

# FINAL REGISTRATION REPORT

**Greenhouses uses**

## **Part B**

### **Section 3**

#### **Efficacy Data and Information**

Concise summary

Product code: SIP41061

Product name: SIP41061

Chemical active substance:

Prothioconazole 400 g/L SC

Central Zone

Zonal Rapporteur Member State: Poland

#### **CORE ASSESSMENT**

(authorization of use – Protected uses)

Applicant: Sipcam Oxon S.p.A.

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## Version history

When	What
June 2022	Correct reference list
January 2023	ZRMs evaluated dRR submitted by Applicant.
June 2023	Changes made in dRR by ZRMs according to commenting period.

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### 3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

#### 3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

##### Abstract

Comments of zRMS: Overall summaries are not necessary here. It was provided at the end of each chapter of the dRR. Below, is presented summary prepared by Applicant.

##### Summary and conclusions on preliminary tests

SIP41061 is a fungicide based on prothioconazole. This active substance is registered and used in several crops worldwide and in Europe since a long time. Therefore, its activity as fungicide is well known as well as the dose response of several target diseases. However, assessment on the minimum effective dose of SIP41061 is reported in this document in Section 3.2.2.

##### Summary and conclusions on the minimum effective dose

The definition of the minimum effective dose of SIP41061 was already assessed based on dose-response curves of preliminary studies and on the experience with the prothioconazole products.

These doses were selected on the basis of its efficacy performance, product safety parameters and environmental limitations. However, efficacy trials included treatments at lower dose rates suitable to show the minimum effective dose under a range of environmental conditions.

SIP41061, applied preventitatively in efficacy trials, was tested at rates that reflect e.g. 60% and 80% of the maximum recommended rate of SIP41061 (100% rate), in accordance with the EPPO standard PP 1/225 '*Minimum effective dose*'.

As intended in the above mentioned guideline, the minimum effective dose assessment is provided for several representative uses under challenging conditions. Therefore, data presented in this chapter are a suitable selection from the whole data package available and presented in chapter 3.2.3.

**Cucurbits / Powdery mildew:** according to the 11 presented trials in greenhouse, the dose delivering 0.3 L PR/ha of SIP41061 provided the optimum and more reliable control and should thus be considered as effective against Powdery mildew on cucurbits with edible and inedible peel in greenhouse, for which activity of SIP41061 is claimed. The most consistent control of Powdery mildew achieved with the recommended rate is confirmed by the higher efficacy and the lower variability. Reduced dosage rates by 33% can still provide useful disease control however with low efficacy than the full recommended dose.

### Summary and conclusions on efficacy

The target crops can be assigned to some main crop groups: orchards, vegetable crops, dry pulses and arable crops. Therefore, this chapter follows this approach in order to cover all the target crops, analysing the efficacy on target diseases in the specific crop and also across crop groups with similar growing systems and therefore plant protection management.

A general overview on efficacy data submitted are available in the specific chapter “Information on trials submitted (3.1 Efficacy data)” and in the relative tables.

**Cucurbits - GREENHOUSE/ Powdery mildew:** a total of 24 efficacy trials were carried out in 2020-2021 to evaluate the efficacy of SIP41061 applied in the range of rates from 0.2 L/ha to 0.3 L/ha (0.1 l/10000 m<sup>2</sup> and 0.12 l/10000 m<sup>2</sup> in leaf wall area) for the control of Powdery mildew on cucurbits with edible and inedible peel cultivated in greenhouse. Out of these, 19 trials were carried out for cucurbits with edible peel and 5 trials were carried out for cucurbits with inedible peel.

Data demonstrated that the efficacy of the SIP41061 at the target rates compare or exceed the efficacy of several reference standards providing good control of the target diseases on the target crops.

Therefore, these rates should thus be considered to be effective against target diseases on target crops.

### Summary on Resistance risk management

Generally, prothioconazole (400 g/L) was applied to a maximum of three treatments on cucurbits at its target dose rates. Due to the limited number of treatments and the limitation to apply during the season, combined with the limitation not to use the product before harvest, the management strategy for this compound is reasonable and will allow growers to continue to use the product in their fungicide programs.

### **Summary and conclusion on adverse effects**

**In cucurbits**, with edible and inedible peel, no phytotoxicity symptoms were recorded in all the efficacy trials presented. Thus, it is concluded that no relevant adverse phytotoxic effects are expected from the use of SIP41061 at the proposed range of rates 0.2 L/ha and 0.3 L/ha (0.1 1/10000 m<sup>2</sup> and 0.12 1/10000 m<sup>2</sup> in leaf wall area) according to the GAP.

#### **Effects on propagation purposes**

No negative effects on products of target crops have been reported after the long-term use of products based on this active substance as a fungicide worldwide.

#### **Impact on treated plants to be used for propagation**

SIP41061 does not lead to unacceptable risk for parts of plants of target crops used for propagating purposes when applied according to the recommendations.

### **Summary and conclusion 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.

**Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)**

Best practice is to copy this table across from Section B0 for consistency. Column 15 (zRMS conclusions) needs to be added manually.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use - No. *	Member state(s)	Crop and/or situation  (crop destination / purpose of crop)	F, Fn, Fnp, G, Gn, Gnp or I**	Pests or Group of pests controlled  (additionally : development al stages of the pest or pest group)	Application				Application rate			PHI (days )	Remarks :  e.g. g safener/ synergist per ha, other dose rate expressio n, dose range (min-max)	zRMS Conclusi on (efficacy)
					Metho d / Kind	Timin g / Growt h stage of crop & season	Max. numb er a) per use b) per crop/ season	Min. interval between applicatio ns (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/seas on	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/seas on	Wate r L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
5	Central EU (NL, DE, AT)	Cucurbits edible peel Cucumber CUMSA Zucchini CUUPG	G	<del>Oidium</del> <del>(Podospheer</del> <del>a xanthii;</del> <del>Golevinomye</del> <del>es</del> <del>eichoracearu</del> <del>m;</del> <del>Sphaerothec</del> <del>a fuliginea)</del> <del>Fusarium</del> <del>spp</del>  Powdery mildew	Spray	BBC H 11-89 20-89	3	10	a) 0.3 b) 0.9	a) 120 b) 360	<del>200-600</del>  500-600	10	Dose LWA should be clarified at national level.	To be confirme d by cMS.
Minor uses according to Article 51 (field uses)														
Minor uses according to Article 51 (interzonal uses)														

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.

\*\* 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

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by CMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

## 3.2 Efficacy data (KCP 6)

### Introduction

This document summarises the information related to the efficacy data for the authorization of the plant protection product SIP41061 containing:

- 400 g/L prothioconazole which was included into Annex I of Council Directive 91/414/EEC amended by Commission Directive 2008/44/EC of 4 April 2008 (then under Commission Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances). The extension of the approval period is currently until 31 July 2022 (as by Commission Implementing Regulation (EU) 2021/745 of 6 May 2021).

### Prothioconazole

The SANCO/EFSA reports for prothioconazole (SANCO/3923 /07 - 10 December 2007 and 26 January 2021- EFSA Scientific Report (2007) are considered to provide the relevant review information or a reference to where such information can be found. The Annex I Inclusion Directive for prothioconazole (as amended by Commission Implementing Regulation (EU) No 540/2011) provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on prothioconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 January 2021 shall be taken into account.

Consideration of active substances for Annex I inclusion does not include an evaluation of efficacy. Therefore, there are no concerns to address arising from the inclusion directive of prothioconazole relating to efficacy.

The data presented in this document fully support the registration of SIP41061 for the control of diseases as specified in the GAP table.

Uses in greenhouse are pertinence of EU zone, in agreement with the EU Reg. 1007/2009, as **interzonal use**.

### Description of active substance

Active substances properties are summarized in Table 3.2-1.

**Table 3.2-1: Details of the active substances**

Active substance	prothioconazole
Concentration (Unit: g/kg or g/L...)	400 g/L
Chemical group	triazolinthiones (DIMs)
Mode of action	DMI-fungicides (DeMethylation Inhibitors) <b>FRAC group 3</b>
Plant translocation	Systemic
Biological action	foliar



## Mode of action

### Prothioconazole

According to FRAC, prothioconazole belongs to Group 3, code#3 (DMI-fungicides (DeMethylation Inhibitors) and to the chemical class of triazolinthiones. Other chemical classes classified as Group 3, code #3 fungicides are piperazines, pyridines, pyrimidines, imidazoles, triazoles.

Their primary biochemical mode of action is the blockage of the C14- demethylase in sterol biosynthesis. The production of these fundamental components of the cell membrane is interrupted and, as a result, the development and growth of the fungal mycelium is blocked. It acts on all stages of the infectious process: from the formation of the appressorium and the haustoria, to the growth of the mycelium and the formation of the spores. The fungal cells collapse and the mycelium is covered with extruded material.

All DMIs inhibit fungi by interacting with the same target site, C14-demethylase (erg11/cyp51) and are therefore considered to be cross-resistant with each other.

## Description of the plant protection product

SIP41061 is an emulsifiable concentrate (EC) containing 400 g/L of prothioconazole.

