUBE of 63.8% (range 61.2-66.3%). Applied in the same trials at 1.0 and 1.2-1.25 L/ha (67% and 80-83% of the proposed maximum label rate), GF-3307 (S7K-3-3) achieved a slightly higher mean level of control of 70.4% at 1.0 L/ha and a lower mean level of control of 57.9% at 1.2-1.25 L/ha with more variable results (range 60.0-80.7 at 1.0 L/ha and range 54.5-65.4% at 1.2-1.25 L/ha).

From 5 trials conducted, GF-3307 (S7K-3-3) applied at 1.5 L/ha achieved mean control of RAMUBE of 64.2% (range 55.0-75.0%). Applied in the same trials at 1.2-1.25 L/ha (80-83% of the proposed maximum label rate), GF-3307 (S7K-3-3) achieved a lower mean level of control of 54.3% with more variable results (range 37.5-68.3%).

Trials results demonstrate that an increase dose rate provided an increase control and furthermore that the minimum effective dose rate of 1.5 L/ha should be applied in order to achieve highest and most consistent efficacy against *Ramularia beticola* in sugar beet.

The results justify the use of a lower rate of 1.2 L/ha as requested by Poland, Hungary, Romania and Slovakia according to the local conditions and infestation pressure (e.g. under low disease pressure) as levels of control were similar to the reference products. However, the maximal rate of 1.5 L/ha is recommended in case of high disease pressure to obtain a better broad spectrum control and in an approach of efficient management of the risk of resistance. Only in Austria, Belgium, Czech Republic and The Netherlands, the recommended rate is 1.5 L/ha according with the local conditions and where in some years and varieties RAMUBE is a higher risk.

Considering all factors, it is the applicants opinion that the range rate of 1.2 to 1.5 L/ha is the most balanced rate of GF-3307 (S7K-3-3) against RAMUBE in sugar beet for Poland, Hungary, Romania and Slovakia where CERCBE should be the driver disease for dose selection by the grower. While in Austria, Belgium, Czech Republic and The Netherlands the proposed rate is 1.5 L/ha for robust control of RAMUBE and a broad spectrum of diseases.



**Table 3.2-28 Minimum effective dose of GF-3307 (S7K-3-3) at the proposed label rate of 1.5 L/ha (100%), 80-83% and 67% dose rates against RAMUBE in sugar beet. Results from 4 trials conducted in the EPPO Maritime climatic zone in 2020 and 2022**

Part	Timing of assessment	EPPO climatic zone	No. of trials	Untreated % INFECT RAMUBE				% Control of RAMUBE																No. of assessments significantly > , = , < GF-3307 (S7K-3-3) at 1.5 L/ha vs.	
								GF-3307 (S7K-3-3) 1.0 L/ha (67%)				GF-3307 (S7K-3-3) 1.2-1.25 L/ha (80-83%)				GF-3307 (S7K-3-3) 1.5 L/ha (100%)				All reference products					
								Fenpicoxamid + Prothioconazole				Fenpicoxamid + Prothioconazole				Fenpicoxamid + Prothioconazole									
								50+100 g a.s./ha				60-62.5 + 120-125 g a.s./ha				75+150 g a.s./ha				GF-3307 (S7K-3-3)					
								Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.			Mean	Min	Max	S.D.
Disease severity on plants	Assessment around 15-20 DA-B	Maritime	3	7.9	5.0	11.8	-	-	-	-	55.6	37.5	79.2	17.5	71.7	60.0	93.8	15.6	70.7	59.6	87.5	12.1	-	0> ; 3= ; 0<	
	Assessment around 30-40 DA-B	Maritime	1	4.5	-	-	80.7	-	-	-	54.5	-	-	-	61.2	-	-	-	81.2	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			4	8.2	4.5	12.3	-	-	-	-	52.6	37.5	68.3	11.0	63.6	55.0	75.0	7.3	65.5	58.3	81.2	9.2	-	1> ; 3= ; 0<	
	Assessment after 40 DA-B	Maritime	1	13.5	-	-	-	-	-	-	40.0	-	-	-	60.4	-	-	-	49.2	-	-	-	-	-	1> ; 0= ; 0<

**Table 3.2-29 Minimum effective dose of GF-3307 (S7K-3-3) at the proposed label rate of 1.5 L/ha (100%), 80-83% and 67% dose rates against RAMUBE in sugar beet. Results from 1 trial conducted in the EPPO Northeast climatic zone in 2023**

Part	Timing of assessment	EPPO climatic zone	No. of trials	Untreated % INFECT RAMUBE			% Control of RAMUBE																No. of assessments significantly > , = , < GF-3307 (S7K-3-3)at 1.5 L/ha vs.	
							GF-3307 (S7K-3-3) 1.0 L/ha (67%)				GF-3307 (S7K-3-3) 1.2-1.25 L/ha (80-83%)				GF-3307 (S7K-3-3) 1.5 L/ha (100%)				All reference products					
							Fenpicoxamid + Prothioconazole				Fenpicoxamid + Prothioconazole				Fenpicoxamid + Prothioconazole									
							50+100 g a.s./ha				60-62.5 + 120-125 g a.s./ha				75+150 g a.s./ha									
							Mean	Min	Max		Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min
Disease severity on plants	Assessment around 15-20 DA-B	Northeast	1	13.8	-	-	54.2	-	-	-	45.8	-	-	-	62.5	-	-	-	21.7	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
	Assessment around 30-40 DA-B	Northeast	1	20.0	-	-	60.0	-	-	-	61.3	-	-	-	66.3	-	-	-	35.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<

**Table 3.2-30 Minimum effective dose of GF-3307 (S7K-3-3) at the proposed label rate of 1.5 L/ha (100%), 80-83% and 67% dose rates against RAMUBE in sugar beet. Results from 5 trials conducted in All EPPO climatic zones in 2020, 2022 and 2023**

Part	Timing of assessment	EPPO climatic zone	No. of trials	Untreated % INFECT RAMUBE			% Control of RAMUBE																No. of assessments significantly > , = , < GF-3307 (S7K-3-3)at 1.5 L/ha vs.	
							GF-3307 (S7K-3-3) 1.0 L/ha (67%)				GF-3307 (S7K-3-3) 1.2-1.25 L/ha (80-83%)				GF-3307 (S7K-3-3) 1.5 L/ha (100%)				All reference products					
							Fenpicoxamid + Prothioconazole				Fenpicoxamid + Prothioconazole				Fenpicoxamid + Prothioconazole									
							50+100 g a.s./ha				60-62.5 + 120-125 g a.s./ha				75+150 g a.s./ha									
							Mean	Min	Max		Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min
Disease severity on plants	Assessment around 15-20 DA-B	All EPPO climatic zones	4	9.1	5.0	13.8	-	-	-	-	53.1	37.5	79.2	15.7	69.4	60.0	93.8	14.1	58.5	21.7	87.5	23.7	-	0> ; 4= ; 0<
	Assessment around 30-40 DA-B	All EPPO climatic zones	2	12.3	4.5	20.0	70.4	60.0	80.7	10.4	57.9	54.5	65.4	3.4	63.8	61.2	66.3	2.6	58.1	35.0	81.2	23.1	0> ; 2= ; 0<	0> ; 2= ; 0<
			5	10.6	4.5	20.0	-	-	-	-	54.3	37.5	68.3	10.5	64.2	55.0	75.0	6.6	59.4	35.0	81.2	14.7	-	1> ; 4= ; 0<

**Comments of zRMS on:**

**Minimum effective dose of GF-3307 (S7K-3-3) for the control of *Ramularia beticola* in sugar beet (3.2.2.4)**

Five efficacy trials present data to determine the minimum effective dose (MED) of GF-3307 (S7K-3-3) applied twice in the control of *Ramularia beticola* on sugar beet. The trials were carried out in 2 EPPO zones: Maritime (Denmark – 1 trial, Germany - 3 trials), North-East (Poland - 1 trial), in 2020, 2022 and 2023.

The maximum recommended dose rate of 1.5 L/ha was compared with lower dose rates: 1.0 L/ha and 1.2-1.25 L/ha corresponding to 67% and 80%-83% of the maximum target dose rate respectively.

Conclusions from the MED trials for individual EPPO climatic zones are presented below.

**Maritime EPPO zone (4 trials)**

Based on the submitted trial results, a clear dose response was seen comparing the efficacy of GF-3307 (S7K-3-3) applied at 1.5 L/ha, with the efficacy results achieved for lower dose rate 1.2-1.25 L/ha. Considering numerical data, a clear differences were noted between dose rates 1.2-1.25 L/ha and 1.5 L/ha. Statistically significant differences (in favor of dose rate 1.5 L/ha) were evident in single trials. The highest efficacy, under various conditions of disease pressure was noted for GF-3307 (S7K-3-3), applied at maximum recommended dose rate of 1.5 L/ha.

**North-East EPPO zone (1 trial)**

A clear dose response was seen comparing the efficacy of GF-3307 (S7K-3-3) applied at 1.5 L/ha with the efficacy results achieved for lower dose rate 1.25 L/ha. Considering numerical data, a clear differences were noted between dose rates 1.25 L/ha and 1.5 L/ha. No statistically significant differences between tested dose rates were evident in a single trial carried out. The highest efficacy was noted for GF-3307 (S7K-3-3), applied at maximum recommended dose rate of 1.5 L/ha.

### 3.2.2.5 Summary and conclusions on the minimum effective dose (MED)

In recent years, *Cercospora beticola* has become more prevalent in Europe<sup>9,10</sup> and has become the most destructive foliar pathogen of sugar beet. It is widely present in most beet-growing regions and can cause major yield losses if not properly controlled. This disease usually appears early in the season and is most severe in wet and warm areas in case of very early attacks<sup>11</sup>.

Data are mainly presented for *Cercospora beticola* as this disease is regularly observed in sugar beet field and can cause severe yield losses. Data from Maritime EPPO climatic zone are mainly presented for UROMBE and ERYSB E as it presents the worst case, though fully support Central registration zone. Ramularia cause less severe impact on yield and thus can be considered as minor disease.

Finally, the data package is fully justified to demonstrate the efficacy of GF-3307 (S7K-3-3) at maximal dose rate of 1.5 L/ha in the Central Registration zone on the diseases complex of sugar beet crop.

Across all data-sets the proposed full dose of 1.5 L/ha GF-3307 (S7K-3-3) demonstrated the highest level of control with less variability. It was the only dose to constantly achieve 70-80% control for CERCBE, UROMBE and ERYSB E at key assessment around 30-40 days after the second applications:

- CERCBE: The proposed dose consistently demonstrated the highest level of control on plants assessed across 30 trials from Maritime, Northeast and Southeast EPPO climatic zones.
- UROMBE: The proposed dose consistently demonstrated the highest level of control on plants assessed across 11 trials from Maritime EPPO climatic zone.
- ERYSB E: The proposed dose consistently demonstrated the highest level of control on plants assessed across 7 trials from Maritime EPPO climatic zone.
- RAMUBE: The proposed dose consistently demonstrated the highest level of control on plants assessed across 5 trials from Maritime and Northeast EPPO climatic zones.

Table 3.2-31 summarises the minimum effective dose of GF-3307 (S7K-3-3) to control sugar beet diseases complex at the last valid assessment after two applications between 2 to 6 weeks after the application (all efficacy trials merged).

**Table 3.2-31: Minimum effective dose of GF-3307 (S7K-3-3) - Sugar beet - All valid efficacy trials - Valid assessment between 2 to 6 weeks after the second application**

Target	EPPO climatic zone	No. of trials	Untreated			Percentage of efficacy (%)								
						GF-3307 (S7K-3-3) 1.0 L/ha (67%)			GF-3307 (S7K-3-3) 1.2-1.25 L/ha (80-83%)			GF-3307 (S7K-3-3) 1.5 L/ha (100%)		
						Fenpicoxamid + Prothioconazole			Fenpicoxamid + Prothioconazole			Fenpicoxamid + Prothioconazole		
						50+100 g a.s./ha			60-62.5+120-125 g a.s./ha			75+150 g a.s./ha		
			Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
CERCBE	Maritime	13	31.3	5.1	63.5	73.8	54.7	89.1	79.0	58.6	97.1	84.4	66.9	100.0
	Northeast	5	38.7	26.7	57.5	66.8	43.3	96.4	74.1	50.0	96.8	78.0	60.3	97.2
	Southeast	6	35.7	12.3	65.0	59.6	52.8	70.5	69.7	58.5	77.2	79.7	65.5	89.0
	All EPPO climatic zones	24	33.9	5.1	65.0	68.8	43.3	96.4	75.7	50.0	97.1	81.9	60.3	100.0
UROMBE	Maritime	10	38.0	14.8	59.1	78.4	35.8	98.0	84.5	43.9	99.6	87.8	53.9	99.5
ERYSB E*	Maritime	5	29.2	4.7	60.0	82.4	38.2	100	92.5	70.6	100	95.0	77.6	100.0
RAMUBE**	All EPPO climatic zones	2	12.3	4.5	20.0	70.4	60.0	80.7	57.9	54.5	65.4	63.8	61.2	66.3
		5	10.6	4.5	20.0	-	-	-	54.3	37.5	68.3	64.2	55.0	75.0

\* Valid assessment after 1 or 2 applications - \*\* Assessment around 30-40 DA-B

<sup>9</sup> <http://bbro.co.uk/bbro-research/bbro-research/crop-protection/cu-integrated-disease-control-in-sugar-beet/>

<sup>10</sup> <https://www.r4p-inra.fr/fr/publication-de-la-note-commune-betterave-2022/>

<sup>11</sup> [https://www.florimond-desprez.com/es/wp-content/uploads/sites/6/2015/11/leaf-diseases\\_eng.pdf](https://www.florimond-desprez.com/es/wp-content/uploads/sites/6/2015/11/leaf-diseases_eng.pdf)

Moreover, according to the efficacy results in 33 trials in total (based on trials with 3 doses, 24 on CERCBE, 10 on UROMBE, 5 on ERYSB and 2 on RAMUBE - some trials had 2 or 3 diseases present), the results justify the use of a lower rate of 1.2 L/ha for CERCBE and the other minor diseases as requested by Poland, Hungary, Romania and Slovakia according to the local conditions and infestation pressure (e.g. under low disease pressure). However, the maximal rate of 1.5 L/ha is recommended in case of high disease pressure to obtain a better control of foliar diseases complex and where CERCBE dominates in an approach of efficient management of the risk of resistance. On the other hand, in Austria, Belgium, Czech Republic and The Netherlands, where tougher disease conditions may be expected and where all four diseases could occur in a field, the proposed dose is the full rate of 1.5 L/ha to support the claims for control of all the proposed diseases in sugar beet.

**By and large, the mean efficacy increases in function of the rate of GF-3307 (S7K-3-3). GF-3307 (S7K-3-3) at 1.5 L/ha reached a very good efficacy to control the diseases complex of sugar beet confirming the selection of 1.5 L/ha as maximum registered dose for Austria, Belgium, Czech Republic and The Netherlands and 1.2-1.5 L/ha for Poland, Hungary, Romania and Slovakia. This choice of dose rate of GF-3307 (S7K-3-3) at 1.5 L/ha for Austria, Belgium, Czech Republic and The Netherlands and 1.2-1.5 L/ha for Poland, Hungary, Romania and Slovakia is also justified on fodder beet by extrapolation in accordance with PP 1/257 FEET 55(1).**

**General conclusion of zRMS on:  
Minimum effective dose tests (3.2.2)**

Based on the submitted trial results it can be concluded, that the dose rate of 1.5 L/ha was the most effective dose under various conditions (high and low disease pressure) and therefore can be considered as the minimum effective dose to provide sufficient efficacy in the control of CERCBE, UROMBE, ERYSB and RAMUBE on sugar beet (across a broad range of disease pressure). Lower dose rate of 1.2 L/ha requested for North-East EPPO zone (PL) and South-East EPPO zone (HU, RO, SK) can be also recommended under low disease pressure conditions.

### **3.2.3 Efficacy tests (KCP 6.2)**

A total of 56 efficacy trials were carried out between 2020 and 2023 to justify the efficacy of GF-3307 (S7K-3-3) applied at 1.5 L/ha for Central registration zone for the control of foliar diseases (CERCBE, UROMBE, ERYSB and RAMUBE) in sugar beet. All trials were carried out in Austria (1), Czech Republic (1), Denmark (6), France (8), Germany (15) and The United-Kingdom (7) in the EPPO Maritime climatic zone, in Lithuania (2) and Poland (6) in EPPO Northeast climatic zone and in Hungary (6) and Romania (4) in EPPO Southeast climatic zone.

18.06.2025/ concerns Poland

Question from authority - BEAVC: CERCBE, ERYSB, RAMUBE, UROMBE.

No efficacy trials of the product conducted in fodder beet were submitted for the evaluation.

In the case of CERCBE, according to the national extrapolation table, it is possible to extrapolate the results of trials from sugar beet to fodder beet, provided that 2 efficacy trials performed in fodder beet in the North-East EPPO zone are submitted. It should be mentioned, that in the case of other diseases, i.e. ERYSB, RAMUBE, UROMBE, according to the current extrapolation table for Poland, it is not possible to extrapolate the results of efficacy trials from sugar beet to fodder beet.

Taking into account, that fodder beet is included in the list of minor crops (Annex No. 1 of the Regulation of the Minister of Agriculture and Rural Development of September 18, 2023, amending the Regulation on minor uses of plant protection product), it is possible to register the above uses under article 51 of regulation 1107/2009, without the requirement to submit efficacy trials.

Reply:

Taking into account, that fodder beet is included in the list of minor crops (Annex No. 1 of the Regulation of the Minister of Agriculture and Rural Development of September 18, 2023, amending the Regulation

on minor uses of plant protection product), the applicant requests to register GF-3307 on CERCBE, ERYSB, RAMUBE and UROMBE in fodder beet under article 51 of regulation 1107/2009, without the requirement to submit efficacy trials.

### 3.2.3.1 Efficacy of GF-3307 (S7K-3-3) for the control of *Cercospora beticola* in sugar beet

This chapter addresses the efficacy of GF-3307 (S7K-3-3) for the control of CERCBE on sugar beet when applied at the proposed label rate of 1.5 L/ha for Austria, Belgium, Czech Republic and The Netherlands, and at the rate range of 1.2-1.5 L/ha for Poland, Hungary, Slovakia and Romania in comparison with SCORE at 0.4 L/ha, SPYRALE at 1.0 L/ha and AMISTAR GOLD at 1.0 L/ha.

**Table 3.2-32 Details on trial methodology - Efficacy - CERCBE**

<b>Guidelines</b>	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/1
<b>Experimental design</b>	Plot design	RCB
	Plot size	16-36 m <sup>2</sup>
	Number of replications	4
<b>Crop</b>	Trials per crop	Sugar beet (42)
	Varieties per crop	Annabella (1), Annarosa (2), Antineea (1), Aries (1), Asketa (3), Balaton (1), Belamia (1), Briga (1), BTS 3865 (1), BTS1140 (1), Calledia (4), Camelia (2), Clemens (1), Danicia (1), Darvas (1), Jamon (1), KWS Florentina (1), Libellule (2), Lunella (2), Marley (1), Marynia (2), Pavo (1), Racoon (2), Rossada (1), Smart Latoria KWS (1), Smart Mondeo (1), Smart Sanya KWS (1), Stingray (1), Surf (1), Traper (2)
	Sowing period	Sugar beet: March - April
<b>Application</b>	Crop stage (BBCH) at application	Sugar beet: two to four applications between BBCH 35-49
	Timing Pest stage at application	1 <sup>st</sup> application: At the appearance of the disease to control the foliar diseases with an interval. The application was timed to cover the main infection period to protect the crop from disease development.
	Number of applications	2 applications: 30 trials with intervals of 14 to 29 days 3 applications: 8 trials with intervals of 14 to 29 days* 4 applications: 4 trials with intervals of 16 to 21 days*
	Spray volumes	200-400 L/ha
<b>Assessment</b>	Assessment types	% infection (severity) % crop injury (phytotoxicity effects)
	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) at each application and then 15-20 days, 30-40 days and 50-60 days after the last application. Yield (15) and quality parameters (Sodium content (11 trials), Potassium content (11 trials), Amino nitrogen content (11 trials) and Sugar content in % (11 trials)).
<b>Other relevant information</b>	E.g. Natural / artificial inoculation...	Natural infection in 33 trials Artificial inoculation in 9 trials
	E.g. 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 CERCBE is an abundant disease.

\* Only valid assessment after the second application were considered for the evaluation

## Introduction

In total, data from 42 field trials are presented in this section to demonstrate the efficacy of GF-3307 (S7K-3-3), for the control of CERCBE in sugar beet. The efficacy trials representative for the Central registration zone were carried out from 2020 to 2023 in Czech Republic (1), Germany (15) and The United-Kingdom (1) in the Maritime, in Poland (6) and Lithuania (2) in the Northeast and in Hungary (6) and Romania (4) in the Southeast EPPO climatic zones. To support the dataset, trials from Southern registration zone were added to the summary from France (7) in the Maritime EPPO climatic zone from 2020 to 2022, where CERCBE can be a key problem in sugar beet and so this presents a worst case

situation on sugar beet.

To support the label claims within the Central registration zone, GF-3307 (S7K-3-3) was tested at the rate of 1.5 L/ha (75+150 g a.s./ha) in accordance with the EPPO standard PP 1/1 'Foliar diseases on sugar beet'. The cross reference product included was SCORE applied at 0.4 L/ha (250 g/L Difenoconazol EC) as European standard reference dose in 35 trials. Moreover, other references at local registered rate with different mode of action (azoxystrobin, fenpropidin) were also used in efficacy trials and presented: AMISTAR GOLD (125+125 g/L azoxystrobin + difenoconazole) applied at 1.0 L/ha and SPYRALE at 1.0 L/ha (100+375 g/L difenoconazole + fenpropidin) are also presented as a common standard across countries.

All trials were carried out by Dow AgroSciences / Corteva Agriscience or officially recognised contract research organisations in accordance with the principles of Good Experimental Practice (Table 3.7-1). On the basis of the EPPO standard 1/241 '*Guidance on comparable climates*', the trials included in the BAD for this section have been grouped and summarized 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.

## Materials and Methods

### Testing facilities or organisations

All trials were carried out by Dow AgroSciences / Corteva Agriscience or officially recognised contract research organisations in accordance with the principles of Good Experimental Practice (Table 3.7-1).

The trials used in this part are presented in

Table 3.2-6 and Table 3.2-7.

### Sites and experimental details

The 42 trials from the Maritime, Northeast and Southeast EPPO climatic zones were carried out in Czech Republic (1), Germany (15), Hungary (6), Romania (4) and Poland (6) for the Central registration zone, in Lithuania (2) for the Northern registration zone and in France (7) for the Southern registration zone and in the United-Kingdom (1) to complete the dataset on the efficacy.

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 CERCBE is an abundant disease. CERCBE is a disease which multiplies rapidly under warm climatic conditions such as found in the EPPO Maritime, Northeast and Southeast climatic zones.

An overview on the geographical distribution of the efficacy trials across the EU countries involved is presented Figure 3.2 - 3.

All 42 efficacy trials were carried out by officially recognized testing organizations according to GEP and followed the appropriate EPPO standards. The experimental design was a randomized complete block with 4 replicates and a plot size ranging between 16 m<sup>2</sup> and 36 m<sup>2</sup>. Application was conducted at crop stage BBCH 35-49 across trials and is therefore very close and within the application window (BBCH 39-49) of the respective label claim.

All treatments were applied at an application volume of 200-400 L/ha, using backpack, bicycle, pneumatic or tractor mounted sprayer equipped with conventional or low drift flat fan nozzles.

### Formulations applied and applications details

In all efficacy trials, the efficacy of GF-3307 (S7K-3-3) applied at 1.5 L/ha was compared the reference standards SCORE, AMISTAR GOLD and SPYRALE (Table 3.2-33). As the trials were undertaken over a number of years and in different development programs across Europe, the same standards may not be present in all trials.

Table 3.2-33 below presents the plant protection products and the rates used in this part.

**Table 3.2-33 Plant protection products used in efficacy trials**

Test product	Formulation type	Active substance	Rate product L/ha	Rate product g a.s./ha
GF-3307 (S7K-3-3)	SC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.0	50+100
			1.2-1.25	60-62.5+120-125
			1.5	75+150
SCORE	EC	250 g/L difenoconazole	0.4	100
SPYRALE	EC	100+375 g/L difenoconazole+fenpropidin	1.0	100+375

Test product	Formulation type	Active substance	Rate product L/ha	Rate product g a.s./ha
AMISTAR GOLD	SC	125+125 g/L azoxystrobin + difenoconazole	1.0	125+125

GF-3307 (S7K-3-3) at the rates tested and the reference products were applied between growth stage BBCH 35 and BBCH 49 when the crop conditions for CERCBE infections were favourable.

**Generally, to control foliar diseases on sugar beet crop, a treatment program with 2 to 4 applications is necessary. Even if two applications are requested in the GAP table, 2 to 4 applications of GF-3307 (S7K-3-3) were carried out in some efficacy trials where disease pressure was high to estimate the intrinsic efficacy of the product to control the diseases during the season. The efficacy data presented is after two applications and was always compared to the reference standards applied in the same conditions.**

Nine trials were artificially inoculated by spraying a *Cercospora beticola* spore suspension just before or after the application of GF-3307 (S7K-3-3) and the reference products. Details of the natural or artificially inoculated trials are shown in Table 3.2-34.

**Table 3.2-34 Trials with natural infections or artificial inoculations - CERCBE**

Trial	Country	Natural or artificial inoculation	Timing of inoculation	CERCBE severity (%) in UNT at the last valid assessment after two applications between 2 to 6 weeks
1 trial	Czech Republic	No	-	33.2
1 trial	Germany	No	-	27.5
1 trial	Germany	No	-	38.8
1 trial	Germany	No	-	16.3
1 trial	Germany	No	-	17.5
1 trial	Germany	No	-	20.8
1 trial	Germany	No	-	17.3
1 trial	Germany	No	-	33.0
1 trial	Germany	Yes	-8 DAA	8.8
1 trial	Germany	Yes	-8 DAA	7.9
1 trial	Germany	No	-	22.5
1 trial	Germany	No	-	13.8
1 trial	Germany	No	-	39.3
1 trial	Germany	Yes	-23 DAA	63.5
1 trial	Germany	Yes	-23 DAA	43.2
1 trial	Germany	No	-	26.3
1 trial	Poland	No	-	72.5
1 trial	Poland	No	-	32.5
1 trial	Poland	No	-	55.0
1 trial	Poland	No	-	37.5
1 trial	Poland	No	-	57.5
1 trial	Poland	No	-	38.3
1 trial	Lithuania	Yes	0 DAA	33.6
1 trial	Lithuania	Yes	+3 DAA	26.7
1 trial	Hungary	No	-	48.8
1 trial	Hungary	No	-	55.0
1 trial	Hungary	No	-	65.0
1 trial	Hungary	No	-	45.0
1 trial	Hungary	No	-	12.3
1 trial	Hungary	No	-	49.6
1 trial	Romania	No	-	13.3
1 trial	Romania	No	-	17.0
1 trial	Romania	No	-	21.6
1 trial	Romania	No	-	20.6
1 trial	United Kingdom	No	-	5.1
1 trial	France	Yes	-12 DAA	8.4
1 trial	France	No	-	8.4
1 trial	France	Yes	+2 DAA	10.6
1 trial	France	No	-	46.0
1 trial	France	Yes	-63 DAA	34.5
1 trial	France	No	-	32.6
1 trial	France	No	-	52.9



This is acknowledged by EPPO PP 1/1 (4), which indicates that inoculation of trials is an acceptable practice for disease control in sugar beet trials. Disease levels in the untreated at assessment were greater in the naturally infected trials at 5.1-72.5% severity, compared to 7.9-63.5% severity in the inoculated trials (see Table 3.2-34). Therefore, the levels of disease were not artificially raised in the inoculated trials and all trials can be considered to be fully valid to support the claims for control of this disease.

#### 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. 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. In trials, assessments data were analysed using an analysis of variance (ANOVA) on untransformed. The probability of non-significance occurring between treatment means is calculated as the F probability value (p(F)). The Student-Newman-Keuls and Tukey's test was applied to separate any treatment differences that may be highlighted by the ANOVA test. These differences are indicated by a letter. When one letter is in common, no significant difference is identified according to the test conducted at a 95% confidence level.

#### Assessment methods

All treatments of each trial are not systematically presented in this dossier, only relevant treatments are summarised. All data are available in individual trial reports in Document K.

As recommended in EPPO PP 1/1(4) guideline, the infestation of diseases at application date has been recorded. Table 3.2-35 reminds the infestation of diseases at application date, regarding the trials used for the compilations presented hereafter.

**Table 3.2-35: Infestation level at application dates - Efficacy trials - Sugar beet - CERCBE**

EPPO	Trial	Country	BBCH Stage	Application	Disease severity (%)	Disease incidence
Maritime	1 trial	Czech Republic	39 <del>38</del>	A	-	45.00
			39 <del>38</del>	B	4.70	100.00
Maritime	1 trial	France	39	A	0.20	-
			39	B	2.70	55.00
			39	C	8.40	97.50
Maritime	1 trial	France	39	A	0.00	-
			39	B	0.00	-
Maritime	1 trial	France	39	A	1.40	-
			39	B	5.00	67.50
			39	C	13.30	100.00
			39	D	48.40	100.00
Maritime	1 trial	France	39	A	2.00	31.00
			39	B	5.90	49.00
Maritime	1 trial	France	39	A	1.10	-
			49	B	14.00	-
Maritime	1 trial	France	39	A	0.80	21.30
			49	B	7.80	70.0
Maritime	1 trial	France	39	A	0.50	-
			39	B	5.90	90.00
Maritime	1 trial	Germany	39	A	1.00	5.00
			39	B	11.00	-
			39	C	16.25	-
Maritime	1 trial	Germany	39	A	1.50	5.00
			39	B	10.00	-
			39	C	27.50	-
Maritime	1 trial	Germany	39	A	2.00	5.00
			39	B	13.00	-
Maritime	1 trial	Germany	39	A	1.00	5.00
			39	B	12.00	-
			39	C	17.50	-
Maritime	1 trial	Germany	39	A	0.20	-
			39	B	6.75	19.50

EPPO	Trial	Country	BBCH Stage	Application	Disease severity (%)	Disease incidence
			39	C	20.75	100.00
			39	D	36.00	100.00
Maritime	1 trial	Germany	39	A	0.50	-
			39	B	2.00	-
Maritime	1 trial	Germany	39	A	1.00	-
			39	B	4.50	-
Maritime	1 trial	Germany	39	A	0.00 0.01	2.00
			39	B	0.30	53.00
Maritime	1 trial	Germany	39	A	0.20	0.20
			39	B	4.50	-
Maritime	1 trial	Germany	39	A	0.00 0.01	2.00
			49 39	B	0.3	47.5 53.00
Maritime	1 trial	Germany	39	A	1.50	-
			39	B	4.50	-
Maritime	1 trial	Germany	39	A	1.00	1.00 -
			39	B	8.50	100.00 8.50
Maritime	1 trial	Germany	39	A	0.01	2.00
			49	B	-	53.00
Maritime	1 trial	Germany	39	A	2.50	25.00 27.50
			39	B	7.00 10.25	-
Maritime	1 trial	Germany	39	A	-	2.00
			49	B	-	53.00
Maritime	1 trial	United Kingdom	39	A	0.00	0.00
			39	B	0.00	0.00
Northeast	1 trial	Lithuania	39	A	0.07	-
			39	B	1.65	98.80
Northeast	1 trial	Lithuania	38	A	0.00	-
			38	B	0.90	-
Northeast	1 trial	Poland	49	A	6.00	6.00
			49	B	27.50	-
			49	C	32.50	-
Northeast	1 trial	Poland	39	A	5.25	-
			39	B	46.25 72.50	-
			39	C	72.50	-
Northeast	1 trial	Poland	39	A	2.50	-
			39	B	10.80	-
			39	C	55.00	-
			39	D	71.30	-
Northeast	1 trial	Poland	39	A	5.00	-
			39	B	37.50 35.00	-
Northeast	1 trial	Poland	39	A	0.23	-
			39	B	6.72	-
Northeast	1 trial	Poland	39	A	4.50	11.80
			39	B	17.50	-
Southeast	1 trial	Hungary	37	A	1.30	-
			38	B	10.60	-
			39	C	48.80	-
Southeast	1 trial	Hungary	36 37	A	1.30	-
			37 38	B	4.80	-
			39	C	54.90	-
Southeast	1 trial	Hungary	39	A	-	10.00
			39	B	10.80	87.50 10.00
Southeast	1 trial	Hungary	39 49	A	1.00	1.00
			39 49	B	7.00	7.00
Southeast	1 trial	Hungary	39 49	A	0.75	-
			39 49	B	2.25	-
Southeast	1 trial	Hungary	35	A	0.26	7.50
			38	B	11.76	85.00

EPPO	Trial	Country	BBCH Stage	Application	Disease severity (%)	Disease incidence
Southeast	1 trial	Romania	39	A	0.01	7.50
			39	B	1.25	62.30 <del>24.95</del>
Southeast	1 trial	Romania	38	A	1.00	6.30
			38	B	5.60	-
			39	C	17.00	-
			49	D	26.10	-
Southeast	1 trial	Romania	39	A	0.20	31.25
			49 <del>39</del>	B	2.10	82.50
Southeast	1 trial	Romania	39	A	0.17	25.00
			49 <del>39</del>	B	2.09	75.00

The tabulated data presented in this section 3 only represent the means of efficacies of selected treatments, without raw data. However, the statistics presented in conjunction with these data are derived from all data points from all treatments within the assessment. Tables of data comprising all treatments means are presented in the individual trial report summaries.

In the detailed tables, data presented correspond to the mean efficacy against each disease for each product in each trial. Only the trials and assessments with a sufficient infestation level in the untreated plot (thresholds of 5% coverage of foliar by the disease) and where the level of efficacy of the reference standards were as expected are considered in this synthesis. In practice, assessments from 4.5% were selected in the available data package notably to enlarge the data package.

According to PP 1/1(4), the level of infection when the crop is treated twice should be recorded several times. Therefore, assessments are presented according to each application date:

- The first valid assessment around 2-3 weeks after the second application;
- The second valid assessment around 4-6 weeks after the second application;
- When available, the last valid assessment beyond 40 days after the second application.
- Finally, all available efficacy trials are merged with the last valid assessment after two applications between 2 to 6 weeks.

However, to simplify the justification of efficacy of GF-3307 (S7K-3-3) in sugar beet, only two key assessments (highlighted in light grey) are presented and commented in conclusion: the second valid assessment around 30-40 DA-B after the second application and the last valid assessment after two applications between 2 to 6 weeks (all efficacy trials merged).

## Results

Forty-two GEP trials were established in order to determine efficacy of GF-3307 (S7K-3-3) for the control of the CERCBE on sugar beet.

Thirty-three trials representative for the Central registration zone were carried out from 2020 to 2023 in Czech Republic (1), Germany (15) and The United-Kingdom (1) in the Maritime, in Poland (6) and Lithuania (2) in the Northeast and in Hungary (6) and Romania (4) in the Southeast EPPO climatic zones. To support the dataset, trials from Southern registration zone were added to the summary from France (7) in the Maritime EPPO climatic zone from 2020 to 2022, where CERCBE can be a key problem in sugar beet and so this presents a worst case situation on sugar beet.

The results are summarized by EPPO climatic zone for the rate at 1.25 L/ha in Table 3.2-37 (Northeast EPPO climatic zone), Table 3.2-39 (Southeast EPPO climatic zone) and Table 3.2-41 (All EPPO climatic zones). The results are summarized by EPPO climatic zone for the maximum requested rate at 1.5 L/ha in Table 3.2-36 (Maritime EPPO climatic zone), (Northeast EPPO climatic zone), Table 3.2-40 (Southeast EPPO climatic zone) and Table 3.2-42 (All EPPO climatic zones).

Generally, to control foliar diseases on sugar beet crop, a treatment program with 2 and up to 4 applications is necessary. Even if only two applications are requested in the GAP table, more than two applications of GF-3307 (S7K-3-3) were carried out in some efficacy trials to estimate the intrinsic efficacy of the product to control the diseases during the season. The efficacy after two applications was always compared to the reference standards applied in the same condition. The results are summarized by EPPO climatic zone in the summary tables. Only results compared to the references at its registered rate are discussed hereafter to justify the efficacy of GF-3307 (S7K-3-3) against CERCBE of sugar beet.

## **Maritime EPPO climatic zone**

### Assessment around 30-40 DA-B:

Across 20 trials from the Maritime EPPO climatic zone, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE superior to the reference standard SCORE at 0.4 L/ha (84.5% vs. 55.1% mean control in 20 trials) and a significant difference was noted in 12 out of 20 trials. In the other 8 trials, no significant difference was noted. Across 15 trials from the Maritime EPPO climatic zone, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE superior to the reference standard AMISTAR GOLD at 1.0 L/ha (85.2% vs. 55.8% mean control in 15 trials) and a significant difference was noted in 7 out of 15 trials. In the other 8 trials, no significant difference was noted. Across 6 trials from the Maritime EPPO climatic zone, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE superior to the reference standard SPYRALE at 1.0 L/ha (83.7% vs. 68.8% mean control in 6 trials) and no significant difference was noted in all trials. Overall, GF-3307 (S7K-3-3) at 1.5 L/ha showed a good control in all trials (84.7% mean control in 21 trials).

### Valid assessment after two applications (2 to 6 weeks after the application – all efficacy trials merged):

Across 23 trials from the Maritime EPPO climatic zone, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE superior to the reference standard SCORE at 0.4 L/ha (83.9% vs. 54.4% mean control in 23 trials) and a significant difference was noted in 13 out of 23 trials. In the other 10 trials, no significant difference was noted. Across 16 trials from the Maritime EPPO climatic zone, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE superior to the reference standard AMISTAR GOLD at 1.0 L/ha (84.6% vs. 55.5% mean control in 16 trials) and a significant difference was noted in 8 out of 16 trials. In the other 8 trials, no significant difference was noted. Across 7 trials from the Maritime EPPO climatic zone, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE superior to the reference standard SPYRALE at 1.0 L/ha (82.6% vs. 66.6% mean control in 7 trials) and no significant difference was noted in 6 out of 7 trials. In the other trial, a significant difference was noted. Overall, GF-3307 (S7K-3-3) at 1.5 L/ha showed a good control in all trials (84.1% mean control in 24 trials).

## **Northeast EPPO climatic zone**

### Assessment around 30-40 DA-B:

Across 3 trials from the Northeast EPPO climatic zone, GF-3307 (S7K-3-3) applied at 1.25 L/ha showed a good control of CERCBE superior to the reference standard SCORE at 0.4 L/ha (79.8% vs. 61.5% mean control in 3 trials) and a significant difference was noted in 1 out of 3 trials. In the other 2 trials, no significant difference was noted. Across 3 trials from the Northeast EPPO climatic zone, GF-3307 (S7K-3-3) applied at 1.25 L/ha showed a good control of CERCBE superior to the reference standard AMISTAR GOLD at 1.0 L/ha (79.8% vs. 65.0% mean control in 3 trials) and a significant difference was noted in 1 out of 3 trials. In the other 2 trials, no significant difference was noted. Across 1 trial from the Northeast EPPO climatic zone, GF-3307 (S7K-3-3) applied at 1.25 L/ha showed a very good control of CERCBE equivalent to the reference standard SPYRALE at 1.0 L/ha (96.8% vs. 95.5% mean control in 1 trial) and no significant difference was noted in the trial.

Across 3 trials from the Northeast EPPO climatic zone, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE superior to the reference standard SCORE at 0.4 L/ha (82.4% vs. 61.5% mean control in 3 trials) and a significant difference was noted in 1 out of 3 trials. In the other 2 trials, no significant difference was noted. Across 3 trials from the Northeast EPPO climatic zone, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE superior to the reference standard AMISTAR GOLD at 1.0 L/ha (82.4% vs. 65.0% mean control in 3 trials) and a significant difference was noted in 1 out of 3 trials. In the other 2 trials, no significant difference was noted. Across 1 trial from the Northeast EPPO climatic zone, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a very good control of CERCBE equivalent to the reference standard SPYRALE at 1.0 L/ha (97.3% vs. 95.5% mean control) and no significant difference was noted in the trial.

### Valid assessment after two applications (2 to 6 weeks after the application – all efficacy trials merged):

Across 5 trials from the Northeast EPPO climatic zone, GF-3307 (S7K-3-3) applied at 1.25 L/ha showed a good control of CERCBE superior to the reference standard SCORE at 0.4 L/ha (74.1% vs. 51.0% mean control in 5 trials) and a significant difference was noted in 3 out of 5 trials. In the other 2 trials,

no significant difference was noted. Across 5 trials from the Northeast EPPO climatic zone, GF-3307 (S7K-3-3) applied at 1.25 L/ha showed a good control of CERCBE superior to the reference standard AMISTAR GOLD at 1.0 L/ha (74.1% vs. 53.2% mean control in 5 trials) and a significant difference was noted in 3 out of 5 trials. In the other 2 trials, no significant difference was noted. Across 3 trials from the Northeast EPPO climatic zone, GF-3307 (S7K-3-3) applied at 1.25 L/ha showed a good control of CERCBE superior to the reference standard SPYRALE at 1.0 L/ha (75.9% vs. 66.6% mean control in 3 trials) and a significant difference was noted in 1 out of 3 trials. In the other 2 trials, no significant difference was noted.

Across 8 trials from the Northeast EPPO climatic zone, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE superior to the reference standard SCORE at 0.4 L/ha (79.0% vs. 54.2% mean control in 8 trials) and a significant difference was noted in 5 out of 8 trials. In the other 3 trials, no significant difference was noted. Across 5 trials from the Northeast EPPO climatic zone, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE superior to the reference standard AMISTAR GOLD at 1.0 L/ha (78.0% vs. 53.2% mean control in 5 trials) and a significant difference was noted in 3 out of 5 trials. In the other 2 trials, no significant difference was noted. Across 4 trials from the Northeast EPPO climatic zone, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE superior to the reference standard SPYRALE at 1.0 L/ha (80.7% vs. 65.7% mean control in 4 trials) and a significant difference was noted in 2 out of 4 trials. In the other 2 trials, no significant difference was noted.

### **Northeast and PL border countries (PL-CZ-DE-LT)**

#### Assessment around 30-40 DA-B:

If the border countries are considered with Poland, across 14 trials, GF-3307 (S7K-3-3) applied at 1.2/1.25 L/ha showed a good control of CERCBE superior to the reference standard SCORE at 0.4 L/ha (76.7% vs. 53.6% mean control in 14 trials) and a significant difference was noted in 8 out of 14 trials. In the other 6 trials, no significant difference was noted. Across 11 trials, GF-3307 (S7K-3-3) applied at 1.25 L/ha showed a good control of CERCBE superior to the reference standard AMISTAR GOLD at 1.0 L/ha (77.7% vs. 52.3% mean control in 11 trials) and a significant difference was noted in 6 out of 11 trials. In the other 5 trials, no significant difference was noted. Across 2 trials, GF-3307 (S7K-3-3) applied at 1.25 L/ha showed a good control of CERCBE superior to the reference standard SPYRALE at 1.0 L/ha (77.7% vs. 70.6% mean control in 2 trials) and no significant difference was noted in all trials. Overall, GF-3307 (S7K-3-3) at 1.25 L/ha showed a good control in all trials (76.7% mean control in 14 trials).

If the border countries are considered with Poland, across 17 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE superior to the reference standard SCORE at 0.4 L/ha (83.1% vs. 55.5% mean control in 17 trials) and a significant difference was noted in 11 out of 17 trials. In the other 6 trials, no significant difference was noted. Across 14 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE superior to the reference standard AMISTAR GOLD at 1.0 L/ha (83.7% vs. 53.7% mean control in 14 trials) and a significant difference was noted in 8 out of 14 trials. In the other 6 trials, no significant difference was noted. Across 2 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE superior to the reference standard SPYRALE at 1.0 L/ha (82.1% vs. 70.6% mean control in 2 trials) and no significant difference was noted in all trials. Overall, GF-3307 (S7K-3-3) at 1.5 L/ha showed a good control in all trials (83.4% mean control in 18 trials).

#### Valid assessment after two applications (2 to 6 weeks after the application – all efficacy trials merged):

If the border countries are considered with Poland, across 16 trials, GF-3307 (S7K-3-3) applied at 1.2/1.25 L/ha showed a good control of CERCBE superior to the reference standard SCORE at 0.4 L/ha (75.3% vs. 51.3% mean control in 16 trials) and a significant difference was noted in 10 out of 16 trials. In the other 6 trials, no significant difference was noted. Across 13 trials, GF-3307 (S7K-3-3) applied at 1.25 L/ha showed a good control of CERCBE superior to the reference standard AMISTAR GOLD at 1.0 L/ha (75.8% vs. 49.7% mean control in 13 trials) and a significant difference was noted in 8 out of 13 trials. In the other 5 trials, no significant difference was noted. Across 4 trials, GF-3307 (S7K-3-3) applied at 1.25 L/ha showed a good control of CERCBE superior to the reference standard SPYRALE at 1.0 L/ha (71.6% vs. 61.4% mean control in 4 trials) and a significant difference was noted in 1 out of

4 trials. In the other 3 trials, no significant difference was noted. Overall, GF-3307 (S7K-3-3) at 1.25 L/ha showed a good control in all trials (75.3% mean control in 16 trials).

If the border countries are considered with Poland, across 23 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE superior to the reference standard SCORE at 0.4 L/ha (81.5% vs. 54.7% mean control in 23 trials) and a significant difference was noted in 15 out of 23 trials. In the other 8 trials, no significant difference was noted. Across 16 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE superior to the reference standard AMISTAR GOLD at 1.0 L/ha (82.2% vs. 51.4% mean control in 16 trials) and a significant difference was noted in 10 out of 16 trials. In the other 6 trials, no significant difference was noted. Across 5 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE superior to the reference standard SPYRALE at 1.0 L/ha (78.0% vs. 61.7% mean control in 5 trials) and a significant difference was noted in 2 out of 5 trials. In the other 3 trials, no significant difference was noted. Overall, GF-3307 (S7K-3-3) at 1.5 L/ha showed a good control in all trials (81.8% mean control in 24 trials).

### **Southeast EPPO climatic zone**

#### Assessment around 30-40 DA-B:

Across 6 trials from the Southeast EPPO climatic zone, GF-3307 (S7K-3-3) applied at 1.25 L/ha showed a good control of CERCBE slightly superior to the reference standard AMISTAR GOLD at 1.0 L/ha (69.7% vs. 65.6% mean control in 6 trials) and a significant difference was noted in 2 out of 6 trials. In 2 trials, AMISTAR GOLD was significantly superior to GF-3307 (S7K-3-3). In the others 2 trials, no significant difference was noted.

In one trial, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE equivalent to the reference standard SCORE at 0.4 L/ha (98.7% vs. 98.6% mean control in 1 trial) and no significant difference was noted. Across 6 trials from the Southeast EPPO climatic zone, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE superior to the reference standard AMISTAR GOLD at 1.0 L/ha (79.7% vs. 65.6% mean control in 6 trials) and a significant difference was noted in 4 out of 6 trials. In the other 2 trials, AMISTAR GOLD was significantly superior to GF-3307 (S7K-3-3). Across 1 trial from, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE equivalent to the reference standard SPYRALE at 1.0 L/ha (98.7% vs. 98.9% mean control in 1 trial) and no significant difference was noted. Overall, GF-3307 (S7K-3-3) at 1.5 L/ha showed a good control in all trials (82.4% mean control in 7 trials).

#### Valid assessment after two applications (2 to 6 weeks after the application – all efficacy trials merged):

Across 6 trials from the Southeast EPPO climatic zone, GF-3307 (S7K-3-3) applied at 1.25 L/ha showed a moderate control of CERCBE slightly superior to the reference standard AMISTAR GOLD at 1.0 L/ha (69.7% vs. 65.6% mean control in 6 trials) and a significant difference was noted in 2 out of 6 trials. In 2 trials, AMISTAR GOLD was significantly superior to GF-3307 (S7K-3-3). In the others 2 trials, no significant difference was noted.

Across 4 trials from the Southeast EPPO climatic zone, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE superior to the reference standard SCORE at 0.4 L/ha (82.4% vs. 64.4% mean control in 4 trials) and a significant difference was noted in 2 out of 4 trials. In the other 2 trials, no significant difference was noted. Across 6 trials from the Southeast EPPO climatic zone, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE superior to the reference standard AMISTAR GOLD at 1.0 L/ha (79.7% vs. 65.6% mean control in 6 trials) and a significant difference was noted in 4 out of 6 trials. In the other 2 trials, AMISTAR GOLD was significantly superior to GF-3307 (S7K-3-3). Across 2 trials from the v EPPO climatic zone, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE equivalent to the reference standard SPYRALE at 1.0 L/ha (92.5% vs. 91.8% mean control in 2 trials) and no significant difference was noted in all trials. Overall, GF-3307 (S7K-3-3) at 1.5 L/ha showed a good control in all trials (80.8% mean control in 10 trials).

### **All EPPO climatic zones**

#### Assessment around 30-40 DA-B:

To support 1.2 L/ha in North East and South East EPPO Zone, across 14 trials, GF-3307 (S7K-3-3) applied at 1.2/1.25 L/ha showed a good control of CERCBE superior to the reference standard SCORE at 0.4 L/ha (76.7% vs. 53.6% mean control in 14 trials) and a significant difference was noted in 8 out of 14 trials. In the other 6 trials, no significant difference was noted. Across 17 trials, GF-3307 (S7K-3-

3) applied at 1.25 L/ha showed a good control of CERCBE superior to the reference standard AMISTAR GOLD at 1.0 L/ha (74.9% vs. 57.0% mean control in 17 trials) and a significant difference was noted in 8 out of 17 trials. In the other 9 trials, no significant difference was noted in 7 trials and in the other 2 trials, AMISTAR GOLD was significantly superior to GF-3307 (S7K-3-3). Across 2 trials, GF-3307 (S7K-3-3) applied at 1.25 L/ha showed a good control of CERCBE superior to the reference standard SPYRALE at 1.0 L/ha (77.7% vs. 70.6% mean control in 2 trials) and no significant difference was noted in all trials. Overall, GF-3307 (S7K-3-3) at 1.25 L/ha showed a good control in all trials (74.6% mean control in 20 trials).

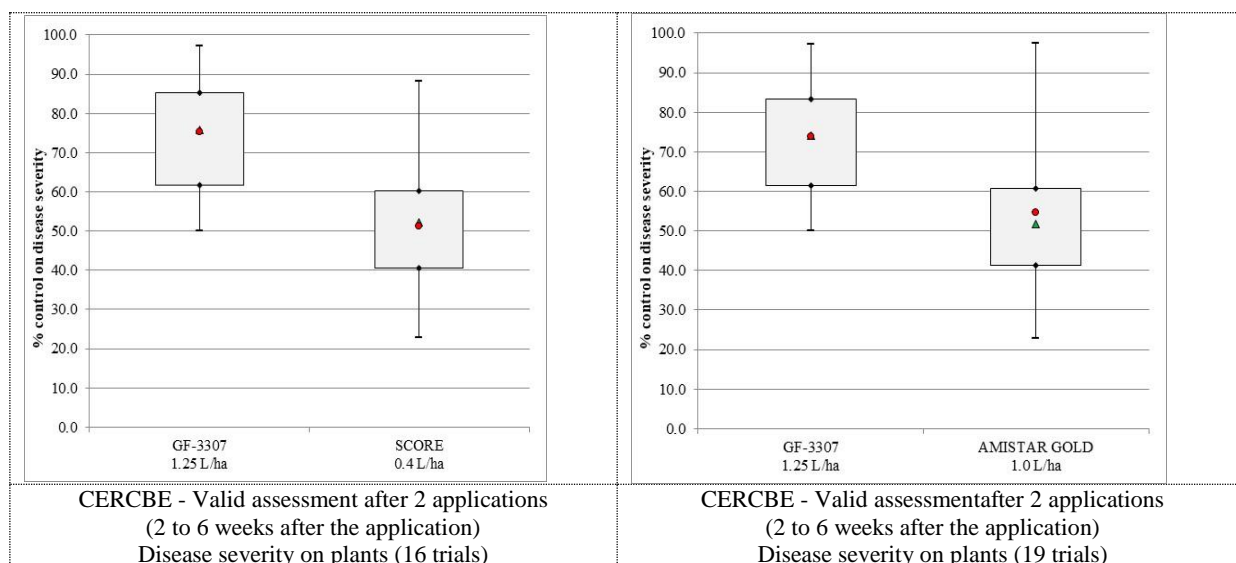
Across 24 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE superior to the reference standard SCORE at 0.4 L/ha (84.9% vs. 57.7% mean control in 24 trials) and a significant difference was noted in 13 out of 24 trials. In the other 11 trials, no significant difference was noted. Across 24 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE superior to the reference standard AMISTAR GOLD at 1.0 L/ha (83.5% vs. 59.4% mean control in 24 trials) and a significant difference was noted in 12 out of 24 trials. In the other 12 trials, no significant difference was noted in 10 trials and in the other 2 trials, AMISTAR GOLD was significantly superior to GF-3307 (S7K-3-3). Across 8 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE superior to the reference standard SPYRALE at 1.0 L/ha (87.3% vs. 75.9% mean control in 8 trials) and no significant difference was noted in all trials. Overall, GF-3307 (S7K-3-3) at 1.5 L/ha showed a good control in all trials (84.0% mean control in 31 trials).

