

FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: SIP 41061

Product name: SIP 41061

Chemical active substance:

Prothioconazole 400 g/L SC

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT - Poland

(authorization of use)

Applicant: Sipcam Oxon S.p.A.

Submission date: April 2022

MS Finalisation date: 03/2023; 06/2023; 11.2023

Version history

When	What
04/2022	Submission date
03/2023	zRMS evaluated dRR submitted by Applicant
03/2023	Assessment regarding section B7, which has been updated by the Applicant
06/2023	RR update following commenting phase. Changes are highlighted in yellow.
11/2023	Updated of label

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PART A

RISK MANAGEMENT

1 Details of the application

This document describes the acceptable use conditions required for the registration of SIP 41061, containing prothioconazole in Central zone, Poland.

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SIP 41061 is the product code used in the core assessment. SIP 41061 contains the active substances prothioconazole which was included in Annex I of Directive 91/414 by Commission Directive 2008/44/EC of 4th April 2008, and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011.

SIP 41061 is a SC formulation containing 400 g/L prothioconazole and acts as fungicide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 0-10 and Part C.

The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national registration by the EU review.

The dRR is for an application of the registration of SIP 41061, for use as a fungicide in wheat, barley, oil seed rape, sugar beet, cucurbits (edible), pome/stone fruit and carrots.

This document describes the specific conditions of use and labelling required for the registration of SIP 41061.

Appendix 1 of this document provides a place for the copy of the product authorization, where the MS assessor can insert details of the product authorization for MS country.

Appendix 2 of this document is a place for the copy of the approved product label, where the MS assessor can present a copy of the approved product label for MS country.

Appendix 3 of this document contains copies of the letters of access to the protected data / third party data that was needed for evaluation of the formulation.

Appendix 4 of this document contains the lists of data considered for national authorization.

1.1 Application background

This dossier is submitted for zonal registration of SIP 41061 in accordance with Article 33 of Regulation (EC) No. 1107/2009. zRMS of the evaluation is Poland. SIP 41061 was not the representative formulation

of the EU review. The product is a new product not previously evaluated.

This application for authorization of SIP 41061, a SC formulation containing 400 g/L prothioconazole, for use as a fungicide in some crops was submitted by Sipcam Oxon S.p.A. in April 2022.

1.2 Letters of Access

The Applicant has access to all studies owned by Sipcam Italia S.p.A. Sipcam Inagra, S.A. and Sipcam UK Ltd. (please refer to the respective letters of access provided with this submission).

Please refer to all Letters of Access in Appendix 3 of dRR Part A to support the registration of the formulation SIP 41061.

1.3 Justification for submission of tests and studies

The tests and study reports are necessary in order to support the authorisation of SIP 41061 as a new product (first authorisation in the EU).

1.4 Data protection claims

SIP 41061 is a new product and therefore, for all data, data protection is claimed for 10 years starting at the date of authorisation in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

2 Details of the authorization decision

2.1 Product identity

Product code	SIP 41061
Product name in MS	SIP 41061
Authorization number	not applicable
Function	fungicide
Applicant	Sipcam Oxon S.p.A.
Active substance(s) (incl. content)	Prothioconazole 400 g/L
Formulation type	SC
Packaging	0.250 L, 0.500 L, 1 L, 2 L, 5 L, 10 L and 20 L in PA/PE
Coformulants of concern for national authorizations	none
Restrictions related to identity	none
Mandatory tank mixtures	none
Recommended tank mixtures	none

2.2 Conclusion

Physical-chemical section:

Data gap: 2 years shelf-life study is on-going (ending date: 2023). Report shall be submitted when finished. Conditional registration of the product is possible and proposed for 2 years

Efficacy section:

In Poland winter wheat (against SEPTTR, FUSASP, PUCCSP: PUCCRE/PUCCRT and PUCCST), winter barley (against RHYNSE and PYRNTE), winter oilseed rape (against SCLESC), sugar beet (against CERCBE), apple (against VENTIN and PODOLE), cherry and plum (against MONILSP), carrot (against ALTEDA and ERYSH) can be accepted according to Article 33.

Quince and medlar (against scab, *Stemphylium*, *Oidium*), pear (against scab, *Stemphylium*, *Oidium*), apricot (against *Sphaerotheca spp.* and *Monilia spp.*), carrot against (SCLESC) and other roots and tuber vegetables (against SCLESC, *Alternaria dauci*, powdery mildew) and spring rye (against SEPTTR, FUSASP, PUCCSP, ERYSSP) and spring oilseed rape (against SCLESC, LEPTSP, PYRPSP, OIDISP) can be accepted only according to Article 51.

Mammalian toxicology:

SIP 41061 is unclassified with phrase EUH 208: Contains 1,2-benzisothiazol-3-one. May produce an allergic reaction. Based on the calculations, for both prothioconazole and its metabolite prothioconazole-desthio, no risk the operator and worker exposure for the intended GAP uses of SIP 41061 is below the limit of 100% AOEL if the relevant PPE is taken into account. No risk for resident and bystander (adult and children)

Metabolism and residues:

MRLs exceedances are expected for pome fruits, stone fruits, cucurbits with edible peel. Use on cucurbits with edible peel is not sufficiently supported by field trials.

It is up to each Member State to decide on the need to provide missing data for oil seed rape (data for TLA and TA in rape seed; residues of TMDs in honey) prior to registration in a given country. According to the evaluator, this data can be submitted as post registration requirement.

In Poland use is accepted by the evaluator with post registration requirement.

Ecotoxicology section:

To protect aquatic organisms respect an unsprayed vegetated buffer zone of:

- 10m for summer oilseed rape;
- 20m for cereals, winter oilseed rape and carrots;
- 20m for pome and stone/pome fruits or 10m + 90% nozzle reduction for pome and stone fruits

In stone fruit BBCH should be change to 51-70.

2.3 Substances of concern for national monitoring

None

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:	Aquatic Acute 1, Aquatic Chronic 1
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	GHS09
Signal word:	Warning
Hazard statement(s):	H400 Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects.
Precautionary statement(s):	P280 Wear protective gloves/protective clothing/eye protection P391 Collect spillage.. P501 Dispose of contents/container in accordance to national regulations.
Additional labelling phrases:	EUH208 “Contains 1,2-benzisothiazol-3-one. May produce an allergic reaction”) EUH401 (“To avoid risk to human health and the environment, comply with the instruction for use”)

Special rule for labelling of plant protection product (PPP):	
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: <ul style="list-style-type: none"> - 10m for summer oilseed rape; - 20m for cereals, winter oilseed rape and carrots; - 20m for pome and stone/pome fruits <i>or</i> - 10m + 90% nozzle reduction for pome and stone fruits

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:	
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--	Field Crops: Work wear during mixing/loading and application Orchard in field: Work wear during mixing/loading and application, gloves during application Orchard manual, hand-held application, upwards: Work wear during mixing/loading and application.
Worker protection:	
--	Field Crops: Work wear (arms, body and legs covered) Sugar beet, bolting: Work wear (arms, body and legs covered) and gloves Stone fruits: Work wear (arms, body and legs covered) Pome fruits: Work wear (arms, body and legs covered) and gloves
Integrated pest management (IPM)/sustainable use:	
	None
Environmental protection	
	To protect aquatic organisms respect an unsprayed vegetated buffer zone of: <ul style="list-style-type: none"> - 10m for summer oilseed rape; - 20m for cereals, winter oilseed rape and carrots; - 20m for pome and stone/pome fruits <i>or</i> - 10m + 90% nozzle reduction for pome and stone fruits
Other specific restrictions	
	None

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

Integrated pest management (IPM)/sustainable use:	
	Not applicable

2.5.2 Specific restrictions linked to the intended uses

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

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
Environmental protection:		Relevant for use no.

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code): SIP 41061
Active substance 1: Prothioconazole
Applicant: Sipcam Oxon SpA
Zone(s): Central zone (Poland)
Verified by MS: yes

Formulation type: SC
Conc. of as 1: 400 g/L
Professional use: X
Non professional use: ☐

Field of use: fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks:
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	PL	Winter Wheat (Soft, Durum), Triticale, Rye TRZSS, TTLSS, SECSS	F	<i>Septoria tritici</i> spp. SEPTTR <i>Fusarium</i> spp. FUSASP <i>Puccinia</i> spp. <i>recondita</i> and <i>striiformis</i> PUCCSPP PUCCRE/PUCCRT; PUC CST) <i>Erysiphe</i> spp. ERYSSP	Spray	BBCH 29-69	a) 2 (14)	a) 0.5 b) 1.0	a) 200 b) 400	200-600 200-300	21 35	For <i>Septoria</i> , <i>Fusarium</i> , <i>Puccinia</i> and <i>Erysiphe</i> control , apply from 0,4 up to 0,5 L/ha. Efficacy section: In PL only winter wheat can be accepted. <i>Erysiphe</i> spp. is not accepted in PL. Accepted water volume is 200-300 L/ha. Metabolism and residues: PHI of 35 is acceptable

1	2	3	4	5	6	7	8	9	10	11	12	13
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks:
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
2	PL	Barley HORVX	F	<i>Rhynchosporium secalis</i> RHYNSE <i>Puccinia hordei</i> PUC- CHD <i>Pyrenophora teres</i> (<i>Helminthosporium</i> spp.) PYRNTE	Spray	BBCH 29-61 30-49.	a) 2 (14)	a) 0.5 b) 1.0	a) 200 b) 400	200-600 200-300	21 35	Efficacy section: In PL, PUCCHD is not accepted. Accepted BBCH is 30-49 and water volume: 200-300 L/ha. RHYNSE and PYRNTE – accepted rate 0.4 L/ha and 0.5 L/ha Metabolism and residues: PHI of 35 is acceptable
3	PL	Oilseed rape BRSNN	F	<i>Sclerotinia SCLESC</i> <i>Phoma</i> LEPTSP <i>Pyrenopeziza</i> PYRPSP <i>Oidium</i> ODISP	Spray	BBCH 30-71 60-69	a) 2 (14)	a) 0.45 b) 0.9	a) 180 b) 360	200-600 200-300	50	For <i>Stem rot</i> , <i>Phoma</i> , <i>Pyrenopeziza</i> and <i>Oidium</i> control, apply from 0,35 up to 0,45 L/ha Efficacy section: in PL only SCLESC is accepted on winter OSR. Accepted BBCH is 60-69 and water volume: 200-300 L/ha.

1	2	3	4	5	6	7	8	9	10	11	12	13
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks:
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
4	PL	Sugar beet BEAVA	F	<i>Cercospora beticola</i> CERCBE <i>Erysiphe betae</i> ERYSBE	Spray	BBCH 39-49	a) 2 (14)	a) 0.4 b) 0.8	a) 160 b) 320	200-600 200-300	28	For <i>Cercospora</i> Leaf spot (<i>Cercospora beticola</i>) and powdery mildew (<i>Erysiphe betae</i>), control apply from 0,3 up to 0,4 L/ha. Cercospora Leaf spot: apply at the first disease appearance, using the high label rate (0,4 L/ha) when applied solo. Powdery mildew and rust (<i>Uromyces spp.</i>): apply at the first disease appearance. The low rate (0,3 L/ha) is sufficient to ensure a control of the disease. When there is a high risk of presence of other diseases, like Leaf spot, apply the max rate (0,4 L/ha). Efficacy section: in PL only CERCBE can be accepted at BBCH 39-49 and water volume 200-300 L/ha.

1	2	3	4	5	6	7	8	9	10	11	12	13
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks:
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
6a	PL	Pome fruits (Ap- ple, Quince, Med- lar) MABSS, CYDOB, MSPGE	F	Scab VENTIN Stemphylium PLEOAL Oidium PODOLE	Spray	BBCH 39-85 51-79	a) 2 (7-9)	a) 0,3 b) 0,6	a) 120 b) 240	500-1500 500-1000	14	For Scab, Brown Spot and Powdery mildew control apply at 20 – 30 mL/100 L (do not exceed 0,3 L/ha per application) Efficacy section: in PL only apple against VENTIN and PODOLE is accepted at BBCH 51-79 and 500- 1000 L/ha water volume. Efficacy section: Pear is not accept- ed in line to Article 33. Metabolism and residues: Use not accepted. MRL exceedance is possible.
6b	PL	Pome fruits (Pear) PYUCO	F	Scab VENTIN Stemphylium PLEOAL Oidium PODOLE	Spray	BBCH 39-85	a) 2 (7-9)	a) 0,3 b) 0,6	a) 120 b) 240	500-1500	21	Metabolism and residues: Use not accepted. MRL exceedance is possible. use is not sufficiently supported by field trials. Efficacy section: Pear is not ac- cepted in line to Article 33.

1	2	3	4	5	6	7	8	9	10	11	12	13
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
7	PL	Stone fruits (Plum, Cherry, Apricot) PRNDO, PRNAV, PRNAR	F	Sphaerotheca spp SPIIRPA Monilia spp. MONILA	Spray	BBCH 51-85 71-89	a) 2 (7)	a) 0.4 b) 0.8	a) 160 b) 320	500-1500 500-1000	3	For Brown Rot and Powdery mil- dew MONILA control apply at 30 – 40 mL/100 L (do not exceed 0,4 L/ha per application) Efficacy section: in PL only plum and cherry against MONILA at BBCH 71-89 and water volume: 500-1000 L/ha are accepted. Metabolism and residues: Use not accepted. MRL exceedance is possible. Ecotoxicology section: In stone fruit only BBCH 51-70 is accepted.
8	PL	Carrot 0213020 and other roots and tuber vegeta- bles (beetroots 0213010; horse radishes 0213040; parsnips 0213060; parsley roots 0213070; salsi- fies 0213090; swedes 0213100; turnips 0213110)	F	Leaf blight (<i>Alternaria dauci</i>) ALTEDA Sclerotinia rot (<i>Sclero-</i> <i>tinia sclerotiorum</i>) SCLESC Powdery mildew (<i>Erysiphe heraclei</i>) ERYSH	Spray	BBCH 16-46 41-49	a) 2 (21)	a) 0.5 b) 1.0	a) 200 b) 400	500-1000 600	24	For Leaf blight, Sclerotinia rot and Powdery mildew control apply at 0,5 L/ha Efficacy section: in PL only ALTEDA and EYSYH on carrot at BBCH 41-49 are accepted. Only water volume 500-600 L/ha

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

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 a light ivory homogeneous liquid with characteristic odour. It is not explosive, has no oxidising properties. The product has no flash point. It has a pH value of 2.8 when undiluted, of 3.6 in 1% aqueous solution and an acidity value of 1.31% w/w, expressed at H₂SO₄. 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 ingredients content nor the technical properties changed. A shelf life study for 2 years at ambient temperature when stored in the packaging material used for commercialization is ongoing; data at six months are available and the product still complies with the original starting quality. Its technical characteristics are acceptable for a CS formulation.

The intended concentration of use 0.02 – 0.25 % (v/v).

3.2 Efficacy (Part B, Section 3)

In order to support the authorization of SIP41061 efficacy and selectivity evaluations are provided from trials carried out over 4 seasons (between 2018-2019-2020-2021) in Czech Republic, Germany, France Maritime, Hungary, The Netherlands, Poland, Romania, Scotland and England, belonging to the Maritime, South-East and North-East EPPO zones.

The Biological Assessment Dossier presents synthesis and conclusions performed on the following:

For Septoria control in Wheat:

33 efficacy trials carried out from 2019 to 2021 in Czech Republic (2 trials), Germany (6 trials), France Maritime (6 trials), United Kingdom (7 trials), Poland (8 trials) and Romania (4 trials) were provided to test the control of SIP41061.

For Puccinia spp control in Wheat:

18 efficacy trials carried out from 2020 to 2021 in Czech Republic (1 trial), Germany (2 trials), France Maritime (4 trials), United Kingdom (3 trials), Poland (4 trials) and Romania (4 trials) were provided to test the control of SIP41061.

For Fusarium spp control in Wheat:

15 efficacy trials carried out from 2020 to 2021 in Germany (2 trials), France Maritime (2 trials), United Kingdom (3 trials), Poland (4 trials) and Romania (4 trials) were provided to test the control of SIP41061.

For Erysiphe graminis control in Wheat:

1 efficacy trial carried out in 2020 in Hungary (1 trial) was provided to test the control of SIP41061.

For Pyrenophora teres control in Barley:

20 efficacy trials carried out from 2020 to 2021 in Czech Republic (3 trials), Germany (3 trials), France Maritime (3 trials), United Kingdom (1 trial), Poland (6 trials) and Romania (4 trials) were provided to test the control of SIP41061.

For Rhynchosporium secalis control in Barley:

13 efficacy trials carried out from 2020 to 2021 in Czech Republic (1 trial), France Maritime (2 trials), United Kingdom (3 trials), Poland (4 trials) and Romania (3 trials) were provided to test the control of SIP41061.

For Puccinia hordei control in Barley:

5 efficacy trials carried out from 2020 to 2021 in Germany (3 trials) and Hungary (2 trials) were provided to test the control of SIP41061.

For Venturia inaequalis control in Apple:

16 efficacy trials carried out from 2020 to 2021 in Germany (3 trials), France Maritime (2 trials), United Kingdom (1 trial), Poland (8 trials) and Hungary (2 trials) were provided to test the control of SIP41061.

For Podosphaera leucotricha control in Apple:

9 efficacy trials carried out from 2020 to 2021 in Germany (2 trials), France Maritime (3 trials), United Kingdom (1 trial) and Poland (3 trials) were provided to test the control of SIP41061.

For Monilia spp control in Stone fruits:

8 efficacy trials carried out from 2020 to 2021 in Germany (3 trials), France Maritime (1 trial) and Poland (4 trials) were provided to test the control of SIP41061.

For Ascochyta pisi control in Legumes:

9 efficacy trials carried out from 2019 to 2021 in France Maritime (4 trials) and UK (5 trials) were provided to test the control of SIP41061.

For Uromyces spp control in Legumes:

4 efficacy trials carried out from 2020 to 2021 in France Maritime (1 trial) and UK (3 trials) were provided to test the control of SIP41061.

For Erysiphe control in Legumes:

2 efficacy trials carried out in 2020 in France Maritime (2 trials) were provided to test the control of SIP41061.

For Sclerotinia sclerotiorum control in oilseed rape:

24 efficacy trials carried out from 2020 to 2021 in Czech Republic (3 trials), Germany (3 trials), France Maritime (5 trials), United Kingdom (3 trials), Poland (5 trials) and Romania (5 trials) were provided to test the control of SIP41061.

For Plenodonum lingam control in oilseed rape:

5 efficacy trials carried out from 2020 to 2021 in Czech Republic (1 trial) and Poland (4 trials) were provided to test the control of SIP41061.

For Cercospora bieticola control in Sugarbeet:

20 efficacy trials carried out from 2019 to 2021 in Czech Republic (3 trials), Germany (6 trials), France Maritime (5 trials), United Kingdom (1 trial), The Netherlands (1 trial) and Poland (4 trials) were provided to test the control of SIP41061

For Erysiphe betae control in Sugarbeet:

4 efficacy trials carried out in 2020 in United Kingdom (3 trials) and The Netherlands (1 trial) were provided to test the control of SIP41061

For Uromyces betae control in Sugarbeet:

4 efficacy trials carried out from 2020 to 2021 in Germany (2 trials), United Kingdom (1 trial) and The Netherlands (1 trial) were provided to test the control of SIP41061

For Powdery mildew control in Cucurbits in greenhouse:

25 efficacy trials carried out from 2020 to 2021 in Germany (5 trials), France (4 trials), The Netherlands (2 trials), Spain (13 trials) and Italy (1 trial) were provided to test the control of SIP41061.

For Alternaria dauci control in Carrot:

20 efficacy trials carried out from 2020 to 2021 in France Maritime (3 trials), The Netherlands (2 trials), United Kingdom (3 trials), Poland (6 trials) and Romania (6 trials) were provided to test the control of SIP41061.

For Erysiphe heraclei control in Carrot:

3 efficacy trials carried out from 2020 to 2021 in Poland (3 trials) were provided to test the control of SIP41061.

3.3 Efficacy data

Preliminary trials:

Large scale efficacy trials are available to evaluate the effectiveness of products containing prothioconazole, so preliminary tests were not necessary in this case in our opinion. Also, some formulations of prothioconazole at 400 g/L which are equivalent to SIP 41061 are currently authorized on cereals, stone and pome fruits, sugar beet, vegetables, legumes and oilseed rape (OSR) against the same target diseases requested for SIP41061.

MED trials

The applicant has proposed doses of SIP41061 (product code: SIP41061) that reflect those of currently authorized prothioconazole products across the EU.

To provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least two lower dose(s) than recommended dose. In the appropriate research of efficacy were tested different doses and to register was chosen the lowest effective, which is in accordance to EPPO 1/225 (2).

Applicant submitted following number of MED valid trials conducted on:

- ✓ *wheat* against SEPTTR – 24 trials - MAR 12 (FR-4; CZ-1; UK-4; DE-3); N-E 8 (PL); S-E 4 (RO). Only winter wheat was studied.
- ✓ *barley* against PYRNTE – 20 trials – MAR 10 (DE-3; FR-3; CZ-3; UK-1); N-E 6 (PL); S-E 4 (RO). In PL 2 trials were carried out on spring barley.
- ✓ *apple* against VENTIN – 6 trials – MAR 3 (UK-1, FR-2); N-E 2 (PL) and S-E (HU);
- ✓ *stone fruits* against MONISP – 8 trials – MAR 4 (DE-3; FR-1) and N-E 4 (PL)
- ✓ *legumes (beans, peas)* against ASCOPI – 9 trials – MAR in FR and UK
- ✓ *oilseed rape* against SCLESC – 16 trials – MAR 7 (CZ-2; DE-1; FR-3; UK-1); N-E 5 (PL) and S-E 4 (RO);
- ✓ *sugar beet* against CERCBE – 18 trials – 14 MAR (CZ-3; DE-4; FR-5; NL-1; UK-1) and N-E 4 (PL);
- ✓ *carrot* against ALTEDA – 20 trials – MAR 8 (UK-3; FR-3; NL-2); N-E 6 (PL) and S-E 6 (RO).

In all these trials, the disease level of infestation in untreated plots was sufficient (at least 5% of pest severity in at least one leaf stage) to validate the trials and reliably assess the efficacy of SIP41061.

During MED trials following different doses were studied:

- 0.3 L/ha (0.6N); 0.375-0.4 L/ha (0.75-0.8N) and 0.45-0.5 L/ha (N recommended) against SEPTTR on winter wheat. The most consistent control of *S. tritici* achieved with the recommended rate is confirmed by the higher efficacy and the lower variability. Reduced dosage rates by 20% (0.4 L PR/ha) can still provide useful disease control however with lower efficacy than the full recommended dose.
- 0.3 L/ha (0.6N); 0.4 L/ha (0.8N) and 0.5 L/ha (N recommended) against PYRNTE on winter barley. Also, in Poland 2 trials were carried out on spring barley. The most consistent control of *P. teres* achieved with the recommended rate is confirmed by the higher efficacy and the lower variability. Reduced dosage rates by 20% (0.4 L PR/ha) can still provide useful disease control however with lower efficacy than the full recommended dose.
- 0.2 L/ha (0.67N); 0.25 L/ha (0.75N) and 0.3 L/ha (N recommended) against VENTIN on apple. The most consistent control of *V. inaequalis* achieved with the recommended rate is confirmed by the higher efficacy and the lower variability. Reduced dosage rates by 20% can still provide useful disease control however

er with low efficacy than the full recommended dose.

- 0.2 L/ha (0.5N); 0.3 L/ha (0.75N) and 0.4 L/ha (N recommended) against MONISP on stone fruits. The most consistent control of *Monilia* spp. achieved with the recommended rate is confirmed by the higher efficacy and the lower variability. Reduced dosage rates by 20-25% can still provide useful disease control however with low efficacy than the full recommended dose.
- 0.2 L/ha (0.5N); 0.3 L/ha (0.75N) and 0.4 L/ha (N recommended) against ASCOPI on legumes (peas, beans). The dose delivering 0.4 L/ha of SIP41061 provided the optimum and more reliable control and should thus be considered as effective against *Ascochyta pisi* on legumes (beans and peas) in field, for which activity of SIP41061 is claimed. The most consistent control of *A. pisi* dosage rate by 25% can still provide useful disease control however with low efficacy than the full recommended dose.
- 0.25 L/ha (0.56N); 0.35 L/ha (0.78N) and 0.45 L/ha (N recommended) against SCLESC on winter oilseed rape. The most consistent control of *S. sclerotiorum* achieved with the recommended rate is confirmed by the higher efficacy and the lower variability. Reduced dosage rate by 20% can still provide useful disease control however with low efficacy than the full recommended dose.
- 0.2 L/ha (0.5N); 0.3 L/ha (0.75N) and 0.4 L/ha (N recommended) against CERCBE on sugar beet. The most consistent control of *C. beticola* achieved with the recommended rate is confirmed by the higher efficacy and the lower variability. Reduced dosage rates by 25% can still provide useful disease control however with low efficacy than the full recommended dose.
- 0.3 L/ha (0.6N); 0.4 L/ha (0.8N) and 0.5 L/ha (N recommended) against ALTEDA on carrot. The most consistent control of *A. dauci* achieved with the recommended rate is confirmed by the higher efficacy and the lower variability. Reduced dosage rates by 20% can still provide useful disease control however with low efficacy than the full recommended dose.

The proposed rates should be considered the minimum effective dose to deliver broad spectrum control of the target diseases on cereals, pome and stone fruits, sugar beet, legumes, carrot and winter oilseed rape under a wide range of environmental conditions in the context of trials conducted on different EPPO zones and carried out studied on different cereal species or existing knowledge on the active substance and other relevant formulations with prothioconazole on the market.

EFFICACY TRIALS:

Justification for the use of biological efficacy data included in this dossier is made according to EPPO PP 1/241(2) "Guidance on comparable climates." All trials carried out in the respective EPPO zones can be extrapolated to each country belonging to this agro-climatic EPPO zone. Moreover, trials conducted at the border of one country are relevant for the neighbouring country. All presented trials can be therefore relevant for a submission in the Central Regulatory zone. However, in the opinion of Evaluator for extrapolating results always should be presented weather and agrotechnical conditions. For example, Poland can use results from neighbouring countries (DE and CZ) but results from other countries and other EPPO zones are not valid. Each country can have own rules, so in the opinion of Evaluator decision about use results or extrapolating them should be made on cMS level.

Trials were conducted according to the EPPO guidelines. The GEP certificates of the official testing organizations were provided. EPPO Standard PP 1/226 Number of efficacy trials provides guidance on the number of trials in target crops needed to demonstrate the efficacy of a plant protection product at the recommended dose. Where authorization is sought across a range of diverse conditions, such as across an authorization zone (PP 1/278 Principles of zonal data production and evaluation), then the number of trials conducted may need to increase. These trials should be done across the range of climatic and environmental conditions likely to be encountered, and over at least 2 years.

The applicant was notified that according to PP 1/226 at least 6 trials from each climatic zone are required (in case of reduced number of trials in major pest on major crop). Details of experiment are presented above by Applicant. All used methodology is in accordance to GEP rules. Applicant carried out studies during different growing seasons, which is in line with EPPO 1/181 (4).

Regarding number of applications, trials were conducted with 3-8 applications to cover the hole season to avoid applications of other formulations in the following crops: apple (8 applications in MAR, N-E and S-E);

stone fruit (3 appl. in MAR); sugar beet (4 appl. in MAR and 3 appl. in N-E) and carrot (4 appl. in N-E and MAR and 3 appl. in S-E). This is a common practice in trials to avoid treatments with other actives to assure efficacy obtained is from the formulation tested. Applicant can confirm that results presented summary tables were obtained from assessments after the 2nd and 3th application to assure maximum reliability with the GAP. In winter wheat and barley, winter oilseed rape, legumes and stone fruit (N-E) were studied in all trials. max. 2 appl. Recommended number of applications for all crops included in GAP table is max. 2 appl. per season.

