

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: **CHR/F/PYRA 250 EC**

Product name(s): **Etiuda 250 EC, Fermata 250 EC**

Chemical active substance:

Pyraclostrobin, 250 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Innvigo Sp. z o.o.

Submission date: October 2021

MS Finalisation date: 15/12/2022

Version history

When	What
December 2021	Dossier sent for evaluation
July 2022	Update
September 2022	zRMS evaluation of dRR
December 2022	Final version prepared by zRMS after Commenting period

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zRMS comments:

The text highlighted in grey was provided by the evaluator.

New and additional information is highlighted in yellow.

Sufficient data on identity, physical and chemical properties and other information are not available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are: none

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Innvigo Sp. z o. o.

Address: Innvigo Sp. z o. o.
Al. Jerozolimskie 178 St.
02-486 Warszawa,
Poland
Teresa Paczkowska
605 270 649

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).

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 Pyraclostrobin

According to the *SANCO/1420/2001-Final*

Pyraclostrobin min. 975 g/kg

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

Trade name: Etiuda 250 EC, Fermata 250 EC

Company code number: CHR/F/PYRA 250 EC

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/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
Pyraclostrobin	250.0 g/L	243.75 – 256.3	256.4	24.10

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

** Based on the density of the formulation = 1.0637 g/ mL

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
Confidential information or data are provided separately (Part C).	

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

Table 1.4-3: Information on Pyraclostrobin

Type	Pyraclostrobin
ISO common name	Pyraclostrobin N/A
IUPAC name	methyl N-(2-{{1-(4-chlorophenyl)-1H-pyrazol-3-yl}oxymethyl}phenyl) N-methoxy carbamate
CAS No.	175013-18-0
EC No.	N/A 605-7747-1
CIPAC No.	657

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: Emulsifiable Concentrate

[Code: EC]

1.6 Function (KCP 1.6)

Fungicide in the form of emulsifiable concentrate

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 light ochre liquid. The product has a sweet solvent odour. It is not explosive, has no oxidising properties. The product is flammable and has a flash point of 81.5 °C. It has a self-ignition temperature of more than 400 °C. In aqueous solution, it has a pH value around 5.60 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 24 year at ambient temperature when stored in HDPE packages. Its technical characteristics are acceptable for a EC formulation.

The intended concentration of use is 0.27 % to 1.1 %.

Recommended cleaning procedure: "Rinse the tank three times with tap water".

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

~~No Classification is necessary~~ No classification and labelling with respect to physical and chemical properties is needed

Notifier Proposals for Risk and Safety Phrases (KCP 12)

~~Not required~~ No hazard and safety phrases are needed for this section.

Compliance with FAO specifications:

The product CHR/F/PYRA 250 EC complies with FAO specifications.

Formulation used for tests

Material: CHR/F/PYRA 250 EC

Active Substances: Pyraclostrobin, 250 g/L

Producer: PUH „Chemirol” Sp. z o.o.

