

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: SIP 41061

Product name: SIP 41061

Chemical active substance:

Prothioconazole 400 g/L SC

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Sipcam Oxon S.p.A

Submission date: April 2022

MS Finalisation date: March 2023; June 2023

Version history

When	What
April 2022	Submission date
March 2023	zRMS evaluated dRR submitted by Applicant.
June 2023	ZRMs made changes in RR according to commenting period.

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0 Product background, regulatory context and GAP information

0.1 Introduction

This document summarises the information related to the product background, the regulatory context and GAP information for the plant protection product SIP 41061 containing the active substance Prothioconazole which was included in Annex I to Directive 91/414/EEC on 1 August 2008 by Commission Directive 2008/44/EC of 4 April 2008, and has 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.

Where appropriate this document refers to all the EFSA Scientific Peer Review Conclusions and the Review Reports for the active substance prothioconazole are considered to provide the relevant review information or a reference to where such information can be found.

Note: this Part B document only reviews data (Annex II or Annex III) and additional information that has not previously been considered within the EU review process, as part of the Annex I inclusion decision. New annex II data must only be included if they are considered essential for the evaluation and in this case a full study summary must be provided.

The dRR is for an application of the registration of SIP 41061, for use as a fungicide in rice, wheat, barley, oil seed rape, sugar beet, peas & beans, chickpea (fresh legumes and dry seed, pulses), carrot (other roots and tubers vegetables), cucurbits edible peel, cucurbits unedible peel, pome fruits, stone fruits, and almond.

0.1.1 Reason for application

This dossier is submitted for zonal registration of SIP 41061 in accordance with Article 33 of Regulation (EC) No. 1107/2009. The application is supported by studies owned by the applicant as well as references to the DAR of the active substance and by letters of access released to the applicant.

SIP 41061 is a SC formulation containing 400 g/L prothioconazole and acts as fungicide herbicide. SIP 41061 was not the representative formulation of the EU review. The product is a new product not previously evaluated.

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

The application is supported by own data, with reference to data out of protection and by letters of access released to the applicant.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
Northern zone	Not applicable	Not Applicable
Central zone	zRMS Poland	cMS1 Germany cMS2 Hungary cMS3 Romania cMS4 Netherland cMS5 Austria cMS6 Belgium cMS7 Czech Republic cMS8 Ireland
Southern zone	zRMS Greece	cMS1 Italy cMS2 Spain cMS3 Portugal cMS4 France cMS5 Bulgaria
Inter-zonal	Not applicable	Not Applicable

0.1.3 Regulatory history of the active

0.1.3.1 Prothioconazole

Table 0.1-2: Summary of regulatory history of CAS No: 99129-21-2

Status	
Approved in EU	Yes
Original Inclusion Directive or Commission Implementing Regulation	COMMISSION DIRECTIVE 2008/44/EC of 4 April 2008 – COMMISSION IMPLEMENTING REGULATION (EU) No 540/2011 of 25 May 2011. Extension of approval Regulation (EU) 2021/745 2022/708
RMS	Poland
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/08/2008
Current expiration of approval	31/07/2022 31/07/2023
Low risk substance or Candidate for Substitution?	No

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

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

The concerned Member States shall request the submission of:

- information to allow the assessment of consumer exposure to triazole metabolite derivatives in primary crops, rotational crops, and products of animal origin,
- a comparison of the mode of action of prothioconazole and the triazole metabolite derivatives to allow the assessment of the toxicity resulting from the combined exposure to these compounds,
- information to further address the long-term risk to granivorous birds and mammals arising from the use of prothioconazole as a seed treatment.

Table 0.1-3: Information on minimum purity of Prothioconazole

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
≥ 970 g/kg	980 g/kg minimum purity of active substance Equivalence report available: Y RMS: NL (2019)
	980 g/kg minimum purity of active substance Equivalence report available: Y RMS: NL (2019)

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

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

0.1.3.2 Active substance 2

Not necessary

0.1.4 Regulatory history of the product

Not relevant as the product has not been authorised yet.

0.2 zRMS conclusion

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

Efficacy section: all

Residues section: 1-4, 8

Environmental fate and behavior section: 1-8

Ecotoxicology section: 1-8

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

Efficacy section: none

Residues section: 5-7

Environmental fate and behavior section: none

Ecotoxicology section: none

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

Residues section: none

Ecotoxicology: all without cucurbits in greenhouse.