Summary of trials and results: (only valid trials were presented)

- **Winter wheat** Recommended are max 2 application per season at dose 0.5 L/ha. ZRMs agree with application window BBCH 29-69 (in the trials was studied BBCH 31-61). Accepted water volume accordingly to trials should be: 200-300 L/ha. Interval: 14 d – accepted.

against SEPTTR – in total 30 trials. In all trials SEPTTR was studied. – 18 MAR (CZ-2, DE-4, FR-6, UK-6) carried out in 2019 and 2021; 8 N-E (PL) in 2020-2021 and 4 S-E (RO) in 2020-2021. cMS from S-E should decide if limited number of trials can be accepted. For MAR and N-E applicant submitted enough number of trials. It can be concluded that SIP41061 at recommended rate (0.5L/ha) effectively control SEPTTR in N-E and S-E and moderately effectively in MAR EPPO zone on winter wheat crops. Results were comparable to standard reference product. In PL, Applicant recommend for use also lower dose: 0.4 L/ha, which is only less effective (ME) than dose 0.5 L/ha. So, both doses 0,4 and 0,5 l/ha can be accepted in PL.

against PUCCSP – in total 18 trials. In all trials PUCCSP was studied. – 10 MAR (CZ-1, DE-2, FR-4, UK-3) in 2020-2021; N-E 4 (PL) in 2020-2021 and S-E 4 (RO) in 2020-2021. cMS from S-E and N-E should decide if limited number of trials can be accepted. For MAR applicant submitted enough number of trials. PL can accept PUCCSP in label on the basis on trials from PL and neighbouring countries (CZ, DE). It can be concluded that SIP41061 at recommended rate (0.5L/ha) effectively control PUCCSP in N-E and S-E and moderately effective in MAR and S-E on winter wheat crops. Results were comparable to standard reference product. In PL, Applicant recommend for use also lower dose: 0.4 L/ha, which is only less effective (ME) than dose 0.5 L/ha. So, both doses 0,4 and 0,5 l/ha can be accepted in PL.

PUCCSP – Applicant presented results together for PUCCRT/PUCCRE and PUCCST which is not in line to EPPO standard. Results for PUCCRT/PUCCRE and PUCCST should be presented separately.

Applicant presented 5 efficacy trials against PUCCRE/PUCCSST in Maritime EPPO zone (FR-2, CZ-1, DE-1, UK) and 6 trials against PUCCST (DE-2, FR-2, UK-2). In one trial from UK, both PUCCSI and PUCCRE was studied in on etrial/ In N-E PUCCRE/PUCCRT was studied in 3 trials and PUCCST in one trial. In S-E – PUCCST was studied in one trial (RO), and PUCCRT/PUCCRE in 3 trials (RO). PUCCRE/ PUCCRT in N-E and S-E was effectively control by SIP41061 at recommended dose 0.5 L/ha and moderetaley effective in MAR. PUCCST was effectively control in all studied zones. In PL, both PUCCRE (on the basis on 5 trials: DE-1, CZ-1, PL-3) and PUCCST (on the basis on 3 trials: DE-2, PL-1) can be accepted in the label.

against FUSASP – in total ~~15~~ 16 trials. In all trials FUSASP was studied. – ~~7~~ 8 MAR (DE-2, FR-2, UK-~~3~~ 4) in 2020-2021; 4 N-E (PL) in 2020-2021 and 4 S-E (RO) in 2020-2021. cMS from S-E and N-E should decide if limited number of trials can be accepted. For MAR applicant submitted enough number of trials. PL can accept FUSASP in label on the basis on trials from PL and neighbouring countries (DE). It can be concluded that SIP41061 at recommended rate (0.5L/ha) effectively control FUSASP in N-E and S-E and moderately effective in MAR on winter wheat crops. Results were comparable to standard reference product. In PL, Applicant recommend for use also lower dose: 0.4 L/ha, which is only less effective (ME) than dose 0.5 L/ha. So, both doses 0,4 and 0,5 l/ha can be accepted in PL. However, no evidence of toxin reduction (DON reduction) was demonstrated. In order to prove the efficacy for this application, efficacy data from the field trials as well as the corresponding data on the reduction of mycotoxin contamination in the crop after fungicide application must be submitted. This evidence is essential for the approval of a plant protection product against *Fusarium* head blight, as high toxin levels in cereals pose a risk to humans and animals.

Erysiphe spp – in the opinion of ZRMs should be deleted from GAP table due to not enough number of trials. It was studied only in one trial in S-E EPPO zone. However, final decision is left to cMS. From Polish label *Erysiphe spp* should be deleted.

Only use on winter wheat should be accepted. Lack of trials for soft and durum wheat, triticale, and rye. cMS should consider extrapolation results from winter wheat. In Poland triticale, rye, soft and durum wheat should be deleted from Polish label project (at least 1-2 eff. trials were required for possibility of extrapolation results from winter wheat).

- **Winter barley:** Recommended are max 2 application per season at dose 0.5 L/ha. ZRMs not agree with proposed application window BBCH 29-61 (in the trials was studied BBCH 30-47). In ZRMs opinion accordingly to trials, application window should be BBCH 30-49. Accepted water volume should be: 200-300 L/ha. Interval: 14 d – accepted.

against PYRNTE – in total 20 trials. In all trials PYRNTE was studied. – 10 MAR (CZ-3, DE-3, FR-3, UK-1) in 2020-2021; 4 N-E (PL) in 2020-2021 and 4 S-E (RO) in 2020-2021. cMS from S-E and N-E should decide if limited number of trials can be accepted. For MAR applicant submitted enough number of trials. PL can accept PYRNTE in label on the basis on trials from PL and neighbouring countries (DE and CZ). It can be concluded that SIP41061 at recommended rate (0.5L/ha) effectively control PYRNTE in N-E and S-E and moderately effectively in MAR EPPO zone on winter barley crops. In PL, Applicant recommend for use also lower dose: 0.4 L/ha, which is only less effective (ME) than dose 0.5 L/ha. So, both doses 0,4 and 0,5 l/ha can be accepted in PL. Results were comparable to standard reference product.

In 2 trials from PL (N-E) spring barley was studied. SIP41061 effectively control PYRNTE on spring barley. Results were comparable to st. ref. product. On the basis on possibility of extrapolation results from winter barley, also spring barley against PYRNTE can be included in Polish label.

against RHYNSE – in total 13 trials. In all trials RHYNSE was studied. – 6 MAR (CZ-1, FR-2, UK-3) in 2020-2021; 4 N-E (PL) in 2020-2021 and 3 S-E (RO) in 2021. cMS from S-E and N-E should decide if limited number of trials can be accepted. For MAR applicant submitted enough number of trials. PL can accept RHYNSE in label on the basis on trials from PL and neighbouring countries (CZ, DE). In the opinion of ZRMs, 5 trials should be acceptable (prothioconazole is used for many years and its efficacy is commonly known). It can be concluded that SIP41061 at recommended rate (0.5L/ha) effectively control RHYNSE in MAR, N-E and S-E on winter barley crops. In PL, Applicant recommend for use also lower dose: 0.4 L/ha, which is only less effective (ME) than dose 0.5 L/ha. So, both doses 0,4 and 0,5 l/ha can be accepted in PL. Results were comparable to standard reference product.

against PUCCHD – in total 5 trials. In all trials PUCCHD was studied. – 3 MAR (DE) in 2020-2021 and 2 S-E (HU) in 2020. cMS from MAR and S-E should decide if limited number of trials can be accepted. cMS from N-E should consider possibility of acceptance results from other zones. Due to not enough number of trials, PUCCHD should be deleted from Polish label. It can be concluded that SIP41061 at recommended rate (0.5L/ha) effectively control PUCCHD in MAR and N-E on winter barley crops. Results were comparable to standard reference product.

- **Apple:** Recommended are max 2 application per season at dose 0.3 L/ha. ZRMs not agree with proposed application window BBCH 39-85 (in the trials was studied BBCH 53-73). In ZRMs opinion accordingly to trials, application window should be BBCH 51-79. Accepted water volume should be: 500-1000 L/ha not 500-1500 L/ha. Interval: 7-9 d – accepted.

against VENTIN – in total 19 trial. In all trials VENTIN was studied. – 8 MAR (DE-4, FR-2, UK-2) in 2020-2021; 8 N-E (PL) in 2020-2021 and 3 S-E (HU) in 2020-2021. cMS from S-E should decide if limited number of trials can be accepted. For MAR and N-E applicant submitted enough number of trials. It can be concluded that SIP41061 at recommended rate (0.3 L/ha) moderately effectively control VENTIN on apple crops. Results were comparable to standard reference product. In PL, Applicant recommend in GAP table also doses 0.2-0.25 L/ha. However, they were characterized by lower efficiency than dose 0.3 L/ha. So, in PL in the opinion of ZRMs dose 0,3 l/ha should be recommended for use on apple.

against PODOLE – in total 9 trials, In all trials PODOLE was studied. – 6 MAR (DE-2, FR-3, UK-1) in 2021 and 3 N-E (PL) in 2021. cMS from N-E should decide if limited number of trials can be accepted. cMS from S-E should consider the possibility of taken results from other EPPO zones. For MAR applicant submitted enough number of trials. PL can accept PODOLE in label on the basis on trials from PL and neighbouring countries (DE). In the opinion of ZRMs, 5 trials should be acceptable (prothioconazole is used for

many years and its efficacy is commonly known). It can be concluded that SIP41061 at recommended rate (0.3 L/ha) effectively control PODOLE on apple crops. Results were comparable to standard reference product. In PL, Applicant recommend in GAP table also doses 0.2-0.25 L/ha. They were characterized by only less low efficiency than dose 0.3 L/ha. However, due to fact that VENTIN was worst control by lower doses in apple, then only dose 0.3 L/ha should be recommended in our opinion.

Lack of trials against *Stemphylium vesicarium* PLEOAL. Final decision is left to each cMS. In PL – not accepted.

Quince, medlar and pear can be accepted in PL according to Article 51 without any trials. In accordance with Article 33 at least 1-2 eff. trials for each crop is required. cMS should decide about possibility of acceptance this crops without any trials.

- **Stone fruits** Recommended are max 2 application per season at dose 0.4 L/ha. ZRMs not agree with proposed application window BBCH 51-85 (in the trials was studied BBCH 75-87). In ZRMs opinion accordingly to trials, application window should be BBCH 71-89. Accepted water volume should be: 500-1000 L/ha not 500-1500 L/ha. Interval: 7 d – accepted

Against *Monilia spp.* – in total 11 trials In trials MONIFG (3 trials) and MONISP (3 trials) – MAR 6 (DE-5, FR-1) in 2020-2021 and 5 N-E (PL) against MONISP (2 trials: cherry and peach) and MONIFG (3 trials: cherry- 1 trial, plum-2 trials) in 2020-2021 and 5 N-E (PL) in 2020-2021. cMS from N-E should decide if limited number of trials can be accepted. For MAR applicant submitted enough number of trials. cMS from S-E should consider the possibility of taken results from other EPPO zones. In MAR trial following crops were studied: amarello cherry (3), cherry (1), peach (1), plum (1). During N-E trials amarello cherry (2), peach (1) and plum (2) was studied. For MAR and N-E applicant submitted enough number of trials. In PL – amarello cherry, peach and plum can be included in label. In PL apricot can be accepted only as minor crop accordingly to Article 51. Also, cMS should decide about possibility of acceptance apricot without any trial. It can be concluded that SIP41061 at recommended rate (0.4 L/ha) effectively control *Monilia spp.* in N-E and moderately effective in MAR on stone fruits crops. Results were comparable to standard reference product. In Polish GAP, Applicant recommended also dose 0.3 L/ha, which efficacy was comparable to dose 0.4 L/ha. So, both doses 0,3 and 0.4 L/ha can be used in PL.

- **Legumes – this use was not included in GAP table by Applicant. So, ZRMs only present number of trial for review by cMS.** Detailed of results was presented by Applicant in this dRR. In PL, only registration legumes according to Article 51 will be possible. During trials following crops were studied: broad bean (2), faba bea (1), field peas (7), forage peas (10 and peas (3). Results were comparable to standard ref. product.

against *Ascochyta pisi* – in total 9 trials – MAR 9 (FR-4, UK-5) in 2019-2021

against *Uromyces spp* – in total 4 trials – MAR 4 (FR-1, UK-3) in 2020-2021

against *Erysiphe spp.* – in total 2 trials – MAR 2 (FR) in 2020-2021.

- **Winter oilseed rape** Recommended are max 2 application per season at dose 0.45 L/ha. ZRMs not agree with proposed application window BBCH 30-71 (in the trials was studied BBCH 65). In ZRMs opinion accordingly to trials, application window should be BBCH 60-69. Accepted water volume should be: 200-300 L/ha not 200-600 L/ha. Interval: 14 d – accepted

against *SCLESC* – in total 23 trials – MAR 13 (CZ-2, DE-3, FR-5, UK-3) in 2020-2021; 5 N-E (PL) in 2020-2021 and 5 S-E (RO) in 2020-2021. cMS from S-E and N-E should decide if limited number of trials can be accepted. For MAR applicant submitted enough number of trials. PL can accept SCLESC in label on the basis on trials from PL and neighbouring countries (CZ, DE). It can be concluded that SIP41061 at recommended rate (0.45L/ha) effectively control SCLESC on winter oilseed tape stem. In PL, Applicant recommend fro use also lower dose: 0.35 L/ha, which is the same effective (E) as dose 0.45 L/ha. So, both doses 0,35 and 0.45 L/ha can be used in PL. Pods were studied only in 3 trials from MAR EPPO zone. Results were comparable to standard reference product.

against *LEPTMA* – in total 4 trials – N-E 4 (PL) in 2020-2021. Number of trials is not enough for registration in PL and cMS in the opinion of ZRMs.

- **Sugar beet** Recommended are max 2 application per season at dose 0.4 L/ha. ZRMs agree with proposed application window BBCH 39-49 (accordingly to trials). Accepted water volume should be: 200-300 L/ha not 200-600 L/ha. Interval: 14 d – accepted

against CERCBE – in total 22 trials – 18 MAR (CZ-3, DE-6, FR-5, UK-3, NL-1) in 2019-2021 and 4 N-E (PL) in 2019-2021. cMS from S-E should consider the possibility of taken results from other EPPO zones. For MAR and N-E Applicant submitted enough number of trials. It can be concluded that SIP41061 at recommended rate (0.4L/ha) effectively control CERCBE on sugar beet. Results were comparable to standard reference product. In PL, Applicant recommend for use also lower dose: 0.30 L/ha, which is the same effective (E) as dose 0.40 L/ha. So, both doses 0,3 and 0,4 l/ha can be accepted in PL.

against ERYSB – in total 4 trials - MAR 4 (UK-3, NL-1) in 2020. cMS from S-E and N-E should consider the possibility of taken results from other EPPO zones. For MAR Applicant submitted enough number of trials. It can be concluded that SIP41061 at recommended rate (0.4L/ha) effectively control ERYSB on sugar beet. Results were comparable to standard reference product. In PL ERYSB on sugar beet can be accepted only according to Article 51 (without valid trials in minor crops).

- **Carrot** Recommended are max 2 application per season at dose 0.5 L/ha. ZRMs not agree with proposed application window BBCH 16-46 (in the trials was studied BBCH 41-46). In ZRMs opinion accordingly to trials, application window should be BBCH 41-49. Accepted water volume should be: 500-600 L/ha not 500-1000 L/ha. Interval: 21 d – accepted

against ALTEDA – in total 20 trials – 8 MAR (FR, UK, NL) in 2020-2021; 6 N-E (PL) in 2021 and 6 S-E (RO) in 2020-2021. Number of trials is acceptable for N-E, S-E and MAR. It can be concluded that SIP41061 at recommended rate (0.5 L/ha) effectively control ALTEDA on carrot. Results were comparable to standard reference product.

against ERYSH – 3 trials – N-E 3 (PL) in 2020-2021. cMS from MAR and S-E should consider possibility of taken results from other zones. In Poland ERYSH can be accepted in label. It can be concluded that SIP41061 at recommended rate (0.5 L/ha) effectively control ERYSH on carrot. Results were comparable to standard reference product.

against SCLESC – lack of trials. SCLESC on carrot can be accepted in PL only in accordance to Article 51. cMS should consider extrapolation results on carrot from winter oilseed rape or using Article 51.

EFFECTIVENESS ACCORDING TO LWA APPROACH:

According to EPPO PP 1/239, the application rate should be calculated per treated leaf wall area unit (LWA) and results of the tested product should be presented and interpreted according to LWA by the applicant. **The applicant submitted and presented results related to LWA score combined with reference to ha ground area** for Maritime and N-E EPPO zone. For S-E applicant did not present any results for LWA in this report (however in one trial – F1/2021 needed data were submitted: 4 x 1,2m rows and 2m height plants – it correspond to 10000 LWA). However, it is only one trial, so these results are not presented in summary below. For S-E is not possible to presented conversion (lack of height plants and information/s about rows). So, cMS from S-E should calculated dose LWA on the basis on average LWA in S-E EPPO zone, row parameters and height of plants or consider the taken of results LWA dose from another zone (MAR or/and N-E).

APPLE:

- ✓ **Maritime EPPO zone:**

VENTIN: These results from countries belonging to the Maritime EPPO climatic zone demonstrated that SIP41061 in the range of rates from 0.2 to 0.3 L/ha and from 0.14 to 0.252 L/10000 m² LWA matched or exceed the efficacy of the reference standards based on difenoconazole (SCORE) and dithianon applied at the registered rates. These rates should thus be considered to be effective against *Venturia inaequalis* on apple.

PODOLE: Results from countries belonging to the Maritime EPPO climatic zone demonstrated that SIP41061 in the range of rates from 0.2 L/ha to 0.3 L/ha and from 0.14 to 0.2 L/10000 m² LWA matched or exceed the efficacy of the reference standards based on penconazole applied at the registered rates and TOPAS applied at 0.125 L/ha/m ch. These rates should thus be considered to be effective against *Podosphaera leucotricha* on apple.

✓ **N-E EPPO zone**

VENTIN: These results from countries belonging to the North-East EPPO climatic zone demonstrated that SIP41061 in the range of rates from 0.2 L/ha to 0.3 L/ha and from 0.14 L/10000 m² to 0.2 L/10000 m² LWA matched or exceed the efficacy of the reference standards based on difenoconazole (SCORE) applied at the registered rates and TOPAS applied at 0.125 L/ha/m ch. These rates should thus be considered to be effective against *Venturia inaequalis* on apple. Dose 0.3 L/ha and 0.2 L/10000 m² LWA should be recommended for PL as most effective.

PODOLE: These results from countries belonging to the North-East EPPO climatic zone demonstrated that SIP41061 in the range of rates from 0.2 L/ha to 0.3 L/ha and from 0.14 L/10000 m² to 0.2 L/10000 m² LWA matched or exceed the efficacy of TOPAS applied at 0.125 L/ha/m ch. These rates should thus be considered to be effective against *Podosphaera leucotricha* on apple. Dose 0.3 L/ha and 0.2 L/10000 m² LWA should be recommended for PL as most effective.

STONE FRUITS

✓ **Maritime EPPO zone:**

Monilia spp. These results from countries belonging to the Maritime EPPO climatic zone demonstrated that SIP41061 at the proposed rates of 0.3 - 0.4 L/ha and 0.22 L/10000 m² LWA - 0.265 L/10000 m² LWA matched or exceeded the efficacy of the reference standard SIGNUM applied at 20.03 + 5.03 gai/ha. These rates should thus be considered to be effective against *Monilia spp.* on stone fruit.

✓ **N-E EPPO zone:**

Monilia spp. These results from Poland that belongs to the North-East EPPO climatic zone demonstrated that SIP41061 at the proposed label rates of 0.3 L/ha - 0.4 L/ha or 0.22 – 0.265 L/10000 m² LWA matched or exceed the efficacy of the reference standard SWITCH or SIGNUM. These rates should thus be considered to be effective against *Monilia spp.* on stone fruit. Also, those rates are recommended for Poland.

Concerned Member States will need to consider the relevance of the submitted formulation comparability data in relation to the current authorized uses for the reference product (a.s. prothioconazole) in their own Member State. It is recommended to authorize the product SIP41061 (product code: SIP41061) in the extent of the authorization of the reference product (a.s. prothioconazole) at the equivalent dose rate. However, this approach is not acceptable by Poland during national rules.

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

SIP41061 is a fungicide containing Prothioconazole intended to be used as preventative fungicide on cereals (wheat, spring and winter barley, rice), oilseed rape, sugar beet, fresh and dry legumes, cucurbits, pome and stone fruits and carrot in Europe. intended to be used in various crops against various diseases having a different risk of resistance development.

Prothioconazole is classified by FRAC¹ within Group G1, code#3, (DMI-fungicides - DeMethylation Inhibitors: SBI, Class I) and belongs to the chemical class of triazolinthiones. Other chemical classes classified as Group 3, code #3 fungicides are piperazines, pyridines, pyrimidines, imidazoles, triazoles.

¹ FRAC Code List ©*2021: Fungal control agents sorted by cross resistance pattern and mode of action (including coding for FRAC Groups on product labels)

The active ingredient: prothioconazole belong to the chemical group of triazoles. Prothioconazole belong to a group of active ingredients which are now commonly characterised as SBI-class I: DeMethylation-Inhibitors (Abbreviation: DMI's), a subgroup of the Sterol Biosynthesis Inhibitors (SBI's).

Due to its mode of action, in the FRAC (Fungicide Resistance Action Committee) classification prothioconazole is classified as follows:

Prothioconazole: 'FRAC Code 3' – MOA Code G1; Target site: C¹⁴-demethylase in sterol biosynthesis; Group name: DMI-fungicides (DeMethylation Inhibitors) (SBI: Class I); Chemical group: Triazole.

The SBI based fungicides have a broad spectrum of activity against a range of economically important pathogens on arable crops, top fruit, vines, plantation crops, etc and they represent an important class of agricultural fungicides. They make a major contribution to world agricultural production.

Resistance is known in various fungal species. Several resistance mechanisms are known including several target site mutations on the cyp51 gene (cytochrome p450) and effects on ABC transporters. Resistance to SBI fungicides has been well characterized during the last 25 years. Problems with SBI performance typically became obvious only after several years of intensive use with efficacy degrading stepwise. The recommendations should be based upon data generated by members of the FRAC-SBI Working Group and upon the work of non-industry collaborators

SBI fungicides have been characterized by FRAC (<http://www.frac.info>) as medium risk resistance but as pathogens have different risk levels, combination of both fungicide and pathogen resistance risk should also be investigated at CMS level.

The pattern of cross-resistance of the sterol biosynthesis inhibitor (SBI) fungicides, of which prothioconazole is a member, is complex and summarized as follows:

FRAC Code	SBI Class	Group Name	Chemical Group	Cross-resistance
G1/3	I	DMI (De-Methylation Inhibitors)	Piperazines, pyridines, pyrimidines, imidazoles, triazoles	Resistance within the DMI group but NOT to other SBI classes.
G2/5	II	Amines (morpholines)	Morpholines, piperidines, spiroketal-amines	Cross-resistance within the group generally found but not to other SBI classes.
G3/17	III	hydroxyanilides	hydroxyanilides	-
G4/18	IV	Squaline-epoxidase inhibitors	Thiocarbamates, allylamines	Resistance does not know

Therefore, fungal pathogen strains that are resistant to DMI fungicides are unlikely to be cross-resistant to other SBI class fungicides and vice versa.

In terms of agronomic practice, the selection pressure on the intended disease target for SIP41061 may be low to high depending on whether a successful crop rotation system is applied, or mono-cropping is carried out in the crop, respectively.

If SIP41061 is used unrestrictedly as a sole product for disease control in cereals, legumes, sugar beet, carrot, pome and stone fruits and oilseed rape, the agronomic risk for the development of pathogen resistance against SIP41061 in this intended indication is considered medium to high.

In the opinion of Evaluator, the following strategy against developing resistance should be put in the label:

- use the product mainly as a preventive measure,

- *not use the product in doses other than recommended,*
- *inclusion in the adopted protection programme of fungicides containing active substances from other groups, with different mechanisms of action (alternate use or tank mix).*

Since the agronomic factors influencing the risk of resistance development tend to vary between the member states, the individual and detailed assessment of the resistance risk (Evaluation of the Agronomic risk of resistance, Management of resistance, Use pattern, Proposed Risk Modifiers) has to be finalised on national level. In Germany, there are hints that there is a loss of sensitivity in *Zymoseptoria tritici* in wheat against prothioconazole. The applicant does not provide actual monitoring data for prothioconazole for *Z. tritici* CYP51 mutations or EC50-values from the maritime EPPO zone, especially Germany from the last three years.

3.3.2 Adverse effects on treated crops

Information on adverse effects is provided from efficacy trials with SIP41061.

Both EU Directive 91/414 (EU, 1991) and EPPO PP 1/226 (3) – Number of efficacy trials requires testing phytotoxicity at normal (N) and double (2N) recommended dose. However, EPPO 1/135 (3) – Phytotoxicity assessment states: ‘EPPO Standards on fungicides, insecticides and plant growth regulators, on the other hand, include only a relatively simple special section on phytotoxicity as-assessment, because, for these types of plant protection products, phytotoxic effects will be less frequent’. Selectivity trials were not required, which is in accordance with EPPO 1/135 (3).

Prothioconazole is used for many years in agriculture practice and there is lack of information's about any adverse effects than already knows. So, no special studies are required in the opinion of Evaluator.

The crop safety of applying SIP41061 at recommended doses was evaluated during efficacy trials carried out in the Maritime, N-E and S-E EPPO zone.

Winter cereals:

- *wheat* – 59 efficacy trials (in which phytotoxicity effect was studied) carried out in Maritime EPPO zone (33 trials); N-E EPPO zone (13 trials) and S-E EPPO zone (13 trials). Trials were performed in 2020 and 2021. Effect of dose 0.45-0.5 L/ha was studied. No phytotoxicity symptom, assessed in terms of general injury (PHYGEN) caused by SIP41061 at the proposed range of rates in efficacy trials was recorded in all trials. Results were comparable to st. ref. product.
- *barley* – 33 efficacy trials (in which phytotoxicity effect was studied) carried out in Maritime EPPO zone (17 trials); N-E EPPO zone (9 trials) and S-E EPPO zone (3 trials). In 2 trials from N-E – spring barley was studied. Trials were performed in 2020 and 2021. Effect of dose 0.5 L/ha was studied. No phytotoxicity symptom, assessed in terms of general injury (PHYGEN) caused by SIP41061 at the proposed range of rates in efficacy trials was recorded in all trials. Results were comparable to st. ref. product.

Pome fruits (trials carried out only on apple):

- *apple* – 26 efficacy trials (in which phytotoxicity effect was studied) carried out in Maritime EPPO zone (14 trials); N-E EPPO zone (9 trials) and S-E EPPO zone (3 trials). Trials were performed in 2020 and 2021. Effect of dose 0.2-0.3 L/ha was studied. No phytotoxicity symptom, assessed in terms of general injury (PHYGEN) caused by SIP41061 at the proposed range of rates in efficacy trials was recorded in all trials. Results were comparable to st. ref. product in S-E and N-E EPPO zones trials. In Maritime EPPO zone phytotoxic effect of SIP41061 was observed in 1 trial from 14 trials (injuries at level 10-15%). However, those symptoms were detected only after the 4th application of SIP41061 whereas the maximum number of applications recommended by GAP are 2 applications.

Stone fruits (in total 10 eff. trials in which phytotoxicity effect was studied):

- *Maritime EPPO zone*. 5 trials carried out on cherry (3 trials), peach (1 trial) and plum (1 trial). Trials were performed in 2020 and 2021. Effect of dose 0.3-0.4 L/ha was studied. No phytotoxicity symptom, assessed in terms of general injury (PHYGEN) caused by SIP41061 at the proposed range of rates in efficacy trials was recorded in all trials. Results were comparable to st. ref. product.
- *N-E EPPO zone*: 5 trials carried out on cherry (1), peach (1) and plum (2). Trials were performed in 2020 and 2021. Effect of dose 0.3-0.4 L/ha was studied. No phytotoxicity symptom, assessed in terms of general injury (PHYGEN) caused by SIP41061 at the proposed range of rates in efficacy trials was recorded in all trials. Results were comparable to st. ref. product.

Legumes (peas, beans):

- *Maritime EPPO zone*. 14 eff. trials (in which phytotoxicity effect was studied) carried out on broad bean (2 trials), faba bean (1 trial), field peas (7 trials), forage peas (1 trial) and peas (3 trials). Trials were performed in 2019, 2020 and 2021 in UK and France. Effect of dose 0.3-0.4 L/ha was studied. No phytotoxicity symptom, assessed in terms of general injury (PHYGEN) caused by SIP41061 at the proposed range of rates in efficacy trials was recorded in all trials. Results were comparable to st. ref. product.