*Valid assessment after two applications (2 to 6 weeks after the application – all efficacy trials merged):*

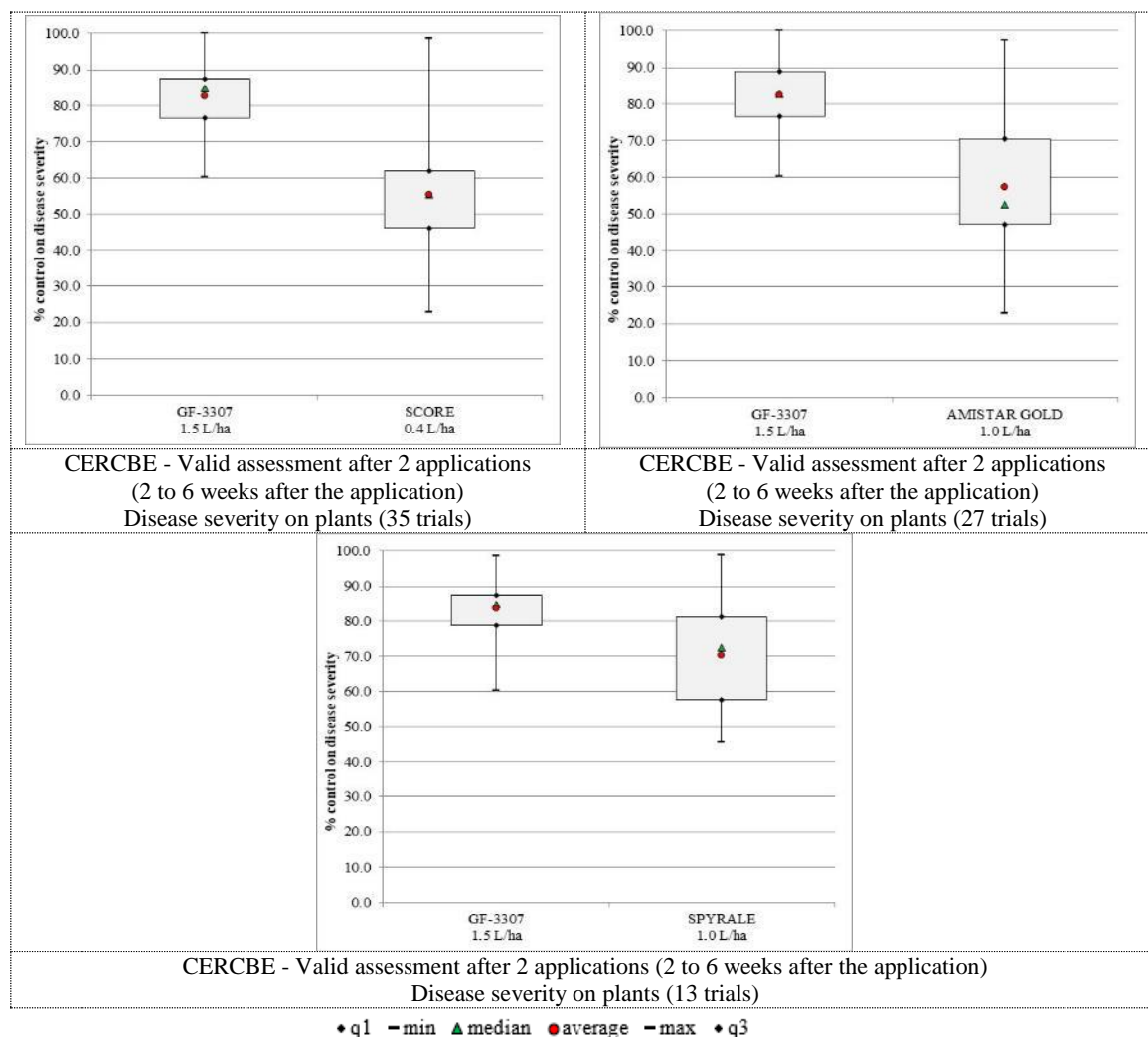
To support 1.2 L/ha in North East and South East EPPO Zone, across 16 trials, GF-3307 (S7K-3-3) applied at 1.2/1.25 L/ha showed a good control of CERCBE superior to the reference standard SCORE at 0.4 L/ha (75.3% vs. 51.3% mean control in 16 trials) and a significant difference was noted in 10 out of 16 trials. In the other 6 trials, no significant difference was noted. Across 19 trials, GF-3307 (S7K-3-3) applied at 1.25 L/ha showed a good control of CERCBE superior to the reference standard AMISTAR GOLD at 1.0 L/ha (73.9% vs. 54.7% mean control in 19 trials) and a significant difference was noted in 10 out of 19 trials. In the other 9 trials, no significant difference was noted in 7 trials and in the other 2 trials, AMISTAR GOLD was significantly superior to GF-3307 (S7K-3-3). Across 4 trials, GF-3307 (S7K-3-3) applied at 1.25 L/ha showed a good control of CERCBE superior to the reference standard SPYRALE at 1.0 L/ha (71.6% vs. 61.4% mean control in 4 trials) and a significant difference was noted in 1 out of 4 trials. In the other 3 trials, no significant difference was noted. Overall, GF-3307 (S7K-3-3) at 1.25 L/ha showed a good control in all trials (73.8% mean control in 22 trials).

Across 35 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE superior to the reference standard SCORE at 0.4 L/ha (82.6% vs. 55.5% mean control in 35 trials) and a significant difference was noted in 20 out of 35 trials. In the other 15 trials, no significant difference was noted. Across 27 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE superior to the reference standard AMISTAR GOLD at 1.0 L/ha (82.3% vs. 57.3% mean control in 27 trials) and a significant difference was noted in 15 out of 27 trials. In the other 12 trials, no significant difference was noted in 10 trials and in the other 2 trials, AMISTAR GOLD was significantly superior to GF-3307 (S7K-3-3). Across 13 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of CERCBE superior to the reference standard SPYRALE (S7K-3-3) at 1.0 L/ha (83.6% vs. 70.2% mean control in 13 trials) and a significant difference was noted in 3 out of 13 trials. In the other 10 trials, no significant difference was noted. Overall, GF-3307 (S7K-3-3) at 1.5 L/ha showed a good control in all trials (82.3% mean control in 42 trials).

The results of the efficacy trials presented in this section confirmed the good efficacy achieved by GF-3307 (S7K-3-3) on CERCBE. At the maximum proposed label rate of 1.5 L/ha, across 42 trials, the efficacy of GF-3307 (S7K-3-3) reached around 82% of efficacy on plants. In the same way, GF-3307 (S7K-3-3) at 1.25 L/ha demonstrated a good level of control on CERCBE (around 74% in 22 trials). Moreover, the difference between the reference standards can be illustrated by box plot graphics (Figure 3.2-9 and Figure 3.2-10).



**Figure 3.2-9 Efficacy of GF-3307 (S7K-3-3) at 1.25 L/ha - Sugar beet - CERCBE - Disease severity on plants - Box Plot graphics in all EPPO Climatic zones data used to support 1.2 L/ha in North East and South East EPPO Zone based on Table 3.2-42**



**Figure 3.2-10 Efficacy of GF-3307 (S7K-3-3) at 1.5 L/ha - Sugar beet - CERCBE - Disease severity on plants - Box Plot graphics in all EPPO Climatic zones based on Table 3.2-42**



### Summary and conclusions - CERCBE

According to the results included in the BAD to evaluate the efficacy of GF-3307 (S7K-3-3) for the control of CERCBE, GF-3307 (S7K-3-3) applied at 1.5 L/ha provides the optimum overall control and is considered to be fully effective against CERCBE in sugar beet by consistently delivering over 80% control.

As a result, according to the efficacy results in 24 valid trials (Table 3.2-36), the proposed rate of 1.5 L/ha of GF-3307 (S7K-3-3) in Austria, Belgium, Czech Republic and The Netherlands should be considered the effective dose to deliver robust control (84% 2-6 weeks after final application) of CERCBE in sugar beet in the Maritime climatic zone compared to a mean control of 57% from the references combined.

Where a range of 1.2-1.5 l/ha is sought in North East and South East EPPO the data is supportive. In 16 trials from the North East/PL and bordering countries where 1.2/1.25 L/ha was applied achieved 75% control vs combined references control of 51% (Table 3.2-37). At the higher dose 1.5L/ha achieved 82% control in 24 trials compared to control by the combined references at 54% (Table 3.2-38). In the South East the data set of 6-10 trials is smaller and may explain the lower levels of control compared to other climatic zones, though the trends are similar. In 6 trials where 1.25 L/ha was applied it achieved 70% control which was comparable to the reference Amistar Gold which achieved 66% control (Table 3.2-39). At the higher dose 1.5L/ha achieved 80% control in the same 6 trials and when compared in 10 trials it achieved 81% control compared to the combined references that obtained 66% (Table 3.2-40). When disease control at 1.2/1.25 L/ha is considered from all EPPO zones GF-3307 (S7K-3-3) delivered 74% control in 22 trials (Table 3.2-41) compared to the combined reference control of 55% after 2 applications (2-6 weeks after application) and the 1.5 L/ha dose of GF-3307 (S7K-3-3) delivered 82% control in 42 trials vs the combined reference control levels of 59% (Table 3.2-42). The conditions for use at a lower rate are detailed in the minimum effective rate part of this section. Thus, a rate range of 1.2-1.5 L/ha of GF-3307 (S7K-3-3) will be recommended in Poland, Hungary, Romania and Slovakia for control of CERCBE to offer growers flexibility to reduce dose where conditions are appropriate as part on sustainable disease management.

**Table 3.2-36 Effectiveness of GF-3307 (S7K-3-3) at proposed maximum label rate of 1.5 L/ha against CERCBE in sugar beet. Results from 24 trials conducted in the EPPO Maritime climatic zone between 2020-2023**

Part	Timing of assessment	EPPO climatic zone	No. of trials	Untreated				Percentage of efficacy (%)																				No. of assessments significantly > , = , < GF-3307 (S7K-3-3) (1.5 L/ha) vs. Reference products				
								GF-3307 (S7K-3-3) 1.5 L/ha				SCORE 0.4 L/ha				AMISTAR GOLD 1.0 L/ha				SPYRALE 1.0 L/ha				All reference products								
								Fenpi. + Prothio.				Difenoconazole				Azoxy. + Difeno.				Difeno. + Fenpro.												
								75+150 g a.s./ha				100 g a.s./ha				125+125 g a.s./ha				100+375 g a.s./ha												
				Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.					
Disease severity on plants	Assessment around 15-20 DA-B	Maritime	18	18.9	5.2	58.8	85.9	75.6	100.0	7.0	59.6	24.2	82.1	15.3	-	-	-	-	-	-	-	-	-	-	-	-	-	9> ; 9= ; 0<				
			12	19.6	5.2	58.8	86.0	75.6	100.0	7.9	-	-	-	-	56.9	34.1	84.9	15.9	-	-	-	-	-	-	-	-	-	8> ; 4= ; 0<				
			4	32.5	13.1	58.8	83.4	76.0	92.0	7.2	-	-	-	-	-	-	-	-	66.2	53.6	85.8	12.0	-	-	-	-	-	1> ; 3= ; 0<				
	Assessment around 30-40 DA-B	Maritime	20	26.0	5.1	63.5	84.5	66.9	100.0	8.0	55.1	23.3	87.9	14.1	-	-	-	-	-	-	-	-	-	-	-	-	-	12> ; 8= ; 0<				
			15	29.8	5.1	63.5	85.2	66.9	100.0	8.8	-	-	-	-	55.8	30.2	86.7	17.0	-	-	-	-	-	-	-	-	-	7> ; 8= ; 0<				
			6	30.6	8.4	52.9	83.7	66.9	97.4	9.3	-	-	-	-	-	-	-	-	68.8	45.7	81.1	11.6	-	-	-	-	-	0> ; 6= ; 0<				
	Assessment after around 40 DA-B	Maritime	21	26.9	5.1	63.5	84.7	66.9	100.0	7.9	-	-	-	-	-	-	-	-	-	-	-	-	57.1	30.2	86.7	15.1	-	11> ; 10= ; 0<				
			9	38.7	20.6	66.5	88.6	73.0	100.0	9.0	60.9	38.8	87.1	12.9	-	-	-	-	-	-	-	-	-	-	-	-	-	7> ; 2= ; 0<				
			10	41.3	20.6	66.5	87.7	73.0	100.0	9.0	-	-	-	-	59.1	20.8	90.5	20.0	-	-	-	-	-	-	-	-	-	6> ; 4= ; 0<				
	Valid assessment after 2 applications (2 to 6 weeks after the application)	Maritime	1	57.8	-	-	91.5	-	-	-	-	-	-	-	-	-	-	-	75.8	-	-	-	-	-	-	-	-	0> ; 1= ; 0<				
			23	25.4	5.1	63.5	83.9	66.9	100.0	7.8	54.4	23.3	87.9	14.0	-	-	-	-	-	-	-	-	-	-	-	-	-	13> ; 10= ; 0<				
			16	30.0	5.1	63.5	84.6	66.9	100.0	8.8	-	-	-	-	55.5	30.2	86.7	16.5	-	-	-	-	-	-	-	-	-	8> ; 8= ; 0<				
			7	30.9	8.4	52.9	82.6	66.9	97.4	9.0	-	-	-	-	-	-	-	-	66.6	45.7	81.1	12.0	-	-	-	-	-	1> ; 6= ; 0<				
			24	26.2	5.1	63.5	84.1	66.9	100.0	7.7	-	-	-	-	-	-	-	-	-	-	-	56.9	30.2	86.7	14.4	-	12> ; 12= ; 0<					

**Table 3.2-37 Effectiveness of GF-3307 (S7K-3-3) at proposed ~~maximum~~ label rate of 1.25 L/ha against CERCBE in sugar beet. Results from 5 trials conducted in the EPPO Northeast climatic zone between 2020-2023 and 16 trials from North East and Border countries**

Part	Timing of assessment	EPPO climatic zone	No. of trials	Untreated			Percentage of efficacy (%)																								No. of assessments significantly > , = , < GF-3307 (S7K-3-3) (1.25 L/ha) vs. Reference products
							GF-3307 (S7K-3-3) 1.2-1.25 L/ha				SCORE 0.4 L/ha				AMISTAR GOLD 1.0 L/ha				SPYRALE 1.0 L/ha				All reference products								
							Fenpi. + Prothio.				Difenoconazole				Azoxy. + Difeno.				Difeno. + Fenpro.												
				60-62.5 + 120-125g a.s./ha				100 g a.s./ha				125+125 g a.s./ha				100+375 g a.s./ha															
Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.				
Disease severity on plants	Assessment around 15-20 DA-B	Northeast	5	29.6	7.0	57.5	78.8	50.0	98.8	15.9	57.5	22.8	98.3	24.4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	3> ; 2= ; 0<		
			5	29.6	7.0	57.5	78.8	50.0	98.8	15.9	-	-	-	-	62.0	22.8	97.6	25.5	-	-	-	-	-	-	-	-	-	-	2> ; 3= ; 0<		
			3	39.7	23.9	57.5	76.6	50.0	98.8	20.2	-	-	-	-	-	-	-	-	67.5	46.9	98.3	22.2	-	-	-	-	-	-	-	1> ; 2= ; 0<	
		Northeast and PL border countries (PL-CZ-DE-LT)	15	21.0	6.3	57.5	78.6	50.0	100.0	12.3	59.3	22.8	98.3	19.7	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	7> ; 8= ; 0<	
			12	21.1	6.3	57.5	78.5	50.0	100.0	13.3	-	-	-	-	54.2	22.8	97.6	19.9	-	-	-	-	-	-	-	-	-	-	-	6> ; 6= ; 0<	
			4	33.0	13.1	57.5	76.3	50.0	98.8	17.5	-	-	-	-	-	-	-	-	65.8	46.9	98.3	19.4	-	-	-	-	-	-	-	1> ; 3= ; 0<	
	Assessment around 30-40 DA-B	Northeast	3	32.9	26.7	38.3	79.8	60.5	96.8	14.9	61.5	39.7	88.2	20.1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1> ; 2= ; 0<	
			3	32.9	26.7	38.3	79.8	60.5	96.8	14.9	-	-	-	-	65.0	46.0	90.4	18.7	-	-	-	-	-	-	-	-	-	-	-	1> ; 2= ; 0<	
			1	38.3	-	-	96.8	-	-	-	-	-	-	-	-	-	-	-	95.5	-	-	-	-	-	-	-	-	-	-	0> ; 1= ; 0<	
		Northeast and PL border countries (PL-CZ-DE-LT)	14	29.7	8.8	63.5	76.7	58.6	97.1	13.3	53.6	23.3	88.2	16.7	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	8> ; 6= ; 0<	
			11	30.3	8.8	63.5	77.7	58.6	97.1	14.6	-	-	-	-	52.3	30.2	90.4	16.9	-	-	-	-	-	-	-	-	-	-	-	6> ; 5= ; 0<	
			2	35.7	33.2	38.3	77.7	58.6	96.8	19.1	-	-	-	-	-	-	-	-	70.6	45.7	95.5	24.9	-	-	-	-	-	-	-	0> ; 2= ; 0<	
	Assessment after around 40 DA-B	Northeast	14	29.7	8.8	63.5	76.7	58.6	97.1	13.3	-	-	-	-	-	-	-	-	-	-	-	-	52.9	30.2	90.4	15.2	-	-	-	8> ; 6= ; 0<	
			1	69.8	-	-	90.8	-	-	-	71.2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0> ; 1= ; 0<	
			1	69.8	-	-	90.8	-	-	-	-	-	-	-	-	-	-	-	88.4	-	-	-	-	-	-	-	-	-	-	0> ; 1= ; 0<	
		Northeast and PL border countries (PL-DE)	6	45.3	24.8	69.8	81.5	56.7	93.9	13.7	60.1	46.6	71.2	7.3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	4> ; 2= ; 0<	
			6	45.3	24.8	69.8	81.5	56.7	93.9	13.7	-	-	-	-	58.8	50.5	76.3	9.6	-	-	-	-	-	-	-	-	-	-	-	4> ; 2= ; 0<	
			6	45.3	24.8	69.8	81.5	56.7	93.9	13.7	-	-	-	-	58.8	50.5	76.3	9.6	-	-	-	-	-	-	-	-	-	-	-	4> ; 2= ; 0<	
	Valid assessment after 2 applications (2 to 6 weeks after the application)	Northeast	5	38.7	26.7	57.5	74.1	50.0	96.8	16.7	51.0	22.8	88.2	21.7	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	3> ; 2= ; 0<	
			5	38.7	26.7	57.5	74.1	50.0	96.8	16.7	-	-	-	-	53.2	22.8	90.4	22.0	-	-	-	-	-	-	-	-	-	-	-	3> ; 2= ; 0<	
			3	44.4	37.5	57.5	75.9	50.0	96.8	19.4	-	-	-	-	-	-	-	-	66.6	46.9	95.5	20.9	-	-	-	-	-	-	-	1> ; 2= ; 0<	
		Northeast and PL border countries (PL-CZ-DE-LT)	16	32.0	8.8	63.5	75.3	50.0	97.1	14.1	51.3	22.8	88.2	17.4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	10> ; 6= ; 0<	
			13	33.0	8.8	63.5	75.8	50.0	97.1	15.4	-	-	-	-	49.7	22.8	90.4	17.4	-	-	-	-	-	-	-	-	-	-	-	8> ; 5= ; 0<	
			4	41.6	33.2	57.5	71.6	50.0	96.8	18.4	-	-	-	-	-	-	-	-	61.4	45.7	95.5	20.2	-	-	-	-	-	-	-	-	1> ; 3= ; 0<
	16	32.0	8.8	63.5	75.3	50.0	97.1	14.1	-	-	-	-	-	-	-	-	-	-	-	-	50.7	22.8	90.4	15.9	-	-	-	-	10> ; 6= ; 0<		

**Table 3.2-38 Effectiveness of GF-3307 (S7K-3-3) at proposed maximum label rate of 1.5 L/ha against CERCBE in sugar beet. Results from 8 trials conducted in the EPPO Northeast climatic zone between 2020-2023 and 24 trials from North East and Border countries**

Part	Timing of assessment	EPPO climatic zone	No. of trials	Untreated			Percentage of efficacy (%)																				No. of assessments significantly > , = , < GF-3307 (S7K-3-3) (1.5 L/ha) vs. Reference products
							GF-3307 (S7K-3-3) 1.5 L/ha				SCORE 0.4 L/ha				AMISTAR GOLD 1.0 L/ha				SPYRALE 1.0 L/ha				All reference products				
							Fenpi. + Prothio. 75+150 g a.s./ha				Difenoconazole 100 g a.s./ha				Azox. + Difeno. 125+125 g a.s./ha				Difeno. + Fenpro. 100+375 g a.s./ha								
				Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	
Disease severity on plants	Assessment around 15-20 DA-B	Northeast	8	38.5	7.0	72.5	80.8	60.3	99.4	10.7	58.2	22.8	98.3	19.3	-	-	-	-	-	-	-	-	-	-	-	5> ; 3= ; 0<	
			5	29.6	7.0	57.5	80.9	60.3	99.4	12.6	-	-	-	-	62.0	22.8	97.6	25.5	-	-	-	-	-	-	-	3> ; 2= ; 0<	
			4	37.9	23.9	57.5	81.3	60.3	99.4	13.9	-	-	-	-	-	-	-	-	66.4	46.9	98.3	19.3	-	-	-	-	2> ; 2= ; 0<
		Northeast and PL border countries (PL-CZ-DE-LT)	21	24.5	6.3	72.5	83.5	60.3	100.0	8.7	60.2	22.8	98.3	17.0	-	-	-	-	-	-	-	-	-	-	-	-	11> ; 10= ; 0<
			13	20.1	6.3	57.5	83.3	60.3	100.0	10.0	-	-	-	-	55.9	22.8	97.6	20.0	-	-	-	-	-	-	-	-	9> ; 4= ; 0<
			5	32.9	13.1	57.5	80.4	60.3	99.4	12.6	-	-	-	-	-	-	-	-	65.2	46.9	98.3	17.4	-	-	-	-	2> ; 3= ; 0<
	Assessment around 30-40 DA-B	Northeast	3	32.9	26.7	38.3	82.4	62.3	97.2	14.7	61.5	39.7	88.2	20.1	-	-	-	-	-	-	-	-	-	-	-	-	1> ; 2= ; 0<
			3	32.9	26.7	38.3	82.4	62.3	97.2	14.7	-	-	-	-	65.0	46.0	90.4	18.7	-	-	-	-	-	-	-	-	1> ; 2= ; 0<
			1	38.3	-	-	97.3	-	-	-	-	-	-	-	-	-	-	-	95.5	-	-	-	-	-	-	-	0> ; 1= ; 0<
		Northeast and PL border countries (PL-CZ-DE-LT)	17	27.3	7.9	63.5	83.1	62.3	100.0	9.9	55.5	23.3	88.2	17.3	-	-	-	-	-	-	-	-	-	-	-	-	11> ; 6= ; 0<
			14	29.1	7.9	63.5	83.7	62.3	100.0	10.7	-	-	-	-	53.7	30.2	90.4	17.9	-	-	-	-	-	-	-	-	8> ; 6= ; 0<
			2	35.7	33.2	38.3	82.1	66.9	97.2	15.2	-	-	-	-	-	-	-	-	70.6	45.7	95.5	24.9	-	-	-	-	0> ; 2= ; 0<
	Assessment after around 40 DA-B	Northeast	18	28.2	7.9	63.5	83.4	62.3	100.0	9.7	-	-	-	-	-	-	-	-	-	-	-	54.2	30.2	90.4	16.0	12> ; 6= ; 0<	
			1	69.8	-	-	87.6	-	-	-	71.2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0> ; 1= ; 0<
			1	69.8	-	-	87.6	-	-	-	-	-	-	-	-	76.3	-	-	-	-	-	-	-	-	-	-	0> ; 1= ; 0<
		Northeast and PL border countries (PL-DE)	8	42.5	20.8	69.8	87.3	73.0	100.0	9.1	63.7	46.6	87.1	10.9	-	-	-	-	-	-	-	-	-	-	-	-	5> ; 2= ; 0<
			9	44.9	20.8	69.8	86.4	73.0	100.0	9.0	-	-	-	-	56.2	20.8	88.7	18.5	-	-	-	-	-	-	-	-	6> ; 2= ; 0<
			8	44.2	26.7	72.5	79.0	60.3	97.2	12.1	54.2	22.8	88.2	17.6	-	-	-	-	-	-	-	-	-	-	-	-	5> ; 3= ; 0<
	Valid assessment after 2 applications (2 to 6 weeks after the application)	Northeast	5	38.7	26.7	57.5	78.0	60.3	97.2	14.4	-	-	-	-	53.2	22.8	90.4	22.0	-	-	-	-	-	-	-	-	3> ; 2= ; 0<
			4	41.4	32.5	57.5	80.7	60.3	97.2	13.2	-	-	-	-	-	-	-	-	65.7	46.9	95.5	18.2	-	-	-	-	2> ; 2= ; 0<
			23	32.2	7.9	72.5	81.5	60.3	100.0	10.0	54.7	22.8	88.2	16.6	-	-	-	-	-	-	-	-	-	-	-	-	15> ; 8= ; 0<
		Northeast and PL border countries (PL-CZ-DE-LT)	16	31.4	7.9	63.5	82.2	60.3	100.0	11.5	-	-	-	-	51.4	22.8	90.4	18.4	-	-	-	-	-	-	-	-	10> ; 6= ; 0<
			5	39.8	32.5	57.5	78.0	60.3	97.2	13.1	-	-	-	-	-	-	-	-	61.7	45.7	95.5	18.1	-	-	-	-	2> ; 3= ; 0<
			24	32.6	7.9	72.5	81.8	60.3	100.0	9.9	-	-	-	-	-	-	-	-	-	53.8	22.8	90.4	15.6	16> ; 8= ; 0<			

**Table 3.2-39 Effectiveness of GF-3307 (S7K-3-3) at proposed ~~maximum~~ label rate of 1.25 L/ha against CERCBE in sugar beet. Results from 6 trials conducted in the EPPO Southeast climatic zones between 2020-2023**

Part	Timing of assessment	EPPO climatic zone	No. of trials	Untreated			Percentage of efficacy (%)																				No. of assessments significantly > , = , < GF-3307 (S7K-3-3) (1.25 L/ha) vs. Reference products
							GF-3307 (S7K-3-3) 1.25 L/ha				SCORE 0.4 L/ha				AMISTAR GOLD 1.0 L/ha				SPYRALE 1.0 L/ha				All reference products				
							Fenpi. + Prothio.				Difenoconazole				Azoxy. + Difeno.				Difeno. + Fenpro.								
							62.5 + 125g a.s./ha				100 g a.s./ha				125+125 g a.s./ha				100+375 g a.s./ha								
				Mean	Min	Max		Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	
Disease severity on plants	Assessment around 15-20 DA-B	Southeast	6	18.8	8.0	44.5	76.6	56.9	90.4	13.0	-	-	-	-	67.5	33.2	100.0	26.3	-	-	-	-	-	-	-	2> ; 2= ; 2<	
	Assessment around 30-40 DA-B	Southeast	6	35.7	12.3	65.0	69.7	58.5	77.2	7.3	-	-	-	-	65.6	27.2	97.5	25.2	-	-	-	-	6	35.7	12.3	65.0	2> ; 2= ; 2<
	Assessment after around 40 DA-B	Southeast	4	32.0	14.0	52.5	67.7	63.5	69.4	2.4	-	-	-	-	75.3	50.6	97.0	21.8	-	-	-	-	-	-	-	1> ; 1= ; 2<	
	Valid assessment after 2 applications (2 to 6 weeks after the application)	Southeast	6	35.7	12.3	65.0	69.7	58.5	77.2	7.3	-	-	-	-	65.6	27.2	97.5	25.2	-	-	-	-	6	35.7	12.3	65.0	2> ; 2= ; 2<

**Table 3.2-40 Effectiveness of GF-3307 (S7K-3-3) at proposed maximum label rate of 1.5 L/ha against CERCBE in sugar beet. Results from 10 trials conducted in the EPPO Southeast climatic zones between 2020-2023**

Part	Timing of assessment	EPPO climatic zone	No. of trials	Untreated				Percentage of efficacy (%)																				No. of assessments significantly > , = , < GF-3307 (S7K-3-3) (1.5 L/ha) vs. Reference products				
								GF-3307 (S7K-3-3) 1.5 L/ha				SCORE 0.4 L/ha				AMISTAR GOLD 1.0 L/ha				SPYRALE 1.0 L/ha				All reference products								
								Fenpi. + Prothio.				Difenoconazole				Azox. + Difeno.				Difeno. + Fenpro.												
								75+150 g a.s./ha				100 g a.s./ha				125+125 g a.s./ha				100+375 g a.s./ha												
Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.					
Disease severity on plants	Assessment around 15-20 DA-B	Southeast	3	40.3	17.0	55.0	77.0	70.4	86.3	6.8	53.0	38.3	74.8	15.7	-	-	-	-	-	-	-	-	-	-	-	-	-	2> ; 1= ; 0<				
			6	18.8	8.0	44.5	85.1	66.8	94.4	10.4	-	-	-	-	67.5	33.2	100.0	26.3	-	-	-	-	-	-	-	-	-	4> ; 1= ; 1<				
			1	17.0	-	-	86.3	-	-	-	-	-	-	-	-	-	-	-	-	84.7	-	-	-	-	-	-	-	0> ; 1= ; 0<				
			9	25.9	8.0	55.0	82.4	66.8	94.4	10.1	-	-	-	-	-	-	-	-	-	-	-	-	63.8	33.2	100.0	25.1	6> ; 2= ; 1<					
	Assessment around 30-40 DA-B	Southeast	1	13.3	-	-	98.7	-	-	-	98.6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0> ; 1= ; 0<				
			6	35.7	12.3	65.0	79.7	65.5	89.0	8.0	-	-	-	-	65.6	27.2	97.5	25.2	-	-	-	-	-	-	-	-	4> ; 0= ; 2<					
			1	13.3	-	-	98.7	-	-	-	-	-	-	-	-	-	-	-	-	98.9	-	-	-	-	-	-	-	0> ; 1= ; 0<				
			7	32.5	12.3	65.0	82.4	65.5	98.7	10.0	-	-	-	-	-	-	-	-	-	-	-	-	70.4	27.2	98.9	26.1	4> ; 1= ; 2<					
	Assessment after around 40 DA-B	Southeast	1	20.3	-	-	97.1	-	-	-	97.2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0> ; 1= ; 0<				
			4	32.0	14.0	52.5	77.5	71.5	82.7	5.1	-	-	-	-	75.3	50.6	97.0	21.8	-	-	-	-	-	-	-	-	2> ; 0= ; 2<					
			1	20.3	-	-	97.1	-	-	-	-	-	-	-	-	-	-	-	-	97.7	-	-	-	-	-	-	-	0> ; 1= ; 0<				
			5	29.6	14.0	52.5	81.4	71.5	97.1	9.1	-	-	-	-	-	-	-	-	-	-	-	-	79.8	50.6	97.6	21.5	2> ; 1= ; 2<					
	Valid assessment after 2 applications (2 to 6 weeks after the application)	Southeast	4	33.5	13.3	55.0	82.4	70.4	98.7	11.1	64.4	38.3	98.6	24.0	-	-	-	-	-	-	-	-	-	-	-	-	-	2> ; 2= ; 0<				
			6	35.7	12.3	65.0	79.7	65.5	89.0	8.0	-	-	-	-	65.6	27.2	97.5	25.2	-	-	-	-	-	-	-	-	-	4> ; 0= ; 2<				
			2	15.2	13.3	17.0	92.5	86.3	98.7	6.2	-	-	-	-	-	-	-	-	91.8	84.7	98.9	7.1	-	-	-	-	-	0> ; 2= ; 0<				
			10	34.8	12.3	65.0	80.8	65.5	98.7	9.5	-	-	-	-	-	-	-	-	-	-	-	-	66.2	27.2	98.9	25.3	6> ; 2= ; 2<					

**Table 3.2-41 Effectiveness of GF-3307 (S7K-3-3) at proposed ~~maximum~~ label rate of 1.25 L/ha against CERCBE in sugar beet. Results from 22 trials conducted in All EPPO climatic zones between 2020-2023 to support 1.2 L/ha in North East and South East EPPO Zone**

Part	Timing of assessment	EPPO climatic zone	No. of trials	Untreated			Percentage of efficacy (%)																				No. of assessments significantly > , = , < GF-3307 (S7K-3-3) (1.25 L/ha) vs. Reference products	
							GF-3307 (S7K-3-3) 1.2-1.25 L/ha				SCORE 0.4 L/ha				AMISTAR GOLD 1.0 L/ha				SPYRALE 1.0 L/ha				All reference products					
							Fenpi. + Prothio. 60-62.5 + 120-125g a.s./ha				Difenoconazole 100 g a.s./ha				Azoxy. + Difeno. 125+125 g a.s./ha				Difeno. + Fenpro. 100+375 g a.s./ha									
				Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.		Mean
Disease severity on plants	Assessment around 15-20 DA-B	All EPPO climatic zones	15	21.0	6.3	57.5	78.6	50.0	100.0	12.3	59.3	22.8	98.3	19.7	-	-	-	-	-	-	-	-	-	-	-	-	-	7> ; 8= ; 0<
			18	20.3	6.3	57.5	77.9	50.0	100.0	13.2	-	-	-	-	58.6	22.8	100.0	23.1	-	-	-	-	-	-	-	-	-	8> ; 8= ; 2<
			4	33.0	13.1	57.5	76.3	50.0	98.8	17.5	-	-	-	-	-	-	-	-	65.8	46.9	98.3	19.4	-	-	-	-	-	1> ; 3= ; 0<
			21	20.4	6.3	57.5	78.0	50.0	100.0	12.6	-	-	-	-	-	-	-	-	-	-	-	-	60.6	22.8	100.0	22.5	9> ; 10= ; 2<	
	Assessment around 30-40 DA-B	All EPPO climatic zones	14	29.7	8.8	63.5	76.7	58.6	97.1	13.3	53.6	23.3	88.2	16.7	-	-	-	-	-	-	-	-	-	-	-	-	-	8> ; 6= ; 0<
			17	32.2	8.8	65.0	74.9	58.5	97.1	13.1	-	-	-	-	57.0	27.2	97.5	21.2	-	-	-	-	-	-	-	-	-	8> ; 7= ; 2<
			2	35.7	33.2	38.3	77.7	58.6	96.8	19.1	-	-	-	-	-	-	-	-	70.6	45.7	95.5	24.9	-	-	-	-	-	0> ; 2= ; 0<
			20	31.5	8.8	65.0	74.6	58.5	97.1	12.3	-	-	-	-	-	-	-	-	-	-	-	-	56.7	27.2	97.5	19.6	10> ; 8= ; 2<	
	Assessment after around 40 DA-B	All EPPO climatic zones	6	45.3	24.8	69.8	81.5	56.7	93.9	13.7	60.1	46.6	71.2	7.3	-	-	-	-	-	-	-	-	-	-	-	-	-	4> ; 2= ; 0<
			10	39.9	14.0	69.8	76.0	56.7	93.9	12.7	-	-	-	-	65.4	50.5	97.0	17.6	-	-	-	-	-	-	-	-	-	5> ; 3= ; 2<
			1	69.8	-	-	90.8	-	-	-	-	-	-	-	-	-	-	-	-	88.4	-	-	-	-	-	-	-	0> ; 1= ; 0<
			10	39.9	14.0	69.8	76.0	56.7	93.9	12.7	-	-	-	-	-	-	-	-	-	-	-	-	65.4	50.5	97.0	17.6	5> ; 3= ; 2<	
	Valid assessment after 2 applications (2 to 6 weeks after the application)	All EPPO climatic zones	16	32.0	8.8	63.5	75.3	50.0	97.1	14.1	51.3	22.8	88.2	17.4	-	-	-	-	-	-	-	-	-	-	-	-	-	10> ; 6= ; 0<
			19	33.8	8.8	65.0	73.9	50.0	97.1	13.7	-	-	-	-	54.7	22.8	97.5	21.5	-	-	-	-	-	-	-	-	-	10> ; 7= ; 2<
			4	41.6	33.2	57.5	71.6	50.0	96.8	18.4	-	-	-	-	-	-	-	-	-	61.4	45.7	95.5	20.2	-	-	-	-	1> ; 3= ; 0<
			22	33.0	8.8	65.0	73.8	50.0	97.1	12.9	-	-	-	-	-	-	-	-	-	-	-	-	54.8	22.8	97.5	20.1	12> ; 8= ; 2<	

**Table 3.2-42 Effectiveness of GF-3307 (S7K-3-3) at proposed maximum label rate of 1.5 L/ha against CERCBE in sugar beet. Results from 42 trials conducted in All EPPO climatic zones between 2020-2023**

Part	Timing of assessment	EPPO climatic zone	No. of trials	Untreated			Percentage of efficacy (%)																				No. of assessments significantly > , = , < GF-3307 (S7K-3-3) (1.5 L/ha) vs. Reference products		
							GF-3307 (S7K-3-3) 1.5 L/ha				SCORE 0.4 L/ha				AMISTAR GOLD 1.0 L/ha				SPYRALE 1.0 L/ha				All reference products						
							Fenpi. + Prothio. 75+150 g a.s./ha				Difenoconazole 100 g a.s./ha				Azoxyl. + Difeno. 125+125 g a.s./ha				Difeno. + Fenpro. 100+375 g a.s./ha										
				Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.		Mean	Min
Disease severity on plants	Assessment around 15-20 DA-B	All EPPO climatic zones	29	26.5	5.2	72.5	83.6	60.3	100.0	8.7	58.5	22.8	98.3	16.7	-	-	-	-	-	-	-	-	-	-	-	-	-	16> ; 13= ; 0<	
			23	21.6	5.2	58.8	84.7	60.3	100.0	10.0	-	-	-	-	60.8	22.8	100.0	21.8	-	-	-	-	-	-	-	-	-	15> ; 7= ; 1<	
			10	33.2	13.1	58.8	82.8	60.3	99.4	10.6	-	-	-	-	-	-	-	-	68.4	46.9	98.3	16.2	-	-	-	-	-	3> ; 6= ; 0<	
			35	25.2	5.2	72.5	83.8	60.3	100.0	9.1	-	-	-	-	-	-	-	-	-	-	-	-	61.0	22.8	100.0	19.5	21> ; 13= ; 1<		
	Assessment around 30-40 DA-B	All EPPO climatic zones	24	26.4	5.1	63.5	84.9	62.3	100.0	9.5	57.7	23.3	98.6	17.1	-	-	-	-	-	-	-	-	-	-	-	-	-	13> ; 11= ; 0<	
			24	31.7	5.1	65.0	83.5	62.3	100.0	9.9	-	-	-	-	59.4	27.2	97.5	20.1	-	-	-	-	-	-	-	-	-	12> ; 10= ; 2<	
			8	29.4	8.4	52.9	87.3	66.9	98.7	10.2	-	-	-	-	-	-	-	-	75.9	45.7	98.9	15.9	-	-	-	-	-	0> ; 8= ; 0<	
			31	28.7	5.1	65.0	84.0	62.3	100.0	9.3	-	-	-	-	-	-	-	-	-	-	-	-	60.9	27.2	98.9	19.3	16> ; 13= ; 2<		
	Assessment after around 40 DA-B	All EPPO climatic zones	11	39.9	20.3	69.8	89.3	73.0	100.0	8.5	65.1	38.8	97.2	15.7	-	-	-	-	-	-	-	-	-	-	-	-	-	7> ; 4= ; 0<	
			15	40.7	14.0	69.8	85.0	71.5	100.0	9.0	-	-	-	-	64.6	20.8	97.0	21.3	-	-	-	-	-	-	-	-	-	8> ; 5= ; 2<	
			3	49.3	20.3	69.8	92.1	87.6	97.1	3.9	-	-	-	-	-	-	-	-	87.3	75.8	97.6	9.0	-	-	-	-	-	0> ; 3= ; 0<	
			16	39.4	14.0	69.8	85.7	71.5	100.0	9.2	-	-	-	-	-	-	-	-	-	-	-	-	66.6	20.8	97.6	22.1	8> ; 6= ; 2<		
	Valid assessment after 2 applications (2 to 6 weeks after the application)	All EPPO climatic zones	35	30.6	5.1	72.5	82.6	60.3	100.0	9.6	55.5	22.8	98.6	16.6	-	-	-	-	-	-	-	-	-	-	-	-	-	20> ; 15= ; 0<	
			27	32.9	5.1	65.0	82.3	60.3	100.0	10.4	-	-	-	-	57.3	22.8	97.5	20.3	-	-	-	-	-	-	-	-	-	15> ; 10= ; 2<	
			13	31.7	8.4	57.5	83.6	60.3	98.7	10.9	-	-	-	-	-	-	-	-	-	70.2	45.7	98.9	16.5	-	-	-	-	-	3> ; 10= ; 0<
			42	31.7	5.1	72.5	82.3	60.3	100.0	9.4	-	-	-	-	-	-	-	-	-	-	-	-	58.9	22.8	98.9	18.7	23> ; 17= ; 2<		

#### Comments of zRMS on:

#### Efficacy of GF-3307 (S7K-3-3) for the control of *Cercospora beticola* in sugar beet (3.2.3.1)

Forty two efficacy trials present data to assess the efficacy of GF-3307 (S7K-3-3) in the control of *Cercospora beticola* (CERCBE) on sugar beet. No trials were performed on fodder beet. The trials were conducted in Maritime EPPO zone (24 trials carried out in Czech Republic (1), Germany (15), United Kingdom (1) and France (7)); North-East EPPO zone (8 trials carried out in Poland (6) and Lithuania (2)) and in South-East EPPO zone (10 trials carried out in Hungary (6) and Romania (4)) in the years 2020-2023.

#### Maritime EPPO zone (24 efficacy trials carried out in 2020, 2021, 2022, 2023)

The test item GF-3307 (S7K-3-3) was applied at maximum recommended dose rate of 1.5 L/ha in all 24 efficacy trials, at BBCH growth stage of the crop 39-49, which was consistent with the requested application timing. The water volume in the trials was 200-400 L/ha, which can be accepted to cover the amount of water requested in the GAP (150-300 L/ha). Lower dose rate of 1.2 L/ha was not claimed for MSs from Maritime EPPO zone. The tested fungicide was applied 2 to 4 times in the presented trials, while



the efficacy results have been properly presented after second application. GF-3307 (S7K-3-3) at target dose rate of 1.5 L/ha, was highly effective in the control of CERCBE on sugar beet with average efficacy results >80% achieved for various assessment timings (from 15 DAB to about 40 DAB). The efficacy of tested fungicide was statistically comparable or higher, than efficacy of reference products: Score, Amistar Gold or Spyrale.

**North-East EPPO zone (8 trials carried out North -East EPPO zone in 2020, 2021, 2023 + 16 supportive trials conducted in Germany (15) and Czech Republic (1) in 2020, 2021, 2022, 2023)**

The test item GF-3307 (S7K-3-3) was applied at maximum recommended dose rate of 1.5 L/ha in all 8 trials carried out in North-East EPPO zone and in all 16 supportive efficacy trials conducted in neighbouring countries: Germany and Czech Republic. The dose rate of 1.25 L/ha was tested in 5 trials carried out in North-East EPPO zone and in 8 trials carried out in Germany and Czech Republic. The recommend dose rate of 1.2 L/ha was tested in 3 supportive efficacy trials carried out in Gemrnay. As the difference between the recommend dose rate 1.2 L/ha and dose rate 1.25 L/ha is less than 5%, efficacy data achieved for GF-3307 (S7K-3-3) applied at 1.25 L/ha may support the recommended dose rate of 1.2 L/ha. The application timing/growth stage of the crop was BBCH 39-49 in the trials, which was consistent with the requested application timing. The water volume in the trials was 200-400 L/ha, which can be accepted to cover the amount of water requested in the GAP (150-300 L/ha). The tested fungicide was applied 2 to 4 times in the presented trials, while the efficacy results have been properly presented after second application. GF-3307 (S7K-3-3) at target dose rate of 1.5 L/ha, was highly effective in the control of CERCBE on sugar beet with average efficacy results mostly >80% achieved for various assessment timings (from 15 DAB to about 40 DAB). The efficacy of tested fungicide was statistically comparable or higher, than efficacy of reference products: Score, Amistar Gold or Spyrale. Moderate efficacy (>70%, but <80%) was achieved for GF-3307 (S7K-3-3) at 1.2/1.25 L/ha during most assessments. The efficacy of target fungicide applied at lower recommended dose rate 1.2/1.25 L/ha was comparable or higher, than efficacy of standards.

**South-East EPPO zone (10 trials carried out in 2020 and 2023)**

The test item GF-3307 (S7K-3-3) was applied at maximum recommended dose rate of 1.5 L/ha in all 10 efficacy trials, at BBCH growth stage of the crop 35-49, which covered the requested in GAP application timing (BBCH 39-49). The dose rate of 1.25 L/ha was tested in 6 trials. As the difference between the recommend dose rate 1.2 L/ha and dose rate 1.25 L/ha is less than 5%, efficacy data achieved for GF-3307 (S7K-3-3) applied at 1.25 L/ha may support the recommended dose rate of 1.2 L/ha. The water volume in the trials was 200-400 L/ha, which can be accepted to cover the amount of water requested in the GAP (150-300 L/ha). The tested fungicide was applied 2 to 4 times in the presented trials, while the efficacy results have been properly presented after second application. GF-3307 (S7K-3-3) at target dose rate of 1.5 L/ha, was highly effective in the control of CERCBE on sugar beet with average efficacy results >80% achieved for various assessment timings (from 15 DAB to about 40 DAB). The efficacy of tested fungicide was mostly statistically comparable or higher, than efficacy of reference products: Score, Amistar Gold or Spyrale. Moderate efficacy (68% - 77%) was achieved for GF-3307 (S7K-3-3) at 1.25 L/ha during assessment timings from 14 DAB to about 40 DAB. The efficacy of target fungicide applied at lower recommended dose rate 1.25 L/ha was comparable or higher, than efficacy of standards in the vast majority of trials.

### 3.2.3.2 Efficacy of GF-3307 (S7K-3-3) for the control of *Uromyces betae* in sugar beet

This chapter addresses the efficacy of GF-3307 (S7K-3-3) for the control of UROMBE on sugar beet when applied at the proposed label rate of 1.5 L/ha for Austria, Belgium, Czech Republic and The Netherlands and at the rate range of 1.2-1.5 L/ha for Poland, Hungary, Slovakia and Romania in comparison with SCORE at 0.4 L/ha, SPYRALE at 1.0 L/ha and AMISTAR GOLD at 1.0 L/ha.

**Table 3.2-43 Details on trial methodology - Efficacy - UROMBE**

<b>Guidelines</b>	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/1
<b>Experimental design</b>	Plot design	RCB
	Plot size	18-36 m <sup>2</sup>
	Number of replications	4
<b>Crop</b>	Trials per crop	Sugar beet (16)
	Varieties per crop	Annabella (2), BTS1140 (1), Clemens (1), Eldorana (2), Falster (1), Katjana (1), Lombok (1), Morgan (1), Nakskov (2), Nasser (1), Pasteur (1), Surf (1), Wren (1)
	Sowing period	EPPO Maritime: March to May
<b>Application</b>	Crop stage (BBCH) at application	BBCH 38-49
	Timing Pest stage at application	1 <sup>st</sup> application: At the appearance of the disease to control the foliar diseases with an interval. The application was timed to cover the main infection period to protect the crop from disease development.
	Number of applications	2 applications: 11 trials with an intervals of 20 to 25 days 3 application: 5 trials with an intervals of 19 to 53 days*
	Spray volumes	150-245 L/ha
<b>Assessment</b>	Assessment types	% infection (severity) % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting) Yield (7) and quality parameters (Sodium content (5 trials), Potassium content (5 trials), Amino nitrogen content (5 trials) and Sugar content in % (5 trials)).
	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) at each application and then 15-20 days, 30-40 days and 50-60 days after the last application.
<b>Other relevant information</b>	E.g. Natural / artificial inoculation...	Natural infection in 16 trials
	E.g. 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 UROMBE is an abundant disease.

\*In 5 trials, only valid assessment after the second application were considered for the evaluation (interval between the two first applications of 19 to 28 days).

#### Introduction

In total, data from 16 field trials are presented in this section to demonstrate the efficacy of GF-3307 (S7K-3-3), for the control of UROMBE in sugar beet. The efficacy trials representative for the Central registration zone were carried out from 2020 to 2022 in Germany (1) and The United-Kingdom (6) in the Maritime EPPO climatic zone where UROMBE can be a key problem in sugar beet and so this presents a worst case situation on sugar beet. To support the dataset, trials carried out from 2020 to 2023 in the Maritime EPPO climatic zone were added to the summary from France (3) and from Denmark (6 trials).

To support the label claims within the Central registration zone, GF-3307 (S7K-3-3) was tested at the rate of 1.5 L/ha (75+150 g a.s./ha) in accordance with the EPPO standard PP 1/1 'Foliar diseases on sugar beet'. The cross reference product included was SCORE applied at 0.4 L/ha (250 g/L Difenoconazole EC) as European standard reference dose in 16 trials. Moreover, other references at local registered rate with different mode of action (azoxystrobin, fenpropidin) were also used in efficacy trials and presented: AMISTAR GOLD (125+125 g/L azoxystrobin + difenoconazole) applied at 1.0 L/ha and SPYRALE at 1.0 L/ha (100+375 g/L difenoconazole + fenpropidin) are also presented as a common standard across countries.

All trials were carried out by Dow AgroSciences / Corteva Agriscience or officially recognised contract research organisations in accordance with the principles of Good Experimental Practice (Table 3.7-1). On the basis of the EPPO standard 1/241 '*Guidance on comparable climates*', the trials included in the BAD for this section have been grouped and summarized 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.

## Materials and Methods

### Testing facilities or organisations

All trials were carried out by Dow AgroSciences / Corteva Agriscience or officially recognised contract research organisations in accordance with the principles of Good Experimental Practice (Table 3.7-1). The trials used in this part are presented in and Table 3.2-7.

### Sites and experimental details

The 16 trials from the Maritime EPPO climatic zone were carried out in Germany (1) for the Central registration zone, in France (3) for the Southern registration zone and in the Denmark (6) for the Northern registration zone to complete the dataset on the efficacy. Six trials from the Maritime EPPO climatic zone was also carried out in the United-Kingdom.

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 UROMBE is an abundant disease. UROMBE is a disease which multiplies rapidly under warm climatic conditions such as found in the EPPO Maritime climatic zone.

An overview on the geographical distribution of the efficacy trials across the EU countries involved is presented Figure 3.2 - 3.

All 16 efficacy trials were carried out by officially recognized testing organizations according to GEP and followed the appropriate EPPO standards. The experimental design was a randomized complete block with 4 replicates and a plot size ranging between 18 m<sup>2</sup> and 36 m<sup>2</sup>. Application was conducted at crop stage BBCH 38-49 across trials and is therefore very close and within the application window (BBCH 39-49) of the respective label claim.

All treatments were applied at an application volume of 150-245 L/ha, using backpack and bicycle, equipped with conventional or low drift flat fan nozzles delivering water volume from 150 L/ha to 245 L/ha.

### Formulations applied and applications details

In all efficacy trials, the efficacy of GF-3307 (S7K-3-3) applied at 1.25 and 1.5 L/ha was compared the reference standards SCORE, SPYRALE and AMISTAR GOLD (Table 3.2-33). As the trials were undertaken over a number of years and in different development programs across Europe, the same standards may not be present in all trials.

Table 3.2-44 below presents the plant protection products and the rates used in this part.

**Table 3.2-44 Plant protection products used in efficacy trials**

Test product	Formulation type	Active substance	Rate product L/ha	Rate product g a.s./ha
GF-3307 (S7K-3-3)	SC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.0	50+100
			1.25	62.5+125
			1.5	75+150
SCORE	EC	250 g/L difenoconazole	0.4	100
SPYRALE	EC	100+375 g/L difenoconazole+fenpropidin	1.0	100+375
AMISTAR GOLD	SC	125+125 g/L azoxystrobin + difenoconazole	1.0	125+125

GF-3307 (S7K-3-3) at the rates tested and the reference products were applied between growth stage BBCH 38 and BBCH 49 when the crop conditions for UROMBE infections were favourable.

**Generally, to control foliar diseases on sugar beet crop, a treatment program with 2 to 4 applications is necessary. Even if two applications are requested in the GAP table, 2 to 4 applications of GF-3307 (S7K-3-3) were carried out in some efficacy trials to estimate the intrinsic efficacy of the product to control the diseases during the season. The efficacy after two applications**

**was always compared to the reference standards applied in the same condition.**

#### 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. 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.

In trials, assessments data were analysed using an analysis of variance (ANOVA) on untransformed. The probability of non-significance occurring between treatment means is calculated as the F probability value (p(F)).

The Student-Newman-Keuls and Tukey's test was applied to separate any treatment differences that may be highlighted by the ANOVA test. These differences are indicated by a letter. When one letter is in common, no significant difference is identified according to the test conducted at a 95% confidence level.

#### **Assessment methods**

All treatments of each trial are not systematically presented in this dossier, only relevant treatments are summarised. All data are available in individual trial reports in Document K.

As recommended in EPPO PP 1/1(4) guideline, the infestation of diseases at application date has been recorded. Table 3.2-45 reminds the infestation of diseases at application date, regarding the trials used for the compilations presented hereafter.

