

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: GLOB1911F

Product name(s): **CURRANDO/ SUBIGON/ COLLECTOR**

Chemical active substance(s):

Difenoconazole, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Globachem NV

Submission date: August 2020

MS Finalisation date: May 2021

Update storage stability study: August 2021

Revision date: October 2021

Version history

| When | What |
|--------------|--|
| August 2020 | Version submitted by the applicant |
| May 2021 | Version evaluated by zRMS |
| August 2021 | Update storage stability study by the applicant |
| October 2021 | Version revised to take into account comments of MSs |

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State whether or not submitted data are sufficient for evaluation. Data gaps and conditions for registration should be listed, if appropriate.

Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are:

- ~~Missing storage stability study at ambient temperature. It is required to set a shelf life for the PPP and may be evaluated in post-registration at national level.~~
- none

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Globachem NV
Address: Brustem Industriepark
Lichtenberglaan 2019
3800 Sint-Truiden
Belgium
Contact: xxxxxxxxxxxxxxxx
Telephone number: xxxxxxxxxxxxxxxx
E-mail: xxxxxxxxxxxxxxxx

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

1.2.1 Producer(s) of the preparation

~~Confidential information or data are provided separately (Part C).~~

• Producer(s) of the preparation

Name: Globachem N.V.
Address: Brustem Industriepark
Lichtenberglaan 2019
3800 Sint-Truiden
Belgium
Contact: xxxxxxxxxxxxxxxx
Telephone number: xxxxxxxxxxxxxxxx
Fax: xxxxxxxxxxxxxxxx
E-mail: xxxxxxxxxxxxxxxxxx

Location of the manufacturing site 1:

Name: Phyteurop
Address: ZI de Champagne
49260 Montreuil-Bellay
France

Location of the manufacturing site 2:

Name: SIPC - Société industrielle de produits chimiques
Address: Rue J.-Coste
Courchelettes, B.P. 613
59506 Douai
France

Location of the manufacturing site 3:

Name Chemark Kft

Address: 8182 Peremarton Gyártelep, Pf 31
Hungary

Location of the manufacturing site 4:

Name Schirm GmbH
Address: Geschwister-Scholl-Strasse 127,
D-39218 Schönebeck (Elbe),
Germany

Location of the manufacturing site 5:

Name Althaller Italia s.r.l.
Address: Strada Comunale Per Campagna,
San Colombano Al Lambro,
MI 20078,
Italy

Location of the manufacturing site 6:

Name Arysta LifeScience Ougrée Production sprl
Address: Rue de Renory 26/2,
4102 Ougrée,
Belgique

Location of the manufacturing site 7:

Name Schirm GmbH
Address: Mecklenburger Str. 229,
23568 Lübeck
Germany

Location of the manufacturing site 8:

Name AgroSmart Ltd
Address: Unit 1C Victoria Court,
Colliers Way,
Clayton West,
HD8 9TR Huddersfield,
West Yorkshire,
UK,

Location of the manufacturing site 9:

Name: Schirm GmbH
Address: Wendessener Straße 11c
38300 Wolfenbüttel
Germany

Location of the manufacturing site 10:

Name: Kwizda Agro GmbH
Address: Werk Leobendorf
Laaer Bundesstraße/Kwizda Allee 1
2100 Leobendorf
Austria

Location of the manufacturing site 11:

Name: Chemia
Address: Via Statale 327
44047 Dosso
Italy

Location of the manufacturing site 12:

Name: Globachem n.v.
Address: Globachem NV
Montenakenweg 535
3800 Sint-Truiden
Belgium

Location of the manufacturing site 13:

Name: Industrial Quínmica Key s.a.
Address: Avda. Cervera 17
25300 Tàrrega (Lleida)
Spain

Location of the manufacturing site 14:

Name: SBM Formulation Manufacturing Plant
Address: ZI Avenue Jean Foucault CS621
34500 Beziers
France

Location of the manufacturing site 15:

Name: Chromos Agro d.o.o.
Address: Radnička cesta 173n
10000 Zagreb
Croatia

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

Confidential information or data are provided separately (Part C).

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

1.2.3.1 Difenoconazole

| | |
|-------------------------------------|---------------|
| Difenoconazole technical (Source 1) | min. 960 g/kg |
| Difenoconazole technical (Source 2) | min. 960 g/kg |

Source 1 of the active ingredient has been confirmed to be equivalent to the annex I source by the RMS Spain.

Source 2 of the active ingredient has been confirmed to be equivalent to the annex I source by the RMS Germany.

Toluene was considered as a relevant impurity according to the Regulation (EU) No 1100/2011, its maximum content in the technical material is 5 g/kg.

