

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: IN002B1760

Product name: Cymofil

Chemical active substance:

Cymoxanil, 450 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(New authorization)

Applicant: Indofil Industries B.V.

Submission date: August 2022, updated January 2024

MS Finalisation date: May 2023 (initial Core Assessment)

January 2024, updated February 2024, April 2024
(final Core Assessment)

Version history

When	What
August 2022	Original version from applicant Indofil Industries (Netherlands) B.V. for submission to z-RMS, Poland, in the frame of the PPP Authorization according to Article 33 of Regulation (EC) No. 1107/2009.
May 2023	Initial assessment by the zRMS The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency.
January 2024	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Information no longer relevant is struck through and shaded.
January 2024	Applicant updates highlighted in turquoise.
February 2024	zRMS assessment after submission of the additional data by the applicant in the scope of the potential tank mix partners. The updated report has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in green. Not agreed or not relevant information are struck through and shaded for transparency.
April 2024	Applicant updates highlighted in orange.
April 2024	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in purple. Not agreed or not relevant information are struck through and shaded for transparency.

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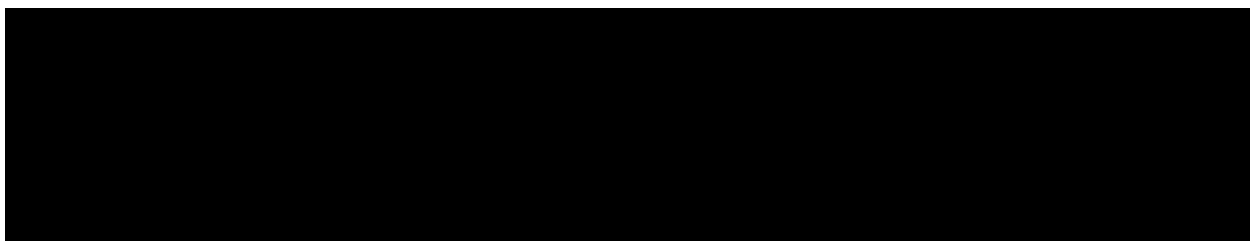
Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substance.

Noticed data gaps are: **none**.

- ~~Ambient temperature study is currently ongoing, and should be provided upon completion.~~

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)



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

1.2.1 Producer of the preparation

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

1.2.2 Producer 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



1.2.3.1 Cymoxanil

Cymoxanil	Commission Directive 2008/125/EC of 19 December 2008	SANCO/179/08–final rev.1, 09th July 2010	EFSA Journal 2008; 167, 1-116 Peer review of cymoxanil	Indofil source*
	min. 970 g/kg	970 g/kg	min. 970 g/kg	min.980 g/kg

* Refer to Part C for more information

No toxicologically relevant impurities have been defined for Cymoxanil (2008/125/EC- 19th December 2008).

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

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

Company code number: IN002B1760

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)

The formulation IN002B1760 is a new formulation of PPP that has not been registered yet.

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

Active substance / variant	Declared content of the pure active substance / variant (g/kg)	FAO Limits (min – max)	Technical content (g/kg)	Technical content* (%w/w)
Cymoxanil	45.00 (450.00 g/kg)	40.5 – 49.50 42.75 – 47.25 % (445.50 – 454.50) (427.5 – 472.5 g/kg)	*463.92 g/kg 459 g/kg (Indofil source)	*46.39 45.9 % (Indofil source)

*considering the minimum purity of inclusion

1.4.2 Information on the active substance (KCP 1.4.2)

Table 1.4-2: Information on Cymoxanil

Type	Name/Code Number
ISO common name	1-[(E/Z)-2-cyano-2-methoxyiminoacetyl]-3-ethylurea
CAS No.	57966-95-7
EC No.	261-043-0
CIPAC No.	419

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)

Fungicide.

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a granular formulation, with a characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. In aqueous solution, it has a pH value around 5.2 at 20°C. ~~Ambient temperature study is currently ongoing, and should be provided upon completion.~~ 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. The stability data after accelerated **and ambient** storage indicates a shelf life of at least 2 years at ambient temperature when stored in polyethylene bag. Its technical characteristics are acceptable for a WG formulation.

The intended concentration of use is **0.066 to 0.11%** ~~0.0166% to 0.22%~~.

The product is not intended to be mixed in the tank together with other products.

Cymoxanil 45 WG was tested with various potential tank mix partners and all tested combinations are considered compatible. Thus, the formulation has good miscibility with water and other products.

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

The product is not classified for any endpoint.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

Not necessary.

Compliance with FAO specifications:

The product IN002B1760 complies with FAO specifications.

Formulation used for tests

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

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

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	OPPTS 830.6302; OPPTS 830.6303; OPPTS 830.6304	IN 002B1760 Batch N. IND_F040_0421_1	Appearance: uniform columnar granules Colour: Light brown Odour: characteristic	Y	Rigamonti, E. 2021a	Accepted.
Explosive properties (KCP 2.2.1)	UN RTDG Manual of Tests and Criteria ST/SG/AC.10/11/Rev. 5 – Part III, Annex 6, Section 3	IN 002B1760 Batch N. IND_F040_0421_1	Total heat of decomposition is < 500 J/g . IN 002B1760 does not show explosive properties.	Y	Rigamonti, E. 2021a	Accepted. IN002B1760 is not explosive. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.
Oxidizing properties (KCP 2.2.2)	UN RTDG Manual of Tests and Criteria ST/SG/AC.10/11/Rev. 5 – Part III, section 34.4.1, Test O.1	IN 002B1760 Batch N. IND_F040_0421_1	IN 002B1760 does not have oxidising properties.	Y	Rigamonti, E. 2021a	Accepted. IN002B1760 has no oxidizing properties. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.
Flash point (KCP 2.3.1)	-	-	Not required, the formulation is not a liquid.	-	-	-
Flammability (KCP 2.3.2)	EC method. A.10 and UN RTDG Manual of Tests and Criteria, Test N.1	IN 002B1760 Batch N. IND_F040_0421_1	Not flammable	Y	Rigamonti, E. 2021a	Accepted. The formulation is not flammable. The formulation does

