

FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: SHA 7273 A

Product name(s): CASINO ROYALE

Chemical active substances:

Boscalid, 267 g/kg

Pyraclostrobin, 67 g/kg

Cental Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: August 2020

MS Finalisation date: 08/2021; 01/2022

Version history

When	What
August 2021	Draft assessment by zRMS
January 2022	Final Registration Report after the commenting period

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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application was submitted by Sharda Cropchem España S.L.

This application is for approval of CASINO ROYALE, a water dispersible granule containing 267 g/kg of boscalid and 67 g/kg of pyraclostrobin, as a fungicide.

zRMS: Poland

1.2 Letters of Access

Not applicable. Letter of access not needed.

1.3 Justification for submission of tests and studies

This dossier relies on new tests and studies, providing data and information specific to the formulation CASINO ROYALE as required by the EU regulations.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No.1107/2009 as provided for in the list of references in Appendix 4.

2 Details of the authorization decision

2.1 Product identity

Product code	SHA 7273 A
Product name in MS	CASINO ROYALE
Authorization number	First authorization
Function	Fungicide
Applicant	Sharda Cropchem España S.L.
Active substance(s) (incl. content)	Boscalid; 267 g/kg Pyraclostrobin; 67 g/kg
Formulation type	Water dispersible granules [Code: WG]
Packaging	150 g, 300 g, 500 g bottle (HDPE) 1 Kg, 3 Kg and 5 Kg jerrycan (HDPE)

Coformulants of concern for national authorizations	-
Restrictions related to identity	-
Mandatory tank mixtures	-
Recommended tank mixtures	-

2.2 Conclusion

The evaluation of the application for CASINO ROYALE resulted in the decision to grant the authorization.

Efficacy section:

Use on sugar beet, tomato against ALTESP and carrot can be accepted according to Article 33. Following minor uses: beetroot, celery root, parsnip, parsley, radish, radish Horseradish, swedes/rutabagas, turnip, chicory roots, shallot, onion, aubergines/eggplants, ornamentals in field and greenhouses, redcurrant, white currant and salsifies can be accepted in line to Article 51. Also, onion and tomato against PHYTIN can be accepted with Art. 51. In Poland, on the basis on SIGNUM 33 WG, which was registered in Poland (R-33/2010, dated 19.04.2010), uses claimed in the GAP table (cabbage, tomato in greenhouses, strawberry, cherry, raspberry, blackcurrant) and Polish label project can be accepted on the basis on unprotected data.

Fate section:

No risk for ground water is expected following application Casino Royale according proposed GAP.

Ecotoxicology Section:

The risk for non-target organism I considered as an acceptable according proposed GAP. .

2.3 Substances of concern for national monitoring

Not relevant.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Eye Irrit. 2 Aquatic acute 1 Aquatic Chronic 1
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	GHS07, GHS09
Signal word:	Warning
Hazard statement(s):	H319, H400, H410
Precautionary statement(s):	P273, P391, P501

	<p>WARNING SECTION OF THE LABEL (first page): P280: Wear eye protection/face protection. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>Other section of the label: P270 – Do not eat, drink or smoke when using this product. P264 – Wash hands thoroughly after handling.</p> <p>And P280 as follows:</p> <p>OPERATOR: „Stosować rękawice ochronne oraz odzież ochronną, zabezpieczającą przed 1/ In case of uses in sugerbeets, tomatos, strawberries, ornamentals: “Stosować rękawice ochronne, ochronę oczu lub twarzy oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy użytkowej oraz odzież roboczą czasie wykonywania zabiegu.. W przypadku oprysku pomidorów w szklarniach stosować dodatkowo ochronę dróg oddechowych (min. maska FFP2).” “Wear protective gloves, eye/face protection and work wear (coverall) during mixing/loading and work wear during application. Use additional respiratory protection (minimum FFP2 mask) when spraying tomatoes in greenhouses” ”</p> <p>2/ In case of use in cherries: “Stosować rękawice ochronne, ochronę oczu lub twarzy oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy użytkowej oraz rękawice ochronne i odzież roboczą w czasie wykonywania zabiegu “Wear protective gloves, eye/face protection and work wear (coverall) during mixing/loading and protective gloves and work wear during application.</p> <p>WORKER: „Stosować rękawice ochronne i odzież roboczą (koszula z długim rękawem i długie spodnie) oraz nie wchodzić na teren poddany zabiegowi wcześniej niż: • po wyschnięciu preparatu na powierzchni roślin w przypadku uprawy: buraka cukrowego, marchwi, buraka, selera, pasternaku, pietruszki naciowej, rzod-kwi, chrzanu, brukwi, rzepy, korzenia cykorii, cebuli szalotki, topinamburu, salsefii, pomidora, cebuli, kapusty, bakłażana; • 2 dni po wykonaniu oprysku w przypadku uprawy: truskawki, maliny, porzeczki; • 2 dni po wykonaniu oprysku w przypadku uprawy: pomidor (szklarnia); • 6 dni po wykonaniu oprysku w przypadku uprawy: roślin ozdobnych; • 7 dni po wykonaniu oprysku w przypadku uprawy wiśni.</p> <p>Wear protective gloves, work wear (covered arms, body and legs) and do not enter the area treated with SHA 7273A: • until spray deposit on plant surfaces has dried in sugerbeet, carrot, beetroot, celery root, parsnip, parsley, radish, horseradish, swedes/rutabagas, turnip, chicory roots, shallot, Jerusalem artichokes, salsifies, tomato, onion, cabbage, aubergines/eggplants; • for 2 days in raspberry, blackcurrant, redcurrant, white currant; • for 2 days in tomato (indoor); • for 6 days in ornamentals; • for 7 days in cherries.</p> <p>Section “First Aid”:</p> <p>P101: If medical advice is needed, have product container or label at hand. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313: If eye irritation persists: Get medical advice/ attention.</p>
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Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
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Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
-	-

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	<p>Sugar beet, Fruiting vegetables and potato, Root vegetables and Bulb vegetables: To protect aquatic organisms respect an unsprayed buffer zone of 5 m to surface water bodies.</p> <p>Leafy vegetables: To protect aquatic organisms respect an unsprayed buffer zone of 10 m with 5m vegetative strip to surface water bodies.</p> <p>Apple (early application): To protect aquatic organisms respect an unsprayed buffer zone of 40 m to surface water bodies OR respect an unsprayed buffer zone of 30 m to surface water bodies with 50% of nozzles reduction OR respect an unsprayed buffer zone of 20 m to surface water bodies with 75% of nozzles reduction</p> <p>Vines (late application): To protect aquatic organisms respect an unsprayed buffer zone of 20 m to surface water bodies OR respect an unsprayed buffer zone of 10 m to surface water bodies with 75% of nozzles reduction OR respect an unsprayed buffer zone of 5 m to surface water bodies with 90% of nozzles reduction.</p>

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

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2.5 Risk management

2.5.1 Restrictions linked to the PPP

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

Operator protection:	
P280	<p>Classification: eye/face protection.</p> <p>Exposure:</p> <p>Work wear (arms, body and legs covered) M/L, gloves are recommended – sugarbeet, tomato, strawberry, ornamentals</p>

	Work wear (arms, body and legs covered) M/L+gloves M/L and A – cherry Work wear (arms, body and legs covered) M/L, gloves are recommended – greenhouses
Worker protection:	
P280	Work wear (arms, body and legs covered) – sugarbeet Work wear (arms, body and legs covered) and gloves – tomato Work wear (arms, body and legs covered) and gloves and Re-entry period of 2 days – starwberry Work wear (arms, body and legs covered) and gloves and Re-entry period of 6 days – ornamentals Work wear (arms, body and legs covered) and gloves and Re-entry period of 15 days – cherry. Bearing in minds that PHI value exceeds the assessed safy re-entry period, the proposed length of re-entry period is 7 days.
Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
SPe3	Sugar beet, Fruiting vegetables and potato, Root vegetables and Bulb vegetables: To protect aquatic organisms respect an unsprayed buffer zone of 5 m to surface water bodies. Leafy vegetables: To protect aquatic organisms respect an unsprayed buffer zone of 10 m with 5m vegetative strip to surface water bodies. Apple (early application): To protect aquatic organisms respect an unsprayed buffer zone of 40 m to surface water bodies OR respect an unsprayed buffer zone of 30 m to surface water bodies with 50% of nozzles reduction OR respect an unsprayed buffer zone of 20 m to surface water bodies with 75% of nozzles reduction Vines (late application): To protect aquatic organisms respect an unsprayed buffer zone of 20 m to surface water bodies OR respect an unsprayed buffer zone of 10 m to surface water bodies with 75% of nozzles reduction OR respect an unsprayed buffer zone of 5 m to surface water bodies with 90% of nozzles reduction.
Other specific restrictions	
-	-

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

Integrated pest management (IPM)/sustainable use:	
-	-

2.5.2 Specific restrictions linked to the intended uses

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

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

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code): CASINO ROYALE / SHA 7273 A
Active substance 1: Boscalid
Active substance 2: Pyraclostrobin
Safener: -
Synergist: -
Applicant: Sharda Cropchem España S.L.
Zone(s): Central
Verified by MS: yes/no
Field of use: Fungicide

Formulation type: GAP rev. 0, date: 2017-Septemeber-12th
 WG (Water Dispersible granules)

Conc. of as 1: 267 g/Kg
Conc. of as 2: 67 g/Kg
Conc. of safener: -
Conc. of synergist: -
Professional use: ☒
Non professional use: ☐

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. (e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (i)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between appli- cations (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

Zonal uses (field or outdoor uses, certain types of protected crops)													
1	CEU	Sugarbeet	F	<i>Cercospora beticola</i>	Foliar Spray	BBCH 31-39	a) 1-2 b) 1-2	8-10	a) 1.5 b) 3.0	a) 0.4 boscalid + 0.1 pyraclostrobin b) 0.8 boscalid + 0.2 pyraclostrobin	300-600	-	
2	CEU	Tomato	F	<i>Phytophthora infestans</i>	Foliar Spray	When first symptoms are visible BBCH 20-87	a) 1-2 b) 1-2	8-10	a) 1.5 b) 3.0	a) 0.4 boscalid + 0.1 pyraclostrobin b) 0.8 boscalid + 0.2 pyraclostrobin	300-600	-	Efficacy section: only in line to Art. 51 could be accepted.
3	CEU	Tomato	F	<i>Alternaria sp.</i>	Foliar Spray	When first symptoms are visible BBCH 20-87	a) 1-3 b) 1-3	8-10	a) 1.5 b) 4.5	a) 0.4 boscalid + 0.1 pyraclostrobin b) 1.2 boscalid + 0.3 pyraclostrobin	300-600	-	Metabolism and Residues: not accepted
4	CEU	Carrot	F	<i>Septoria apiicola</i> , <i>Cercospora sp.</i> , <i>Alternaria sp.</i>	Foliar Spray	When first symptoms are visible BBCH 41-49	a) 1-2 b) 1-2	8-10	a) 1.5 b) 3.0	a) 0.4 boscalid + 0.1 pyraclostrobin b) 0.8 boscalid + 0.2 pyraclostrobin	300-600	-	
5	CEU	Onion	F	<i>Puccinia allii</i>	Foliar Spray	When first symptoms are visible BBCH 41-49	a) 1-2 b) 1-2	14	a) 1.5 b) 3.0	a) 0.4 boscalid + 0.1 pyraclostrobin b) 0.8 boscalid + 0.2 pyraclostrobin	300-600	-	Efficacy section: only in line to Art. 51 could be accepted. Ecotox Section: Only one application is acceptable.
Unprotected use in SIGNUM													
6	PL	Cabbage	F	<i>Alternaria</i> , <i>Botrytis cinerea</i>	Spray	BBCH 41-49	a) 1-3 b) 1-3	7	a) 1.0 b) 3.0	a) 0.267 boscalid + 0.067 pyraclostrobin b) 0.8 boscalid + 0.2 pyraclostrobin	600-800	14	Unprotected use in SIG- NUM Metabolism and Residues: not accepted
7	PL	Tomatoe in greenhouses	G	<i>Botrytis cinerea</i> ,	Spray	BBCH 51-85	a) 1-2	7	a) 2.0	a) 0.534	1000	3	Unprotected use in SIG-

				<i>Phytophthora infestans</i>			b) 1-2		b) 4.0	boscalid + 0.134 pyra- elostrobin b) 1.068 + 0.268 pyra- elostrobin			NUM Metabolism and Resi- dues: not accepted
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8	PL	Strawberry	F	<i>Botrytis cinerea</i> ; <i>Ramularia grevilleana</i> <i>Spaerotheca macularis</i> ;	Spray	BBCH 60-81	a) 1-2 b) 1-2	5	a) 1.8 b) 3.6	a) 0.481 boscalid + 0.121 pyraclostrobin b) 0.961 boscalid + 0.241 pyraclostrobin	500-700	3	Unprotected use in SIG- NUM Metabolism and Resi- dues: not accepted Ecotox: Only one appli- cation are acceptable.
9	PL	Cherry	F	<i>Monilinia sp.</i>	Spray	BBCH 60-67	a) 1-2 b) 1-2	5	a) 1.0 b) 2.0	a) 0.267 boscalid + 0.067 pyraclostrobin b) 0.534 boscalid + 0.134 pyraclostrobin	500-750	7	Unprotected use in SIG- NUM Metabolism and Resi- dues: not accepted
10	PL	Raspberry	F	<i>Botrytis cinerea</i> ; <i>Didymella applanata</i>	Spray	BBCH 51-90	a) 1-2 b) 1-2	7	a) 1.8 b) 3.6	a) 0.481 boscalid + 0.121 pyraclostrobin b) 0.961 boscalid + 0.241 pyraclostrobin	600-700	3	Unprotected use in SIG- NUM Metabolism and Resi- dues: not accepted
11	PL	Blackcurrant	F	<i>Drepanopeziza ribis</i> <i>Cronartium ribicola</i>	Spray	BBCH 55-90	a) 1-2 b) 1-2	7-10	a) 1.8 b) 3.6	a) 0.481 boscalid + 0.121 pyraclostrobin b) 0.961 boscalid + 0.241 pyraclostrobin	600-800	3	Unprotected use in SIG- NUM Metabolism and Resi- dues: not accepted

Minor uses according to Article 51 (zonal uses)

12	PL	Beetroot	F	<i>Erysiphe betae</i>	Spray	BBCH 15-49	a) 1-2 b) 1-2	10-14	a) 1.0 b) 2.0	a) 0.267 boscalid + 0.067 pyraclostrobin b) 0.534 boscalid + 0.134 pyraclostrobin	300-600	14	
13	PL	Celery root	F	<i>Sclerotinia sclerotiorum</i>	Spray	BBCH 15-49	a) 1-2 b) 1-2	10-14	a) 1.5 b) 3.0	a) 0.4 boscalid + 0.1 pyraclostrobin	300-600	14	

										b) 0.8 bos- calid + 0.2 pyraclostrobin			
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14	PL	Parsnip, Parsley	F	<i>Alternaria sp. alternata, Erysiphe heraclei</i>	Spray	BBCH 15-49	a) 1-2 b) 1-2	21-28	a) 0.75 b) 1.5	a) 0.200 boscalid + 0.050 pyra- clostrobin b) 0.400 boscalid + 0.100 pyra- clostrobin	600- 800	14	
15	PL	Radish	F	<i>Botrytis cinerea,</i>	Spray	BBCH 11-49	a) 1-2 b) 1-2	14-21	a) 1.5 b) 3.0	a) 0.4 bos- calid + 0.1 pyraclostrobin b) 0.8 bos- calid + 0.2 pyraclostrobin	300- 600	14	
16	PL	Radish	F	<i>Rhizoctonia solani</i>	Spray	BBCH 11-12	a) 1 b) 1	NR	a) 1.5 b) 1.5	a) 0.4 bos- calid + 0.1 pyraclostrobin b) 0.4 bos- calid + 0.1 pyraclostrobin	300- 600	14	
17	PL	Horseradish	F	<i>Peronospora sp. Alternaria Erysiphe sp.</i>		BBCH 15-49	a) 1-2 b) 1-2	14-21	a) 1.5 b) 3.0	a) 0.4 bos- calid + 0.1 pyraclostrobin b) 0.8 bos- calid + 0.2 pyraclostrobin	300- 600	14	
18	PL	Swedes/rutabagas	F	<i>Peronospora sp. Cercospora beticola Erysiphe sp.</i>	Spray	BBCH 15-49	a) 1-2 b) 1-2	10-14	a) 1.0 b) 2.0	a) 0.267 boscalid + 0.067 pyra- clostrobin b) 0.534 boscalid + 0.134 pyra- clostrobin	300- 600	14	
19	PL	Turnip	F	<i>Botrytis cinerea, Thanatephorus cucumeris</i>	Spray	BBCH 11-49	a) 1-2 b) 1-2	14-21	a) 1.5 b) 3.0	a) 0.4 bos- calid + 0.1 pyraclostrobin b) 0.8 bos- calid + 0.2 pyraclostrobin	300- 600	14	
20	PL	Chicory roots	F	<i>Chicory Alterna- ria, Chicory Puccinia</i>	Spray	BBCH 13-47	a) 1-2 b) 1-2	14-21	a) 1.5 b) 3.0	a) 0.4 bos- calid + 0.1 pyraclostrobin b) 0.8 bos-	300- 600	14	

