REGISTRATION REPORT

Part A

Risk Management

Product code: FHO04

Product name(s): Prothioconazole/Sulphur (50+625) SC, /Patton Supra

Chemical active substance(s):

Prothioconazole 50 g/L,

Sulphur 625 g/L

Central Zone

Zonal Rapporteur Member State: Poland

National Assessment

(authorization)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: May 2024

MS Finalisation date: November 2024 (initial National Assessment)

January 2025, update February 2025, update September 2025

(final National Assessment)

Version history

When	What
May 2024	Initial dRR – UPL Holdings Coöperatief U.A.
November 2024	Initial zRMS assessment In order to facilitate tracking of changes of the intended uses of the product due to the performed evaluation, amendments of the GAP table and in the product label (Appendix 2) and Lists of data considered for national authorization (Appendix 4) are highlighted in grey, while not agreed use pattern ~~is struck through~~ and shaded.
January 2025	Final report (National Assessment updated following the commenting period) No additional information or assessments after the commenting period.
February 2025	Final report (National Assessment updated after the correction of Appendix 4 prepared by the Applicant) In order to facilitate tracking of changes in the Lists of data considered for national authorization (Appendix 4), amendments are highlighted in yellow, while not agreed use pattern is ~~struck through~~ and shaded.
September 2025	Final report (update National Assessment following the comments recived from Polish Ministry of Agriculture) Additional information/assessments included by the zRMS in the report in response to comments received from Polish Ministry of Agriculture are highlighted in yellow in the Points 2.4.1. and 3.8.2 and in the label. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.

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PART A
RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application is being submitted in support of the authorisation of the new product Prothioconazole/Sulphur (50+625) SC, 'Patton Supra' (code FHO04) in accordance with Article 33 of Regulation (EC) 1107/2009 in Poland. The product is a suspension concentrate (SC) formulation containing 625 g/L of sulphur and 50 g/L of prothioconazole for use as a fungicide on wheat. This dossier has been prepared in accordance with Regulation (EU) 284/2013.

1.2 Letters of Access

An Access Agreement is part of this application (see Appendix 3).

1.3 Justification for submission of tests and studies

The tests and study reports which have been generated are required to satisfy the data requirements outlined in Regulation (EU) 283/2013 (or Regulation (EU) 544/2011 where appropriate) and Regulation (EU) 284/2013.

1.4 Data protection claims

This application is for a new product under Article 33 and therefore data protection is claimed for all eligible studies. Eligible studies should be afforded 10 years data protection from the date of product authorisation in each Member State in accordance with Article 59 of Regulation (EC) 1107/2009.

2 Details of the authorization decision

2.1 Product identity

Product code	FHO04
Product name in MS	Prothioconazole/Sulphur (50+625) SC, 'Patton Supra'
Authorization number	N/A – new product
Function	Fungicide
Applicant	UPL Holdings Coöperatief U.A.
Active substance(s) (incl. content)	Sulphur; 625 g/L Prothioconazole; 50 g/L
Formulation type	SC
Packaging	Professional User 0.5, 1, 2, 3, 5, 10 and 20 L (HDPE/EVOH, HDPE/PA and HDPE/F)
Coformulants of concern for national authorizations	None
Restrictions related to identiy	None
Mandatory tank mixtures	None
Recommended tank mixtures	In the case of a mixture with other pesticide products, it is advisable to first establish the physical compatibility of each mixture by preparing a small amount separately before use

2.2 Conclusion

The authorisation of FHO04 for the uses specified in 2.6 of this document can be granted.

Based on the currently available MSDSs and other information provided by applicant or manufacturer of co-formulant, the product **FHO04/Patton Supra** does not contain any unacceptable co-formulant/ingredient listed in the **Commission Regulation (EU) 2021/383** amending **Annex III** to Regulation (EC) No 1107/2009. According to the current knowledge and available information none of the co-formulants in the plant protection product **FHO04/Patton Supra** meets the Annex to **Regulation (EU) 2023/574** criteria for identification of co-formulants that are unacceptable for inclusion in a plant protection products. Taking this into account, none of the co-formulants/ingredients in this product is considered to be a candidate for inclusion in Annex III of Regulation (EU) 1107/2009.
Detailed assessment of co-formulants according to Article 3 of **Regulation (EU) 2023/574** can be found in annex to Part C of this submission.

2.3 Substances of concern for national monitoring

Not applicable.

2.4 Classification and labelling

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

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

Hazard class(es), categories:	Skin corrosion/irritation, Category 2 Acute aquatic, Category 1 Chronic aquatic, Category 2

The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold:**

Hazard pictograms:	 GHS07  GHS09
Signal word:	Warning
Hazard statement(s):	H315 – Causes skin irritation **H410** ~~1~~ – very toxic to aquatic life with long lasting effects
Precautionary statement(s):	P264 - Wash hands, forearms and face thoroughly after handling. ~~P273 – Avoid release to the environment~~. P280 - ~~Wear eye protection, face protection,~~ protective clothing, protective gloves. P302+P352 - IF ON SKIN: Wash with plenty of water/… P332+P313 - If skin irritation occurs: Get medical advice/attention. P362+P364 - Take off contaminated clothing and wash it before reuse. P391 - Collect spillage. P501 - Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	EUH208 - Contains 1,2-benzisothiazol-3(2H)-one; 1,2-benzisothiazolin-3-one. May produce an allergic reaction.

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	

EUH 208	Contains 1,2-benzisothiazol-3(2H)-one; 1,2-benzisothiazolin-3-one. May produce an allergic reaction.

See Part C for justifications of the classification and labelling proposals.

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	To protect aquatic organisms, respect 5 meter vegetative buffer zone to surface water bodies (all uses).

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

None.

2.5 Risk management

2.5.1 Restrictions linked to the PPP

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

Operator protection:	
	Work wear (arms, body and legs covered) during mixing and loading, and application
Worker protection:	
	Work wear (arms, body and legs covered)
Resident and bystander protection:	
	A buffer zone of 5m **or** 50% drift reduction technology is required
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
SPe3	To protect aquatic organisms, respect 5 meter vegetative buffer zone to surface water bodies (all uses).
Other specific restrictions	
	None

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

Integrated pest management (IPM)/sustainable use:	
	None

2.5.2 Specific restrictions linked to the intended uses

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

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

respective code if available	-5 meter vegetative buffer zone is required for the protection of aquatic organisms	All uses

2.6 Intended uses (only NATIONAL GAP)

GAP rev.1, date: November 2024

PPP (product name/code):	Prothioconazole/Sulphur (50+625) SC, 'Patton Supra' / FHO04	Formulation type:	Suspension concentrate (SC)[a, b]
Active substance 1:	Sulphur	Conc. of as 1:	625 g/L [c]
Active substance 2:	Prothioconazole	Conc. of as 2:	50 g/L[c]
Safener:	-	Conc. of safener:	-
Synergist:	-	Conc. of synergist:	-
Applicant:	UPL Holdings Coöperatief U.A.	Professional use:	☒
Zone(s):	Central [d]	Non professional use:	☐
Verified by MS:	No		
Field of use:	Fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15								
Use - No. *	**Member state(s)**	**Crop and/ or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp or I ****	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application dose**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha, other dose expression, dose range (min-max)	**zRMS Conclusion**							
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. dose per appl. b) max. total dose per crop/season	g or kg a.s./ha a) max. dose per appl. b) max. total dose per crop/season	Water L/ha min/max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
1	PL	Winter wheat (TRZAW)	F	Septoria (*Zymoseptoria tritici*) SEPTTR Yellow rust (*Puccinia striiformis*) ~~PUCCSI~~ PUCCST Brown rust (*Puccinia triticina*) PUCCRT	Foliar spraying	~~BBCH 27-69~~ BBCH 30-69 ~~BBCH 27-69~~ BBCH 30-69	~~a) 1 b) 2~~ a) 2 b) 2 ~~a) 1 b) 2~~ a) 2 b) 2	14	a) 4 b) 8	a) 0.2 + 2.5 b) 0.4 + 5.0	100-400	35		A	A	R B&R NDE	A	A	R Aquatics A Remained species	A	A
2	PL	Spring wheat (TRZAS)	F	Septoria (*Zymoseptoria tritici*) SEPTTR Yellow rust (*Puccinia striiformis*) ~~PUCCSI~~ PUCCST Brown rust (*Puccinia triticina*) PUCCRT	Foliar spraying	~~BBCH 27-69~~ BBCH 30-69 ~~BBCH 27-69~~ BBCH 30-69	~~a) 1 b) 2~~ a) 2 b) 2 ~~a) 1 b) 2~~ a) 2 b) 2	14	a) 4 b) 8	a) 0.2 + 2.5 b) 0.4 + 5.0	100-400	35		A	A	R B&R NDE	A	A	R Aquatics A Remained species	A	N
3	PL	Winter triticale (TTLWI)	F	Septoria (*Zymoseptoria tritici*) SEPTTR Yellow rust (*Puccinia*	Foliar spraying	~~BBCH 27-69~~ BBCH	~~a) 1 b) 2~~ a) 2	14	a) 4 b) 8	a) 0.2 + 2.5 b) 0.4 + 5.0	100-400	35		A	A	R B&R NDE	A	A	R Aquatics	A	A

				striiformis) PUCCSI PUCCST Brown rust (*Puccinia triticina*) PUCCRT		30-69 BBCH 27-69 BBCH 30-69	b) 2 a) 1 b) 2 a) 2 b) 2											A Remained species			
4	PL	Spring triticale (TTLSO)	F	Septoria (*Zymoseptoria tritici*) SEPTTR Yellow rust (*Puccinia striiformis*) PUCCSI PUCCST Brown rust (*Puccinia triticina*) PUCCRT	Foliar spraying	BBCH 27-69 BBCH 30-69 BBCH 27-69 BBCH 30-69	a) 1 b) 2 a) 2 b) 2 a) 1 b) 2 a) 2 b) 2	14	a) 4 b) 8	a) 0.2 + 2.5 b) 0.4 + 5.0	100-400	35		A	A	R B&R NDE	A	A	R Aquatics A Remained species	A	N
5	PL	Winter rye (SECCW)	F	Brown rust (*Puccinia recondita f. sp. recondita*) PUCCRR	Foliar spraying	BBCH 27-69 BBCH 30-69	a) 1 b) 2 a) 2 b) 2	14	a) 4 b) 8	a) 0.2 + 2.5 b) 0.4 + 5.0	100-400	35		A	A	R B&R NDE	A	A	R Aquatics A Remained species	A	A
Minor uses according to Article 51 (field uses)																						
6	PL	Durum wheat (TRZDU)	F	Septoria (*Zymoseptoria tritici*) SEPTTR Yellow rust (*Puccinia striiformis*) PUCCSI PUCCST Brown rust (*Puccinia triticina*) PUCCRT	Foliar spraying	BBCH 27-69	a) 1 b) 2 a) 2 b) 2 a) 1 b) 2 a) 2 b) 2	14	a) 4 b) 8	a) 0.2 + 2.5 b) 0.4 + 5.0	100-400	35		A	A	R B&R NDE	A	A	R Aquatics A Remained species	A	n.r.
7	PL	Spelt (TRZSP)	F	Septoria (*Zymoseptoria tritici*) SEPTTR Yellow rust (*Puccinia striiformis*) PUCCSI PUCCST Brown rust (*Puccinia triticina*) PUCCRT	Foliar spraying	BBCH 27-69	a) 1 b) 2 a) 2 b) 2 a) 1 b) 2 a) 2 b) 2	14	a) 4 b) 8	a) 0.2 + 2.5 b) 0.4 + 5.0	100-400	35		A	A	R B&R NDE	A	A	R Aquatics A Remained species	A	n.r.
8	PL	Spring rye (SECCS)	F	Brown rust (*Puccinia recondita f. sp. recondita*) PUCCRR	Foliar spraying	BBCH 27-69	a) 1 b) 2 a) 2 b) 2	14	a) 4 b) 8	a) 0.2 + 2.5 b) 0.4 + 5.0	100-400	35		A	A	R B&R NDE	A	A	R Aquatics A Remained species	A	n.r.

* Minor crop according to Article 51

Remark: The shape of the GAP table has been aligned with the updated GAP table presented in Part B3 (the update only concerned the listing of crops on separate lines and the visible listing of crops claimed under Article 51)

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

Explanation for 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

3 Background of authorization decision and risk management

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

'Pattan Supra' (FHO04) is a suspension concentrate (SC). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a light yellow opaque viscous liquid without characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. Self-ignition was not observed at temperatures below 600 °C. In aqueous solution, it has a pH value around 6.3 at 20.7 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active substance content nor the technical properties were changed. The stability data of the product when stored in HDPE/EVOH indicates a shelf life of at least 2 years. Its technical characteristics are acceptable for a suspension concentrate formulation. The intended concentration of use, covering all crops, is 0.75 % (3 L in 400 L water) to 4 % (4 L in 100 L water).
The formulation is not classified with respect to its physical and chemical properties.

For SC formulation extrapolation from HDPE/EVOH to HDPE co-extruded (HDPE/PA an HDPE-F) is acceptable.

