

# REGISTRATION REPORT

## **Part A**

### **Risk Management**

Product code: SAP2101F

Product name(s): ZELORA START

Chemical active substance(s):

Prothioconazole, 120 g/L

Folpet, 300 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland

(authorization)

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

Submission date: December 2023, update April 2024

MS Finalisation date: June 2024 (initial National Assessment)

August 2024 (final National Assessment),

September 2024, October 2024 (updated final National Assessment)

## Version history

When	What
December 2023	V0 - Initial version submitted by the Selectis Produtos para a Agricultura, S.A. for submission to Poland in the frame of new PPP registration (According Art. 33 of Regulation EC No 1107/2009)
April 2024	V1 – Updated version from Applicant submitted by the Selectis Produtos para a Agricultura, S.A. answering Poland request in the frame of new PPP registration (According Art. 33 of Regulation EC No 1107/2009). Updates are highlighted in yellow.
June 2024	<p>Initial zRMS assessment</p> <p>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 <del>is struck through</del> and shaded.</p> <p>Following the evaluation and before sending the document for commenting, all coloured highlighting was removed, from the parts updated by the Applicant, for better legibility</p>
August 2024	<p>Final report (National Assessment updated following the commenting period)</p> <p>Additional information/assessments included by the zRMS in the report are highlighted in yellow. Not agreed or not relevant information are <del>struck through</del> and shaded for transparency.</p>
September 2024	<p>Updated Final report (National Assessment updated with consideration the comments received from Ministry of Agriculture after commenting period process)</p> <p>Additional information/assessments included by the zRMS in the report are highlighted in yellow. Not agreed or not relevant information are <del>struck through</del> and shaded for transparency.</p>
October 2024	<p>Updated Final report (National Assessment updated after LoA submission)</p> <p>Additional information included by the zRMS in the report are highlighted in yellow. Not agreed or not relevant information are <del>struck through</del> and shaded for transparency.</p>

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# RISK MANAGEMENT

## 1 Details of the application

This document describes the specific conditions of use and labelling required for Poland for the authorisation of the plant protection product SAP2101F, a suspension concentrate (SC) formulation containing 120 g/L of prothioconazole and 300 g/L of folpet to be used as fungicide in wheat and barley.

Applicant details:

Selectis Produtos para a Agricultura, S.A.  
Avenida do Rio Tejo  
Herdade das Praias  
2910-440 Setúbal  
Portugal

This application is based on the data package and assessments included in the full dossier submitted to zRMS and cMS that includes this Part A, Part B (including all Sections) and Part C which includes the confidential information.

This submission is made pursuant article 33 of Regulation (EC) 1107/2009 as a new Authorization in zRMS and all cMS.

Appendix 2 of this document includes a copy of the draft product label for Poland.

### 1.1 Application background

This application was submitted to allow the registration of SAP2101F, a SC formulation containing 120 g/L of prothioconazole and 300 g/l of folpet for use as fungicide on wheat and barley in Central Zone. Full details of all intended uses are summarized in GAP table, point 2.6.

### 1.2 Letters of Access

Not required.

### 1.3 Justification for submission of tests and studies

The study reports submitted within this application are in agreement with the data requirements of the Regulation 284/2013. No vertebrate studies are performed with the intent of the present application.

### 1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 on all data submitted in support of this application. Please refer to the reference lists within Part B for further information.

## 2 Details of the authorization decision

### 2.1 Product identity

Product code	SAP2101F
Product name in MS	ZELORA START
Authorization number	Not authorized yet.
Function	fungicide
Applicant	Selectis Produtos para a Agricultura, S.A.
Active substance(s) (incl. content)	Prothioconazole: 120 g/L Folpet: 300 g/L
Formulation type	Suspension concentrate [Code: SC]
Packaging	Size: 1 L, 5 L, 10 L and 20 L Packaging type: HDPE or Coex (HDPE/PA and HDPE/EVOH) Professional
Coformulants of concern for national authorizations	None
Restrictions related to identity	None
Mandatory tank mixtures	Not applicable
Recommended tank mixtures	Not applicable

### 2.2 Conclusion

The evaluation of the application for Zelora Start resulted in the decision to grant the authorization within the range of uses consistent with the conclusions included in the column 15 of the GAP table.

The evaluator also verified whether the co-formulants contained in plant protection product SAP2101F/Zelora Start are listed in Annex III to Regulation (EC) No 1107/2009 and/or could be considered unacceptable based on the criteria indicated in the Annex to the Commission Implementing Regulation (EU) 2023/574 of 13 March 2023.

Based on the currently available MSDSs and other information provided by applicant or manufacturer of co-formulant, the product SAP2101F/Zelora Start 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 SAP2101F/Zelora Start 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:	Carc. 2, Eye Irrit. 2, Skin Sens. 1, Aquatic Acute 1 and Aquatic Chronic 1
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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:	<b>GHS07, GHS08 and GHS09</b>
Signal word:	<b>Warning</b>
Hazard statement(s):	<b>H351: Suspected of causing cancer.</b> <b>H319: Causes serious eye irritation.</b> <b>H317: May cause an allergic skin reaction</b> H400: Very toxic to aquatic life <b>H410: Toxic to aquatic life with long lasting effects</b>
Precautionary statement(s):	P102: Keep out of reach of children. <b>P201: Obtain special instructions before use.</b> <b>P261: Avoid breathing spray.</b> P264: Wash thoroughly after handling. <b>P280: Wear protective gloves/protective clothing/eye protection/face protection</b> <b>P302+P352: IF ON SKIN: Wash with plenty of water.</b> <b>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes.</b> <b>Remove contact lenses, if present and easy to do. Continue rinsing.</b> <b>P308+P313: IF exposed or concerned: Get medical advice/attention.</b> P391: Collect spillage. P501: Dispose of the contents/containers in accordance with the current legislation on waste treatment
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

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:	
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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 an unsprayed buffer zone of 20 m, including a 20 m of vegetated filter strip, to surface water bodies in multiple application to spring and winter cereals.

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

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## 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:	
-	Operator must wear adequate work clothing and protective gloves during mixing/loading and application. In addition to the above, the use of eye/face protection is required during mixing/loading.
Worker protection:	
-	Treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried. In case a worker enters the treated area, protective gloves, long trousers and long-sleeved shirt should be worn.
Integrated pest management (IPM)/sustainable use:	
Environmental protection	
SPe3	To protect aquatic organisms respect an unsprayed buffer zone of 20 m, including a 20 m of vegetated filter strip, to surface water bodies in multiple application to spring and winter cereals.
Other specific restrictions	

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

Integrated pest management (IPM)/sustainable use:	

## 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.
Environmental protection:		Relevant for use no.



2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code):

SAP2101F/ZELORA START

Active substance 1:

prothioconazole

Active substance 2:

folpet

Safener:

-

Synergist:

-


Applicant:

Selectis Produtos para a Agricultura, S.A.

Zone(s):

central <sup>(d)</sup>

Verified by MS:

yes 

Field of use:

Fungicide

GAP rev. **21**, date: June 2024 ~~June 2022~~

Formulation type:

SC <sup>(a, b)</sup>

Conc. of as 1:

120 g/L <sup>(c)</sup>

Conc. of as 2:

300 g/L <sup>(c)</sup>

Conc. of safener:

conc. <sup>(c)</sup>

Conc. of synergist:

conc. <sup>(c)</sup>

Professional use:

X

Non professional use:

☐

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15							
Use- No. <sup>(e)</sup>	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/sy nergist per ha <sup>(f)</sup>	Overall conclusion							
					Method / Kind	Timing/ Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applicatio ns (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water r L/ha  min / max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy

Zonal uses (field or outdoor uses, certain types of protected crops)																					
1	PL	Soft wheat (spring) (TRZAS); Soft wheat (winter) (TRZAW); Durum wheat (spring) (TRZDS); Durum wheat (winter) (TRZDW)	F	<i>Septoria</i> ( <i>Zymoseptoria tritici</i> , SEPTTR)	Tractor mounted spray	BBCH 32- <del>59</del> 61	a) 2 b) 2	14 days	a) 1.5 L/ha b) 3 L/ha	a) 180 g ai/ha + 450 g ai/ha b) 360 g ai/ha + 900 g ai/ha	150-400	42	Range: 1 L/ha - 1,5 L/ha	A	A	A	A	A	R Aquatic (R1 scenario)	A	A TRZAW
																			A Remained species		N TRZAS
																				N TRZDW TRZDS (possible registration on the grounds of article 51)	
2	PL	Barley (spring) (HORVS); Barley (winter) (HORVW)	F	<i>Helminstorpori</i> um ( <i>Pyrenophora teres</i> , PYRNTE)	Tractor mounted spray	BBCH 30-61	a) 2 b) 2	14 days	a) 1.5 L/ha b) 3 L/ha	a) 180 g ai/ha + 450 g ai/ha b) 360 g ai/ha + 900 g ai/ha	150-400	42	Range: 1 L/ha - 1,5 L/ha	A	A	A	A	A	R Aquatic (R1 scenario)	A	N
																			A Remained species		

**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.

\* Explanation for column 15 "Overall conclusions"

<b>A</b>	Acceptable
<b>R</b>	Acceptable with further restriction
<b>C</b>	To be confirmed by CMS
<b>N</b>	Not acceptable / evaluation not possible

- 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/m<sup>3</sup> 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
- 15 Overall conclusions - explanation for the column 15 is below \*

## 3 Background of authorization decision and risk management

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

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 liquid beige to brown liquid concentrated suspension, with a characteristic odour. It is not explosive, has no oxidising properties. The product has a flash point of 102 °C. It didn't ignite until 570 °C. In aqueous solution, it has a pH value around 4.5 at 19.5 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 8 weeks at 40 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE and Coex (HDPE/PA and HDPE/EVOH). Its technical characteristics are acceptable for a suspension concentrate formulation.

The intended concentration of use is 0.375% to 1%.

No tank mixes are recommended.

No classification or labelling nor risk or safety phrases for physical chemical properties are proposed.

The product SAP2101F complies with FAO specifications.

### 3.2 Efficacy (Part B, Section 3)

**SAP2101F** is a Suspension Concentrate (SC) containing 120 g of Prothioconazole/L and 300 g of Folpet/L intended for use as a protectant fungicide for control of *Septoria* (*Zimoseptoria tritici*) in Wheat and *Helminthosporium* (*Pyrenophora teres*) in Barley, in Poland.

A total of 38 trials have been established in order to justify the mixture of the active substances (15 trials), the ratio which has been chosen (9 trials) as well as a justification of a bridging between trials made with ready-mix and tan-mix products (28 trials).

Results showed are considered to be enough to justify all these parameters.

In conclusion, it has been proved that **SAP2101F** provided satisfying efficacy to control *Septoria* (*Zimoseptoria tritici*) in Wheat from 1 L/ha to 1,5 L/ha. According to the zRMS conclusion, the presented efficacy data package for *Helminthosporium* (*Pyrenophora teres*) in Barley is not sufficient to support this use in Poland.

### 3.3 Efficacy data

A total of 48 (39) efficacy trials have been presented in wheat and barley. Results from 27 valid efficacy trials have been presented for the evaluation of SAP2101F in the control of SEPTTR in wheat including:

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

Results from 12 valid efficacy trials have been presented for the evaluation of SAP2101F in the control of PYRNTE in barley including:

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

All trials included multiple rates of **SAP2101F** in order to justify the minimum effective dose. Data have showed that the dose rate of 1,5 L/ha was the most effective dose under various conditions (high and low disease pressure) and therefore can be considered as the Minimum Effective Dose to provide sufficient efficacy in the control of SEPTTR on wheat (across a broad range of disease pressure) in North-East EPPO zone. Lower requested dose rates 1,0 and 1,25 L/ha can be also recommended under low disease pressure.

The lower dose rates of the requested range (1,0 L/ha 1,25 L/ha), as well of the highest requested dose (1,5 L/ha) have been compared to reference authorized products. Average efficacy values reported of trials conducted showed a robust control of the diseases, similar to reference products which were tested.

These data are enough to confirm the effectiveness of SAP2101F against *Septoria (Zimoseptoria tritici)* in Wheat at 1,0 L/ha, 1,25 L/ha and 1,5 L/ha. According to the zRMS conclusion, the presented efficacy data package for *Helminthosporium (Pyrenophora teres)* in Barley is not sufficient to support this use in Poland.

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

Requested GAP of SAP2101F complies with specific recommendations of FRAC to the management DMI-fungicides group. In addition, resistance management strategy has been proposed.

In resume, SAP2101F is a product which complies with recommendations of FRAC to avoid occurrence of the development of resistance and has a component with a multi-site contact activity (Folpet), demonstrating to be a tool for a good resistance management.

### **3.3.2 Adverse effects on treated crops**

Phytotoxicity has been evaluated in all the efficacy trials, as well as in 9 other transformation trials, with no phytotoxicity symptoms.

Besides, 4 bread-making trials in wheat and 5 brewing trials in barley were conducted in order to analyze other undesirable effects on transformation processes.

Field phase being finished, has showed no phytotoxicity and has proved that yield in treated plots with SAP2101F is higher than the untreated plots and similar to the ones treated with reference products.

SAP2101F at 1,5 l/ha (N dose) on barley for brewing and on wheat for bread-making, showed consistent results to demonstrate the absence of non-intentional effects.

According to data submitted, adverse effect of SAP2101F on other plants including succeeding plants and adjacent crops is not expected when it is applied following the corresponding GAP.

## **3.4 Methods of analysis (Part B, Section 5)**

Methods of analysis for the quantification of prothioconazole and folpet in the plant protection product and relevant commodities have been submitted and are fully validated according to the applicable guidelines.

### **3.4.1 Analytical method for the formulation**

An analytical method has been developed for the determination of the active substances prothioconazole and folpet in SAP2101F. A HPLC-PDA method was submitted to analyse both active ingredients in the formulation. The method was successfully validated.

Toluene and prothioconazole-desthio are considered relevant impurities of prothioconazole and perchloromethylmercaptan and carbon tetrachloride of folpet. Three distinct analytical methods were submitted for the determination of the relevant impurities and all of them were considered fully validated.

### **3.4.2 Analytical methods for residues**

The SAP2101F / Zelora Start product is intended to be used in cereals (wheat and barley).

