

FINAL REGISTRATION REPORT

Part B

Section 1: Identity

Section 2: Physical and chemical properties

Section 4: Further information

Detailed summary of the risk assessment

Product code: SHA 7273 A

Product name(s): CASINO ROYALE

Chemical active substances:

Boscalid, 267 g/kg

Pyraclostrobin, 67 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: August 2020

MS Finalisation date: 04/2021; 01/2022

Version history

| When | What |
|--------------|---------------------------|
| March 2021 | Draft assessment by zRMS |
| January 2022 | Final Registration Report |
| | |
| | |

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zRMS comment:

Sufficient data on identity, physical and chemical properties and other information are available for CASINO ROYALE (SHA 7273 A) and the contained technical active substances.

Noticed data gaps: the shelf-life study is on-going and the report shall be submitted when finished. Based on the composition of the product and results of accelerated storage tests in the commercial packaging, one-year conditional registration of the product is possible and proposed. Final registration will be feasible after completion of the 2-year ambient storage tests.

Packaging: Based on accelerated storage results, proposed commercial packaging – PE bottle and jarrycan, are appropriate and accepted. No leakage, panelling, deformations etc. were reported. According to the guidelines of the polish Ministry of Agriculture and Rural Development, extrapolation from the rigid to elastic packaging types is not acceptable for WG formulation and therefore bags and sacs were crossed out.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Sharda Cropchem España S.L.
Address: Edificio Atalayas Business Center,
Carril Condomina nº 3, 12th Floor,
30006 Murcia, Spain
Phone: +34868127589
FAX: +34868127588

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

1.2.1 Producer(s) of the preparation

Name: Sharda Cropchem Ltd.
Address: Prime Business Park
Dashrathlal Joshi Road
Vile Parle (West)
Mumbai – 400 056
India
Phone number: + 91 22 6678 2800
Fax number: + 91 22 6678 2828/ 2808
Email: shardaint@vsnl.com
regn@shardaintl.com

1.2.2 Producer(s) of the active substance(s)

Name: Sharda Cropchem Ltd.
Address: Prime Business Park
Dashrathlal Joshi Road
Vile Parle (West)
Mumbai – 400 056

India
Phone number: + 91 22 6678 2800
Fax number: + 91 22 6678 2828/ 2808
Email: shardaint@vsnl.com
regn@shardaintl.com

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

1.2.3.1 Pyraclostrobin

Pyraclostrobin min. 975 g/kg (Sharda source)
min. 975 g/kg (Commission Directive 2004/30/EC and SANCO/1420/2001 – Final (8 September 2004))
Relevant impurity:
Dimethylsulfate max 0.0001% in the technical product (Commission Directive 2004/30/EC and SANCO/1420/2001 – Final (8 September 2004))

1.2.3.2 Boscalid

Boscalid min. 970 g/kg (Sharda source)
min. 960 g/kg (Commission Directive 2008/44/EC and SANCO/3919/2007 – rev. 5 (21 January 2008))

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

Trade name: CASINO ROYALE
Company code number: SHA 7273 B
Boscalid 26.7% + Pyraclostrobin 6.7% WG
Pyraclostrobin 6.7% + Boscalid 26.7% WG

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

1.4.1 Composition of the plant protection product (KCP 1.4.1)

Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)

| Active substance / variant | Declared content of the pure active substance / variant (g/kg) | FAO Limits** (min – max) | Technical content* (g/L or g/kg) | Technical content (%w/w) |
|----------------------------|--|---|----------------------------------|--------------------------|
| Pyraclostrobin | 67.0 | 60.3 – 73.7 g/kg (± 10% of the declared content) | 68.7 | 6.87 |
| Boscalid | 267.0 | 253.7 – 280.4 g/kg | 275.3 | 27.53 |

| Active substance / variant | Declared content of the pure active substance / variant (g/kg) | FAO Limits** (min – max) | Technical content* (g/L or g/kg) | Technical content (%w/w) |
|----------------------------|--|--------------------------------|----------------------------------|--------------------------|
| | | (± 5% of the declared content) | | |