The compatibility of Prothioconazole/Sulphur 50 + 625 SC (FHO04) with a selected range of other pesticides was tested:

Product A	Product A test concentration	Product B	Product B test concentration
Prothioconazole/sulphur 50 + 625 SC	4L/Ha/100L water	Vacciplant Max SL	2L/Ha/500L water
Prothioconazole/sulphur 50 + 625 SC	4L/Ha/100L water	Caramba EC	1L/Ha/200L water
Prothioconazole/sulphur 50 + 625 SC	4L/Ha/100L water	Chamane 25 SC	1L/Ha/100L water
Prothioconazole/sulphur 50 + 625 SC	4L/Ha/100L water	Comet 200 EC	1.1/Ha/100L water
Prothioconazole/sulphur 50 + 625 SC	4L/Ha/100L water	Elatus EC	1L/Ha/100L water
Prothioconazole/sulphur 50 + 625 SC	4L/Ha/100L water	Revystar EC	1.5L/Ha/100L water

All tested mixtures proved to be compatible (meanwhile a constant agitation must be applied while spraying).

3.2 Efficacy (Part B, Section 3)

The BAD supports an Article 33 submission for the authorisation of a new fungicide, FHO04. This product contains the active substances prothioconazole (50 g/L) and, sulphur (625 g/L), formulated as a Suspension concentrate (SC). Its intended use is as a fungicide for the control of foliar diseases of cereals in Poland.

3.3 Efficacy data

The BAD supports an Article 33 submission for the authorisation of a new fungicide, FHO04. This product contains the active substances prothioconazole (50 g/L) and, sulphur (625 g/L), formulated as a Suspension concentrate (SC). Its intended use is as a fungicide for the control of foliar diseases of cereals in Poland.

Preliminary tests
Leaf spot (*Zymoseptoria tritici* - SEPTTR) is the major problematic disease in cereals. Therefore, the objective of this preliminary part is to justify the interest to associate sulphur with prothioconazole to control leaf spot (*Zymoseptoria tritici* - SEPTTR).
In 5 trials carried out in Maritime EPPO climatic zone and provided as supportive data, FHO04 applied at 4.0 L/ha (200 g a.s./ha prothioconazole + 2500 g a.s./ha sulphur) was compared to Prothioconazole based products applied straight at 200 g a.s./ha, Sulphur based products applied straight at 2475 g a.s./ha and the extemporaneous tank-mix prothioconazole + sulphur.
In these 5 trials, different ratios of prothioconazole and sulphur was also tested to determine the best ratio between both active substances.
In 28 trials, FHO04 applied at 4.0 L/ha (200 g a.s./ha prothioconazole + 2500 g a.s./ha sulphur) was compared only to Prothioconazole based products applied straight at 200 g a.s./ha. According to the trial, Prothioconazole based product used in the trials was an internal preparation (code name FGR06, Prothioconazole, 250 g/L) applied at 0.8 L/ha or Proline also applied at 0.8 L/ha.
Based on the benefits with respect to resistance prevention, the knowledge of each active substances, and technical possibilities on formulation, the combination of the active substances prothioconazole + sulphur in FHO04 and their rate ratio can be considered as justified.

Minimum effective dose tests
The confirmation of required doses of FHO04 was supported by the data from 58 valid efficacy trials carried out from 2020 to 2023 in the Northeast EPPO climatic zone (28 trials in Poland, 6 trials in Latvia and 4 trials in Lithuania) and Poland border countries (1 trial in Czech Republic, and 19 trials in Germany) in winter wheat (41 trials), durum wheat (1 trial) or winter triticale (6 trials) or winter rye (10 trials) against SEPTTR (33 trials) , PUCCRE (22 trials) and/or PUCCST (13 trials). Some trials contained more than one target disease, therefore the total number of trials for all diseases exceeds 58 valid trials.
The mean efficacy increases in function of the dose rate of FHO04. FHO04 at 4.0 L/ha reached a superior efficacy than the lower rates and a good efficacy to control the disease complex on cereals confirming the selection of 4.0 L/ha as maximum registered dose.

Efficacy tests
A total of 59 valid efficacy trials carried out from 2019 to 2023 are provided to confirm the efficacy of FHO04 at 4.0 L/ha in Poland in winter cereals. Detailed summaries of efficacy results are available in Section B Part 3 of the dossier.
Considered the minimum requirements set by the EPPO PP 1/226 (3) *Number of efficacy trials*, the data submitted are sufficient to authorize FHO04 for double application at 4.0 L/ha at BBCH 30-69 in control of SEPTTR, PUCCRT and PUCCST in soft winter wheat (TRZAW) and in control of PUCCRR in winter rye (SECCW). Based on extrapolation of data from wheat and rye the authorization may also be granted for the use, at the same dose rate and growth stage, in winter triticale (TTLWI), in control of SEPTTR, PUCCRE and PUCCST.

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

FHO04 is a new fungicide containing a mixture of two known active substances: prothioconazole (chemical group: triazoles, group name: DMI-fungicides, SBI: Class I; FRAC code: 3) and sulphur (chemical group: multi-site contact activity, group name: inorganic (electrophiles), FRAC code: M02). The mode of action of prothioconazole is inhibiting the ergosterol synthesis by the inhibition of the steroid reduction and the target site is C14-demethylase in sterol biosynthesis. The most acknowledged mode of action of sulphur is disrupting electron transport while acting on cytochrome C, therefore preventing ATP formation. However, sulphur is also commonly classified as one of multi-site actives, the classification reflecting some knowledge of possible other sites of action and, at the same time, some level of uncertainty as to the precise identity of these other sites. As the result, the FHO04 contains active substances with different modes of action with no documented cross resistance in the control of pathogens.

The resistance risk of prothioconazole belonging to DMI-fungicides has been defined by FRAC as medium. Sulphur, on the other hand, as contact fungicide, affects multiple biochemical sites in fungi and is consequently classified by FRAC as low-risk of resistance an active. Since multi-site fungicides are considered important components to the fungicide resistance management strategy, the combination of sulphur with other, medium-risk active, should be considered appropriate, from the resistance management perspective.

3.3.2 Adverse effects on treated crops

The crop sensitivity was assessed in 59 efficacy trials in winter soft wheat, 2 efficacy trials in durum wheat, 10 efficacy trials in winter triticale and 12 efficacy trials in winter rye. No phytotoxicity symptoms caused by FHO04 at the proposed dose of 4.0 L/ha were recorded in any of the efficacy trials. No effect is expected in cereals if FHO04 is applied at the maximum requested rate of 4.0 L/ha according to the Good Agricultural Practices and label recommendations.
Concerning the effect on the yield and the quality of harvested grains, sulphur and prothioconazole are existing active substances and no effect on the yield is known. In addition, no adverse effect and no difference with the reference standards was noted in valid efficacy trials harvested. No adverse effect on the yield and on the quality of cereals is expected if FHO04 is applied at the maximum requested rate of 4.0 L/ha according to the Good Agricultural Practices and label recommendations.
The possible effect of FHO04 on the transformation processes was studied from a set of 3 confirmatory processing trials implemented in 2022 in France in the Maritime (2 trials) and the Mediterranean EPPO climatic zone (1 trial). No adverse influence on the transformation processes is expected if FHO04 is used in accordance with good agricultural practices, including label instructions.
A summary of the range of varieties tested and the extent of crop damage observed is provided to support the use of FHO04. It is concluded that no negative impact on plants should be expected on these crops.

3.3.3 Observations on other undesirable or unintended side-effects

Fungicides usually do not exhibit herbicidal activity. Phytotoxicity was considered as acceptable on cereals (wheat, rye and triticale) in any of the 83 efficacy trials where FHO04 was applied as a straight product up to 4.0 L/ha.
In addition, any potential impact of FHO04 on succeeding and adjacent crops would principally be related to the active substances. Sulphur and prothioconazole are used in Europe for many years and no side-effects are known in Europe, therefore the damage risk to adjacent and succeeding crops is considered as acceptable, provided the FHO04 is used according to label instruction.
No side-effect on beneficial and other non - target organisms were observed in the 83 efficacy trials carried out in on cereals (wheat, rye and triticale) where FHO04 was applied as a straight product up to 4.0 L/ha.
Therefore, no side-effect is expected if FHO04 is used according to the Good Agricultural Practices and label recommendations.

3.4 Methods of analysis (Part B, Section 5)

Sufficiently sensitive and selective analytical methods are available for the active substances and relevant impurities in FHO04.

3.4.1 Analytical method for the formulation

Analytical methods for the determination of prothioconazole, sulphur, and the relevant impurities in FHO04 are available and validated in accordance with SANCO 3030/99 rev. 5.

Prothioconazole
An HPLC-PDA method for the determination of prothioconazole in FHO04 has been provided and validated in terms of linearity, precision, accuracy, and specificity.

Sulphur
A titration method for the determination of sulphur in FHO04 has been provided and validated in terms of linearity, precision, accuracy, and specificity.

Relevant Impurities
An HPLC-PDA method for the determination of prothioconazole-desthio and toluene in FHO04 has been provided and validated in terms of linearity, precision, accuracy, and specificity.

3.4.2 Analytical methods for residues

Prothioconazole
Sufficiently sensitive analytical methods are available and validated for all components included in the prothioconazole residue definition, for soil, water, air, food of plant origin, food of animal origin and in body fluids.

The Applicant submitted a number of methods for analysis of residues of prothioconazole for the generation of pre-authorization data and methods for post-authorization control and monitoring purposes.
The details of the evaluation of new and additional studies are referred in Appendix 2 of Part B5.

Since many MRLs have been lowered to 0.01 mg/kg, the validated LOQ of the EU agreed methods by Weeren and Pelz (2000) and Class (2001) are not sufficient to monitor these lowered MRLs for food of plant origin. To cover the current residue definition and MRL limits, the applicant provided the analytical method of Pearson (2022, Report No. QG/20/011) and its ILV (Boubakri, 2023, Report No. S21-08354) for the determination of prothioconazole-desthio residues in/on matrices of plant origin (high water content, high acid, high oil content and high protein/high starch content) with LOQ of 0.005 mg/kg. The ILV is acceptable. The analytical method of Pearson (2022, Report No. QG/20/011) was successfully independently validated. The details of the evaluation of new study is referred in Appendix 2 of Part B5.

The Applicant provided new method (D. Kleinhenz, 2023, Report No. S21-08355) validated for the determination of prothioconazole-desthio (as sum of isomers) in five (milk, egg, fat, liver and meat) different matrices of food of animal origin with the LOQ of 0.004 mg/kg for milk and 0.01 mg/kg for remaining matrices and its ILV (T. Rastogi, 2023, Report No. S21-08868) for the determination of prothioconazole-desthio residues in milk and fat with LOQ of 0.004 mg/kg and 0.01 mg/kg, respectively.

The Applicant provided new method (N. Boubakri, 2023, Report No, S21-08361) validated for the determination of prothioconazole-desthio in urine with the LOQ of 0.01 mg/L.
No additional data are required.

Applicant submitted the LC-MS/MS analytical method (D. Kaiser, 2022, Report No. S21-08359) with its ILV (S. Jooß, 2023, Report No. S21-08869) for the determination of prothioconazole and prothioconazole-desthio in drinking water with LOQ of 0.05 µg/L.
No additional data are required.

Sulphur
Sulphur is included in Annex IV of the Regulation (EC) 396/2005 and is therefore no residue definition has been set. In accordance with the EFSA Scientific Report (2008) 221, 36-70, monitoring/enforcement analytical methods for the determination of sulphur in soil, water, air, food of plant origin, food of animal origin and in body fluids and tissues are not required.

3.5 Mammalian toxicology (Part B, Section 6)

3.5.1 Acute toxicity

The classification of FHO04 has been determined by calculation. The assessment of all acute toxicological properties of FHO04 is derived from the classification of the active substances and co-formulants. Based on this, FHO04 is classified as Skin Corrosion Cat. 2 (H315).

3.5.2 Operator exposure

Operator exposure was estimated using the Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022 and modelled using the EFSA 2022 OPEX v.1.0.1 calculator.
Using a worst-case scenario of 100% conversion of prothioconazole to prothioconazole-desthio, a predicted exposure to operators of 32 % of the AOEL is expected when work wear is worn during mixing/loading and application.
A combined exposure assessment was performed and an acceptable risk was demonstrated.

3.5.3 Worker exposure

Worker exposure was estimated using the Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022 and modelled using the EFSA 2022 OPEX v.1.0.1 calculator.
Using a worst-case scenario of 100% conversion of prothioconazole to prothioconazole-desthio, a predicted exposure to workers of 56.8 % of the AOEL is expected when work wear is worn during mixing/loading and application.
A combined exposure assessment was performed and an acceptable risk was demonstrated.

3.5.4 Bystander and resident exposure

No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.
Resident exposure was estimated using the Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022 and modelled using the EFSA 2022 OPEX v.1.0.1 calculator.
A combined exposure assessment was performed and an acceptable risk was demonstrated with a 5m buffer zone or 50% drift reduction technology was applied.

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

A list of all intended uses within Poland is given in Part B, Section 0.
Two critical GAP uses for wheat and rye were selected based on the highest application rate and the latest application timing (BBCH) per season of the active substances.

3.6.1 Residues

Wheat and rye are the major crops in northern Europe (SANTE/2019/12752). A minimum of eight trials are required. Based on the SANTE/2019/12752, 8 residue trials on wheat can be used for extrapolation to rye, before and after forming of the edible part.