#### Prothioconazole

The analytical methods are active substance data and were provided in the EU review of prothioconazole

and were considered adequate.

New analytical methods for the determination of prothioconazole for the generation of pre-authorization data have been submitted by Applicant. The detailed of the methods are presented in Appendix 2 of Part B5.

#### Plant matrices:

According to the EFSA Journal 2014;12(5):3689:

##### **Methods for enforcement of residues in food of plant origin**

*During the peer review under Directive 91/414/EEC, an analytical method using GC-MS and its ILV were evaluated and validated for the determination of prothioconazole-desthio in plant matrices with an LOQ of 0.02 mg/kg in high water content (tomato), high oil content (rape seed), acidic (orange), dry (wheat grain) commodities and an LOQ of 0.05 mg/kg in straw. This method can be confirmed by an independent analytical method using HPLC-MS/MS fully validated for the determination of prothioconazole-desthio in high water content commodities and in straw with an LOQ of 0.05 mg/kg and in high oil content and in dry commodities with an LOQ of 0.01 mg/kg (United Kingdom, 2004). The analytical methods are not enantioselective, hence the sum of isomers will be analyzed.*

*The multi-residue QuEChERS method in combination with HPLC-MS/MS, as described by CEN (2008), is also available to analyse the prothioconazole-desthio in plant commodities. Nevertheless, the validation data reported are too limited to conclude on the validity of this analytical method (EURL, 2013).*

*Hence it is concluded that prothioconazole-desthio can be enforced in food of plant origin with an LOQ of 0.02 mg/kg in high oil content and dry commodities and an LOQ of 0.05 mg/kg in high water content commodities and in straw taking into account the highest LOQ of both methods.*

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) is not sufficient to monitor these lowered MRLs for food of plant origin. Analytical methods with appropriate ILVs with a lower LOQ value for plant matrices should be provided.

In our opinion analytical methods with appropriate ILVs for the determination of prothioconazole in all major matrix groups with an LOQ of 0.01 mg/kg is required according to the requirement of SANTE/2020/12830, Rev.2, 14. February 2023 and should be provided as a post-registration requirement.

#### Animal matrices:

According to the EFSA Journal 2014;12(5):3689:

##### **Methods for enforcement of residues in food of animal origin**

*During the peer review under Directive 91/414/EEC, an analytical method using HPLC-MS/MS and its ILV were evaluated and validated for the determination of prothioconazole-desthio only in food of animal origin with an LOQ of 0.004 mg/kg in milk and an LOQ of 0.01 mg/kg in muscle, fat, liver and kidney (United Kingdom, 2004; EFSA, 2007b). Hence it is concluded that prothioconazole-desthio can be enforced in food of animal origin with an LOQ of 0.004 mg/kg in milk and an LOQ of 0.01 mg/kg in muscle, fat, liver and kidney. Nevertheless, prothioconazole-desthio cannot be enforced in eggs. Therefore, **a fully validated analytical method for the determination of prothioconazole-desthio in eggs is required.***

*The available analytical method is not enantioselective, hence the sum of isomers will be analyzed.*

Since many MRLs have been lowered to 0.01 mg/kg, the validated LOQ of the EU agreed methods by Heinemann, O. (2001) is not sufficient to monitor these lowered MRLs for animal origin. Analytical methods with appropriate ILVs with a lower LOQ value for animal matrices should be provided.

Additionally according to EFSA's findings presented in the EFSA Journal 2014; 12(5):3689, validation of the method for the determination of prothioconazole-desthio in eggs is also required.

In our opinion analytical methods with ILVs with appropriate LOQ for the determination of prothioconazole in animal matrices is required according to the requirement of SANTE/2020/12830, Rev.2, 14. February 2023 and should be provided as a post-registration requirement.

#### Soil, air, water

Analytical method is available to determine residues of prothioconazole-desthio and prothioconazole in soil, air and water (EFSA, 2007).

An independent laboratory validation (ILV) for the method for the determination of residues of prothioconazole in drinking water is missing. Based on the indication of the SANTE/2020/12830, Rev.2 14. February 2023, the ILV for drinking water should be submitted (data gap).

It is necessary to supply the above-mentioned method for determining the residues of prothioconazole in water at the renewal of the active substance and/or re-evaluation of plant production product.

#### Body fluids and tissues

According to the EFSA Scientific Report (2007) 106, 1-98, Conclusion on the peer review of Prothioconazole, the point regarding analytical methods for body fluids and tissues for prothioconazole is open, data will be required if ECB classify the active substance as toxic.

The active substance prothioconazole was evaluated at the EU level according to the old data requirements. The Commission Regulation (EU) No 284/2013 is applicable now.

In Regulation (EU) No 283/2013 it is stated that “...methods, with a full description, shall be submitted for the analysis in body fluids and tissues for the active substance and relevant metabolites” and this is a new requirement of SANTE/2020/12830. According to the SANTE/2020/12830: “Analytical methods for monitoring residues in body fluids and tissues are required for detection of active substances and/or metabolites in humans and animals after possible intoxications or for biomonitoring purposes, regardless of their toxicological classification.”

Therefore, an analytical method for the residues of prothioconazole in body fluids and tissues is required (data gap).

It is necessary to supply the above-mentioned method for determining the residues of prothioconazole in body fluids at the renewal of the active substance and/or re-evaluation of plant production product (data gap).

#### Folpet

All analytical methods submitted are new and are under EU revision in RAR. They were successfully validated according to the applicable guidelines. Additional validated analytical methods have been submitted in support of new residue studies performed in plant matrices.

Sufficient analytical methods for the determination of folpet (Sum of folpet and phthalamide, expressed as folpet) in plant matrices (all kinds of matrices) with appropriate LOQ are available.

Sufficient analytical methods for the determination of folpet (phthalamide, expressed as folpet) in animal matrices with appropriate LOQ are available.

Sufficient analytical method for the determination of folpet in soil with LOQ of 0.01 mg/kg is available.

Sufficient analytical methods for the determination of folpet in drinking and surface water with LOQ of 0.1 µg/L is available.

Sufficient analytical method for the determination of folpet in air with LOQ of 10.8 µg/m<sup>3</sup> is available.

Analytical methods for the determination of folpet in body fluids and tissues have been submitted under this application. The limit of quantification was established at 0.05 mg/L for phthalimide in urine and 0.01 mg/kg for phthalimide in meat. According to SANTE/2020/12830 – rev.2, which is now in force, the LOQ shall be at 0.01 mg/L for body fluids. Therefore, a data gap is proposed for a lower LOQ of 0.01 mg/L in accordance to the Guidance Document.

### Conclusions:

Commodity/crop	Supported/ Not supported
Dry commodities / Wheat	Supported
Dry commodities / Barley	Supported

Noticed data gaps are:

#### Folpet:

- lower LOQ at 0.01 mg/L for phthalimide for body fluids and should be provided at the renewal of the active substance and/or re-evaluation of plant production product.

#### Prothioconazole:

- analytical methods with appropriate ILVs for the determination of prothioconazole in all major matrix groups with an LOQ of 0.01 mg/kg is required and should be provided as a post-registration requirement;
- analytical methods with ILVs with appropriate LOQ for the determination of prothioconazole in animal matrices is required and should be provided as a post-registration requirement;
- an independent laboratory validation (ILV) for the method for the determination of prothioconazole residues in drinking water is required and should be provided at the renewal of the active substance and/or re-evaluation of plant production product;
- an analytical method for the residues of prothioconazole in body fluids and tissues is required and should be provided at the renewal of the active substance and/or re-evaluation of plant production product.

## 3.5 Mammalian toxicology (Part B, Section 6)

### Product information and toxicological reference values used for exposure assessment

Product name and code	SAP2101F		
Formulation type	SC		
Category	Fungicide		
Active substance(s) and Relevant Metabolite (incl. content) (Technical content)	<b>Prothioconazole</b> 120 g/L (122.45g/L)	<b>Prothio-desthio</b> (JAU 6476-desthio) 108.84 g/L Conversion at 100%: (111.06 g/L) Conversion at 50%: (55.47 g/L)	<b>Folpet</b> 300 g/L (312.5 g/L)
AOEL systemic	0.2 mg/kg bw/d	0.01 mg/kg bw/d	0.1 mg/kg bw/d
Inhalation absorption	100%	100%	100%
Oral absorption	100%	100%	50%
Dermal absorption	Concentrate: 10% Dilution: 50% (Default)	Concentrate: 1.2% Dilution: 17% (0.40815 g/L) (Based on product (Prothioconazole + Folpet (120+300) g/L SC ))	Concentrate: 10% Dilution: 50% (Default)

***The calculations were carried out with the concentration of technical active substance, since AOEL has been established based on the technical substance.***

All the calculations were performed for minimum and maximum application rate. However, only the calculations for the maximum application rate were presented on sections 6.6.2/6.6.3 and 6.6.4. For the calculations with the minimum application rate (that are covered by the maximum dose) please see appendix 4.

According to the EFSA conclusion (EFSA Scientific Report 2007; 106, 1-98) the metabolite JAU 6476-



desthio (M04) is considered more toxic than the parent. Therefore, a detailed risk assessment for all population groups is required for JAU 6476-desthio.

***Relevant notes for prothioconazole-desthio risk assessment:***

Since the conversion rate of prothioconazole to prothioconazole-desthio is not known, the following assumptions were used in the exposure calculations:

- For the exposure assessment to prothioconazole-desthio a conversion of 100% and 50% prothioconazole to prothioconazole-desthio were assumed. To calculate the amount of prothioconazole-desthio, a conversion factor of 0.907 and 0.453 was applied (based on a molecular weight of 344.254 g/mol for prothioconazole and 312.194 g/mol for prothioconazole-desthio);
- For operator exposure, the assessment considering as a worst-case scenario exposure to 100% prothioconazole when handling the concentrate during mixing/loading and exposure to 100% prothioconazole-desthio during application of the spray dilution. Therefore, for the values of dermal absorption of prothioconazole-desthio in the concentrate and of prothioconazole in the dilution were set to 0 % and the values were adjusted corresponding model calculations for prothioconazole-desthio and prothioconazole, respectively.
- Additionally, exposure assessment was also performed considering a 50% conversion factor of prothioconazole into prothioconazole-desthio. Based on this, pro-rata corrections were applied for concentrate and dilution considering that the analysed values are lower than the tested values for prothioconazole-desthio.
- No conversion of prothioconazole-desthio to prothioconazole was considered for the exposure assessment of prothioconazole.

### 3.5.1 Acute toxicity

Hazard class(es), categories	Carc. 2: Carcinogenicity, Category 2 Eye Irrit. 2: Eye irritation, Category 2 Skin Sens. 1: Sensitisation, skin, Category 1
Hazard pictograms or Code(s) for hazard pictogram(s)	GHS07, GHS08
Signal word	Warning
Hazard statement(s)	Carc. 2: H351 - Suspected of causing cancer. Eye Irrit. 2: H319 - Causes serious eye irritation. Skin Sens. 1: H317 - May cause an allergic skin reaction
Precautionary statement(s)	P102: Keep out of reach of children. <b>P201: Obtain special instructions before use.</b> <b>P261: Avoid breathing spray.</b> P264: Wash thoroughly after handling. <b>P280: Wear protective gloves/protective clothing/eye protection/face protection</b> <b>P302+P352: IF ON SKIN: Wash with plenty of water.</b> <b>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</b> <b>P308+P313: IF exposed or concerned: Get medical advice/attention.</b>
Additional labelling phrases	--

### 3.5.2 Operator exposure

The operator exposure to SAP2101F was not evaluated as part of the EU review of Prothioconazole and

Folpet. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate. Estimations of potential operator exposure have been undertaken for prothioconazole, prothioconazole-desthio and folpet using the following models:

Critical use(s)	Cereals (Wheat and Barley) (min. 1 L product/ha - max. 1.5 L product/ha)
Model(s)	EFSA (European Food Safety Authority), Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032, 134 pp. <a href="https://doi.org/10.2903/j.efsa.2022.7032">https://doi.org/10.2903/j.efsa.2022.7032</a>

Operator exposure levels were found to be below the respective AOEL values of prothioconazole, prothio-desthio and folpet, when adequate work clothing and protective gloves are worn, during mixing/loading and application. The combined exposure was also considered. For details, please also refer to section 6.6.5 - Combined exposure.

The use of protective gloves during mixing/loading and application is also supported by the toxicological properties of the formulation (H317, H351). Moreover, considering that the product is also classified for eye irritation (H319), eye/face protection should be used by the operator during mixing/loading.

Overall, based on the operator exposure estimates and considering also the hazardous properties of the product, the following phrases should be included in the product label:

- Operator must wear adequate work clothing and protective gloves during mixing/loading and application. In addition to the above, the use of eye/face protection is required during mixing/loading.

### 3.5.3 Worker exposure

The worker exposure to SAP2101F was not evaluated as part of the EU review of Prothioconazole and Folpet. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate. Estimations of potential worker exposure have been undertaken for prothioconazole, prothioconazole-desthio and folpet using the following models:

Critical use(s)	Cereals (Wheat and Barley) (min. 1 L product/ha - max. 1.5 L product/ha)
Model(s)	EFSA (European Food Safety Authority), Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032, 134 pp. <a href="https://doi.org/10.2903/j.efsa.2022.7032">https://doi.org/10.2903/j.efsa.2022.7032</a>

The total systemic exposure levels were found to be below the respective AOEL values of prothioconazole, folpet and the metabolite prothioconazole-desthio even considered the combined exposure.

The inclusion of data from dislodgeable foliar residue trials for each active substance and metabolite will allow to reduce the mitigation measure for work wear only. However, the use of protective gloves is recommended and supported by the toxicological properties of the formulation (H317, H351), therefore, the following phrases should be included in the product label:

*“Treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried. In case a worker enters the treated area, protective gloves, long trousers and long-sleeved shirt should be worn.”*

### 3.5.4 Bystander and resident exposure

The resident exposure to SAP2101F was not evaluated as part of the EU review of Prothioconazole and Folpet. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate. Estimations of potential resident exposure have been undertaken for prothioconazole, prothioconazole-desthio and folpet using the following models:

Critical use(s)	Cereals (Wheat and Barley) (min. 1 L product/ha - max. 1.5 L product/ha)
Model(s)	EFSA (European Food Safety Authority), Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032, 134 pp. <a href="https://doi.org/10.2903/j.efsa.2022.7032">https://doi.org/10.2903/j.efsa.2022.7032</a>

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 estimations (NDE) carried out indicated that the acceptable exposure level (AOEL) will not be exceeded.

