

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: IN005B1570

Product name: ~~INDOFIL~~ Difenoconazole 250 G/L EC greener

Chemical active substance:

Difenoconazole, 250 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Article 33: Application for authorisation)

Applicant: Indofil Industries (Netherlands) B.V.

Submission date: January 2022

Update: October 2023, February 2024

MS Finalisation date: 10.2022, 12.2023, 05.2024

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Version history

When	What
January 2022	V0 – 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
October 2022	zRMS first evaluation
October 2023	Applicant inclusion of final reports of studies underway at time of original submission
December 2023	zRMS evaluation after changes
February 2024	Applicant dRR update commenting period
May 2024	zRMS changes after commenting phase (fRR)

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zRMS summary:

Submitted data are sufficient for evaluation

~~Data gap: 2 years study is on going. Based on the composition of the formulation and results of the accelerated storage study, two years conditional registration of the product is proposed. Final registration will be possible after submission of the 2 year shelf life study (according to the Study Plan Urbani M. 2021e – June 2023)~~

Packaging: Based on the stability tests, proposed packaging type – PA/HDPE is acceptable

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Submitted by:

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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

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substance(s)

1.2.3.1 Difenoconazole

to Part C (confidential information).

Difenoconazole

min. 940 g/kg (Reg. No 1100/2011)

min. 970 g/kg (Indofil source B 1)

min. 965 g/kg (Indofil source A 2)

If relevant, provide information on impurities of toxicological/ ecotoxicological concern

Toluene

Max. 5 g/kg

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

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

Trade name: Difenoconazole 250 G/L EC greener

Company code number: IN005B1570 / INDOFIL Difenoconazole 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	Declared content of the pure active substance (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
Difenoconazole	250	235 - 265	257.73 (source 1) 259.07 (source 2)	22.6 (source 1) 22.7 (source 2)

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

** Based on the density of the formulation = 1.1401 (Note: only applies if a liquid formulation – delete this comment if not needed)

Table 1.4-2: Safener and synergists

Neither safener nor synergist were used for the formulation.

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Table 1.4-3: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg) in the formulation
Toluene	1.25 1.29

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

Table 1.4-4: Information on Difenoconazole

Type	Name/Code Number
ISO common name	Difenoconazole
CAS No.	119446-68-3
EC No.	601-613-1
CIPAC No.	687

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

No safener/synergist are present in the formulation.

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

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of dark yellow liquid, with an aromatic odour. It is not explosive, has no oxidising properties. The product is not flammable/has a flash point of 102 °C. It has a self ignition temperature of 336 °C. In aqueous solution, it has a pH value around 5.9 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 Accelerated storage and 2 year shelf life data indicate a shelf life of at least 2 years at ambient temperature when stored in PA/HDPE bottles (see KCP 2.7.5). Its technical characteristics are acceptable for an emulsifiable concentrate formulation.

The intended concentration of use is 0.04 g/L to 1.25 g/L, 0.02 to 0.25 %.

No tank mixtures are recommended.

Difenoconazole 250 G/L EC greener 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

No classification or labelling for physical chemical properties is proposed.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

No risk or safety phrases for physical chemical properties are proposed. P280

Compliance with FAO specifications:

The product IN005B1570 complies with FAO specifications.

At the time of evaluation there is no FAO specification for difenoconazole

Formulation used for tests

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

Formulation used for tests:

Batch No. IND_F021_0321_1; Difenoconazole content: 259 g/L

Batch No. IND_F021_0823_1

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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	Difenoconazole 250 EC – IN005B1570 Batch no. IND_F021_0321_1	Physical state (appearance): Liquid Colour: Dark Yellow Odour: Aromatic odour	Y	Urbani, M. 2021a 2021b	Accepted
Explosive properties (KCP 2.2.1)	ST/SG/AC.10/11/Rev. 5 (2009), Appendix 6, Section 3	Difenoconazole 250 EC – IN005B1570 Batch no. IND_F021_0321_1	Total heat of decomposition of the test item is lower than 500 J.g ⁻¹ and the test item is not a candidate for classification as a UN Class 1 explosive substance.	Y	Urbani, M. 2021b	Accepted Not explosive
Oxidizing properties (KCP 2.2.2)	ST/SG/AC.10/11/Rev.5 (2009): Part III, Section 34.4.2, Test O2	Difenoconazole 250 EC – IN005B1570 Batch no. IND_F021_0321_1	It can be concluded that the sampe is classified as “Not Division 5.1”.	Y	Urbani, M. 2021b	Accepted No oxidizing properties
Flash point (KCP 2.3.1)	EC Regulation No. 440/2008 A.9	Difenoconazole 250 EC – IN005B1570 Batch no. IND_F021_0321_1	It can be concluded that the flash point of the test item sample was 102 °C (as mean of three measurements); it can be concluded that the sample is classified as “not Flammable liquid”.	Y	Urbani, M. 2021b	Accepted
Flammability (KCP 2.3.2)	-	-	Please see KCP 2.8.6.1.	-	-	Not required
Self-heating (KCP 2.3.3)	EC 440/2008 No. A.15	Difenoconazole 250 EC – IN005B1570 Batch no.	It can be concluded that the auto-ignition temperature of the test item sample was 336°C (ignition delay time: 8.47 s; quantity of test item: 100 µL)”. IND_F021_0321_1	Y	Urbani, M. 2021b	Accepted

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		IND_F021_0321_1				
Acidity or alkalinity and pH (KCP 2.4.1)	-	-	Acidity or alkalinity is not required, because the pH of SAP250F IN005B1570 preparation is higher than 4 and lower than 10.	-	-	Not required
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Difenconazole 250 EC – IN005B1570 Batch no. IND_F021_0321_1	pH value of a 1 % w/v aqueous dispersion dilution of the test item sample was 5.9 (rounded mean value of two measurements) at 20 °C. pH value of the neat test item without dilution was 10.2 (rounded mean value of two measurements) at 20 °C.	Y	Urbani, M. 2021a, 2021b	Accepted pH of the neat product is an additional study, it is required for aqueous formulations only
Viscosity (KCP 2.5.1)	CIPAC MT 192, OECD No. 114 (2012)	Difenconazole 250 EC – IN005B1570 Batch no. IND_F021_0321_1	T (°C)	Y	Urbani, M. 2021b	Accepted PPP does not contain co-formulants classified as an aspiration hazard
			Dynamic/Kinematic Viscosity			
			Shear-rate range			
			20			
			40			
Surface tension (KCP 2.5.2)	OECD No. 115, EC 440/2008 No. A.5	Difenconazole 250 EC – IN005B1570 Batch no. IND_F021_0321_1	The surface tension at 20 °C of the undiluted test item is 38.9 mN/m and the surface tension at 20 °C of 0.1 mL/L (0.01 % v/v) and 5 mL/L (0.50 % v/v) test item aqueous solutions is 43 mN/m and 40.0 mN/m, respectively.	Y	Urbani, M. 2021b	Accepted Surface active