Further information relating to the impurities is confidential information – data is provided separately (Part C).

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

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

Company code number: GLOB1911F

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)

GLOB1911F was not the representative formulation during the EU evaluation of Difenoconazole.

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/L) | FAO Limits (min – max) | Technical content* (g/L) | Technical content** (%w/w) |
|----------------------------|---|------------------------|--------------------------|----------------------------|
| Difenoconazole | 500 | 475-525 g/L | 520.83 | 0.452 |

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

** Based on the density of the formulation = 1.1532 g/mL

Table 1.4-2: Relevant impurities

| Relevant impurity | Maximum content (g/kg) |
|-------------------|------------------------|
| Toluene | 5 g/kg |

1.4.2 Information on the active substance(s) (KCP 1.4.2)

Table 1.4-3: Information on Difenoconazole

| Type | Difenoconazole |
|-----------------|----------------|
| ISO common name | Difenoconazole |
| CAS No. | 119446-68-3 |
| EC No. | 82657-04-3 |
| CIPAC No. | 687 |

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

There are no safeners or synergists in the formulation. Information regarding the co-formulants is confidential.

CONFIDENTIAL information is provided separately (Part C).

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

Type: Suspension concentrate

[Code: SC]

1.6 Function (KCP 1.6)

Fungicide

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of white opaque liquid, with a musty type odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self ignition temperature higher than 400 °C. In aqueous solution, it has a pH value around 6.39 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. ~~The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE, HDPE/F, HDPE/PA or HDPE/EVOH bottles.~~ The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE, HDPE/F, HDPE/PA or HDPE/EVOH bottles. Its technical characteristics are acceptable for a *Suspension concentrate* formulation. The intended concentration of use is 0.0625% to 0.25%.

No tank mixes are required for GLOB1911F.

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

No implications for labelling from physical chemical part.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

None

Compliance with FAO specifications:

The product GLOB1911F complies with FAO specifications.

Formulation used for tests

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

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

| Annex point | Method used / deviations | Test material | Findings | GLP Y/N | Reference | Acceptability / comments |
|--|--|-------------------------------|---|---------|-------------------------|--------------------------|
| Colour and physical state (KCP 2.1) | Visual assessment | GLOB1911F (Batch No. BRN3030) | The sample was a uniform white liquid, opaque and there was no light visible through the sample. The sample was free-flowing and coated the walls of a beaker. There were no signs of separation in to oil, cream, sediment or suspended solids. The sample had a musty type odour. | Y | Sowle, J., 2019 DNA5103 | Accepted |
| Explosive properties (KCP 2.2.1) | Theoretical certificate | / | No explosive properties Applicant provided statement for the a.s and consideration for each co-formulant that they have no explosive properties | N | Sowle, J., 2020 | Accepted |
| Oxidizing properties (KCP 2.2.2) | Theoretical certificate | / | No oxidizing properties Applicant provided statement for the a.s and consideration for each co-formulant that they have no oxidizing properties | N | Sowle, J., 2020 | Accepted |
| Flash point (KCP 2.3.1) | EEC A9 | GLOB1911F (Batch No. BRN3030) | No flash below 100 °C. GLOB1911F is not considered to be highly flammable. | Y | Sowle, J., 2019 DNA5103 | Accepted |
| Flammability (KCP 2.3.2) | - | - | Not applicable for an SC formulation. | - | - | |
| Self-heating (KCP 2.3.3) | EEC A15 | GLOB1911F (Batch No. BRN3030) | The sample did not auto-ignite below 400°C and is therefore not considered highly flammable. | Y | Sowle, J., 2019 DNA5103 | Accepted |
| Acidity or alkalinity and pH (KCP 2.4.1) | CIPAC MT 75.3 (pH neat formulation) CIPAC MT 191 (for acidity/alkalinity) | GLOB1911F (Batch No. BRN3030) | The pH of the neat formulation was found to be 5.65 at 20.0°C. The acidity/alkalinity of the sample was not performed as the pH of the 1% dilution was found to be between 4 | Y | Sowle, J., 2019 DNA5103 | Accepted |