**Table 3.2-45: Infestation level at application dates - Efficacy trials - Sugar beet - UROMBE**

EPPO climatic zone	Trial	Country	Crop stage (BBCH)	Application	Disease severity (%)	Disease incidence (%)
Maritime	1 trial	France	39	A	0.6	-
			39	B	2.6	-
			39	C	14.7	-
Maritime	1 trial	France	39	A	0.0	-
			39	B	17.7	86.0
Maritime	1 trial	France	39	A	0.0	0.0
			49	B	14.0	-
Maritime	1 trial	Germany	39	A	0.0	-
			39	B	0.0	-
Maritime	1 trial	Denmark	39	A	-	8.0
			39	B	-	15.0
			39	C	-	25.0
Maritime	1 trial	Denmark	39	A	-	5.0
			39	B	-	10.0
			39	C	-	20.0
Maritime	1 trial	Denmark	39	A	1.0	-
			39	B	5.0	-
Maritime	1 trial	Denmark	39	A	2.0	-
			39	B	n.a	n.a
Maritime	1 trial	Denmark	39	A	0.04	-
			39	B	0.87	-
Maritime	1 trial	Denmark	39	A	0.0	-
			39	B	0.3	-
Maritime	1 trial	United Kingdom	39	A	Pustul visible	-
			49	B	6.8	61.9
			49	C	11.5	100.0
Maritime	1 trial	United Kingdom	39	A	Pustul visible	-
			49	B	Pustul visible	-
			49	C	11.5	91.3
Maritime	1 trial	United Kingdom	39	A	-	-
			39	B	1.5	-
Maritime	1 trial	United Kingdom	39	A	0.1	-
			39	B	14.4	-
Maritime	1 trial	United Kingdom	39	A	1.0	-
			39	B	1.5	-
Maritime	1 trial	United Kingdom	39	A	0.1	-
			39	B	21.1	-

The tabulated data presented in this section 3 only represent the means of efficacies of selected treatments, without raw data. However, the statistics presented in conjunction with these data are derived from all data points from all treatments within the assessment. Tables of data comprising all treatments means are presented in the individual trial report summaries.

In the detailed tables, data presented correspond to the mean efficacy against each disease for each product in each trial. Only the trials and assessments with a sufficient infestation level in the untreated plot (thresholds of 5% coverage of foliar by the disease) and where the level of efficacy of the reference standards were as expected are considered in this synthesis. In practice, assessments from 4.5% were selected in the available data package notably to enlarge the data package.

According to PP 1/1(4), the level of infection when the crop is treated twice should be recorded several times. Therefore, assessments are presented according to each application date:

- The first valid assessment around 2-3 weeks after the second application;
- The second valid assessment around 4-6 weeks after the second application;
- When available, the last valid assessment beyond 40 days after the second application.
- Finally, all available efficacy trials are merged with the last valid assessment after two applications between 2 to 6 weeks.

However, to simplify the justification of efficacy of GF-3307 (S7K-3-3) in sugar beet, only two key assessments (highlighted in light grey) are presented in conclusion and commented: the second valid assessment around 30-40 DA-B after the second application and the last valid assessment after two applications between 2 to 6 weeks (all efficacy trials merged).

## Results

Sixteen GEP trials were established in order to determine efficacy of GF-3307 (S7K-3-3) for the control of the UROMBE on sugar beet.

Seven trials from Central registration zone were carried out from 2020 to 2023 from Germany (1) and The United-Kingdom (6) for the Maritime EPPO climatic zone. To support the efficacy demonstration, an additional nine trials from the Maritime EPPO climatic zone were carried out from 2020 to 2022 in France (3) and Denmark (6).

The results are summarized by EPPO climatic zone (Maritime EPPO climatic zone) for the rate at 1.25 L/ha in Table 3.2-46 and for the rate at 1.5 L/ha in

Table 3.2-47.

Generally, to control foliar diseases on sugar beet crop, a treatment program with 2 and up to 4 applications is necessary. Even if only two applications are requested in the GAP table, more than two applications of GF-3307 (S7K-3-3) were carried out in some efficacy trials to estimate the intrinsic efficacy of the product to control the diseases during the season. The efficacy after two applications was always compared to the reference standards applied in the same condition. The results are summarized by EPPO climatic zone in the summary table. Only results compared to the references at its registered rate are discussed hereafter to justify the efficacy of GF-3307 (S7K-3-3) against UROMBE of sugar beet.

### Maritime EPPO climatic zone

#### Assessment around 30-40 DA-B:

Across 9 trials, GF-3307 (S7K-3-3) applied at 1.25 L/ha showed a good control of UROMBE superior to the reference standard SCORE at 0.4 L/ha (82.9% vs. 62.7% mean control in 9 trials) and a significant difference was noted in 3 out of 9 trials. In the other 6 trials, no significant difference was noted. Across 9 trials, GF-3307 (S7K-3-3) applied at 1.25 L/ha showed a good control of UROMBE equivalent to the reference standard AMISTAR GOLD at 1.0 L/ha (82.9% vs. 81.0% mean control in 9 trials) and a significant difference was noted in 1 out of 8 trials. In the other 8 trials, no significant difference was noted. Across 1 trial, GF-3307 (S7K-3-3) applied at 1.25 L/ha showed a good control of UROMBE lower to the reference standard SPYRALE at 1.0 L/ha (83.0% vs. 93.4% mean control in 1 trial) and no significant difference was noted in the trial.

Across 11 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of UROMBE superior to the reference standard SCORE at 0.4 L/ha (87.6% vs. 66.2% mean control in 11 trials) and a significant difference was noted in 5 out of 11 trials. In the other 6 trials, no significant difference was noted. Across 10 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of UROMBE superior to the reference standard AMISTAR GOLD at 1.0 L/ha (87.9% vs. 82.9% mean control in 10

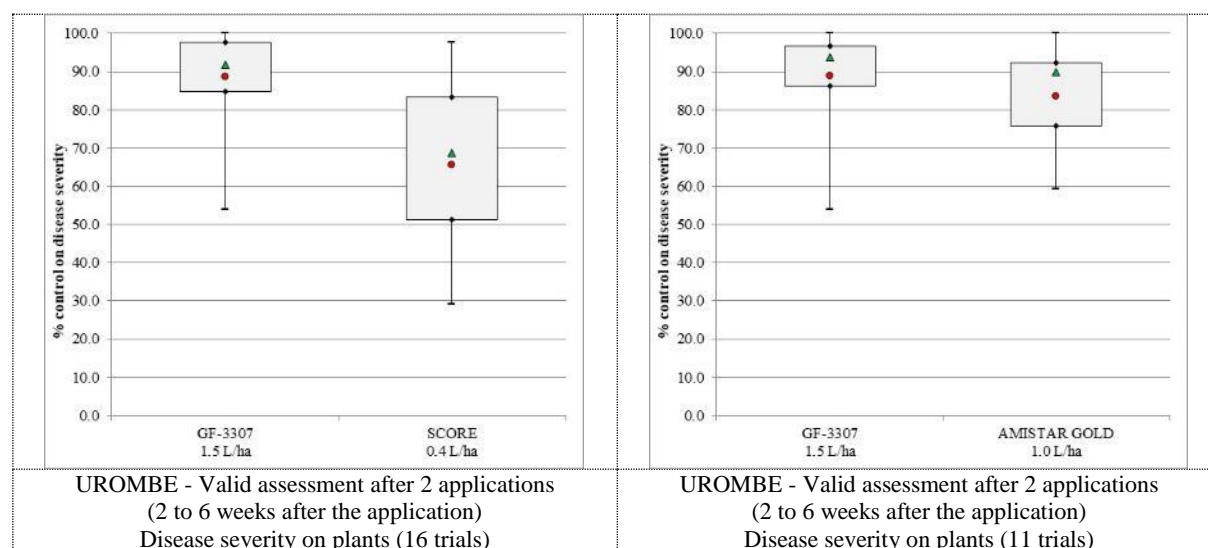
trials) and a significant difference was noted in 1 out of 10 trials. In the other 9 trials, no significant difference was noted. Across 2 trials, GF-3307 applied at 1.5 L/ha showed a good control of UROMBE slightly lower to the reference standard SPYRALE at 1.0 L/ha (87.5% vs. 93.6% mean control in 2 trials) and no significant difference was noted in all trials.

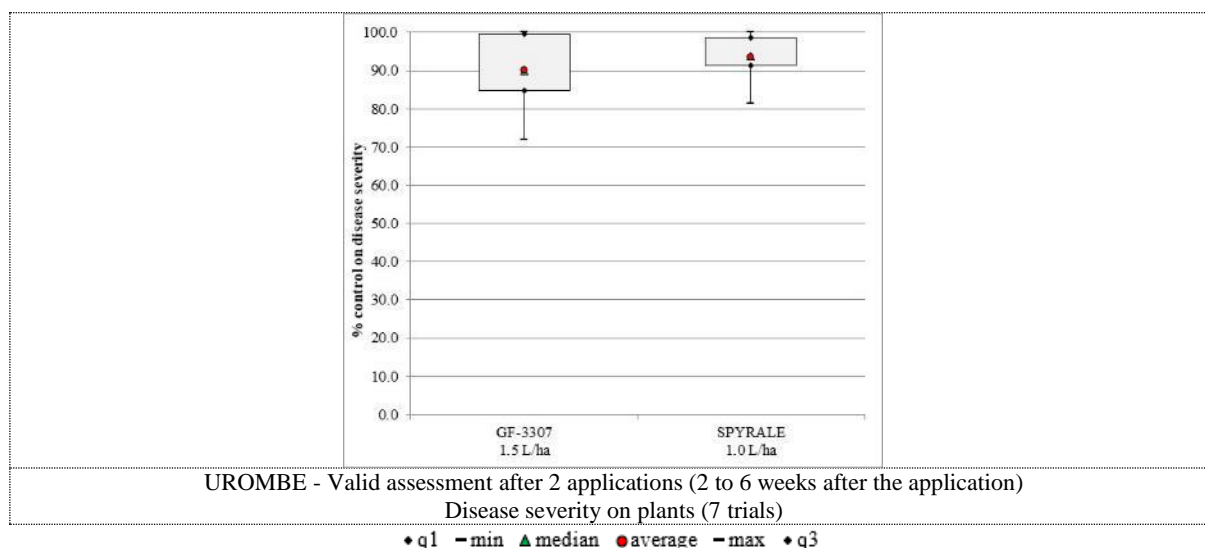
*Valid assessment after two applications (2 to 6 weeks after the application – all efficacy trials merged):*

Across 10 trials, GF-3307 (S7K-3-3) applied at 1.25 L/ha showed a good control of UROMBE superior to the reference standard SCORE at 0.4 L/ha (84.5% vs. 63.6% mean control in 10 trials) and a significant difference was noted in 4 out of 10 trials. In the other 6 trials, no significant difference was noted. Across 10 trials, GF-3307 (S7K-3-3) applied at 1.25 L/ha showed a good control of UROMBE equivalent to the reference standard AMISTAR GOLD at 1.0 L/ha (84.5% vs. 81.9% mean control in 10 trials) and a significant difference was noted in 1 out of 10 trials. In the other 9 trials, no significant difference was noted. Across 2 trials, GF-3307 applied at 1.25 L/ha showed a good control of UROMBE slightly lower to the reference standard SPYRALE at 1.0 L/ha (91.3% vs. 95.4% mean control in 2 trials) and no significant difference was noted in all trials.

Across 16 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of UROMBE superior to the reference standard SCORE at 0.4 L/ha (88.7% vs. 65.7% mean control in 16 trials) and a significant difference was noted in 7 out of 16 trials. In the other 9 trials, no significant difference was noted. Across 11 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of UROMBE superior to the reference standard AMISTAR GOLD at 1.0 L/ha (88.9% vs. 83.6% mean control in 11 trials) and a significant difference was noted in 1 out of 11 trials. In the other 10 trials, no significant difference was noted. Across 7 trials, GF-3307 applied at 1.5 L/ha showed a good control of UROMBE slightly lower to the reference standard SPYRALE at 1.0 L/ha (90.1% vs. 93.6% mean control in 7 trials) and no significant difference was noted in all trials.

The results of the efficacy trials presented in this section confirmed the good efficacy achieved by GF-3307 (S7K-3-3) on UROMBE. At the proposed label rate of 1.5 L/ha, across 16 trials, the efficacy of GF-3307 (S7K-3-3) reached around 89% of efficacy on plants. In the same way, GF-3307 (S7K-3-3) at 1.25 L/ha demonstrated a good level of control on UROMBE (around 85% in 10 trials). Moreover, the difference between the reference standard can be illustrated by box plot graphics (Figure 3.2-11).





**Figure 3.2-11 Efficacy of GF-3307 (S7K-3-3) at 1.5 L/ha - Sugar beet - UROMBE - Disease severity on plants - Box Plot graphics - Maritime EPPO climatic zone**

### Summary and conclusions - UROMBE

According to the results included in the BAD to evaluate the efficacy of GF-3307 (S7K-3-3) for the control of UROMBE, GF-3307 (S7K-3-3) applied at 1.5 L/ha provides the optimum overall control and is considered to be fully effective against UROMBE in sugar beet. Data are only presented from Maritime where the disease is major. Maritime EPPO climatic zone is considered to be a more challenging situation for UROMBE control. Finally, the data package is fully justified to demonstrate the efficacy of GF-3307 (S7K-3-3) at a maximum rate of 1.5 L/ha in the Central Registration zone.

As a result, according to the efficacy results in 16 valid trials, the proposed rate of 1.5 L/ha of GF-3307 (S7K-3-3) in Austria, Belgium, Czech Republic and The Netherlands should be considered the effective dose to deliver robust control of UROMBE in sugar beet in the Central registration zone. However, according to the local conditions and infestation pressure (e.g. under low disease pressure), it is possible to use the proposed lower dose of 1.2 L/ha. Indeed, under certain conditions, GF-3307 (S7K-3-3) at 1.25 L/ha demonstrated overall good control equivalent to the reference Amistar Gold. The conditions for use at a lower rate are detailed in the minimum effective rate part of this section. Thus, a rate range of 1.2-1.5 L/ha of GF-3307 (S7K-3-3) will be recommended in Poland, Hungary, Romania and Slovakia where CERCBE should be the driver disease and UROMBE is generally less prevalent.

18.06.2025/ concerns Poland

### Question from authority - BEAVA: UROMBE

No trials performed in the North-East EPPO zone were submitted for the evaluation. There is 1 trial from Germany available in the efficacy data package, which could be used to support registration in Poland provided trials performed in the North-East EPPO zone are submitted.

UROMBE, according to the methodology of integrated beet protection is a disease of minor importance in beet cultivation. According to national harmonization arrangements, in the case of disease entities of minor importance, there is a possibility to reduce the number of trials to a minimum of 3 especially in the case of products on the market containing a substance or mixture of substances. UROMBE is a new use for a registered mixture, and according to the evaluating unit, under article 33 registration for this application, a total of min. 6 efficacy trials performed in 2 growing seasons are required. The trials should be carried out in North-East EPPO zone (min. 2-3 trials) and in the countries neighbouring to Poland (Germany, Czech Republic, Slovakia).

Taking into account that UROMBE is included in the list of minor uses (Annex No. 2 of the Regulation of the Minister of Agriculture and Rural Development of September 18, 2023, amending the Regulation on minor uses of a plant protection product), it is possible to register this use under article 51 of

regulation 1107/2009, without the requirement to submit efficacy trials.

Reply:

The main disease of sugar beet in Poland is CERCBE, and other diseases occur very sporadically under the conditions of the Polish or north-eastern EPPO climate zone.

UROMBE is a disease of minor importance in beet cultivation in Poland.

Taking into account that UROMBE is included in the list of minor uses (Annex No. 2 of the Regulation of the Minister of Agriculture and Rural Development of September 18, 2023, amending the Regulation on minor uses of a plant protection product), the applicant requests to register GF-3307 on UROMBE under article 51 of regulation 1107/2009, without the requirement to submit efficacy trials.

**Comments of zRMS:**

For Poland, in the case of disease entities of minor importance, there is a possibility to reduce the number of trials to a minimum of 3 especially in the case of products on the market containing a substance or mixture of substances. Regarding minor importance of *Uromyces betae* in Poland and the fact, that GF-3307 (S7K-3-3) is currently authorized, minimum 3 trials would be considered sufficient for Poland, if carried out in the required locations (North-East EPPO zone (obligatory) and countries neighbouring to Poland (Germany, Czech Republic, Slovakia)).



**Table 3.2-46 Effectiveness of GF-3307 (S7K-3-3) at proposed maximum label dose rate of 1.25 L/ha against UROMBE in sugar beet. Results from 10 trials conducted in the EPPO Maritime climatic zone between 2020-2023.**

Part	Timing of assessment	EPPO climatic zone	No. of trials	Untreated			Percentage of efficacy (%)																No. of assessments significantly > , = , < GF-3307 (S7K-3-3) (1.25 L/ha) vs. Reference products
							GF-3307 (S7K-3-3) 1.25 L/ha				SCORE 0.4 L/ha				AMISTAR GOLD 1.0 L/ha				SPYRALE 1.0 L/ha				
							Fenpi. + Prothio. 62.5+125 g a.s./ha				Difenoconazole 100 g a.s./ha				Azoxyst. + Difeno. 125+125 g a.s./ha				Difeno. + Fenpro. 100+375 g a.s./ha				
				Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.				
Disease severity on plants	Assessment around 15-20 DA-B	Maritime	10	24.3	8.2	35.0	89.0	61.5	99.7	11.5	72.5	41.1	95.0	16.8	-	-	-	-	-	-	-	4> ; 6= ; 0<	
			10	24.3	8.2	35.0	89.0	61.5	99.7	11.5	-	-	-	-	85.5	68.3	99.1	9.4	-	-	-	-	1> ; 9= ; 0<
			2	21.5	20.2	22.7	95.6	91.5	99.6	4.0	-	-	-	-	-	-	-	-	93.0	88.6	97.4	4.4	0> ; 2= ; 0<
	Assessment around 30-40 DA-B	Maritime	9	40.4	18.6	59.1	82.9	43.9	95.5	15.0	62.7	35.6	86.1	18.7	-	-	-	-	-	-	-	3> ; 6= ; 0<	
			9	40.4	18.6	59.1	82.9	43.9	95.5	15.0	-	-	-	-	81.0	59.2	93.4	11.8	-	-	-	-	1> ; 8= ; 0<
			1	18.9	-	-	83.0	-	-	-	-	-	-	-	-	-	-	-	93.4	-	-	-	0> ; 1= ; 0<
	Assessment after around 40 DA-B	Maritime	2	46.5	41.1	51.9	67.6	61.3	73.8	6.3	79.5	77.3	81.7	2.2	-	-	-	-	-	-	-	0> ; 1= ; 1<	
			2	46.5	41.1	51.9	67.6	61.3	73.8	6.3	-	-	-	-	80.6	70.5	90.6	10.0	-	-	-	-	0> ; 2= ; 0<
	Valid assessment after 2 applications (2 to 6 weeks after the application)	Maritime	10	38.4	18.6	59.1	84.5	43.9	99.6	15.1	63.6	35.6	86.1	18.0	-	-	-	-	-	-	-	4> ; 6= ; 0<	
			10	38.4	18.6	59.1	84.5	43.9	99.6	15.1	-	-	-	-	81.9	59.2	93.4	11.5	-	-	-	-	1> ; 9= ; 0<
2			19.6	18.9	20.2	91.3	83.0	99.6	8.3	-	-	-	-	-	-	-	-	95.4	93.4	97.4	2.0	0> ; 2= ; 0<	

**Table 3.2-47 Effectiveness of GF-3307 (S7K-3-3) at proposed maximum label rate of 1.5 L/ha against UROMBE in sugar beet. Results from 16 trials conducted in the EPPO Maritime climatic zone between 2020-2023**

Part	Timing of assessment	EPPO climatic zone	No. of trials	Untreated				Percentage of efficacy (%)																No. of assessments significantly > , = , < GF-3307 (S7K-3-3) (1.5 L/ha) vs. Reference products
								GF-3307 (S7K-3-3) 1.5 L/ha				SCORE 0.4 L/ha				AMISTAR GOLD 1.0 L/ha				SPYRALE 1.0 L/ha				
								Fenpi. + Prothio. 75+150 g a.s./ha				Difenoconazole 100 g a.s./ha				Azoxystrobin + Difeno. 125+125 g a.s./ha				Difeno. + Fenpro. 100+375 g a.s./ha				
				Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.					
Disease severity on plants	Assessment around 15-20 DA-B	Maritime	15	23.3	8.2	38.8	92.0	71.9	100.0	9.3	71.5	29.2	96.1	20.0	-	-	-	-	-	-	-	-	5> ; 10= ; 0<	
			11	23.5	8.2	35.0	93.1	73.8	100.0	8.0	-	-	-	-	86.9	68.3	100.0	9.8	-	-	-	-	1> ; 10= ; 0<	
			6	22.3	9.5	38.8	91.4	71.9	100.0	10.4	-	-	-	-	-	-	-	-	92.8	81.3	100.0	6.9	0> ; 6= ; 0<	
	Assessment around 30-40 DA-B	Maritime	11	36.9	14.7	59.1	87.6	53.9	100.0	12.1	66.2	35.6	97.8	19.7	-	-	-	-	-	-	-	-	5> ; 6= ; 0<	
			10	39.1	18.6	59.1	87.9	53.9	100.0	12.7	-	-	-	-	82.9	59.2	100.0	12.6	-	-	-	-	1> ; 9= ; 0<	
			2	16.8	14.7	18.9	87.5	85.1	89.9	2.4	-	-	-	-	-	-	-	-	93.6	93.4	93.8	0.2	0> ; 2= ; 0<	
	Assessment after around 40 DA-B	Maritime	5	38.7	11.5	77.5	62.3	45.6	84.9	13.7	72.2	47.1	83.3	13.2	-	-	-	-	-	-	-	-	0> ; 3= ; 2<	
			3	56.8	41.1	77.5	68.8	52.5	84.9	13.2	-	-	-	-	82.5	70.5	90.6	8.6	-	-	-	-	0> ; 2= ; 1<	
			2	11.5	11.5	11.5	52.5	45.6	59.3	6.9	-	-	-	-	-	-	-	-	66.1	55.2	77.0	10.9	0> ; 1= ; 1<	
	Valid assessment after 2 applications (2 to 6 weeks after the application)	Maritime	16	32.3	9.5	59.1	88.7	53.9	100.0	12.0	65.7	29.2	97.8	20.3	-	-	-	-	-	-	-	-	7> ; 9= ; 0<	
			11	37.4	18.6	59.1	88.9	53.9	100.0	12.5	-	-	-	-	83.6	59.2	100.0	12.2	-	-	-	-	1> ; 10= ; 0<	
			7	20.7	9.5	38.8	90.1	71.9	100.0	9.8	-	-	-	-	-	-	-	-	93.6	81.3	100.0	6.2	0> ; 7= ; 0<	

**Comments of zRMS on:**

**Efficacy of GF-3307 (S7K-3-3) for the control of *Uromyces betae* in sugar beet (3.2.3.2)**

Sixteen efficacy trials present data to assess the efficacy of GF-3307 (S7K-3-3) in the control of *Uromyces betae* (UROMBE) on sugar beet. No trials were performed on fodder beet. The trials were conducted only in Maritime EPPO zone (16 trials carried out Germany (1), Denmark (6) and France (3) and United Kingdom (6)), in the years 2020-2023.

**Maritime EPPO zone (16 trials carried out in 2020, 2022, 2023)**

The test item GF-3307 (S7K-3-3) was applied at maximum recommended dose rate of 1.5 L/ha in all 16 efficacy trials, at BBCH growth stage of the crop 38-49, which was consistent with the requested application timing. The water volume in the trials was 150-245 L/ha, which can be accepted to cover the amount of water requested in the GAP (150-300 L/ha). Lower dose rate of 1.2 L/ha was not claimed for MSs from Maritime EPPO zone, however efficacy results for dose rate 1.25 L/ha (results from 10 trials) have been also presented for possible use by cMSs from other zones. As the difference between the dose rate 1.2 L/ha and dose rate 1.25 L/ha is less than 5%, efficacy data achieved for GF-3307 (S7K-3-3) applied at 1.25 L/ha may support the recommended for North-East EPPO zone (PL) and South-East EPPO zone (HU, RO, SK) dose rate of 1.2 L/ha. The tested fungicide was applied 2 to 3 times in the presented trials, while the efficacy results have been properly presented after second application. GF-3307 (S7K-3-3) at target dose rate of 1.5 L/ha, was highly effective in the control of UROMBE on sugar beet with average efficacy results >80% and >90% achieved for most assessment timings (from 15 DAB to about 40 DAB). The efficacy of tested fungicide was statistically comparable or higher, than efficacy of reference products: Score, Amistar Gold or Spyrle in the vast majority of trials. High efficacy (>80%, and >90%) was achieved for GF-3307 (S7K-3-3) at 1.25 L/ha during most assessments. The efficacy of target fungicide applied at lower dose rate of 1.25 L/ha was mostly comparable or higher, than efficacy of standards.

### 3.2.3.3 Efficacy of GF-3307 (S7K-3-3) for the control of *Erysiphe betae* in sugar beet

This chapter addresses the efficacy of GF-3307 (S7K-3-3) for the control of ERYSB on sugar beet when applied at the proposed label rate of 1.5 L/ha for Austria, Belgium, Czech Republic and The Netherlands and at the rate range of 1.2-1.5 L/ha for Poland, Hungary, Slovakia and Romania in comparison with SCORE at 0.4 L/ha, SPYRALE at 1.0 L/ha and AMISTAR GOLD at 1.0 L/ha.

**Table 3.2-48 Details on trial methodology - Efficacy - ERYSB**

<b>Guidelines</b>	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/1
<b>Experimental design</b>	Plot design	RCB
	Plot size	20-36 m <sup>2</sup>
	Number of replications	4
<b>Crop</b>	Trials per crop	Sugar beet (12)
	Varieties per crop	Callesia (2), Falster (1), Jamon (1), Libellule (1), Lombok (1), Lunella KWS (1), Pasteur (1), Racoon (2), Sixtus (1), Wren (1)
	Sowing period	Sugar beet: March - May
<b>Application</b>	Crop stage (BBCH) at application	Sugar beet: two applications between BBCH 39-49*
	Timing Pest stage at application	1 <sup>st</sup> application: At the appearance of the disease to control the foliar diseases with an interval. The application was timed to cover the main infection period to protect the crop from disease development.
	Number of applications	1 application: 1 trial* 2 applications: 6 trials with intervals of 16 to 22 days 3 applications: 4 trials with an intervals of 19 to 29 days** 4 applications: 1 trial with intervals of 20 to 21 days**
	Spray volumes	200-400 L/ha
<b>Assessment</b>	Assessment types	% infection (severity) % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting) Yield (4 trials) and quality parameters (Sodium content (4 trials), Potassium content (4 trials), Amino nitrogen content (4 trials) and Sugar content in % (4 trials)).
	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) at each application and then 15-20 days, 30-40 days and 50-60 days after the last application.
<b>Other relevant information</b>	E.g. Natural / artificial inoculation...	Natural infection of ERYSB in all trials
	E.g. 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 ERYSB is an abundant disease.

\* In one trial, only one late application was performed.

\*\* In five trials, only valid assessment after the second application were considered for the evaluation (interval between the two first applications of 19 to 23 days).

#### Introduction

In total, data from 12 field trials are presented in this section to demonstrate the efficacy of GF-3307 (S7K-3-3), for the control of ERYSB in sugar beet. The efficacy trials representative for the Central registration zone were carried out from 2020 to 2023 in Austria (1) and Germany (5). To support the dataset, trials carried out from 2020 to 2023 in the Northern and Southern registration zones were added to the summary from France (2), Denmark (3) and The United-Kingdom (1) in the Maritime EPPO climatic zone where ERYSB can be a key problem in sugar beet and so this presents a worst case situation on sugar beet.

To support the label claims within the Central registration zone, GF-3307 (S7K-3-3) was tested at the rate of 1.5 L/ha (75+150 g a.s./ha) in accordance with the EPPO standard PP 1/1 'Foliar diseases on sugar beet'. The cross reference product included was SCORE applied at 0.4 L/ha (250 g/L Difenoconazol EC) as European standard reference dose in 11 trials. Moreover, other references at local registered rate with different mode of action (azoxystrobin, fenpropidin) were also used in efficacy trials and presented: AMISTAR GOLD (125+125 g/L azoxystrobin + difenoconazole) applied at 1.0 L/ha and

SPYRALE at 1.0 L/ha (100+375 g/L difenoconazole + fenpropidin) are also presented as a common standard across countries.

All trials were carried out by Dow AgroSciences / Corteva Agriscience or officially recognised contract research organisations in accordance with the principles of Good Experimental Practice (Table 3.7-1). On the basis of the EPPO standard 1/241 '*Guidance on comparable climates*', the trials included in the BAD for this section have been grouped and summarized 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.

## Materials and Methods

### Testing facilities or organisations

All trials were carried out by Dow AgroSciences / Corteva Agriscience or officially recognised contract research organisations in accordance with the principles of Good Experimental Practice (Table 3.7-1).

The trials used in this part are presented in

Table 3.2-6 and Table 3.2-7.

### Sites and experimental details

The 12 trials from the Maritime EPPO climatic zone were carried out in Austria (1) and Germany (5) for the Central registration zone, in France (2), for the Southern registration zone and in the Denmark (3) for the Northern registration zone to complete the dataset on the efficacy. One trial from the Maritime EPPO climatic zone was also carried out in the United-Kingdom.

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 ERYSE is an abundant disease.

An overview on the geographical distribution of the efficacy trials across the EU countries involved is presented Figure 3.2 - 3.

All 12 efficacy trials were carried out by officially recognized testing organizations according to GEP and followed the appropriate EPPO standards. The experimental design was a randomized complete block with 4 replicates and a plot size ranging between 20 m<sup>2</sup> and 36 m<sup>2</sup>. Application was conducted at crop stage BBCH 39-49 across trials and is within the application window (BBCH 39-49) of the respective label claim.

All treatments were applied at an application volume of 200-400 L/ha, using backpack and bicycle, equipped with conventional or low drift flat fan nozzles.

### Formulations applied and applications details

In all efficacy trials, the efficacy of GF-3307 (S7K-3-3) applied at 1.5 L/ha was compared the reference standards SCORE, AMISTAR GOLD and SPYRALE (Table 3.2-49). As the trials were undertaken over a number of years and in different development programs across Europe, the same standards may not be present in all trials.

Table 3.2-49 below presents the plant protection products and the rates used in this part.

**Table 3.2-49 Plant protection products used in efficacy trials**

Test product	Formulation type	Active substance	Rate product L/ha	Rate product g a.s./ha
GF-3307 (S7K-3-3)	SC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.0	50+100
			1.2-1.25	60-62.5+120-125
			1.5	75+150
SCORE	EC	250 g/L difenoconazole	0.4	100
SPYRALE	EC	100+375 g/L difenoconazole+fenpropidin	1.0	100+375
AMISTAR GOLD	SC	125+125 g/L azoxystrobin + difenoconazole	1.0	125+125

GF-3307 (S7K-3-3) at the rates tested and the reference products were applied between growth stage BBCH 39 and BBCH 49 when the crop conditions for ERYSE infections were favourable.

**Generally, to control foliar diseases on sugar beet crop, a treatment program with 2 to 4 applications is necessary. Even if two applications are requested in the GAP table, until 4 applications of GF-3307 (S7K-3-3) were carried out in some efficacy trials to estimate the intrinsic efficacy of the product to control the diseases during the season. The efficacy after two applications**

was always compared to the reference standards applied in the same conditions. Moreover, as in 3 trials the disease can be assessed only after one application, the efficacy of GF-3307 (S7K-3-3) after the first application is also synthetised in the section.

#### 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. 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.

In trials, assessments data were analysed using an analysis of variance (ANOVA) on untransformed. The probability of non-significance occurring between treatment means is calculated as the F probability value (p(F)).

The Student-Newman-Keuls and Tukey's test was applied to separate any treatment differences that may be highlighted by the ANOVA test. These differences are indicated by a letter. When one letter is in common, no significant difference is identified according to the test conducted at a 95% confidence level.

#### Assessment methods

All treatments of each trial are not systematically presented in this dossier, only relevant treatments are summarised. All data are available in individual trial reports in Document K.

As recommended in EPPO PP 1/1(4) guideline, the infestation of diseases at application date has been recorded.

Table 3.2-50 reminds the infestation of diseases at application date, regarding the trials used for the compilations presented hereafter.

**Table 3.2-50: Infestation level at application dates - Efficacy trials - Sugar beet - ERYSB**

EPPO climatic zone	Trial	Country	Crop stage (BBCH)	Application	Disease severity (%)	Disease incidence (%)
Maritime	1 trial	Austria	39	A	3.0	36.0
Maritime	1 trial	Germany	39	A	0.0	-
			39	B	0.0	-
			39	C	16.8	-
Maritime	1 trial	Germany	39	A	0.0	-
			39	B	0.0	-
			39	C	11.0	-
Maritime	1 trial	Germany	39	A	0.0	-
			39	B	18.5	-
Maritime	1 trial	Germany	39	A	0.8	6.0
			49	B	-	75.0
Maritime	1 trial	Germany	39	A	-	6.0
			49	B	-	75.0
Maritime	1 trial	Denmark	39	A	-	20.0
			39	B	-	80.0
			39	C	-	100.0
Maritime	1 trial	Denmark	39	A	-	5.0
			39	B	-	60.0
			39	C	-	70.0
Maritime	1 trial	Denmark	39	A	0.0	-
			39	B	0.0	-
Maritime	1 trial	France	39	A	6.2	-
			39	B	14.5	-
Maritime	1 trial	France	39	A	0.0	-
			39	B	0.0	-
			39	C	14.3	-
			39	D	8.4	-
Maritime	1 trial	United Kingdom	39	A	1.7	-
			39	B	3.0	-

The tabulated data presented in this section 3 only represent the means of efficacies of selected treatments, without raw data. However, the statistics presented in conjunction with these data are derived

from all data points from all treatments within the assessment. Tables of data comprising all treatments means are presented in the individual trial report summaries.

In the detailed tables, data presented correspond to the mean efficacy against each disease for each product in each trial. Only the trials and assessments with a sufficient infestation level in the untreated plot (thresholds of 5% coverage of foliar by the disease) and where the level of efficacy of the reference standards were as expected are considered in this synthesis. In practice, assessments from 4.5% were selected in the available data package notably to enlarge the data package.

According to PP 1/1(4), the level of infection when the crop is treated twice should be recorded several times. Therefore, assessments are presented according to each application date:

- The last valid assessment after the first application application (as in 3 trials the disease can be assessed only after one application) to confirm the efficacy and complete the datapackage;
- The first valid assessment around 2-3 weeks after the second application;
- The second valid assessment around 4-6 weeks after the second application;
- When available, the last valid assessment beyond 40 days after the second application.
- Finally, all available efficacy trials are merged with the last valid assessment after one or two applications between 2 to 6 weeks as in 3 trials the disease can be assessed only after one application.

However, to simplify the justification of efficacy of GF-3307 (S7K-3-3) in sugar beet, only two key assessments (highlighted in light grey) are presented in conclusion and commented: the second valid assessment around 15-20 DA-B after the second application and the last valid assessment after one or two applications between 2 to 6 weeks (all efficacy trials merged).

## Results

Twelve GEP trials were established in order to determine efficacy of GF-3307 (S7K-3-3) for the control of the ERYSB on sugar beet.

Six trials representative for the Central registration zone were carried out from 2020 to 2023 in Austria (1) and Germany (5). To support the dataset, trials carried out from 2020 to 2023 in the Northern and Southern registration zones were added to the summary from France (2), Denmark (3) and The United-Kingdom (1) in the Maritime EPPO climatic zone

The results are summarized by EPPO climatic zone (Maritime EPPO climatic zone) for the rate at 1.25 L/ha in Table 3.2-51 and for the rate at 1.5 L/ha in Table 3.2-52.

Generally, to control foliar diseases on sugar beet crop, a treatment program with 2 to 4 applications is necessary. Even if two application is requested in the GAP table, more than two application of GF-3307 (S7K-3-3) were carried out in several efficacy trials to estimate the intrinsic efficacy of the product to control the diseases during the season. The efficacy after two applications was always compared to the reference standards applied in the same conditions.

Moreover, in order to complete the datapackage, the efficacy of GF-3307 (S7K-3-3) after the first application is also synthetised as only valid assessments after one application are available in three trials. The results are summarized by EPPO climatic zone in the summary table. Only results compared to the references at its registered rate are discussed hereafter to justify the efficacy of GF-3307 (S7K-3-3) against ERYSB of sugar beet.

### Maritime EPPO climatic zone

#### Assessment around 15-20 DA-B:

Across 3 trials, GF-3307 (S7K-3-3) applied at 1.2/1.25 L/ha showed a good control of ERYSB lower to the reference standard SCORE at 0.4 L/ha (76.0% vs. 88.3% mean control in 3 trials) and a significant difference was noted in 1 out of 3 trials. In 1 trial, SCORE was significantly superior to GF-3307 (S7K-3-3). In the other trial, no significant difference was noted. Across 2 trials, GF-3307 (S7K-3-3) applied at 1.25 L/ha showed a good control of ERYSB slightly lower to the reference standard AMISTAR GOLD at 1.0 L/ha (85.3% vs. 90.5% mean control in 2 trials) and no significant difference was noted all trials.

Across 8 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a very good control of ERYSB superior to the reference standard SCORE at 0.4 L/ha (92.0% vs. 82.6% mean control in 8 trials) and a significant difference was noted in 2 out of 8 trials. In the other 6 trials, no significant difference was noted. Across 2 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of ERYSB equivalent to the reference standard AMISTAR GOLD at 1.0 L/ha (88.8% vs. 90.5% mean control in 2 trials) and no

significant difference was noted all trials. Across 3 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a very good control of ERYSB E superior to the reference standard SPYRALE at 1.0 L/ha (96.5% vs. 90.5% mean control in 3 trials) and no significant difference was noted in all trials.

*Valid assessment after one or two applications (2 to 6 weeks after the application – all efficacy trials merged):*

Across 6 trials, GF-3307 (S7K-3-3) applied at 1.2/1.25 L/ha showed a good control of ERYSB E slightly lower to the reference standard SCORE at 0.4 L/ha (84.5% vs. 89.5% mean control in 6 trials) and a significant difference was noted in 1 out of 6 trials. In 1 trial, SCORE was significantly superior to GF-3307 (S7K-3-3). In the other 4 trials, no significant difference was noted. Across 5 trials, GF-3307 (S7K-3-3) applied at 1.25 L/ha showed a very good control of ERYSB E equivalent to the reference standard AMISTAR GOLD at 1.0 L/ha (92.5% vs. 95.7% mean control in 5 trials) and no significant difference was noted all trials.

Across 11 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a very good control of ERYSB E superior to the reference standard SCORE at 0.4 L/ha (92.2% vs. 84.4% mean control in 11 trials) and a significant difference was noted in 2 out of 11 trials. In the other 9 trials, no significant difference was noted. Across 6 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a very good control of ERYSB E equivalent to the reference standard AMISTAR GOLD at 1.0 L/ha (95.8% vs. 96.4% mean control in 6 trials) and no significant difference was noted all trials. Across 3 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a very good control of ERYSB E superior to the reference standard SPYRALE at 1.0 L/ha (97.1% vs. 91.2% mean control in 3 trials) and no significant difference was noted in all trials. Overall, GF-3307 (S7K-3-3) at 1.5 L/ha showed a good control in all trials (92.8% mean control in 12 trials).

**Summary and conclusions - ERYSB E**

According to the results included in the BAD to evaluate the efficacy of GF-3307 (S7K-3-3) for the control of ERYSB E, GF-3307 (S7K-3-3) applied at 1.5 L/ha provides the optimum overall control and is considered to be fully effective against ERYSB E in sugar beet. Data are only presented from Maritime where the disease can be major in some countries (like in Germany). Maritime EPPO climatic zone is considered to be a more challenging situation for ERYSB E control. The data package is fully justified to demonstrate the efficacy of GF-3307 (S7K-3-3) at a maximum rate of 1.5 L/ha in the Central registration zone.

As a result, according to the efficacy results in 12 valid trials, the proposed rate of 1.5 L/ha of GF-3307 (S7K-3-3) in Austria, Belgium, Czech Republic and The Netherlands should be considered the effective dose to deliver robust control of ERYSB E in sugar beet in the Central registration zone. However, according to the local conditions and infestation pressure (e.g. under low disease pressure), it is possible to use the lower dose of 1.2 L/ha. Indeed, under certain conditions, GF-3307 (S7K-3-3) at 1.2-1.25 L/ha demonstrated overall good control. The conditions for use at a lower rate are detailed in the minimum effective rate part of this section. Thus, a rate range of 1.2-1.5 L/ha of GF-3307 (S7K-3-3) will be recommended in Poland, Hungary, Romania and Slovakia where the disease is less prevalent and the driver disease is CERCBE.

18.06.2025/ concerns Poland

Question from authority - BEAVA: ERYSB E

No trials performed in the North-East EPPO zone were submitted for the evaluation. There are 5 trials from Germany available in the dossier, which could be used to support registration in Poland, provided that trials carried out in the North-East EPPO zone are submitted.

A total of 6-15 (optimally 10) efficacy trials conducted in 2 growing seasons should be submitted for the evaluation. The trials should be carried out in North-East EPPO zone (min. 2-3 trials) and in the countries neighbouring to Poland (Germany, Czech Republic, Slovakia).

Reply:

The main disease of sugar beet in Poland is CERCBE, and other diseases occur very sporadically under the conditions of the Polish or north-eastern EPPO climate zone. This was the reason why, despite many trials conducted in Poland, no successful results with ERYSB E were obtained that could be included in the BAD.

Disease pressure and control of ERYSB E are considered more difficult in the EPPO Maritime climate zone (like in Germany). Therefore, the applicant considers that the data package from 12 trials from the EPPO Maritime climate zone, including 5 trials from neighbouring Germany, showing that GF-3307 is fully effective against ERYSB E in sugar beet, provides strong evidence that GF-3307 will provide robust control of ERYSB E under Polish conditions and justifies the authorisation of GF-3307 against ERYSB E in Poland. It is proposed that a dose of 1.5 l/ha be considered as an effective dose in the EPPO Maritime climate zone. However, taking into account lower disease pressure and occurrence in Poland and the fact that under certain conditions GF-3307 at a rate 1.2-1.25 L/ha demonstrated overall good control the rate range of 1.2-1.5 L/ha of GF-3307 may be recommended for control of ERYSB E in Poland where the disease is less prevalent, and the driver disease is CERCBE.

**Comments of zRMS:**

Regarding Poland, according to the latest methodology of integrated beet production issued in 2023, *Erysiphe betae*, currently is pathogen of local importance. For Poland, in the case of disease entities of local importance, there is a possibility to reduce the number of trials to a minimum of 3 especially in the case of products on the market containing a substance or mixture of substances. Regarding local importance of *Erysiphe betae* in Poland and the fact, that GF-3307 (S7K-3-3) is currently authorized, minimum 3 trials would be considered sufficient for Poland, if carried out in the required locations (North-East EPPO zone (obligatory) and countries neighbouring to Poland (Germany, Czech Republic, Slovakia)).



**Table 3.2-51** Effectiveness of GF-3307 (S7K-3-3) at ~~proposed maximum label~~ dose rate of 1.2/1.25 L/ha L/ha against ERYSB in sugar beet. Results from 6 trials conducted in the EPPo Maritime climatic zone between 2020-2023.

[illegible]

**Table 3.2-52 Effectiveness of GF-3307 (S7K-3-3) at proposed maximum label rate of 1.5 L/ha against ERYSB E in sugar beet. Results from 12 trials conducted in the EPPO Maritime climatic zone between 2020-2023.**

Part	Timing of assessment	EPPO climatic zone	No. of trials	Percentage of efficacy (%)																								No. of assessments significantly > , = , < GF-3307 (S7K-3-3) (1.5 l/ha) vs. Reference products
				Untreated			GF-3307 (S7K-3-3) 1.5 L/ha				SCORE 0.4 L/ha				AMISTAR GOLD 1.0 L/ha				SPYRALE 1.0 L/ha				All reference products					
							Fenpi. + Prothio. 75+150 g a.s./ha				Difenoconazole 100 g a.s./ha				Azoxy. + Difeno. 125+125 g a.s./ha				Difeno. + Fenpro. 100+375 g a.s./ha									
				Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.		
Disease severity on plants	Last valid assessment after application A	Maritime	5	43.1	14.5	97.5	86.8	70.4	100.0	13.3	63.9	17.8	100.0	31.6	-	-	-	-	-	-	-	-	-	-	-	-	1> ; 4= ; 0<	
			3	27.2	18.0	44.1	99.8	99.5	100.0	0.3	-	-	-	-	99.1	97.4	100.0	1.3	-	-	-	-	-	-	-	-	0> ; 3= ; 0<	
			3	51.1	14.5	97.5	78.2	70.4	93.1	10.5	-	-	-	-	-	-	-	-	76.7	69.2	88.1	8.2	-	-	-	-	0> ; 3= ; 0<	
			6	39.1	14.5	97.5	89.0	70.4	100.0	13.1	-	-	-	-	-	-	-	-	-	-	-	-	87.9	69.2	100	12.7	0> ; 6= ; 0<	
	Assessment around 15-20 DA-B	Maritime	8	32.8	4.7	90.0	92.0	75.0	100.0	9.3	82.6	62.5	100.0	12.4	-	-	-	-	-	-	-	-	-	-	-	-	2> ; 6= ; 0<	
			2	13.7	4.7	22.8	88.8	77.6	100.0	11.2	-	-	-	-	90.5	80.9	100.0	9.6	-	-	-	-	-	-	-	-	0> ; 2= ; 0<	
	Assessment around 30-40 DA-B	Maritime	3	69.8	31.9	90.0	96.5	95.3	97.4	0.9	-	-	-	-	-	-	-	-	90.5	82.4	97.5	6.2	-	-	-	-	0> ; 3= ; 0<	
			1	18.1	11.0	26.5	90.6	72.5	100.0	12.8	86.8	77.5	92.8	6.7	-	-	-	-	-	-	-	-	-	-	-	-	0> ; 3= ; 0<	
	Assessment after around 40 DA-B	Maritime	1	60.0	-	-	97.9	-	-	-	100.0	-	-	-	-	100.0	-	-	-	-	-	-	-	-	-	-	-	0> ; 1= ; 0<
	Valid assessment after 1 or 2 applications	Maritime	11	36.0	4.7	90.0	92.2	72.5	100.0	10.6	84.4	62.5	100.0	11.7	-	-	-	-	-	-	-	-	-	-	-	-	-	2> ; 9= ; 0<
			6	28.2	4.7	60.0	95.8	77.6	100.0	8.2	-	-	-	-	96.4	80.9	100.0	7.0	-	-	-	-	-	-	-	-	-	0> ; 6= ; 0<
			3	68.0	26.5	90.0	97.1	95.3	99.3	1.7	-	-	-	-	-	-	-	-	91.2	82.4	99.4	7.0	-	-	-	-	0> ; 3= ; 0<	
			12	34.6	4.7	90.0	92.8	72.5	100.0	10.4	-	-	-	-	-	-	-	-	-	-	-	-	90.9	71.4	100	9.9	0> ; 12= ; 0<	

#### Comments of zRMS on:

#### Efficacy of GF-3307 (S7K-3-3 ) for the control of *Erysiphe betae* in sugar beet (3.2.3.3)

The efficacy of GF-3307 (S7K-3-3) in the control of *Erysiphe betae* (ERYSB E) on sugar beet was tested in 12 efficacy trials carried out only in Maritime EPPO zone. No trials were performed on fodder beet. The trials were conducted in Austria (1), Germany (5), Denmark (3) and France (2) and United Kingdom (1), in the years 2020-2023.

#### Maritime EPPO zone (12 trials carried out in 2020, 2021, 2022, 2023)

Twelve trials present efficacy data for the test item GF-3307 (S7K-3-3) applied at maximum recommended dose rate of 1.5 L/ha, at BBCH growth stage of the crop 39-49, which was consistent with the requested application timing. The water volume in the trials was 200-400 L/ha, which can be accepted to cover the amount of water requested in the GAP (150-300 L/ha). Lower dose rate of 1.2 L/ha was not claimed for MSs from Maritime EPPO zone, however efficacy results for dose rate 1.2 L/ha (results from 1 trial) and for similar dose rate 1.25 L/ha (results from 5 trials) have been also presented for possible use by cMSs from other zones. As the difference between the dose rate 1.2 L/ha and dose rate 1.25 L/ha is less than 5%, efficacy data achieved for GF-3307 (S7K-3-3) applied at 1.25 L/ha may support the recommended for North-East EPPO zone (PL) and South-East EPPO zone (HU, RO, SK) dose rate of 1.2 L/ha. The tested fungicide was applied 1 to 4 times in the presented trials, while the efficacy results

have been properly presented after second application (results from 9 trials) and also after 1 application (results from 6 trials). GF-3307 (S7K-3-3) at target dose rate of 1.5 L/ha, was highly effective in the control of ERYSB on sugar beet with average efficacy results >80% and >90% achieved for various assessment timings (from 15 DAB to about 40 DAB). The efficacy of tested fungicide was statistically comparable or higher, than efficacy of reference products: Score, Amistar Gold or Spyrale. High efficacy (>80%, and >90%) was achieved for GF-3307 (S7K-3-3) at 1/2/1.25 L/ha during most assessments. The efficacy of target fungicide applied at lower dose rate of 1.2/1.25 L/ha was mostly comparable or higher, than efficacy of standards.

### 3.2.3.4 Efficacy of GF-3307 (S7K-3-3) for the control of *Ramularia beticola* in sugar beet

This chapter addresses the efficacy of GF-3307 (S7K-3-3) for the control of RAMUBE on sugar beet when applied at the proposed label rate of 1.5 L/ha for Austria, Belgium, Czech Republic and The Netherlands and at the rate range of 1.2-1.5 L/ha for Poland, Hungary, Slovakia and Romania in comparison with SCORE at 0.4 L/ha, SPYRALE at 1.0 L/ha and AMISTAR GOLD at 1.0 L/ha.

**Table 3.2-53 Details on trial methodology - Efficacy - RAMUBE**

<b>Guidelines</b>	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/1
<b>Experimental design</b>	Plot design	RCB
	Plot size	21-30 m <sup>2</sup>
	Number of replications	4
<b>Crop</b>	Trials per crop	Sugar beet (9)
	Varieties per crop	Annarosa (1), Eldorana (2), Lunella (1), Marley (1), Marynia RH (1), Nasser (1), Racoon (2)
	Sowing period	Sugar beet: March - April
<b>Application</b>	Crop stage (BBCH) at application	Sugar beet: two applications between BBCH 38-49*
	Timing Pest stage at application	1 <sup>st</sup> application: At the appearance of the disease to control the foliar diseases with an interval. The application was timed to cover the main infection period to protect the crop from disease development.
	Number of applications	2 applications: 3 trials with intervals of 21-24 days 3 applications: 5 trials with an intervals of 23 to 53 days* 4 applications: 1 trial with intervals of 17 to 21 days*
	Spray volumes	200-300 L/ha
<b>Assessment</b>	Assessment types	% infection (severity) % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting) Yield (3 trials) and quality parameters (Sodium content (1 trial), Potassium content (1 trial), Amino nitrogen content (1 trial) and Sugar content in % (1 trial)).
	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) at each application and then 15-20 days, 30-40 days and 50-60 days after the last application.
<b>Other relevant information</b>	E.g. Natural / artificial inoculation...	Natural infection in 9 trials
	E.g. 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 RAMUBE is an abundant disease.

\*In six trials, only valid assessment after the second application were considered for the evaluation (interval between the two first applications of 17 to 28 days).

#### Introduction

In total, data from 9 field trials are presented in this section to demonstrate the efficacy of GF-3307 (S7K-3-3), for the control of RAMUBE in sugar beet. The efficacy trials representative for the Central registration zone were carried out from 2020 to 2023 in Germany (5) and Poland (1). To support the dataset, trial carried out in 2022 in the Northern registration zone was added to the summary from Denmark (1) and also two trials from The United-Kingdom in the Maritime EPPO climatic zone where RAMUBE can be a key problem in sugar beet.

To support the label claims within the Central registration zone, GF-3307 (S7K-3-3) was tested at the rate of 1.5 L/ha (75+150 g a.s./ha) in accordance with the EPPO standard PP 1/1 'Foliar diseases on sugar beet'. The cross reference product included was SCORE applied at 0.4 L/ha (250 g/L Difenconazole EC) as European standard reference dose in 9 trials. Moreover, other references at local registered rate with different mode of action (azoxystrobin, fenpropidin) were also used in efficacy trials and presented: AMISTAR GOLD (125+125 g/L azoxystrobin + difenoconazole) applied at 1.0 L/ha and SPYRALE at 1.0 L/ha (100+375 g/L difenoconazole + fenpropidin) are also presented as a common

standard across countries.

All trials were carried out by Dow AgroSciences / Corteva Agriscience or officially recognised contract research organisations in accordance with the principles of Good Experimental Practice (Table 3.7-1). On the basis of the EPPO standard 1/241 '*Guidance on comparable climates*', the trials included in the BAD for this section have been grouped and summarized 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.

## Materials and Methods

### Testing facilities or organisations

All trials were carried out by Dow AgroSciences / Corteva Agriscience or officially recognised contract research organisations in accordance with the principles of Good Experimental Practice (Table 3.7-1).

The trials used in this part are presented in

Table 3.2-6 and Table 3.2-7.

### Sites and experimental details

The 8 trials from the Maritime EPPO climatic zone were carried out in Germany (5) for the Central registration zone, in the Denmark (1) for the Northern registration zone and in The United-Kingdom (2) to complete the dataset on the efficacy. One trial from the Northeast EPPO climatic zone was also carried out in Poland (1) for the Central registration zone.

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 RAMUBE is an abundant disease.

An overview on the geographical distribution of the efficacy trials across the EU countries involved is presented Figure 3.2 - 3.

All 9 efficacy trials were carried out by officially recognized testing organizations according to GEP and followed the appropriate EPPO standards. The experimental design was a randomized complete block with 4 replicates and a plot size ranging between 21 m<sup>2</sup> and 30 m<sup>2</sup>. Application was conducted at crop stage BBCH 38-49 across trials and is within or very close to the application window (BBCH 39-49) of the respective label claim.