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Relative density (KCP 2.6.1)	CIPAC MT 3.2, OECD No. 109 (2012), EC Regulation No. 440/2008 A.3	Difenconazole 250 EC – IN005B1570 Batch no. IND_F021_0321_1	The test item density is 1.1401 g/mL at 20 °C, the relative density (D ₂₀ ²⁰) is 1.1422 and the relative density (D ₄ ²⁰) is 1.1401.	Y	Urbani, M. 2021b	Accepted
Bulk density (KCP 2.6.2)	-	-	Not applicable as the preparation is a liquid.	-	-	Not required
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3 HPLC/UV GC/FID OPPTS 830.6302; OPPTS 830.6303; OPPTS 830.6304 CIPAC MT 75.3 CIPAC MT 47.3 and MT 18 CIPAC MT 36.3 and MT 18	Difenconazole 250 EC – IN005B1570 Batch no. IND_F021_0321_1	After 14 days of storage at 54 °C, there was no observable (0.00 %) variation in weight of the test item sample. The commercial container (PA/HDPE bottle) didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena. Difenconazole active ingredient content: 22.3 ± 0.2 % w/w (254 g/L ± 2 g/L) (- 0.63 % from T0: 22.4 ± 0.3 % w/w (256 ± 3 g/L)) Toluene (T0 and after storage): < LOQ (100.00 µg/g) Appearance: dark yellow liquid with aromatic odour pH value (neat test item): 10.2 pH value (1% aqueous dilution) 5.9 Persistent foam after 1 minute: 0.01 % v/v = 12 mL 0.50 % v/v = 38 mL	Y	Urbani, M. 2021a	Accepted A.s. decrease was less than 5 %. All results are acceptable. Formulation was not affected by elevated temperature. A.s. content was performed by HPLC/UV and impurity content by GC/FID. The methods were validated according to SANCO/3030/99 rev. 5 (see Part B5 for details).

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			Emulsion characteristics and re-emulsification properties: Complete initial emulsification (0h); complete re-emulsification (24h) for both application rates (0.01 % v/v and 0.50 % v/v)			
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	GIFAP Monograph No. 17	Difenconazole 250 EC – IN005B1570	A 2-year storage study is underway and will be provided when complete.	Y	Urbani, M. 2021c	Not required
Minimum content after heat stability testing (KCP 2.7.3)	Internal Analytical Method No. 0330/2021	Difenconazole 250 EC – IN005B1570 Batch no. IND_F021_0321_1	After 14 days of storage at 54 °C, the change in the active substance was found to be – 0.63 %. As this is less than the 5 % decrease (Commission Regulations (EU) No. 284/2013) the result is considered to comply with the regulation.	Y	Urbani, M. 2021a	Accepted
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	Difenconazole 250 EC – IN005B1570 Batch no. IND_F021_0321_1	At the end of the storage stability period (7 days at 0 ± 2 °C and 24 hours of thermal equilibrium at 23 ± 2 °C and a single inversion: no visual separation of solid or liquid material, nor changes in its physical state were observed. Emulsion characteristics and re-emulsification properties: Complete initial emulsification (0h); complete re-emulsification (24h) for both application rates (0.01 % v/v and 0.50 % v/v)	Y	Urbani, M. 2021b	Accepted
Ambient temperature	GIFAP Monograph No.	Difenconazole	After 2 years of storage at ambient temperature.	Y	Nichetti, S 2023	Data gap, study report

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
shelf life (KCP 2.7.5)	17 HPLC/UV GC/FID OPPTS 830.6302; OPPTS 830.6303; OPPTS 830.6304 CIPAC MT 75.3 CIPAC MT 47.3 and MT 18 CIPAC MT 36.3 and MT 18	250 EC – IN005B1570 Batch no: IND_F021_0321_1	there was no observable (0.00 %) variation in weight of the test item sample. The container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena. Difenconazole active ingredient content: T0: 22.4 ± 0.3 % w/w (256 ± 3 g/L) T24: 21.4 ± 0.4 % w/w (244 ± 4 g/L)) 22.3 ± 0.2 % w/w (254 g/L ± 2 g/L) (- 4.80 % from T0: 21.4 ± 0.4 % w/w (244 ± 4 g/L)) Toluene (T0 and after storage): < LOQ (100.00 µg/g) T0 and T24: Appearance: dark yellow liquid with aromatic odour pH value (neat test item): 10.0 pH value (1% aqueous dilution) T0: 5.9 T24: 5.4 Persistent foam after 1 minute: 0.01 % v/v = 6 mL 0.50 % v/v = 16 mL Emulsion characteristics and re-emulsification properties: Complete initial emulsification (0h); 1 mL of liquid separation on the top (24h) for 0.50 % v/v solution; complete re-emulsification (24h) for both			shall be submitted when finished (according to the study plan – June 2023). Based on accelerated storage tests shelf life of 2 years can be assumed. Shelf life data have to be subsequently provided for confirmation and final registration. Accepted The initial physico-chemical properties were obtained from the study 0329/2021, the a.s. initial content from the study 0330/2021 and the impurity content from the study 0331/2021. A.s. content was performed by HPLC/UV and impurity content by GC/FID. The methods were validated according to