Batch number: 04/2020

Production date: 23.04.2020

All the product samples used in the tests presented to support the present dossier were equivalent to the formulation described 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	Material: CHR/F/PYRA 250 EC Active Substances: Pyraclostrobin, 250 g/L Producer: PUH „Chemiroł” Sp. z o.o. Batch number: 04/2020 Production date: 23.04.2020	Initial preparation: The sample was a light ochre. The sample was clear and free flowing. There were no signs of separation into oil, cream, sediment or suspended solids. There were no signs of claying. The sample had a sweet solvent odour. After accelerated storage: The sample appearance remained unchanged. After one year storage: The sample appearance remained unchanged After two years storage: The sample appearance remained unchanged	Y	KCP 2.1/01 Pomeroy, D., 2021, <i>Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing 250g/L Pyraclostrobin in initial preparation and stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice.</i> KCP 2.1/02 Pomeroy, D., 2022, <i>Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing 250g/L Pyraclostrobin stored at Ambient Temperature for 2 years, in Compliance with Good Laboratory Practice.</i>	Acceptable
Explosive properties (KCP 2.2.1)	A.14 -	Material: CHR/F/PYRA 250 EC Active Substances: Pyraclostrobin, 250 g/L Producer: PUH „Chemiroł” Sp. z o.o. Batch number: 04/2020 Production date: 23.04.2020 Teoretical evaluation	From the assessment of the active substance and other ingredients it was established that the formulation CHR/F/PYRA 250 EC does not have explosive properties – the individual components of the formulation are not classified as explosive. Pyraclostrobin contains no phosphore or strong oxidising groupings, therefore represents no explosive hazards in the formulation.	Y	KCP 2.2.1 Pomeroy, D., 2021, <i>Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing 250g/L Pyraclostrobin in initial preparation and stored at 54°C±2°C for Two Weeks, in Compliance with Good</i>	Acceptable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
					Laboratory Practice.	
Oxidizing properties (KCP 2.2.2)	A.21 -	Material: CHR/F/PYRA 250 EC Active Substances: Pyraclostrobin, 250 g/L Producer: PUH „Chemiroł” Sp. z o.o. Batch number: 04/2020 Production date: 23.04.2020 Teoretical evaluation	From the assessment of the active substance and other ingredients it was established that the formulation CHR/F/PYRA 250 EC does not have oxidizing properties - the individual components of the formulation are not oxidizing. Pyraclostrobin contains no plosophore or strong oxidising groupings, therefore represents no oxidizing hazards in the formulation.	Y	KCP 2.2.2 Pomeroy, D., 2021, <i>Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing 250g/L Pyraclostrobin in initial preparation and stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice.</i>	Acceptable
Flash point (KCP 2.3.1)	EEC A.9	Material: CHR/F/PYRA 250 EC Active Substances: Pyraclostrobin, 250 g/L Producer: PUH „Chemiroł” Sp. z o.o. Batch number: 04/2020 Production date: 23.04.2020	Flash point: 81.5 °C. Flash point is > 60°C, therefore the product is to be classified as non-flammable.	Y	KCP 2.3.1 Pomeroy, D., 2021, <i>Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing 250g/L Pyraclostrobin in initial preparation and stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice.</i>	Acceptable
Flammability (KCP 2.3.2)	EEC A.9	Material: CHR/F/PYRA 250 EC Active Substances: Pyraclostrobin, 250 g/L Producer: PUH „Chemiroł” Sp. z o.o. Batch number: 04/2020 Production date: 23.04.2020	The sample did not auto-ignite below 400°C and is therefore not considered highly flammable.		KCP 2.3.2 Pomeroy, D., 2021, <i>Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing 250g/L Pyraclostrobin in initial preparation and stored at 54°C±2°C for Two Weeks, in Compliance with Good</i>	Acceptable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
					Laboratory Practice.	
Self-heating (KCP 2.3.3)	EEC A.15	Material: CHR/F/PYRA 250 EC Active Substances: Pyraclostrobin, 250 g/L Producer: PUH „Chemiol” Sp. z o.o. Batch number: 04/2020 Production date: 23.04.2020	The sample did not auto-ignite below 400°C and is therefore not considered highly flammable.	Y	KCP 2.3.3 Pomeroy, D., 2021, <i>Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing 250g/L Pyraclostrobin in initial preparation and stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice.</i>	Acceptable Remarks: The amount of sample used for the study is missing from the report.
Acidity or alkalinity and pH (KCP 2.4.1)	N/A	N/A	Not required as the pH of formulation was found to be between 4 and 10.	N/A	N/A	N/A
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	MT 75.3	Material: CHR/F/PYRA 250 EC Active Substances: Pyraclostrobin, 250 g/L Producer: PUH „Chemiol” Sp. z o.o. Batch number: 04/2020 Production date: 23.04.2020	Initial preparation: 1% (w/v) emulsion – 5.60 at 20°C After accelerated storage: 1% (w/v) emulsion – 5.37 at 20°C After one year storage: 1% (w/v) emulsion – 5.72 at 20°C After two years storage: 1% (w/v) emulsion – 5.32 at 20°C	Y	KCP 2.4.2/01 Pomeroy, D., 2021, <i>Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing 250g/L Pyraclostrobin in initial preparation and stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice.</i> KCP 2.4.2/02 Pomeroy, D., 2022, <i>Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing 250g/L</i>	Acceptable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
					<i>Pyraclostrobin stored at Ambient Temperature for 2 years, in Compliance with Good Laboratory Practice.</i>	
Viscosity (KCP 2.5.1)	OECD 114	Material: CHR/F/PYRA 250 EC Active Substances: Pyraclostrobin, 250 g/L Producer: <i>PUH „Chemiol” Sp. z o.o.</i> Batch number: 04/2020 Production date: 23.04.2020	The sample is a Newtonian liquid with a Dynamic Viscosity of 38.06mPa.s and Kinematic Viscosity of 0.3578cm ² /s at 20.0°C. The sample is a Newtonian liquid with a Dynamic Viscosity of 25.88 mPa.s and Kinematic Viscosity of 0.2455cm ² /s at 40.0°C.	Y	KCP 2.5.1 Pomeroy, D., 2021, <i>Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing 250g/L Pyraclostrobin in initial preparation and stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice.</i>	Acceptable
Surface tension (KCP 2.5.2)	EEC A.5	Material: CHR/F/PYRA 250 EC Active Substances: Pyraclostrobin, 250 g/L Producer: <i>PUH „Chemiol” Sp. z o.o.</i> Batch number: 04/2020 Production date: 23.04.2020	At 20°C: 32.86 mN/m SD 0.199 At 25°C: 32.58 mN/m SD 0.100	Y	KCP 2.5.2 Pomeroy, D., 2021, <i>Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing 250g/L Pyraclostrobin in initial preparation and stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice.</i>	Acceptable Remarks: The formulation CHR/F/PYRA 250 EC is surface active.
Relative density (KCP 2.6.1)	A.3	Material: CHR/F/PYRA 250 EC Active Substances: Pyraclostrobin, 250 g/L Producer: <i>PUH „Chemiol” Sp. z o.o.</i> Batch number: 04/2020	At 20°C: 1.0637 g/mL At 40°C: 1.0538 g/mL	Y	KCP 2.6.1 Pomeroy, D., 2021, <i>Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing 250g/L Pyraclostrobin in initial</i>	Acceptable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Production date: 23.04.2020			<i>preparation and stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice.</i>	
Bulk density (KCP 2.6.2)	N/A	N/A	N/A	N/A	N/A	N/A
Storage Stability after 14 days at 54° C (KCP 2.7.1)	Visual Assessment, HPLC, MT 75.3, MT 36.3	Material: CHR/F/PYRA 250 EC Active Substances: Pyraclostrobin, 250 g/L Producer: <i>PUH „Chemiroł” Sp. z o.o.</i> Batch number: 04/2020 Production date: 23.04.2020	Please refer to each individual raw for each following property: appearance, stability of packaging, active ingredient content, pH determination, emulsifiability	Y	KCP 2.7.1 Pomeroy, D., 2021, <i>Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing 250g/L Pyraclostrobin in initial preparation and stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice.</i>	Acceptable
Storage Stability after 12 weeks at 35 °C (KCP 2.7.2)	N/A	N/A	N/A Not relevant for liquid formulations	N/A	N/A	N/A
Minimum content after heat stability testing (KCP 2.7.3)	Method described in DNA5716 HPLC-DAD	Material: CHR/F/PYRA 250 EC Active Substances: Pyraclostrobin, 250 g/L Producer: <i>PUH „Chemiroł” Sp. z o.o.</i> Batch number: 04/2020 Production date: 23.04.2020	Initial preparation: 253.1 g/L (101.2% of declared content) After accelerated storage: 248.8 g/L (99.53% of declared content) After one year storage: 248.6 g/L (99.45% of declared content) After two years storage: 246.2 g/L (98.48% of declared content)	Y	KCP 2.7.3/01 Pomeroy, D., 2021, <i>Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing 250g/L Pyraclostrobin in initial preparation and stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice.</i> KCP 2.7.3/02 Pomeroy, D., 2022, <i>Determination of Storage</i>	Acceptable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
					<i>Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing 250g/L Pyraclostrobin stored at Ambient Temperature for 2 years, in Compliance with Good Laboratory Practice.</i>	
Effect of low temperatures on stability (KCP 2.7.4)	N/A	N/A	N/A	N/A	N/A	N/A Remarks: An emulsion storage stability study was performed after storage (see section. 2.8.6.2.).
Ambient temperature shelf life (KCP 2.7.5)	Visual Assessment, HPLC, MT 75.3, MT 36.3	Material: CHR/F/PYRA 250 EC Active Substances: Pyraclostrobin, 250 g/L Producer: <i>PUH „Chemiol” Sp. z o.o.</i> Batch number: 04/2020 Production date: 23.04.2020	Please refer to each individual raw for each following property: appearance, stability of packaging, active ingredient content, pH determination, emulsifiability	Y	KCP 2.7.5 Pomeroy, D., 2022, <i>Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing 250g/L Pyraclostrobin stored at Ambient Temperature for 2 years, in Compliance with Good Laboratory Practice.</i>	Acceptable All tested parameter are accepted.
Shelf life in months (if less than 2 years) (KCP 2.7.6)	Visual Assessment, HPLC, MT 75.3, MT 36.3	Material: CHR/F/PYRA 250 EC Active Substances: Pyraclostrobin, 250 g/L Producer: <i>PUH „Chemiol” Sp. z o.o.</i> Batch number: 04/2020	Please refer to each individual raw for each following property: appearance, stability of packaging, active ingredient content, pH determination, emulsifiability	Y	KCP 2.7.6 Pomeroy, D., 2021, <i>Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing 250g/L Pyraclostrobin stored at Ambient</i>	Acceptable All tested parameter are accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Production date: 23.04.2020			Temperature for 2 years, in Compliance with Good Laboratory Practice.	
Wettability (KCP 2.8.1)	N/A	N/A	N/A Not relevant for liquid formulations	N/A	N/A	N/A
Persistence of foaming (KCP 2.8.2)	MT 47.3	Material: CHR/F/PYRA 250 EC Active Substances: Pyraclostrobin, 250 g/L Producer: PUH „Chemrol” Sp. z o.o. Batch number: 04/2020 Production date: 23.04.2020	At the minimum application rate (0.04% v/v) After 1 minute: 0.0 mL After 12 minutes: 0.0 mL At the maximum application rate (1.0% v/v) After 1 minute: 0.0 mL After 12 minutes: 0.0 mL	Y	KCP 2.8.2 Pomeroy, D., 2021, <i>Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing 250g/L Pyraclostrobin in initial preparation and stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice.</i>	Acceptable