Sulphur
No new data were submitted in the framework of this application. The meeting of experts did not

propose a residue definition for monitoring and an MRL for elemental sulphur (EFSA, 2008).

Sulphur was included in the Annex IV of the Regulation (EC) No 396/2005 (Reg. 459/2010). Therefore, no residue definition and an MRL for sulphur was set up and no residue trials were considered as required. Consequently, intended uses on wheat, durum wheat, triticale, spelt and rye are acceptable and no further data are required.

Prothioconazole
One magnitude of residue study was submitted in the framework of this application: F. Lebrun (2024), study Report No. 645-2023.
Eight residue trials (4 decline and 4 harvest) on wheat were conducted in northern Europe in accordance with the following GAP: 2 x 200 g a.s. /ha, application interval - 14±1 days, 2nd application at BBCH 69, outdoor. Samples were taken at harvest.

Residues of prothioconazole-desthio in wheat grain at harvest were <0.01 mg/kg.
Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest were between <0.01 mg/kg and 0.02 mg/kg.

Residues of 1,2,4-triazole and triazole lactic acid, in wheat grain at harvest were < 0.01 mg/kg.
Residues of triazole alanine, in wheat grain at harvest ranged between 0.12 and 0.74 mg/kg.
Residues of triazole acetic acid, in wheat grain at harvest ranged between 0.04 and 0.17 mg/kg.

Available results show that the in force MRL of prothioconazole on wheat of 0.1 mg/kg and on rye of 0.05 (Reg. (EU) 2024/1318) will not be exceeded. The current EU MRL for prothioconazole is sufficient to support the proposed uses.
The trials are supported by valid storage stability data and validated analytical methods.

The proposed uses on wheat and rye are considered acceptable.

3.6.2 Consumer exposure

Sulphur
According to the Peer review of the pesticide risk assessment of the active substance sulphur (EFSA Scientific Report (2008) 221, 1-70) the mammalian toxicology assessment concluded that sulphur was a substance of low toxicity, and it was not necessary to set an ADI or ARfD. A risk for consumers through the consumption of food possibly containing residues of the active substances is not expected. Sulphur has been included in Annex IV to Reg. (EC) No 396/2005.

Prothioconazole
In view of additional supportive residues data having been submitted for wheat, in the interests of completeness and transparency, consumer risk assessments were performed and presented.
The consumer risk assessments were performed using the latest version of the EFSA Pesticides Residues Intake Model (PRIMo, rev. 3.1). For chronic risk assessments, the consumer intakes were compared to the EU agreed Acceptable Daily Intake (ADI) value for prothioconazole-desthio (sum of isomers) (0.01 mg/kg bw/day) set during the last EU review of the active substance for Annex I inclusion/approval.
For acute consumer risk assessments, the consumer intakes were compared to the EU agreed Acute Reference Dose (ARfD) value for prothioconazole-desthio (sum of isomers) (0.01 mg/kg bw).

The calculation of the TMDI using EFSA model (version 3.1) and MRLs values according to the Regulation (EU) 2024/1318 and appropriate conversion factors for enforcement to risk assessment led to a utilisation of the ADI of 42% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is wheat with 8% of the ADI. The intended uses will not result in a consumer chronic exposure exceeding the ADI for prothioconazole-desthio.

An acute consumer risk assessment was performed only for the crops under consideration , based on the STMRs of wheat, rye and animals commodities and appropriate conversion factors for enforcement to risk assessment. The IESTI is at 19% of the ARfD for the consumption of Bovine:Liver by children and at 16% of the ARfD for the consumption of Swine:Other products by adults respectively.

TDMs
The dietary risk assessment was calculated using PRIMo rev 3.1 for each TDM. Toxicological reference values and input values from EFSA conclusion on confirmatory data on TDMs (EFSA, 2018) were taken into account.

1,2,4-Triazole
IEDI (% ADI) according to EFSA PRIMo: 1st contributor 42% Milk:Cattle
IESTI (% ARfD) according to EFSA PRIMo: Wheat/milling (flour): 0.6%,Wheat/bread/pizza: 0.2%

Triazole Lactic Acid
IEDI (% ADI) according to EFSA PRIMo: 1st contributor 0.1% Wheat
IESTI (% ARfD) according to EFSA PRIMo: Wheat/milling (flour): 0.1%,Wheat/bread/pizza: 0.06% Wheat/milling (flour): 0.1% ,Wheat/bread/pizza: 0.0%.

Triazole Acetic Acid
IEDI (% ADI) according to EFSA PRIMo: 1st contributor 0.2% Milk: Cattle
IESTI (% ARfD) according to EFSA PRIMo: Wheat 1%,Wheat/milling (flour): 0.1%, Wheat/bread/pizza: 0.0%

Triazole Alanine
IEDI (% ADI) according to EFSA PRIMo: 1st contributor 0.7% Wheat
IESTI (% ARfD) according to EFSA PRIMo: Wheat 4%, 2%,Wheat/milling (flour): 1%, Wheat/bread/pizza: 0. 4% wheat/bread/pizza: 0.0%

The data available are considered sufficient for risk assessment. The chronic and the short-term intakes of prothioconazole residues and TDMs are unlikely to present a public health concern.
The intended uses of FHO04/Patton Supra are accepted.

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

Predicted environmental concentrations (PEC) were calculated for both active substances, prothioconazole and sulphur, and relevant metabolites for the environmental exposure risk assessment. The assessments undertaken for the soil, groundwater and surface water compartments are described in the following sections.

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

Soil exposure for prothioconazol and their relevant metabolites and for sulphur was calculated using approach described in respective FOCUS guidance for the intended uses of FHO04/Patton Supra. For all compounds, EU agreed data were taken into account. Soil exposure for the formulated product was also calculated. The results for PEC_{soil} for the active substances and their metabolites were used for the ecotoxicological risk assessment.

3.7.2 Predicted environmental concentrations in groundwater (PECgw)

Prothioconazole
The groundwater exposure assessment was conducted according to FOCUS guidance using models PEARL v5.5.5 and PELMO v6.6.4. The active substance prothioconazole was assessed along with its major soil metabolites, prothioconazole S-methyl (M01) and prothioconazole-desthio (M04). All

endpoints were taken from the peer review conclusion for prothioconazole (EFSA, 2007). The maximum 80th percentile PEC_{gw} values for the parent compound and metabolites were <0.001 µg/L for all relevant Polish scenarios for both spring and winter cereals. Therefore, the risk to the groundwater environment is concluded to be low. It was not considered necessary to perform additional modelling using the MACRO v5.5.4 model.

Sulphur
Sulphur and sulphate are inorganic substances, predicted environmental concentrations in groundwater (PEC_{gw}), following application of sulphur to spring and winter cereals were calculated using total percolate as obtained from the FOCUS models PEARL v5.5.5, PELMO v6.6.4 and MACRO v5.5.4 for the assessed crop.
For PECgw calculation the worst case assumption was applied that 100 % of sulphur applied to soil is oxidised to sulphates and 100 % of sulphates will leach to groundwater. The total amount of sulphur applied to soil, and the equivalence in SO_4^{2-} (1 S_8 giving 8 SO_4^{2-}) were determined for a period of 26 years, based on an application rate of 2500 kg S/ha (sulphur applied to cereals twice a year, with 20 % crop interception). The maximum PECgw value for sulphate was obtained for the Châteaudun scenario (value of 11.097 mg/L) following application to winter cereals, indicated that the potential for groundwater contamination from sulphates is below the drinking water limit of 250 mg/L set in the Drinking Water Directive 98/83/CE. Therefore, applications of sulphur can be considered not to pose a risk to groundwater.

3.7.3 Predicted environmental concentrations in surface water (PECsw)

Prothioconazole
The surface water modelling was performed for the intended use pattern of FHO04/Patton Supra in line with recommendations of respective FOCUS guidance documents using most up-to-date versions of the models. Obtained PECSW/SED values were used in the risk assessment for aquatic organisms.

Sulphur
In accordance with EFSA (2008) no PEC_{sw} values have been calculated, the risk assessment to aquatic organisms was based on an absence of effects on organisms at the greatest water solubility limit of sulphur (maximum determined water solubility: 63 µg/L). Step 1 and Step 2 maximum initial PEC_{sed} for sulphur were calculated according to the conservative approach proposed in the Sulphur Addendum to the DAR Volume 3 B5, B6 and B9 for Confirmatory Data (April 2012).

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

Prothioconazole
The fate and behaviour of prothioconazole in air was considered in the EFSA conclusion (2007). The vapour pressure at 20 °C of the prothioconazole is < 10^{-5} Pa and so it is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance prothioconazole due to volatilization with subsequent deposition should not be considered. Based on expert judgement on the vapour pressure, Henry's Law Constant and the experimental information on volatilisation, it was considered that calculation of PEC_{air} is not necessary.

Sulphur
The vapour pressure at 20 °C of the active substance sulphur is between 10^{-5} and 10^{-4} Pa. Hence the active substance sulphur is regarded as semi-volatile (volatilisation only from plant surfaces). Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance sulphur due to volatilization with subsequent deposition should be considered. However, in EFSA (2008) conclusion it is stated that sulphur it not volatile and consequently calculation of PEC_{air} is not necessary.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

Birds risk assessment
For the active substance prothioconazole, the acute and long-term risks were acceptable at the screening level. Whereas for the active substance sulphur and prothioconazole metabolite prothioconazole-desthio, the acute and long-term risks were acceptable at Tier 1.
The risk to the mixture was calculated using the Finney's equation for acute toxicity and the risk quotient approach for chronic toxicity. The acute and chronic risks to the mixture (including metabolite prothioconazole-desthio) was acceptable at Tier 1.
The risk from exposure to contaminated drinking water and secondary poisoning was also considered acceptable following the proposed use of Patton Supra.

Mammals risk assessment
The acute risks for prothioconazole, prothioconazole-desthio and sulphur, and the long-term risks for prothioconazole and sulphur were acceptable at the screening assessment, indicating a low risk to mammals. However, the long-term risks for the metabolite prothioconazole-desthio did not pass the screening and first tier assessments. As such, additional refinement options were required to show an acceptable level of risk for the vole scenario. Three refinement options were presented (which all resulted in a safe use of Patton Supra to voles (TER >5).
The risk to the mixture for acute toxicity and TERmix for chronic toxicity. The acute and chronic risks to the mixture (including metabolite prothioconazole-desthio) was acceptable.

The risk from exposure to contaminated drinking water and secondary poisoning was also considered acceptable following the proposed use of Patton Supra.
It may therefore be concluded that the proposed use of the formulated product, Patton Supra, in cereal crops in accordance with Good Agricultural Practice poses no unacceptable acute and reproductive risk to birds and mammals.

3.8.2 Effects on aquatic species

The risk assessment for aquatic organisms was carried out according to the Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge–of-field surface waters (EFSA Journal 2013; 11 (7): 3290).
For the active substance sulphur, only the sediment dwelling risk assessment was considered relevant and acceptable risk is concluded.
The active substance prothioconazole and two metabolites (prothioconazole S-methyl and 1,2,4-triazole) pass spring and winter applications at BBCH 27 and BBCH 69 at FOCUS Step 2, requiring no mitigations. In spring applications, the metabolite prothioconazole-desthio passes at FOCUS Step 3, for the relevant scenarios for Poland. However, to ensure an acceptable risk for prothioconazole-desthio in winter cereals for Poland, a mitigation of a 20 m combined no-spray buffer zone and VFS is required. With VFSmod, mitigation can be reduced overall to a 5 m combined no-spray buffer zone and VFS.
and VFS.
The risk from R scenarios not defined for spring cereals (referred to R1 scenario in case of Poland) is covered by the risk assessment performed for these scenarios available for winter cereals.
Therefore finally, taking into account all relevant scenarios for Poland including D3, D4 and R1 for spring cereals and winter cereals - **a 5 m combined no-spray buffer zone and VFS is required** to surface water bodies.
According to EFSA Scientific Report (2008) 221, active substances with a very low water solubility limit can be considered in general as having a non-significant risk to aquatic organisms. This is relevant for the active substance sulphur, with a very low water solubility (0.063 mg a.s./L). Furthermore, no effects were observed at concentrations that exceeded the water solubility, by several orders of magnitude.

Therefore, it was not considered necessary to assess the risk for aquatic organisms by calculating Toxicity Exposure Ratios (TER) as sulphur can be considered of no concern for aquatic organisms. For this reason, a mixture toxicity considering the theoretical toxicity to each aquatic group assuming concentration addition, according to the EFSA guidance document, is not deemed necessary.
As a result, the mixture toxicity is covered by the individual assessment of the active substance prothioconazole and its metabolite prothioconazole-desthio, as well the risk assessment with the formulation measured toxicity.
The ratios between PEC_{SW} of the formulation due to drift (calculated based on the total amount of formulation that could be applied (4.0 L/ha)) and the aquatic organisms regulatory acceptable concentrations (RAC) for the formulation did indicate an acceptable risk for all groups of aquatic organisms.
It may therefore be concluded that the proposed use of the formulated product, Patton Supra, in cereal crops in accordance with Good Agricultural Practice poses no unacceptable risk to aquatic organisms when using the necessary mitigations.