										calid + 0.2 pyraclostrobin			
21	PL	Shallot	F	<i>Peronospora destructor</i> <i>Alternaria</i> , <i>Stemphylium</i>	Spray	BBCH 13-48	a) 1-2 b) 1-2	14	a) 1.0 b) 3.0	a) 0.267 boscalid + 0.067 pyra- clostrobin b) 0.8 bos- calid + 0.2 pyraclostrobin	300- 600	14	Ecotox: Only one appli- cation are acceptable.
22	PL	Onion "seven years old"	F	<i>Puccinia porri</i> <i>Phytophthora porri</i> <i>Alternaria</i> ,	Spray	BBCH 13-47	a) 1-2 b) 1-2	21-28	a) 1.5 b) 3.0	a) 0.4 bos- calid + 0.1 pyraclostrobin b) 0.8 bos- calid + 0.2 pyraclostrobin	300- 600	14	Ecotox: Only one appli- cation are acceptable.
23	PL	Aubergines/eggplants	G	<i>Botrytis cinerea</i> , <i>Sclerotinia sclerotiorum</i> <i>Leveillula taurica</i>	Spray	BBCH 12-89	a) 1-2 b) 1-2	7-10	a) 1.5 b) 3.0	a) 0.4 bos- calid + 0.1 pyraclostrobin b) 0.8 bos- calid + 0.2 pyraclostrobin	1000	14	Metabolism and Resi- dues: not accepted
24	PL	aubergines/eggplants	F	<i>Phytophthora infestans</i> ,	Foliar Spray	When first symptoms are visible BBCH 20-87	a) 1-2 b) 1-2	8-10	a) 1.5 b) 3.0	a) 0.4 bos- calid + 0.1 pyraclostrobin b) 0.8 bos- calid + 0.2 pyraclostrobin	300- 600	-	
25	PL	aubergines/eggplants	F	<i>Alternaria sp.</i>	Foliar Spray	When first symptoms are visible BBCH 20-87	a) 1-3 b) 1-3	8-10	a) 1.5 b) 4.5	a) 0.4 bos- calid + 0.1 pyraclostrobin b) 1.2 bos- calid + 0.3 pyraclostrobin	300- 600	-	Metabolism and Resi- dues: not accepted
26	PL	Ornamentals in field and greenhouses	F/G	<i>Alternaria</i>	Spray	BBCH 13-47	a) 1-2 b) 1-2	7-14	a) 0.1 b) 0.2	a) 0.0267 boscalid + 0.0067 pyra- clostrobin b) 0.0534 boscalid + 0.00134 pyraclostrobin	100	-	
27	PL	Ornamentals in field and greenhouses	F/G	<i>Erysiphales</i>	Spray	BBCH 13-47	a) 1-2	7-14	a) 0.18	a) 0.0481	100	-	

							b) 1-2		b) 0.36	boscalid + 0.0121 pyraclostrobin b) 0.0962 boscalid + 0.0242 pyraclostrobin			
28	PL	Ornamentals in field and greenhouses	F/G	<i>Botrytis cinerea</i> , <i>Sclerotinia sclerotiorum</i> <i>Thanatephorus cucumeris</i>	Spray	BBCH 13-47	a) 1-2 b) 1-2	7-14	a) 0.15 b) 0.3	a) 0.04 boscalid + 0.01 pyraclostrobin b) 0.08 boscalid + 0.02 pyraclostrobin	100	-	
29	PL	Redcurrant, White currant	F	<i>Drepanopeziza ribis</i> , <i>Drepanopeziza rubric</i> , <i>Botrytis cinerea</i> ,	Spray	BBCH 55-90	a) 1-2 b) 1-2	7-10	a) 1.8 b) 3.6	a) 0.4806 boscalid + 0.1206 pyraclostrobin b) 0.9612 boscalid + 0.2412 pyraclostrobin	600-800	3	Metabolism and Residues: not accepted Ecotox: Only one application are acceptable.
30	PL	Salsifies	F	<i>Botrytis cinerea</i> , <i>Sclerotinia sclerotiorum</i> <i>Rhizoctonia</i>	Foliar Spray	When first symptoms are visible BBCH 41-49	a) 1-2 b) 1-2	8-10	a) 1.5 b) 3.0	a) 0.4 boscalid + 0.1 pyraclostrobin b) 0.8 boscalid + 0.2 pyraclostrobin	300-600	-	
Minor uses according to Article 51 (zonal uses)													
Minor uses according to Article 51 (interzonal uses)													

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l

(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

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

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of dark brown granules, with a characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. The relative self-ignition temperature is 245 °C. In aqueous solution, it has a pH value around 5.9 at 20 °C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. A shelf life of at least 2 years at ambient temperature is on-going and the final report will be provided as soon as available. Its technical characteristics are acceptable for a *water dispersible granules* formulation.

The intended concentration of use is 0.1 % to 0.5 % w/v..

3.2 Efficacy (Part B, Section 3)

CASINO ROYAL is Water Dispersible Granular (WG) formulation containing 267 g/kg boscalid and 67 g/kg pyraclostrobin for use on sugarbeet, tomato, carrot and onion. It is used protectively and curative to control a range of diseases, hereunder *Cercospora beticola*, *Phytophthora infestans*, *Alternaria* sp., *Alternaria dauci*, *Botrytis cinerea*, *Ramularia grevilleana*, *Spaerotheca macularis*, *Monilinia* sp., *Didymella applanata*, *Drepanopeziza ribis*, *Drepanopeziza rubric*, *Cronartium ribicola*, *Erysiphe betae*, *Erysiphe heracleid*, *Sclerotinia sclerotiorum*, *Rhizoctonia solani*, *Peronospora* sp., *Puccinia allii*, *Thanatephorus cucumeris*, *Chicory Alternaria*, *Chicory Puccinia*, *Peronospora destructor*, *Stemphylium*, *Puccinia porri*, *Phytophthora porri*, *Leveillula taurica* a range of crops.

In compliance with the GAP the following dose rates are applied for registration:

- Two applications in sugarbeet to control *Cercospora beticola* (CERCBE), target rate: 1.5 kg/ha
- Two applications in tomato to control *Phytophthora infestans* (PHYTIN), target rate: 1.5 kg/ha
- Three applications in tomato to control *Alternaria* sp. (ALTESP), target rate: 1.5 kg/ha
- Two applications in carrot to control *Alternaria dauci* (ALTEDA), target rate: 1.5 kg/ha
- Two applications in onion to control *Puccinia allii* (PUCCAL), target rate: 1.5 kg/ha
- Three applications in cabbage to control *Alternaria* and *Botrytis cinerea*, target rate: 1.0 kg/ha
- Two applications in tomato in greenhouse to control *Botrytis cinerea* and *Phytophthora infestans*, target rate: 2.0 kg/ha
- Two applications in strawberry to control *Botrytis cinerea*, *Ramularia grevilleana* and *Spaerotheca macularis*, target rate: 1.8 kg/ha
- Two applications in cherry to control *Monilinia* sp., target rate: 1.0 kg/ha
- Two applications in raspberry to control *Botrytis cinerea* and *Didymella applanata*, target rate: 1.8 kg/ha
- Two applications in blackcurrant to control *Drepanopeziza ribis* and *Cronartium ribicola*, target rate: 1.8 kg/ha
- Two applications in beetroot to control *Erysiphe betae*, target rate: 1.0 kg/ha
- Two applications in celery root to control *Sclerotinia sclerotiorum*, target rate: 1.5 kg/ha

- Two applications in parsnip and parsley to control *Alternaria sp.* and *Erysiphe heraclei*, target rate: 0.75 kg/ha
- Two applications in radish to control *Botrytis cinerea* and *Rhizoctonia solani*, target rate: 1.5 kg/ha
- Two applications in horseradish to control *Peronospora sp.*, *Alternaria* and *Erysiphe sp.*, target rate: 1.5 kg/ha
- Two applications in swedes/rutabagas to control *Peronospora sp.*, *Cercospora beticola* and *Erysiphe sp.*, target rate: 1.0 kg/ha
- Two applications in turnip to control *Botrytis cinerea* and *Thanatephorus cucumeris*, target rate: 1.5 kg/ha
- Two applications in chicory roots to control *Chicory Alternaria* and *Chicory Puccinia*, target rate: 1.5 kg/ha
- Two applications in shallot to control *Peronospora destructor*, *Alternaria* and *Stemphylium*, target rate: 1.0 kg/ha
- Two applications in onion to control *Puccinia porri*, *Phytophthora porri* and *Alternaria*, target rate: 1.5 kg/ha
- Two/three applications in aubergines/eggplants to control *Botrytis cinerea*, *Sclerotinia sclerotiorum*, *Phytophthora infestans*, *Alternaria sp.* and *Leveillula taurica*, target rate: 1.5 kg/ha
- Two applications in ornamentals in field and greenhouses to control *Alternaria*, target rate: 0.1 kg/ha
- Two applications in ornamentals in field and greenhouses to control *Erysiphales*, target rate: 0.18 kg/ha
- Two applications in ornamentals in field and greenhouses to control *Botrytis cinerea*, *Sclerotinia sclerotiorum* and *Thanatephorus cucumeris* target rate: 0.15 kg/ha
- Two applications in redcurrant, white currant to control *Botrytis cinerea*, *Drepanopeziza ribis* and *Drepanopeziza rubric* target rate: 1,8 kg/ha
- Two applications in salsifies to control *Botrytis cinerea*, *Sclerotinia sclerotiorum* and *Rhizoctonia* target rate: 1,5 kg/ha

This document serves the registration of Boscalid 26.7% + Pyraclostrobin 6.7% WG in the Central zone of the EU. The objective of this biological assessment dossier is to prove and support the label claims of the fungicidal efficacy and crop safety of Boscalid 26.7% + Pyraclostrobin 6.7% WG in sugarbeet, tomato, carrot, onion, cabbage, tomato in greenhouse, strawberry, cherry, raspberry, blackcurrant, beetroot, celery, parsnip, radish, horseradish, swedes/rutabagas, turnip, chicory, shallot, aubergines/eggplants, ornamentals in field and greenhouses, redcurrant, white currant, salsifies as claimed in the GAP table.

Comprehensive field trials were conducted in 2016, 2017 and 2019 in a wide range of European countries in the Maritime (i.e. -France, United Kingdom, Czech Republic and Germany), the North-East (Latvia and Poland) the South-east (i.e. Hungary) and the Mediterranean (i.e. France, Greece, Italy and Spain) EPPO zones. The trials followed the corresponding EPPO guidelines. The GEP-requirement and the Uniform Principles are taken care of.

The data demonstrate that the disease control and safety to the crop of Boscalid 26.7% + Pyraclostrobin 6.7% WG is comparable to that of the Boscalid 26.7% + Pyraclostrobin 6.7% WG standard reference product, and the applicant therefore wishes to cite the original registrant's data on boscalid and pyraclostrobin now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal evaluator extrapolate from those data.

3.3 Efficacy data

Preliminary tests

The activity of Boscalid is well known, as it has been marketed since 2001 by BASF to control of *Botrytis Sclerotinia*, *Alternaria* and *Phoma*, in Grape, oilseed rape, peas, beans and other crops, as granular and seed treatment products. The activity of Pyraclostrobin is also well known, as it has been marketed since 2003 by BASF and it has been used applied in foliar spray, to control diseases such as *Colletotrichum gloeosporioides*, *Uromyces phaseoli* or *Puccinia graminis* in barley, apple or potato.

Based on the knowledge about the active substances (+15 years) and the experiences with using Boscalid and Pyraclostrobin in the label claimed crops at the proposed dose rates, the necessary application rates of the mixture to obtain sufficient control of the pest organism are already known. Therefore, preliminary tests in glasshouses and field trials to assess the biological activity of the active substance or dose range for the plant protection product were not deemed necessary.

Minimum effective dose tests

Field trials were established to determine the minimum effective dose for the control of the targets claimed in this dossier. In the following, summaries of the performance of Boscalid 26.7% + Pyraclostrobin 6.7% WG on the key disease in sugarbeet, tomato, carrot and onion are presented.

Boscalid 26.7% + Pyraclostrobin 6.7% WG was tested at a range of dose rates, but to demonstrate minimum effective dose rate, the control obtained with Boscalid 26.7% + Pyraclostrobin 6.7% WG applied at different dose rates was evaluated in 19 sugarbeet, 13 tomato, 7 onion and 8 carrot trials. In the 47 trials, Boscalid 26.7% + Pyraclostrobin 6.7% WG was applied at 0.6, 1 and 1.5 kg/ha for the control of *Cercosporabeticola*(CERCBE) in sugarbeet, *Phytophthorainfestans* (PHYTIN) and *Alternaria* sp. (ALTESP) in tomato, *Septoriaapiicola* (SEPTAP), *Cercospora* sp.(CERCSP) and *Alternaria* sp. (ALTESP) in Carrot and *Pucciniaallii* (PUCCAL) in onion. The dose rates tested reflects 40% to 67% of the recommended rate of Boscalid 26.7% + Pyraclostrobin 6.7% WG, in accordance with the EPPO guideline PP 1/225(2) “Minimum effective dose”. The dose is selected on the basis of its efficacy performance, product safety parameters and environmental limitations. Efficacy is tested under a range of environmental conditions to fully challenge the product. Data are presented from trials conducted in the Maritime EPPO zone (N-France, Germany and United Kingdom), North-East EPPO zone (Latvia and Poland), South-East EPPO zone (Hungary) and Mediterranean EPPO zone (Italy, S-France, Greece and Spain).

Conclusion: In summary, reducing the application rate from the proposed dose rates of 1.5 kg/ha to 40% or 67% of that rate, showed a decrease in the efficacy against *Cercosporabeticola*(CERCBE) in sugarbeet, *Phytophthorainfestans* (PHYTIN) and *Alternaria* sp.(ALTESP) in tomato, *Septoriaapiicola* (SEPTAP), *Cercospora* sp.(CERCSP) and *Alternaria* sp. (ALTESP) in Carrot and *Pucciniaallii* (PUCCAL) in onion.

According to the presented results, the dose of 1.5 kg/ha of Boscalid 26.7% + Pyraclostrobin 6.7% WG provided the optimum overall control and should be considered as effective against the diseases, for which activity Boscalid 26.7% + Pyraclostrobin 6.7% WG is claimed. A control may be obtained with lower than recommended dose rates, if treating susceptible disease under optimal conditions (pre-infection/low infestation and good weather conditions), but as diseases often occur as complexes of several pathogens throughout a season, two or three applications of Boscalid 26.7% + Pyraclostrobin 6.7% WG at 1.5 kg/ha per application should be used to efficiently control all pathogens claimed on the label's crops.

A strong dataset was presented to demonstrate the efficiency of the tested product in a wide range of crops and target diseases. Therefore, for any label claims not adequately supported for one crop type, the applicant requests that the evaluators reads across to the data on the other crop types.

This document clearly demonstrates – as will be demonstrated in the following section – that the efficacy and crop safety of Boscalid 26.7% + Pyraclostrobin 6.7% WG is equivalent to that of the standard bos-

calid and pyraclostrobin reference product to which it was compared. Therefore, the applicant wishes to cite the original registrant's data on boscalid and pyraclostrobin now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Efficacy tests and conclusions regarding authorization of intended uses

All details about efficacy methodology used during efficacy trials are presented above by Applicant. The reports include a detailed data on soil and field conditions, agro-technological procedures, fore-crop as well as meteorological conditions and technical details of the spraying etc. Submitted efficacy trials are correctly performed according to appropriate EPPO standards. Studies were carried out by testing unit mandated to conduct research in the field of efficacy of plant protection products by the Chief Inspector of Plant Health and Seed Inspection and are officially GEP recognized.

The applicant submitted 47 reports (in total) showing the results in research into product efficacy carried out in 2016, 2017 and 2019. So, the field trials were performed during different growing seasons, accordingly to EPPO PP 1/181(4).

For **sugar beet** against **CERCBE** in total 19 trials were presented:

- Maritime – 7 trials (FR-5, DE-1, UK-1), eff. ME
- Mediterranean – 3 trials (IT-1, ES-2), eff. ME
- South-East – 2 trials (HU), eff. ME
- North-East – 7 trials (PL), eff. ME

At least 6 trials are required for major pest and major crop. Applicant submitted enough trials for N-E and Maritime EPPO zone. For Poland we can also take into consideration results from neighbouring countries. In this way we have 8 valid trials: 1-DE, 7-PL. However, only extrapolation results from different EPPO zones can allow to register product in Mediterranean and South-East EPPO zone. So, concerned Member States will need to consider claims for these uses taking into account the limited amount of data and the current authorized uses for the reference product in their own Member State.

For **tomato** against **PHYTIN** in total 6 trials were presented:

- Maritime – 1 trials (DE), eff. L
- Mediterranean – 2 trials (IT), eff. ME
- South-East – 3 trials (HU), eff. E
- North-East – lack of trials

At least 2 trials are required for pest and 2-3 trials for minor crop. Applicant submitted enough trials for MED and S-E EPPO zone. For Poland we can take into consideration results from neighbouring countries. But, only one German trial is not sufficient. Applicant should submit at least 2-3 efficacy trials. Only extrapolation results from different EPPO zones can allow to register product in Maritime and North-East EPPO zone. So, concerned Member States will need to consider claims for these uses taking into account the limited amount of data and the current authorized uses for the reference product in their own Member State. For Poland, such extrapolation is not acceptable, so use against PHYTIN on tomato should be excluded from Polish label. Only according to Article 51 this use can be registered in Poland.