Suspensibility (KCP 2.8.3.1)	N/A	N/A	N/A Not relevant for liquid formulations	N/A	N/A	N/A
Spontaneity of dispersion (KCP 2.8.3.2)	N/A	N/A	N/A Not relevant for liquid formulations	N/A	N/A	N/A
Dispersion stability (KCP 2.8.3.3)	N/A	N/A	N/A Not relevant for liquid formulations	N/A	N/A	N/A
Degree of dissolution and dilution stability (KCP 2.8.4)	N/A	N/A	N/A Not relevant for liquid formulations	N/A	N/A	N/A
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	N/A	N/A	N/A Not relevant for liquid formulations	N/A	N/A	N/A
Wet sieve test (KCP 2.8.5.1.2)	N/A	N/A	N/A Not relevant for liquid formulations	N/A	N/A	N/A
Dust content (KCP 2.8.5.2.1)	N/A	N/A	N/A Not relevant for liquid formulations	N/A	N/A	N/A
Particle size of dust (KCP 2.8.5.2.2)	N/A	N/A	N/A Not relevant for liquid formulations	N/A	N/A	N/A
Attrition (KCP 2.8.5.3)	N/A	N/A	N/A Not relevant for liquid formulations	N/A	N/A	N/A
Hardness and integrity (KCP 2.8.5.4)	N/A	N/A	N/A Not relevant for liquid formulations	N/A	N/A	N/A

