

FINAL REGISTRATION REPORT

Part B

Section 1: Identity

Section 2: Physical and chemical properties

Section 4: Further information

Detailed summary of the risk assessment

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 of use)

Applicant: Sipcam Oxon S.p.A.

Submission date: May 2023

MS Finalisation date: January 2023; June 2023

Version history

When	What
April 2022	Applicant version submission date
January 2023	Initial zRMS assessment
May 2023	dRR update according to MS comments highlighted in yellow
June 2023	Final RR after commenting phase

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zRMS comments:

Submitted data are sufficient for evaluation.

Data gap: 2 years shelf-life study is on-going (ending date: 2023). Results after accelerated and 6 months storage demonstrate the stability of a.s. and characteristics of the formulation on storage. Conditional registration of the product is possible and proposed for 2 years.

Packaging: preparation is to be packed in containers made of PA/PE, which were used in storage studies and remained unaffected. Proposed packaging type is considered acceptable.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Sipcam Oxon S.p.A.
Address: Via Sempione 195, 20016 Pero (MI), Italy
Contact: ---
Telephone number: + ...
Fax: +...
E-mail: ---

1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

1.2.1 Producer of the preparation

Name: Sipcam Oxon S.p.A.
Address: Via Sempione 195, 20016 Pero (MI), Italy
Phone number: +39 02 35378205
Fax number: +39 02 3390275
Email:

Confidential information on manufacturing site is provided separately (Part C).

1.2.2 Producers of the active substances

Producer 1

Name	Hailir Pesticides and Chemicals Group Co., Ltd.,
Address	n. 216 Guocheng Road Chengyang District 266109 Qingdao China
Phone number	+86 532 58659173
Email	-

Location of manufacturing plant: confidential information provided separately (Part C).

Producer 2

Name Anhui JiuYi Agriculture Co., Ltd.
Address Hefei Circulate Economy Zone
Hefei City
Anhui Province
231602
China
Phone number +86 551-65596131
Email [...](#)

Location of manufacturing plant: confidential information provided separately (Part C).
Please refer to the Letter of Access provided in part A.

1.2.3 Statement of purity (and detailed information on impurities) of the active substances

1.2.3.1 Active substance

Prothioconazole	Commission Directive 2008/44/EC of 4 April 2008	Equivalence obtained under 20181143 PWSG of 9 May 2019 (Hailir Pesticides and Chemicals Group Co., Ltd.)*	Equivalence obtained under 20181688 PWSG of 21 February 2019 (Anhui JiuYi Agriculture Co., Ltd.)*
	min. 970 g/kg	min. 980 g/kg	min. 980 g/kg

Relevant impurities ¹

Toluene max. 5.0 g/kg

Prothioconazole-desthio max. 0.5 g/kg

1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name: please refer to Registration Report Part A for the relevant country

Product Name -
Company code number: SIP 41061
Function Fungicide
Applicant Sipcam Oxon S.p.A.
Composition Prothioconazole 400 g/L

¹ : Commission Directive 2008/44/EC of 4 April 2008

Formulation type SC
Packaging 0.25 L, 0.5 L, 1 L, 2 L, 5 L, 10 L, 20 L

1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

Table 1.4-1: Active substances and variants of the active substances

Active substance	Declared content of the pure active substance (g/L)	FAO Limits (min – max)	Technical content* (g/L)	Technical content** (% w/w)
Prothioconazole	400.0	380 – 420	408.2	35.13

* based on the minimum purity of the active substance declared for registration in the active substance dossiers

** based on the density of the formulation = 1.162 kg/L

Table 1.4-2: Safener and synergists

Synergist	Declared content of the synergist (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
-	-	-	-	-
-	-	-	-	-

Table 1.4-3: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg) ¹
Toluene	max 1.72 g/kg
Prothioconazole-desthio	max 0.17 g/kg

1.4.2 Information on the active substance (KCP 1.4.2)

Table 1.4-4: Information on active substance

Type	Name/Code Number
ISO common name	Prothioconazole
CAS n.	178928-70-6
EC n.	605-841-2
CIPAC n.	745

¹ Commission Directive 2008/44/EC of 4 April 2008

1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

Composition and coformulants are CONFIDENTIAL information provided separately (Part C).