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

** FAO tolerance limits for a declared content above 25 to 100 is ±10%.

FAO tolerance limits for a declared content above 250 to 500 is ±5%

Table 1.4-2: Relevant impurities

| Relevant impurity | Maximum content (g/L or g/kg) |
|-------------------|---|
| Dimethylsulfate | < 0.067 µg/g (maximum allowed in the product) |

1.4.2 Information on the active substances (KCP 1.4.2)

Table 1.4-2: Information on Pyraclostrobin

| Type | Name/Code Number |
|-----------------|------------------|
| ISO common name | Pyraclostrobin |
| CAS No. | 175013-18-0 |
| EC No. | Not assigned |
| CIPAC No. | 657 |

Table 1.4-3: Information on Boscalid

| Type | Name/Code Number |
|-----------------|------------------|
| ISO common name | Boscalid |
| CAS No. | 188425-85-6 |
| EC No. | not assigned |
| CIPAC No. | 673 |

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

CONFIDENTIAL information is provided separately (Part C).

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

Type: Water Dispersible Granules

[Code: WG]

1.6 Function (KCP 1.6)

The product CASINO ROYALE is intended to be used as a fungicide.

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of 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 ~~0.093755~~ 0.1 % to 0.5 % w/v.

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

Neither classification nor labelling are relevant for this section.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

No risk and safety phrases are relevant for this section.

Compliance with FAO specifications:

The product CASINO ROYALE complies with FAO specifications.

Formulation used for tests

The product used to determine the physical, chemical and technical properties is the one cited in Part C.

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

| Annex point | Method used / deviations | Test material | Findings | GLP Y/N | Reference | Acceptability / comments |
|-------------------------------------|---|---|---|---------|--|---|
| Colour and physical state (KCP 2.1) | OPPTS 830.6302, OPPTS 830.6303, OPPTS 830.6304 | Pyraclostrobin 6.7% + Boscalid 26.7% WG, batch No SCL-20604 | Dark brown granules with characteristic odour. (Sigma-Aldrich Color Chart shortcode: BR 4) | Y | Rigamonti E., 2017, ChemService, report CH - 865/2017 | Accepted |
| Explosive properties (KCP 2.2.1) | computer software CHETAH (Chemical Thermodynamic and Hazard evaluation) | Pyraclostrobin 6.7% + Boscalid 26.7% WG, batch No SCL-65489 | From the criteria results obtained with CHETAH software based on the molecular structure of the active ingredients and main co-formulants of the test item, it can be concluded that the Pyraclostrobin 6.7% + Boscalid 26.7% WG sample may not be expected to have an explosive behaviour. | Y | Elena Rigamonti, 2018, ChemService, report CH - 159/2018 | Acceptable Results obtained with CHETAH are sufficient to conclude that the formulation do not present explosive properties |
| Oxidizing properties (KCP 2.2.2) | computer software CHETAH (Chemical Thermodynamic and Hazard evaluation) | Pyraclostrobin 6.7% + Boscalid 26.7% WG, batch No SCL-65489 | From the criteria results obtained with CHETAH software based on the molecular structure of the active ingredients and main co-formulants of the test item, only Lignosulfonic acid could have oxidizing behaviour. Considering the conservative setting of the CHETAH software and the Lignosulfonic acid C3 oxygen balance value of -153.291 g O ₂ /100g, very close to the low level classification (lower than -160 g O ₂ /100g), it can be concluded that the Pyraclostrobin 6.7% + Boscalid 26.7% WG sample may not be expected to have an oxidizing behaviour. | Y | Elena Rigamonti, 2018, ChemService, report CH - 159/2018 | Acceptable Results obtained with CHETAH are sufficient to conclude that the formulation do not present oxidising properties |
| Flash point (KCP 2.3.1) | - | - | Not relevant for WG formulations. | - | - | Not required |
| Flammability (KCP 2.3.2) | EC 440/2008 No. A.10 | Pyraclostrobin 6.7% + Boscalid 26.7% WG, | Not highly flammable. | Y | Rigamonti E., 2017, ChemService, report CH - | Accepted The test item is not flammable, as it |