For **tomato** against **ALTESP** in total 7 trials were presented:

- Maritime – lack of trials
- Mediterranean – 5 trials (GR-1, IT-2, ES-2), eff. ME
- South-East – lack of trials
- North-East – 2 trials (PL), eff. ME

At least 2 trials are required for pest and 2-3 trials for minor crop. Applicant submitted enough trials for MED and N-E EPPO zone. Only extrapolation results from different EPPO zones can allow to register product in Maritime and South-East EPPO zone. So, concerned Member States will need to consider claims for these uses taking into account the limited amount of data and the current authorized uses for the reference product in their own Member State.

For **onion** against **PUCAL** in total 7 trials were presented:

- Mediterranean – 4 trials (GR-1, IT-2, ES-1), eff. ME

- Maritime – 3 trials (FR-2, DE-1), eff. L
- North-East – lack of trials
- South-East – lack of trials

At least 2 trials are required for pest and 2-3 trials for minor crop. Applicant submitted enough trials for MED and MAR EPPO zone. For Poland we can take into consideration results from neighbouring countries. But, only one German trial is not sufficient. Applicant should submit at least 2-3 efficacy trials. Only extrapolation results from different EPPO zones can allow to register product in South-East and North-East EPPO zone. So, concerned Member States will need to consider claims for these uses taking into account the limited amount of data and the current authorized uses for the reference product in their own Member State. For Poland, such extrapolation is not acceptable, so use against PUCAL on onion should be excluded from Polish label. Only, in line to Article 51 this use can be registered in Poland.

For **carrot** against **CERCCA** in total 3 trials were presented:

- Mediterranean – lack of trials
- North-East – 2 trials (LV), eff. ME
- South-East – lack of trials
- Maritime – 1 trial (DE), eff. L

At least 2-3 trials are required for minor crop. Applicant submitted enough trials for N-E EPPO zone. For Poland we can also take into consideration results from neighbouring countries. In this way we have 3 valid trials: 1-DE, 2-LV. However, only extrapolation results from different EPPO zones can allow to register product in Mediterranean, Maritime and South-East EPPO zone. So, concerned Member States will need to consider claims for these uses taking into account the limited amount of data and the current authorized uses for the reference product in their own Member State.

For **carrot** against **ALTESP** in total 5 trials were presented:

- Mediterranean – lack of trials
- North-East – 3 trials (LV-1, PL-2), eff. ME
- South-East – 1 trial (HU), eff. E
- Maritime – 1 trial (DE), eff. ME

At least 2-3 trials are required for minor crop. Applicant submitted enough trials for N-E EPPO zone. For Poland we can also take into consideration results from neighbouring countries. In this way we have 4 valid trials: 1-DE, 1-LV, 2-PL. However, only extrapolation results from different EPPO zones can allow to register product in Mediterranean, Maritime and South-East EPPO zone. So, concerned Member States will need to consider claims for these uses taking into account the limited amount of data and the current authorized uses for the reference product in their own Member State.

Following BBCH were studied during trials:

- *sugar beet*: MAR: 34-49, N-E: 39-49; S-E: 41-49; MED: 31-40. In the opinion of Evaluataor, proposed window application for sugar beet can be accepted (BBCH 31-39).
- *tomato against PHYTIN*: MAR: 17-25; MED: 17-25; S-E: 63-72. In the opinion of Evaluator, proposed window application for tomato against PHYTIN can be accepted (BBCH: 20-87).
- *tomato against ALTESP*: N-E: 73-84; MED: 21-87. In the opinion of Evaluataor, proposed window application for tomato against ALTESP can be accepted (BBCH 20-87).
- *carrot*: MAR: 41-45; N-E: 43-47; S-E: 41-44. In the opinion of Evaluataor, proposed window application for carrot can be accepted (BBCH 41-49).
- *onion*: MAR: 16-43; MED: 15-47. In the opinion of Evaluataor, proposed window application for onion can be accepted (BBCH 41-49).

On the basis on submitted documentation, max 2 application per season for sugar beet, tomato against PHYTIN, carrot and onion can be accepted, and for tomato against ALTESP – max 3 application per season can be accepted.

The evaluation was carried out in accordance with the Uniform Principles. The presented data show that the efficacy rates of Casino Royal (SHA 7273 B) at 1,5 kg/ha are equivalent to the efficacy rates of the standard reference products.

Due to the limited number of results for most uses, it is difficult to make a clear conclusion for the label, especially for pest which are considered to be major. Therefore the sufficiency of results should be considered on the national level based on importance of pests in their country, in the opinion of Evaluator.

The applicant wishes to cite the original registrant's data on boscalid and pyraclostrobin out of protection in support of those recommendations on the draft label that are not adequately supported. Such extrapolations should be considered by individual member states on a national level based on current registration, data protection and experience with similar boscalid products. The spectrum of pests should be checked with label claims on these reference products. In Poland, on the basis on SIGNUM 33 WG, which was registered in Poland (R-33/2010, dated 19.04.2010), uses claimed in the GAP table (cabbage, tomato in greenhouses, strawberry, cherry, raspberry, blackcurrant) and Polish label project can be accepted. SIGNUM 33 WG contain the same amount of boscalid and pyraclostrobin as tested plant protection product – Casino Royal and have the same formulation (WG). Also, in efficacy trials this product was used in some efficacy trials. Also, during efficacy studies it was shown that both products have similar efficacy against annalizing diseases.

Minor uses without any efficacy trials can be registered only in accordance to Article 51. So, following monor uses included in GAP table and label project can be accepted: beetroot, celery root, parsnip, parsley, radish, radish Horseradish, swedes/rutabagas, turnip, chicory roots, shallot, onion, aubergines/eggplants, ornamentals in field and greenhouses, redcurrant, white currant and salsifies.

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

CASINO ROYAL contains boscalid and pyraclostrobin.

Boscalid belongs to the chemical class of pyridine carboxamides in the group of complex II: succinate-dehydrogenase fungicides and is classified in Group 7 by FRAC (FRAC MOA Code: complex II : succinate-dehydrogenase, Group code 7).

Pyraclostrobin belongs to the chemical class of methoxy-carbamates in the group of complex III: cytochrome bc1 (ubiquinol oxidase) at Qo site (cyt b gene) and is classified in the Group 11 by FRAC (FRAC MOA Code: complex III: cytochrome bc1 (ubiquinol oxidase) at Qo site (cyt b gene), Group code 11).

To aid the reduction of selection pressure within disease populations, the label recommends alternating the use of CASINO ROYAL with a fungicide with a different mode of action to avoid build-up of resistant strains of disease.

The resistance management strategy consists of:

- Use in alternation with fungicides comprising different mode of action
- Maintaining the recommended doses when applied at the maximum number of applications (up to three applications per season).
- And where necessary (e.g. in situation of high disease pressure) mixing with a non DMI fungicide to achieve a higher level of disease control
- Application is made at an early stage of development (e.g. at the first signs of disease or as soon as disease symptoms appear) or as a protective application.

The Registration of CASINO ROYAL is endorsed.

3.3.2 Adverse effects on treated crops

Phytotoxicity to host crop

As Boscalid 26.7% + Pyraclostrobin 6.7% WG is a fungicide, no specific studies are required as long as in the efficacy trials no negative effects are observed. The crop safety of applying Boscalid 26.7% + Pyraclostrobin 6.7% WG at the recommended rates in sugarbeet, tomato, onion and carrot was evaluated in 88 efficacy trials (37 MAR, 13 NE, 21 SE and 17 MED). In the efficacy trials, Boscalid 26.7% + Pyra-

clostrobien 6.7% WG EC was applied at 0.6 Kg/ha to 1.5 Kg/ha. Furthermore, to give additional evidence to the safe use of Boscalid 26.7% + Pyraclostrobin 6.7% WG in the GAP claimed crops, the results obtained in 23 selectivity trials (10 MAR, 7 N-E and 6 MED) are reported. In the selectivity trials, Boscalid 26.7% + Pyraclostrobin 6.7% WG was applied at 1.5 Kg/ha to 3 Kg/ha.

Boscalid 26.7% + Pyraclostrobin 6.7% WG applied at the recommended dose rate did not cause phytotoxicity in any of the trials conducted on sugarbeet, tomato, carrot and onion when applied as recommended. In the trials where Boscalid 26.7% + Pyraclostrobin 6.7% WG was applied at dose rates higher than the recommended, no detrimental effects were observed on selectivity, when assessed in the vast majority of the trials.

For crops claimed on the label not sufficiently supported with trials, the applicant wishes to bridge to the trials conducted in sugarbeet, tomato, carrot and onion where selectivity data demonstrated the safe use following application of Boscalid 26.7% + Pyraclostrobin 6.7% WG as recommended. Therefore, for any label claims not adequately supported for one crop, Sharda requests that the zonal evaluators read across to the data on sugarbeet, tomato, carrot and onion. This document also clearly demonstrates that the crop safety of Boscalid 26.7% + Pyraclostrobin 6.7% WG is equivalent to the standard Boscalid 26.7% + Pyraclostrobin 6.7% WG products (Signum) to which it was compared. The applicant therefore wishes to cite the original registrant's data on Boscalid 26.7% + Pyraclostrobin 6.7% WG now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Effects on yield and quality

Thirty six efficacy and selectivity trials treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG were harvested and yields and/or quality of yield recorded. In a number of these assessments on the potential impact of treatment on a range of quality parameters including sugar content, Na, K and AMN content, weight increase, fresh weight, marketable and unmarketable fruits were conducted.

Boscalid 26.7% + Pyraclostrobin 6.7% WG applied at the proposed dose rate, at a range of growth stages within the label recommended range, in sugarbeet, tomato, carrot and onion did not affect crop yield nor the quality of the crop yield significantly in any of the twenty four trials harvested. Furthermore, the data obtained in trials harvested demonstrate that Boscalid 26.7% + Pyraclostrobin 6.7% WG is as safe as the reference products used in the trials.

For recommendations on the label not sufficiently supported with trials harvested, the applicant wishes to bridge to the trials conducted in sugarbeet, tomato, carrot and onion where harvest data demonstrated the safe use following application of Boscalid 26.7% + Pyraclostrobin 6.7% WG as recommended. Furthermore, the data presented in this document also clearly demonstrates that the efficacy and crop safety of Boscalid 26.7% + Pyraclostrobin 6.7% WG is equivalent to the standard Boscalid 26.7% + Pyraclostrobin 6.7% WG products to which it was compared. The applicant therefore wishes to cite the original registrant's data on Boscalid 26.7% + Pyraclostrobin 6.7% WG now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

3.3.3 Observations on other undesirable or unintended side-effects

Impact on treated plants or plant products to be used for propagations

CASINO ROYAL is composed of boscalid and pyraclostrobin, which has been widely used for several years on a range of crops, without identifying any issues in regards to ability of grains of treated plants to germinate.

Thus, negative effects of boscalid and pyraclostrobin on parts of plant used for propagating purposes can be excluded. Furthermore, phytotoxicity assessments in the performed trials demonstrated the complete crop safety of the product and the absence of any negative effect on the plants or plant products.

Impact on succeeding crops.

Boscalid

According to Monograph of Boscalid, the EU agreed endpoints have been used in the risk assessment.

Two trials were performed applying boscalid to either vegetables or winter rape in order to investigate the residue situation. In both cases, wheat was planted on those plots in the succeeding season. Wheat samples were taken in normal practical conditions.

Pyraclostrobin

According to Monograph of Pyraclostrobin, the EU agreed endpoints have been used in the risk assessment.

The total radioactive residues in the edible parts of succeeding crops destined for human consumption are very low (radish roots, lettuce: < 0.040 mg/kg; wheat grain: < 0.089 mg/kg) after all 3 plant back intervals.

There is no accumulation of pyraclostrobin (BAS 500 F) or its degradation products in the parts of plants used for human food or animal feed consumption.

In the case of root vegetables (radish), leafy vegetables (lettuce), the concentration of parent was < 0.0106 mg/kg. For wheat straw, the concentration of parent was < 0.0147 mg/kg and in wheat grain parent was not detectable.

The levels of individual metabolites present were below 0.01 mg/kg.

Due to the low concentration of pyraclostrobin (BAS 500 F) and its degradation products in succeeding crops, no field trials are required.

Impact on other plants including adjacent crops

Greenhouse studies on vegetative vigour were conducted with the representative formulation BAS 510 01 F, were submitted in DAR of boscalid and greenhouse studies on vegetative vigour were conducted with the representative formulation BAS 500 00 F, were submitted in DAR of pyraclostrobin. The results obtained were used to assess TER and compare to the trigger value of 1 in field crops, fruiting crops and orchards to cover all the claimed uses in GAP. The calculated TER values are higher than trigger of 1 for all crop groups. Therefore, no risk mitigation measures are required.

Effects on beneficial and other non-target organisms

There were no adverse effects on beneficial and other non-target organisms observed in any of the efficacy and crop safety trial conducted.

3.4 Methods of analysis (Part B, Section 5)

Analytical methods for Pyraclostrobin and Boscalid in water, air, soil, tissues and in the formulation Pyraclostrobin 6.7% + Boscalid 26.7% WG are available.

3.4.1 Analytical method for the formulation

3.4.1.1 Determination of the active substances in the plant protection product

An analytical method for the determination of Pyraclostrobin and Boscalid in the formulation CASINO ROYALE has been developed and sufficiently validated. The determination of the active ingredient is performed by HPLC using an internal standard and UV detector. The quantification of both Pyraclostrobin and Boscalid is achieved by comparing the ratio of each reference materials peak area versus Dibutyl phthalate internal standard peak area and the same ratio determined for a sample containing a

known amount of internal standard.

According to the SANCO/3030/99 rev.4 guidance document, the analytical method for the determination of Pyraclostrobin and Boscalid in CASINO ROYALE was validated.

	Pyraclostrobin	Boscalid
Author(s), year	Elena, Rigamonti, 2017	
Principle of method	High performance liquid chromatography using an internal standard and UV detector	
Linearity (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r)	Range: 15.58 to 36.36 µg/mL (4.08 – 9.72% w/w) ± 40% of the solution concentration used for the quantification analysis Correlation coefficient > 0.99 $y = 264561x - 239395$ n = 5	Range: 61.74 to 144.06 µg/mL (17.17 – 39.7% w/w) ± 40% of the solution concentration used for the quantification analysis Correlation coefficient > 0.99 $y = 68467x + 37887$ n = 5
Precision – Repeatability Mean n = 6 (%RSD)	Mean Pyraclostrobin content: 7.0 ± 0.1 % w/w % RSD: 1.29% Acceptable % RSD (Horwitz): 2.00	Mean Boscalid content: 26.5 ± 0.3 % w/w % RSD: 1.31% Acceptable % RSD (Horwitz): 1.64
Accuracy n = 6 (% Recovery)	Lower level % recovery: 101.2 Nominal level % recovery: 100.9 Upper level % recovery: 101.3 Mean % recovery: 101.1 Acceptable limit (SANCO): 97 - 103	Lower level % recovery: 101.2 Nominal level % recovery: 101.1 Upper level % recovery: 100.3 Mean % recovery: 100.9 Acceptable limit (SANCO): 98 – 102
Interference/ Specificity	No interference. Chromatograms submitted	
Comment	-	

From the results of the analytical method validation, it is concluded that the analytical method is specific, sensitive, precise, and accurate for the analysis of CASINO ROYALE. The results of validation criteria are within the specified limits of SANCO/3030/99 rev.4 dated 11/07/00.

3.4.1.2 Determination of relevant impurities

An analytical method for the determination of the relevant impurity Dimethylsulfate (DMS) in the formulation CASINO ROYALE has been developed and sufficiently validated. The determination of the Dimethylsulphate (DMS) relevant impurity is performed by Gas Chromatography using an external standard and MS/MS detector in the MRM mode.

	Dimethylsulfate maximum 0.07 µg/g in formulation sample
Author(s), year	Elena Rigamonti, 2017
Principle of method	Gas Chromatography using an external standard and MS/MS detector in the MRM mode
Linearity (linear between mg/L) (correlation coefficient, expressed as r)	Concentration range: 10 ng/mL to 150 ng/mL Concentration range (nominal content): 0.010 µg/g to 0.150 µg/g Correlation coefficient > 0.99 $y = 7x + 24$ for m/z 125 → 95 (quantification) n = 5

	Dimethylsulfate maximum 0.07 µg/g in formulation sample
Precision – Repeatability Mean n = 6 (%RSD)	Mean DMS content: lower than the limit of detection (LOD = 0.005 µg/g) Since the Dimethylsulfate impurity content was not detectable in repeatability test, the precision was determined via the accuracy test with the lowest fortification level and was fixed at ±10 % of the lowest fortification level. Mean DMS content: 0.016 ± 0.002 µg/g % RSD: 3.64 Acceptable % RSD (Horwitz): 19.32
Accuracy n = 6 (% Recovery)	Low level (0.020 µg/g) % recovery: from 79.76 to 86.14 Low level % mean recovery: 82.7 High level (0.070 µg/g) % recovery: from 80.21 to 87.08 High level % mean recovery: 81.8 Acceptable limit (SANCO): 75 – 125
Interference/ Specificity	No interference. Chromatograms submitted
LOQ	The limit of quantification (L.O.Q.), as the lowest fortification level tested, was a final injected solution for Dimethylsulfate (DMS) in the test item of about 20.00 ng/mL (corresponding to 0.020 µg/g).
Comment	-

The analytical method was shown to be specific for Dimethylsulfate (DMS) as relevant impurity content in CASINO ROYALE formulation samples.