Conclusions:

Physical-chemical section:

Data gap: The 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:

Detailed assessment is presented in dRR B3. Final decision about acceptance or not uses included in GAP table, was left by ZRMs to cMS. 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 ER-YSHE) 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 and stone fruits, ~~cucurbits with edible peel.~~

Intended 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. This data can be submitted at national level. In Poland use is accepted by the evaluator.

Fate and behaviour:

the SIP 41061 does not pose any risk to groundwater for prothioconazole and its metabolites for proposed uses 1-8.

Ecotoxicology:

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

A product SIP 41061 in ecotoxicology section approved for use in cucurbits edible peel only in greenhouses with a durable structure, isolated from the ground.

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

Appendix 1 GAP - ALL intended uses

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

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: developmen- tal 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 mix- tures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between appli- cations) 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	Central EU (DE, PL, CZ, RO, HU, BE, NL, AT, IE)	Wheat (Soft, Durum), Triticale, Rye TRZSS, TTLSS, SECSS	F	<i>Septoria trititic</i> spp. (SEPTTR) <i>Fusarium</i> spp. FUSASP <i>Puccinia</i> spp. PUC CSP PUCCRE/PUC CRT; PUC CST <i>Erysiphe</i> spp. <i>Blumeria</i> <i>graminis</i> ERY SSP ERY- SYGR	Spray	BBCH 29-69	a) 2 (14)	a) 0.5 b) 1.0	a) 200 b) 400	200- 600 200- 300	21 35	Eff. section: In PL soft and durum wheat, triticale, rye – not accepted. <i>Erysiphe</i> spp.is not accepted in PL, To be confirmed by cMS. Accepted water volume: 200-300 L/ha. DE accepted only wheat against SEPTTR, SEPTTR, PUCCRE/PUC CRT and PUC CST. AT not accepted rye and triticale. 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: developmen- tal 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 mix- tures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between appli- cations) 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	Central EU (DE, PL, CZ, RO, HU, BE, NL, AT, IE)	Barley HORVX	F	<i>Rhynchosporium secalis</i> RHYNSE <i>Puccinia hordei</i> PUCCHD <i>Pyrenophora teres</i> (Helmin- thosporium spp.) PYRNTE	Spray	BBCH 29-61 BBCH 30-49	a) 2 (14)	a) 0.5 b) 1.0	a) 200 b) 400	200-600 200-300	21 35	Eff. section: In PL, PUCCHD is not accepted. To be con- firmed by cMS Accepted BBCH 30-49 and water volume: 200-300 L/ha. DE accepted only PYRNTE and RHYNSE. Metabolism and residues: PHI of 35 is acceptable
3	Central EU (DE, CZ, PL, HU, RO, BE, AT, IE)	Oilseed rape BRSNN	F	<i>Sclerotinia SCLESC</i> <i>Phoma LEPTSP</i> <i>Pyrenopeziza PYRPSP</i> <i>Oidium OIDISP</i>	Spray	BBCH 30-71 BBCH 60-69	a) 2 (14)	a) 0.45 b) 0.9	a) 180 b) 360	200-600 200-300	50	Eff. section: In PL and DE only SCLESC is accepted. To be confirmed by cMS. Accept- ed BBCH: 60-69 and water volume: 200-300 L/ha. AT agrees that only a use against Sclerotinia should be recom- mended. Between BBCH 60- 69 only one application recommended in Austria. Metabolism and residues: 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. This data can be submitted at national level.. In Poland use is accepted.