| Annex point | Method used / deviations | Test material | Findings | GLP Y/N | Reference | Acceptability / comments |
|---|--------------------------|---|--|---------|---|---|
| | | batch No SCL-20604 | | | 865/2017 | carbonised when the Bunsen burner flame came close ($n=2$) and the combustion did not propagated. |
| Self-heating (KCP 2.3.3) | A 16 | Pyraclostrobin 6.7% + Boscalid 26.7% WG, batch No SCL-20604 | The relative self-ignition temperature is 245 °C. | Y | Mazzei A., 2018 Innovhub Report - 1704583 | Accepted |
| Acidity or alkalinity and pH (KCP 2.4.1) | - | - | Since the pH value ranged from 4 to 10 (see below), the acidity or alkalinity test was not performed . | - | - | Not required |
| pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2) | CIPAC MT 75.3 | Pyraclostrobin 6.7% + Boscalid 26.7% WG, batch No SCL-20604 | pH = 5.9 at 20 °C. | Y | Rigamonti E., 2017, ChemService, report CH - 865/2017 | Accepted |
| Viscosity (KCP 2.5.1) | - | - | Not relevant for WG formulations. | - | - | Not required |
| Surface tension (KCP 2.5.2) | - | - | Not relevant for WG formulations. | - | - | Not required |
| Relative density (KCP 2.6.1) | - | - | Not relevant for WG formulations. | - | - | Not required |
| Bulk density (KCP 2.6.2) | CIPAC MT 186 | Pyraclostrobin 6.7% + Boscalid 26.7% WG, batch No | Pour density: 0.66 g/mL Bulk density: 0.76 g/mL | Y | Rigamonti E., 2017, ChemService, report CH - 865/2017 | Accepted |

| Annex point | Method used / deviations | Test material | Findings | | | GLP Y/N | Reference | Acceptability / comments |
|--|--|---|--|---|---|---------|---|--|
| | | SCL-20604 | | | | | | |
| Storage Stability after 14 days at 54° C (KCP 2.7.1) | CIPAC MT 46 | Pyraclostrobin 6.7% + Boscalid 26.7% WG, batch No SCL-20604 | | | | Y | Rigamonti E., 2017, ChemService, report CH - 868/2017 | Accepted Tests performed according to GIFAP No. 17. All tests required for a WG formulation were submitted and accepted. No significant change in active ingredients content, neither physical and packaging characteristics after storage. The impurity – dimethylsulfate (DMS) content was lower than the LOD (0.005 µg/g) and below the maximum limit allowed. |
| | GIFAP No. 17 | | | Initial time | 14 Days at 54°C | | | |
| | HPLC/UV analysis | | Packaging | - | PE bottle with screw cap “A” and “B” | | | |
| | GC | | Weight variation | - | A: -0.04% B: -0.04% | | | |
| | OPPTS 830.6302, OPPTS 830.6303, OPPTS 830.6304 CIPAC MT 75.3 | | Compatibility of the packaging material | - | The container didn’t present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena | | | |
| | CIPAC MT 53.3 and MT 18 (Standard Water D) | | Active content | Pyraclostrobin: 7.0 ± 0.1 % w/w Boscalid: 26.5 ± 0.3 % w/w | Pyraclostrobin: 6.9 ± 0.1 % w/w Boscalid: 26.5 ± 0.3 % w/w | | | |
| | CIPAC MT 47.2 and MT 18 (Standard Water D) | | Dimethyl sulfate relevant impurity content | < 0.067 µg/g * | < 0.067 µg/g * | | | |
| | OECD No. 110; CIPAC MT 187 | | Physical state, Colour, odour | Dark brown granules with characteristic odour (shortcode: BR 4) | Dark brown granules with characteristic odour (shortcode: BR 4) | | | |
| | CIPAC MT 178.2 | | pH of a 1% | 5.9 | 6.0 | | | |
| | CIPAC MT 171 | | Wettability | Without swirling: 3 sec With swirling: 1 sec | Without swirling: 2 sec With swirling: 1 sec | | | |
| | CIPAC MT 184 and MT 18 (Standard Water D) | | Persistence foaming | Foam after 1 minute: 0.05 % w/v = 0 mL 0.50 % w/v = 10 mL | Foam after 1 minute: 0.05 % w/v = 0 mL 0.50 % w/v = 8 mL | | | |
| | CIPAC MT 174 and MT 18 (Standard Water D) | | Particle size distribution | Dv 10: 315 µm Dv 50: 479 µm Dv 90: 730 µm % under 45 µm: 0.00 % above 75 µm: 100.00 | Dv 10: 348 µm Dv 50: 511 µm Dv 90: 752 µm % under 45 µm: 0.00 % above 75 µm: 100.00 | | | |
| | | | Attrition resistance | 100.1 % | 99.9 % | | | |