**Table 3.2-2: Simplified table of requested uses for the product code SIP41061 – Interzonal Regulatory zone**

USES		Member State	Requested registered uses (e.g. rates + no. applications)	Comments/other relevant details on the GAPs
Crop(s)	Target(s)			
Cucurbits edible peel	<i>Oidium (Podosphaera xanthii,</i> <i>Golovinomyces cichoracearum,</i> <i>Sphaerotheca fuliginea)</i> <i>Fusarium spp</i> <i>Didymella spp</i>	ES, IT, EL, PT	Max 0.3 L/ha	Greenhouse use: 3 appl.s. at BBCH= 11-89
Cucurbits edible peel	<i>Oidium (Podosphaera xanthii,</i> <i>Golovinomyces cichoracearum,</i> <i>Sphaerotheca fuliginea)</i> <i>Fusarium spp</i>	FR, NL, DE, AT	Max 0.3 L/ha	Greenhouse use: 3 appl.s. at BBCH= 11-89

Further details are in the table “All intended uses” in Part B - Section 0.

### Description of the target diseases

The list of the diseases presented in this document is given in the table below. A full description of the main pathogens and species covered within this document is presented in the Biological Assessment Dossier.

**Table 3.2-3: Glossary of pests mentioned in the dossier.**

EPPO code	Scientific name	Common name
PODOXA	<i>Podosphaera xanthii</i>	powdery mildew of cucurbits
ERYSCI	<i>Golovinomyces cichoracearum</i>	powdery mildew of cucurbits
SPHRFU	<i>Sphaerotheca fuliginea</i>	powdery mildew of cucurbits
FUSAOX	<i>Fusarium oxysporum</i>	basal rot
DIDYBR	<i>Stagonosporopsis cucurbitacearum</i> ( <i>Didymella bryoniae</i> )	black rot of cucumber
POLTFU	<i>Polystigma fulvum</i>	Leaf blotch

### Major / minor status of intended uses (for all cMS and zRMS).

**Table 3.2-4: Major / minor status of intended uses (for all cMS and zRMS).**

Crop and/or situation	Crop status		Disease or group of diseases controlled	Disease status	
	Major	minor		major	minor
Cucurbits edible peel GH	South EU (EL, ES, FR)	South EU (IT, PT)	Oidium ( <i>Podosphaera xanthii</i> , <i>Golovinomyces cichoracearum</i> , <i>Sphaerotheca fuliginea</i> )	South EU (PT)	South EU (EL, ES, IT)
			<i>Fusarium oxysporum</i>	South EU (PT)	South EU (EL, ES, IT)
			<i>Didymella bryoniae</i>	South EU (PT)	South EU (EL, ES, IT)
Cucurbits edible peel GH		Central EU (AT, DE, NL)	Oidium ( <i>Podosphaera xanthii</i> , <i>Golovinomyces cichoracearum</i> , <i>Sphaerotheca fuliginea</i> )	South EU (FR) Central EU (NL)	Central EU (AT, DE)
			<i>Fusarium oxysporum</i>	South EU (FR) Central EU (NL)	Central EU (AT, DE)
			<i>Didymella bryoniae</i>	South EU (FR) Central EU (NL)	Central EU (AT, DE)

### Compliance with the Uniform Principles

All trials presented in this document were implemented in accordance with the GEP principles and according to relevant EPPO guidelines. All the trials were carried out by GEP certified test facilities.

The assessments and compilation of this document were performed in compliance with the uniform principles for evaluation of plant protection products. These include general principles as the evaluation of data in the light of current knowledge, taking account of the particular conditions prevailing in the zone in which the product is to be used and specific principles concerning, among other things, the efficacy and the absence of unacceptable effects on target crops.

The overall assessment was performed according to the Uniform Principles.

### Information on trials submitted (3.1 Efficacy data)

#### TRIALS on CUCURBITS

**Table 3.2-5: Presentation of efficacy trials on CUCURBITS**

Crop(s)	Target(s)	GH/F	Edible or Inedible peel	Country	Years	Type of trial**	Number of trials (number of valid trials)		GEP, non-GEP, official***	Comments (any other relevant information)	
							MARz	MEDz			
Crop(s)	Powdery mildew	GH	E	DEU	2020-2021	MED + E	5		GEP	GE20-SIP-103-03	
				DEU		E				21 1069 5185	
				FRA		E				1	S21-02557-02
				NL		MED + E				1	21 1069 5186
				ESP		E	9			S21-02557-01	
										21F FCUOXO FR09	
										NL20-SIP-103-02	
										F2034-10	
										F2116-1	
										F2116-2	
										F2117-1	
										F2117-2	
										F1913-1	
										F2034-12	
										F2034-11	
										F2034-9	
				FRA		E	3			SO2131 (AGL21FR236)	
						MED + E				20F FCUOXO FR12	
				ITA		MED + E	4			20F FCUOXO FR09	
										F2034-1	
										F2034-2(168)	
										F2034-3	
										F2034-4	
TOTAL	-	-	-	-	-	7	17	-	AGG_20_41061_CUMME_PODOXA_1	-	

According to the GAP table. \*\* P = preliminary trial, MED = minimum effective dose, E = efficacy trial. \*\*\* GEP: Good Experimental Practices. Official: carried out by a national official organisation.

**Table 3.2-6: Presentation of reference standards used in trials on cucurbits (efficacy trials, preliminary trials...) CUCURBITS**

Crop	Country where the product is registered <sup>(1)</sup>	Reference standard	Authorization number	Active substance(s)	Active substance content (g/L or g/kg)	Registered application rate(2)	Application rate in trials (per treatment)
CUCURBITS	DEU	TOPAS 100	033590-00	penconazole	100	0.5 L/ha	50 gai/ha
	DEU	ORTIVA	024560-00	azoxystrobin	250	0.8 L/ha	200 gai/ha
	FRA	TOPAZE	8300025	penconazole	100	0.5 L/ha	50 gai/ha
	ITA	ORTIVA	10161	azoxystrobin	250	0.8-1 L/ha - F 0.7-1 L/ha - GH	175 gai/ha
	ITA	TOPAS 200 EW	9280	penconazole	200	0.2 L/ha	50 gai/ha
	NL	TOPAZ 100 EC	9364	penconazole	100	0.5 L/ha	50 gai/ha
	SP	TOPAS 200 EW	21291	penconazole	200	0.2 L/ha	50 gai/ha
	SP	ORTIVA	22000	azoxystrobin	200	0.7-0.8 L/ha	140 gai/ha
	NL	TOPAZ 100 EC	9364	penconazole	250	0.8 L/ha	200 gai/ha

(1) only on use(s) applied for (with the test product).

(2) e.g. WP (wetttable powder), EC (emulsifiable concentrate), etc.

Comments of zRMS:	<p>This document summarizes the information related to the efficacy of the plant protection product – SIP41061 (product code: SIP 41061) for interzonal uses (in greenhouses). CMS for those uses are: NL, DE, AT.</p> <p>SIP 41061 is an emulsifiable concentrate (EC) containing 400 g/L prothioconazole. Prothioconazole is a fungicide belonging to the group of SBI-Class I: Demethylation-Inhibitors (DMI) a subgroup of the Sterol Biosynthesis Inhibitors (SBI)-triazoles. Triazoles are the largest class of fungicides commonly used in medical and agriculture. They were first introduced for crop protection in 1973 by Bayer (triadimefon) [Morton and Staub 2008]. In the following years, the following substances were commercialized further substances from this group, including: tebuconazole [1986], epoxiconazole [1990] and prothioconazole [2002], which are currently the most widely used [Parker et al. 2014]. The active ingredient is classified after the target site and code by FRAC to inhibition of biosynthesis in membrane G1: C14- demethylase in sterol biosynthesis. The biochemical mode of action of the DMI is the inhibition of C14- demethylase in sterol biosynthesis. The active ingredient has systemic properties, is very rapidly absorbed into the plant and acropetal distributed in the transpiration stream. This results in both a protective and curative action. The result of the effect of prothioconazole is the abnormal formation of fungal infection structures and a strong inhibition of mycelial growth and spore germination. A penetration of the plant or the seed is thus prevented. The active ingredient is selective on a wide range of dicotyledonous and monocotyledonous crop species. Prothioconazole is used for foliar application and seed treatment.</p> <p>For now, this mentioned active substance (prothioconazole) is on the list of approved active substances. What is important, a large-scale efficacy trials are available to evaluate the effectiveness of products containing this active compound. All necessary information's about tested plant protection products, active substance, studied fungal diseases, reference products, etc. are correctly presented in this drr by Applicant. In Poland 95 plant protection products containing prothioconazole as an active substance are already registered.</p> <p>The product – SIP 41061 (product code: SIP 41061) containing prothioconazole by SIPCAM OXON S. p. A. was evaluated by Poland as ZRMs. Each cMs should decide if major/minor status of pest or crop was corrected assigned by the Applicant.</p>
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### 3.2.2 Preliminary tests (KCP 6.1)

SIP41061 is a fungicide based on prothioconazole. This active substance is registered and used in several crops worldwide and in Europe since a long time. Therefore, its activity as fungicide is well known as well as the dose response of several target diseases. However, assessment on the minimum effective dose of SIP41061 is reported in this document in Section 3.2.2.