A Drift-reduction (50%) and 2-3 m of buffer-zone should be considered.

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

### 3.6.1 Residues

#### Prothioconazole:

No new residue data including the quantification of prothioconazole and its hydroxy metabolites has been provided. Reference to the available unprotected data from the DAR is made and, until the renewal of the active substance takes place, this information is considered sufficient to support the proposed uses in cereals.

For wheat and barley grain, 13 and 13 trials are available, assessing Prothioconazole residue level in grain; for straw, 15 and 12 trials are available.

New information has been provided with the quantification of residues of TDMs in field samples. Moreover, reference is made to the unprotected TDM confirmatory data in all relevant points. Therefore, the residue levels of the triazole derivative metabolites is considered covered.

As residues of prothioconazole exceeding 0.1 mg/kg are not expected in the treated crops, there is no need to investigate the magnitude of prothioconazole residues in processed commodities.

Regarding TDMs, processing studies on wheat and barley grain have been evaluated in confirmatory data for Triazole Derivate Metabolites (UK, 2018).

Considering dietary burden, metabolism data and livestock feeding studies, the requested uses do not modify the theoretical maximum daily intake for animals, and there is no risk for animal MRL to be exceeded.

Regarding TDMs arising from prothioconazole uses, as concluded by the UK, “further consideration is not required due to the fact that none of the TDMs were identified” in the available livestock metabolism studies conducted with prothioconazole.

Regarding succeeding crops, enough unprotected data is available to cover this point. It is very unlikely that residues will be present in succeeding crops.

Regarding TDMs, in the framework of the confirmatory data, a number of field rotational crop trials

have been conducted to investigate the magnitude of TDM residues in rotational crops after the use of triazole active substances. Residues of TA, TLA and TAA were found above 0.01 mg/kg in succeeding crops. These results were considered in the consumer risk assessment performed in the framework of the review of TDMs confirmatory data.

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of SAP2101F. Therefore, other special studies are not needed. Specifically, residues in honey should not be required until the renewal of the active substance take place.

#### Folpet:

New residue studies are provided for wheat and barley according with the proposed use. Residues of folpet and phthalimide are quantified in all samples. Data package provided is considered to be enough to cover the proposed use in cereals.

Nature of the residues in rotational crops does not need to be investigated due to its low persistence in soil (<100 days). Residue data in succeeding crops are not required.

One study already assessed in RAR – that has also been summarized here for the sake of completeness – addresses the nature of residues in processed commodities. Processing studies in wheat are not required since the residues are in all trials below 0.1 mg/kg and its impact in diet is below 10% of ADI and ARfD. Regarding barley, new processing studies have been submitted.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

October 2024: The applicant submitted a letter of access for folpet to the metabolism study on poultry. The above conclusions are still valid.

Regarding other studies, residues in honey should not be required until the renewal of the active substance take place. Indeed, AIR peer review under new data requirements is still ongoing at the time of this submission. Therefore, currently the old data requirements still apply and residues in honey do not need to be addressed at this stage.

### **3.6.2 Consumer exposure**

#### Prothioconazole:

The calculation of the IEDI using EFSA model (version 3.1) and STMR values and appropriate conversion factors for enforcement to risk assessment led to a utilisation of the ADI of 15% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is milk: Cattle with 3% 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 based on the highest residue values (HR) and STMR values of crops and animal commodities. The highest International Estimated Short-Term Intake (IESTI) is at 19% and 16% of the ARfD for the consumption of Bovine: Liver by children and Swine: Other products by adults respectively.

If only commodities proposed in the framework of this application are considered for acute exposure, the highest International Estimated Short-Term Intake (IESTI) will be at 3% and 1% of the ARfD for the consumption of wheat and barley 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.

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.

#### Folpet:

A consumer risk assessment was performed with revision 3.1 of EFSA Pesticide Residues Intake Model (PRIMo Rev. 3.1). The Reg. (EU) 2023/1042 for folpet is now in force.

The highest Theoretical Maximum Daily Intake (TMDI) is 59% of the ADI for the PT General. The highest contribution (50% of the ADI) is from wine grapes.

The highest International Estimated Short-Term Intake (IESTI) is at 6% and 5% of the ARfD for the consumption of barley by children and by adults respectively and for processed commodities at 4% of the ARfD from the consumption of barley/cooked for children and 0.9% of the ARfD from the consumption of wheat/bread/pizza for adults.

The proposed uses of folpet in the product SAP2101F do not represent unacceptable acute and chronic risks for the consumer.

#### Combined consumer exposure:

The product is a mixture of two active substances and for both of them an acute reference dose has been allocated. Therefore, combined acute exposure can be considered. The Hazard Index is <1. Thus combined exposure to all active substances in SAP2101F is not expected to present a consumer risk.

Until an EU agreed methodology is not available, additional information on combined exposure and RA is not required.

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

#### **3.7.1 Predicted environmental concentrations in soil (PEC<sub>soil</sub>)**

The PEC<sub>soil</sub> of SAP2101F and the active substances prothioconazole and folpet were calculated using equations proposed in the FOCUS soil persistence. For all compounds, EU agreed data were taken into account. The PEC<sub>soil</sub> values for metabolites were calculated based on pseudo-application rates derived using parent application rate corrected for molar ratio and maximum occurrence. Soil exposure for the formulated product was also calculated. The results for PEC<sub>soil</sub> for the active substances and their metabolites were used for the ecotoxicological risk assessment.

#### **3.7.2 Predicted environmental concentrations in groundwater (PEC<sub>gw</sub>)**

The leaching behaviour of the active substances and significant components from the formulated product SAP2101F were assessed using FOCUS PEARL 5.5.5 and FOCUS PELMO 6.6.4 on the basis of the EU agreed input parameters and intended use pattern. Performed calculations resulted with PEC<sub>GW</sub> values <0.1 µg/L in all relevant Polish scenarios for both active substances prothioconazole and folpet and their metabolites following application to winter and spring cereals.

Based on the performed assessment no unacceptable leaching of prothioconazole and folpet and their metabolites is expected when SAP2101F is used according to recommendations.

Therefore, no groundwater contamination is expected for parents and its metabolites following the use of the formulation for winter cereals and spring cereals.

### 3.7.3 Predicted environmental concentrations in surface water (PEC<sub>sw</sub>)

The surface water modelling was performed for the intended use pattern of SAP2101F in line with recommendations of respective FOCUS guidance documents using most up-to-date versions of the models. Obtained PEC<sub>SW/SED</sub> values were used in the risk assessment for aquatic organisms.

### 3.7.4 Predicted environmental concentrations in air (PEC<sub>air</sub>)

The vapour pressure of prothioconazole at 20 °C is  $< 10^{-5}$  Pa. ( $4 \times 10^{-7}$  Pa). Hence, prothioconazole is regarded as non-volatile. Therefore, an assessment of the exposure of adjacent surface waters and terrestrial ecosystems due to volatilisation with subsequent deposition is not triggered and not performed. The long-range transport potential has to be considered in case the DT<sub>50</sub> in air  $> 2$  days. Since the photochemical oxidative half-life of prothioconazole in air is 1.1 hours no long-range transport potential is indicated.

Vapour pressure of folpet is  $> 10^{-5}$  Pa, so volatilisation from soil and plant surfaces is possible. However, based on the air DT<sub>50</sub>  $< 2$  days, the short- and long-range transport of this compound in the atmosphere is not expected.

No environmentally relevant impact to air or risk from exposure via air can be expected following use of SAP2101F.

## 3.8 Ecotoxicology (Part B, Section 9)

### 3.8.1 Effects on terrestrial vertebrates

An acceptable risk was obtained for Prothioconazole at the screening phase for acute and long-term exposure. For the prothioconazole metabolite JAU 6476-desthio and for Folpet, an acceptable risk was obtained at the first-tier for acute and long-term exposure. The acute and long-term risk to birds exposed to SAP2101F via drinking water is acceptable for the intended uses. An acceptable risk was also obtained for the secondary poisoning scenarios. Overall, birds present an acceptable risk towards SAP2101F when used according to the proposed application patterns.

An acceptable risk was obtained for Prothioconazole and Folpet at the screening phase for acute and long-term exposure. For the prothioconazole metabolite JAU 6476-desthio, an acceptable risk was obtained at the higher-tier for long-term exposure. The acute and long-term risk to mammals exposed to SAP2101F via drinking water is acceptable for the intended uses. An acceptable risk was also obtained for the secondary poisoning scenarios. Overall, mammals present an acceptable risk towards SAP2101F when used according to the proposed application patterns.

No further data for to reptiles and amphibians.

### 3.8.2 Effects on aquatic species

Regarding the active substance prothioconazole and its respective metabolites, the max PEC<sub>sw</sub> are below the RAC with FOCUS Step 1-2 calculations with the exception for the metabolite **prothioconazole-desthio**, for which Step 4 calculations were needed (i.e. mitigation measures).

The detailed results of FOCUS Step 3 and Step 4 calculations for both maximum and minimum dose demonstrate a safe use to aquatic organisms in the following mitigated scenarios:

Maximum dose:

Winter cereals:

- a non-spray buffer zone of 20 m of vegetated filter strip, for multiple applications for R1,

Spring cereals:

- a non-spray buffer zone of 20 m of vegetated filter strip, for multiple application for R1 scenario

(from winter cereals)

Regarding **folpet** active substance, FOCUS Step 3 and Step 4 were simulated. For the folpet metabolites the max PEC<sub>sw</sub> are below the RAC with Step 1-2 calculations.

The detailed results of the FOCUS Step 3 and 4 calculations demonstrate a safe use to aquatic organisms in the following mitigated scenarios:

Maximum dose:

Winter cereals:

- a non-spray buffer zone of 10 m of vegetated filter strip, for multiple application for R1

Spring cereals:

- a non-spray buffer zone of 20 m of vegetated filter strip, for multiple application for R1,

It should be noted that the risk from R scenarios not defined for spring cereals is covered by the risk assessment performed for these scenarios available for winter cereals.

Finally, 20 m of vegetated filter strip, for max dose and multiple applications is required for winter and spring cereals.

### **3.8.3 Effects on bees**

The risk assessment for bees was conducted according to SANCO/10329/2002 rev 2 final and according to EFSA Journal 2013;11(7):3295 for illustrative purposes only as the last-mentioned guidance document is not yet noted. The risk assessment performed for both the active substances and the formulated product derived hazard quotients lower than 50, indicating that the active substance prothioconazole, folpet and the formulation SAP2101F pose an acceptable risk to bees from oral and contact, both acute and chronic exposure, according to the proposed use.

### **3.8.4 Effects on other arthropod species other than bees**

No unacceptable risks are expected to the non-target arthropods (*T. pyri*, *A. rhopalosiphi*, *C. septempunctata* L. and *C. carnea*) due to exposure to SAP2101F formulation. The assessed risk in- and off-field at extended exposure showed acceptable risk, according to SAP2101F proposed uses.

### **3.8.5 Effects on soil organisms**

No unacceptable long-term risks are expected for earthworms and other non-target soil organisms (meso- and macrofauna) due to exposure to either prothioconazole, folpet, relevant metabolites and SAP2101F formulation on its intended uses based on the TER values significantly higher than 5 trigger. The use of prothioconazole, folpet, respective metabolites and SAP2101F according to the proposed use patterns, will not have unacceptable effects on soil micro-organisms. The applied maximum concentration used in RA did not cause any significant effects on soil nitrogen transformation.

### **3.8.6 Effects on non-target terrestrial plants**

The worst-case ER<sub>50</sub> values are greater than the maximum single application dose rate and therefore it is considered that risks to non-target plants after SAP2101F formulation applications are acceptable according to its proposed use.

### **3.8.7 Effects on other terrestrial organisms (Flora and Fauna)**

Not relevant.

### **3.9 Relevance of metabolites (Part B, Section 10)**

The metabolites from prothioconazole (JAU 6476-S-methyl and JAU 6476-desthio) and from folpet (phthalimide, phthalamic acid and phthalic acid) are predicted to occur in groundwater at concentrations below 0.1 µg/L (see chapter 8.8.1 and 8.8.2 in dRR Part B, Section 8). Further assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.11 is therefore not required.

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

Not applicable.

## **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 following claimed uses have not been accepted to be registered on the ground of article 33 of regulation 1107/2009:

1. Spring wheat (TRZAS): septoria leaf blotch (SEPTTR).  
Justification: not supported by efficacy trials.
2. Durum wheat (TRZDW, TRZDS): septoria leaf blotch (SEPTTR).  
Justification: not supported by efficacy trials.
3. Winter barley (HORVW): net blotch of barley (PYRNTE).  
Justification: not supported by sufficient efficacy trials (3 valid trials instead of min. 6 trials).
4. Spring barley (HORVS): net blotch of barley (PYRNTE).  
Justification: not supported by sufficient efficacy trials (1 valid trial instead of 2 trials).

There is possible registration on the grounds of article 51 of regulation 1107/2009 (without efficacy trials) for the use: Durum wheat (TRZDW, TRZDS): septoria leaf blotch (SEPTTR).

For the use in spring wheat, winter barley and spring barley the Applicant has expressed a willingness to submit additional trials, as post-authorisation confirmatory data. (Applicant's response to zRMS inquiry dated on 16.04.2024). Therefore, a conditional approval is proposed, subject to the submission of the following trials:

- 2 trials (the number of trials specified in the national extrapolation table), carried out in North-East EPPO in spring wheat to support the use: Spring wheat (TRZAS): septoria leaf blotch (SEPTTR),
- minimum 3 trials, carried out in North-East EPPO zone and or in neighboring countries (DE, CZ, SK) in winter barley to support the use: Winter barley (HORVW): net blotch of barley (PYRNTE),
- 1 trial (to meet the requirement of total 2 trials specified in the national extrapolation table), carried out in North-East EPPO in spring barley, to support the use: Spring barley (HORVS): net blotch of barley (PYRNTE) or min 5 trials carried out in North-East EPPO zone and in neighboring countries (DE, CZ, SK) for spring barley – in case of no-completion efficacy data package for winter barley, and therefore no extrapolation possibility to spring barley.