| Annex point | Method used / deviations | Test material | Findings | GLP Y/N | Reference | Acceptability / comments |
|---|--------------------------------|-------------------------------|---|---------|-------------------------|---|
| | | | and 10. | | | |
| pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2) | CIPAC MT 75.3 (pH 1% dilution) | GLOB1911F (Batch No. BRN3030) | The pH of a 1% dilution in deionised water (pH = 6.91) was found to be 6.39 at 20.0°C. | Y | Sowle, J., 2019 DNA5103 | Accepted |
| Viscosity (KCP 2.5.1) | OECD 114 | GLOB1911F (Batch No. BRN3030) | At 20 °C: from 38392.0 to 1341.35 mPa.s for shear rates going from 0.10 to 6.80 s ⁻¹ . At 40 °C: from 33747.0 to 537.488 mPa.s for shear rates going from 0.10 to 17.0 s ⁻¹ . The sample is a non-Newtonian liquid. The lowest calculated kinematic viscosity is 467.38 5 mm ² /s (at 40 °C). | Y | Sowle, J., 2019 DNA5103 | Accepted Dynamic viscosity may be converted to kinematic viscosity using relative density's value. Based on high values of dynamic viscosity, kinematic one is far above 20.5 mm ² /s (no indication for a Category 1 aspiration hazard). |
| Surface tension (KCP 2.5.2) | EEC A5 | GLOB1911F (Batch No. BRN3030) | At the highest application rate (0.25L in 100L of water) Mean corrected surface tension at 20 °C: 43.82 mN/m ± 0.056. Mean corrected surface tension at 25 °C: 42.89 mN/m ± 0.029. | Y | Sowle, J., 2019 DNA5103 | Accepted The surface tension is performed with the highest use rate and the product is considered as a surface active |
| Relative density (KCP 2.6.1) | EEC A3 | GLOB1911F (Batch No. BRN3030) | At 20°C: 1.1532 g/mL | Y | Sowle, J., 2019 DNA5103 | Accepted |
| Bulk density (KCP 2.6.2) | - | - | Not applicable for an SC formulation. | - | - | |

| Annex point | Method used / deviations | Test material | Findings | | | GLP Y/N | Reference | Acceptability / comments |
|--|--------------------------|--|---|---|--|---------|-------------------------|---|
| Storage Stability after 14 days at 54° C (KCP 2.7.1) | - | GLOB1911F (Batch No. BRN3030) Packaging: HDPE | | Before storage | After storage | Y | Sowle, J., 2019 DNA5103 | Accepted Concentrations of the a.s. before and after storage are in the FAO/WHO tolerance. All other parameters meet requirements for SC formulation, Furthermore, a rigid HDPE pack remained intact after storage. Analytical methods used for analysing a.s. and toluene in the PPP are assessed in B5 section. They are validated in accordance with SANCO/3030/99 rev.5 |
| | | | Appearance (visual assessment) | The sample remained a white uniform liquid. The sample remained opaque, free-flowing and coated the walls of the beaker. There was no separation into oil, cream, sediment or suspended solids. The sample retained a musty type odour. | | | | |
| | | | Stability of packaging (DNAL in house methodology) | The sample was stored in HDPE bottle. There were no signs of seepage, leaks or panelling. | The sample was stored in HDPE bottle. There were no signs of seepage, leaks or panelling. The packaging remained unchanged post accelerated storage. | | | |
| | | | Difenoconazole content (DNAL in house methodology validated in study DNA5105) | 521.5g/L equivalent to 104.3 % of the declared amount. | 518.7g/L equivalent to 103.7 % of the declared amount. | | | |
| | | | Impurity Toluene content (DNAL in house methodology) | <0.5g/Kg equivalent | <0.5g/Kg equivalent | | | |

| Annex point | Method used / deviations | Test material | Findings | | | GLP Y/N | Reference | Acceptability / comments |
|---|--------------------------|-------------------------------|---|---|--|---------|-------------------------|--------------------------|
| | | | validated in study DNA5105) | to <1.0g/Kg relative to the active ingredient content. | to <1.0g/Kg relative to the active ingredient content. | | | |
| | | | pH neat at 20.0°C (CIPAC MT 75.3) | 5.65 | 5.55 | | | |
| | | | pH 1 % dilution at 20.0°C (CIPAC MT 75.3) | 6.39 | 6.32 | | | |
| | | | Suspensibility (CIPAC MT 184) | CIPAC Water D High application rate (0.25L in 100L of water) | | | | |
| | | | | 100.7 % | 99.76 % | | | |
| | | | | CIPAC Water D Low application rate (0.25L in 400L of water) | | | | |
| | | | | 100.2 % | 98.91 % | | | |
| | | | Spontaneity of dispersion (CIPAC MT 160) | CIPAC Water D 12.5mL per 250 mL | | | | |
| | | | | 101.1 % | 100.3 % | | | |
| | | | | CIPAC Water A 12.5mL per 250 mL | | | | |
| | | | | 101.0 % | 100.7 % | | | |
| | | | Wet sieve test (CIPAC MT 185) | 0.2145 % | 0.3139 % | | | |
| | | | Pourability (CIPAC MT 148.1) | | | | | |
| | | | Poured Residue | 3.5749 % | 3.2185 % | | | |
| | | | Water Rinsed Residue | 0.1018 % | 0.0921 % | | | |
| | | | Acetone Rinsed Residue | 0.0019 % | 0.0019 % | | | |
| Stability after storage for other periods and/or temperatures (KCP 2.7.2) | - | - | Not required as GLOB1911F is stable after storage for 14 days at 54 °C. | | | - | - | |
| Minimum content after heat stability testing | In house method | GLOB1911F (Batch No. BRN3030) | Pre-storage: Sample had a content of 521.5 g/L equivalent to 104.3% of the average declared amount. | | | Y | Sowle, J., 2019 DNA5103 | Not required |