All treatments were applied at an application volume of 200-300 L/ha, using backpack and bicycle, equipped with conventional or low drift flat fan nozzles.

### Formulations applied and applications details

In all efficacy trials, the efficacy of GF-3307 (S7K-3-3) applied at 1.5 L/ha was compared the reference standards SCORE, AMISTAR GOLD and SPYRALE (Table 3.2-54). As the trials were undertaken over a number of years and in different development programs across Europe, the same standards may not be present in all trials.

Table 3.2-54 below presents the plant protection products and the rates used in this part.

**Table 3.2-54 Plant protection products used in efficacy trials**

Test product	Formulation type	Active substance	Rate product L/ha	Rate product g a.s./ha
GF-3307 (S7K-3-3)	SC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.0	50+100
			1.2-1.25	60-62.5+120-125
			1.5	75+150
SCORE	EC	250 g/L difenoconazole	0.4	100
SPYRALE	EC	100+375 g/L difenoconazole+fenpropidin	1.0	100+375
AMISTAR GOLD	SC	125+125 g/L azoxystrobin + difenoconazole	1.0	125+125

GF-3307 (S7K-3-3) at the rates tested and the reference products were applied between growth stage BBCH 38 and BBCH 49 when the crop conditions for RAMUBE infections were favourable.

**Generally, to control foliar diseases on sugar beet crop, a treatment program with 2 to 4 applications is necessary. Even if two applications are requested in the GAP table, 2 to 4 applications of GF-3307 (S7K-3-3) were carried out in some efficacy trials to estimate the intrinsic efficacy of the product to control the diseases during the season. The efficacy after two applications was always compared to the reference standards applied in the same condition.**

### 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. 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.

In trials, assessments data were analysed using an analysis of variance (ANOVA) on untransformed. The probability of non-significance occurring between treatment means is calculated as the F probability value (p(F)).

The Student-Newman-Keuls and Tukey's test was applied to separate any treatment differences that may be highlighted by the ANOVA test. These differences are indicated by a letter. When one letter is in common, no significant difference is identified according to the test conducted at a 95% confidence level.

### Assessment methods

All treatments of each trial are not systematically presented in this dossier, only relevant treatments are summarised. All data are available in individual trial reports in Document K.

As recommended in EPPO PP 1/1(4) guideline, the infestation of diseases at application date has been recorded.

Table 3.2-55 reminds the infestation of diseases at application date, regarding the trials used for the compilations presented hereafter.

**Table 3.2-55: Infestation level at application dates - Efficacy trials - Sugar beet - RAMUBE**

EPPO climatic zone	Trial	Country	Crop stage (BBCH)	Application	Disease severity (%)	Disease incidence (%)
Maritime	1 trial	Germany	39	A	0	-
			39	B	0	-
			39	C	11	-
Maritime	1 trial	Germany	39	A	0	-
			39	B	0	-
			39	C	10	-
Maritime	1 trial	Germany	39	A	2.3	-
			39	B	10.3	-
			39	C	15.3	-
			39	D	19.5	-
Maritime	1 trial	Denmark	39	A	0	-
			39	B	0	-
Maritime	1 trial	United Kingdom	39	A	n.a (Disease lesion visible)	n.a
			49	B	6.5	60.6
			49	C	n.a (Disease lesion visible)	n.a
Maritime	1 trial	United Kingdom	39	A	n.a (Disease lesion visible)	n.a
			49	B	n.a (Disease lesion visible)	n.a
			49	C	n.a (Disease lesion visible)	n.a
Maritime	1 trial	Germany	39	A	0	-
			39	B	0	-
			39	C	5	-
Maritime	1 trial	Germany	39	A	0	-
			39	B	0	-
Northeast	1 trial	Poland	39	A	Primary	-
			39	B	8.8	-

The tabulated data presented in this section 3 only represent the means of efficacies of selected treatments, without raw data. However, the statistics presented in conjunction with these data are derived from all data points from all treatments within the assessment. Tables of data comprising all treatments means are presented in the individual trial report summaries.

In the detailed tables, data presented correspond to the mean efficacy against each disease for each product in each trial. Only the trials and assessments with a sufficient infestation level in the untreated plot (thresholds of 5% coverage of foliar by the disease) and where the level of efficacy of the reference standards were as expected are considered in this synthesis. In practice, assessments from 4.5% were selected in the available data package notably to enlarge the data package.

According to PP 1/1(4), the level of infection when the crop is treated twice should be recorded several times. Therefore, assessments are presented according to each application date:

- The first valid assessment around 2-3 weeks after the second application;
- The second valid assessment around 4-6 weeks after the second application;
- When available, the last valid assessment beyond 40 days after the second application.
- Finally, all available efficacy trials are merged with the last valid assessment after two applications between 2 to 6 weeks.

However, to simplify the justification of efficacy of GF-3307 (S7K-3-3) in sugar beet, only two key assessments (highlighted in light grey) are presented in conclusion and commented: the second valid assessment around 30-40 DA-B after the second application and the last valid assessment after two applications between 2 to 6 weeks (all efficacy trials merged).

## Results

Nine GEP trials were established in order to determine efficacy of GF-3307 (S7K-3-3) for the control of the RAMUBE on sugar beet.

The efficacy trials representative for the Central registration zone were carried out from 2020 to 2023 in Germany (5) and Poland (1). To support the dataset, trial carried out in 2022 in the Northern registration zone was added to the summary from Denmark (1) and also two trials from The United-Kingdom in the Maritime EPPO climatic zone where RAMUBE can be a key problem in sugar beet.

The results are summarized by EPPO climatic zone for the rate at 1.2/1.25 L/ha in Table 3.2-56 (Maritime EPPO climatic zone), Table 3.2-58 (Northeast EPPO climatic zone) and Table 3.2-60 (All EPPO climatic zones) and for the rate at 1.5 L/ha in Table 3.2-57 (Maritime EPPO climatic zone), Table 3.2-59 (Northeast EPPO climatic zone) and Table 3.2-61 (All EPPO climatic zones). Generally, to control foliar diseases on sugar beet crop, a treatment program with 2 and up to 4 applications is necessary. Even if only two applications are requested in the GAP table, more than two applications of GF-3307 (S7K-3-3) were carried out in some efficacy trials to estimate the intrinsic efficacy of the product to control the diseases during the season. The efficacy after two applications was always compared to the reference standards applied in the same condition. The results are summarized by EPPO climatic zone in the summary tables. Only results compared to the references at its registered rate are discussed hereafter to justify the efficacy of GF-3307 (S7K-3-3) against RAMUBE of sugar beet.

### Maritime EPPO climatic zone

#### Assessment around 30-40 DA-B:

Across 4 trials, GF-3307 (S7K-3-3) applied at 1.2/1.25 L/ha showed a moderate control of RAMUBE lower to the reference standard SCORE at 0.4 L/ha (52.6% vs. 63.8% mean control in 4 trials) and no significant difference was noted in 3 out of 4 trials. In the other trial, SCORE was significantly superior to GF-3307 (S7K-3-3).

Across 5 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a moderate control of RAMUBE equivalent to the reference standard SCORE at 0.4 L/ha (66.9% vs. 64.0% mean control in 5 trials) and no significant difference was noted in all trials. For information, across 1 trial, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a moderate control of RAMUBE lower to the reference standard AMISTAR GOLD at 1.0 L/ha (61.2% vs. 81.2% mean control in 1 trial) and no significant difference was noted.

#### Valid assessment after two applications (2 to 7 weeks after the application – all efficacy trials merged):

Across 8 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a moderate control of RAMUBE superior to the reference standard SCORE at 0.4 L/ha (66.3% vs. 63.4% mean control in 8 trials) and no significant difference was noted in all trials. For information, across 1 trial, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a moderate control of RAMUBE lower to the reference standard AMISTAR GOLD at 1.0 L/ha (61.2% vs. 81.2% mean control in 1 trial) and no significant difference was noted. Across 2 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a good control of RAMUBE equivalent to the reference standard SPYRALE at 1.0 L/ha (73.1% vs. 76.2% mean control in 2 trials) and no significant

difference was noted in all trials.

### **Northeast EPPO climatic zone**

#### Assessment around 30-40 DA-B:

For information, across 1 trial, GF-3307 (S7K-3-3) applied at 1.25 L/ha showed a moderate control of RAMUBE superior to the reference standard SCORE at 0.4 L/ha (61.3% vs. 47.5% mean control), to the reference standard AMISTAR GOLD at 1.0 L/ha (61.3% vs. 35.0% mean control) and to the reference standard SPYRALE at 1.0 L/ha (61.3% vs. 57.5% mean control). No significant difference was noted in the trial.

For information, across 1 trial, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a moderate control of RAMUBE superior to the reference standard SCORE at 0.4 L/ha (66.3% vs. 47.5% mean control), to the reference standard AMISTAR GOLD at 1.0 L/ha (66.3% vs. 35.0% mean control) and to the reference standard SPYRALE at 1.0 L/ha (66.3% vs. 57.5% mean control). No significant difference was noted in the trial.

### **Northeast and PL border countries (PL-DE)**

#### Assessment around 30-40 DA-B:

If the border countries are considered with Poland, across 4 trials, GF-3307 (S7K-3-3) applied at 1.2/1.25 L/ha showed a moderate control of RAMUBE slightly lower to the reference standard SCORE at 0.4 L/ha (54.3% vs. 57.1% mean control in 4 trials) and no significant difference was noted in 3 out of 4 trials. In the other trial, SCORE was significantly superior to GF-3307 (S7K-3-3).

If the border countries are considered with Poland, across 5 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a moderate control of RAMUBE superior to the reference standard SCORE at 0.4 L/ha (67.9% vs. 58.7% mean control in 5 trials) and no significant difference was noted in all trials.

#### Valid assessment after two applications (2 to 6 weeks after the application – all efficacy trials merged):

If the border countries are considered with Poland, across 6 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a moderate control of RAMUBE superior to the reference standard SCORE at 0.4 L/ha (64.9% vs. 55.9% mean control in 6 trials) and no significant difference was noted in all trials.

### **All EPPO climatic zones**

#### Assessment around 30-40 DA-B:

Across 5 trials, GF-3307 (S7K-3-3) applied at 1.2/1.25 L/ha showed a moderate control of RAMUBE lower to the reference standard SCORE at 0.4 L/ha (54.3% vs. 60.5% mean control in 5 trials) and no significant difference was noted in 4 out of 5 trials. In the other trial, SCORE was significantly superior to GF-3307 (S7K-3-3). Across 2 trials, GF-3307 (S7K-3-3) applied at 1.25 L/ha showed a moderate control of RAMUBE equivalent to the reference standard AMISTAR GOLD at 1.0 L/ha (57.9% vs. 58.1% mean control in 2 trials) and no significant difference was noted in all trials. Across 1 trial, GF-3307 (S7K-3-3) applied at 1.25 L/ha showed a moderate control of RAMUBE superior to the reference standard SPYRALE at 1.0 L/ha (61.3% vs. 57.5% mean control in 1 trial) and no significant difference was noted in the trial.

Across 6 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a moderate control of RAMUBE superior to the reference standard SCORE at 0.4 L/ha (66.8% vs. 61.3% mean control in 6 trials) and no significant difference was noted in all trials. Across 2 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a moderate control of RAMUBE superior to the reference standard AMISTAR GOLD at 1.0 L/ha (63.7% vs. 58.1% mean control in 2 trials) and no significant difference was noted in all trials. Across 1 trial, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a moderate control of RAMUBE superior to the reference standard SPYRALE at 1.0 L/ha (66.3% vs. 57.5% mean control in 1 trial) and no significant difference was noted in the trial.

#### Valid assessment after two applications (2 to 6 weeks after the application – all efficacy trials merged):

Across 9 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a moderate control of RAMUBE superior to the reference standard SCORE at 0.4 L/ha (66.3% vs. 61.6% mean control in 9 trials) and no significant difference was noted in all trials. Across 2 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a moderate control of RAMUBE superior to the reference standard AMISTAR GOLD at 1.0 L/ha (63.7% vs. 58.1% mean control in 2 trials) and no significant difference was noted in all trials.



Across 3 trials, GF-3307 (S7K-3-3) applied at 1.5 L/ha showed a moderate control of RAMUBE equivalent to the reference standard SPYRALE at 1.0 L/ha (70.8% vs. 70.0% mean control in 3 trials) and no significant difference was noted in all trials.

### **Summary and conclusions - RAMUBE**

According to the results included in the BAD to evaluate the efficacy of GF-3307 (S7K-3-3) for the control of RAMUBE, GF-3307 (S7K-3-3) applied at 1.5 L/ha provides the optimum overall control and is considered to be fully effective against RAMUBE in sugar beet. Data are only presented from Maritime where the disease can be major in some countries (like in Germany). Maritime EPPO climatic zone is considered to be a more challenging situation for RAMUBE control. The data package is fully justified to demonstrate the efficacy of GF-3307 (S7K-3-3) at a maximum rate of 1.5 L/ha in the Central registration zone.

As a result, according to the efficacy results in 9 valid trials, the proposed rate of 1.5 L/ha of GF-3307 (S7K-3-3) in Austria, Belgium, Czech Republic and The Netherlands should be considered the effective dose to deliver robust control of RAMUBE in sugar beet in the Central registration zone. However, according to the local conditions and infestation pressure (e.g. under low disease pressure), it is possible to use the lower dose of 1.2 L/ha. Indeed, under certain conditions, GF-3307 (S7K-3-3) at 1.2-1.25 L/ha demonstrated overall good control. The conditions for use at a lower rate are detailed in the minimum effective rate part of this section. Thus, a rate range of 1.2-1.5 L/ha of GF-3307 (S7K-3-3) will be recommended in Poland, Hungary, Romania and Slovakia.

18.06.2025/ concerns Poland

Question from authority - BEAVA: RAMUBE

1 trial conducted in the North-East EPPO zone was submitted for the evaluation. There are also 54 trials from Germany available in the dossier, which can be used to support registration in Poland, provided that more trials performed in the North-East EPPO zone are submitted.

A total of 6-15 (optimally 10) efficacy trials carried out in 2 growing seasons should be submitted for the evaluation. The trials should be carried out in North-East EPPO zone (min. 2-3 trials) and in the countries neighbouring to Poland (Germany, Czech Republic, Slovakia).

Reply:

The main disease of sugar beet in Poland is CERCBE, and other diseases occur very sporadically under the conditions of the Polish or north-eastern EPPO climate zone. This was the reason why, despite many trials conducted in Poland, only 1 successful result with RAMUBE was obtained that could be included in the BAD.

Disease pressure and control of RAMUBE are considered more difficult in the EPPO Maritime climate zone (like in Germany). Therefore, the applicant considers that the data package from 8 trials from the EPPO Maritime climate zone, including 5 trials from neighbouring Germany, showing that GF-3307 is fully effective against RAMUBE in sugar beet, provides strong evidence that GF-3307 will provide robust control of RAMUBE under Polish conditions and justifies the authorisation of GF-3307 against RAMUBE in Poland. It is proposed that a dose of 1.5 l/ha be considered as an effective dose in the EPPO Maritime climate zone. However, taking into account lower disease pressure and occurrence in Poland and the fact that under certain conditions GF-3307 at a rate 1.2-1.25 L/ha demonstrated overall good control the rate range of 1.2-1.5 L/ha of GF-3307 may be recommended for control of RAMUBE in Poland where the disease is less prevalent, and the driver disease is CERCBE.

**Comments of zRMS:**

Regarding Poland, according to the latest methodology of integrated beet production issued in 2023, *Ramularia beticola* is currently pathogen of local importance. For Poland, in the case of disease entities of local importance, there is a possibility to reduce the number of trials to a minimum of 3 especially in the case of products on the market containing a substance or mixture of substances. Regarding local importance of *Ramularia beticola* in Poland and the fact, that GF-3307 (S7K-3-3) is currently authorized, minimum 3 trials could be considered sufficient for Poland, if carried out in the required locations (North-East EPPO zone (obligatory) and countries neighbouring to Poland (Germany, Czech Republic, Slovakia)).

**Table 3.2-56 Effectiveness of GF-3307 (S7K-3-3) at proposed maximum label dose rate of 1.2/1.25 L/ha against RAMUBE in sugar beet. Results from 4 trials conducted in the EPPO Maritime climatic zone between 2020-2022**

Part	Timing of assessment	EPPO climatic zone	No. of trials	Untreated			Percentage of efficacy (%)																No. of assessments significantly > , = , < GF-3307 (S7K-3-3) (1.25 l/ha) vs. Reference products
							GF-3307 (S7K-3-3) 1.2-1.25 L/ha				SCORE 0.4 L/ha				AMISTAR GOLD 1.0 L/ha				SPYRALE 1.0 L/ha				
							Fenpi. + Prothio.				Difenoconazole				Azoxyl. + Difeno.				Difeno. + Fenpro.				
							60-62.5+120-125 g a.s./ha				100 g a.s./ha				125+125 g a.s./ha				100+375 g a.s./ha				
							Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	
Disease severity on plants	Assessment around 15-20 DA-B	Maritime	3	7.9	5.0	11.8	55.6	37.5	79.2	17.5	70.7	59.6	87.5	12.1	-	-	-	-	-	-	-	-	0> ; 3= ; 0<
	Assessment around 30-40 DA-B	Maritime	4	8.2	4.5	12.3	52.6	37.5	68.3	11.0	63.8	58.3	74.2	6.2	-	-	-	-	-	-	-	-	0> ; 3= ; 1<
	Assessment after around 40 DA-B	Maritime	1	13.5	-	-	40.0	-	-	-	49.2	-	-	-	-	-	-	-	-	-	-	-	0> ; 1= ; 0<

**Table 3.2-57 Effectiveness of GF-3307 (S7K-3-3) at proposed maximum label rate of 1.5 L/ha against RAMUBE in sugar beet. Results from 8 trials conducted in the EPPO Maritime climatic zone between 2020-2022**

Part	Timing of assessment	EPPO climatic zone	No. of trials	Untreated			Percentage of efficacy (%)																No. of assessments significantly > , = , < GF-3307 (S7K-3-3) (1.5 l/ha) vs. Reference products
							GF-3307 (S7K-3-3) 1.5 L/ha				SCORE 0.4 L/ha				AMISTAR GOLD 1.0 L/ha				SPYRALE 1.0 L/ha				
							Fenpi. + Prothio. 75+150 g a.s./ha				Difenoconazole 100 g a.s./ha				Azoxyl. + Difeno. 125+125 g a.s./ha				Difeno. + Fenpro. 100+375 g a.s./ha				
							Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	
Disease severity on plants	Assessment around 15-20 DA-B	Maritime	6	8.1	4.5	15.3	72.1	49.8	93.8	16.2	67.7	41.8	87.5	14.6	-	-	-	-	-	-	-	0> ; 6= ; 0<	
			1	4.5	-	-	77.5	-	-	-	-	-	-	-	-	-	-	-	77.5	-	-	-	0> ; 1= ; 0<
	Assessment around 30-40 DA-B	Maritime	5	8.6	4.5	12.3	66.9	55.0	80.0	9.2	64.0	58.3	74.2	5.6	-	-	-	-	-	-	-	0> ; 5= ; 0<	
			1	4.5	-	-	61.2	-	-	-	-	-	-	-	-	81.2	-	-	-	-	-	-	0> ; 1= ; 0<
	Assessment after around 40 DA-B	Maritime	3	14.1	13.5	14.5	64.2	60.4	68.7	3.4	53.8	44.5	67.8	10.1	-	-	-	-	-	-	-	1> ; 2= ; 0<	
			2	14.3	14.1	14.5	66.1	63.5	68.7	2.6	-	-	-	-	-	-	-	-	70.7	66.6	74.8	4.1	0> ; 2= ; 0<
	Valid assessment after 2 applications (2 to 6 weeks after the application)	Maritime	8	9.6	4.5	15.3	66.3	49.8	80.0	10.2	63.4	41.8	77.5	10.3	-	-	-	-	-	-	-	0> ; 8= ; 0<	
			1	4.5	-	-	61.2	-	-	-	-	-	-	-	-	81.2	-	-	-	-	-	-	0> ; 1= ; 0<
2			9.5	4.5	14.5	73.1	68.7	77.5	4.4	-	-	-	-	-	-	-	-	-	76.2	74.8	77.5	1.3	0> ; 2= ; 0<

**Table 3.2-58** Effectiveness of GF-3307 (S7K-3-3) at ~~proposed maximum label~~ dose rate of 1.2/1.25 L/ha against RAMUBE in sugar beet. Results from 1 trial conducted in the EPP0 Northeast climatic zone between 2020-2023

[illegible]

**Table 3.2-59** Effectiveness of GF-3307 (S7K-3-3) at proposed maximum label rate of 1.5 L/ha against RAMUBE in sugar beet. Results from 1 trial conducted in the EPPO Northeast climatic zone between 2020-2023

[illegible]

**Table 3.2-60 Effectiveness of GF-3307 (S7K-3-3) at proposed maximum label dose rate of 1.2/1.25 L/ha against RAMUBE in sugar beet. Results from 5 trials conducted in All EPPO climatic zones between 2020-2023**

Part	Timing of assessment	EPPO climatic zone	No. of trials	Untreated			Percentage of efficacy (%)																No. of assessments significantly > , = , < GF-3307 (S7K-3-3) (1.25 l/ha) vs. Reference products
							GF-3307 (S7K-3-3) 1.2-1.25 L/ha				SCORE 0.4 L/ha				AMISTAR GOLD 1.0 L/ha				SPYRALE 1.0 L/ha				
							Fenpi. + Prothio.				Difenoconazole				Azoxy. + Difeno.				Difeno. + Fenpro.				
							60-62.5+120-125 g a.s./ha				100 g a.s./ha				125+125 g a.s./ha				100+375 g a.s./ha				
				Mean	Min	Max		Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	
Disease severity on plants	Assessment around 15-20 DA-B	All EPPO climatic zones	4	9.4	5.0	13.8	53.1	37.5	79.2	15.7	61.4	33.3	87.5	19.3	-	-	-	-	-	-	-	-	0> ; 4= ; 0<
	Assessment around 30-40 DA-B	All EPPO climatic zones	5	10.6	4.5	20.0	54.3	37.5	68.3	10.5	60.5	47.5	74.2	8.6	-	-	-	-	-	-	-	-	0> ; 4= ; 1<
			2	12.3	4.5	20.0	57.9	54.5	61.3	3.4	-	-	-	-	58.1	35.0	81.2	23.1	-	-	-	-	0> ; 2= ; 0<
			1	20.0	-	-	61.3	-	-	-	-	-	-	-	-	-	-	-	57.5	-	-	-	-

**Table 3.2-61 Effectiveness of GF-3307 (S7K-3-3) at proposed maximum label rate of 1.5 L/ha against RAMUBE in sugar beet. Results from 9 trials conducted in All EPPO climatic zones between 2020-2023**

Part	Timing of assessment	EPPO climatic zone	No. of trials	Untreated			Percentage of efficacy (%)																No. of assessments significantly > , = , < GF-3307 (S7K-3-3) (1.5 l/ha) vs. Reference products
							GF-3307 (S7K-3-3) 1.5 L/ha				SCORE 0.4 L/ha				AMISTAR GOLD 1.0 L/ha				SPYRALE 1.0 L/ha				
							Fenpi. + Prothio.				Difenoconazole				Azoxystrobin + Difeno.				Difeno. + Fenpro.				
							75+150 g a.s./ha				100 g a.s./ha				125+125 g a.s./ha				100+375 g a.s./ha				
				Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	
Disease severity on plants	Assessment around 15-20 DA-B	All EPPO climatic zones	7	8.9	4.5	15.3	70.7	49.8	93.8	15.4	62.8	33.3	87.5	18.1	-	-	-	-	-	-	-	0> ; 7= ; 0<	
			1	13.8	-	-	62.5	-	-	-	-	-	-	-	21.7	-	-	-	-	-	-	1> ; 0= ; 0<	
			2	9.1	4.5	13.8	70.0	62.5	77.5	7.5	-	-	-	-	-	-	-	-	64.2	50.8	77.5	13.3	0> ; 2= ; 0<
	Assessment around 30-40 DA-B	All EPPO climatic zones	6	10.5	4.5	20.0	66.8	55.0	80.0	8.4	61.3	47.5	74.2	8.0	-	-	-	-	-	-	-	0> ; 6= ; 0<	
			2	12.3	4.5	20.0	63.7	61.2	66.3	2.6	-	-	-	-	58.1	35.0	81.2	23.1	-	-	-	0> ; 2= ; 0<	
			1	20.0	-	-	66.3	-	-	-	-	-	-	-	-	-	-	-	57.5	-	-	-	0> ; 1= ; 0<
	Valid assessment after 2 applications (2 to 6 weeks after the application)	All EPPO climatic zones	9	10.8	4.5	20.0	66.3	49.8	80.0	9.6	61.6	41.8	77.5	10.9	-	-	-	-	-	-	-	0> ; 9= ; 0<	
			2	12.3	4.5	20.0	63.7	61.2	66.3	2.6	-	-	-	-	58.1	35.0	81.2	23.1	-	-	-	-	0> ; 2= ; 0<
			3	13.0	4.5	20.0	70.8	66.3	77.5	4.8	-	-	-	-	-	-	-	-	70.0	57.5	77.5	8.9	0> ; 3= ; 0<

**Comments of zRMS on:**

**Efficacy of GF-3307 (S7K-3-3) for the control of *Ramularia beticola* in sugar beet (3.2.3.4)**

The efficacy of GF-3307 (S7K-3-3) in the control of *Ramularia beticola* (RAMUBE) on sugar beet has been presented in 9 trials carried out in Maritime EPPO zone (8) and North-East EPPO zone (1). No trials were performed on fodder beet. The trials were conducted in Denmark (1), Germany (5), United Kingdom (2) and Poland (1) in the years 2020-2023.

**Maritime EPPO zone (8 efficacy trials carried out in 2020, 2021, 2022)**

The test item GF-3307 (S7K-3-3) was applied at maximum recommended dose rate of 1.5 L/ha in all 8 efficacy trials, at BBCH growth stage of the crop 38-49, which was consistent with the requested application timing. The water volume in the trials was 200-300 L/ha, which can be accepted to cover the amount of water requested in the GAP (150-300 L/ha). Lower dose rate of 1.2 L/ha was not claimed for MSs from Maritime EPPO zone, however efficacy results for dose rate 1.2 L/ha (results from 3 trials) and for similar dose rate 1.25 L/ha (results from 1 trial) have been also presented for possible use by cMSs from other zones. As the difference between the dose rate 1.2 L/ha and dose rate 1.25 L/ha is less than 5%, efficacy data achieved for GF-3307 (S7K-3-3) applied at 1.25 L/ha may support the recommended for North-East EPPO zone (PL) and South-East EPPO zone (HU, RO, SK) dose rate of 1.2 L/ha. The tested fungicide was applied 2 to 4 times in the presented trials, while the efficacy results have been properly presented after second application. GF-3307 (S7K-3-3) at target dose rate of 1.5 L/ha, was moderately effective in the control of RAMUBE on sugar beet with average efficacy results >60% and >70% achieved for various assessment timings (from 15 DAB to about 40 DAB). The efficacy of tested fungicide was statistically comparable with the efficacy of reference products: Score, Amistar Gold or Spyrale in the vast majority of trials. The efficacy of GF-3307 (S7K-3-3) at lower dose rate of 1.2/125 L/ha was visibly lower (effectiveness of 40% - 56%) and was statistically comparable with the efficacy of reference products: Score, Amistar Gold or Spyrale in the vast majority of trials.

**North-East EPPO zone (1 trial carried out in North -East EPPO in 2023 + 5 supportive trials conducted in Germany in 2020, 2021, 2022)**

The test item GF-3307 (S7K-3-3) was applied at maximum recommended dose rate of 1.5 L/ha in 1 trial carried out in North-East EPPO zone and in 5 supportive efficacy trials conducted in Germany. The recommended dose rate of 1.2 L/ha was tested in 3 trials carried out in North-East EPPO zone. The dose rate of 1.25 L/ha was tested in 2 efficacy trials carried out in Germany and Poland. As the difference between the recommended dose rate 1.2 L/ha and dose rate 1.25 L/ha is less than 5%, efficacy data achieved for GF-3307 (S7K-3-3) applied at 1.25 L/ha may support the recommended dose rate of 1.2 L/ha. The application timing/growth stage of the crop was BBCH 38-49 in the trials, which was consistent with the requested application timing. The water volume in the trials was 200-300 L/ha, which can be accepted to cover the amount of water requested in the GAP (150-300 L/ha). The tested fungicide was applied 2 to 4 times in the presented trials, while the efficacy results have been properly presented after second application. GF-3307 (S7K-3-3) at target dose rate of 1.5 L/ha, was moderately effective in the control of RAMUBE on sugar beet with average efficacy results mostly >60% achieved for various assessment timings (from 15 DAB to about 40 DAB). The efficacy of tested fungicide was statistically comparable with the efficacy of reference products: Score, Amistar Gold or Spyrale. The efficacy of GF-3307 (S7K-3-3) at lower dose rate of 1.2/125 L/ha was visibly lower (effectiveness of 46% - 61%) and was statistically comparable with the efficacy of reference products: Score, Amistar Gold or Spyrale in the vast majority of trials.

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

A total of 56 trials were carried out between 2020 and 2023 to evaluate the efficacy of GF-3307 (S7K-3-3) at the proposed label rate of 1.5 L/ha for the control of the foliar diseases in sugar beet.

Twenty-two trials were taken to yield to confirm the yield response of GF-3307 (S7K-3-3) in the presence of foliar diseases between 2020 and 2023 in the Maritime, Northeast and Southeast climatic zones in Czech Republic (1), Denmark (5), France (1), Germany (2), The United-Kingdom (2), Lithuania (1), Poland (3), Hungary (3) and Romania (4).

#### **Results**

##### **Maritime EPPO climatic zone**

Across 11 trials, GF-3307 (S7K-3-3) at the proposed maximum label rate 1.5 L/ha clearly had a positive effect on the yield of sugar beet in the presence of foliar diseases. In fact, there was an increase of respectively + 7.0% in net yield over the untreated similar to SCORE (104.4%). No significant difference was noted with the reference standard in all trials.

Across 7 trials, GF-3307 (S7K-3-3) at the proposed maximum label rate 1.5 L/ha clearly had a positive effect on the yield of sugar beet in the presence of foliar diseases. In fact, there was an increase of respectively + 8.9% in net yield over the untreated similar to AMISTAR GOLD (105.5%). No significant difference was noted with the reference standard in all trials.

Across 6 trials, GF-3307 (S7K-3-3) at the proposed maximum label rate 1.5 L/ha clearly had a positive effect on the yield of sugar beet in the presence of foliar diseases. In fact, there was an increase of respectively + 5.3% in net yield over the untreated similar to SPYRALE (107.9%). No significant difference was noted with the reference standard in all trials.

The same conclusion can be noted with the other yield parameters sugar content in percent.

##### **Northeast EPPO climatic zone**

Across 4 trials, GF-3307 (S7K-3-3) at the proposed maximum label rate 1.5 L/ha clearly had a positive effect on the yield of sugar beet in the presence of foliar diseases. In fact, there was an increase of respectively + 1.2% in net yield over the untreated similar to SCORE (101.2%). No significant difference was noted with the reference standard in all trials.

Across 3 trials, GF-3307 (S7K-3-3) at the proposed maximum label rate 1.5 L/ha clearly had a positive effect on the yield of sugar beet in the presence of foliar diseases. In fact, there was an increase of respectively + 2.1% in net yield over the untreated similar to AMISTAR GOLD (102.4%). No significant difference was noted with the reference standard in all trials.

Across 2 trials, GF-3307 (S7K-3-3) at the proposed maximum label rate 1.5 L/ha clearly had a positive effect on the yield of sugar beet in the presence of foliar diseases. In fact, there was an increase of respectively + 2.8% in net yield over the untreated similar to SPYRALE (101.3%). No significant difference was noted with the reference standard in all trials.

The same conclusion can be noted with the other yield parameters sugar content in percent.

##### **Northeast and PL borders countries**

Across 7 trials, GF-3307 (S7K-3-3) at the proposed maximum label rate 1.5 L/ha clearly had a positive effect on the yield of sugar beet in the presence of foliar diseases. In fact, there was an increase of respectively + 4.4% in net yield over the untreated similar to SCORE (102.1%). No significant difference was noted with the reference standard in all trials.

Across 6 trials, GF-3307 (S7K-3-3) at the proposed maximum label rate 1.5 L/ha clearly had a positive effect on the yield of sugar beet in the presence of foliar diseases. In fact, there was an increase of respectively + 5.4% in net yield over the untreated similar to AMISTAR GOLD (103.5%). No significant difference was noted with the reference standard in all trials.

Across 3 trials, GF-3307 (S7K-3-3) at the proposed maximum label rate 1.5 L/ha clearly had a positive effect on the yield of sugar beet in the presence of foliar diseases. In fact, there was an increase of respectively + 5.0% in net yield over the untreated similar to SPYRALE (103.5%). No significant difference was noted with the reference standard in all trials.

The same conclusion can be noted with the other yield parameters sugar content in percent.



### **Southeast EPPO climatic zones**

Across 2 trials, GF-3307 (S7K-3-3) at the proposed maximum label rate 1.5 L/ha clearly had a positive effect on the yield of sugar beet in the presence of foliar diseases. In fact, there was an increase of respectively + 10.9% in net yield over the untreated similar to SCORE (108.2%). No significant difference was noted with the reference standard in all trials.

Across 5 trials, GF-3307 (S7K-3-3) at the proposed maximum label rate 1.5 L/ha clearly had a positive effect on the yield of sugar beet in the presence of foliar diseases. In fact, there was an increase of respectively + 4.9% in net yield over the untreated similar to AMISTAR GOLD (105.8%). No significant difference was noted with the reference standard in all trials.

Across 2 trials, GF-3307 (S7K-3-3) at the proposed maximum label rate 1.5 L/ha clearly had a positive effect on the yield of sugar beet in the presence of foliar diseases. In fact, there was an increase of respectively + 10.9% in net yield over the untreated similar to SPYRALE (110.0%). No significant difference was noted with the reference standard in all trials.

The same conclusion can be noted with the other yield parameters sugar content in percent.

### **All EPPO climatic zones**

Across 17 trials, GF-3307 (S7K-3-3) at the proposed maximum label rate 1.5 L/ha clearly had a positive effect on the yield of sugar beet in the presence of foliar diseases. In fact, there was an increase of respectively + 6.1% in net yield over the untreated similar to SCORE (104.1%). No significant difference was noted with the reference standard in all trials.

Across 15 trials, GF-3307 (S7K-3-3) at the proposed maximum label rate 1.5 L/ha clearly had a positive effect on the yield of sugar beet in the presence of foliar diseases. In fact, there was an increase of respectively + 6.2% in net yield over the untreated similar to AMISTAR GOLD (105.0%). No significant difference was noted with the reference standard in all trials.

Across 10 trials, GF-3307 (S7K-3-3) at the proposed maximum label rate 1.5 L/ha clearly had a positive effect on the yield of sugar beet in the presence of foliar diseases. In fact, there was an increase of respectively + 5.9% in net yield over the untreated similar to SPYRALE (107.0%). No significant difference was noted with the reference standard in all trials. The same conclusion can be noted with the other yield parameters sugar content in percent. A summary of the yield (t/ha) and sugar content (%) from efficacy trials is presented in Table 3.2-62 (Maritime EPPO climatic zone), Table 3.2-63 (Northeast EPPO climatic zone), Table 3.2-64 (Southeast EPPO climatic zone) and Table 3.2-65 (All zones).

**Table 3.2-62: Impact of GF-3307 (S7K-3-3) on the yield amount and sugar content (%) when applied at 1.5 L/ha for the control of foliar diseases on sugar beet in EPPO Maritime climatic zone, efficacy trials in sugar beet**

Parameters	EPPO climatic zone	Parts	No. of trials	Untreated			Percentage of Untreated control (%)																No. of assessments significantly > , = , < GF-3307 (S7K-3-3) (1.5 L/ha) vs. Reference products
							GF-3307 (S7K-3-3) 1.5 L/ha				SCORE 0.4 L/ha				AMISTAR GOLD 1.0 L/ha				SPYRALE 1.0 L/ha				
							Fenpicoxamid + Prothioconazole 75+150 g a.s./ha				Difenoconazole 100 g a.s./ha				Azoxystrobin + Difenoconazole 125 +125 g a.s./ha				Difenoconazole + Fenpropidin 100+375 g a.s./ha				
				Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.				
Yield (t/ha)	Maritime	Roots	11	92.0	75.7	105.4	107.0	94.4	116.3	6.7	104.4	99.6	112.7	4.1	-	-	98.2	-	-	-	-	-	0> ; 11= ; 0<
			7	93.1	76.9	101.5	108.9	103.6	116.3	4.1	-	-	-	-	105.5	-	111.9	4.2	-	-	-	-	0> ; 7= ; 0<
			6	88.6	75.7	105.4	105.3	94.4	115.0	7.5	-	-	-	-	-	-	-	-	107.9	103.1	113.9	3.5	0> ; 6= ; 0<
Sugar (%)	Maritime	Roots	11	16.9	15.7	19.1	104.9	100.5	109.0	2.9	103.8	100.0	111.8	3.0	-	-	-	-	-	-	-	-	1> ; 8= ; 0<
			7	17.2	15.7	19.1	104.4	100.5	109.0	2.7	-	-	-	-	103.0	100.4	105.4	2.1	-	-	-	-	1> ; 6= ; 0<
			5	16.2	15.7	16.9	105.5	100.7	108.1	2.7	-	-	-	-	-	-	-	-	102.6	98.9	107.6	3.1	0> ; 3= ; 0<

**Table 3.2-63: Impact of GF-3307 (S7K-3-3) on the yield amount and sugar content (%) when applied at 1.5 L/ha for the control of foliar diseases on sugar beet in EPPO Northeast climatic zone, efficacy trials in sugar beet**

Parameters	EPPO climatic zone	Parts	No. of trials	Untreated			Percentage of Untreated control (%)																No. of assessments significantly > , = , < GF-3307 (S7K-3-3) (1.5 L/ha) vs. Reference products
							GF-3307 (S7K-3-3) 1.5 L/ha				SCORE 0.4 L/ha				AMISTAR GOLD 1.0 L/ha				SPYRALE 1.0 L/ha				
							Fenpicoxamid + Prothioconazole				Difenoconazole				Azoxystrobin + Difenoconazole				Difenoconazole + Fenpropidin				
							75+150 g a.s./ha				100 g a.s./ha				125 +125 g a.s./ha				100+375 g a.s./ha				
				Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.				
Yield (t/ha)	Northeast	Roots	4	74.3	57.0	109.1	101.2	98.2	105.9	2.9	101.2	98.4	103.5	2.3	-	-	-	-	-	-	-	0> ; 4= ; 0<	
			3	75.2	57.0	109.1	102.1	99.7	105.9	2.7	-	-	-	-	102.4	98.8	105.3	2.7	-	-	-	-	0> ; 3= ; 0<
			2	83.1	57.0	109.1	102.8	99.7	105.9	3.1	-	-	-	-	-	-	-	-	101.3	99.2	103.3	2.1	0> ; 2= ; 0<
	Northeast and PL borders countries	Roots	7	83.9	57.0	109.1	104.4	98.2	113.1	5.0	102.1	98.4	110.3	3.8	-	-	-	-	-	-	-	0> ; 7= ; 0<	
			6	85.9	57.0	109.1	105.4	99.7	113.1	4.7	-	-	-	-	103.5	98.2	108.3	3.9	-	-	-	-	0> ; 6= ; 0<
			3	86.8	57.0	109.1	105.0	99.7	109.3	4.0	-	-	-	-	-	-	-	-	103.5	99.2	108.0	3.6	0> ; 3= ; 0<
Sugar (%)	Northeast	Roots	4	15.3	9.8	18.7	102.8	96.7	108.8	4.4	100.6	96.9	102.6	2.3	-	-	-	-	-	-	-	0> ; 3= ; 0<	
			3	17.1	15.3	18.7	100.8	96.7	104.0	3.1	-	-	-	-	99.6	96.7	102.7	2.5	-	-	-	-	0> ; 2= ; 0<
			2	16.4	15.3	17.5	102.9	101.8	104.0	1.1	-	-	-	-	-	-	-	-	102.4	101.1	103.7	1.3	0> ; 2= ; 0<
	Northeast and PL borders countries	Roots	7	16.0	9.8	19.1	103.2	96.7	109.0	4.1	101.4	96.9	103.8	2.1	-	-	-	-	-	-	-	0> ; 6= ; 0<	
			6	17.0	15.3	19.1	102.3	96.7	109.0	3.7	-	-	-	-	100.5	96.7	102.8	2.1	-	-	-	-	0> ; 5= ; 0<
			2	16.4	15.3	17.5	102.9	101.8	104.0	1.1	-	-	-	-	-	-	-	-	102.4	101.1	103.7	1.3	0> ; 2= ; 0<

**Table 3.2-64: Impact of GF-3307 (S7K-3-3) on the yield amount and sugar content (%) when applied at 1.5 L/ha for the control of foliar diseases on sugar beet in EPPO Southeast climatic zone, efficacy trials in sugar beet**

Parameters	EPPO climatic zone	Parts	No. of trials	Untreated			Percentage of Untreated control (%)																No. of assessments significantly > , = , < GF-3307 (S7K-3-3) (1.5 L/ha) vs. Reference products
							GF-3307 (S7K-3-3) 1.5 L/ha				SCORE 0.4 L/ha				AMISTAR GOLD 1.0 L/ha				SPYRALE 1.0 L/ha				
							Fenpicoxamid + Prothioconazole 75+150 g a.s./ha				Difenoconazole 100 g a.s./ha				Azoxystrobin + Difenoconazole 125 +125 g a.s./ha				Difenoconazole + Fenpropidin 100+375 g a.s./ha				
				Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.				
Yield (t/ha)	Southeast	Roots	2	53.6	47.4	59.8	110.9	102.2	119.5	8.7	108.2	102.1	114.2	6.1	-	-	-	-	-	-	-	0> ; 2= ; 0<	
			5	65.0	42.0	91.5	104.9	95.1	111.0	6.1	-	-	-	-	105.8	99.2	110.3	4.7	-	-	-	-	0> ; 5= ; 0<
			2	53.6	47.4	59.8	110.9	102.2	119.5	8.7	-	-	-	-	-	-	-	-	110.0	102.4	117.6	7.6	0> ; 2= ; 0<
Sugar (%)	Southeast	Roots	2	16.5	15.7	17.3	104.4	103.0	105.8	1.4	103.3	100.9	105.8	2.4	-	-	-	-	-	-	-	0> ; 2= ; 0<	
			3	17.5	13.1	24.5	102.7	101.8	103.2	0.6	-	-	-	-	97.6	95.3	101.9	3.1	-	-	-	-	0> ; 3= ; 0<
			2	16.5	15.7	17.3	104.4	103.0	105.8	1.4	-	-	-	-	-	-	-	-	103.8	102.0	105.6	1.8	0> ; 2= ; 0<

**Table 3.2-65: Impact of GF-3307 (S7K-3-3) on the yield amount and sugar content (%) when applied at 1.5 L/ha for the control of foliar diseases on sugar beet in All EPPO climatic zones, efficacy trials in sugar beet**

Parameters	EPPO climatic zone	Parts	No. of trials	Untreated			Percentage of Untreated control (%)																No. of assessments significantly > , = , < GF-3307 (S7K-3-3) (1.5 L/ha) vs. Reference products
							GF-3307 (S7K-3-3) 1.5 L/ha				SCORE 0.4 L/ha				AMISTAR GOLD 1.0 L/ha				SPYRALE 1.0 L/ha				
							Fenpicoxamid + Prothioconazole 75+150 g a.s./ha				Difenoconazole 100 g a.s./ha				Azoxystrobin + Difenoconazole 125 +125 g a.s./ha				Difenoconazole + Fenpropidin 100+375 g a.s./ha				
				Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.				
Yield (t/ha)	All EPPO climatic zones	Roots	17	83.3	47.4	109.1	106.1	94.4	119.5	7.0	104.1	98.4	114.2	4.5	-	-	-	-	-	-	-	0> ; 17= ; 0<	
			15	80.2	42.0	109.1	106.2	95.1	116.3	5.4	-	-	-	-	105.0	98.2	111.9	4.3	-	-	-	-	0> ; 15= ; 0<
			10	80.5	47.4	109.1	105.9	94.4	119.5	7.6	-	-	-	-	-	-	-	-	107.0	99.2	117.6	5.3	0> ; 10= ; 0<
Sugar (%)	All EPPO climatic zones	Roots	17	16.5	9.8	19.1	104.3	96.7	109.0	3.3	103.0	96.9	111.8	3.1	-	-	-	-	-	-	-	1> ; 13= ; 0<	
			13	17.3	13.1	24.5	103.2	96.7	109.0	2.9	-	-	-	-	101.0	95.3	105.4	3.3	-	-	-	-	1> ; 11= ; 0<
			9	16.3	15.3	17.5	104.7	100.7	108.1	2.4	-	-	-	-	-	-	-	-	102.8	98.9	107.6	2.6	0> ; 7= ; 0<

## Summary and conclusion

GF-3307 (S7K-3-3) at the proposed maximum label rate of 1.5 L/ha, had an overall positive effect on the yield and sugar content of sugar beet, treated in the presence of foliar diseases.

### Comments of zRMS:

The trial conducted in Lithuania (LT23E7B029-KFB12C) was not included in the compilation of data on root yield and sugar content. The results from this trial showed no statistically significant differences between GF-3307 (S7K-3-3) and the reference products (Amistar Gold and Score), while compared to the untreated control, GF-3307 (S7K-3-3) provided a significantly higher root yield and sugar content. These results confirm that two applications of GF-3307 (S7K-3-3) at the recommended dose rate range of 1.2–1.5 L/ha had no adverse effect on either the quantity or quality of yield.

### 3.2.3.6 Summary and conclusions on effectiveness

A set of 56 efficacy trials carried out from 2020 to 2023 in the Maritime, Northeast and Southeast EPPO climatic zones are provided in this BAD to confirm efficacy of GF-3307 (S7K-3-3) at rate of 1.5 L/ha for Austria, Belgium, Czech Republic and The Netherlands and at the rate range of 1.2-1.5 L/ha for Poland, Hungary, Slovakia and Romania in sugar beet crops.

In recent years, *Cercospora beticola* has become more prevalent in Europe<sup>12, 13</sup> and has become the most destructive foliar pathogen of sugar beet. It is widely present in most beet-growing regions and can cause major yield losses if not properly controlled. This disease usually appears early in the season and is most severe in wet and warm areas in case of very early attacks<sup>14</sup>.

Data are mainly presented from Maritime. However, this zone can be considered to reflect the full range of climatic conditions across the Central registration zone that encourage the development of foliar diseases on sugar beet crop and are a robust test of the product. CERCBE data from the Maritime zone is supportive of North-East and South-East countries as the threat of the disease occurrence and disease pressure is similar if not greater in Maritime locations including Germany. Additionally, ERYSB and RAMUBE data from Maritime are supportive of North-East and South-East countries as the threat of the disease is major, like in Germany (major diseases). Additionally, the United-Kingdom and Denmark present highest risk situations for UROMBE as *Cercospora* is generally less prevalent.

Control of UROMBE, ERYSB and RAMUBE is fully supported at the proposed maximum dose rate in Austria, Belgium, Czech Republic, and The Netherlands of 1.5 L/ha and at the rate range of 1.2-1.5 L/ha in Poland, Hungary, Slovakia and Romania. Although no data or very few data is presented for North-East and South-East on UROMBE, ERYSB and RAMUBE, the applicant wishes the regulators to consider Northern and Southern Zone data from Denmark and France and additional Maritime data presents the worst case scenario and supports control of these diseases at the proposed maximum dose 1.5 L/ha in Austria, Belgium, Czech Republic, and The Netherlands with CERCBE being the driver disease.

Finally, the data package is fully justified to demonstrate the efficacy of GF-3307 (S7K-3-3) at maximal dose rate of 1.5 L/ha for Austria, Belgium, Czech Republic and The Netherlands and at the rate range of 1.2-1.5 L/ha in Poland, Hungary, Slovakia and Romania in the Central Registration zone to control diseases complex in the sugar beet crop.

Table 3.2-66 summarises the efficacy of GF-3307 (S7K-3-3) to control sugar beet diseases complex at the valid assessment between 2 to 7 weeks after the second application (all efficacy trials merged).

<sup>12</sup> <http://bbro.co.uk/bbro-research/bbro-research/crop-protection/cu-integrated-disease-control-in-sugar-beet/>

<sup>13</sup> <https://www.r4p-inra.fr/fr/publication-de-la-note-commune-betterave-2022/>

<sup>14</sup> [https://www.florimond-desprez.com/es/wp-content/uploads/sites/6/2015/11/leaf-diseases\\_eng.pdf](https://www.florimond-desprez.com/es/wp-content/uploads/sites/6/2015/11/leaf-diseases_eng.pdf)

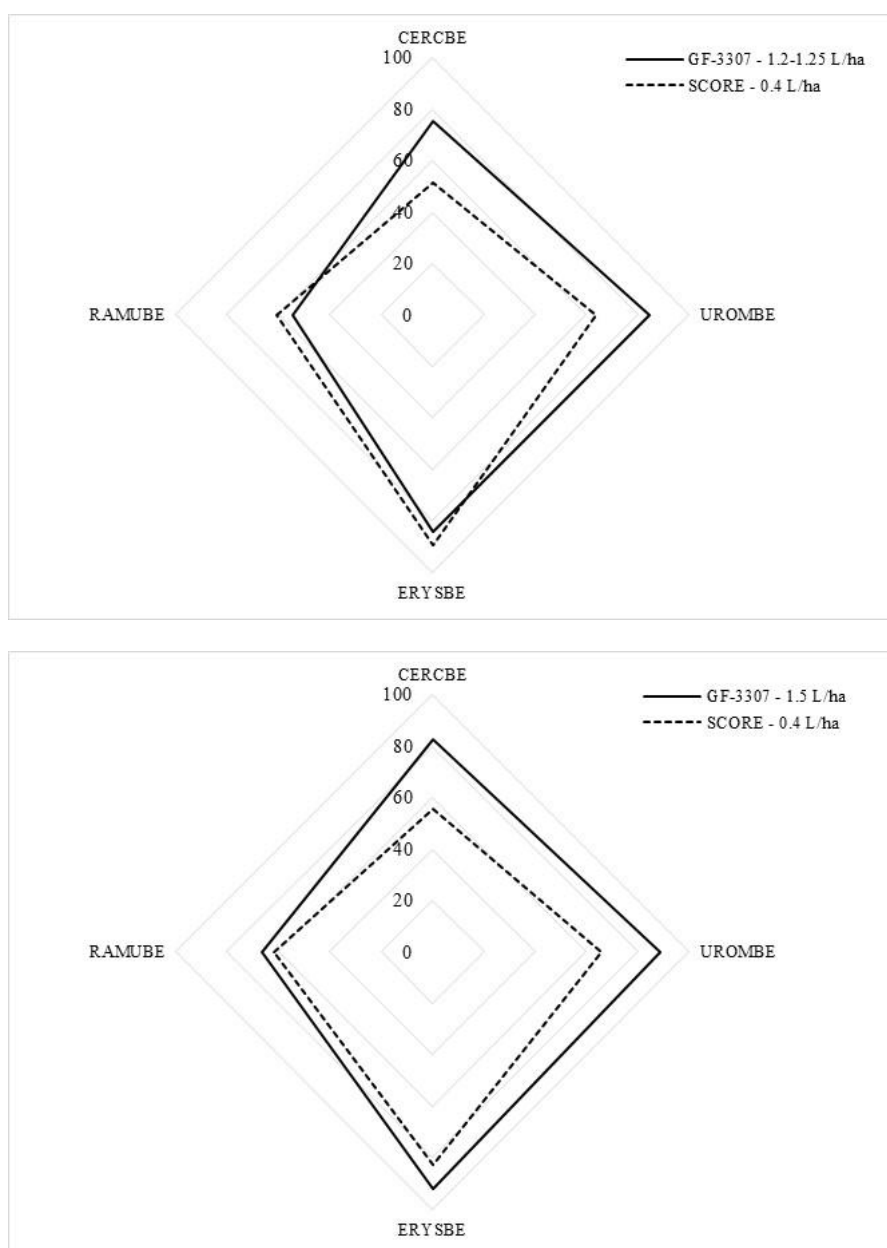
**Table 3.2-66: Efficacy of GF-3307 (S7K-3-3) - Sugar beet - All valid efficacy trials - Valid assessment between 2 to 7 weeks after the second application**

Target	EPPO climatic zone	No. of trials	<i>Untreated</i>			Percentage of efficacy (%)					
						GF-3307 (S7K-3-3) 1.2-1.25 L/ha (80-83%)			GF-3307 (S7K-3-3) 1.5 L/ha (100%)		
						Fenpicoxamid + Prothioconazole 60-62.5 + 120-125g a.s./ha			Fenpicoxamid + Prothioconazole 75+150 g a.s./ha		
			<i>Mean</i>	Min	Max	<i>Mean</i>	Min	Max	<i>Mean</i>	Min	Max
CERCBE	Maritime	24	<b>26.2</b>	5.1	63.5	-	-	-	<b>84.1</b>	66.9	100.0
	Northeast	5	<b>38.7</b>	26.7	57.5	<b>74.1</b>	50.0	96.8	-	-	-
		8	<b>44.2</b>	26.7	72.5	-	-	-	<b>79.0</b>	60.3	97.2
	Southeast	6	<b>35.7</b>	12.3	65.0	<b>69.7</b>	58.5	77.2	-	-	-
		10	<b>34.8</b>	12.3	65.0	-	-	-	<b>80.8</b>	65.5	98.7
	All zones	22	<b>33.0</b>	8.8	65.0	<b>73.8</b>	50.0	97.1	-	-	-
UROMBE	Maritime	42	<b>31.7</b>	5.1	72.5	-	-	-	<b>82.3</b>	60.3	100.0
		10	<b>38.4</b>	18.6	59.1	<b>84.5</b>	43.9	99.6	-	-	-
ERYSBE	Maritime	16	<b>32.3</b>	9.5	59.1	-	-	-	<b>88.7</b>	53.9	100.0
		6	<b>26.8</b>	4.7	60.0	<b>84.5</b>	44.6	100.0	-	-	-
RAMUBE	Maritime	8	<b>32.8</b>	4.7	90.0	-	-	-	<b>92.0</b>	75.0	100.0
		4	<b>8.2</b>	4.5	12.3	<b>52.6</b>	37.5	68.3	-	-	-
	Northeast	8	<b>9.6</b>	4.5	15.3	-	-	-	<b>66.3</b>	49.8	80.0
		1	<b>20.0</b>	-	-	<b>61.3</b>	-	-	-	-	-
	Northeast and border countries (PL-DE)	1	<b>20.0</b>	-	-	-	-	-	<b>66.3</b>	-	-
		4	<b>12.1</b>	5.0	20.0	<b>54.3</b>	37.5	68.3	-	-	-
	All zones	6	<b>12.3</b>	5.0	20.0	-	-	-	<b>64.9</b>	49.8	80.0
		5	<b>10.6</b>	4.5	20.0	<b>54.3</b>	37.5	68.3	-	-	-
RAMUBE	All zones	9	<b>10.8</b>	4.5	20.0	-	-	-	<b>66.3</b>	49.8	80.0

GF-3307 (S7K-3-3) at 1.5 L/ha applied twice controlled all diseases of sugar beet with a good to very good level of efficacy. Overall, GF-3307 (S7K-3-3) at 1.2-1.25 L/ha demonstrated a moderate to very good control against diseases complex of sugar beet. As a result, the proposed maximum rate of 1.5 L/ha of GF-3307 (S7K-3-3) in Austria, Belgium, Czech Republic and The Netherlands should be considered the effective dose to deliver robust control of diseases complex in sugar beet in the Central registration zone. However, according to the local conditions and infestation pressure (e.g. under low disease pressure), it is possible to use the lower dose of 1.2 L/ha. Indeed, under certain conditions, GF-3307 (S7K-3-3) at 1.2-1.25 L/ha demonstrated overall good control at least as good as references. The conditions for use at a lower rate are detailed in the minimum effective rate part of this section. Thus, a rate range of 1.2-1.5 L/ha of GF-3307 (S7K-3-3) will be recommended in Poland, Hungary, Slovakia and Romania and this dose range is driven by the major disease CERCBE.

