REGISTRATION REPORT

Part B

Section 0

Product Background,

Regulatory Context and GAP information

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

CORE ASSESSMENT
(authorization)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: May 2024

MS Finalisation date: November 2024 (initial Core Assessment)

February 2025 (final Core Assessment)

Version history

When	What
May 2024	Initial dRR – UPL Holdings Coöperatief U.A.
November 2024	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.
February 2025	Final report (Core Assessment updated following the commenting period) No additional information or assessments after the commenting period.

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0 Product background, regulatory context and GAP information

0.1 Introduction

This document summarises the information related to the product background, the regulatory context and GAP information for the plant protection product Prothioconazole/Sulphur (50+625) SC, 'Patton Supra' (code FHO04) containing the active substances prothioconazole 50g/L and sulphur 625 g/L, which were approved under Regulation (EU) 540/2011.
This dossier is submitted in accordance with Commission Regulation (EU) No 284/2013. The product FHO04 was not the representative formulation of the EU reviews.
All the available documents on the active substances (Review Reports, EFSA Scientific Peer Review Conclusions, and their updates, together with original DAR, RAR, and confirmatory data) are considered to provide the relevant review information or a reference to where such information can be found.

0.1.1 Reason for application

This dossier is submitted for the new authorisation of FHO04 in accordance with Article 33 of Regulation (EC) No. 1107/2009. The application is supported by studies owned by the applicant as well as references to the DAR, RAR, confirmatory data and different addenda of the active substance.
This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 (or Regulation (EC) No. 544/2011 where appropriate for prothioconazole) and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	**(if relevant) Concerned MS, MS' product name and authorization number (if applicable)**
Northern zone	LT Product name – Prothioconazole/Sulphur (50+625) SC, 'Patton Supra' Product code - FHO04 Authorisation number – N/A	DK, EE, FI, LV Product name – Prothioconazole/Sulphur (50+625) SC, 'Patton Supra' Product code - FHO04 Authorisation number – N/A
Central zone	PL Product name – Prothioconazole/Sulphur (50+625) SC, 'Patton Supra' Product code - FHO04 Authorisation number – N/A	N/A
Southern zone	ES Product name – Prothioconazole/Sulphur (50+625) SC, 'Patton Supra' Product code - FHO04 Authorisation number – N/A	IT Product name – Prothioconazole/Sulphur (50+625) SC, 'Patton Supra' Product code - FHO04 Authorisation number – N/A
Southern zone	FR Product name – Prothioconazole/Sulphur (50+625) SC, 'Nebbia Supra' Product code - FHO04 Authorisation number – N/A	N/A

0.1.3 Regulatory history of the actives

0.1.3.1 Prothioconazole

Table 0.1-2: Summary of regulatory history of CAS No: 178928-70-6

Status	
Approved in EU	Y
Commission Implementing Regulation	Commission Implementing Regulation (EU) No 540/2011
RMS	United Kingdom
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.08.2008
Current expiration of approval	15.08.2025
Low risk substance or Candidate for Substitution?	No

Issues that need to be considered as part of the EU approval are listed below.
In this overall assessment Member States must pay particular attention to:

- The operator safety in spray applications. Conditions of use shall include adequate protective measures.
- The protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate.
- The protection of birds and small mammals. Risk mitigation measures shall be applied, where appropriate. Conditions of use shall include risk

The SANCO report for prothioconazole (SANCO/3923/07 – final 10 December 2007 and the update 26 January 2021) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 12 July 2007.

Table 0.1-3: Information on minimum purity of prothioconazole

EU agreed minimum purity from Inclusion Directive or Implementing regulation	**(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
≥ 970 g/kg	Sources 1-3: ≥ 980 g/kg Equivalence report available: yes RMS: Czech Republic (sources 1 and 3), UK (source 2)

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

** If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.
No such table is provided here. Information on deviating endpoints, if applicable at all, will be specified in the respective Part B documents.

0.1.3.2 Sulphur

Table 0.1-4: Summary of regulatory history of CAS No: 7704-34-9

Status	
Approved in EU	Y
Original Inclusion Directive	Commission Directive 2009/70/EC repealed by Commission Implementing Regulation (EU) No 540/2011/EC of 25 May 2011
RMS	France
Date of Approval (or most recent renewal) of	0.1.01.2010

Status	
Active Substance (date of Regulation to be applied)	
Current expiration of approval	15.04.2025
Low risk substance or Candidate for Substitution?	N/A

Issues that need to be considered as part of the EU approval are listed below.
In this overall assessment Member States must pay particular attention to:

- The protection of birds, mammals, aquatic organisms and non-target arthropods. Conditions of authorisation shall include risk mitigation measures, where appropriate.

The Member States concerned shall ensure that the notifier submits to the Commission further information to confirm the risk assessment for birds, mammals, sediment dwelling organisms and non-target arthropods. They shall ensure that the notifier at whose request sulphur has been included in this Annex provide such data to the Commission at latest by 30 June 2011.
The confirmatory data were submitted by the Sulphur Working Group on 29 June 2011 (date of covering letter) to the RMS France, ANSES, DPR-UGAMM for evaluation. The confirmatory data have already been reviewed and accepted by the RMS (Addendum to the DAR for Sulphur Confirmatory Data, December 2011.
The SANCO report for sulphur (SANCO/2676/08-final, 22 October 2009) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 19 December 2008 (EFSA Scientific Report (2008) 221, 1 – 70).

Table 0.1-5: Information on minimum purity of sulphur

EU agreed minimum purity from Inclusion Directive or Implementing regulation	**(if different) Minimum purity of active substance used in the product / information on available equivalency report *, ** **
≥ 990 g/kg	Minimum purity not different Equivalence report available: yes RMS: France (source 3)

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).
** If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.
No such table is provided here. Information on deviating endpoints, if applicable at all, will be specified in the respective Part B documents.

0.1.4 Regulatory history of the product

Not relevant as the product has not yet been authorised. The product has not been evaluated as the representative formulation.

0.2 zRMS conclusion

See column 15 of the GAP table presented in Appendix 1 of this document.

Uses to be considered safe on the basis of EU methodology:

See column 15 of the GAP table presented in Appendix 1 of this document.

Uses to be considered non-safe on the basis of EU methodology:

See column 15 of the GAP table presented in Appendix 1 of this document.

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant cMS:

See column 15 of the GAP table presented in Appendix 1 of this document.

All uses/ GAPs are covered by established MRLs.

Appendix 1 ALL intended uses

GAP rev. 1 ~~0~~ , date: November ~~May~~ 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:	Yes~~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	~~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 Aquatica A remaining 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	~~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 Aquatica A remaining species	A	N

3	PL	Winter triticale (TTLWI)	F	Septoria (*Zymoseptoria tritici*) SEPTTR Yellow rust (*Puccinia striiformis*) ~~PUCCSI~~ PUCCST Brown rust (*Puccinia triticina*) PUCCRT	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 Aquatica A remaining species	A	A
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	~~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 Aquatica A remaining 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 Aquatica A remaining 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	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 Aquatica A remaining 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	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 Aquatica A remaining 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 Aquatica A remaining 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