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.
Self-heating (KCP 2.3.3)	UN RTDG Manual of Tests and Criteria, Part III, section 33.3.1, Test N.4	IN 002B1760 Batch N. IND_F040_0421_1	The autoignition temperature is higher than 140°C. The formulation is not classified in division 4.2.	Y	Rigamonti, E. 2021a	Accepted. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.
Acidity or alkalinity and pH (KCP 2.4.1)	-	-	Not required, pH of the formulation is >4 and <10	-	-	-
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	IN 002B1760 Batch N. IND_F040_0421_1	Diluted 1%w/v (sol. in HPLC grade water): 5.2 at 20°C	Y	Rigamonti, E. 2021a	Accepted.
Viscosity (KCP 2.5.1)	-	-	Not required since not a liquid	-	-	-
Surface tension (KCP 2.5.2)	-	-	Not required since not a liquid	-	-	-
Relative density (KCP 2.6.1)	-	-	Not required since not a liquid	-	-	-
Bulk density (KCP 2.6.2)	CIPAC MT 186	IN 002B1760 Batch N. IND_F040_0421_1	Pour density: 0.64 g/mL Bulk density: 0.72 g/mL	Y	Rigamonti, E. 2021a	Accepted.
Storage Stability after	CIPAC MT 46.4	IN 002B1760	Stable, physical-chemical properties comparable with those of fresh sample.	Y	Rigamonti, E.	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
14 days at 54° C (KCP 2.7.1)	<p>CIPAC MT 75.3 CIPAC MT 53.3 CIPAC MT 47.3 CIPAC MT 187 (OECD 110) CIPAC MT 171.1 CIPAC MT 178.2 CIPAC MT 185 CIPAC MT 184.1 CIPAC MT 174</p> <p>Cymoxanil 45 WG (IN 002B1760) packaged in the original commercial packaging (PE bag)</p> <p>The content of Cymoxanil in the formulated is analysed by HPLC-UV/DAD analytical method val- idated according to SANCO 3030/99 rev. 5 guidance documents. Please refer part B5.</p>	Batch N. IND_F040_0421_1	<p>a.i. content: 45.0 ± 0.1 % w/w pH: 5.3 Wettability: Static: 206sec; dynamic: 2 sec</p> <p>Persisting foaming: 0.0166 % w/v = 20 mL 0.22 % w/v = 22 mL</p> <p><u>Particle size distribution:</u> Dv 10 (µm): 785 µm Dv 50 (µm): 1140 µm Dv 90 (µm): 1770 µm % < 45 µm: 0.00 % % > 75 µm: 100.00 % Dustiness: 1.0 mg (nearly dust-free) Attrition resistance of dispersible granules: 100% Wet sieve test: No residue onto 75 µm sieve</p> <p><u>Suspensibility:</u> Susp. 0.0166 % w/v: 99.4 % Susp. 0.22 % w/v: 92.5 % Dispersibility: 1.00 % w/v: 95.4 %</p> <p>Full results of the study, before and after storage are presented in the table below:</p>		2021b	<p>The product showed no significant physical changes after accelerated storage.</p> <p>No significant changes were observed in the packaging and therefore it can be concluded that the test item was not corrosive to the container material.</p> <p>No toxicologically, ecotoxicologically or environmentally relevant impurities are formed upon storage.</p> <p>The accelerated stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging (PE bag).</p>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																																												
			<table><tr><th>Test</th><th>Method</th><th>Initial characterisation</th><th>After 14 days at 54°C</th></tr><tr><td>Cymoxanil a.i. content</td><td>No. 0526/2021</td><td>45.8 ± 0.2 % w/w</td><td>45.0 ± 0.1 % w/w (ΔT0= - 1.84 %)</td></tr><tr><td>Weight variation (%)</td><td>-</td><td>-</td><td>B: - 0.30%; C: - 0.25%</td></tr><tr><td>Appearance (Colour, odour and physical state)</td><td>OPPTS 830.6302; 830.6303; 830.6304</td><td>Light Brown (shortcode BR 8) uniform columnar granules with characteristic odour</td><td>Light Brown (shortcode BR 8) uniform columnar granules with characteristic odour</td></tr><tr><td>Compatibility (resistance) of the packaging material (Visual examination of packaging both externally and internally)</td><td>-</td><td>-</td><td>The container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena</td></tr><tr><td>pH value (1% aqueous dilution) (*)</td><td>CIPAC MT 75.3</td><td>5.2</td><td>5.3</td></tr><tr><td>Wettability</td><td>CIPAC MT 53.3; CIPAC MT 18 (using Standard Water D)</td><td>Without swirling: 208sec With swirling: 3 sec</td><td>Without swirling: 206sec With swirling: 2 sec</td></tr><tr><td>Persistent foam</td><td>CIPAC MT 47.3 and MT 18 (using Standard Water D)</td><td>Foam after 1 minute: 0.0166 % w/v = 21 mL 0.22 % w/v = 24 mL</td><td>Foam after 1 minute: 0.0166 % w/v = 20 mL 0.22 % w/v = 22 mL</td></tr><tr><td>Particle size distribution</td><td>CIPAC MT 187; OECD No. 110</td><td>Dv 10 (µm): 758 µm Dv 50 (µm): 1210 µm Dv 90 (µm): 2070 µm % < 45 µm: 0.00 % % > 75 µm: 100.00 %</td><td>Dv 10 (µm): 785 µm Dv 50 (µm): 1140 µm Dv 90 (µm): 1770 µm % < 45 µm: 0.00 % % > 75 µm: 100.00 %</td></tr><tr><td>Dustiness</td><td>CIPAC MT 171.1</td><td>1.2 mg (nearly dust-free)</td><td>1.0 mg (nearly dust-free)</td></tr></table> <table><tr><th>Test</th><th>Method</th><th>Initial characterisation</th><th>After 14 days at 54°C</th></tr><tr><td>Attrition resistance of dispersible granules</td><td>CIPAC MT 178.2</td><td>99.4 %</td><td>100.0 %</td></tr><tr><td>Wet sieve test</td><td>CIPAC MT 185</td><td>No residue onto 75 µm sieve</td><td>No residue onto 75 µm sieve</td></tr><tr><td>Suspensibility</td><td>CIPAC MT 184.1; CIPAC MT 18 (using Standard Water D)</td><td>Susp. 0.0166 % w/v: 103.2 % Susp. 0.22 % w/v: 99.0 %</td><td>Susp. 0.0166 % w/v: 99.4 % Susp. 0.22 % w/v: 92.5 %</td></tr><tr><td>Dispersibility</td><td>CIPAC MT 174; CIPAC MT 18 (using Standard Water D)</td><td>Disp. 1.00 % w/v: 99.7 %</td><td>Disp. 1.00 % w/v: 95.4 %</td></tr></table>	Test	Method	Initial characterisation	After 14 days at 54°C	Cymoxanil a.i. content	No. 0526/2021	45.8 ± 0.2 % w/w	45.0 ± 0.1 % w/w (ΔT0= - 1.84 %)	Weight variation (%)	-	-	B: - 0.30%; C: - 0.25%	Appearance (Colour, odour and physical state)	OPPTS 830.6302; 830.6303; 830.6304	Light Brown (shortcode BR 8) uniform columnar granules with characteristic odour	Light Brown (shortcode BR 8) uniform columnar granules with characteristic odour	Compatibility (resistance) of the packaging material (Visual examination of packaging both externally and internally)	-	-	The container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena	pH value (1% aqueous dilution) (*)	CIPAC MT 75.3	5.2	5.3	Wettability	CIPAC MT 53.3; CIPAC MT 18 (using Standard Water D)	Without swirling: 208sec With swirling: 3 sec	Without swirling: 206sec With swirling: 2 sec	Persistent foam	CIPAC MT 47.3 and MT 18 (using Standard Water D)	Foam after 1 minute: 0.0166 % w/v = 21 mL 0.22 % w/v = 24 mL	Foam after 1 minute: 0.0166 % w/v = 20 mL 0.22 % w/v = 22 mL	Particle size distribution	CIPAC MT 187; OECD No. 110	Dv 10 (µm): 758 µm Dv 50 (µm): 1210 µm Dv 90 (µm): 2070 µm % < 45 µm: 0.00 % % > 75 µm: 100.00 %	Dv 10 (µm): 785 µm Dv 50 (µm): 1140 µm Dv 90 (µm): 1770 µm % < 45 µm: 0.00 % % > 75 µm: 100.00 %	Dustiness	CIPAC MT 171.1	1.2 mg (nearly dust-free)	1.0 mg (nearly dust-free)	Test	Method	Initial characterisation	After 14 days at 54°C	Attrition resistance of dispersible granules	CIPAC MT 178.2	99.4 %	100.0 %	Wet sieve test	CIPAC MT 185	No residue onto 75 µm sieve	No residue onto 75 µm sieve	Suspensibility	CIPAC MT 184.1; CIPAC MT 18 (using Standard Water D)	Susp. 0.0166 % w/v: 103.2 % Susp. 0.22 % w/v: 99.0 %	Susp. 0.0166 % w/v: 99.4 % Susp. 0.22 % w/v: 92.5 %	Dispersibility	CIPAC MT 174; CIPAC MT 18 (using Standard Water D)	Disp. 1.00 % w/v: 99.7 %	Disp. 1.00 % w/v: 95.4 %			
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Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not required; the formulation is not heat sensitive.	-	-	-																																																												
Minimum content after heat stability	Analytical method validated according to	IN 002B1760 Batch N.	a.i. content: Cymoxanil: Fresh 45.8%; Aged 45.0% [-1.84%]	Y	Rigamonti, E. 2021b	Accepted.																																																												