3.8.3 Effects on bees

Patton Supra was not the representative formulation assessed at EU-level as part of active substances approval. Effects on bees are therefore assessed using endpoints from the new formulation studies.
The risk assessment to bees was conducted according to the interim approach suggested by Northern Zone, 2021 "Guidance document on work-sharing in the Northern zone in the authorisation of plant protection products" (Version 11, July 2023) was followed. As such, the evaluation of the acute risk for bees was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002).
For formulation FHO04, no unacceptable acute risks are expected to arise for honeybees from both acute contact and oral exposure and from chronic risks to honeybees' adults and larvae.
HQ acute oral and HQ acute contact for bumblebees, calculated as described for honeybees in SANCO/10329/2002, were below the trigger of 50, therefore no unacceptable acute risks is concluded also for bumblebees. The chronic studies for adult and larvae bees for formulation have been conducted according to Reg.284/2009.
However, the chronic risk assessment for larvae and adult bees (included in Core Dossier for product) is not required for Poland until Bee GD will be implemented in zonal level.
Overall, it can be reasonably concluded that all intended GAP uses of Patton Supra are of low risk to bees under field conditions.

3.8.4 Effects on other arthropod species other than bees

The risk assessment was conducted according to the ESCORT 2 Guidance document (2000) and the SANCO Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2 (final), October 17, 2002).
Patton Supra was not the representative formulation assessed at EU-level as part of active substances approval. Formulation endpoints are considered to be more relevant in terms of non-target arthropod exposure under field conditions than effects of the active substances applied as technical grade. Effects on non-target arthropods are therefore assessed using endpoints from the new formulation studies.
In-field and off-field HQ Higher tier and Tier I values based on laboratory and aged residue studies with the formulation Patton Supra and the test organisms *Aphidius rhopalosiphi*, *Typhlodromus pyri* and *Coccinella septempunctata* were below relevant trigger values indicating that the risk to in-field and off-field non-target arthropods is acceptable following the use of Patton Supra according to the proposed use pattern. Risk mitigation measures are not required.

3.8.5 Effects on soil organisms

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the "Guidance Document on Terrestrial

Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).
According to the current guidance document SANCO/10239, EC 2002, endpoints (LC_{50}, NOEC or EC_{10}) considered in the risk assessment for soil macro- and mesofauna should be divided by a factor of 2, if the log P_{ow} is greater than 2, unless it can be demonstrated by soil sorption data or other evidence that the toxicity is independent of organic carbon content in the substrate.
As stated in the EFSA Scientific Report (2007) 106, the log P_{ow} for prothioconazole was determined > 2 and thus, a correction factor must be considered. The log P_{ow} values for the major metabolites of prothioconazole in soil were determined to be 4.19 (prothioconazole-methyl) and 3.04 (prothioconazole-desthio). As these values are above the relevant threshold of 2 as well, a correction factor of 2 was applied for the metabolite of concern for maximum conservatism.
The worst-case PEC_{soil} for risk assessments covering the proposed use patterns are taken from Section 8 (Environmental Fate), Chapter 8.7.2. According to the assessment of environmental-fate data, multi-annual accumulation in soil does not need to be considered for either prothioconazole or sulphur.
Toxicity Exposure Ratios (TER) calculated with the endpoints for chronic effects on earthworms and other soil organisms (*Hypoaspis aculeifer, Folsomia candida*) and the relevant PEC_{soil} values are all above the trigger value of 5, indicating that Patton Supra poses an acceptable chronic risk to earthworms, meso-, and macrofauna at the proposed GAP.
The risk to soil microorganisms following the proposed use of Patton Supra were performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002). TER values for sulphur and formulation Patton Supra are above the trigger value of 5 indicating there is acceptable chronic risk to earthworms, meso-, and macrofauna at the proposed GAP. TER values for prothioconazole and its relevant metabolite are below the trigger value of 5 for earthworm, however a field study indicates that the chronic risk to earthworms is acceptable at the proposed GAP.

3.8.6 Effects on non-target terrestrial plants

The risk assessment was conducted according to the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002).

With a TER value above the Annex VI trigger of 5 for all tested species, it may be concluded that the proposed use of Patton Supra in cereal crops in accordance with Good Agricultural Practice will present no unacceptable risk to non-target plants in off crop areas. No mitigation measures need to be applied.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Not relevant.

3.9 Relevance of metabolites (Part B, Section 10)

Prothioconazole

The PEC_{gw} values for the prothioconazole metabolites JAU 6476-S-methyl (M01) and JAU 6476-desthio (M04) are by far below 0.1 µg/L, therefore no further assessment of their relevance is necessary.

Sulphur

The relevance of the groundwater transformation product sulphate has already been assessed and the assessment agreed at EU level (see EFSA, 2008), and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR). Sulphate is not considered

relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. Sulphate is an inorganic compound (not containing a heavy metal) and is considered a transformation product of no concern and additional data are not required.
Furthermore, tier 1 PECgw of sulphate at 1 m depth from all relevant FOCUS PELMO, PEARL and MACRO groundwater scenarios as provided in Section 8.8 of the dRR Part B, Section 8 (Environmental fate and behaviour) are considerably less than the drinking water indicator parameter of 250 mg/L for each GAP use of the formulation on winter and spring cereals. Therefore, it can be concluded that the transformation product sulphate does not pose an unacceptable risk to groundwater if the products are used in compliance with the label recommendations.

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

Not relevant for 'Patton Supra' since prothioconazole and sulphur are not candidates for substitution.

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

The residue storage stability study KCA 6.1/01 (Giancola, D., 2024, Study No. QG/21/001) is provided as an interim report with storage stability data presented for 8-12 months, which covers the submitted residue trials. The residue storage stability study is set to run for 24 months, with the final report due in January 2025.

Efficacy:
The extrapolation, from winter forms of wheat and triticale, to spring forms that are currently claimed in the GAP table, is not possible based on the present data set. The reason for that is the complete absence (n=0) of trials in spring forms, while the submission of 1-2 trials in the crop to which one extrapolates is, according to national requirements, the *sine qua non* condition making extrapolation possible. **Since FHO04 is a new product**, then in order to enable authorization based on extrapolation **no less than 2** trials would be required for each use, with the "use" defined as each one of the combinations: *crop x pathogen*.
Authorization of the uses in durum wheat, in spelt wheat and in spring rye is possible following the article 51 of the regulation 1107/2009, i.e. with no requirement for efficacy trials.

Appendix 1 Copy of the product authorization

Appendix 2 Copy of the product label

Komentarz oceniających:

Etykieta została sprawdzona w zakresie fizykochemii, metod analitycznych, pozostałości, toksykologii i istotności toksykologicznej metabolitów, losu i zachowania, ekotoksykologii oraz skuteczności. Zmiany wynikające z oceny wprowadzono do poniższej etykiety w widoczny sposób, poprzez zaznaczenie ich szarym kolorem, fragmenty usunięte zostały ~~przekreślone~~ i zaznaczone szarą czcionka.

Sekcja właściwości fizykochemiczne:

1. Środek nie wykazuje właściwości wybuchowych i utleniających, znakowanie środka wynikające z wyżej wymienionych właściwości fizykochemicznych zgodne z zapisami Rozporządzenia Parlamentu Europejskiego i Rady (WE) NR 1272/2008 z dnia 16 grudnia 2008 r. nie jest wymagane.
2. Okres ważności: 2 lata na podstawie 2-letnich badań stabilności środka ochrony roślin przechowywanego w opakowaniach wykonanych z HDPE/EVOH. Zgodnie z zapisami aktualnie obowiązującej wytycznej Ministerstwa Rolnictwa i Rozwoju Wsi (z dnia 05/09/2023) w sprawie zasad zatwierdzania opakowań środków ochrony roślin dla formulacji SC możliwa jest ekstrapolacja wyników badania stabilności z opakowań HDPE/EVOH na HDPE/F i HDPE/PA. W związku z powyższym wszystkie opakowania wymienione w punkcie 4.1 Sekcji 1,2,4 oraz w punkcie 2.1 dokumentu A można uznać za odpowiednie do celów transportu i magazynowania środka ochrony roślin (, F-HDPE, HDPE/PA i HDPE/EVOH).
3. Brak uwag do zaproponowanych w etykiecie zapisów dotyczących warunków przechowywania i bezpiecznego usuwania środka ochrony roślin.
4. Brak uwag do zawartości substancji czynnych. (zgodnie z punktem 2.6.1 Sekcji 1,2,4 gęstość d=1.355 g/mL). Uzupełniono nazwę substancji czynnej protiokonazol.
5. Zgodnie z informacjami zawartymi w tabeli 2-1, w punkcie 2.9.1 i 2.9.2 Sekcji 1 Raportu Rejestracyjnego środek może być stosowany łączenie ze środkami: Vacciplant Max SL, Caramba EC, Chamane 25 SC, Comet 200 EC, Elatus EC i Revystar EC, podczas oprysku mieszaniną należy stosować ciągłe mieszanie.

Sekcja skuteczność:

1. Uzupełniono zaklasyfikowanie protiokonazolu zgodnie z klasyfikacją FRAC, w rozdziale „OPIS DZIAŁANIA" jak i w części „ŚRODKI OSTROŻNOŚCI […]".
2. Skorygowano nieznacznie okno BBCH, z 27-69 na 30-69, w oparciu o warunki występujące w przeprowadzonych badaniach.
3. Wykreślono z etykiety formy jare pszenicy i pszenżyta, z uwagi na całkowity brak badań i spowodowany tym także brak możliwości ekstrapolacji zastosowań z form ozimych. Jednak ze względu na fakt iż obie substancje występujące w FHO04 są znane i sprawdzone w ochronie zbóż przed patogenami, ekspert sugeruje możliwość wydania warunkowego zezwolenia obejmującego pszenicę i pszenżyto jare, dla zastosowania w tej samej dawce i w tych samych fazach rozwojowych jak w formach ozimych. Wnioskodawca dwukrotnie prosi o takie rozwiązanie w dokumencie B3. W pkt 5 niniejszego dokumentu (Part A) oceniający zdefiniował liczbę badań do uzupełnienia na formach jarych (2 dla każdego zastosowania), na wypadek wydania zezwolenia warunkowego dla pszenicy jarej i pszenżyta jarego.
4. Zastosowania w pszenicy twardej, pszenicy orkisz, oraz w pszenżycie jarym, jako wnioskowane w trybie Artykułu 51, nie podlegają ocenie w zakresie skuteczności.
5. W części: ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA: zmodyfikowano/uzupełniono zalecenia dla strategii zarządzania odpornością.
6. W części: POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY: doprecyzowano zapis dotyczący mycia aparatury.

Sekcja metody analityczne:

1. Brak uwag do etykiety.

Sekcja toksykologia i istotność toksykologiczna metabolitów:

1. W części dotyczącej środków ostrożności dla osób stosujących środek odpowiedni zapis został zmodyfikowany zgodnie z klasyfikacją zagrożeń oraz szacowaniem NDE dRR B6 (wymagania harmonizacyjne, Min. Rol., Toksykologia wer. 24.06.2024).

Sekcja pozostałości:

1. W zakresie zapisów dotyczących roślin następczych nie ma potrzeby wpisywania restrykcji. Opcjonalnie można do etykiety dodać następujący zapis:
   „Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny

uprawiane następczo: nie ma ograniczeń co do okresu od ostatniego zastosowania środka do dnia, w którym można siać lub sadzić rośliny uprawiane następczo."

Sekcja los i zachowanie w środowisku:
1. Brak uwag.

Sekcja ekotoksykologia:
1. Zmieniono klasyfikację z H411 na H410. ~~Zmieniono klasyfikację z H410 na H411.~~
2. Wprowadzono zwrot 501.

Posiadacz zezwolenia:
UPL Holdings Coöperatief U.A., Claudius Prinsenlaan 144a, Block A, 4818CP Breda, Królestwo Niderlandów, tel.: +31 85 071 23 00, e-mail: uplholdingscoop@upl-ltd.com

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:
UPL Polska Sp. z o.o., ul. Stawki 40, 01-040 Warszawa, tel.: +48 22 434 00 90, e-mail: sekretariat@upl-ltd.com

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:
…….

Podmiot odpowiedzialny za końcowe etykietowanie środka ochrony roślin:
……

Patton Supra

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Substancje czynne:
protiokonazol (związek z grupy triazoli) - 50 g/l (3,69%)
siarka - 625 g/l (46,12%)

Zezwolenie MRiRW nr R - xx/2025 z dnia xx.xx.2025 r.

Uwaga	
H315	Działa drażniąco na skórę.
H410 ~~10~~	Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH208	Zawiera 1,2-benzizotiazol-3(2H)-on; 1,2-benzizotiazolin-3-on. Może powodować wystąpienie reakcji alergicznej.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P264	Dokładnie umyć ręce, przedramiona i twarz po użyciu.
P280	Stosować rękawice ochronne/odzież ochronną/~~ochronę oczu/ochronę twarzy~~.
P302+P352	W PRZYPADKU KONTAKTU ZE SKÓRĄ: Umyć dużą ilością wody.
P332+P313	W przypadku wystąpienia podrażnienia skóry: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
P362+P364	Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.