1.5 Type and code of the plant protection product (KCP 1.5)

Type: Suspension concentrate

Code: SC

1.6 Function (KCP 1.6)

Fungicide

2 Section 2: Physical, chemical and technical properties of the plant protection product

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a light ivory homogeneous liquid with characteristic odour. It is not explosive, has no oxidising properties. The product has no flash point. It has a pH value of 2.8 when undiluted, of 3.6 in 1% aqueous solution and an acidity value of 1.31% w/w, expressed at H₂SO₄. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredients content nor the technical properties changed. A shelf life study for 2 years at ambient temperature when stored in the packaging material used for commercialization is ongoing; data at six months are available and the product still complies with the original starting quality. Its technical characteristics are acceptable for a CS formulation.

The intended concentration of use is ~~0.005% to 0.1%~~ 0.02 – 0.25 % (v/v).

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

None.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

None.

Compliance with FAO specifications:

The product SIP 41061 complies with FAO specifications.

Formulation used for tests

The product used in the tests has the same composition as the one cited in Part C.

Table 2-1: Physical, chemical and technical properties of the plant protection product

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Subjective assessment	SIP 41061 batch 20006/P02	Homogeneous liquid Colour: RAL 1015, light ivory Odour: characteristic PA/PE plastic bottle	Y	Massardi E. (2021)	Accepted
Explosive properties (KCP 2.2.1)	(EC) 440/2008, Annex Part A test A.14	SIP 41061 batch 20006/P02	Bam Fallhammer: Negative Koenen Tube: Negative	Y	Younis S. (2021)	Accepted No reaction (explosion) was observed Considered non-explosive
Oxidizing properties (KCP 2.2.2)	(EC) 440/2008, Annex Part A test A.21	SIP 41061 batch 20006/P02	not classified as an oxidising liquid.	Y	Younis S. (2021)	Accepted No oxidising properties
Flash point (KCP 2.3.1)			not required since SIP 41061 is a water based formulation			Although test is a requirement, based on the formulation composition and MSDSs, SIP 41061 is considered non-flammable
Flammability (KCP 2.3.2)			not required since SIP 41061 is a liquid formulation			Not required
Self-heating (KCP 2.3.3)	(EC) 440/2008, Annex Part A test A.15	SIP 41061 batch 20006/P02	T = 443°C	Y	Younis S. (2021)	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																											
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 191	SIP 41061 batch 20006/P02	1.31% (at 25.0 ± 0.5°C)	Y	Massardi E. (2021)	Accepted																											
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	SIP 41061 batch 20006/P02	pH (undiluted): 2.8 (at 25.0 ± 0.5°C) pH (diluted 1% w/v): 3.6 (at 25.0 ± 0.5°C)	Y	Massardi E. (2021)	Accepted																											
Viscosity (KCP 2.5.1)	CIPAC MT 192	SIP 41061 batch 20006/P02	<div>The test item is a non-Newtonian fluid:<table><tr><td></td><td colspan="2">Mean dynamic viscosity (cP)</td></tr><tr><td>speed (rpm)</td><td>20°C</td><td>40°C</td></tr><tr><td>0.3</td><td>36058.7</td><td>22895.0</td></tr><tr><td>0.6</td><td>22128.3</td><td>14913.7</td></tr><tr><td>1.5</td><td>11304.7</td><td>8144.7</td></tr><tr><td>3.0</td><td>6479.0</td><td>4932.3</td></tr><tr><td>6.0</td><td>3785.7</td><td>3035.7</td></tr><tr><td>12.0</td><td>2160.7</td><td>1795.0</td></tr><tr><td>30.0</td><td>-</td><td>877.1</td></tr></table></div>		Mean dynamic viscosity (cP)		speed (rpm)	20°C	40°C	0.3	36058.7	22895.0	0.6	22128.3	14913.7	1.5	11304.7	8144.7	3.0	6479.0	4932.3	6.0	3785.7	3035.7	12.0	2160.7	1795.0	30.0	-	877.1	Y	Massardi E. (2021)	Accepted Non-Newtonian behaviour Dynamic viscosity can be converted to kinematic. Based on the results formulation is not considered an aspiration hazard
	Mean dynamic viscosity (cP)																																
speed (rpm)	20°C	40°C																															
0.3	36058.7	22895.0																															
0.6	22128.3	14913.7																															
1.5	11304.7	8144.7																															
3.0	6479.0	4932.3																															
6.0	3785.7	3035.7																															
12.0	2160.7	1795.0																															
30.0	-	877.1																															
Surface tension (KCP 2.5.2)	(EC) 440/2008 A.5 OECD 115	SIP 41061 batch 20006/P02	49.5 mN/m (sample diluted at 0.1% v/v)	Y	Massardi E. (2021)	Accepted Conducted at room temperature: 25°C ± 5 °C The highest concentration																											