Emulsifiability (KCP 2.8.6.1)	MT 36.3	Material: CHR/F/PYRA 250 EC Active Substances: Pyra- clostrobin, 250 g/L Producer: <i>PUH „Chemrol”</i> <i>Sp. z o.o.</i> Batch number: 04/2020 Production date: 23.04.2020	<p>Initial preparation: For the high (1.0% v/v) and low (0.04% v/v) application rate storage sample remained a uniform white emulsion with no signs of separation into cream, oil or crystals with no sign of sediment.</p> <p>After accelerated storage: For the high (1.0% v/v) and low (0.04% v/v) application rate storage sample remained a uniform white emulsion with no signs of separation into cream, oil or crystals with no sign of sediment</p> <p>After low temperature storage: For the high (1.0% v/v) and low (0.04% v/v) application rate storage sample remained a uniform white emulsion with no signs of separation into cream, oil or crystals with no sign of sediment</p> <p>After one year storage: For the high (1.0% v/v) and low (0.04% v/v) application rate storage sample remained a uniform white emulsion with no signs of separation into cream, oil or crystals with no sign of sediment</p> <p>After two years storage: For the high (1.0% v/v) and low (0.04% v/v) application rate storage sample remained a uniform white emulsion with no signs of separation into cream, oil or crystals with no sign of sediment</p>	Y	<p>KCP 2.8.6.1/01 Pomeroy, D., 2021, <i>Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing 250g/L Pyraclostrobin in initial preparation and stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice.</i></p> <p>KCP 2.8.6.1/02 Pomeroy, D., 2022, <i>Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing 250g/L Pyraclostrobin stored at Ambient Temperature for 2 years, in Compliance with Good Laboratory Practice.</i></p>	Acceptable
Emulsion stability (KCP 2.8.6.2)	MT 36.3	Material: CHR/F/PYRA 250 EC Active Substances: Pyra- clostrobin, 250 g/L Producer: <i>PUH „Chemrol”</i> <i>Sp. z o.o.</i> Batch number: 04/2020 Production date: 23.04.2020	<p>Initial preparation: For the high (1.0% v/v) and low (0.04% v/v) application rate storage sample remained a uniform white emulsion with no signs of separation into cream, oil or crystals with no sign of sediment.</p> <p>After accelerated storage: For the high (1.0% v/v) and low (0.04% v/v) application rate storage sample remained a uniform white emulsion with no signs of separation into cream, oil or crystals with no sign of sediment</p> <p>After low temperature storage: For the high (1.0% v/v) and low (0.04% v/v) application rate</p>	Y	<p>KCP 2.8.6.2/01 Pomeroy, D., 2021, <i>Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing 250g/L Pyraclostrobin in initial preparation and stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice.</i></p> <p>KCP 2.8.6.2/02</p>	Acceptable