GF-3307 (S7K-3-3) up to 1.5 L/ha had an overall positive effect on yield and quality of crops treated in the presence of disease.

The efficacy of GF-3307 (S7K-3-3) against sugar beet disease complex can be illustrated by graphic after two applications (CERCBE, ERYSE, RAMUBE and UROMBE) (Figure 3.2-12). According to the efficacy results and as illustrated on the graphic hereafter, GF-3307 (S7K-3-3) at rate 1.2-1.25 L/ha and 1.5 L/ha controlled all diseases of sugar beet with a level of efficacy similar or higher to the reference standard SCORE at 0.4 L/ha or Amistar Gold.



**Figure 3.2-12 Efficacy of GF-3307 (S7K-3-3) at 1.2-1.25 L/ha and 1.5 L/ha - Sugar beet - Diseases complex (efficacy against CERCBE, ERYSB, RAMUBE, UROMBE) after two applications**

**It is therefore considered that the proposed claims for control of diseases complex (CERCBE, UROMBE, ERYSB and RAMUBE) in sugar beet crops, following two application of 1.5 L/ha GF-3307 (S7K-3-3) applied between BBCH 39-49 of the crop in Austria, Belgium, Czech Republic and The Netherlands and following two application of 1.2 L/ha to 1.5 L/ha GF-3307 (S7K-3-3) applied between BBCH 39-49 of the crop in Poland, Hungary, Slovakia and Romania are fully supported.**

**In accordance with the table PP 1/257 FEET 55(1), this result can be extrapolated on fodder beet.**

## **General conclusion of zRMS on: Efficacy tests (3.2.3)**

Results from 56 valid efficacy trials carried out between 2020 and 2023 have been presented to support the evaluation of the fungicide GF-3307 (S7K-3-3). The trials were carried out in Maritime EPPO zone (Austria, Czech Republic, Germany, Denmark, France, the United Kingdom), North-East EPPO zone (Lithuania, Poland) and South-East EPPO zone (Hungary, Romania). All the efficacy trials were carried out by the officially GEP-recognized testing units.

GF-3307 (S7K-3-3) is intended to be authorized for the control of *Cercospora beticola* (CERCBE), *Uromyces betae* (UROMBE), *Erysiphe betae* (ERYSBE), *Ramularia beticola* (RAMUBE) on sugar beet and fodder beet in Austria, Belgium, Czech Republic, the Netherlands (Maritime EPPO zone); Poland (North-East EPPO zone), Hungary, Romania, Slovakia (South-East EPPO zone),

Detailed conclusions from the evaluation are contained in zRMS commenting boxes under the chapters 3.2.3.1, 3.2.3.2, 3.2.3.3 and 3.2.3.4.

## **General Conclusions on efficacy**

### **Maritime EPPO climatic zone**

#### **GAP claims:**

Sugar beet (BEAVP), fodder beet (BEAVC): *Cercospora beticola* (CERCBE), *Uromyces betae* (UROMBE), *Erysiphe betae* (ERYSBE), *Ramularia beticola* (RAMUBE)

Application rate: 1.5 L/ha

Water volume: 150-300 L/ha

GF-3307 (S7K-3-3) is intended to be used twice per growing season within the crop growth stage ranging from BBCH 39 to 49.

#### **CERCBE, UROMBE, ERYSB, RAMUBE**

Based on the efficacy data package from Maritime EPPO zone, the use of GF-3307 (S7K-3-3) at recommended application rate 1.5 L/ha in the control of *Cercospora beticola*, *Uromyces betae*, *Erysiphe betae*, *Ramularia beticola* on sugar beet, under conditions of use consistent with GAP may be granted. It is recommended to include in the product label remark about moderate level of efficacy of GF-3307 (S7K-3-3) applied at recommended dose rate of 1.5 L/ha in the control of *Ramularia beticola*.

As no efficacy data has been submitted for fodder beet, the decision on acceptance uses: *Cercospora beticola*, *Uromyces betae*, *Erysiphe betae*, *Ramularia beticola* on fodder beet is to be taken at the national level, according to the national requirements regarding extrapolation of efficacy data from sugar beet to fodder beet or using the extrapolation possibilities indicated in EPPO guidelines PP 1/257 (2) or PP 1/331 (1), depending on minor or major importance of beet cultivation in a given cMS. The zRMS is kindly asking the cMS to not only take their decisions, but also to share the underlying information with the zRMS PL, within the commenting period framework.

After the commenting period, and taking into account the decision of cMS AT and NL regarding the extrapolation of data from BEAVA to BEAVC, the use on BEAVC has been accepted for AT and NL.

### **North-East EPPO climatic zone**

#### **GAP claims:**

Sugar beet (BEAVP), fodder beet (BEAVC): *Cercospora beticola* (CERCBE), *Uromyces betae* (UROMBE), *Erysiphe betae* (ERYSBE), *Ramularia beticola* (RAMUBE)

Application rate: 1.2-1.5 L/ha

Water volume: 150-300 L/ha

GF-3307 (S7K-3-3) is intended to be used twice per growing season within the crop growth stage ranging from BBCH 39 to 49.

#### **CERCBE**

Based on the efficacy data package from North-East EPPO zone and regarding supportive efficacy data from Germany and Czech Republic, the use of GF-3307 (S7K-3-3) at recommended application rate range 1.2-1.5

L/ha in the control of *Cercospora beticola* on sugar beet, under conditions of use consistent with GAP may be granted in Poland. It is recommended to include in the product label remark about moderate level of efficacy of GF-3307 (S7K-3-3) applied at 1.2 L/ha and to use the target fungicide at lower dose rate under conditions of low diseases pressure.

As no efficacy data has been submitted for fodder beet, the use *Cercospora beticola* on fodder beet can not be accepted to be authorized on the grounds of article 33 of regulation 1107/2009. While fodder beet is minor crop in Poland, use *Cercospora beticola* on fodder beet may be registered on the grounds of article 51 of regulation 1107/2009.

#### UROMBE

As no efficacy data from North-East EPPO zone has been submitted for sugar beet and fodder beet, the use *Uromyces betae* on sugar beet and fodder beet can not be accepted to be authorized on the grounds of article 33 of regulation 1107/2009. While *Uromyces betae* it pathogen of minor importance in Poland and fodder beet is minor crop in Poland, use *Uromyces betae* on sugar beet and fodder beet may be registered on the grounds of article 51 of regulation 1107/2009.

#### ERYSBE

As no efficacy data from North-East EPPO zone has been submitted for sugar beet and fodder beet, the use *Erysiphe betae* on sugar beet and fodder beet **does not meet the national requirements for authorization** can not be accepted to be authorized on the grounds of article 33 of regulation 1107/2009.

While fodder beet is minor crop in Poland, use *Erysiphe betae* on fodder beet may be registered on the grounds of article 51 of regulation 1107/2009.

#### RAMUBE

Based on the efficacy data package from North-East EPPO zone and regarding supportive efficacy trials from Germany, the use of GF-3307 (S7K-3-3) at recommended dose rate of 1.5 L/ha in the control of *Ramularia beticola* on sugar beet, under conditions of use consistent with GAP may be granted in Poland. It is recommended to include in the product label remark about moderate level of efficacy of GF-3307 (S7K-3-3) applied at target dose rate of 1.5 L/ha. Due to low efficacy level achieved for dose rate of 1.2/1.25 L/ha (efficacy from 5 trials: around 50%), the lower dose rate 1.2 L/ha is not recommended by zRMS for this use in Poland.

As no efficacy data has been submitted for fodder beet, the use *Ramularia beticola* on fodder beet can not be accepted to be authorized on the grounds of article 33 of regulation 1107/2009. While fodder beet is minor crop in Poland, use *Ramularia beticola* on fodder beet may be registered on the grounds of article 51 of regulation 1107/2009.

#### South-East EPPO climatic zone

Sugar beet (BEAVP), fodder beet (BEAVC): *Cercospora beticola* (CERCBE), *Uromyces betae* (UROMBE), *Erysiphe betae* (ERYSBE), *Ramularia beticola* (RAMUBE)

#### GAP claims:

Sugar beet (BEAVP), fodder beet (BEAVC): *Cercospora beticola* (CERCBE), *Uromyces betae* (UROMBE), *Erysiphe betae* (ERYSBE), *Ramularia beticola* (RAMUBE)

Application rate: 1.2-1.5 L/ha

Water volume: 150-300 L/ha

GF-3307 (S7K-3-3) is intended to be used twice per growing season within the crop growth stage ranging from BBCH 39 to 49.

#### CERCBE

Based on the efficacy data package from South-East EPPO zone, the use of GF-3307 (S7K-3-3) at recommended application rate range 1.2-1.5 L/ha in the control of *Cercospora beticola* on sugar beet, under conditions of use consistent with GAP may be granted. It is recommended to include in the product label remark about moderate level of efficacy of GF-3307 (S7K-3-3) applied at 1.2 L/ha and to use the target fungicide at lower dose rate under conditions of low diseases pressure.

As no efficacy data has been submitted for fodder beet the decision on acceptance this claimed use is to be taken at the national level, according to the national regarding possible extrapolation of efficacy data from sugar beet to fodder beet; using the extrapolation possibilities indicated in EPPO guidelines PP 1/257 (2) or PP 1/331 (1), depending on minor or major importance of beet cultivation in a given cMS. The zRMS is kindly asking the



cMS to not only take their decisions, but also to share the underlying information with the zRMS PL, within the commenting period framework.

#### UROMBE, ERYSB, RAMUBE

As no efficacy data has been submitted for sugar beet and fodder beet, the decision on acceptance uses: *Uromyces betae*, *Erysiphe betae*, *Ramularia beticola* on sugar beet and fodder beet is to be taken at the national level, according to the national requirements regarding possible extrapolation of efficacy data from Maritime EPPO zone; extrapolation of efficacy data from sugar beet to fodder beet; using the extrapolation possibilities indicated in EPPO guidelines PP 1/257 (2) or PP 1/331 (1), depending on minor or major importance of beet cultivation and target pathogens in a given cMS. The zRMS is kindly asking the cMS to not only take their decisions, but also to share the underlying information with the zRMS PL, within the commenting period framework.

**Summarizing the evaluation, the following uses have been accepted by the zRMS:**

#### Maritime EPPO zone (AT, BE, CZ, NL)

BEAVA: CERCBE, UROMBE, ERYSB, RAMUBE

#### North-East EPPO zone (PL)

BEAVA: CERCBE, RAMUBE

**BEAVA: ERYSB (possible authorization with further restrictions)**

#### South-East EPPO zone (HU, RO, SK)

BEAVA: CERCBE

**The following uses are have not been accepted by the zRMS:**

#### North-East EPPO zone (PL)

~~BEAVA: ERYSB~~

BEAVA: UROMBE (possible authorization on the grounds of article 51)

BEAVC: CERCBE, UROMBE, ERYSB, RAMUBE (possible authorization on the grounds of article 51)

**The following uses should be confirmed by cMSs:**

#### Maritime EPPO zone (AT, BE, CZ, NL)

BEAVC: CERCBE, UROMBE, ERYSB, RAMUBE

#### South-East EPPO zone (HU, RO, SK)

BEAVA: UROMBE, ERYSB, RAMUBE

BEAVC: CERCBE, UROMBE, ERYSB, RAMUBE

#### **General conclusion on yield and sugar content for all EPPO climatic zones**

Based on the results from 22 trials conducted across the Maritime, North-East, and South-East EPPO zones, it can be concluded, that GF-3307 (S7K-3-3) at the maximum recommended dose rate of 1.5 L/ha has no adverse effect on yield quantity. In none of the trials statistically significant differences in root yield were recorded between GF-3307 (S7K-3-3), and the reference products.

A positive effect on the yield was demonstrated as compared GF-3307 (S7K-3-3) at maximum recommended dose rate of 1.5 L/ha, with untreated control.

Sugar content was assessed in 20 out of the 22 trials. A significantly higher sugar content for GF-3307 (S7K-3-3), compared to the reference products (Score and Amistar Gold) was recorded in one trial conducted in France. In other trials no statistically significant differences in sugar content were recorded between GF-3307 (S7K-3-3), and the reference products. A positive effect on sugar content was demonstrated as compared GF-3307 (S7K-3-3) at maximum recommended dose rate of 1.5 L/ha, with untreated control.

Therefore, it can be concluded no negative impact on yield and sugar content is expected, when GF-3307 (S7K-3-3) is used in accordance with GAP recommendations.

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

#### Summary

GF-3307 (S7K-3-3) is a co-formulation containing 50 g/L of fenpicoxamid (DE-777) and 100 g/L of prothioconazole and is effective against diseases complex in sugar beet. This section follows the guidance laid out in EPPO Guideline PP1/213(4) in order to determine the resistance risk associated with the product and the target pathogen.

Fenpicoxamid is a fungicide with a mode of action belonging to the picolinamide class of chemistry with primary activity on ascomycete and basidiomycete pathogens. It is a potent inhibitor of fungal respiration acting via binding to the Quinone Inside (Qi) site of the cytochrome bc1 (ubiquinone reductase) complex (complex III) in the electron transport chain. Fenpicoxamid belongs to the FRAC resistance group 21, Mode of Action FRAC group C4#21.

Prothioconazole is a broad-spectrum synthetic fungicide of the triazolinthione family of compounds with curative, preventative and eradicated action. The biological mode of action of prothioconazole has been shown to be based on inhibition of the sterol biosynthesis pathway in fungi. At the target site level prothioconazole inhibits C-14 demethylase and belongs to the group of compounds collectively termed as De-Methylation Inhibitors (DMIs). The molecule is classified by FRAC in group 3 (G1, C-14 demethylase in sterol biosynthesis (erg11/cyp51)).

Studies indicated that fenpicoxamid is not cross-resistant with other fungicide classes, including DMI fungicides. Also, fungicides affecting ergosterol biosynthesis are not cross-resistant with fungicides inhibiting other biochemical target sites. On the other hand, for the purposes of effective resistance risk management it is prudent to consider that cross-resistance is present between DMI fungicides (including prothioconazole) active against the same target disease.

The first year of sensitivity baseline has been established in 2023 for fenpicoxamid on *Cercospora beticola*, using isolates from different European countries. A second year of baseline data is planned in 2024 and will be available to top up the baseline in Q2 2025.

The mode of action of GF-3307 (S7K-3-3) on target pathogens, as well as a recent history of resistance to DMI groups, suggests that the risk of development of resistance in high and medium-risk pathogens from unrestricted use is unacceptable and that measures must be taken to prevent or at least delay the risk of resistance developing. A resistance management strategy is proposed which relies on the use of tank mixtures, alternation with other fungicides with a different mode of action and limiting the number of GF-3307 (S7K-3-3) applications to two per season in sugar beet with a 21 day interval between applications which prevents sequential applications. The total number of Picolinamides based products (GF-3307 / S7K-3-3) applied should not exceed more than two in total and should not make up more than a third of the spray program and not applied in repetition. It is considered that with these modifiers in place the risk is reduced to an acceptable level in sugar beet crops as the reality is that European growers will typically apply 2 to 3 fungicide applications per season. In cereal crops a single application per season is recommended and is aligned with those published by the Fungicide Resistance Action Committee (FRAC).

#### Introduction

GF-3307 (S7K-3-3) is a co-formulation of 50g/L of fenpicoxamid + 100g/L of prothioconazole and will be registered for use against *Cercospora beticola*, *Uromyces betae*, *Erysiphe betae* and *Ramularia beticola* in sugar beet.

Fenpicoxamid has been combined with prothioconazole in order to build in resistance management by combination of two different modes of action (MOAs). This dossier section will mainly concentrate on analysis of resistance risk to fenpicoxamid since this will be a new active substance in sugar beet in Europe whereas prothioconazole and its associated resistance risk is well understood. The applicant also refers the assessing authority to data submitted in support of prothioconazole efficacy and resistance risk management by Bayer Crop Sciences to which Dow AgroSciences/Corteva Agriscience has been granted a letter of access.

Resistance to crop protection chemicals is a natural biological phenomenon that occurs in insects, weeds and fungi. It usually becomes evident after the repeated use of a particular pesticide selects the naturally-

occurring resistant strains within the wild population and allows them to multiply over several seasons until they become dominant in the population and pose a control problem.

The fungicide-resistant population develops because the sensitive population is suppressed and the rare fungicide-resistant individual is allowed to multiply and occupy the biological niche previously filled by the sensitive population. An increase in the frequency of such resistant strains may result in loss of disease control. As a general principle, resistance develops at different rates depending on the nature of the pathogen and its interactions with the crop, environment and fungicide.

Reports of the appearance of resistant strains in laboratory studies do not necessarily imply that any loss of control is expected in the field. Likewise, the appearance of less-sensitive strains in the field does not always result in failure of disease control. When the frequency of resistant individuals is low and/or the level of resistance is moderate, fungicide applications in most cases will provide satisfactory control.

To avoid the misinterpretation of potential resistance cases, the Fungicide Resistance Action Committee (FRAC) states that the term “resistance” be limited to situations where the conditions in both (a) and (b) below are met:

- (a) the development of resistance leads to failure of disease control under practical field conditions following application of a fungicide correctly and according to the label and
- (b) a demonstration that a loss of control is due to the presence of pathogenic strains with reduced fungicide sensitivity.

From a regulatory and product stewardship standpoint it is essential to evaluate the potential resistance risk posed by a product and to ensure that a practical and effective management strategy is put in place in order to mitigate against the potential risk. The resistance risk analysis for GF-3307 (S7K-3-3) presented within this section follows the requirements set out in EPPO Guideline PP1/213(2).

### **3.3.1 Mode of Action**

#### **Fenpicoxamid**

Fenpicoxamid when formulated as an EC formulation (as in GF-3307 / S7K-3-3) is a protectant and curative fungicide for control of a range of diseases. Fenpicoxamid is rapidly activated in the presence of fungi and inside 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 bc1 (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 sugar beet fungicide market and will be assigned to FRAC group C4#21.

The cytochrome bc1 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.

The MET III Qi site is quite distinct from the MET III Qo site with which the strobilurins interact, so that no cross-resistance of field isolates of *Cercospora beticola* and *Uromyces betae* resistant to strobilurin fungicides has been observed or would be anticipated.

#### **Prothioconazole**

Prothioconazole is a broad-spectrum synthetic fungicide produced by Bayer CropScience of the triazolinthione family of compounds with curative, preventative and eradicated action. The mode of action of prothioconazole is as a Sterol Biosynthesis Inhibitor (SBI) class 1 DeMethylation Inhibitors (DMI) and it is classified in FRAC group G1. It can be used as both a seed treatment and a foliar treatment. After absorption it moves into cells of the target organisms, effecting sterol biosynthesis and thereby disrupting membrane structure. This ultimately effects hyphal growth and germ tube elongation. Fungi susceptible to prothioconazole include diseases caused by ascomycetes, basidiomycetes and deuteromycetes. Prothioconazole is currently authorised across the EU for use on a range of cereal crops and in sugar beet. Prothioconazole is sold in combination with numerous other fungicides, including

bixafen, spiroxamine, tebuconazole, fluoxastrobin, trifloxystrobin and fluopyram. Prothioconazole is one of the strongest triazole fungicides used in crop protection. Although there have been some shifts in triazole sensitivity to a number of diseases in the last decade, prothioconazole is still highly effective against these diseases in many countries. Prothioconazole is especially beneficial in mixture with strong partners and brings as a mix partner, robust activity against a wide range of diseases where reduced sensitivity is not an issue for triazole fungicides.

### 3.3.2 Mechanism of Resistance and Evidence of Resistance

#### Individual active substance components of the combination - GF-3307 (S7K-3-3).

##### Prothioconazole

DMI fungicides are considered to have a medium risk of resistance development. Resistant isolates to DMI fungicides have been detected in *Cercospora beticola* (laboratory and field studies on sugar beet)<sup>15</sup>. The primary mechanism of resistance is the accumulation of several independent mutations in the target site. Each individual mutation typically causes only a small reduction in sensitivity, and it is not observed to impact efficacy under field conditions until multiple mutations accumulate in an isolate that are large enough to cause a reduction in sensitivity. Since the mid-1980's, reports of decreased levels of field efficacy have been attributed to reduced levels of sensitivity in target populations for DMI fungicides (Fletcher and Wolfe, 1981). Several studies have shown that shifts toward reduced sensitivity to DMI fungicides follow a quantitative or progressive pattern typical of changes controlled by several genes (Berg et al. 1990). Unlike benzimidazole and QoI fungicides for which the resistance is qualitative or disruptive (i.e. higher rates may not control resistant strains and field activity is lost), the development of less sensitive strains with DMI fungicides is quantitative or progressive. Higher rates can offset a slight decrease of activity.

Resistance development towards DMI fungicides (G1-3 / Sterol biosynthesis in membranes C14-demethylase in sterol biosynthesis (*erg11/cyp51*)) was observed for *Cercospora beticola* in sugar beet:

- In Austria in 2008 with a severe impact of resistance in the field. The mechanism of resistance detected is Target-site resistance (TSR) with a gene alteration CYP51;
- In Germany in 2015 with a minimal impact of resistance in the field. The mechanism of resistance detected is both TSR and NTSR.

Case of resistance found in Austria and Germany concerned the following active substances: Cyproconazole, Difenoconazole, Epoxiconazole, Propiconazole in Germany and Cyproconazole, Difenoconazole, Epoxiconazole, Tetraconazole in Austria<sup>16</sup>. Currently, prothioconazole is not concerned.

*Cercospora beticola* is the only foliar pathogen considered to be medium risk pathogens<sup>17</sup>.

##### Fenpicoxamid (DE-777)

As this is the first use of fenpicoxamid in sugar beet there is no evidence of resistance for fenpicoxamid/mode of action on European field populations of *Cercospora beticola*, *Uromyces betae*, *Erysiphe betae* and *Ramularia beticola*.

### 3.3.3 Cross Resistance

What is cross-resistance? Assessing patterns of cross resistance both between different fungicide classes as well as among members of the same class is an important element in the understanding of resistance risk and risk management. Cross resistance means a correlation in sensitivity within a group of inhibitors toward specific pest targets, while absence of cross-resistance indicates no correlation in sensitivity within the group. In the case of target site mutations that reduce sensitivity to specific inhibitors, if sensitivity to other inhibitors against the same target also is reduced, then those compounds exhibit positive cross resistance (or just “cross resistance”). In the case where reduced sensitivity to one inhibitor

<sup>15</sup> FRAC (2020), FRAC list of first confirmed cases of plant pathogenic organisms resistant to disease control agents

<sup>16</sup> [https://resistance.eppo.int/database/cases\\_list](https://resistance.eppo.int/database/cases_list)

<sup>17</sup> <https://www.frac.info/docs/default-source/publications/pathogen-risk/frac-pathogen-list-2019.pdf>

results in increased sensitivity to other inhibitors, however, those groups exhibit negative cross resistance. Confirmation of positive or negative cross-resistance depends only on the directions of sensitivity shifts and not on their magnitude. Identification of patterns of positive cross-resistance is important in resistance risk assessment because use of these fungicides together may represent increased selection pressure and a greater risk of resistance development and spread. Patterns of negative cross resistance, although rarer, also may be important since they may be used to reduce selection pressure and reduce the probability and rate of resistance development.

### **Prothioconazole**

Despite sharing a common target site cross resistance patterns between C-14 demethylase inhibitors are not necessarily straight forward due to the multiple mechanisms and polygenic nature of resistance as previously discussed. However, for the purposes of effective resistance risk management it is prudent to consider that cross resistance is present between DMI fungicides (including prothioconazole) active against the same fungal target. In common with other DMIs used in the cereal fungicide segment prothioconazole does not show target site based cross resistance to other key MOAs used in this market space - including QoIs, morpholines and Succinate Dehydrogenase Inhibitors (SDHIs).

### **Fenpicoxamid (DE-777)**

Since DE-777 does not have activity against oomycete pathogens whilst amisulbrom and cyazofamid are not active on sugar beet pathogens any potential cross resistance within the Qi inhibitor group is not considered relevant at this stage. Dow AgroSciences/Corteva Agriscience has however conducted laboratory testing to look for evidence of cross resistance between DE-777 and other key commercially important MOAs used in the cereal fungicide segment e.g. QoIs, DMIs and SDHIs. This work has been conducted in *Mycosphaerella graminicola* and was already described in detailed wheat dossier submitted to Poland /Queen (GF-3307 / S7K-3-3)) registration No R-140/2023. The conclusion of the study is described below.

### **Conclusions**

*In vitro* susceptibility testing of SEPTTR field strains showed no cross-resistance between fenpicoxamid/ DE-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. DE-777 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 DE-777 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.

Although no cross resistance testing was performed with DE-777 outside of CERCBE it is argued that these results can be extrapolated to sugar beet pathogens i.e. with the assumption that DE-777 has a different mode of action to fungicides currently used to control CERCBE and UROMBE and will be a potential resistance management partner for combinations with these other MOAs.

## **3.3.4 Sensitivity data – Sensitivity baseline for European *Cercospora beticola* population versus fenpicoxamid (DE-777) and prothioconazole**

Having fully entered the Label extension phase for sugar beet uses in 2022, work was initiated with Fenpicoxamid and prothioconazole to begin the process of establishing a pre-launch sensitivity baseline in 2023 (with a second year of sampling planned in 2024) for the molecules against *Cercospora beticola* (CERCBE). This is required as a component of the EU registration dossier application as well as a reference point for future sensitivity monitoring post launch. It was thought that two years of residue studies would be required but as there were no residues detected in 2023 samples and no need to set an EU MRL then the second year of residue studies in 2024 were not required. This meant the registration application could be made ahead of time, but with only one year of resistance baseline setting. The baseline for year one of testing already strong from 280 isolates of CERCBE from across Europe. At the European Level, the mean EC50 for fenpicoxamid was found to be 0.691 mg/L (Table 1) and the EC50 classes (Figure 1) show that 85% of the isolates tested exhibited EC50 values below 1 ppm, indicating a high sensitivity to fenpicoxamid for the isolates tested and high potency of the molecule on European CERCBE

populations. A second year of sampling in 2024 is planned across Europe for CERCBE that will be available in Q2 2025 and incorporated with the 2023 data to form a solid baseline for two years before the anticipated product launch in 2026.

## Methodology and analysis

### Sampling and pathogen isolation

*Cercospora beticola*-infected plant material (leaves) is taken from field sites in different EU sugar beet growing areas and sent to EpiLogic laboratories. Each sample includes several infected leaves bearing specific symptoms (small roundish grey leaf spots with reddish-brown edges and black dots on the inside) of the pathogen. At EpiLogic, the infected plant material is dried and stored at room temperature. The pathogen is isolated directly from the remoistened plant material by using a small sterile brush to transfer a conidium from the edge of one necrosis onto PDA (potato dextrose agar). After 5-6 days in an incubator (25 °C, darkness), followed by a further multiplication step on V8 agar (2 % agar, 15 % vegetable juice, 0,3 % CaCO<sub>3</sub>) using the same incubation conditions, isolates are ready to be used in sensitivity assays. The 250 isolates were taken from France, Germany, Austria, Belgium, Netherlands, Czech Republic, Poland, Romania, Spain, Italy and Hungary in 2023.

The total number of samples tested: 57 (54 from CORTEVA and 3 joint samples from Epillogic).

This number does not include the 3 CORTEVA samples (2 from Hungary and 1 from Poland) from which CERCBE isolates were unable to be obtained. The total number of isolates tested: 280 (265 from the CORTEVA sampling, 15 from the joint sampling program)

Origin (country) of samples tested:

- 2 samples (10 isolates) from Austria
- 1 sample (5 isolates) from Belgium
- 5 samples (23 isolates) from Czech Republic
- 13 samples (65 isolates) from Germany
- 2 samples (10 isolates) from Spain
- 8 samples (39 isolates) from France
- 5 samples (25 isolates) from Hungary
- 3 samples (15 isolates) from Italy
- 3 samples (15 isolates) from the Netherlands
- 10 samples (48 isolates) from Poland
- 5 samples (25 isolates) from Romania

### Analysis

The sensitivity of each single isolate is determined using a fungicide/nutrient broth dilution assay in 96-well microtiter plates (Pijls et al., 1994). The fungicide concentrations are graded logarithmically to obtain an accurate EC<sub>50</sub> and EC<sub>98</sub> evaluation. The different fungicide concentrations are prepared by diluting appropriate volumes of a stock solution of the respective active ingredient in sterile H<sub>2</sub>O demin. Pure, sterile H<sub>2</sub>O demin representing the untreated control and seven fungicide solutions containing double the amount of the final concentration are transferred with adjusted volumes of 50 µl/well into the 96-well plates by an automated pipette workstation.

Spore suspensions of the isolates are produced directly within the nutrient broth (yeast extract-peptone-glycerol solution) by diluting conidia from the respective culture in the broth. The number of spores in the solution is doubled to obtain the final conidial concentration of approx. 500 conidia/well. For blank samples, a conidia-free nutrient solution is added to each plate in separate wells.

After incubation in the climate chamber for six days (18 °C, darkness, 70 % RH), the adsorption (optical density) of mycelial growth is measured automatically in a 96-well plate photometer (wavelength:  $\lambda = 405$  nm). Dose-response of the test isolate at each fungicide concentration is assessed relative to the corresponding untreated control. EC<sub>50</sub> and EC<sub>98</sub> values are calculated from the assessed data of each isolate by Probit analysis (Weber, 1980). Besides the sensitivity of the test isolates from the different regions, the sensitivity of so-called standard isolates with an unselected 'wild type' sensitivity towards the active substance are determined. These isolates also serve as a control for the methods.

## Sensitivity towards fenpicoxamid

### Results

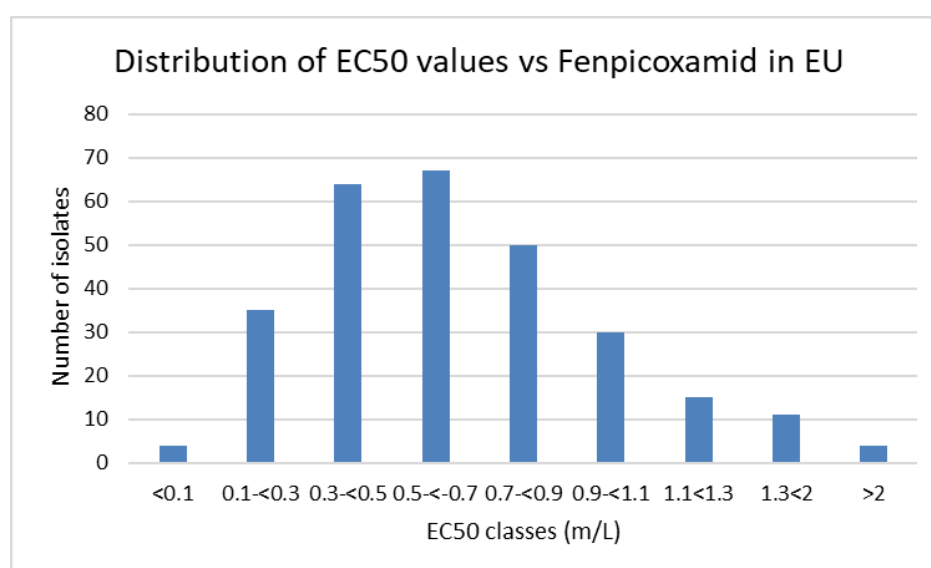
The data presented here has been generated in 2023. The applicant is currently generating data with samples collected in 2024 which will be being analysed in Q1 2025.

**Table 3.3.4-1: Summary of Mean EC50s (versus fenpicoxamid) by country of 2023 CERCBE samples**

Country	Arithmetic mean MEC50 (mg/L)	No. of isolates
Austria	0.512	10
Belgium	0.815	5
Czech Republic	0.653	23
Germany	0.649	65
Spain	0.954	10
France	0.645	39
Hungary	0.540	25
Italy	0.631	15
Netherlands	0.862	15
Poland	0.749	48
Romania	0.598	25
EU wide	0.691	280

**Table 3.3.4-2: Minimum and maximum EC50 values measured within countries for 2023 CERCBE samples (Diversity factor - Max EC50/Min EC50) for fenpicoxamid**

Year	No. (Isolates)	EC50min (mg/L)	EC50max (mg/L)	Diversity factor
Austria	10	0.112	0.95	8.48
Belgium	5	0.277	1.536	5.55
Czech Republic	23	0.15	1.97	13.13
Germany	65	0.063	1.654	26.25
Spain	10	0.41	2.16	5.27
France	39	0.042	2.286	54.43
Hungary	25	0.172	1.026	5.97
Italy	15	0.13	1.27	9.77
Netherlands	15	0.203	1.7	8.37
Poland	48	0.06	2.51	41.83
Romania	25	0.083	1.048	12.63
EU wide	280	0.15	1.64	17.43



**Figure 3.3.4 - 1 Sensitivity classes of CERCBE solates for fenpicoxamid**

## Sensitivity towards prothioconazole

The same methodology and field samples were used as for fenpicoxamid.

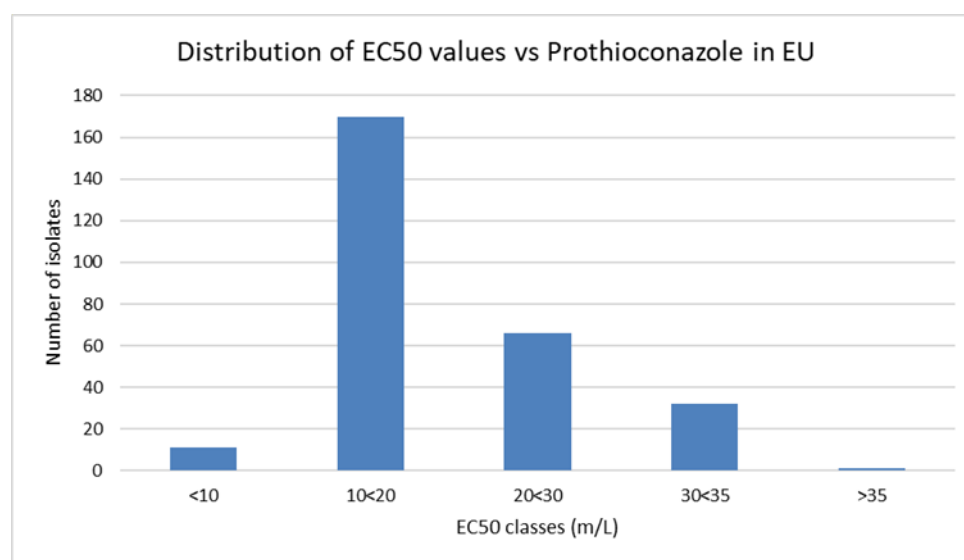
## Results

**Table 3.3.4-3: Summary of Mean EC50s (versus prothioconazole) by country of 2023 CERCBE samples**

Country	Arithmetic mean MEC50 (mg/L)	No. of isolates
Austria	17.2	10
Belgium	15.4	5
Czech Republic	20.5	23
Germany	20.4	65
Spain	19.5	10
France	20.4	39
Hungary	19.7	25
Italy	18.8	15
Netherlands	20.3	15
Poland	18.8	48
Romania	21.1	25
<b>EU wide</b>	<b>19.28</b>	<b>280</b>

**Table 3.3.4-4: Minimum and maximum EC50 values measured within countries for 2023 CERCBE samples (Diversity factor - Max EC50/Min EC50) for prothioconazole**

Year	No. (Isolates)	EC50min (mg/L)	EC50max (mg/L)	Diversity factor
Austria	10	11	28.1	2.55
Belgium	5	6.9	26.8	3.88
Czech Republic	23	11	19.4	1.76
Germany	65	6.5	33.4	5.14
Spain	10	10.8	30.2	2.80
France	39	10	31.5	3.15
Hungary	25	7.1	35.4	4.99
Italy	15	9.7	32.4	3.34
Netherlands	15	6	30.5	5.08
Poland	48	9.1	34.2	3.76
Romania	25	11	31.1	2.83
<b>EU wide</b>	<b>280</b>	<b>9</b>	<b>30.27</b>	<b>3.36</b>



**Figure 3.3.4 - 2 Sensitivity classes of CERCBE isolates for prothioconazole**

## Summary and Conclusions

In 2023, a bioassay was conducted to test the sensitivity to fenpicoxamid of 280 isolates collected from 57 European regions of 11 countries (Listed on Tables 1-4). The results generated are very consistent and show very good performance of fenpicoxamid for controlling the CERCBE strains tested.



At the European Level, the mean EC50 was found to be 0.691 mg/L (Table 1) and the EC50 classes (Figure 1) show that 85% of the isolates tested exhibited EC50 values below 1 ppm, indicating a high sensitivity to fenpicoxamid for the isolates tested and high potency of the molecule on European CERBCE populations. The same populations and strains were tested for their sensitivity to prothioconazole, a mixing partner that can potentially help to manage resistance to fenpicoxamid. In Europe, the CERBCE populations exhibited a mean EC50 of 19.28 mg/L for prothioconazole (Table 3). The difference observed with the mean EC50 observed for fenpicoxamid is related to the mode of action and the less intrinsic activity associated with azole fungicides. The highest diversity factor (at country level) was found to be below 6, showing that the European CERBCE populations are sensitive to prothioconazole. Multiple FRAC member companies have been monitoring the sensitivity of European CERBCE populations to azole fungicides since many years and found a stable sensitivity situation in Europe (<https://www.frac.info/frac-teams/working-groups/sbi-fungicides/recommendations-for-sbi>).

The overall data generated show that fenpicoxamid and prothioconazole are very effective for controlling EU populations of CERBCE. Therefore, combining the two molecules can provide a very good solution for controlling this fungal pathogen and protect sugarbeet crops.

### 3.3.5 Use pattern

The proposed use of GF-3307 (S7K-3-3) on sugar beet is for maximum two applications at a maximum rate of 1.5 L/ha in Great Britain and Northern Ireland (75 g fenpicoxamid/ha + 150 g prothioconazole/ha), applied between BBCH 39-49 of the crop. The maximum number applications containing of picolinamide products should not exceed more than two in total and should not make up more than one third of the spray program and not applied in repetition/blocks with a minimum 21 days between applications.

### 3.3.6 Resistance risk associated with unrestricted use pattern

In order to assess the risk of practical resistance in the target pests, it is necessary to evaluate the different factors contributing to the risk. The inherent risk depends on various factors, some of which are associated with the pest and others with the product. These factors do not necessarily operate in isolation and do not apply in all cases. Local growing conditions also can play an important role and should be considered. These are usually referred to as the agronomic risk. The actual risk of evolution of resistance to a fungicide depends on three main parameters.

#### Mechanism of resistance against the compound (intrinsic fungicide risk)

##### Fenpicoxamid DE-777

Fenpicoxamid (DE-777) is a single site inhibitor at the QiI site.

FRAC has published the following specific guidance on resistance risk for fenpicoxamid (Group 21 (C4) fenpicoxamid (QiI) Recommendations 12<sup>th</sup> February 2021)<sup>18</sup> and will be amended in the future to include sugar beet.

“Field resistance not currently known to this molecule. Resistance risk unknown but assumed to be medium to high risk. Resistance management required.”

There are to date no reports of field resistance to QiI inhibitors in sugar beet pathogens as would be expected since this MOA is not currently commercialised in this segment and no other current MOA used in sugar beet would be expected to have target site based cross resistance to Fenpicoxamid (DE-777). It is not known if the mutations generated in yeast and SEPTTR *in vitro* which confer reduced sensitivity to QiI inhibitors will also occur in CERCBE, UROMBE, ERYSB and RAMUBE and furthermore if they would appear and persist in the field population. 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.

**Consequently, the resistance risk development to fenpicoxamid is considered as (inherent risk of pathogen + inherent risk of substance):**

---

<sup>18</sup> <https://www.frac.info/fungicide-resistance-management/by-frac-working-group-expert-forum>

- medium for *Cercospora beticola* (CERCBE), *Uromyces betae* (UROMBE), *Erysiphe betae* (ERYSB) and *Ramularia beticola* (RAMUBE).

### Prothioconazole

Available information on mode of action and resistance risk with the triazole class of inhibitors is probably the most complete of any fungicide group. Numerous publications are available on the mechanisms functioning with respect to DMI resistance. The most significant of these mechanisms is based on the accumulation of different mutations within the Cyp51 locus. Multiple different Cyp51 mutations have been identified and it is now clear that the different mutations and combinations of mutations have varying impacts on the efficacy of different triazoles. Although prothioconazole is a DMI it will be a new introduction to sugar beet with good efficacy alone (as shown in the preliminary mixture studies) with a different cross resistance spectrum compared to Fenpicoxamid.

The resistance risk of DMI fungicides including prothioconazole is classified by FRAC as medium. Resistance management for prothioconazole in sugar beet is coordinated as for all DMIs by the FRAC SBI working group of which the applicant is an active member. FRAC SBI Working Group Minutes of the 2023 meeting 20th of April 2023 –Recommendations for 2023<sup>19</sup>.

### Consequently, the resistance risk development to prothioconazole is considered as (inherent risk of pathogen + inherent risk of substance):

- medium for *Cercospora beticola* (CERCBE), *Uromyces betae* (UROMBE), *Erysiphe betae* (ERYSB) and *Ramularia beticola* (RAMUBE).

All the recommendations of the group are applied for prothioconazole and will be covered by the proposed use pattern for GF-3307 (S7K-3-3). The applicant also refers the assessing authority to data previously submitted in support of prothioconazole efficacy and resistance risk management by Bayer Crop Sciences to which Dow AgroSciences/Corteva Agriscience has been granted a letter of access .

### Biology of the pathogen (pathogen risk)

No scientific criteria are available to accurately determine the risk of a pathogen to develop resistance. Thus, FRAC's classification is based on experience and reported resistance claims over the last 45 years. Generally, the risk increases when a pathogen undergoes many and short disease cycles per season, the dispersal through spores over time and space is high, sexual recombination is mandatory in the disease cycle and the competitive ability of resistant individual is at least as high as that of the wild type (in the absence of selection pressure). Pathogens with shorter life cycles generally require more frequent fungicide application resulting in greater selection pressure and more rapid resistance development. Pathogens producing more spores have higher potential for resistance development due to more genetic diversity available for selection as well as more rapid and extensive dispersal of resistant isolates. Pathogens with sexual stages will have a different resistance risk compared to strictly asexual organisms. Finally, pathogens in isolated populations will have higher resistance risk due to limited genetic variability.

*Cercospora beticola* is viewed by FRAC as having a medium risk of resistance development and *Uromyces betae*, *Erysiphe betae* and *Ramularia beticola* as low risk of resistance development<sup>20</sup>.

### Agronomical factors (agronomic risk)

Agronomic factors comprising effects of locally variable factors such as disease pressure, climate, or complexity of cultivars are most important in assessing the risk (Kuck, 2005). Resistance is more likely to develop first in areas of intensive cropping and fungicide use that are, as a result, areas of severe disease outbreaks because environmental conditions favoured the development and spread of the disease. 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 sugar beet diseases, however fungicides remain the key component of strategies to manage this disease effectively. In the most intensive sugar beet growing regions of Europe and particularly in seasons where weather

---

<sup>19</sup> <https://www.frac.info/frac-teams/working-groups/sbi-fungicides/recommendations-for-sbi>

<sup>20</sup> [https://www.frac.info/docs/default-source/publications/pathogen-risk/frac-pathogen-list-2019.pdf?sfvrsn=caf3489a\\_2](https://www.frac.info/docs/default-source/publications/pathogen-risk/frac-pathogen-list-2019.pdf?sfvrsn=caf3489a_2)

conditions are favourable for build-up of high pressure up to four sprays per sugar beet crop may be applied for CERCBE, UROMBE, ERYSBЕ and RAMUBE control.

### Combined resistance risk

Overall, considering the above parameters (both active substances being medium risk, the pathogen being low to medium risk and depending on the agronomic risk), the combined risk ranges from 1-4 (see Figure 3.3.6 - 1 from FRAC Pathogen Risk List<sup>21</sup>). It can therefore be considered that the overall resistance risk for GF-3307 (S7K-3-3) used alone within an unrestricted use pattern scenario is low to medium, in relation with CERCBE, UROMBE, ERYSBЕ and RAMUBE. In high risk agronomic situation (short rotations for sugar beet crops, other susceptible crops in the rotation, susceptible varieties, etc.), the resistance risk would be medium (4-8). In other lower risk situations (long rotations, resistant varieties, etc.) the risk would be low (1-2).

**Figure 3.3.6 - 1 Combined resistance risk diagram based on inherent fungicide risk, inherent pathogen risk, and agronomic risk**

↓Fungicide Classes	↓Fungicide Risk	Combined Risk			↓Agronomic Risk
benzimidazoles dicarboximides phenylamides QoI fungicides SDHI fungicides** SBI fungicides anilinopyrimidines phenylpyrroles	high = 6	6 3 1.5	12 6 3	18 9 4.5	high = 1 medium = 0.5 low = 0.25
multi site fungicides (e.g. dithiocarbamates) MBI-R inhibitors SAR inducers	low = 1	1 0.5 0.25	2 1 0.5	3 1.5 0.75	high = 1 medium = 0.5 low = 0.25
Pathogen risk →		low = 1	medium = 2	high = 3	
Pathogen groups * →		<i>Uromyces betae</i> (UROMBE) <i>Erysiphe betae</i> (ERYSBЕ) <i>Ramularia beticola</i> (RAMUBE)	<i>Cercospora beticola</i> (CERCBE)	-	

\*only most important classes and groups mentioned, \*\* medium to high risk

### 3.3.7 Test methods.

See ‘Sensitivity data’ section (3.3.5).

### 3.3.8 Acceptability of the resistance risk

The risk of development of resistance in populations of *Cercospora beticola*, *Uromyces betae*, *Erysiphe betae* and *Ramularia beticola* from unrestricted use is considered low to medium. As there is a potential of resistance developing over time, it is considered that unmodified use is not recommended and a management strategy is required to ensure the risk from use of GF-3307 (S7K-3-3) is acceptable.

### 3.3.9 Management Strategy for GF-3307 (S7K-3-3)

GF-3307 (S7K-3-3) will provide crop growers with a valuable new resistance management option for CERCBE, UROMBE, ERYSBЕ and RAMUBE control in sugar beet. Because fenpicoxamid and prothioconazole do not share the same mode of action, the mixture represents a valid resistance management practice for the control of diseases complex of sugar beet. Given the history of resistance associated with DMI fungicides, we propose that the following modifiers be applied to the product use

<sup>21</sup> [https://www.frac.info/docs/default-source/publications/pathogen-risk/frac-pathogen-list-2019.pdf?sfvrsn=caf3489a\\_2](https://www.frac.info/docs/default-source/publications/pathogen-risk/frac-pathogen-list-2019.pdf?sfvrsn=caf3489a_2)

pattern in order to reduce the potential risk of resistance. The Management strategy presented below is to represent all picolinamide products including GF-3307 (S7K-3-3) (fenpicoxamid\_prothioconazole):

- In order to manage resistance risk, picolinamides containing fungicides such as GF-3307 (S7K-3-3) should be used under protectant conditions (preventatively) before the disease is established in the crop
- Application: maximum of 2 applications of GF-3307 (S7K-3-3) per season to sugar beet at a maximum dose of 1.5 L/ha, In Poland, Slovakia, Hungary and Romania a dose range is proposed from 1.2-1.5 l/ha with the lower dose proposed under lower disease pressure situations. No consecutive applications of fenpicoxamid based products are allowed in sugar beet crops. Do not exceed a maximum of 33% of total sprays (one third of spray program) whichever is lower. For best practice, Corteva recommends a maximum of one fenpicoxamid based product spray in sugar beet per season to manage resistance.
- Picolinamide fungicides must be integrated into a robust spray program in strict alternation with fungicides from a different cross-resistance group providing effective control of the target disease
- Use picolinamides as part of an Integrated Crop Management (ICM) strategy incorporating other methods of control.
- Strongly reduced rate programs including multiple 'split' applications must not be used.
- Always follow product specific label recommendations for resistance management.

Resistance management of fenpicoxamid, prothioconazole and the mixtures of both should align with that of the picolinamide and DMI fungicides as specified by the Fungicide Resistance Action Committee (FRAC).

The above recommendations are based on the combinations of different strategies i.e. mixtures, alternation, restricted number of applications, preventive use and chemical diversity. This integrated approach is supported by FRAC as described in the FRAC Monograph No. 1. The FRAC guidelines are available on the internet (<http://www.frac.info>) and are available to plant protection advisors in European countries. The GF-3307 (S7K-3-3) label includes a statement reflecting the above guidelines for the control of sugar beet diseases.

The applicant also undertakes to actively promote the resistance management plan, via product literature and during product technical presentations with customers and growers.

### **3.3.10 Implementation of the Management Strategy**

There are a number of steps in the implementation of the resistance management strategy, ultimately based on methods of communication with the grower, either directly or indirectly. Proposals are outlined below:

1. An internal training program of sales and development representatives prior to and during the launch of GF-3307 (S7K-3-3) in sugar beet will be organized with emphasis on resistance management. Educational material on resistance and resistance management will be presented at launch meetings with customers.
2. The principles of good plant protection practice will be promoted both during training sessions and within commercial advisory literature. These include the use of both cultural and chemical control measures and recommendations to ensure that fungicide application is made under favourable environmental conditions.
3. The use of GF-3307 (S7K-3-3) in program with differing modes of action either in tank-mix or in sequence will be promoted within training meetings and on all commercial support literature.
4. The statements / modifiers relating to resistance management presented in the preceding sections will appear on the label. Study of the label is recommended prior to the use of the product.
5. Two application per season of GF-3307 (S7K-3-3) with 21 days between applications. No consecutive applications.
6. For resistance management, apply a maximum of 33% of total sprays (one third of spray program) whichever is lower.

The applicant will also undertake to actively promote the resistance management plan, via product literature and during product technical presentations with customers and growers. The fenpicoxamid

and prothioconazole resistance management strategies are communicated on the FRAC website (Working Group #21 “QiIs” and Working Group #3 “SBI-Fungicides”, respectively) and in the form of technical publications in appropriate journals or conferences.

### 3.3.11 Monitoring, reporting and reaction to the changes in performance

The applicant is an active member of FRAC and would anticipate joining the FRAC QiI sugar beet task force group once fenpicoxamid (DE-777) is commercialised. Monitoring of the sensitivity of the EU CERCBE populations to fenpicoxamid (DE-777) and prothioconazole 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 the applicant to rapidly adapt the resistance management strategy should the need arise.

#### Conclusion

The active substances of GF-3307 (S7K-3-3) (fenpicoxamid at 50 g/L and prothioconazole at 100 g/L), are a pre-mixture of non-cross resistant fungicides effective against foliar diseases in sugar beet.

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 and help farmers and advisors to make a better diagnosis after a control failure with any of its products.

If this should occur, the applicant will be able to provide sound recommendations in terms of chemical control and agronomic practices to come back to a manageable situation.