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
								reommended should be tested (0.25 %) Considered as surface ative
Relative density (KCP 2.6.1)	(EC) 440/2008 A.3 OECD 109 CIPAC MT 3.3.2	SIP 41061 batch 20006/P02	Density: 1.162 g/cm ³ (20 ± 0.5)°C Relative density: 1.162			Y	Massardi E. (2021)	Accepted
Bulk density (KCP 2.6.2)			not required, since SIP 41061 is not solid					Not required
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3 OPPTS 830.6302, OPPTS 830.6303, OPPTS 830.6304 HPLC/UV-DAD GC/MS CIPAC MT 75.3, OECD 122 CIPAC MT 191, OECD 122 CIPAC MT 187 CIPAC MT 184.1 and MT	SIP 41061 batch 20006/P02	Test product is stable after 14 days at 54°C and it will most likely comply with the shelf life specification of 2 years. Furthermore, the obtained results in the physical chemical characterization for the test product are considered correct, since the changes observed are not significant and do not imply any critical change in the properties of the formulation. The following properties has been determined and assessed to remain unaltered:			Y	Massardi E. (2021)	Accepted Results demonstrate the stability of a.s. and characteristics of the formulation on storage. pH tested at room temp.: 25.0 ± 0.5°C Wet sieve study – recommended concentration was tested (10g/10mL, 10g/100mL) Suspensibility test
			measured property	t=0	after 2 weeks @ 54°C			
			appearance	light ivory homogeneous liquid with characteristic odour	unaltered			
			Prothioconazole	412.7 g/L	407.8 g/L			
			Prothioconazole-desthio	< 0.13 g/kg	< 0.13 g/kg			
			Toluene	0.049 g/kg	0.039 g/kg			
			pH (undiluted)	2.8	2.8			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
	18.1 CIPAC MT 160 and MT 18.1 CIPAC MT 185 CIPAC MT 148		pH (1% diluted)	3.6	3.6			<p>– 0.1% tested is the lowest concentration within the scope of the CIPAC method. The highest concentration recommended should also had been tested (0.25 %).</p> <p>Pourability results are outside the limit 5%. Still, rinsed residue is < 0.25 % limit and other characteristics are acceptable.</p> <p>Commercial packaging was used (PA/PE bottle) and it has remained unaltered.</p>
			acidity (expressed as H ₂ SO ₄)	1.31%	1.29%			
			particle size by laser diffraction	D (v, 0.5) = 0.604 µm D (v, 0.9) = 2.67 µm	D (v, 0.5) = 0.553 µm D (v, 0.9) = 2.47 µm			
			suspensibility (at 0.1% v/v)	99.0%	99.0%			
			spontaneity of dispersion (at 5% w/w)	98.5%	99.7%			
			wet sieve (on 75 µm sieve)	no residue	no residue			
			pourability	5.72%	5.36%			
			rinsibility	0.21%	0.16%			
			packaging material resistance	-	no deformation on bottom, top and lateral side, no loss of sample or evident corrosion phenomena			
Stability after storage for other periods and/or temperatures (KCP 2.7.2)			not necessary					Not required
Minimum content			not necessary					See KCP 2.7.1