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			application rates (0.01 % v/v and 0.50 % v/v)			<p>SANCO/3030/99 rev. 5 (see Part B5 for details).</p> <p>Mean temp recorded: 18.2°C.</p> <p>Commercial packaging (PA/HDPE bottle) has remained unchanged – no leakage, deformation, deterioration etc. reported. No weight change.</p> <p>A.s. decrease after storage: – 4.69 %</p> <p>Emulsion characteristics – the study was performed with a concentration lower and higher than the min-max conc. recommended (0.0225 – 0.25%).</p> <p>Formulation has remained a stable concentrate.</p> <p>IN005B1570 shelf-life – 2 years.</p>
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Not required. A shelf life of at least 2 years is proposed based on results of accelerated storage testing (point 2.7.1).	-	-	See KCP 2.7.5

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Wettability (KCP 2.8.1)	-	-	Not applicable for an EC formulation.	-	-	Not required
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3 and MT 18	Difenoconazole 250 EC – IN005B1570 Batch no. IND_F021_0321_1	In standard water D, it can be concluded that, after 1 minute, the persistent foam of test item formulation sample is 10 mL for 0.01 % v/v suspension and 38 mL for 0.50 % v/v suspension, as mean of two determinations	Y	Urbani, M. 2021a 2021b	Accepted
Suspensibility (KCP 2.8.3.1)	-	-	Not applicable for an EC formulation.	-	-	Not required
Spontaneity of dispersion (KCP 2.8.3.2)	-	-	Not applicable for an EC formulation.	-	-	Not required
Dispersion stability (KCP 2.8.3.3)	-	-	Not applicable for an EC formulation.	-	-	Not required
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not applicable for an EC formulation.	-	-	Not required
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	-	-	Not applicable for an EC formulation.	-	-	Not required
Wet sieve test (KCP 2.8.5.1.2)	-	-	Not applicable for an EC formulation.	-	-	Not required
Dust content (KCP 2.8.5.2.1)	-	-	Not applicable for an EC formulation.	-	-	Not required
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not applicable for an EC formulation.	-	-	Not required

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Attrition (KCP 2.8.5.3)	-	-	Not applicable for an EC formulation.	-	-	Not required
Hardness and integrity (KCP 2.8.5.4)	-	-	Not applicable for an EC formulation.	-	-	Not required
Emulsifiability (KCP 2.8.6.1)	CIPAC MT 36.3 and MT 18	Difenoconazole 250 EC – IN005B1570 Batch no. IND_F021_0321_1	A complete initial emulsification was noted after a single inversion and waiting for 30 seconds either for 0.1 mL/L (0.01 % v/v) and 5 mL/L (0.50 % v/v) suspensions.	Y	Urbani, M. 2021a 2021b	Accepted
Emulsion stability (KCP 2.8.6.2)	-	-	Please see KCP 2.8.6.1.	-	-	See KCP 2.8.6.1
Re-emulsifiability (KCP 2.8.6.3)	CIPAC MT 36.3 and MT 18	Difenoconazole 250 EC – IN005B1570 Batch no. IND_F021_0321_1	A complete re-emulsification was noted after 24 h and 10 inversions and waiting for 30 seconds either for 0.1 mL/L (0.01 % v/v) and 5 mL/L (0.50 % v/v) suspensions.	Y	Urbani, M. 2021a 2021b	Accepted
Flowability (KCP 2.8.7.1)	-	-	Not applicable for an EC formulation.	-	-	Not required
Pourability (KCP 2.8.7.2)	-	-	Not applicable for an EC formulation.	-	-	Not required
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not applicable for an EC formulation.	-	-	Not required
Physical compatibility of tank mixes (KCP 2.9.1)	ASTM E1518 – 05	Difenoconazole 250 EC – IN005B1570 Batch no. IND_F021_0823_1	Not required as tank mixtures are not recommended in the label. Difenoconazole 250 EC (IN005B1570) was tested with various potential tank mix partners (Afinto 50WG, Merpan 80 WDG, Mikal Flash, Delan	GEP	Narkiewicz-Jodko, J. (2024a) Narkiewicz-Jodko, J. (2024b)	Not requested Accepted No sedimentation or