P391	Zebrać wyciek
P501	Zawartość/pojemnik usuwać do odpowiedniego miejsca utylizacji zgodnie z lokalnymi i krajowymi przepisami

OPIS DZIAŁANIA
FUNGICYD w formie stężonej zawiesiny do rozcieńczania wodą (SC), o działaniu powierzchniowym oraz układowym, do stosowania zapobiegawczego i interwencyjnego w ochronie przed chorobami powodowanymi przez grzyby.
Zgodnie z klasyfikacją FRAC substancja czynna protiokonazol zaliczana jest do grupy ~~3~~ G1 w klasyfikacji FRAC (# 3 fungicydy DMI, SBI klasa I), a substancja czynna siarka do grupy M02.

STOSOWANIE ŚRODKA
Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych.

Pszenica ozima, ~~pszenica jara,~~ pszenżyto ozime~~, pszenżyto jare~~
Septorioza paskowana liści pszenicy, rdza żółta zbóż i traw, rdza brunatna pszenicy

Maksymalna / zalecana dawka dla jednorazowego zastosowania: 4,0 l/ha.
Termin stosowania: środek stosować zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów chorób wiosną od fazy pełni krzewienia do fazy końca kwitnienia (BBCH 30-69 ~~BBCH 27-69~~).
Liczba zabiegów: 2.
Odstęp między zabiegami: co najmniej 14 dni.
Zalecana ilość wody: 100 - 400 l/ha.
Zalecane opryskiwanie: drobnokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Żyto ozime
Rdza brunatna żyta

Maksymalna / zalecana dawka dla jednorazowego zastosowania: 4,0 l/ha.
Termin stosowania: Środek stosować zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów choroby wiosną od fazy pełni krzewienia do fazy końca kwitnienia (BBCH 30-69 ~~BBCH 27-69~~).
Liczba zabiegów: 2.
Odstęp między zabiegami: co najmniej 14 dni.
Zalecana ilość wody: 100 - 400 l/ha.
Zalecane opryskiwanie: drobnokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

STOSOWANIE ŚRODKA OCHRONY ROŚLIN W UPRAWACH I ZASTOSOWANIACH MAŁOOBSZAROWYCH

Odpowiedzialność za skuteczność działania i fitotoksyczność środka ochrony roślin stosowanego w uprawach małoobszarowych ponosi wyłącznie jego użytkownik.

Pszenica durum, pszenica orkisz
Septorioza paskowana liści pszenicy, rdza żółta zbóż i traw, rdza brunatna pszenicy

Maksymalna / zalecana dawka dla jednorazowego zastosowania: 4,0 l/ha.
Termin stosowania: środek stosować zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów chorób wiosną od fazy pełni krzewienia do fazy końca kwitnienia (BBCH 27-69).
Liczba zabiegów: 2.
Odstęp między zabiegami: co najmniej 14 dni.
Zalecana ilość wody: 100 - 400 l/ha.
Zalecane opryskiwanie: drobnokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Żyto jare
Rdza brunatna żyta

Maksymalna / zalecana dawka dla jednorazowego zastosowania: 4,0 l/ha.
Termin stosowania: Środek stosować zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów choroby wiosną od fazy pełni krzewienia do fazy końca kwitnienia (BBCH 27-69).
Liczba zabiegów: 2.
Odstęp między zabiegami: co najmniej 14 dni.
Zalecana ilość wody: 100 - 400 l/ha.
Zalecane opryskiwanie: drobnokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA
Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):
Pszenica ozima, pszenica jara, pszenżyto ozime, pszenżyto jare, żyto ozime, pszenica durum, pszenica orkisz, żyto jare – 35 dni.

W specyficznych warunkach pogodowych niektóre rośliny uprawne mogą być wrażliwe na działanie siarki. Z tego względu nie należy wykonywać zabiegu przy temperaturze powyżej 25°C oraz w okresach ciepłej i bardzo suchej pogody.

Środek zawiera dwie substancje czynne o różnym mechanizmie działania: protiokonazol z grupy triazoli (fungicydy inhibitory biosyntezy steroli – inhibitory demetylacji, SBI-DMI, grupa FRAC G1, # 3) oraz siarkę, o oddziaływaniu na różne procesy metaboliczne na poziomie komórkowym patogenów (multi-site activity) (wg FRAC grupa M02). W ramach strategii przeciwdziałania rozwojowi odporności w populacjach sprawców chorób zaleca się m.in.:

- stosować środek wyłącznie w zalecanej~~ych~~ dawce~~kach~~ (także w przypadku stosowania środka w mieszaninach zbiornikowych z innymi środkami grzybobójczymi), ,
- nie przekraczać maksymalnej zalecanej w sezonie wegetacyjnym liczby zabiegów,
- stosować środek głównie do zabiegów zapobiegawczych (tj. na początku okresów infekcji pierwotnych lub wtórnych),
- ~~stosować środek przemiennie ze środkami grzybobójczymi zawierającymi substancje czynne z innych grup chemicznych, o odmiennym mechanizmie działania~~ włączyć do przyjętego programu ochrony środki grzybobójcze, zawierające substancje czynne z innych grup wg klasyfikacji FRAC, o odmiennych mechanizmach działania (stosowanie środków przemienne lub w mieszaninie zbiornikowej),
- włączyć do przyjętego programu ochrony przed chorobami inne niż chemiczne metody zwalczania, zgodne z zasadami integrowanej ochrony np. uprawa odmian odpornych, właściwe zmianowanie.

Podczas stosowania środka nie dopuścić do:

- znoszenia cieczy użytkowej na sąsiednie rośliny uprawne,
- nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach

SPORZĄDZANIE CIECZY UŻYTKOWEJ
Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.
Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Zawartością opakowania przed użyciem wstrząsnąć. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).
Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlaniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać. W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY
Po pracy aparaturę dokładnie wymyć, postępując zgodnie z zasadami dobrej praktyki ochrony roślin.

Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy:
– jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg lub
– unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin lub
– unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

~~Po pracy aparaturę dokładnie wymyć.~~

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH
Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.
Unikać wdychania rozpylonej cieczy.
~~Stosować rękawice ochronne, ochronę oczu i twarzy oraz odzież roboczą (kombinezon), w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.~~

Stosować rękawice ochronne i odzież roboczą (kombinezon), w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu

Zdjąć zanieczyszczoną odzież i wyprać ją przed ponownym użyciem.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):
nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO
Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 5 m od zbiorników i cieków wodnych.
W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od terenów nieużytkowanych rolniczo.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY

ROŚLIN I OPAKOWANIA
Chronić przed dziećmi.
Środek ochrony roślin przechowywać:
- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0 ºC-30ºC.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.
Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.
Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC
Antidotum: brak, stosować leczenie objawowe.
W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.
W przypadku kontaktu ze skórą: umyć dużą ilością wody.
W przypadku wystąpienia podrażnienia skóry: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Okres ważności - 2 lata
Data produkcji - .....
Zawartość netto - .....
Nr partii - .....

Appendix 3 Letter of Access

A copy of the third and fourth amendment to UPL's Access Agreement, with the Triazole Derived Metabolite Group (TDMG), is provided with this application. The amendments provide UPL with access to a small number of TDMG studies which are being used either:

- to directly address the data gaps, relevant for prothioconazole, identified during the peer review of the TDM metabolites (EFSA, 2018, amended 2019) or
- to support UPL studies addressing the data gaps, relevant for prothioconazole, identified during the peer review of the TDM metabolites (EFSA, 2018, amended 2019).

For more information, please refer to the dRR Part B7 (residues section).