| Annex point | Method used / deviations | Test material | Findings | GLP Y/N | Reference | Acceptability / comments |
|--|--------------------------|---------------|---|---------|----------------------------|--------------------------|
| (KCP 2.7.3) | | | Content after storage for 2 weeks at 54°C: Sample had a content of 518.7 g/L equivalent to 103.7% of the average declared amount. | | | |
| Effect of low temperatures on stability (KCP 2.7.4) | | | Appearance of the sample after Low Temperature Storage at 0°C for 7 days (CIPAC MT 39.3): <u>Appearance after one hour at 0°C:</u> The sample remained uniform white. There were no signs of separation into oil, cream, sediment or crystals. <u>After 7 days at 0°C:</u> The sample remained uniform white. There were no signs of separation into oil, cream, sediment or crystals. <u>After 7 days at 0°C and 30 minutes at room temperature:</u> The sample remained uniform white. There were no signs of separation into oil, cream, sediment or crystals. <u>After 7 days at 0°C and 3 hours at room temperature:</u> The sample remained uniform white. There were no signs of separation into oil, cream, sediment or crystals. Appearance of the sample after Low Temperature Storage at 0°C for 7 days with the addition of a crystal of Difenoconazole after 24 hours (CIPAC MT 39.3): <u>Appearance after one hour at 0°C:</u> The sample remained uniform white. There were no signs of separation into oil, cream, sediment or crystals. <u>Appearance after twenty four hour at 0°C:</u> A crystal of Difenoconazole was added and the crystal remained on the surface. The sample remained uniform white. There were no signs of separation into oil, cream, sediment or crystals. <u>After 7 days at 0°C:</u> The sample remained uniform white. There were no signs of separation into oil, cream, sediment or crystals. The crystal of Difenoconazole had dissolved. <u>After 7 days at 0°C and 30 minutes at room temperature:</u> | Y | Sowle, J., 2019 DNA5103 | Accepted |

| Annex point | Method used / deviations | Test material | Findings | GLP Y/N | Reference | Acceptability / comments | | | | | | | | | | | | |
|--|--|--|---|---------|---|---|-------------------------------|--|--|---------|---|---------|-------------------------------|--|----------|--|--|--|
| | | | <p>The sample remained uniform white. There were no signs of separation into oil, cream, sediment or crystals.</p> <p><u>After 7 days at 0°C and 3 hours at room temperature:</u></p> <p>The sample remained uniform white. There were no signs of separation into oil, cream, sediment or crystals.</p> <table><tr><td></td><td></td><td>After storage</td></tr><tr><td rowspan="4">Suspensibility (CIPAC MT 184)</td><td rowspan="4"></td><td>CIPAC Water D High application rate (0.25L in 100L of water)</td></tr><tr><td>100.5 %</td></tr><tr><td>CIPAC Water D Low application rate (0.25L in 400L of water)</td></tr><tr><td>99.65 %</td></tr><tr><td colspan="2">Wet sieve test (CIPAC MT 185)</td><td>0.2465 %</td></tr></table> | | | After storage | Suspensibility (CIPAC MT 184) | | CIPAC Water D High application rate (0.25L in 100L of water) | 100.5 % | CIPAC Water D Low application rate (0.25L in 400L of water) | 99.65 % | Wet sieve test (CIPAC MT 185) | | 0.2465 % | | | |
| | | After storage | | | | | | | | | | | | | | | | |
| Suspensibility (CIPAC MT 184) | | CIPAC Water D High application rate (0.25L in 100L of water) | | | | | | | | | | | | | | | | |
| | | 100.5 % | | | | | | | | | | | | | | | | |
| | | CIPAC Water D Low application rate (0.25L in 400L of water) | | | | | | | | | | | | | | | | |
| | | 99.65 % | | | | | | | | | | | | | | | | |
| Wet sieve test (CIPAC MT 185) | | 0.2465 % | | | | | | | | | | | | | | | | |
| Ambient temperature shelf life (KCP 2.7.5) | <p>These studies are ongoing. The expected finalization date is July 2021 (2 year storage) and July 2022 (3 year storage) and the type of packaging is HDPE bottle.</p> <p>The 2 year storage stability study is finished and reported here. The 3 year storage stability study is ongoing and its expected finalisation</p> | GLOB1911F (Batch No. BRN3030) | <p>Storage for 2 years days at ambient temperatures, in 0.5L white HDPE bottle.</p> <p><u>Appearance</u></p> <p>The sample remained a white uniform liquid. The sample remained opaque, free-flowing and coated the walls of the beaker before and after storage. There were no signs of separation into oil, cream, sediment, claying or suspended solids. The sample retained a musty odour. The packaging remained intact with no evidence of panning or leaks.</p> <p><u>Difenoconazole content (in house validated in study DNA 5105)</u></p> <p>Before: 521.5 g/L After: 513.9 g/L</p> <p><u>Impurity Toluene content (in house validated in</u></p> | Y | <p>2 year storage stability study: Sowle, J., 2021 DNA5104</p> <p>3 year storage stability study: Studies ongoing</p> | <p>DATA GAP</p> <p>Study is ongoing</p> <p>It has to be assessed in the post registration at national level to cover all requirements for assigning a shelf life for the PPP.</p> <p>Accepted</p> <p>Applicant provided the study after zonal commenting stage. We</p> | | | | | | | | | | | | |