#### Comments of zRMS on:

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

GF-3307 (S7K-3-3) contains a mixture of two active substances:

- fenpicoxamid (chemical group: picolinamides, group name: QiI-fungicides (Quinone inside Inhibitors), FRAC group code: 21),
- prothioconazole (chemical group: triazolinthiones, group name: DMI-fungicides (DeMethylation Inhibitors), SBI: Class I; FRAC group code: 3).

According to FRAC, the resistance risk for QiI-fungicides is classified as medium to high, depending on the pathogen, while the risk for DMI-fungicides is considered medium.

A mixture of two active substances with various modes of action (MoA): fenpicoxamid, which inhibits mitochondrial respiration and prothioconazole, which blocks ergosterol biosynthesis, is an effective tool in resistance management strategies.

Fenpicoxamid is a relatively new active substance within the QiI group of fungicides, which was authorized for marketing and sale in the European Union in 2019. It is a picolinamide fungicide, that inhibits fungal respiration, acting via binding to the Quinone Inside (Qi) site of the cytochrome bc1 (ubiquinone reductase) complex in the electron transport chain. This MoA leads to energy depletion and cell death.

The MoA of prothioconazole, involves the inhibition of ergosterol biosynthesis by blocking the enzyme C14-demethylase, which plays a key role in the sterol biosynthetic pathway.

Although fenpicoxamid does not represent a novel MoA, it is the first QiI fungicide to demonstrate effective activity against both *Ascomycete* and *Basidiomycete* fungi in row crops (such as cereals, oilseeds, and sugar beet), as well as in bananas, ornamentals, and various fruit and vegetable crops, while exhibiting no activity against *Oomycete* pathogens.

According to the FRAC Pathogen Risk List (revised in September 2019), *Cercospora beticola* is defined as medium risk of resistance pathogen and *Uromyces* spp. as low risk of resistance pathogen. For *Erysiphe betae* and *Ramularia beticola* risk of resistance is not defined by FRAC. The combined (pathogen x product) inherent resistance risk of the target pathogens is considered medium, while the overall risk of resistance regarding additionally agronomic risk has been defined as low to medium.

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

- for DMIs, for sugar beet/*Cercospora beticola*, in 2022 monitoring was carried out in Austria, Croatia, Czech Republic, France, Germany, Greece, Hungary, Italy, Lithuania, Poland, Romania, Spain, Switzerland, and the United Kingdom. European populations of *C. beticola* showed a stable sensitivity range, as in the previous years.

Only in 2019, FRAC reported that single isolates with increased EC50 values had previously been detected in France and Germany but their frequency remained stable and low.

FRAC List of first confirmed cases of plant pathogenic organisms resistant to disease control agents (revised in May 2020) includes cases of resistance of *Cercospora beticola* on sugar beet to DMI fungicides. To date, FRAC has not documented any cases of resistance in *Uromyces betae*, *Erysiphe betae*, or *Ramularia beticola* to demethylation inhibitor (DMI) or quinone inside inhibitor (QiI) fungicides.

The applicant provided information on the monitoring of sensitivity in key target sugar beet pathogen, *Cercospora beticola*, to fenpicoxamid and prothioconazole. This monitoring began in 2023 and continued into 2024. The applicant focused primarily on the resistance risk assessment for fenpicoxamid, as it is a new active substance in sugar beet cultivation in Europe, whereas prothioconazole and its associated resistance risk are already well characterised. Based on the 2023 data, sensitivity results for fenpicoxamid and prothioconazole from 280 isolates collected across 57 regions in 11 European countries demonstrated that both active substances remain highly effective against *C. beticola* populations in the EU.

No cross-resistance between DMI fungicides and QiI fungicides has been reported to date, as they target different biochemical pathways in fungal pathogens.

Field and laboratory studies (including those provided by the applicant) have not confirmed any documented cases of cross-resistance between these two classes of fungicides, which supports their use in complementary resistance management strategies.

In summary, the applicant concluded, that a mixture of two active substances with different MoA provides an effective solution for controlling this fungal pathogen and contributes to the protection of sugar beet crops.

Based on the submitted data, in order to prevent the potential development of resistance, the following resistance management strategy (concerning both cereals and the currently claimed sugar beet and fodder beet), is recommended for GF-3307 (S7K-3-3):

- The product GF-3307 (S7K-3-3) should be used in accordance with the principles of Good Plant Protection Practice and Integrated Pest Management (IPM), including the alternation use of fungicides containing active substances from different FRAC groups, i.e. with various modes of action (MoA), applied at recommended dose rates, that ensure effective control of the target pathogens,
- Whenever possible, the fungicide GF-3307 (S7K-3-3) should be applied in tank mixtures with fungicides containing active substances with different modes of action, than prothioconazole and fenpicoxamid (INATREQ™). In such cases, the instructions for use provided on the labels of all components of the tank mixture must be strictly followed,
- Apply the product mainly preventively, in accordance with the recommended dose rates and timing of application as specified on the product label,
- GF-3307 (S7K-3-3) shall be used exclusively for the control of the fungal diseases specified on the product label,
- Do not exceed the maximum number of GF-3307 (S7K-3-3) applications permitted per growing season, as specified on the product label,
- Use non-chemical control measures for the management of fungal diseases in cereals, sugar beet, and fodder beet, in accordance with the principles of, including the cultivation of disease-resistant or less susceptible varieties.
- Regular check the most recent FRAC resistance management recommendations for fungicides intended for use cereals, sugar beet, and fodder beet.

The cMSs are kindly encouraged to adopt or adjust the wording, according to their local circumstances and 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-3307 (S7K-3-3) up to 1.5 L/ha, on sugar beet (see section 3.4.1.1) and yield results from these trials demonstrated no adverse effects in the presence of diseases (see section 3.2.3).

In line with EPPO PP 1/135(4) 'Phytotoxicity Assessment', no specific crop safety/selectivity trials to assess adverse effects on treated crops (yield and quality) are included in this dossier, as they are not required to support a fungicide product where no adverse effects have been reported in the effectiveness trials.

### 3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

#### Introduction

Data presented in this section covers phytotoxicity from 56 efficacy trials conducted to evaluate the effectiveness of GF-3307 (S7K-3-3) at 1.5 L/ha. The crops involved in the testing were all sugar beet (BEAVA). An overview of the crop tolerance data using GF-3307 (S7K-3-3) is presented in Table 3.4-1.

**Table 3.4-1: Sugar beet crop tolerance of GF-3307 (S7K-3-3) found in efficacy trials**

Trial type	Crop	GF-3307 (S7K-3-3) 1N rate	Number of GEP trials	Maximum phytotoxicity recorded during the trials
Efficacy	BEAVA	1N	56	0

#### 3.4.1.1 Phytotoxicity in efficacy trials to sugar beet (BEAVA)

#### Introduction

In total, 56 trials were carried out on sugar beet (BEAVA) to evaluate the efficacy of GF-3307 (S7K-3-3), applied at maximum rate of 1.5 L/ha against CERCBE, UROMBE, ERYSB and RAMUBE.

All trials were conducted according to GEP and were of a 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 35-49.

The trials were conducted in Austria (1), Czech Republic (1), Denmark (6), France (8), Germany (15) and The United-Kingdom (7) in the EPPO Maritime climatic zone, in Lithuania (2) and Poland (6) in EPPO Northeast climatic zone and in Hungary (6) and Romania (4) in EPPO Southeast climatic zone and are representative of the proposed GAP between 2020 and 2023.

#### Results

No phytotoxicity symptoms were seen at any point, using GF-3307 (S7K-3-3) at dose rates up to 1.5 L/ha (1N) or using the commercial standards, in any of the 56 efficacy trials carried out in sugar beet (BEAVA) across a wide range of varieties (40 39). These results are summarised in Table 3.4-2.

**Table 3.4-2: Maximum phytotoxicity on sugar beet recorded for the duration of the effectiveness trials in treatments with GF-3307 (S7K-3-3) and the reference standards.**

Number of trials with...		GF-3307 (S7K-3-3) 1N	Reference standards
Maximum of phytotoxicity recorded during the trials	0%	56	56
	>0 - 4.9%	0	0
	5 - 9.9%	0	0
	10 - 14.9%	0	0
	15% and more	0	0
Level of symptoms at the last assessments	0%	56	56
	>0 - 4.9%	0	0
	5 - 9.9%	0	0
	10 - 14.9%	0	0
	15% and more	0	0

The potential impact of variety on the occurrence of phytotoxicity was tested on 40 39 different varieties of sugar beet (Table 3.4-3).

**Table 3.4-3: Phytotoxicity assessments of GF-3307 (S7K-3-3) - Varieties tested in efficacy trials**

Crop (EPPO)	No of trials	No of varieties	Variety names (No of trials)
Sugar beet (BEAVA)	56	40 39	Annabella (2), Annarosa (2), Antineea (1), Aries (1), Asketa (3), Balaton (1), Belamia (1), Briga (1), BTS 3865 (1), BTS1140 (1), Calledia (4), Camelia (2), Clemens (1), Danicia (1), Darvas (1), Eldorana (2), Falster (1), Florentina (1), Jamon (1), Katjana (1), Libellule (2), Lombok (1), Lunella (2), Marley (1), Marynia (2), Morgan (1), Nakskov (2), Nasser (1), Pasteur (1), Pavo (1), Racoon (2), Rossada (1 2), Sixtus (1), Smart Latoria KWS (1), Smart Mondeo (1), Smart Sanya (1), Stingray (1), Surf (1), Traper (2), Wren (2)

Therefore, no unacceptable phytotoxicity symptom is expected on sugar beet if GF-3307 (S7K-3-3) is used according to the Good Agricultural Practices and label recommendations.

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

GF-3307 (S7K-3-3) applied once or twice, at recommended maximum dose rate of 1.5 L/ha caused no phytotoxicity symptoms in any of 56 efficacy trials carried out on sugar beet.

As no phytotoxicity symptoms were observed in the presented trials, it can be concluded, that GF-3307 (S7K-3-3), applied in accordance with GAP, can be safely used on sugar beet.

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

In line with EPPO PP 1/135(4) '*Phytotoxicity Assessment*', no specific crop safety/selectivity trials to assess adverse effects on treated crops (yield) are included in this dossier, as they are not required to support a fungicide product, where no adverse effects have been reported in the effectiveness trials. All 56 efficacy trials reported no phytotoxicity or adverse effects to treated crops at dose rates up to 1.5 L/ha GF-3307 (S7K-3-3), (see section 3.4.1.1) and yield results from these trials demonstrated no adverse effects on sugar beet yields, in the presence of disease (see section 3.2.3).

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

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

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

In line with EPPO PP 1/135(4) '*Phytotoxicity Assessment*', no specific crop safety/selectivity trials to assess adverse effects on treated crops (quality) are included in this dossier, as they are not required to support a fungicide product, where no adverse effects have been reported in the effectiveness trials. The possible impact of GF-3307 (S7K-3-3) on the quality was studied in 16 harvested efficacy trials in disease presence. All trials were carried out by testing facilities officially recognised according to Good Experimental Practice (GEP).

In this part, the objective is to compare the possible adverse effect on the quality of the root. Different quality parameters (sodium content, potassium content and amino content) were measured in percentage or mmol/1000g.

All quality parameter results are summarised in Table 3.4-4 (Maritime EPPO climatic zone), Table 3.4-5 (Northeast EPPO climatic zone), Table 3.4-6 (Southeast EPPO climatic zone) and Table 3.4-7 (All EPPO climatic zones).

Overall, no adverse effect on different quality parameters (sodium content, potassium content and amino content) was noted after the applications of GF-3307 (S7K-3-3) applied at 1.5 L/ha. Moreover, across the 16 trials, no significant difference was noted with the reference standard SCORE in 9 trials for sodium, in 10 trials for potassium, in 9 trials for amino-nitrogen content, with the reference standard AMISTAR GOLD in 10 trials for sodium, in 11 trials for potassium, in 12 trials for amino-nitrogen content or SPYRALE in 2 trials for sodium, in 3 trials for potassium, in 3 trials for amino-nitrogen content.

Therefore, no adverse effect on the quality of sugar beet is expected if GF-3307 (S7K-3-3) is applied at the maximum requested rate of 1.5 L/ha according to the Good Agricultural Practices and label recommendations.



**Table 3.4-4: Impact of GF-3307 (S7K-3-3) on the quality parameters when applied at 1.5 L/ha for the control of foliar diseases in EPPO Maritime climatic zone, efficacy trials in sugar beet**

Parameters	Unit	EPPO climatic zone	No. of trials	Untreated			Percentage of Untreated control (%)																No. of assessments significantly > , = , < GF-3307 (S7K-3-3) (1.5 L/ha) vs.	
							GF-3307 (S7K-3-3) 1.5 L/ha				SCORE 0.4 L/ha				AMISTAR GOLD 1.0 L/ha				SPYRALE 1.0 L/ha					
							Fenpicoxamid + Prothioconazole				Difenoconazole				Azoxystrobin + Difenoconazole				Difenoconazole + Fenpropidin					
				75+150 g a.s./ha				100 g a.s./ha				125 +125 g a.s./ha				100+375 g a.s./ha								
				Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Reference products	Untreated
Sodium content	Mmol / 1000 g	Maritime	6	4.5	3.0	6.8	10.3	3.5	40.0	13.3	8.7	2.6	30.0	9.6	-	-	-	-	-	-	-	0> ; 6= ; 0<	1> ; 4= ; 1<	
			6	4.5	3.0	6.8	10.3	3.5	40.0	13.3	-	-	-	-	8.6	3.0	30.0	9.6	-	-	-	-	0> ; 6= ; 0<	1> ; 4= ; 1<
	%	Maritime	3	0.5	0.4	0.5	0.3	0.3	0.4	0.1	0.4	0.3	0.5	0.1	-	-	-	-	-	-	-	0> ; 0= ; 1<	0> ; 0= ; 1<	
			3	0.5	0.4	0.5	0.3	0.3	0.4	0.1	-	-	-	-	-	-	-	-	0.4	0.3	0.5	0.1	0> ; 0= ; 1<	0> ; 0= ; 1<
Potassium content	Mmol / 1000 g	Maritime	6	39.9	29.2	62.1	42.6	30.6	66.8	12.3	42.1	30.1	61.4	10.4	-	-	-	-	-	-	-	0> ; 6= ; 0<	1> ; 5= ; 0<	
			6	39.9	29.2	62.1	42.6	30.6	66.8	12.3	-	-	-	-	42.1	29.6	61.7	10.7	-	-	-	-	0> ; 6= ; 0<	1> ; 5= ; 0<
	%	Maritime	3	4.0	3.2	4.8	4.1	3.3	4.6	0.6	4.2	3.3	4.6	0.6	-	-	-	-	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			3	4.0	3.2	4.8	4.1	3.3	4.6	0.6	-	-	-	-	-	-	-	-	4.0	3.3	4.7	0.6	0> ; 1= ; 0<	0> ; 1= ; 0<
Amino nitrogen content	Mmol / 1000 g	Maritime	6	12.8	4.4	20.0	13.4	3.0	29.0	9.6	12.8	2.6	22.2	8.1	-	-	-	-	-	-	-	1> ; 5= ; 0<	0> ; 5= ; 1<	
			6	12.8	4.4	20.0	13.4	3.0	29.0	9.6	-	-	-	-	12.5	2.5	21.7	8.2	-	-	-	-	0> ; 6= ; 0<	0> ; 5= ; 1<
	%	Maritime	3	1.6	0.6	2.2	1.3	0.6	2.0	0.6	1.5	0.7	2.0	0.6	-	-	-	-	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			3	1.6	0.6	2.2	1.3	0.6	2.0	0.6	-	-	-	-	-	-	-	-	1.7	0.6	2.5	0.8	0> ; 1= ; 0<	0> ; 1= ; 0<
			1	0.6	-	-	0.6	-	-	-	-	-	-	-	0.6	-	-	-	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	

**Table 3.4-5: Impact of GF-3307 (S7K-3-3) on the quality parameters when applied at 1.5 L/ha for the control of foliar diseases in EPP0 Northeast climatic zone, efficacy trials in sugar beet**

Parameters	Unit	EPPO climatic zone	No. of trials	Untreated			Percentage of Untreated control (%)																No. of assessments significantly > , = , < GF-3307 (S7K-3-3) (1.5 L/ha) vs.		
							GF-3307 (S7K-3-3) 1.5 L/ha					SCORE 0.4 L/ha				AMISTAR GOLD 1.0 L/ha				SPYRALE 1.0 L/ha					
							Fenpicoxamid + Prothioconazole					Difenoconazole				Azoxystrobin + Difenoconazole				Difenoconazole + Fenpropidin					
							75+150 g a.s./ha					100 g a.s./ha				125 +125 g a.s./ha				100+375 g a.s./ha					
				Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Reference products	Untreated	
Sodium content	Mmol / 1000 g	Northeast	3	6.8	5.5	7.9	6.3	5.5	7.1	0.7	6.8	5.4	8.1	1.1	-	-	-	-	-	-	-	0> ; 3= ; 0<	0> ; 3= ; 0<		
			2	6.2	5.5	7.0	6.0	5.5	6.4	0.5	-	-	-	-	6.4	5.5	7.3	0.9	-	-	-	-	0> ; 2= ; 0<	0> ; 2= ; 0<	
			2	6.2	5.5	7.0	6.0	5.5	6.4	0.5	-	-	-	-	-	-	-	-	6.4	5.6	7.2	0.8	0> ; 2= ; 0<	0> ; 2= ; 0<	
		Northeast and border countries (PL-CZ-DE)	6	5.4	3.0	7.9	11.4	4.3	40.0	12.9	9.9	4.3	30.0	9.1	-	-	-	-	-	-	-	0> ; 6= ; 0<	0> ; 6= ; 0<		
			5	4.9	3.0	7.0	12.2	4.3	40.0	13.9	-	-	-	-	10.3	3.9	30.0	9.9	-	-	-	-	0> ; 5= ; 0<	0> ; 5= ; 0<	
			2	6.2	5.5	7.0	6.0	5.5	6.4	0.5	-	-	-	-	-	-	-	-	6.4	5.6	7.2	0.8	0> ; 2= ; 0<	0> ; 2= ; 0<	
Potassium content	Mmol / 1000 g	Northeast	3	32.4	26.3	39.3	34.3	29.3	41.1	5.0	34.1	28.6	41.5	5.4	-	-	-	-	-	-	-	0> ; 3= ; 0<	0> ; 3= ; 0<		
			2	28.9	26.3	31.6	30.9	29.3	32.5	1.6	-	-	-	-	30.8	29.5	32.1	1.3	-	-	-	-	0> ; 2= ; 0<	0> ; 2= ; 0<	
			2	28.9	26.3	31.6	30.9	29.3	32.5	1.6	-	-	-	-	-	-	-	-	29.9	27.0	32.8	2.9	0> ; 2= ; 0<	0> ; 2= ; 0<	
		Northeast and border countries (PL-CZ-DE)	6	36.0	26.3	44.0	38.4	29.3	45.1	5.9	38.6	28.6	45.5	6.1	-	-	-	-	-	-	-	0> ; 6= ; 0<	1> ; 5= ; 0<		
			5	35.3	26.3	44.0	37.8	29.3	45.1	6.3	-	-	-	-	38.5	29.5	44.6	6.4	-	-	-	-	0> ; 5= ; 0<	1> ; 4= ; 0<	
			2	28.9	26.3	31.6	30.9	29.3	32.5	1.6	-	-	-	-	-	-	-	-	29.9	27.0	32.8	2.9	0> ; 2= ; 0<	0> ; 2= ; 0<	
Amino nitrogen content	Mmol / 1000 g	Northeast	3	14.0	6.3	23.6	15.3	7.4	21.6	5.9	15.5	6.5	23.3	6.9	-	-	-	-	-	-	-	0> ; 3= ; 0<	0> ; 3= ; 0<		
			2	9.2	6.3	12.0	12.1	7.4	16.8	4.7	-	-	-	-	13.1	6.5	19.7	6.6	-	-	-	-	0> ; 2= ; 0<	0> ; 2= ; 0<	
			2	9.2	6.3	12.0	12.1	7.4	16.8	4.7	-	-	-	-	-	-	-	-	10.4	6.5	14.3	3.9	0> ; 2= ; 0<	0> ; 2= ; 0<	
		Northeast and border countries (PL-CZ-DE)	6	16.9	6.3	23.6	18.8	7.4	29.0	6.4	18.1	6.5	23.3	5.6	-	-	-	-	-	-	-	1> ; 5= ; 0<	0> ; 5= ; 1<		
			5	15.5	6.3	20.0	18.3	7.4	29.0	6.9	-	-	-	-	17.6	6.5	21.7	5.6	-	-	-	-	0> ; 5= ; 0<	0> ; 5= ; 0<	
			2	9.2	6.3	12.0	12.1	7.4	16.8	4.7	-	-	-	-	-	-	-	-	10.4	6.5	14.3	3.9	0> ; 2= ; 0<	0> ; 2= ; 0<	

**Table 3.4-6: Impact of GF-3307 (S7K-3-3) on the quality parameters when applied at 1.5 L/ha for the control of foliar diseases in EPPO Southeast climatic zone, efficacy trials in sugar beet**

Parameters	Unit	EPPO climatic zone	No. of trials	Untreated			Percentage of Untreated control (%)																No. of assessments significantly > , = , < GF-3307 (S7K-3-3) (1.5 L/ha) vs.	
							GF-3307 (S7K-3-3) 1.5 L/ha				SCORE 0.4 L/ha				AMISTAR GOLD 1.0 L/ha				SPYRALE 1.0 L/ha					
							Fenpicoxamid + Prothioconazole				Difenoconazole				Azoxystrobin + Difenoconazole				Difenoconazole + Fenpropidin					
							75+150 g a.s./ha				100 g a.s./ha				125 +125 g a.s./ha				100+375 g a.s./ha					
							Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Reference products	Untreated
Sodium content	Mmol / 1000 g	Southeast	2	6.2	6.0	6.3	6.8	6.2	7.5	0.6	-	-	-	-	8.0	7.0	9.0	1.0	-	-	-	-	0> ; 2= ; 0<	0> ; 2= ; 0<
	%	Southeast	1	0.2	-	-	0.5	-	-	-	0.3	-	-	-	-	-	-	-	-	-	-	-	1> ; 0= ; 0<	0> ; 0= ; 1<
			1	0.2	-	-	0.5	-	-	-	-	-	-	-	-	-	-	-	0.5	-	-	-	1> ; 0= ; 0<	0> ; 0= ; 1<
Potassium content	Mmol / 1000 g	Southeast	2	35.5	25.7	45.2	31.5	24.0	38.9	7.5	-	-	-	-	36.5	32.2	40.9	4.3	-	-	-	-	0> ; 2= ; 0<	0> ; 2= ; 0<
	%	Southeast	1	0.2	-	-	0.3	-	-	-	0.2	-	-	-	-	-	-	-	-	-	-	-	-	-
			1	0.2	-	-	0.3	-	-	-	-	-	-	-	-	-	-	-	0.3	-	-	-	-	-
Amino nitrogen content	Mmol / 1000 g	Southeast	2	27.9	17.2	38.6	25.7	14.6	36.9	11.1	-	-	-	-	29.8	21.8	37.7	8.0	-	-	-	-	0> ; 2= ; 0<	0> ; 2= ; 0<
	%	Southeast	1	2.6	-	-	3.0	-	-	-	2.7	-	-	-	-	-	-	-	-	-	-	-	-	-
			1	2.6	-	-	3.0	-	-	-	-	-	-	-	-	-	-	-	2.8	-	-	-	-	-
			1	0.7	-	-	0.6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<

**Table 3.4-7: Impact of GF-3307 (S7K-3-3) on the quality parameters when applied at 1.5 L/ha for the control of foliar diseases in All EPPO climatic zones, efficacy trials in sugar beet**

Parameters	Unit	EPPO climatic zone	No. of trials	Untreated			Percentage of Untreated control (%)																No. of assessments significantly > , = , < GF-3307 (S7K-3-3) (1.5 L/ha) vs.		
							GF-3307 (S7K-3-3) 1.5 L/ha				SCORE 0.4 L/ha				AMISTAR GOLD 1.0 L/ha				SPYRALE 1.0 L/ha						
							Fenpicoxamid + Prothioconazole				Difenoconazole				Azoxystrobin + Difenoconazole				Difenoconazole + Fenpropidin						
							75+150 g a.s./ha				100 g a.s./ha				125 +125 g a.s./ha				100+375 g a.s./ha						
				Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Reference products	Untreated	
Sodium content	Mmol / 1000 g	All EPPO climatic zones	9	5.3	3.0	7.9	9.0	3.5	40.0	11.0	8.1	2.6	30.0	7.9	-	-	-	-	-	-	-	-	0> ; 9= ; 0<	1> ; 7= ; 1<	
			10	5.2	3.0	7.0	8.8	3.5	40.0	10.5	-	-	-	-	8.0	3.0	30.0	7.5	-	-	-	-	0> ; 10= ; 0<	1> ; 8= ; 1<	
			2	6.2	5.5	7.0	6.0	5.5	6.4	0.5	-	-	-	-	-	-	-	-	6.4	5.6	7.2	0.8	0> ; 2= ; 0<	0> ; 2= ; 0<	
	%	All EPPO climatic zones	4	0.4	0.2	0.5	0.4	0.3	0.5	0.1	0.4	0.3	0.5	0.1	-	-	-	-	-	-	-	-	0> ; 0= ; 1<	0> ; 0= ; 1<	
			1	0.5	-	-	0.4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0> ; 0= ; 1<	0> ; 0= ; 1<	
			4	0.4	0.2	0.5	0.4	0.3	0.5	0.1	-	-	-	-	-	-	-	-	0.4	0.3	0.5	0.1	0> ; 0= ; 1<	0> ; 0= ; 1<	
Potassium content	Mmol / 1000 g	All EPPO climatic zones	9	37.4	26.3	62.1	39.8	29.3	66.8	11.1	39.4	28.6	61.4	9.8	-	-	-	-	-	-	-	-	0> ; 9= ; 0<	1> ; 8= ; 0<	
			10	36.8	25.7	62.1	38.0	24.0	66.8	11.6	-	-	-	-	38.7	29.5	61.7	9.7	-	-	-	-	0> ; 10= ; 0<	1> ; 9= ; 0<	
			2	28.9	26.3	31.6	30.9	29.3	32.5	1.6	-	-	-	-	-	-	-	-	29.9	27.0	32.8	2.9	0> ; 2= ; 0<	0> ; 2= ; 0<	
	%	All EPPO climatic zones	4	3.1	0.2	4.8	3.1	0.3	4.6	1.7	3.2	0.2	4.6	1.8	-	-	-	-	-	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			1	3.2	-	-	3.3	-	-	-	-	-	-	-	-	3.2	-	-	-	-	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
			4	3.1	0.2	4.8	3.1	0.3	4.6	1.7	-	-	-	-	-	-	-	-	3.1	0.3	4.7	1.7	0> ; 1= ; 0<	0> ; 1= ; 0<	
Amino nitrogen content	Mmol / 1000 g	All EPPO climatic zones	9	13.2	4.4	23.6	14.0	3.0	29.0	8.6	13.7	2.6	23.3	7.8	-	-	-	-	-	-	-	-	1> ; 8= ; 0<	0> ; 8= ; 1<	
			10	15.1	4.4	38.6	15.6	3.0	36.9	10.5	-	-	-	-	16.1	2.5	37.7	10.4	-	-	-	-	0> ; 10= ; 0<	0> ; 9 ; 1<	
			2	9.2	6.3	12.0	12.1	7.4	16.8	4.7	-	-	-	-	-	-	-	-	10.4	6.5	14.3	3.9	0> ; 2= ; 0<	0> ; 2= ; 0<	
	%	All EPPO climatic zones	4	1.8	0.6	2.6	1.7	0.6	3.0	0.9	1.8	0.7	2.7	0.7	-	-	-	-	-	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			2	0.7	0.6	0.7	0.6	0.6	0.6	0.0	-	-	-	-	0.6	0.6	0.6	0.0	-	-	-	-	0> ; 2= ; 0<	0> ; 2= ; 0<	
			4	1.8	0.6	2.6	1.7	0.6	3.0	0.9	1.8	0.7	2.7	0.7	-	-	-	-	1.9	0.6	2.8	0.9	0> ; 1= ; 0<	0> ; 1= ; 0<	

All 56 efficacy trials reported no phytotoxicity or adverse effects to treated crops at dose rates up to 1.5 L/ha GF-3307 (S7K-3-3), (see section 3.4.1.1) and quality results from sixteen trials demonstrated no adverse effects on quality parameters, in the presence of diseases (see section 3.2.3).

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

Root quality parameters (sodium, potassium, and amino nitrogen content) were assessed in 16 efficacy trials. No statistically significant differences in quality parameters were recorded between GF-3307 (S7K-3-3) and the reference products or the untreated control in the vast majority of trials. Therefore, it can be concluded, that no negative impact on yield quality is expected, when GF-3307 (S7K-3-3) is used in accordance with GAP recommendations.

### **3.4.4 Effects on transformation processes (KCP 6.4.4)**

Sugar beet seed is not subject to any transformation processes, as it is used for extraction of sugar (industrial processing with no biological activity). Therefore, no selectivity trials to investigate the possible adverse effects of GF-3307 (S7K-3-3) on the transformation process of sugar beet, are included in this dossier. This is in line with the guidance in EPPO standard PP 1/243 '*Effects of plant protection products on transformation processes*'. Sugar beet is also not subject to any processes that would impact on taint (EPPO PP 1/242 (2) '*Taint tests*').

It is considered that GF-3307 (S7K-3-3) can be used on sugar beet without any specific label warnings relating to transformation processes.

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

Accepted.

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

No selectivity trials were carried out to specifically investigate the possible adverse effects of GF-3307 (S7K-3-3) on propagation materials (sugar beet seed). In line with EPPO PP 1/135(3) '*Phytotoxicity Assessment*' (Table 2: 'The circumstances under which data on plant parts for propagation are required'), as no phytotoxicity effects have been reported in the effectiveness trials, it is considered that data on seed germination, using sugar beet seed from crops treated with GF-3307 (S7K-3-3), are not required.

Moreover, no problem with respect to propagation has been encountered during the experimental testing of GF-3307 (S7K-3-3) which has been used to treat plants with no negative impact. Based on this, further investigation of the effects of treatments with GF-3307 (S7K-3-3) was considered unnecessary.

However, a summary of the range of varieties tested and the extent of crop damage observed is provided in Section 3.4.1 to support the use of GF-3307 (S7K-3-3) on plants used for propagation purposes.

Finally, it is concluded that no negative impact on plant propagation will occur on sugar beet crops.

Therefore, no effect on parts of plant used for propagating purposes is expected if GF-3307 (S7K-3-3) is applied in accordance with the Good Agricultural Practices and label recommendations.

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

Accepted. The impact of GF-3307 (S7K-3-3) on treated plants or plants products to be used for propagation is not expected.

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

#### **3.5.1 Impact on succeeding crops (KCP 6.5.1)**

Fungicides usually do not exhibit herbicidal activity. No phytotoxicity was observed on sugar beet in any of the 56 efficacy trials where GF-3307 (S7K-3-3) applied as a straight product up to 1.5 L/ha at BBCH 39-49. For more details on phytotoxicity results, please refer to Section 3.4.1.

Fenpicoxamid (XDE-777) and prothioconazole are registered for use in cereals in Europe for four years and no effect on succeeding crops has been observed in Europe.

Finally, further information on the fate and behaviour of the active substances in the soil can be found in the relevant section in Part B Section 8 (“Environmental fate”) of the Registration Report.

Therefore, no impact is expected on succeeding crops if GF-3307 (S7K-3-3) is used according to the Good Agricultural Practices and label recommendations.

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

Accepted.

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

Fungicides usually do not exhibit herbicidal activity. No phytotoxicity was observed on sugar beet in any of the 56 efficacy trials where GF-3307 (S7K-3-3) was applied as a straight product up to 1.5 L/ha at BBCH 39-49. For more details on phytotoxicity results, please refer to Section 3.4.1.

Fenpicoxamid (XDE-777) and prothioconazole are registered for use in cereals in Europe for four years and no effect on adjacent crops has been observed in Europe. Finally, further information on the non - target plant studies can be found in Part B Section 9 (“Ecotoxicological studies”) of the Registration Report.

Therefore, no impact is expected on adjacent crops if GF-3307 (S7K-3-3) is used according to the Good Agricultural Practices and label recommendations.

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

Accepted.

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

No observations on adverse effects to beneficials have been made in the efficacy 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).

GF-3307 (S7K-3-3) is currently authorised on wheat, rye and triticale at a higher dose rate of 2.0 L/ha. It is considered that the effects on the majority of beneficials assessed as part of the wheat, rye and triticale application are equally applicable to use on sugar beet.

Moreover, information on beneficial organisms’ studies can be found in Part B Section 9 (“Ecotoxicological studies”) of the Registration Report.

No positive claims in relation to beneficials or IPM compatibility are specified on the label.

#### **Summary and conclusions on other undesirable or unintended side-effects**

The above information on succeeding and adjacent crops was previously submitted in support of uses on cereals.

It considered that the use of GF-3307 (S7K-3-3) as proposed will have no other undesirable or unintended side-effects on succeeding crops, adjacent crops or on beneficial and other non-target organism.

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

Adverse effects on non-target organisms were not observed in a part of efficacy trials. In other trials no observations on beneficial or non-target organisms have been reported. Detailed studies are contained in Part B, Section 9 (Ecotoxicology).

### 3.6 Other/special studies

None.

### 3.7 List of test facilities including the corresponding certificates

**Table 3.7-1: List of test facilities**

Test facility	Address	Certificate
Aarhus University	Research Centre Flakkebjerg 4200 Slagelse, Denmark	Yes
Agrartest GmbH	Geißbühl 3 D-97273 Kürnach, Germany	Yes
Agricola	Tannenstraße 2 D-94339 Leiblfling, Germany	Yes
Agropass Hungária Kft.	H-9028 Győr Napóleon utca 10, Hungary	Yes
AgroProspect SRL	Principala Street no.1, Fantana, Brasov, 507099, Romania	Yes
Anadiag	16, Rue Ampère 67500 Haguenau, France	Yes
Antedis	48 rue de la Madeleine 60000 Beauvais, France	Yes
Armstrong Fisher Ltd	Hillcrest, Main Street Ufford, Stamford Lincolnshire PE9 3BH, United Kingdom	Yes
Armstrong Agriculture Ltd	Hillcrest, Main Street Ufford, Stamford Lincolnshire PE9 3BH, United Kingdom	Yes
Cerestis	La ferme du Parc, ZI de Saint Christophe 10500 Saint Leger sous Brienne, France	Yes
Corteva Agriscience Poland Sp z o.o.	ul. Józefa Piłsa Dziekoniskiego 1 00-728 Warszawa, Poland	Yes
Corteva Crop Solutions HUN Kft.	Field Research Center H-6728 Szeged Kotanyi Janos koz 4, Hungary	Yes
CPR Europe Kft.	Torok Ignac utca 30., Szombathely, 9700, Hungary	Yes
Dow AgroSciences Poland	DowAgroSciences Polska Sp. z o.o. ul. Domaniewska 50 A, 02-672 Warszawa, Poland	Yes
Dow AgroSciences Hungary	Dow agrosiences development station. Hu Szolnok station, Vizpart Korut 32, h-5000 Szolnok, Hungary	Yes
Ephydia	1, rue de Courcelette 62450 Martinpuich, France	Yes
Essais+	Rue du 8 Mai, 1 62128 Boyelles, France	Yes
Eurofins Agrartest GmbH	Geißbühl 3 D-97273 Kürnach, Germany	Yes
Eurofins Agrosience Services SRL	Str. Muntele Mic, nr. 20, Giarmata, judetul Timis, cod 307210, Romania	Yes
Field Research Support	Ul. Dworcowa 2; 64-000 Koscian, Poland	Yes
FieldArm Ltd	Willow Fields The Street, Ramsey, Harwich, England, CO12 5HL, United-Kingdom	Yes
Lithuanian research centre for agriculture and forestry	Instituto al. 1, Akademija, LT-58344 Kėdainiai distr., Lithuania	Yes
Nordic Beet Research	Sofiehøj, Højbygaardvej 14 DK 4960 Holeby, Denmark	Yes
PerfectBAD	Ul. Przytargowa 4;	Yes

Test facility	Address	Certificate
	99-412 Kiernozia, Poland	
Staphyt, Austria GmbH	Staphyt Austria GmbH Am Futerplatz 1 2471 Rohrau, Austria	Yes
Trialtec GmbH	Kampenredder 5 24363 Haby, Germany	Yes
Zemědělská zkušební stanice KUJAVY, s.r.o.	Kujavy 48, 742 45 Kujavi, Czech Republic	Yes



## Certificate of GEP compliance Aarhus University



# Certificate

GEP approval is granted to

Testing unit: Aarhus University  
Department of Agroecology (diseases and pests)  
Flakkebjerg  
DK-4200 Slagelse

The approval applies to the execution of GEP efficacy trials of pesticides within

Testing areas: Field Trials  
Fruit growing / Forestry  
Greenhouse Trials

**GEP**

The GEP Recognition Unit at the Danish Centre for Food and Agriculture, Aarhus University, controls organisation, staff, premises, trial fields, trial equipment, standard operation procedures and trial reports. The testing unit is subject to continuous control and inspection.

The certificate is valid for a period of 6 years. Expiration date: 31 December 2025

Date of approval: 1 January 2020

Signed: 11 December 2019

Henrik Brødsgaard  
Danish Environmental  
Protection Agency

Else Thordahl Meyer  
Aarhus University

Peter Kryger Jensen  
Aarhus University

*Regulation 1107/2009 concerning plant protection products and ministerial order no. 815 dated 18 June 2018 from Danish Ministry of the Environment states that investigations of the efficacy of plant protection products carried out in Denmark for registration purposes must be performed by testing units which have been approved to carry out these investigations by the Danish Centre for Food and Agriculture, Aarhus University.*

## Certificate of GEP compliance Agrartest GmbH



**Deutscher Pflanzenschutzdienst  
German Plant Protection Service**



### **GEP – Anerkennungsbescheinigung GEP - Recognition Certificate**

Die  
Versuchseinrichtung  
mit Hauptsitz in

**AGRARTEST GmbH**

D-65326 Aarbergen - Panrod  
Palmbachstr. 37

The  
testing facility  
with headquarter in

und  
organisatorisch  
zugehöriger  
Arbeitseinheit in

Grabau (SH), Groß Lobke (NS) Rosenow (MV),  
Salbitz (SA), Sonneborn/Friedrichswerth (TH),  
Schwieberdingen, Beimerstetten, Bad Säckingen, (BW),  
Kümmach, Unterföhring (BY)

and  
subsidiary  
testing unit in

Des Trägers der  
Versuchseinrichtung

**AGRARTEST GmbH**

supported by

ist auf Antrag vom

22.10.2015

on application from

und durchgeführter  
Besichtigung durch

Dr. Monica Frosch (He),  
Dr. Friedrich Merz (BW)

and inspection by

vom

Regierungspräsidium Gießen  
- Pflanzenschutzdienst Hessen –

from the

Referat 33 - Pflanzliche und tierische Erzeugung  
- Regierungspräsidium Stuttgart

am

02.05.2016

on

amtlich anerkannt worden im Sinne des §8  
Absatz 6 der  
Pflanzenschutzmittelverordnung

has been officially recognized under  
paragraph (6) of Article 8 of the  
Plant Protection Products Ordinance  
following its application  
dated

Wetzlar, den 14.06.2016

(Dr. M. Frosch)

Anschrift der  
Anerkennungsbehörde

Regierungspräsidium Gießen  
-Pflanzenschutzdienst Hessen-  
Schanzenfeldstraße 8  
35578 Wetzlar

Address of the  
Recognising authority

## GEP-Anerkennungs-Zertifikat / Recognition Certificate

### Anerkennungsbescheinigung

Die Versuchseinrichtung  
mit Hauptsitz in

**Eurofins Agrosience  
Service GmbH/Agrartest  
GmbH  
Carl-Goerdeler-Weg 5  
21684 Stade**

und organisatorisch  
zugehörigen Arbeitseinheiten in

siehe Seite 2

ist auf Antrag vom

**14.04.2020**

und nach durchgeführter  
Besichtigung  
durch

**15.12.2015**

**Frau Warnecke-Busch**

vom

**LWK-Niedersachsen**

am

**15.01.2016**

In den Versuchskategorien

**Ackerbau, Gemüsebau,  
Obstbau, Zierpflanzen,  
Forst, Sonderkulturen**

als Einrichtung für die Prüfung  
der Wirksamkeit von  
Pflanzenschutzmitteln im Sinne  
des § 8 Abs. 6 der  
Pflanzenschutzmittelverordnung  
und gemäß Verordnung (EU)  
Nr. 284/2013 für 5 Jahre  
amtlich anerkannt worden.

### Recognition Certificate

The testing facility  
with headquarters in

and subsidiary testing units  
in

on application from

and after inspection

by

dated

on

in the trial cate

has been officially  
recognised as an  
organisation for efficacy  
testing facility of plant  
protection products  
according to § 8 par. 6 of  
the Plant Protection  
Products Ordinance and  
the Commission  
Regulation (EU) No  
284/2013 for 5 years.

22.4.2020

*D. Wallas*

Datum

Unterschrift

Date

Sign

**Wunstorfer  
Landstraße 9  
30453 Hannover**

Adresse der  
Anerkennungsbehörde  
address of the  
recognising authority



Stamp

Seite 2

Organisatorisch zugehörigen Arbeitseinheiten/ subsidiary testing units

Baden-Württemberg	Agrartest GmbH Scheerwiesenweg 41 D-71701 Schwieberdingen
Baden-Württemberg	Agrartest GmbH Neue Straße 54 D-89179 Beimerstetten
Baden-Württemberg	Eurofins Agrarservice GmbH Lempenseite 50/1 D-69168 Wiesloch
Bayern	Agrartest GmbH Geißbühl 3 D-97273 Kürnach
Brandenburg	Eurofins Agrosience Services GmbH Karl-Liebkecht-Str. 53 16321 Bernau
Hessen	Agrartest GmbH Steedener Weg 8 D-65594 Runkel-Dehrn
Mecklenburg-Vorpommern	Agrartest GmbH Am Rehnhagen 13 D-17091 Rosenow
Niedersachsen	Eurofins Agrosience Services GmbH Pastor-Reins-Str. 14 D-49586 Merzen
Niedersachsen	Agrartest GmbH Andreasplatz 2 D-31191 Groß Lobke
Nordrhein-Westfalen	Eurofins Agrosience Services GmbH Bad Meinberger Str. 168 D-32760 Detmold
Sachsen	Agrartest GmbH Friedensstraße 30 D-04769 Salbitz
Schleswig-Holstein	Agrartest GmbH Ringstraße 33c D-23845 Grabau
Sachsen-Anhalt	Eurofins Agrosience Service GmbH Wallstraße 7 D-39343 Hundisburg

22.04.2020

Datum

Date

*P. Delius*

Unterschrift

Sign

Wunstorfer  
Landstraße 9  
30453 Hannover

Adresse der  
Anerkennungsbehörde  
address of the  
recognising authority



Stamp

## Certificate of GEP compliance Agricola

### GEP-Anerkennungs-Zertifikat / Recognition Certificate

#### Anerkennungsbescheinigung

Die Versuchseinrichtung mit  
Hauptsitz in Agricola  
Tannenstr. 2  
94339 Leiblfing

und organisatorisch zugehöriger  
Arbeitseinheit in Grafentraubach  
84082 Laberweinting

ist auf Antrag vom 07.12.2017

in den Versuchskategorien Ackerbau/agriculture  
Gemüsebau/vegetable gar-  
dening

als Einrichtung für die Prüfung  
der Wirksamkeit von Pflanzen-  
schutzmitteln im Sinne des § 2  
Abs. 2 der Pflanzenschutzmit-  
telverordnung und gemäß Ver-  
ordnung (EU) Nr. 545/2011 für  
5 Jahre amtlich verlängert wor-  
den bis zum 17.04.2023

#### Recognition Certificate

the testing facility  
with headquarters in

and subsidiary testing unit in

on application from

in the trial categories

has been officially prolonged  
as an organisation for efficacy  
testing facility of plant protec-  
tion products according to § 2  
Abs. 2 of the Plant Protection  
Products Ordinance and the  
Commission Regulation (EU)  
Nr. 545/2011 for 5 years  
to April 17, 2023

Datum  
date

01.03.2018

Unterschrift  
sign

Wolfgang Kroll

Adresse der anerkennenden Behörde  
address of the recognising authority



Bayerische Landesanstalt  
für Landwirtschaft

Stempel  
stamp

Institut für Pflanzenschutz IPS 3d  
Lange Point 10  
85354 Freising



## Certificate of GEP compliance Agropass Hungária Kft.

Signatory: Dr. BRANDENBURG Tamás (30 January 2023 14:18:47)

[State coat of arms]

### PEST COUNTY GOVERNMENT OFFICE

File No.: PE/NV/00027-4/2023  
Administrator: FERENCZI Júlia  
Phone: 06-1/236-3975  
E-mail: ferenczi.julia@pest.gov.hu

Subject: GEP certification of the  
testing site of Agropass Hungária Kft.  
Attachment: -

The Pest County Government Office (hereinafter referred to as the "Authorising Authority") has made the following

### DECISION

in the procedure initiated on the basis of the application for inspection and recognition of the testing site of Agropass Hungária Kft. (registered office: 9028 Győr, Napóleon utca 10. tax number: 25395781-2-08, FELIR: AA6424961 hereinafter referred to as the "Client") under the Good Experimental Practice (hereinafter referred to as "GEP"):

I will issue a GEP for the Client's test site to carry out biological impact assessments for licensing purposes.

The GEP certification is valid for 5 years from the date of the finality of my decision.

The GEP certification will be issued for the following categories and types of cultivation:

- Qualification category: herbicides, fungicides and bactericides, zoocides, growth regulators and plant growth regulators, additives
- Fields of cultivation: arable land, vegetables, fruit, vines, ornamental plants, forest, public land and others

This qualification is without prejudice to any other statutory authorisations required for the operation/activity or the client's obligation to obtain them.

The Client shall notify the licensing authority within 15 days of any significant change to the qualified activities of its testing facilities.

Compliance with the legislation on GEP certification and this Decision will be subject to random checks by my authority. If the inspection reveals that the test site does not comply with the GEP requirements applicable to it, the licensing authority may suspend the activity in the qualified area indicated in the decision for a period of up to 2 months or may withdraw the GEP qualification issued.

If the inspection reveals deficiencies in a particular experiment, the authorising authority may, depending on the extent of the deficiencies, exclude the experiment from the list of those that are acceptable for authorisation.

The inspection and re-approval of a test site under the GEP is subject to a fee. The fee is HUF 250.000,-, which the Client has paid, according to Annex 1, point 8.19.2. of VM Decree No. 63/2012 (VII. 2.) on the amount of administrative service fees payable in procedures initiated before the National Food Chain Safety Office and the agricultural administrative bodies of the county government offices.

Department of Food Chain Safety, Animal Health, Plant and Soil Protection  
Address: 1135 Budapest, Lehel u. 43-47.;  
Phone: (06-1) 236-4160; KRID: 511509738  
E-mail: nto@pest.gov.hu Web: <http://www.kormanyhivatal.hu/hu/pest>

Die Übersetzung stimmt mit  
dem Originaltext überein.  
The translation corresponds to  
the original text.

Lőrincz-Véger  
Szakfordító Bt.

[www.lorincz-veger.hu](http://www.lorincz-veger.hu)

FORDÍTÓIRODA - ÜBERSETZUNGSBÜRO - TRANSLATION AGENCY - PREKLADATELSKÁ AGENTURA - BUREAU DE TRADUCTION  
Cégjegyzékszám - Handelsregister-Nr. - Trade Register No. - Registri pod číslom - Registre de Commerce N°: 08-06-002431  
HU-9400 Sopron, Béke út 13. - Tel.: +36 70 311 1779 - E-mail: forditoiroda@lorincz-veger.hu - Web: [www.lorincz-veger.hu](http://www.lorincz-veger.hu)

There is no right of appeal against this decision in administrative proceedings, however, the Client may request a review of this decision, which becomes final upon notification, by filing an action against the Licensing Authority that issued the decision with the Budapest Metropolitan Court within thirty days of the notification of the decision, on the grounds of a breach of law. The application must be submitted electronically to the Department of Plant and Seed Protection of the Pest County Government Office for Food Chain Safety, Animal Health, Plant and Seed Protection (1135 Budapest, Lehel u. 43-47.).

## JUSTIFICATION

In a letter received on 02 December 2022, the Client requested an inspection of its testing site by the licensing authority.

On 18 January 2023, the Licensing Authority carried out an on-site inspection at the Client's premises, the findings of which were recorded in the reports under case number PE/NV/00027-1/2023.

During the on-site inspection, the Licensing Authority found that the testing site did not fully comply with the requirements of the provisions on biological impact assessments set out in Article 22 of FVM Decree No. 89/2004 (V 15.) of 15 May 2004 on the authorisation of the placing on the market and use of plant protection products and on the packaging, labelling, storage and transport of plant protection products (hereinafter: the Decree), and ordered the Client to remedy the deficiencies in the Order No. PE/NV/00027-2/2023.

The Client has corrected the deficiencies and submitted the documentation proving this to the licensing authority on 24 January 2023.

**On the basis of the above, I have concluded that the conditions for granting the GEP qualification have been met and I have decided accordingly as set out in the operative part.**

According to Article 22 of the Regulation, "(5) On the basis of an application, the licensing authority shall carry out an on-site inspection of the test site and shall decide by means of a decision on the GEP certification of the test site. The decision shall include the categories and types of cultivation for which the test site has obtained GEP certification.

(6) The validity period of the GEP certification is 2 years for the first certification and up to 5 years after renewal of the certification.

(7) The GEP certification procedure shall be subject to the payment of a fee as provided for in a separate act.

(8) A GEP-certified testing facility shall notify the licensing authority within 15 days of any significant change affecting its certified activity.

(9) The licensing authority shall carry out random inspections of GEP-certified test facilities. If it is found that the test site does not comply with the GEP requirements applicable to it, the authority may suspend the activity in the qualified area indicated in the decision for a period not exceeding 2 months or revoke the GEP qualification issued. If the inspection reveals deficiencies in relation to a particular experiment, the authorising authority may, depending on the extent of the deficiencies, exclude the experiment from the list of those acceptable for authorisation."

The authorising authority made its decision in accordance with the provisions of Article 19 of Government Decree 383/2016 (XII.2.) on the designation of bodies performing the tasks of agricultural authorities and administrations and in accordance with the powers granted in Article 33(e) of Act XLVI of 2008 on the Food Chain and its official supervision.

The possibility to appeal against the present decision is excluded pursuant to Article 116(1)(4)(d) of the General Administrative Procedure Act. The information on the possibility of bringing an action is laid down in Article 112(1) and Article 114(1) of the General Administrative Procedure Act.

Lőrincz-Véger Bt.  
A fordítás az eredeti szöveggel megegyezik.  
Die Übersetzung stimmt mit dem Originaltext überein.  
The translation corresponds to the original text.



Lőrincz-Véger  
Szakfordító Bt.

[www.lorincz-veger.hu](http://www.lorincz-veger.hu)

FORDÍTÓIRODA - ÜBÉRSÉZSÜBÜRO - TRANSLATION AGENCY - PREKLADATELSKÁ AGENTURA - BUREAU DE TRADUCTION  
Cégjegyzékszám - Handelsregister-Nr. - Trade Register No. - Registri pod číslom - Registre de Commerce N°: 08-06-002431  
HU-9400 Sopron, Béke út 13. - Tel.: +36 70 311 1779 - E-mail: forditiroda@lorincz-veger.hu - Web: www.lorincz-veger.hu



On the possibility and rules of judicial review and the filing of an action, Section 39/A of the Food Act; Section 28 (1)-(2) of Act I of 2017 on Administrative Procedure, Section 29 (1), Section 38, Section 39, Section 50, Section 52, Section 77, Section 157. (1); Section 21 (6) of Act CLXI of 2011 on the Organisation and Administration of Courts; Section 605 of Act CXXX of 2016 on the Code of Civil Procedure; and Section 9 (1) of Act CCXXII of 2015 on the General Rules of Electronic Administration and Confidential Services.

Budapest, 30 January 2023

For and on behalf of  
Dr. TARNAI Richárd lord lieutenant

Dr. BRANDENBURG Tamás  
Head of Department

The Decision is addressed to:

1. Client
2. Department of Finance and Economy of the Pest County Government Office
3. Records Office

Lőrincz-Véger  
Szakfordító Bt.

[www.lorincz-veger.hu](http://www.lorincz-veger.hu)

FORDÍTÓIRODA - ÜBERSETZUNGSBÜRO - TRANSLATION AGENCY - PREKLADATELSKÁ AGENTURA - BUREAU DE TRADUCTION  
Cégjegyzékszám - Handelsregister-Nr. - Trade Register No. - Registri pod číslom - Registre de Commerce N°: 08-06-002431  
HU-9400 Sopron, Béke út 13. - Tel.: +36 70 311 1779 - E-mail: forditoiroda@lorincz-veger.hu - Web: www.lorincz-veger.hu

Lőrincz-Véger Bt.  
A fordítás az eredeti szöveggel megegyezik.  
Die Übersetzung stimmt mit dem Originaltext überein.  
The translation corresponds to the original text.