The SANCO/1420/2001-Final, 8 September 2004 for relevant impurity in technical, requires a limit of 1 µg/g (0.0001 % w/w) for Dimethyl sulphate content in Pyraclostrobin technical. Considering a nominal content in the test item of about 6.7 % w/w, the limit becomes 0.07 µg/g (0.000007 % w/w).

3.4.2 Analytical methods for residues

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

Noticed data gaps are:

- none

Commodity/crop	Supported/ Not supported
High starch/protein content (sugar beet, carrot, beetroot, celery root, parsnip, parsley, radish, horseradish, turnip, swedes, rutabagas, chicory roots, salsifies)	Supported
High water content (Onion, tomatoes, cabbage, cherry, shallot, onion “seven years old”, aubergines/eggplants, jerusalem artichokes)	Supported
High acid content (Strawberries, Raspberry, Blackcurrant, Redcurrant, White currant)	Supported
Ornamentals	Not required

3.5 Mammalian toxicology (Part B, Section 6)

Acute toxicity studies for CASINO ROYALE were not evaluated as part of the EU review of pyraclostrobin and boscalid. All relevant data were provided and are considered adequate. The assessment of all acute toxicological properties of CASINO ROYALE was derived from the additivity formula based on the classification of the active substances and co-formulants of SHA 7273 A / CASINO ROYALE.

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat	-	Yes	None	Estimation based on the composition of the product (additivity formula)
LD ₅₀ dermal, rat	-	Yes	None	Estimation based on the composition of the product (additivity formula)
LC ₅₀ inhalation	> 5mg/L air	Yes	None	Estimation based on the composition of the product (additivity formula)
Skin irritation, rabbits	Not-irritant	Yes	None	Estimation based on the composition of the product (additivity formula)
Eye irritation, rabbits	Irritant	Yes	Eye Irrit. 2, H319	Estimation based on the composition of the product (additivity formula)
Skin sensitisation, mouse	Non-sensitising	Yes	None	Estimation based on the composition of the product (additivity formula)
Supplementary studies for combinations of plant protection products	No data – not required	-		

Classification in regards to mammalian toxicology: none

3.5.1 Operator exposure

Operator exposure to CASINO ROYALE was not evaluated as part of the EU review of Pyraclostrobin

and Boscalid for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate.

Estimations of potential operator exposure have been undertaken for Pyraclostrobin and Boscalid using the AOEM, ECPA greenhouses model and Dutch greenhouse model.

Conclusion

The results of the estimations presented by the Applicant indicate that the exposure of an unprotected operator (no PPE) to pyraclostrobin and boscalid contained in the product SHA 7273A / Casino Royale does not cause an unacceptable risk, i.e. the values are significantly below the value of AOEL for the active substances, for all in-tended uses presented in the GAP Table except of the use in cherries.

Additionally, the results performed based on Dutch greenhouse model indicate that protective gloves and coverall must be worn to maintain the exposure value below AOEL for the active substances.

In case of the use of SHA 7273A / Casino Royale in cherries the acceptable exposure of an operator to pyraclostrobin and boscalid contained in SHA 7273A / Casino Royale is expected only if the operator is equipped with work wear and protective gloves during M&L and application.

However, taking into account the classification of the product (Eye Irrit. 2, H319), it is recommended to include on the label a note on the need of the use of eye/face protection and protective gloves in all intended uses (in the section regarding the precautions for people using the formulation).

Taking into account the information presented above, the following sentence is recommended by the evaluator to be placed in the label:

1/ In case of uses in **sugarbeets, tomatoes, strawberries ornamentals**:

“Stosować rękawice ochronne, ochronę oczu lub twarzy oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy użytkowej oraz odzież roboczą w czasie wykonywania zabiegu. W przypadku oprysku pomidorów w szklarniach stosować dodatkowo ochronę dróg oddechowych (min. maska FFP2).”

“Wear protective gloves, eye/face protection and work wear (coverall) during mixing/loading and work wear during application. Use additional respiratory protection (minimum FFP2 mask) when spraying tomatoes in greenhouses”

2/ In case of use in **cherries**:

“Stosować rękawice ochronne, ochronę oczu lub twarzy oraz odzież roboczą (kombi-nezon) w trakcie przygotowywania cieczy użytkowej oraz rękawice ochronne i odzież roboczą w czasie wykonywania zabiegu.”

“Wear protective gloves, eye/face protection and work wear (coverall) and protective gloves and work wear during application.

3.5.2 Worker exposure

Worker exposure to CASINO ROYALE was not evaluated as part of the EU review of Pyraclostrobin and Boscalid for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate.

Estimations of potential operator exposure have been undertaken for Pyraclostrobin and Boscalid using the AOEM.

Conclusions:

Taking into account the results of exposure estimations (AOEL model) to pyraclostrobin and boscalid contained in the product SHA 7273A / Casino Royale, as well as hygienic rules, a worker should be equipped with **work wear (long trousers, long-sleeve shirt) and protective gloves**.

Bearing in minds PHI values for intended crops and the results of exposure assessment, it is forbidden to re-enter treated area for inspection and/or picking:

- until spray deposit on plant surfaces has dried in case of SHA 7273A use **in sugarbeet and tomatoes**

- for 2 days in case of SHA 7273A use **in strawberries**
- for 6 days in case of SHA 7273A use **in ornamentals**
- for 7 days in case of SHA 7273A use **in cherries**

A precautionary phrase referring to the worker should be included in the label:

WORKER:

„Stosować rękawice ochronne i odzież roboczą (koszula z długim rękawem i długie spodnie) oraz nie wchodzić na teren poddany zabiegowi wcześniej niż:

- po wyschnięciu preparatu na powierzchni roślin w przypadku uprawy: buraka cukrowego, marchwi, buraka, selera, pasternaku, pietruszki naciowej, rzodkwi, chrzanu, brukwi, rzepy, korzenia cykorii, cebuli szalotki, topinamburu, salsefii, pomidora, cebuli, kapusty, bakłażana;
- 2 dni po wykonaniu oprysku w przypadku uprawy: truskawki, maliny, porzeczki;
- 2 dni po wykonaniu oprysku w przypadku uprawy: pomidor (szklarnia)
- 6 dni po wykonaniu oprysku w przypadku uprawy: roślin ozdobnych;
- 7 dni po wykonaniu oprysku w przypadku uprawy wiśni.

Wear protective gloves, work wear (covered arms, body and legs) and do not enter the area treated with SHA 7273A:

- until spray deposit on plant surfaces has dried in sugerbeet, carrot, beetroot, celery root, parsnip, parsley, radish, horseradish, swedes/rutabagas, turnip, chicory roots, shallot, Jerusalem artichokes, salsifies, tomato, onion, cabbage, aubergines/eggplants;
- for 2 days in raspberry, blackcurrant, redcurrant, white currant;
- for 2 days in tomato (indoor);
- for 6 days in ornamentals;

for 7 days in cherries

3.5.3 Bystander and resident exposure

Bystander and resident exposures to CASINO ROYALE was not evaluated as part of the EU review of Pyraclostrobin and Boscalid. Therefore, all relevant data and risk assessments have been provided and are considered adequate. Calculations were made using the AOEM.

The reference values acutely toxic active substance (RVAAS) for pyraclostrobin and boscalid contained in SHA 7273A / Casino Royale are not allocated. Consequently, it is assumed that the estimations of bystander exposure are covered by the calculations of resident exposure towards both active substances.

Conclusions:

The results of the estimations indicate that the exposure of a resident (both child and adult) to pyraclostrobin and boscalid contained in SHA 7273A / Casino Royale is below the value of AOEL.

The **incidental short-time exposure of bystander and resident (children and adult)** to pyraclostrobin and boscalid contained in SHA 7273A / Casino Royale **causes no risk** to human health if the product is used in accordance to the intended uses listed in the GAP Table.

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

The preparation CASINO ROYALE is composed of Pyraclostrobin and Boscalid.

Toxicological reference values for the dietary risk assessment of Pyraclostrobin and Boscalid

Reference value	Source	Year	Value	Study relied upon	Safety factor
Pyraclostrobin					

Reference value	Source	Year	Value	Study relied upon	Safety factor
ADI	EC	2008	0.04 mg/kg bw per day	2 years rat oral feed	100
ARfD	EC	2008	Not necessary		
Boscalid					
ADI	EC	2004	0.03 mg/kg bw/d	Chronic rat	100
ARfD	EC	2004	0.03 mg/kg bw	Rabbit developmental toxicity	100

3.6.1 Residues

Boscalid

Storage stability

Storage stability of Boscalid was demonstrated for a period of 16 months at -18 °C in commodities with high acid content (grape) and 24 months at -18 °C in commodities with high water content (cabbage, peach, pea), high oil content (rape seed), dry commodities (wheat grain) and cereal straw. Degradation of residues during storage of the trial samples is therefore not expected.

Storage stability of Boscalid and M510F01 in milk, muscle, fat, liver, kidney and egg for up to 5 months was demonstrated, when stored deep frozen. No additional studies are required.

Metabolism in plants and animals

Metabolism of boscalid was investigated for foliar treatment on fruits and fruiting vegetables (grapes), on pulses and oilseeds (beans) and on leafy vegetables (lettuce), using U-¹⁴C-diphenyl and 3-¹⁴C-pyridine labelled boscalid.

Plant residue definition for monitoring and risk assessment: boscalid

Animal residue definition for monitoring: Boscalid in muscle, fat milk and eggs; Sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates expressed as Boscalid in liver and kidney

Animal residue definition for risk assessment:

Boscalid in muscle, fat milk and eggs;

Sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates expressed as Boscalid in liver and kidney;

Sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates and the bound residues (measured as M510F52 or M510F53) expressed as Boscalid in Liver (ruminant and pig);

(EFSA 2014)

Magnitude of residues in plants

Sugar beet

Proposed GAP: BBCH 31-39, 2 application, interval 8-10 days, 0.4 kg a.s/ha, PHI – 14 days

Sufficient new trials on sugar beet are available to support the proposed uses (8 trials). The residue data are valid with regard to storage stability data. Trials GAP is consistent with the proposed (2 application 0.4 kg a.i./ha of boscalid, interval between application of 8 days, at BBCH 31-39, PHI = 14 days).

The determination of Boscalid residues has been performed by liquid chromatography, and consists in an

separation on a reversed-phase column and detection by tandem mass spectrometry (MS/MS) by electrospray (ESI) operating with optimized conditions (LOQ = 0.01 mg/kg).

During the growing season of 2018, a total of 8 trials were conducted in sugarbeet in Northern Europe (Germany, Poland and United Kingdom).

Results: $3x < 0.01$, 2×0.05 , 0.07, 0.09, 0.14 mg/kg

The residues arising from the proposed uses will not exceed the MRLs established for sugar beet (0.4 mg/kg, (Reg. (EU) 2021/590).

Clarifications regarding the independence of the following trials:

Łukaszewski K., Report No. 18SGS17 (Ożarów Mazowiecki) and Rafal Figurski, 2019. Study No. PB-2018-10 (Ożarów Mazowiecki)

Trials can be considered as independent as:

-were done in two different places - the distance is about 20 km.

18SGS017 PL01 – post code 05-830

D-2018-10-F01 – post code 05-850

- different kind of soil

18SGS017 PL01 – silt loam (1.5% of organic matter)

D-2018-10-F01 – sandy loam (2.21 % of organic matter)

Tomato

Proposed GAP: BBCH 20-87, 2 or 3 application, interval 8-10 days, 0.4 kg a.s/ha, PHI – 3 days

Sufficient new trials on tomato are available to support the proposed use No 2 (with max. 2 applications). The residue data are valid with regard to storage stability data. Trials GAP is consistent with the proposed (2 application 0.4 kg a.i./ha of boscalid, interval between application of 8 days, at BBCH 20-87, PHI = 3 days). There is no study available to cover use No 3 (max. 3 applications).

Residues: $2x < 0.01$, 0.05, $2x 0.08$, 0.09, 0.25, 0.56 mg/kg

The determination of Boscalid residues has been performed by liquid chromatography, and consists in an separation on a reversed-phase column and detection by tandem mass spectrometry (MS/MS) by electrospray (ESI) operating with optimized conditions (LOQ = 0.01 mg/kg).

During the growing season of 2018, a total of 5 trials were conducted in tomato in Northern Europe (Poland).

During the growing season of 2019, a total of 3 trials were conducted in tomato in Northern Europe (Hungary).

The residues arising from the proposed uses will not exceed the MRLs established for tomato (3.0 mg/kg, (Reg. (EU) 2021/590).

Carrot

Proposed GAP: BBCH 41-49, 2 application, interval 8-10 days, 0.4 kg a.s/ha, PHI – 14 days

8 new trials were provided. Trials GAP: 2 application 0.4 kg a.i./ha of boscalid, interval between application of 14 days, at BBCH 48, PHI= 14 days

The residue data are valid with regard to storage stability data. Trials GAP is consistent with the proposed

Residues: $2x < 0.01$, 0.05, 0.05, 0.07, 0.10, 0.14, 0.23 mg/kg

The residues arising from the proposed uses will not exceed the MRLs established for carrot (2.0 mg/kg, (Reg. (EU) 2021/590).

Onion

Proposed GAP: BBCH 41-49, 2 application, interval 14 days, 0.4 kg a.s/ha, PHI – 14 days

8 new trials were provided. GAP: 2 application 0.4 kg a.i./ha of boscalid, interval between application of 14 days, at BBCH 43-49, PHI= 14 days

Three trials were conducted in Hungary in 2019 and five in Poland in 2018.

Results: 5x <0.01, 0.01, 2x 0.02 mg/kg

The residues arising from the proposed uses will not exceed the MRLs established for onion (5.0 mg/kg, (Reg. (EU) 2021/590).

Unprotected data from Signum 33 WG

Cabbage

There is not enough data available to make an assessment.

Tomatoe in greenhouses

There is not enough data available to make an assessment.

Strawberry

There is not enough data available to make an assessment.

Cherry

Raspberry

There is not enough data available to make an assessment.

Blackcurrant

There is not enough data available to make an assessment.

Minor uses according to Article 51 (zonal uses)

Beetroot, Celery root, Parsnip, Parsley, Radish, Horseradish, Swedes/rutabagas, Turnip, Chicory roots

Beetroot

Proposed GAP: BBCH 15-49, 2 application, interval 10-14 days, 0.267 kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from carrot to whole subgroup (c) other root and tuber vegetables except sugar beets is possible.

Celery root

Proposed GAP: BBCH 15-49, 2 application, interval 10-14 days, 0.4 kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from carrot to whole subgroup (c) other root and tuber vegetables except sugar beets is possible.

Parship, Parsley

Proposed GAP: BBCH 15-49, 2 application, interval 21-28 days, 0.2 kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from carrot to whole subgroup (c) other root and tuber vegetables except sugar beets is possible.

Radish, Horseradish, turnip

Proposed GAP: BBCH 11-49 (radish, turnip), 15-49 (horse radish), 2 application, interval 14-21 days, 0.4 kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from carrot to whole subgroup (c) other root and tuber vegetables except sugar beets is possible.

Swedes/rutabagas

Proposed GAP: BBCH 15-49, 2 application, interval 10-14 days, 0.267 kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from carrot to whole subgroup (c) other root and tuber vegetables except sugar beets is possible.

Chicory roots

Proposed GAP: BBCH 13-47, 2 application, interval 14-21 days, 0.4 kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from carrot or sugar beet to chicory roots is possible.

Salsifies (0213090)

Proposed GAP: BBCH 41-49, 2 application, interval 8-10 days, 0.4 kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from carrot or sugar beet to chicory roots is possible.

Note:

MRLs for whole subgroup (c) other root and tuber vegetables except sugar beets below.

(c) other root and tuber vegetables except sugar beets	Mg/kg
Beetroots	4
Carrots	2
Celeriacs/turnip rooted celeries	2
Horseradishes	2
Jerusalem artichokes	2
Parsnips	2
Parsley roots/Hamburg roots parsley	2
Radishes	2
Salsifies	2
Swedes/rutabagas	2
Turnips	2
Others (2)	2

An exceedance of the current MRLs is not expected.

Shallot, Onion “seven years old”

Proposed GAP: BBCH 13-48, 2 application, interval 14 (shallot), 21-28 (Onion “seven years old”) days, 0.267 (shallot), 0.4 (onion “seven years old”) kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from onion is possible.

MRLs for onion, shallot and onion “seven years old”: 5 mg/kg. An exceedance of the current MRLs is not expected.

Aubergines/eggplants (field)

Proposed GAP: BBCH 20-87, 2 or 3 application, interval 7-10 days, 0.4 kg a.s/ha, PHI – 3 days

According to the SANTE/2019/12752 extrapolation from tomato is possible.

Only uses with two applications are acceptable.

MRLs for tomato and aubergines/eggplants: 3 mg/kg. An exceedance of the current MRLs is not expected.

According to the SANTE/2019/12752 extrapolation from field tomato to greenhouse Aubergines/eggplants is not possible.

Redcurrant, White currant

There is not enough data available to make an assessment.

Ornamentals in field and greenhouses

Uses are accepted

Magnitude of residues in livestock

There is no risk for animal MRL to be exceeded (Reg. (EU) 2021/590). Additional studies are not required.

Processing studies

Additional tests are not required.