| Annex point | Method used / deviations | Test material | Findings | GLP Y/N | Reference | Acceptability / comments |
|-------------|--------------------------|---------------|--|---------|-----------|---|
| | date is July 2022. | | <p><u>study DNA 5105)</u> Before: < 0.5 g/kg equivalent to < 1.0 g/kg relative to the active ingredient content After: < 0.5 g/kg equivalent to < 1.0 g/kg relative to the active ingredient content <u>pH neat at 20°C (MT 75.3)</u> Before: 5.65 After: 5.62 <u>pH 1% dispersion at 20°C (MT 75.3)</u> Before: 6.39 After: 6.34 <u>Spontaneity of dispersion (MT160), 12.5 mL per 250 mL, CIPAC Water A</u> Before: 101.0% After: 97.14% <u>Spontaneity of dispersion (MT160), 12.5 mL per 250 mL, CIPAC Water D</u> Before: 101.1% After: 97.60% <u>Suspensibility (MT184), high appl. rate, CIPAC Water D</u> Before: 100.7% After: 99.78% <u>Suspensibility (MT184), low appl. rate, CIPAC Water D</u> Before: 110.2% After: 99.56% <u>Pourability (MT 148.1)</u> Before: Poured residue = 3.5749% Rinsed residue = 0.1018% Acetone rinsed residue = 0.0019% After: Poured residue = 3.2077% Water rinsed residue = 0.1416%</p> | | | <p>included that study into final report.</p> <p>Two-year shelf life is accepted for the PPP. The method from DNA 5105 (assessed in B.5 section) study was used for analysing active substance.</p> |

| Annex point | Method used / deviations | Test material | Findings | GLP Y/N | Reference | Acceptability / comments |
|---|--------------------------|-------------------------------|---|---------|-------------------------|--|
| | | | Acetone rinsed residue = 0.0056% Wet sieve (MT158) Before: 0.2145% retained on 75µm sieve After: 0.4178% retained on 75µm sieve | | | |
| Shelf life in months (if less than 2 years) (KCP 2.7.6) | - | - | Not required as GLOB1911F should be stable for at least 2 years at ambient temperature. | - | - | Each member state must consider whether conditional shelf life may be assigned for the PPP until finalization of the ambient storage stability study. Not relevant |
| Wettability (KCP 2.8.1) | - | - | Not required as GLOB1911F is not a solid formulation. | - | - | |
| Persistence of foaming (KCP 2.8.2) | CIPAC MT 47.3 | GLOB1911F (Batch No. BRN3030) | Using CIPAC water D <u>Minimum application rate (0.25L in 400L of water):</u> after 1 min.: 3.0 mL after 12 min.: 0.0 mL <u>Maximum application rate (0.25L in 100L of water):</u> after 1 min.: 3.0 mL after 12 min.: 0.0 mL | Y | Sowle, J., 2019 DNA5103 | Accepted |
| Suspensibility (KCP 2.8.3.1) | CIPAC MT 184 | GLOB1911F (Batch No. BRN3030) | Max. application rate (0.25L in 100L of water) in CIPAC water D: 100.7 %. Min. application rate (0.25L in 400L of water) in CIPAC water D: 100.2 %. | Y | Sowle, J., 2019 DNA5103 | Accepted |
| Spontaneity of dispersion (KCP 2.8.3.2) | CIPAC MT 160 | GLOB1911F (Batch No. BRN3030) | Using 12.5mL of sample in 250mL of CIPAC water A: 101.0 %. Using 12.5mL of sample in 250mL of CIPAC water D: 101.1%. | Y | Sowle, J., 2019 DNA5103 | Accepted |
| Dispersion stability (KCP 2.8.3.3) | - | - | Not required for an SC formulation. | - | - | |