Appendix 4 Lists of data considered for national authorization

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1 KCP 2.2.1 KCP 2.2.2 KCP 2.3.1 KCP 2.3.3 KCP 2.4.2 KCP 2.5.1 KCP 2.5.2 KCP 2.7.1 KCP 2.7.4 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.3.2 KCP 2.8.5.1.2 KCP 2.8.7.2 KCP 4.2.2 KCP 5.1.2/11	V. Buchholz	2022	Physical and Chemical Properties in one batch of Prothioconazole/Sulphur (50+625) g/L SC (Formulation code FHO04). Initial tests. ANADIAG Report No. R C1254 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 2.5.7	V. Buchholz	2024	Physical and Chemical Properties in one batch of Prothioconazole/Sulphur (50+625) g/L SC (Formulation code FHO04) after a storage period. Shelf life after ambient temperature for 2 years ANADIAG Report No. R C1256 Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 2.6.1 KCP 2.7.3	V. Buchholz	2022	Physical and Chemical Properties in one batch of Prothioconazole/Sulphur (50+625) g/L SC (Formulation code FHO04). Tests after accelerated storage. ANADIAG Report No. R C1255 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.9.1	A. Jakubiak	2023	The compatibility of Prothioconazole/Sulphur 50 + 625 SC (FHO04) with other pesticides. UPL Europe Limited Report No. UPL/2023/2018 Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 5.1.1/01	V. Buchholz	2022	Method(s) validation and determination of Prothioconazole, Sulphur, Prothioconazole-Desthio & Toluene content in one batch of Prothioconazole/Sulphur (50+625) g/L SC (Formulation code FHO04 Company Report No R. C1253 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 5.1.2/01	J. Pearson	2022	Prothioconazole-desthio: Method Validation in Crops Company Report No. QG/20/011 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 5.1.2/02	D. Giancola	2023	Hydroxy Metabolites of prothioconazole-desthio: Method Validation in Crops Report No. QG/22/001 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 5.1.2/03	B. Phipps	2024	Triazole Derived Metabolites (TDM's) (1,2,4-Ttriazole, triazole acetic acid, triazole alanine and triazole lactic acid): Method Validation in Crops Report No. QG/20/012 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 5.1.2/04	M. Patel	2023	Validation of the Analytical Method for Determination of Active Substance Concentration and Stability of Prothioconazole + Sulphur in Matrix, Following the Application of Prothioconazole/Sylphur (50 + 625) G/L SC Report No. 228-2-13-29109 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 5.1.2/05 (filed in	Ripperger, D.	2022a	Prothioconazole/Sulphur (50+625) g/L SC (FHO04): Acute Oral and Contact Toxicity to the Bumble Bee *Bombus terrestris* L. (Hymenoptera, Apidae) under Laboratory Conditions	N	Y	Study report never submitted before to MS	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.1.1/02)			Report No. S21-06042 GLP Unpublished				
KCP 5.1.2/06 (filed in KCP 10.3.1.2/01)	Ansaloni, T.	2022b	Prothioconazole/Sulphur (50+625) g/L SC: Honey Bee (*Apis mellifera* L.) Chronic Oral Toxicity Test (10-Day Feeding) under Laboratory Conditions Report No. S21-06044 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 5.1.2/07 (filed in KCP 10.3.1.2/01)	Ansaloni, T.	2022c	Prothioconazole/Sulphur (50+625) g/L SC: Honey Bee (*Apis mellifera* L.) Larval Toxicity Test following Repeated Exposure under laboratory conditions Report No. S21-06046 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 5.1.2/08 (filed in KCP 10.4.1.2/01)	Vollmer, T.	2023	A Field Study to Evaluate the Effects of Metabolites of Prothioconazole on Earthworm Populations Report No S21-03781 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 5.1.2/09 (filed in KCP 10.6.2/01)	Ripperger, D	2022b	Prothioconazole/Sulphur (50+625) g/L SC (FHO04): Effects on the Seedling Emergence and Seedling Growth of Terrestrial Plant Species UPL report No.: S21-05533 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 5.1.2/10 (filed in KCP 10.6.1/01)	Ripperger, D	2023	Prothioconazole/Sulphur (50+625) g/L SC (FHO04): Effects on the Vegetative Vigour of Terrestrial Plant Species UPL report No.: S21-05534 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 5.1.2/11 (filed in KCP 2.1)	V. Buchholz	2022	Physical and Chemical Properties in one batch of prothioconazole/Sulphur (50+625) g/L SC (Formulation code FHO04) Initial tests Report No. R C1254 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 5.2/01	J. Pearson	2022	Prothioconazole-desthio: Method Validation in Crops	N	Y	Study report never submitted	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
(filed in KCP 5.1.2/01)			Company Report No. QG/20/011 GLP Unpublished			before to MS	
KCP 5.2/02	N. Boubakri	2023	Independent Laboratory Validation of Multi Residue Method for Determination of Prothioconazole-desthio in Different Matrices of Plant Origin Report No. S21-08354 GLP Unpublished	N	Y	Study report never submitted before to S	UPL
KCP 5.2/03	D. Kleinhenz	2023	Development and Validation of an Analytical Method for Determination of Prothioconazole-desthio in Food of Animal Origin Report No. S21-08355 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 5.2/04	T. Rastogi	2023	Independent Laboratory Validation of Prothioconazole-desthio in Different Matrices of Animal Origin Report No. S21-08868 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 5.2/05	J. Hitchens	2023	Prothioconazole-desthio and hydroxy metabolites: Method Validation in Honey Report No. QG/21/009 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 5.2/06	J. Wanger	2023	Independent Laboratory Validation of an Analytical Method for the Determination of Prothioconazole-desthio in Honey Report No. S21-08357 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 5.2/07	M. Kaiser	2022	Development and Validation of an Analytical Method for Determination of Prothioconazole and Prothioconazole-desthio in Soil Report No. S21-08358 GLP Unpublished	N	Y	Study report never submitted before tMS	UPL
KCP 5.2/08	M. Kaiser	2022	Development and Validation of an Analytical Method for Determination of Prothioconazole and Prothioconazole-desthio	N	Y	Study report never submitted before to MS	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			in Water Report No. S21-08359 GLP Unpublished				
KCP 5.2/09	S. Jooß	2023	Independent Laboratory Validation of an Analytical Method for the Determination of Prothioconazole-desthio in Water Report No. S21-08869 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 5.2/10	N. Boubakri	2023	Development and Validation of an Analytical Method for Determination of Prothioconazole-desthio in Urine Report No, S21-08361 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /001	Furman-Fratczak, K.	2021	The efficacy of FGR06 and FHO04 applied post-emergence of wheat for the control of *Zymoseptoria tritici* (SEPTTR) in Europe. Agreco, Poland, Report No. 21UPL0904-1 UPL Report No. F21EU-006-011-019 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /002	Furman-Fratczak, K.	2021	The efficacy of FGR06 and FHO04 applied post-emergence of wheat for the control of *Zymoseptoria tritici* (SEPTTR) in Europe. Agreco, Poland, Report No. 21UPL0904-2 UPL Report No. F21EU-006-011-020 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /003	Furman-Fratczak, K.	2021	The efficacy of FGR06 and FHO04 applied post-emergence of wheat for the control of *Zymoseptoria tritici* (SEPTTR) in Europe. Agreco, Poland, Report No. 21UPL0904-3 UPL Report No. F21EU-006-011-021 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1	Furman-Fratczak, K.	2021	The efficacy of FGR06 and FHO04 applied post-emergence of wheat for the control of *Zymoseptoria tritici* (SEPTTR) in Europe.	N	Y	Study report never submitted before to MS	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
/004			Agreco, Poland, Report No. 21UPL0907-1 UPL Report No. F21EU-006-011-022 GEP Unpublished				
KCP 6.1 KCP 6.2 KCP 6.4.1 /005	Furman-Fratczak, K.	2022	The efficacy of FGR06 and FHO04 applied post-emergence of wheat for the control of *Zymoseptoria tritici* (SEPTTR) in Europe. Agreco, Poland, Report No. 22UPL01071-1 UPL Report No. F22EU-024-AMA-016 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /006	Furman-Fratczak, K.	2022	The efficacy of FGR06 and FHO04 applied in winter wheat for the control of *Zymoseptoria tritici* (SEPTTR). Agreco, Poland, Report No. 22UPL01071-2 UPL Report No. F22EU-024-AMA-017 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /007	Furman-Fratczak, K.	2023	The efficacy of FGR06, FGR07 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Agreco, Poland, Report No. 23UPL01222-1 UPL Report No. F23EU-008-AMA-005 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /008	Rusek, K.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST), Poland 2023 Fertico, Poland, Report No. 113_02_F23_331 UPL Report No. F23EU-011-AMA-012 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /009	Umiński, P.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Blumeria graminis tritici* (ERYSGT), *Zymoseptoria tritici* (SEPTTR)on winter wheat in Poland. Field Research Support, Poland, Report No. FRS 529/23 – V1 UPL Report No. F23EU-014-AMA-016 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.1 KCP 6.2	Umiński, P.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Blumeria graminis tritici* (ERYSGT), *Zymoseptoria*	N	Y	Study report never submitted before to MS	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4.1 /010			*tritici* (SEPTTR), *Pyrenophora tritici-repentis* (PYRNTR), Puccinia recondite (PUCCRE) on winter wheat in Poland Field Research Support, Poland, Report No. FRS 529/23 – V2 UPL Report No. F23EU-014-AMA-017 GEP Unpublished				
KCP 6.1 KCP 6.2 KCP 6.4.1 /011	Pszczółkowski, M.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Pyrenophora tritici-repentis* (PYRNTR) and *Zymoseptoria tritici* (SEPTTR) in Poland. Staphyt, Poland, Report No. MP2-23-105429-01-PL02 UPL Report No. F23EU-015-AMA-012 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /012	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied in cereals for the control of *Zymoseptoria tritici* (SEPTTR) in Europe. Field Research Support, Latvia, Report No. FRS198/22-V2-LV UPL Report No. F22EU-033-AMA-002 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /013	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied post-emergence of winter wheat for the control of *Puccinia striiformis* (PUCCST) in Europe. Field Research Support, Latvia, Report No. FRS200/22-V2-LV UPL Report No. F22EU-034-AMA-002 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /014	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied post-emergence of winter wheat for the control of *Puccinia striiformis* (PUCCST) in Europe. Field Research Support, Latvia, Report No. FRS200/22-V3-LV UPL Report No. F22EU-034-AMA-003 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /015	Packwood, J.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Pyrenophora tritici-repentis* (PYRNTR) in Europe. Eurofins, Latvia, Report No. S23-101657-06 UPL Report No. F23EU-015-AMA-009	N	Y	Study report never submitted before to MS	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP Unpublished				
KCP 6.1 KCP 6.2 KCP 6.4.1 /016	Vaitiekiene, E.	2021	The efficacy of FCG08, FGR06 and FHO04 applied post-emergence of winter wheat for the control of *Zymoseptoria tritici* (SEPTTR) in Europe. Agrolab, Lithuania UPL Report No. F21EU-007-011-003 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /017	Vaitiekiene, E.	2021	The efficacy of FCG08, FGR06 and FHO04 applied post-emergence of winter wheat for the control of *Zymoseptoria tritici* (SEPTTR) in Europe. Agrolab, Lithuania UPL Report No. F21EU-007-011-004 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /018	Zöllner, H. Siebold, M.	2021	Field study to evaluate the efficacy of FGR06 and FHO04 applied in winter wheat for the control of *Zymoseptoria tritici* (SEPTTR) in Europe. Field Research Support, Germany, Report No. FRS275/21-V1 UPL Report No. F21EU-006-011-006 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /019	Zöllner, H. Siebold, M.	2021	Field study to evaluate the efficacy of FGR06 and FHO04 applied in triticale for the control of *Zymoseptoria tritici* (SEPTTR) and *Blumeria graminis tritici* (ERYSGT) in Europe. Field Research Support, Germany, Report No. FRS275/21-V2 UPL Report No. F21EU-006-011-007 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /020	Zöllner, H. Siebold, M.	2021	Field study to evaluate the efficacy of FGR06 and FHO04 applied in wheat for the control of *Puccinia striiformis* (PUCCST) and *Zymoseptoria tritici* (SEPTTR) in Europe. Field Research Support, Germany, Report No. FRS276/21-V2 UPL Report No. F21EU-008-011-005 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.1	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04	N	Y	Study report never submitted	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2 KCP 6.4.1 /021			applied in cereals for the control of *Zymoseptoria tritici* (SEPTTR) in Europe. Field Research Support, Germany, Report No. FRS197/22-V3 UPL Report No. F22EU-024-AMA-005 GEP Unpublished			before to MS	
KCP 6.1 KCP 6.2 KCP 6.4.1 /022	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST) in Europe. Field Research Support, Germany, Report No. FRS199/22-V2 UPL Report No. F22EU-025-AMA-004 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /023	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Field Research Support, Germany, Report No. FRS202/22-V2 UPL Report No. F22EU-026-AMA-004 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /024	Siebold, M.	2023	The effecacy of FGR06, FGR07 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Field Research Support, Germany, Report No. FRS028/23 UPL Report No. F23EU-008-AMA-004 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /025	Packwood, J.	2023	The efficacy of FGR06, FGR07 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST) in Europe. Eurofins, Germany, Report No. S23-101654-02 UPL Report No. F23EU-012-AMA-005 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /026	Oudin, V.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Blumeria graminis tritici* (ERYSGT) in Europe. GEP Trial, GERMANY, 2023. Staphyt, Germany, Report No. VON-23-105349-01-DE07 UPL Report No. F23EU-014-AMA-003 GEP	N	Y	Study report never submitted before to MS	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 6.1 KCP 6.2 KCP 6.4.1 /027	Packwood, J.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Pyrenophora tritici-repentis* (PYRNTR) in Europe. Eurofins, Germany, Report No. S23-101657-04 UPL Report No. F23EU-015-AMA-004 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.1 KCP 6.2 KCP 6.4.1 /028	Oudin, V. Schmidt, I.	2019	The efficacy of FHO applied to winter wheat for the control of foliar diseases (SEPTTR) Staphyt, Germany, Report No. VON-19-38651-DE02 UPL Report No. F-19-EU-TRZAW-009E01-02DE GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.2 KCP 6.4.1 /029	Furman-Fratczak, K.	2020	The efficacy of FGF06 and FHO04 applied to wheat for the control of foliar diseases. Agreco, Poland, Report No. 20UPL0688-1 UPL Report No. F20EU-002-010-015 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.2 KCP 6.4.1 /030	Furman-Fratczak, K.	2021	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST) in Europe. Agreco, Poland, Report No. 21UPL0905-1 UPL Report No. F21EU-008-011-016 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.2 KCP 6.4.1 /031	Furman-Fratczak, K.	2021	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST) in Europe. Agreco, Poland, Report No. 21UPL0908-1 UPL Report No. F21EU-008-011-017 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.2 KCP 6.4.1 /032	Furman-Fratczak, K.	2021	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Agreco, Poland, Report No. 21UPL0906-1 UPL Report No. F21EU-009-011-016 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.2	Furman-Fratczak, K.	2021	The efficacy of FGR06 and FHO04 applied in cereals for the	N	Y	Study report never submitted	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4.1 /033			control of *Puccinia triticina* (PUCCRT) in Europe. Agreco, Poland, Report No. 21UPL0906-2 UPL Report No. F21EU-009-011-017 GEP Unpublished			before to MS	
KCP 6.2 KCP 6.4.1 /034	Furman-Fratczak, K.	2021	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Agreco, Poland, Report No. 21UPL0909-1 UPL Report No. F21EU-009-011-018 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.2 KCP 6.4.1 /035	Furman-Fratczak, K.	2021	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Agreco, Poland, Report No. 21UPL0910-1 UPL Report No. F21EU-009-011-019 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.2 KCP 6.4.1 /036	Furman-Fratczak, K.	2021	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Agreco, Poland, Report No. 21UPL0910-2 UPL Report No. F21EU-009-011-020 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.2 KCP 6.4.1 /037	Furman-Fratczak, K.	2022	The efficacy of FGR06 and FHO04 applied in winter wheat for the control of *Puccinia striiformis* (PUCCST). Agreco, Poland, Report No. 22UPL01072-1 UPL Report No. F22EU-025-AMA-017 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.2 KCP 6.4.1 /038	Furman-Fratczak, K.	2022	The efficacy of FGR06 and FHO04 applied in winter wheat for the control of *Puccinia striiformis* (PUCCST). Agreco, Poland, Report No. 22UPL01072-2 UPL Report No. F22EU-025-AMA-018 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.2 KCP 6.4.1 /039	Furman-Fratczak, K.	2022	The efficacy of FGR06 and FHO04 applied in winter rye for the control of *Puccinia triticina* (PUCCRT). Agreco, Poland, Report No. 22UPL01073-1	N	Y	Study report never submitted before to MS	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			UPL Report No. F22EU-025-AMA-026 GEP Unpublished				
KCP 6.2 KCP 6.4.1 /040	Furman-Fratczak, K.	2022	The efficacy of FGR06 and FHO04 applied in winter rye for the control of *Puccinia triticina* (PUCCRT). Agreco, Poland, Report No. 22UPL01073-2 UPL Report No. F22EU-025-AMA-027 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.2 KCP 6.4.1 /041	Furman-Fratczak, K.	2022	The efficacy of FGR06 and FHO04 applied in winter wheat for the control of *Puccinia triticina* (PUCCRT). Agreco, Poland, Report No. 22UPL01074-1 UPL Report No. F22EU-026-AMA-019 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.2 KCP 6.4.1 /042	Furman-Fratczak, K.	2022	The efficacy of FGR06 and FHO04 applied in winter rye for the control of *Puccinia triticina* (PUCCRT). Agreco, Poland, Report No. 22UPL01075-1 UPL Report No. F22EU-026-AMA-028 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.2 KCP 6.4.1 /043	Furman-Fratczak, K.	2022	The efficacy of FGR06 and FHO04 applied in winter rye for the control of *Puccinia triticina* (PUCCRT). Agreco, Poland, Report No. 22UPL01075-2 UPL Report No. F22EU-026-AMA-029 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.2 KCP 6.4.1 /044	Rusek, K.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST), Poland 2023 Fertico, Poland, Report No. 113_01_F23_330 UPL Report No. F23EU-011-AMA-011 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.2 KCP 6.4.1 /045	Rusek, K.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST), Poland 2023 Fertico, Poland, Report No. 114_01_F23_332 UPL Report No. F23EU-011-AMA-013 GEP	N	Y	Study report never submitted before to MS	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 6.2 KCP 6.4.1 /046	Ruja, E.	2020	The efficacy of FGF06 and FHO04 applied to wheat for the control of foliar diseases. Agrolab, Latvia UPL Report No. F20EU-002-010-022 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.2 KCP 6.4.1 /047	Packwood, J.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST) in Europe. Eurofins, Latvia, Report No. S23-101655-02 UPL Report No. F23EU-013-AMA-005 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.2 KCP 6.4.1 /048	Ruja, E.	2020	The efficacy of FGF06 and FHO04 applied to wheat for the control of foliar diseases. Agrolab, Lithuania UPL Report No. F20EU-002-010-007 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.2 KCP 6.4.1 /049	Ruja, E.	2020	The efficacy of FGF06 and FHO04 applied to wheat for the control of foliar diseases. Agrolab, Lithuania UPL Report No. F20EU-002-010-016 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.2 KCP 6.4.1 /050	Hötzel, S. Siebold, M.	2020	The efficacy and ratio justification of FGF06 and FHO04 applied to winter wheat for the control of foliar diseases. Field Research Support, Germany, Report No. FRS055/20-V1 UPL Report No. F20EU-001-010-001 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.2 KCP 6.4.1 /051	Mahkamov, S. Siebold, M.	2020	The efficacy and ratio justification of FGF06 and FHO04 applied to winter wheat for the control of foliar diseases. Field Research Support, Germany, Report No. FRS055/20-V2 UPL Report No. F20EU-001-010-004 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.2	Birkinshaw, N.	2021	The efficacy of FGR06 and FHO04 applied in cereals for the	N	Y	Study report never submitted	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4.1 /052			control of *Puccinia striiformis* (PUCCST) in Europe. Eurofins, Germany, Report No. S21-03654-07 UPL Report No. F21EU-008-011-002 GEP Unpublished			before to MS	
KCP 6.2 KCP 6.4.1 /053	Zöllner, H. Siebold, M.	2021	Field study to evaluate the efficacy of FGR06 and FHO04 applied in rye for the control of *Puccinia triticina* (PUCCRT) and *Rhynchosporium secalis* (RHYNSE) in Europe. Field Research Support, Germany, Report No. FRS277/21-V2 UPL Report No. F21EU-009-011-007 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.2 KCP 6.4.1 /054	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST) in Europe. Field Research Support, Germany, Report No. FRS199/22-V1 UPL Report No. F22EU-025-AMA-003 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.2 KCP 6.4.1 /055	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST) in Europe. Field Research Support, Germany, Report No. FRS201/22-V1 UPL Report No. F22EU-025-AMA-024 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.2 KCP 6.4.1 /056	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Field Research Support, Germany, Report No. FRS202/22-V1 UPL Report No. F22EU-026-AMA-003 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.2 KCP 6.4.1 /057	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Field Research Support, Germany, Report No. FRS205/22-V2 UPL Report No. F22EU-026-AMA-027	N	Y	Study report never submitted before to MS	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP Unpublished				
KCP 6.2 KCP 6.4.1 /058	Siebold, M.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Field Research Support, Germany, Report No. FRS029/23 UPL Report No. F23EU-009-AMA-006 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.2 KCP 6.4.1 /059	Siebold, M.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Blumeria graminis tritici* (ERYSGT) in Europe. Field Research Support, Czech Republic, Report No. F-23-G-559-01 UPL Report No. F23EU-014-AMA-004 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.4.1 /060	Ruja, E.	2020	The efficacy of FGF06 and FHO04 applied to wheat for the control of foliar diseases. Agrolab, Latvia UPL Report No. F20EU-002-010-008 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.4.1 /061	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied post-emergence of winter wheat for the control of *Puccinia triticina* (PUCCRT) in Europe. Field Research Support, Latvia, Report No. FRS203/22-V5-LV UPL Report No. F22EU-035-AMA-005 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.4.1 /062	Lelešius, E.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Agrolab, Latvia UPL Report No. F23EU-010-AMA-004 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.4.1 /063	Vaitiekiene, E.	2021	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST) in Europe. Agrolab, Lithuania UPL Report No. F21EU-008-011-019	N	Y	Study report never submitted before to MS	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP Unpublished				
KCP 6.4.1 /064	Vaitiekiene, E.	2021	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST) in Europe. Agrolab, Lithuania UPL Report No. F21EU-008-011-020 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.4.1 /065	Vaitiekiene, E.	2021	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Agrolab, Lithuania UPL Report No. F21EU-009-011-022 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.4.1 /066	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied in cereals for the control of *Zymoseptoria tritici* (SEPTTR) in Europe. Field Research Support, Lithuania, Report No. FRS198/22-V1-LT UPL Report No. F22EU-033-AMA-001 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.4.1 /067	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied post-emergence of winter wheat for the control of *Puccinia striiformis* (PUCCST) in Europe. Field Research Support, Lithuania, Report No. FRS200/22-V1-LT UPL Report No. F22EU-034-AMA-001 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.4.1 /068	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied post-emergence of winter wheat for the control of *Puccinia triticina* (PUCCRT) in Europe. Field Research Support, Lithuania, Report No. FRS203/22-V3-LT UPL Report No. F22EU-035-AMA-003 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4.1 /069	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied post-emergence of winter wheat for the control of *Puccinia triticina* (PUCCRT) in Europe. Field Research Support, Lithuania, Report No. FRS203/22-V4-LT UPL Report No. F22EU-035-AMA-004 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.4.1 /070	Packwood, J.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Eurofins, Lithuania, Report No. S23-101652-02 UPL Report No. F23EU-010-AMA-005 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.4.1 /071	Lelešius, E.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Agrolab, Lithuania UPL Report No. F23EU-010-AMA-006 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.4.1 /072	Packwood, J.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Eurofins, Lithuania, Report No. S23-101652-03 UPL Report No. F23EU-010-AMA-007 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.4.1 /073	Lelešius, E.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST) in Europe. Agrolab, Lithuania UPL Report No. F23EU-013-AMA-006 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.4.1 /074	Lelešius, E.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST) in Europe. Agrolab, Lithuania UPL Report No. F23EU-013-AMA-007 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4.1 KCP 6.4.2 /075	Oudin, V. Schmidt, I.	2019	The efficacy of FHO applied to winter wheat for the control of foliar diseases (SEPTTR) Staphyt, Germany, Report No. VON-19-38651-DE01 UPL Report No. F-19-EU-TRZAW-009E01-01DE GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.4.1 /076	Birkinshaw, N.	2021	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Eurofins, Germany, Report No. S21-03654-10 UPL Report No. F21EU-009-011-003 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.4.1 /077	Birkinshaw, N.	2021	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Eurofins, Germany, Report No. S21-03654-12 UPL Report No. F21EU-009-011-005 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.4.1 /078	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST) in Europe Field Research Support, Germany, Report No. FRS201/22-V2 UPL Report No. F22EU-025-AMA-025 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.4.1 /079	Birkinshaw, N.	2022	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Eurofins, Germany, Report No. S22-03523-03 UPL Report No. F22EU-026-AMA-023 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.4.1 /080	Birkinshaw, N.	2022	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Eurofins, Germany, Report No. S22-03523-04 UPL Report No. F22EU-026-AMA-024 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.4.1	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04	N	Y	Study report never submitted	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
/081			applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Field Research Support, Germany, Report No. FRS204/22 UPL Report No. F22EU-026-AMA-025 GEP Unpublished			before to MS	
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 /082	Siebold, M.	2022	Field study to evaluate the efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia triticina* (PUCCRT) in Europe. Field Research Support, Germany, Report No. FRS205/22-V1 UPL Report No. F22EU-026-AMA-026 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.4.1 /083	Siebold, M.	2023	The efficacy of FGR06 and FHO04 applied in cereals for the control of *Puccinia striiformis* (PUCCST) in Europe. Field Research Support, Germany, Report No. FRS030/23 UPL Report No. F23EU-011-AMA-004 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.4.4 /084	Siebold, M. Genty, M.	2022	Unintentional effects of FHO04 and FGR06 on bread making process in winter wheat (field part). Field Research Support, Germany, Report No. FRS162/22-V1-FR UPL Report No. F22EU-036-AMA-001 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.4.4 /085	Siebold, M. Peyrou-Pouquet, P.	2022	Unintentional effects of FHO04 and FGR06 on bread making process in winter wheat (field part). Field Research Support, Germany, Report No. FRS162/22-V2-FR UPL Report No. F22EU-036-AMA-002 GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 6.4.4 /086	Siebold, M. Laurent, C.	2022	Unintentional effects of FHO04 and FGR06 on bread making process in winter wheat (field part). Field Research Support, Germany, Report No. FRS162/22-V3-FR UPL Report No. F22EU-036-AMA-003	N	Y	Study report never submitted before to MS	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP Unpublished				
KCP 6.4.4 /087	Siebold, M. Laurent, C.	2022	Processing trial report - Unintentional effects of FHO04 and FGR06 on bread making process in winter wheat (field part). Syntech, Germany, Report No. EU-22-1236 UPL Report No. F22EU-036-AMA GEP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 7.3/01	[redacted]	2022	Prothioconazole + Sulphur (50 + 625) g/L SC: The In Vitro Percutaneous Absorption of Radiolabelled Prothioconazole in a Concentrate Formulation and Two In-Use Dilutions and Prothioconazole-desthio in Two In-Use Dilutions through Human Split-Thickness Skin Company Report No. 20321440 [redacted] GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 7.3/02	[redacted]	2022	Prothioconazole + Sulphur (50 + 625) g/L SC: The In Vitro Percutaneous Absorption of Radiolabelled Sulphur in a Concentrate Formulation and Two In-Use Dilutions through Human Split-Thickness Skin Company Report No. 20321446 [redacted] GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 8/ KCA 6.1/01	Giancola, D.	2024	Prothioconazole-desthio and 5 hydroxy metabolites: Frozen Storage Stability in Crops – Interim report Report No.: QG/21/001 GLP Battelle UK, Essex, UK Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 8/ KCA 6.1/02	Phipps, B.	2024	Triazole Derived Metabolites: Frozen Storage Stability in Crops for 12 Months – Study Plan Study No.: QG/21/002 GLP Battelle UK, Essex, UK Unpublished	N	Y	Study plan never submitted before to MS	UPL
KCP 8/	[redacted]	2020	Storage Stability of Triazole Alanine (TA), Triazole Acetic	Y	Y	Study not submitted anywhere in	TDMG