## Certificate of GEP compliance AgroProspect SRL

<b>MINISTERUL AGRICULTURII ȘI DEZVOLTĂRII RURALE</b> Autoritatea Națională Fitosanitară Comisia Națională de Omologare a Produselor de Protecție a Plantelor	<b>MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT</b> National Phytosanitary Authority National Commission for Registration of Plant Protection Products
---	--

Nr.întreg/ Registration Not 36/F/09.01.2018

**Certificat de recunoaștere oficială a testelor de eficacitate biologică**  
**în conformitate cu bunele practici experimentale / Certificate of official**  
**recognition of the efficacy biological tests according to the good**  
**experimental practices**

**Se acordă: SC AgroProspect SRL**  
**It is granted to: SC AgroProspect SRL**  
**cu sediul: Comuna Hoghiz, satul Fântâna, nr. 1, județul Brașov, cod 507099**  
**with headquarters: Hoghiz, Fântâna Village, no. 1, Brașov county, cod 507099**

**domeniile de activitate: Culturi agricole de câmp și pajiști, pomicultură, viticultură, legumicultură,**  
**floricultura, plante aromatice și medicinale, silvicultura și zone non - agricole**  
**domains of activity: Field crops and meadows, fruit growing, viticulture, vegetable growing, floriculture,**  
**aromatic and medicinal plants, forestry, non agricultural areas**

Prezentul certificat se eliberează în conformitate cu prevederile Ordinului ministrului agriculturii și dezvoltării rurale, al ministrului sănătății și al ministrului mediului și schimbărilor climatice nr. 60/512/1258/2013 și prevederile Procedurii naționale de omologare a produselor de protecție a plantelor care conțin substanțe active notificate și pentru care nu s-a luat încă o decizie de includere în lista cu substanțe active autorizate în Uniunea Europeană, aprobată prin ordinul ministrului agriculturii, pădurilor și dezvoltării rurale, al ministrului sănătății și al ministrului mediului și gospodăriei apelor nr. 134/197/412/2006, cu modificările și completările ulterioare.

This certificate is issued according to the provisions of the Order of the ministry of agriculture and rural development, of the ministry of health and of the ministry of environment and climate change no. 60/512/1258/2013 and the provisions of the National Procedure for Registration of Plant Protection Products which contain notified active substances and for which isn't taken yet a decision for inclusion in European Union list of authorized active substances, approved by the Order of the ministry of agriculture, forests and rural development, of the ministry of health and of the ministry of environment and waters husbandry no. 134/197/412/2006, with subsequent amendments and completions.

<b>Data emiterii certificatului: 08.01.2018</b> Issuance date of the certificate	<b>PREȘEDINTE/CHAIRMAN,</b>
<b>Data expirării certificatului: 08.01.2023</b> Expiry date of the certificate	<b>Doina BAICULESCU</b>



## Certificate of GEP compliance Anadiag



### MINISTÈRE DE L'AGRICULTURE ET DE L'ALIMENTATION

#### DÉCISION D'AGRÈMENT POUR RÉALISER DES ESSAIS OFFICIELLEMENT RECONNUS

Annule et remplace les courriers du 7/02/2020

Conformément à l'article R. 253-38 du code rural et de la pêche maritime et à l'article 6 de l'arrêté du 26 avril 2007 relatif aux essais officiels et officiellement reconnus pour l'évaluation des produits mentionnés à l'article L. 253-1 du code rural et de la pêche maritime,

Vu la convention passée avec le Cofrac n° 4609,

Vu le rapport d'évaluation réalisé par le Cofrac, en date du 26/11/2019,

L'agrément pour réaliser des essais officiellement reconnus est maintenu et étendu, à l'organisme :

**Anadiag France**  
174 impasse du plan d'eau  
38300 RUY MONTCEAU

sous le numéro : **BPE - 105**

ET POUR LE PÉRIMÈTRE SUIVANT :

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
ANADIAG FRANCE 174 impasse du plan d'eau 38300 RUY MONTCEAU ( <i>unité centrale</i> )	- Traitement des semences : <i>grandes cultures</i>
UE 01 – Harnes (UE 62) ZI la Motte au Bois 62440 HARNES	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Zones non agricoles
UE 03 – Saint Pierre du Bû (UE 14) Couvrigny 14700 SAINT PIERRE DU BU	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Zones non agricoles
UE 04 – Cintré (UE 35) Rue du puisatier ZA du moulin à vent 35310 CINTRE	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Zones non agricoles
UE 06 – Varois et Chaignot (UE 21) 8 route de gray 21490 VAROIS ET CHAIGNOT	- Grandes cultures - Vigne - Cultures fruitières et arboriculture - Zones non agricoles

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
UE 08 – Saint Barthélémy (UE 38) 700 route de Pisieu 38270 SAINT BARTHELEMY	<ul style="list-style-type: none"> <li>- Grandes cultures</li> <li>- Vigne</li> <li>- Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum</li> <li>- Cultures fruitières et arboriculture</li> <li>- Productions horticoles et plantes d'intérieur</li> <li>- Zones non agricoles</li> </ul>
UE 10 – Saint Etienne de Fougères (UE 47) ZA Bel Air 47380 SAINT ETIENNE DE FOUGERES	<ul style="list-style-type: none"> <li>- Grandes cultures</li> <li>- Vigne</li> <li>- Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum</li> <li>- Cultures fruitières et arboriculture</li> <li>- Productions horticoles et plantes d'intérieur</li> <li>- Zones non agricoles</li> <li>- Désinfection et désinsectisation des sols, des matériels et des locaux de culture et de stockage des végétaux</li> </ul>
UE 12 – Saint Germain des Prés (UE 49) ZA la Potherie 49170 SAINT GERMAIN DES PRES	<ul style="list-style-type: none"> <li>- Grandes cultures</li> <li>- Vigne</li> <li>- Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum</li> <li>- Cultures fruitières et arboriculture</li> <li>- Productions horticoles et plantes d'intérieur</li> <li>- Zones non agricoles</li> </ul>
UE 13 – Castillon du Gard (UE 30) ZA les Codes Bas 3 30210 CASTILLON DU GARD	<ul style="list-style-type: none"> <li>- Grandes cultures</li> <li>- Vigne</li> <li>- Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum</li> <li>- Cultures fruitières et arboriculture</li> <li>- Productions horticoles et plantes d'intérieur</li> <li>- Zones non agricoles</li> </ul>
UE 15 – Haguenau (UE 67) 16 rue Ampère 67500 HAGUENAU	<ul style="list-style-type: none"> <li>- Grandes cultures</li> <li>- Vigne</li> <li>- Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum</li> <li>- Cultures fruitières et arboriculture</li> <li>- Zones non agricoles</li> <li>- Processus de transformation : <ul style="list-style-type: none"> <li>Vinification</li> <li>Transformation de pomme de terre</li> <li>Transformation de fruits (compote, jus de fruit, nectar, fruit au sirop, confiture, fruits séchés)</li> <li>Transformation de légumes (jus, concentré de tomates, conserve de légumes, ketchup, choucroute)</li> <li>Extraction d'huile</li> </ul> </li> </ul>

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
UE 16 – Thorée les Pins (UE 72) La Belle Métairie 72800 THOREE LES PINS	<ul style="list-style-type: none"><li>- Grandes cultures</li><li>- Vigne</li><li>- Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum</li><li>- Cultures fruitières et arboriculture</li><li>- Zones non agricoles</li></ul>
UE 17 – Toulouse (UE 31) 75 voie du TOEC Bâtiment entreprise 2 31076 TOULOUSE Cedex 3	<ul style="list-style-type: none"><li>- Grandes cultures</li><li>- Vigne</li><li>- Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum</li><li>- Cultures fruitières et arboriculture</li><li>- Zones non agricoles</li></ul>

Cet agrément est valable jusqu'au 08/10/2022. La prochaine évaluation de votre organisme est prévue au planning sur septembre / octobre 2020.

Date : 07/02/2020

La sous directrice de la qualité,  
de la santé et de la protection  
des végétaux



Anne-Cécile COTILLON

## Certificate of GEP compliance Antedis



### DÉCISION D'AGRÈMENT POUR REALISER DES ESSAIS OFFICIELLEMENT RECONNUS

Conformément à l'article R. 253-38 du code rural et de la pêche maritime et à l'article 6 de l'arrêté du 26 avril 2007 relatif aux essais officiels et officiellement reconnus pour l'évaluation des produits mentionnés à l'article L. 253-1 du code rural et de la pêche maritime,

Vu la convention passée avec le Cofrac n° 3323,

Vu le rapport d'évaluation réalisé par le Cofrac, en date du 22/03/2022,

L'agrément pour réaliser des essais officiellement reconnus est étendu, à l'organisme :

**ANTEDIS**

48 rue de la Madeleine  
60000 BEAUVAIS

sous le numéro : **BPE - 082**

ET POUR LE PERIMETRE SUIVANT :

UNITE(S)	SECTEUR(S) D'ACTIVITE
<b>ANTEDIS</b> Beau Repaire RN 3 51150 JALONS (unité centrale)	- Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum
<b>UE 01 – Unité de Coings</b> 1 rue des Champs Grands « Céré » 36130 COINGS	- Grandes cultures
<b>UE 02 – Unité d'Arras</b> 4 rue François Hennebique 62223 SAINT LAURENT BLANGY	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum
<b>UE 03 – Unité de Brux</b> Chez Saboureau 86510 BRUX	- Grandes cultures - Vigne
<b>UE 04 – Unité de Catillon</b> Ferme de Morvillers 60130 CATILLON FUMECHON	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum
<b>UE 05 – Unité de Saint Vérand</b> La Roche 71570 SAINT VERAND	- Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum

UNITE(S)	SECTEUR(S) D'ACTIVITE
<b>UE 06 – Unité de Beaupuy</b> 70 route des Crêtes 32600 BEAUPUY	<ul style="list-style-type: none"> <li>- Grandes cultures</li> <li>- Vigne</li> <li>- Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum</li> </ul>
<b>UE 07 – Unité de Prunay Le Gillon</b> 4 rue des Sours Crossay 28360 PRUNAY LE GILLON	<ul style="list-style-type: none"> <li>- Grandes cultures</li> <li>- Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum</li> <li>- Cultures fruitières et arboriculture</li> </ul>
<b>UE 08 – Unité de Pontivy</b> Lycée agricole de Kerlebost, St Thuriau 56306 PONTIVY	<ul style="list-style-type: none"> <li>- Grandes cultures</li> <li>- Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum</li> </ul>
<b>UE 09 – Unité de Combronde</b> 98 Belle Allée 63460 COMBRONDE	<ul style="list-style-type: none"> <li>- Grandes cultures</li> <li>- Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum</li> <li>- Traitement des semences : <i>Grandes cultures</i></li> </ul>
<b>UE 10 – Unité d'Acquigny</b> ZA des Patis 27400 ACQUIGNY	<ul style="list-style-type: none"> <li>- Grandes cultures</li> <li>- Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum</li> <li>- Cultures fruitières et arboriculture</li> </ul>
<b>UE 11 – Unité de Thuir</b> 16 avenue de la Côte Vermeille 66300 THUIR	<ul style="list-style-type: none"> <li>- Vigne</li> <li>- Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum</li> <li>- Cultures fruitières et arboriculture</li> </ul>
<b>UE 12 – Unité de Revel</b> Les Tandous 31540 SAINT FELIX DE LAURAGAIS	<ul style="list-style-type: none"> <li>- Grandes cultures</li> </ul>
<b>UE 13 – Unité de Magny</b> ZA La Chaume de Bonjuan 89200 MAGNY	<ul style="list-style-type: none"> <li>- Grandes cultures</li> </ul>

Cet agrément est valable **jusqu'au 21/03/2026**. En application de l'article 5 de l'arrêté susmentionné, une nouvelle évaluation aura lieu dans un délai compris entre vingt-quatre et trente-six mois à compter du **22/03/2021**.

Date : **13 MAI 2022**

Le sous-directeur de la santé  
et de la protection des  
végétaux  
Le sous-directeur de la santé  
et de la protection des végétaux

Emmanuel KOEN



**Certificate of GEP compliance Armstrong Fisher Ltd.**



*Certificate of*

**Official Recognition of Efficacy Testing Facilities  
or Organisations in the United Kingdom**

---

*This certifies that*

**Armstrong-Fisher Limited**

complies with the minimum standards laid down in  
Regulation (EC) 1107/2009 for efficacy testing.

The above Facility/Organisation has been officially  
recognised as being competent to carry out efficacy trials/tests  
in the United Kingdom in the following categories:

**Agriculture/Horticulture  
Stored Crops**

Date of issue: 5 April 2019  
Effective date: 23 February 2019  
Expiry date: 22 February 2024

Signature   
Authorised signatory

Certification Number <b>ORETO 419</b>
--



**HSE**  
Chemicals Regulation Division



Department of  
**Agriculture and  
Rural Development**

**Certificate of GEP compliance Armstrong Agriculture Ltd.**



# Certificate of

## Official Recognition of Efficacy Testing Facilities or Organisations in Great Britain

*This certifies that*

**Armstrong Agriculture Limited**

complies with the minimum standards laid down in  
Regulation (EC) 1107/2009<sup>1</sup> for efficacy testing.

The above Facility/Organisation has been officially  
recognised as being competent to carry out efficacy trials/tests  
in Great Britain in the following categories:

**Agriculture/Horticulture  
Stored Crops**

**Date of issue:** 14 April 2021  
**Effective date:** 5 January 2021  
**Expiry date:** 22 February 2024

Digitally signed by:  
Wayne Mcleod  
Date: 2021.04.14 13:  
27:53 Z

HSE Digital Signature



Chemicals Regulation Division

**Certification Number**

**ORETO 432**



Department of  
**Agriculture and  
Rural Development**

<sup>1</sup> Regulation (EC) 1107/2009 as it has effect in Great Britain



## Certificate of GEP compliance Cerestis



**MINISTÈRE  
DE L'AGRICULTURE  
ET DE L'ALIMENTATION**  
*Liberté  
Égalité  
Fraternité*

### **DÉCISION D'AGRÈMENT POUR REALISER DES ESSAIS OFFICIELLEMENT RECONNUS**

Conformément à l'article R. 253-38 du code rural et de la pêche maritime et à l'article 6 de l'arrêté du 26 avril 2007 relatif aux essais officiels et officiellement reconnus pour l'évaluation des produits mentionnés à l'article L. 253-1 du code rural et de la pêche maritime,

Vu la convention passée avec le Cofrac n° 7040,

Vu le rapport d'évaluation réalisé par le Cofrac, en date du 15/03/2021,

L'agrément pour réaliser des essais officiellement reconnus est maintenu, à l'organisme :

**CERESTIS**

La Ferme du Parc  
ZI de Saint Christophe  
10500 SAINT LEGER SOUS BRIENNE

sous le numéro : **BPE - 137**

ET POUR LE PERIMETRE SUIVANT :

UNITE(S)	SECTEUR(S) D'ACTIVITE
La Ferme du Parc ZI de Saint Christophe 10500 Saint Leger sous Brienne ( <i>unité centrale</i> )	- <b>Grandes cultures</b> - <b>Vigne</b> - <b>Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum</b>

Cet agrément est valable jusqu'au 21 février 2023. L'évaluation de renouvellement devra impérativement avoir lieu 5 mois avant cette échéance.

Date : **14 AVR. 2021**

**La sous directrice de la qualité,  
de la santé et de la protection  
des végétaux**

**Anne-Cécile COTILLON**

## Certificate of GEP compliance Corteva Agriscience Poland Sp z o.o.



GLÓWNY INSPEKTOR  
OCHRONY ROŚLIN I NASIENICTWA

*Andrzej Chodkewski*

BOR/T.510.15.2021

Warszawa, 21 września 2021 r.

### DECYZJA Nr 15/2021

Na podstawie art. 155 ustawy z dnia 14 czerwca 1960 r. Kodeks postępowania administracyjnego (Dz.U. z 2021 r. poz. 735, z późn. zm.), po rozpatrzeniu wniosku Corteva Agriscience Poland Sp. z o.o. z dnia 9 września 2021 r. zmieniam decyzję Nr 7/2005 z dnia 1 maja 2005 r., zmienioną decyzjami Nr 1/2006 z dnia 21 lutego 2006 r., Nr 2/2007 z dnia 4 kwietnia 2007 r. oraz Nr 1/2021 z dnia 22 stycznia 2021 r. w sprawie udzielenia upoważnienia do prowadzenia badań skuteczności działania środków ochrony roślin, w ten sposób, że rozstrzygnięcie decyzji otrzymuje następujące brzmienie:

„Upoważniam Corteva Agriscience Poland Sp. z o.o. (ul. Józefa Piłsudskiego 1; 00-726 Warszawa) do prowadzenia badań skuteczności działania środków ochrony roślin z grupy fungicydów, herbicydów, insektycydów, regulatorów wzrostu w uprawach polowych zbóż, rzepaku, ziemniaka, kukurydzy, buraka cukrowego i buraka pastewnego, słonecznika, gorczycy, marchwi, kapusty, kalafiora, brokuła, cebuli, pora, salaty i cykorii, w uprawach sadowniczych jabłoni, gruszy, śliwy, czereśni, wiśni, w szkółkach drzew owocowych, na trawnikach i boiskach piłkarskich, na łąkach i pastwiskach, nieużytkach rolnych i na ścierniskach.”

### Uzasadnienie

Wnioskiem z dnia 9 września 2021 r. spółka Corteva Agriscience Poland Sp. z o.o. zwróciła się do Głównego Inspektora Ochrony Roślin i Nasiennictwa z prośbą o rozszerzenie zakresu upoważnienia do prowadzenia badań skuteczności działania środków ochrony roślin Nr 7/2005 (z dnia 1 maja 2005 r.), zmienionego decyzjami Nr 1/2006 (z dnia 21 lutego 2006 r.), Nr 2/2007 (z dnia 4 kwietnia 2007 r.) oraz Nr 1/2021 (z dnia 22 stycznia 2021 r.) o możliwość prowadzenia takich badań w uprawach buraka pastewnego oraz na ścierniskach i nieużytkach rolnych. Ponadto strona poprosiła o usunięcie z treści w/w upoważnienia zwrotu „oraz łącznego stosowania środków ochrony roślin”.

Mając na uwadze przepis art. 15 ustawy z dnia 2 marca 2020 r. o szczególnych rozwiązaniach związanych z zapobieganiem, przeciwdziałaniem i zwalczaniem COVID-19, innych chorób zakaźnych oraz wywołanych nimi sytuacji kryzysowych (Dz. U. z 2020 r. poz. 1842, z późn. zm.), która czasowo wyłącza niektóre obowiązki wynikające z ustawy z dnia 8 marca 2013 r. o środkach ochrony roślin,

Główny Inspektor Ochrony Roślin i Nasiennictwa przed zmianą zakresu upoważnienia do prowadzenia badań skuteczności działania środka ochrony roślin odstąpił od przeprowadzenia kontroli, o której mowa w art. 17 ust. 6 ustawy o środkach ochrony roślin. Ocena spełniania wymagań dobrej praktyki doświadczalnej przez Corteva Agriscience Poland Sp. z o.o. przeprowadzona została w oparciu o złożony wniosek.

Biorąc pod uwagę powyższe należy uznać, że Corteva Agriscience Poland Sp. z o.o. wymagania dobrej praktyki doświadczalnej, wobec czego postanowiono jak w rozstrzygnięciu decyzji.

#### Pouczenie

Od niniejszej decyzji odwołanie nie przysługuje. Strona niezadowolona z decyzji może zwrócić się do Głównego Inspektora Ochrony Roślin i Nasiennictwa z wnioskiem o ponowne rozpatrzenie sprawy, w terminie 14 dni od dnia doręczenia decyzji, zgodnie z art. 127 § 3 kpa.

W trakcie biegu terminu do złożenia wniosku ponowne rozpatrzenie sprawy strona może zrzec się tego prawa wobec organu administracji publicznej, który wydał decyzję. Z dniem doręczenia Głównemu Inspektorowi Ochrony Roślin i Nasiennictwa oświadczenia o zrzeczeniu się prawa do złożenia wniosku o ponowne rozpatrzenie sprawy, decyzja staje się ostateczna i prawomocna, co oznacza, iż decyzja podlega natychmiastowemu wykonaniu i brak jest możliwości zaskarżenia decyzji do Wojewódzkiego Sądu Administracyjnego.

Jeżeli strona nie uważa, że decyzja jest zgodna z jej wnioskiem, a nie chce skorzystać z prawa zwracania się z wnioskiem o ponowne rozpatrzenie sprawy, może wnieść do Wojewódzkiego Sądu Administracyjnego w Warszawie skargę na decyzję w terminie 30 dni od dnia doręczenia decyzji stronie. Skargę wnosi się za pośrednictwem Głównego Inspektora Ochrony Roślin i Nasiennictwa.

Zgodnie z § 2 ust. 1 pkt 2 rozporządzenia Rady Ministrów z dnia 16 grudnia 2003 r. w sprawie wysokości oraz szczegółowych zasad pobierania wpisu w postępowaniu przed sądami administracyjnymi (Dz. U. z 2021 r. poz. 535) wpis stały bez względu na przedmiot zaskarżonego aktu lub czynności w sprawach skarg na akty lub czynności z zakresu administracji publicznej dotyczące uprawnień lub obowiązków wynikających z przepisów prawa wynosi 200 zł.

Na wniosek strony złożony przed wszczęciem lub w toku postępowania sądowego może być stronie przyznane prawo pomocy, w zakresie całkowitego lub częściowego zwolnienia od kosztów sądowych oraz ustanowienia adwokata lub radcy prawnego, gdy strona wykaże, że nie jest w stanie ponieść jakichkolwiek lub pełnych kosztów postępowania.

Została pobrana opłata skarbową w wysokości 1 000 zł.

#### Otrzymanie:

- 1) Corteva Agriscience Poland Sp. z o.o.  
ul. Józefa Piłsudskiego 1  
00-728 Warszawa
- 2) a/a



Zaproszenie  
GŁÓWNEGO INSPEKTORA  
Tadeusz Łęczyński

## Certificate of GEP compliance Crop Solutions HUN Kft.



### PEST MEGYEI KORMÁNYHIVATAL

Ügyirat-szám: PE/NV/01445-11/2021

Ügyintéző: Ferenczi Júlia

Telefon: 06-1/236-3975

E-mail: ferenczi.julia@pest.gov.hu

Tárgy: Dow AgroSciences

Hungary Kft. Szabadföldi Kísérleti

Állomás vizsgálóhelyének GEP

tanúsítása

Melléklet:-

A Pest Megyei Kormányhivatal (a továbbiakban: Engedélyező Hatóság) a Dow AgroSciences Hungary Kft. Szabadföldi Kísérleti Állomás (székhely: 2040 Budaörs, Neumann János u. 1 sz., telephely: 6710 Szeged, Back Bernát utca 01416/20 hrsz. továbbiakban: Ügyfél) vizsgálóhelyének Helyes Kísérleti Gyakorlat = *Good Experimental Practice* (a továbbiakban: GEP) szerinti inspekciója és ismételt elismerése iránti kérelme alapján indult eljárásban meghozta az alábbi

### H A T Á R O Z A T O T :

Engedélyezési célú biológiai hatásvizsgálatok végzéséhez az Ügyfél vizsgálóhelyének GEP-minősítését kiadom.

A GEP - minősítés 5 évig érvényes döntésem közléssel véglegessé válásától számítva.

A vizsgálóhely GEP-minősítés az alábbi minősítési kategóriákra és művelési ágakra kerül kiadásra:

- minősítési kategória: herbicidek, fungicidek és baktericidek, zoocidek, növekedésszabályozó és terménynövelő készítmények, adalékanyagok
- művelési ág: szántóföld, zöldség, gyümölcs, szőlő, dísznövény, erdő, közterület, egyéb

Jelen minősítés nem érinti a működéssel/tevékenységgel folytatásával kapcsolatos egyéb jogszabályban előírt engedélyeket, illetve ügyfélnek azok beszerzésére vonatkozó kötelezettségét.

Az Ügyfél a vizsgálóhelyeinek minősített tevékenységét érintő jelentős változásról 15 napon belül köteles értesíteni az engedélyező hatóságot.

A GEP-minősítéssel kapcsolatos jogszabályokban és a jelen határozatban foglaltak betartását hatóságom szűrőpróbaszerűen ellenőrzi. Amennyiben az ellenőrzés során megállapítást nyer, hogy a vizsgálóhely nem tartja be a rá vonatkozó GEP - követelményeket, akkor az engedélyező hatóság a határozatban feltüntetett minősített területre vonatkozó tevékenység végzését legfeljebb 2 hónapra felfüggesztheti, illetve a kiadott GEP- minősítését visszavonhatja.

Ha az ellenőrzés során egy adott kísérlettel kapcsolatban hiányosságok kerülnek megállapításra, a kísérletet a hiányosságok mértékétől függően az engedélyező hatóság kizárhatja az engedélyezésnél elfogadhatók közül.

A vizsgálóhely GEP szerinti felülvizsgálata és az elismerés meghosszabbítása eljárás díjköteles, amely a Nemzeti Élelmiszerlánc-biztonsági Hivatal, valamint a megyei kormányhivatalok mezőgazdasági szakigazgatási szervei előtt kezdeményezett eljárásokban fizetendő igazgatási szolgáltatási díjak mértékéről, valamint az igazgatási szolgáltatási díj fizetésének szabályairól szóló 63/2012. (VII. 2.) VM rendelet 1. sz. mellékletének 8.19.2. pontja szerint: 250.000,- Ft.



Ezen határozattal szemben közigazgatási eljárás keretében fellebbezésnek helye nincs, ugyanakkor az Ügyfél jogszabály-sértésre való hivatkozással kérheti jelen, a közléssel véglegessé váló határozat felülvizsgálatát, a határozat közlésétől számított harminc napon belül a Fővárosi Törvényszéktől, a határozatot hozó Engedélyező Hatóság elleni kereset indításával. A keresetlevelet a Pest Megyei Kormányhivatal Élelmiszerlánc-biztonsági, Állategészségügyi, Növény- és Talajvédelmi Főosztály Növény- és Talajvédelmi Osztályához (1135 Budapest, Lehel u. 43-47.) elektronikus úton kell benyújtani.

## INDOKOLÁS

Az Ügyfél 2020. július 09-én érkezett levelében vizsgálóhelyének inspekciónak és ismételt elismerését kérte az engedélyező hatóságtól.

Az engedélyező hatóság 2021. december 02-án az Ügyfél telephelyén helyszíni ellenőrzést tartott, amelyeknek megállapításait a PE/NV/01445-2/2021 ügyiratszámú jegyzőkönyvben rögzítette.

A helyszíni ellenőrzés során az engedélyező hatóság megállapította, hogy a növényvédő szerek forgalomba hozatalának és felhasználásának engedélyezéséről, valamint a növényvédő szerek csomagolásáról, jelöléséről, tárolásáról és szállításáról szóló 89/2004. (V. 15.) FVM rendelet (továbbiakban: Rendelet) 22. §-ban foglalt biológiai hatásvizsgálatokkal kapcsolatos előírásoknak a vizsgálóhely nem felelt meg hiánytalanul, és az ügyfelet a PE/NV/01445-7/2021 ügyiratszámú végzésben a hiányosságok megszüntetésére szólította fel.

Az Ügyfél a hiányosságokat megszüntette és annak bizonyításáról szóló dokumentációt az engedélyező hatóságnak 2021. december 17-én megküldte.

A fentiek alapján megállapítottam, hogy a GEP-minősítés megadásának feltételei teljesültek, ennek megfelelően döntöttem a rendelkező részben foglaltak szerint.

A Rendelet 22. §-a értelmében „(5) Kérelem alapján az engedélyező hatóság helyszíni ellenőrzést folytat le a vizsgálóhelyen, majd határozatban dönt a vizsgálóhely GEP-minősítéséről. A határozatnak ki kell terjednie arra, hogy a vizsgálóhely milyen kategóriákra, illetve művelési ágakra szerezte meg a GEP-minősítést.

(6) A GEP-minősítés érvényességi ideje első tanúsítás esetén 2 év, a tanúsítás megújítását követően legfeljebb 5 év.

(7) A GEP-minősítési eljárásért a külön jogszabályban meghatározott díjat kell fizetni.

(8) A GEP-minősítéssel rendelkező vizsgálóhely minden, a minősített tevékenységét érintő jelentős változásról 15 napon belül köteles értesíteni az engedélyező hatóságot.

(9) Az engedélyező hatóság szűrőpróbaszerűen ellenőrzi a GEP-minősítéssel rendelkező vizsgálóhelyeket. Amennyiben megállapítást nyer, hogy a vizsgálóhely nem tartja be a rá vonatkozó GEP-követelményeket, a hatóság a határozatban feltüntetett minősített területre vonatkozó tevékenységet legfeljebb 2 hónapra felfüggesztheti, illetve a kiadott GEP-minősítést visszavonhatja. Ha az ellenőrzés során egy adott kísérlettel kapcsolatban hiányosságok kerülnek megállapításra, a kísérletet a hiányosságok mértékétől függően az engedélyező hatóság kizárhatja az engedélyezésnél elfogadhatók közül.”

Jelen eljárás nem tartozik a veszélyhelyzet megszűnésével összefüggő átmeneti szabályokról és a járványügyi készültségről szóló 2020. évi LVIII. törvény (a továbbiakban: Tv.) hatálya alá.

A Tv. 398. § (2) bekezdése kimondja:

*„E fejezet hatálya nem terjed ki:*

- b) azokra az ügyekre, amelyekben a kérelmezett jog Magyarország nemzetközi jogi kötelezettségei, valamint az Európai Unió kötelező jogi aktusai alapján kizárólag engedéllyel gyakorolható,*
- d) azokra az engedélyezésekre, amelynek tárgya valamely jogosultság mértékének megállapítása.”*

Az engedélyező hatóság a határozatát a földművelésügyi hatósági és igazgatási feladatokat ellátó szervek kijelöléséről szóló 383/2016. (XII.2.) Kormányrendelet 19. §-ában és az élelmiszerláncról és hatósági felügyeletéről szóló 2008. évi XLVI. törvény 33. § e) pontjában biztosított jogkörében, foglaltaknak megfelelően hozta.

Jelen határozat elleni fellebbezés lehetősége az Ákr. 116. § (1) bekezdése, (4) bekezdés d) pontja alapján került kizárásra. A keresetindítás lehetőségéről szóló tájékoztatást az Ákr. 112. § (1) bekezdése, 114. § (1) bekezdése határozza meg.

A bírósági felülvizsgálat és a kereset benyújtásának lehetőségéről és szabályairól, az Éltv. 39/A. §-a; a közigazgatási perrendtartásról szóló 2017. évi I. törvény 28. § (1)-(2) bekezdése, 29. § (1) bekezdése 38. §-a, 39. §-a, 50. §-a, 52. §-a, 77. §-a, 157. §. (1) bekezdése; a bíróságok szervezetéről és igazgatásáról szóló 2011. évi CLXI. törvény 21. § (6) bekezdése; a polgári perrendtartásról szóló 2016. évi CXXX. törvény 605. §-a; valamint az elektronikus ügyintézés és a bizalmi szolgáltatások általános szabályairól szóló 2015. évi CCXXII. törvény 9. § (1) bekezdése rendelkezik.

Budapest, 2021. december 17.

Dr. Tarnai Richárd kormány megbízott  
nevében és megbízásából

Dr. Vincze Eleonóra  
osztályvezető

A határozatot kapiák:

1. Ügyfél
2. Irattár



PEST MEGYEI  
KORMÁNYHIVATAL

Ügyirat-szám: PE/NV/02252-6/2021  
Ügyintéző: Ferenczi Júlia  
Telefon: 06-1/236-3975  
E-mail: ferenczi.julia@pest.gov.hu

Tárgy: Corteva Crop Solution HUN  
Kft. vizsgálóhelyének GEP  
tanúsításának módosítása  
Melléklet:-

A Pest Megyei Kormányhivatal (a továbbiakban: Engedélyező Hatóság) a Corteva Crop Solution HUN Kft. (adószám: 11762085244, FELIR azonosító: AA0141949, székhely: 2040 Budaörs, Neumann János u. 1 sz., telephely: 6728 Szeged, Kotányi János köz 4. továbbiakban: Ügyfél) vizsgálóhelyének Helyes Kísérleti Gyakorlat = *Good Experimental Practice* (a továbbiakban: GEP) szerinti inspekciója a vizsgálóhely név és címváltozásának bejelentése kapcsán az ügyfél kérelme alapján indult eljárásban meghozta az alábbi

H A T Á R O Z A T O T :

Az engedélyező hatóság a PE/NV/01445-11/2021 számú határozat szerinti (a továbbiakban: Alaphatározat) GEP-minősítést - az egyéb rendelkezések változatlanul hagyása mellett – az alábbiak szerint *m ó d o s í t j a*.

*Az Alaphatározat rendelkező részében szereplő szövegrész*

*Dow AgroSciences Hungary Kft. Szabadföldi Kísérleti Állomás (székhely: 2040 Budaörs, Neumann János u. 1 sz., telephely: 6710 Szeged, Back Bernát utca 01416/20 hrsz. továbbiakban: Ügyfél)*

*az alábbiak szerint módosul*

*Corteva Crop Solution HUN Kft. (adószám: 11762085244, FELIR azonosító: AA0141949, székhely: 2040 Budaörs, Neumann János u. 1 sz., telephely: 6728 Szeged, Kotányi János köz 4. továbbiakban: Ügyfél)*

Ezen határozattal szemben közigazgatási eljárás keretében fellebbezésnek helye nincs, ugyanakkor az Ügyfél jogszabály-sértésre való hivatkozással kérheti jelen, a közléssel véglegessé váló határozat felülvizsgálatát, a határozat közlésétől számított harminc napon belül a Fővárosi Törvényszéktől, a határozatot hozó Engedélyező Hatóság elleni kereset indításával. A keresetlevelet a Pest Megyei Kormányhivatal Élelmiszerlánc-biztonsági, Állategészségügyi, Növény- és Talajvédelmi Főosztály Növény- és Talajvédelmi Osztályához (1135 Budapest, Lehel u. 43-47.) elektronikus úton kell benyújtani.

I N D O K O L Á S

Az Ügyfél 2022. október 7-én érkezett levelében a PE/NV/01445-11/2021 számú határozat szerinti GEP-minősítésének módosítását kérte vizsgálóhelyének név és címváltozása okán.

Az engedélyező hatóság a tényállás tisztázása érdekében 2022. december 1-én az Ügyfél telephelyén helyszíni ellenőrzést tartott, amelyeknek megállapításait a PE/NV/02252-5/2021 ügyiratszámú jegyzőkönyvben rögzítette.

A helyszíni ellenőrzés során az engedélyező hatóság megállapította, hogy a növényvédő szerek forgalomba hozatalának és felhasználásának engedélyezéséről, valamint a növényvédő szerek csomagolásáról, jelöléséről, tárolásáról és szállításáról szóló 89/2004. (V. 15.) FVM rendelet (továbbiakban: Rendelet) 22. §-ban foglalt biológiai hatásvizsgálatokkal kapcsolatos előírásoknak a vizsgálóhely megfelel továbbá, hogy a vizsgálóhely a PE/NV/01445-11/2021 ügyiratszámú határozatban foglalt GEP-minősítés előírásait változatlanul teljesíti.

A fentiek alapján megállapítottam, hogy a GEP-minősítés módosításának feltételei teljesültek, ennek megfelelően döntöttem a rendelkező részben foglaltak szerint.

Az engedélyező hatóság a határozatát a földművelésügyi hatósági és igazgatási feladatokat ellátó szervek kijelöléséről szóló 383/2016. (XII.2.) Kormányrendelet 19. §-ában és az élelmiszerláncról és hatósági felügyeletéről szóló 2008. évi XLVI. törvény 33. § e) pontjában biztosított jogkörében, foglaltaknak megfelelően hozta.

Jelen határozat elleni fellebbezés lehetősége az Ákr. 116. § (1) bekezdése, (4) bekezdés d) pontja alapján került kizárásra. A keresetindítás lehetőségéről szóló tájékoztatást az Ákr. 112. § (1) bekezdése, 114. § (1) bekezdése határozza meg.

A bírósági felülvizsgálat és a kereset benyújtásának lehetőségéről és szabályairól, az Éltv. 39/A. §-a; a közigazgatási perrendtartásról szóló 2017. évi I. törvény 28. § (1)-(2) bekezdése, 29. § (1) bekezdése 38. §-a, 39. §-a, 50. §-a, 52. §-a, 77. §-a, 157. §. (1) bekezdése; a bíróságok szervezetéről és igazgatásáról szóló 2011. évi CLXI. törvény 21. § (6) bekezdése; a polgári perrendtartásról szóló 2016. évi CXXX. törvény 605. §-a; valamint az elektronikus ügyintézés és a bizalmi szolgáltatások általános szabályairól szóló 2015. évi CCXXII. törvény 9. § (1) bekezdése rendelkezik.

Budapest, 2022. december 05.

Dr. Tarnai Richárd főispán  
nevében és megbízásából

Dr. Brandenburg Tamás  
főosztályvezető

A határozatot kapják:

1. Ügyfél
2. Irattár



## Certificate of GEP compliance CPR Europe Kft.

Aláíró: dr. Vincze Eleonóra (2022.05.23.)



### PEST MEGYEI KORMÁNYHIVATAL

Ügyirat-szám: PE/NV/00330-10/2022

Ügyintéző: Ferenczi Júlia

Telefon: 06-1/236-3975

E-mail: ferenczi.julia@pest.gov.hu

Tárgy: CPR Europe Kft. vizsgáló-

helyének GEP tanúsítása

Melléklet:-

A Pest Megyei Kormányhivatal (a továbbiakban: Engedélyező Hatóság) az CPR Europe Kft. (székhely: 9700 Szombathely, Török Ignác utca 30., adószám: 13710754-2-18, FELIR azonosító: AA6232182, telephelyek: 6800 Hódmezővásárhely, Kisfaludy út 127., 4030 Debrecen, Óvoda utca 28. A. ép., 9840 Csurgó, Zrínyi u. 61., 8175 Balatonfüzfő, Aradi u. 23., a továbbiakban: Ügyfél) vizsgálóhelyének Helyes Kísérleti Gyakorlat = *Good Experimental Practice* (a továbbiakban: GEP) szerinti inspekcója és elismerése iránti kérelme alapján indult eljárásban meghozta az alábbi

### HATÁROZATOT:

**Engedélyezési célú biológiai hatásvizsgálatok végzéséhez az Ügyfél vizsgálóhelyének GEP-minősítését kiadom.**

A GEP - minősítés 5 évig érvényes döntésem közléssel véglegessé válásától számítva.

A GEP-minősítés az alábbi minősítési kategóriákra és művelési ágakra kerül kiadásra:

- **minősítési kategória:** herbicidek, fungicidek és baktericidek, zoocidok, növekedésszabályozó és termésnövelő készítmények, adalékanyagok

- **művelési ág:** szántóföld, zöldség, gyümölcs, szőlő, dísnövény, erdő, közterület és egyéb

Jelen minősítés nem érinti a működéssel/tevékenységgel folytatásával kapcsolatos egyéb jogszabályban előírt engedélyeket, illetve Ügyfélnek azok beszerzésére vonatkozó kötelezettségét.

Az Ügyfél a vizsgálóhelyeinek minősített tevékenységét érintő jelentős változásról 15 napon belül köteles értesíteni az engedélyező hatóságot.

A GEP-minősítéssel kapcsolatos jogszabályokban és a jelen határozatban foglaltak betartását hatóságom szűrőpróbaszerűen ellenőrzi. Amennyiben az ellenőrzés során megállapítást nyer, hogy a vizsgálóhely nem tartja be a rá vonatkozó GEP - követelményeket, akkor az engedélyező hatóság a határozatban feltüntetett minősített területre vonatkozó tevékenység végzését legfeljebb 2 hónapra felfüggesztheti, illetve a kiadott GEP-minősítését visszavonhatja.

Ha az ellenőrzés során egy adott kísérlettel kapcsolatban hiányosságok kerülnek megállapításra, a kísérletet a hiányosságok mértékétől függően az engedélyező hatóság kizárhatja az engedélyezésnél elfogadhatók közül.

A vizsgálóhely GEP szerinti inspekcója és ismételt elismerése eljárás díjköteles. A díjtétel a Nemzeti Élelmiszerlánc-biztonsági Hivatal, valamint a megyei kormányhivatalok mezőgazdasági szakigazgatási szervei előtt kezdeményezett eljárásokban fizetendő igazgatási szolgáltatási díjak mértékéről, valamint az igazgatási szolgáltatási díj fizetésének szabályairól szóló 63/2012. (VII. 2.) VM rendelet 1. sz. mellékletének 8.19.2. pontja szerint: 250.000,- Ft, amelyet az Ügyfél megfizetett.

Élelmiszerlánc-biztonsági, Állategészségügyi, Nővény- és Talajvédelmi Főosztály

Cím: 1135 Budapest, Lehel u. 43-47.

Telefon: (06-1)236-4160, KRID: 511509738

E-mail: nio@pest.gov.hu Web: <http://www.kormanyhivatal.hu/hu/pest>

Ezen határozattal szemben közigazgatási eljárás keretében fellebbezésnek helye nincs, ugyanakkor az Ügyfél jogszabály-sértésre való hivatkozással kérheti jelen, a közléssel véglegessé váló határozat felülvizsgálatát, a határozat közlésétől számított harminc napon belül a Fővárosi Törvényszéktől, a határozatot hozó Engedélyező Hatóság elleni kereset indításával. A keresetlevelet a Pest Megyei Kormányhivatal Élelmiszerlánc-biztonsági, Állategészségügyi, Növény- és Talajvédelmi Főosztály Növény- és Talajvédelmi Osztályához (1135 Budapest, Lehel u. 43-47.) elektronikus úton kell benyújtani.

## INDOKOLÁS

Az Ügyfél 2022. március 02. napján érkezett levelében vizsgálóhelyének inspekciónak kérte az engedélyező hatóságtól.

Az engedélyező hatóság 2022. április 22-én az Ügyfél székhelyén, 2022. április 27-én a hódmezővásárhelyi-, 2022. április 28-án a debreceni-, 2022. április 29-én a balatonfüzfői-, illetve a csurgói telephelyen helyszíni ellenőrzést tartott, amelyeknek megállapításait a PE/NV/00330-3/2022, PE/NV/00330-4/2022, PE/NV/00330-5/2022, PE/NV/00330-6/2022, PE/NV/00330-7/2022, ügyiratszámú jegyzőkönyvekben rögzítette.

A helyszíni ellenőrzés során az engedélyező hatóság megállapította, hogy a növényvédő szerek forgalomba hozatalának és felhasználásának engedélyezéséről, valamint a növényvédő szerek csomagolásáról, jelöléséről, tárolásáról és szállításáról szóló 89/2004. (V. 15.) FVM rendelet (továbbiakban: Rendelet) 22. §-ban foglalt biológiai hatásvizsgálatokkal kapcsolatos előírásoknak a vizsgálóhely nem felelt meg hiánytalanul, és az Ügyfelet a PE/NV/00330-8/2022 ügyiratszámú végzésben a hiányosságok megszüntetésére, pótlására szólította fel.

Az Ügyfél a hiányosságokat megszüntette és annak bizonyításáról szóló dokumentációt az engedélyező hatóságnak 2022. május 19. napján napján megküldte.

**A fentiek alapján megállapítottam, hogy a GEP-minősítés megadásának feltételei teljesültek, ennek megfelelően döntöttem a rendelkező részben foglaltak szerint.**

A Rendelet 22. §-a értelmében „(5) Kérelem alapján az engedélyező hatóság helyszíni ellenőrzést folytat le a vizsgálóhelyen, majd határozatban dönt a vizsgálóhely GEP-minősítéséről. A határozatnak ki kell terjednie arra, hogy a vizsgálóhely milyen kategóriákra, illetve művelési ágakra szerezte meg a GEP-minősítést.

(6) A GEP-minősítés érvényességi ideje első tanúsítás esetén 2 év, a tanúsítás megújítását követően legfeljebb 5 év.

(7) A GEP-minősítési eljárásért a külön jogszabályban meghatározott díjat kell fizetni.

(8) A GEP-minősítéssel rendelkező vizsgálóhely minden, a minősített tevékenységét érintő jelentős változásról 15 napon belül köteles értesíteni az engedélyező hatóságot.

(9) Az engedélyező hatóság szűrőpróbaszerűen ellenőrzi a GEP-minősítéssel rendelkező vizsgálóhelyeket. Amennyiben megállapítást nyer, hogy a vizsgálóhely nem tartja be a rá vonatkozó GEP-követelményeket, a hatóság a határozatban feltüntetett minősített területre vonatkozó tevékenységet legfeljebb 2 hónapra felfüggesztheti, illetve a kiadott GEP-minősítést visszavonhatja. Ha az ellenőrzés során egy adott kísérlettel kapcsolatban hiányosságok kerülnek megállapításra, a kísérletet a hiányosságok mértékétől függően az engedélyező hatóság kizárhatja az engedélyezésnél elfogadhatók közül.”

Jelen eljárás nem tartozik a veszélyhelyzet megszűnésével összefüggő átmeneti szabályokról és a járványügyi készségről szóló 2020. évi LVIII. törvény (a továbbiakban: Tv.) hatálya alá.

A Tv. 398. § (2) bekezdése kimondja:

*„E fejezet hatálya nem terjed ki:*

- b) azokra az ügyekre, amelyekben a kérelmezett jog Magyarország nemzetközi jogi kötelezettségei, valamint az Európai Unió kötelező jogi aktusai alapján kizárólag engedéllyel gyakorolható,*
- d) azokra az engedélyezésekre, amelynek tárgya valamely jogosultság mértékének megállapítása.”*

Az engedélyező hatóság a határozatát a földművelésügyi hatósági és igazgatási feladatokat ellátó szervek kijelöléséről szóló 383/2016. (XII.2.) Kormányrendelet 19. §-ában és az élelmiszerláncról és hatósági felügyeletéről szóló 2008. évi XLVI. törvény 33. § e) pontjában biztosított jogkörében, foglaltaknak megfelelően hozta.

Jelen határozat elleni fellebbezés lehetősége az Ákr. 116. § (1) bekezdése, (4) bekezdés d) pontja alapján került kizárára. A keresetindítás lehetőségéről szóló tájékoztatást az Ákr. 112. § (1) bekezdése, 114. § (1) bekezdése határozza meg.

A bírósági felülvizsgálat és a kereset benyújtásának lehetőségéről és szabályairól, az Éltv. 39/A. §-a; a közigazgatási perrendtartásról szóló 2017. évi I. törvény 28. § (1)-(2) bekezdése, 29. § (1) bekezdése 38. §-a, 39. §-a, 50. §-a, 52. §-a, 77. §-a, 157. § (1) bekezdése; a bíróságok szervezetéről és igazgatásáról szóló 2011. évi CLXI. törvény 21. § (6) bekezdése; a polgári perrendtartásról szóló 2016. évi CXXX. törvény 606. §-a; valamint az elektronikus ügyintézés és a bizalmi szolgáltatások általános szabályairól szóló 2015. évi CCXXII. törvény 9. § (1) bekezdése rendelkezik.

Budapest, 2022. május 23.

**Dr. Tarnai Richárd** kormány megbízott  
névében és megőléséből

**Dr. Vincze Eleonóra**  
osztályvezető

A határozatot kapják:

1. Ügyfél
2. Pest Megyei Kormányhivatal Pénzügyi és Gazdálkodási Főosztálya
3. Irattár

## Certificate of GEP compliance Dow AgroSciences Poland

**GŁÓWNY INSPEKTOR  
OCHRONY ROŚLIN I NASIENICTWA**

*Mirosława Konicka*

Nr ewidencyjny: WO-505-2/2004

Warszawa, dnia 04.04.2007 r.

**DECYZJA Nr 2/2007**

Na podstawie art. 155 ustawy z dnia 14 czerwca 1960 r. Kodeks postępowania administracyjnego (Dz. U. z 2000 r. Nr 98, poz. 1071 z późn. zm.), po rozpatrzeniu wniosku z dnia 19 marca 2007 r., uzupełnionego pismem z dnia 23 marca 2007 r. o zmianę zakresu upoważnienia do prowadzenia badań skuteczności działania środka ochrony roślin zmieniam decyzję Nr 7/2005 z dnia 1 maja 2005 r. zmienioną decyzją Nr 1/2006 z dnia 21 lutego 2006 r. Rozstrzygnięciu decyzji nadaje następujące brzmienie:

**upoważniam**

**Dow AgroSciences Polska Sp. z o.o.  
ul. Domaniewska 50 A, 02-672 Warszawa**

**do prowadzenia badań skuteczności działania środka ochrony roślin**

z grupy fungicydów, herbicydów, insektycydów, regulatorów wzrostu oraz łącznego stosowania środków ochrony roślin na trawnikach i boiskach piłkarskich, w szkółkach drzew owocowych, a także na łąkach i pastwiskach, w uprawach polowych: zbóż, rzepaku, gorczycy, słoneczników, ziemniaków, buraków cukrowych, marchwi, kapusty, kalafiorów, brokułów, cebuli, porów, sałaty i cykori oraz w uprawach sadowniczych: jabłoni, gruszy, śliw, czereśni, wiśni, a także w uprawie kukurydzy.

Okres ważności upoważnienia pozostaje bez zmian.

**Uzasadnienie**

Wniosek z dnia 19 marca 2007 r. firma Dow AgroSciences Polska Sp. z o.o., ul. Domaniewska 50 A, 02-672 Warszawa wystąpiła o zmianę Decyzji Nr 7/2005 z dnia 1 maja 2005 r. zmienionej decyzją Nr 1/2006 z dnia 21 lutego 2006 r. ze względu na zmianę siedziby i adresu firmy. Mając na uwadze powyższe, postanowiono jak w rozstrzygnięciu decyzji.

**Pouczenie**

Od niniejszej decyzji odwołanie nie przysługuje. Jednakże strona niezadowolona z decyzji może zwrócić się do Głównego Inspektora Ochrony Roślin i Nasiennictwa z wnioskiem o ponowne rozpatrzenie sprawy w terminie 14 dni od dnia doręczenia decyzji, zgodnie z art. 127 § 3 Kodeksu postępowania administracyjnego.







## GŁÓWNY INSPEKTORAT OCHRONY ROŚLIN I NASIENNICTWA

ul. Młynarska 42, 01-171 Warszawa  
tel. 022 385 57 70, fax 022 385 57 50  
www.piorin.gov.pl, e-mail: gi@piorin.gov.pl

WO-505- 34 /2010

Warszawa, 16.06.2010 r.

### Dow AgroSciences Polska Sp. z o.o.

ul. Domaniewska 50 A  
02-672 Warszawa

Główny Inspektor Ochrony Roślin i Nasiennictwa uprzejmie informuje, że zgodnie z przepisami art. 50 ustawy z dnia 4 marca 2010 r. o świadczeniu usług na terytorium Rzeczypospolitej Polskiej (Dz.U. Nr 47 poz. 278), upoważnienie do prowadzenia badań skuteczności działania środków ochrony roślin Nr 7/2005 z dnia 1 maja 2005 r., zmienione decyzjami Nr 1/2006 (z dnia 21 lutego 2006 r.) oraz Nr 2/2007 (z dnia 4 kwietnia 2007 r.), stało się upoważnieniem wydanym na czas nieokreślony.

Upoważnienie do prowadzenia badań skuteczności działania środków ochrony roślin, udzielone przez Głównego Inspektora Ochrony Roślin i Nasiennictwa, stanowi potwierdzenie spełniania warunków organizacyjno-techniczne, zwanych „Zasadami Dobrej Praktyki Eksperymentalnej” (Good Experimental Practice - GEP), zapewniających prawidłowe przeprowadzanie badań skuteczności działania środków ochrony roślin.

Dariusz Winiarski  
Z-ca Głównego Inspektora

## Certificate of GEP compliance Dow AgroSciences Hungary



**n é b i h**  
Termőfölddel az asztalig

**National Food Chain Safety Office**  
Directorate of Plant Protection, Soil Conservation  
and Agri-environment



H-1118 Budapest, Budaiúti út 143-145,  
Hungary  
Tel: 36/1/305-1800 Fax: 36/1/266-2962  
E-mail: [ni@nehbih.gov.hu](mailto:ni@nehbih.gov.hu)  
[www.nehbih.gov.hu](http://www.nehbih.gov.hu)

Your ref.: -

Our ref.: 04.2/4827-8/2016

2 September 2016

Subject: Certificate of Official Recognition of Efficacy Testing Facilities or Organisations in Hungary

Having received the application submitted by the **Dow AgroSciences Hungary Kft. Szabadföldi Kísérleti Állomása (H-5000 Szolnok, Vizpart krt. 32, Hungary)**, the client, for completing a certification procedure of first instance concerning the Official Recognition of Efficacy Testing Facilities/Organisations, i.e. Good Experimental Practices (*hereinafter*: GEP), I, acting as the food chain control body, has made the following

### DECISION:

**I issue the client's GEP certificate for its premises at Szolnok, Vizpart krt. 32 for carrying out efficacy trials for authorisation purposes. The GEP certificate is effective for 5 years from the entry into force of this Decision.**

The client's GEP certificate is given for the following categories of products and cultivation:

- product categories:** herbicides, fungicides and bactericides, zoocides, growth regulators and yield enhancing substances, additives;
- cultivation categories:** field crops, vegetables, fruits, grapevines, ornamentals, forest, public place, others.

I inform you that the present certification is without prejudice to either the licences concerning the operation/follow-up of activity laid down in other provisions of legislation or the client's obligation for obtaining them.

The client is obliged to notify the competent authority, within 15 days, of any important changes concerning the certified activity of the testing facility.

I call your attention that respect of the provisions laid down in the legislation on GEP certification and in this Decision shall be randomly controlled by my competent authority. If during the official inspection it is stated that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate.

If during the official inspection it is found that some details are missing in relation to a particular trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization.

The fee of the present procedure is 250.000 HUF (i.e. two hundred and fifty thousand Hungarian Forints) paid by the client.

No further complaint shall be lodged against the present Decision, effective by its publication, through state administration, though with reference to infringement of law, judicial review of the Decision may be requested at the Capital Administrative and Employment Court. The claim note shall be submitted to my competent authority within 30 days of the communication of the Decision.

