

# **REGISTRATION REPORT**

## **Part B**

### **Section 1: Identity**

### **Section 2: Physical and chemical properties**

### **Section 4: Further information**

Detailed summary of the risk assessment

Product name(s): **INTUITY PLUS**

**(Mandestrobin 40 SC)**

Chemical active substance:  
Mandestrobin, 400 g/L

Central Zone

Zonal Rapporteur Member State: Poland

## **CORE ASSESSMENT**

(authorization)

Applicant: XXXX

Submission date: February 2024

MS Finalisation date: August 2025

## Version history

When	What
February 2024	Article 33 submission – Initial Applicant’s version
May 2024	- Update of the cover page with the product trade name ‘Intuity Plus’. Mandestrobin 40 SC is the internal unique name. The internal name Mandestrobin 40 SC is the one used across the dRR content. - Update of Appendix 1: studies source updated
April 2025	Update of Section 2 with 2 year ambient storage stability results
August 2025	Evaluated by zRMS considering the RT stage comments.

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

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

Noticed data gaps are: **none**.

- ~~data gap 1~~
- ~~data gap 2~~
- ~~data gap 3~~

## **1 Section 1: Identity of the plant protection product**

### **1.1 Applicant (KCP 1.1)**

Name: XXXX  
Address: XXXX  
XXXX  
XXXX

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

#### **1.2.1 Producer(s) of the preparation**

Manufacturer of the preparation:

Name: XXXX.  
Address: XXXX,  
XXXX,  
XXXX

Location of the manufacturing site of the plant protection product:

Confidential information (Part C).

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

Manufacturer of the active substance:

Name: XXXX  
Address: XXXX,  
XXXX  
XXXX

Location of the manufacturing site of the active substance:

Confidential information (Part C).

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

#### 1.2.3.1 Mandestrobin

Mandestrobin  $\geq 950$  g/kg (dry weight basis)  
 $\geq 840$  g/kg (TK)

The following impurities are considered relevant and should not exceed the stated amounts in the technical material.

Xylenes (ortho, meta, para), ethyl benzene  $< 5$  g/kg (TK)

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

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

Company code number: S-2200 40 SC

### 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)	FAO Limits (min – max) (g/L)	Technical content* (g/L)	Technical content** (%w/w)
Mandestrobin	400	380 - 420 ( $\pm 5\%$ )	421 on dry weight basis	38.99

\* Based on the minimum purity of the active substance declared for registration in the active substance dossiers (95%)

\*\* Based on the density of the formulation = 1.08 g/mL

**Table 1.4-2: Relevant impurities**

Relevant impurity	Maximum content (g/L)
Xylenes (ortho, meta, para), ethyl benzene	2.4 2.1

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

**Table 1.4-3: Information on Mandestrobin**

Type	Name/Code Number
ISO common name	Mandestrobin

Type	Name/Code Number
CAS No.	173662-97-0
EC No.	694-980-2
CIPAC No.	Not assigned

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

The formulation does not contain any safeners or synergists.

CONFIDENTIAL information is provided separately (Part C).

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

Type: Suspension Concentrate

[Code: SC]

#### **1.6 Function (KCP 1.6)**

Fungicide

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of opaque white liquid, with a chemical odour. It is not explosive, has no oxidising properties. The product has a flash point of > 93°C. It has an auto-ignition temperature of 488°C. A 1% aqueous suspension has a pH value of 7.75 at 20°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE packaging. Extrapolation to other packaging materials (HDPE/PA, HDPE/EVOH and HDPE/F) is possible since the product is a water-based formulation. Its technical characteristics are acceptable for a suspension concentrate formulation.

The intended concentration of use is 0.16% to 0.5%.

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

None.

### **Notifier Proposals for Risk and Safety Phrases (KCP 12)**

None.

### **Compliance with FAO specifications:**

The product Mandestrobin 40SC complies with FAO specifications. There are no FAO specifications for mandestrobin.

