

REGISTRATION REPORT

Part A

Risk Management

Product code: SAP50SCF

Product name(s): FOLPEC

Chemical active substance:

Folpet, 500 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 Selectis Produtos para a Agricultura, S.A. after completeness check by Poland. All the changes are highlighted in yellow.
April 2024	V2 - Updated version submitted by the Selectis Produtos para a Agricultura, S.A. to comply with Poland Data Gaps requests in the frame of new PPP registration (According Art. 33 of Regulation EC No 1107/2009). The changes include: 1) inserting, into the GAP table, the EPPO codes for the species of wheat and barley, 2) inserting, into Appendix 1, the list of submitted trials, that could not be found initially in its proper place: under the headline “Part B Section 3”.
June 2024	Initial zRMS assessment In order to facilitate tracking of changes of the intended uses of the product due to the performed evaluation, amendments of the GAP table and in the product label (Appendix 2) and Lists of data considered for national authorization (Appendix 4) are highlighted in grey, while not agreed use pattern is struck through and shaded. 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.
August 2024	Final report (National Assessment updated following the commenting period) No additional information or assessments after the commenting period.
September 2024	Updated Final report (National Assessment updated with consideration the comments received from Ministry of Agriculture after commenting period process) Additional information/assessments included by the zRMS in the report are highlighted in yellow. Not agreed or not relevant information are struck through and shaded for transparency.
October 2024	Updated Final report (National Assessment updated after LoA submission) Additional information included by the zRMS in the report are highlighted in yellow. Not agreed or not relevant information are struck through and shaded for transparency.

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PART A

RISK MANAGEMENT

1 Details of the application

This document describes the specific conditions of use and labelling required for Poland for the authorisation of the plant protection product SAP50SCF, a suspension concentrate (SC) formulation containing 500 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.

1.1 Application background

This application was submitted to allow the registration of SAP50SCF, a SC formulation containing 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	SAP50SCF
Product name in MS	FOLPEC

Authorization number	Not authorized yet.
Function	Fungicide
Applicant	Selectis Produtos para a Agricultura, S.A.
Active substance(s) (incl. content)	Folpet: 500 g/L
Formulation type	Suspension concentrate [Code: SC]
Packaging	Size: 250 mL, 1 L, 5 L, 10 L, 20 L, Packaging type: HDPE, Coex PA, Coex EVOH Professional
Coformulants of concern for national authorizations	None
Restrictions related to identiy	None
Mandatory tank mixtures	Not applicable
Recommended tank mixtures	Not applicable

2.2 Conclusion

The evaluation of the application for Folpec 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 Folpec 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 Folpec 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 Folpec 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:	Eye Irrit. 2, Skin Sens. 1 and Carc.2, Aquatic Chronic 1 \neq Aquatic Acute 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 must be determined for the **label is formatted bold**:

Hazard pictograms:	GHS07, GHS08 and GHS09
Signal word:	Warning

Hazard statement(s):	H319, H317, H351 and H410
Precautionary statement(s):	<p>P102: Keep out of reach of children P201: Obtain special instructions before use P261: Do not breathe dust/fume/gas/mist/vapours/spray. P302 + P352: IF ON SKIN: Wash with plenty of water/... P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308 + P313: IF exposed or concerned: Get medical advice/attention. P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P337 + P313: If eye irritation persists: Get medical advice/attention. P362 + P364: Take off contaminated clothing and wash it before reuse. P280: Wear protective gloves/protective clothing/eye protection/face protection. P405: Store locked up. P501: Dispose of the contents/containers in accordance with the current legislation on waste treatment</p>
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:	
-	-

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 vegetated buffer zone of 20 meters to surface water bodies

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 protective gloves/protective clothing during mixing/loading and application. In addition, the use of eye 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, long trousers and long-sleeved shirt should be worn. The use of gloves is recommended.
Integrated pest management (IPM)/sustainable use:	

Environmental protection	
SPe3	To protect aquatic organisms respect vegetated buffer zone of 20 meters to surface water bodies
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.
SPe3	To protect aquatic organisms respect vegetated buffer zone of 20 meters to surface water bodies	All uses

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code): SAP50SCF
Active substance 1: folpet
Active substance 2: -
Safener: -
Synergist: -
Applicant: Selectis Produtos para a Agricultura, S.A.
Zone(s): central ^(d)
Verified by MS: ~~yes~~/no
Field of use: fungicide

GAP rev. 2 ⁺, date: June 2024 ~~June 2022~~

Formulation type: SC ^(a, b)
Conc. of as 1: 500 g/L
Conc. of as 2: conc. ^(c)
Conc. of safener: conc. ^(c)
Conc. of synergist: conc. ^(c)
Professional use: X
Non professional use: ☐

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15							
Use- No. (e)	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 : development al stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha ^(f)	zRMS conclusion							
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. 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 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	Poland	Soft wheat (spring) (TRZAS); Soft wheat (winter) (TRZAW); Durum wheat (spring) (TRZDS); Durum wheat (winter) (TRZDW)	F	<i>Septoria</i> (SEPTTR)	Tractor mounted spray	BBCH 30-59	a) 2 b) 2	14	a) 1,2 L/ha b) 2,4 L/ha	a) 600 g ai/ha b) 1200 g ai/ha	150-400	42		A	A	A	A	A	R Aquatics (R1 scenario)	A	A TRZAW TRZAS
																			A Remained species		N TRZDW TRZDS (possible registration on the grounds of article 51)
2	Poland	Barley (spring) (HORVS);	F	<i>Helminthosporium</i> (PYRNTE)	Tractor mounted spray	BBCH 30-59	a) 2 b) 2	14	a) 1,2 L/ha b) 2,4 L/ha	a) 600 g ai/ha b) 1200 g	150-400	42		A	A	A	A	A	Aquatics (R1 scenario)	A	N

Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(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.

* Explanation for column 15 “Overall conclusions”

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible

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 cream liquid suspension concentrate, with a characteristic odour. It is not explosive, has no oxidising properties. No flash point was observed. It did not self-ignite at temperature of up to 400 °C. In aqueous solution, it has a pH value around 6.0 at 20.1 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active 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 PA and Coex EVOH. Its technical characteristics are acceptable for a *suspension concentrate* formulation. The intended concentration of use is 0.3% to 0.8%.

No tank mixes are recommended.

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

The product SAP50SCF complies with FAO specifications.

3.2 Efficacy (Part B, Section 3)

SAP50SCF is a Suspension Concentrate (SC) containing 500 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 Central European Union zone.

In conclusion, it has been proved that **SAP50SCF** provided satisfying efficacy to control *Septoria (Zimoseptoria tritici)* in wheat at the dose rate of 1.2 L/ha. On the contrary, the efficacy in barley in control of *Helminthosporium (Pyrenophora teres)* has been demonstrated insufficiently to allow for authorization in Poland: only 2 valid trials have been submitted in the NE zone overall.

3.3 Efficacy data

A total of 38 (30) efficacy trials have been presented in wheat and barley. All trials included multiple rates of **SAP50SCF** in order to justify the minimum effective dose. Data have demonstrated that the proposed dose of 0.9 L/ha has achieved insufficient and inconsistent control of both target pathogens and that the dose of 1.2 L/ha is necessary to control the diseases in any conditions. Furthermore, another 2 trials have been performed and are on-going, in Maritime EPPO zone, in Barley against *Helminthosporium*.

The requested doses (0.9 L/ha and 1.2 L/ha) have been compared to reference authorized products. Average efficacy values reported of trials conducted showed a robust control of the diseases only at the 1.2 L/ha dose rate, similar to reference products which were tested. The 0.9 L/ha dose rate proved inadequate. These data are sufficient to confirm the effectiveness of SAP50SCF against *Septoria (Zimoseptoria tritici)* in wheat at 1.2 L/ha.

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

Requested GAP of **SAP50SCF** complies with specific recommendations of FRAC to the management the phthalimide fungicides. **SAP50SCF** is a product which complies with recommendations of FRAC to avoid development of resistance, as the active Folpet shows multi-site activity, thus being itself a tool for a good resistance management.

In order to play a role of the effective mixture partner for other actives, **SAP50SCF** must always be used at its target dose rate of **1.2 L/ha**.

3.3.2 Adverse effects on treated crops

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

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

Trials which were done to evaluate the effects of **SAP50SCF** at 1.5 l/ha (1.25 N dose rate) on barley for brewing and on wheat for bread-making, showed consistent results to demonstrate the absence of non-intentional effects.

3.4 Methods of analysis (Part B, Section 5)

Methods of analysis for the quantification of 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 substance folpet in SAP50SCF. A HPLC-PDA method was submitted to analyse the active ingredient in the formulation. The method was successfully validated.

Perchloromethylmercaptan and carbon tetrachloride are considered relevant impurities of folpet. Two analytical methods were submitted for the determination of those impurities. Both methods were considered fully validated.

3.4.2 Analytical methods for residues

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.

The SAP50SCF / Folpet 500 SC product is intended to be used in cereals (wheat and barley).

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

Sufficient analytical methods for the determination of folpet (phthalimide, 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/m³ 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.

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

Noticed data gaps are:

- lower LOQ at 0.01 mg/L for phthalimide for body fluids. This data gap should be addressed at active substance level.

3.5 Mammalian toxicology (Part B, Section 6)

3.5.1 Acute toxicity

Hazard class(es), categories	Eye Irrit. 2, Skin Sens. 1 and Carc.2
Hazard pictograms or Code(s) for hazard pictogram(s)	GHS07 and GHS08
Signal word	Warning
Hazard statement(s)	H319: Causes serious eye irritation. H317: May cause an allergic skin reaction H351: Suspected of causing cancer.
Precautionary statement(s)	P102: Keep out of reach of children P201: Obtain special instructions before use P261: Do not breathe dust/fume/gas/mist/vapours/spray. P302 + P352: IF ON SKIN: Wash with plenty of water/... P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308 + P313: IF exposed or concerned: Get medical advice/attention. P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P337 + P313: If eye irritation persists: Get medical advice/attention. P362 + P364: Take off contaminated clothing and wash it before reuse. P280: Wear protective gloves/protective clothing/eye protection/face protection. P405: Store locked up. 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]
Other phrases:	Operator must wear adequate protective gloves/protective clothing during mixing/loading and application. In addition, the use of eye protection is required during mixing/loading. Treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried. In case a worker enters the treated area, long trousers and long-sleeved shirt should be worn. The use of gloves is recommended.