Magnitude of residues in representative succeeding crops

Taking relatively low application rate of boscalid into account it can be concluded that specific plant-back restrictions related to the use of Boscalid 26.7% + Pyraclostrobin 6.7% WG are not required, provided that the product is used according to GAP. Exceedance of the MRLs set based on rotational crops residue studies is unlikely.

Pyraclostrobin

Storage stability

Storage stability of pyraclostrobin and compound 500M07 under frozen conditions (below 10°C) was demonstrated for at least 18 months in high water, high acid, high oil, dry/high starch content and other commodities (Germany, 2001). No additional studies are required.

Metabolism in plants and animals

No new information has been submitted under the current application. Data included in EFSA Journal 2011;9(8):2344 are still applicable.

Plant residue definition for monitoring: Pyraclostrobin (Regulation n°2020/856)

Plant residue definition for risk assessment: Pyraclostrobin (EFSA 2011)

Animal residue definition for monitoring: Pyraclostrobin (Regulation n°2020/856)

Animal residue definition for risk assessment: sum of pyraclostrobin and its metabolites containing the 1-(4-chlorophenyl)-1H-pyrazole moiety or the 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazole moiety, expressed as pyraclostrobin (EFSA, 2011)

Conversion factor: 4 on ruminant liver and 1 on all other commodities (EFSA 2011)

Magnitude of residues in plants

Sugar beet

Proposed GAP: BBCH 31-39, 2 application, interval 8-10 days, 0.1 kg a.s/ha, PHI – 14 days

Sufficient new trials on sugar beet are available to support the proposed uses (8 trials). The residue data are valid with regard to storage stability data. Trials GAP is consistent with the proposed (2 application 0.1 kg a.i./ha of pyraclostrobin, interval between application of 8 days, at BBCH 31-39, PHI = 14 days).

The determination of pyraclostrobin residues has been performed by liquid chromatography, and consists in an separation on a reversed-phase column and detection by tandem mass spectrometry (MS/MS) by electrospray (ESI) operating with optimized conditions (LOQ = 0.01 mg/kg).

During the growing season of 2018, a total of 8 trials were conducted in sugarbeet in Northern Europe (Germany, Poland and United Kingdom).

Results: $3x < 0.01$, 3×0.02 , 0.03, 0.04 mg/kg

The residues arising from the proposed uses will not exceed the MRLs established for sugar beet (0.2 mg/kg, (Reg. (EU) 2021/590).

Clarifications regarding the independence of the following trials:

Łukaszewski K., Report No. 18SGS17 (Ożarów Mazowiecki) and Rafal Figurski, 2019. Study No. PB-2018-10 (Ożarów Mazowiecki)

Trials can be considered as independent as:

-were done in two different places - the distance is about 20 km.

18SGS017 PL01 – post code 05-830

D-2018-10-F01 – post code 05-850

- different kind of soil

18SGS017 PL01 – silt loam (1.5% of organic matter)

D-2018-10-F01 – sandy loam (2.21 % of organic matter)

Tomato

Proposed GAP: BBCH 20-87, 2 or 3 application, interval 8-10 days, 0.1 kg a.s/ha, PHI – 3 days

Sufficient new trials on tomato are available to support the proposed use No 2 (with max. 2 applications). The residue data are valid with regard to storage stability data. Trials GAP is consistent with the proposed (2 application 0.1 kg a.i./ha of pyraclostrobin, interval between application of 8 days, at BBCH 20-87, PHI = 3 days). There is no study available to cover use No 3 (max. 3 applications).

Results: $3x < 0.01$, 0.01, 2×0.02 , 0.04, 0.07 mg/kg

The determination of pyraclostrobin residues has been performed by liquid chromatography, and consists in an separation on a reversed-phase column and detection by tandem mass spectrometry (MS/MS) by electrospray (ESI) operating with optimized conditions (LOQ = 0.01 mg/kg).

During the growing season of 2018, a total of 5 trials were conducted in tomato in Northern Europe (Poland).

During the growing season of 2019, a total of 3 trials were conducted in tomato in Northern Europe (Hungary).

The residues arising from the proposed uses will not exceed the MRLs established for tomato (0.3 mg/kg, (Reg. (EU) 2021/590).

Carrot

Proposed GAP: BBCH 41-49, 2 application, interval 8-10 days, 0.1 kg a.s/ha, PHI – 14 days

8 new trials were provided. Trials GAP: 2 application 0.1 kg a.i./ha of pyraclostrobin, interval between application of 14 days, at BBCH 48, PHI= 14 days

The residue data are valid with regard to storage stability data. Trials GAP is consistent with the proposed

Residues: $2x < 0.01$, 5×0.02 , 0.03 mg/kg

The residues arising from the proposed uses will not exceed the MRLs established for carrot (0.5 mg/kg, (Reg. (EU) 2021/590).

Onion

Proposed GAP: BBCH 41-49, 2 application, interval 14 days, 0.1 kg a.s/ha, PHI – 14 days

8 new trials were provided. GAP: 2 application 0.4 kg a.i./ha of pyraclostrobin, interval between application of 14 days, at BBCH 43-49, PHI= 14 days

Three trials were conducted in Hungary in 2019 and five in Poland in 2018.

Results: $8 \times < 0.01$ mg/kg

The residues arising from the proposed uses will not exceed the MRLs established for onion (1.5 mg/kg, (Reg. (EU) 2021/590).

Unprotected data from Signum 33 WG

Cabbage

There is not enough data available to make an assessment.

Tomatoe in greenhouses

There is not enough data available to make an assessment.

Strawberry

There is not enough data available to make an assessment.

Cherry

Raspberry

There is not enough data available to make an assessment.

Blackcurrant

There is not enough data available to make an assessment.

Minor uses according to Article 51 (zonal uses)

Beetroot, Celery root, Parsnip, Parsley, Radish, Horseradish, Swedes/rutabagas, Turnip, Chicory roots

Beetroot

Proposed GAP: BBCH 15-49, 2 application, interval 10-14 days, 0.0.067 kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from carrot to whole subgroup (c) other root and tuber vegetables except sugar beets is possible.

Celery root

Proposed GAP: BBCH 15-49, 2 application, interval 10-14 days, 0.1 kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from carrot to whole subgroup (c) other root and tuber vegetables except sugar beets is possible.

Parship, Parsley

Proposed GAP: BBCH 15-49, 2 application, interval 21-28 days, 0.05 kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from carrot to whole subgroup (c) other root and tuber vegetables except sugar beets is possible.

Radish, Horseradish, turnip

Proposed GAP: BBCH 11-49 (radish, turnip), 15-49 (horse radish), 2 application, interval 14-21 days, 0.1 kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from carrot to whole subgroup (c) other root and tuber vegetables except sugar beets is possible.

Swedes/rutabagas

Proposed GAP: BBCH 15-49, 2 application, interval 10-14 days, 0.067 kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from carrot to whole subgroup (c) other root and tuber vegetables except sugar beets is possible.

Chicory roots

Proposed GAP: BBCH 13-47, 2 application, interval 14-21 days, 0.1 kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from carrot or sugar beet to chicory roots is possible.

Salsifies (0213090)

Proposed GAP: BBCH 41-49, 2 application, interval 8-10 days, 0.1 kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from carrot or sugar beet to chicory roots is possible.

Note:

MRLs for whole subgroup (c) other root and tuber vegetables except sugar beets below.

(c) other root and tuber vegetables except sugar beets	Mg/kg
Beetroots	0.1
Carrots	0.5
Celeriacs/turnip rooted celeries	0.5
Horseradishes	0.3
Jerusalem artichokes	0.06
Parsnips	0.3
Parsley roots/Hamburg roots parsley	0.1
Radishes	0.5
Salsifies	0.1
Swedes/rutabagas	0.09
Turnips	0.09
Others (2)	0.02*

An exceedance of the current MRLs is not expected.

Shallot, Onion “seven years old”

Proposed GAP: BBCH 13-48, 2 application, interval 14 (shallot), 21-28 (Onion “seven years old”) days, 0.067 (shallot), 0.1 (onion “seven years old”) kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from onion is possible.

MRLs for onion, shallot and onion “seven years old”: 0.3 mg/kg (shallots), 1.5 (Spring onions/green onions and Welsh onions). An exceedance of the current MRLs is not expected.

Aubergines/eggplants (field)

Proposed GAP: BBCH 20-87, 2 or 3 application, interval 7-10 days, 0.1 kg a.s/ha, PHI – 3 days

According to the SANTE/2019/12752 extrapolation from tomato is possible.

Only uses with two applications are acceptable.

MRLs for tomato and aubergines/eggplants: 0.3 mg/kg. An exceedance of the current MRLs is not expected.

According to the SANTE/2019/12752 extrapolation from field tomato to greenhouse Aubergines/eggplants is not possible.

Redcurrant, White currant

There is not enough data available to make an assessment.

Ornamentals in field and greenhouses

Uses are accepted

Magnitude of residues in livestock

There is no risk for animal MRL to be exceeded (Reg. (EU) 2021/590). Additional studies are no required.

Processing studies

Additional tests are not required.

Magnitude of residues in representative succeeding crops

Taking relatively low application rate into account it can be concluded that specific plant-back restrictions related to the use of Boscalid 26.7% + Pyraclostrobin 6.7% WG are not required, provided that the product is used according to GAP. Exceedance of the MRLs set based on rotational crops residue studies is unlikely.

Noticed data gaps are:

Residue trials according to uses No 3, No 6-11, 23, 25 and 29

3.6.2 Consumer exposure

Consumer exposure regarding Pyraclostrobin

TMDI (% ADI) according to EFSA PRIMo	86 % (based on NL Toddler)
IEDI (% ADI) according to EFSA PRIMo	Not relevant
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities: Results for children Cherries (sweet): 122% Onions: 114% Carrots: 106% Raspberries: 92% Celeriacs: 92% Strawberries: 82% Currants: 79% Head cabbages: 59% Tomatoes: 58% Radishes: 41% Parsnips: 36% Aubergines/egg plants: 25% Beetroots: 19% Swedes: 16% Turnips: 11% Results for adults Cherries (sweet): 100% Onions: 74%

	<p> Currants: 66% Head cabbages: 56% Raspberries: 54% Strawberries: 47% Carrots: 33% Aubergines/egg plants: 27% Celeriacs: 20% Radishes: 17% Tomatoes: 16% Parsnips: 14% Swedes: 10% Beetroots: 8% Horseradishes: 7% </p> <p>Processed commodities:</p> <p> Results for children Currants/juice: 266% Raspberries/juice: 117% Sugar beets (root/sugar): 73% Carrots/juice: 60% Parsnips/boiled: 51% Celeriacs/juice: 24% Tomatoes/juice: 19% Shallots/boiled: 16% Turnips/boiled: 15% Beetroots/boiled: 15% Tomatoes.sauce.puree: 10% Salsifies/boiled: 9% Head Cabbages/canned: 8% Jerusalem artichokes/boiled: 5% Chicory roots/processed: 0.2% </p> <p> Results for adults Currants/juice: 128% Onions/boiled: 47% Celeriacs/boiled: 30% Sugar beets (root)/sugar: 29% Parsnips/boiled: 21% Carrots/canned: 14% Beetroots/boiled: 13% Head cabbages/canned: 13% Tomatoes/sauce/puree: 8% Shallots/boiled: 6% Turnips/boiled: 6% Salsifies/boiled: 3% Jerusalem artichokes/boiled: 2% Chicory roots/processed: 0.08% </p> <p>Results considering STMR/HR</p> <p>Unprocessed commodities:</p> <p> Results for children Celeriacs: 92% Strawberries: 82% Cherries (sweet): 65% Head Cabbages: 59% Tomatoes: 58% Currants: 55% Radishes: 41% Raspberries: 40% Parsnips: 36% </p>
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	<p>Aubergines/egg plants: 25% Beetroots: 19% Onions: 16% Swedes: 16% Carrots: 13% Turnips: 11%</p> <p>Results for adults: Head cabbages: 56% Cherries (sweet): 53% Strawberries: 47% Currants: 46% Aubergines/egg plants: 27% Raspberries: 23% Celeriacs: 20% Radishes: 17% Tomatoes: 16% Parsnips: 14% Onions: 10% Swedes: 10% Beetroots: 8% Horseradishes: 7% Carrots: 4%</p> <p>Processed commodities: Results for children Currants/juice: 90% Sugar beets (root)/sugar: 73% Parsnips/boiled: 51% Raspberries/juice: 34% Celeriacs/juice: 24% Tomatoes/juice: 19% Shallots/boiled: 16% Turnips/boiled: 15% Beetroots/boiled: 15% Tomatoes/sauce/puree: 10% Salsifies/boiled: 9% Head cabbages/canned: 8% Jerusalem artichokes/boiled: 5% Carrots/juice: 5% Chicory roots/processed: 0.2%</p> <p>Results for adults: Currants/juice: 40% Celeriacs/boiled: 30% Sugar beets (root)/sugar: 29% Parsnips/boiled: 21% Beetroots/boiled: 13% Head cabbages/canned: 13% Tomatoes/sauce/puree: 8% Onions/boiled: 7% Shallots/boiled: 6% Turnips/boiled: 6% Salsifies/boiled: 3% Jerusalem artichokes/boiled: 2% Carrots/canned: 1% Chicory roots/prcessed: 0.08%</p>
NTMDI (% ADI) **	-
NEDI (% ADI)**	-

NESTI (% ARfD) **	-
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The proposed uses of Pyraclostrobin in the formulation Pyraclostrobin 6.7% + Boscalid 26.7% WG do not represent unacceptable acute and chronic risks for the consumer.

Consumer exposure regarding Boscalid

TMDI (% ADI) according to EFSA PRIMo	398% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	84 % (based on NL toddler)

The accepted uses of Boscalid in the formulation Pyraclostrobin 6.7% + Boscalid 26.7% WG do not represent unacceptable chronic risks for the consumer.

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

Concentrations of Boscalid and Pyraclostrobin in various environmental compartments are predicted following the GAP. The predicted environmental concentrations (PEC values) in soil, surface water, sediment and ground water are provided.

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

PEC_{soil} calculations have been conducted with Pyraclostrobin and its relevant metabolites BF 500-6 and BF 500-7, and with Boscalid using the EU agreed endpoints (SANCO/3919 /2007-rev. 5 and SANCO/1420/2001-Final, respectively).

Maximum PEC_{soil} value for Boscalid was 0.928 mg/kg, following the worst case.

Maximum PEC_{soil} value for Pyraclostrobin was 0.199 mg/kg, 0.112 mg/kg for BF 500-6 and 0.046 mg/kg for BF 500-7, following the worst case

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

PEC_{gw} have been realised for Boscalid, and for Pyraclostrobin and its relevant metabolites BF 500-3, BF 500-6 and BF 500-7 using the FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 models and EU agreed endpoints (SANCO/3919 /2007-rev. 5 and SANCO/1420/2001-Final, respectively).

PEC_{gw} values were all below 0.01 µg/l for both Boscalid and Pyraclostrobin (including its metabolites).

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

The PEC_{SW/SED} of Boscalid and Pyraclostrobin and its relevant metabolites BF 500-6, BF 500-7, BF 500-3, BF 500-11, BF 500-13, BF 500-14, BF 500-15 and 500 M 58 have been assessed with the models FOCUS STEP 1, 2 and 3 and 4 (when necessary), using EU agreed endpoints (SANCO/3919 /2007-rev. 5 and SANCO/1420/2001-Final, respectively). Please refer to Part B, Section 9, Point 8.9 for more details about the results obtained.

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

The vapour pressure at 20 °C of Boscalid and Pyraclostrobin is $< 10^{-5}$ Pa. Hence Pyraclostrobin and Boscalid are regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the Boscalid and Pyraclostrobin due to volatilization with subsequent deposition should not be considered.

3.8 Ecotoxicology (Part B, Section 9)

According to the risk assessment for CASINO ROYALE, the following risk mitigation measure should be considered:

Sugar beet, Fruiting vegetables and potato, Root vegetables and Bulb vegetables – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 5 m to surface water bodies.

Leafy vegetables – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 10 m with 5m vegetative strip to surface water bodies.

Apple (early application) – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 40 m to surface water bodies OR respect an unsprayed buffer zone of 30 m to surface water bodies with 50% of nozzles reduction OR respect an unsprayed buffer zone of 20 m to surface water bodies with 75% of nozzles reduction OR respect an unsprayed buffer zone of 15 m to surface water bodies with 90% of nozzles reduction.

Vines (late application) – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 20 m to surface water bodies OR respect an unsprayed buffer zone of 15 m to surface water bodies with 50% of nozzles reduction OR respect an unsprayed buffer zone of 10 m to surface water bodies with 75% of nozzles reduction OR respect an unsprayed buffer zone of 5 m to surface water bodies with 90% of nozzles reduction.