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			700WG, Profiler 71,1 WG, Orondis Plus, Coragen 200SC, Secardis 300SC, Cymoxanil 45WG, Revus 250 SC, Amistar 250 SC, Presidium, Banjo 500SC, Bushi 200EC). During field and laboratory analysis full compatabolity and miscibility was observed. No symptoms of mismatches, sediments were noted. Therefore, it can be concluded that tested Difenoconazole 250 EC (IN005B1570) with checked pesticides shows full compatibility.			flocculation were reported. Nevertheless, tank mixtures are not recommended in the label.
Chemical compatibility of tank mixes (KCP 2.9.2)	ASTM E1518 – 05	Difenoconazole 250 EC – IN005B1570 Batch no. IND_F021_0823_1	Not required as tank mixtures are not recommended in the label. Please see KCP 2.9.1.	GEP	Narkiewicz-Jodko, J. (2024a) Narkiewicz-Jodko, J. (2024b)	Not requested See KCP 2.9.1
Adhesion to seeds (KCP 2.10.1)	-	-	Not required as the preparation is not for seed treatment.	-	-	Not required
Distribution to seed (KCP 2.10.2)	-	-	Not required as the preparation is not for seed treatment.	-	-	Not required
Other/special studies (KCP 2.11)	Compatibility (resistance) of the packaging material (Visual examination of packaging both externally and internally)	Difenoconazole 250 EC – IN005B1570 Batch no. IND_F021_0321_1	The container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena after accelerated storage	Y	Urbani, M. 2021a	Packaging not affected by elevated temperature Accepted
	PSD Efficacy Guideline 305 2016 OEPP/EPPO, Bulletin OEPP/EPPO	Difenoconazole 250 EC – IN005B1570 Batch no. IND_F021_0321_1	The percentage of active substance removed after triple rinsing: 99.98%	Y	Longhi, D. 2022	Accepted

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	Bulletin 46, 371–378), PP 1/292 (1) “Cleaning pesticide application equipment (PAE) – efficacy aspects”					

3 Section 3 is presented as a separate document

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

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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 for 0.25 L bottle

Type	Description
Material:	Polyamide / High Density Polyethylene
Shape/size:	Round Height (without cap) 128 ± 3 Diameter at centre 63 ± 3 Min. Capacity (mL) 310
Opening:	50 ± 3 mm
Closure:	Plain or Tamper evident cap
Seal:	Cap with Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-2: Packaging information for 0.5 L bottle

Type	Description
Material:	Polyamide / High Density Polyethylene
Shape/size:	Round Height (without cap) 181.5 ± 3 Diameter at centre 68.5 ± 3 Min. Capacity (mL) 550
Opening:	50 ± 3 mm
Closure:	Plain or Tamper evident cap
Seal:	Cap with Induction seal
Manner of construction	extruded
UN/ADR	compliant

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Table 4.1-3: Packaging information for 1 L bottle

Type	Description
Material:	Polyamide / High Density Polyethylene
Shape/size:	Round Height (without cap) 233 ± 5 Diameter at centre 87.5 ± 3 Min. Capacity (mL) 1120
Opening:	50 ± 3 mm
Closure:	Plain or Tamper evident cap
Seal:	Cap with Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-2: Packaging information for 5 L bottle