Additional trials should be carried out in accordance with conditions of use contained in the GAP table, including range of dose rates, application timing, number of applications etc.



### **Analytical methods:**

Data gap:

#### Folpet:

- lower LOQ at 0.01 mg/L for phthalimide for body fluids and should be provided at the renewal of the active substance and/or re-evaluation of plant production product.

#### Prothioconazole:

- analytical methods with appropriate ILVs for the determination of prothioconazole in all major matrix groups with an LOQ of 0.01 mg/kg is required and should be provided as a post-registration requirement;
- analytical methods with ILVs with appropriate LOQ for the determination of prothioconazole in animal matrices is required and should be provided as a post-registration requirement;
- an independent laboratory validation (ILV) for the method for the determination of prothioconazole residues in drinking water is required and should be provided at the renewal of the active substance and/or re-evaluation of plant production product;
- an analytical method for the residues of prothioconazole in body fluids and tissues is required and should be provided at the renewal of the active substance and/or re-evaluation of plant production product.

### ~~Metabolism and residues:~~

~~The applicant should submit a letter of access to the metabolism study for folpet on poultry.~~

## **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 czcionką.

### Sekcja właściwości fizykochemiczne:

1. Środek nie wykazuje właściwości wybuchowych i utleniających, znakowanie środka wynikające z wyżej wymienionych właściwości fizykochemicznych zgodnie 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 zaakceptowanych 2-letnich badań stabilności środka ochrony roślin przechowywanego w opakowaniach wykonanych z HDPE. Zgodnie z zapisami aktualnie obowiązującej wytycznej Ministerstwa Rolnictwa i Rozwoju Wsi (z dnia 05/09/2023) w sprawie zasad zatwierdzania opakowań środków ochrony roślin możliwa jest ekstrapolacja wyników badań stabilności z HDPE na HDPE/EVOH i HDPE/PA. W związku z powyższym, wszystkie opakowania wymienione, w punkcie 4.1 Sekcji 1,2,4 można uznać za odpowiednie do celów transportu i magazynowania środka ochrony roślin.
3. Brak uwag do zaproponowanych w etykiecie zapisów dotyczących warunków przechowywania i bezpiecznego usuwania środka ochrony roślin.
4. Brak uwag do zapisu nazwy substancji czynnej. Skorygowano zawartość substancji czynnych (zgodnie z punktem 2.6.1 Sekcji 1,2,4 gęstość  $d = 1.18$ ).
5. Zgodnie z informacjami zawartymi w tabeli 2-1, w punkcie 2.9.1 i 2.9.2 Sekcji 1 Raportu Rejestracyjnego środek nie jest dedykowany do łącznego stosowania.

### Sekcja skuteczność:

1. W części OPIS DZIAŁANIA, na podstawie przeprowadzonej oceny i uznania zastosowania środka jedynie w pszenicy ozimej, usunięto informację o stosowaniu środka w jęczmieniu, a także dopisano formę pszenicy: ozimą.
2. W części STOSOWANIE ŚRODKA:
  - usunięto pszenicę jary; uzasadnienie: brak badań skuteczności dla zastosowania pszenica jara: septorioza paskowana liści pszenicy; informacje o liczbie brakujących badań oraz możliwości udzielenia warunkowego zezwolenia zawarte są w punkcie 5. Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization,
  - usunięto jęczmień ozimy i jęczmień jary; uzasadnienie: niewystarczające liczba badań dla zastosowania jęczmień ozimy, jęczmień jary: plamistość siatkowa jęczmienia; informacje o liczbie brakujących badań oraz możliwości udzielenia warunkowego zezwolenia zawarte są w punkcie 5. Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization. **Biorąc pod uwagę możliwość udzielenia warunkowego zezwolenia dla jęczmienia ozimego i jarego, skorygowano dawkę środka na 1,0-1,5 l/ha i ilość wody na 150-400 l/ha , zgodnie z tabelą GAP,**
  - zgodnie z przeprowadzoną oceną, na podstawie terminów stosowania środka w przedłożonych badaniach ograniczono zakres faz BBCH dla pszenicy ozimej z BBCH 32-61 na BBCH 32-59, a także jednocześnie poprawiono opis słowny terminu stosowania środka/ faz BBCH w pszenicy ozimej,
  - wprowadzono właściwą nazwę jednostki chorobowej w pszenicy ozimej tj. septorioza paskowana liści pszenicy zamiast septorioza liści pszenicy,
  - **dopisano uwagę o stosowaniu niższej dawki środka w warunkach mniejszego nasilenia występowania choroby.**
3. Wprowadzono brakującą nazwę części etykiety: ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA, a w niej:
  - w części dotyczącej mycia opryskiwacza dopisano informację: Postępować zgodnie z zasadami dobrej praktyki ochrony roślin,
  - wprowadzono zalecenia mające na celu ograniczenie ryzyka wpływu środka na uprawy sąsiednie,
  - zamieszczono brakujące zalecenia dla strategii zarządzania odpornością.
4. Zgodnie z tabelą GAP, wniosek dotyczy także zastosowania środka w pszenicy twardej w ochronie przed septoriozą paskowaną liści pszenicy. Wobec braku badań oraz biorąc pod uwagę, że pszenica twarda znajduje się na liście upraw małoobszarowych rozporządzenia Ministra Rolnictwa i Rozwoju Wsi z dnia

18 września 2023 r. zmieniającego rozporządzenie w sprawie zastosowań małoobszarowych środka ochrony roślin, istnieje możliwość rejestracji tego zastosowania w trybie art. 51 rozporządzenia 1107/2009.

**Sekcja metody analityczne:**

1. Brak uwag.

**Sekcja toksykologia i istotność toksykologiczna metabolitów:**

1. W części dotyczącej klasyfikacji zagrożeń zmodyfikowano zwrot P261 oraz dodano zwrot P280 zgodnie z wymaganiami: *Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008 Version 4.2 March 2021*
2. W części dotyczącej środków ostrożności dla osób stosujących środek odpowiedni zapis został zmodyfikowany zgodnie z wymaganiami harmonizacyjnymi (Min Rol Toksykologia wer. 25.09.2023 r.)

**Sekcja pozostałości:**

1. W zakresie pozostałości zastosowanie środka w ochronie pszenicy i jęczmienia zostało zaakceptowane.
2. Brak restrykcji, jeżeli chodzi o rośliny następcze i wcześniejszą likwidację plantacji.

**Sekcja los i zachowanie w środowisku:**

1. Brak uwag do etykiety w zakresie losu i zachowania w środowisku.

**Sekcja ekotoksykologia:**

1. Zmodyfikowano zarządzanie ryzykiem dla organizmów wodnych.

**Załącznik do zezwolenia MRiRW nr R .... z dnia .....**

Posiadacz zezwolenia:

Selectis Produtos para a Agricultura, S.A.  
Avenida do Rio Tejo, Herdade das Praias  
2910-440 Setúbal, Republika Portugalska

.....

**ZELORA START**

**Środek przeznaczony do stosowania przez użytkowników profesjonalnych.**

Zawartość substancji czynnej:

protiokonazol (substancja z grupy triazoli) - 120 g/l (10,2%)  
folpet (substancja z grupy ftalimidów) - 300 g/l (25,4%)

**Zezwolenie MRiRW nr R - .....**

Hazard pictograms:

GHS07, GHS08, GHS09



H319 Działa drażniąco na oczy

H317 Może powodować reakcję alergiczną skóry

H351 Podejrzewa się, że powoduje raka w wyniku wdychania  
H410 Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.

P102: Chronić przed dziećmi

P201: Przed użyciem zapoznać się ze specjalnymi środkami ostrożności

P261: Unikać wdychania oparów rozpylonej cieczy.

P273: Unikać uwalniania do środowiska

P280: Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy

P302+P352: W PRZYPADKU KONTAKTU ZE SKÓRĄ: umyć dużą ilością wody z mydłem

P305+P351+P338: W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać

P308+ P313: W przypadku narażenia lub styczności: Zasięgnąć porady/ zgłosić się pod opiekę lekarza.

P391: Zebrać wyciek

P501: Zawartość/pojemnik usuwać jako odpad niebezpieczny.

EUH 401 – W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.

SPe 1. Nie zanieczyszczać wody produktem lub jego pojemnikiem (nie czyścić sprzętu do wykonywania zabiegów w pobliżu wód powierzchniowych/unikać zanieczyszczenia przez odpływy z podwórek i dróg).

SPe 3. Aby chronić organizmy wodne, należy przestrzegać nieopryskiwanej, porośniętej roślinnością strefy buforowej o szerokości 20 metrów od zbiorników i cieków wodnych jednolitych partii wód powierzchniowych w przypadku więcej niż jednorazowego zastosowania jednorazowego stosowania w zbożach jarych i ozimych.

~~SPe 3. Aby chronić organizmy wodne, należy przestrzegać nieopryskiwanej, porośniętej roślinnością strefy buforowej o szerokości 10 metrów od powierzchniowych zbiorników wodnych podczas stosowania w zbożach ozimych i jarych w wielu zastosowaniach w zbożach ozimych.~~

Operator powinien używać odpowiedniej odzieży ochronnej podczas przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

## OPIS DZIAŁANIA

FUNGICYD w formie koncentratu w postaci stężonej zawiesiny (SC) zawierający dwie substancje czynne o uzupełniającym się mechanizmie działania: układowym (protiokonazol) oraz kontaktowym (folpet). Środek przeznaczony jest do stosowania zapobiegawczego i interwencyjnego w ochronie przed chorobami grzybowymi pszenicy ozimej i jęczmienia.

Zgodnie z klasyfikacją FRAC substancja czynna protiokonazol zaliczana jest do grupy 3, natomiast folpet przynależy do grupy M4.

## STOSOWANIE ŚRODKA

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

### Pszenica ozima i pszenica jara

Septorioza paskowana liści pszenicy.

Maksymalna / zalecana dawka do jednorazowego stosowania: 1 -1,5 l/ha.

~~Maksymalna~~ Liczba zabiegów w sezonie wegetacyjnym: 2.

Odstęp pomiędzy zabiegami: co najmniej 14 dni.

Terminy stosowania:

Środek stosować zapobiegawczo, w fazie BBCH 32-64 ~~59~~ od fazy strzelania w źdźbło (2 kolanko) do początku fazy kwitnienia zakończenia fazy kłoszenia.

Zalecana ilość wody: 150-400 l/ha.  
Zalecane opryskiwanie: drobnokropliste.

**Uwaga:** Niższą z zalecanych dawek środka stosować w warunkach niskiego nasilenia występowania choroby.

#### **Jęczmień ozimy i jęczmień jary**

*Plamistość siatkowa jęczmienia*

Maksymalna / zalecana dawka do jednorazowego stosowania: 1,0-1,5 l/ha.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2.

Odstęp pomiędzy zabiegami: co najmniej 14 dni.

Terminy stosowania:

Środek stosować zapobiegawczo, w fazie BBCH 30-61 od fazy strzelania w źdźbło do początku fazy kwitnienia

Zalecana ilość wody: 150-400 l/ha.

Zalecane opryskiwanie: drobnokropliste.

**Uwaga:** Niższą z zalecanych dawek środka stosować w warunkach niskiego nasilenia występowania choroby.

### **ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA**

#### **SPORZĄDZANIE CIECZY UŻYTKOWEJ**

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość. Zawartością opakowania wstrząsnąć przed użyciem. Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem). Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wylać do zbiornika opryskiwacza z cieczą użytkową. Następnie zbiornik opryskiwacza uzupełnić wodą do potrzebnej ilości. Opryskiwać z włączonym mieszadłem. Po wlaniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz w zbiorniku mechanicznie wymieszać. W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy należy dokładnie wymieszać ciecz użytkową w zbiorniku opryskiwacza.

#### **POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY**

Po pracy aparaturę dokładnie wymyć. Postępować 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.

#### **WARUNKI BEZPIECZNEGO STOSOWANIA ŚRODKA**

Podczas stosowania nie dopuścić do:

- znoszenia cieczy użytkowej na sąsiadujące rośliny uprawne,
- nakładania się cieczy użytkowej na styki pasów zabiegowych i uwrociach.

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy roboczej i które zwróciły się o taką informację.

### **Strategia zarządzania odpornością**

Środek zawiera dwie substancje czynne: protiokonazol z grupy triazoli (inhibitory biosyntezy steroli - inhibitory demetylacji, SBI- I DMI fugicydy, wg FRAC grupa 3) oraz folpet z grupy ftalimidów (grupa FRAC M04)

W ramach strategii antyodpornościowej zaleca się m. in.:

- stosowanie środka głównie do zabiegów zapobiegawczych,
- stosowanie środka w zalecanej dawce,
- przemienne stosowanie z innymi środkami grzybobójczymi, zawierającymi substancje czynne z innych grup chemicznych, o odmiennych mechanizmach działania,
- włączenie niechemicznych metod ochrony jak np. stosowanie odmian odpornych, dbanie o higienę roślin, a także przestrzeganie zasad dobrej praktyki rolniczej.

W przypadku niesatysfakcjonującej skuteczności działania środka, należy poinformować o tym posiadacza zezwolenia.

### **Środki ostrożności dla osób stosujących środek:**

Nie jeść, nie pić, ani nie palić podczas używania produktu.

~~Stosować rękawice ochronne oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin oraz odpowiednie obuwie w trakcie przygotowywania cieczy roboczej~~

Stosować rękawice ochronne, ochronę oczu i twarzy oraz odzież ochronną zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu

### **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 roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od terenów nieużytkowanych rolniczo.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie **zadarnionej** strefy ochronnej o szerokości **20** m od zbiorników i cieków wodnych.

**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

**Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji)**

Pszenica - **42 dni**.

Jęczmień - **42 dni**.

### **WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA**

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,
- w temperaturze 0°C-30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

## **PIERWSZA POMOC**

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

Okres ważności - 2 lata

Data produkcji - .....

Zawartość netto - .....

Nr partii - .....