			<p>storage sample remained a uniform white emulsion with no signs of separation into cream, oil or crystals with no sign of sediment</p> <p>After one year storage: For the high (1.0% v/v) and low (0.04% v/v) application rate storage sample remained a uniform white emulsion with no signs of separation into cream, oil or crystals with no sign of sediment</p> <p>After two years storage: For the high (1.0% v/v) and low (0.04% v/v) application rate storage sample remained a uniform white emulsion with no signs of separation into cream, oil or crystals with no sign of sediment</p>		<p>Pomeroy, D., 2022, <i>Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing 250g/L Pyraclostrobin stored at Ambient Temperature for 2 years, in Compliance with Good Laboratory Practice.</i></p>	
Re-emulsifiability (KCP 2.8.6.3)	N/A	N/A	Where no oil or cream separation after 2 hours, then the 24 hour test is not required.	N/A	N/A	N/A
Flowability (KCP 2.8.7.1)	N/A	N/A	N/A Not relevant for liquid formulations	N/A	N/A	N/A
Pourability (KCP 2.8.7.2)	N/A	N/A	N/A Not relevant for liquid formulations	N/A	N/A	N/A
Dustability following accelerated storage (KCP 2.8.7.3)	N/A	N/A	N/A Not relevant for liquid formulations	N/A	N/A	N/A
Physical compatibility of tank mixes (KCP 2.9.1)	N/A	N/A	N/A Not relevant for liquid formulations	N/A	N/A	N/A
Chemical compatibility of tank mixes (KCP 2.9.2)	N/A	N/A	N/A Not relevant for liquid formulations	N/A	N/A	N/A
Adhesion to	N/A	N/A	N/A Not relevant for liquid formulations	N/A	N/A	N/A

seeds (KCP 2.10.1)						
Distribution to seed (KCP 2.10.2)	N/A	N/A	N/A Not relevant for liquid formulations	N/A	N/A	N/A

Stability of packaging (KCP 2.11)	SPB/38	Material: CHR/F/PYRA 250 EC Active Substances: Pyraclostrobin, 250 g/L Producer: <i>PUH „Chemrol” Sp. z o.o.</i> Batch number: 04/2020 Production date: 23.04.2020	<p>After accelerated storage: Change in weight – 0.013 [%]</p> <p>After one year storage: The sample appearance remained unchanged post 1 year storage at Ambient Temperature, from the Pre Storage sample.</p> <p>After two years storage: The sample appearance remained unchanged post 2 years storage at Ambient Temperature, from the Pre Storage sample.</p>	Y	<p>KCP 2.11/01 Pomeroy, D., 2021, <i>Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing 250g/L Pyraclostrobin in initial preparation and stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice.</i></p> <p>KCP 2.11/02 Pomeroy, D., 2022, <i>Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing 250g/L Pyraclostrobin stored at Ambient Temperature for 2 years, in Compliance with Good Laboratory Practice.</i></p>	Acceptable
Effectiveness of cleaning (KCP 2.12)	David Norris In House Methodology	Material: CHR/F/PYRA 250 EC Active Substances: Pyraclostrobin, 250 g/L Producer: <i>PUH „Chemrol” Sp. z o.o.</i> Batch number: 04/2020 Production date: 23.04.2020	The EC Formulation containing 250 g/L Pyraclostrobin has a mean Effectiveness of cleaning result 0.00263% residues for Pyraclostrobin using three water rinses.	Y	<p>KCP 2.12 Pomeroy, D., 2021, <i>Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing 250g/L Pyraclostrobin in initial preparation and stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice.</i></p>	Acceptable

3 Section 3 is presented as a separate document

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

4 Section 4: Further information on the plant protection product

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

Table 4.1-1: Packaging information

Type	JAR
Material:	HDPE
size:	63/64 mm / 91.5 mm
Opening:	46 mm minimum
Closure:	screw cap with seal
Capacity	188 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-2: Packaging information

Type	BOTTLE
Material:	HDPE
size:	64 mm± 2 mm/130 mm ± 3 mm
Opening:	40 mm ± 2 mm
Closure:	screw cap with seal
Capacity	250 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-3: Packaging information

Type	BOTTLE
Material:	HDPE
size:	72 mm± 2 mm/111,8 mm ± 3 mm
Opening:	38 mm ± 2 mm
Closure:	screw cap with seal
Capacity	250 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-4: Packaging information

Type	BOTTLE
Material:	HDPE
size:	72±1 mm/111.8±2 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	250 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-5: Packaging information

Type	BOTTLE
Material:	HDPE
size:	69 mm± 2 mm/186.5 mm ± 2 mm
Opening:	45.65± 2 mm
Closure:	screw cap with seal
Capacity	564 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-6: Packaging information

Type	BOTTLE
Material:	HDPE
size:	90,5 mm± 2 mm/151 mm ± 3 mm
Opening:	40,6 mm ± 2 mm
Closure:	screw cap with seal
Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-7: Packaging information

Type	BOTTLE
Material:	HDPE
size:	77,6 mm± 2 mm/160,6 mm ± 3 mm
Opening:	38 mm ± 2 mm
Closure:	screw cap with seal
Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded

UN/ADR	compliant
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Table 4.1-8: Packaging information

Type	BOTTLE
Material:	HDPE
size:	77.6 ±1 mm/160.6±2 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-9: Packaging information

The jar is set in an inner box (cardboard box). The inner box is grouped into an outer box
Material: HDPE
Type of construction: jar
Size: approximate diameter/height: 80 mm/138 mm
Capacity: 510 ml overflow
Type of closure: screw-cap with seal
Size of opening: 46 mm minimum
Accessories: one measuring device per each jar