Type	Description
Material:	Polyamide / High Density Polyethylene
Shape/size:	Rectangular Height (without cap) 311 ± 5 375 ± 10 389 ± 10 Length 195 ± 3 Width 120 ± 3 Min. Capacity (mL) 5600
Opening:	50 ± 3 mm
Closure:	Plain or Tamper evident cap
Seal:	Cap with Induction seal
Manner of construction	extruded
UN/ADR	compliant

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Table 4.1-2: Packaging information for 10 L bottle

Type	Description
Material:	Polyamide / High Density Polyethylene
Shape/size:	Rectangular Height (without cap) 375 ± 10 Length 180 ± 3 Width 238 ± 5 Min. Capacity (mL) 310 550 1120 5600 11850 22800
Opening:	63 ± 3 mm
Closure:	Plain or Tamper evident cap
Seal:	Cap with Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-2: Packaging information for 20 L bottle

Type	Description
Material:	Polyamide / High Density Polyethylene
Shape/size:	Rectangular Height (without cap) 389 ± 10 Length 290 ± 5 Width 240 ± 5 Min. Capacity (mL) 22800
Opening:	68 ± 3 mm
Closure:	Plain or Tamper evident cap
Seal:	Cap with Induction seal
Manner of construction	extruded
UN/ADR	compliant

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Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.
 MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1	Urbani, M.	2021a 2021b	Difenconazole 250 g/L EC greener – IN005B1570: Determination of the Accelerated Storage Stability and Corrosion Characteristics Report No CH – 0332/2021 Difenconazole 250 g/L EC greener – IN005B1570: Determination of the Physico-chemical Properties Report No CH – 0329/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	INDOFIL Industries (Netherlands) B.V.
KCP 2.2.1	Urbani, M.	2021b	Difenconazole 250 g/L EC greener – IN005B1570: Determination of the Physico-chemical Properties Report No CH – 0329/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	INDOFIL Industries (Netherlands) B.V.
KCP 2.2.2	Urbani, M.	2021b	Difenconazole 250 g/L EC greener – IN005B1570: Determination of the Physico-chemical Properties Report No CH – 0329/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	INDOFIL Industries (Netherlands) B.V.

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.3.1	Urbani, M.	2021b	Difenoconazole 250 g/L EC greener – IN005B1570: Determination of the Physico-chemical Properties Report No CH – 0329/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	INDOFIL Industries (Netherlands) B.V.
KCP 2.3.3	Urbani, M.	2021b	Difenoconazole 250 g/L EC greener – IN005B1570: Determination of the Physico-chemical Properties Report No CH – 0329/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	INDOFIL Industries (Netherlands) B.V.
KCP 2.4.2	Urbani, M.	2021a 2021b	Difenoconazole 250 g/L EC greener – IN005B1570: Determination of the Accelerated Storage Stability and Corrosion Characteristics Report No CH – 0332/2021 Difenoconazole 250 g/L EC greener – IN005B1570: Determination of the Physico-chemical Properties Report No CH – 0329/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	INDOFIL Industries (Netherlands) B.V.
KCP 2.5.1	Urbani, M.	2021b	Difenoconazole 250 g/L EC greener – IN005B1570: Determination of the Physico-chemical Properties Report No CH – 0329/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	INDOFIL Industries (Netherlands) B.V.
KCP 2.5.2	Urbani, M.	2021b	Difenoconazole 250 g/L EC greener – IN005B1570: Determination of the Physico-chemical Properties Report No CH – 0329/2021 ChemService S.r.l. Controlli e Ricerche GLP	N	INDOFIL Industries (Netherlands) B.V.