| Annex point | Method used / deviations | Test material | Findings | GLP Y/N | Reference | Acceptability / comments |
|---|--------------------------|-------------------------------|--|---------|-------------------------|--------------------------|
| Degree of dissolution and dilution stability (KCP 2.8.4) | - | - | Not required for an SC formulation. | - | - | |
| Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1) | CIPAC MT 185 | GLOB1911F (Batch No. BRN3030) | According to Reg. 284/2013 the method to be used for determination of Particle size distribution of water dispersible products, like SC formulations, is CIPAC Method MT 185: Wet sieve. Therefore reference is made to KCP 2.8.5.1.2. | Y | Sowle, J., 2019 DNA5103 | Accepted |
| Wet sieve test (KCP 2.8.5.1.2) | CIPAC MT 185 | GLOB1911F (Batch No. BRN3030) | Sieve mesh size: 75 µm 0.2145 % | Y | Sowle, J., 2019 DNA5103 | Accepted |
| Dust content (KCP 2.8.5.2.1) | - | - | Not required as GLOB1911F is a liquid. | - | - | |
| Particle size of dust (KCP 2.8.5.2.2) | - | - | Not required as GLOB1911F is a liquid. | - | - | |
| Attrition (KCP 2.8.5.3) | - | - | Not required as GLOB1911F is a liquid. | - | - | |
| Hardness and integrity (KCP 2.8.5.4) | - | - | Not required as GLOB1911F is a liquid. | - | - | |
| Emulsifiability (KCP 2.8.6.1) | - | - | Not applicable as GLOB1911F is a suspension concentrate. | - | - | |
| Emulsion stability (KCP 2.8.6.2) | - | - | Not applicable as GLOB1911F is a suspension concentrate. | - | - | |
| Re-emulsifiability (KCP 2.8.6.3) | - | - | Not applicable as GLOB1911F is a suspension concentrate. | - | - | |
| Flowability (KCP 2.8.7.1) | - | - | Not required as GLOB1911F is a liquid. | - | - | |
| Pourability (KCP 2.8.7.2) | CIPAC MT 148 | GLOB1911F (Batch No. | Poured Residue: 3.5749 %. Water Rinsed Residue: 0.1018 %. | Y | Sowle, J., 2019 DNA5103 | Accepted |

| Annex point | Method used / deviations | Test material | Findings | GLP Y/N | Reference | Acceptability / comments |
|---|--------------------------|---------------|---|---------|-----------|--------------------------|
| | | BRN3030) | Acetone Rinsed Residue: 0.0019 %. | | | |
| Dustability following accelerated storage (KCP 2.8.7.3) | - | - | Not required as GLOB1911F is a liquid. | - | - | |
| Physical compatibility of tank mixes (KCP 2.9.1) | - | - | Not relevant: no tank mix on the label. | - | - | |
| Chemical compatibility of tank mixes (KCP 2.9.2) | - | - | Not relevant: no tank mix on the label. | - | - | |
| Adhesion to seeds (KCP 2.10.1) | - | - | GLOB1911F is not used for seed treatment. | - | - | |
| Distribution to seed (KCP 2.10.2) | - | - | GLOB1911F is not used for seed treatment. | - | - | |
| Other/special studies (KCP 2.11) | - | - | - | - | - | |

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)

Nature and characteristics of the packaging: Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

The packaging has been designed according to the FAO “Guidelines for the Packaging and Storage of Pesticides”. GLOB1911F is to be marketed in 250, 500 ml and 1, 2, 3, 5, 10, 15 and 20 litre containers. The specifications are presented in the tables below.

As specified in the “Guidance document for the generation and evaluation of data on the physical, chemical and technical properties of plant protection products under Regulation (EC) No. 1107/2009 of the EU Parliament and Council on placing plant protection products on the market” (final draft, July 2018), all rigid packaging types, apart from metal, are supported with no further data, regardless of the packaging using in the shelf-life study (except metal). Therefore, packaging containers can consist of other plastic materials besides HDPE, such as HDPE/PA, HDPE/F and HDPE/EVOH.