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: developmen- tal 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 mix- tures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between appli- cations) 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	Central EU (DE, NL, BE, PL, CZ, AT, IE)	Sugar beet BEAVA	F	<i>Cercospora beticola</i> CERCBE <i>Erysiphe betae</i> ERYSB	Spray	BBCH 39-49	a) 2 (14)	a) 0.4 b) 0.8	a) 180 b) 320	200-600 200-300	28	Eff. section: In PL and DE only CERCBE is accepted. Erysiphe betae can be accepted only in line to Article 51. To be confirmed by cMS. Accepted water volume: 200-300 L/ha.
5	Central EU (NL, DE, AT)	Cucurbits edible peel CUMSS, CUUPG	G*	Oidium (Podosphaera xanthii, Gelovinomycetes eichoracearum, Sphaerotheca fuliginea) Fusarium spp Powdery mildew	Spray	BBCH 11-89 BBCH 20-89	a) 3 (10)	a) 0.3 b) 0.9	a) 120 b) 360	200-600 500-600	10	Eff. section: To be confirmed by cMS. Accepted BBCH 20- 89 and water volume 500-600 L/ha. Powdery mildew should be pest controlled only. Details in B3. Dose LWA should be clarified at cMS level Metabolism and residues: Use not accepted.. MRL exceedance is possible. use is not sufficiently support- ed by field trials.
6a	Central EU (PL, HU, DE, BE, AT, IE)	Pome fruits (Apple, Quince, Medlar) MABSS, CYDOB, MSPGE	F	Scab VENTIN Stemphylium PLEOAL Oidium PODOLE	Spray	BBCH 39-85 BBCH 51-79	a) 2 (7-9)	a) 0.3 b) 0.6	a) 120 b) 240	500- 1500 500- 1000	14	Eff. section: Stemphylium and Oidium in PL not accepted. Quince and medlar can be accepted only in line to Article 51 against all pests.. To be confirmed by cMS. Accepted BBCH: 51-79 and water volume: 500-1000 L/ha. Dose LWA should be clarified at cMS level Metabolism and residues: Use not accepted. MRL exceedance is possible.

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: developmental 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		
6b	Central EU (PL, HU, DE, BE, AT, IE)	Pome fruits (Pear) PYUCO	F	Scab VENTIN Stemphylium PLEOAL Oidium PODOLE	Spray	BBCH 39-85 BBCH 51-79	a) 2 (7-9)	a) 0.3 b) 0.6	a) 120 b) 240	500- 1500 500- 1000	21	Eff. section: Pear in PL can be accepted only in line to Article 51. To be confirmed by cMS Accepted BBCH: 51-79 and water volume: 500-1000 L/ha. Dose LWA should be clarified at cMS level Metabolism and residues: Use not accepted. MRL exceedance is possible.
7	Central EU DE, PL, HU, AT	Stone fruits (Plum, Cherry, Apricot) PRNDO, PRNAV, PRNAR	F	<i>Sphaerotheca</i> spp SPHRPA <i>Monilia</i> spp. MONILA	Spray	BBCH 51-85 BBCH 71-89	a) 2 (7)	a) 0.4 b) 0.8	a) 160 b) 320	500- 1500 500- 1000	3	Eff. section: In PL only <i>Monilia</i> spp is accepted on cherry and plum. <i>Sphaerotheca</i> spp and apricot can be accepted only in line to Article 51, To be confirmed by cMS. Accepted BBCH 71-89 and water volume: 500-1000 L/ha. Dose LWA should be clarified at cMS level Metabolism and residues: Use not accepted. MRL exceedance is possible. Ecotoxicology section: In stone fruit only BBCH 51-70 is accepted.

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: developmen- tal 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 mix- tures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between appli- cations) 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		
8	Central EU (PL, RO, NL, BE, AT, IE)	Carrot (0213020) and other roots and tuber vegetables (beetroots 0213010; horse rad- ishes 0213040; pars- nips 0213060; parsley roots 0213070; salsi- fies 0213090; swedes 0213100; turnips 0213110)	F	Leaf blight (<i>Alternaria dauci</i>) ALTEDA Sclerotinia rot (<i>Sclerotinia sclerotiorum</i>) SCLESC Powdery mildew (<i>Erysiphe heraclei</i>) ERYSH	Spray	BBCH 16-46 BBCH 41-49	a) 2 (21)	a) 0.5 b) 1.0	a) 200 b) 400	500- 1000 600	21	Eff section: SCLESC on carrot and other roots and tubers vegetables can be accepted in PL only in line to Article 51. To be confirmed by eMS. Accepted BBCH 41-49. Accepted water volume 500- 600 L/ha.

**Remarks
columns:**

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|---|--|
| <p>1 Numeration necessary to allow references</p> <p>2 Use official codes/nomenclatures of EU Member States</p> <p>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)</p> <p>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</p> <p>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.</p> <p>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.</p> | <p>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</p> <p>8 The maximum number of application possible under practical conditions of use must be provided. Minimum interval (in days) between applications of the same product</p> <p>9 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.</p> <p>10 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).</p> <p>11 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".</p> <p>12 PHI - minimum pre-harvest interval</p> <p>13 Remarks may include: Extent of use/economic importance/restrictions</p> |
|---|--|

* Ecotoxicology section: A product SIP 41061 in ecotoxicology section approved for use in cucurbits edible peel only in greenhouses with a durable structure, isolated from the ground **(not intended for the walk-in tunnels).**