| Annex point | Method used / deviations | Test material | Findings | | | GLP Y/N | Reference | Acceptability / comments |
|---|---|---------------|--|--|--|---------|-----------|---|
| | ard Water D) CIPAC MT 185 CIPAC MT 30.5 | | Dust content | “Nearly dust free” (0.8 mg; 0.003 % w/w) | “Nearly dust free” (0.8 mg; 0.003 % w/w) | | | |
| | | | Suspensibility | Pyraclostrobin: 0.05 % w/v: 98.3 % 0.50 % w/v: 97.9 % Boscalid: 0.05 % w/v: 98.3 % 0.50 % w/v: 97.3 % | Pyraclostrobin: 0.05 % w/v: 81.5 % 0.50 % w/v: 95.6 % Boscalid: 0.05 % w/v: 89.4 % 0.50 % w/v: 95.8 % | | | |
| | | | Degree of dispersion | Pyraclostrobin: 1.00 % w/v: 96.5 % Boscalid: 1.00 % w/v: 96.1 % | Pyraclostrobin: 1.00 % w/v: 92.5 % Boscalid: 1.00 % w/v: 93.2 % | | | |
| | | | Wet sieve test | No residue onto 75 µm sieve | No residue onto 75 µm sieve | | | |
| | | | Water content | 3.33% w/w | 2.89% w/w | | | |
| | | | *0.067 µg/g is the maximum allowed in the product. | | | | | |
| Stability after storage for other periods and/or temperatures (KCP 2.7.2) | - | - | Not required. | | | - | - | Not required |
| Minimum content after heat stability testing (KCP 2.7.3) | - | - | Not required. | | | - | - | Not required |
| Effect of low temperatures on stability (KCP 2.7.4) | - | - | Not relevant for WG formulations. | | | - | - | Not required |
| Ambient temperature shelf life (KCP 2.7.5) | - | - | Study on-going. | | | - | - | The shelf-life study report shall be submitted when finished. Based on the |