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testing (KCP 2.7.3)	SANCO/3030/99 rev.5	IND_F040_0421_1				
Effect of low temperatures on stability (KCP 2.7.4)	-	-	Not required, since not a liquid	-	-	-
Ambient temperature shelf life (KCP 2.7.5)	<p>GIFAP Monograph No. 17, 2nd edition, June 2009: Guidelines for Specifying the Shelf Life of Plant Protection Products</p> <p>The content of Cymoxanil in the formulated is analysed by HPLC-UV/DAD analytical method validated according to SANCO 3030/99 rev. 5 guidance documents. Please refer part B5.</p>	<p>IN 002B1760 Batch N. IND_F040_0421_1</p>	<p>The study is on going</p> <p>The Test Facility conducted this study to determine the stability of the test item in its commercial packaging during and after two years storage period at ambient warehouse temperature.</p>	Y	Rigamonti, E. 2023	<p>Ambient temperature study is currently ongoing, and should be provided upon completion.</p> <p>Accepted. The product showed no significant physical changes after storage.</p> <p>No significant changes were observed in the packaging and therefore it can be concluded that the test item was not corrosive to the container material.</p> <p>No toxicologically, ecotoxicologically or environmentally relevant impurities are formed upon storage.</p> <p>The stability data indicate a shelf life of 2 years at ambient temperature when stored in commercial</p>