Comments of zRMS:	<p>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 many crops. Applicant presented several dozens of equivalents currently authorized formulations to SIP41061 in Central regulatory zone.</p>
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### 3.2.3 Minimum effective dose tests (KCP 6.2)

The definition of the minimum effective dose of SIP41061 was already assessed based on dose-response

curves of preliminary studies and on the experience with the prothioconazole products.

These doses were selected on the basis of its efficacy performance, product safety parameters and environmental limitations. However, efficacy trials included treatments at lower dose rates suitable to show the minimum effective dose under a range of environmental conditions.

SIP41061, applied preventatively in efficacy trials, was tested at rates that reflect e.g. 60–33% (4.0 0.1 L/ha) and 80–67% (0.2 L/ha) of the maximum recommended rate of SIP41061 (100% rate – 0.3 L/ha), in accordance with the EPPO standard PP 1/225 '*Minimum effective dose*'.

As intended in the above mentioned guideline, the minimum effective dose assessment is provided for several representative uses under challenging conditions. Therefore, data presented in this chapter are a suitable selection from the whole data package available and presented in chapter 3.2.3.

For material and method of the trials refer to chapter 3.2.3 (KCP 6.2).

#### 3.2.4 Summary and conclusions on the minimum effective dose

**Cucurbits / Powdery mildew:** according to the 11 presented trials in greenhouse, the dose delivering 0.3 L PR/ha of SIP41061 provided the optimum and more reliable control and should thus be considered as effective against Powdery mildew on cucurbits with edible and inedible peel in greenhouse, for which activity of SIP41061 is claimed. The most consistent control of Powdery mildew achieved with the recommended rate is confirmed by the higher efficacy and the lower variability. Reduced dosage rates by 33% can still provide useful disease control however with low efficacy than the full recommended dose.

A summary of the dose response results is provided in tables below.

**Table 3.2-7: Minimum effective dose of SIP41061 against Powdery mildew on cucurbit edible peel - GH**

Crop		edible cucurbits - GH				Name	Untreated Check		SIP41061		SIP41061		SIP41061	
Pest		powdery mildew (including PODOXA; PODOSP)				Conc			400 g/L		400 g/L		400 g/L	
Part rated		leaf				ai			Prothioconazole SC		Prothioconazole SC		Prothioconazole SC	
Rating type, unit		PESSEV, %				Type			0.1 L/ha		0.2 L/ha		0.3 L/ha	
Trial ID	Crop	Rating Date	GS at assess.	DALA	GS at 1st appl.	Rate PR, unit			40 g/ha		80 g/ha		120 g/ha	
						Rate ai, unit			33%		67%		100%	
						Pressure %	%CTRL		%CTRL		%CTRL		%CTRL	
F2034-9	Cucumber	08/01/2021	88	11 DA-C	82	11.1	0		62.9	b	71.2	ab	85.5	a
GE20-SIP-103-03	Cucumber	22/08/2020	73	8 DA-C	71	62.7	0		87.2	b	96.4	a	97.8	a
NL20-SIP-103-02	Cucumber	09/09/2020	82	9 DA-C	19	5.8	0	c	100	a	100	a	100	a
F2034-11	Zucchini	10/03/2021	85	7 DA-C	81	9.8	0		62.3	b	69.1	b	100	a
F2034-12	Zucchini	12/04/2021	87	13 DA-C	82	34.3	0		96.1	a	99.4	a	100	a
20F FCUOXO FR09	Zucchini	16/07/2020	85	7 DA-B	82	70.6	0		78.1	a	89.5	a	85.4	a

		N. trials	Pressure%	% CONTROL				
EDIBLE PESSEV, % GH		6	Mean	32.4	(0)	81.1	87.6	94.8
			min	5.8	(0)	62.3	69.1	85.4
			max	70.6	(0)	100.0	100.0	100.0

**Table 3.2-8: Minimum effective dose of SIP41061 against Powdery mildew on cucurbit inedible peel - GH**

Crop Pest Part rated Rating type, unit		inedible cucurbits - GH powdery mildew (including PODOXA) leaf PESSEV, %				Name Conc ai Type Rate PR, unit Rate ai, unit	Untreated Check		SIP41061 400 g/L Prothioconazole SC 0.1 L/ha 40 g/ha <b>33%</b>		SIP41061 400 g/L Prothioconazole SC 0.2 L/ha 80 g/ha <b>67%</b>		SIP41061 400 g/L Prothioconazole SC 0.3 L/ha 120 g/ha <b>100%</b>	
Trial ID	Crop	Rating Date	GS at asses s.	DALA	GS at 1st appl.	Pressure%	%CTRL		%CTRL		%CTRL		%CTRL	
AGG_20_41061_CUMME_POD OXA_1	muskmelon	03/06/2020	82	14 DA-C	71	12.7	0		38.9	b	88.4	a	83.5	a
F2034-1	melon	25/05/2020	89	10 DA-D	66	13.5	0		87.2	a	77.7	a	96.1	a
F2034-2(168)	melon	12/06/2020	69	8 DA-C	74	30.6	0		94.1	a	97.2	a	94	a
F2034-3	watermelon	05/06/2020	74	9 DA-C	63	50.6	0		81.8	a	91.3	a	89.5	a
F2034-4	watermelon	26/06/2020	87	9 DA-C	71	67.5	0		94.5	ab	97.8	a	98.4	a
						Pressure%	% CONTROL							
						35.0	(0)	79.3		90.5		92.3		
						12.7	(0)	38.9		77.7		83.5		
						67.5	(0)	94.5		97.8		98.4		

		N. trials	Pressure%	% CONTROL				
INEDIBLE PESSEV, % GH	5	Mean	35.0	(0)	79.3	90.5	92.3	
		min	12.7	(0)	38.9	77.7	83.5	
		max	67.5	(0)	94.5	97.8	98.4	



Comments of zRMS:	<p>The applicant has proposed doses of SIP41061 (product code: SIP41061) that reflect those of currently authorised 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).</p> <p>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: 0.1 L/ha (0.33N0; 0.2 L/ha (0.67N) and 0.3 L/ha (N). Trials (in total 11) were carried out on cucurbits (inedible and edible) against Powdery mildew in greenhouses conditions.</p> <p>Cucurbits with edible peel were studied in 6 trials carried out in 2020-2021 in glasshouses conditions in Maritime EPPO zone. During those trials: cucumber (3 trials) and zucchini (3 trials) were studied. The most effective against Powdery mildew was dose 0.3 L/ha. Results were comparable to st. ref. product.</p> <p>Cucurbits with inedible peel were studied in 5 trials performed in 2020 in glasshouses conditions in the Maritime EPPO zone. During those trials melon (2 trials), watermelon (2 trials) and muskmelon (1 trial) were studied. The most effective against Powdery mildew was dose 0.3 L/ha. Results were comparable to st. ref. product</p> <p><b>According to the 11 presented trials in greenhouse, the dose delivering 0.3 L PR/ha of SIP41061 provided the optimum and more reliable control and should thus be considered as effective against Powdery mildew on cucurbits in greenhouse, for which activity of SIP41061 is claimed.</b></p>
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### 3.2.5 Efficacy tests (KCP 6.2)

The efficacy of SIP41061 against target diseases is presented.

Data are presented and summarized per crop and per EPPO climatic zone, per each use (crop/disease combination).

Provided efficacy data package and argumentations are presented to fully support the first registration of SIP41061.

#### Description of the methodology used

Trials were conducted according to the EPPO guidelines stated in table below.

Full details of the sites and applications are provided in Appendix 2 of the Biological Assessment Dossier. Normal crop maintenance was applied to trials by the growers, according to crop requirements and good agricultural practices. Trials included a range of locations to determine crop tolerance and efficacy on the most representative growing areas in relevant member states. All trials were placed within regions where target crops are commonly grown and data have been recorded in presence of the target diseases. In all of the trials, efficacy data were obtained in comparison to the untreated check. Crop phytotoxicity was assessed at various intervals.

Multiple comparison analysis statistics were used to examine pairwise and subgroup differences after the full ANOVA has found significance. Please note that from all of the above trials, the results in the summary tables were extracted from trial reports where treatments of no relevance to this submission



could be also included. As statistical analyses were conducted across the whole range of treatments, significance letters relate to the whole treatment list and not just to the data shown in the extracted tables.