Oilseed rape in total 23 eff. trials (in which phytotoxicity effect was studied):

- *Maritime EPPO zone*. 10 trials; *N-E EPPO zone*: 5 trials; *S-E EPPO zone*: 5 trials carried out in 2020-2021. Effect of dose 0.35-0.45 L/ha was studied. No phytotoxicity symptom, assessed in terms of general injury (PHYGEN) caused by SIP41061 at the proposed range of rates in efficacy trials was recorded in all trials. Results were comparable to st. ref. product.

Carrot: in total 20 eff. trials (in which phytotoxicity effect was studied):

- *Maritime EPPO zone*. 8 trials; *N-E EPPO zone*: 6 trials; *S-E EPPO zone*: 6 trials carried out in 2020-2021. Effect of dose 0.4-0.5 L/ha was studied. No phytotoxicity symptom, assessed in terms of general injury (PHYGEN) caused by SIP41061 at the proposed range of rates in efficacy trials was recorded in all trials. Results were comparable to st. ref. product.

Sugar beet: in total 21 eff. trials (in which phytotoxicity effect was studied):

- *Maritime EPPO zone*. 17 trials; *N-E EPPO zone*: 4 trials carried out in 2019; 2020 and 2021. Effect of dose 0.3-0.4 L/ha was studied. No phytotoxicity symptom, assessed in terms of general injury (PHYGEN) caused by SIP41061 at the proposed range of rates in efficacy trials was recorded in all trials. Results were comparable to st. ref. product.

Lack of trials for soft and durum wheat, triticale, rye, quince, medlar, pear, apricot, and other roots vegetables. Each cMS should decide if those mentioned crops can be accepted without any trials. It is important to remember that extrapolation of phytotoxic studies is always risky. **In Poland quince, medlar, pear, apricot and other roots vegetables can be accepted only on the basis Article 51 without any trials. Soft and durum wheat, triticale and rye should be excluded from Polish label – at least 1-2 eff./phytotoxicity trials are required.**

Each cMS should decide if presented documentation is sufficient for acceptance winter wheat and barley, apple, pome fruits, winter oilseed rape, carrots, legumes and sugar beet. **For Poland Applicant presented enough trials against winter wheat, winter barley, apple as a stone fruit, pome fruits (cherry, peach, plum), winter oilseed rape, sugar beet and carrot. Legumes should be excluded from Polish label (trials from FR and UK are not acceptable for PL). Legumes can be accepted only as minor crops according to Article 51. Also, spring oilseed rape can be accepted on the basis Art. 51 without any trial. However, legumes were not included by Applicant in GAP table.**

In conclusion, no negative influence of the product SIP 41061 (product code: SAP250F) is to be expected when at the intended rate and used according to the label recommendations.

Effect on yield: Winter wheat: Yield data on wheat are presented from 15 efficacy trials. These trials were carried out in Maritime (13) and North-East (2) EPPO zone. The objective was to confirm the impact on

yield of grains of SIP41061 in the range of rates of 0.5 L/ha. The standards, based on prothioconazole (195-198 gai/ha) and bixafen + prothioconazole (75 + 150/160 L/ha), were used in the trials for comparison with SIP41061.

Maritime EPPO zone: SIP41061 at 0.5 L/ha (111.2 % yield) had a positive effect on grain yield in comparison to the untreated check (=100%), similar to that provided by the reference standards based on prothioconazole (195-198 gai/ha).

N-E EPPO zone: SIP41061 at 0.5 L/ha (114.5% yield) had a positive effect on grain yield in comparison to the untreated check (=100%), similar to that provided by the reference standards based on prothioconazole (195-198 gai/ha).

Winter barley: Yield data on barley are presented from 14 efficacy trials. These trials were carried out in 2020-2021 in Maritime (8) and North-East (6) EPPO zone. The objective was to confirm the impact on yield of grains of SIP41061 in the range of rates from 0.4 L/ha to 0.5 L/ha. The standards, based on prothioconazole (195-198 gai/ha) were used in the trials for comparison with SIP41061.

Maritime EPPO zone: SIP41061 at 0.4 L/ha (109.7% yield) and at 0.5 L/ha (111.9% yield) had a positive effect on grain yield in comparison to the untreated check (=100%), similar to that provided by the reference standards based on prothioconazole (195-198 gai/ha).

N-E EPPO zone: SIP41061 at 0.4 L/ha (104.9% yield) and at 0.5 L/ha (109.3% yield) had a positive effect on grain yield in comparison to the untreated check (=100%), similar to that provided by the reference standards based on prothioconazole (195-198 gai/ha).

Apple (pome fruit): No data about yield. Not studied during trials. According to EPPO 1/69 - It may be useful to weigh and evaluate the fruits (against national standards), which is an indicator of fruit quality. But it is not mandatory. According to EPPO 1/5 - quantitative yield data are not required. Quality of the fruit should be assessed in accordance with national or international requirements. So, lack of yield results can be accepted in the opinion of ZRMs.

Stone fruits: No data about yield. Not studied during trials. EPPO's specific guidelines for evaluating efficacy against diseases of cherry or other stone trees do not indicate the need to evaluate and yield quality. So, lack of yield results can be accepted in the opinion of ZRMs.

Legumes: No data about yield. Not studied during trials. Not relevant but could be useful. So cMS should decide if lack of yield for legumes can be accepted. However, this crop was not included in GAP table.

Winter oilseed rape: Yield data on oilseed rape are presented from 13 efficacy trials. These trials were carried out in 2020-2021 in Maritime (7), North-East (3) and South-East (3) EPPO zone. The objective was to confirm the impact on yield of grains of SIP41061 in the range of rates from 0.35 L/ha to 0.45 L/ha.

Maritime EPPO zone: SIP41061 at 0.35 L/ha (116.3 % yield) and at 0.45 L/ha (115.8% yield) had a positive effect on grain yield in comparison to the untreated check (=100%), similar to that provided by the reference standards based on prothioconazole (173-175 gai/ha).

N-E EPPO zone: SIP41061 at 0.35 L/ha (108.5% yield) and at 0.45 L/ha (115.8% yield) had a positive effect on grain yield in comparison to the untreated check (=100%), similar to that provided by the reference standards based on prothioconazole (173-175 gai/ha).

S-E EPPO zone: SIP41061 at 0.35 L/ha (102.2% yield) and at 0.45 L/ha (105.5% yield) had a positive effect on grain yield in comparison to the untreated check (=100%), similar to that provided by the reference standards based on prothioconazole (173-175 gai/ha).

Sugar beet: Yield data on sugar beet are presented from 9 efficacy trials. These trials were carried out in 2020-2021 in Maritime (5) and North-East (4) EPPO zone. The objective was to confirm the impact on yield of roots of SIP41061 in the range of rates from 0.3 L/ha to 0.4 L/ha.

Maritime EPPO zone: In 4 trials, SIP41061 at 0.3 L/ha (108.8% yield) and at 0.4 L/ha (111.6% yield) had a positive effect on root yield in comparison to the untreated check (=100%), similar to that provided by the

reference standards based on tetraconazole at 80-100 gai/ha (106.4 % yield). In one trial, SIP41061 at 0.3 L/ha (101.3% yield) and at 0.4 L/ha (105% yield) had a positive effect on root yield at harvest in comparison to the untreated check (=100%), similar to that provided by the reference standard SPYRALE at 375 gai/ha + 100 gai/ha (100% yield).

N-E EPPO zone: SIP41061 at 0.3 L/ha (108.5% yield) and at 0.4 L/ha (109.1% yield) had a positive effect on root yield in comparison to the untreated check (=100%), similar to that provided by the reference standards based on tetraconazole at 80-100 gai/ha (107.1% yield).

Carrot Yield data on carrot are presented from 4 efficacy trials. These trials were carried out in 2020-2021 in Maritime (1) and North-East (3) EPPO zone. The objective was to confirm the impact on yield of roots of SIP41061 in the target rates of 0.4 L/ha. The standard, SIGNUM (334 gai/kg: 67 gai/L boscalid + 267 gai/L pyraclostrobin) applied at 1 kg/ha, was used in the trial for comparison with SIP41061 at 0.4 L/ha.

Maritime EPPO zone: SIP41061 at 0.4 L/ha (97.8% yield) had a positive effect on root yield in comparison to the untreated check (=100%), similar to that provided by the reference standard SIGNUM (67 gai/ha + 267 gai/ha).

N-E EPPO zone: SIP41061 at 0.4 L/ha (135.4% yield) had a positive effect on root yield in comparison to the untreated check (=100%), similar to that provided by the reference standard SIGNUM (67 gai/ha + 267 gai/ha).

In conclusion, no negative influence of the product SIP41061 (product code: SIP41061) on the yield is to be expected when at the intended rate and used according to the label recommendations.

Effect on quality of yield: Winter oilseed rape: Quality data were presented from 7 efficacy trials. These trials were carried out in 2020-2021 in Maritime (4) and South-East (3) EPPO zones. The objective was to confirm the impact on oil seed content and in the quality parameter, Thousand Kernel Weight (TKW), of grains of SIP41061 in the range of rates from 0.35 L/ha to 0.45 L/ha. The standards, based on prothioconazole (250-275-300 gai/L) applied in the range of 0.58 L/ha and 0.7 L/ha, were used in the trials for comparison with SIP41061. These results demonstrated that SIP41061 at the proposed label rate of 0.35 L/ha and 0.45 L/ha was able to control the target diseases providing a positive effect on TKW in comparison to the untreated check. Similar to that provided by the reference standards based on prothioconazole.

Winter barley Quality data on barley are presented from 12 efficacy trials. These trials were carried out in Maritime (6) and North-East (6) EPPO zones. The objective was to confirm the impact on Thousand Grain Weight (TGW) and Hectolitre Weight of grains of SIP41061 at the rate of 0.4 L/ha and 0.5 L/ha. The standards, based on prothioconazole (250-275-300 gai/L) applied in the range of 0.65 L/ha and 0.8 L/ha, were used in the trials for comparison with SIP41061. These results demonstrated that SIP41061 at the proposed label rate of 0.4 L/ha and 0.5 L/ha was able to control the target diseases providing a positive effect on TKW and HLW in comparison to the untreated check, similar to that provided by the reference standards based on prothioconazole.

Winter wheat Quality data on wheat are presented from 20 efficacy trials. These trials were carried out in Maritime (12), and North-East (8) EPPO zones. The objective was to confirm the impact on Thousand Grain Weight (TGW) and Hectolitre Weight of grains of SIP41061 at the rate of 0.5 L/ha. The standards, based on prothioconazole (250-275-300 gai/L) applied in the range of 0.65 L/ha and 0.8 L/ha and bixafen + prothioconazole (75+150/160 gai/L) applied at 1-1.25 L/ha, were used in the trials for comparison with SIP41061. These results demonstrated that SIP41061 at the proposed label rate of 0.5 L/ha was able to control the target diseases providing a positive effect on TKW and HLW in comparison to the untreated check. Similar to that provided by the reference standards based on prothioconazole.

Lack of quality of yield trials for legumes, sugar beet, carrot is accepted by ZRMs. **Applicant should present quality of yield trials for apple (pome fruits) and cherry (stone fruit).** EPPO's specific guidelines for assessing efficacy against diseases of cherry or other stone trees do not indicate such a need, but in the case of protection of apple trees against scab and powdery mildew, the guidelines suggest or explicitly indicate the need to assess the impact of the product on fruit quality. In the prepared report, the applicant did not provide more extensive data or information on this subject. No information was found on effects on fruit russetting. **However, in 3 of the submitted trials conducted in Poland the russetting data were already present (trials:**

JTF-21-50758; JTF-21-50758-PL02; JTF-21-50759-PL02). Data were not summarized in dRR but trials showed no symptoms, or acceptable symptoms, or lower than russetting symptoms in the Untreated plots and consequently not due to SIP41061 application. Consequently, the request of 3-4 trials on russetting is already satisfied. Further to this, since russetting is a phytotoxicity symptom where in the trials no phytotoxicity symptoms are detected, we could conclude that russetting was not showed. ~~We propose to include a provision that the negative effect of SIP41061 on apple russetting and yield quality cannot be ruled out. The registration of apples should be conditional, and within 2 years of obtaining registration, the Applicant should present studies on the effects on apple fruit russetting in the number of at least 3-4 carried out in N-E Eppo zone.~~

In conclusion, no negative influence of the product SIP41061 (product code: SIP41061) on the quality of yield is to be expected when at the intended rate and used according to the label recommendations.

3.3.3 Observations on other undesirable or unintended side-effects

SIP41061 is a fungicide and is not expected to have any significant effect on succeeding crops or on other plants including adjacent crops. Furthermore, efficacy trials show optimum selectivity on the different crops.

No adverse effect on beneficial and other non-target organisms were observed during all the efficacy trials presented with this document.

In conclusion, no undesirable or unintended side-effects on succeeding crops, other plants including adjacent crops, beneficial or other non-target organisms are expected from the use of SIP41061 when applied according to the recommendations.

3.4 Methods of analysis (Part B, Section 5)

Adequate analytical methods are here provided for the determination of active ingredient, its relevant impurity and for all analytes included in the residue definitions.

3.4.1 Analytical method for the formulation

Sufficiently sensitive and selective analytical methods are available for the active substance and relevant impurities in the plant protection product.

In particular, an HPLC/UV-DAD method for prothioconazole and prothioconazole-desthio is available and has been successfully validated according to SANCO/3030/99 rev.5. A GC/MS analytical method for toluene is also available and has been successfully validated according to SANCO/3030/99 rev.5.

Methods for the determination of active substance and relevant impurities in the formulated product are provided in Section 5.2.1.1 and Section 5.2.1.2 of dRR Part B5.

3.4.2 Analytical methods for residues

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions. All of them have been successfully validated according to SANCO/825/00 rev.8.1 and to SANCO/3030/99 rev.4 and those more recent, according to SANTE/2020/12830, rev.1 (24/02/2021).

Noticed data gaps are:

- Monitoring methods with lowered LOQs for high water content (in relation to use on fruits and sugar beet roots) and high starch content matrices (to comply with the lowest MRL). This data gap can be fulfilled as a post-registration requirement. The assessment should be revised when the active substance is renewed and the new methods should be provided by the applicant for re-evaluation.

- ILV method for determination prothioconazole residues in drinking water (post registration requirement).
- ILV method for the determination of residues in honey for monitoring purpose (post registration requirement).
- Extraction efficiency for the plant and animal methods (post registration requirement).

Commodity/crop	Supported/ Not supported
high water content matrices	Supported
high starch content matrices	Supported
high oil content matrices	Supported

3.5 Mammalian toxicology (Part B, Section 6)

No test was performed on SIP 41061 (see confidential addendum on Part C). The results of the evaluation are summarized below:

3.5.1 Acute toxicity

SIP 41061 is unclassified with EUH208 “Contains 1,2-benzisothiazol-3-one. May produce an allergic reaction

3.5.2 Operator exposure

Operator exposure to SIP 41061 was assessed against the AOEL(s) agreed in the EU review (EFSA (2007) 106, 1-98, Conclusion on the peer review of prothioconazole) for both Prothioconazole and its metabolite Prothioconazole-desthio. Since prothioconazole-desthio is a suspected developmental toxicant, it was agreed with the RMS for Annex I approval of prothioconazole that non-dietary risk assessments for prothioconazole-desthio would also be provided. This will only be relevant where diluted prothioconazole is involved. The assessment has been conducted for Prothioconazole and its metabolite Prothioconazole-desthio considering 100% of each one separately. Assuming 100% conversion of prothioconazole to prothioconazole-desthio and taking into account the molar ratio of prothioconazole-desthio to prothioconazole ($312.2/344.3 = 0.907$), prothioconazole-desthio rates have been recalculated appropriately for the assessment

This approach is very conservative and extremely worst case as a complete transformation of prothioconazole into prothioconazole-desthio does not occur within the timeframe considered for activities according to the proposed cGAP. It should also be considered that in the RAR of the ongoing review of Prothioconazole, updated and more favourable endpoints based on available data have been considered for both active ingredient and metabolite. With the updated endpoints mitigations due to the worst-case assessment for 100% prothioconazole-desthio would not be needed.

Active substance(s) (incl. content)	Prothioconazole 400 g/L	Prothioconazole-desthio
AOEL systemic	0.2 mg/kg bw/d	0.01 mg/kg bw/d

Operator exposure was modelled using the EFSA model (2015) except for greenhouse where ECPA/CropLife model was used.

According to the model calculations, for both prothioconazole and its metabolite prothioconazole-desthio, the operator exposure for the intended GAP uses of SIP 41061 is below the limit of 100% AOEL if the following PPEs are taken into account:

Field Crops (max. 2 x 0.5 l product/ha at 14 days interval)

- Tractor-mounted boom sprayer, downwards

⇒ Work wear during mixing/loading and application

Orchard (max. 2 x 0.4 l product/ha at 7 days interval)

- Tractor-mounted airblast sprayer, upwards

⇒ Work wear during mixing/loading and application, gloves during application

- Manual, hand-held application, upwards

⇒ Work wear during mixing/loading and application.

Tractor mounted spray application outdoors to high crops (stone fruits)

⇒ Work wear (arms, body and legs covered) M/L and A + gloves A

3.5.3 Worker exposure

Worker exposure to SIP 41061 was modelled using the EFSA model.

According to the model calculations, the worker exposure for the intended GAP uses of SIP 41061 is below the limit of 100% AOEL if the following label mitigations are taken into account:

Field Crops (max. 2 x 0.5 l product/ha at 14 days interval)

⇒ Work wear (arms, body and legs covered)

Sugar beet, bolting (max. 2 x 0.4 l product/ha at 14 days interval))

⇒ Work wear (arms, body and legs covered) and gloves

Stone fruits (max. 2 x 0.4 l product/ha at 7 days interval)

⇒ Work wear (arms, body and legs covered)

Pome fruits (max. 2 x 0.3 l product/ha at 7 days interval)

⇒ Work wear (arms, body and legs covered) and gloves

3.5.4 Bystander and resident exposure

Bystander

The acute exposure assessment for bystanders covers the exposure that a resident could reasonably be expected to incur in a single day. Therefore, there is no need for a separate acute risk assessment for residents.

No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. This is the case for Prothioconazole and Prothioconazole-desthio for which no acute toxicity has been identified and no AAOEL has been established. Therefore, exposure assessment for residents also covers bystander exposure.

Resident

Residents exposure to SIP 41061 was modelled using the EFSA model.

The resident exposure for the intended GAP uses of SIP 41061 is generally below the limit of 100% AOEL. In the following situations the indicated label mitigations should be considered:

Cereals (max. 2 x 0.5 l product/ha at 14 days interval)

⇒ 300L water min or DRT or 5 m buffer zone

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

3.6.1 Residues

Storage stability

- High water content matrices (prothioconazole) in regard to following proposed uses: cucurbits edible peel (courgette, cucumber), pome fruits (apple, quince, medlar), pome fruits (pear), stone fruits (plum, apricot, cherries), carrot (other roots and tubers vegetables)

In the framework of the peer review, storage stability of prothioconazole and its metabolite prothioconazole-desthio residues was demonstrated at -18 °C for 18 months in wheat green matter and for 24 months in spinach, sugarbeet and in tomato.

According to OECD 506 if the stability of test substance in three diverse commodities in this category is confirmed, further examination with other crops that belong to this category is unnecessary.

- High starch content matrices (prothioconazole) in regard to following proposed uses: wheat (soft, durum), triticale, rye, barley and sugar beet.

In the framework of the peer review, storage stability of prothioconazole and its metabolite prothioconazole-desthio residues was demonstrated at -18 °C for 18 months in cereal grain and 24 month in sugar beet.

In the framework of the peer review, storage stability of prothioconazole and its metabolite prothioconazole-desthio residues was demonstrated at -18 °C for 18 months in cereal straw.

- High oil content

In the framework of the peer review, storage stability of prothioconazole and its metabolite prothioconazole-desthio residues was demonstrated at -18 °C for months in Canola seeds.

EFSA Journal 2020;18(2):5999 (confirmatory data following the Article 12 MRL review):

Hydroxylated metabolite included in the risk assessment residue definition:

Freezer storage stability of prothioconazole- α -hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio was investigated in high water content (tomatoes), high starch content (potatoes), high oil content (soya beans, oilseed rape) and high acid content (oranges) commodities for a period of 24 months.

EFSA accepted the storage stability data on potatoes (high starch matrix) to address the storage stability in cereals.

Regarding prothioconazole, prothioconazole-desthio and its hydroxy metabolites, the available data sufficiently covers the maximum storage interval for commodities measured in the samples coming from residue trials.

TDMs

Storage stability data for TDMs are presented in EFSA Journal 2018;16(7):5376.

Plant products (Category)	Commodity	Stability (Months)			
		1,2,4-Triazole	TA	TAA	TLA

High water content	Apples, tomatoes, mustard leaves, wheat forage, radishes tops/roots, turnips roots, sugar beet roots, cabbages, lettuces	6	53	53	48 ((lettuce only)
High starch content	Barley, wheat	12	26	26	48
High oil content	Oilseed rape (seed), soya beans	12 (soya bean only; not stable in rape seed)	26 (soya bean only; not stable in rape seed)	53	48
High protein content	Peas, dry; Navy beans	No data	15	25	48
High acid content	Oranges	No data	No data	No data	48
Others	Cereal straw	12	53	40	No data
Animal	Animal commodity	Stability (Month/Year)			
	Muscle	18	No data	No data	No data
	Liver	12	No data	No data	No data
	Kidney	12	No data	No data	No data
	Milk	12	No data	No data	No data
	Egg	12	No data	No data	No data

New study - Freezer storage stability of Prothioconazole-desthio (M04) and its hydroxy metabolites M14, M15, M16, M17 and M18 in 5 different matrices: high water commodity (zucchini), high oil commodity (oilseed rape seeds), high acid commodity (grape), dry commodity (peas dry seeds) and high starch commodity (sugar beet root) is ongoing. 6 months checkpoint was presented.

Final Report was provided. In the new storage stability study submitted by the applicant, residues of prothioconazole-desthio (M04) and its hydroxy metabolites (M14, M15, M16, M17 and M18) which are all components included in the risk assessment residue definition, are stable in the 5 crop groups for 12 months when they are stored at -18°C. The only exceptions are the metabolites M14, M15 and M17 which degrade in high starch matrix after 6, 3 and 9 months respectively

Data gap: Storage stability data for 1,2,4-T and TA in rapeseeds.

03/2023 Assessment of updated dRR part B7 (TDMs):

A new storage stability study on 1,2,4 Triazole is ongoing in the various matrix groups to support 2020 residue trials. The stability will be evaluated once available the results of storage study, however according to the available data reported in the Interim report, no degradation of 1,2,4 Triazole is expected in high water and high starch matrix, while a strong degradation was observed in oil seed rape seed.

Final Report was provided. According to the available data, 1, 2 4 triazole is stable in high water (apple), high starch (sugar beet root) and dry commodity (peas dry seed) for 12 months when they are stored at -18°C. In grape samples a degradation was observed after 6 months.

Strong degradation was observed in high oil matrix (OSR seed) confirming the 1,2,4 triazole is not stable in this crop.

Metabolism in plants and animals

Plant residue definition for monitoring (RD-Mo): Prothioconazole: Prothioconazole-desthio (sum of isomers)

Plant residue definition for risk assessment (RD-RA):

a) Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA, 2014)

b)TDMs (EFSA, 2018, SANCO/3923 /07 – final 10 December 2007, 26 January 2021), with separate assessment of:

- Triazole alanine (TA) and triazole lactic acid (TLA)
- Triazole acetic acid (TAA)
- 1,2,4-triazole (1,2,4-T)

Magnitude of residues in plants

Wheat (Soft, Durum), Triticale, Rye

Proposed GAP:

2 applications (14 days interval), BBCH 29-69; 200 g as/ha, PHI: 21 days

Prothioconazole

8 residue trials in Northern Europe were submitted for wheat. Residues measured in the trials are all < the LOQ except for one sample in which residue was above the LOQ but below the fixed MRL.

Trials GAP: 2x 200 g as/ha, BBCH 39-69, interval between appl. 14d; PHI 35d

Mo: 7x <0.01; 0.03 mg/kg

According to SANTE/2019/12752, wheat data could be extrapolated to rye and triticale.

The data submitted show that no exceedance of the current MRL of 0.1 mg/kg (wheat, triticale, durum, spelt) and 0.05 mg/kg (oat, rye) will occur when the PPP is applied according to the intended GAP.

With regard to Prothioconazole the use is considered acceptable with PHI=35.

TDMs:

Applicant's note: *An analytical method for the determination of triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) was validated in plant commodities. However, due to the difficulty related to the validation of the method, analysis of the samples coming from residue trials are still ongoing at the time of the first dossier submission. Once available all the data, a revised dRR Section B7 will be submitted, and an update consumer risk assessment will be provided.*

TDMs:

The proposed use can only be accepted after providing data on the TDMs residues after the use of PPP.

03/2023 Assessment of updated dRR part B7 (TDMs):

A reference has done to open data (4 NEU, 4 SEU trials).

EFSA Journal 2018;16(7):5376, United Kingdom, 2018. Triazole Derivative Metabolites Addendum – Confirmatory Data. United Kingdom, February 2018.

Trials GAP: 3x 187.5 g as/ha, BBCH 32-69, interval 14-35 d, PHI = 28d

No data is available for TLA, the applicant has planned with other Companies new residue trials on cereals in 2023 in order to analyse it. In any case, evaluating all the available TDMs data in the various crops, in

particular to TLA measured in barley grain (HR = 0.01 mg/kg), residues expected in this matrix are quite low and no consumer risk is expected.

New residue trials on wheat are ongoing this year. The final report could be submitted as post registration data requirement at national level.

The data available are considered sufficient for risk assessment.

Uses are accepted.

Barley

Proposed GAP:

2 applications (14 days interval), BBCH 29-61; 200 g as/ha, PHI: 21 days

Prothioconazole

8 residue trials in Northern Europe were submitted for barley. Residues measured are all below the fixed MRL.

Trials GAP: 2x 200 g as/ha, BBCH 39-69, interval between appl. 14d; PHI 35d

Mo: <0.01; 0.08; 0.02; 0.11; 0.03; 0.02; 0.02; 0.01 mg/kg

According to SANTE/2019/12752, barley data could be extrapolated to oat.

The data submitted show that no exceedance of the current MRL of 0.2 mg/kg will occur when the PPP is applied according to the intended GAP.

Additionally open data on barley are available and can support the intended use.

With regard to Prothioconazole the use is considered acceptable with PHI=35.

TDMs:

Applicant's note: *An analytical method for the determination of triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) was validated in plant commodities. However, due to the difficulty related to the validation of the method, analysis of the samples coming from residue trials are still ongoing at the time of the first dossier submission. Once available all the data, a revised dRR Section B7 will be submitted, and an update consumer risk assessment will be provided.*

TDMs:

The proposed use can only be accepted after providing data on the TDMs residues after the use of PPP.

03/2023 Assessment of updated dRR part B7 (TDMs):

A reference has done to open data (4 NEU, 4 SEU trials).

EFSA Journal 2018;16(7):5376, United Kingdom, 2018. Triazole Derivative Metabolites Addendum – Confirmatory Data. United Kingdom, February 2018

Trials GAP: 2x 150/200 g as/ha, BBCH 37-61, interval 9/27 d, PHI = 28/35d

The data available are considered sufficient for risk assessment.

Use is accepted.

Oilseed rape

Proposed GAP:

2 applications (14 days interval), BBCH 30-71; 180 g as/ha, PHI: 50 days

Prothioconazole

8 residue trials in Northern Europe were submitted for Oil seed rape as it is a major crop in the EU.

Trials GAP: 2x 180 g as/ha, BBCH 30-71, interval between appl. 14d; PHI 50d

Residues (Mo): 6x <0.01; 0.01; 0.02 mg/kg

Residues measured in the trials conducted by the applicant showed results all below the LOQ except for two samples in which residues were above the LOQ but below the fixed MRL.

The data submitted show that no exceedance of the current MRL of 0.15 mg/kg will occur when the PPP is applied according to the intended GAP.

With regard to Prothioconazole the use is considered acceptable.

TDMs:

The proposed use can only be accepted after providing data on the TDMs residues after the use of PPP with prothioconazole in the protection of oilseed rape (from the new studies or unprotected EU data).

03/2023 Assessment of updated dRR part B7 (TDMs):

A reference has done to open data (20 NEU) and new trials (8 NEU).