Annex point	Method used / deviations	Test material	Findings						GLP Y/N	Reference	Acceptability / comments																																																			
			<table><tr><th>Test</th><th>Method</th><th>Initial characterisation</th><th>After 6 months</th><th>After 12 months</th><th>After 24 months</th></tr><tr><td>Cymoxanil a.i. content</td><td>No. 0526/2021</td><td>45.8 ± 0.2 % w/w</td><td>45.7 ± 0.1 % w/w (ΔT0= - 0.12 %)</td><td>45.2 ± 0.0 % w/w (ΔT0= - 1.27 %)</td><td>45.1 ± 0.1 % w/w (ΔT0= - 1.45 %)</td></tr><tr><td>Weight variation (%)</td><td>-</td><td>-</td><td>D: - 0.02%</td><td>E: - 0.06%</td><td>F: - 0.13%; G: - 0.34%</td></tr><tr><td>Appearance (Colour, odour and physical state)</td><td>OPPTS 830.6302; 830.6303; 830.6304</td><td>Light Brown (shortcode BR 8) uniform columnar granules with characteristic odour</td><td>Light Brown (shortcode BR 8) uniform columnar granules with characteristic odour</td><td>Light Brown (shortcode BR 8) uniform columnar granules with characteristic odour</td><td>Light Brown (shortcode BR 8) uniform columnar granules with characteristic odour</td></tr><tr><td>Compatibility (resistance) of the packaging material (Visual examination of packaging both externally and internally)</td><td>-</td><td>-</td><td>The container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena</td><td>The container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena</td><td>The container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena</td></tr><tr><td>pH value (1% aqueous dilution) (*)</td><td>CIPAC MT 75.3</td><td>5.2</td><td>5.3</td><td>5.3</td><td>5.2</td></tr><tr><td>Wettability</td><td>CIPAC MT 53.3; CIPAC MT 18 (using Standard Water D)</td><td>Without swirling: 208sec With swirling: 3sec</td><td>Without swirling: 203 sec With swirling: 3sec</td><td>Without swirling: 203sec With swirling: 3sec</td><td>Without swirling: 134sec With swirling: 3sec</td></tr><tr><td>Persistent foam</td><td>CIPAC MT 47.3 and MT 18 (using Standard Water D)</td><td>Foam after 1 minute: 0.0166 % w/v = 21 mL 0.22 % w/v = 24 mL</td><td>Foam after 1 minute: 0.0166 % w/v = 20 mL 0.22 % w/v = 24 mL</td><td>Foam after 1 minute: 0.0166 % w/v = 21 mL 0.22 % w/v = 24 mL</td><td>Foam after 1 minute: 0.0166 % w/v = 29 mL 0.22 % w/v = 27 mL</td></tr><tr><td>Particle size distribution</td><td>CIPAC MT 187; OECD No. 110</td><td>Dv 10 (µm): 758 µm Dv 50 (µm): 1210 µm Dv 90 (µm): 2070 µm % < 45 µm: 0.00 % % > 75 µm: 100.00 %</td><td>Dv 10 (µm): 803 µm Dv 50 (µm): 1140 µm Dv 90 (µm): 1700 µm % < 45 µm: 0.00 % % > 75 µm: 100.00 %</td><td>Dv 10 (µm): 726 µm Dv 50 (µm): 1290 µm Dv 90 (µm): 2350 µm % < 45 µm: 0.00 % % > 75 µm: 100.00 %</td><td>Dv 10 (µm): 785 µm Dv 50 (µm): 1370 µm Dv 90 (µm): 2430 µm % < 45 µm: 0.00 % % > 75 µm: 100.00 %</td></tr></table>	Test	Method	Initial characterisation	After 6 months	After 12 months	After 24 months	Cymoxanil a.i. content	No. 0526/2021	45.8 ± 0.2 % w/w	45.7 ± 0.1 % w/w (ΔT0= - 0.12 %)	45.2 ± 0.0 % w/w (ΔT0= - 1.27 %)	45.1 ± 0.1 % w/w (ΔT0= - 1.45 %)	Weight variation (%)	-	-	D: - 0.02%	E: - 0.06%	F: - 0.13%; G: - 0.34%	Appearance (Colour, odour and physical state)	OPPTS 830.6302; 830.6303; 830.6304	Light Brown (shortcode BR 8) uniform columnar granules with characteristic odour	Light Brown (shortcode BR 8) uniform columnar granules with characteristic odour	Light Brown (shortcode BR 8) uniform columnar granules with characteristic odour	Light Brown (shortcode BR 8) uniform columnar granules with characteristic odour	Compatibility (resistance) of the packaging material (Visual examination of packaging both externally and internally)	-	-	The container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena	The container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena	The container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena	pH value (1% aqueous dilution) (*)	CIPAC MT 75.3	5.2	5.3	5.3	5.2	Wettability	CIPAC MT 53.3; CIPAC MT 18 (using Standard Water D)	Without swirling: 208sec With swirling: 3sec	Without swirling: 203 sec With swirling: 3sec	Without swirling: 203sec With swirling: 3sec	Without swirling: 134sec With swirling: 3sec	Persistent foam	CIPAC MT 47.3 and MT 18 (using Standard Water D)	Foam after 1 minute: 0.0166 % w/v = 21 mL 0.22 % w/v = 24 mL	Foam after 1 minute: 0.0166 % w/v = 20 mL 0.22 % w/v = 24 mL	Foam after 1 minute: 0.0166 % w/v = 21 mL 0.22 % w/v = 24 mL	Foam after 1 minute: 0.0166 % w/v = 29 mL 0.22 % w/v = 27 mL	Particle size distribution	CIPAC MT 187; OECD No. 110	Dv 10 (µm): 758 µm Dv 50 (µm): 1210 µm Dv 90 (µm): 2070 µm % < 45 µm: 0.00 % % > 75 µm: 100.00 %	Dv 10 (µm): 803 µm Dv 50 (µm): 1140 µm Dv 90 (µm): 1700 µm % < 45 µm: 0.00 % % > 75 µm: 100.00 %	Dv 10 (µm): 726 µm Dv 50 (µm): 1290 µm Dv 90 (µm): 2350 µm % < 45 µm: 0.00 % % > 75 µm: 100.00 %	Dv 10 (µm): 785 µm Dv 50 (µm): 1370 µm Dv 90 (µm): 2430 µm % < 45 µm: 0.00 % % > 75 µm: 100.00 %					packaging (PE bag).
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			<table><tr><th>Test</th><th>Method</th><th>Initial characterisation</th><th>After 6 months</th><th>After 12 months</th><th>After 24 months</th></tr><tr><td>Dry sieve analysis of water dispersible granules</td><td>CIPAC MT 170</td><td>-</td><td>-</td><td>-</td><td>more than 96.47 % of the test item presents a particle size higher than 0.710 mm and more than 100.0 % is higher than 0.045 mm</td></tr><tr><td>Dustiness</td><td>CIPAC MT 171.1</td><td>1.2 mg (nearly dust-free)</td><td>1.2 mg (nearly dust-free)</td><td>1.1 mg (nearly dust-free)</td><td>1.2 mg (nearly dust-free)</td></tr><tr><td>Attrition resistance of dispersible granules</td><td>CIPAC MT 178.2</td><td>99.4 %</td><td>100.0 %</td><td>100.0 %</td><td>99.8 %</td></tr><tr><td>Wet sieve test</td><td>CIPAC MT 185</td><td>No residue onto 75 µm sieve</td><td>No residue onto 75 µm sieve</td><td>No residue onto 75 µm sieve</td><td>No residue onto 75 µm sieve</td></tr><tr><td>Suspensibility</td><td>CIPAC MT 184.1; CIPAC MT 18 (using Standard Water D)</td><td>Susp. 0.0166 % w/v: 103.2 % Susp. 0.22 % w/v: 99.0 %</td><td>Susp. 0.0166 % w/v: 100.8 % Susp. 0.22 % w/v: 99.7 %</td><td>Susp. 0.0166 % w/v: 101.0 % Susp. 0.22 % w/v: 98.8 %</td><td>Susp. 0.0166 % w/v: 100.4 % Susp. 0.22 % w/v: 100.1 %</td></tr><tr><td>Dispersibility</td><td>CIPAC MT 174; CIPAC MT 18 (using Standard Water D)</td><td>Disp. 1.00 % w/v: 99.7 %</td><td>Disp. 1.00 % w/v: 100.5 %</td><td>Disp. 1.00 % w/v: 99.8 %</td><td>Disp. 1.00 % w/v: 98.0 %</td></tr></table> <p>The Manual on development and use of FAO and WHO specifications for pesticides, November 2016 - third revision of the First Edition, give the following requirements.