### **TRIALS on CUCURBITS**

**Table 3.2-9: Details on trial methodology – Efficacy trials in Cucurbits-Interzonal use (greenhouse) (24 trials)**

<b>Guidelines</b>	General guidelines	PP1/57(3)
	Specific guidelines	PP 1/135(4); PP 1/152(4); PP 1/181(4); 1/214 (4); 1/226 (3)
<b>Experimental design</b>	Plot design	RACOB (24)
	Number of replications	4 (24)
<b>Crop</b>	Trials per crop	Cucumber(11); marrow squash (1); melon (2) muskmelon (1); watermelon (2); zucchini (7);
	Varieties per crop	Augusta(2); Black beauty(1); Egnazio F1(1); Euphoria RZ(2); Galia(2); Granada(1); Leila(1); Lucia(3); Poseidón(1); rockker(1); Satellite(2); Sinatra(2); Sonja(1); TANJA(1); Urano(1); Verdena(1);
<b>Application</b>	Crop stage (BBCH) at application	BBCH at first appl.=20-84 (24)
	Timing	Preventive (24)
	Number of applications	Max 5 applications (24)
	Spray volumes	500-1200 L/ha (23); not reported (1);
<b>Assessment</b>	Assessment types	Efficacy: PESSEV (%); PESINC (%); vigor (1-10); Phygen (%)
	Assessment dates	Generally 10-15 DALA, at BBCH 65-90 (24)
<b>Other relevant information</b>	Soil type	artificial substrate(s)(2); clay loam(7); fine sand(2); gravelly sand(1); loamy clay sand(1); loamy sand(2); sand(3); sandy clay loam(1); sandy loam(1); silty clay(1); not reported (3);

### **Summary and conclusion of the efficacy part 3.2.3**

The target crops can be assigned to some main crop groups: orchards, vegetable crops, dry pulses and arable crops. Therefore, this chapter follows this approach in order to cover all the target crops, analysing the efficacy on target diseases in the specific crop and also across crop groups with similar growing systems and therefore plant protection management.

A general overview on efficacy data submitted are available in the specific chapter “Information on trials submitted (3.1 Efficacy data)” and in the relative tables.

**Cucurbits - GREENHOUSE/ Powdery mildew:** a total of 24 efficacy trials were carried out in 2020-2021 to evaluate the efficacy of SIP41061 applied in the range of rates from 0.2 L/ha to 0.3 L/ha (0.1 1/10000 m<sup>2</sup> and 0.12 1/10000 m<sup>2</sup> in leaf wall area) for the control of Powdery mildew on cucurbits with edible and inedible peel cultivated in greenhouse. Out of these, 19 trials were carried out for cucurbits with edible peel and 5 trials were carried out for cucurbits with inedible peel.

Data demonstrated that the efficacy of the SIP41061 at the target rates compare or exceed the efficacy of several reference standards providing good control of the target diseases on the target crops.

Therefore, these rates should thus be considered to be effective against target diseases on target crops.

**Table 3.2-10: Summary on efficacy of SIP41061 against Powdery mildew on CUCURBITS with edible and inedible peel – GREENHOUSE**

GH/F	ED/IN peel	Rating type, unit	N. trials	Pressure%		U TC	% CONTROL											
							SIP41061 400 g/L Prothioconazole SC 0.2 L/ha 80 gai/ha		SIP41061 400 g/L Prothioconazole SC 0.3 L/ha 120 gai/ha		SIP41061 LEAF WALL AREA SC 0.1 l/10000 m <sup>2</sup> lwa		SIP41061 LEAF WALL AREA SC 0.12 l/10000 m <sup>2</sup> lwa		Ref. Std. 100-200 g/L Penconazole EC 0.25-0.5 L/ha 50 gai/ha		Ref. Std. 250 g/L Azoxystrobin SC 0.7-0.8 L/ha 175-200 gai/ha	
				Me an	min-max		Me an	min-max	Me an	min-max	Me an	min-max	Me an	min-max	Me an	min-max	Me an	min-max
Efficacy GH	EDIBLE GH	PESSEV, %	15	29.2	5.8-70.6	0	87.8	63.3-100	94.8	80-100	-	-	-	-	83.5	51.2-100	-	-
		PESINC, %	2	27.9	7.5-48.3	0	65.7	51.3-80	88.6	87.5-89.7	-	-	-	-	76	51.9-100	67.4	49.8-85
		PESINC, %	2	34	10.5-57.5	0	-	-	-	-	84.6	72.1-97	90.8	85.8-95.7	64	62.1-65.8	-	-
Efficacy GH	INEDIBLE GH	PESSEV, %	5	35	12.7-67.5	0	90.5	77.7-97.8	92.3	83.5-98.4	-	-	-	-	89.6	81.8-95.7	67.5	19.1-91.7

Comments of zRMS:	<p>Justification for the use of biological efficacy data included in this dossier is made according to EPPO PP 1/241(2) “<i>Guidance on comparable climates.</i>” As intended use is in glasshouses, so results from all zones could be relevant.</p> <p>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. 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). For edible cucurbits 2 growing seasons were studied but for inedible – only one (2020). So, each CMS should decide if it can be acceptable, considering the validity of the crops in each country. However, cucurbits with inedible peel are not included in GAP table by Applicant.</p> <p>Regarding number of applications, trials were conducted with 5 applications to cover the hole season to avoid applications of other formulations in the studied crops. 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 3<sup>rd</sup> and 4<sup>th</sup> application to assure maximum reliability with the GAP. Recommended number of applications for cucurbits crops included in GAP table is max. 3 appl. per season.</p> <p><b>Summary of trials and results for cucurbits:</b> (only valid trials were presented)</p> <ul style="list-style-type: none"> <li><i>with edible peel Recommended are max 3 application per season at dose 0.3 L/ha. ZRMs not agree with application window BBCH 11-89 (in the trials was studied BBCH 20-84). ZRMs proposed following application window: BBCH 20-89. Accepted water volume accordingly to trials should be: 500-600 not 200-600 L/ha (during trials water volume: 500-</i></li> </ul>
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	<p>1200 L/ha was studied). Interval: 10 d – accepted.</p> <ul style="list-style-type: none"> <li>• <b>with inedible peel:</b> Recommended are max 3 application per season at dose 0.3 L/ha. ZRMs not agree with application window BBCH 11-89 (in the trials was studied BBCH 20-84). ZRMs proposed following application window: BBCH 20-89. Accepted water volume accordingly to trials should be: 500-600 not 200-600 L/ha (during trials water volume: 500-1200 L/ha was studied). Interval: 10 d – accepted.</li> </ul> <p><b>against Powdery mildew</b> – in total 19 trials carried out in 2020-2021 in glasshouses conditions. So, all EPPO zones are relevant. It can be concluded that SIP41061 at recommended rate (0.3L/ha) effectively control Powdery mildew on cucurbits with edible peel. Results were comparable to standard reference product.</p> <p>Trials were carried out on cucumber (11 trials), marrow squash (1), zucchini (7) – edible peel and inedible peel (5 trials): melon (2), muskmelon (1) and watermelon (2). So, cMS should decide if number of trials for mentioned below crops is sufficient for registration.</p> <p>According to EPPO 1/57 – organisms studied should be: <i>Erysiphe cichoracearum</i> (ERYSCI), <i>Sphaerotheca fuliginea</i> (SPHRFU)1 on squash; <i>E. cichoracearum</i> (ERYSCI) on mustard; <i>E. cruciferarum</i> (ERYSCR) on brassicas; <i>E. pisi</i> (ERYSPI) on peas. In some trials carried out on cucumber and zucchini – PODOXA was studied as a fungal diseases. In the opinion of ZRMs those trials should be taken by cMS as acceptable. Numerous vegetable crops are susceptible to powdery mildew, but cucurbits are arguably the group most severely affected. <i>Podosphaera fusca</i> (synonym <i>Podosphaera xanthii</i>) is the main causal agent of cucurbit powdery mildew and one of the most important limiting factors for cucurbit production worldwide.</p> <p><u>During trials on edible peel cucurbits (19) following fungal diseases were studied:</u></p> <ul style="list-style-type: none"> <li>– cucumber (11): PODOXA (6 trials), ERYSCI (3 trials), PODOSP (1 trial);</li> <li>- zucchini (7): PODOXA (6) and ERYSCI (1)</li> <li>- marrow squash: (1): SPHFRU (1).</li> </ul> <p><u>During trials on inedible peel cucurbits (5) following fungal diseases were studied:</u></p> <ul style="list-style-type: none"> <li>– water melon (2): PODOXA (2)</li> <li>- melon (2): PODOXA (2)</li> <li>- muskmelon (1): PODOXA (1).</li> </ul> <p>The EPPO extrapolation PP1-19722FEET_2014_Cucurbitaceae-effectiveness.pdf indicates that for minor uses data from cucumber or melon can be extrapolated to all crops within the group. Therefore the trials in melon can support the trials in cucumber and the vice versa. In the GAP table only edible peel cucurbits were included by Applicant. However, in the opinion of ZRMs inedible peel cucurbits could be accepted by cMS. However, maybe their crops are not so popular in maritime climates, even in greenhouse conditions.</p> <p style="text-align: center;"><b>EFFECTIVENESS ACCORDING TO LWA APPROACH</b></p> <p style="text-align: center;"><b>FOR CUCUMBER CROPS:</b></p> <p>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. <b>The applicant submitted and presented results related to LWA score combined with reference to ha</b></p>
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**ground area** for glasshouses use on cucurbits.