RMS conclusion:

Based on the accelerated and two-year ambient storage study in HDPE pack, all packs, listed below, are accepted. In case of aqueous formulations like SC extrapolation from HDPE is allowed for other plastics (used as PPP packaging materials).

Table 4.1-1: Packaging information for 250 mL bottle

| Type | Description |
|------------------------|---|
| Material: | HDPE, HDPE/PA, HDPE/F, HDPE/EVOH |
| Shape/size: | cylindrical / approx. 60 mm diameter x 125 mm |
| Opening: | 42 mm inner diameter |
| Closure: | polyethylene screw cap |
| Seal: | Induction seal |
| Manner of construction | extruded |
| UN/ADR | compliant |

Table 4.1-2: Packaging information for 500 mL bottle

| Type | Description |
|-------------|---|
| Material: | HDPE, HDPE/PA, HDPE/F, HDPE/EVOH |
| Shape/size: | cylindrical / approx. 60 mm diameter x 185 mm |
| Opening: | 42 mm inner diameter |
| Closure: | polyethylene screw cap |

| Type | Description |
|------------------------|----------------|
| Seal: | Induction seal |
| Manner of construction | extruded |
| UN/ADR | compliant |

Table 4.1-3: Packaging information for 1L bottle

| Type | Description |
|------------------------|---|
| Material: | HDPE, HDPE/PA, HDPE/F, HDPE/EVOH |
| Shape/size: | cylindrical / approx. 88.5 mm diameter x 234 mm |
| Opening: | 42 mm inner diameter |
| Closure: | polyethylene screw cap |
| Seal: | Induction seal |
| Manner of construction | extruded |
| UN/ADR | compliant |

Table 4.1-4: Packaging information for 2L container

| Type | Description |
|------------------------|--|
| Material: | HDPE, HDPE/PA, HDPE/F, HDPE/EVOH |
| Shape/size: | rectangular / approx. 106 mm width x 155 mm length x 189 mm height |
| Opening: | 42 mm inner diameter |
| Closure: | polyethylene screw cap |
| Seal: | Induction seal |
| Manner of construction | extruded |
| UN/ADR | compliant |

Table 4.1-5: Packaging information for 3L container

| Type | Description |
|------------------------|--|
| Material: | HDPE, HDPE/PA, HDPE/F, HDPE/EVOH |
| Shape/size: | rectangular / approx. 160 mm width x 262 mm length x 115 mm height |
| Opening: | 63 mm inner diameter |
| Closure: | polyethylene screw cap |
| Seal: | Induction seal |
| Manner of construction | extruded |
| UN/ADR | compliant |

Table 4.1-6: Packaging information for 5 litre container

| Type | Description |
|-----------|----------------------------------|
| Material: | HDPE, HDPE/PA, HDPE/F, HDPE/EVOH |

| Type | Description |
|------------------------|--|
| Shape/size: | rectangular / approx. 140 mm x 190 mm x 313 mm |
| Opening: | 55 mm inner diameter |
| Closure: | polyethylene screw cap |
| Seal: | induction seal |
| Manner of construction | extruded |
| UN/ADR | compliant |

Table 4.1-7: Packaging information for 10 litre container

| Type | Description |
|------------------------|--|
| Material: | HDPE, HDPE/PA, HDPE/F, HDPE/EVOH |
| Shape/size: | rectangular / approx. 179 mm x 240 mm x 375 mm |
| Opening: | 63 mm inner diameter |
| Closure: | polyethylene screw cap |
| Seal: | induction seal |
| Manner of construction | extruded |
| UN/ADR | compliant |

Table 4.1-8: Packaging information for 15 litre container

| Type | Description |
|------------------------|--|
| Material: | HDPE, HDPE/PA, HDPE/F, HDPE/EVOH |
| Shape/size: | rectangular / approx. 245 mm width x 294 mm length x 311 mm height |
| Opening: | 55 mm inner diameter |
| Closure: | polyethylene screw cap |
| Seal: | induction seal |
| Manner of construction | extruded |
| UN/ADR | compliant |

Table 4.1-9: Packaging information for 20 litre container

| Type | Description |
|------------------------|--|
| Material: | HDPE, HDPE/PA, HDPE/F, HDPE/EVOH |
| Shape/size: | rectangular / approx. 263 mm width x 292 mm length x 372 mm height |
| Opening: | 55 mm inner diameter |
| Closure: | polyethylene screw cap |
| Seal: | induction seal |
| Manner of construction | extruded |
| UN/ADR | compliant |

Suitability of the packaging and closures:

The packaging material is standardly used for water based plant protection products like suspension concentrates. The 2 weeks accelerated storage stability study at 54°C was conducted in commercial packaging and showed that the product and packaging are stable and thus that the packaging is suitable.