3.8.1 Effects on terrestrial vertebrates

3.8.1.1 Effects on birds

Fruiting vegetables, bush and cane fruit, leafy vegetables and strawberry

According to the screening assessment, all the TER_a and TER_{lt} values for the active substance Pyraclostrobin are greater than the Annex VI trigger of 10 and 5, respectively. After screening assessment for active substance Boscalid, the TER_a value are greater than the trigger of 10, indicating that Casino Royale presents no unacceptable acute risk to birds. However, according to the first-tier assessment, TER_{lt} values are lower than the Annex VI trigger of 5 for frugivorous bird "crow" and frugivorous bird "Starling" (fruiting vegetables), frugivorous bird "blackcap" and small insectivorous bird "warbler" (bush and cane fruit), medium herbivorous/granivorous bird "pigeon" (leafy vegetables) and frugivorous bird "starling" (strawberries), indicating that Casino Royale presents an unacceptable long-term risk to birds. A refinement of the risk was done by refining of RUD, diet type, deposition factor and MAF, and the TER values were above the trigger showing no risk. Therefore, the acute and long-term risk to birds after the application of Casino Royale according to the GAP is considered acceptable

Sugar beet, root and stem vegetables, bulbs and onion like crops, cherry and ornamentals

According to the screening and first-tier assessments, all the TER_a and TER_{lt} values for active substances Pyraclostrobin and Boscalid are greater than the Annex VI trigger of 10 and 5, respectively, indicating that Casino Royale presents no unacceptable acute and long-term risk to birds according to the intended uses on sugar beet, root and stem vegetables, bulbs and onion like crops, cherry and ornamentals.

Pyraclostrobin has been shown to have the potential for bioaccumulation, however, there is no risk to earthworm and fish-eating birds according to the intended uses of Casino Royale.
The combined risk assessment for birds (acute and chronic) is considered acceptable.

3.8.1.2 Effects on mammals

Sugar beet, cherry and ornamentals

According to the screening and first-tier assessments, all the TER_a and TER_{lt} values for active substances Pyraclostrobin and Boscalid are greater than the Annex VI trigger of 10 and 5, respectively, indicating that Casino Royale presents no unacceptable acute and long-term risk to mammals according to the intended uses on sugar beet, cherry and ornamentals.

Fruiting vegetables and leafy vegetables

According to the screening assessments, all the TER_a values for the active substance Pyraclostrobin and Boscalid are greater than the Annex VI trigger of 10. After first-tier assessment for active substance Pyraclostrobin and Boscalid, some TER_{lt} values are lower than the Annex VI trigger of 5, for small herbivorous mammal "vole" in both active substance and frugivorous mammal "rat" for Pyraclostrobin in fruiting vegetables, indicating that Casino Royale presents an unacceptable long-term risk to mammals. A refinement of the risk was done by refining of RUD and DF, and the TER values were above the trigger showing no risk. Therefore, the acute and long-term risk to mammals after the application of Casino Royale according to the GAP is considered acceptable.

Bush and cane fruits, root and stem vegetables, bulbs and onion like crops and strawberry

According to the screening assessments, all the TER_a values for the active substance Pyraclostrobin and Boscalid are greater than the Annex VI trigger of 10. After first-tier assessment for active substance Pyraclostrobin, the TER_{lt} values are lower than the Annex VI trigger of 5 for small herbivorous mammal "vole", indicating that Casino Royale presents an unacceptable long-term risk to mammals. A refinement of the risk was done by refining of RUD and DF, and the TER values were above the trigger showing no risk. Therefore, the acute and long-term risk to mammals after the application of Casino Royale according to the GAP is considered acceptable.

Pyraclostrobin has been shown to have the potential for bioaccumulation, however, there is no risk to earthworm and fish-eating mammals according to the intended uses of Casino Royale.

In case of combined long-term risk assessment some of scenarios did not pass the TER_{LT} values.

However, due to differences in evaluated endpoints and the dependency of the derived NOEL of the test design, the calculated TER_{mix} value was used for illustrating purposes. ~~The risk for each active substances is sufficient to conclude acceptable risk for uses for Poland.~~

The applicant provided the risk assessment after commenting period for combined chronic exposure to mammals. Based on this the reduction of application dose for strawberry and bulbs crops, indicating an acceptable risk for mammals from exposure of active substances (the trigger closed to 5).

3.8.2 Effects on aquatic species

3.8.2.1 Conclusions related to Pyraclostrobin and its metabolites

For all intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish as characterised by an LC₅₀ for *Oncorhynchus mykiss* of 6 µg a.s./L in connection with an assessment factor of 100) in all FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of

surface water bodies. For all the intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in R4 stream scenario in fruiting vegetables, R4 stream scenario in root vegetables, R4 stream scenario in bulb vegetables, R4 1st stream and R4 2nd stream scenarios in leafy vegetables, R4 stream scenario in apple early application and R1 stream and R4 stream scenarios in vines late application. Therefore, a further refinement was necessary. A refinement for fish with RAC value of 0.248 µg a.s./L based on a geomean LC₅₀ from 7 acute toxicity laboratory studies on different fish species available in the monograph of Pyraclostrobin was used. The RAC_{chronic} was covered by RAC_{acute} geomean approach due to small difference between RAC values (RAC_{acute}=0.248 µg a.s./L , RAC_{chronic}= 0.2 µg a.s./L).

Moreover a refinement for the other aquatic organisms with a RAC value of 2 µg a.s./L based on meso-coms study available in Monograph of the active substance was also used.

After the refinement of both a.s., an acceptable risk was obtained with the following mitigation measures:

- Sugar beet: no-spray buffer zone of 5 m
- Fruiting vegetables and potato: no-spray buffer zone of 5m
- Root vegetables: no-spray buffer zone of 5m
- Bulb vegetables: no-spray buffer zone of 5m
- Leafy vegetables: no-spray buffer zone of 10m including 5 meter vegetative buffer strip
- Apple (early application): no-spray buffer zone of 40m OR no-spray buffer zone of 30m + 50% nozzles OR no-spray buffer zone of 20m + 75% nozzles
- Vines (late application): no-spray buffer zone of 20 m OR no-spray buffer zone of 10m + 75% nozzles OR no-spray buffer zone of 5m + 90% nozzles

Metabolites of Pyraclostrobin

For all intended uses, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms. Therefore, no further assessment is necessary.

3.8.2.2 Conclusions related to Boscalid

For all intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish as characterised by a NOEC for *Oncorhynchus mykiss* of 125 µg a.s./L in connection with an assessment factor of 10) in D6 2nd/ditch for bulb vegetables, D6/ditch and R4 1st/stream for leafy vegetables and D3 ditch, D4 stream, D5 stream, R1 stream, R2 stream, R3 stream and R4 stream for apple early application. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies. After step 4 calculations, the PEC/RAC ratio values calculated were below the trigger of 1 for all intended uses.

An acceptable risk was obtained with the following mitigation measures:

- Leafy vegetables: no-spray buffer zone of 5m with 5m vegetative strip.
- Apple early application: 5m + 50% of nozzle reduction.

However, the PEC/RAC ratio values calculated were still above the trigger of 1 for D6 2nd ditch in bulb vegetables and D6 ditch scenario in leafy vegetables for multiple application. However, D6 scenario is not relevant for CEU countries.

3.8.2.3 Overall conclusions

Sugar beet, Fruiting vegetables and potato, Root vegetables and Bulb vegetables – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 5 m to surface water bodies.

Leafy vegetables – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 10 m with 5m

vegetative strip to surface water bodies.

Apple (early application) – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 40 m to surface water bodies OR respect an unsprayed buffer zone of 30 m to surface water bodies with 50% of nozzles reduction OR respect an unsprayed buffer zone of 20 m to surface water bodies with 75% of nozzles reduction

Vines (late application) – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 20 m to surface water bodies OR respect an unsprayed buffer zone of 10 m to surface water bodies with 75% of nozzles reduction OR respect an unsprayed buffer zone of 5 m to surface water bodies with 90% of nozzles reduction.

In addition, it should be indicated that greenhouse uses are covered by field uses.

3.8.3 Effects on bees

First-tier assessments indicate that no unacceptable risk for bees exposed to the product Casino Royale is expected according to the proposed intended uses.

According to Reg. 284/2009 the chronic adult and chronic larvae tests for bees should be submitted by the applicant when **GD for Bees will be applied at EU level.**

3.8.4 Effects on other arthropod species other than bees

The in-field and off-field HQ values calculated for the product Casino Royale for the representative species *Typhlodromus pyri* and *A. rhopalosiphi* are lower than the trigger of 2 for Tier I tests, indicating no risk to non-target arthropods in vegetated off-field areas following application according to the proposed use patterns.

3.8.5 Effects on soil organisms

All the TERa values on earthworms for both active substances are higher than the Annex VI trigger value of 10, indicating that Casino Royale poses low acute risk to earthworms when applied according to the proposed use rates. The TERlt values on earthworms, *Folsomia* and *Hypoaspis* were higher than the Annex VI trigger value of 5, indicating low risk for non-target soil organisms with the application of Casino Royale.

However, TERlt values on earthworms for both active substances are lower than the Annex VI trigger value of 5, being necessary a further refinement. After refinement considering the field studies submitted in DAR for both active substances, a low long-term risk is expected indicating that Casino Royale poses low long-term risk to earthworms and other non-target soil organisms when applied according to the proposed use rates.

Risk assessments conducted with relevant PEC_{soil} for Casino Royale indicate a low risk to soil microorganisms when applied according to the proposed use rates.

3.8.6 Effects on non-target terrestrial plants

Risk assessment conducted with relevant toxicity data on non-target terrestrial plants for Casino Royale shows that the Annex VI trigger value of 5 is not exceeded, indicating that Casino Royale poses a low risk to non-target terrestrial plants when applied according to the proposed use rates.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

No additional data are available.

3.9 Relevance of metabolites (Part B, Section 10)

Not relevant. Boscalid doesn't have metabolites in soil and the Pyraclostrobin metabolites BF 500-3, BF 500-6 and BF 500-7 are predicted to occur in groundwater at concentrations below 0.001 µg/L.

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

Not relevant. CASINO ROYALE does not contain active substances considered as candidate for substitution.

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

Insert any data that the notifier needs to submit following authorization. As a rule, this is restricted to storage stability and monitoring data.

Insert the data that is still required for the evaluation of the product in the case where the product authorization is not granted.

Appendix 1 Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

Appendix 2 Copy of the product label

Sekcja pozostałości:

Brak zgody na następujące zastosowania:

Pomidor, bakłażan uprawa polowa – 3 aplikacje w sezonie

Pomidor – szklarnie; bakłażan - szklarnie

Kapusta

Truskawki, wiśnie, maliny, porzeczki

Załącznik do zezwolenia MRiRW nr R -/..... z dnia2020

Posiadacz zezwolenia:

Sharda Cropchem España S.L., Edificio Atalayas Business Center
Carril Condomina nº3, 12th Floor, 30006 Murcia, Hiszpania tel. +34868127589, e-mail:
eu.sales@shardaintl.com

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:

Sharda Poland Sp. z o.o., ul. Bonifraterska 17, 00-203 Warszawa, tel.: +48 17 240 13 07, e-mail:
eu.sales@shardaintl.com.

CASINO ROYALE (SHA 7273 A)



Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

Boskalid (substancja z grupy anilidów) - **267 g/kg** (26,7%)

Pyraklostrobina (substancja z grupy strobiluryn) – **67 g/kg** (6,7%)

Zezwolenie MRiRW nr R- /2020 z dnia . .2020 r.

 	
UWAGA	
H319 H410	Działa drażniąco na oczy. Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska należy postę-

	pować zgodnie z instrukcją użycia.
P273	Nie wypuszczać do środowiska.
P280	Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy.
P305 + P351 + P338	W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
P391	Zebrać wyciek.
P501	Zawartość / pojemnik usuwać zgodnie z przepisami miejscowymi / regionalnymi / narodowymi / międzynarodowymi

OPIS DZIAŁANIA

CASINO ROYALE jest środkiem grzybobójczym w formie granul do sporządzania zawiesiny wodnej. CASINO ROYALE jest fungicydem o działaniu układowym przeznaczonym do stosowania zapobiegawczego i interwencyjnego w zwalczaniu chorób.

STOSOWANIE ŚRODKA

Burak cukrowy

Cercospora beticola (chwościk buraka)

Maksymalna dawka dla jednorazowego zastosowania: 1,5 kg/ha

Zalecana dawka dla jednorazowego zastosowania: 1,5 kg/ha

Liczba zabiegów: 2

Termin stosowania środka: stosować od początku fazy wzrostu rozety (początek zakrywania międzyrzędzi – liście pokrywają 10% powierzchni gleby) do końca fazy zakrywania międzyrzędzi (liście pokrywają 90% powierzchni gleby) (BBCH 31-39)

Zalecana ilość wody: **300-600 l/ha.**

Odstęp między zabiegami: 8-10 dni

Zalecane opryskiwanie: **średniokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Pomidor (uprawiany w polu)

Phytophthora infestans

Maksymalna dawka dla jednorazowego zastosowania: 1,5 kg/ha

Zalecana dawka dla jednorazowego zastosowania: 1,5 kg/ha

Liczba zabiegów: 2

Termin stosowania środka: stosować po pojawieniu się pierwszych widocznych objawów choroby, od początku fazy rozwoju pędów bocznych do fazy gdy 70% owoców uzyskuje typową barwę (BBCH 20-87)

Zalecana ilość wody: **300-600 l/ha.**

Odstęp między zabiegami: 8-10 dni

Zalecane opryskiwanie: **średniokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Pomidor (uprawiany w polu)

Alternaria sp.

Maksymalna dawka dla jednorazowego zastosowania: 1,5 kg/ha

Zalecana dawka dla jednorazowego zastosowania: 1,5 kg/ha

Liczba zabiegów: 3

Termin stosowania środka: stosować po pojawieniu się pierwszych widocznych objawów choroby, od początku fazy rozwoju pędów bocznych do fazy gdy 70% owoców uzyskuje typową barwę (BBCH 20-87)

Zalecana ilość wody: **300-600 l/ha.**

Odstęp między zabiegami: 8-10 dni

Zalecane opryskiwanie: **średniokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 3

Marchew

Septoria apiicola, Cercospora sp, Alternaria sp.

Maksymalna dawka dla jednorazowego zastosowania: 1,5 kg/ha

Zalecana dawka dla jednorazowego zastosowania: 1,5 kg/ha

Liczba zabiegów: 2

Termin stosowania środka: stosować po pojawieniu się pierwszych widocznych objawów choroby, od początku fazy rozwoju części roślin przeznaczonych do zbioru (Korzenie zaczynają się poszerzać) do całkowitego rozwoju (korzeń osiąga typową wielkość i kształt) (BBCH 41-49)

Zalecana ilość wody: **300-600 l/ha.**

Odstęp między zabiegami: 8-10 dni

Zalecane opryskiwanie: **średniokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Cebula

Puccinia allii

Maksymalna dawka dla jednorazowego zastosowania: 1,5 kg/ha

Zalecana dawka dla jednorazowego zastosowania: 1,5 kg/ha

Liczba zabiegów: 2

Termin stosowania środka: stosować po pojawieniu się pierwszych widocznych objawów choroby, od początku fazy rozwoju części roślin przeznaczonych do zbioru (Podstawa liści grubieje lub rozszerza się) do fazy zamierania liści (szezyt cebuli usycha, przejście w stan spoczynku) (BBCH 41-49)

Zalecana ilość wody: **300-600 l/ha.**

Odstęp między zabiegami: 14 dni

Zalecane opryskiwanie: **średniokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Kapusta

Alternaria, Botrytis cinerea

Maksymalna dawka dla jednorazowego zastosowania: 1,0 kg/ha

Zalecana dawka dla jednorazowego zastosowania: 1,0 kg/ha

Liczba zabiegów: 3

Termin stosowania środka: stosować od fazy gdy zaczyna się tworzyć główka do fazy gdy główka osiąga typową wielkość, kształt i twardość (BBCH 41-49)

Zalecana ilość wody: 600-800 l/ha.

Odstęp między zabiegami: 7 dni

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 3

Pomidory (uprawiane pod osłonami)

Botrytis cinerea, Phytophthora infestans

Maksymalna dawka dla jednorazowego zastosowania: 2,0 kg/ha

Zalecana dawka dla jednorazowego zastosowania: 2,0 kg/ha

Liczba zabiegów: 2

Termin stosowania środka: środek stosować od fazy gdy widoczny jest pierwszy kwiatostan do fazy gdy 50% owoców uzyskuje typową barwę (BBCH 51-85)

Zalecana ilość wody: 600-800 l/ha.

Odstęp między zabiegami: 7 dni

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Truskawka

Botrytis cinerea, Ramularia grevilleana, Spaerotheca macularis,

Maksymalna dawka dla jednorazowego zastosowania: 1,8 kg/ha

Zalecana dawka dla jednorazowego zastosowania: 1,8 kg/ha

Liczba zabiegów: 2

Termin stosowania środka: środek stosować od fazy gdy widoczny jest pierwszy kwiatostan do fazy gdy 50% owoców uzyskuje typową barwę (BBCH 51-85)

Zalecana ilość wody: 500-700 l/ha.

Odstęp między zabiegami: 5 dni

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Wiśnia

Monilinia sp.