| Annex point | Method used / deviations | Test material | Findings | GLP Y/N | Reference | Acceptability / comments |
|---|--|---|---|---------|---|---|
| | | | | | | composition of the product and results of accelerated storage tests in the commercial packaging, one-year conditional registration of the product is possible and proposed. Final registration will be feasible after completion of the 2-year ambient storage tests. |
| Shelf life in months (if less than 2 years) (KCP 2.7.6) | - | - | Not required. | - | - | Not required |
| Wettability (KCP 2.8.1) | CIPAC MT 53.3 and MT 18 (Standard Water D) | Pyraclostrobin 6.7% + Boscalid 26.7% WG, batch No SCL-20604 | Tested concentration 5% w/v in CIPAC water D) Without swirling: 4 sec : 4 3 sec With swirling: 1 sec | Y | Rigamonti E., 2017, ChemService, report CH - 865/2017 | Accepted |
| Persistence of foaming (KCP 2.8.2) | CIPAC MT 47.2 and MT 18 (Standard Water D) | Pyraclostrobin 6.7% + Boscalid 26.7% WG, batch No SCL-20604 | Foam after 1 minute (in CIPAC water D at 20 °C): 0.05 % w/v = 0 mL 0.50 % w/v = 10 mL | Y | Rigamonti E., 2017, ChemService, report CH - 865/2017 | Accepted |
| Suspensibility (KCP 2.8.3.1) | CIPAC MT 184 and MT 18 | Pyraclostrobin 6.7% + | Pyraclostrobin: 0.05 % w/v: 98.3 % | Y | Rigamonti E., 2017, | Accepted |

| Annex point | Method used / deviations | Test material | Findings | GLP Y/N | Reference | Acceptability / comments |
|---|----------------------------|---|---|---------|---|--|
| | | Boscalid 26.7% WG, batch No SCL-20604 | 0.50 % w/v: 97.9 % Boscalid: 0.05 % w/v: 98.3 % 0.50 % w/v: 97.3 % | | ChemService, report CH - 865/2017 | |
| Spontaneity of dispersion (KCP 2.8.3.2) | CIPAC MT 174 and MT 18 | Pyraclostrobin 6.7% + Boscalid 26.7% WG, batch No SCL-20604 | Pyraclostrobin: 1.00 % w/v: 96.5 % Boscalid: 1.0 % w/v: 96.1 % | Y | Rigamonti E., 2017, ChemService, report CH - 865/2017 | Accepted |
| Dispersion stability (KCP 2.8.3.3) | - | - | Not relevant for WG formulations. | - | - | Not required |
| Degree of dissolution and dilution stability (KCP 2.8.4) | - | - | Not relevant for WG formulations. | - | - | Not required |
| Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1) | OECD No. 110; CIPAC MT 187 | Pyraclostrobin 6.7% + Boscalid 26.7% WG, batch No SCL-20604 | Dv 10: 315 µm Dv 50: 479 µm Dv 90: 730 µm % under 45 µm: 0.00 % above 75 µm: 100.00 | Y | Rigamonti E., 2017, ChemService, report CH - 865/2017 | Accepted Based on the test results no inhalation toxicity is expected |
| Wet sieve test (KCP 2.8.5.1.2) | CIPAC MT 185 | Pyraclostrobin 6.7% + Boscalid 26.7% WG, batch No SCL-20604 | No residue onto 75 µm sieve. | Y | Rigamonti E., 2017, ChemService, report CH - 865/2017 | Accepted |
| Dust content (KCP 2.8.5.2.1) | CIPAC MT 171 | Pyraclostrobin 6.7% + Boscalid 26.7% WG, | “Nearly dust free”. (0.8 mg; 0.003 % w/w) | Y | Rigamonti E., 2017, ChemService, report CH - | Accepted The gravimetric method was used |