Source	Residue zone	Evaluation GAP Residue levels (mg/kg)	STMR (mg/kg)	HR (mg/kg)
UK, 2018	20 NEU	GAP: 2x 125/150 g as/ha, BBCH 30-73/85, interval between appl. 14d; PHI nr	T: 0.01 TA: 0.24 TAA: 0.01 TLA: 0.015	T: 0.018 TA: 2.17 TAA: 0.062 TLA: 0.05
New trials	NEU	GAP: 2x 180 g as/ha, BBCH 30-71, interval between appl. 14d; PHI 50d RA: <ul style="list-style-type: none"> T: 8x <0.04 TA: 0.114; 0.18; 0.277; 0.297; 0.487; 0.81; 0.92; 6.23 TAA: 7x <0.04, 0.104 TLA: 5x <0.04, 0.056; 0.061; 0.204 	T: 0.04 TA: 0.39 TAA: 0.04 TLA: 0.04	T: 0.04 TA: 6.23 TAA: 0.1 TLA: 0.2

Strong degradation of TLA and TA was observed in oil seed rape seed (storage stability data).

According to that, new residue trials will be planned in 2023 with the aim to analyse the samples within 30 days from harvest to avoid storage stability issue. New trials could be sent as soon as finalised and/or as post registration requirement.

In any case, since no risk for consumers is expected when the PPP is applied according to the intended GAP, at the moment enough data is available to perform provisional consumer risk assessment. It is up to each Member State to decide on the need to provide the above-mentioned data prior to registration in a given country. This data can be submitted at national level.

It should be noted that Triazol Alanine is a common biological compound and can normally be found in the environment.

Although the evaluation is provisional, the use can be accepted.

It is up to each Member State to decide on the need to provide missing data for oil seed rape (data for TLA and TA in rape seed; residues of TMDs in honey) prior to registration in a given country. According to the evaluator, this data can be submitted as post registration requirement.

In Poland use is accepted by the evaluator with post registration requirement.

Sugar beet

Proposed GAP:

2 applications (14 days interval), BBCH 39-49; 160 g as/ha, PHI: 28 days

Prothioconazole

Four residue trials on sugar beet were conducted in Northern Europe on sugar beet. Residues measured are all below the LOQ.

According to SANTE 2019/12752 rev. 10.3 (Appendix d) and to Commission Regulation (EU) No 283/2013, the numbers of studies to be performed may be reduced if residue trials show that the residue levels in plant or plant products are lower than the LOQ. Four trials are sufficient to support sugar beet use.

Trials GAP: 2x 160 g as/ha, BBCH 39-49, interval between appl. 14d; PHI 28d

Residues: 4x <0.01 mg/kg

The data submitted show that no exceedance of the current MRL of 0.01 mg/kg will occur when the PPP is applied according to the intended GAP.

With regard to Prothioconazole the use is considered acceptable.

TDMs:

The proposed use can only be accepted after providing data on the TDMs residues after the use of PPP with prothioconazole in the protection of sugar beet (from the new studies or unprotected EU data).

03/2023 Assessment of updated dRR part B7 (TDMs):

A reference has done to new trials (7 NEU). Field phase and analytical method used are acceptable.

New trials	NEU	GAP: 2x 160 g as/ha, BBCH 39-49, interval between appl. 14d; PHI 28d RA: <ul style="list-style-type: none">• T: 7x <0.04• TA: 5x <0.04; 0.053; 0.08• TAA: 7x <0.04• TLA: 7x <0.04
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T, TA, TAA:

All trials are acceptable with regard to storage stability data.

TLA

4 trials are acceptable with regard to storage stability data. The number of acceptable trials is sufficient since residues are below LOQ.

It should be noted that Triazol Alanine is a common biological compound and can normally be found in the environment.

Use is accepted.

Pome fruits (Apple, Quince, Medlar, Pear)

Proposed GAP:

Apple, Quince, Medlar: 2 applications (7-10 days interval), BBCH 39-85; 120 g as/ha, PHI: 14 days

Pear: 2 applications (7-10 days interval), BBCH 39-85; 120 g as/ha, PHI: 21 days

Prothioconazole

8 residue trials on apple conducted in Northern Europe have been submitted by the applicant.

Trials GAP: apple, 2x 120 g as/ha, BBCH 39-85, interval between appl. 7d; PHI 14d

Residues are above 0.01 mg/kg (MRL)

Considering the intended use on pome fruits, an exceedance of the MRL for prothioconazole is expected (0.01 mg/kg, Reg. (EU) 2019/552)

Assessment of application to modify the current EU MRL in various crops is ongoing. Approval for the use in protection of pome fruits will be possible after the change of the MRLs for this crops. Uses are not accepted.

TDMs

Data gap: TDMs residues after the use of PPP with prothioconazole in the protection of pome fruit (from the new studies or unprotected EU data).

03/2023 Assessment of updated dRR part B7 (TDMs):

Although new triazole residue trials have been provided, the use of the product in the protection of pome fruits cannot be accepted due to the risk of exceeding the MRL

Stone fruits (Plum, Apricot, Cherries)

Proposed GAP:

Plum, Apricot, Cherries: 2 applications (7 days interval), BBCH 51-85; 160 g as/ha, PHI: 3 days

Prothioconazole

6 residue trials on peaches, 8 residue trials on plums and 8 residue trials on cherries conducted in Northern Europe have been submitted by the applicant.

Trials GAP: 2x 160 g as/ha, BBCH 39-85, interval between appl. 7d; PHI 3d

Residues are above 0.01 mg/kg (MRL)

Considering the intended use on stone fruits, an exceedance of the MRL for prothioconazole is expected (0.01 mg/kg, Reg. (EU) 2019/552)

Assessment of application to modify the current EU MRL in various crops is ongoing. Approval for the use in protection of stone fruits will be possible after the change of the MRLs for this crops. Uses are not accepted.

TDMs

Data gap: TDMs residues after the use of PPP with prothioconazole in the protection of stone fruit (from the new studies or unprotected EU data).

03/2023 Assessment of updated dRR part B7 (TDMs):

Although new triazole residue trials have been provided, the use of the product in the protection of stone fruits cannot be accepted due to the risk of exceeding the MRL

Cucurbits with edible peel (courgette, cucumber)

Proposed GAP:

courgette, cucumber: 3 applications (10 days interval), BBCH 11-89; 200 g as/ha, PHI: 10 days

Prothioconazole

8 residue trials on zucchini (courgette in greenhouse conditions) conducted in Northern Europe have been submitted by the applicant

Trials GAP: 3x 120 g as/ha, BBCH 11-89, interval between appl. 10d; PHI 10d

The use cannot be accepted due to the possibility of exceeding the MRL.

TDMs

Data gap: TDMs residues after the use of PPP with prothioconazole in the protection of cucurbits with edible peel (from the new studies or unprotected EU data).

03/2023 Assessment of updated dRR part B7 (TDMs):

Although new triazole residue trials have been provided, the use of the product in the protection of courgette, cucumber cannot be accepted due to the risk of exceeding the MRL. Intended use is not sufficiently supported. At least 4 trials with residue levels below LOQ are required (reduced dataset). For a PHI of 10 days, residue levels are below LOQ, and no MRL exceedance is expected, but only 2 trials are available.

Carrot (other roots and tubers vegetables)

Proposed GAP:

2 applications (21 days interval), BBCH 16-46; 200 g as/ha, PHI: 21 days

Prothioconazole

8 residue trials conducted in carrot have been submitted by the applicant.

Trials GAP

a) GAP: 2x 160 g as/ha, BBCH 16-46, interval between appl. 7-10d; PHI 21d

Mo: <0.01; 0.011; 0.024; 0.083 mg/kg

Proportionality approach: 1x 200 g as/ha:

Mo: <0.01; 0.01; 0.03; 0.1 mg/kg

The value of 0.1 mg/kg was presented by the applicant as an outlier. It does not exceed the MRL value, so it was taken into account by zRMS in the assessment.

b) GAP: 2x 200 g as/ha, BBCH 16-46, interval between appl. 7-10d; PHI 21d

Mo: <0.01; 0.0137; 0.03; 0.103 mg/kg

Number of trials is sufficient.

According to SANTE/2019/12752, carrot data could be extrapolated to Whole subgroup (c) other root and tuber vegetables except sugar beets (0213000) and except celeriacs/turnip rooted celeries (213030), Jerusalem artichokes (213050) and radishes (213080) which EU MRLs are set at lower level.

The data submitted show that no exceedance of the current MRL of 0.1 mg/kg (beetroots, carrots, horseradishes, parsnips, parsley roots/hamburg roots parsley, salsifies, swedes/rutabagas and turnips) will occur when the PPP is applied according to the intended GAP.

With regard to Prothioconazole the uses in protection beetroots, carrots, horseradishes, parsnips, parsley roots/hamburg roots parsley, salsifies, swedes/rutabagas and turnips are considered acceptable.

TDMs

Data gap: TDMs residues after the use of PPP with prothioconazole in the protection of carrots (from the new studies or unprotected EU data)

03/2023 Assessment of updated dRR part B7 (TDMs):

A reference has done to open data (5 NEU) and new trials (4 NEU).

Source	Residue zone	Evaluation GAP Residue levels (mg/kg)	STMR (mg/kg)	HR (mg/kg)
UK, 2018	5 NEU	GAP: 3x 192 g as/ha, interval between application 14d, PHI 21d	T: 0.01 TA: 0.025 TAA: 0.01 TLA: 0.01	T: 0.016 TA: 0.029 TAA: 0.010 TLA: 0.010

New trials	NEU	<p>GAP: 2x 200 g as/ha, BBCH 16-46, interval between appl. 7-10d; PHI 21d</p> <p>RA:</p> <ul style="list-style-type: none"> T: 4x <0.04 TA: 4x <0.04 TAA: 4x <0.04 TLA: 4x <0.04 <p>[†]Only one year data package was analysed for NEU since all residues were found ND (not detectable, below LOD, <0.01 mg/kg)</p>	<p>T: 0.04</p> <p>TA: 0.04</p> <p>TAA: 0.04</p> <p>TLA: 0.04</p>	<p>T: 0.04</p> <p>TA: 0.04</p> <p>TAA: 0.04</p> <p>TLA: 0.04</p>
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Applications for the protection of beetroots, carrots, horseradishes, parsnips, parsley roots/hamburg roots parsley, salsifies, swedes/rutabagas and turnips are considered acceptable.

Magnitude of residues in livestock

The calculated dietary burdens were found to exceed the trigger value of 0.004 mg/kg bw/day. Further investigation of residues in livestock is required. Applicant refers to out of protection EU data.

No exceedances of the existing EU MRLs for prothioconazole in animal commodities are anticipated as a result of the proposed uses.

TDMs

EFSA Journal 2018;16(7):5376:

The livestock exposure assessment cannot be finalised with regard to the outstanding data for acceptable residue trials in primary and rotational crops.

Data gap:

Poultry and ruminant feeding studies conducted with TLA or, alternatively, metabolism studies performed in accordance with the current recommendations as a surrogate to these feeding studies to determine the magnitude of TLA residues in products of animal origin (data gap at EU level).

Industrial Processing and/or Household Preparation:

Prothiconazole

Studies are currently not required, as the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the ADI for the individual crops under assessment.

Such studies are not expected to affect the outcome of the risk assessment.

TDMs

The TDMs remained stable under the standard hydrolysis conditions simulating processing of pasteurisation, baking, brewing and boiling and sterilisation (EFSA Journal 2018;16(7):5376).

Additional data are not required.

Magnitude of residues in representative succeeding crops

Considering available data dealing with nature of residues, no study dealing with magnitude of residues in succeeding crops is needed

TDMs

Data gap: Rotational crops field residue trials supported by acceptable storage stability data on TDMs (data gap at EU level).

Other / special studies

The applicant has conducted a residue study on honey in order to determine the magnitude of residue of prothioconazole-desthio in this matrix.

2 residue trials were conducted in Northern Europe and 2 in Southern EU in tunnel conditions. As surrogate crop, phacelia was used. A worst case GAP has been selected for residue trials in order to cover all the uses in the intended GAP. The trials were done according to the Guideline SANTE/11956/2016 rev. 9, 14 September 2018. The analytical part of the study is still ongoing however, an Interim Report (KCA 6.10, Report N. QS21003) is available with the field data and the results of prothioconazole-desthio.

When prothioconazole-desthio is applied according to the intended GAP, no residue higher than MRL is expected.

No data have been submitted for the residue situation of TDMs in honey (oilseed rape use).

Applicant's comment:

“correct, unfortunately there was some issue with the development of the analytical method for the determination of TDMs in honey matrix. Please take note new residue trials on honey are ongoing in 2023, if needed, the final report could be submitted as post registration data requirement at national level.

However, no risk for consumer is expected when the PPP is applied according to the intended GAP. Please see EFSA 2023 (*Reasoned Opinion on the modification of the existing maximum residue levels for prothioconazole in garlic, onions and shallots. EFSA Journal 2023;21(1):7717, 48 pp.*), where new residue trials investigating the prothioconazole and TDM residues to honey from the use of prothioconazole on oilseed rape have been evaluated. The data indicates that residues of prothioconazole in honey would not exceed the existing MRL of 0.05 mg/kg (LOQ). Moreover, please consider according to EFSA, 2023 “*the nature of prothioconazole in honey is not addressed to conclude on the relevant residues for enforcement purposes. Therefore, EFSA recommends considering this aspect further under the renewal assessment.*” Following the above information, no new data is considered to be relevant in the Art. 33 context. If required, according to EFSA, if needed, after the active renewal new data on honey will be submitted by the applicant in Art. 43 dossier.”

Storage stability studies, neither for prothioconazole-desthio nor for TDMs in honey (oilseed rape use)

Applicant's comment:

“Storage stability study is ongoing for prothioconazole-desthio in honey. The final report could be submitted as soon as available (expected for September 2023), according to the preliminary data no degradation is expected. The final report could be submitted as post registration data requirement at national level. No data is needed for TDMs according to EFSA, 2023”.

zRMS: It is up to each Member State to decide on the need to provide the above-mentioned data prior to registration in a given country. This data can be submitted as post registration requirement.

Noticed data gaps are:

- **Data gap 1:** MRLs existence is expected for pome fruits and stone fruits.
- Cucurbits: Intended use is not sufficiently supported by field trials. At least 4 trials with residue levels below LOQ are required.
- **Data gap 2:** No data is available for TLA in wheat. New residue trials on wheat are ongoing. The final report could be submitted as post registration data requirement at national level.
- **Data gap 3:** Oilseed rape - TLA and TA in rape seed; Residues of TMDs in honey. It is up to each Member State to decide on the need to provide this data prior to registration in a given country. This data can be submitted as post registration requirement.

3.6.2 Consumer exposure

- Risk assessment for residue definition 1: Prothioconazole-desthio

Chronic and acute exposure calculations were performed using EFSA PRIMo revision 3.1 and calculated exposures were compared with the established toxicological reference values. The proposed uses of prothioconazole in the formulation SIP 41061 do not represent unacceptable acute and chronic risks for the consumer. All calculation provided by the Applicant are accepted.

03/2023 Assessment of updated dRR part B7 (TDMs):

- Risk assessment for residue definition 2: Triazole alanine and triazole lactic acid;

Risk assessment residue definition 3: Triazole acetic acid;

Risk assessment residue definition 4: 1,2,4-triazole

Consumer risk assessment was performed separately for each definitions using and input values residue coming from applicant residue trials.

No risk to the consumer identified.

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

Appropriate endpoints for the assessment were applied to calculate PECs for prothioconazole and its metabolites in the respective compartments for the assessed use on all crops according to the intended GAP.

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

According to definitions of residue for risk assessment in soil reported in LoEP (EFSA Scientific Report (2007) 106, 1-98), the PEC_{soil} have been calculated for prothioconazole and prothioconazole-desthio (M04) and prothioconazole-S-methyl (M01), using ESCAPE tool (Version 2.0 – 26 November 2019)

All details on the calculations are included in the Part B, Section 8.

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

According to the residue definition provided in the EFSA conclusions (EFSA Scientific Report (2007) 106, 1-98) prothioconazole and its metabolites prothioconazole-desthio (M04) and prothioconazole-S-methyl (M01) were considered for environmental exposure assessment in groundwater.

For groundwater modelling the FOCUS programs PEARL 5.5.5 and PELMO 6.6.4 were applied with all the respective scenarios defined for each crop of the GAP. The input parameters related to the assessed (critical) uses are summarized in dRR Par B, section 8.

All FOCUS Models provided PEC_{gw} for prothioconazole and its metabolites prothioconazole-desthio (M04) and prothioconazole-S-methyl (M01) well below 0.1 µg/L.

Considering the GW assessment, it can be concluded that SIP 41061 does not pose any risk to groundwater for prothioconazole and its metabolites.

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

PEC_{sw} and PEC_{SED} calculations for active substance prothioconazole and its metabolites were performed according to input data listed into EFSA Scientific Report (2007) and DAR (Draft Assessment Report) 2005 using FOCUS Step 1/2 v 3.2 and FOCUS SWASH v5.3.

According to EFSA Conclusions², prothioconazole and its metabolites prothioconazole, prothioconazole-desthio (M04) and 1,2,4-triazole were assessed for surface water and sediment exposure.

PEC_{sw} values for prothioconazole meet the aquatic trigger at Step 3, in scenarios relevant for Poland (D3, D4, R1).

PEC_{sw} values for metabolite prothioconazole-desthio don't meet the trigger at step 3; Step 4 mitigations are therefore needed. An overall summary with the maxima PEC_{sw} and PEC_{SED} values at STEP 4 for M04 are summarised in the below tables, for relevant scenarios for Poland (D3, D4, R1). Scenarios not reported meet the aquatic trigger at Step 3.

Due to the fact that the Applicant did not provide the National Addendum for Poland, PEC_{sw} for scenarios relevant to Poland are included below.

Table 3.7.3-2: FOCUS Step 4 PEC_{sw} for prothioconazole-desthio following multiple application of SIP 41061 to winter cereals (BBCH 29)

PEC _{sw} [µg/L]	Scenario	STEP 4		
Nozzle reduction	Vegetative strip [m]	None	10	20
	No spray buffer [m]	5	10	20
Single applications				
None	R1 stream	0.360	0.164	0.086
50 %		0.360	-	-
90 %		0.360	-	-
Multiple applications				
None	R1 stream	1.053	0.478	0.250
50 %		1.053	0.478	-
90 %		1.053	0.478	-

Table 3.7.3-3: FOCUS Step 4 PEC_{sw} for prothioconazole-desthio following multiple application of SIP 41061 to winter cereals (BBCH 69)

PEC _{sw} [µg/L]	Scenario	STEP 4		
Nozzle reduction	Vegetative strip [m]	None	10	20
	No spray buffer [m]	5	10	20
<i>Multiple applications</i>				

² EFSA Scientific Report (2007) 106, 1-98

PEC _{sw} [µg/L]	Scenario	STEP 4		
Nozzle reduction	Vegetative strip [m]	None	10	20
	No spray buffer [m]	5	10	20
None	R1 stream	0.765	0.348	0.182
50 %		0.765	0.348	-
90 %		0.765	0.348	-

Table 3.7.3-4: FOCUS Step 4 PEC_{sw} for Prothioconazole desthio (M04) following multiple application(s) to winter OSR (BBCH 30)

PEC _{sw} [µg/L]	Scenario	STEP 4		
Nozzle reduction	Vegetative strip [m]	None	10	20
	No spray buffer [m]	5	10	20
<i>Multiple applications</i>				
None	R1 stream	0.874	0.396	0.208
50 %		0.874	0.396	-
90 %		0.874	0.396	-

Table 3.7.3-5: FOCUS Step 4 PEC_{sw} for Prothioconazole desthio (M04) following single/multiple application(s) to winter OSR (BBCH 71)

PEC _{sw} [µg/L]	Scenario	STEP 4		
Nozzle reduction	Vegetative strip [m]	None	10	20
	No spray buffer [m]	5	10	20
Single applications				
None	R1 stream	0.466	0.211	0.111
50 %		0.466	-	-
90 %		0.466	-	-
Multiple applications				
None	R1 stream	0.790	0.354	0.185
50 %		0.790	0.354	-
90 %		0.790	0.354	-

Table 3.7.3-6: FOCUS Step 4 PEC_{sw} for Prothioconazole desthio (M04) following single/multiple application(s) to summer OSR (BBCH 30)

PEC _{sw} [µg/L]	Scenario	STEP 4		
Nozzle reduction	Vegetative strip [m]	None	10	20
	No spray buffer [m]	5	10	20
Single applications				
None	R1 stream	0.549	0.249	0.130
50 %		0.549	-	-
90 %		0.549	-	-
Multiple applications				
None	R1 stream	0.645	0.293	0.154
50 %		0.645	-	-
90 %		0.645	-	-

Table 3.7.3-7: FOCUS Step 4 PEC_{sw} for Prothioconazole desthio (M04) following single/multiple application(s) to pome/stone fruit (BBCH 39, 120 g a.i./ha)

PEC _{sw} [µg/L]	Scenario	STEP 4		
Nozzle reduction	Vegetative strip [m]	None	10	20
	No spray buffer [m]	5	10	20
Single applications				
None	D3 ditch	0.802	0.492	0.112
50 %		0.401	0.246	-
90 %		0.080	-	-
None	D4 stream	0.525	0.322	0.074
50 %		0.262	0.161	-
90 %		0.052	-	-
None	R1 stream	0.465	0.286	0.065
50 %		0.232	0.143	-
90 %		0.152	-	-
Multiple applications				
None	D3 ditch	0.875	0.516	0.133
50 %		0.437	0.258	-
90 %		0.087	-	-
None	D4 pond	0.402	0.227	0.068
50 %		0.200	0.113	-
90 %		0.039	-	-
None	D4 stream	0.467	0.276	0.071
50 %		0.233	0.138	-
90 %		0.047	-	-
None	R1 pond	0.385	0.218	0.065
50 %		0.191	0.108	-
90 %		0.039	-	-

PEC _{sw} [µg/L]	Scenario	STEP 4		
Nozzle reduction	Vegetative strip [m]	None	10	20
	No spray buffer [m]	5	10	20
None	R1 stream	0.392	0.232	0.079
50 %		0.355	0.153	-
90 %		0.355	-	-

Table 3.7.3-8: FOCUS Step 4 PEC_{sw} for Prothioconazole desthio (M04) following single/multiple application(s) to pome/stone fruit (BBCH 51, 160 g a.i./ha)

PEC _{sw} [µg/L]	Scenario	STEP 4		
Nozzle reduction	Vegetative strip [m]	None	10	20
	No spray buffer [m]	5	10	20
Single applications				
None	D3 ditch	1.383	0.848	0.194
50 %		0.691	0.424	-
90 %		0.138	0.085	-
None	D4 stream	0.700	0.430	0.098
50 %		0.395	0.215	-
90 %		0.070	-	-
None	R1 stream	0.620	0.381	0.231
50 %		0.310	0.190	-
90 %		0.212	-	-
Multiple applications				
None	D3 ditch	1.167	0.689	0.178
50 %		0.582	0.344	-
90 %		0.116	0.069	-
None	D4 pond	0.490	0.276	0.082
50 %		0.242	0.137	-
90 %		0.047	0.027	-
None	D4 stream	0.811	0.479	0.124
50 %		0.405	0.239	-
90 %		0.239	0.048	-
None	R1 pond	0.515	0.291	0.087
50 %		0.256	0.144	-
90 %		0.053	0.029	-
None	R1 stream	0.523	0.309	0.110
50 %		0.498	0.215	-
90 %		0.498	0.215	-

Table 3.7.3-9: FOCUS Step 4 PEC_{sw} for Prothioconazole desthio (M04) following single/multiple application(s) to pome/stone fruit (BBCH 85, 160 g a.i./ha)

PEC _{sw} [µg/L]	Scenario	STEP 4		
Nozzle reduction	Vegetative strip [m]	None	10	20
	No spray buffer [m]	5	10	20
Single applications				
None	D3 ditch	0.534	0.239	0.073
50 %		0.267	0.119	-
90 %		0.053	-	-
None	D4 stream	0.292	0.130	0.040
50 %		0.146	0.065	-
90 %		0.032	-	-
Multiple applications				
None	D3 ditch	0.827	0.395	0.111
50 %		0.412	0.197	-
90 %		0.082	-	-
None	D4 stream	0.259	-	-
50 %		-	-	-
90 %		-	-	-
None	D5 stream	0.429	0.206	-
50 %		0.214	-	-
90 %		-	-	-

Table 3.7.3-10: FOCUS Step 4 PEC_{sw} for Prothioconazole desthio (M04) following single/multiple application(s) to carrots

PEC _{sw} [µg/L]	Scenario	STEP 4		
Nozzle reduction	Vegetative strip [m]	None	10	20
	No spray buffer [m]	5	10	20
Single applications				
None	R1 stream	0.415	0.189	0.099
50 %		0.415	0.189	
90 %		0.415	0.189	
Multiple applications				
None	R1 stream	0.806	0.366	0.192
50 %		0.806	0.366	-
90 %		0.806	0.366	-

PEC_{sw} results for M04 meet the aquatic trigger at Step 4. All results are reported into dRR Part B, Section 8. Only STEP1/2 calculation were reported for 1,2,4-triazole metabolite.

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

The nature of the formulation does not expect to influence the volatility of the active ingredients therefore no additional studies have been performed.

The vapour pressure at 20 °C of the active substance prothioconazole is $< 10^{-5}$ Pa. Considering available data reported in the EFSA conclusion (2007), the active substance prothioconazole and prothioconazole-desthio are regarded as non-volatile.

3.8 Ecotoxicology (Part B, Section 9)

Following the application of SIP 41061 according to the proposed use pattern, the risk for birds, mammals, aquatic organisms, bees and other non-target arthropods, soil meso-macro fauna, soil micro-organisms and terrestrial non-target plants can be considered acceptable.

To protect aquatic organisms respect an unsprayed vegetated buffer zone of:

- 10m for summer oilseed rape;
- 20m for cereals, winter oilseed rape and carrots;
- 20m or 10m + 90% nozzle reduction for pome and stone fruits

3.8.1 Effects on terrestrial vertebrates

BIRDS

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438). Safe use of prothiconazole and prothioconazole-desthio (M04) for birds were confirmed based on TER_A and TER_{LT} above the trigger values of 10 and 5, respectively, indicating the acute and long-term risk is acceptable for all the intended uses of SIP 41061 crops apart from cucurbits at BBCH 71-89, where prothioconazole-desthio fails Tier-1 assessment for the frugivorous bird “crow”. The refinement risk assessment for birds was provided by Applicant.

Safe use of prothiconazole and prothioconazole-desthio (M04) for birds were confirmed based on TER_A and TER_{LT} above the trigger values of 10 and 5, respectively, indicating the acute and long-term risk is acceptable for all the intended uses of SIP 41061 crops.

As SIP 41061 is not intended for leafy crops forming heads, the leaf scenario does not have to be therefore considered based on the proposed uses. Evaluation of exposing for mammals through the drinking water puddle scenario for the active substance and metabolite M04, demonstrate that the acceptable risk for birds for proposed use pattern of SIP 41061.

The risk for fish-eating birds and earthworms-eating birds due to exposure to prothioconazole and its metabolites (M04) is considered as acceptable for the worst case scenario. Since prothioconazole-S-methyl is not relevant for surface water, the risk to fish-eating birds and mammals was not necessary.

MAMMALS

The risk assessment at first-tier performed according to Document on Risk Assessment for Birds and Mammals EFSA (EFSA Journal 2009; 7(12): 1438) was accepted. Safe use of prothioconazole for mammals were confirmed based on TER_A and TER_{LT} above the trigger values of 10 and 5, respectively. In case, prothioconazole-desthio (M04) several scenarios trigger higher-tier reproductive assessment.

The refinement long-term risk assessment for lagomorph was accepted by RMS based on DT_{50} value for cereals and refined parameter of ftwa 0.22 according to EFSA Conclusion 2007. $MAF \times TWA$ of 0.389 was accepted in refinement risk assessment. Safe use of prothioconazole-desthio (M04) for mammals were confirmed based on TER_{LT} above the trigger values of 5, respectively, indicating the long-term risk is acceptable for cereals.

The refinement long-term risk assessment for vole was accepted by RMS. based on DT_{50} value for cereals and refined parameter of ftwa 0.22 according to EFSA Conclusion 2007. Safe use of prothioconazole-desthio (M04) for vole were confirmed based on TER_{LT} above the trigger values of 5.