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.1/03			Acid (TAA) and Triazole Lactic Acid (TLA) in Animal Matrices under Deep Frozen Conditions. Report No. 869333 [redacted] GLP Unpublished			in EU until 2021 (information from TDMG) and UPL Access agreement never submitted before to MS (to be confirmed by TDMG)	(Access agreement to UPL)
KCP 8/ KCA 6.3/01	Lebrun, F.	2024	Magnitude of the residue of prothioconazole metabolites in wheat in Northern and Southern Europe – 2023 Report No.; 645-2023 Testapi, 49650 Allonnes – France GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 8/ KCA 6.4.2/01	[redacted]	2021	Determination of the Triazole Derived Metabolites in Eggs and Tissues of Laying Hens following Multiple Oral Administration of Triazole Lactic Acid Report No. IF19-05004879 [redacted] GLP Unpublished	Y	Y	Study not submitted anywhere in in EU until 2021 (information from TDMG) and UPL Access agreement never submitted before to MS (to be confirmed by TDMG)	TDMG (Access agreement to UPL)
KCP 8/ KCA 6.4.2/02	[redacted]	2021	Determination of the Triazole Derived Metabolites in Milk and Tissues of Dairy Cows Multiple Oral Administration of Triazole Lactic Acid Report No. IF19-05004884 [redacted] GLP Unpublished	Y	Y	Study not submitted anywhere in in EU until 2021 (information from TDMG) and UPL Access agreement never submitted before to MS (to be confirmed by TDMG)	TDMG (Access agreement to UPL)
KCP 8/ KCA 6.6.1/01	Bloß, K	2019	[^{14}C]Prothioconazole-desthio Hydrolysis under Typical Conditions (pH, Temperature and Time) of Processing. Report No.: S21-04814 Eurofins Agroscience Services EcoChem GmbH GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 8/ KCA 6.6.2/01	Semrau, J.	2022	Determination of residues of prothioconazole metabolites and triazole derivative metabolites in rotational crops (turnip, leaf lettuce, wheat) after one application of Prothioconazole 250g/L EC on bare soil at 2 sites in Northern Europe and 2 sites in Southern Europe 2022-2024 – Study Plan Study No. S22-02433	N	Y	Study plan never submitted before to MS	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Eurofins Agroscience Services EcoChem GmbH GLP Unpublished				
KCP 9.1.3/01 KCP 9.2.4/01 KCP 9.2.5/01	Smith, H.	2024	Predicted environmental concentrations of prothioconazole following applications on spring and winter cereals in the Central Zone E2023-51 Enviresearch Ltd Not GLP (modelling study) Unpublished	N	N ~~Y~~	Study report never submitted before to MS	UPL
KCP 9.1.3/02 KCP 9.2.4/02 KCP 9.2.5/02	Tilston, E.L.	2024	Predicted environmental concentrations of sulphur and sulphate following applications on spring and winter cereals in the Central and Southern Zones. E2023-33 Enviresearch Ltd Not GLP (modelling study) Unpublished	N	N ~~Y~~	Study report never submitted before to MS	UPL
KCP 10.2.1/01	Singh, P.D.	2023a	Acute immobilisation study of prothioconazole/sulphur (50+625) g/l sc to *Daphnia magna* Report NO. 502-3-07-29112 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 10.2.1/02	Singh, P.D.	2023b	Alga (*Pseudokirchneriella subcaptitata*), growth inhibition test with prothioconazole/sulphur (50+625) g/l Report No. 502-3-07-29111 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 10.3.1.1/01	Ansaloni, T.	2022a	Prothioconazole/Sulphur (50+625) g/L SC: Honey Bee (*Apis mellifera* L.) Acute Oral and Contact Toxicity Test under Laboratory Conditions Report No. S21-06043 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 10.3.1.1/02	Ripperger, D.	2022a	Prothioconazole/Sulphur (50+625) g/L SC (FHO04): Acute Oral and Contact Toxicity to the Bumble Bee *Bombus terrestris* L. (Hymenoptera, Apidae) under Laboratory Conditions Report No. S21-06042 GLP	N	Y	Study report never submitted before to MS	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 10.3.1.2/01	Ansaloni, T.	2022b	Prothioconazole/Sulphur (50+625) g/L SC: Honey Bee (*Apis mellifera* L.) Chronic Oral Toxicity Test (10-Day Feeding) under Laboratory Conditions Report No. S21-06044 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 10.3.1.2/01	Ansaloni, T.	2022c	Prothioconazole/Sulphur (50+625) g/L SC: Honey Bee (*Apis mellifera* L.) Larval Toxicity Test following Repeated Exposure under laboratory conditions Report No. S21-06046 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 10.3.2.1/01	Leopold, J.	2022a	Prothioconazole/Sulphur (50+625) g/L SC: Effects on the Predatory Mite *Typhlodromus pyri* (Acari: Phytoseiidae) in the Laboratory. A Dose Response Test on Glass Plates Report No. 163391063 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 10.3.2.1/02	Leopold, J.	2022b	Prothioconazole/Sulphur (50+625) g/L SC: Effects on the Parasitoid *Aphidius rhopalosiphi* (Hymenoptera: Braconidae) in the Laboratory. A Dose Response Test on Glass Plates Report No. 163391001 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 10.3.2.2/01	Leopold, J.	2022c	Prothioconazole/Sulphur (50+625) g/L SC: Effects on the Predatory Mite *Typhlodromus pyri* (Acari: Phytoseiidae), Extended Laboratory Study - Dose Response Test Report No. 163391062 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 10.3.2.2/02	Leopold, J.	2022d	Prothioconazole/Sulphur (50+625) g/L SC: Effects on the Parasitoid *Aphidius rhopalosiphi* (Hymenoptera, Braconidae), Extended Laboratory Study - Dose Response Testt Report No. 163391002 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP	Leopold, J.	2022e	Prothioconazole/Sulphur (50+625) g/L SC: Effects on the	N	Y	Study report never submitted	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
10.3.2.2/03			Parasitoid *Aphidius rhopalosiphi* (Hymenoptera, Braconidae), Extended Laboratory Study - Dose Response Test Report No. 163391002 GLP Unpublished			before to MS	
KCP 10.3.2.2/04	Leopold, J.	2022f	Prothioconazole/Sulphur (50+625) g/L SC: Effects on the Ladybird Beetle *Coccinella septempunctata* (Coleoptera, Coccinellidae), Extended Laboratory Study - Dose Response Test Report No. 163391012 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 10.3.2.2/05	Fallowfield, L.	2023	Prothioconazole/Sulphur (50+625) SC – A Series of Aged-Residue Extended Laboratory Tests to Determine Effects on the Predatory Mite *Typhlodromus pyri* (Acari: Phytoseiidae) Report No. UPL-23-01 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 10.3.2.2/06	Stevens, J.	2022	Prothioconazole/Sulphur (50+625) SC – A Series of Aged-Residue Extended Laboratory Tests to Determine Effects on the Predatory Mite *Typhlodromus pyri* (Acari: Phytoseiidae) Report No. UPL-22-03 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 10.3.2.2/07	White-Hall, C.	2022	Prothioconazole/Sulphur (50+625) SC – A Series of Aged-Residue Extended Laboratory Tests to Determine Effects on the Ladybird Beetle *Coccinella septempunctata* (Coleoptera: Coccinellidae) Report No. UPL-22-05 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 10.4.1/01	Rana, J.R.	2022	Reproduction toxicity test of prothioconazole/sulphur (50+625) g/l sc to earthworm, *Eisenia fetida* UPL/2021/0569 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 10.4.1.2/01	Vollmer, T.	2023	A Field Study to Evaluate the Effects of Metabolites of Prothioconazole on Earthworm Populations	N	Y	Study report never submitted before to MS	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report No S21-03781 GLP Unpublished				
KCP 10.4.2/01	Hübner, S.	2022a	Effects on reproduction of collembola (*Folsomia candida*) in artificial soil UPL/2021/0225 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 10.4.2/02	Hübner, S.	2022b	Effects on reproduction of the predatory mite (*Hypoaspis aculeifer*) in artificial soil UPL/2021/0224 GLP Upublished	N	Y	Study report never submitted before to MS	UPL
KCP 10.5/01	Bhosale, J.D.	2022	Effect of prothioconazole/sulphur (50+625) g/l sc on soil microorganisms: nitrogen transformation test UPL report No.: UPL/2021/0538 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 10.6.2/01	Ripperger, D	2022b	Prothioconazole/Sulphur (50+625) g/L SC (FHO04): Effects on the Seedling Emergence and Seedling Growth of Terrestrial Plant Species UPL report No.: S21-05533 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL
KCP 10.6.2/02	Ripperger, D	2023	Prothioconazole/Sulphur (50+625) g/L SC (FHO04): Effects on the Vegetative Vigour of Terrestrial Plant Species UPL report No.: S21-05534 GLP Unpublished	N	Y	Study report never submitted before to MS	UPL