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments	
after heat stability testing (KCP 2.7.3)									
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	SIP 41061 batch 20006/P02	Test product is stable after 7 days at 0°C since the following properties remained unaltered: appearance, pH value, acidity, suspensibility, wet sieve test			Y	Massardi E. (2021)	Accepted Not affected by low temperature	
			Suspensibility (CIPAC MT 184.1 and MT 18.1) (conc used: 0.1% v/v)		99.0%				
			Wet sieve test (CIPAC MT 185) (conc. used: 10g/10mL)		No residue on 75 µm sieve				
			Appearance and pH – no changes						
Ambient temperature shelf life (KCP 2.7.5)		SIP 41061 batch 20006/P02	Shelf life study ongoing			Y	Massardi E. (2021)	Data gap Ending date: 2023	
Shelf life in months (if less than 2 years) (KCP 2.7.6)	OPPTS 830.6302, OPPTS 830.6303, OPPTS 830.6304 HPLC/UV-DAD GC/MS CIPAC MT 75.3, OECD 122 CIPAC MT 191, OECD 122 CIPAC MT 187	SIP 41061 batch 20006/P02	An interim check point after six months at ambient temperature is available; the product has been assessed to be stable for the following parameters:			Y	Massardi E. (2021)	Accepted Results demonstrate the stability of a.s. and characteristics of the formulation on storage. pH tested at room temp.: 25.0 ± 0.5°C Wet sieve study – recommended concentration was	
			measured property		t=0				after 6 months @ room temperature
			appearance	light ivory homogeneous liquid with characteristic odour	unaltered				
			Prothioconazole	412.7 g/L	427.2 g/L				
			Prothioconazole-desthio	< 0.13 g/kg	< 0.13 g/kg				
			Toluene	0.049 g/kg	0.080 g/kg				
			pH (undiluted)	2.8	2.7				
			pH (1% diluted)	3.6	3.5				

Annex point	Method used / deviations	Test material	Findings						GLP Y/N	Reference	Acceptability / comments
	CIPAC MT 47.3 CIPAC MT 184.1 and MT 18.1 CIPAC MT 160 and MT 18.1 CIPAC MT 185 CIPAC MT 148		Acidity (expressed as H ₂ SO ₄)	1.31%	1.33%						tested (10g/10mL)
			particle size by laser diffraction	D (v, 0.5) = 0.604 µm D (v, 0.9) = 2.67 µm	D (v, 0.5) = 0.719 µm D (v, 0.9) = 3.08 µm						Suspensibility test – 0.1% tested is the lowest concentration within the scope of the CIPAC method. The highest concentration recommended should also had been tested (0.25 %).
			persistent foaming	dose	after 1 minute	after 12 minutes					Pourability results are outside the limit 5%. Still, rinsed residue is < 0.25 % limit and other characteristics are acceptable.
				0.005% v/v	2 mL	0 mL	4 mL	3 mL			Commercial packaging was used (PA/PE bottle) and it has remained unaltered.
				0.1% v/v	19 mL	16 mL	19 mL	17 mL			Conditional registration of the
			suspensibility (at 0.1% v/v)	99.0%	99.0%						
			spontaneity of dispersion (at 5% w/w)	98.5%	99.7%						
			wet sieve (on 75 µm sieve)	no residue	no residue						
			Pourability	5.72%	5.82%						
			rinsibility	0.21%	0.17%						
			packaging material resistance	-	no deformation on bottom, top and lateral side, no loss of sample or evident corrosion phenomena						

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						product is possible and proposed for 2 years.
Wettability (KCP 2.8.1)			not applicable			Not required
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	SIP 41061 batch 20006/P02	after 1 minute (0.005% v/v): 2 mL after 12 minute (0.005% v/v): 0 mL after 1 minute (0.1 % v/v): 19 mL after 12 minute (0.1 % v/v): 16 mL	Y	Massardi E. (2021)	Accepted Although the highest concentration recommended (0.25 %) was not tested, based on the results presented it can be assumed that for higher concentration the result would be also within the limit
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184.1	SIP 41061 batch 20006/P02	Prothioconazole suspensibility (at 0.1% v/v of dilution): 99.0%	Y	Massardi E. (2021)	Accepted Suspensibility test – 0.1% tested is the lowest concentration within the scope of the CIPAC method. The highest concentration recommended