| Annex point | Method used / deviations | Test material | Findings | GLP Y/N | Reference | Acceptability / comments |
|---|---------------------------------------|---|--|---------|---|--------------------------|
| | | batch No SCL-20604 | | | 865/2017 | |
| Particle size of dust (KCP 2.8.5.2.2) | - | - | Not required since the product is considered as nearly dust free. | - | - | Not required |
| Attrition (KCP 2.8.5.3) | CIPAC MT 178.2 | Pyraclostrobin 6.7% + Boscalid 26.7% WG, batch No SCL-20604 | Attrition resistance: 100.1 % | Y | Rigamonti E., 2017, ChemService, report CH - 865/2017 | Accepted |
| Hardness and integrity (KCP 2.8.5.4) | - | - | Not relevant for WG formulations. | - | - | Not required |
| Emulsifiability (KCP 2.8.6.1) | - | - | Not relevant for WG formulations. | - | - | Not required |
| Emulsion stability (KCP 2.8.6.2) | - | - | Not relevant for WG formulations. | - | - | Not required |
| Re-emulsifiability (KCP 2.8.6.3) | - | - | Not relevant for WG formulations. | - | - | Not required |
| Flowability (KCP 2.8.7.1) | OECD No. 110; CIPAC MT 172 and MT 187 | Pyraclostrobin 6.7% + Boscalid 26.7% WG, batch No SCL-20604 | No significant variation. Dv 10: 330 µm Dv 50: 503 µm Dv 90: 761 µm % under 45 µm: 0.00 % above 75 µm: 100.00 | Y | Rigamonti E., 2017, ChemService, report CH - 865/2017 | Accepted |
| Pourability (KCP 2.8.7.2) | - | - | Not relevant for WG formulations. | - | - | Not required |
| Dustability following accelerated storage | - | - | Not relevant for WG formulations. | - | - | Not required |

| Annex point | Method used / deviations | Test material | Findings | GLP Y/N | Reference | Acceptability / comments |
|--|--|---|--|---------|---|--------------------------|
| (KCP 2.8.7.3) | | | | | | |
| Physical compatibility of tank mixes (KCP 2.9.1) | - | - | Not required since the product is not intended for tank mixes. | - | - | Not required |
| Chemical compatibility of tank mixes (KCP 2.9.2) | - | - | Not required since the product is not intended for tank mixes. | - | - | Not required |
| Adhesion to seeds (KCP 2.10.1) | - | - | Not relevant for WG formulations. | - | - | Not required |
| Distribution to seed (KCP 2.10.2) | - | - | Not relevant for WG formulations. | - | - | Not required |
| Other/special studies (KCP 2.11) | CIPAC MT 30.5 Internal Analytical Method No. 867/2017 | Pyraclostrobin 6.7% + Boscalid 26.7% WG, batch No SCL-20604 | Water content before storage: 3.33 % w/w Water content after storage: 2.89% w/w Dimethyl sulfate relevant impurity content: not determined since content is lower than the LOD of 0.005 µg/g | Y | Rigamonti E., 2017, ChemService, reports CH - 865/2017 Rigamonti E., 2017, ChemService, report CH - 868/2017 | Accepted |

3 Section 3 is presented as a separate document

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

4 Section 4: Further information on the plant protection product

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

| | |
|----------------------|---|
| zRMS comment: | Based on accelerated storage results, proposed commercial packaging – PE bottle and jarrycan, are appropriate and accepted. No leakage, panelling, deformations etc. were reported. According to the guidelines of the polish Ministry of Agriculture and Rural Development, extrapolation from the rigid to elastic packaging types is not acceptable for WG formulation and therefore bags and sacs were crossed out. |
|----------------------|---|

The bags used for packaging 100, 200, 250, 500, 750 and 1000 grams are obtained from a coil, and the material of these bags consists in PE* multifilm with the next layers:

| | | | |
|--------------------|---|---------------------------|---|
| Material 1: | OPP (Oriented polypropylene) | Thickness: 20.0 me | Outside layer |
| Material 2: | PET met (Metallized ethylene polyterephthalate) | Thickness: 12.0 me | Middle layer |
| Material 3: | PEBD TR (Thermoplastic low density polyethylene) | Thickness: 70.0 me | Inside layer (in contact with the product) |

The specifications of size for these bags are in the next tables:

Table 4.1-1: Packaging information for 100 grams

| Type | Description |
|-------------------------------|-------------------------------|
| Material: | PE* |
| Shape/size: | bag / approx. 195 mm x 130 mm |
| Seal: | Heat seal |
| Manner of construction | extruded |
| UN/ADR | compliant |