</p> <table><tr><th colspan="4">Cymoxanil nominal content: 45.0 w/w</th></tr><tr><th>Point</th><th colspan="2">Requirement for a.i. tolerance</th><th>Compliance</th></tr><tr><td>Point 3.5.3</td><td>± 5%</td><td>Above 10 % w/w up to 50 % w/w</td><td>Yes</td></tr><tr><td>Point 3.6.4.2</td><td colspan="2">Maximum 5% decrease from T0</td><td>Yes</td></tr></table> <p>From the obtained results, it can be concluded that no significant change was found in the Cymoxanil active ingredient content for the sample stored in the PE bag for 24 months at warehouse temperature, comparing the obtained results</p>	Test	Method	Initial characterisation	After 6 months	After 12 months	After 24 months	Dry sieve analysis of water dispersible granules	CIPAC MT 170	-	-	-	more than 96.47 % of the test item presents a particle size higher than 0.710 mm and more than 100.0 % is higher than 0.045 mm	Dustiness	CIPAC MT 171.1	1.2 mg (nearly dust-free)	1.2 mg (nearly dust-free)	1.1 mg (nearly dust-free)	1.2 mg (nearly dust-free)	Attrition resistance of dispersible granules	CIPAC MT 178.2	99.4 %	100.0 %	100.0 %	99.8 %	Wet sieve test	CIPAC MT 185	No residue onto 75 µm sieve	No residue onto 75 µm sieve	No residue onto 75 µm sieve	No residue onto 75 µm sieve	Suspensibility	CIPAC MT 184.1; CIPAC MT 18 (using Standard Water D)	Susp. 0.0166 % w/v: 103.2 % Susp. 0.22 % w/v: 99.0 %	Susp. 0.0166 % w/v: 100.8 % Susp. 0.22 % w/v: 99.7 %	Susp. 0.0166 % w/v: 101.0 % Susp. 0.22 % w/v: 98.8 %	Susp. 0.0166 % w/v: 100.4 % Susp. 0.22 % w/v: 100.1 %	Dispersibility	CIPAC MT 174; CIPAC MT 18 (using Standard Water D)	Disp. 1.00 % w/v: 99.7 %	Disp. 1.00 % w/v: 100.5 %	Disp. 1.00 % w/v: 99.8 %	Disp. 1.00 % w/v: 98.0 %	Cymoxanil nominal content: 45.0 w/w				Point	Requirement for a.i. tolerance		Compliance	Point 3.5.3	± 5%	Above 10 % w/w up to 50 % w/w	Yes	Point 3.6.4.2	Maximum 5% decrease from T0		Yes			
Test	Method	Initial characterisation	After 6 months	After 12 months	After 24 months																																																											
Dry sieve analysis of water dispersible granules	CIPAC MT 170	-	-	-	more than 96.47 % of the test item presents a particle size higher than 0.710 mm and more than 100.0 % is higher than 0.045 mm																																																											
Dustiness	CIPAC MT 171.1	1.2 mg (nearly dust-free)	1.2 mg (nearly dust-free)	1.1 mg (nearly dust-free)	1.2 mg (nearly dust-free)																																																											
Attrition resistance of dispersible granules	CIPAC MT 178.2	99.4 %	100.0 %	100.0 %	99.8 %																																																											
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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments						
			at the beginning of the storage stability, that it complies with the tolerance and it is in accordance with the declared value. No change in the sample appearance, colour or odour, was found in the Cymoxanil 45 WG (IN 002B1760) formulation stored in PE bag for 24 months at warehouse temperature and no variation was found in colour or in either the internal or external configuration, or loss of sample or evident corrosion phenomena. Moreover, no significant changes in physical properties (pH value, persistent foam, wet sieve, wettability, dustiness, attrition characteristics, particle size distribution, suspensibility and dispersibility) were found for the test item stored in the PE bag for 24 months at warehouse temperature, comparing the initial characterization. From the above reported data, it can be concluded that the sample of Cymoxanil 45 WG (IN 002B1760) formulation sample is stable in its commercial packaging under the two years storage conditions at ambient warehouse temperature.									
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	-	-	-	-						
Wettability (KCP 2.8.1)	CIPAC MT 53.3 and MT 18	IN 002B1760 Batch N. IND_F040_0421_1	Static: 208 sec Dynamic: 3 sec	Y	Rigamonti, E. 2021a	Accepted. Based on the results of the wettability (with and without swirling) the following application condition should be included on the label “continuous agitation during application”.						
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3 (Standard Water D)	IN 002B1760 Batch N. IND_F040_0421_1	<table><tr><td>Time</td><td>Foam</td></tr><tr><td>1 minute</td><td>0.0166 % w/v = 21 mL</td></tr><tr><td>1 minute</td><td>0.22 % w/v = 24 mL</td></tr></table>	Time	Foam	1 minute	0.0166 % w/v = 21 mL	1 minute	0.22 % w/v = 24 mL	Y	Rigamonti, E. 2021a	Accepted.
Time	Foam											
1 minute	0.0166 % w/v = 21 mL											
1 minute	0.22 % w/v = 24 mL											
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184.1	IN 002B1760 Batch N. IND_F040_0421_1	Suspensibility 103.2% at 0.0166 % w/v Suspensibility 99.0% at 0.22 % w/v	Y	Rigamonti, E. 2021a	Accepted.						
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 174	IN 002B1760 Batch N. IND_F040_0421_1	Suspension at 1 % w/v Dispersibility: 99.7 %	Y	Rigamonti, E. 2021a	Accepted.						