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						should also had been tested (0.25 %).
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	SIP 41061 batch 20006/P02	Prothioconazole spontaneity of dispersion (at 5% w/w of dilution): 98.5%	Y	Massardi E. (2021)	Accepted Recommended concentration was tested
Dispersion stability (KCP 2.8.3.3)			not applicable			Not required
Degree of dissolution and dilution stability (KCP 2.8.4)			not applicable			Not required
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187 OECD 110	SIP 41061 batch 20006/P02	D[v, 0.1]: 0.191 µm D[v, 0.5]: 0.604 µm D[v, 0.9]: 2.67 µm	Y	Massardi E. (2021)	Accepted
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	SIP 41061 batch 20006/P02	no residue on 75 µm sieve	Y	Massardi E. (2021)	Accepted Recommended concentration was tested (10g/10mL 10g/100mL)
Dust content (KCP 2.8.5.2.1)			not applicable, SIP 41061 is liquid			Not required
Particle size of dust (KCP 2.8.5.2.2)			not applicable, SIP 41061 is liquid			Not required

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Attrition (KCP 2.8.5.3)			not applicable, SIP 41061 is liquid			Not required
Hardness and integrity (KCP 2.8.5.4)			not applicable, SIP 41061 is liquid			Not required
Emulsifiability (KCP 2.8.6.1)			not applicable, SIP 41061 is not an emulsifiable concentrate			Not required
Emulsion stability (KCP 2.8.6.2)			not applicable, SIP 41061 is not an emulsifiable concentrate			Not required
Re-emulsifiability (KCP 2.8.6.3)			not applicable, SIP 41061 is not an emulsifiable concentrate			Not required
Flowability (KCP 2.8.7.1)			not applicable			Not required
Pourability (KCP 2.8.7.2)	CIPAC MT 148	SIP 41061 batch 20006/P02	residue : 5.72% rinsibility: 0.21%	Y	Massardi E. (2021)	Accepted Although formulation is outside the residue limit (5%), still, rinsed residue is below max acceptable limit (0.25%). It is recommended to rinse the spray tank three times
Dustability following accelerated storage (KCP 2.8.7.3)			not applicable, SIP 41061 is liquid			Not required

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments										
Physical compatibility of tank mixes (KCP 2.9.1)			not requested			Not required										
Chemical compatibility of tank mixes (KCP 2.9.2)			not requested			Not required										
Adhesion to seeds (KCP 2.10.1)			not applicable			Not required										
Distribution to seed (KCP 2.10.2)			not applicable			Not required										
Other/special studies: corrosivity (KCP 2.11)	NACE/ASTM G31	Prothioconazole 400 SC batch n. 19090/P01	<div>detected corrosion rates after 7 days:</div> <table><tr><th>material</th><th>corrosion rate (mm/year)</th></tr><tr><td>carbon steel</td><td>0.0231</td></tr><tr><td>aluminium</td><td>0.0226</td></tr><tr><td>copper</td><td>0.0028</td></tr><tr><td>brass</td><td>0.0017</td></tr></table>	material	corrosion rate (mm/year)	carbon steel	0.0231	aluminium	0.0226	copper	0.0028	brass	0.0017	Y	de Pinho, S. (2020)	<div>Not required</div> <div>Accepted</div> <div>No classification required</div>
material	corrosion rate (mm/year)															
carbon steel	0.0231															
aluminium	0.0226															
copper	0.0028															
brass	0.0017															

3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

4 Section 4: Further information on the plant protection product

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

Table 4.1-1: Packaging information for 0.250 L bottle

Type	Description
Material:	PA/PE (external layer HDPE, internal layer PA)
Shape/size:	cylindrical bottle with a diameter of 62.5 mm and height of 127.0 mm
Opening:	44.5 mm diameter
Closure:	screw cap
Seal:	heat sealing disk
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-2: Packaging information for 0.5 L bottle