Resistance of the packaging materials to its content:

The 2 weeks accelerated storage stability study at 54°C was conducted in commercial packaging and showed that the product is stable and thus that the packaging is suitable.

4.2 Procedures for Cleaning Application Equipment

4.2.1 Procedures for cleaning application equipment and protective clothing

4.2.2 Effectiveness of the cleaning procedures (KCP 4.2)

The effectiveness of tank cleaning was assessed in the study to determine the physico-chemical properties of the product (Sowle J., 2019). The formulation was added to 8L of water in the spray tank at the required application rate. After spraying, the tank was washed with three 400mL water rinses followed by collection of remaining residue with 100mL Methanol. The collected residue was then assayed by HPLC-DAD.

It was concluded that three rinsings with water allowed to reduce the concentrations of Difenconazole to 0.0585% of the initial one.

4.3 Recommended methods and precautions (KCP 4.2)

Reference is made to the submitted SDS (KCP 1.4.3) where all the required and detailed information can be found. A summary is given below:

4.3.1 Procedures for storage

| | |
|-------------------------|--|
| Storage conditions: | Keep only in the original container in a cool, well ventilated place away from: Keep container closed when not in use. |
| Incompatible products: | Strong bases. Strong acids. |
| Incompatible materials: | Sources of ignition. Direct sunlight |

4.3.2 Transport

In accordance with ADN / ADR / IATA / IMDG / RID

- UN number is 3082.
- UN Proper shipping name is “ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (difenoconazole)”
- Transport hazard class is 9.
- Packaging group is III

4.3.3 Firefighting measures

Suitable extinguishing media: Foam. Dry powder. Carbon dioxide. Water spray. Sand.

Unsuitable extinguishing media : Do not use a heavy water stream.

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent firefighting water from entering the environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

4.3.4 Exposure control

All unnecessary exposure should be avoided. For personal protection measures reference is made to dRR Part B Section 6.

4.3.5 Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters. Avoid release to the environment.

4.4 Emergency measures (KCP 4.3)

Reference is made to the submitted SDS for KCP 4.3 where all the required and detailed information can be found.

A short summary is given below:

4.4.1 Accidental release measures

Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

Dispose in a safe manner in accordance with local/national regulations. Avoid release to the environment

Evacuate unnecessary personnel. Equip clean-up crew with proper protection. Ventilate area.

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

Avoid release to the environment.

4.4.2 First aid measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation: Assure fresh air breathing. Allow the victim to rest.

First-aid measures after skin contact: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

First-aid measures after eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

4.5 Procedures for destruction and neutralisation (KCP 4.5)

In the event of accidental spillages the neutralisation procedures are as follows: Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials (reference is also made to 4.4.1 above).

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 1.4.3 (filled in Part C) | Divens, J. | 2020 | MSDS of GLOB1911F and its co-formulants Globachem NV, document GLOB1911F Not GLP or GEP Unpublished | N | Globachem NV |
| KCP 2.1 2.3.1 2.3.3 2.4.1 2.4.2 2.5.1 2.5.2 2.6.1 2.7.1 2.7.3 2.7.4 2.8.2 2.8.3.1 2.8.3.2 2.8.5.1.2 2.8.7.2 4.2 | Sowle, J. | 2019 | Determination of storage stability and shelf life specification data for a suspension concentrate formula- tion GLOB1911F containing 500g/L Difenconazole, stored at 54 °C ± 2 °C for two weeks, in compliance with good laboratory practice. Laboratory: David Norris Analytical Laboratories Ltd. Study number: DNA5103 GLP Unpublished | N | Globachem NV |

| 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 2.7.5 | Sowle, J. | 2021 | Determination of storage stability and shelf life specification data for a suspension concentrate formulation GLOB1911F containing 500g/L Difenconazole, stored at ambient temperature for 2 years, in compliance with good laboratory practice. Laboratory: David Norris Analytical Laboratories Ltd. Study number: DNA5104 GLP Unpublished | N | Globachem NV |
| KCP 2.2.1 and 2.2.2 (filed in Part C) | Sowle, J. | 2020 | Theoretical certificate of explosive and oxidizing properties for a soluble concentrate formulation containing Difenconazole. Laboratory: David Norris Analytical Laboratories Ltd. Not GLP, unpublished | N | Globachem NV |

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 Difenoconazole

Not applicable.