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Dispersion stability (KCP 2.8.3.3)	-	-	Not required for this kind of formulation.	-	-	-
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not required for this kind of formulation.	-	-	-
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187 OECD No. 110	IN 002B1760 Batch N. IND_F040_0421_1	Dv 10 (µm): 758 µm Dv 50 (µm): 1210 µm Dv 90 (µm): 2070 µm % < 45 µm: 0.00 % % > 75 µm: 100.00 % The particle size distribution of the test item is higher than 0.075 mm.	Y	Rigamonti, E. 2021a	Accepted.
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	IN 002B1760 Batch N. IND_F040_0421_1	No residue was found on the 0.075 mm (75 µm) sieve.	Y	Rigamonti, E. 2021a	Accepted.
Dust content (KCP 2.8.5.2.1)	CIPAC MT 171.1	IN 002B1760 Batch N. IND_F040_0421_1	1.1 mg (nearly dust free)	Y	Rigamonti, E. 2021a	Accepted.
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not required for WG.	-	-	-
Attrition (KCP 2.8.5.3)	CIPAC MT 178.2	IN 002B1760 Batch N. IND_F040_0421_1	Number of particles retained on the 125 µm sieve expressed as percentage of the formulation 99.4%	Y	Rigamonti, E. 2021a	Accepted.
Hardness and integrity (KCP 2.8.5.4)	-	-	Not required for WG.	-	-	-
Emulsifiability (KCP 2.8.6.1)	-	-	Not required since the formulation is not an emulsion.	-	-	-
Emulsion stability (KCP 2.8.6.2)	-	-	Not required since the formulation is not an emulsion.	-	-	-
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not required since the formulation is not an emulsion.	-	-	-
Flowability (KCP 2.8.7.1)	CIPAC MT 171.2	IN 002B1760 Batch N.	The sample flows naturally through the sieve.	Y	Rigamonti, E. 2021a	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																
		IND_F040_0421_1																																				
Pourability (KCP 2.8.7.2)	-	-	Not required, since the formulation is a granular preparation	-	-	-																																
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not required, since the formulation is a granular preparation	-	-	-																																
Physical compatibility of tank mixes (KCP 2.9.1)	ASTM E1518 – 05 (Reapproved 2019)	IN002B1760	<p>Cymoxanil 45 WG was tested with various potential tank mix partners (Enervin® SC, Pergado SC®, Ranman Top, Nando® Maxi, Folpan 80 WDG, R6 Erresei Bordeaux WG, Orondis®, Aliette®, Copperfield 17 WG, Zoxium® 240 SC, Ossiclor 50 PB Manica®, Polyram® DF, Century SL, R6 Erresei Albis®, Previter). The mixture and the residues on the sieve and in the bottle were observed. According to the guideline ASTM E-1518-5 all tested combinations are considered compatible, since the formulation is a well-dispersed mixture of the pesticides in water and no non-rinsible residue was found on the 50-mesh sieve or remaining on bottle walls.</p> <p>The formulation is not intended to be used in tank mix.</p> <p>Tested plant protection products:</p> <table><tr><th>Active Ingredient</th><th>Commercial name</th></tr><tr><td>Amectotradin</td><td>ENERVIN® SC</td></tr><tr><td>Mandipropamid</td><td>PERGADO SC®</td></tr><tr><td>Cyazofamid</td><td>RANMAN TOP</td></tr><tr><td>Fluazinam</td><td>NANDO® MAXI</td></tr><tr><td>Folpet</td><td>FOLPAN 80 WDG</td></tr><tr><td>Copper Bourdeaux mix</td><td>R6 ERRESEI BORDEAUX WG</td></tr><tr><td>Oxathiapiprolin</td><td>ORONDIS®</td></tr><tr><td>Fosetyl-Al</td><td>ALIETTE®</td></tr><tr><td>Copper hydroxide</td><td>COPPERFIELD 17 WG</td></tr><tr><td>Zoxamide</td><td>ZOXIUM® 240 SC</td></tr><tr><td>Copper oxychloride</td><td>OSSICLOR 50 PB MANICA®</td></tr><tr><td>Metiram</td><td>POLYRAM® DF</td></tr><tr><td>K-Phosphonate</td><td>CENTURY SL</td></tr><tr><td>Fluopicolide + Fosethyl Al</td><td>R6 ERRESEI ALBIS®</td></tr><tr><td>Propamocarb hydrochloride</td><td>PREVITER</td></tr></table> <p>Results - please refer Table 2-2 and Table 2-3.</p>	Active Ingredient	Commercial name	Amectotradin	ENERVIN® SC	Mandipropamid	PERGADO SC®	Cyazofamid	RANMAN TOP	Fluazinam	NANDO® MAXI	Folpet	FOLPAN 80 WDG	Copper Bourdeaux mix	R6 ERRESEI BORDEAUX WG	Oxathiapiprolin	ORONDIS®	Fosetyl-Al	ALIETTE®	Copper hydroxide	COPPERFIELD 17 WG	Zoxamide	ZOXIUM® 240 SC	Copper oxychloride	OSSICLOR 50 PB MANICA®	Metiram	POLYRAM® DF	K-Phosphonate	CENTURY SL	Fluopicolide + Fosethyl Al	R6 ERRESEI ALBIS®	Propamocarb hydrochloride	PREVITER	Y	Longhi, D. 2023	Accepted. Compatibility has been confirmed.
Active Ingredient	Commercial name																																					
Amectotradin	ENERVIN® SC																																					
Mandipropamid	PERGADO SC®																																					
Cyazofamid	RANMAN TOP																																					
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Oxathiapiprolin	ORONDIS®																																					
Fosetyl-Al	ALIETTE®																																					
Copper hydroxide	COPPERFIELD 17 WG																																					
Zoxamide	ZOXIUM® 240 SC																																					
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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Chemical compatibility of tank mixes (KCP 2.9.2)	ASTM E1518 – 05 (Reapproved 2019)	IN002B1760	Please see KCP 2.9.1 The formulation is not intended to be used in tank mix.	Y	Longhi, D. 2023	Please see KCP 2.9.1
Adhesion to seeds (KCP 2.10.1)	-	-	Not used for seed treatment.	-	-	-
Distribution to seed (KCP 2.10.2)	-	-	Not used for seed treatment.	-	-	-
Other/special studies (KCP 2.11)	-	-	Not applicable. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual and Annex points under KCP 2.2.1; 2.2.2; 2.3.1 and 2.3.3.	-	-	-
Other/special studies (KCP 2.11) IN002B1760 (Cymoxanil 45 WG): equipment cleaning procedure	SANTE/2020/12830, Rev.1 (24/02/2021)	IN002B1760 Batch N. IND_P040_0421-1	The objective of this study was the execution of an equipment cleaning procedure test of the product IN002B1760 (Cymoxanil 45 WG). The test was carried out as small case test, according to the guidelines: —PSD Efficacy Guideline 305 “Cleaning Application Equipment—Small scale jar test protocol” (December 2004) —European and Mediterranean Plant Protection Organization (2016 OEPP/EPPO, Bulletin OEPP/EPPO, Bulletin 46, 371–378), PP_1/292 (1) “Cleaning pesticide application equipment (PAE)—efficacy aspects” The test item was used to prepare a solution at a concentration equal to the maximum one reported in its GAP table, that is when 0.33 kg/ha are dissolved into 150 L/ha of water: this means a nominal concentration of the a.s. (active substance) Cymoxanil of 0.90 g/L. The determination of residues of Cymoxanil after a single, double and triple rinsing of water was carried out washing the bottle with acetonitrile that was analysed using a high performance liquid chromatography with UV detector (HPLC-UV). The analytical method was validated according SANTE/2020/12830, Rev.1 (24/02/2021) guideline. Each rinsing condition was tested in triplicate and the obtained results were averaged. The percentage of active substance removed with the applied each rinsing procedure was:	Y	Longhi D., 2022	Accepted