The refinement long-term risk assessment for dormouse was not accepted by RMS based on DT_{50} value for stone fruits and refined parameter of $DT_{50} = 6.6d$. Safe use of prothioconazole-desthio (M04) for dormouse were not confirmed.

The presented by the Applicant refinement risk assessment for the vertebrates was evaluated by the RMS, but found not acceptable due to the uncertainties related to the kinetic analysis of the data of the residue trials. Please see KCP 10.1.1.2 point (Higher tier data on birds and mammals).

zRMS proposes a BBCH phase change. In stone fruit BBCH should be change to 51-70.
After the BBCH phase change, the risk to mammals is acceptable.

After refinement based on BBCH phase change (in stone fruit BBCH should be change to 51-70), the safe use of prothioconazole-desthio for mammals were also confirmed.

As SIP 41061 is not intended for leafy crops forming heads, the leaf scenario does not have to be therefore considered based on the proposed uses. Evaluation of exposing for mammals through the drinking water puddle scenario for the active substance and metabolite M04, demonstrate that the acceptable risk for mammals for proposed use pattern of SIP 41061.

The risk for fish-eating mammals and earthworms-eating mammals due to exposure to prothioconazole and its metabolites (M04) is considered as acceptable for the worst case scenario. Since prothioconazole-S-methyl is not relevant for surface water, the risk to fish-eating birds and mammals was not necessary.

3.8.2 Effects on aquatic species

The evaluation of the risk for aquatic organisms was performed in accordance with the recommendations of the “Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters” (EFSA Journal 2013;11(7):3290).

For Prothioconazole the PEC/RAC ratios calculated with FOCUS modelling showed an acceptable risk to aquatic organisms at Steps 1-3 for all the intended apart from pome/stone fruits, where Step 4 calculation was required.

For 1,2,4-Triazole, acceptable risk to aquatic organisms was demonstrated for all the intended uses with FOCUS Steps 1-2 scenarios.

For the metabolite Prothioconazole-desthio an acceptable risk to aquatic organisms was demonstrated for all the intended uses with FOCUS Steps 1-4. Considering the FOCUS scenarios relevant for Poland (D3, D4, R1), the following mitigation measures are required:

To protect aquatic organisms respect an unsprayed vegetated buffer zone of:

- 10m for summer oilseed rape;
- 20m for cereals, winter oilseed rape and carrots;
- 20m or 10m + 90% nozzle reduction for pome and stone fruits

In the following tables, the PEC/RAC ratios calculations with FOCUS step 4 for the scenarios relevant for Poland are reported. Full details on PEC/RAC ratios calculations with all FOCUS scenarios are provided in Part B9 of this dRR.

3.8.3 Effects on bees

Based on the acute risk assessment with the consideration SANCO/10329/2002 rev.2 (final), October 17, 2002), HQ values for adult bees from exposure of SIP 41061 are < 50 , indicating un acceptable risk to adult bees.

Based on the chronic risk assessment with the consideration SANCO/10329/2002 rev.2 (final), October 17, 2002), HQ values from exposure of SIP 41061 are >1 , indicating an acceptable chronic risk to bees. The evaluation of the risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002) as according to conclusions of the Central Zone Steering Committee (CZSC), recommendations of EFSA (2013) should not be considered for the zonal evaluations until the guidance is noted at the EU level.

3.8.4 Effects on other arthropod species other than bees

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

Based on the results of laboratory (glass-plate) tests on *Aphidius rhopalosiphi* and *Typhlodromus pyri* performed with SIP 41061, acceptable in-field and off-field risk can be concluded for all the intended uses. No risk mitigations are needed. The results of the in-field and off-field risk assessment are reported in the tables below.

3.8.5 Effects on soil organisms

SOIL MESO AND MACROFAUNA

The chronic TER values for earthworms and other soil macro-organism for ppp SIP 41061 were above the relevant Annex VI trigger of 5.

However in case of a.s. – prothioconazole and its metabolite M04 further refinement was needed.

Taking into account that the risk for a.s. calculated from ppp for earthworm was above the trigger value of 5, the risk is considered acceptable by zRMS.

In addition, no adverse effects are to be expected, as proven by the results of the field study (EFSA Scientific Report, 2007). Desthio-metabolite was confirmed as being present in field study after application of Prothioconazole with a maximum concentration recorded of 0.106 mg/kg at 7 days after second application. The depth of soil from which the sample cores were taken is not stated in the study report, but is highly unlikely to have been less than 5 cm and would more typically be expected to be 10 cm. As such, the maximum PEC for prothioconazole and the metabolite JAU 6476-desthio is likely to be an overestimation, with the level of exposure in the field study being considered more realistic. In the field study, from the 5 identified earthworm species, only the number of juveniles of 1 (*Aporrectodea caliginosa*) was affected. In fact, by the end of the study, an overall increase in the number and biomass of earthworms in the treated plots was observed (11 months of exposure with 3 applications of 200g a.s./ha).

Therefore, it is concluded that SIP 41061 and metabolites such as: M01 and M04 do not pose long-term risk to earthworms and other soil macro- and mesofauna when applied according to the proposed uses rates.

SOIL MICROBIAL ACTIVITY

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the Guidance Document on terrestrial ecotoxicology (SANCO/10329/2002). No significant effects on N-transformation were observed in soil at concentrations of Prothioconazole and its metabolites at rates much higher than the one expected from product application. Therefore, it is possible to conclude that the proposed uses of SIP 41061 pose an acceptable risk to the biological activity of micro-organisms in soil.

3.8.6 Effects on non-target terrestrial plants

The Applicant submitted a study on the effects of SIP 41061 on non-target terrestrial plants for the vegetative vigour test (OECD 227 "Terrestrial Plant Test: Vegetative Vigour Test). (Effects of the SIP 41061 on terrestrial plants – Vegetative vigour Test. Report No. BT150/21 Colli M., 2022). The study on the effects of SIP 41061 on non-target terrestrial plants in terms of seedling emergence and seedling growth test (OECD Guideline for the Testing of Chemicals No. 208 "Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test") was not provided by Applicant.

However, in this case – in opinion RMS - the available data are sufficient to indicate acceptable risk for non-target plants, including emergence seed, for these reasons:

- The data reported in the EFSA Conclusion (2007) show very low toxicity to non-target plants for the a.s. prothioconazole and for its representative formulation, both following "pre-emergence test" (= seedling emergence) and following "post-emergence test" (=vegetative vigour). In particular, in the preemergence test the a.s. prothioconazole showed 5% effect at the rate of 200 g a.s./ha, which is the maximum intended rate for SIP 41061.
- Also the vegetative vigour test (limit test) performed with SIP 41061 showed low toxicity to NTPs, with $ER_{50} > 570$ g prod/ha (equivalent to 200.64 g a.s./ha, the only tested rate). As reported in Section B9, the risk assessment based on this endpoint concluded acceptable risk for SIP 41061.
- SIP 41061 is not a herbicide. It is a fungicide applied at post-emergence of crops. Due to the period of application and since the available studies with SIP 41061 and with the a.s. indicate low toxicity to NTPs, a vegetative vigour test appears the study most representative and sufficient to assess the risk of SIP 41061 to NTPs.

Nevertheless, if a quantitative assessment should be provided also for emerging seeds, this could be performed considering the EU endpoint of the a.s. prothioconazole ($ER_{50} > 200$ g a.s./ha) and considering the worst-case $PER_{off-field}$ calculated in section B9 (use on stone fruits). The risk assessment for emerging seeds based the EU data was performed by zRMS. The results of such assessment confirm that SIP 41061, applied according to the intended use, poses acceptable risk to non-target plants, included emerging seeds.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

No additional data are considered necessary.

3.9 Relevance of metabolites (Part B, Section 10)

No metabolite is predicted to occur in groundwater at concentrations > 0.1 µg/L, so no further relevance evaluation is required.

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

Not relevant, Prothioconazole is not a candidate for substitution.

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

Appendix 1 Copy of the product authorization

Appendix 2 Copy of the product label

Skuteczność uwagi:

W Polsce pszenica ozima (przeciwko SEPTTR, FUSASP, **PUCCSP**, **PUCCRE/PUCCRT**, **PUCCST**), jęczmień ozimy (przeciwko RHYNSE i PYRNTE), rzepak ozimy (przeciwko SCLESC), burak cukrowy (przeciwko CERCBE), jabłko (przeciwko VENTIN i PODOLE), wiśnia i śliwa (przeciwko MONILSP), marchew (przeciwko ALTEDA i ERSYSHE) mogą być akceptowane zgodnie z art. 33.

Pigwa i śliwa (przeciwko parchowi, Stemphylium, Oidium), grusza (przeciwko parchowi, Stemphylium, Oidium), morela (przeciwko Sphaerotheca spp. i Monilia spp.), marchew przeciwko (SCLESC) i inne warzywa korzeniowe i bulwiaste (przeciwko SCLESC, Alternaria dauci, mączniakowi rzekomemu) oraz rzepak jary i żyto jare mogą być dopuszczone tylko zgodnie z art. 51.

~~Proponujemy umieszczenie zapisu, że nie można wykluczyć negatywnego wpływu SIP41061 na ordzawienie jabłek i jakość plonu.~~

Zmieniono zalecaną ilość wody przy zbożach, rzepaku ozimym, buraku cukrowym, jabłoni i owocach pestkowych.

Zaproponowano inne okienko aplikacyjne dla jęczmienia, rzepaku ozimego, jabłoni, owocach pestkowych i marchwi.

Dla wiśni i śliwy rekomendowana dawka to 0,3-0,4 l/ha. Dla jabłoni – 0,3 l/ha. **Dla jęczmienia – dawka 0.4 L/ha i 0.5 L/ha.** Pozostałe dawki zaakceptowano bez zmian.

Zaproponowano dawki LWA dla jabłoni i owoców pestkowych.

Środek dobrze zwalczał zaakceptowane choroby zbóż, rzepaku ozimego, marchwi, buraka cukrowego, owoców pestkowych i mączniaka prawdziwego jabłoni. Średnio skutecznie zwalczał parcha jabłoni.

Toksykologia:

Dodano kalosze.

Metabolizm i pozostałości:

Brak zgody na następujące zastosowania: • jabłoni, grusza, pigwa, nieszpulka, śliwa, wiśnia, morela

Okres karencji dla zbóż: 35 dni

Z grupy roślin „inne rośliny korzeniowe i bulwiaste” możliwa jest zgoda tylko na następujące zastosowania:

buraki 0213010; chrzan 0213040; pasternak 0213060; korzenie pietruszki 0213070; salsefia 0213090; brukiew 0213100; rzepa 0213110

Los i zachowanie w środowisku: brak uwag

Ekotoksykologia:

Zaproponowano inne okienko aplikacyjne dla owoców pestkowych.

Strefy ochronne dla organizmów wodnych:

Rzepak jary

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 10 m od zbiorników i cieków wodnych.

Zboża, rzepak ozimy, marchew

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

Drzewa pestkowe, drzewa ziarnkowe

W celu ochrony organizmów wodnych niebędących celem działania środka konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

20 m od zbiorników i cieków wodnych lub,

10 m od zbiorników i cieków wodnych z równoczesnym zastosowaniem rozpylaczy redukujących

Posiadacz zezwolenia:

SIPCAM OXON S.P.A., Via Sempione 195, 20016 Pero (MI) – Republika Włoska

tel: +39 (0)2 35378400, fax: +39 (0)2 3390275; e-mail: sipcamoxon@sipcam.com


SIP 41061

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

protriokonazol (związek z grupy triazoli) – 400 g/l (34,42 %).

•Zezwolenie MRRW nr R- z dnia r.

	
Uwaga	
H410	Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH208	Zawiera 1,2-benzisothiazol-3-one. Może powodować wystąpienie reakcji alergicznej.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P273	Unikać uwalniania do środowiska.
P280	Stosować rękawice ochronne, odzież ochronną, ochronę oczu
P391	Zebrać wyciek.

OPIS DZIAŁANIA

FUNGICYD w formie koncentratu w postaci stężonej zawiesiny przeznaczonej do rozcieńczania wodą (SC) o działaniu układowym, do stosowania zapobiegawczego i interwencyjnego w ochronie przed chorobami powodowanymi przez grzyby. Środek zawiera substancję czynną protriokonazol z grupy triazoli (fungicydy inhibitory biosyntezy steroli - inhibitory demetylacji, SBI- DMI, wg FRAC grupa 3).

Po wchłonięciu środek przedostaje się do komórek organizmów docelowych, wpływając na biosyntezę steroli i strukturę błony, co ostatecznie zaburza wzrost strzępek i wydłużenie rurki zarodkowej.

• STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnego lub ciągnikowego opryskiwacza polowego.

• ~~Pszenica ozima, pszenica jara, pszenica durum, pszenżyto ozime, pszenżyto jare, żyto ozime, żyto jare~~

septorioza paskowana liści pszenicy, fuzaryjna zgorzel podstawy źdźbła i korzeni, rdza brunatna pszenicy
rdza żółta, mączniak prawdziwy – dobry poziom zwalczania w dawce 0.5 L/ha i średni stopień zwalczania w dawce 0.4 L/ha

Maksymalna dawka dla jednorazowego zastosowania: 0,5 l/ha

Zalecana dawka dla jednorazowego zastosowania: 0,4-0,5 l/ha

Termin stosowania: Środek stosować zapobiegawczo lub natychmiast po zauważeniu pierwszych objawów chorób od końca fazy krzewienia do końca fazy kwitnienia (BBCH 29-69).

Zalecana ilość wody: 200-300 ~~600~~ l/ha Za-

lecane opryskiwanie: drobnokropliste
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2
Odstęp między zabiegami: co najmniej 14 dni

- **Jęczmień ozimy, jęczmień jary**

rynchosporioza zbóż, rdza jęczmienia, plamistość siatkowa jęczmienia – dobry poziom zwalczania w dawce 0.5 L/ha i średni stopień zwalczania w dawce 0.4 L/ha

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,5 l/ha

Zalecana dawka dla jednorazowego zastosowania: 0,4-0,5 l/ha

Termin stosowania: Środek stosować zapobiegawczo lub natychmiast po zauważeniu pierwszych objawów chorób, od końca fazy krzewienia początku wzrostu źdźbła do początku fazy kwitnienia widocznych pierwszych ości (BBCH 29-64 30-49).

Zalecana ilość wody: 200-300 600 l/ha Za-

lecane opryskiwanie: drobnokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Odstęp między zabiegami: co najmniej 14 dni

- **Rzepak ozimy, rzepak jary**

zgnilizna twardzikowa, sucha zgnilizna kapustnych, cylindrosporioza roślin, mączniak prawdziwy – dobry poziom zwalczania

Maksymalna dawka dla jednorazowego zastosowania: 0,45 l/ha

Zalecana dawka dla jednorazowego zastosowania: 0,35-0,45 l/ha

Termin stosowania: Środek stosować zapobiegawczo lub natychmiast po zauważeniu pierwszych objawów chorób, od początku fazy wydłużania lodygi do początku fazy rozwoju owoców do końca kwitnienia (BBCH 30-74 60-69).

Zalecana ilość wody: 200-300 600 l/ha Za-

lecane opryskiwanie: drobnokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Odstęp między zabiegami wiosennymi: co najmniej 14 dni

- **Burak cukrowy**

chwościk buraka, mączniak prawdziwy buraka – dobry poziom zwalczania

Maksymalna dawka dla jednorazowego zastosowania: 0,4 l/ha

Zalecana dawka dla jednorazowego zastosowania: 0,3-0,4 l/ha

Termin stosowania: Środek stosować zapobiegawczo lub natychmiast po zauważeniu pierwszych objawów chorób, od końca fazy rozwoju rozety do momentu gdy korzeń osiąga wielkość wymaganą do zbioru (BBCH 39-49).

Zalecana ilość wody: 200-300 600 l/ha Za-

lecane opryskiwanie: drobnokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Odstęp między zabiegami: co najmniej 14 dni

- **Jabłoń, grusza, pigwa, nieszpulka**

parcz jabłoni (średni stopień zwalczania), parcz gruszy, brązowa plamistość gruszy, mączniak prawdziwy jabłoni (dobry stopień zwalczania)

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,3 l/ha ((0.2 L/10 000 m² powierzchni ściary liści (LWA))

Termin stosowania: Środek stosować zapobiegawczo lub natychmiast po zauważeniu pierwszych objawów chorób, od momentu gdy pędy osiągają około 90% typowej długości do fazy zaawansowanego dojrzewania od początku kwitnienia do końca rozwoju owoców (BBCH 39 85 51 79).

Zalecana ilość wody: 500 1000 1500 l/ha

Zalecane opryskiwanie: drobnokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Odstęp między zabiegami: co najmniej 7-9 dni

• ~~Śliwa, wiśnia, morela~~

~~brunatna zgnilizna drzew pestkowych, mączniak prawdziwy – dobry poziom zwalczania~~

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,4 l/ha ((0,265 L/10000 m² po wierzchni ściany liści (LWA))

Zalecana dawka dla jednorazowego zastosowania: 0,3-0,4 l/ha ((0,22 – 0,265 L/10000 m² powierzchni ściany liści (LWA))

Termin stosowania: Środek stosować zapobiegawczo lub natychmiast po zauważeniu pierwszych objawów chorób, od początku rozwoju owoców fazy rozwoju kwiatostanu do momentu zaawansowanego wybarwienia owoców do końca dojrzewania owoców i nasion (BBCH 51-85-71-89).

Zalecana ilość wody: 500-1000-1500 l/ha

Zalecane opryskiwanie: drobnokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Odstęp między zabiegami: co najmniej 7 dni

• **Marchew (oraz inne rośliny korzeniowe i bulwiaste)**

~~alternarioza naci marchwi, zgnilizna twardej marchwi, mączniak prawdziwy baldaszkowaty – dobry poziom zwalczania~~

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,5 l/ha

Termin stosowania: Środek stosować zapobiegawczo lub natychmiast po zauważeniu pierwszych objawów chorób, od rozwoju części roślin przeznaczonych do zbioru fazy 6 liścia do momentu gdy korzeń osiąga 60% typowej średnicy (BBCH 46-46-41-49).

Zalecana ilość wody: 500-600-1000 l/ha

Zalecane opryskiwanie: drobnokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Odstęp między zabiegami: co najmniej 21 dni

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

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

rzepak – 50 dni,

burak cukrowy – 28 dni,

pszenica, ~~pszenica durum~~, pszenżyto, żyto, jęczmień: 35 dni

grusza, marchew (oraz inne rośliny korzeniowe i bulwiaste) – 21 dni,

jabłoń, pigwa, nieszpulka – 14 dni,

śliwa, wiśnia, morela – 3 dni.

1. Środek w niższej z zalecanych dawek w ochronie zbóż oraz rzepaku i owoców pestkowych stosować tylko w warunkach słabszej presji infekcyjnej ze strony sprawców chorób.
2. Środek zawiera substancję czynną protiokonazol z grupy triazoli. W ramach strategii antyodpornościowej zaleca się m.in.:
 - stosowanie środka głównie do zabiegów zapobiegawczych,
 - niestosowanie środka w dawkach innych niż jest zalecana,
 - włączenie do przyjętego programu ochrony środków grzybobójczych, zawierających substancje czynne z innych grup, o odmiennych mechanizmach działania (stosowanie przemienne).
3. Środek można mieszać z innymi środkami ochrony roślin oraz z nawozami. Przy łącznym stosowaniu zaleca się wykonanie próbnego zabiegu w celu sprawdzenia czy nie występują objawy fitotoksyczności oraz przestrzegać okresów karencji poszczególnych środków.
4. Praktyki sanitarne mają kluczowe znaczenie dla wyeliminowania zimujących źródeł patogenu. Zmniejsza ilość dostępnego inokulum i zmniejsza ryzyko infekcji.
 - Podczas przycinania usuwaj mumie owocowe, raki na gałęziach i zniszczone kwiaty.
 - Zapewnij dobrą cyrkulację powietrza w koronie (np. wybór miejsca, odpowiednie przycinanie ziemi i latem oraz unikanie nadmiernego nawożenia).

- Usuwać zainfekowane lub uszkodzone owoce przez cały sezon wegetacyjny.
 - Ustanowić właściwe zarządzanie podłożem w sadzie, w tym usuwanie opadłych owoców.
- Zawsze postępuj zgodnie z wskazówkami na etykiecie.

• **SPORZĄDZANIE CIECZY UŻYTKOWEJ**

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlewniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać. W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

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

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.

Bezpośrednio po pracy aparaturę dokładnie wymyć oraz przepłukać ją co najmniej trzykrotnie wodą.

• **ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH**

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

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

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

Podczas wykonywania zabiegu w uprawach polowych przy zastosowaniu opryskiwaczy ciągnikowych stosować odzież roboczą podczas mieszania/załadunku i aplikacji, w uprawach sadowniczych przy zastosowaniu opryskiwacza pneumatycznego dodatkowo podczas aplikacji zaleca się używanie rękawic.

Podczas wykonywania zabiegu w przypadku wysokich upraw (drzewa pestkowe) należy używać odzieży roboczej (zakryte ramiona, tułów i nogi) podczas mieszania/załadunku i rękawice podczas aplikacji.

Dla upraw zbożowych obowiązuje strefa buforowa 5 m

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):

Nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

• **ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO**

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

Rzepak jary

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 10 m od zbiorników i cieków wodnych.

Zboża, rzepak ozimy, marchew

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

Drzewa pestkowe, drzewa ziarnkowe

W celu ochrony organizmów wodnych niebędących celem działania środka konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

- 20 m od zbiorników i cieków wodnych lub,
- 10 m od zbiorników i cieków wodnych z równoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90%.

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

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0°C - 30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów. Nie-wykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

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

• **PIERWSZA POMOC**

Antidotum: brak, stosować leczenie objawowe.

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

W przypadku połknięcia: W przypadku złego samopoczucia skontaktować się z ośrodkiem zatruc lub lekarzem.

W przypadku dostania się na skórę: Umyć dużą ilością wody z mydłem.

W przypadku dostania się do oczu: Ostrożnie płukać wodą kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.

Okres ważności – 2 lata

Data produkcji –

Zawartość netto –

Numer partii -

Appendix 3 Letter of Access

Letters of Access were provided.

Appendix 4 Lists of data considered for national authorization

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection n claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1- KCP 2.11	Massardi, E.	2021	SIP41061 (PROTHIOCONAZOLE 400 g/L SC) Physical and chemical properties on fresh sample, after accelerated stability at +54°C for 14 days and after low stability at 0°C for 7 days Report n.: CPU-026-21 Research Center BioSphereS by Biotechnologie BT GLP not published	N	Y	new study	Sipcam Oxon S.p.A.
KCP 2.2.1 KCP 2.3.3	Wojsiat, P.	2021	Physical and Chemical Properties Testing on a Sample of SIP 41061 Report n.: GLP3016008493R1/2021 Dekra UK Ltd GLP not published	N	Y	new study	Sipcam Oxon S.p.A.
KCP 2.7.6	Aversa, S.	2018	SIP41061 (PROTHIOCONAZOLE 400 g/L SC) Shelf life at room temperature – <i>checkpoint 6 months</i> Report n.: CPU-027-21 Research Center BioSphereS by Biotechnologie BT GLP unpublished	N	Y	new study	Sipcam Oxon S.p.A.
KCP 4.4/01	Anonymous	-	PROTHIOCONAZOLE 400 g/L SC (SIP 41061) DESCRIPTION OF PACKAGING SIPCAM Oxon S.p.A. Report n.: - not GLP not published	N	Y	new study	Sipcam Oxon S.p.A.
KCP 2.11/01	de Pinho, S	2020	Prothioconazole 400 SC Determination of corrosivity in metals Report n.: RL19441/2019CV-B ALS Laboratorios LS Ltda GLP not published	N	Y	new study	Sipcam Oxon S.p.A.
KCP 5.1.1/01 KCP 5.1.1/02	Massardi E.	2021	SIP41061 (PROTHIOCONAZOLE 400 g/L SC) Physical and chemical properties on	N	Y	new study	Sipcam Oxon S.p.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 n claimed Y/N	Justification if data protection is claimed	Owner
			fresh sample, after accelerated stability at +54°C for 14 days and after low stability at 0°C for 7 days CPU-026-21 Research Center BioSpheres by Biotechnologie BT GLP not published				
KCP 5.1.2/01	Massardi E.	2021	Validation of the analytical method to determine prothioconazole metabolites in high water commodity (plum), high acid commodity (grape), high oil commodity (oilseed rape seeds), high protein commodity (peas dry seeds) and high starch commodity (sugar beet roots) RAU-003-21 Research Center BioSphereS by Biotechnologie BT GLP not published	N	Y	new study	Sipcam Oxon S.p.A.
KCP 5.1.2/02	Massardi E.	2022	Validation of the analytical method to determine Triazole Derivative Metabolites (TDMs) in high water commodity (zucchini), high acid commodity (grapes), oil commodity (oilseed rape seeds) and dry commodity (peas dry seeds) – amended 1 Study Plan RAU-027-21 Research Center BioSphereS by Biotechnologie BT GLP not published	N	Y	new study	Sipcam Oxon S.p.A.
KCP 5.1.2/03	Aversa S.	2020	Validation of an HPLC-MS/MS analytical method for the determination of Prothioconazole and Azoxystrobin in water and sugar feeding solutions coming from ecotox laboratory tests (honeybees) BT214/20 Biotechnologie BT GLP not published	N	Y	new study	Sipcam Oxon S.p.A.
KCP 5.1.2/04	Fifi A. P.	2022	Validation of the analytical method (SANTE/2020/12830 Rev.1) for the determination of Prothioconazole and Prothioconazole-desthio in aqueous matrix and sugar feeding solutions with product SIP 41061 BT193/21 Biotechnologie BT GLP	N	Y	new study	Sipcam Oxon SpA

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
			not published				
KCP 5.1.2/05	Aversa S.	2020	Validation of an HPLC-MS/MS analytical method for the determination of Prothioconazole in soil coming from ecotox laboratory tests (earthworms) BT215/20 Biotechnologie BT GLP not published	N	Y	new study	Sipcam Oxon S.p.A.
KCP 5.1.2/06	Desiante A.	2021	Determination of dislodgeable foliar residue of prothioconazole and prothioconazole-desthio in raw agricultural commodity peach followin two applications of SIP41061 (Prothioconazole 400 g/L SC) BIU-011-21 Research Center BioSphereS GLP not published	N	Y	new study	Sipcam Oxon S.p.A.
KCP 6	Anonymous	2022	Biological Assessment Dossier for SIP41061	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/04 Also cited in KCP 6.4	Mateusz Płoceniak	2021	efficacy of SIP41061 in control of Zymoseptoria tritici in winter wheat, Poland 2021 S02107 Fertico GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/05 Also cited in KCP 6.4	Mateusz Płoceniak	2021	efficacy of SIP41061 in control of Puccinia spp in winter wheat, Poland 2021 S02109 Fertico GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/06 Also cited in KCP 6.4	Dariusz Porzecki	2021	efficacy of SIP41061 in control of Fusarium ssp in winter wheat, Poland 2021 S02110 Fertico GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/07 Also cited in KCP 6.4	Costin Paduraru	2021	Determination of efficacy of Prothioconazole against Zymoseptoria tritici in winter wheat, 2021 S21-02375-01 EUROFINS AGROSCIENCE SERVICES GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP	Mihai Robe	202	Determination of efficacy of Prothi-	N	Y	New	Sipcam

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebra te study Y/N	Data protectio n claimed Y/N	Justificatio n if data protection is claimed	Owner
6.2/08 Also cited in KCP 6.4		1	oconazole against Zymoseptoria tritici in winter wheat, 2021 S21-02375-02 EUROFINS AGROSCIENCE SERVICES GEP Unpublished			study	Oxon S.p.A.
KCP 6.2/09 Also cited in KCP 6.4	Andreea Alexandru	2021	Determination of efficacy of Prothioconazole against Zymoseptoria tritici in winter wheat, 2021 S21-02375-03 EUROFINS AGROSCIENCE SERVICES GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/10 Also cited in KCP 6.4	Costin Padurar	2021	Determination of efficacy of SIP41061 (prothioconazole) against Puccinia spp. in winter wheat, 2021 S20-02376-01 EUROFINS AGROSCIENCE SERVICES GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/11 Also cited in KCP 6.4	Mihai Robe	2021	Determination of efficacy of SIP41061 (prothioconazole) against Puccinia spp. in winter wheat, 2021 S21-02376-02 EUROFINS AGROSCIENCE SERVICES GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/12 Also cited in KCP 6.4	Pavel Dragila	2021	Determination of efficacy of SIP41061 (prothioconazole) against Puccinia spp. in winter wheat, 2021 S20-02376-03 EUROFINS AGROSCIENCE SERVICES GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/13 Also cited in KCP 6.4	Costin Padurar	2021	Determination of efficacy of SIP41061 (prothioconazole) against Fusarium head blight in winter wheat, 2021 S21-02377-01 EUROFINS AGROSCIENCE SERVICES GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/14 Also cited in KCP 6.4	Mihai Robe	2021	Determination of efficacy of SIP41061 (prothioconazole) against Fusarium head blight in winter wheat, 2021 S21-02377-02 EUROFINS AGROSCIENCE	N	Y	New study	Sipcam Oxon S.p.A.