Product information and toxicological reference values used for exposure assessment

Product name and code	SAP50SCF / FOLPECE
Formulation type	SC
Category	Fungicide
Active substance(s) (incl. content)	Folpet 500 g/L
AOEL systemic	0.1 mg/kg bw/d
Inhalation absorption	100%
Oral absorption	100%
Dermal absorption	Concentrate: 0.5% Dilution: 5.2 % (1.125 g/L, based on <i>pro rata</i> approach. Please see section A 2.10.1 for detailed calculations) (Based on product (Folpet 50 SC))

3.5.2 Operator exposure

The operator exposure to SAP50SCF was not evaluated as part of the EU review of 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 folpet using the following models:

	Model(s)
Field	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. https://doi.org/10.2903/j.efsa.2022.7032

According to the results obtained from EFSA on-line calculator an acceptable risk was verified for operator without specific mitigations measures. However, considering classification of the formulation as H317 and H351, the use of protective gloves/protective clothing is required during mixing/loading and application. In addition, considering classification as considering classification of the formulation as H319, the use of eye protection is required during mixing/loading.

Overall, the following phrases should be included in the product label:

“Operator must wear adequate protective clothing and protective gloves during mixing/loading and application. In addition, the use of eye protection is required during mixing/loading”.

3.5.3 Worker exposure

The worker exposure to SAP50SCF was not evaluated as part of the EU review of 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 folpet using the following models:

	Model(s)
Field	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. https://doi.org/10.2903/j.efsa.2022.7032

An acceptable risk has been identified for a worker re-entering the treated field, even without gloves, assuming only adequate work clothing.

However, considering classification of the formulation as H317 and H351, the use of gloves is recommended.

In terms of good agriculture practice, 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, long trousers and long-sleeved shirt should be worn. The use of gloves is recommended”.

3.5.4 Bystander and resident exposure

The resident exposure to SAP50SCF was not evaluated as part of the EU review of 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 folpet using the following models:

	Model(s)
Field	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. https://doi.org/10.2903/j.efsa.2022.7032

According to the results obtained from EFSA calculator an acceptable risk was verified for resident. No specific mitigations measure it was considered necessary.

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

3.6.1 Residues

The proposed uses for SAP50SCF are wheat and barley.

New information regarding the nature of the residue in plants and animals has not been provided. Available information from the DAR and RAR has been considered enough to support the proposed use in cereals.

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.

Wheat and barley are the major crops in northern Europe. A minimum of eight trials representative of the proposed growing area are required (SANTE/2019/12752).

16 independent trials were conducted in Northern Europe according to the OECD Test No. 509 to gain the residue level of folpet and its two metabolites phthalimide and phthalic acid in wheat (8 trials) and barley (8 trials) specimens (whole plant, grain and straw) following two foliar applications of SAP50SCF, containing folpet as active ingredient (500 g a.s./L, equivalent to 600 g a.s./ha).

Trials GAP for wheat: 2 x 0.60 kg a.s. /ha with 12-21 days between application, up to BBCH 61, PHI 34-78 days.

Trials GAP for barley: 2 x 0.60 kg a.s. /ha with 12-21 days between application, up to BBCH 61, PHI 34-50 days.

The presented residue trials cover the intended uses.

The residues of folpet (sum of folpet and phthalimide expressed as folpet) in the wheat grain samples were $4 \times < 0.03$, 0.032, 0.044, 0.060, 0.087 mg/kg.

The residues of folpet (sum of folpet and phthalimide expressed as folpet) in the barley grain samples were < 0.03 , 0.047, 0.050, 0.072, 0.28, 0.29, 0.34, 0.75 mg/kg.

The value of EU MRL for folpet on wheat and barley equals 0.4 mg/kg and 2 mg/kg, respectively (Reg. (EU) 2023/1042). The residues arising from the proposed uses will not exceed the MRLs established for cereals.

The current EU MRLs for folpet are sufficient to support the proposed uses.

Additional studies are not required to support the proposed uses of SAP50SCF.

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.

Data gaps:

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

3.6.2 Consumer exposure

The consumer risk assessment has been performed with the MRLs as they are set in Regulation (EU) No 2023/1042 (TMDI).

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 SAP50SCF do not represent unacceptable acute and chronic risks for the consumer.

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

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

The PEC_{soil} of SAP50SCF and the active substance folpet were calculated using equations proposed in the FOCUS soil persistence. For all compounds, EU agreed data were taken into account. The PEC_{soil} 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_{soil} for the active substance and its metabolites were used for the ecotoxicological risk assessment.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

The leaching behaviour of folpet and its soil metabolites 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 of SAP50SCF. Performed calculations resulted with PEC_{GW} values <0.1 µg/L in all relevant Polish scenarios for folpet and its metabolites following application to winter and spring cereals.

Based on the performed assessment no unacceptable leaching of folpet and its metabolites is expected when SAP50SCF is used according to recommendations.

Therefore, no groundwater contamination is expected for parent 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_{sw})

The surface water modelling was performed for the intended use pattern of SAP50SCF in line with recommendations of respective FOCUS guidance documents using most up-to-date versions of the models. Obtained PEC_{SW/SED} values were used in the risk assessment for aquatic organisms.

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

Vapour pressure of folpet is $>10^{-5}$ Pa, so volatilisation from soil and plant surfaces is possible. However, based on the air DT₅₀ <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 SAP50SCF.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

The risk assessment to birds and mammals was conducted according to the EFSA Guidance Document for the Risk Assessment for Birds and Mammals.

An acceptable risk was obtained for SAP50SCF at the screening phase for acute exposure and at the first-tier for long-term exposure. The risk assessment for drinking water was not triggered. An acceptable risk was also obtained for the secondary poisoning scenarios. Overall, birds present an acceptable risk towards SAP50SCF when used according to the proposed application patterns.

An acceptable risk was obtained for SAP50SCF at the screening phase for both acute and long-term exposure. The risk assessment for drinking water was not triggered. An acceptable risk was also obtained for the secondary poisoning scenarios. Overall, mammals present an acceptable risk to-wards SAP50SCF when used according to the proposed application patterns.

3.8.2 Effects on aquatic species

An acceptable risk of SAP50SCF can be concluded when the appropriate mitigation measures are in place:

Dose	Application number	Mitigation measure
Maximum dose 600 g a.s./ha	Multiple (2x)	20 meter vegetative buffer zone

3.8.3 Effects on bees

Acceptable acute risk was determined towards bees (honey, bumblebees) after exposure to SAP50SCF in the proposed application patterns. No chronic studies for adult bees and larvae bees are required for formulation SAP50SCF due to those chronic studies for the a.s. – folpet are available and cover the formulation studies. No chronic risk assessment is required for Poland until Bee GD will be applied at EU level.

3.8.4 Effects on other arthropod species other than bees

The risk assessment for non-target arthropods was conducted according to SANCO/10329/2002 rev 2 final, and in consideration of the recommendations of the guidance document ESCORT 2.. Acceptable in- and off-field risks were determined towards bees after exposure to SAP50SCF in the proposed application patterns.

3.8.5 Effects on soil organisms

The risk assessment for soil macro- and mesofauna was conducted according to SANCO/10329/2002 rev 2 final. An acceptable risk is proven for earthworms when exposed to the active substance, its metabolites and the formulated product. No data on springtail and mites is submitted since no unacceptable risks were concluded for non-target terrestrial arthropods and earthworms. Therefore, springtail and mites are not expected to be affected at the proposed application rates.

The risk assessment for microorganisms was conducted according to SANCO/10329/2002 rev 2 final. An acceptable risk is proven for microorganisms when exposed to the active substance, its metabolites and the formulated product.

3.8.6 Effects on non-target terrestrial plants

The risk assessment for non-target terrestrial plants was conducted according to SANCO/10329/2002 rev 2 final. Since folpet is a fungicide, a tier 1 risk assessment was conducted, and an acceptable risk is proven when SAP50SCF is applied at the proposed application rates.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

No available data and not relevant as an acceptable is proven for all assessed organisms.

3.9 Relevance of metabolites (Part B, Section 10)

The metabolites phthalimide, phthalamic acid and phthalic acid are predicted to occur in groundwater at concentrations below 0.1 µg/L (see chapter 8.8.1 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

Efficacy:

The following uses have not been accepted for authorization following article 33 of the regulation 1107/2009:

- the control of PYRNTE in winter and spring barley,
- the control of SEPTTR in winter and spring durum wheat.

In order to enable authorization of the use in barley against PYRNTE in Poland, 4 additional trials are required, preferably from the North-East EPPO zone, but possibly also from the neighboring CZ, DE or SK. This supplementary data set should also include spring barley.

Authorization of the use in durum wheat (winter and spring) is possible following the article 51 of the regulation 1107/2009, i.e. without efficacy trials.

Analytical methods:

- lower LOQ at 0.01 mg/L for phthalimide for body fluids is required. This data gap should be addressed at active substance level.

~~Metabolism and residues:~~

~~— the applicant should submit a letter of access to the metabolism study 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, toksykologii i istotności toksykologicznej metabolitów, pozostałości, losu i zachowania, ekotoksykologii oraz skuteczności. Zmiany wynikające z oceny wprowadzono do poniższej etykiety w widoczny sposób, poprzez zaznaczenie ich szarym podświetleniem tekstu (fragmenty dodane) lub ~~przekreśleniem~~ i jasno-szarym ~~czcionką~~ (fragmenty usunięte).

Sekcja właściwości fizykochemiczne:

1. Środek nie wykazuje właściwości wybuchowych i utleniających, znakowanie środka wynikające z wyżej wymienionych właściwości fizykochemicznych zgodne z zapisami Rozporządzenia Parlamentu Europejskiego i Rady (WE) NR 1272/2008 z dnia 16 grudnia 2008 r. nie jest wymagane.
2. Okres ważności: 2 lata na podstawie 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 czynnej (zgodnie z punktem 2.6.1 Sekcji 1,2,4 gęstość $d=1,24$).
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. Spośród 68 badań przedłożonych ogółem, do rejestracji środka w Polsce przydatne były 24 badania, w tym 10 badań skuteczności i łącznie 14 badań dotyczących wpływu na rośliny sąsiadujące i następce, procesów transformacji oraz mycia opryskiwacza. Spośród badań skuteczności 8 dotyczy zwalczania *Zymoseptoria tritici* w pszenicy (4 badania z Polski i 4 z Niemiec), a 2 – zwalczania *Pyrenophora teres* w jęczmieniu (wyłącznie badania z Polski). Przeciwnie niż dla pszenicy, dla zwalczania *Pyrenophora teres* w jęczmieniu wnioskodawca nie przedstawił żadnych badań z krajów sąsiadujących z Polską, które mogłyby stanowić wsparcie dla danych ze strefy Północno-Wschodniej.
2. W oparciu o dobre wyniki skuteczności możliwe jest zarejestrowanie wnioskowanego środka do zwalczania *Zymoseptoria tritici* w pszenicy ozimej w dawce 1,2 L/ha, w fazie BBCH 30-59, która znajduje pokrycie w terminach wykonywania zabiegu w przedłożonych badaniach. Jedno badanie na pszenicy jarej z Niemiec pozwala na ekstrapolację oceny skuteczności z pszenicy ozimej, zatem rejestracja w pszenicy jarej, w tej samej dawce i fazie rozwojowej, jest również możliwa.
3. W treści etykiety skorygowano dawkę zgodnie z wynikiem oceny: zakres dawek 0,9-1,2 l/ha nie jest uzasadniony wynikami badań skuteczności, zwłaszcza w zakresie badania minimalnej dawki skutecznej, gdzie wykazano niezadowalającą skuteczność dawki 0,9 l/ha.
4. Nie wprowadzono do etykiety zastosowania w jęczmieniu do zwalczania plamistości siatkowej, z powodu niewystarczającej liczby badań w strefie Północno-Wschodniej i całkowitego braku badań z krajów ościennych (Czechy, Niemcy, Słowacja). Wnioskowany środek jest **nowym** produktem **znanej** substancji. Zdaniem eksperta, uzasadnione może być zatem zarejestrowanie warunkowe tego zastosowania, z uwagi na dobrą skuteczność przeciwko *P. teres*, przekraczającą w tych dwóch badaniach z Polski 80%. Jak zaznaczono w pkt. 5 Part A: „Further information to permit a decision [...], niezbędne do tego byłyby dane z 4 badań skuteczności przeciwko *P. teres* w jęczmieniu, ze strefy Północno-Wschodniej EPPO (preferowane), lub przynajmniej z krajów sąsiadujących ze stref Południowo-Wschodniej lub Morskiej. Zestaw powinien uwzględniać także jęczmień jary (minimum jedno z badań).
5. Z etykiety wykreślono zastosowanie w jęczmieniu do zwalczania rynchosporiozy w jęczmieniu, które nie jest przedmiotem niniejszego wniosku.
6. W oparciu o dobre wyniki skuteczności w zwalczaniu *Z. tritici* w pszenicy ozimej i jarej (*T. aestivum*), pomimo braku badań z pszenicy twardej (*T. durum*) ozimej i jarej, możliwe jest zarejestrowanie środka do analogicznego zastosowania w tych uprawach, ponieważ są one w Polsce uprawami małoobszarowymi.
7. Uzupełniono zaproponowane przez wnioskodawcę zalecenia w zakresie mycia opryskiwacza po zabiegu.
8. Wbrew deklaracji w części B3 wnioskodawca nie proponował strategii antyodpornościowej, lecz zdaniem eksperta jest to dopuszczalne z uwagi na wieloraki mechanizm działania fungicydów z grupy M4, do której należy substancja czynna folpet. Ograniczenie liczby zabiegów w sezonie oraz przestrzeganie dawki 1,2 l/ha stanowi wystarczający ekwiwalent takiej strategii. Folpet nadaje się do łącznego stosowania z innymi

fungicydami, ale nie jest to przedmiotem niniejszego wniosku. Dlatego w tym zakresie również nie wprowadzono dodatkowych sugestii w etykiecie.

Sekcja metody analityczne:

1. Brak uwag.

Sekcja toksykologia i istotność toksykologiczna metabolitów:

1. W części etykiety dotyczącej klasyfikacji CLP odpowiednie zwroty określające zagrożenia oraz zwroty wskazujące środki ostrożności zostały zmodyfikowane zgodnie z *Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008*, Version 4.2 March 2021.
2. W części etykiety dotyczącej pierwszej pomocy umieszczono zwroty: „*W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza*” oraz „*W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza.*”, oba zwroty są zawarte w części B6 Tabela 6.1-2.
3. W części etykiety dotyczącej środków ostrożności dla osób stosujących środek odpowiedni zapis zmodyfikowano zgodnie z wymaganiami harmonizacyjnymi ponadto zostały dodane zwroty wynikające z klasyfikacji CLP (Zwroty wskazujące środki ostrożności – reagowania): *Zdjść zanieczyszczoną odzież i uprać ją przed ponownym użyciem* oraz *Chronić przed dziećmi*.
4. W odniesieniu do zwrotu H351 przypisanego s.cz. folpet, Recenzent usunął informację dotyczącą drogi narażenia. Zgodnie z raportem CLH przygotowanym przez DS. Austria (AGES) z dnia 15.06.2022, zmiany o charakterze nowotworowym były identyfikowane u myszy po narażeniu doustnym i dotyczyły odcinka jelita cienkiego (dwunastnica): „(..) Carcinogenicity attributable to oral administration of folpet has been demonstrated in a single species (mouse) and in a single target tissue (duodenum) in three independent studies(..). W wyżej wspomnianym raporcie CLH DS AT podtrzymał wcześniej zaakceptowany zwrot H351 (patrz: ECHA Current entry in Annex VI of CLP Regulation).

Sekcja pozostałości:

1. W zakresie pozostałości zaakceptowano zastosowanie środka w ochronie pszenicy i jęczmienia.
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. Usunięto zwrot P273.
2. Zmieniono 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

.....

FOLPEC 500 SC

Środek przeznaczony do stosowania przez użytkowników profesjonalnych.

Zawartość substancji czynnej:

folpet (substancja z grupy ftalimidów) - 500 g/l (40,3%)

Zezwolenie MRiRW nr R -

GHS07, GHS08, GHS09



UWAGA

H319 Działa drażniąco na oczy

H317 Może powodować reakcję alergiczną skóry

~~H332 Działa szkodliwie w następstwie wdychania.~~

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

~~P270: Nie jeść, nie pić ani nie palić podczas używania produktu~~

P261: Unikać wdychania rozpylonej cieczy

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

~~P273: Unikać uwalniania do środowiska~~

~~P301+P310: W PRZYPADKU POŁKNIECIA: natychmiast skontaktować się z OŚRODKIEM ZATRUĆ/lekarzem/~~

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

P302 + P352 W PRZYPADKU DOSTANIA SIĘ NA SKÓRĘ: Umyć dużą ilością wody lub...

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. Kontynuować płukanie.

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.

SP 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).

~~SPe3 Aby chronić organizmy wodne, należy przestrzegać nieopryskiwanej, porośniętej roślinnością strefy buforowej o długości 10 metrów od jednolitych części wód powierzchniowych w przypadku jednorazowego stosowania zbóż jarych.~~

~~SPe3 Aby chronić organizmy wodne, należy przestrzegać nieopryskiwanej, porośniętej roślinnością strefy buforowej o długości 5 metrów od jednolitych części wód powierzchniowych w wielu zastosowaniach w zbożach ozimych.~~

OPIS DZIAŁANIA

FUNGICYD w formie koncentratu w postaci stężonej zawiesiny (SC) o działaniu kontaktowym do stosowania zapobiegawczego.

STOSOWANIE ŚRODKA

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

Pszenica ozima i pszenica jara

Septorioza pszenicy

Maksymalna / zalecana dawka do jednorazowego stosowania: ~~1,5 l/ha~~ 1,2 l/ha.

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

Odstęp pomiędzy zabiegami: co najmniej 14 dni.

Terminy stosowania:

Środek stosować zapobiegawczo, w fazie BBCH 30-59 od fazy strzelania w źdźbło do końca fazy kłoszenia (BBCH 30-59)

Zalecana ilość wody: 150-400 l/ha.

Zalecane opryskiwanie: drobnokropliste.

~~Jęczmień ozimy i jęczmień jary~~

~~Rhynchosporioza zbóż~~

~~Maksymalna / zalecana dawka do jednorazowego stosowania: 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 30-59 od fazy strzelania w źdźbło do końca fazy kłoszenia (BBCH 30-59)~~

~~Zalecana ilość wody: 15-400 l/ha.~~

~~Zalecane opryskiwanie: drobnokropliste.~~

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 mieszałem). Opróżnione opakowania przeplukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową. Następnie zbiornik opryskiwacza uzupełnić wodą do potrzebnej ilości. Opryskiwać z włączonym mieszałem. Po wlaniu środka do zbiornika opryskiwacza niewyposażonego w mieszało 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, postępując zgodnie z zasadami dobrej praktyki ochrony roślin. Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy:

- jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

~~Po pracy aparatury dokładnie wymyć.~~

WARUNKI BEZPIECZNEGO STOSOWANIA ŚRODKA

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.

Środki ostrożności dla osób stosujących środek:

Chronić przed dziećmi

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

Zdjąć zanieczyszczoną odzież i uprać ją przed ponownym użyciem.

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 nienależących do celu 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 ~~5m~~ 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.

W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

Not relevant.