In 2 trials the mean disease severity on leaf (% of affected leaves) in the untreated plots was 34%, ranging between 10.5% and 57.5%. This represents a severe test to the products and considers different pressures of disease. SIP41061 at 0.1 l/10000 m<sup>2</sup> LWA and 0.12 l/10000 m<sup>2</sup> LWA was compared with the commercial reference standards as described below. In 2 trials, SIP41061 at 0.1 l/10000 m<sup>2</sup> LWA (84.6% control) and at 0.12 l/10000 m<sup>2</sup> LWA (90.8% control) showed superior efficacy to the reference standard based on penconazole applied at 50 gai/ha (64% control).

**Table** Efficacy of SIP41061 against Powdery mildew on cucurbits EDIBLE peel GH (PESINC, % - Leaf Wall Area)

Crop Pest Part rated Rating type, unit		edible cucurbits - GH powdery mildew (including PODOXA; ERYSCI) leaf PESINC, %				Name Conc ai Type Rate PR, unit Rate ai, unit	Untreated Check		SIP41061 Prothioco nazole SC 0.1 l/10000 m2 lwa		SIP41061 Prothioco nazole SC 0.12 l/10000 m2 lwa		Ref. Std. 100-200 g/L Penconazole EC 0.25-0.5 L/ha 50 gai/ha
Trial ID	Crop	Rating Date	GS at asse ss.	DALA	GS at 1st appl .	Pressur e%	%CTRL		%CTRL		%CTRL		%CT RL
21 1069 5185	Cucu mber	25/08/2 021	79	0 DA- F	61	57.5	0	b	97	a	95.7	a	65.8
S21- 02557- 02	Cucu mber	02/08/2 021	75	14 DA-F	16	10.5	0		72.1	a	85.8	a	62.1
N. trials						Pressur e%	% CONTROL						
EDIBL E GH	PESSEV, %				Me an min max	34.0	(0)		84.6		90.8		64.0
						10.5	(0)		72.1		85.8		62.1
						57.5	(0)		97.0		95.7		65.8

**Summary:** These results demonstrated that efficacy of SIP41061 at the proposed label rate of 0.3 L/ha and 0.12 L/10000 m<sup>2</sup> LWA exceed the efficacy of the reference standard based on penconazole applied at 50 ga/ha and the reference standard based on azoxystrobin applied at 175-200 gai/ha. These rates should thus be considered to be effective against Powdery mildew on cucurbits with edible peel in greenhouse. cMS could also consider the dose 0.2 L/ha and 0.1 l/10000m<sup>2</sup> LWA as acceptable for use (it was not included in GAP table by Applicant).

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. prothiiconazole) 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. prothiiconazole) at the equivalent dose rate.

What is important in all trials information's about LWA was included in reports from trials. LWA vary from 9048 to even 44000. The average LWA from all trials was at the level: 29202, which corresponds to dose 0.1 L/ha LWA (on the basis on dose 0.3 L/ha per ground). If cMS consider also dose 0.2 L/ha per ground, then recommended dose LWA will be: 0.07 L/ha LWA. It was considered that the dose is dependent on the value of LWA, so it should be determined at the national level, but in our opinion, it should be proposed between range 0.07 and 0.12 L/ha LWA.

	<p>In the opinion of ZRMS, in the GAP table should be included powdery mildew as a pest controlled. <i>P. xanthii</i> causes powdery mildew on cucurbits. <i>Golovinomyces cichoracearum</i> V.P. Heluta - a species of fungi belonging to the mealybug family fungal family <i>Erysiphaceae</i>. <i>Golovinomyces cichoracearum</i> is synonym of <i>Erysiphe cichoracearum</i>. It occurs mainly on numerous species of plants of the asteraceae family. An obligate parasite that causes a disease called powdery mildew of asteraceae. Powdery mildew, caused by the fungi <i>Sphaerotheca fuliginea</i> and <i>Erysiphe cichoracearum</i>, is widespread on cucurbits, especially during dry, hot periods. In the opinion of ZRMs for cucurbits relevant pest are only: <i>P. xanthii</i>, <i>Sphaerotheca fuliginea</i> and <i>Erysiphe cichoracearum</i>.</p> <p><i>Fusarium spp.</i> Was not assessed during efficacy trials so should be excluded from GAP table.</p>
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### 3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

The risk of resistance to SIP41061 (prothioconazole 400 g/L) under an unrestricted use pattern is analysed in a two-stage process - resistance risk assessment and resistance risk management, according to EPPO guideline PP 1/213 (4).

The intrinsic risk for resistance evolution to a given fungicide group is estimated to be low, medium or high according to the principles described in FRAC Monographs 1, 2 and 3. Resistance management is driven by intrinsic risk of fungicide, pathogen risk and agronomic risk (see FRAC pathogen risk list).

- The risk of the possible development of resistance inherent in SIP41061 depends on the risks inherent in prothioconazole as SBI fungicide. In the present state of knowledge, the risk inherent in prothioconazole can be assumed to correspond to that of other compounds in FRAC Group 1, code#3 (SBI (sterol biosynthesis inhibitors)): **medium**.
- According to the FRAC pathogen risk list, and to the list of plant pathogenic organisms resistant to disease control agents, the target diseases are classified **from low to high risk** pathogens for development of resistance to fungicides.
- According to these good agronomic practices commonly used in Europe for row crops and for the use of SIP41061, depending from climatic conditions favouring these diseases or not, the **agronomic risk can be judged from low to medium**.

The overall resistance risk is composed of three factors: the agronomical risk, the intrinsic fungicide risk and the pathogen risk as described in the FRAC Pathogen Risk List<sup>1</sup>.

The combined risk on a specific use is calculated as the mathematical product among the index associated with the agronomical risk, the fungicide risk and the pathogen risk.

**COMBINED RISK = agronomical risk \* fungicide risk \* pathogen risk**

**Table 3.3-1: Combined resistance risk diagram based on inherent fungicide risk, inherent pathogen risk, and agronomic risk for target uses of prothioconazole (SIP41061).**

		Agronomic Risk					
Fungicide Risk: SDHIs Medium=2	Combined risk	low=0.25	medium=0.5	low=0.25	medium=0.5	low=0.25	medium=0.5
		0.5	1	1	2	1.5	3
Pathogen Risk		low=1		medium=2		high=3	
		Golovinomyces cichoracearum*				Podosphaera xanthii	
		Sphaeroteca fuliginea*				Dydimella spp.	
		Polystigma fulvum*					
		Fusarium spp.					
* Not classified in FRAC Pathogen Risk List. Since only most important classes and groups are mentioned in the FRAC document, this pathogen is assumed to be LOW a risk pathogen.							

Bearing in mind that the maximum calculated risk proposed by FRAC may reach values of 18, according to the risk assessment presented above in this section, the overall resistance risk for prothioconazole (SIP41061) can be judged in general low (always below the first third), as summarized in the table above.

Nevertheless, considering that the unmodified risk is the risk of practical resistance (inherent risk combined with agronomic risk) under “unrestricted” conditions of prothioconazole (SIP41061) use, a resistance management is recommended.

<sup>1</sup> FRAC: PATHOGEN RISK LIST (September 2019)

In conclusion, if SIP41061 (prothioconazole 400 g/L) is used according to the label instructions, the risk of the target pathogens developing resistance to the active ingredient within SIP41061 can be considered acceptable.

### 3.3.1 Resistance Risk Management

Generally, prothioconazole (400 g/L) was applied to a maximum of three treatments on cucurbits at its target dose rates. Due to the limited number of treatments and the limitation to apply during the season, combined with the limitation not to use the product before harvest, the management strategy for this compound is reasonable and will allow growers to continue to use the product in their fungicide programs.