Table 4.1-10: Packaging information

Type	BOTTLE
Material:	HDPE
size:	145.5mm± 2 mm/78mm ± 2 mm
Opening:	56mm ± 2 mm
Closure:	screw cap with seal
Capacity	600 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-11: Packaging information

Type	JAR
Material:	HDPE
size:	79/80 mm/ 201 mm
Opening:	46 mm minimum
Closure:	screw cap with seal
Capacity	800 ml
Seal:	Induction seal

Manner of construction	extruded
UN/ADR	compliant

Table 4.1-12: Packaging information

Type	BOTTLE
Material:	HDPE
size:	80 mm± 2 mm/201 mm ± 2 mm
Opening:	64 mm
Closure:	screw cap with seal
Capacity	800 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-13: Packaging information

Type	BOTTLE
Material:	HDPE
size:	88.5 mm± 2 mm/283.5 mm ± 2 mm
Opening:	45.30 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-14: Packaging information

Type	BOTTLE
Material:	HDPE
size:	88 mm± 4 mm/242 mm ± 6 mm
Opening:	39mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-15: Packaging information

Type	BOTTLE
Material:	HDPE
size:	238 mm± 2 mm/90mm ± 2 mm
Opening:	39 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml

Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-16: Packaging information

Type	BOTTLE
Material:	HDPE
size:	234 mm± 2 mm/88.5mm ± 2 mm
Opening:	42 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-17: Packaging information

Type	BOTTLE
Material:	HDPE
size:	84 mm± 2 mm/248.2 mm ± 2 mm
Opening:	50 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-18: Packaging information

Type	BOTTLE
Material:	HDPE
size:	234 mm± 2 mm/88.5mm ± 2 mm
Opening:	42 mm ± 2 mm
Closure:	cap with seal
Capacity	1200 ± 50 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-19: Packaging information

Type	BOTTLE
Material:	HDPE
size:	84 ± 1.5 mm/230.1 ± 3 mm
Opening:	38 mm

Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-20: Packaging information

Type	BOTTLE
Material:	HDPE
size:	157,2 mm± 2 mm/101mm ± 2 mm
Opening:	72 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-21: Packaging information

Type	JAR
Material:	HDPE
size:	108/110 mm/ 266 mm
Opening:	46 mm minimum
Closure:	screw cap with seal
Capacity	2000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-22: Packaging information

Type	CONTAINER
Material:	HDPE
size:	232 mm± 2 mm/195mm± 2 mm/130mm ± 2 mm
Opening:	50 mm ± 2 mm
Closure:	screw cap with seal
Capacity	3000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-23: Packaging information

Type	BOTTLE
Material:	HDPE
size:	94 ± 1 mm/103 ± 1 mm/272.5 ± 3 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	2000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-24: Packaging information

Type	BOTTLE
Material:	HDPE
size:	224,1 mm± 2 mm/122mm ± 2 mm
Opening:	73 mm ± 2 mm
Closure:	screw cap with seal
Capacity	2000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-25: Packaging information

Type	CONTAINER
Material:	HDPE
size:	232 mm± 2 mm/195mm± 2 mm/130mm ± 2 mm
Opening:	50 mm ± 2 mm
Closure:	screw cap with seal
Capacity	3000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-26: Packaging information

Type	CANNISTER
Material:	HDPE
size:	96 ± 3 mm/195 ± 3.5 mm/297.2 ± 4 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	4000 ml
Seal:	Induction seal
Manner of construction	extruded

UN/ADR	compliant
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Table 4.1-27: Packaging information

Type	CONTAINER
Material:	HDPE
size:	305mm± 5 mm/193 mm± 5 mm/142 mm ± 5 mm
Opening:	59.20 mm minimum ± 5 mm
Closure:	screw cap with seal
Capacity	5850 ml±150 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-28: Packaging information

Type	CONTAINER
Material:	HDPE
size:	336 mm± 5 mm/195mm± 5 mm/130mm ± 5 mm
Opening:	50 mm ± 5 mm
Closure:	screw cap with seal
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-29: Packaging information

Type	CONTAINER
Material:	HDPE
size:	310,5 mm± 5 mm/195mm± 5 mm/130mm ± 5 mm
Opening:	63 mm ± 5 mm
Closure:	screw cap with seal
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-30: Packaging information

Type	CANNISTER
Material:	HDPE
size:	190 mm± 5 mm /140 mm± 5 mm/ 314 mm ± 5 mm
Opening:	54.5 mm ± 5 mm
Closure:	screw cap with seal
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded

UN/ADR	compliant
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Table 4.1-31: Packaging information

Type	CANNISTER
Material:	HDPE
size:	127±2 mm/192±2 mm/285±5 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-32: Packaging information

Type	CANNISTER
Material:	HDPE
size:	145±2 mm/190.8±3/294±4 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	6000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-33: Packaging information