Rinsing condition	% Cymoxanil removed
Single rinsing	99.95
Double rinsing	100.0
Triple rinsing	100.0

Table 2-2: Results summary – 10 ± 2°C, hard water (hardness of 35°F, 350 ppm as CaCO₃)

Test Item			Formulate product tested			Test result
Name	Highest dose	Tested Concentration*	Commercial name	Highest dose	Tested Concentration*	
IN002B1760	0.33 kg/ha	220 g/hL	ENERVIN® SC	1.5 L/ha	1000 mL/hL	Compatible
IN002B1760	0.33 kg/ha	220 g/hL	PERGADO SC®	0.6 L/ha	400 mL/hL	Compatible
IN002B1760	0.33 kg/ha	220 g/hL	RANMAN TOP	0.625 L/ha	417 mL/hL	Compatible
IN002B1760	0.33 kg/ha	220 g/hL	NANDO® MAXI	1.5 L/ha	1000 mL/hL	Compatible
IN002B1760	0.33 kg/ha	220 g/hL	FOLPAN 80 WDG	3 kg/ha	2000 g/hL	Compatible
IN002B1760	0.33 kg/ha	220 g/hL	R6 ERRESEI BORDEAUX WG	6 kg/ha	4000 g/hL	Compatible
IN002B1760	0.33 kg/ha	220 g/hL	ORONDIS®	0.6 L/ha	400 mL/hL	Compatible
IN002B1760	0.33 kg/ha	220 g/hL	ALIETTE®	6 kg/ha	4000 g/hL	Compatible
IN002B1760	0.33 kg/ha	220 g/hL	COPPERFIELD 17 WG	4.1 kg/ha	2733 g/hL	Compatible
IN002B1760	0.33 kg/ha	220 g/hL	ZOXIUM® 240 SC	0.75 L/ha	500 mL/hL	Compatible
IN002B1760	0.33 kg/ha	220 g/hL	OSSICLOR 50 PB MANICA®	4 Kg/ha	2667 g/hL	Compatible
IN002B1760	0.33 kg/ha	220 g/hL	POLYRAM® DF	2.6 kg/ha	1733 g/hL	Compatible
IN002B1760	0.33 kg/ha	220 g/hL	CENTURY SL	4 L/ha	2667 mL/hL	Compatible
IN002B1760	0.33 kg/ha	220 g/hL	R6 ERRESEI ALBIS®	3 kg/ha	2000 g/hL	Compatible
IN002B1760	0.33 kg/ha	220 g/hL	PREVITER	3 L/ha	2000 mL/hL	Compatible

* concentration calculated considering a spray volume of 150 L/ha, that is the lower volume reported on the GAP table of IN002B1760 (worst case)

Table 2-3: Results summary – 20 ± 2°C, soft water (hardness of 5°F, 50 ppm as CaCO₃)

Test Item			Formulate product tested			Test result
Name	Highest dose	Tested Concentration*	Commercial name	Highest dose	Tested Concentration*	
IN002B1760	0.33 kg/ha	220 g/hL	ENERVIN® SC	1.5 L/ha	1000 mL/hL	Compatible
IN002B1760	0.33 kg/ha	220 g/hL	PERGADO SC®	0.6 L/ha	400 mL/hL	Compatible
IN002B1760	0.33 kg/ha	220 g/hL	RANMAN TOP	0.625 L/ha	417 mL/hL	Compatible
IN002B1760	0.33 kg/ha	220 g/hL	NANDO® MAXI	1.5 L/ha	1000 mL/hL	Compatible
IN002B1760	0.33 kg/ha	220 g/hL	FOLPAN 80 WDG	3 kg/ha	2000 g/hL	Compatible
IN002B1760	0.33 kg/ha	220 g/hL	R6 ERRESEI BORDEAUX WG	6 kg/ha	4000 g/hL	Compatible
IN002B1760	0.33 kg/ha	220 g/hL	ORONDIS®	0.6 L/ha	400 mL/hL	Compatible
IN002B1760	0.33 kg/ha	220 g/hL	ALIETTE®	6 kg/ha	4000 g/hL	Compatible
IN002B1760	0.33 kg/ha	220 g/hL	COPPERFIELD 17 WG	4.1 kg/ha	2733 g/hL	Compatible
IN002B1760	0.33 kg/ha	220 g/hL	ZOXIUM® 240 SC	0.75 L/ha	500 mL/hL	Compatible
IN002B1760	0.33 kg/ha	220 g/hL	OSSICLOR 50 PB MANICA®	4 Kg/ha	2667 g/hL	Compatible
IN002B1760	0.33 kg/ha	220 g/hL	POLYRAM® DF	2.6 kg/ha	1733 g/hL	Compatible
IN002B1760	0.33 kg/ha	220 g/hL	CENTURY SL	4 L/ha	2667 mL/hL	Compatible
IN002B1760	0.33 kg/ha	220 g/hL	R6 ERRESEI ALBIS®	3 kg/ha	2000 g/hL	Compatible
IN002B1760	0.33 kg/ha	220 g/hL	PREVITER	3 L/ha	2000 mL/hL	Compatible

* concentration calculated considering a spray volume of 150 L/ha, that is the lower volume reported on the GAP table of IN002B1760 (worst case)

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)

Comments of zRMS:	<p>Ambient temperature study is currently ongoing, will be provided upon completion.</p> <p>The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging (PE bag).</p>
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The product IN002B1760 is intended to be commercialized in the following sizes: 0.1, 0.2, 0.5, 1.0, 5.0 kg. Detailed specifications are reported in the following tables.

Table 4.1-1: Packaging information for 0.1 kg pack (plastic bags)

Type	Description
Material:	Polyethylene lined laminate paper bag/pouch (packed in outer CFB) Polyethylene bag/pouch in inner duplex carton (packed in outer CFB)
Shape/size:	rectangular / 190 ±3 mm (L) x 150 ± 3 mm (W)
Opening:	N/A
Closure:	Top sealing
Seal:	3 side sealed pouch with top sealing
Manner of construction	combination
UN/ADR	compliant

Detailed specifications for the cited outer CFB are reported in the following table.

Type	Description
Material:	Outer corrugated fibreboard box (CFB) ; 5 ply box with inner partition
Shape/size:	rectangular /470 ±10 mm (L) x 290 ±5 mm (W) x 190 ±3 mm (H)
Packaging per box	100 x 0.1 kg
UN/ADR	compliant

Table 4.1-2: Packaging information for 0.2 kg pack (plastic bags)

Type	Description
Material:	Polyethylene lined laminate paper bag/pouch (packed in outer CFB) Polyethylene bag/pouch in inner duplex carton (packed in outer CFB)
Shape/size:	rectangular / 250 ±5 mm (L) x 180 ± 3 mm (W)
Opening:	N/A
Closure:	Top sealing
Seal:	3 side sealed pouch with top sealing
Manner of construction	combination
UN/ADR	compliant

Detailed specifications for the cited outer CFB are reported in the following table.

Type	Description
Material:	Outer corrugated fibreboard box (CFB) ; 5 ply box with inner partition
Shape/size:	rectangular /470 ±10 mm (L) x 290 ±5 mm (W) x 190 ±3 mm (H)
Packaging per box	50 x 0.2 kg

Type	Description
UN/ADR	compliant

Table 4.1-3: Packaging information for 0.5 kg pack (plastic bags)

Type	Description
Material:	Polyethylene lined laminate paper bag/pouch (packed in outer CFB) Polyethylene bag/pouch in inner duplex carton (packed in outer CFB)
Shape/size:	rectangular / 250 ±5 mm (L) x 245 ± 5 mm (W)
Opening:	N/A
Closure:	Top sealing
Seal:	3 side sealed pouch with top sealing
Manner of construction	-
UN/ADR	compliant

Detailed specifications for the cited outer CFB are reported in the following table.