Comments of zRMS:	<p>Applicant presented the Information on the occurrence or possible occurrence of the development of resistance. The active ingredient: prothioconazole belong to the chemical group of triazoles. Pothioconazole 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: C<sup>14</sup>-demethylase in sterol biosynthesis; Group name: DMI-fungicides (DeMethylation Inhibitors) (SBI: Class I); Chemical group: Triazole.</p> <p>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.</p> <p>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</p> <p>SBI fungicides have been characterized by FRAC (<a href="http://www.frac.info">http://www.frac.info</a>) 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.</p> <p>The pattern of cross-resistance of the sterol biosynthesis inhibitor (SBI) fungicides, of which prothioconazole is a member, is complex and summarized as follows:</p>															
	<table><tr><th>FRAC Code</th><th>SBI Class</th><th>Group Name</th><th>Chemical Group</th><th>Cross-resistance</th></tr><tr><td>G1/3</td><td>I</td><td>DMI (DeMethylat ion Inhibitors)</td><td>Piperazines, pyridines, pyrimidines, imidazoles, triazoles</td><td>Resistance within the DMI group but NOT to other SBI classes.</td></tr><tr><td>G2/5</td><td>II</td><td>Amines (morpholine s)</td><td>Morpholines, piperidines, spiroketal-amines</td><td>Cross-resistance within the group generally found but not to other SBI classes.</td></tr></table>	FRAC Code	SBI Class	Group Name	Chemical Group	Cross-resistance	G1/3	I	DMI (DeMethylat ion Inhibitors)	Piperazines, pyridines, pyrimidines, imidazoles, triazoles	Resistance within the DMI group but NOT to other SBI classes.	G2/5	II	Amines (morpholine s)	Morpholines, piperidines, spiroketal-amines	Cross-resistance within the group generally found but not to other SBI classes.
FRAC Code	SBI Class	Group Name	Chemical Group	Cross-resistance												
G1/3	I	DMI (DeMethylat ion Inhibitors)	Piperazines, pyridines, pyrimidines, imidazoles, triazoles	Resistance within the DMI group but NOT to other SBI classes.												
G2/5	II	Amines (morpholine s)	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
<p>Therefore, fungal pathogen strains that are resistant to DMI fungicides are unlikely to be cross-resistant to other SBI class fungicides and vice versa.</p> <p>The overall resistance risk is composed of three factors: the agronomical risk, the intrinsic fungicide risk and the pathogen risk as described in the FRAC Pathogen Risk List.</p> <p><u>In the opinion of Evaluator, the following strategy against developing resistance should be put in the label:</u></p> <ul style="list-style-type: none"> <li>- use the product mainly as a preventive measure,</li> <li>- not use the product in doses other than recommended,</li> <li>- inclusion in the adopted protection programme of fungicides containing active substances from other groups, with different mechanisms of action (alternate use or tank mix).</li> </ul> <p><b>In conclusion, if SIP41061 (prothioconazole 400 g/L) is used according to the label instructions, the risk of the target pathogens developing resistance to the active ingredient within SIP41061 can be considered acceptable.</b></p> <p>Powdery mildew fungi (<i>Erysiphales</i>) are among the most common and important plant fungal pathogens. These fungi are obligate biotrophic parasites that attack nearly 10,000 species of angiosperms, including major crops, such as cereals and grapes.</p> <p>The FRAC and the European and Mediterranean Plant Protection Organization (EPPO) have classified powdery mildew species depending on the risk of the pathogen developing resistance to fungicides under specific agronomic conditions. In this regard, <i>Blumeria graminis</i> (wheat and barley powdery mildew), <i>E. necator</i> (powdery mildew of grape) and <i>P. xanthii</i> (cucurbit powdery mildew) are considered to be pathogens with high risk of resistance development because they show short disease cycles per season, their dispersal through conidia over time and space is high, and they have evolved resistance to several classes of fungicides after a few years of product use. These characteristics make these pathogens serious threats to the commercial success of site-specific fungicides. Other species, such as <i>Leveillula taurica</i> and <i>Oidium neolycopersici</i> (tomato powdery mildews), <i>Sphaerotheca macularis</i> (powdery mildew of several hosts) and <i>Sphaerotheca mors-uvae</i> (gooseberry powdery mildew), possess medium risk, meaning that resistance is not a major problem or has been slow to develop, and for this reason, in commercial practice, fungicide resistance has not created major disease control problems. For other powdery mildews, such as <i>Podosphaera leucotricha</i> (powdery mildew of apple), resistance against only a small number of chemical classes has been observed; therefore, this species is considered to be a low-risk pathogen with low importance in commercial market terms. Although cultural and biological practices may reduce the risk of infection by powdery mildew, they do not provide sufficient protection. Therefore, in practice, chemical control, including the use of fungicides from multiple chemical groups, is the most effective tool for managing powdery mildew. Unfortunately, the risk of resistance development is high because typical spray programs include multiple applications per season. In addition, some of the most economically destructive species of powdery mildew fungi are considered to be high-risk pathogens and are able to</p>					



	<p>develop resistance to several chemical classes within a few years. In addition, the molecular mechanisms underlying resistance to fungicides are also outlined. Finally, a number of recommendations are provided to decrease the probability of resistance development when fungicides are employed.</p> <p>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.</p>
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### 3.4 Adverse effects on treated crops (KCP 6.4)

Information on adverse effect are provided from efficacy trials.

#### 3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

##### 3.4.1.1 Phytotoxicity on CUCURBITS

Phytotoxicity was investigated on cucurbits for the application of SIP41061 at the proposed range of rates of 0.2 L/ha and 0.3 L/ha (0.1 1/10000 m<sup>2</sup> and 0.12 1/10000 m<sup>2</sup> in leaf wall area) in efficacy trials. The reference standards used in efficacy trials is based on penconazole (100-200 gai/L) applied at 0.25-0.5 L/ha, or based on azoxystrobin (250 gai/L) applied at 0.7 L/ha or 0.8 L/ha.

Table 3.4-1 lists the efficacy trials and varieties where the assessment of phytotoxicity was performed, either as a data set containing values or within the comments section.

**Table 3.4-1: Varieties of Cucurbits in efficacy trials where phytotoxicity assessment was performed**

SIP41061 (prothioconazole 400 g/L)						
Trial ID	Variety	G/F	ED/IN peel	EPPO zone	Remarks	Presence of disease
NL20-SIP-103-02	Lausanne	GREENH	ED	EPOMAR	Max 37.5 % PHYCHL	Yes
S21-02557-01	Black beauty	GREENH	ED	EPOMAR	No symphtoms	Yes
21 1069 5185	Euphoria RZ	GREENH	ED	EPOMAR	No symphtoms	Yes
GE20-SIP-103-03	Euphoria RZ	GREENH	ED	EPOMAR	No symphtoms	Yes
21 1069 5186	Leila	GREENH	ED	EPOMAR	No symphtoms	Yes
S21-02557-02	Sonja	GREENH	ED	EPOMAR	No symphtoms	Yes
21F FCUOXO FR09	TANJA	GREENH	ED	EPOMAR	No symphtoms	Yes
20F FCUOXO FR12	ROCKKER	GREENH	ED	EPOMAR	No symphtoms	Yes
F1913-1	Granada	GREENH	ED	EPOMED	No symphtoms	Yes
F2117-2	Lucia	GREENH	ED	EPOMED	No symphtoms	Yes
F2116-2	Lucía	GREENH	ED	EPOMED	No symphtoms	Yes
F2117-1	Lucía	GREENH	ED	EPOMED	No symphtoms	Yes
F2034-9	Poseidón	GREENH	ED	EPOMED	No symphtoms	Yes
SO2131 (AGL21FR236)	Satellite	GREENH	ED	EPOMED	No symphtoms	Yes
F2034-11	Sinatra	GREENH	ED	EPOMED	No symphtoms	Yes
F2034-12	Sinatra	GREENH	ED	EPOMED	No symphtoms	Yes
F2034-10	Urano	GREENH	ED	EPOMED	No symphtoms	Yes
F2116-1	Verdena	GREENH	ED	EPOMED	No symphtoms	Yes
20F FCUOXO FR09	SATELLITE	GREENH	ED	EPOMED	No symphtoms	Yes
F2034-3	Augusta	GREENH	IN	EPOMED	No symphtoms	Yes
F2034-4	Augusta	GREENH	IN	EPOMED	No symphtoms	Yes
AGG_20_41061_CUMME_PODOXA_1	EGNAZIO F1	GREENH	IN	EPOMED	No symphtoms	Yes
F2034-1	Galia	GREENH	IN	EPOMED	No symphtoms	Yes
F2034-2(168)	Galia	GREENH	IN	EPOMED	No symphtoms	Yes

Some phytotoxicity symptoms are assessed in two trials in terms of general injury (PHYGEN) caused by

SIP41061 at the proposed range of rates of 0.2 L/ha and 0.3 L/ha.

Summary of results on cucurbits relative to phytotoxicity assessments coded with PHY... in the relative detailed tables, are hereafter reported.

**Table 3.4-2: Phytotoxicity of SIP41061 on Cucurbits with edible peel – greenhouse**

CUCURBITS - edible peel / greenhouse			
Number of trials with...		Efficacy trials (n=19)	
		SIP41061	Ref. Standard
		N 0.2-0.3 L/ha	N rates
Maximum of phytotoxicity recorded during the trials	0% to 5%	19	19
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-
Level of symptoms at the last assessments	0% to 5%	19	19
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-

**Table 3.4-3: Phytotoxicity of SIP41061 on Cucurbits with inedible peel – greenhouse**

CUCURBITS - inedible peel / greenhouse			
Number of trials with...		Efficacy trials (n=5)	
		SIP41061	Ref. Standard
		N 0.2-0.3 L/ha	N rates
Maximum of phytotoxicity recorded during the trials	0% to 5%	5	5
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-
Level of symptoms at the last assessments	0% to 5%	5	5
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-

## Conclusion

**In cucurbits**, with edible and inedible peel, no phytotoxicity symptoms were recorded in all the efficacy trials presented.

Thus, it is concluded that no relevant adverse phytotoxic effects are expected from the use of SIP41061 at the proposed range of rates 0.2 L/ha and 0.3 L/ha (0.1 1/10000 m<sup>2</sup> and 0.12 1/10000 m<sup>2</sup> in leaf wall area) according to the GAP.