Appendix 4 Lists of data considered for national authorization

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte- brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
Part B Section 1,2,4							
KCP 2.1/01 KCP 2.4.2/01 KCP 2.5.1/01 KCP 2.5.2/01 KCP 2.6.1/01 KCP 2.7.1/01 KCP 2.7.4/01 KCP 2.8.3.1/01 KCP 2.8.3.2/01 KCP 2.8.5.1.1/01 KCP 2.8.5.1.2/01 KCP 2.8.7.2/01	Boas, P.	2011	Folpet 50 SC: Stability Study and Physical Properties of the Formulation Study EF/88/11 Final Report – Control sample and accelerated storage stability SAPEC 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 2.1/02 KCP 2.4.2/02 KCP 2.6.1/02 KCP 2.7.5/01 KCP 2.8.3.1/02 KCP 2.8.3.2/02 KCP 2.8.5.1.1/02	Vieira, R.	2013	Folpet 50 SC: Stability Study and Physical Properties of the formulation Study EF/88/11 – Final Report – T24 SAPEC 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 KCP 2.2.2/01	Correia, C.	2022	Theoretical Assessment of Explosive and Oxidising properties of Folpet 50 SC (SAP50SCF) Doc. no. TR/22/04 - Explosive and Oxidising Properties of SAP50SCF ASCENZA Agro, S.A. Non GLP Unpublished	N	N		ASCENZA Agro, S.A.
KCP 2.3.1/01 KCP 2.3.2/01 KCP 2.3.3/01	Campbell, N.	2011	Determination of specified phys-chem data for ‘FOLPET 50SC’, a suspension concentrate formulation, in compliance with Good Laboratory Practice. Study Number: OA02062 Oxford Analytical Ltd	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
			GLP Unpublished			previously granted at CEU zone.	
KCP 2.5.1/02 KCP 2.8.2/01 KCP 2.8.3.1/03 KCP 2.8.5.1.1/03	Morais, F.	2022	FOLPET 500 g/L SC (SAP50SCF) – Physical, chemical and technical properties of the plant protection product Study EF/375/21 – Final Report 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.
Part B Section 3							
KCP 3 (0)	ASCENZA AGRO	2022	Biological Assessment Dossier of SAP50SCF	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 (1)	Castella, G.	2020	Study the benefit of SAP50SCF in the preventions on resistances in Wheat against Zimoseptoria tritici under controled conditions. Italy 2021 Sagea Centro di Saggio s.r.l; 63-F-2020-FR01 GEP Unpublished	N	YES	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 6.2 (1)	Zöllner, H.	2020	Field study to evaluate the efficacy and crop selectivity of SAP50SCF against Septoria on Wheat Field Research Support; 17-F-2020-DE01 GEP Unpublished	N	YES	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 6.2 (2)	Herrera, D.	2020	Evaluate the efficacy of SAP50SCF against Septoria on Wheat STAPHYT; 17-F-2020-DE02 GEP Unpublished	N	YES	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-6.2 (3)	Biaunier, M.	2020	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 17-F-2020-FR01 GEP Unpublished	N	YES	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-6.2 (4)	Biaunier, M.	2020	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 17-F-2020-FR04 GEP Unpublished	N	YES	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-6.2 (5)	Biaunier, M.	2020	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 17-F-2020-FR05 GEP Unpublished	N	YES	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-6.2 (6)	Crepin, D.	2020	Evaluate the efficacy of SAP50SCF against Puccinia striiformis on Wheat ESSAIS+; 17-F-2020-FR06 GEP Unpublished	N	YES	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-6.2 (7)	Hernández, J.M.	2020	Evaluate the efficacy of SAP50SCF against Septoria on Wheat Agroensayos; 17-F-2020-SP01 GEP Unpublished	N	YES	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-6.2 (8)	Ord, S.	2020	Field study to evaluate the efficacy and crop selectivity Of SAP50SCF against Septoria on Wheat i2LResearch; 17-F-2020-UK01 GEP	N	YES	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation)	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			Data protection rights not previously granted at CEU zone.	
KCP 6.2 (9)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Septoria tritici and Puccinia recondita on Wheat. Bulgaria 2021 (EPPOSE). SAGEA OOD; 05-F-2021-BG01 GEP Unpublished	N	YES	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 6.2 (10)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Septoria tritici and Puccinia recondita on Wheat. Bulgaria 2021 (EPPOSE). SAGEA OOD; 05-F-2021-BG02 GEP Unpublished	N	YES	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 6.2 (11)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Septoria on Wheat (Germany) Field Research Support; 05-F-2021-DE01 GEP Unpublished	N	YES	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 6.2 (12)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Septoria on Wheat (Germany) Field Research Support; 05-F-2021-DE02 GEP Unpublished	N	YES	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 6.2 (13)	Biaunier, M.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 05-F-2021-FR01 GEP Unpublished	N	YES	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-6.2 (14)	Biaunier, M.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 05-F-2021-FR02 GEP Unpublished	N	YES	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-6.2 (15)	Biaunier, M.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 05-F-2021-FR03 GEP Unpublished	N	YES	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-6.2 (16)	Biaunier, M.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 05-F-2021-FR04 GEP Unpublished	N	YES	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-6.2 (17)	Szénási, Z.R.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat Agrofil SZMI Kft.; 05-F-2021-HU01 GEP Unpublished	N	YES	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-6.2 (18)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Zymoseptoria tritici on Wheat, Italy 2021 SAGEA Centro di Saggio s.r.l.; 05-F-2021-IT01 GEP Unpublished	N	YES	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-6.2 (19)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Zymoseptoria tritici on Wheat, Italy 2021 SAGEA Centro di Saggio s.r.l.; 05-F-2021-IT02 GEP	N	YES	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation)	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			Data protection rights not previously granted at CEU zone.	
KCP 6.2 (20)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Septoria on Wheat (Poland) FIELD RESEARCH SUPPORT; 05-F-2021-PL01 GEP Unpublished	N	YES	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 6.2 (21)	Rusek, K.	2021	Evaluate the efficacy of mixtures based on SAP50SCF against Septoria on Winter Wheat, Poland Fertico Sp. z.o.o.; 05-F-2021-PL02 GEP Unpublished	N	YES	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 6.2 (22)	Herrera, D.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat STAPHYT; 05-F-2021-PL04 GEP Unpublished	N	YES	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 6.2 (23)	Herrera, D.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat STAPHYT; 05-F-2021-PL05 GEP Unpublished	N	YES	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 6.2 (24)	Botoman, G.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat AgroProspect SRL; 05-F-2021-RO01 GEP Unpublished	N	YES	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-6.2 (25)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Septoria on Wheat (United Kingdom) Field Research Support; 05-F-2021-UK01 GEP Unpublished	N	YES	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-6.2 (26)	Hernández, J.M.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat AGROENSAYOS, ENSAYOS Y TÉCNICAS AGRÍCOLAS S.L.; 05-F-2021-SP01 GEP Unpublished	N	YES	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-6.2 (27)	Hernández, J.M.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat AGROENSAYOS, ENSAYOS Y TÉCNICAS AGRÍCOLAS S.L.; 05-F-2021-SP02 GEP Unpublished	N	YES	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-6.2 (28)	Zöllner, H.	2020	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley Field Research Support; 18-F-2020-DE01 GEP Unpublished	N	YES	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-6.2 (29)	Zöllner, H.	2020	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley Field Research Support; 18-F-2020-DE02 GEP Unpublished	N	YES	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-6.2 (30)	Biaunier, M.	2020	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley QUALIPHYT; 18-F-2020-FR01 GEP	N	YES	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation)	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			Data protection rights not previously granted at CEU zone.	
KCP-6.2 (31)	Biaunier, M.	2020	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley QUALIPHYT; 18-F-2020-FR02 GEP Unpublished	N	YES	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-6.2 (32)	Rivet, J.	2020	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley ESSAIS+; 18-F-2020-FR03 GEP Unpublished	N	YES	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-6.2 (33)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Pyrenophora teres on Barley, Bulgaria 2021 (EPPOSE). SAGEA OOD; 06-F-2021-BG01 GEP Unpublished	N	YES	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-6.2 (34)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Pyrenophora teres on Barley, Bulgaria 2021 (EPPOSE). SAGEA OOD; 06-F-2021-BG02 GEP Unpublished	N	YES	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-6.2 (35)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Helminthosporium on Barley (Germany) Field Research Support; 06-F-2021-DE01 GEP Unpublished	N	YES	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-6.2 (36)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Helminthosporium on Barley (Germany) Field Research Support; 06-F-2021-DE02 GEP Unpublished	N	YES	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-6.2 (37)	Crepin, D.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley ESSAIS+; 06-F-2021-FR01 GEP Unpublished	N	YES	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-6.2 (38)	Crepin, D.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley ESSAIS+; 06-F-2021-FR02 GEP Unpublished	N	YES	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-6.2 (39)	Crepin, D.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley ESSAIS+; 06-F-2021-FR03 GEP Unpublished	N	YES	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-6.2 (40)	Biaunier, M.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley QUALIPHYT; 06-F-2021-FR04 GEP Unpublished	N	YES	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-6.2 (41)	Biaunier, M.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley QUALIPHYT; 06-F-2021-FR05 GEP	N	YES	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation)	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			Data protection rights not previously granted at CEU zone.	
KCP 6.2 (42)	Herrera, D.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley, GEP Trial, FRANCE, 2021 STAPHYT; 06-F-2021-FR07 GEP Unpublished	N	YES	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 6.2 (43)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Ramularia collo-cygni on Barley, Italy 2021 SAGEA Centro di Saggio s.r.l.; 06-F-2021-IT01 GEP Unpublished	N	YES	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 6.2 (44)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Ramularia collo-cygni on Barley, Italy 2021 SAGEA Centro di Saggio s.r.l.; 06-F-2021-IT02 GEP Unpublished	N	YES	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 6.2 (45)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Helminthosporium on Barley (Poland) Field Research Support; 06-F-2021-PL01 GEP Unpublished	N	YES	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 6.2 (46)	Rusek, K.	2021	Evaluate the efficacy of mixtures based on SAP50SCF against Helminthosporium on winter barley, Poland 2020/2021 Fertico Sp. z.o.o.; 06-F-2021-PL02 GEP Unpublished	N	YES	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-6.2 (47)	Herrera, D.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley GEP Trial, POLAND, 2021 STAPHYT; 06-F-2021-PL04 GEP Unpublished	N	YES	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-6.2 (48)	Herrera, D.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley GEP Trial, POLAND, 2021 STAPHYT; 06-F-2021-PL05 GEP Unpublished	N	YES	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-6.2 (49)	Botoman, G.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley GEP Trial, ROMANIA, 2021 AgroProspect; 06-F-2021-RO01 GEP Unpublished	N	YES	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-6.2 (50)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Helminthosporium on Barley (United Kingdom) Field Research Support; 06-F-2021-UK01 GEP Unpublished	N	YES	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-6.2 (51)	Hernández, J.M.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley AGROENSAYOS, ENSAYOS Y TÉCNICAS AGRÍCOLAS S.L.; 06-F-2021-SP01 GEP Unpublished	N	YES	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-6.2 (52)	Hernández, J.M.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley AGROENSAYOS, ENSAYOS Y TÉCNICAS AGRÍCOLAS S.L.; 06-F-2021-SP02	N	YES	Product data submitted with an application under Article 33 of the Regulation (new product under Regulation)	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
			GEP Unpublished			Data protection rights not previously granted at CEU zone.	
KCP 6.2 (53)	Herrera, D.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley, GEP Trial, FRANCE, 2021 STAPHYT; 06 F 2021 FR06 GEP Unpublished	N	YES	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 6.2 (54)	Kasztner, G.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley Agrofili SZMI Kft.; 06 F 2021 HU01 GEP Unpublished	N	YES	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 6.4 (1)	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	YES	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 6.4 (2)	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	YES	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 6.4 (3)	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	YES	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 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-FR02 GEP Unpublished	N	YES	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 6.4 (5)	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	YES	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 6.4 (6)	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	YES	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 6.4 (7)	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	YES	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 6.4 (8)	Gless, A.E.	2021	INTERMEDIARY STUDY REPORT N°2: MALTING STUDY 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	YES	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 6.4 (9)	Gaia, U.	2021	EVALUATION OF NON-INTENTIONAL EFFECTS OF SAP2101F AND SAP50SCF ON TRANSFORMATION PROCESS (BREWING) ON BARLEY – ITALY (2021)	N	YES	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
			SAGEA Centro di Saggio s.r.l.; 26-TT-BW-2021-IT01 GEP Unpublished			product under Regulation) Data protection rights not previously granted at CEU zone.	
KCP 6.4 (10)	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	YES	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 6.5 (1)	Morais, F.	2022	FOLPET 500 g/L SC (SAP50SCF) Effectiveness of Cleaning Procedure ASCENZA Agro, S.A.; Study EF/376/21 GLP Unpublished	N	YES	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 6.5 (2)	Eley, R.	2008	Evaluation of the Phytotoxicity of Folpet 80% WG Non Target Terrestrial Plant Seedling Emergence and Growth Test AgroChemex Ltd.; ACE-08-259 GLP Unpublished	N	YES	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 6.5 (3)	Gless, A.E.	2021	INTERMEDIARY STUDY REPORT N°2: MALTING STUDY 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	YES	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 6.0 (1)	Eley, R.	2008	Evaluation of the Phytotoxicity of Folpet 80% WG Non Target Terrestrial Plant Vegetative Vigour Test AgroChemex Ltd.; ACE-08-260 GLP Unpublished	N	YES	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
						previously granted at CEU zone.	
Part B Section 5							
KCP 5.1.1/01	Morais, F.	2022	FOLPET 500 g/L SC (SAP50SCF): Physical, chemical and technical properties of the plant protection product Report No EF/375/21 – Final Report: Annex 1 – Folpet 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 5.1.1/02	Morais, F.	2022	FOLPET 500 g/L SC (SAP50SCF): Physical, chemical and technical properties of the plant protection product Report No EF/375/21 – Final Report: Annex 2 – 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 5.1.1/03	Morais, F.	2022	FOLPET 500 g/L SC (SAP50SCF): Physical, chemical and technical properties of the plant protection product Report No EF/375/21 – Final Report: Annex 3 – CCl4 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	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 5.1.2/02	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.