Table 4.1-2: Packaging information for 200 grams

| Type | Description |
|-------------------------------|-------------------------------|
| Material: | PE* |
| Shape/size: | bag / approx. 190 mm x 170 mm |
| Seal: | Heat seal |
| Manner of construction | extruded |
| UN/ADR | compliant |

Table 4.1-3: Packaging information for 250 grams

| Type | Description |
|------------------------|-------------------------------|
| Material: | PE* |
| Shape/size: | bag / approx. 190 mm x 170 mm |
| Seal: | Heat seal |
| Manner of construction | extruded |
| UN/ADR | compliant |

Table 4.1-4: Packaging information for 500 grams

| Type | Description |
|------------------------|-------------------------------|
| Material: | PE* |
| Shape/size: | bag / approx. 190 mm x 210 mm |
| Seal: | Heat seal |
| Manner of construction | extruded |
| UN/ADR | compliant |

Table 4.1-5: Packaging information for 750 grams

| Type | Description |
|------------------------|-------------------------------|
| Material: | PE* |
| Shape/size: | bag / approx. 190 mm x 260 mm |
| Seal: | Heat seal |
| Manner of construction | extruded |
| UN/ADR | compliant |

Table 4.1-6: Packaging information for 1 kg

| Type | Description |
|------------------------|-------------------------------|
| Material: | PE* |
| Shape/size: | bag / approx. 190 mm x 260 mm |
| Seal: | Heat seal |
| Manner of construction | extruded |
| UN/ADR | compliant |

Table 4.1-7: Packaging information for 5 kg and 10 kg

| Type | Description |
|-------------|--|
| Material: | PE |
| Shape/size: | Sac / approx. 380 mm (width) x 570 mm (length) x 100 mm (bottom) |

| Type | Description |
|------------------------|---|
| | <p>Layers of sac:</p> <ol style="list-style-type: none"> 1. Semi stretchable white (70 g/m²) 2. Straight (70 g/m²) 3. Straight (70 g/m²) <p>Inner bag: approx. 390 mm (width) x 680 mm (length) [thickness:45 µm]</p> |
| Seal: | Heat seal |
| Manner of construction | extruded |
| UN/ADR | compliant |

Table 4.1-8: Packaging information for 20 kg and 25 kg

| Type | Description |
|------------------------|---|
| Material: | PE |
| Shape/size: | <p>Sac / approx. 550 mm (width) x 810 mm (length) x 130 mm (bottom)</p> <p>Layers of sac:</p> <ol style="list-style-type: none"> 1. Semi stretchable white (70 g/m²) 2. Semi stretchable (70 g/m²) 3. Semi stretchable (70 g/m²) <p>Inner bag: approx. 560 mm (width) x 910 mm (length) [thickness:37 µm]</p> |
| Seal: | Heat seal |
| Manner of construction | extruded |
| UN/ADR | compliant |

Table 4.1-9: Packaging information for 150 grams (0.250 liter bottle)

| Type | Description |
|------------------------|--|
| Material: | HDPE |
| Shape/size: | Round bottle / approx. 62.5 mm diameter x 128.0 mm |
| Opening: | 41.7 mm inner diameter |
| Closure: | polyethylene screw cap |
| Seal: | Induction heat seal |
| Manner of construction | extruded |
| UN/ADR | compliant |

Table 4.1-10: Packaging information for 300 grams (0.500 liter bottle)

| Type | Description |
|-------------|--|
| Material: | HDPE |
| Shape/size: | Round bottle / approx. 69.5 mm diameter x 188.5 mm |
| Opening: | 41.7 mm inner diameter |
| Closure: | polyethylene screw cap |
| Seal: | Induction heat seal |

| Type | Description |
|------------------------|-------------|
| Manner of construction | extruded |
| UN/ADR | compliant |