I inform you that the court shall judge the case out of court, but shall carry on a lawsuit at the request of any of the parties. The client may ask for carrying on a lawsuit, but in default of so doing, no verification is accepted. Submission of the claim note has no delaying force on the implementation of this Decision.

## J U S T I F I C A T I O N

In its application of 7 July 2016, the client submitted an application to the competent authority for a procedure of GEP certification.

As a follow-up to this application, the competent authority made a local inspection at the client's facility of Szolnok, Vizpart krt. 32 on 13 July 2016. Statements made during the local inspection are reported in the protocol Nr. 04.2/4827-4/2016. Based on the results of the local inspection the competent authority concluded that the client's testing facility does not meet the requirements concerning the efficacy trials specified in Article 22 of the Decree 89/2004 (V. 13.) FVM on the authorization of placing on the market and use, as well as on the packaging, labelling, storage and transport of plant protection products (hereinafter: Decree 89/2004) and in the Decision Nr. 04.2/4827-5/2016 it calls the client to fill the data gaps.

*Article 22(5) of Decree 89/2004 - Based on request, the competent authority shall make local inspections at the testing facility and decide on the GEP qualification of the testing facility. The decision shall include the product categories and the cultivation categories for which the testing facility obtained the GEP-certificate.*

*(6) The validity of GEP-certification is 2 years in case of the first request and maximum 5 years in case of renewal of the certification.*

*(7) A fee laid down in specific legislation shall be paid for the GEP-certification procedure.*

*(8) The testing facility having GEP-certification shall notify the competent authority, within 15 days, about any important changes concerning the certified activity of the testing facility.*

*(9) The competent authority shall randomly control the testing facility having GEP-certification. If it is found that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate. If during the official inspection it is established that some details are missing in relation to a trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization."*

Client filled the missing data gaps and reported on it in the letter of 11 August 2016, therefore I made the Decision as specified in the first part. Therefore I stated that conditions for issuing the certificate specified above are met, so I made the Decision as specified in the first part.

The fee of the present procedure is HUF 250.000 and was established in accordance with point 8.19.2 of Annex 1 to the Decree 63/2012. (VII. 2.) VM on the extent of administrative servicing fees due for the procedures by the agricultural administrative bodies of the National Food Chain Safety Office and the county government offices and on the rules of paying the administrative servicing fees. The client paid the fee.

I made this Decision within my jurisdiction laid down in Article 3 paragraph (1) and Article 5 point c) of Government Decree 22/2012. (II. 29.) concerning the National Food Chain Safety Office, Article 3, Article 22 paragraph (1) of Decree 89/2004 and in compliance with Articles 71 paragraph (1) and Article 72 paragraph (1) of Act CXL of 2004 on general rules of administrative official procedure and service (hereinafter: Act CXL of 2004).

I excluded the possibility of appeal in compliance with Article 100 paragraph (1) point e) of Act CXL of 2004 and provided the possibility of judicial review in compliance with Article 109 paragraph (1) of Act CXL of 2004 and Article 330 paragraph (2) of Act III of 1952 on Civil Procedure.

on behalf of  
dr. Márton Oravecz  
president



## Certificate of GEP compliance Ephydia



MINISTÈRE DE L'AGRICULTURE ET DE L'ALIMENTATION

### DÉCISION D'AGRÈMENT POUR RÉALISER DES ESSAIS OFFICIELLEMENT RECONNUS

Conformément à l'article R. 253-38 du code rural et de la pêche maritime et à l'article 6 de l'arrêté du 26 avril 2007 relatif aux essais officiels et officiellement reconnus pour l'évaluation des produits mentionnés à l'article L. 253-1 du code rural et de la pêche maritime,

Vu la convention passée avec le Cofrac n° 2859,

Vu le rapport d'évaluation réalisé par le Cofrac, en date du 13/10/2017,

L'agrément pour réaliser des essais officiellement reconnus est renouvelé, à l'organisme :

EPHYDIA  
1 rue de courcelette  
62450 MARTINPUICH

sous le numéro : **BPE - 035**

POUR LE PERIMÈTRE SUIVANT :

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
EPHYDIA 48 bis grand rue 62450 Martinpuich ( <i>unité centrale</i> )	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum
unité d'expérimentation morisel route d'ailly sur noye 80110 Morisel	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum

Cet agrément est délivré pour une durée de cinq ans à compter du 30/01/2018 jusqu'au 29/01/2023. En application de l'article 5 de l'arrêté susmentionné, une nouvelle évaluation aura lieu dans un délai compris entre vingt-quatre et trente-six mois à compter du 30/01/2018.

Date : 08 JAN 2018

Le Chef du Service des Actions Sanitaires  
en Production Primaire

Alain TRIDON



## Certificate of GEP compliance Essais+



### DÉCISION D'AGRÈMENT POUR RÉALISER DES ESSAIS OFFICIELLEMENT RECONNUS

Conformément à l'article R. 253-38 du code rural et de la pêche maritime et à l'article 6 de l'arrêté du 26 avril 2007 relatif aux essais officiels et officiellement reconnus pour l'évaluation des produits mentionnés à l'article L. 253-1 du code rural et de la pêche maritime,

Vu la convention passée avec le Cofrac n° 2948,

Vu le rapport d'évaluation réalisé par le Cofrac, en date du 11/01/2022,

L'agrément pour réaliser des essais officiellement reconnus est maintenu, à l'organisme :

**ESSAIS +**

1 rue du 8 mai  
62128 BOYELLES

sous le numéro : BPE - 036

ET POUR LE PERIMETRE SUIVANT :

UNITE(S)	SECTEUR(S) D'ACTIVITE
ESSAIS + 1 rue du 8 mai 62128 BOYELLES (unité centrale)	<ul style="list-style-type: none"><li>- Grandes cultures</li><li>- Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum</li><li>- Zones non agricoles</li><li>- Traitement des semences : Cultures légumières</li></ul>

Cet agrément est valable jusqu'au 16 février 2024. L'évaluation de renouvellement devra impérativement avoir lieu 5 mois avant cette échéance.

Date : 04 JAN 2022

Le sous-directeur de la santé  
et de la protection des  
végétaux

L'adjointe à la sous-directrice de la santé  
et de la protection des végétaux

Anne GIREL

## Certificate of GEP compliance Eurofins Agrartest GmbH

### GEP-Anerkennungs-Zertifikat / Recognition Certificate

#### Anerkennungsbescheinigung

Die Versuchseinrichtung  
mit Hauptsitz in

und organisatorisch  
zugehörigen Arbeitseinheiten in

ist auf Antrag vom

und nach durchgeführter  
Besichtigung  
durch

vom

am

in den Versuchskategorien

als Einrichtung für die Prüfung  
der Wirksamkeit von  
Pflanzenschutzmitteln im Sinne  
des § 8 Abs. 6 der  
Pflanzenschutzmittelverordnung  
und gemäß Verordnung (EU)  
Nr. 284/2013 für 5 Jahre  
amtlich anerkannt worden.

**Eurofins Agrosience  
Services GmbH/  
Agrartest GmbH  
Carl-Goerdeler-Weg 5  
21684 Stade**

**siehe Seite 2**

**26.01.2021**

**Frau Warnecke-Busch**

**LWK-Niedersachsen**

**Januar 2021**

**Ackerbau, Gemüsebau,  
Obstbau, Zierpflanzen,  
Forst, Sonderkulturen**

#### Recognition Certificate

The testing facility  
with headquarters in

and subsidiary testing units  
in

on application from

and after inspection

by

dated

on

in the trial cate

has been officially  
recognised as an  
organisation for efficacy  
testing facility of plant  
protection products  
according to § 8 par. 6 of  
the Plant Protection  
Products Ordinance and  
the Commission  
Regulation (EU) No  
284/2013 for 5 years.

18.5.21 *[Signature]*

Datum

Unterschrift

Date

Sign

**Wunstorfer  
Landstraße 9  
30453 Hannover**

Adresse der  
Anerkennungsbehörde  
address of the  
recognising authority



Stamp

Seite 2

Organisatorisch zugehörigen Arbeitseinheiten/ subsidiary testing units

Baden-Württemberg	Agrartest GmbH Scheerwiesenweg 41 D-71701 Schwieberdingen
Baden-Württemberg	Agrartest GmbH Neue Straße 54 D-89179 Beimerstetten
Baden-Württemberg	Eurofins Agrarservice GmbH Lempenseite 50/1 D-69168 Wiesloch
Bayern	Agrartest GmbH Geißbühl 3 D-97273 Kürnach
Brandenburg	Eurofins Agrosience Services GmbH Karl-Liebknecht-Str. 53 16321 Bernau
Hessen	Agrartest GmbH Steedener Weg 65594 Runkel-Dehm
Mecklenburg-Vorpommern	Agrartest GmbH Am Rehnhagen 13 D-17091 Rosenow
Niedersachsen	Eurofins Agrosience Services GmbH Pastor-Reins-Str. 14 D-49586 Merzen
Niedersachsen	Eurofins Agrosience Services GmbH Andreasplatz 2 D-311912 Groß Lobke
Nordrhein-Westfalen	Eurofins Agrosience Services GmbH Bad Meinberger Str. 168 D-32760 Detmold
Sachsen	Agrartest GmbH Friedensstraße 30 D-04769 Salbitz
Schleswig-Holstein	Agrartest GmbH Ringstraße 33c D-23845 Grabau
Sachsen-Anhalt	Eurofins Agrosience Service GmbH Wallstraße 7 D-39343 Hundisburg

18.5.21 *D. Wolke*

Datum

Unterschrift

Date

Sign

Wunstorfer  
Landstraße 9  
30453 Hannover

Adresse der  
Anerkennungsbehörde  
address of the  
recognising authority



Stamp

## Certificate of GEP compliance Eurofins Agrosience Services SRL

<b>MINISTERUL AGRICULTURII ȘI DEZVOLTĂRII RURALE</b> Autoritatea Națională Fitosanitară Comisia Națională de Omologare a Produselor de Protecție a Plantelor	<b>MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT</b> National Phytosanitary Authority National Commission for Registration of Plant Protection Products
---	--

Nr.Întreg/ Registration No: **15582 / 29.12.2020**

**Certificat de recunoaștere oficială a testelor de eficacitate biologică**  
**În conformitate cu bunele practici experimentale / Certificate of official**  
**recognition of the efficacy biological tests according to the good**  
**experimental practices**

**Se acordă:** SC EUROFINS AGROSCIENCES SERVICES SRL  
**It is granted to:** SC EUROFINS AGROSCIENCES SERVICES SRL  
**cu sediul:** Str. Muntele Mic, nr. 20, Giarmata, Jud. Timiș  
**with headquarters:** Muntele Mic street, no. 20, Giarmata, Timiș county

**domeniile de activitate:** culturi agricole de câmp și pajiști, pomicultură, viticultură, legumicultură, floricultură, plante aromatice și medicinale, plante ornamentale și de interior, silvicultură, zone non-agricole  
**domains of activity:** field and meadow crops, pomiculture, viticulture, vegetable growing, floriculture, aromatic and medicinal plants, ornamental and indoor plants, forestry, non-agricultural areas

Prezentul certificat se eliberează în conformitate cu prevederile Ordinului ministrului agriculturii și dezvoltării rurale, al ministrului sănătății și al ministrului mediului și schimbărilor climatice nr. 605/12/1258/2013 și prevederile Procedurii naționale de omologare a produselor de protecție a plantelor care conțin substanțe active notificate și pentru care nu s-a luat încă o decizie de includere în lista cu substanțe active autorizate în Uniunea Europeană, aprobată prin ordinul ministrului agriculturii, pădurilor și dezvoltării rurale, al ministrului sănătății și al ministrului mediului și gospodăriei apelor nr. 124/1978/12/2006, cu modificările și completările ulterioare.

This certificate is issued according to the provisions of the Order of the ministry of agriculture and rural development, of the ministry of health and of the ministry of environment and climate change no. 605/12/1258/2013 and the provisions of the National Procedure for Registration of Plant Protection Products which contain notified active substances and for which isn't taken yet a decision for inclusion in European Union list of authorized active substances, approved by the Order of the ministry of agriculture, forests and rural development, of the ministry of health and of the ministry of environment and waters husbandry no. 124/1978/12/2006, with subsequent amendments and completions.

**Data acordării certificatului: 24.11.2020**  
**Issuance date of the certificate**

**Data expirării certificatului: 24.11.2025**  
**Expiry date of the certificate**

**PREȘEDINTE/CHAIRMAN,**  
**Florentin Gheorghe MILEA**



## Certificate of GEP compliance Field Research Support

### A CERTIFIED TRANSLATION FROM POLISH INTO ENGLISH



MAIN INSPECTOR  
OF PLANT HEALTH AND SEED INSPECTION

*Tadeusz Klos*

WO-505-16/13

Warsaw, this day of 07.06.2013

#### DECISION No. 9/2013

On the basis of art. 155 of the Act of 14 June 1960 of Administrative Proceedings Code (Dz.U. of 2013, item 267) and art. 3 par.1, p.1 letter d of the Act of 8 March 2013 on Plant Protection Products (Dz.U. of 2013, item 455) in connection with art. 54 of the Regulation (EC) of the European Parliament and of the Council No. 1107/2009 of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (Official Journal of the EU L 309 of 24.11.2009, page 1, as amended) and art. 79 par. 3 of the above mentioned act on Plant Protection Products, having considered the motion of 4 May 2013, supplemented by the letter of 29 May 2013, I hereby change the decision No. 5/2006 of 9 June 2006, changed by the decisions No. 6/2007 of 21 May 2007 and No. 3/2010 of 14 May 2010.

The final decision is as follows:

**I authorise**

**Mr. Helmut Zöllner**

**conducting business activity under the company name of**

**Field Research Support**

**ul. Dworcowa 2; 64-000 Kościan**

**to conduct the research on the effectiveness of plant protection products**

**of the group of acaricides, fungicides, herbicides, insecticides, molluscicides and substances**



influencing growth in field production, closed places of plant production, nurseries, silvicultures and stands, fruit farming and grasslands. The research shall be conducted on the following cultivations: cereal, corn, root plants, rape and other oil plants, sunflowers, pulses, pears, plums, cherries, apples, sour cherries, peaches, apricots, strawberries, gooseberries, currants, chokeberries, cowberries, raspberries, blackberries, grapevines, asparagus, vegetables, grass, flowering plants, ornamentals and special plants (tobacco and hop).

#### Justification

By the letter of 4 May 2013, supplemented by the letter of 29 May 2013, Mr. Piotr Umiński, acting on the basis of the power of attorney granted to him, applied for extension of the scope of decision No. 5/2006 (of 9.06.2006), changed by the decisions No. 6/2007 (of 21.05.2007) and No. 3/2010 (of 14.05.2010) authorising Mr. Helmut Zöllner, conducting business activity under the company name of Field Research Support (ul. Dworcowa 2; 64-000 Kościan), to conduct the research on the effectiveness of plant protection products, to conduct the research on the cultivations of "apples, sour cherries, peaches, apricots, gooseberries, currants, chokeberries, cowberries, raspberries, blackberries, grapevines, asparagus, flowering plants, ornamentals, special plants (tobacco and hop) and grass". The application applied also to "grasslands" as a place of such research.

Mr. Helmut Zöllner, conducting business activity under the company name of Field Research Support, complies with the rules of Good Experimental Practice (GEP), assuring proper conducting of the research on the effectiveness of a plant protection product.

According to art.155 of the Administrative Proceedings Code, the final decision, by which the party was granted a right, may be, at any time, with the consent of the party, revoked or changed by the public administration authority granting thereof, if the specific regulations are not contrary to it and the public interest or justified interest of the party argue for such revocation or change. The procedure under art.155 of the Administrative Proceedings Code is possible, if there is the identicalness of the specific rights and obligations and if there is continuity of legal regulations. Furthermore, the party has to consent to such revocation or change, if the specific regulations are not contrary to it and the public interest or justified interest of the party argue for such revocation or change.



In the case above, the party applied for the change of administrative decision to extend the rights. Such application shall be considered as the party's consent to the change of the decision, since the request of change is definitely equivalent to clear and direct declaration to the public administration authority. What is more, in this case, we are dealing with the same rights of the same subject, determined by the valid administrative decision, with the continuity of law and legally unchanged state of affairs. Justified interest of the party argues for the change of the decision and there is no contradiction with any specific regulations.

Having considered the case in question, it was decided as stated hereinabove.

#### Directions

This decision is subject to no appeal. However, a party dissatisfied with the decision may apply to the Main Inspector of Plant Health and Seed Inspection for the review of the decision within 14 days from the date of it being served, according to art. 127 § 3 of Administrative Proceedings Code.

Stamp Duty of PLN 1000 collected, according to Part I par. 36c of the Annex to the Act of 16 November 2006 on Stamp Duty (Dz.U. of 2012, item 1282 as amended).

Małgorzata Kukula – main Specialist in Main Inspectorate of Plant Health and Seed Inspection.

*/-/ signature illegible*

*round seal with the national emblem of the Republic of Poland and the inscription:*  
MAIN INSPECTOR OF PLANT HEALTH AND SEED INSPECTION

*oblong seal with the inscription:*

Deputy MAIN INSPECTOR  
Dariusz Wiraszka

*/-/ signature illegible*

I, Grzegorz Zielinski, sworn translator, hereby certify that this translation conforms to the document in Polish.

Leszno, 10<sup>th</sup> July, 2013

Reg. No. 122 / 13





Certificate of GEP compliance FieldArm Ltd



# Certificate of

## Official Recognition of Efficacy Testing Facilities or Organisations in the United Kingdom

*This certifies that*

**FieldArm Limited**

complies with the minimum standards laid down in  
Regulation (EC) 1107/2009 for efficacy testing.

The above Facility/Organisation has been officially  
recognised as being competent to carry out efficacy trials/tests  
in the United Kingdom in the following categories:

**Agriculture/Horticulture  
Biologicals and Semiochemicals  
Stored Crops**

**Date of issue:** 29 January 2019  
**Effective date:** 1 February 2019  
**Expiry date:** 31 January 2024

**Signature**

Authorised signatory

Certification Number

ORETO 417



Chemicals Regulation Division



Department of  
**Agriculture and  
Rural Development**



**Certificate of GEP compliance Lithuanian research centre for agriculture and forestry.**

		
<b>VALSTYBINĖ AUGALININKYSTĖS TARNYBA PRIE ŽEMĖS ŪKIO MINISTERIJOS / STATE PLANT SERVICE UNDER THE MINISTRY OF AGRICULTURE</b>		
<b>GEROSIOS AUGALŲ APSAUGOS PRODUKTŲ VEIKSMINGUMO BANDYMŲ PRAKTIKOS SERTIFIKATAS / CERTIFICATE OF GOOD EXPERIMENTAL PRACTICE</b>		
<u>2019 m. gruodžio 6 d. Nr. AS4-02(2019)</u> <u>Vilnius</u>		
Šiuo sertifikatu patvirtinama, kad / This is to certify that Viešoji įstaiga Lietuvos agrarinių ir miškų mokslų centras		
(juridinio asmens pavadinimas, teisinė forma arba fizinio asmens vardas, pavardė / name, type of legal entity or name, surname of natural person)		
302471203		
(juridinio arba fizinio asmens kodas / code of legal entity or natural person)		
Instituto al. 1, Akademijos mstl., 58344 Kėdainių r.		
(juridinio asmens buveinės adresas arba fizinio asmens adresas / address of legal entity or natural person)		
laikosi gerosios augalų apsaugos produktų veiksmingumo bandymų praktikos ir turi teisę atlikti augalų apsaugos produktų veiksmingumo bandymus šioje (šiose) srityje (srityse) / complies with the requirements of good experimental practice and has the right to perform plant protection product efficacy testing in the following field (fields): lauko augalai (išskyrus daržoves) (adresu Instituto al. 1, Akademijos mstl., 58344 Kėdainių r.)		
Sertifikatas patikslintas / date of certificate specification: <u>2021 m. gruodžio 6 d.</u>		
Direktorius (pareigos / office)	 (parašas / signature)	Sergejus Fedotovas (vardas, pavardė / name, surname)

## Certificate of GEP compliance Nordic Beet Research



# Certificate

GEP approval is granted to

Testing unit: Nordic Beet Research Foundation  
Sofiehøj  
Højbygaardvej 14  
DK-4960 Holeby

The approval applies to the execution of GEP efficacy trials of pesticides within

Testing areas: Field Trials

GEP

The GEP Recognition Unit at the Danish Centre for Food and Agriculture, Aarhus University, controls organisation, staff, premises, trial fields, trial equipment, standard operation procedures and trial reports. The testing unit is subject to continuous control and inspection.

The certificate is valid for a period of 6 years. Expiration date: 31 December 2025

Date of approval: 1 January 2020

Signed: 11 December 2019

  
Henrik Brødsgaard  
Danish Environmental  
Protection Agency

  
Else Thordahl Meyer  
Aarhus University

  
Peter Kryger Jensen  
Aarhus University

*Regulation 1107/2009 concerning plant protection products and ministerial order no. 815 dated 18 June 2018 from Danish Ministry of the Environment states that investigations of the efficacy of plant protection products carried out in Denmark for registration purposes must be performed by testing units which have been approved to carry out these investigations by the Danish Centre for Food and Agriculture, Aarhus University.*

## Certificate of GEP compliance PerfectBAD

*certified translation from Polish*

*[image of the national emblem of Poland]*

**CHIEF INSPECTOR  
OF PLANT PROTECTION  
AND SEED PRODUCTION**

*Andrzej Chodkowski*

BORiT.510.6.2020

Warsaw, 27 April 2020

### **DECISION No 3/2020**

Pursuant to art 17 paras. 1 and 2 of the Act of 8 March 2013 on Plant Protection Products (Journal of Laws of 2019, section 1900 with subsequent amendments), having considered the application of 5 March 2020, supplemented by documents sent electronically (22 March 2020) and photographic documentation (30 March 2020) and the letter of 3 April 2020.,

#### **I authorise**

**Ms Justyna Rezmerska-Piętka, conducting business activity under the  
business name of**

**PerfectBAD Justyna Rezmerska-Piętka,  
(ul. Przytargowa 4; 99-412 Kiernozia)**

**to conduct efficacy study on plant protection products from the following groups: herbicides, fungicides, insecticides and growth regulators. The tests will be conducted in the field cultivation of spring cereals (wheat, triticale, barley, oats) and winter cereals (rye, wheat, triticale, barley), maize, rape, potato, sugar beet, vegetables (onion, cabbage, carrot, cucumber, tomato) and horticultural cultivation (apple tree).**

#### **Justification**

By virtue of the application of 5 March 2020, supplemented by the letter of 3 April 2020, Ms Justyna Rezmerska-Piętka conducting business activity under the business name PerfectBAD Justyna Rezmerska-Piętka (ul. Przytargowa 4; 99-412 Kiernozia), filed for authorization to the Chief Inspector of Plant Protection and Seed Production to conduct efficacy study of plant protection products.





Having regard to the provision of art 15zzzzy, para. 1 of the Act of 2 March 2020 on Detailed Solutions Related to the Prevention, Counteraction and Combating of COVID-19, Other Infectious Diseases and Crisis Situations Caused by them (Journal of Laws, sections 374, 567, 568 and 695), which temporarily excludes certain obligations resulting from the Act of 8 March 2013 on Plant Protection Products, the Chief Inspector of Plant Protection and Seed Production, prior to granting the authorization to conduct efficacy study on plant protection products, waived to conduct the inspection referred to in art 17 para. 6 of the Act on Plant Protection Products.

The assessment of meeting the requirements of good experimental practice by Ms Justyna Rezmerska-Piętka, conducting business activity under the business name of PerfectBAD Justyna Rezmerska-Piętka, was conducted on the basis of the application and attached documents and photos sent electronically on 22 March 2020 and 30 March 2020.

Considering the above, it should be recognized that Ms Justyna Rezmerska-Piętka, conducting business activity under the business name of the PerfectBAD Justyna Rezmerska-Piętka, meets the requirements of good experimental practice, so it was determined as in the decision.

### Instruction

There is no right of appeal against this decision. The party dissatisfied with the decision may apply to the Chief Inspector of Plant Protection and Seed Production to reconsider the case within 14 days from the date of service of the decision, pursuant to art 127 § 3 of the Code of Administrative Procedure.

During the time limit for submitting an application for the reconsideration of the case, the party may waive this right before the public authority which issued the decision. As of the date of service to the Chief Inspector of Plant Protection and Seed Production, the decision becomes final and valid, which means that the decision is immediately enforceable and it is not possible to appeal against the decision to the Provincial Administrative Court.

If the party does not believe that the decision is consistent with the application and does not wish to exercise its right to apply for reconsideration of the case, it may file a complaint against the decision with the Provincial Administrative Court in Warsaw within 30 days from the date of service of the decision to the party. The complaint is lodged through the Chief Inspector of Plant Protection and Seed Production.



Pursuant to § 2 para. 1 item 2 of the Regulation of the Council of Ministers of 16 December 2003 on the amount and detailed rules for collecting an entry fee in proceedings before administrative courts (Journal of Laws No 221, section 2193 with subsequent amendments), a permanent entry fee, regardless of the object of the contested deed or actions in cases of complaints against deeds or actions in the area of public administration concerning rights or obligations arising from the provisions of law, amounts to 200 PLN.

At the request of a party made before the commencement or in the course of court proceedings, the party may be granted the right to assistance in respect of total or partial exemption from court costs and the appointment of a counsel or solicitor where the party demonstrates that they are unable to bear any or all of the costs of proceedings.

A stamp duty was collected in accordance with part I para. 36b of the Appendix to the Act of 16 November 2006 on Stamp Duty (Journal of Laws of 2019, section 1000 with subsequent amendments) in the amount of 5 000 PLN.

CC:

1. Justyna Rezmierska-Piętka  
ul. Przytargowa 4  
99-412 Kiernozia  
2. on file

*[round seal with an image of the national emblem of Poland:*

*Chief Inspector of Plant Protection and Seed Production]*

*[stamp:*

*pp Chief Inspector*

*General Manager*

*Teresa Stachowicz-Janke]*

*(-) illegible signature on the stamp*

XX  
I, Robert Dzitowski MA, the signatory to this document, as competent legal translator duly licensed and sworn by the Minister of Justice, listed in the register of sworn translators kept by the Minister of Justice under number TP/2176/06, do hereby certify that the enclosed translation is accurate, correct and identical to the submitted (Polish) document.

Płońsk, 15 May 2020

Translation no 2720 / 2020



## Certificate of GEP compliance Staphyt, Austria GmbH



Spargelfeldstraße 191, 1220 Wien, Österreich

Datum: 05.06.2019  
Kontakt: Clemens Hurt LL.B. LL.M.  
Telefon: +43 (0) 505 55-32353, Fax: 33404  
E-Mail: clemens.hurt@baes.gv.at  
Geschäftszahl: BAES-PSM-2018-0525

### GEP-Bestätigung

#### Gute Experimentelle Praxis

Das Bundesamt für Ernährungssicherheit  
bestätigt hiermit, dass die

**Staphyt Austria GmbH**  
**Am Futerplatz 1**  
**2471 Rohrau**

in den Versuchskategorien Ackerbau, Grünland,  
Forst, Gemüsebau-Freiland, Gemüsebau-  
geschützte Kultur, Weinbau, Obstbau und  
Hopfenbau, Zierpflanzenbau-Freiland und  
Nichtkulturland

eine amtlich anerkannte Versuchseinrichtung  
für die Prüfung der Wirksamkeit von  
Pflanzenschutzmitteln gemäß § 9 Abs 2 der  
österreichischen Pflanzenschutzmittel-  
verordnung 2011 iVm der Verordnung (EU) Nr.  
545/2011 der Kommission vom  
10.06.2011 zur Durchführung der Verordnung  
(EG) Nr. 1107/2009 ist.

Die Anerkennung wurde mit Bescheid vom  
05.06.2019 auf der Grundlage des Gutachtens  
vom 25.03.2019 ausgesprochen und ist bis zum  
Ablauf des 31.12.2023 gültig.

### GEP-Certificate

#### Good Experimental Practice

The Federal Office for Food Safety  
hereby certifies that the

**Staphyt Austria GmbH**  
**Am Futerplatz 1**  
**2471 Rohrau**

is in the trial categories arable land, grassland,  
forest, vegetable production (field and  
protected conditions), viniculture, fruit  
production, hop growing, ornamental  
cultivations (field conditions) and non-cultivated  
areas

an official recognized organisation  
for the evaluation of efficacy of plant protection  
products according to § 9(2) Austrian Plant  
Protection Products Regulation 2011 in  
conjunction with the Commission Regulation  
(EU) No 545/2011 from  
10.06.2011 implementing Regulation  
(EC) No 1107/2009.

The recognition was granted on the decision  
dated 05.06.2019 (based on the evaluation  
report dated 25.03.2019) and is valid until  
31.12.2023.



Bundesamt für Ernährungssicherheit | [www.baes.gv.at](http://www.baes.gv.at)  
Spargelfeldstraße 191 | 1220 Wien | Österreich  
DVR: 0014541 | BAWAG P.S.K. AG | IBAN: AT85 6000 0000 9605 1513 | BIC: BAWAATWW  
Dokument-Nr.: 1908\_2

1 von 1

## GEP-Anerkennungs-Zertifikat

als Einrichtung für die Prüfung der Wirksamkeit von Pflanzenschutzmitteln im Sinne des § 8 Abs. 6 der Pflanzenschutzmittelverordnung und gemäß Verordnung (EU) 284/2013 für 5 Jahre bis zum 22.04.2023 amtlich anerkannt worden.

Datum date	Unterschrift sign	Adresse der anerkennenden Behörde address of the recognising authority	Stempel stamp
08.05.2019		Landwirtschaftskammer Schleswig-Holstein (Chamber of Agriculture Schleswig-Holstein) Grüner Kamp 15-17 24768 Rendsburg	



**Certificate of GEP compliance Zemědělská zkušební stanice KUJAVY, s.r.o.**

**ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ**

Odbor přípravků na ochranu rostlin

Zemědělská 1a, Brno, PSČ 613 00

Příloha rozhodnutí č.j.: UKZUZ 057358/2021 ze dne 6. 4. 2021

**OSVĚDČENÍ**

**GEP/KUJ/2021**

**o způsobilosti k provádění zkoušek  
v souladu se zásadami správné pokusnické praxe**

**Official Recognition Certificate / GEP - Certificate**

*právnícká osoba:* **Zemědělská zkušební stanice KUJAVY, s.r.o.**

*sídlo právnické osoby:* Kujavy 48, 742 45 Kujavy

*IČ právnické osoby:* 25816349

je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe podle § 45 odst. 1 zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, v platném znění, v návaznosti na Směrnici 01/411/EHS.

*oblasti zkoušení / categories of official recognition:*

- polní plodiny a zelenina / *field crops and vegetables*
- trvalé kultury / *high crops*
- skleníky a jiné kryté prostory / *protected areas and storage rooms*
- moření osiva / *seed treatment*
- laboratorní testy a analýzy / *laboratory tests and analyses*

Ústřední kontrolní a zkušební ústav zemědělský  
Sekce zemědělských vstupů  
Odbor přípravků na ochranu rostlin  
613 00 Brno, Zemědělská 1a  
-2-



Ing. Pavel Mjňář, Ph.D.  
ředitel odboru



## Appendix 1 Lists of data considered in support of the evaluation

### Appendix 1A - Lists of data considered in support of the evaluation

Reports in grey should be sanitised and not shared publically

Data point	Author(s)	Year	Title Company, Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner
KCP 6.2 KCP 6.4.1 #1	Zotter, C.	2023	Performance of GF-3307 on pathogen complex (CERCBE, UROMBE, ERYSB, RAMUBE) in sugar beets Staphyt, Austria, Report No. CH3-23-106294-01-AT01 Report No. AT23E7B029-FSA05C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.1 KCP 6.2 KCP 6.4.1 KCP 6.4.3 #2	Daňa, P.	2023	Performance of GF-3307 on pathogen complex (CERCBE, UROMBE, ERYSB, RAMUBE) in sugar beets, Europe 2023. Zemědělská zkušební stanice KUJAVy, s.r.o., Czech Republic, Report No. CZ23E7B029-PVL014C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2 KCP 6.4.1 KCP 6.4.3 #3	Jørgensen, L N.	2020	Efficacy and dose response of XDE-481 EC (GF-4480) and SC (GF-4505 + GF-4493) on Cercospora beticola and other key diseases in sugar beet. EU 2020 Aarhus University, Denmark, Report No. EA20F9B001F-DHW005 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2 KCP 6.4.1 KCP 6.4.3 #4	Jørgensen, L N.	2020	Efficacy and dose response of XDE-481 EC (GF-4480) and SC (GF-4505 + GF-4493) on Cercospora beticola and other key diseases in sugar beet. EU 2020 Aarhus University, Denmark, Report No. Report No. EA20F9B001F-DHW006 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.1 KCP 6.2 KCP 6.4.1 #5	Nistrup Jørgensen, L.	2022	Performance of GF-3307 on pathogen complex (CERCBE, UROMBE, ERYSB, RAMUBE) in sugar beets, Europe Aarhus University, Denmark, Report No. 22392-1 Report No. DK22E7B026-KFB06C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.1 KCP 6.2 KCP 6.4.1 KCP 6.4.3 #6	Hansen, A-L.	2022	Performance of GF-3307 on pathogen complex (CERCBE, UROMBE, ERYSB, RAMUBE) in sugar beets, Europe Nordic Beet Research, Rohrau, Denmark Report No. DK22E7B026-KFB07C Corteva Agriscience	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company, Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner
			GEP Unpublished		
KCP 6.1 KCP 6.2 KCP 6.4.1 KCP 6.4.3 #7	Kemezys, A-H.	2023	Performance of GF-3307 on pathogen complex (UROMBE, ERYSB, RAMUBE, CERCBE) in sugar beets, Europe 2023. Nordic Beet Research, Rohrau, Denmark, Report No. 481 2023 838 Report No. DK23E7B037-KFB05C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.1 KCP 6.2 KCP 6.4.1 KCP 6.4.3 #8	Kemezys, A-H.	2023	Performance of GF-3307 on pathogen complex (UROMBE, ERYSB, RAMUBE, CERCBE) in sugar beets, Europe 2023. Nordic Beet Research, Rohrau, Denmark Report No. DK23E7B037-KFB06C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2 KCP 6.4.1 #9	Chambon, J.	2020	Efficacy and dose response of XDE-481 EC (GF-4480) and SC (GF-4505 + GF-4493) on Cercospora beticola and other key diseases in sugar beet. EU 2020 Cerestis, France Report No. EA20F9B001F-DDB015 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2 KCP 6.4.1 #10	Lombart, L.	2020	Efficacy and dose response of XDE-481 EC (GF-4480) and SC (GF-4505 + GF-4493) on Cercospora beticola and other key diseases in sugar beet. EU 2020 Ephydia, France Report No. EA20F9B001F-DDB016 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2 KCP 6.4.1 #11	Rouane, W.	2020	Efficacy and dose response of XDE-481 EC (GF-4480) and SC (GF-4505 + GF-4493) on Cercospora beticola and other key diseases in sugar beet. EU 2020 Anadiag, France, Report No. EA20F9B001F-DDB017 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2 KCP 6.4.1 #12	Chambon, J.	2021	Efficacy of mixtures of Adavelt (GF-3840) + Score (difenoconazole) at 1:1.33 ratio for control CERCBE on sugar beet, Europe 2021. Cerestis, France, Report No. CEE-21281 Report No. EA21G1C011F-DBW006 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.1	Lefranc, M. Vinet, C.	2022	Performance of GF-3307 on pathogen complex (CERCBE, UROMBE, ERYSB, RAMUBE) in sugar beets. France, EPPO MAR ANTEDIS, France, Report No. COR-FE22BE-04372-CA	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company, Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner
KCP 6.2 KCP 6.4.1 #13			Report No. FR22E7B026-MBC01C Corteva Agriscience GEP Unpublished		
KCP 6.1 KCP 6.2 KCP 6.4.1 #14	Deruy, M.	2022	PERFORMANCE OF GF-3307 ON PATHOGEN COMPLEX (CERCBE, UROMBE, ERYSB, RAMUBE) IN SUGAR BEETS, EUROPE 2022. Essais+, France, Report No. 22 14 F08 Report No. FR22E7B025-MBC05C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.1 KCP 6.2 KCP 6.4.1 KCP 6.4.3 #15	Chambon, J.	2022	Performance of GF-3307 on pathogen complex (CERCBE, UROMBE, ERYSB, RAMUBE) in sugar beets, Europe 2022. Cerestis, France, Report No. CEE-22561 Report No. FR22E7B025-MBC07C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.1 KCP 6.2 KCP 6.4.1 #16	Deruy, M.	2022	Performance of gf-3307 on pathogen complex (CERCBE, UROMBE, ERYSB, RAMUBE) in sugar beets, europe 2022. Essais+, France, Report No. 22 14 F09 Report No. FR22E7B026-MBC03C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.1 KCP 6.2 KCP 6.4.1 #17	Wönckhaus, S.	2020	Efficacy of Inatreq (Fenpicoxami) applied straight and in tank mix with Difenconazole for control of CERCBE on sugar beet in Germany, 2020. Agrartest GmbH, Germany Report No. EA20E7B095F-DNZ091 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.1 KCP 6.2 KCP 6.4.1 #18	Wönckhaus, S.	2020	Efficacy of Inatreq (Fenpicoxami) applied straight and in tank mix with Difenconazole for control of CERCBE on sugar beet in Germany, 2020. Agrartest GmbH, Germany Report No. EA20E7B095F-DNZ093 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.1 KCP 6.2 KCP 6.4.1 #19	Wönckhaus, S.	2020	Efficacy of Inatreq (Fenpicoxami) applied straight and in tank mix with Difenconazole for control of CERCBE on sugar beet in Europe, 2020 Agrartest GmbH, Germany Report No. EA20E7B016F-DNZ062 Corteva Agriscience	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company, Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner
			GEP Unpublished		
KCP 6.2 KCP 6.4.1 #20	Wönckhaus, S.	2020	Efficacy of Adavelt (GF-3840) applied straight and in tank mix with Difenconazole for control of CERCBE on sugar beet in Europe, 2020 Agrartest GmbH, Germany Report No. EA20G1C011F-DNZ010 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2 KCP 6.4.1 #21	Wönckhaus, S.	2021	Efficacy of mixtures of Adavelt (GF-3840) +Score (difenconazole) at 1:1.33 ratio for control CERCBE on sugar beet, Europe 2021. Agrartest GmbH, Germany Report No. EA21G1C011F-DNZ012 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.1 KCP 6.2 KCP 6.4.1 #22	Rohr, J.	2022	Performance of GF-3307 on pathogen complex (CERCBE, UROMBE, ERYSE, RAMUBE) in sugar beets, Europe 2022. Trialtec GmbH, Germany Report No. DE22E7B025-FSA01C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.1 KCP 6.2 KCP 6.4.1 #23	Rohr, J.	2022	Performance of GF-3307 on pathogen complex (CERCBE, UROMBE, ERYSE, RAMUBE) in sugar beets, Europe 2022. Trialtec GmbH, Germany Report No. DE22E7B025-FSA02C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.1 KCP 6.2 KCP 6.4.1 KCP 6.4.3 #24	Wolf, P.	2022	Performance of GF-3307 on pathogen complex (CERCBE, UROMBE, ERYSE, RAMUBE) in sugar beets, Europe 2022 Agricola, Germany, Report No. DE22E7B025-FSA03C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2 KCP 6.4.1 #25	Wolf, P.	2022	Performance of GF-3307 and Copper based products on pathogen complex (CERCBE, UROMBE, ERYSE, RAMUBE) in sugar beets, Europe 2022 Agricola, Germany, Report No. DE22E7B073-FSA01C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2 KCP 6.4.1 #26	Korporal, H.	2022	Performance of GF-3307 and Copper based products on pathogen complex (CERCBE, UROMBE, ERYSE, RAMUBE) in sugar beets, Europe 2022. Trialtec GmbH, Germany,	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company, Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner
			Report No. DE22E7B073-FSA02C Corteva Agriscience GEP Unpublished		
KCP 6.1 KCP 6.2 KCP 6.4.1 #27	Wönckhaus, S.	2022	Performance of GF-3307 on pathogen complex (CERCBE, UROMBE, ERYSB, RAMUBE) in sugar beets, Europe 2022. Eurofins Agrartest GmbH, Germany, Report No. DE22E7B025-FSA04C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.1 KCP 6.2 KCP 6.4.1 #28	Rohr, J.	2023	Performance of GF-3307 on pathogen complex (CERCBE, UROMBE, ERYSB, RAMUBE) in sugar beets, Europe 2023. Trialtec GmbH, Germany, Report No. DE23E7B029-FSA03C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.1 KCP 6.2 KCP 6.4.1 KCP 6.4.3 #29	Wolf, P.	2023	Performance of GF-3307 on pathogen complex (CERCBE, UROMBE, ERYSB, RAMUBE) in sugar beets, Europe 2023. Agricola, Germany, Report No. DE23E7B029-FSA04C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2 KCP 6.4.1 #30	Wolf, P.	2023	Impact of copper on the performance of GF-3307 on CERCBE in sugar beets, Europe/Germany 2023 Agricola, Germany Report No. DE23E7B030-FSA01C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2 KCP 6.4.1 #31	Wönckhaus, S.	2023	Performance of GF-3307 on pathogen complex (CERCBE, UROMBE, ERYSB, RAMUBE) in sugar beets, Europe 2023 Eurofins Agrartest GmbH, Germany Report No. DE23E7B029-FSA06C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2 KCP 6.4.1 #32	Armstrong, A.	2020	Efficacy and dose response of XDE-481 EC (GF-4480) and SC (GF-4505 + GF-4493) on Cercospora beticola and other key diseases in sugar beet. EU 2020 Armstrong Fisher Ltd, United Kingdom Report No. EA20F9B001F-DEH010 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2 KCP 6.4.1	Armstrong, A.	2020	Efficacy and dose response of XDE-481 EC (GF-4480) and SC (GF-4505 + GF-4493) on Cercospora beticola and other key diseases in sugar beet. EU 2020	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company, Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner
#33			Armstrong Fisher Ltd, United Kingdom Report No. EA20F9B001F-DEH011 Corteva Agriscience GEP Unpublished		
KCP 6.2 KCP 6.4.1 #34	Good, R.	2022	Performance of GF-3307 on pathogen complex (CERCBE, UROMBE, ERYSB, RAMUBE) in sugar beets, Europe 2022. FieldArm Limited, United Kingdom, Report No. F22062 T1 Report No. GB22E7B026-GKA05C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company, Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner
KCP 6.1 KCP 6.2 KCP 6.4.1 #35	Haigh, I.	2023	Performance of GF-3307 on pathogen complex (UROMBE, ERYSB, RAMUBE, CERCBE) in sugar beets, Europe 2023. FieldArm Ltd, United Kingdom Report No. GB23E7B037-MAF02C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.1 KCP 6.2 KCP 6.4.1 #36	Armstrong, A.	2023	Performance of GF-3307 on pathogen complex (UROMBE, ERYSB, RAMUBE, CERCBE) in sugar beets, Europe 2023. Armstrong Agriculture Ltd, United Kingdom Report No. GB23E7B037-MAF01C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.1 KCP 6.2 KCP 6.4.1 #37	Armstrong, A.	2023	Performance of GF-3307 on pathogen complex (UROMBE, ERYSB, RAMUBE, CERCBE) in sugar beets, Europe 2023. Armstrong Agriculture Ltd, United Kingdom Report No. GB23E7B037-MAF03C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.1 KCP 6.2 KCP 6.4.1 #38	Haigh, I.	2023	Performance of GF-3307 on pathogen complex (UROMBE, ERYSB, RAMUBE, CERCBE) in sugar beets, Europe 2023. FieldArm Ltd, United Kingdom Report No. GB23E7B037-MAF04C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.1 KCP 6.2 KCP 6.4.1 #39	Semaškienė, R.	2023	Performance of GF-3307 on pathogen complex (CERCBE, UROMBE, ERYSB, RAMUBE) in sugar beets, Europe 2023. Lithuanian research centre for agriculture and forestry, Lithuania Report No. LT23E7B029-KFB12C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.1 KCP 6.2 KCP 6.4.1 #40	Semaškienė, R.	2023	Performance of GF-3307 on pathogen complex (CERCBE, UROMBE, ERYSB, RAMUBE) in sugar beets, Europe 2023. Lithuanian research centre for agriculture and forestry, Lithuania Report No. LT23E7B029-KFB13C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2 KCP 6.4.1 KCP 6.4.3 #41	Umiński, P.	2020	Efficacy of Adavelt (GF-3840) applied straight and in tank mix with Difenoconazole for control of CERCBE on sugar beet in Europe, 2020. Dow AgroSciences, Poland Report No. EA20G1C011F-PLY053 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company, Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner
KCP 6.2 KCP 6.4.1 #42	Tomczak, B.	2020	Efficacy and dose response of XDE-481 EC (GF-4480) and SC (GF-4505 + GF-4493) on Cercospora beticola and other key diseases in sugar beet Dow AgroSciences, Poland Report No. EA20F9B001F-PLY008 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2 KCP 6.4.1 #43	Umiński, P.	2021	Efficacy of mixtures of Adavelt (GF-3840) + Score (difenoconazole) at 1:1.33 ratio for control CERCBE on sugar beet, Europe 2021. Field Research Support, Poland Report No. EA21G1C011F-PLY001 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.1 KCP 6.2 KCP 6.4.1 KCP 6.4.3 #44	Umiński, P.	2023	Performance of GF-3307 on pathogen complex (CERCBE, UROMBE, ERYSB, RAMUBE) in sugar beets, Europe 2023. Field Research Support, Poland Report No. PL23E7B029-LMA09C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.1 KCP 6.2 KCP 6.4.1 #45	Luboiński, A.	2023	Performance of GF-3307 on pathogen complex (CERCBE, UROMBE, ERYSB, RAMUBE) in sugar beets, Europe 2023 Corteva Agriscience Poland Sp. z o. o., Poland Report No. PL23E7B029-LMA07 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.1 KCP 6.2 KCP 6.4.1 KCP 6.4.3 #46	Rezmerska-Piętka, J.	2023	Performance of GF-3307 on pathogen complex (CERCBE, UROMBE, ERYSB, RAMUBE) in sugar beets, Europe 2023. PerfectBAD, Poland Report No. PL23E7B029-LMA08C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2 KCP 6.4.1 #47	Perényi, J.	2020	Efficacy of Adavelt (GF-3840) applied straight and in tank mix with Difenoconazole for control of CERCBE on sugar beet in Europe, 2020 Dow AgroSciences, Hungary Report No. EA20G1C011F-EAN014 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2 KCP 6.4.1 #48	Perényi, J.	2020	Efficacy of Adavelt (GF-3840) applied straight and in tank mix with Difenoconazole for control of CERCBE on sugar beet in Europe, 2020 Dow AgroSciences, Hungary Report No. EA20G1C011F-EAN015 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience



Data point	Author(s)	Year	Title Company, Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner
KCP 6.1 KCP 6.2 KCP 6.4.1 KCP 6.4.3 #49	Kukorelli, G.	2023	Performance of GF-3307 on pathogen complex (CERCBE, UROMBE, ERYSB, RAMUBE) in sugar beets, Europe 2023. AGROPASS Hungária Kft., Hungary Report No. HU23E7B038-ZBA01C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.1 KCP 6.2 KCP 6.4.1 KCP 6.4.3 #50	Boldizsár, Z.	2023	Performance of GF-3307 on pathogen complex (CERCBE, UROMBE, ERYSB, RAMUBE) in sugar beets, Europe 2023. Corteva Crop Solutions HUN Kft., Hungary Report No. HU23E7B038-ZBA02 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.1 KCP 6.2 KCP 6.4.1 #51	Makó, I.	2023	Performance of GF-3307 on pathogen complex (CERCBE, UROMBE, ERYSB, RAMUBE) in sugar beets, Europe 2023 CPR Europe Kft., Hungary Report No. HU23E7B038-ZBA03C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.1 KCP 6.2 KCP 6.4.1 KCP 6.4.3 #52	Varga, A.	2023	Performance of GF-3307 on pathogen complex (CERCBE, UROMBE, ERYSB, RAMUBE) in sugar beets, Europe 2023 CPR Europe Kft., Hungary Report No. HU23E7B038-ZBA04C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2 KCP 6.4.1 #53	Lunca, A-M.	2020	Efficacy and dose response of XDE-481 EC (GF-4480) and SC (GF-4505 + GF-4493) on Cercospora beticola and other key diseases in sugar beet. EU 2020 Eurofins Agrosience Services S.R.L., Romania Report No. EA20F9B001F-AMT003 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2 KCP 6.4.1 KCP 6.4.3 #54	Botoman, C.	2020	Efficacy and dose response of XDE-481 EC (GF-4480) and SC (GF-4505 + GF-4493) on Cercospora beticola and other key diseases in sugar beet. AgroProspect SRL, Romania Report No. EA20F9B001F-AMT004 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company, Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner
KCP 6.1 KCP 6.2 KCP 6.4.1 KCP 6.4.3 #55	Lunca, A-M.	2023	Performance of GF-3307 on pathogen complex (CERCBE, UROMBE, ERYSB, RAMUBE) in sugar beets, Europe 2023. Eurofins Agroscience Services SRL, Romania Report No. RO23E7B038-MST05C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.1 KCP 6.2 KCP 6.4.1 KCP 6.4.3 #56	Lunca, A-M.	2023	Performance of GF-3307 on pathogen complex (CERCBE, UROMBE, ERYSB, RAMUBE) in sugar beets, Europe 2023. Eurofins Agroscience Services SRL, Romania Report No. RO23E7B038-MST06C Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.1 #57	Karaiskou, G, Kaehler, E	2023	Performance of Corteva™ products GF-3308 and GF-3307 for control of <i>Cercospora beticola</i> following protectant and curative applications Corteva Agriscience, Indianapolis, USA Report No. GL23E7B004F Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.3 6.4.5 #58	Mboup, M, Leader A.J	2023	Sensitivity baseline 2023 for European <i>Cercospora Beticola</i> population versus Fenpicoxamid and prothioconazole Corteva Agriscience, Germany Report No. no Number Corteva Agriscience GEP Unpublished	N	Corteva Agriscience

## Appendix 1B - Published Literature

### List of Published Literature Used in Support of the Evaluation - Documents Not Submitted

The following is a list of published literature references that are specific to this biological assessment document.

Data point	Author(s)	Year	Title
KCP 6.3	Anonymous	2019	FRAC Pathogen Risk List, 2019 version. Online - <a href="https://www.frac.info/">https://www.frac.info/</a>
KCP 6.3	Anonymous	2022	FRAC Code List, 2022 version . Online - <a href="https://www.frac.info/">https://www.frac.info/</a>
KCP 6.3	Anonymous	2021	FRAC Fenpicoxamid resistance management recommendations . Online: <a href="https://www.frac.info/fungicide-resistance-management/by-frac-working-group-expert-forum">https://www.frac.info/fungicide-resistance-management/by-frac-working-group-expert-forum</a>
KCP 6.3	Anonymous	2023	FRAC Minutes of SBI working group, April 2023. Online - <a href="https://www.frac.info/frac-teams/working-groups/sbi-fungicides/recommendations-for-sbi">https://www.frac.info/frac-teams/working-groups/sbi-fungicides/recommendations-for-sbi</a>

## Appendix 2 Draft label

Univoq/Queen (GF-3307) is an EC formulation containing 50 g as/L fenpicoxamid and 100 g as/L Prothioconazole

Crops: sugar beet.

Univoq/Queen is a protectant and curative fungicide with translaminar properties for the control of:

CERCBE, UROMBE, ERYSB and RAMUBE in sugar beet.

1.5 L/ha for CERCBE, UROMBE, ERYSB and RAMUBE in sugar beet in Austria, Belgium, Czech Republic, The Netherlands and a rate range of 1.2-1.5 L/ha in Poland, Hungary, Slovakia and Romania.

Univoq is applied after warnings by advisory services between BBCH stage 39 and 49 of the crop.

Apply a maximum of 2 applications of GF-3307 per season to sugar beet with 21 days application interval and a maximum dose of 1.5 L/ha. In Poland, Slovakia, Hungary and Romania a dose range is proposed from 1.2-1.5 l/ha with the lower dose proposed under lower disease pressure situations. No consecutive applications of fenpicoxamid based products are allowed in sugar beet crops and do not exceed a maximum of 33% of total sprays (one third of spray program) whichever is lower. ~~For best practice, Corteva recommends a maximum of one fenpicoxamid based product spray in sugar beet per season to manage resistance.~~

PHI 21 (F)

Rainfastness - once the spray cover has dried;

Resistance management: Univo/Queen is a co-formulated mixture of fenpicoxamid and prothioconazole. Apply GF-3307 according to the instructions for the target diseases at the specific growth stage indicated. Use Univoq as part of an Integrated Crop Management (ICM) strategy incorporating other methods of control, in a robust spray program including other fungicides with a different mode of action at a dose that will give robust control. Apply fenpicoxamid based fungicides in strict alternation with fungicides from a different cross-resistance group. No consecutive applications of fenpicoxamid based products are advised. Apply a maximum of 33% of total sprays (one third of spray program) whichever is lower.

Univoq/Queen contains fenpicoxamid assigned to FRAC group C4#21 (Inhibition of respiration at complex III; Qil fungicides). Fenpicoxamid is not cross-resistant to any of the commercial fungicide currently used in oilseed rape. Univoq/Queen also contains prothioconazole, a member of the DMI cross resistance group FRAC group G1#3 (C14- demethylase in sterol biosynthesis (*erg11/cyp51*)). For further advice on resistance management in DMI's contact your agronomist or advisor and consult the FRAC website. Disease control may be reduced if strains of pathogens with reduced sensitivity to Univoq develop in field populations.

Follow resistance management guidelines.