Comments of zRMS:	<p>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 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).</p> <p>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 specials studies are required in the opinion of Evaluator.</p> <p>The crop safety of applying SIP41061 at recommended doses was evaluated</p>
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	<p>during efficacy trials carried out in glasshouses conditions. So, trials from all EPPO zones can be assessed together.</p> <p><b>Cucurbits:</b></p> <ul style="list-style-type: none"> <li>- <i>edible peel</i>– 19 efficacy trials (in which phytotoxicity effect was studied). Effect of dose 0.2-0.3 L/ha was studied on cucumber (11 trials), zucchini (7 trials) and marrow squash (1 trial) in the glasshouses conditions. 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.</li> <li>- <i>inedible peel</i> – 5 efficacy trials (in which phytotoxicity effect was studied) carried out in glasshouses condition on melon (2 trials), watermelon (2 trials) and musk melon (1 trial). 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.</li> </ul> <p><b>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.</b></p>
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### 3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

Data on yield assessment, if available for efficacy trials, are presented in efficacy chapter.

Comments of zRMS:	<p>According to EPPO 1/57 – in the case of squash, the quantity, weight and quality of the fruits can be recorded for each plot of the experimental plot (or, if possible, for each plant) at each harvest date fruit. For melons, the content of sugar. For other crops, record the yields (and determine their quality, if possible, possibility) to get additional information on phytotoxicity and disease control. Describe the quality using national or international standards.</p> <p>During efficacy trials no assessment of yield was recorded. However, in the opinion of ZRMs it could be acceptable. No phytotoxicity of SIP41061 was noted during trials, so cucurbits crops can be assessed as a safe in the opinion of Evaluator. However, final decision is left to each cMS.</p>
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### 3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

No data on quality of plants are presented for Interzonal uses.

Comments of zRMS:	<p>According to EPPO 1/57 – in the case of squash, the quantity, weight, and quality of the fruits can be recorded for each plot of the experimental plot (or, if possible, for each plant) at each harvest date fruit. For melons, the content of sugar. For other crops, record the yields (and determine their quality, if possible, possibility) to get additional information on phytotoxicity and disease control. Describe the quality using national or international standards.</p> <p>During efficacy trials no assessment of quality of yield was recorded. However, in the opinion of ZRMs it could be acceptable. No phytotoxicity of SIP41061 was noted during trials, so cucurbits crops can be assessed as a safe in the opinion of</p>
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	Evaluator. However, final decision is left to each cMS.
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### 3.4.4 Effects on transformation processes (KCP 6.4.4)

No specific tests for effects on processing procedure conducted with SIP41061 formulation are available.

Nevertheless, no negative effects on crop products of target crops have been reported after the long-term use of products based on this active substance as a fungicide worldwide.

Comments of zRMS:	Since the market introduction no effects on transformation processes have been recorded for any of these products, nor no prothioconazole containing products have any label restrictions concerning their use on crops destined for processing. In the opinion of Evaluator, no undesirable effects are expected on transformation processes.
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### 3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

According to the EPPO PP 1/135(3) 'Phytotoxicity assessment', no data are required for fungicide foliar treatments applied before the inflorescence initiation such as SIP41061. Therefore, negative effects on plant parts used for propagating purposes (seeds) are not expected with SIP41061.

Furthermore, seeds obtained from target crop cultivations are not normally used for propagating purposes.

In conclusion, SIP41061 does not lead to unacceptable risk for parts of plants used for propagating purposes when applied according to the recommendations.

Comments of zRMS:	No phytotoxicity symptoms occurring during the field trials suggested that product application in accordance with label recommendation has no negative impact on parts of plant used for propagating purposes. Also, the fungicides containing active ingredients prothioconazole have been allowed to use for many years. The presented data correspond with the requirements of the EPPO Standards PP 1/135 and PP 1/243. Through the application of the fungicide with the active substances prothioconazole, in the mean no negative effects on the process and on treated plants or plant products used for propagation were detected. Based on this submitted data and on the expert knowledge about prothioconazole, it can be concluded to accept the data provided by the applicant. <b>According to the above statement additional research are not required in this range, in the opinion of Evaluator.</b>
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## 3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

### 3.5.1 Impact on succeeding crops (KCP 6.5.1)

SIP41061 is specifically designed as a fungicide product and there is no requirement for the evaluation of secondary effect on succeeding crops.

Moreover, the effects on vegetative vigour of SIP 41061 have been assessed testing plant species likely to be very sensitive to the active substance.

The summary and results have been detailed in Appendix 2 of core dRR Part B9, Report n° BT150/21.

No phytotoxic effects were observed. Application of the product according to the intended uses does not present an unacceptable risk for non-target terrestrial plants.

Therefore, as foreseen by EPPO PP1/207(2) no management practices to reduce the risk to rotational or replacement crops are required.

Comments of zRMS:	<p>A review of available literature as well as the lack of phytotoxicity symptoms recorded during the field trials suggest that product application in accordance with label recommendation shall not adversely impact on succeeding crops. Also, based on the absence of any adverse effects in typical cropping situations, it was concluded that the fungicide SIP41061 poses no risk to succeeding crops.</p> <p>Prothioconazole has a short half-life in soil. It is considered that adverse effects to succeeding crops from the use of SIP41061 are unlikely to occur. There is no restriction on the choice of succeeding crops. Therefore, no negative impact on succeeding crops is awaited if SIP41061 is used according to proposed GAP table.</p> <p><b>Based on this submitted data and expert knowledge about prothioconazole it can be concluded to accept the data provided by the Applicant.</b></p>
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### 3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

SIP41061 is specifically designed as a fungicide product and there is no requirement for the evaluation of secondary effect on adjacent crops.

Moreover, the effects on vegetative vigour of SIP 41061 have been assessed testing plant species likely to be very sensitive to the active substance.

The summary and results have been detailed in Appendix 2 of core dRR Part B9, Report n° BT150/21.

No phytotoxic effects were observed. Application of the product according to the intended uses does not present an unacceptable risk for non-target terrestrial plants. No mitigation measures are required.

Comments of zRMS:	<p>Prothioconazole is a well-known, documented and already authorised active substance. There are no concerns regarding the safety of SIP41061 (prothioconazole, 400 g/L, EC) to adjacent crops when applied according to the GAP. Drift onto adjacent crops should be avoided. However, due to the good safety of SIP41061 on plants, there is no risk for adjacent crop to become injured, even in case of improper applications. No negative effects of applications of prothioconazole containing products on adjacent crops are known, neither from field trials nor from long term agricultural use when the products were applied according to the use instructions. <b>According to the above statement additional research are not required in this range, in the opinion of Evaluator.</b></p>
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For the above-mentioned reasons and following the risk assessment scheme detailed in EPPO PP1/256, no further testing is herewith necessary.

#### Tank cleaning

The following calculation has been done according to Appendix 4 of EPPO PP 1/292 (1). Based on the example of a 1000 L spray tank, a water volume of 100 L/ha (extreme case considering recommended water volume indicated in the GAP) and the proposed maximum dose rate for SIP 41061 of 0.5 L/ha.

20 L of SIP 41061 would have been in the spray tank when full. It corresponds to 2000 g a.s./ha of prothioconazole. The amount left after spraying in the spray tank after use would be 2.6% which correspond to 52 g prothioconazole/ha. After the first stage of wash procedure with water, 2.6% of this residue would remain in the spray tank, which equates to 1.35 g prothioconazole/ha. The amount left after the second stage of washout procedure (2.6%) correspond to 0,035 g prothioconazole/ha.

If the spray tank was used again without further cleaning, filled to 1000 L and applied on the next crop at 400 L/ha to 2.5 ha, then 0.014 g prothioconazole/ha.

Based on the information presented in vegetative vigour study performed with SIP 41061 (Report n° BT150/21, detailed summary in Appendix 2 of dRR Part B9), all ER50 for all the tested species were > 570 g test item/ha (equivalent to 200.64 g a.s./ha – max dose rate per application).

Application of the product according to the intended uses does not present an unacceptable risk for non-target plants. No mitigation measures are required.

Therefore, according to the available data it is considered that the potential dose rate of 0.014 g prothioconazole/ha would have no adverse effects on any subsequently treated crops.

No further testing is necessary.

Comments of zRMS:	ZRMs agree with the Applicant.
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### 3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

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

Compatibility with current management practices including IPM

No specific studies submitted.

Comments of zRMS:	It may be concluded that there are no grounds for expecting a risk of damage to following crops due to application of SIP41061. Without any herbicide effect SIP41061 poses an acceptable risk to terrestrial non-target plants following the proposed uses.
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### Summary and conclusion

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.

### **3.6 Other/special studies (KCP 6.6)**

No other/special studies are submitted under this point.