## **Appendix 3   Letter of Access**

## 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	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
<b>Section B1, B2, B4</b>							
KCP 2.1/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product Study EF/371/21 – Interim Report (T0) ASCENZA Agro, S.A. GLP Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 2.2.1/01	Nichetti, S.	2022	Prothioconazole 120 g/L + Folpet 300 g/L SC – SAP2101F: Determination of the Physico-chemical Properties Report No.: CH – 0508/2021 ChemService GLP Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 2.2.2/01	Nichetti, S.	2022	Prothioconazole 120 g/L + Folpet 300 g/L SC – SAP2101F: Determination of the Physico-chemical Properties Report No.: CH – 0508/2021 ChemService GLP Unpublished <b>(Submitted in KCP 2.2.1/01)</b>	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 2.3.1/01	Nichetti, S.	2022	Prothioconazole 120 g/L + Folpet 300 g/L SC – SAP2101F: Determination of the Physico-chemical Properties Report No.: CH – 0508/2021 ChemService GLP Unpublished <b>(Submitted in KCP 2.2.1/01)</b>	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.3.3/01	Nichetti, S.	2022	Prothioconazole 120 g/L + Folpet 300 g/L SC – SAP2101F: Determination of the Physico-chemical Properties Report No.: CH – 0508/2021 ChemService GLP Unpublished (Submitted in KCP 2.2.1/01)	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 2.4.1/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product Study EF/371/21 – Interim Report (T0) ASCENZA Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 2.4.2/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product Study EF/371/21 – Interim Report (T0) ASCENZA Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 2.5.1/01	Morais, F.	<del>2022</del> 2024	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product Study EF/371/21 – Interim Report (T0-T24) ASCENZA Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 2.5.2/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product Study EF/371/21 – Interim Report (T0) ASCENZA Agro, S.A.	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data	ASCENZA Agro, S.A.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Unpublished (Submitted in KCP 2.1/01)			protection rights not previously granted at CEU zone.	
KCP 2.6.1/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product Study EF/371/21 – Interim Report (T0) ASCENZA Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 2.7.2/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product Study EF/371/21 – Interim Report (T0) ASCENZA Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 2.7.4/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product Study EF/371/21 – Interim Report (T0) ASCENZA Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 2.7.5/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product Study EF/371/21 – Interim Report (T0) ASCENZA Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 2.8.2/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical	N	Y	Product data submitted with an application under	ASCENZA Agro, S.A.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			properties of the plant protection product Study EF/371/21 – Interim Report (T0) ASCENZA Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)			Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	
KCP 2.8.3.1/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product Study EF/371/21 – Interim Report (T0) ASCENZA Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 2.8.3.2/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product Study EF/371/21 – Interim Report (T0) ASCENZA Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 2.8.5.1.1/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product Study EF/371/21 – Interim Report (T0) ASCENZA Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 2.8.5.1.2/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product Study EF/371/21 – Interim Report (T0) ASCENZA Agro, S.A. GLP Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not	ASCENZA Agro, S.A.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			(Submitted in KCP 2.1/01)			previously granted at CEU zone.	
KCP 2.8.7.2/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) – Physical, chemical and technical properties of the plant protection product Study EF/371/21 – Interim Report (T0) ASCENZA Agro, S.A. GLP Unpublished (Submitted in KCP 2.1/01)	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
<b>Section B3</b>							
KCP 3 6 (0)	ASCENZA AGRO	2022	Biological Assessment Dossier of SAP2101F	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 6 (1)	ASCENZA AGRO	2024	Erratum on Biological Assessment Dossier of SAP2101F	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.1 (1)	Castella, G.	2020	Study the benefit of SAP50SCF in the preventions on resistances in Wheat against <i>Zimoseptoria tritici</i> under controled conditions. Italy 2021 Sagea Centro di Saggio s.r.l; 63-F-2020-FR01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (1) 6.1 6.2 6.4	Desogus, S.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against <i>Septoria</i> on Winter wheat. Bulgaria 2020 Sagea Centro di Saggio s.r.l; 10B-F-2020-BG01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
<del>KCP 6.2 (2) 6.4</del>	<del>Biaunier, M.</del>	<del>2020</del>	<del>Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against Septoria on Wheat QUALIPHYT; 10B-F-2020-FR01</del>	<del>N</del>	<del>Y</del>	<del>Data/study report never submitted before to Poland</del>	<del>ASCENZA AGRO</del>

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			<del>GEP</del> <del>Unpublished</del>				
KCP 6.2 (3) 6.4	Herrera, D.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against <i>Septoria</i> on Wheat STAPHYT; 10B-F-2020-FR02 <del>GEP</del> <del>Unpublished</del>	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (4) 6.2 6.4	Zöllner, H.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against <i>Septoria</i> on Wheat Field Research Support; 10B-F-2020-PL01 <del>GEP</del> <del>Unpublished</del>	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (5) 6.2 6.4	Zöllner, H.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against <i>Septoria</i> on Wheat Field Research Support; 10B-F-2020-PL02 <del>GEP</del> <del>Unpublished</del>	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (6) 6.2 6.4	Herrera, D.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against <i>Septoria</i> on Wheat STAPHYT; 10B-F-2020-PL03 <del>GEP</del> <del>Unpublished</del>	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (7) 6.2 6.4	Herrera, D.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against <i>Septoria</i> on Wheat STAPHYT; 10B-F-2020-PL04 <del>GEP</del> <del>Unpublished</del>	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (8) 6.2 6.4	Herrera, D.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against <i>Septoria</i> on Wheat STAPHYT; 10B-F-2020-RO04 <del>GEP</del> <del>Unpublished</del>	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2 (9) 6.2 6.4	Herrera, D.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against <i>Septoria</i> on Wheat STAPHYT; 10B-F-2020-RO02 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (10) 6.1 6.2 6.4	Botoman, G.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against <i>Septoria</i> on Wheat AgroProspect SRL; 10B-F-2020-RO03 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (11) 6.2 6.4	Zöllner, H.	2020	Field study to evaluate the efficacy and crop selectivity of mixtures based on SAP250F and SAP50SCF against <i>Septoria</i> on Wheat Field Research Support; 10-F-2020-DE01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (12) 6.2 6.4	Zöllner, H.	2020	Field study to evaluate the efficacy and crop selectivity of mixtures based on SAP250F and SAP50SCF against <i>Septoria</i> on Wheat Field Research Support; 10-F-2020-DE02 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (13) 6.1 6.2 6.4	Biaunier, M.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against <i>Septoria</i> on Wheat QUALIPHYT; 10-F-2020-FR01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (14) 6.1 6.2 6.4	Biaunier, M.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against <i>Septoria</i> on Wheat QUALIPHYT; 10-F-2020-FR02 GEP	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO



Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 6.2 (15) 6.1 6.2 6.4	Rivet, J. Crepin, D.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against <i>Septoria</i> on Wheat ESSAIS+; 10-F-2020-FR03 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (16) 6.1 6.4	Desogus, S.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against <i>Septoria</i> on Wheat, Italy 2020 SAGEA Centro di Saggio s.r.l.; 10-F-2020-IT01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (17) 6.1 6.4	Hernández, J. M.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against <i>Septoria</i> on Wheat Agroensayos; 10-F-2020-SP01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
<del>KCP 6.2 (18) 6.4</del>	<del>Ord, S.</del>	<del>2020</del>	<del>Field study to evaluate the efficacy and crop selectivity of mixtures based on SAP250F and SAP50SCF against <i>Septoria</i> on Wheat i2LResearch; 10-F-2020-UK01 GEP Unpublished</del>	<del>N</del>	<del>Y</del>	<del>Data/study report never submitted before to Poland</del>	<del>ASCENZA AGRO</del>
KCP 6.2 (19) 6.1 6.2 6.4	Desogus, S.	2021	Evaluate the efficacy of mixtures based on SAP2101F against <i>Septoria tritici</i> and <i>Erysiphe graminis</i> on Wheat. Bulgaria 2021 SAGEA Centro di Saggio s.r.l.; 03A-F-2021-BG01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (20) 6.1 6.2	Zöllner, H.	2021	Field study to evaluate the efficacy and crop selectivity of SAP2101F (mixtures based on SAP250F and SAP50SCF) against <i>Septoria</i> on Wheat	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
6.4			FIELD RESEARCH SUPPORT; 03A-F-2021-DE01 GEP Unpublished				
KCP 6.2 (21) 6.1 6.4	Biaunier, M.	2021	Evaluate the efficacy of SAP2101F against <i>Septoria</i> on Wheat QUALIPHYT; 03A-F-2021-FR01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (22) 6.1 6.2 6.4	Crepin, D.	2021	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against <i>Septoria</i> on wheat ESSAIS+; 03A-F-2021-FR02 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (23) 6.1 6.2 6.4	Zöllner, H.	2021	Field study to evaluate the efficacy and crop selectivity of SAP2101F (mixtures based on SAP250F and SAP50SCF) against <i>Septoria</i> on Wheat (Poland) FIELD RESEARCH SUPPORT; 03A-F-2021-PL01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (24) 6.1 6.2 6.4	Herrera, D.	2021	Evaluate the efficacy of SAP2101F (mixtures based on SAP250F and SAP50SCF) against <i>Septoria</i> on Wheat, GEP Trial, POLAND, 2021 STAPHYT; 03A-F-2021-PL02 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (25) 6.1 6.2 6.4	Botoman, G.	2021	Evaluate the efficacy of SAP2101F against <i>Septoria</i> on wheat GEP Trial, ROMANIA, 2021 Agroprospect; 03A-F-2021-RO01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2 (26) 6.1 6.2 6.4	Desogus, S.	2021	Evaluate the efficacy of mixtures based on SAP2101F against <i>Zymoseptoria tritici</i> and <i>Blumeria graminis tritici</i> on Wheat. Bulgaria 2021 SAGEA Centro di Saggio s.r.l.; 03B-F-2021-BG01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (27) 6.1 6.2 6.4	Desogus, S.	2021	Evaluate the efficacy of mixtures based on SAP2101F against <i>Septoria</i> on Wheat. Bulgaria 2021 SAGEA Centro di Saggio s.r.l.; 03B-F-2021-BG02 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (28) 6.1 6.4	Biaunier, M.	2021	Evaluate the efficacy of SAP2101F against <i>Septoria</i> on Wheat Qualiphyt; 03B-F-2021-FR01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (29) 6.1 6.2 6.4	Crepin, D.	2021	Evaluate the efficacy of SAP2101F against <i>Septoria</i> on wheat ESSAIS+; 03B-F-2021-FR02 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
<del>KCP 6.2 (30) 6.4</del>	<del>Kasztner, G.</del>	<del>2021</del>	<del>Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against <i>Septoria</i> on Wheat AGROFIL; 03B-F-2021-HU01 GEP Unpublished</del>	<del>N</del>	<del>Y</del>	<del>Data/study report never submitted before to Poland</del>	<del>ASCENZA AGRO</del>
KCP 6.2 (31) 6.2 6.4	Rusek, K.	2021	Evaluate the efficacy of mixtures based on SAP2101F against <i>Septoria</i> on Winter Wheat, Poland 2020/2021 FERTICO Sp. z.o.o.; 03B-F-2021-PL01 GEP	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 6.2 (32) 6.2 6.4	Herrera, D.	2021	Evaluate the efficacy of SAP2101F (mixtures based on SAP250F and SAP50SCF) against <i>Septoria</i> on Wheat, GEP Trial, POLAND, 2021 STAPHYT; 03B-F-2021-PL02 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (33) 6.1 6.2 6.4	Herrera, D.	2021	Evaluate the efficacy of SAP2101F (mixtures based on SAP250F and SAP50SCF) against <i>Septoria</i> on Wheat, GEP Trial, POLAND, 2021 STAPHYT; 03B-F-2021-PL03 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (34) 6.1 6.2 6.4	Botoman, G.	2021	Evaluate the efficacy of SAP2101F against <i>Septoria</i> on wheat GEP Trial, ROMANIA, 2021 AgroProspect SRL; 03B-F-2021-RO01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (35) 6.4	Hernández, J.M.	2021	Evaluate the efficacy of mixtures based on SAP2101F against <i>Septoria</i> on Wheat Agroensayos; 03B-F-2021-SP01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (36) 6.1 6.4	Hernández, J.M.	2021	Evaluate the efficacy of mixtures based on SAP2101F against <i>Septoria</i> on Wheat Agroensayos; 03B-F-2021-SP02 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (37) 6.1 6.2	Zöllner, H.	2021	Field study to evaluate the efficacy and crop selectivity of SAP2101F (mixtures based on SAP250F and	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
6.4			SAP50SCF) against <i>Septoria</i> on Wheat (United Kingdom) Field Research Support; 03B-F-2021-UK01 GEP Unpublished				
KCP 6.2 (38) 6.1 6.4	Desogus, S.	2021	Evaluate the efficacy of mixtures based on SAP2101F against <i>Zymoseptoria tritici</i> on Wheat. Italy 2021 SAGEA Centro di Saggio s.r.l.; 03A-F-2020-IT01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (39) 6.4	Zöllner, H.	2020	Field study to evaluate the efficacy and crop selectivity of mixtures based on SAP250F and SAP50SCF against <i>Helmintosporium</i> on Barley Field Research Support; 11-F-2020-DE01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (40) 6.4	Zöllner, H.	2020	Field study to evaluate the efficacy and crop selectivity of mixtures based on SAP250F and SAP50SCF against <i>Helmintosporium</i> on Barley Field Research Support; 11-F-2020-DE02 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (41) 6.1 6.2 6.4	Biaunier, M.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against <i>Helmintosporium</i> on Barley QUALIPHYT; 11-F-2020-FR01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (42) 6.4	Biaunier, M.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against <i>Helmintosporium</i> on Barley QUALIPHYT; 11-F-2020-FR02 GEP	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 6.2 (43) 6.1 6.2 6.4	Rivet, J.	2020	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against <i>Helminthosporium</i> on Barley ESSAIS+; 11-F-2020-FR03 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (44) 6.4	Zöllner, H.	2021	Field study to evaluate the efficacy and crop selectivity of SAP2101F (mixtures based on SAP250F and SAP50SCF) against <i>Helminthosporium</i> on Barley (Germany) FIELD RESEARCH SUPPORT; 04A-F-2021-DE01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (45) 6.1 6.2 6.4	Biaunier, M.	2021	Evaluate the efficacy of SAP2101F against <i>Helminthosporium</i> on Barley QUALIPHYT; 04A-F-2021-FR01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (46) 6.1 6.2 6.4	Desogus, S.	2021	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against <i>Pyrenophora teres</i> on Barley. Bulgaria 2021 (EPPOSE). SAGEA OOD; 04B-F-2021-BG01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (47) 6.1 6.2 6.4	Desogus, S.	2021	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against <i>Pyrenophora teres</i> on Barley. Bulgaria 2021 (EPPOSE). SAGEA OOD; 04B-F-2021-BG02 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2 (48) 6.4	Zöllner, H.	2021	Field study to evaluate the efficacy and crop selectivity of SAP2101F (mixtures based on SAP250F and SAP50SCF) against <i>Helminthosporium</i> on Barley (Germany) FIELD RESEARCH SUPPORT; 04B-F-2021-DE01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (49) 6.4	Zöllner, H.	2021	Field study to evaluate the efficacy and crop selectivity of SAP2101F (mixtures based on SAP250F and SAP50SCF) against <i>Helminthosporium</i> on Barley (Germany) FIELD RESEARCH SUPPORT; 04B-F-2021-DE02 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (50) 6.1 6.2 6.4	Crepin, D.	2021	Evaluate the efficacy of SAP2101F against <i>Helminthosporium</i> on Barley ESSAIS +; 04B-F-2021-FR01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (51) 6.1 6.2 6.4	Crepin, D.	2021	Evaluate the efficacy of SAP2101F against <i>Helminthosporium</i> on Barley ESSAIS +; 04B-F-2021-FR02 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (52) 6.4	Biaunier, M.	2021	Evaluate the efficacy of SAP2101F against <i>Helminthosporium</i> on Barley QUALIPHYT; 04B-F-2021-FR03 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
<del>KCP 6.2 (53)</del> 6.4	<del>Blaumier, M.</del>	<del>2021</del>	<del>Evaluate the efficacy of SAP2101F against <i>Helminthosporium</i> on Barley QUALIPHYT; 04B-F-2021-FR04 GEP Unpublished</del>	<del>N</del>	<del>Y</del>	<del>Data/study report never submitted before to Poland</del>	<del>ASCENZA AGRO</del>
KCP 6.2 (54) 6.1 6.4	Herrera, D.	2021	Evaluate the efficacy of SAP2101F (mixture based on SAP250F and SAP50SCF) against <i>Helminthosporium</i> on Barley STAPHYT; 04B-F-2021-FR06 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (55) 6.1 6.4	Desogus, S.	2021	Evaluate the efficacy of mixtures based on SAP2101F against <i>Pyrenophora teres</i> on Barley. Italy 2021 SAGEA Centro di Saggio s.r.l.; 04B-F-2021-IT01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (56) 6.1 6.4	Desogus, S.	2021	Evaluate the efficacy of mixtures based on SAP2101F against <i>Pyrenophora teres</i> on Barley. Italy 2021 SAGEA Centro di Saggio s.r.l.; 04B-F-2021-IT02 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (57) 6.1 6.2 6.4	Zöllner, H.	2021	Field study to evaluate the efficacy and crop selectivity of SAP2101F against <i>Helminthosporium</i> on Barley (Poland) FIELD RESEARCH SUPPORT; 04B-F-2021-PL01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (58) 6.1 6.2 6.4	Rusek, K.	2021	Evaluate the efficacy of mixtures based on SAP2101F against <i>Helminthosporium</i> on Winter Barley, Poland 2021 FERTICO Sp. z.o.o.; 04B-F-2021-PL02	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO



Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP Unpublished				
KCP 6.2 (59) 6.2 6.4	Herrera, D.	2021	Evaluate the efficacy of SAP2101F (mixtures based on SAP250F and SAP50SCF) against <i>Helminthosporium</i> on Barley, GEP Trial, POLAND, 2021 STSPHYT; 04B-F-2021-PL04 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (60) 6.1 6.2 6.4	Herrera, D.	2021	Evaluate the efficacy of SAP2101F (mixtures based on SAP250F and SAP50SCF) against <i>Helminthosporium</i> on Barley, GEP Trial, POLAND, 2021 STSPHYT; 04B-F-2021-PL05 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (61) 6.1 6.2 6.4	Botoman, G.	2021	Evaluate the efficacy of SAP2101F against <i>Helminthosporium</i> on Barley GEP Trial, ROMANIA, 2021 AgroProspect; 04B-F-2021-RO01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (62) 6.4	Hernández, J.M.	2021	Evaluate the efficacy of mixtures based on SAP2101F against <i>Helminthosporium</i> on Barley AGROENSAYOS, ENSAYOS Y TÉCNICAS AGRÍCOLAS S.L.; 04B-F-2021-SP01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.2 (63) 6.4	Hernández, J.M.	2021	Evaluate the efficacy of mixtures based on SAP2101F against <i>Helminthosporium</i> on Barley AGROENSAYOS, ENSAYOS Y TÉCNICAS AGRÍCOLAS S.L.; 04B-F-2021-SP02 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4.1 (1)	Kasztner, G.	2021	Evaluate the efficacy of mixtures based on SAP250F and SAP50SCF against <i>Helmintosporium</i> on Barley Agrofil SZMI Kft; 04B-F-2020-HU01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.4.1 (2)	Herrera, D.	2021	Evaluate the efficacy of SAP2101F (mixture based on SAP250F and SAP50SCF) against <i>Helmintosporium</i> on Barley STAPHYT; 04B-F-2021-FR05 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.4.2; KCP 6.4.3 (1) 6.4.4	Gaia, U.	2021	EVALUATION OF NON-INTENTIONAL EFFECTS OF SAP2101F AND SAP50SCF ON TRANSFORMATION PROCESS (BREADMAKING) ON WHEAT- ITALY (2021) SAGEA Centro di Saggio s.r.l.; 25-TT-BM-2021-IT01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.4.2; KCP 6.4.3 (2) 6.4.4	Gaia, U.	2021	EVALUATION OF NON-INTENTIONAL EFFECTS OF SAP2101F AND SAP50SCF ON TRANSFORMATION PROCESS (BREADMAKING) ON WHEAT- ITALY (2021) SAGEA Centro di Saggio s.r.l.; 25-TT-BM-2021-IT02 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.4.2; KCP 6.4.3 (3) 6.4.4	Milhan, C.	2021	Unintentional effects of SAP2101F and SAP50SCF on transformation process (bread making) on wheat - 2021 STAPHYT; 25-TT-BM-2021-FR01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.4.2; KCP 6.4.3 (4) 6.4.4	Milhan, C.	2021	Unintentional effects of SAP2101F and SAP50SCF on transformation process (bread making) on wheat - 2021	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			STAPHYT; 25-TT-BM-2021-FR02 GEP Unpublished				
KCP 6.4.2; KCP 6.4.3 (5) 6.4.4	Herrera, D.	2021	Non-intentional effects of SAP2101F and SAP50SCF on transformation process (brewing) on barley, GEP Trial, FRANCE, 2021 STAPHYT; 26-TT-BW-2021-FR01 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.4.2; KCP 6.4.3 (6) 6.4.4	Herrera, D.	2021	Non-intentional effects of SAP2101F and SAP50SCF on transformation process (brewing) on barley, GEP Trial, FRANCE, 2021 STAPHYT; 26-TT-BW-2021-FR02 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.4.2; KCP 6.4.3 (7) 6.4.4	Herrera, D.	2021	Non-intentional effects of SAP2101F and SAP50SCF on transformation process (brewing) on barley, GEP Trial, FRANCE, 2021 STAPHYT; 26-TT-BW-2021-FR03 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.4.2; KCP 6.4.3 (8) 6.4.4	Gless, A.E.	2021	STUDY OF UNINTENTIONAL EFFECTS OF SAP2101F AND SAP50SCF PRODUCTS APPLIED ON WINTER BARLEY, HARVEST 2021, ON MALT AND BEER QUALITY AND PROCESS I.F.B.M.; R-A-I-1173 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.4.2; KCP 6.4.3 (9) 6.4.4	Gaia, U.	2021	EVALUATION OF NON-INTENTIONAL EFFECTS OF SAP2101F AND SAP50SCF ON TRANSFORMATION PROCESS (BREWING) ON BARLEY – ITALY (2021) SAGEA Centro di Saggio s.r.l.;	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			26-TT-BW-2021-IT01 GEP Unpublished				
KCP 6.4.2; KCP 6.4.3 (10) 6.4.4	Gaia, U.	2021	EVALUATION OF NON-INTENTIONAL EFFECTS OF SAP2101F AND SAP50SCF ON TRANSFORMATION PROCESS (BREWING) ON BARLEY – ITALY (2021) SAGEA Centro di Saggio s.r.l.; 26-TT-BW-2021-IT02 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.5.2 (1) 6.5.2	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F) Effectiveness of Cleaning Procedure ASCENZA Agro S.A.; Study EF/372/21 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.5.2 (2) 6.5.2	Huerta, F.	2021	‘Prothioconazole + Folpet 120+300 g/L SC - SAP2101F’: Effects on the Vegetative Vigour of Six Non-Target Terrestrial Plant Species under Greenhouse Conditions Eurofins Trialcamp S.L.U ; S21-05017 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
KCP 6.5.2 (3) 6.5.1	Huerta, F.	2021	‘Prothioconazole + Folpet 120+300 g/L SC - SAP2101F’: Effects on the Seedling Emergence and Growth of Six Non-Target Terrestrial Plant Species under Greenhouse Conditions Eurofins Trialcamp S.L.U ; S21-05016 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	ASCENZA AGRO
<b>Section B5</b>							
KCP 5.1.1/01	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F): Physical, chemical and technical properties of the plant protection product	N	Y	Product data submitted with an application under Article 33 of the Regulation (new	ASCENZA Agro, S.A.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report no EF/371/21 – Interim Report (T0): Annex 1 – Prothioconazole and Folpet method validation and quantification ASCENZA Agro, S.A. GLP Unpublished			product under Regulation) Data protection rights not previously granted at CEU zone.	
KCP 5.1.1/02	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F): Physical, chemical and technical properties of the plant protection product Report no EF/371/21 – Interim Report (T0): Annex 3 – Prothioconazole-desthio and Toluene method validation and quantification ASCENZA Agro, S.A. GLP Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 5.1.1/03	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F): Physical, chemical and technical properties of the plant protection product Report no EF/371/21 – Interim Report (T0): Annex 4 – PMM method validation and quantification ASCENZA Agro, S.A. GLP Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 5.1.1/04	Morais, F.	2022	PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L SC (SAP2101F): Physical, chemical and technical properties of the plant protection product Report no EF/371/21 – Interim Report (T0): Annex 5 – CCl <sub>4</sub> method validation and quantification ASCENZA Agro, S.A. GLP Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 5.1.2/01	Stolze, J.	2022	Study on the Residue Behaviour of Prothioconazole in Oilseed Rape after Treatment with Prothioconazole 300 EC at six Sites under Field Conditions in Southern Europe,	N	Y	Product data submitted with an application under Article 33 of the Regulation (new	ASCENZA Agro, S.A.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			2021 Report no IF21-05707367 SGS INSTITUT FRESENIUS GmbH GLP Unpublished			product under Regulation) Data protection rights not previously granted at CEU zone.	
KCP 5.1.2/02 (equivalent to KCP 10.2.1/01)	Schuler L.	2022	Analytical Summary: Analytical Method for the Determination of Prothioconazole and Folpet Eurofins Agroscience Services Study No S21-05200 GLP Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 5.1.2/03 (equivalent to KCP 10.2.1/02)	Schuler L.	2022	Analytical Summary: Analytical Method for the Determination of Prothioconazole and Folpet Eurofins Agroscience Services Study No S21-05199 GLP Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 5.1.2/04 (equivalent to KCP 10.6.2/01)	Lingott J.	2022	Analytical phase report: 'Prothioconazole + Folpet 120+300 g/L SC – SAP2101F': Effects on the Seedling Emergence and Growth of Six Non-Target Terrestrial Plant Species under Greenhouse Conditions Eurofins Agroscience Services Study No S21-05017-L2 GLP Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 5.1.2/05 (equivalent to KCP 10.6.2/02)	Lingott J.	2022	Analytical phase report: Prothioconazole + Folpet 120+300 g/L SC – SAP2101F': Effects on the Vegetative Vigour of Six Non-Target Terrestrial Plant Species under Greenhouse Conditions Eurofins Agroscience Services Study No S21-05016-L2 GLP Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 5.1.2/06	Rastogi T.	2022	Analytical phase plan:SAP2101F: Honey Bee ( <i>Apis</i>	N	Y	Product data submitted with	ASCENZA

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
(equivalent to KCP 10.3.1.3/02)			<i>mellifera</i> L.) Larval Toxicity Test following Repeated Exposure under laboratory conditions Eurofins Agroscience Services Study No.S21-05007-L3 GLP Unpublished			an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	Agro, S.A.
KCP 5.1.2/07	Jooß, S.	2022	Validation of a Residue Analytical Method for the Determination of Folpet and its Metabolites in Cereal Matrices. Report No. S22-01156 Eurofins Agroscience Services. GLP Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 5.1.2/08	Jooß, S.	2022	Study on the Residue Behaviour of Folpet and its Metabolites in Processed Fractions of Barley after one Application of SAP 50SCF (Folpet 500 g/L, SC) in Northern Europe – 2021 Report No S22-04739 Eurofins Agroscience Services. GLP Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 5.1.2/09 (equivalent to KCP 10.3.1.3/01)	Schreitmüller J.	2016	Analysis of Folpet in dosage solutions from Honey Bee Larvae Toxicity Innovative Environmental Services (IES) Ltd. Study No TRC14-245BA GLP Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	Sapex Agro S.A and Belchim Crop Protection
KCP 5.1.2/10	Gordo, J	2022	Validation of the Analytical Method for the Determination of Folpet and Metabolites Residues in Wheat Report No. VAL22/21 Laboratório de Resíduos de Pesticidas ASCENZA AGRO, S.A. GLP	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU	ASCENZA Agro, S.A