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			SERVICES GEP Unpublished				
KCP 6.2/15 Also cited in KCP 6.4	Pavel Dragila	2021	Determination of efficacy of SIP41061 (prothioconazole) against Fusarium head blight in winter wheat, 2021 S21-02377-03 EUROFINS AGROSCIENCE SERVICES GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/16 Also cited in KCP 6.4	Kevin Livingstone		To provide tolerance and efficacy data for PROTHIOCONAZOLE at different rates against Ear fusarium head blight incidence and severity in winter wheat. S21004 T1 Scottish Agri trials service GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/17 Also cited in KCP 6.4	Mr Florent NOYGUES	2021	Efficacy and selectivity of SIP41061 against leaf blotch on winter wheat with 2 applications in France in 2021 SO2107 AGROLIS CONSULTING GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/18 Also cited in KCP 6.4	Anna Pietryga	2021	Efficacy and selectivity of SIP 41061 against Zymoseptoria tritici and other diseases on winter wheat, Poland 2021 SO2107-01 Biotek Agriculture Sp. z o.o. Polska GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/19 Also cited in KCP 6.4	Anna Pietryga	2021	Efficacy and selectivity of SIP 41061 against Zymoseptoria tritici and other diseases on winter wheat, Poland 2021 SO2107-02 Biotek Agriculture Sp. z o.o. Polska GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/20 Also cited in KCP 6.4	Sven Wichmann	2021	Efficacy of SIP41061 against SEPTTR in wheat S21-02537-01 Agrartest GmbH GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/21 Also	Kerstin Grote	2021	Efficacy of SIP41061 against SEPTTR in wheat S21-02537-02	N	Y	New study	Sipcam Oxon S.p.A.

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cited in KCP 6.4			EAS Germany, Detmold GEP Unpublished				
KCP 6.2/22 Also cited in KCP 6.4	Anna Pietryga	2021	Efficacy and selectivity of SIP 41061 against Puccinia sp. on winter wheat, Poland 2021 SO2109-01 BIOTEK Agriculture GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/23 Also cited in KCP 6.4	Anna Pietryga	2021	Efficacy and selectivity of SIP 41061 against Puccinia sp. on winter wheat, Poland 2021 SO2109-02 BIOTEK Agriculture GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/24 Also cited in KCP 6.4	Marta Bruder	2021	Efficacy and selectivity of SIP 41061 against Fusarium spp. on winter wheat, Poland 2021 SO2110-01 Biotek Agriculture Sp. z o.o. Polska GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/25 Also cited in KCP 6.4	Marta Bruder	2021	Efficacy and selectivity of SIP 41061 against Fusarium spp. on winter wheat, Poland 2021 SO2110-02 Biotek Agriculture Sp. z o.o. Polska GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/26 Also cited in KCP 6.4	Sabine Bach	2021	Efficacy of SIP41061 against Fusarium spp. in wheat S21-02540-02 Agrartest GmbH GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/27 Also cited in KCP 6.4	Julien Rivet	2021	Evaluate the efficacy of SIP41061 (prothioconazole 400 gai/l) sprayed on winter soft wheat against Septoria. France maritime, 2021. 21 20 F01 ESSAIS+ GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/28 Also cited in KCP 6.4	Julien RIV-ET	2021	Evaluate the efficacy of SIP41061 (prothioconazole 400 gai/l) sprayed on winter soft wheat against Septoria. France maritime, 2021. 21 20 F02 ESSAIS + GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP	Julien Rivet	2021	Evaluate the efficacy of SIP41061 (N	Y	New	Sipcam

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6.2/29 Also cited in KCP 6.4		1	prothioconazole 400 gai/l) sprayed on winter soft wheat against rust. France maritime, 2021. 21 20 F03 ESSAIS+ GEP Unpublished			study	Oxon S.p.A.
KCP 6.2/30 Also cited in KCP 6.4	Julien Rivet	202 1	Evaluate the efficacy of SIP41061 (prothioconazole 400 gai/l) sprayed on winter soft wheat against rust. France maritime, 2021. 21 20 F04 ESSAIS+ GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/31 Also cited in KCP 6.4	Julien Rivet	202 1	Evaluate the efficacy of SIP41061 (prothioconazole 400 gai/l) sprayed on winter soft wheat against fusari- um. France maritime, 2021. 21 20 F05 ESSAIS+ GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/32 Also cited in KCP 6.4	Julien Rivet	202 1	Evaluate the efficacy of SIP41061 (prothioconazole 400 gai/l) sprayed on winter soft wheat against fusari- um. France maritime, 2021. 21 20 F06 ESSAIS+ GEP, Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/33 Also cited in KCP 6.4	Immogen Morris	202 1	Efficacy of SIP41061 on Fusarium head blight in winter wheat 21-00401-01 SGS United Kingdom Ltd GEP Unpublished	N	Y	New study	SIPCAM UK Ltd
KCP 6.2/34 Also cited in KCP 6.4	Danny Rich- ardson	202 1	Efficacy of SIP41061 on Fusarium head blight in winter wheat 21-00401-02 SGS United Kingdom Ltd GEP Unpublished	N	Y	New study	SIPCAM UK Ltd
KCP 6.2/35 Also cited in KCP 6.4	Valentin Leneschi	202 1	Efficacy of SIP41061 against rusts in winter wheat. UK efficacy trial, 2021 F21054 T1 Fieldarm Limited GEP Unpublished	N	Y	New study	SIPCAM ITALIA
KCP 6.2/44 Also cited in KCP 6.4	Bastian Lorenz	201 9	Prothioconazole straight and tank mix - Septoria 19 1069 5141 BioChem agrar GmbH Niederlas- sung Agroplan	N	Y	New study	Sipcam Oxon S.p.A.

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			GEP Unpublished				
KCP 6.2/45 Also cited in KCP 6.4	Julien Rivet	2019	Efficacy of SIP41061(solo or mixed with adjuvant SIP40992), SIP41013, SIP41075 against septoria tritici on winter wheat in France in 2019 19 20 F 03 ESSAIS+ GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/46 Also cited in KCP 6.4	Julien Rivet	2019	Efficacy of SIP41061(solo or mixed with adjuvant SIP40992), SIP41013, SIP41075 against septoria tritici on winter wheat in France in 2019 19 20 F 04 ESSAIS+ GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/47 Also cited in KCP 6.4	Kristin Lamers	2020	Prothioconazole straight and mixtures against wheat brown/yellow rust 20 1069 5160 BioChem agrar GmbH Niederlassung Agroplan GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/48 Also cited in KCP 6.4	Kristin Lamers	2020	Prothioconazole straight and mixtures against wheat fusarium head blight 20 1069 5162 BioChem agrar GmbH Niederlassung Agroplan GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/49 Also cited in KCP 6.4	Julien RIV-ET	2020	Efficacy of SIP41061, SIP41099, SIP41100 and SIP41098 against septoria tritici on winter wheat in France in 2020 20 20 F 07 ESSAIS + GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/50 Also cited in KCP 6.4	Julien RIV-ET	2020	Efficacy of SIP41061, SIP41099, SIP41100 and SIP4098 against septoria tritici on winter wheat in France in 2020 20 20 F 08 ESSAIS + GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/51 Also cited in KCP 6.4	Julien RIV-ET	2020	Efficacy of SIP41061, SIP41099 and SIP41100 against brown rust on winter wheat in France in 2020 20 20 F 10 ESSAIS + GEP	N	Y	New study	Sipcam Oxon S.p.A.

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			Unpublished				
KCP 6.2/52 Also cited in KCP 6.4	Julien RIV-ET	2020	Efficacy of SIP41061, SIP41099 and SIP41100 against yellow rust on winter wheat in France in 2020 20 20 F 13 ESSAIS + GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/53 Also cited in KCP 6.4	CA-ZENEUVE Mickaël	2020	prothioconazole straight and mixtures against wheat septoria leaf blotch 20F FCEOXO FR03 PROMO-VERT TOULOUSE GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/54 Also cited in KCP 6.4	Veronika Gezova	2019	Determine the efficacy and selectivity of fungicides applied on winter wheat for the control of Septoria in Czech Republic, spring 2019 F-19-G-545-01 InTec Agro Trials, s.r.o. GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/55 Also cited in KCP 6.4	Jiri Kopacek	2020	Prothioconazole straight and mixtures against wheat septoria leaf blotch F-20-G-596-01 InTec Agro Trials, s.r.o. GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/56 Also cited in KCP 6.4	Pavlina Otrhalkova	2020	Prothioconazole straight and mixtures against wheat brown/yellow rust F-20-G-597-01 InTec Agro Trials, s.r.o. GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/57 Also cited in KCP 6.4	James Breen	2019	Efficacy of Sipcam Oxon prothioconazole formulations applied alone and in tank mixes against Septoria tritici. UK efficacy trial, 2019 F19063 T1 FieldArm Ltd GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/58 Also cited in KCP 6.4	James Breen	2020	Efficacy of Sipcam Oxon prothioconazole formulations against Septoria tritici in winter wheat. UK efficacy trials, 2020 F20052 T1 FieldArm Ltd GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/59	James Breen	2020	Efficacy of Sipcam Oxon prothioconazole formulations against Sep-	N	Y	New study	Sipcam Oxon

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Also cited in KCP 6.4			torial tritici in winter wheat. UK efficacy trials, 2020 F20052 T2 FieldArm Ltd GEP Unpublished				S.p.A.
KCP 6.2/60 Also cited in KCP 6.4	Ian Haigh	2020	Efficacy of Sipcam Oxon prothio- conazole formulations against yel- low rust in winter wheat. UK effica- cy trials, 2020 F20053 T1 FieldArm Ltd GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/61 Also cited in KCP 6.4	Valentin Leneschi	2020	Efficacy of Sipcam Oxon prothio- conazole formulations against yel- low rust in winter wheat. UK effica- cy trials, 2020 F20053 T2 Fieldarm Limited GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/69 Also cited in KCP 6.4	Éva Abdai	2020	Efficacy trial against leaf diseases in winter wheat OXONWW-HU2020-AE03 Government Office of Komárom- Esztergom County GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/70 Also cited in KCP 6.4	Kevin Liv- ingstone		To provide tolerance and efficacy data for PROTHIO straight and tank mixed against Septoria on cereals S19010 T1 Scottish Agri trials service GEP Unpublished	N	Y	New study	SIPCAM OXON
KCP 6.2/71 Also cited in KCP 6.4	Aura Fil- ipoiu	2020	Determination of efficacy of fungi- cides applied in post-em against Zymoseptoria tritici in wheat, 2020. S20-03045-01 EAS Romania, Timisoara GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/72 Also cited in KCP 6.4	Aura Fil- ipoiu	2020	Determination of efficacy of pro- thioconazole straight and mixtures against Fusarium head blight in wheat, 2020. S20-03047-01 EAS Romania, Timisoara GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/73 Also	Aura Fil- ipoiu	2020	Determination of efficacy of fungi- cides applied in post-em against Puccinia in wheat, 2020.	N	Y	New study	Sipcam Oxon S.p.A.

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cited in KCP 6.4			S20-03048-01 EAS Romania, Timisoara GEP Unpublished				
KCP 6.2/74 Also cited in KCP 6.4	Tony Allen	2020	Efficacy of Prothioconazole straight and in mixtures against Zymoseptoria tritici in Winter wheat SIP1162-01 OAT GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/75 Also cited in KCP 6.4	Anna Pietryga	2020	Efficacy and selectivity of tested products SIP 41061, SIP 41099, SIP 41100 against diseases in winter wheat, Poland 2020 SO2018-01 BIOTEK Agriculture GEP Unpublished	N	Y	New study	SIPCAM OXON
KCP 6.2/76 Also cited in KCP 6.4	Marta Bruder	2020	Efficacy and selectivity of tested products SIP 41061, SIP 41099, SIP 41100 against diseases in winter wheat, Poland 2020 SO2018-02 BIOTEK Agriculture GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/77 Also cited in KCP 6.4	Michael Härle	2020	Prothio against Septoria Germany 2020 S20-3517-02 Agrartest GmbH GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/78 Also cited in KCP 6.4	Marta Bruder	2020	The evaluation of efficacy and selectivity of SIP 41061, SIP 41099, SIP 41100 for the control of foliar diseases in winter wheat SO2024-01 BIOTEK Agriculture GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/79 Also cited in KCP 6.4	Marta Bruder	2020	Efficacy and selectivity of tested products SIP 41061, SIP 41099, SIP 41100 against diseases in winter wheat, Poland 2020 SO2025-01 BIOTEK Agriculture GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/80 Also cited in KCP 6.4	Michael Ingenerf	2021	SIP41061 against Rhynchosporium spp and Helminthosporium spp in barley 21 1069 5179 BioChem agrar GmbH Niederlas-	N	Y	New study	Sipcam Oxon S.p.A.

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			sung Agroplan GEP Unpublished				
KCP 6.2/81 Also cited in KCP 6.4	Kristin Lamers	2021	SIP41061 against Rhynchosporium spp and Helminthosporium spp in barley 21 1069 5180 BioChem agrar GmbH Niederlassung Agroplan GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/82 Also cited in KCP 6.4	Michael Ingenerf	2021	SIP41061 against Rhynchosporium spp and Helminthosporium spp in barley 21 1069 5181 BioChem agrar GmbH Niederlassung Agroplan GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/83 Also cited in KCP 6.4	Thorsten Houben	2021	SIP41061 against Rhynchosporium spp and Helminthosporium spp in barley 21 1069 5182 BioChem agrar GmbH Niederlassung Agroplan GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/84 Also cited in KCP 6.4	Julien Rivet	2021	Evaluate the efficacy of SIP41061 (prothioconazole 400 gai/l) sprayed on winter barley against net blotch (PYRNTE). France maritime, 2021. 21 20 F07 ESSAIS+ GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/85 Also cited in KCP 6.4	Julien Rivet	2021	Evaluate the efficacy of SIP41061 (prothioconazole 400 gai/l) sprayed on winter barley against net blotch (PYRNTE). France maritime, 2021. 21 20 F08 ESSAIS+ GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/86 Also cited in KCP 6.4	CAULLET Maxime	2021	Rhynchosporium secalis on winter barley 21F FCEOXO FR01 PROMO-VERT TOURS GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/87 Also cited in KCP 6.4	JORAND Matthieu	2021	Rhynchosporium secalis on winter barley 21F FCEOXO FR02 PROMO-VERT REIMS GEP	N	Y	New study	Sipcam Oxon S.p.A.

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			Unpublished				
KCP 6.2/88 Also cited in KCP 6.4	Ian Haigh	2021	Efficacy of SIP41061 against foliar disease in winter barley UK efficacy trials, 2021 F21055 T1 FieldArm Limited GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/89 Also cited in KCP 6.4	Ian Haigh	2021	Efficacy of SIP41061 against foliar disease in winter barley UK efficacy trials, 2021 F21055 T2 FieldArm Limited GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/93 Also cited in KCP 6.4	Błażej Koralewski	2021	efficacy of SIP41061 in control of Pyrenophora teres in winter barley, Poland 2021 S02111 pyrenophora Fertico Sp. z o.o. GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/94 Also cited in KCP 6.4	Dariusz Porzecki	2021	efficacy of SIP41061 in control of Rhynchosporium secalis in winter barley, Poland 2021 S02111 Rhynchosporium Fertico GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/95 Also cited in KCP 6.4	Maria Ferencz	2021	Determination of efficacy of SIP41061 (Prothioconazole) against Helmithosporium sp and Rynchosporium sp. in winter barley, 2021 S21-02378-01 EUROFINS AGROSCIENCE SERVICES GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/96 Also cited in KCP 6.4	Andreea Alexandru	2021	Determination of efficacy of SIP41061 (Prothioconazole) against Helmithosporium sp and Rynchosporium sp. in winter barley, 2021 S21-02378-02 EUROFINS AGROSCIENCE SERVICES GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/97 Also cited in KCP 6.4	Pavel Dragila	2021	Determination of efficacy of SIP41061 (Prothioconazole) against Helmithosporium sp and Rynchosporium sp. in winter barley, 2021	N	Y	New study	Sipcam Oxon S.p.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
			S21-02378-03 EUROFINS AGROSCIENCE SERVICES GEP Unpublished				
KCP 6.2/98 Also cited in KCP 6.4	Costin Paduraru	2021	Determination of efficacy of SIP41061 (Prothioconazole) against <i>Helmithosporium</i> sp and <i>Rynchosporium</i> sp. in winter barley, 2021 S21-02378-04 EUROFINS AGROSCIENCE SERVICES GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/99 Also cited in KCP 6.4	Mihai Robe	2021	Determination of efficacy of SIP41061 (Prothioconazole) against <i>Helmithosporium</i> sp and <i>Rynchosporium</i> sp. in winter barley, 2021 S21-02378-05 EUROFINS AGROSCIENCE SERVICES GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/100 Also cited in KCP 6.4	Andreea Alexandru	2021	Determination of efficacy of SIP41061 (Prothioconazole) against <i>Helmithosporium</i> sp and <i>Rynchosporium</i> sp. in winter barley, 2021 S21-02378-06 EUROFINS AGROSCIENCE SERVICES GEP; Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/101 Also cited in KCP 6.4	Anna Pietryga	2021	Efficacy and selectivity of SIP 41061 against <i>Rynchosporium</i> spp. and <i>Helmintosporium</i> spp. on winter barley, Poland 2021 SO2111-01 Biotek Agriculture Sp. z o.o. Polska GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/102 Also cited in KCP 6.4	Marta Bruder	2021	Efficacy and selectivity of SIP 41061 against <i>Rynchosporium</i> spp. and <i>Helmintosporium</i> spp. on winter barley, Poland 2021 DPE2SO2011-01-053-01 Biotek Agriculture Sp. z o.o. Polska GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/103 Also cited in	Anna Pietryga	2021	Efficacy and selectivity of SIP 41061 against <i>Rynchosporium</i> spp. and <i>Helmintosporium</i> spp. on winter barley, Poland 2021	N	Y	New study	Sipcam Oxon S.p.A.

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KCP 6.4			SO2111-02 Biotek Agriculture Sp. z o.o. Polska GEP Unpublished				
KCP 6.2/104 Also cited in KCP 6.4	Marta Bruder	2021	Efficacy and selectivity of SIP 41061 against <i>Rhynchosporium</i> spp. and <i>Helminthosporium</i> spp. on winter barley, Poland 2021 DPE2SO2011-01-053-02 Biotek Agriculture Sp. z o.o. Polska GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/105 Also cited in KCP 6.4	Veronika Gezova	2021		N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/106 Also cited in KCP 6.4	Jaroslav Subr	2021	Prothioconazole efficacy against barley <i>Rhynchosporium</i> and <i>Helminthosporium</i> F-21-G-566-02 Zkusebni stanice Trutnov s.r.o. GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/108 Also cited in KCP 6.4	Kristin Lamers	2020	Prothioconazole straight and mixtures against barley <i>Rhynchosporium</i> and <i>Helminthosporium</i> 20 1069 5164 BioChem agrar GmbH Niederlassung Agroplan GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/109 Also cited in KCP 6.4	Julien Rivet	2020	Efficacy of SIP41061, SIP41099 and SIP41100 against <i>Pyrenophora</i> teres on winter barley in France in 2020 20 20 F 11 ESSAIS+ GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/110 Also cited in KCP 6.4	Pavlina Otrhalkova	2020	Prothioconazole straight and mixtures against barley <i>Rhynchosporium</i> and <i>Helminthosporium</i> F-20-G-595-01 InTec Agro Trials, s.r.o. GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/111 Also cited in KCP 6.4	Ian Haigh	2020	Efficacy of Sipcam Oxon prothioconazole formulations applied alone and in tank mixes against <i>Rhynchosporium secalis</i> in winter barley. UK efficacy trial, 2020 F20035 T1 FieldArm Ltd	N	Y	New study	Sipcam Oxon S.p.A.

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			GEP Unpublished				
KCP 6.2/113 Also cited in KCP 6.4	Éva Abdai	2020	Efficacy trial against leaf diseases in winter barley OXONWW-HU2020-AE04 Government Office of Komárom-Esztergom County GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/114 Also cited in KCP 6.4	Aura Filipoiu	2020	Determination of efficacy of fungicides applied in post-em against Pyrenophora graminea in barley, 2020. S20-03046-01 EAS Romania, Timisoara GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/115 Also cited in KCP 6.4	Andrew Thorpe	2020	Efficacy of Prothioconazole straight and in mixtures against Rhynchosporium secalis and Pyrenophora teres in Winter barley Leaf blotch of cereals leaf and netblotch in Winter barley SIP1164-01 OAT South West GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/116 Also cited in KCP 6.4	Annamaria Tuh	2020	Examination of fungicide efficiency against winter barley diseases F6-2-2020 Zala Barley Government Office of Zala County GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/131 Also cited in KCP 6.4	Margit Kopp	2020	Prothioconazole straight and mixtures: preventative activity against apple scab SO2008 Hetterich Hetterich Fieldwork GbR GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/132 Also cited in KCP 6.4	Anna Pietryga	2020	Efficacy for the tested product SIP 41061, SIP 41098 for the control of Venturia inaequalis on apple in Poland, 2020 SO2008-01 BIOTEK Agriculture GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/133 Also cited in KCP 6.4	Marta Bruder	2020	Efficacy for the tested product SIP 41061, SIP 41098 for the control of Venturia inaequalis on apple in Poland, 2020 SO2008-02 BIOTEK Agriculture	N	Y	New study	Sipcam Oxon S.p.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebra te study Y/N	Data protectio n claimed Y/N	Justificatio n if data protection is claimed	Owner
			GEP Unpublished				
KCP 6.2/134 Also cited in KCP 6.4	Marta Bruder	2020	Efficacy and selectivity of SIP 41061 for the control of Venturia inaequalis on apple in Poland, 2021 SO2123-02 Biotek Agriculture Polska Sp. z o.o. GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/135 Also cited in KCP 6.4	Anna Pietryga	2021	Efficacy and selectivity of SIP 41061 for the control of Phodospaera leucotrica on apple in Poland, 2021 OXON SO2124-01 BIOTEK Agriculture GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/136 Also cited in KCP 6.4	Anna Pietryga	2021	Efficacy and selectivity of SIP 41061 for the control of Phodospaera leucotrica on apple in Poland, 2021 OXON SO2124-02 BIOTEK Agriculture GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/139 Also cited in KCP 6.4	Danny Rich- ardson	2021	Podospaera leucotrica Fungicide trials on Apples. 21-00380-02 SGS United Kingdom Ltd GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/140 Also cited in KCP 6.4	D Slater	2021	Evaluation of the efficacy of Prothioconazole against Venturia inaequalis in apples SIP1254-01 OAT Ltd GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/141 Also cited in KCP 6.4	Federico Torturu	2021	Evaluation of the efficacy of Prothioconazole against Venturia inaequalis in apples SIP1254-02 OAT Ltd GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/142 Also cited in KCP 6.4	Margit Kop- pi	2021	Prothioconazol against Venturia inaequalis SO2123-1 Hetterich Fieldwork GbR GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/143 Also	Clemens Groth	2021	Efficacy of SIP41061 against VENTIN applied in apple S21-02421-01	N	Y	New study	Sipcam Oxon S.p.A.

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cited in KCP 6.4			EUROFINS AGROSCIENCE SERVICES GEP Unpublished				
KCP 6.2/144 Also cited in KCP 6.4	Tobias Görbing	2021	Efficacy of SIP41061 against PODOLE in apple S21-02556-01 EAS GmbH Germany GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/145 Also cited in KCP 6.4	Asong Ngwenwo	2021	Efficacy of SIP41061 against PODOLE in apple S21-02556-02 Agrartest GmbH GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/149 Also cited in KCP 6.4	CAULLET Maxime	2020	protioconazole straight against powdery mildew on apples 21F FPFOXO FR03 PROMO-VERT TOURS GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/150 Also cited in KCP 6.4	CHENEVA L-PALLUD Sylvie	2020	protioconazole straight against powdery mildew on apples 21F FPFOXO FR04 PROMO-VERT TOURS GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/151 Also cited in KCP 6.4	TERZIEFF Frédéric	2020	protioconazole straight against powdery mildew on apples 21F FPFOXO FR05 PROMO-VERT REIMS GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/152 Also cited in KCP 6.4	BLANC Amandine	2021	Efficacy of SIP41061 against Apple on apple in 2021 in France. F21CP12QZP01 Cotesia GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/153 Also cited in KCP 6.4	BLANC Amandine	2021	Efficacy of SIP41061 against Apple on apple in 2021 in France. F21CP12QZP02 Cotesia GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/154 Also cited in KCP 6.4	Mr Benoit COR-REARD	2021	Evaluate the efficacy of SIP41061 against Podosphaera leucotricha on Apple tree. AGL21FR235 AGROLIS CONSULTING GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP	Lukasz	202	Evaluation of SIP41061 against	N	Y	New	Sipcam

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6.2/161 Also cited in KCP 6.4	KMIECIAK	1	apple scab (<i>Venturia inaequalis</i>) on apple in Poland in 2021 JFT-21-50758-PL01 STAPHYT GEP Unpublished			study	Oxon S.p.A.
KCP 6.2/162 Also cited in KCP 6.4	Lukasz KMIECIAK	2021	Evaluation of SIP41061 against powdery mildew (<i>Podosphaera leucotrica</i>) on apple in Poland in 2021 JFT-21-50759-PL02 STAPHYT GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/163 Also cited in KCP 6.4	Marta Bruder	2020	Efficacy and selectivity of SIP 41061 for the control of <i>Venturia inaequalis</i> on apple in Poland, 2021 SO2123-01 Biotek Agriculture Polska Sp. z o.o. GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/164 Also cited in KCP 6.4	Miklos Varga	2020	Control of apple scab F-7/1/2020 Government office of Szabolcs-Szatmar-Bereg County GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/165 Also cited in KCP 6.4	Peter Vido	2020	- F-7/2/2020 Government office of Nograd County GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/166 Also cited in KCP 6.4	Margit Kopp	2021	Prothioconazole against <i>Venturia inaequalis</i> SO2123 1_2 Hetterich Fieldwork GbR GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/167 Also cited in KCP 6.4	Peter Vido	2021	Efficacy study against scab in apples F-1/2021 Government office of Nograd County GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/190 Also cited in KCP 6.4	Anna Pietryga	2020	Efficacy and safety of SIP 41061 and SIP 41098 applied before harvest against <i>Monilia fructigena</i> on plum SO2010 BIOTEK Agriculture GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP	Armin Gör-	2020		N	Y	New	Sipcam

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
6.2/191 Also cited in KCP 6.4	lich	0	SO2010 Hetterich Hetterich Fieldwork GbR GEP Unpublished			study	Oxon S.p.A.
KCP 6.2/192 Also cited in KCP 6.4	Margit Koppi	2021	Prothioconazole against Monilia spp. on fruit SO21120-HET3 Hetterich Fieldwork GbR GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/193 Also cited in KCP 6.4	Uwe Gerdau	2021	Efficacy of SIP41061 against MONISP on fruits S21-02554-02 EAS Agrartest, Rosenow GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/194 Also cited in KCP 6.4	Lukasz KMIĘCIAK	2021	Evaluation of SIP41061 against Monilia sp on Dwarf Cherry in Poland in 2021 JFT-21-50774-PL01 STAPHYT GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/195 Also cited in KCP 6.4	Marta Bruder	2021	Efficacy and selectivity of SIP 41061 against Monillia sp. used before harvest on cherry, Poland 2021 SO2120-01 Biotek Agriculture Polska Sp. z o.o. GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/196 Also cited in KCP 6.4	Eveline Maring	2020	Preparation against Monilia O-F-MONISP-01-2020 Thüringer Landesamt GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/197 Also cited in KCP 6.4	Tobias Görbing	2021	Efficacy of SIP41061 against MONISP on fruits S21-02554-01 EAS Germany, Stade GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/199 Also cited in KCP 6.4	BLANC Amandine	2021	Efficacy of SIP41061 against Monilia fructigena on peach in 2021 in France. F21CP11QZP01 Cotesia GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/200 Also cited in KCP 6.4	RIGAT Didier	2021	Evaluation of the efficacy of SIP41061 on stone fruits against Monilia sp. SO2120 (ACG-FE21AR-03168-TH) ANTEDIS	N	Y	New study	Sipcam Oxon S.p.A.