Maksymalna dawka dla jednorazowego zastosowania: 1,0 kg/ha

Zalecana dawka dla jednorazowego zastosowania: 1,0 kg/ha

Liczba zabiegów: 2

~~Termin stosowania środka: Pierwszy zabieg wykonać na początku kwitnienia (w okresie rozchylania się pierwszych pąków) (BBCH 60), drugi zabieg należy wykonać w fazie pełni kwitnienia (BBCH 67).~~

~~Zalecana ilość wody: 500-700 l/ha.~~

~~Odstęp między zabiegami: 5 dni~~

~~Zalecane opryskiwanie: średniokropliste~~

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2~~

Malina

Botrytis cinerea, Didymella applanata

~~Maksymalna dawka dla jednorazowego zastosowania: 1,8 kg/ha~~

~~Zalecana dawka dla jednorazowego zastosowania: 1,8 kg/ha~~

~~Liczba zabiegów: 2~~

~~Termin stosowania środka: środek stosować od fazy gdy pąki kwiatowe są zamknięte do końca fazy gdy wszystkie owoce są zebrane (BBCH 51-90). Środek stosować zapobiegawczo lub z chwilą pojawienia się pierwszych objawów choroby.~~

~~Do zwalczania szarej pleśni środek stosować od początku fazy kwitnienia (BBCH 61).~~

~~Do zwalczania przypąkowego zamierania pędów maliny pierwszy zabieg wykonać przed kwitnieniem, gdy nowe pędy osiągną wysokość 10-20 cm (BBCH 51), kolejne zabiegi wykonać w okresie kwitnienia (BBCH 61-69) lub po zbiorze owoców, po wycięciu starych pędów owoconośnych (BBCH 89-90).~~

~~Zalecana ilość wody: 600-700 l/ha.~~

~~Odstęp między zabiegami: 7 dni~~

~~Zalecane opryskiwanie: średniokropliste~~

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2~~

Czarna porzeczka

Drepanopeziza ribis, Cronartium ribicola

~~Maksymalna dawka dla jednorazowego zastosowania: 1,8 kg/ha~~

~~Zalecana dawka dla jednorazowego zastosowania: 1,8 kg/ha~~

~~Liczba zabiegów: 2~~

~~Termin stosowania środka: środek stosować zapobiegawczo lub z chwilą pojawienia się pierwszych objawów choroby. Pierwszy zabieg należy wykonać bezpośrednio przed kwitnieniem (BBCH 55-59), kolejny po kwitnieniu (BBCH 69-90).~~

~~Zalecana ilość wody: 600-800 l/ha.~~

~~Odstęp między zabiegami: 7-10 dni~~

~~Zalecane opryskiwanie: średniokropliste~~

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2~~

STOSOWANIE ŚRODKA OCHRONY ROŚLIN W UPRAWACH I ZASTOSOWANIACH MAŁOBSZAROWYCH

**Odpowiedzialność za skuteczność działania i fitotoksyczność środka ochrony roślin
stosowanego w uprawach małoobszarowych ponosi wyłącznie jego użytkownik**

Burak

Erysiphe betae

Maksymalna dawka dla jednorazowego zastosowania: 1,0 kg/ha

Zalecana dawka dla jednorazowego zastosowania: 1,0 kg/ha

Liczba zabiegów: 2

Termin stosowania środka: środek stosować od fazy 5. liścia do całkowitego rozwoju korzenia (korzenie osiągają średnicę wymaganą na zbiór do spożycia) (BBCH 15 – 49)

Zalecana ilość wody: **300-600 l/ha.**

Odstęp między zabiegami: 10 -14 dni

Zalecane opryskiwanie: **średniokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Seler

Sclerotinia sclerotiorum

Maksymalna dawka dla jednorazowego zastosowania: 1,5kg/ha

Zalecana dawka dla jednorazowego zastosowania: 1,5 kg/ha

Liczba zabiegów: 2

Termin stosowania środka: środek stosować od fazy 5. liścia do całkowitego rozwoju korzenia (korzenie osiągają średnicę wymaganą na zbiór do spożycia) (BBCH 15 – 49)

Zalecana ilość wody: **300-600 l/ha.**

Odstęp między zabiegami: 10 -14 dni

Zalecane opryskiwanie: **średniokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Pasternak, Pietruszka

Alternaria sp. alternata, Erysiphe heracleid

Maksymalna dawka dla jednorazowego zastosowania: 0,75kg/ha

Zalecana dawka dla jednorazowego zastosowania: 0,75 kg/ha

Liczba zabiegów: 2

Termin stosowania środka: środek stosować od fazy 5. liścia do całkowitego rozwoju korzenia (korzenie osiągają średnicę wymaganą na zbiór do spożycia) (BBCH 15 – 49)

Zalecana ilość wody: **600-800 l/ha.**

Odstęp między zabiegami: 21 -28 dni

Zalecane opryskiwanie: **średniokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Rzodkiewka

Botrytis cinerea

Maksymalna dawka dla jednorazowego zastosowania: 1,5 kg/ha

Zalecana dawka dla jednorazowego zastosowania: 1,5 kg/ha

Liczba zabiegów: 2

Termin stosowania środka: środek stosować od fazy 1. liścia do całkowitego rozwoju korzenia (korzenie osiągają średnicę wymaganą na zbiór do spożycia) (BBCH 11 – 49)

Zalecana ilość wody: **600-800 l/ha.**

Odstęp między zabiegami: 14 -21 dni

Zalecane opryskiwanie: **średniokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Rhizoctonia solani

Maksymalna dawka dla jednorazowego zastosowania: 1,5 kg/ha

Zalecana dawka dla jednorazowego zastosowania: 1,5 kg/ha

Liczba zabiegów: 1

Termin stosowania środka: środek stosować od fazy 1. liścia do fazy 2. liścia (BBCH 11 – 12)

Zalecana ilość wody: **300-600 l/ha.**

Zalecane opryskiwanie: **średniokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Chrzan

Peronospora sp., Alternaria, Erysiphe sp.

Maksymalna dawka dla jednorazowego zastosowania: 1,5 kg/ha

Zalecana dawka dla jednorazowego zastosowania: 1,5 kg/ha

Liczba zabiegów: 2

Termin stosowania środka: środek stosować od fazy 5. liścia do całkowitego rozwoju korzenia (korzenie osiągają średnicę wymaganą na zbiór do spożycia) (BBCH 15 – 49)

Zalecana ilość wody: **300-600 l/ha.**

Odstęp między zabiegami: 14 -21 dni

Zalecane opryskiwanie: **średniokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Brukiew

Peronospora sp., Cercospora beticola, Erysiphe sp.

Maksymalna dawka dla jednorazowego zastosowania: 1,0 kg/ha

Zalecana dawka dla jednorazowego zastosowania: 1,0 kg/ha

Liczba zabiegów: 2

Termin stosowania środka: środek stosować od fazy 5. liścia do całkowitego rozwoju korzenia (korzenie osiągają średnicę wymaganą na zbiór do spożycia) (BBCH 15 – 49)

Zalecana ilość wody: **300-600 l/ha.**

Odstęp między zabiegami: 10 -14 dni

Zalecane opryskiwanie: **średniokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Rzepa

Botrytis cinerea, Thanatephorus cucumeris

Maksymalna dawka dla jednorazowego zastosowania: 1,5 kg/ha

Zalecana dawka dla jednorazowego zastosowania: 1,5 kg/ha

Liczba zabiegów: 2

Termin stosowania środka: środek stosować od fazy 1. liścia do całkowitego rozwoju korzenia (korzenie osiągają średnicę wymaganą na zbiór do spożycia) (BBCH 11 – 49)

Zalecana ilość wody: **300-600 l/ha.**

Odstęp między zabiegami: 14 -21 dni

Zalecane opryskiwanie: **średniokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Korzenie cykorii

Chicory Alternaria, Chicory Puccinia

Maksymalna dawka dla jednorazowego zastosowania: 1,5 kg/ha

Zalecana dawka dla jednorazowego zastosowania: 1,5 kg/ha

Liczba zabiegów: 2

Termin stosowania środka: środek stosować od fazy 3. liścia do gdy korzeń osiąga 70% typowej średnicy (BBCH 13 – 47)

Zalecana ilość wody: **300-600 l/ha.**

Odstęp między zabiegami: 14 -21 dni

Zalecane opryskiwanie: **średniokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Szalotka

Peronospora destructor, Alternaria, Stemphylium

Maksymalna dawka dla jednorazowego zastosowania: 1,0 kg/ha

Zalecana dawka dla jednorazowego zastosowania: 1,0 kg/ha

Liczba zabiegów: 2

Termin stosowania środka: środek stosować od fazy 3. liścia do fazy gdy 50% liści rośliny zgina się (BBCH 13 – 48)

Zalecana ilość wody: **300-600 l/ha.**

Odstęp między zabiegami: 14 dni

Zalecane opryskiwanie: **średniokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2-1

Cebula siedmiolatka

Puccinia porri, Phytophthora porri, Alternaria

Maksymalna dawka dla jednorazowego zastosowania: 1,5 kg/ha

Zalecana dawka dla jednorazowego zastosowania: 1,5 kg/ha

Liczba zabiegów: 2-1

Termin stosowania środka: środek stosować od fazy 3. liścia do fazy gdy 10% liści rośliny zgina się (BBCH 13 – 47)

Zalecana ilość wody: **300-600 l/ha.**

Odstęp między zabiegami: 21-28 dni

Zalecane opryskiwanie: **średniokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2-1

Bakłażan uprawiany pod osłoną

Botrytis cinerea, Sclerotinia sclerotiorum, Leveillula Taurica

Maksymalna dawka dla jednorazowego zastosowania: 1,5 kg/ha

~~Zalecana dawka dla jednorazowego zastosowania: 1,5 kg/ha~~

~~Liczba zabiegów: 2~~

~~Termin stosowania środka: środek stosować od fazy 2. liścia do pełnej dojrzałości owoców (BBCH 12 – 89)~~

~~Zalecana ilość wody: 300-600 l/ha.~~

~~Odstęp między zabiegami: 7-10 dni~~

~~Zalecane opryskiwanie: średniokropliste~~

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2~~

Bakłażan uprawiany na polu

Phytophthora infestans

Maksymalna dawka dla jednorazowego zastosowania: 1,5 kg/ha

Zalecana dawka dla jednorazowego zastosowania: 1,5 kg/ha

Liczba zabiegów: 2

Termin stosowania środka: środek stosować po pojawieniu się pierwszych widocznych objawów choroby od fazy 2. liścia do fazy gdy 70% owoców uzyskuje typową barwę (BBCH 12 – 87)

Zalecana ilość wody: 300-600 l/ha.

Odstęp między zabiegami: 8-10 dni

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Alternaria sp.

~~**Maksymalna dawka dla jednorazowego zastosowania: 1,5 kg/ha**~~

~~**Zalecana dawka dla jednorazowego zastosowania: 1,5 kg/ha**~~

~~**Liczba zabiegów: 3**~~

~~**Termin stosowania środka: środek stosować po pojawieniu się pierwszych widocznych objawów choroby od fazy 2. liścia do fazy gdy 70% owoców uzyskuje typową barwę (BBCH 12 – 87)**~~

~~**Zalecana ilość wody: 300-600 l/ha.**~~

~~**Odstęp między zabiegami: 8-10 dni**~~

~~**Zalecane opryskiwanie: średniokropliste**~~

~~**Maksymalna liczba zabiegów w sezonie wegetacyjnym: 3**~~

Rośliny ozdobne uprawiane pod osłoną lub na polu

Alternaria

Maksymalna dawka dla jednorazowego zastosowania: 0,1 kg/ha

Zalecana dawka dla jednorazowego zastosowania: 0,1 kg/ha

Liczba zabiegów: 2

Termin stosowania środka: środek stosować od fazy 3. liścia do fazy pojawienia się pędy kwiatowego (BBCH 13 – 47)

Zalecana ilość wody: 100 l/ha.

Odstęp między zabiegami: 7-14 dni

Zalecane opryskiwanie: drobnokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Erysiphales

Maksymalna dawka dla jednorazowego zastosowania: 0,18 kg/ha

Zalecana dawka dla jednorazowego zastosowania: 0,18 kg/ha

Liczba zabiegów: 2

Termin stosowania środka: środek stosować od fazy 3. liścia do fazy pojawienia się pędy kwiatowego (BBCH 13 – 47)

Zalecana ilość wody: **100 l/ha.**

Odstęp między zabiegami: 7-14 dni

Zalecane opryskiwanie: **drobnokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Botrytis cinerea, Sclerotinia sclerotiorum, Thanatephorus cucumeris

Maksymalna dawka dla jednorazowego zastosowania: 0,15 kg/ha

Zalecana dawka dla jednorazowego zastosowania: 0,15 kg/ha

Liczba zabiegów: 2

Termin stosowania środka: środek stosować od fazy 3. liścia do fazy pojawienia się pędy kwiatowego (BBCH 13 – 47)

Zalecana ilość wody: **100 l/ha.**

Odstęp między zabiegami: 7-14 dni

Zalecane opryskiwanie: **drobnokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

~~Biała porzeczka, czerwona porzeczka~~

~~*Drepanopeziza ribis, Drepanopeziza rubric, Botrytis cinerea*~~

~~**Maksymalna dawka dla jednorazowego zastosowania:** 1,8 kg/ha~~

~~**Zalecana dawka dla jednorazowego zastosowania:** 1,8 kg/ha~~

~~Liczba zabiegów: 2~~

~~Termin stosowania środka: środek stosować zapobiegawczo lub z chwilą pojawienia się pierwszych objawów choroby. Pierwszy zabieg należy wykonać bezpośrednio przed kwitnieniem (BBCH 55-59), kolejny po kwitnieniu (BBCH 69-90).~~

~~Zalecana ilość wody: **600-800 l/ha**~~

~~Odstęp między zabiegami: 7-10 dni~~

~~Zalecane opryskiwanie: **drobnokropliste**~~

~~**Maksymalna liczba zabiegów w sezonie wegetacyjnym:** 2~~

Salsefia

Botrytis cinerea, Sclerotinia sclerotiorum, Rhizoctonia

Maksymalna dawka dla jednorazowego zastosowania: 1,5 kg/ha

Zalecana dawka dla jednorazowego zastosowania: 1,5 kg/ha

Liczba zabiegów: 2

Termin stosowania: stosować po pojawieniu się pierwszych widocznych objawów choroby, od początku fazy rozwoju części roślin przeznaczonych do zbioru (Korzenie zaczynają się poszerzać) do całkowitego rozwoju (korzeń osiąga typową wielkość i kształt) (BBCH 41-49)

Zalecana ilość wody: **300-600 l/ha**

Odstęp między zabiegami: 8-10 dni

Zalecane opryskiwanie: **drobnokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Zabieg wykonać opryskiwaczem wyposażonym w rozpylacze antyznoszeniowe.

ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ

Środka nie stosować:

- na rośliny osłabione i uszkodzone przez przymrozki, suszę, szkodniki lub choroby
- na plantacjach nasiennych.

Podczas stosowania środka nie dopuścić do:

- znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych
- nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość.

Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego do połowy wodą (z włączonym mieszadłem). Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlaniu środka do zbiornika opryskiwacza nie wyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać. W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Z resztkami cieczy użytkowej po zabiegu należy postępować w sposób ograniczający ryzyko skażenia wód powierzchniowych i podziemnych w rozumieniu przepisów Prawa wodnego oraz skażenia gruntu, tj.:

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

Po pracy aparaturę dokładnie wymyć.

Z wodą użytą do mycia aparatury należy postąpić tak, jak z resztkami cieczy użytkowej.

WARUNKI BEZPIECZNEGO STOSOWANIA ŚRODKA

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

Środki ostrożności dla osób stosujących środek: (pracowników oraz osób postronnych)

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

Operator:

Stosować rękawice ochronne, ochronę oczu lub twarzy oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy użytkowej oraz odzież roboczą czasie wykonywania zabiegu. W przypadku oprysku pomidorów w szklarniach stosować dodatkowo ochronę dróg oddechowych (min. maska FFP2).

W uprawie wiśni: Stosować rękawice ochronne, ochronę oczu lub twarzy oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy użytkowej oraz rękawice ochronne i odzież roboczą w czasie wykonywania zabiegu.

Pracownik polowy:

Stosować rękawice ochronne i odzież roboczą (koszula z długim rękawem i długie spodnie) oraz nie wchodzić na teren poddany zabiegowi wcześniej niż:

- po wyschnięciu preparatu na powierzchni roślin: burak cukrowy, marchew, burak, seler, pasternak, pietruszka naciowa, rzodkiew, chrzan, brukiew, rzepa, korzeń cykorii, cebula szalotka, topinambur, salsefia, pomidor, cebula, kapusta, bakłażan)
- 2 dni po wykonaniu oprysku: truskawka, malina, porzeczka;
- 2 dni po wykonaniu oprysku w przypadku uprawy: pomidor (szklarnia);
- 6 dni po wykonaniu oprysku: rośliny ozdobne;
- 7 dni po wykonaniu oprysku: wiśnia.

~~Stosować rękawice ochronne oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin w trakcie przygotowywania cieczy roboczej oraz w trakcie wykonywania zabiegu.~~

Środki ostrożności związane z ochroną środowiska naturalnego:

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.

Nie myć aparatury w pobliżu wód powierzchniowych.

Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

Burak cukrowy, pomidor, marchew, cebula, burak, seler, ~~pasternak, pietruszka~~, chrzan, brukiew, rzepa, korzenie cykorii, szalotka, cebula siedmiolotka, bakłażan, salsefia, ~~truskawka~~

SPe3

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 40 5 m od zbiorników i cieków wodnych.

Kapusta, truskawka, pasternak, pietruszka

SPe3

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 10m , w tym 5 metrowej strefy zadarnionej od zbiorników i cieków wodnych.

Malina, porzeczki, rośliny ozdobne

SPe3

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

~~LUB~~

~~wyznaczenie strefy ochronnej o szerokości 15m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%~~

~~LUB~~

wyznaczenie strefy ochronnej o szerokości 10m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75%

LUB

wyznaczenie strefy ochronnej o szerokości 5m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90%

Wiśnie

SPe3

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 40 m od zbiorników i cieków wodnych.