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished			zone.	
KCP 5.2/01	Perny, A.	2015	Validation of the Analytical Method for the Determination of Folpet and Phthalimide in Grapes, Wine, Tomato, Cereal Grain and Sunflower Seeds Source: ANADIAG Report No.: R B4225 Date: 07/07/2015 GLP: yes Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	Sapec Agro S.A. and ADAMA
KCP 5.2/02	Perny, A.	2015	Validation of the Analytical Method for the Determination of Folpet and Phthalimide in Grapes, Wine, Tomato, Cereal Grain and Sunflower Seeds – Amendment No. 1 Source: ANADIAG Report No.: R B4225 Date: 19/08/2015 GLP: yes Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	Sapec Agro S.A. and ADAMA
KCP 5.2/03	Meseguer, C.	2015	Independent laboratory validation of the analytical method for the determination of folpet and phthalimide in crop matrices by LC-MS/MS Source: Eurofins Agrosience Services Chem SAS Report No.: S14-05779 Date: 24/03/2016 GLP: yes Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	Sapec Agro S.A. and ADAMA
KCP 5.2/04	Wiesner, F., Breyer, N.	2016	Validation of the multi-residue method DFG-S19 for the determination of folpet and phthalimide in cereal grain and sunflower seeds Source: Eurofins Agrosience Services Chem GmbH Report No.: S16-00559 (BEL-1601V) Date: 24/03/2016 GLP: yes Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	Sapec Agro S.A. and ADAMA
KCP 5.2/05	Wiesner, F.	2016	Validation of the multi-residue method DFG-S19 for the	N	Y	Product data submitted with	Sapec Agro



Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			determination of folpet and phthalimide in cereal grain and sunflower seeds – Amendment No. 1 Source: Eurofins Agroscience Services Chem GmbH Report No.: S16-00559 (BEL-1601V) Date: 29/04/2016 GLP: yes Unpublished			an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	S.A. and ADAMA
KCP 5.2/06	Hegmanns, C.	2016	Independent Laboratory Validation of the analytical method for the determination of folpet and phthalimide in cereal grain and sunflower seeds Source: Eurofins Agroscience Services EcoChem GmbH Report No.: S16-00716 Date: 02/05/2016 GLP: yes Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	Sapeac Agro S.A. and ADAMA
KCP 5.2/07	Wiesner, F., Breyer, N., Trümper, C.	2016	Validation of the multi-residue method DFG S19 for the determination of phthalimide in milk, fat and eggs Source: Eurofins Agroscience Services Chem GmbH Report No.: S16-00672 Date: 07/04/2016 GLP: yes Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	Sapeac Agro S.A. and ADAMA
KCP 5.2/08	Mewis, A.	2016	Independent Laboratory Validation of an analytical method for the determination of phthalimide in milk, eggs and fat Source: Eurofins Agroscience Services EcoChem GmbH Report No.: S16-00717 Date: 09/05/2016 GLP: yes Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	Sapeac Agro S.A. and ADAMA
KCP 5.2/09	Schlewitz, P.	2015	Validation of the analytical method for the determination of phthalimide, expressed as folpet, in milk, eggs, meat, fat and liver/kidney	N	Y	Product data submitted with an application under Article 33 of the Regulation (new	Sapeac Agro S.A. and ADAMA

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
			Source: ANADIAG Report No.: R B4281 Date: 09/09/2015 GLP: yes Unpublished			product under Regulation) Data protection rights not previously granted at CEU zone.	
KCP 5.2/10	Meseguer, C.	2016	Independent Laboratory Validation of the analytical method for the determination of phthalimide in animal matrices by LC-MS/MS Source: Eurofins Agrosience Services Chem SAS Report No.: S14-05780 Date: 13/04/2016 GLP: yes Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	Saptec Agro S.A. and ADAMA
KCP 5.2/11	Schlewitz, P.	2015b	Validation of the analytical method for the determination of folpet in soil Source: ANADIAG Report No.: R B4282 Date: 27/10/2015 GLP: yes Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	Saptec Agro S.A. and ADAMA
KCP 5.2/12	Aris, D.	2011	Folpet and phthalimide: Validation of Methodology for the Determination of Residues of Folpet and Phthalimide in Drinking Water Source: Huntingdon Life Sciences, Ltd. Report No.: ZEF0005 Date: 25/10/2011 (Amendment No. 1: 17/02/2012) GLP: yes Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	Saptec Agro S.A. and ADAMA
KCP 5.2/13	Maas, X., Bendig, P.	2015	Independent Laboratory Validation (ILV) of Analytical Methods for the Determination of Folpet and of Phthalimide in Water. Source: PTRL Europe Report No.: P 3812 G Date: 09/12/2015	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU	Saptec Agro S.A. and ADAMA

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP: yes Unpublished			zone.	
KCP 5.2/14	Aris, D.	2012	Folpet and phthalimide: Validation of Methodology for the Determination of Residues of Folpet and Phthalimide in Air. Source: Huntingdon Life Sciences, Ltd. Report No.: ZEF0006 Date: 27/02/2012 GLP: yes Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	Sapeco Agro S.A. and ADAMA
KCP 5.2/15	Wiesner, F., Breyer, N.	2016	Validation of the multi-residue method DFG S19 for the determination of phthalimide in urine Source: Eurofins Agrosience Services Chem GmbH Report No.: S16-02058 Date: 17/04/2016 GLP: yes Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	Sapeco Agro S.A. and ADAMA
KCP 5.2/16	Gordo, J.	2023	Cross validation of an internal extraction method from LabRP vs. an Extraction Method Applied in <sup>14</sup> C-metabolism Studies for the Determination of Folpet and Metabolites in Wheat Report VAL 25/21 Laboratorio de Residuos de Pesticidas - ASCENZA AGRO, S.A. GLP Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A
<b>Section B6</b>							
KCP 7.2/01 (Field phase)	Torres, M.	2022	SAP2101F (PROTHIOCONAZOLE 120 g/L + FOLPET 300 g/L) – DISLODGEABLE FOLIAR RESIDUE DECLINE STUDY ON CEREALS (WHEAT OR BARLEY) IN NORTHERN/CENTRAL EUROPE IN 2021  512SRES21X04 GLP	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at SEU zone	Ascenza Agro S.A.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 7.2/02 (Analytical phase)	Gaffney, V.	2022	Determination of the Decline of Prothioconazole, Prothioconazole-desthio and Folpet Dislodgeable Foliar Residues on Cereals (Wheat and Barley) in Northern Europe in 2021 after Application of SAP2101F DFR11/21 GLP Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at SEU zone	Ascenza Agro S.A.
KCP 7.3/01	Imart, C.	2021	IN-VITRO HUMAN SKIN PENETRATION OF PROTHIOCONAZOLE-DESTHIO IN PROTHIOCONAZOLE + FOLPET 120+300 g/L SC S21-04572 Eurofins Agrosience Services Chem SAS GLP Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
<b>Section B7</b>							
KCP 7.2.3/01	Grall, E.	2022	Prothioconazole – Residue Study on Barley in Northern and Southern Europe – 2020 Staphyt report no EGL-20-42539 GLP Unpublished	N	Y	data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 7.2.3/02	Grall, E.	2022	Prothioconazole – Residue Study on Barley in Northern Europe – 2020 Staphyt report no EGL-20-45487 GLP Unpublished	N	Y	data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 7.2.3/03	Thirkell, C.	2022	Study on the Residue Behaviour of Prothioconazole in Barley after Treatment with Prothioconazole 300 EC at two Sites under Field Conditions Northern Europe, 2021 SGS report no IF21-05704459 GLP	N	Y	data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not	ASCENZA Agro, S.A.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished			previously granted at CEU zone.	
KCP 7.2.3/04	Grall, E.	2022	Prothioconazole – Residue Study on Wheat in Northern Europe – 2020 Staphyt report no EGL-20-42538 GLP Unpublished	N	Y	data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 7.2.3/05	Thirkell, C.	2022	Study on the Residue Behaviour of Prothioconazole in Wheat after Treatment with Prothioconazole 300 EC at six Sites under Field Conditions in Northern Europe, 2021 SGS report no IF21-05705310 GLP Unpublished	N	Y	data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 7.2.3/06	Thirkell, C.	2023	Study on the Residue Behaviour of Prothioconazole in Wheat after Treatment with Prothioconazole 300 EC at two Sites under Field Conditions in Northern Europe, 2022 SGS report no IF22-06125006 GLP Unpublished	N	Y	data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 7.3.1/01	J. Gordo	2024	Stability Study of Folpet and Metabolites in Cereals Stored Under Deep Freezing Conditions Laboratorio Residuos de Pesticidas Ascenza Agro SA. Report n° EST06/22 (study ongoing, final report May2024). GLP Unpublished	N	Y	data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 7.3.1/02	S. Jooss	2024	Storage Stability of Folpet and its Metabolites in Various Matrices under Deep Frozen Conditions Eurofins Agroscience Services. Report N°: S22-07592 (study ongoing, final report May2024). GLP	N	Y	data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not	ASCENZA Agro, S.A.

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
			Unpublished			previously granted at CEU zone.	
KCP 7.3.3/01 (field phase)	A.S. Lesbazeilles Beauvalon	2022	Magnitude of the residue of folpet in representative winter wheat Raw Agricultural Commodities after two applications of SAP50SCF (Folpet 500 g/L, SC) in Northern Europe- 2021 SGS Report n° 21-00160 GLP Unpublished	N	Y	data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 7.3.3/02 (analytical phase)	S. Jooss	2022	Study on the residue behaviour of folpet and its metabolites in winter wheat after two applications of SAP50SCF (Folpet 500 g/l, SC) in Northern Europe – 2021. Eurofins Agroscience Services Report No: S22-03719 GLP Unpublished	N	Y	data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 7.3.3/03 (field phase)	A.S. Lesbazeilles Beauvalon	2022	Magnitude of the residue of folpet in representative barley Raw Agricultural Commodities after two applications of SAP50SCF (Folpet 500 g/L, SC) in Northern Europe SGS Report n° 21-00139 GLP Unpublished	N	Y	data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 7.3.3/04 (analytical phase)	S. Jooss	2022	Study on the residue behaviour of folpet and its metabolites in barley after two applications of SAP50SCF (Folpet 500 g/l, SC) in Northern Europe – 2021 Eurofins Agroscience Services Report No: S22-01157 GLP Unpublished	N	Y	data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.3.5/01 (processing phase)	C. Milhan	2022	Magnitude of the residue of folpet in processed fractions of barley after two applications of SAP50SCF (Folpet 500 g/L, SC) in Northern and Southern Europe Staphyt Report n° CMN-21-48321 GLP Unpublished	N	Y	data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 7.3.5/02 (analytical phase)	S. Jooss	2022	Study on the residue behaviour of folpet and its metabolites in processed fractions of barley after one application of SAP50SCF (Folpet 500 g/l) in Northern Europe – 2021 Eurofins Agrosience Services Report No: S22-04739 GLP Unpublished	N	Y	data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
<b>Section B8</b>							
KCP 9.2.4/01	Fernandes, V.	2021a	Predicted Environmental Concentrations of Prothioconazole and its metabolites in Groundwater (PEC <sub>gw</sub> ) based on FOCUS PELMO 6.6.4, FOCUS PEARL 5.5.5 and MACRO 5.5.4 for risk assessment of SAP2101F on Cereals ASC123-2021 non GLP Unpublished	N	N	-	ASCENZA Agro, S.A
KCP 9.2.4/02	Fernandes, V.	2021b	Predicted Environmental Concentrations of Folpet and its metabolites in Groundwater (PEC <sub>gw</sub> ) based on FOCUS PELMO 6.6.4, FOCUS PEARL 5.5.5 and MACRO 5.5.4 for risk assessment of SAP2101F on Cereals ASC124-2021 non GLP Unpublished	N	N	-	ASCENZA Agro, S.A
KCP 9.2.5/01	Fernandes, V.	2021c	Predicted Environmental Concentrations of Prothioconazole and its metabolites in Surface Water and Sediment (PEC <sub>sw</sub> and PEC <sub>sed</sub> ) based on Tiered FOCUS Approach for risk assessment of SAP2101F on Cereals ASC111-2021	N	N	-	ASCENZA Agro, S.A

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			non GLP Unpublished				
KCP 9.2.5/02	Fernandes, V.	2021d	Predicted Environmental Concentrations of Folpet and its metabolites in Surface Water and Sediment (PEC <sub>sw</sub> and PEC <sub>sed</sub> ) based on Tiered FOCUS Approach for risk assessment of SAP2101F on Cereals ASC112-2021 non GLP Unpublished	N	N	-	ASCENZA Agro, S.A
<b>Section B9</b>							
KCP 10.2.1/01	Schuler L.	2022	Prothioconazole + Folpet 120 + 300 g/L SC: Toxicity to the Water Flea <i>Daphnia magna</i> Straus under Laboratory Conditions (Acute Immobilisation Test – Semi-Static) Eurofins Agroscience Services Study No. S21-05200 GLP Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 10.2.1/02	Schuler L.	2022	Prothioconazole + Folpet 120 + 300 g/L SC: Toxicity to the Single Cell Green Alga <i>Pseudokirchneriella subcapitata</i> Hindák under Laboratory Conditions Eurofins Agroscience Services Study No. S21- 05199 GLP Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 10.2.1/03		2023	Toxicity to the Rainbow Trout <i>Oncorhynchus mykiss</i> under Laboratory Conditions (Acute Toxicity Test – Semi-Static) 23-100707 GLP Unpublished	Y	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 10.3.1.1/01	Schmitzer S., Pavie B.	2007	Effects of Folpet 80 WG (Acute Contact and Oral) on Honey Bees ( <i>Apis mellifera</i> L.) in the laboratory Ibacon Study No. 33893035	N	Y	Study previously submitted under the Renewal process	Belchim Crop Protection



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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Unpublished			of folpet. Data protection not granted before.	ASCENZA AGRO S.A.
KCP 10.3.1.1/02	Fausser-Misslin A.	2015	Folpet: Acute Oral and Contact Toxicity to Bumble-Bee ( <i>Bombus terrestris</i> L.) under Laboratory Conditions Innovative Environmental Services (IES) Ltd. Study no. 20140156 GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	Belchim Crop Protection  ASCENZA AGRO S.A.
KCP 10.3.1.1/03	Amsel, K.	2015	Acute toxicity of Folpet 80 WG to the bumblebee <i>Bombus terrestris</i> L. under laboratory conditions Biochemagrar Study No. 15-10-48-167-B GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	Belchim Crop Protection  ASCENZA AGRO S.A.
KCP 10.3.1.1/04	Schnurr A.	2015	Acute toxicity of Folpet 80 WG to the solitary bee <i>Osmia bicornis</i> L. under laboratory conditions Biochemagrar Study No. 15-10-48-114-B GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	Belchim Crop Protection  ASCENZA AGRO S.A.
KCP 10.3.1.1/05	Ansaloni T.	2022	SAP2101F: Honey Bee ( <i>Apis mellifera</i> L.) Acute Oral and Contact Toxicity Test under Laboratory Conditions Trialcamp Study No. S21-05005 GLP Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 10.3.1.2/01	Ansaloni T.	2015	Chronic toxicity of FOLPET TECHNICAL on honeybees ( <i>Apis mellifera</i> L.) Trialcamp S.L.L. Study No. TRC14-246BA GLP	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	Belchim Crop Protection