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			GEP Unpublished				
KCP 6.2/201 Also cited in KCP 6.4	Mr Sébastien ROBERT	2021	Evaluation of the efficacy of SIP41061 on stone fruits against Monilia sp. AGL21FR234 AGROLIS CONSULTING GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/202 Also cited in KCP 6.4	Mr Sébastien ROBERT	2021	Evaluation of the efficacy of SIP41061 on stone fruits against Monilia sp. AGL21FR259 AGROLIS CONSULTING GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/206 Also cited in KCP 6.4	0	2021	Evaluation of SIP41061 against Monilia sp on Dwarf Cherry / Peach in Poland in 2021 JFT-21-50774-PL02 STAPHYT GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/211 Also cited in KCP 6.4	Marta Bruder	2021	Efficacy and selectivity of SIP 41061 against Monillia sp. used before harvest on plum, Poland 2021 SO2120-02 Biotek Agriculture Polska Sp. z o.o. GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/212 Also cited in KCP 6.4	ANLIKER Kevin	2021	Evaluation of the efficacy of SIP41061 on stone fruits against Monilia sp. SO2120 (ACG-FE21AR-03169-TH) ANTEDIS GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/213 Also cited in KCP 6.4	Julien Rivet	2020	To evaluate the efficacy of SIP41061, SIP41099, SIP41100, SIP41098 against Ascochyta pinodes on peas and beans in France in 2020 20 20 F 05 ESSAIS+ GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/214 Also cited in KCP 6.4	Matthew Valentine	2020	Protioconazole straight and mixtures against pea and bean rust/aschochyta blight 20-169 i2LResearch GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.

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KCP 6.2/215 Also cited in KCP 6.4	Matthew Valentine	2020	Prothioconazole straight and mixtures against pea and bean rust/ascochyta blight 20-170 i2LResearch GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/217 Also cited in KCP 6.4	Valentin Leneschi	2021	Efficacy of SIP41061 against Ascochyta fabae in field beans. UK efficacy trials, 2021 F21059 T2 Fieldarm Limited GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/218 Also cited in KCP 6.4	Julien RVET	2019	To evaluate the efficacy of SIP41061 against Ascochyta pinodes on pea in France in 2019 19 20 F 05 ESSAIS + GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/219 Also cited in KCP 6.4	CAULLET Maxime	2020	test of various fungicide items against ascochyta in peas/beans crops 20F FHBOXO FR14 PROMO-VERT TOURS GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/221 Also cited in KCP 6.4	Richard Good	2019	Efficacy of Sipcam Oxon prothioconazole formulations applied alone and in tank mixes against Ascochyta pisi. UK efficacy trial, 2019 F19062 T1 FieldArm Ltd GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/222 Also cited in KCP 6.4	Valentin Leneschi	2020	Efficacy of Sipcam Oxon prothioconazole formulations against Ascochyta pisi. UK efficacy trials, 2020 F20070 T1 Fieldarm Limited GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/223 Also cited in KCP 6.4	James Breen	2020	Efficacy of Sipcam Oxon prothioconazole formulations against Ascochyta pisi. UK efficacy trials, 2020 F20070 T2 FieldArm Ltd GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/225	Julien Rivet	2021	Evaluate the efficacy of SIP41061 (prothioconazole 400 gai/l) sprayed	N	Y	New study	Sipcam Oxon

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Also cited in KCP 6.4			on peas or beans against Ascochyta pinodes. France maritime, 2021. 21 20 F14 ESSAIS+ GEP Unpublished				S.p.A.
KCP 6.2/226 Also cited in KCP 6.4	Julien Rivet	202 1	Evaluate the efficacy of SIP41061 (prothioconazole 400 gai/l) sprayed on peas or beans against Ascochyta pinodes. France maritime, 2021. 21 20 F15 ESSAIS+ GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/227 Also cited in KCP 6.4	James Breen	202 1	Efficacy of SIP41061 against Asco- chyta pisi in field peas. UK efficacy trials, 2021 F21056 T1 FieldArm Limited GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/228 Also cited in KCP 6.4	Valentin Leneschi	202 1	Efficacy of SIP41061 against Asco- chyta pisi in field peas. UK efficacy trials, 2021 F21056 T2 Fieldarm Limited GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/229 Also cited in KCP 6.4	Julien RVET	201 9	Efficacy against OSR Sclerotinia, 2019 19 20 F 01 ESSAIS + GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/230 Also cited in KCP 6.4	Julien RVET	201 9	Efficacy against OSR Sclerotinia, 2019 19 20 F02 ESSAIS + GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/231 Also cited in KCP 6.4	Julien RIV- ET	202 0	Prothioconazole straight and mix- tures against oilseed rape white mold, Sclerotinia sclerotiorum 20 20 F 02 ESSAIS + GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/232 Also cited in KCP 6.4	Jiri Kopacek	202 0	Prothioconazole straight and mixtures against oilseed rape white mold, Sclerotinia spp F-20-A-598-01 InTec Agro Trials, s.r.o. GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebra te study Y/N	Data protectio n claimed Y/N	Justificatio n if data protection is claimed	Owner
KCP 6.2/233 Also cited in KCP 6.4	Kathleen Ziegler	201 9	Prothio OSR WM Germany 2019 S-1903260 Agrartest GmbH GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/234 Also cited in KCP 6.4	Kevin Liv- ingstone	201 9	To provide tolerance and efficacy data for PROTHIO straight and tank mixed against Sclerotinia in oil seed rape. S19011 T1 Scottish Agri Trials Service GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/235 Also cited in KCP 6.4	Bogdan Plugaru	202 0	Determination of efficacy of fungi- cides applied in post-em against Sclerotinia in oilseed rape S20-03049-01 EAS Romania, Timisoara GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/236 Also cited in KCP 6.4	Constantin Macsim	202 0	Determination of efficacy of fungi- cides applied in post-em against Sclerotinia in oilseed rape S20-03049-02 EAS Romania, Timisoara GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/237 Also cited in KCP 6.4	Kevin Liv- ingstone	202 0	To provide tolerance and efficacy data for PROTHIO straight and tank mixed against Sclerotinia in oil seed rape. S20003 T1 Scottish Agri Trials Service GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/238 Also cited in KCP 6.4	Anna Pietryga	202 0	Efficacy and selectivity of tested product SIP41061, SIP 41098, SIP 41099, SIP 41100 against Sclero- tinia on oilseed rape, Poland 2020 SO2005-01 BIOTEK Agriculture GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/239 Also cited in KCP 6.4	Marta Bruder	202 0	Efficacy and selectivity of tested product SIP41061, SIP 41098, SIP 41099, SIP 41100 against Sclero- tinia on oilseed rape, Poland 2020 SO2005-02 BIOTEK Agriculture GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/240 Also	Uwe Gerdau	202 0	Protiocanazole straight and mixtures against oilseed rape white mold, Scelerotinia sp 2020	N	Y	New study	Sipcam Oxon S.p.A.

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cited in KCP 6.4			S20-03516-02 Agrartest GmbH GEP Unpublished				
KCP 6.2/241 Also cited in KCP 6.4	Kevin Livingstone		To provide tolerance and efficacy data for PROTHIOCONAZOLE at different rates against Sclerotinia in oil seed rape. SO2112-bis Scottish Agri trials service GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/242 Also cited in KCP 6.4	Pavel Dragila	2021	Determination of efficacy of SIP41061 (prothioconazole) applied in post-em against Sclerotinia in oilseed rape S21-02379-03 EAS Romania , Timisoara GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/243 Also cited in KCP 6.4	Constantin Macsim	2021	Determination of efficacy of SIP41061 (prothioconazole) applied in post-em against Sclerotinia in oilseed rape S21-02379-02 EUROFINS AGROSCIENCE SERVICES GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/244 Also cited in KCP 6.4	Andreea Alexandru	2021	Determination of efficacy of SIP41061 (prothioconazole) applied in post-em against Sclerotinia in oilseed rape S21-02379-01 EUROFINS AGROSCIENCE SERVICES GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/245 Also cited in KCP 6.4	Marta Bruder	2021	Efficacy and selectivity of SIP 41061 against Sclerotinia sclerotinium on winter oilseed rape, Poland 2021 SO2112-02 Biotek Agriculture Polska Sp. z o.o. GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/246 Also cited in KCP 6.4	Marta Bruder	2021	Efficacy and selectivity of SIP 41061 against Sclerotinia sclerotinium on winter oilseed rape, Poland 2021 SO2112-01 Biotek Agriculture Polska Sp. z o.o. GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebra te study Y/N	Data protectio n claimed Y/N	Justificatio n if data protection is claimed	Owner
KCP 6.2/247 Also cited in KCP 6.4	Błażej Koralewski	202 1	Efficacy of SIP41061 in control of Sclerotinia spp in winter rape, Po- land 2021 S02112 Fertico Sp. z o.o. GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/248 Also cited in KCP 6.4	Julien RIV- ET	202 1	Evaluate the efficacy of SIP41061 (prothioconazole 400 gai/l) sprayed on winter OSR against sclerotinia. France maritime, 2021. 21 20 F10 ESSAIS + GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/249 Also cited in KCP 6.4	Julien Rivet	202 1	Evaluate the efficacy of SIP41061 (prothioconazole 400 gai/l) sprayed on winter OSR against sclerotinia. France maritime, 2021. 21 20 F09 ESSAIS+ GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/250 Also cited in KCP 6.4	Uwe Gerdau	202 1	Efficacy of SIP41061 against SCLESC in winter oilseed rape S21-02550-02 EAS Agrartest, Rosenow GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/251 Also cited in KCP 6.4	Veronika Gezova	202 1	Prothioconazole against oilseed rape white mold, Scelerotinia spp SO2112 InTec Agro Trials, s.r.o. GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/252 Also cited in KCP 6.4	Bastian Lorenz	201 9	Prothioconazole Sugarbeet - Cerco- spora 19 1069 5142 BioChem agrar GmbH Niederlas- sung Agroplan GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/253 Also cited in KCP 6.4	Julien RVET	201 9	Efficacy of SIP41061 (solo or mixed with SIP40992), against Cercospora on sugarbeet in France in 2019 19 20 F 07 ESSAIS + GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/254 Also cited in	Thorsten Houben	202 0	Prothioconazole Sugarbeet - Cerco- spora 20 1069 5225 BioChem agrar GmbH Niederlas-	N	Y	New study	Sipcam Oxon S.p.A.

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KCP 6.4			sung Agroplan GEP Unpublished				
KCP 6.2/255 Also cited in KCP 6.4	Julien RIV-ET	2020	Efficacy of SIP41061, SIP41099, SIP 41100 against Cercospora on sugarbeet in France in 2020 20 20 F 09 ESSAIS + GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/256 Also cited in KCP 6.4	Danny Richardson	2020	protioconazole straight and mixtures against sugarbeet cercospora leaf spot 20-00489-01 SGS United Kingdom Ltd GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/260 Also cited in KCP 6.4	dr Katarzyna Furman-Fratczak	2019	Efficacy and selectivity of tested products on sugar beet SUGAR BEET 2019 EFF01PL BIOTEK Agriculture GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/261 Also cited in KCP 6.4	Veronika Gezova	2019	Efficacy evaluation of different fungicides against Cercospora beticola on sugarbeet F-19-Z-547-01 InTec Agro Trials, s.r.o. GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/262 Also cited in KCP 6.4	Pavlina Otrhalkova	2020	Prothioconazole straight and mixtures against sugarbeet Cercospora leaf spot F-20-Z-599-01 InTec Agro Trials, s.r.o. GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/265 Also cited in KCP 6.4	Christoph Thiele	2020	Prothioconazole straight and mixtures against sugarbeet cercospora leaf spot 2020 S20-05709 EAS Germany, Hundisburg GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/266 Also cited in KCP 6.4	Wilma van de Ven	2020	Prothioconazole straight and mixtures against sugarbeet cercospora leaf spot S20-04171-01 Eurofins-De Bredelaar GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/267 Also	D Slater	2020	Prothioconazole straight and mixtures against ERYSPHE in sugar-beet	N	Y	New study	Sipcam Oxon S.p.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
cited in KCP 6.4			SIP1260-01 OAT Ltd GEP Unpublished				
KCP 6.2/268 Also cited in KCP 6.4	Marta Bruder	2020	Efficacy of tested product SIP 41061, SIP 41099 for the control of Cercospora betae on sugar beet , Poland 2020 SO2019 BIOTEK Agriculture GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/269 Also cited in KCP 6.4	William Edwards	2020	Investigation of the efficacy of fungicide programs with treatments applied at up to two spray timings for the control of Cercospora Beticola, Ramularia Beticola, Erysiphe Betae, Uromyces Betae, on a commercial crop. SO2019-A RSK ADAS Ltd GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/270 Also cited in KCP 6.4	Veronika Gezova	2021	Prothioconazole against sugarbeet Cercospora leaf spot SO2114 InTec Agro Trials, s.r.o. GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/271 Also cited in KCP 6.4	Thorsten Houben	2021	SIP41061 against Cercospora betae in sugar beets 21 1069 5183 BioChem agrar GmbH Niederlassung Agroplan GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/272 Also cited in KCP 6.4	Michael Ingenerf	2021	SIP41061 against Cercospora betae in sugar beets 21 1069 5184 BioChem agrar GmbH Niederlassung Agroplan GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/273 Also cited in KCP 6.4	Sabine Bach	2021	Efficacy of SIP41061 against CER-CBE in sugar beet S21-02551-01 Agrartest GmbH GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/276 Also cited in KCP 6.4	Julien Rivet	2021	Evaluate the efficacy of SIP41061 (prothioconazole 400 gai/l) sprayed on sugar beets against cercospora beticola. France maritime, 2021. 21 20 F11	N	Y	New study	Sipcam Oxon S.p.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 n claimed Y/N	Justification if data protection is claimed	Owner
			ESSAIS+ GEP Unpublished				
KCP 6.2/277 Also cited in KCP 6.4	Julien Rivet	2021	Evaluate the efficacy of SIP41061 (prothioconazole 400 gai/l) sprayed on sugar beets against cercospora beticola. France maritime, 2021. 21 20 F12 ESSAIS+ GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/278 Also cited in KCP 6.4	Julien Rivet	2021	Evaluate the efficacy of SIP41061 (prothioconazole 400 gai/l) sprayed on sugar beets against cercospora beticola. France maritime, 2021. 21 20 F13 ESSAIS+ GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/281 Also cited in KCP 6.4	Marta Bruder	2021	Efficacy and selectivity of SIP 41061 against Cercospora beicola on sugar beet, Poland 2021 SO2114-01 BIOTEK Agriculture GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/282 Also cited in KCP 6.4	Marta Bruder	2021	Efficacy and selectivity of SIP 41061 against Cercospora beicola on sugar beet, Poland 2021 SO2114-02 BIOTEK Agriculture GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/283 Also cited in KCP 6.4	Juan Francisco García Cabello	2020	To test the efficacy and crop selectivity of SIP 41061, SIP 41099 and SIP 41100 against Powdery Mildew (Podosphaera xanthii, Golovinomyces cichoracearum) on Cucurbits F2034-3 Agricultura y Ensayo S.L. GEP Unpublished	N	Y	New study	SIPCAM INAGRA, S.A.
KCP 6.2/284 Also cited in KCP 6.4	Juan Francisco García Cabello	2020	To test the efficacy and crop selectivity of SIP 41061, SIP 41099 and SIP 41100 against Powdery Mildew (Podosphaera xanthii, Golovinomyces cichoracearum) on Cucurbits F2034-4 Agricultura y Ensayo S.L. GEP Unpublished	N	Y	New study	SIPCAM INAGRA, S.A.
KCP 6.2/296 Also	VERGNES Emilie	2020	prothioconazole straight and mixtures: preventative activity against cucurbits powdery mildew	N	Y	New study	Sipcam Oxon S.p.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 n if data claimed Y/N	Justification if data protection is claimed	Owner
cited in KCP 6.4			20F FCUOXO FR09 PROMO-VERT AVIGNON GEP Unpublished				
KCP 6.2/297 Also cited in KCP 6.4	VER-DURON Aurore	2020	protioconazole straight and mixtures: preventative activity against cucurbits powdery mildew 20F FCUOXO FR12 PROMO-VERT TOURS GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/298 Also cited in KCP 6.4	José Joaquín Sarrias	2020	To test the efficacy and crop selectivity of SIP 41061, SIP 41099 and SIP 41100 against Powdery Mildew (<i>Podosphaera xanthii</i> , <i>Golovinomyces cichoracearum</i>) on Cucurbits F2034-10 SIPCAM IBERIA S.L. GEP Unpublished	N	Y	New study	SIPCAM INAGRA, S.A.
KCP 6.2/299 Also cited in KCP 6.4	José Joaquín Sarrias	2020	To test the efficacy and crop selectivity of SIP 41061, SIP 41099 and SIP 41100 against Powdery Mildew (<i>Podosphaera xanthii</i> , <i>Golovinomyces cichoracearum</i>) on Cucurbits F2034-9 SIPCAM IBERIA S.L. GEP Unpublished	N	Y	New study	SIPCAM INAGRA, S.A.
KCP 6.2/300 Also cited in KCP 6.4	Kristin Lamers	2020	Prothioconazole straight and mixtures: preventative activity against cucurbits powdery mildew, 2020 GE20-SIP-103-03 BioChem agrar GmbH Niederlassung Agroplan GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/301 Also cited in KCP 6.4	Chiel van der Voort	2020	Prothioconazole straight and mixtures: preventative activity against cucurbits powdery mildew, 2020 NL20-SIP-103-02 Cultus Crop Research GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/302 Also cited in KCP 6.4	Michael Ingenerf	2021	SIP41061 against powdery mildew in cucumber (green house) 21 1069 5185 BioChem agrar GmbH Niederlassung Agroplan GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.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 n claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/303 Also cited in KCP 6.4	TERZIEFF Frédéric	2020	protioconazole straight against cucurbits powdery mildew 21F FCUOXO FR09 PROMO-VERT REIMS GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/304 Also cited in KCP 6.4	Manuel Román Moreno	2021	To test the efficacy and crop selectivity of SIP 41061 against Powdery Mildew (<i>Podosphaera xanthii</i> , <i>Golovinomyces cichoracearum</i>) on Cucumber F2116-1 Agricultura y Ensayo S.L. GEP Unpublished	N	Y	New study	SIPCAM INAGRA, S.A.
KCP 6.2/305 Also cited in KCP 6.4	Juan García	2021	To test the efficacy and crop selectivity of SIP 41061 against Powdery Mildew (<i>Podosphaera xanthii</i> , <i>Golovinomyces cichoracearum</i>) on Cucumber F2116-2 Agricultura y Ensayo S.L. GEP Unpublished	N	Y	New study	SIPCAM INAGRA, S.A.
KCP 6.2/306 Also cited in KCP 6.4	Sebastian Heinzmann	2021	Efficacy of SIP41061 against PODOXA in cucumber 2021 S21-02557-02 EAS Germany, Heidelberg GEP Unpublished	N	Y	New study	SIPCAM INAGRA, S.A.
KCP 6.2/307 Also cited in KCP 6.4	José Joaquín Sarrias	2020	To test the efficacy and crop selectivity of SIP 41061, SIP 41099 and SIP 41100 against Powdery Mildew (<i>Podosphaera xanthii</i> , <i>Golovinomyces cichoracearum</i>) on Cucurbits F2034-11 SIPCAM IBERIA SL GEP Unpublished	N	Y	New study	SIPCAM INAGRA, S.A.
KCP 6.2/308 Also cited in KCP 6.4	José Joaquín Sarrias	2020	To test the efficacy and crop selectivity of SIP 41061, SIP 41099 and SIP 41100 against Powdery Mildew (<i>Podosphaera xanthii</i> , <i>Golovinomyces cichoracearum</i>) on Cucurbits F2034-12 SIPCAM IBERIA SL GEP Unpublished	N	Y	New study	SIPCAM INAGRA, S.A.
KCP 6.2/309 Also cited in KCP 6.4	Michael Ingenerf	2021	SIP41061 against powdery mildew in zucchini (poly tunnel) 21 1069 5186 BioChem agrar GmbH Niederlassung Agroplan	N	Y	New study	Sipcam Oxon S.p.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				
KCP 6.2/310 Also cited in KCP 6.4	Manuel Román Moreno	2021	To test the efficacy and crop selectivity of SIP 41061 against Powdery Mildew (<i>Podosphaera xanthii</i> , <i>Golovinomyces cichoracearum</i>) on Zucchini F2117-1 Agricultura y Ensayo S.L. GEP Unpublished	N	Y	New study	SIPCAM INAGRA, S.A.
KCP 6.2/311 Also cited in KCP 6.4	Juan García	2021	To test the efficacy and crop selectivity of SIP 41061 against Powdery Mildew (<i>Podosphaera xanthii</i> , <i>Golovinomyces cichoracearum</i>) on Zucchini F2117-2 Agricultura y Ensayo S.L. GEP Unpublished	N	Y	New study	SIPCAM INAGRA, S.A.
KCP 6.2/312 Also cited in KCP 6.4	Clemens Groth	2021	Efficacy of SIP41061 against PODOXA/ERYSCI in courgette 2021 S21-02557-01 EUROFINS AGROSCIENCE SERVICES GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/313 Also cited in KCP 6.4	Mrs Laure BELLO	2021	To evaluate the efficacy of prothioconazole against powdery mildew in cucurbits in Mediterranean zone. SO2131 (AGL21FR236) AGROLIS CONSULTING GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/317 Also cited in KCP 6.4	G. Di Raimondo	2020	Efficacy and selectivity evaluation of potioconazole straight and mixtures: preventative activity against cucurbits powdery mildew AGG_20_41061_CUMME_PODOXA_1 Agrigeos srl GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/318 Also cited in KCP 6.4	Juan Francisco García Cabello	2020	To test the efficacy and crop selectivity of SIP 41061, SIP 41099 and SIP 41100 against Powdery Mildew (<i>Podosphaera xanthii</i> , <i>Golovinomyces cichoracearum</i>) on Cucurbits F2034-1 Agricultura y Ensayo S.L. GEP Unpublished	N	Y	New study	SIPCAM INAGRA, S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebra te study Y/N	Data protectio n claimed Y/N	Justificatio n if data protection is claimed	Owner
KCP 6.2/319 Also cited in KCP 6.4	Juan Fran- cisco García Cabello	202 0	To test the efficacy and crop selec- tivity of SIP 41061, SIP 41099 and SIP 41100 against Powdery Mildew (Podosphaera xanthii, Golovinomy- ces cichoracearum) on Cucurbits F2034-2(168) Agricultura y Ensayo S.L. GEP Unpublished	N	Y	New study	SIPCAM INAGR A, S.A.
KCP 6.2/320 Also cited in KCP 6.4	Ester Rubio	201 9	EVALUATION OF EFFICACY AND SELECTIVITY OF SEVER- AL FUNGICIDES FOR THE CONTROL OF Sphaerotheca fulig- inea IN PROTECTED CUCUM- BER. SPAIN, 2019 F1913-1 Métodos Servicios Agrícolas S.L. GEP Unpublished	N	Y	New study	SIPCAM INAGR A, S.A.
KCP 6.2/324 Also cited in KCP 6.4	Julien RIV- ET	202 0	To evaluate the efficacy of SIP41061, SIP41099, SIP41100, SIP41098 against foliar diseases (alternaria/powdery mil- dew/sclerotinia on carrots in France in 2020 20 20 F 06 ESSAIS + GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/327 Also cited in KCP 6.4	Ruud Hoi- tink	202 0	Prothioconazole straight and mix- tures against carrot alternaria, 2020. NL20-SIP-102-01 Verify GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/328 Also cited in KCP 6.4	Titus Cornea	202 0	Determination of efficacy of fungi- cides applied in post-em against Alternaria leaf blight in carrot (SO2016) S20-03050-01 EAS Romania, Timisoara GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/329 Also cited in KCP 6.4	Marta Bruder	202 0	Efficacy of tested products SIP 41061, SIP 41099, SIP 41098, SIP 41100 for the control of alternaria, powdery midlew, sclerotinia on carrot, Poland 2020 DPE20/047/FWA-01 BIOTEK Agriculture GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/334	Julien Rivet	202 1	Evaluate the efficacy of SIP41061 (prothioconazole 400 gai/l) sprayed	N	Y	New study	Sipcam Oxon

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Also cited in KCP 6.4			on carrots against Alternaria. France maritime, 2021. 21 20 F16 ESSAIS+ GEP Unpublished				S.p.A.
KCP 6.2/335 Also cited in KCP 6.4	Julien Rivet	2021	Evaluate the efficacy of SIP41061 (prothioconazole 400 gai/l) sprayed on carrots against Alternaria. France maritime, 2021. 21 20 F17 ESSAIS+ GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/337 Also cited in KCP 6.4	Ingrid Comman-deur	2021	Prothioconazole straight (SIP41061) against carrot alternaria, 2021. NL21-SIP-101-02 Verify GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/338 Also cited in KCP 6.4	Krzysztof Slowiak	2021	Prothioconazole straight (SIP41061) against carrot alternaria, 2021. PL21-SIP-101-03 Odmian Roslin Uprawnych SDOO GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/339 Also cited in KCP 6.4	Krzysztof Slowiak	2021	Prothioconazole straight (SIP41061) against carrot alternaria, 2021. PL21-SIP-101-04 Odmian Roslin Uprawnych SDOO GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/340 Also cited in KCP 6.4	Marta Bruder	2021	Efficacy and selectivity of SIP 41061 against Alternaria dauci and Erysiphe heraclei on carrot, Poland 2021 SO2137-01 BIOTEK Agriculture GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/341 Also cited in KCP 6.4	Marta Bruder	2021	Efficacy and selectivity of SIP 41061 against Alternaria dauci and Erysiphe heraclei on carrot, Poland 2021 SO2137-02 BIOTEK Agriculture GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/342 Also cited in KCP 6.4	Dawid Michałowicz	2021	Efficacy of SIP41061 in control of Alternaria dauci, Erysiphe heraclei in carrot. SO2137 Fertico Sp. z o.o. GEP	N	Y	New study	Sipcam Oxon S.p.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 n claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 6.2/343 Also cited in KCP 6.4	Ianc Ioan Vasile	2021	Prothioconazole straight (SIP41061) against carrot alternaria, 2021. RO21-SIP-101-05 SC Agrotest Romania SRL GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/344 Also cited in KCP 6.4	Burnea Gabriela	2021	Prothioconazole straight (SIP41061) against carrot alternaria, 2021. RO21-SIP-101-06 AgroProspect SRL GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/345 Also cited in KCP 6.4	Maria Ferencz	2021	Determination of efficacy of SIP41061 (prothioconazole) applied in post-em against Alternaria dauci in carrot, 2021 S21-02380-01 EUROFINS AGROSCIENCE SERVICES GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/346 Also cited in KCP 6.4	Andreea Alexandru	2021	Determination of efficacy of SIP41061 (prothioconazole) applied in post-em against Alternaria dauci in carrot, 2021 S21-02380-02 EUROFINS AGROSCIENCE SERVICES GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/347 Also cited in KCP 6.4	Costin Paduraru	2021	Determination of efficacy of SIP41061 (prothioconazole) applied in post-em against Alternaria dauci in carrot, 2021 S21-02380-03 EUROFINS AGROSCIENCE SERVICES GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/348 Also cited in KCP 6.4	Danny Richardson	2021	Control of Alternaria dauci, Erysiphe heraclei, in Carrots. 21-00402-01 SGS United Kingdom Ltd GEP Unpublished	N	Y	New study	SIPCAM UK, Ltd
KCP 6.2/349 Also cited in KCP 6.4	Duncan Carr	2021	Prothioconazole straight (SIP41061) against carrot alternaria, 2021. UK21-SIP-101-07 OAT Scotland GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 6.2/350	Andy Hunt	2021	Prothioconazole straight (SIP41061) against carrot alternaria, 2021.	N	Y	New study	Sipcam Oxon