LUB

wyznaczenie strefy ochronnej o szerokości 30 m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%

LUB

wyznaczenie strefy ochronnej o szerokości 20 m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75%

LUB

~~wyznaczenie strefy ochronnej o szerokości 15m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90%~~

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

Nie dotyczy

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

~~Pomidor uprawiany na polu i pod przykryciem, truskawka, malina, czarna porzeczka, biała porzeczka, czerwona porzeczka, bakłażan – 3 dni~~

~~Wiśnia – 7 dni~~

Burak cukrowy, marchew, ~~cebula~~, ~~kapusta~~, burak, seler, pietruszka, pasternak, rzodkiewka, chrzan, brukiew, rzepa, korzenie cykorii, szalotka, cebula siedmiolatka, salsefia – 14 dni

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,
- w temperaturze 0°C - 30°C, z dala od źródeł ciepła.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

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

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

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

W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.

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

Okres ważności - 1 rok

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

No letters of Access to protected data are required.

Appendix 4 Lists of data considered for national authorization

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1 KCP 2.3.2 KCP 2.4.2 KCP 2.6.2 KCP 2.8.1 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.3.2 KCP 2.8.5.1.1 KCP 2.8.5.1.2 KCP 2.8.5.2.1 KCP 2.8.5.3 KCP 2.8.7.1 KCP 2.11	Elena Rigamonti	2017	Pyraclostrobin 6.7% + Boscalid 26.7% WG: Determination of the Physico-chemical Properties Company Report No CH – 865/2017 ChemService GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 2.3.3	Antonella Mazzei	2018	Determination of relative self-ignition of temperature for solids on the sample prycalostrobin 6.7% + boscalid 26.7 % WG. Report – 1704583 Innovhub GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.7.1	Elena Rigamonti	2017	Pyraclostrobin 6.7% + Boscalid 26.7% WG: Determination of the Accelerated Storage Stability and Corrosion Characteristics Company Report No CH – 868/2017 ChemService GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 2.11.1	Elena Rigamonti	2017	Pyraclostrobin 6.7% + Boscalid 26.7% WG: Washing efficacy after application Company Report No CH – 870/2017 ChemService GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 4.4.2	Rigamonti E.	2017	Pyraclostrobin 6.7% + Boscalid 26.7% WG: Washing efficacy after application Company Report No CH – 870/2017 ChemService GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
CP 6.0-001	Anonymous	2020	Biological Assessment Dossier: Boscalid 26.7% + Pyraclostrobin 6.7% WG – EU Central zone Sharda Cropchem España -, - Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 5.1.1/01	Elena Rigamonti	2017	Pyraclostrobin 6.7% + Boscalid 26.7% WG: Validation of the Analytical Method for the Determination of the Active Ingredients Content Company Report No CH – 866/2017 ChemService GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.1/02	Elena Rigamonti	2017	Pyraclostrobin 6.7% + Boscalid 26.7% WG: Validation of the Analytical Method for the Determination of Dimethylsulfate (DMS) as Relevant Impurity Content Company Report No CH – 867/2017 ChemService GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 7.6.2	Ashwinkumar V Meru	2020	In Vitro percutaneous dermal absorption study of Pyraclostrobin 6.7% + Boscalid 26.7% WG, through human skin, G18514_DER-ABS GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 8.3.1.1	Serena Kull	2019	Residue study (Decline) in sugarbeet following two sequential applications with Pyraclostrobin 6.7% + Boscalid 26.7% WG in Germany 2018 – field part. Study No. CT18-1-19. CropTrials GmbH Unpublished GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 8.3.1.2	Zofia Hordyjewicz-Baran	2019	Pyraclostrobin and boscalid residues in sugarbeet after application of pyraclostrobin 6.7% + boscalid 26.7% WG – analytical part. Study No. 45/2019. Institute of Heavy Organic Synthesis “Blachownia” Unpublished GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 8.3.1.3	K. Łukaszewski	2019	Magnitude of the residue of Pyraclostrobin and Boscalid in sugarbeet (Raw Agricultural Commodity) after two applications of Pyraclostrobin 6.7% and Boscalid 26.7% WG – two harvest trials in Poland – 2018 – field part Report No. 18SGS17 SGS Polska Unpublished GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.1.4	Zofia Hordyjewicz-Baran	2019	Magnitude of the residue of pyraclostrobin + boscalid in sugar beet (Raw Agricultural Commodity – RAC) grown in open field conditions after two applications of pyraclostrobin 6.7% + boscalid 26.7% - two harvest trials in Poland, 2018. Study No. 18/2019 Institute of Heavy Organic Synthesis “Blachownia” Unpublished GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 8.3.1.5	Rafal Figurski	2019	Magnitude of the residue of pyraclostrobin + boscalid in sugar beet (Raw Agricultural Commodity – RAC) grown in open field conditions after two applications of formulated product pyraclostrobin 6.7% + boscalid 26.7% - two harvest trials in North Europe – Poland, 2018. Study No. PB-2018-10 Fertico Sp. z o.o. Unpublished GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 8.3.1.6	Zofia Hordyjewicz-Baran	2019	Pyraclostrobin and boscalid residues in sugar beets after application of pyraclostrobin 6.7 + boscalid 26.7% WG. Study No. 4/2019 Institute of Heavy Organic Synthesis “Blachownia” Unpublished GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 8.3.1.7	Zofia Hordyjewicz-Baran	2019	Decline residue of pyraclo 6.7 + boscalid 26.7 % WG in sugar beet. Raw Agricultural commodity in the United Kingdom, 2018. Study No. 50/2019 Institute of Heavy Organic Synthesis “Blachownia” Unpublished GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.2.1	Rafal Figurski	2019	Magnitude of the residue of pyraclostrobin + boscalid in tomato (raw agricultural commodity – RAC) grown in open field conditions after two applications of formulated product pyraclostrobin 6.7% + boscalid 26.7% WG – two harvest trials in Northern Europe – Poland, 2018. Study No. PB-2018-11 Fertico Sp. z o.o. Unpublished GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 8.3.2.2	Zofia Hordyjewicz-Baran	2019	Pyraclostrobin and boscalid residues in tomatoes after application of Pyraclostrobin 6.7 + boscalid 26.7 % WG – analytical part. Study No. 5/2019 Institute of Heavy Organic Synthesis “Blachownia” Unpublished GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 8.3.2.3	K. Łukaszewski	2019	Magnitude of the residue of pyraclostrobin + boscalid in tomato (Raw Agricultural Commodity) after two applications of Pyraclostrobin 6.7% + Boscalid 26.7% WG – two harvest trials and one decline curve trial in Poland – 2018 – Field part Study No. 18SGS18 SGS Polska Unpublished GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 8.3.2.4	Zofia Hordyjewicz-Baran	2019	Magnitude of the residue of pyraclostrobin + boscalid in tomato (raw agricultural commodity) after two applications of pyraclostrobin 6.7% + boscalid 26.7% WG – two harvest trials and one decline curve trial in Poland – 2018. Study No. 22/2019 Institute of Heavy Organic Synthesis “Blachownia” Unpublished GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.2.5	P. Iszak	2020	Determination of the residues of Boscalid + Pyraclostrobin in/on tomato (outdoor) after two applications of Boscalid 26.7% + Pyraclostrobin 6.7% WG in Northern Europe – Hungary in 2019 – Field part Study No. 034SRHU19R27 Suntech Research Hungary Unpublished GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 8.3.2.6	M. Zarębska	2020	Determination of the residue of boscalid + pyraclostrobin in/on tomato (outdoor) after two foliar applications of Boscalid 26.7% + Pyraclostrobin 6.7% WG in northern Europe – Hungary in 2019 – analytical part Study No. 173/2019 Unpublished GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 8.3.3.1	Rafal Figurski	2019	Magnitude of the residue of pyraclostrobin + boscalid in onion (raw agricultural commodity – RAC) grown in open field conditions after two applications of formulated product pyraclostrobin 6.7 % + boscalid 26.7% WG – two harvest trials in Northern Europe – Poland, 2018. Study No. PB-2018-12. Fertico Sp. z o.o. Unpublished GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 8.3.3.2	Zofia Hordyjewicz-Baran	2019	Pyraclostrobin and boscalid residues in onion after application of pyraclostrobin 6.7 + boscalid 26.7 % WG – analytical part. Study No. 3/2019 Institute of Heavy Organic Synthesis “Blachownia” Unpublished GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.3.3	K. Łukaszewski	2019	Magnitude of the residue of pyraclostrobin + boscalid in onion (Raw Agricultural Commodity) after two applications of Pyraclostrobin 6.7% + Boscalid 26.7% WG – two harvest trials and two decline curve trials in Poland – 2018 – field part Study No. 18SGS19 SGS Polska Unpublished GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 8.3.3.4	Zofia Hordyjewicz-Baran	2019	Magnitude of the residue of pyraclostrobin + boscalid in onion (raw agricultural commodity) after two applications of pyraclostrobin 6.7% + boscalid 26.7% WG – two harvest trials and one decline curve trial in Poland -2018 – analytical phase. Study No. 20/2019 Institute of Heavy Organic Synthesis “Blachownia” Unpublished GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 8.3.3.5	P. Iszak	2020	Determination of the residues of boscalid + pyraclostrobin in/on onion after two applications of Boscalid 26.7% + Pyraclostrobin 6.7% WG in Northern Europe – Hungary in 2019 – field part Study No. 034SRHU19R28 Syntech Research Hungary Unpublished GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 8.3.3.6	M. Zarębska	2020	Determination of the residue of boscalid + pyraclostrobin in/on onion after two foliar applications of Boscalid 26.7% + Pyraclostrobin 6.7% WG in northern Europe – Hungary in 2019 – analytical part Study No. 175/2019 Institute of Heavy Organic Synthesis “Blachownia” Unpublished GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.4.1	K. Łukaszewski	2019	Magnitude of the residue of Pyraclostrobin + Boscalid in carrot (Raw Agricultural Commodity) after two applications of Pyraclostrobin 6.7% + Boscalid 26.7% WG – two harvest trials and two decline curve trials in Poland – 2018 – Field part Study No. 18SGS20 SGS Polska Unpublished GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 8.3.4.2	Zofia Hordyjewicz-Baran	2019	Magnitude of the residue of pyraclostrobin and boscalid in carrot (raw agricultural commodity) after two applications of pyraclostrobin 6.7% and boscalid 26.7% WG – two harvest trials and two decline curve trials in Poland – 2018. – analytical phase. Study No. 21/2019 Institute of Heavy Organic Synthesis “Blachownia” Unpublished GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 8.3.4.3	Rafał Figurski	2019	Magnitude of the residue of pyraclostrobin + boscalid in carrot (raw agricultural commodity – RAC) grown in open field conditions after two applications of formulated product pyraclostrobin 6.7 % + boscalid 26.7% WG – two harvest trials in Northern Europe – Poland, 2018. Study No. PB-2018-13 Fertico Sp. z o.o. Unpublished GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 8.3.4.4	Zofia Hordyjewicz-Baran	2019	Pyraclostrobin and boscalid residues in carrots after application of pyraclostrobin 6.7 + boscalid 26.7 % WG – analytical part. Study No. 6/2019 Institute of Heavy Organic Synthesis “Blachownia” Unpublished GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.4.5	Zofia Hordyjewicz-Baran	2019	Decline residue of pyraclo 6.7 + boscalid 26.7% WG. Raw agricultural commodity in the United Kingdom, 2018. Study No. 54/2019. Unpublished GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 8.3.4.6	Á. Horváth	2020	Determination of the residues of Boscalid + Pyraclostrobin in/on carrot after two applications of Boscalid 26.7% + Pyraclostrobin 6.7% WG in northern Europe – Hungary in 2019 – Field Part Study No. 034SRHU19R29 Syntech Research Hungary Unpublished GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 8.3.4.7	M. Zarębska	2020	Determination of the residue of boscalid + pyraclostrobin in/on carrot after two foliar applications of Boscalid 26.7% + Pyraclostrobin 6.7% WG in northern Europe – Hungary in 2019 – analytical part Study No. 174/2019 Insitite of Heavy Organic Synthesis “Blachownia” Unpublished GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 10.1.1.2-01	Łukaszewski, K.	2019	Magnitude of the residue of pyraclostrobin + boscalid in tomato (Raw Agricultural Commodity) after two application of Pyraclostrobin 6.7% + Boscalid 26.7% WG – two harvest trials and one decline curve trial in Poland – 2018 Report No. 18SGS18. SGS Polska Sp. Z o.o. GLP. Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 10.1.1.2-02	Iszak, P.	2020	Determination of the residues of Boscalid + Pyraclostrobin in/on tomato (outdoor) after two applications of Boscalid 26.7% + Pyraclostrobin 6.7% WG in Northern Europe – Hungary in 2019 Report No. 034SRHU19R27. CPR Europe Kft. GLP. Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.2.1-01	xxx	2018	Pyraclostrobin 6.7% + Boscalid 26.7% WG Rainbow Trout, Acute Toxicity Test Report No. W/140/17 xxx GLP Unpublished	Y	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 10.2.1-02	Kulec-Płoszczyca, E.	2018	Pyraclostrobin 6.7% + Boscalid 26.7% WG <i>Daphnia magna</i> , acute immobilisation test Report No. W/142/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 10.2.1-03	Kulec-Płoszczyca, E.	2018	Pyraclostrobin 6.7% + Boscalid 26.7% WG <i>Raphidocelis subcapitata</i> SAG 61.81 (formerly <i>Pseudokirchneriella subcapitata</i>) Growth inhibition test Report No. W/141/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 10.2.1-04	Kulec-Płoszczyca, E.	2018	Pyraclostrobin 6.7% + Boscalid 26.7% WG <i>Lemna gibba</i> CPCC 310, Growth inhibition test Report No. W/143/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 10.3.1.1.1	Glanas, A.	2017	Boscalid 26.7% + Pyraclostrobin 6.7% WG Honeybees (<i>Apis mellifera</i> L.), Acute Oral Toxicity Test Report No. B/108/16 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.

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KCP 10.3.1.1.2	Glanas, A.	2017	Boscalid 26.7% + Pyraclostrobin 6.7% WG. Honeybees (<i>Apis mellifera</i> L.), Acute Contact Toxicity Test Report No. B/109/16 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 10.3.1.2.1	Radha, S.	2020	Chronic oral toxicity study of Pyraclostrobin Technical on adult honey bee (<i>Apis mellifera</i>). Report No. 5028/2019 Bioscience Research Foundation GLP. Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 10.3.1.3.1	Radha, S.	2020	Effect of Pyraclostrobin Technical on larvae of honey bee, <i>Apis mellifera</i> (L.) following repeated exposure. Report No. 5029/2019 Bioscience Research Foundation GLP. Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 10.3.1.2.2	Radha, S.	2020	Chronic oral toxicity study of Boscalid Technical on adult honey bee (<i>Apis mellifera</i>) Report No. 5031/2019 Bioscience Research Foundation GLP. Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 10.3.1.3.2	Radha, S.	2020	Effect of Boscalid Technical on larvae of honey bee, <i>Apis mellifera</i> (L.) following repeated exposure. Report No. 5032/2019 Bioscience Research Foundation GLP. Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 10.3.2.1-01	Glanas, A.	2018	A laboratory test for evaluating the effects of Boscalid 26.7% + Pyraclostrobin 6.7% WG on the predatory mite, <i>Typhlodromus pyri</i> (Sch.) Report No. B/111/16 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.

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KCP 10.3.2.1-02	Grzesica, M.	2018	A laboratory test for evaluating the effects of Boscalid 26.7% + Pyraclostrobin 6.7% WG on the parasitic wasp, <i>Aphidius rhopalosiphi</i> (De Stefani - Perez) Report No. B/110/16 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 10.4.1.1	Weronika, D.	2018	Boscalid 26.7% + Pyraclostrobin 6.7% WG Earthworm Reproduction Test (<i>Eisenia andrei</i>) Report No. G/203/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 10.4.2.1-01	Anton, B.	2019	Pyraclostrobin 6.7 % + Boscalid 26.7 % WG Effects on the Reproductive Output of the Springtail <i>Folsomia candida</i> Willem (Collembola, Isotomidae) in Artificial Soil Report No. S18-07887 TRIALCAMP S.L.U. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 10.4.2.1-02	Lozano, J.	2019	Pyraclostrobin 6.7% + Boscalid 26.7% WG: Effects on the Reproductive Output of the Predatory Soil Mite <i>Hypoaspis (Geolaelaps) aculeifer</i> Canestrini (Acari: Laelapidae) in Artificial Soil Report No. S18-06116 TRIALCAMP S.L.U. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 10.5.1	Weronika, D.	2018	Boscalid 26.7% + Pyraclostrobin 6.7% WG Soil Microorganisms: Nitrogen Transformation Test Report No. G/202/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.

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KCP 10.5.2	Weronika, D.	2018	Boscalid 26.7% + Pyraclostrobin 6.7% WG Soil Microorganisms: Carbon Transformation Test Report No. G/201/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 10.6.2-01	Weronika, D.	2018	Boscalid 26.7% + Pyraclostrobin 6.7% WG Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Report No. G/206/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 10.6.2-02	Weronika, D.	2018	Boscalid 26.7% + Pyraclostrobin 6.7% WG Terrestrial Plant Test: Vegetative Vigour Test Report No. G/207/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd.

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

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

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

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