Table 4.1-21: Packaging information for 500 grams (1liter bottle)

| Type | Description |
|------------------------|--|
| Material: | HDPE |
| Shape/size: | Round bottle / approx. 89 mm diameter x 240 mm |
| Opening: | 41.7 mm inner diameter |
| Closure: | polyethylene screw cap |
| Seal: | Induction heat seal |
| Manner of construction | extruded |
| UN/ADR | compliant |

Table 4.1-12: Packaging information for 1 kg (2 liters jerrycan)

| Type | Description |
|------------------------|----------------------------------|
| Material: | HDPE |
| Shape/size: | bottle / approx. 227 mm x 117 mm |
| Closure: | polyethylene screw cap |
| Seal: | Induction heat seal |
| Manner of construction | extruded |
| UN/ADR | compliant |

Table 4.1-13: Packaging information for 3 kg (5 liters jerrycan)

| Type | Description |
|------------------------|---|
| Material: | HDPE |
| Shape/size: | jerrycan / approx. 285 mm x 136 mm x 191 mm |
| Opening: | 54.4 mm inner diameter |
| Closure: | polyethylene screw cap |
| Seal: | Induction heat seal |
| Manner of construction | extruded |
| UN/ADR | compliant |

Table 4.1-14: Packaging information for 5 kg (10 liters jerrycan)

| Type | Description |
|-------------|---|
| Material: | HDPE |
| Shape/size: | jerrycan / approx. 313 mm x 232 mm x 192 mm |

| Type | Description |
|------------------------|------------------------|
| Opening: | 47 mm inner diameter |
| Closure: | polyethylene screw cap |
| Seal: | Induction heat seal |
| Manner of construction | extruded |
| UN/ADR | compliant |

4.2 Procedures for cleaning application equipment (KCP 4.4.2)

The cleanout efficiency of a specific tank mix using a triple rinse cleanout procedure, was been evaluated for a solution of the test item Boscalid 26.7% + Pyraclostrobin 6.7% WG at the highest rate of use.

Reference: KCP 4.4.2

Report “Pyraclostrobin 6.7% + Boscalid 26.7% WG: Washing efficacy after application”, Rigamonti E., 2017, Report No. CH-870/2017.

Guideline(s): Efficacy Guideline 305, Efficacy Guideline 302.

GLP: Yes

Residues after the cleaning test were analyzed to determine the residual content of Pyraclostrobin and Boscalid.

Percentage of analyte removed:

- Pyraclostrobin: 99.9%,
- Boscalid: 99.9%

| | |
|----------------------|---|
| zRMS comment: | Accepted. Method used for cleaning application equipment is sufficient and effective |
|----------------------|---|

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

| Data point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Owner |
|---|-----------------|------|--|----------------------------|----------------------------|
| KCP 2.1 KCP 2.3.2 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 | Rigamonti E. | 2017 | Pyraclostrobin 6.7% + Boscalid 26.7% WG: Determination of the Physico-chemical Properties Company Report No CH – 865/2017 ChemService GLP Unpublished | N | Sharda Cropchem Ltd. |
| KCP 2.2.1 KCP 2.2.2 | Elena Rigamonti | 2018 | Pyraclostrobin 6.7% + Boscalid 26.7 % WG: determination of the oxidizing properties and explosive properties. Report No. CH-159/2018 ChemService GLP Unpublished | N | 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 | Owner |
|-------------------|------------------|-------------|---|-------------------------------------|----------------------|
| KCP 2.3.3 | Mazzei A. | 2018 | Determination of relative self-ignition of temperature for solids on the sample pryclostrobin 6.7% + boscalid 26.7 % WG. Report – 1704583 Innovhub GLP Unpublished | N | Sharda Cropchem Ltd. |
| KCP 2.7.1 | Rigamonti E. | 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 | 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 | 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 | 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 | Owner |
|-------------------|------------------|-------------|--|-------------------------------------|--------------|
| - | - | - | - | - | - |

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

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

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

A 2.1 Pyraclostrobin

Not relevant. There is no additional data on the active substance.

A 2.2 Boscalid

Not relevant. There is no additional data on the active substance