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Also cited in KCP 6.4			UK21-SIP-101-08 OAT (Central) GEP Unpublished				S.p.A.
KCP 6.2/356	Lukasz KMIECIAK	2021	Evaluation of SIP41061 against apple scab (<i>Venturia inaequalis</i>) on apple in Poland in 2021 JFT-21-50758-PL02 STAPHYT GEP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCA 6.1	Massardi E.	2022	Freezer storage stability of Prothioconazole Metabolites in 5 different matrices: high water commodity (zucchini), high oil commodity (oilseed rape seeds), high acid commodity (grape), dry commodity (peas dry seeds) and high starch commodity (sugar beet root) – 6 months checkpoint Report RAU-026-21 Research Center BioSphereS by Biotechnologie BT GLP, unpublished.	N	Y	New study	Sipcam Oxon S.p.A.
KCA 6.3.1/01	Terranegra A.	2021	Prothioconazole – Residue study on apple in Northern Europe – 2020 Report N. SPK-20-45305 Staphyt GLP, unpublished.	N	Y	New study	Sipcam Oxon S.p.A.
KCA 6.3.1/02	Massardi E.	2022	Determination of prothioconazole metabolites residues in raw agricultural commodity apple after two applications of SIP41061 (Prothioconazole 400 g/L SC) – Central Europe, 4 decline trials, year 2021 Report N. RAU-008-21 Research Center BioSphereS by Biotechnologie BT GLP, unpublished.	N	Y	New study	Sipcam Oxon S.p.A.
KCA 6.3.2/01	Massardi E.	2021	Determination of prothioconazole metabolites residues in raw agricultural commodity plum after two applications of SIP41061 (Prothioconazole 400 g/L SC) - Northern Europe, 4 trials, year 2020 Report N. RAU-024-20 Research Center BioSphereS by Biotechnologie BT GLP, unpublished.	N	Y	New study	Sipcam Oxon S.p.A.
KCA 6.3.2/02	Massardi E.	2022	Determination of Prothioconazole metabolites residues in raw agricultural commodity plum after two applications of SIP41061 (Prothio-	N	Y	New study	Sipcam Oxon S.p.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
			conazole 400 g/L SC) – (Central Europe, 4 decline trials, year 2021). Report N. RAU-010-21 BioTecnologie BT. GLP, unpublished				
KCA 6.3.3/01	Terranegra A.	2021	Prothioconazole – Residue study on apricot and peach in Northern Europe – 2020 Report N. SPK-20-45307 Staphyt GLP, unpublished.	N	Y	New study	Sipcam Oxon S.p.A.
KCA 6.3.3/02	Massardi E.	2022	Determination of prothioconazole metabolites residues in raw agricultural commodity apricot and peach after two applications of SIP41061 (Prothioconazole 400 g/L SC) – Central Europe, 2 trials, year 2021 Report N. RAU-009-21 Research Center BioSphereS by Biotechnologie BT GLP, unpublished.	N	Y	New study	Sipcam Oxon S.p.A.
KCA 6.3.4/01	Massardi E.	2021	Determination of prothioconazole metabolites residues in raw agricultural commodity cherry after two applications SIP41061 (Prothioconazole 400 g/L SC) in open field conditions - 4 trials, Northern Europe, year 2020 RAU-017-20 Research Center BioSphereS by Biotechnologie BT GLP, unpublished.	N	Y	New study	Sipcam Oxon S.p.A.
KCA 6.3.4/02	Massardi E.	2021	Determination of prothioconazole metabolites residues in raw agricultural commodity cherry after two applications of SIP41061 (Prothioconazole 400 g/L SC) – Central Europe, 4 decline trials, year 2021 RAU-011-21 Research Center BioSphereS by Biotechnologie BT GLP, unpublished.	N	Y	New study	Sipcam Oxon S.p.A.
KCA 6.3.5/01	Casalinuovo L.	2021	Determination of prothioconazole in raw agricultural commodity zucchini following three applications of SIP41099 (Prothioconazole 200 g/L + azoxystrobin 250 g/L SC) in greenhouse conditions - Southern Europe, 4 trials, year 2020 Report N. BIU-021-20 Research Center BioSphereS by Biotechnologie BT GLP, unpublished.	N	Y	New study	Sipcam Oxon S.p.A.
KCA	Casalinuovo	2022	Determination of prothioconazole	N	Y	New	Sipcam

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebra te study Y/N	Data protectio n claimed Y/N	Justificatio n if data protection is claimed	Owner
6.3.5/02	L.	2	metabolites residues in raw agricultural commodity zucchini following three applications of SIP41061 (Prothioconazole 400 g/L) in greenhouse conditions - Southern Europe, 4 trials, year 2021 Report N. BIU-017-21 Research Center BioSphereS by Biotechnologie BT			study	Oxon S.p.A.
KCA 6.3.6/01	Massardi E.	2021	Determination of prothioconazole metabolites residues in raw agricultural commodity carrot after two applications of SIP41099 (Prothioconazole 200 g/L + azoxystrobin 250 g/L SC) in open field conditions - 4 trials, Northern Europe, year 2020 Report N. RAU-021-20 Research Center BioSphereS by Biotechnologie BT GLP, unpublished.	N	Y	New study	Sipcam Oxon S.p.A.
KCA 6.3.6/02	Massardi E.	2022	Determination of Prothioconazole metabolites residues in raw agricultural commodity carrot after two applications of SIP41061 (Prothioconazole 400 g/L SC) – (Central Europe, 4 trials, year 2021). Report N. RAU-017-21 BioTecnologie BT. GLP, unpublished.	N	Y	New study	Sipcam Oxon S.p.A.
KCA 6.3.7/01	Massardi E.	2021	Determination of prothioconazole metabolites residues in raw agricultural commodity oilseed rape after two applications of SIP41099 (Prothioconazole 200 g/L + azoxystrobin 250 g/L SC) in open field conditions - 4 trials, Northern Europe, year 2020 Report N. RAU-015-20 BioTecnologie BT. GLP, unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCA 6.3.7/02	Massardi E.	2022	Determination of prothioconazole metabolites residues in raw agricultural commodity oilseed rape after two applications of SIP41061 (Prothioconazole 400 g/L SC) in open field conditions – Central Europe, 4 trials, year 2021 Report N. RAU-014-21 BioTecnologie BT. GLP, unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCA 6.3.8/01	Massardi E.	2021	Determination of prothioconazole metabolites residues in raw agricultural commodity sugar beet	N	Y	New study	Sipcam Oxon S.p.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebra te study Y/N	Data protectio n claimed Y/N	Justificatio n if data protection is claimed	Owner
			after two applications of SIP41099 (Prothioconazole 200 g/L + azoxystrobin 250 g/L SC) in open field conditions - 3 trials, Northern Europe, year 2020 Report N. RAU-020-20 BioTecnologie BT. GLP, unpublished				
KCA 6.3.8/02	Massardi E.	2022	Determination of prothioconazole metabolites residues in raw agricultural commodity sugar beet (roots) after two applications of SIP41061 (Prothioconazole 400 g/L SC) in open field conditions – Central Europe, 5 trials, year 2021 Report N. RAU-015-21 BioTecnologie BT. GLP, unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCA 6.3.9	Andrews G.	2022	Magnitude of Residues of Prothioconazole-desthio and Hydroxyprothioconazole- desthio Metabolites Following Two Applications of a 250 g/L EC Formulation to Wheat in Northern and Southern Europe, 2020. Interim report N. QG20005 Battelle UK GLP, unpublished	N	Y	New study	Sipcam Oxon S.p.A, Jiangsu Rotam Chemistry Co Ltd., Barclay chemicals, UPL Europe limited
KCA 6.3.10	Andrews G.	2022	Magnitude of Residues of Prothioconazole-desthio and Hydroxyprothioconazole- desthio Metabolites Following Two Applications of a 250 g/L EC Formulation to Barley in Northern and Southern Europe, 2020. Interim report N. QG20006 Battelle UK GLP, unpublished	N	Y	New study	Sipcam Oxon S.p.A, Jiangsu Rotam Chemistry Co Ltd., Barclay chemicals, UPL Europe limited
KCA 6.10	Andrews G.	2022	Interim report - Magnitude of Residues of Prothioconazole-desthio and Hydroxy-prothioconazole-desthio Metabolites in Honey Following Two Tunnel Applications of a Prothioconazole 250 g/L EC Formulation (FF-065) to Phacelia in Northern and Southern Europe, 2021	N	Y	New study	Sipcam Oxon S.p.A, Jiangsu Rotam Chemistry Co Ltd., Barclay

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 n claimed Y/N	Justification if data protection is claimed	Owner
			Report N. QG21003 Battelle UK GLP, unpublished				chemicals, UPL Europe limited
KCP 7.2/01	Desiante A.	2022	Determination of dislodgeable foliar residues of prothioconazole and prothioconazole – desthio in raw agricultural commodity peach following two applications of SIP 41061 (prothioconazole 400 g/l SC). (Southern Europe, 1 trial, year 2021) Report No BIU-011-21 Research Center BioSphereS by Biotechnologie BT GLP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 7.2/02	Desiante A.	2022	Determination of dislodgeable foliar residues of prothioconazole and prothioconazole – desthio in raw agricultural commodity plum following two applications of SIP 41061 (prothioconazole 400 g/l SC). (Southern Europe, 1 trial, year 2021) Report No RAU-022-21 Research Center BioSphereS by Biotechnologie BT GLP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 7.2/03	Desiante A.	2022	Determination of dislodgeable foliar residues of prothioconazole and prothioconazole – desthio in raw agricultural commodity apple following two applications of SIP 41061 (prothioconazole 400 g/l SC). (Southern Europe, 1 trial, year 2021) Report No BIU-027-21 Research Center BioSphereS by Biotechnologie BT GLP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 7.2/04	Casalinuovo L.	2022	Determination of dislodgeable foliar residues of prothioconazole and Prothio-conazole-desthio in raw agricultural commodity apple following two applications of SIP41061 (prothioconazole 400 g/l SC) (Southern and Central Europe, 3 trial, year 2021) Report No RAU-023-21 Research Center BioSphereS by	N	Y	New study	Sipcam Oxon S.p.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebra te study Y/N	Data protectio n claimed Y/N	Justificatio n if data protection is claimed	Owner
			Biotechnologie BT GLP Unpublished				
KCP 7.3/01	Spa S.	202 1	The In Vitro Percutaneous Absorption of Radiolabelled Prothioconazole in a Concentrate Formulation and Two In-Use Dilutions through Human Split-Thickness Skin. Report No 20287173 Charles River Laboratories GLP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 7.3/02	Spa S.	202 1	The In Vitro Percutaneous Absorption of radiolabelled Prothioconazoledesthio in an In-Use Dilution and from a Transferred Dried Surface Residue hereof through Human Split-Thickness Skin Report No 20309159 Charles River Laboratories GLP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 10.1.1.2	Infatino A., Bonzini S.	202 2	Prothioconazole-desthio (M04) residue decline in orchards and cucur-bits – Kinetic evaluation of residue trials. Report N. KINPT_01 Non GLP Unpublished	N	N	-	Sipcam Oxon SpA
KCP 10.2.1/01	Corboli M.	202 1	Acute immobilization test on <i>Daphnia magna</i> under semi-static conditions with test item SIP 41061. Report N. BT137/21 BioTecnologie BT Srl GLP Unpublished	N	Y	New study	Sipcam Oxon S.p.A
	Fifi A. P.	202 2	Validation of the analytical method (SANTE/2020/12830 Rev.1) for the determination of Prothioconazole and Prothioconazole-desthio in aqueous matrix and sugar feeding solutions with product SIP 41061 Report N. BT193/21 BioTecnologie BT S.r.l GLP Unpublished Submitted as KCP 5.1.2/04 in dRR Section B5	N	Y	New study	Sipcam Oxon S.p.A.
KCP 10.2.1/02	Mantilacci S.	202 1	Toxicity evaluation of test item SIP 41061 on green alga <i>Pseudokirchneriella subcapitata</i> in a growth inhibition test	N	Y	New study	Sipcam Oxon S.p.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 n claimed Y/N	Justification if data protection is claimed	Owner
			Report N. BT138/21 BioTecnologie BT Srl GLP Unpublished				
	Fifi A. P.	2022	Validation of the analytical method (SANTE/2020/12830 Rev.1) for the determination of Prothioconazole and Prothioconazole-desthio in aqueous matrix and sugar feeding solutions with product SIP 41061 Report N. BT193/21 BioTecnologie BT S.r.l GLP Unpublished Submitted as KCP 5.1.2/04 in dRR Section B5	N	Y	New study	Sipcam Oxon S.p.A.
KCP 10.3.1.1/01	Rossini L.	2021	Acute oral and acute contact toxicity effects of SIP 41061 to adult worker honeybees (<i>Apis mellifera</i> L.) in a laboratory test Report N. BT139/21 BioTecnologie BT S.r.l GLP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 10.3.1.1/02	Rossini L.	2021	Acute oral and acute contact toxicity effects of SIP 41061 to adult worker bumblebees <i>Bombus terrestris</i> L., Laboratory Limit Test Report N. BT140/21 BioTecnologie BT S.r.l GLP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 10.3.1.2/01	Rossini L.	2021	Acute oral and acute contact toxicity effects of SIP 41061 to adult worker honeybees (<i>Apis mellifera</i> L.) in a laboratory test Report N. BT139/21 BioTecnologie BT S.r.l GLP Unpublished Submitted as KCP 10.3.1.1/01	N	Y	New study	Sipcam Oxon S.p.A.
KCP 10.3.1.2/02	Rossini L.	2021	Acute oral and acute contact toxicity effects of SIP 41061 to adult worker bumblebees <i>Bombus terrestris</i> L., Laboratory Limit Test Report N. BT140/21 BioTecnologie BT S.r.l GLP Unpublished Submitted as KCP 10.3.1.1/02	N	Y	New study	Sipcam Oxon S.p.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 10.3.1.2	Venturi S.	2020	Chronic oral effects of SIP 41061 on adult worker honeybees (<i>Apis mellifera</i> L.) 10-day feeding laboratory test Report N. BT115/0 BioTecnologie BT S.r.l GLP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
	Aversa S.	2020	Validation of an HPLC-MS/MS analytical method for the determination of Prothioconazole and Azoxystrobin in water and sugar feeding solutions coming from ecotox laboratory tests (honeybees) Report N. BT214/20 BioTecnologie BT S.r.l GLP Unpublished Submitted as KCP 5.1.2/03 in dRR Section B5	N	Y	New study	Sipcam Oxon S.p.A.
KCP 10.3.1.3	Colli M.	2020	Effects of SIP 41061 on honeybees (<i>Apis mellifera</i> L.) 22-day larval toxicity test with repeated exposure. Report N. BT116/20 BioTecnologie BT S.r.l GLP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
	Aversa S.	2020	Validation of an HPLC-MS/MS analytical method for the determination of Prothioconazole and Azoxystrobin in water and sugar feeding solutions coming from ecotox laboratory tests (honeybees) Report N. BT214/20 BioTecnologie BT S.r.l GLP Unpublished Submitted as KCP 5.1.2/05 in dRR Section B5	N	Y	New study	Sipcam Oxon S.p.A.
KCP 10.3.2.1/01	Lucchetti F.	2021	Effects of SIP 41061 on the parasitic wasp <i>Aphidius rhopalosiphii</i> under Laboratory Conditions Report N. BT141/21 BioTecnologie BT S.r.l GLP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 10.3.2.1/02	Venturi S.	2021	Effects of SIP41061 on the predatory mite <i>Typhlodromus pyri</i> Scheuten (Acari: Phytoseiidae) under laboratory Conditions. Report N. BT142/21 BioTecnologie BT S.r.l GLP Unpublished	N	Y	New study	Sipcam Oxon SpA

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 n claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.4.1.1	Pecorari. F.	2020	Effects of the product SIP 41061 on reproduction and growth of the earthworm <i>Eisenia Andrei</i> in artificial soil. Report N. BT118/20 BioTecnologie BT S.r.l., GLP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
	Aversa S.	2020	Validation of an HPLC-MS/MS analytical method for the determination of Prothioconazole in soil coming from ecotox laboratory tests (earthworms) Report N. BT215/20 BioTecnologie BT S.r.l., GLP Unpublished Submitted as KCP 5.1.2/03 in dRR Section B5	N	Y	New study	Sipcam Oxon S.p.A.
KCP 10.4.2.1/01	Grandolini G.	2020	Effects of SIP 41061 on reproduction of the collembolan <i>Folsomia candida</i> in artificial soil. Report N. BT119/20 BioTecnologie BT S.r.l., GLP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 10.4.2.1/02	Grandolini G.	2020	Effects of SIP 41061 on reproduction of the predatory mite <i>Hypoaspis aculeifer</i> in soil. Report N. BT117/20 BioTecnologie BT S.r.l., GLP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 10.5	Rossini L.	2021	Assessment of the effects of the product SIP 41061 on soil microorganisms nitrification. Report No. BT143/21 BioTecnologie BT S.r.l., GLP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
KCP 10.6.2	Colli M.	2022	Effects of the SIP 41061 on terrestrial plants – Vegetative vigour test. Report No. BT150/221 BioTecnologie BT S.r.l., GLP Unpublished	N	Y	New study	Sipcam Oxon S.p.A.
	Fifi A. P.	2022	Validation of the analytical method (SANTE/2020/12830 Rev.1) for the determination of Prothioconazole and Prothioconazole-desthio in aqueous matrix and sugar feeding solutions with product SIP 41061	N	Y	New study	Sipcam Oxon S.p.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 N. BT193/21 BioTecnologie BT S.r.l GLP Unpublished Submitted as KCP 5.1.2/04 in dRR Section B5				

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 5.1.2/07	Heinemann O.	2000a	Analytical determination of residues of JAU 6476 and desthio-JAU 6476 in/on cereals by HPLC/MS/MS 00598 Bayer AG GLP published	N	N	-	Bayer AG
KCP 5.1.2/08	Heinemann O.	2000b	Analytical determination of residues of JAU 6476 and desthio-JAU 6476 in/on cereals and canola by HPLC/MS/MS (method modification 00598/M001) 00598/M001 Bayer AG GLP published	N	N	-	Bayer AG
KCP 5.1.2/09	Schramel O.	2000	Residue analytical method 00610 (MR-643/99) for the determination of JAU 6476 and the metabolites JAU 6476-desthio and JAU 6476-S-methyl in soil by HPLC/MS/MS 00610 Bayer AG GLP published	N	N	-	Bayer AG
KCP 5.1.2/10	Sommer H.	2001b	Enforcement method 00684 for determination of JAU 6476 and JAU 6476-desthio in drinking and surface water by HPLC/MS/MS 00684 Bayer AG GLP published	N	N	-	Bayer AG
KCP 5.1.2/11	Maasfeld W.	2002	Method for the determination of JAU 6476 in air by HPLC/MS/MS 00724 Bayer AG	N	N	-	Bayer AG

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 published				
KCP 5.1.2/12	Heinemann O.	2001a	Analytical determination of residues of JAU6476-sulfonic acid and JAU6476-desthio in/on cereals and canola by HPLC/MS/MS (method modification 00598/M001) 00647 Bayer AG GLP published	N	N	-	Bayer AG
KCP 5.1.2/13	Weeren R.D., Pelz S.	2000	Modification M033 of method 00086: validation of DFG method S 19 (extended revision) for the determination of residues of JAU 6476-desthio in materials of plant and animal origin 00684 Bayer AG GLP published	N	N	-	Bayer AG
KCP 5.1.2/14	Heinemann O.	2001b	Analytical determination of residues of JAU6476-3-hydroxy-desthio, JAU6476-4-hydroxy-desthio and JAU6476-desthio in/on matrices of animal origin by HPLC/MS/MS 00655 Bayer AG GLP published	N	N	-	Bayer AG
KCP 5.1.2/15	Heinemann O.	2001c	Analytical determination of residues of JAU6476-3-hydroxy-desthio, JAU6476-4-hydroxy-desthio and JAU6476-desthio in milk by HPLC/MS/MS 00655/M001 Bayer AG GLP published	N	N	-	Bayer AG
KCP 5.1.2/16	Steinhauer S.	2001	Enforcement method 00086/M038 for the determination of the residues of JAU 6476-desthio in soil - : validation of DFG method S 19 (extended revision) 00086/M038 Dr. Specht&Partner GLP published	N	N	-	Bayer AG
KCP 5.1.2/17	Sommer H.	1999	Method for the determination of JAU6476 in test water from aquatic toxicity tests by HPLC [Tox/Ecotox method]	N	N	-	Bayer AG

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
			00699 Bayer AG GLP published				
KCA 6.0	Heinemann, O.	2001a	18 months storage stability of residues of JAU 6476 and JAU 6476-Desthio during frozen storage in/on wheat matrices Bayer AG, Report No.: MR-282/00, Date: 2001-09-13	N	N	-	Bayer AG
KCA 6.1.1 /01	Haas, M.; Bornatsch, W.	2000	Metabolism of JAU6476 in spring wheat (after foliar application) Bayer AG, Report No.: MR-198/99, Date: 2000-07-10	N	N		Bayer AG
KCA 6.1.1 /02	Haas, M.	2001a	Metabolism of JAU 6476 in spring wheat after seed dressing Bayer AG, Report No.: MR-467/99, Date: 2001-05-10	N	N		Bayer AG
KCA 6.1.1 /03	Vogeler, K.; Sakamoto, H.; Brauner, A.	1993	Metabolism of SXX 0665 in summer wheat Bayer AG, Report No.: PF3906, Date: 1993-08-13	N	N		Bayer AG
KCA 6.1.1.1 /01	Haas, M.	2001b	Extraction efficiency testing of the residue method (00647) for the determination of JAU 6476 residues in spring wheat using aged radioactive residues Bayer AG, Report No.: MR-084/01, Date: 2001-05-15	N	N		Bayer AG
KCA 6.1.2 /01	...	2001d	Metabolism of [phenyl-UL-14C]JAU6476 in peanuts ..., Date: 2001-11-27	Y	N		Bayer AG
KCA 6.2.2.1 /01	...	2001a	[Phenyl-UL-14C]JAU6476 Absorption, distribution, excretion and metabolism in the lactating goat ..., Date: 2001-09-19	Y	N		Bayer AG
KCA 6.2.2.2 /01	2002a	[Phenyl-UL-14C]JAU6476-desthio Absorption, distribution, excretion, and metabolism in the lactating goat ..., Date: 2002-02-28	Y	N		Bayer AG
KCA 6.2.2.2.1 /01	Weber, H.; Weber, E.; Spiegel, K.	2002b	Validation of the residue analytical method for the determination of JAU6476-desthio, JAU6476-3-hydroxy-desthio and JAU6476-4-hydroxy-desthio	N	N		Bayer AG

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
			residues in animal matrices using aged radioactive residues Bayer AG, Report No.: MR-091/01Part 2, Date:2002-02-28				
KCA 6.2.2.3 /01	...	2001b	[Phenyl-UL-14C]JAU6476 Absorption, distribution, excretion and metabolism in laying hens ... Date:2001-10-29	Y	N	-	Bayer AG
KCA 6.3.2.1.1 /01	Heinemann, O.	2001b	Determination of residues of JAU 6476-Desthio on spring wheat following seed treatment of JAU 6476200 FS in Great Britain, Germany and France Bayer AG, Report No.: RA-2010/99, Report includes Trial Nos.: R 1999 0173/9 R 1999 0174/7 R 1999 0175/5 R 1999 0176/3 Date:2001-09-18	N	N	-	Bayer AG
KCA 6.3.2.1.1 /02	Heinemann, O.	2001c	Determination of residues of JAU 6476-desthio on spring wheat following seed treatment of JAU 6476200 FS in Germany and France Bayer AG, Report No.: RA-2091/00, Report includes Trial Nos.: R 2000 0002/2 R 2000 0424/9 Date:2001-09-28	N	N	-	Bayer AG
KCA 6.3.2.1.1 /03	Heinemann, O.	2001d	Determination of residues of JAU 6476-desthio in/on spring wheat following seed treatment of JAU 6476200 FS in Italy and France Bayer AG, Report No.: RA-2090/00, Report includes Trial Nos.: R 2000 0003/0 R 2000 0423/0 Date:2001-09-17	N	N	-	Bayer AG
KCA 6.3.2.1.2 /01	Heinemann, O.	2001h	Determination of residues of JAU 6476-desthio on spring wheat and winter wheat following seed treatment of JAU 6476 200 FS and spray application of JAU 6476 250 EC in Germany, Northern France, and	N	N	-	Bayer AG

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
			Great Britain Bayer AG, Report No.: RA-2003/99, Report includes Trial Nos.: R 1999 0023/6 R 1999 0025/2 R 1999 0026/0 R 1999 0027/9 R 1999 0266/2 Date: 2001-10-04				
KCA 6.3.2.1.2 /02	Heinemann, O.	2001i	Determination of residues of JAU 6476-desthio on spring wheat after spray application of JAU 6476 250 EC in Sweden, Germany, Northern France and Great Britain Bayer AG, Report No.: RA-2104/00, Report includes Trial Nos.: R 2000 0454/0 R 2000 0457/5 R 2000 0474/5 R 2000 0475/3 R 2000 0476/1 Date: 2001-11-29	N	N	-	Bayer AG
KCA 6.3.2.1.2 /04	Heinemann, O.	2001 l	Determination of residues of JAU 6476-desthio in/on wheat and triticale after spray application of JAU 6476 250 EC in Spain and France Bayer AG, Report No.: RA-2105/00, Report includes Trial Nos.: R 2000 0482/6 R 2000 0479/6 R 2000 0478/8 R 2000 0455/9 Date: 2001-12-06	N	N	-	Bayer AG
KCA 6.3.2.1.3 /01	Heinemann, O.	2001e	Determination of residues of JAU 6476-desthio on spring barley following seed treatment of JAU 6476 200 FS and spray application of JAU 6476 250 EC in Germany Bayer AG, Report No.: RA-2150/98, Date: 2001-09-24	N	N	-	Bayer AG
KCA 6.3.2.1.3 /03	Heinemann, O.	2001j	Determination of residues of JAU 6476-desthio on spring barley after spray application of JAU 6476 250 EC in Sweden, Germany, Northern France and Great Britain Bayer AG, Report No.: RA-2101/00, Report includes Trial Nos.: R 2000 0452/4	N	N	-	Bayer AG

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
			R 2000 0456/7 R 2000 0462/1 R 2000 0464/8 R 2000 0465/6Date:2001-11-21				
KCA 6.3.2.1.3 /05	Heinemann, O.;Elke, K.	2001b	Determination of residues of JAU 6476-desthio in/on winter barley after spray application of JAU 6476 250 ECin France, Italy and Portugal Bayer AG, Report No.: RA-2144/98,Report includes Trial Nos.: R 1998 1317/6 R 1998 1571/3 R 1998 1572/1Date:2001-09-24	N	N	-	Bayer AG
KCA 6.3.2.1.3 /06	Heinemann, O.	2001k	Determination of residues of JAU 6476-desthio in/on spring barley after spray application of JAU 6476 250 ECin Spain, Italy and Southern France Bayer AG, Report No.: RA-2103/00, Report includes Trial Nos.: R 2000 0473/7 R 2000 0472/9 R 2000 0470/2 R 2000 0453/2Date:2001-11-21	N	N	-	Bayer AG
KCA 6.4 /01	2001	JAU 6476-desthio - Dairy cattle feeding study Bayer AG, Report No.: MR-535/00, Report includes Trial Nos.: ... Date:2001-10-15	Y	N	-	Bayer AG
KCA 6.5 /01	Gilges, M.	2001	Hydrolysis of JAU 6476 under conditions of processing Bayer AG, Report No.: MR-166/00, Date:2001-01-29	N	N	-	Bayer AG
KCA 6.6 /01	Haas, M.	2001c	Confined rotational crop study with JAU6476 Bayer AG, Report No.: MR-159/00, Date:2001-05-14	N	N	-	Bayer AG

The following tables are to be completed by MS

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	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of first authorization>	Owner

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	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of first authorization>	Owner