Type	Description
Material:	Outer corrugated fibreboard box (CFB) ; 5 ply box with inner partition
Shape/size:	rectangular /470 ±10 mm (L) x 290 ±5 mm (W) x 190 ±3 mm (H)
Packaging per box	20 x 0.5 kg
UN/ADR	compliant

Table 4.1-4: Packaging information for 1.0 kg pack (plastic bags)

Type	Description
Material:	Polyethylene lined laminate bag/pouch (packed in outer CFB) Polyethylene bag/pouch in inner duplex carton (packed in outer CFB)
Shape/size:	rectangular / 285 ±5 mm (L) x 245 ± 5 mm (W)
Opening:	-
Closure:	Top sealing
Seal:	3 side sealed pouch with top sealing
Manner of construction	-
UN/ADR	compliant

Detailed specifications for the cited outer CFB are reported in the following table.

Type	Description
Material:	Outer corrugated fibreboard box (CFB) ; 5 ply box with inner partition
Shape/size:	rectangular /470 ±10 mm (L) x 290 ±5 mm (W) x 190 ±3 mm (H)
Packaging per box	10 x 1.0 kg
UN/ADR	compliant

Table 4.1-5: Packaging information for 5.0 kg pack (plastic bags)

Type	Description
Material:	Laminate bag with inner polyethylene bag (packed in outer CFB) Polyethylene bag/pouch in inner duplex carton (packed in outer CFB)
Shape/size:	rectangular / 560 ±10 mm (L) x 400 ± 10 mm (W)

Type	Description
Opening:	-
Closure:	Top sealing
Seal:	3 side sealed pouch with top sealing
Manner of construction	-
UN/ADR	compliant

Detailed specifications for the cited outer CFB are reported in the following table.

Type	Description
Material:	Outer corrugated fibreboard box (CFB); 5 ply box with inner partition
Shape/size:	rectangular /470 ±10 mm (L) x 290 ±5 mm (W) x 190 ±3 mm (H)
Packaging per box	2 x 5.0 kg
UN/ADR	compliant

The abovementioned packaging and closures are suitable for containing, handling and transport of the formulation IN002B1760. In the accelerated storage and ambient temperature shelf life studies (see Point IIIA 2.7.1, and IIIA 2.7.2), IN002B1760 was stable in its commercial package over the whole observation period. The polyethylene bag container showed no deformation, loss, or any corrosion phenomena.

4.2 Equipment cleaning procedure (Longhi D, 2022)

Comments of zRMS:	Accepted.
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The objective of this study was the execution of an equipment cleaning procedure test of the product IN002B1760 (Cymoxanil 45 WG). The test was carried out as small case test, according to the guidelines:

- PSD Efficacy Guideline 305 “Cleaning Application Equipment –Small scale jar test protocol” (December 2004)
- European and Mediterranean Plant Protection Organization (2016 OEPP/EPPO, Bulletin OEPP/EPPO Bulletin 46, 371–378), PP 1/292 (1) “Cleaning pesticide application equipment (PAE) – efficacy aspects”
- SANTE/2020/12830, Rev.1 (24/02/2021)

The test item (batch number IND_F040_0421_1) was used to prepare a solution at a concentration equal to the maximum one reported in its GAP table, that is when 0.33 kg/ha are dissolved into 150 L/ha of water: this means a nominal concentration of the a.s. (active substance) Cymoxanil of 0.99 g/L.

The determination of residues of Cymoxanil after a single, double and triple rinsing of water was carried out washing the bottle with acetonitrile that was analysed using a high-performance liquid chromatography with UV detector (HPLC-UV). The analytical method was validated according SAN-TE/2020/12830, Rev.1 (24/02/2021) guideline. Each rinsing condition was tested in triplicate and the obtained results were averaged.

The percentage of active substance removed with the applied each rinsing procedure was as reported in the following table:

Rinsing condition	% Cymoxanil removed
Single rinsing	99.95
Double rinsing	100.0
Triple rinsing	100.0

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	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Indofil Industries (Netherlands) B.V.
KCP 2.2.1-	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Indofil Industries (Netherlands) B.V.
KCP 2.2.2	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Indofil Industries (Netherlands) B.V.
KCP 2.3.2	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Indofil Industries (Netherlands) B.V.
KCP 2.3.3	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Indofil Industries (Netherlands) B.V.
KCP 2.4.2	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Indofil Industries (Netherlands) B.V.

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 2.6.2	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Indofil Industries (Netherlands) B.V.
KCP 2.7.1	Rigamonti, E	2021b	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Accelerated Storage Stability and Corrosion Characteristics Company Report No: CH-0527/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Indofil Industries (Netherlands) B.V.
KCP 2.7.3	Rigamonti, E	2021b	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Accelerated Storage Stability and Corrosion Characteristics Company Report No: CH-0527/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Indofil Industries (Netherlands) B.V.
KCP 2.7.5	Rigamonti, E	2023	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Two Years Storage Stability and Corrosion Characteristics Company Report CH – 0528/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Indofil Industries (Netherlands) B.V.
KCP 2.8.1	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Indofil Industries (Netherlands) B.V.
KCP 2.8.2	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Indofil Industries (Netherlands) B.V.
KCP 2.8.3.1	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties	N	Indofil

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
			Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished		Industries (Netherlands) B.V.
KCP 2.8.3.2	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Indofil Industries (Netherlands) B.V.
KCP 2.8.5.1.1	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Indofil Industries (Netherlands) B.V.
KCP 2.8.5.1.2	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Indofil Industries (Netherlands) B.V.
KCP 2.8.5.2.1	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Indofil Industries (Netherlands) B.V.
KCP 2.8.5.3	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Indofil Industries (Netherlands) B.V.
KCP 2.8.7.1	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Indofil Industries (Netherlands) B.V.

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 2.9.1	Longhi, D.	2023	Title: Compatibility test of IN002B1760 (Cymoxanil 45WG) Company Report No: LBN-0124-2023 Source: LabAnalysis s.r.l. GLP Unpublished	N	Indofil Industries (Netherlands) B.V.
KCP 2.9.2	Longhi, D.	2023	Title: Compatibility test of IN002B1760 (Cymoxanil 45WG) Company Report No: LBN-0124-2023 Source: LabAnalysis s.r.l. GLP Unpublished	N	Indofil Industries (Netherlands) B.V.
KCP 2.11 KCP 4.2	Longhi, D.	2022	Title: IN002B1760 (Cymoxanil 45 WG): equipment cleaning procedure Company Report No: LBN-0065-2022, 02/12/2022 GLP Unpublished	N	Indofil Industries (Netherlands) B.V.

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

No further studies proposed.