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 5.1.2/03	██████	2011	Acute toxicity of Folpet Sapec 500 SC to Rainbow Trout (Oncorhynchus mykiss) in a 96-hour semi static test ██████ 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 5.1.2/04	██████	2007	Acute toxicity of Folpet 80 WG to Rainbow Trout (Oncorhynchus mykiss) in a 96-hour semi static test ██████ GLP Unpublished	Y	N	Product data submitted with an under Article 33 of the Regulation (new product under Regulation) in SEU zone and for renewal of a.s.	ASCENZA Agro, S.A.
KCP 5.1.2/05	Grade, R., Wydra, V.	2007	Acute toxicity of Folpet 80 WG to Daphnia magna in a semi static 48-hour immobilization test Ibacon Report No. 33892220 GLP Unpublished	N	N	Product data submitted with an under Article 33 of the Regulation (new product under Regulation) in SEU zone and for renewal of a.s.	ASCENZA Agro, S.A.
KCP 5.1.2/06	Grade, R., Wydra, V.	2007	Influence of Folpet technical to Daphnia magna in a reproduction test Ibacon Report No. 33881221 GLP Unpublished	N	N	Product data submitted with an under Article 33 of the Regulation (new product under Regulation) in SEU zone and for renewal of a.s.	ASCENZA Agro, S.A.
KCP 5.1.2/07	Turner, B.	2009	Analysis of Folpet 80% WG Spray Solutions Huntingdon Life Sciences Report No. ACX0104 GLP Unpublished	N	N	Product data submitted with an under Article 33 of the Regulation (new product under Regulation) in SEU zone and for renewal of a.s.	ASCENZA Agro, S.A.
KCP 5.1.2/08	Turner, B.	2009	Analysis of Folpet 80% WG Spray Solution Huntingdon Life Sciences Report No. ACX0105 GLP Unpublished	N	N	Product data submitted with an under Article 33 of the Regulation (new product under Regulation) in SEU zone and for renewal of a.s.	ASCENZA Agro, S.A.
KCP 5.1.2/09	Schreitmüller, J.	2016	Analysis of Folpet in dosage solutions from Honey Bee Larvae Toxicity Study TRC14-245BA IES Report No. 20150171 GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA Agro, S.A.
KCP 5.1.2/10	Gordo, J	2022	Validation of the Analytical Method for the Determination of Folpet and Metabolites Residues in Wheat	N	Y	Product data submitted with an application under Article	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. VAL22/21 Laboratório de Resíduos de Pesticidas ASCENZA AGRO, S.A. GLP Unpublished			33 of the Regulation (new product under Regulation) Data protection rights not previously granted at CEU zone.	
KCP 5.1.2/11	Hemm, C.	2024	Analysis of folpet in Test Samples obtained from AscDaph study (CLOVER-A-01-2023) Eurofins Report No. S23-106026 GLP Unpublished	N	Y		ASCENZA Agro, S.A
KCP 5.2/01 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 Source: ANADIAG Report No.: R B4225 Date: 07/07/2015 GLP: yes Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA 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	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA 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	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA Agro S.A. and ADAMA
KCP 5.2/05	Wiesner, F.	2016	Validation of the multi-residue method DFG-S19 for the determination of folpet and phthalimide in cereal grain and sunflower seeds – Amendment No. 1 Source: Eurofins Agrosience Services Chem GmbH Report No.: S16-00559 (BEL-1601V)	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA 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
			Date: 29/04/2016 GLP: yes Unpublished				
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	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA 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	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA 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	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA 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 Source: ANADIAG Report No.: R B4281 Date: 09/09/2015 GLP: yes Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA Agro S.A. and ADAMA
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 Agroscience Services Chem SAS	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA 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
			Report No.: S14-05780 Date: 13/04/2016 GLP: yes Unpublished				
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	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA 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	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA 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 GLP: yes Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA Agro S.A. and ADAMA
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	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA 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	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA 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				
KCP 5.2/16	Gordo, J.	2023	Cross validation of an internal extraction method from LabRP vs. an Extraction Method Applied in ¹⁴ 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
Part B Section 7							
KCP 7.2.1/01	J. Gordo	2024	Stability Study of Folpet and Metabolites in Cereals Stored Under Deep Freezing Conditions Laboratorio Residuos de Pesticidas Ascenza Agro SA. Report nº EST06/22 (study ongoing, final report May2024). Interim report for 12 months storage time. 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 7.2.1/02	S. Jooss	2024	Storage Stability of Folpet and its Metabolites in Various Matrices under Deep Frozen Conditions Eurofins Agrosience Services. Report N°: S22-07592 (study ongoing, final report May2024). Interim report for 12 months storage time. 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.

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 7.2.3/01 (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	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 7.2.3/02 (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 Agrosience Services Report No: S22-03719 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 7.2.3/03 (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	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 7.2.3/04 (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 Agrosience Services Report No: S22-01157 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 7.2.5/01 (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	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 7.2.5/02 (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	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.
KCA 6.1/01	A. Perny	2007	Frozen storage stability of residues of folpet in tomato RAC and processing fractions Report No A7068 Source 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.
KCA 6.3.1/01	A. S. Beauvalon	2021	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 (study plan) Report n° 21-00160 Analytical phase: QUT23/21 (study plan) Source 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.
KCA 6.3.1/02	A. S. Beauvalon	2021	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 (study plan) Report n° 21-00139 Analytical phase: QUT31/21 (study plan) Source 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.

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 6.5.1	M Fitzmaurice and B Mackenzie,	2007	[14C] 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	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.
KCA 6.5.3	C. Milhan	2021	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 (study plan) Report n° CMN-21-48321 Analytical phase: QUT33/21 (study plan) 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.
KCA 6.10	A.S. Beauvalon,	2021	Magnitude of the residue of folpet in honey produced from phacelia after two applications of SAP50SCF (Folpet 500 g/L, SC) at four trial sites in northern and southern Europe (study plan) Report n° 21-00141 Analytical phase: QUT19/21 (study plan) 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.
Part B Section 8							
KCP 9.2.4/01	Fernandes, V.	2022a	Predicted Environmental Concentrations of Folpet and its metabolites in Groundwater (PEC _{gw}) based on FOCUS PELMO 6.6.4, FOCUS PEARL 5.5.5 and MACRO 5.5.4 for risk assessment of SAP50SCF on Cereals ASC100-2022 non GLP Unpublished	N	N	-	ASCENZA Agro, S.A.
KCP 9.2.5/01	Fernandes, V.	2022b	Predicted Environmental Concentrations of Folpet and its metabolites in Surface Water and Sediment (PEC _{sw} and PEC _{sed}) based on Tiered FOCUS Approach for risk assessment of SAP50SCF on Cereals ASC101-2022	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				
Part B Section 9							
KCP 10.2.1/01		2011	Acute toxicity of folpet Sapec 500 SC to Rainbow Trout (<i>Oncorhynchus mykiss</i>) in a 96-hour semi static test N°. 63141230 GLP Unpublished	Y	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.2.1/02		2007	Acute toxicity of Folpet 80 WG to Rainbow Trout (<i>Oncorhynchus mykiss</i>) in a 96-hour semi static test N°. 33891230 GLP Unpublished	Y	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.2.1/03	Grade, R., Wydra, V.	2007	Acute toxicity of Folpet 80 WG to <i>Daphnia magna</i> in a semi-static 48-hour immobilization test Ibacon Report N°. 33892220 GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.2.1/04	Grade, R., Wydra, V.	2007	Influence of Folpet technical to <i>Daphnia magna</i> in a reproduction test Ibacon Report N°. 33881221 GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec 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 Report N°. 33893035 GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.2.1/05	Alves, D.	2023	Toxicity of SAP50SCF to the Water Flea <i>Daphnia magna</i> under Laboratory Conditions (48h Acute Immobilisation Test with Semi-static design) CloverStrategy Report N°. CLOVER-A-01-2023 GLP Unpublished	N	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)	Study not previously submitted.	ASCENZA AGRO S.A. (formerly Sapec 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 BioChem agrar Report N°. 15-10-48-167-B GLP	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly

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				Sapec 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 BioChem agrar Report N°. 15-10-48-114-B GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec 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 Report N°. TRC14-246BA GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.3.1.3/04	Ansaloni, T.	2015	Toxicity of FOLPET TECHNICAL on honey bee larvae (<i>Apis mellifera</i> L.) after repeated exposure under laboratory conditions Trialcamp Report N°. TRC14-245BA GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.3.2.1/01	Moll, M.	2007	Effects of Folpet 80 WG on the Predatory Mite <i>Typhlodromus pyri</i> in the laboratory—Dose response test Ibacon Report N°. 33895063 GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.3.2.2/01	Schwarz, A.	2011	Effects of Folpet Sapec 500 SC on the predatory mite <i>Typhlodromus pyri</i> , extended laboratory study – Dose response test Ibacon Report N°. 63142062 GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.3.2.2/02	Moll, M.	2007	Effects of Folpet 80 WG on the Lacewing <i>Chrysoperla carnea</i> , extended laboratory study—Dose response test Ibacon Report N°. 33898047 GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.3.2.2/03	Moll, M.	2007	Effects of Folpet 80 WG on the Ladybird Beetle <i>Coccinella septempunctata</i> , extended laboratory study—Dose response test Ibacon Report N°. 33897012 GLP	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec 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-10.3.2.2/04	Moll, M.	2007	Effects of Folpet 80 WG on the Parasitoid <i>Aphidius rhopalosiphii</i> , extended laboratory study— Aged residue test Ibacon Report N°. 33899003 GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP-10.4.1.1/01	Ansaloni, T.	2014	A laboratory test to determine the chronic (sub-lethal) effects of Folpet 80 WG to the earthworm <i>Eisenia foetida foetida</i> (Oligochaeta: Lumbricidae) in artificial substrate at 2% peat content Trialeamp Report N°. TRC14-250BA GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP-10.4.1.1/02	Ansaloni, T.	2014	A laboratory test to determine the chronic (sub-lethal) effects of Folpet 80 WG to the earthworm <i>Eisenia foetida foetida</i> (Oligochaeta: Lumbricidae) in artificial substrate at 5% peat content Trialeamp Report N°. TRC14-251BA GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP-10.4.1.1/03	Ansaloni, T.	2014	A laboratory test to determine the chronic (sub-lethal) effects of Folpet 80 WG to the earthworm <i>Eisenia foetida foetida</i> (Oligochaeta: Lumbricidae) in artificial substrate at 10% peat content Trialeamp Report N°. TRC14-252BA GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP-10.4.1.1/04	Lühns, U.	2007	Effects of Folpet 80 WG on Reproduction and Growth of Earthworms <i>Eisenia fetida</i> in Artificial Soil with 5% peat Ibacon Report N°. 33896022 GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP-10.4.1.1/05	Pavie, B.	2014	Effects of BCP324F on Reproduction and Growth of Earthworms <i>Eisenia fetida</i> in Artificial Soil with 5% Peat Ibacon Report N°. 84831022 GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec 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 10.5/01	Gimeno, C.	2015	Effects of the formulated product Folpet 80 WG on activity of the soil microflora under laboratory conditions Trialecamp Report N°. TRC14-299SM GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.6.2/01	Eley, R.	2009	Evaluation of the Phytotoxicity of Folpet 80% WG Non Target Terrestrial Plant Seedling Emergence and Growth Test (Based on OECD Guideline 208) AgroChemex Report N°. ACE-08-259 GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.6.2/02	Eley, R.	2009	Evaluation of the Phytotoxicity of Folpet 80% WG Non Target Terrestrial Plant Vegetative Vigour Test (Based on OECD Guideline 227) AgroChemex Report N°. ACE-08-260 GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.3.1.3/02	Marín, M.	2022	Folpet Technical: Honey Bee (Apis mellifera L.) Larval Toxicity Test following Repeated Exposure under Laboratory Conditions Eurofins Report N°. S21-05947 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.