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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
			Unpublished		
KCP 2.6.1	Urbani, M.	2021b	Difenoconazole 250 g/L EC greener – IN005B1570: Determination of the Physico-chemical Properties Report No CH – 0329/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	INDOFIL Industries (Netherlands) B.V.
KCP 2.7.1	Urbani, M.	2021a	Difenoconazole 250 g/L EC greener – IN005B1570: Determination of the Accelerated Storage Stability and Corrosion Characteristics Report No CH – 0332/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	INDOFIL Industries (Netherlands) B.V.
KCP 2.7.2	Urbani, M. Nichetti, S.	2021a 2023	Difenoconazole 250 g/L EC greener – IN005B1570: Two Years Storage Stability and Corrosion Characteristics. FINAL REPORT Study Plan No CH – 0333/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	INDOFIL Industries (Netherlands) B.V.
KCP 2.7.3	Urbani, M.	2021a	Difenoconazole 250 g/L EC greener – IN005B1570: Determination of the Accelerated Storage Stability and Corrosion Characteristics Report No CH – 0332/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	INDOFIL Industries (Netherlands) B.V.
KCP 2.7.4	Urbani, M.	2021b	Difenoconazole 250 g/L EC greener – IN005B1570: Determination of the Physico-chemical Properties Report No CH – 0329/2021 ChemService S.r.l. Controlli e Ricerche	N	INDOFIL Industries (Netherlands)

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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
			GLP Unpublished		B.V.
KCP 2.7.5	Urbani, M.	2021c	Difenoconazole 250 g/L EC greener – IN005B1570: Two Years Storage Stability and Corrosion Characteristics Study Plan No CH – 0333/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	INDOFIL Industries (Netherlands) B.V.
KCP 2.8.2	Urbani, M.	2021a 2021b	Difenoconazole 250 g/L EC greener – IN005B1570: Determination of the Accelerated Storage Stability and Corrosion Characteristics Report No CH – 0332/2021 Difenoconazole 250 g/L EC greener – IN005B1570: Determination of the Physico-chemical Properties Report No CH – 0329/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	INDOFIL Industries (Netherlands) B.V.
KCP 2.8.6.1	Urbani, M.	2021a 2021b	Difenoconazole 250 g/L EC greener – IN005B1570: Determination of the Accelerated Storage Stability and Corrosion Characteristics Report No CH – 0332/2021 Difenoconazole 250 g/L EC greener – IN005B1570: Determination of the Physico-chemical Properties Report No CH – 0329/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	INDOFIL Industries (Netherlands) B.V.
KCP 2.8.6.3	Urbani, M.	2021a 2021b	Difenoconazole 250 g/L EC greener – IN005B1570: Determination of the Accelerated Storage Stability and Corrosion Characteristics Report No CH – 0332/2021	N	INDOFIL Industries (Netherlands)

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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
			Difenoconazole 250 g/L EC greener – IN005B1570: Determination of the Physico-chemical Properties Report No CH – 0329/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished		B.V.
KCP 2.9.1-1 (KCP 2.9.2)	Narkiewicz-Jodko, J.	2024a	Field miscibility study of difenoconazole 250 EC (IN005B1570) evaluation- Tank-mix partners Report No. TMC19122023GP/01 Green & Property Consulting GEP Unpublished	N	INDOFIL Industries (Netherlands) B.V.
KCP 2.9.1-2 (KCP 2.9.2)	Narkiewicz-Jodko, J.	2024b	Laboratory miscibility study of Difenoconazole 250 EC (IN005B1570) with tank-mix partner Report No. TMC19122023GP/02 Green & Property Consulting GEP Unpublished	N	INDOFIL Industries (Netherlands) B.V.
KCP 2.11	Urbani, M.	2021a	Difenoconazole 250 g/L EC greener – IN005B1570: Determination of the Accelerated Storage Stability and Corrosion Characteristics Report No CH – 0332/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	INDOFIL Industries (Netherlands) B.V.
	Longhi, D.	2022	IN005B1570: equipment cleaning procedure Report No FR LBN-0040-2022 LabAnalysis s.r.l. GLP Unpublished	N	INDOFIL Industries (Netherlands) B.V.

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte- brate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte- brate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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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	Verte- brate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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

No further studies proposed