Type	Description
Material:	HDPE
Size:	745 mm x 493 mm
Opening:	BCS 70x6/ BCS 38x6
Closure:	Bung
Capacity	124 L
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-34: Packaging information

Type	Description
Material:	HDPE
Size:	90000mm/59000mm \pm 2 mm
Opening:	45mm \pm 2 mm
Closure:	screw cap with seal
Capacity	22000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-35: Packaging information

Type	Description
Material:	HDPE
Size:	935 mm x 581 mm
Opening:	BCS 70x6/ BCS 56x4
Closure:	Bung
Capacity	220 L
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-37: Packaging information

Type	Description
Material:	HDPE
Size:	942 mm \pm 10 mm x 582 mm \pm 10 mm
Opening:	70x6 / 56 x4
Closure:	Openings on top, 3 high, straight wrapped with cover on top Bungs 70x6 and 56 x 4 lose screw
Capacity	222 L
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-33: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
size:	50 ± 1 mm/93 ± 1 mm
Opening:	28,4 ± 0,3 mm
Closure:	screw cap with seal
Capacity	120 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-34: Packaging information

Packaging information for 120 ml BOTTLE	
Type	BOTTLE
Material:	HDPE/PA COEX
size:	50 ± 1 mm/93 ± 1 mm
Opening:	28,4 ± 0,3 mm
Closure:	screw cap with seal
Capacity	120 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-35: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
size:	62.5±1 mm/131.3±1 mm
Opening:	45.65±3 mm
Closure:	screw cap with seal
Capacity	323 ± 5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-36: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	59 ± 1 mm/143 ± 1 mm/
Opening:	41.7±0.7 mm
Closure:	screw cap with seal
Capacity	275 ml
Seal:	Induction seal

Manner of construction	extruded
UN/ADR	compliant

Table 4.1-37: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	59 ± 1 mm/143 ± 1 mm/
Opening:	41.7±0.7 mm
Closure:	screw cap with seal
Capacity	275 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-38: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	69 mm ± 2 mm/186.5 mm ± 2 mm
Opening:	45.65±3 mm
Closure:	screw cap with seal
Capacity	574 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-39: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
size:	74± 1 mm/177 ± 1 mm/
Opening:	41.7±0.7 mm
Closure:	screw cap with seal
Capacity	550 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-40: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
size:	74± 1 mm/177 ± 1 mm/
Opening:	41.7±0.7 mm
Closure:	screw cap with seal
Capacity	550 ml
Seal:	Induction seal

Manner of construction	extruded
UN/ADR	compliant

Table 4.1-41: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	65 mm/234.8 mm \pm 2 mm
Opening:	27.4 mm
Closure:	screw cap with seal
Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-42: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
size:	88 mm \pm 2 mm/238 mm \pm 2 mm
Opening:	50 mm \pm 2 mm
Closure:	screw cap with cutter
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-43: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	248.5 \pm 3 mm/84 \pm 1.5mm
Opening:	50 mm \pm 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-44: Packaging information

Type	BOTTLE
Material:	HDPE/PA
size:	248.5 \pm 3 mm/84 \pm 1.5mm
Opening:	50 mm \pm 5 mm
Closure:	screw cap with seal
Capacity	1000 ml

Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-45: Packaging information

Type	BOTTLE
Material:	PE-PA
size:	234 mm± 2 mm/88.5mm ± 2 mm
Opening:	42 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-46: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
size:	238± 1 mm/88 ± 1 mm/
Opening:	41.7±0,7 mm
Closure:	screw cap with seal
Capacity	1100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-47: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
size:	84± 1.5 mm/248.5 ± 3 mm
Opening:	50 mm ± 3mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-48: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
size:	233.5± 1.5 mm/88.5 ± 1 mm/
Opening:	39 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1100 ml

Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-49: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
size:	84± 1.5 mm/248.5 ± 3 mm
Opening:	50 mm ± 3mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-50: Packaging information

Type	CONTAINER
Material:	HDPE/PA COEX
size:	305mm± 5 mm/193 mm± 5 mm/142 mm ±5 mm
Opening:	63 mm minimum ± 5 mm
Closure:	screw cap with seal
Capacity	5850 ml±150 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-51: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
size:	193 ± 3/ 142 ± 5 mm/320 mm± 5 mm
Opening:	63,3 ± 3mm
Closure:	screw cap with seal
Capacity	5500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-52: Packaging information

Type	BOTTLE
Material:	HDPE/PA COEX
size:	195 ± 3/ 130 ± 5 mm/310,5 mm± 5 mm
Opening:	63,3 ± 3mm
Closure:	screw cap with seal

Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-53: Packaging information

Type	CANNISTER
Material:	HDPE/PA COEX
size:	313± 5mm/190±3/140±5mm
Opening:	50 mm ± 3mm
Closure:	screw cap with seal
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-54: Packaging information

Type	CONTAINER
Material:	HDPE/PA COEX
size:	305mm/193 mm/142 mm ± 5 mm
Opening:	63 mm minimum ± 5 mm
Closure:	screw cap with seal
Capacity	10000 ml±150 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-55: Packaging information