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.1.1	████	2011a	Acute oral toxicity study of Folpet Sapec 50 SC in Rats ████ Study No. 401-1-01-2050 Date 2011-08-03 GLP: yes Not published	Y	N	Product data submitted with an under-data matching of Folpet	ASCENZA Agro, S.A.
KCP 7.1.2	████	2011b	Acute dermal toxicity study of Folpet Sapec 50 SC in Rats ████ Study No. 403-1-01-2051 Date 2011-08-03 GLP: yes Not published	Y	N	Product data submitted with an under-data matching of Folpet	ASCENZA Agro, S.A.
KCP 7.1.4	████	2011c	Acute dermal irritation study of Folpet Sapec 50 SC in rabbits ████ Study No. 406-1-01-2052 Date 2011-08-03 GLP: yes Not published	Y	N	Product data submitted with an under-data matching of Folpet	ASCENZA Agro, S.A.
KCP 7.1.5	████	2011d	Acute eye irritation study of Folpet Sapec 50 SC in rabbits ████ Study No. 407-1-01-2053 Date 2011-08-03 GLP: yes Not published	Y	N	Product data submitted with an under-data matching of Folpet	ASCENZA Agro, S.A.
KCP 7.1.6	████	2011e	Skin sensitization study of Folpet Sapec 50 SC by local lymph node assay in mice ████ Study No. 409-1-01-2054 Date 2011-08-02 GLP: yes Not published	Y	N	Product data submitted with an under-data matching of Folpet	ASCENZA Agro, S.A.
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 folpet. 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 6.1	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 folpet. 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 folpet. Data protection rights are expired	Makhteshim
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 folpet. 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 folpet. Data protection rights are expired	Makhteshim
KCA 6.2.1	Toia, R.F Collins, E.H	1994	Nature of residue (¹⁴ 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 folpet. Data protection rights are expired	Makhteshim
KCA 6.2.1	Cheng, H.M.	1980	[Carbonyl- ¹⁴ 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 folpet. 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 folpet. 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 6.2.2	████████	1997a	14C-folpet metabolism in the lactating goat (part A). ¹⁴ C trichloromethyl folpet: material balance of dosed radioactivity. ██████████ GLP, unpublished	N Y	N	Study submitted under first inclusion process of folpet. Data protection rights are expired	Makhteshim
KCA 6.2.2	████████	2015	Metabolism and disposition of [¹⁴ C]Folpet in the Laying Hen ████████ GLP, unpublished	Y	N	Study submitted under confirmatory data inclusion process of folpet. No data protected	ADM
KCA 6.5.1	M Fitzmaurice and E Mackenzie,	2007	[14C]-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 folpet. Data protection rights are expired	Makhteshim
KCP 3.2.2.1; (+)	Castella, G.	2020	Study the benefit of SAP50SCF in the preventions on resistances in Wheat against Zimoseptoria tritici under controlled conditions. Italy 2021 Sagea Centro di Saggio s.r.l.; 63 F 2020 FR01 GEP Unpublished	N	YES	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 3.2.2.1; KCP 3.2.3.1 (+)	Zöllner, H.	2020	Field study to evaluate the efficacy and crop selectivity of SAP50SCF against Septoria on Wheat Field Research Support; 17 F 2020 DE01 GEP Unpublished	N	YES	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 3.2.2.1; KCP 3.2.3.1	Herrera, D.	2020	Evaluate the efficacy of SAP50SCF against Septoria on Wheat	N	YES	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
(2)			STAPHYT; 17 F 2020 DE02 GEP Unpublished			Article 33 of the Regulation (new-product under Regulation) Data protection rights not previously granted at CEU zone.	
KCP 3.2.2.1; KCP 3.2.3.1 (3)	Biaunier, M.	2020	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 17 F 2020 FR01 GEP Unpublished	N	YES	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 3.2.2.1; KCP 3.2.3.1 (4)	Biaunier, M.	2020	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 17 F 2020 FR04 GEP Unpublished	N	YES	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 3.2.3.1 (5)	Biaunier, M.	2020	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 17 F 2020 FR05 GEP Unpublished	N	YES	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 3.2.2.1; KCP 3.2.3.1 (6)	Crepin, D.	2020	Evaluate the efficacy of SAP50SCF against Puccinia striiformis on Wheat ESSAIS+; 17 F 2020 FR06 GEP Unpublished	N	YES	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 3.2.2.1; KCP 3.2.3.1 (7)	Hernández, J.M.	2020	Evaluate the efficacy of SAP50SCF against Septoria on Wheat Agroensayos; 17 F 2020-SP01 GEP Unpublished	N	YES	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 3.2.2.1; KCP 3.2.3.1 (8)	Ord, S.	2020	Field study to evaluate the efficacy and crop selectivity Of SAP50SCF against Septoria on Wheat i2L Research; 17 F 2020-UK01 GEP Unpublished	N	YES	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 3.2.2.1; KCP 3.2.3.1 (9)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Septoria tritici and Puccinia recondita on Wheat. Bulgaria 2021 (EPPOSE). SAGEA OOD; 05 F 2021 BG01 GEP Unpublished	N	YES	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 3.2.2.1; KCP 3.2.3.1 (10)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Septoria tritici and Puccinia recondita on Wheat. Bulgaria 2021 (EPPOSE). SAGEA OOD; 05 F 2021 BG02 GEP Unpublished	N	YES	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 3.2.2.1; KCP 3.2.3.1 (11)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Septoria on Wheat (Germany) Field Research Support; 05 F 2021-DE01 GEP Unpublished	N	YES	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
						previously granted at CEU zone.	
KCP 3.2.2.1; KCP 3.2.3.1 (12)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Septoria on Wheat (Germany) Field Research Support; 05-F-2021-DE02 GEP Unpublished	N	YES	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 3.2.2.1; KCP 3.2.3.1 (13)	Biaunier, M.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 05-F-2021-FR01 GEP Unpublished	N	YES	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 3.2.2.1; KCP 3.2.3.1 (14)	Biaunier, M.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 05-F-2021-FR02 GEP Unpublished	N	YES	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 3.2.2.1; KCP 3.2.3.1 (15)	Biaunier, M.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 05-F-2021-FR03 GEP Unpublished	N	YES	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 3.2.2.1; KCP 3.2.3.1 (16)	Biaunier, M.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 05-F-2021-FR04 GEP Unpublished	N	YES	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
						protection rights not previously granted at CEU zone.	
KCP 3.2.2.1; KCP 3.2.3.1 (17)	Szónási, Z.R.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat Agrofil SZMI Kft.; 05 F 2021 HU01 GEP Unpublished	N	YES	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 3.2.2.1; KCP 3.2.3.1 (18)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Zymoseptoria tritici on Wheat. Italy 2021 SAGEA Centro di Saggio s.r.l.; 05 F 2021 IT01 GEP Unpublished	N	YES	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 3.2.2.1; KCP 3.2.3.1 (19)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Zymoseptoria tritici on Wheat. Italy 2021 SAGEA Centro di Saggio s.r.l.; 05 F 2021 IT02 GEP Unpublished	N	YES	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 3.2.2.1; KCP 3.2.3.1 (20)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Septoria on Wheat (Poland) FIELD RESEARCH SUPPORT; 05 F 2021 PL01 GEP Unpublished	N	YES	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 3.2.2.1; KCP 3.2.3.1 (21)	Rusek, K.	2021	Evaluate the efficacy of mixtures based on SAP50SCF against Septoria on Winter Wheat, Poland Fertico Sp. z o.o.; 05 F 2021 PL02 GEP	N	YES	Product data submitted with an application under Article 33 of the Regulation (new product	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			under Regulation) Data protection rights not previously granted at CEU zone;	
KCP 3.2.2.1; KCP 3.2.3.1 (22)	Herrera, D.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat STAPHYT; 05-F-2021-PL04 GEP Unpublished	N	YES	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 3.2.2.1; KCP 3.2.3.1 (23)	Herrera, D.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat STAPHYT; 05-F-2021-PL05 GEP Unpublished	N	YES	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 3.2.2.1; KCP 3.2.3.1 (24)	Botoman, G.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat AgroProspect SRL; 05-F-2021-RO01 GEP Unpublished	N	YES	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 3.2.2.1; KCP 3.2.3.1 (25)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Septoria on Wheat (United Kingdom) Field Research Support; 05-F-2021-UK01 GEP Unpublished	N	YES	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 3.2.2.1; KCP 3.2.3.1 (26)	Hernández, J.M.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat	N	YES	Product data submitted with an application under Article 33 of the	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
			AGROENSAYOS, ENSAYOS Y TÉCNICAS AGRÍCOLAS S.L.; 05-F-2021-SP01 GEP Unpublished			Regulation (new-product under Regulation)-Data protection rights not previously granted at CEU zone.	
KCP-3.2.2.1; KCP-3.2.3.1 (27)	Hernández, J.M.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat AGROENSAYOS, ENSAYOS Y TÉCNICAS AGRÍCOLAS S.L.; 05-F-2021-SP02 GEP Unpublished	N	YES	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-3.2.2.2; KCP-3.2.3.2 (1)	Zöllner, H.	2020	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley Field Research Support; 18-F-2020-DE01 GEP Unpublished	N	YES	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-3.2.2.2; KCP-3.2.3.2 (2)	Zöllner, H.	2020	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley Field Research Support; 18-F-2020-DE02 GEP Unpublished	N	YES	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-3.2.2.2; KCP-3.2.3.2 (3)	Biaunier, M.	2020	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley QUALIPHYT; 18-F-2020-FR01 GEP Unpublished	N	YES	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-3.2.2.2; KCP-3.2.3.2	Biaunier, M.	2020	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley	N	YES	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