Comments of zRMS:	Statement accepted.
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### 3.7 List of test facilities including the corresponding certificates

**Table 3.7-1: List of test facilities**

Country	Test facility	Hyperlink to make certificate download
Germany	BioChem agrar GmbH Niederlassung Agroplan	<a href="http://gepcertibase.eu/documents/GEP%20Zertifikat%20BC%20Uedem.pdf">http://gepcertibase.eu/documents/GEP%20Zertifikat%20BC%20Uedem.pdf</a>
		<a href="http://gepcertibase.eu/certificate/download/1d68f7c3a27">http://gepcertibase.eu/certificate/download/1d68f7c3a27</a>
	EAS Germany, Heidelberg	<a href="http://gepcertibase.eu/certificate/download/1d6914a91b4">http://gepcertibase.eu/certificate/download/1d6914a91b4</a>
	EUROFINS AGROSCIENCE SERVICES	<a href="http://gepcertibase.eu/certificate/download/1d6914a91b4">http://gepcertibase.eu/certificate/download/1d6914a91b4</a>
France	AGROLIS CONSULTING	<a href="http://gepcertibase.eu/documents/2306_GEP_agreement_AGROLIS_CONSULTING_France_2020_to_2025.pdf">http://gepcertibase.eu/documents/2306_GEP_agreement_AGROLIS_CONSULTING_France_2020_to_2025.pdf</a>
		<a href="http://gepcertibase.eu/certificate/download/1d691c7b092">http://gepcertibase.eu/certificate/download/1d691c7b092</a>
	PROMO-VERT AVIGNON	<a href="http://gepcertibase.eu/certificate/download/1d6cafb8d39">http://gepcertibase.eu/certificate/download/1d6cafb8d39</a>
	PROMO-VERT REIMS	<a href="http://gepcertibase.eu/certificate/download/1d6cafb8d39">http://gepcertibase.eu/certificate/download/1d6cafb8d39</a>
	PROMO-VERT TOURS	<a href="http://gepcertibase.eu/documents/1852_PROMOVERT_GEP_Certificate_2017_2022.pdf">http://gepcertibase.eu/documents/1852_PROMOVERT_GEP_Certificate_2017_2022.pdf</a>
Italy	AgriGeos s.r.l	<a href="http://gepcertibase.eu/certificate/download/1d6cafb8d39">http://gepcertibase.eu/certificate/download/1d6cafb8d39</a>
Spain	Agricultura y Ensayo S.L.	<a href="http://gepcertibase.eu/documents/GEP%20certificate%20for%20efficacy%20trials%202016-2021.pdf">http://gepcertibase.eu/documents/GEP%20certificate%20for%20efficacy%20trials%202016-2021.pdf</a>
		<a href="http://gepcertibase.eu/documents/GEP_certificate_for_efficacy_trials_2016-2021.pdf">http://gepcertibase.eu/documents/GEP_certificate_for_efficacy_trials_2016-2021.pdf</a>
	Agro Research Services	<a href="http://gepcertibase.eu/certificate/download/1d61704aece">http://gepcertibase.eu/certificate/download/1d61704aece</a>
	SIPCAM IBERIA S.L.	<a href="http://gepcertibase.eu/documents/2141_GEP%20Accreditation%20-%20Holder%20change%20-%20Renewal.pdf">http://gepcertibase.eu/documents/2141_GEP%20Accreditation%20-%20Holder%20change%20-%20Renewal.pdf</a>
		<a href="http://gepcertibase.eu/documents/2141_GEP_Accreditation_-_Holder_change_-_Renewal.pdf">http://gepcertibase.eu/documents/2141_GEP_Accreditation_-_Holder_change_-_Renewal.pdf</a>



## Appendix 1 Lists of data considered in support of the 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	Owner
KCP 6	Anonymous	2022	Biological Assessment Dossier for SIP41061	N	SIPCAM OXON S.P.A.
KCP 6.2/283	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	SIPCAM INAGRA S.A. and SIPCAM OXON S.P.A.
KCP 6.2/284	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	SIPCAM INAGRA S.A. and SIPCAM OXON S.P.A.
KCP 6.2/296	VERGNES Emilie	2020	protioconazole straight and mixtures: preventative activity against cucurbits powdery mildew 20F FCUOXO FR09 PROMO-VERT AVIGNON GEP Unpublished	N	SIPCAM OXON S.P.A.
KCP 6.2/297	VERDURON Aurore	2020	protioconazole straight and mixtures: preventative activity against cucurbits powdery mildew 20F FCUOXO FR12 PROMO-VERT TOURS GEP Unpublished	N	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	Owner
KCP 6.2/298	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	SIPCAM INAGRA S.A. and SIPCAM OXON S.P.A.
KCP 6.2/299	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	SIPCAM INAGRA S.A. and SIPCAM OXON S.P.A.
KCP 6.2/300	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	SIPCAM OXON S.P.A.
KCP 6.2/301	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	SIPCAM OXON S.P.A.
KCP 6.2/302	Michael Ingenerf	2021	SIP41061 against powdery mildew in cucumber (green house) 21 1069 5185 BioChem agrar GmbH Niederlassung Agroplan GEP Unpublished	N	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	Owner
KCP 6.2/303	TERZIEFF Frédéric	2020	protioconazole straight against cucurbits powdery mildew 21F FCUOXO FR09 PROMO-VERT REIMS GEP Unpublished	N	SIPCAM OXON S.P.A.
KCP 6.2/304	Manuel Román Moreno	2021	To test the efficacy and crop selectivity of SIP 41061 against Powdery Mildew (Podosphaera xanthii, Golovinomyces cichoracearum) on Cucumber F2116-1 Agricultura y Ensayo S.L. GEP Unpublished	N	SIPCAM INAGRA and SIPCAM OXON
KCP 6.2/305	Juan García	2021	To test the efficacy and crop selectivity of SIP 41061 against Powdery Mildew (Podosphaera xanthii, Golovinomyces cichoracearum) on Cucumber F2116-2 Agricultura y Ensayo S.L. GEP Unpublished	N	SIPCAM INAGRA and SIPCAM OXON
KCP 6.2/306	Sebastian Heinzmann	2021	Efficacy of SIP41061 against PODOXA in cucumber 2021 S21-02557-02 EAS Germany, Heidelberg GEP Unpublished	N	SIPCAM OXON S.P.A.
KCP 6.2/307	José Joaquín Sarrias	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 F2034-11 SIPCAM IBERIA S.L. GEP Unpublished	N	SIPCAM INAGRA S.A. and 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	Owner
KCP 6.2/308	José Joaquín Sarrias	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 F2034-12 SIPCAM IBERIA GEP Unpublished	N	SIPCAM INAGRA S.A. and SIPCAM OXON S.P.A.
KCP 6.2/309	Michael Ingenerf	2021	SIP41061 against powdery mildew in zucchini (poly tunnel) 21 1069 5186 BioChem agrar GmbH Niederlassung Agroplan GEP Unpublished	N	SIPCAM OXON S.P.A.
KCP 6.2/310	Manuel Román Moreno	2021	To test the efficacy and crop selectivity of SIP 41061 against Powdery Mildew (Podosphaera xanthii, Golovinomyces cichoracearum) on Zucchini F2117-1 Agricultura y Ensayo S.L. GEP Unpublished	N	SIPCAM INAGRA S.A. and SIPCAM OXON S.P.A.
KCP 6.2/311	Juan García	2021	To test the efficacy and crop selectivity of SIP 41061 against Powdery Mildew (Podosphaera xanthii, Golovinomyces cichoracearum) on Zucchini F2117-2 Agricultura y Ensayo S.L. GEP Unpublished	N	SIPCAM INAGRA S.A. and SIPCAM OXON S.P.A.
KCP 6.2/312	Clemens Groth	2021	Efficacy of SIP41061 against PODOXA/ERYSCI in courgette 2021 S21-02557-01 EUROFINS AGROSCIENCE SERVICES GEP Unpublished	N	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	Owner
KCP 6.2/313	Mrs Laure BELLO	2021	To evaluate the efficacy of prothioconazole against powdery mildew in cucurbits in Mediterranean zone. AGL21FR236 AGROLIS CONSULTING GEP Unpublished	N	SIPCAM OXON S.P.A.
KCP 6.2/317	G. Di Raimondo	2020	Efficacy and selectivity evaluation of SIP 41061, SIP41099 and SIP41100 (Prothioconazole) in preventative activity against powdery mildew in greenhouse Melon AGG-20_CUMME_PODOXA_1 Agrigeos srl GEP Unpublished	N	SIPCAM OXON S.P.A.
KCP 6.2/318	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 F2034-1 Agricultura y Ensayo S.L. GEP Unpublished	N	SIPCAM INAGRA S.A. and SIPCAM OXON S.P.A.
KCP 6.2/319	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 F2034-2 Agricultura y Ensayo S.L. GEP Unpublished	N	SIPCAM INAGRA S.A. and SIPCAM OXON S.P.A.
KCP 6.2/320	Ester Rubio	2019	EVALUATION OF EFFICACY AND SELECTIVITY OF SEVERAL FUNGICIDES FOR THE CONTROL OF Sphaerotheca fuliginea IN PROTECTED CUCUMBER. SPAIN, 2019 F1913-1 Métodos Servicios Agrícolas S.L. GEP Unpublished	N	SIPCAM IBERIA