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				ASCENZA AGRO S.A.
KCP 10.3.1.3/02	Ansaloni T.	2022	SAP2101F: Honey Bee ( <i>Apis mellifera</i> L.) Larval Toxicity Test following Repeated Exposure under laboratory conditions Eurofins Agroscience Services Study No. S21-05007 GLP Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 10.3.2.1/01	Varela S.	2022	Prothioconazole + Folpet 120+300 g/L - SAP 2101F: Toxicity to the Predatory Mite, <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) under Extended Laboratory Conditions Eurofins Agroscience Services Study No. S21-05009 GLP Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 10.3.2.1/02	Varela S.	2022	Prothioconazole + Folpet 120+300 g/L - SAP 2101F: Toxicity to the Aphid Parasitoid <i>Aphidius rhopalosiphii</i> De Stefani Perez (Hymenoptera, Braconidae) under Extended Laboratory Conditions Eurofins Agroscience Services Study No. S21-05008 GLP Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 10.3.2.1/03	Varela S.	2022	Prothioconazole + Folpet 120+300 g/L - SAP 2101F: Toxicity to the Ladybird, <i>Coccinella septempunctata</i> L. (Coleoptera: Coccinellidae) Using an Extended Laboratory Test with Freshly Applied Spray Deposits Eurofins Agroscience Services Study No. S21-05010 GLP Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 10.3.2.1/04	Luna, F.	2022	Prothioconazole + Folpet 120+300 g/L - SAP 2101F: Toxicity to the Green Lacewing, <i>Chrysoperla carnea</i>	N	Y	Product data submitted with an application under	ASCENZA Agro, S.A.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Steph. (Neuroptera: Chrysopidae) Using an Extended Laboratory Test with Freshly Applied Spray Deposits Eurofins Agroscience Services Study No. S21-05012 GLP Unpublished			Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	
KCP 10.4.1.1/01	Queralt M.	2022	Prothioconazole + Folpet 120+300 g/L - SAP2101F: Sublethal Toxicity to the Earthworm <i>Eisenia andrei</i> (Oligochaeta, Lumbricidae) in Artificial Soil with 5 % Peat Eurofins Agroscience Services Study No. S21-05013 GLP Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 10.5/01	Queralt M.	2022	Prothioconazole + Folpet 120+300 g/L - SAP2101F: Effects on the Activity of Soil Microflora under Laboratory Conditions (Nitrogen Transformation) Eurofins Agroscience Services Study No. S21-05015 GLP Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 10.6.2/01	Huerta F.	2022	Prothioconazole + Folpet 120+300 g/L - SAP2101F: Effects on the Seedling Emergence and Growth of Six Non-Target Terrestrial Plant Species under Greenhouse Conditions Eurofins Agroscience Services Study No. S21-05016 GLP Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
<b>Section B10</b>							
KCP 9.2.4/01	Fernandes, V.	2021a	Predicted Environmental Concentrations of Prothioconazole and its metabolites in Groundwater (PEC <sub>gw</sub> ) based on FOCUS PELMO 6.6.4, FOCUS PEARL 5.5.5 and MACRO 5.5.4 for risk assessment of SAP2101F on Cereals ASC123-2021	N	N		ASCENZA Agro, S.A.

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Verte- brate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
			non GLP Unpublished				
KCP 9.2.4/02	Fernandes, V.	2021b	Predicted Environmental Concentrations of Folpet and its metabolites in Groundwater (PEC <sub>gw</sub> ) based on FOCUS PELMO 6.6.4, FOCUS PEARL 5.5.5 and MACRO 5.5.4 for risk assessment of SAP2101F on Cereals ASC124-2021 non GLP Unpublished	N	N		ASCENZA Agro, S.A

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

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCA 5.1.2	Heinemann	2001	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: yes Unpublished	N	N	Study submitted under first inclusion process of a.s. Data protection rights are expired	BAY
KCA 5.1.2	Billian P. and Druskus	2009	Residue analytical method 01132 for the determination of 1,2,4-triazole, triazole alanine, triazole acetic acid, triazole lactic acid in/on milk, egg, muscle, fat, liver and kidney by HPLC-MS/MS. Bayer CropScience AG, Report no 01132 GLP: yes Unpublished	N	N	Study submitted under first inclusion process of a.s. Data protection rights are expired	BAY
KCP 5.2	Weeren, R. D., Pelz, S.	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, Date: 2000-11-20 GLP: Yes Unpublished	N	N	Study submitted under first inclusion process of a.s. Data protection rights are expired	BAY
KCA 5.2	Class, Th.	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, Date: 2001-05-15 GLP: Yes Unpublished	N	N	Study submitted under first inclusion process of a.s. Data protection rights are expired	BAY
KCA 5.2	Heinemann, O.	2000	Analytical determination of residues of JAU 6476 and desthio-JAU 6476 in/ on cereals by HPLC/MS/MS. Bayer AG, Report No.: 00598. Date: 2000-03-20 GLP: Yes Unpublished	N	N	Study submitted under first inclusion process of a.s. Data protection rights are expired	BAY
KCA 5.1.2 KCA 5.2	Heinemann, O.	2001	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.	N	N	Study submitted under first inclusion process of a.s. Data protection rights are expired	BAY

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Bayer AG, Report No.: 00655, Date: 2001-02-27 GLP: Yes Unpublished				
KCA 5.1.2 KCA 5.2	Heinemann, O.	2001	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, Date: 2001-05-04 GLP: Yes Unpublished	N	N	Study submitted under first inclusion process of a.s. Data protection rights are expired	BAY
KCA 5.2	Dubey, L.	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, JAU6476-desthio in/on matrices of animal origin by HPLC-MS/MS. Battelle, Geneva Research Centres, Carouge/Geneva, Switzerland. Bayer AG, Report No.: A-14-01-01, Date: 2001-10-16 GLP: Yes Unpublished	N	N	Study submitted under first inclusion process of a.s. Data protection rights are expired	BAY
KCP 5.2	Schramel, O.	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, Date: 2000-07-13 GLP: Yes Unpublished	N	N	Study submitted under first inclusion process of a.s. Data protection rights are expired	BAY
KCP 5.2	Steinhauer, S.	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, Date: 2001-07-25 GLP: Yes Unpublished	N	N	Study submitted under first inclusion process of a.s. Data protection rights are expired	BAY
KCP 5.2	Sommer, H.	1999	Method for the determination of JAU 6476 and SXX 0665 in test water from aquatic toxicity tests by HPLC [Tox/Ecotox method] Bayer AG, Report No.: 00586, Date: 1999-05-28 GLP: Yes	N	N	Study submitted under first inclusion process of a.s. Data protection rights are expired	BAY

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 5.2	Sommer, H.	2001b	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, Date: 2001-10-23 GLP: Yes Unpublished	N	N	Study submitted under first inclusion process of a.s. Data protection rights are expired	BAY
KCP 5.2	Maasfeld, W.	2002	Method for the determination of JAU 6476 in air by HPLC-MS/MS. Bayer AG, Report No.: 00724, Date: 2002-01-22 GLP: Yes Unpublished	N	N	Study submitted under first inclusion process of a.s. Data protection rights are expired	BAY
KCP 5.2	Maasfeld, W.	2002	Method for the determination of JAU 6476-desthio (SXX 0665) in air by HPLC-MS/MS (Method-No. 00731) MR-003/02 ! 00731 ! P 605 00 6012 ! MO-02-002585 ! M-036729-01-1 GLP: Yes Unpublished	N	N	Study submitted under first inclusion process of a.s. Data protection rights are expired	BAY
KCA 6.1	Fuchsbichler, G	1995	Folpet, investigation of the storage stability in white and red grapes. Report n° HVA 12/94 Company file: R-8096 ADAMA Makhteshim Ltd., V20481, R-34718 GLP, unpublished	N	N	Study submitted under first inclusion process of a.s. Data protection rights are expired	Makhteshim
KCA 6.1	Byast, M.G.	1997	Determination of freezer storage stability for folpet in wheat, grain and straw over a period of 12 months in compliance with good laboratory practice. Oxford Analytical Ltd., Report No.: OA00382. Company file: R-9156 GLP, Unpublished	N	N	Study submitted under first inclusion process of a.s. Data protection rights are expired	Makhteshim
KCA 6.1	Singer, G.M.	-	Summary of storage stability studies of folpet on various raw agricultural commodities. American Agricultural Services, Inc., company file: R-9142 Not GLP, unpublished	N	N	Study submitted under first inclusion process of a.s. Data protection rights are expired	Makhteshim

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.2.1	Crowe, A.	1995	Folpet: distribution and metabolism in winter wheat. Pharmaco LSR Ltd., Report No. 95/MAK204/0049 (company file: R-7823) GLP, unpublished	N	N	Study submitted under first inclusion process of a.s. Data protection rights are expired	Makhteshim
KCA 6.2.1	O'Connor, J. Mester, T.C	1994	Folpet: nature of residue on grapes. Pharmaco LSR Ltd., Report No 93/WLS019/0962 GLP, unpublished  Field report: Nature of the residue study LX1145-05[(14C)-folpet] on grapes in California. Landis International, Inc. report Protocol No.14503B004. (company file: R-6403a). GLP, Unpublished.	N	N	Study submitted under first inclusion process of a.s. Data protection rights are expired	Makhteshim
KCA 6.2.1	Toia, R.F Collins, E.H	1994	Nature of residue ( <sup>14</sup> C)-folpet (LX1145-05) in avocados applied under field conditions. PREL West Inc., Report No.417W-2. (Company file: R-7302) GLP, Unpublished	N	N	Study submitted under first inclusion process of a.s. Data protection rights are expired	Makhteshim
KCA 6.2.1	Cheng, H.M.	1980	[Carbonyl- <sup>14</sup> C] folpet metabolism in tomato plants. Chevron Chemical Company, Report No.721.14 (Company file: R-7036) Not GLP, Unpublished	N	N	Study submitted under first inclusion process of a.s. Data protection rights are expired	Makhteshim
KCA 6.2.1	Crowe, A.	1999	Folpet: metabolism in potatoes. Huntigdon Life Sciences Ltd., Report No. MAK506/992098 (Company file: R-10347). GLP, Unpublished	N	N	Study submitted under first inclusion process of a.s. Data protection rights are expired	Makhteshim
KCA 6.2.2	██████	1997a	<sup>14</sup> C-folpet metabolism in the lactating goat (part A). <sup>14</sup> C trichloromethyl folpet: material balance of dosed radioactivity. ██████ GLP, unpublished	<del>N</del> Y	N	Study submitted under first inclusion process of a.s. Data protection rights are expired	Makhteshim



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 6.2.2		2015	Metabolism and disposition of [ <sup>14</sup> C]Folpet in the Laying Hen GLP, unpublished	Y	N	Study submitted under first inclusion process of a.s. in confirmatory data Data protection rights are expired	ADM
KCA 6.5.1	M Fitzmaurice and E Mackenzie,	2007	[ <sup>14</sup> C]-Folpet: Investigation of the Nature of the Potential Residue in the Products of Industrial Processing or Household Preparation Report n° OZ/07/007 GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet.Data protection not granted before.	ASCENZA Agro, S.A.
KCA 6.5.3	Perney, A	2002b	Determination of folpet and phthalimide residues in processed fractions (grain, flour, total bran, regrinding and bread) after treatment of winter wheat with the preparation Fopan 80 WDG under field conditions in France in 2001. Anadiag S.A., Report No RA1044 PRO (company file R- 13053) GLP, Unpublished	N	N	Study submitted under first inclusion process of a.s. Data protection rights are expired	Makhteshim

**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
KCP 5.1.2/01	Stolze, J.	2022	Study on the Residue Behaviour of Prothioconazole in Oilseed Rape after Treatment with Prothioconazole 300 EC at six Sites under Field Conditions in Southern Europe, 2021 Report no IF21-05707367 SGS INSTITUT FRESENIUS GmbH GLP Unpublished	N	Y	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	ASCENZA Agro, S.A.
KCP 10.3.1.1/01	Schmitzer S., Pavic B.	2007	Effects of Folpet 80 WG (Acute Contact and Oral) on Honey Bees (Apis mellifera L.) in the laboratory Ibacon Study No. 33893035 GLP	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	Belchim Crop Protection

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Verte- brate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
			Unpublished				ASCENZA AGRO S.A.
KCP 10.3.1.1/02	Fausser-Misslin A.	2015	Folpet: Acute Oral and Contact Toxicity to Bumble Bee ( <i>Bombus terrestris</i> L.) under Laboratory Conditions Innovative Environmental Services (IES) Ltd. Study no. 20140156 GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	Belchim Crop Protection  ASCENZA AGRO S.A.
KCP 10.3.1.1/03	Amsel, K.	2015	Acute toxicity of Folpet 80 WG to the bumblebee <i>Bombus terrestris</i> L. under laboratory conditions Biochemagrar Study No. 15 10 48 167 B GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	Belchim Crop Protection  ASCENZA AGRO S.A.
KCP 10.3.1.1/04	Schnurr A.	2015	Acute toxicity of Folpet 80 WG to the solitary bee <i>Osmia bicornis</i> L. under laboratory conditions Biochemagrar Study No. 15 10 48 114 B GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	Belchim Crop Protection  ASCENZA AGRO S.A.
KCP 10.3.1.2/01	Ansaloni T.	2015	Chronic toxicity of FOLPET TECHNICAL on honeybees ( <i>Apis mellifera</i> L.) Trialcamp S.L.L. Study No. TRC14-246BA GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	Belchim Crop Protection  ASCENZA AGRO S.A.

**List of data relied on and not submitted by the applicant but necessary for evaluation**

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