(4)			QUALIPHYT; 18 F 2020 FR02 GEP Unpublished			Article 33 of the Regulation (new-product under Regulation) Data protection rights not previously granted at CEU zone.	
KCP 3.2.2.2; KCP 3.2.3.2 (5)	Rivet, J.	2020	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley ESSAIS+; 18 F 2020 FR03 GEP Unpublished	N	YES	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 3.2.2.2; KCP 3.2.3.2 (6)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Pyrenophora teres on Barley. Bulgaria 2021 (EPPOSE). SAGEA OOD; 06 F 2021 BG01 GEP Unpublished	N	YES	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 3.2.2.2; KCP 3.2.3.2 (7)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Pyrenophora teres on Barley. Bulgaria 2021 (EPPOSE). SAGEA OOD; 06 F 2021 BG02 GEP Unpublished	N	YES	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 3.2.2.2; KCP 3.2.3.2 (8)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Helminthosporium on Barley (Germany) Field Research Support; 06 F 2021 DE01 GEP Unpublished	N	YES	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 3.2.2.2; KCP 3.2.3.2 (9)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Helminthosporium on Barley (Germany) Field Research Support; 06 F 2021-DE02 GEP Unpublished	N	YES	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 3.2.2.2; KCP 3.2.3.2 (10)	Crepin, D.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley ESSAIS+; 06 F 2021-FR01 GEP Unpublished	N	YES	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 3.2.2.2; KCP 3.2.3.2 (11)	Crepin, D.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley ESSAIS+; 06 F 2021-FR02 GEP Unpublished	N	YES	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 3.2.2.2; KCP 3.2.3.2 (12)	Crepin, D.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley ESSAIS+; 06 F 2021-FR03 GEP Unpublished	N	YES	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 3.2.2.2; KCP 3.2.3.2 (13)	Biaunier, M.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley QUALIPHYT; 06 F 2021-FR04 GEP Unpublished	N	YES	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
						previously granted at CEU zone;	
KCP 3.2.2.2; KCP 3.2.3.2 (14)	Braunier, M.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley QUALIPHYT; 06 F 2021 FR05 GEP Unpublished	N	YES	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 3.2.2.2; KCP 3.2.3.2 (15)	Herrera, D.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley, GEP Trial, FRANCE, 2021 STAPHYT; 06 F 2021 FR07 GEP Unpublished	N	YES	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 3.2.2.2; KCP 3.2.3.2 (16)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Ramularia collo-cygni on Barley. Italy 2021 SAGEA Centro di Saggio s.r.l.; 06 F 2021 IT01 GEP Unpublished	N	YES	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 3.2.2.2; KCP 3.2.3.2 (17)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Ramularia collo-cygni on Barley. Italy 2021 SAGEA Centro di Saggio s.r.l.; 06 F 2021 IT02 GEP Unpublished	N	YES	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 3.2.2.2; KCP 3.2.3.2 (18)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Helminthosporium on Barley (Poland) Field Research Support; 06 F 2021 PL01 GEP Unpublished	N	YES	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
						protection rights not previously granted at CEU zone.	
KCP 3.2.2.2; KCP 3.2.3.2 (19)	Rusek, K.	2021	Evaluate the efficacy of mixtures based on SAP50SCF against Helminthosporium on winter barley, Poland 2020/2021 Fertico Sp. z o.o.; 06 F 2021 PL02 GEP Unpublished	N	YES	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 3.2.2.2; KCP 3.2.3.2 (20)	Herrera, D.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley GEP Trial, POLAND, 2021 STAPHYT; 06 F 2021 PL04 GEP Unpublished	N	YES	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 3.2.2.2; KCP 3.2.3.2 (21)	Herrera, D.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley GEP Trial, POLAND, 2021 STAPHYT; 06 F 2021 PL05 GEP Unpublished	N	YES	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 3.2.2.2; KCP 3.2.3.2 (22)	Botoman, G.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley GEP Trial, ROMANIA, 2021 AgroProspect; 06 F 2021 RO01 GEP Unpublished	N	YES	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 3.2.2.2; KCP 3.2.3.2 (23)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Helminthosporium on Barley (United Kingdom) Field Research Support; 06 F 2021 UK01 GEP	N	YES	Product data submitted with an application under Article 33 of the Regulation (new product	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			under Regulation) Data protection rights not previously granted at CEU zone;	
KCP 3.2.2.2; KCP 3.2.3.2 (24)	Hernández, J.M.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley AGROENSAYOS, ENSAYOS Y TÉCNICAS AGRÍCOLAS S.L.; 06-F-2021-SP01 GEP Unpublished	N	YES	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 3.2.2.2; KCP 3.2.3.2 (25)	Hernández, J.M.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley AGROENSAYOS, ENSAYOS Y TÉCNICAS AGRÍCOLAS S.L.; 06-F-2021-SP02 GEP Unpublished	N	YES	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 3.4.1; (1)	Herrera, D.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley, GEP Trial, FRANCE, 2021 STAPHYT; 06-F-2021-FR06 GEP Unpublished	N	YES	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 3.4.1; (2)	Kasztner, G.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley Agrofil SZMI Kft.; 06-F-2021-HU01 GEP Unpublished	N	YES	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 3.4.2; KCP 3.4.3 (1)	Gaia, U.	2021	EVALUATION OF NON INTENTIONAL EFFECTS OF SAP2101F AND SAP50SCF ON TRANSFORMATION	N	YES	Product data submitted with an application under Article 33 of the	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
			PROCESS (BREADMAKING) ON WHEAT – ITALY (2021) SAGEA Centro di Saggio s.r.l.; 25 TT BM 2021 IT01 GEP Unpublished			Regulation (new-product under Regulation)-Data protection rights not previously granted at CEU zone.	
KCP-3.4.2; KCP-3.4.3 (2)	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	YES	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-3.4.2; KCP-3.4.3 (3)	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	YES	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-3.4.2; KCP-3.4.3 (4)	Milhan, C.	2021	Unintentional effects of SAP2101F and SAP50SCF on transformation process (bread-making) on wheat – 2021 STAPHYT; 25 TT BM 2021 FR02 GEP Unpublished	N	YES	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-3.4.2; KCP-3.4.3 (5)	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	YES	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 3.4.2; KCP 3.4.3 (6)	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	YES	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 3.4.2; KCP 3.4.3 (7)	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	YES	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 3.4.2; KCP 3.4.3 (8)	Gless, A.E.	2021	INTERMEDIARY STUDY REPORT N°2: MALTING STUDY 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	YES	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 3.4.2; KCP 3.4.3 (9)	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 IT01 GEP Unpublished	N	YES	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 3.4.2; KCP 3.4.3 (10)	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	YES	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
						previously granted at CEU zone.	
KCP 3.5.2 (1)	Morais, F.	2022	FOLPET 500 g/L SC (SAP50SCF) Effectiveness of Cleaning Procedure ASCENZA Agro, S.A.; Study EF/376/21 GLP Unpublished	N	YES	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 3.5.2 (2)	Eley, R.	2008	Evaluation of the Phytotoxicity of Folpet 80% WG Non Target Terrestrial Plant Seedling Emergence and Growth Test AgroChemex Ltd.; ACE 08 259 GLP Unpublished	N	YES	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 3.4.2; KCP 3.4.3 (8)	Gless, A.E.	2021	INTERMEDIARY STUDY REPORT N°2: MALTING STUDY 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	YES	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 3.5.2 (3)	Eley, R.	2008	Evaluation of the Phytotoxicity of Folpet 80% WG Non Target Terrestrial Plant Vegetative Vigour Test AgroChemex Ltd.; ACE 08 260 GLP Unpublished	N	YES	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 10.3.1.1/02	Fausser-Misslin, A.	2015	Folpet: Acute Oral and Contact Toxicity to Bumble Bee (<i>Bombus terrestris</i> L.) under Laboratory Conditions IES Report N°. 20140156 GLP Unpublished	N	Yes	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec 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 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 BioChem agrar Report N°. 15 10 48 167 B GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec 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 BioChem agrar Report N°. 15 10 48 114 B GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec 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 Report N°. TRC14-246BA GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.3.2.1/01	Moll, M.	2007	Effects of Folpet 80 WG on the Predatory Mite <i>Typhlodromus pyri</i> in the laboratory – Dose response test Ibacon Report N°. 33895063 GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.3.2.2/04	Moll, M.	2007	Effects of Folpet 80 WG on the Parasitoid <i>Aphidius rhopalosiphii</i> , extended laboratory study – Aged residue test Ibacon Report N°. 33899003 GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.3.2.2/02	Moll, M.	2007	Effects of Folpet 80 WG on the Lacewing <i>Chrysoperla carnea</i> , extended laboratory study – Dose response test Ibacon Report N°. 33898047 GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.3.2.2/03	Moll, M.	2007	Effects of Folpet 80 WG on the Ladybird Beetle <i>Coccinella septempunctata</i> , extended laboratory study – Dose response test Ibacon Report N°. 33897012 GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)