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 5/KCA 4/01 (IIA 8.2.4/01)	F. Heimbach	1999	Acute toxicity of JAU 6476 (tech.) to water fleas (Daphnia magna) Bayer AG, Report No.: HBF/DM 212 GLP Unpublished	N	Bayer
KCP 5/KCA 4/02 (IIA 8.2.2.2/02)	[redacted]	2002	JAU 6476-desthio: Early life-stage toxicity test with rainbow trout (Oncorhynchus mykiss) under flowthrough conditions [redacted] Bayer AG, Report No.: 1022.013.321 GLP Unpublished	Y	Bayer
KCP 5/ KCA 4/03 (IIA 4.2.4.1/01)	W. Maasfeld	2002a	Method for the determination of JAU 6476 in air by HPLC-MS/MS Bayer AG, Report No.: 00724 GLP Unpublished	N	Bayer
KCP 5/ KCA 4/04 (IIA 4.2.4.1/02)	W. Maasfeld	2002b	Method for the determination of JAU 6476-desthio in air by HPLC-MS/MS Bayer AG, Report No.: 00731 GLP Unpublished	N	Bayer
KCP 5/ KCA 4/05 (IIA 4.2.1.1/06)	R. D. Weeren and S Pelz	2000	Modification M033 of method 00086: Validation of DFG method S 19 (extended revision) for the determination of residues of JAU 6476-desthio in materials of plant and animal origin. Dr. Specht & Partner, Chemische Laboratorien GmbH, Hamburg, Germany Bayer AG, Report No.: 00086/M033 GLP Unpublished	N	Bayer
KCP 5/ KCA 4/06 (IIA 4.2.1.1/07)	Th. Class	2001	Independent laboratory validation of DFG method S19 (extended revision) for the determination of residues of JAU 6476-desthio (BAYER method 00086/M033) in plant materials PTRL Europe, Ulm, Germany Bayer AG, Report No.: P/B 484 G GLP Unpublished	N	Bayer

KCP 5/ KCA 4/07 (IIA 4.2.1.1/03)	O. Heinemann	2001a	Analytical determination of residues of JAU6476-sulfonic acid and JAU6476-desthio in/on cereals and canola by HPLC-MS/MS Bayer AG, Report No.: 00647, GLP Unpublished	N	Bayer
KCP 5/ KCA 4/08 (IIA 6.1.1.1/04)	M. Haas	2001	Extraction efficiency testing of the residue method (00647) for the determination of JAU 6476 residues in spring wheat using aged radioactive residues Bayer AG, Report No.: MR-084/01 GLP Unpublished	N	Bayer
KCP 5/ KCA 4/09 (IIA 4.2.1.1/05)	O. Heinemann	2001b	Analytical determination of residues of JAU6476-3-hydroxy-desthio, JAU6476-4-hydroxy-desthio, and JAU6476-desthio in milk by HPLC-MS/MS (00655/M001) Bayer AG, Report No.: 00655/M001 GLP Unpublished	N	Bayer
KCP 5/ KCA 4/10 (IIA 4.2.1.1/04)	O. Heinemann	2001c	Analytical determination of residues of JAU6476-3-hydroxy-desthio, JAU6476-4-hydroxy-desthio, and JAU6476-desthio in/on matrices of animal origin by HPLC-MS/MS Bayer AG, Report No.: 00655 GLP Unpublished	N	Bayer
(KCP 5/ KCA 4/11 (IIA 4.2.1.1/08)	L. Dubey	2001	Independent laboratory validation of bayer methods 00655 and 00655/M001 for the determination of residues of JAU6476-3-hydroxy-desthio, JAU6476-4-hydroxy-desthio, and JAU6476-desthio in/on matreces of animal origin by HPLC-MS/MS Battelle, Geneva Research Centres, Carouge/Geneva, Switzerland Bayer AG, Report No.: A-14-01-01 GLP Unpublished	N	Bayer
KCP 5/ KCA 4/12 (IIA 4.2.2.1/01)	O. Schramel	2000	Residue analytical method 00610 (MR-643/99) for the determination of JAU 6476 and the metabolites JAU6476-desthio and JAU6476-S-methyl in soil by HPLC-MS/MS Bayer AG, Report No.: 00610 GLP Unpublished	N	Bayer
KCP 5/ KCA 4/13 (IIA 4.2.2.1/03)	S. Steinhauer	2001	Enforcement method 00086/M038 for the determination of the residues of JAU 6476-desthio in soil - validation of DFG method S 19 (extended revision) -Dr. Specht & Partner, Chemische Laboratorien GmbH, Hamburg, Germany Bayer AG, Report No.: 00086/M038 GLP Unpublished	N	Bayer

KCP 5/ KCA 4/14 (IIA 4.2.3.1/03)	H. Sommer	2001	Enforcement method 00684 for determination of JAU 6476 and JAU 6476-desthio in drinking and surface water by HPLC-MS/MS Bayer AG, Report No.: 00684 GLP Unpublished	N	Bayer
KCP 8/ KCA 6/01 (IIA, 6.0/01)	Heinemann, O.	2001	18 months storage stability of residues of JAU 6476 and JAU 6476-desthio during frozen storage in/on wheat matrices Report No. : MR-282/00 Bayer AG GLP Unpublished	N	Bayer
KCP 8/ KCA 6/02 (IIA, 6.4/01)	[redacted]	2001	JAU 6476-desthio – Dairy cattle feeding study Report No.: MR-535/00 GLP Unpublished	Y	Bayer
KCP 8/ KCA 6/03 (IIA, 6.1.1/01)	Haas, M.; Bornatsch, W.	2000	Metabolism of JAU 6476 in spring wheat (after foliar application) Report no.: MR-198/99 Bayer AG GLP Unpublished	N	Bayer
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KCP 8/ KCA 6/05 (IIA, 6.1.1/02)	Haas, M.	2001a	Metabolism of JAU 6476 in spring wheat after seed dressing Report No.: MR-467/99 Bayer AG GLP Unpublished	N	Bayer
KCP 8/ KCA 6/06 (IIA, 6.6./01)	Haas, M.	2001b	Confined rotational crop study with JAU 6476 Report No.: MR-159/00 Bayer AG GLP Unpublished	N	Bayer
KCP 8/ KCA 6/07 (IIA 6.2.2.1/01)	[redacted]	2001a	[Phenyl-UL-14C]JAU 6476 Absorption, distribution, excretion and metabolism in the lactating goat Report No.: MR-092/01 GLP Unpublished	Y	Bayer

KCP 8/ KCA 6/08 (IIA, 6.2.2.2/01)	[redacted]	2002	[Phenyl-UL-14C] JAU 6476-desthio Absorption, distribution, excretion, and metabolism in the lactating goat Report no. MR-091/01 GLP Unpublished	Y	Bayer
KCP 8/ KCA 6/09 (IIA, 6.2.2.3/01)	[redacted]	2001b	[Phenyl-UL-14C]JAU 6476 Absortion, distribution, excretion and metabolism in laying hens Report No.: MR-309/01 [redacted] GLP Unpublished	Y	Bayer

List of data submitted by the applicant and not relied on

Data point	**Author(s)**	**Year**	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Verte-brate study Y/N**	**Data protection claimed Y/N**	**Justification if data protection is claimed**	**Owner**
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List of data relied on and not submitted by the applicant but necessary for evaluation

Data point	**Author(s)**	**Year**	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Verte-brate study Y/N**	**Data protection claimed Y/N**	**Justification if data protection is claimed**	**Owner**
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