Type	CONTAINER
Material:	HDPE/PA COEX
size:	377,7mm/178 mm/239,5 mm ± 5 mm
Opening:	54 mm min ± 5 mm
Closure:	screw cap with seal
Capacity	10000 ml±150 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-56: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm ± 2 mm
Opening:	54,2 mm ± 1 mm

Closure:	screw cap with seal
Capacity	5950 ml \pm 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-57: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm \pm 2 mm
Opening:	63.4 mm min \pm 1 mm
Closure:	screw cap with seal
Capacity	5950 ml \pm 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-58: Packaging information

Type	BOTTLE
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm \pm 2 mm
Opening:	67,5 mm \pm 1 mm
Closure:	screw cap with seal
Capacity	5950 ml \pm 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-59: Packaging information

Type	CANNISTER
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm \pm 2 mm
Opening:	54,2 mm min \pm 1 mm
Closure:	screw cap with seal
Capacity	5950 ml \pm 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-60: Packaging information

Type	CANNISTER
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm \pm 2 mm
Opening:	63,4 mm min \pm 1 mm

Closure:	screw cap with seal
Capacity	5950 ml \pm 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-61: Packaging information

Type	CANNISTER
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm \pm 2 mm
Opening:	67,5 mm min \pm 1 mm
Closure:	screw cap with seal
Capacity	5950 ml \pm 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-62: Packaging information

Type	Description
Material:	HDPE/EvOH
Size:	69 mm \pm 2 mm/186.5 mm \pm 2 mm
Opening:	45.30 mm \pm 2 mm
Capacity	500 ml
Closure:	screw cap with cutter
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-63: Packaging information

Type	Description
Material:	HDPE/EvOH
size:	65 mm/234.8 mm \pm 2 mm
Opening:	27.4 mm
Closure:	screw cap with seal
Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-64: Packaging information

Type	Description
Material:	HDPE/EvOH
size:	234±3 mm/88.5±2mm
Opening:	42 mm ± 2 mm
Closure:	screw cap with cutter
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-65: Packaging information

Type	Description
Material:	HDPE/EvOH
Size:	234±3 mm/88.5±2mm
Opening:	42 mm ± 2 mm
Closure:	screw cap with cutter
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-66: Packaging information

Type	Description
Material:	HDPE/EvOH
Size:	234±3 mm/88.5±2mm
Opening:	50 mm ± 3 mm
Closure:	screw cap with cutter
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-67: Packaging information

Type	Description
Material:	HDPE/EvOH
Size:	165 mm ± 2 mm/195 mm ± 2 mm/228mm± 2 mm
Opening:	48 mm ± 2 mm

Type	Description
Closure:	screw cap with cutter
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-68: Packaging information

Type	Description
Material:	HDPE/EvOH
Size:	195 mm \pm 2 mm/225mm \pm 2 mm/306mm \pm 2 mm
Opening:	48 mm \pm 2 mm
Closure:	screw cap with cutter
Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-69: Packaging information

Type	Description
Material:	HDPE/EvOH
Size:	375 mm \pm 2 mm/290mm \pm 2 mm/245mm \pm 2 mm
Opening:	85mm \pm 2 mm
Closure:	Screw cap with seal
Capacity	20000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

According to guideline from Ministry of Agriculture and Rural Development (*Wytyczna w sprawie zasad zatwierdzania opakowań w środkach ochrony roślin*) data of stability in the material HDPE are extrapolable to the all materials (HDPE/PA; HDPE/F; HDPE/EvOH). Therefore, no further studies are required for the additional packaging materials.

Appendix 1 Lists of data considered in support of the evaluation

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 2.1/01 KCP 2.2.1 KCP 2.2.2 KCP 2.3.1 KCP 2.3.2 KCP 2.3.3 KCP 2.4.2/01 KCP 2.5.1 KCP 2.5.2 KCP 2.6.1 KCP 2.7.1 KCP 2.7.3/01 KCP 2.8.2 KCP 2.8.6.1/01 KCP 2.8.6.2/01 2.11/01 2.12	Pomeroy, D.	2021	<i>Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing 250g/L Pyraclostrobin in initial preparation and stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice.</i> DNA5713 David Norris Analytical Laboratories Ltd., Dartford, United Kingdom GLP Unpublished	N	Chemiroil

KCP 2.1/02 KCP 2.4.2/02 KCP 2.7.3/02 KCP 2.7.5 KCP 2.8.6.1/02 KCP 2.8.6.2/02 KCP 2.11/02	Pomeroy, D.	2022	<i>Pomeroy, D., 2021, Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing 250g/L Pyraclostrobin stored at Ambient Temperature for 2 years, in Compliance with Good Laboratory Practice.</i> DNA5714 David Norris Analytical Laboratories Ltd., Dartford, United Kingdom GLP Unpublished	N	Chemirool
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Appendix 2 Additional data on the physical, chemical and technical properties of the active substance