Type	Description
Material:	PA/PE (external layer HDPE, internal layer PA)
Shape/size:	cylindrical bottle with a diameter of 90.0 mm and height of 150.0 mm
Opening:	41.7 mm diameter
Closure:	screw cap
Seal:	heat sealing disk
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-3: Packaging information for 1 L bottle

Type	Description
Material:	PA/PE (external layer HDPE, internal layer PA)
Shape/size:	cylindrical bottle with a diameter of 88.5 mm and height of 234 mm
Opening:	41.6 mm diameter
Closure:	screw cap
Seal:	heat sealing disk
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-4: Packaging information for 2 L Jerrycan

Type	Description
Material:	PA/PE (external layer HDPE, internal layer PA)
Shape/size:	parallelepiped of length 142.0 mm, width 90.0 mm, height 236.0 mm
Opening:	43.5 mm inner diameter
Closure:	screw cap
Seal:	heat sealing disk
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-5: Packaging information for 5 L Jerrycan

Type	Description
Material:	PA/PE (external layer HDPE, internal layer PA)
Shape/size:	parallelepiped of length .0 mm, width 138.0 mm, height 305.0 mm
Opening:	54.0 mm diameter
Closure:	screw cap
Seal:	heat sealing disk
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-6: Packaging information for 10 L Jerrycan

Type	Description
Material:	PA/PE (external layer HDPE, internal layer PA)
Shape/size:	parallelepiped with depth 163.5 mm, width 255.0 mm, height 378.0 mm
Opening:	57.8 mm diameter
Closure:	screw cap
Seal:	heat sealing
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-7: Packaging information for 20 L Jerrycan

Type	Description
Material:	PA/PE (external layer HDPE, internal layer PA)
Shape/size:	parallelepiped with depth 243.0 mm, width 293.0 mm, height 397.0 mm
Opening:	54 mm diameter
Closure:	screw cap
Seal:	heat seal
Manner of construction	extruded
UN/ADR	compliant

For more information about packaging, please refer to KCP 4.4/01.

The packaging material has been chosen taking the properties of the product into account. SIP 41061 is not expected to react with the packaging materials, it does not contain any strong acidic or alkaline components or organic solvents and shelf life study assessed that physico-chemical properties are not negatively influenced by the contact with it.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1 - KCP 2.11 [submitted as KCP 2.1/01]	Massardi, E.	2021	SIP 41061 (PROTHIOCONAZOLE 400 g/L SC) Physical and chemical properties on fresh sample, after accelerated stability at +54°C for 14 days and after low stability at 0°C for 7 days Report n.: CPU-026-21 Research Center BioSphereS by Biotecnologie BT GLP not published	N	Sipcam Oxon S.p.A.
KCP 2.2.1 KCP 2.3.3 [submitted as KCP 2.2.1/01]	Wojsiat, P.	2021	Physical and Chemical Properties Testing on a Sample of SIP 41061 Report n.: GLP3016008493R1/2021 Dekra UK Ltd GLP not published	N	Sipcam Oxon S.p.A.
KCP 2.7.6	Massardi, E.	2021	SIP 41061 (PROTHIOCONAZOLE 400 g/L SC) Shelf life at room temperature – <i>checkpoint 6 months</i> Report n.: CPU-027-21 Research Center BioSphereS by Biotecnologie BT GLP not published	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 2.11/01	de Pinho, S.	2020	Prothioconazole 400 SC Determination of corrosivity in metals Report n.: RL19441/2019CV-B ALS Laboratorios LS Ltda GLP not published	N	Sipcam Oxon S.p.A.
KCP 4.4/01	Anonimous	-	PROTHIOCONAZOLE 400 g/L SC (SIP 41061) DESCRIPTION OF PACKAGING Report n.: - Sipcam Oxon S.p.A. not GLP not published	N	Sipcam Oxon S.p.A.

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner

Appendix 2 Additional data on the physical, chemical and technical properties of the active substance

A 2.1 Active substance

There are no new data on the physical and chemical properties of the active substance.