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 6.2 (3)	Biaunier, M.	2020	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 17-F-2020-FR01 GEP Unpublished	N	YES	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 6.2 (4)	Biaunier, M.	2020	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 17-F-2020-FR04 GEP Unpublished	N	YES	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 6.2 (5)	Biaunier, M.	2020	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 17-F-2020-FR05 GEP Unpublished	N	YES	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 6.2 (6)	Crepin, D.	2020	Evaluate the efficacy of SAP50SCF against Puccinia striiformis on Wheat ESSAIS+; 17-F-2020-FR06 GEP Unpublished	N	YES	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 6.2 (7)	Hernández, J.M.	2020	Evaluate the efficacy of SAP50SCF against Septoria on Wheat Agroensayos; 17-F-2020-SP01 GEP Unpublished	N	YES	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 6.2 (8)	Ord, S.	2020	Field study to evaluate the efficacy and crop selectivity Of SAP50SCF against Septoria on Wheat i2LResearch; 17-F-2020-UK01 GEP Unpublished	N	YES	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 6.2 (9)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Septoria tritici and Puccinia recondita on Wheat. Bulgaria 2021 (EPPOSE). SAGEA OOD; 05-F-2021-BG01 GEP Unpublished	N	YES	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	Verte- brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2 (10)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Septoria tritici and Puccinia recondita on Wheat. Bulgaria 2021 (EPPOSE). SAGEA OOD; 05-F-2021-BG02 GEP Unpublished	N	YES	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 6.2 (13)	Biaunier, M.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 05-F-2021-FR01 GEP Unpublished	N	YES	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 6.2 (14)	Biaunier, M.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 05-F-2021-FR02 GEP Unpublished	N	YES	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 6.2 (15)	Biaunier, M.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 05-F-2021-FR03 GEP Unpublished	N	YES	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 6.2 (16)	Biaunier, M.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat QUALIPHYT; 05-F-2021-FR04 GEP Unpublished	N	YES	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 6.2 (17)	Szénási, Z.R.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat Agrofil-SZMI Kft.; 05-F-2021-HU01 GEP Unpublished	N	YES	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 6.2 (18)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Zymoseptoria tritici on Wheat. Italy 2021 SAGEA Centro di Saggio s.r.l.; 05-F-2021-IT01 GEP Unpublished	N	YES	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 6.2 (19)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Zymoseptoria tritici on Wheat. Italy 2021 SAGEA Centro di Saggio s.r.l.; 05-F-2021-IT02	N	YES	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
			GEP Unpublished			product under Regulation) Data protection rights not previously granted at CEU zone.	
KCP 6.2 (24)	Botoman, G.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat AgroProspect SRL; 05-F-2021-RO01 GEP Unpublished	N	YES	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 6.2 (25)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Septoria on Wheat (United Kingdom) Field Research Support: 05-F-2021-UK01 GEP Unpublished	N	YES	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 6.2 (26)	Hernández, J.M.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat AGROENSAYOS, ENSAYOS Y TÉCNICAS AGRÍCOLAS S.L.; 05-F-2021-SP01 GEP Unpublished	N	YES	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 6.2 (27)	Hernández, J.M.	2021	Evaluate the efficacy of SAP50SCF against Septoria on Wheat AGROENSAYOS, ENSAYOS Y TÉCNICAS AGRÍCOLAS S.L.; 05-F-2021-SP02 GEP Unpublished	N	YES	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 6.2 (28)	Zöllner, H.	2020	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley Field Research Support; 18-F-2020-DE01 GEP Unpublished	N	YES	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 6.2 (29)	Zöllner, H.	2020	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley Field Research Support; 18-F-2020-DE02 GEP Unpublished	N	YES	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 6.2 (30)	Biaunier, M.	2020	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley QUALIPHYT; 18-F-2020-FR01 GEP Unpublished	N	YES	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 6.2 (31)	Biaunier, M.	2020	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley QUALIPHYT; 18-F-2020-FR02 GEP Unpublished	N	YES	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 6.2 (32)	Rivet, J.	2020	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley ESSAIS+; 18-F-2020-FR03 GEP Unpublished	N	YES	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 6.2 (33)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Pyrenophora teres on Barley. Bulgaria 2021 (EPPOSE). SAGEA OOD; 06-F-2021-BG01 GEP Unpublished	N	YES	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 6.2 (34)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Pyrenophora teres on Barley. Bulgaria 2021 (EPPOSE). SAGEA OOD; 06-F-2021-BG02 GEP Unpublished	N	YES	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 6.2 (35)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Helminthosporium on Barley (Germany) Field Research Support; 06-F-2021-DE01 GEP Unpublished	N	YES	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 6.2 (36)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Helminthosporium on Barley (Germany) Field Research Support; 06-F-2021-DE02 GEP Unpublished	N	YES	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 6.2 (37)	Crepin, D.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley ESSAIS+; 06-F-2021-FR01 GEP Unpublished	N	YES	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 6.2 (38)	Crepin, D.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley ESSAIS+; 06-F-2021-FR02 GEP	N	YES	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
			Unpublished				
KCP 6.2 (39)	Crepin, D.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley ESSAIS+; 06-F-2021-FR03 GEP Unpublished	N	YES	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 6.2 (40)	Biaunier, M.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley QUALIPHYT; 06-F-2021-FR04 GEP Unpublished	N	YES	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 6.2 (41)	Biaunier, M.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley QUALIPHYT; 06-F-2021-FR05 GEP Unpublished	N	YES	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 6.2 (42)	Herrera, D.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley, GEP Trial, FRANCE, 2021 STAPHYT; 06-F-2021-FR07 GEP Unpublished	N	YES	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 6.2 (43)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Ramularia collo-cygni on Barley. Italy 2021 SAGEA Centro di Saggio s.r.l.; 06-F-2021-IT01 GEP Unpublished	N	YES	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 6.2 (44)	Desogus, S.	2021	Evaluate the efficacy of SAP50SCF against Ramularia collo-cygni on Barley. Italy 2021 SAGEA Centro di Saggio s.r.l.; 06-F-2021-IT02 GEP Unpublished	N	YES	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 6.2 (47)	Herrera, D.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley GEP Trial, POLAND, 2021 STAPHYT; 06-F-2021-PL04 GEP Unpublished	N	YES	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 6.2 (48)	Herrera, D.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley GEP Trial, POLAND, 2021 STAPHYT; 06-F-2021-PL05 GEP Unpublished	N	YES	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 6.2 (49)	Botoman, G.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley GEP Trial, ROMANIA, 2021 AgroProspect; 06-F-2021-RO01 GEP Unpublished	N	YES	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 6.2 (50)	Zöllner, H.	2021	Field study to evaluate the efficacy of SAP50SCF against Helminthosporium on Barley (United Kingdom) Field Research Support; 06-F-2021-UK01 GEP Unpublished	N	YES	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 6.2 (51)	Hernández, J.M.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley AGROENSAYOS, ENSAYOS Y TÉCNICAS AGRÍCOLAS S.L.; 06-F-2021-SP01 GEP Unpublished	N	YES	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 6.2 (52)	Hernández, J.M.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley AGROENSAYOS, ENSAYOS Y TÉCNICAS AGRÍCOLAS S.L.; 06-F-2021-SP02 GEP Unpublished	N	YES	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 6.2 (53)	Herrera, D.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley, GEP Trial, FRANCE, 2021 STAPHYT; 06-F-2021-FR06 GEP Unpublished	N	YES	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 6.2 (54)	Kasztner, G.	2021	Evaluate the efficacy of SAP50SCF against Helminthosporium on Barley Agrofil-SZMI Kft.; 06-F-2021-HU01	N	YES	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
			GEP Unpublished			product under Regulation) Data protection rights not previously granted at CEU zone.	
KCP 10.2.1/04	Grade, R., Wydra, V.	2007	Influence of Folpet technical to <i>Daphnia magna</i> in a reproduction test Ibacon Report N°. 33881221 GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.4.1/01	Witte, B.	2009	Acute Toxicity (14 Days) of FOLPET 80 WG to the Earthworm Eisenia fetida in Artificial Soil with 5% Peat Ibacon Report N°. 51141021 GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.2.1/02		2007	Acute toxicity of Folpet 80 WG to Rainbow Trout (<i>Oncorhynchus mykiss</i>) in a 96-hour semi static test 33891230 GLP Unpublished	Y	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.2.1/03	Grade, R., Wydra, V.	2007	Acute toxicity of Folpet 80 WG to <i>Daphnia magna</i> in a semi static 48-hour immobilization test Ibacon Report N°. 33892220 GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.2.1/04	Grade, R., Wydra, V.	2007	Influence of Folpet technical to <i>Daphnia magna</i> in a reproduction test Ibacon Report N°. 33881221 GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec 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 (<i>Apis mellifera</i> L.) in the laboratory Ibacon Report N°. 33893035 GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec 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 BioChem agrar Report N°. 15 10 48 167 B GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec 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 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 BioChem agrar Report N°. 15 10 48 114 B GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.3.1.3/01	Ansaloni, T.	2015	Toxicity of FOLPET TECHNICAL on honey bee larvae (<i>Apis mellifera</i> L.) after repeated exposure under laboratory conditions Trialcamp Report N°. TRC14-245BA GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.3.2.2/02	Moll, M.	2007	Effects of Folpet 80 WG on the Lacewing <i>Chrysoperla carnea</i> , extended laboratory study – Dose response test Ibacon Report N°. 33898047 GLP Unpublished	N	Y	Study previously sub-mitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.3.2.2/03	Moll, M.	2007	Effects of Folpet 80 WG on the Ladybird Beetle <i>Coccinella septempunctata</i> , extended laboratory study – Dose response test Ibacon Report N°. 33897012 GLP Unpublished	N	Y	Study previously sub-mitted under the Renewal process of folpet. Data protection not granted before.	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.3.2.2/04	Moll, M.	2007	Effects of Folpet 80 WG on the Parasitoid <i>Aphidius rhopalosiphi</i> , extended laboratory study – Aged residue test Ibacon Report N°. 33899003 GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.;	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.4.1.1/01	Ansaloni, T.	2014	A laboratory test to determine the chronic (sub-lethal) effects of Folpet 80 WG to the earthworm <i>Eisenia foetida foetida</i> (Oligochaeta: Lumbricidae) in artificial substrate at 2% peat content Trialcamp Report N°. TRC14-250BA GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.;	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.4.1.1/02	Ansaloni, T.	2014	A laboratory test to determine the chronic (sub-lethal) effects of Folpet 80 WG to the earthworm <i>Eisenia foetida foetida</i> (Oligochaeta: Lumbricidae) in artificial substrate at 5% peat content	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.;	ASCENZA AGRO S.A. (formerly Sapec 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
			Trialcamp Report N°. TRC14-251BA GLP Unpublished				
KCP 10.4.1.1/03	Ansaloni, T.	2014	A laboratory test to determine the chronic (sub-lethal) effects of Folpet 80 WG to the earthworm <i>Eisenia foetida foetida</i> (Oligochaeta: Lumbricidae) in artificial substrate at 10% peat content Trialcamp Report N°. TRC14-252BA GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.:	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.4.1.1/04	Lühns, U.	2007	Effects of Folpet 80 WG on Reproduction and Growth of Earthworms <i>Eisenia fetida</i> in Artificial Soil with 5% peat Ibacon Report N°. 33896022 GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.:	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.4.1.1/05	Pavic, B.	2014	Effects of BCP324F on Reproduction and Growth of Earthworms <i>Eisenia fetida</i> in Artificial Soil with 5% Peat Ibacon Report N°. 84831022 GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.:	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)
KCP 10.5/01	Gimeno, C.	2015	Effects of the formulated product Folpet 80 WG on activity of the soil microflora under laboratory conditions Trialcamp Report N°. TRC14-299SM GLP Unpublished	N	Y	Study previously submitted under the Renewal process of folpet. Data protection not granted before.:	ASCENZA AGRO S.A. (formerly Sapec Agro S.A.)

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

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