### **Formulation used for tests**

All tests have been performed using the product Mandestrobin 40SC as 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	Mandestrobin 40SC 400 g/L mandestrobin Batch No.: AE20-2F2102	Physical state at ambient temperature: liquid with a thin clear liquid layer on the top but without sediment on the bottom (no claying), homogeneous after gentle shaking.  Colour: opaque white.  Odour: chemical odour.	Y	Lecocq, V., 2025. ROF-0025	Accepted
Explosive properties (KCP 2.2.1)	DSC Screen  Theoretical assessment UN MTC (UNRTDG Appendix 6) ST/SG/AC.10/11/Rev.7	Mandestrobin 40SC 400 g/L mandestrobin Batch No.: AE20-2F2102	During DSC analysis of Mandestrobin 40 SC, the total exothermic decomposition energy was found to be 223.0 J/g. Given this is <500 J/g, the classification procedure for explosive properties need not be applied according to the UN-MTC(RTDG) Appendix 6 screening procedures, therefore Mandestrobin 40 SC is not classified as explosive.	Y	Michnik, I., 2023 ROF-0022	Accepted
Oxidizing properties (KCP 2.2.2)	Theoretical assessment UN MTC (UNRTDG Appendix 6) ST/SG/AC.10/11/Rev.7	Mandestrobin 40SC 400 g/L mandestrobin Batch No.: AE20-2F2102	A theoretical assessment of the active ingredient and each formulant has been conducted, in which it was concluded that no individual formulant is expected to have oxidising properties, therefore Mandestrobin 40 SC is not expected to be oxidising.	Y	Michnik, I., 2023 ROF-0022	Accepted
Flash point (KCP 2.3.1)	EC A.9	Mandestrobin 40SC 400 g/L mandestrobin	Flash point (closed cup): > 93°C  The test item is not flammable.	Y	Lecocq, V., 2025. ROF-0025	Accepted



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Batch No.: AE20-2F2102				
Flammability (KCP 2.3.2)			Not applicable to suspension concentrates			
Self-heating (KCP 2.3.3)	EC A.15	Mandestrobin 40SC 400 g/L mandestrobin Batch No.: AE20-2F2102	The auto-ignition temperature of Mandestrobin 40SC is 488°C	Y	Michnik, I., 2023 ROF-0022	Accepted
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 75.3	Mandestrobin 40SC 400 g/L mandestrobin Batch No.: AE20-2F2102	pH of the test item: 7.56 (20°C) Acidity/alkalinity not required as the pH is >4 and <10.	Y	Lecocq, V., 2025, ROF-0025	Accepted
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Mandestrobin 40SC 400 g/L mandestrobin Batch No.: AE20-2F2102	pH at 1% in water: 7.75 (20°C)	Y	Lecocq, V., 2025, ROF-0025	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Viscosity (KCP 2.5.1)	CIPAC MT 192	Mandestrobin 40SC 400 g/L mandestrobin Batch No.: AE20-2F2102	20°C ± 0.5°C: 3404 mPa.s to 102 mPa.s 40°C ± 0.5°C: 2504 mPa.s to 76 mPa.s Shear rate applied to the sample: 0.34 - 68 s <sup>-1</sup> The viscosity is dependent on the shear rate applied to the sample. The test item did not display Newtonian flow behaviour.	Y	Lecocq, V., 2025, ROF-0025	Accepted
	Calculation	-	Kinematic viscosity at 40°C ± 0.5°C: 71.18 mm <sup>2</sup> /s (at shear rate 68 s <sup>-1</sup> )	Y	Lecocq, V., 2025, ROF-0025	Accepted
Surface tension (KCP 2.5.2)	EC A.5	Mandestrobin 40SC 400 g/L mandestrobin Batch No.: AE20-2F2102	Surface tension of diluted (0.5% v/v) test item at 20°C ± 0.5°C: 38.4 mN/m The test item is surface active. time between preparation of the dilution and the measurement which was 3 min	Y	Lecocq, V., 2025, ROF-0025	Accepted
Relative density (KCP 2.6.1)	CIPAC MT 3.3.2	Mandestrobin 40SC 400 g/L mandestrobin Batch No.: AE20-2F2102	Density at 20°C ± 0.5°C: 1.0825 g/mL Relative density: D <sup>20</sup> <sub>4</sub> = 1.0825	Y	Lecocq, V., 2025, ROF-0025	Accepted
Bulk density (KCP 2.6.2)			Not applicable to suspension concentrates			
Storage Stability after	CIPAC MT 46.4	Mandestrobin	No significant variation in the active substance	Y	Lecocq, V., 2025,	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
14 days at 54° C (KCP 2.7.1)		40SC 400 g/L mandestrobin Batch No.: AE20-2F2102	content was observed following the 14-day storage period at 54 ± 2°C in a 2L HDPE can. There was no variation in the packaging during study.  No significant variation in the individual parameters was observed following storage (presented in Table 2.7-1 below).		ROF-0025	
Stability after storage for other periods and/or temperatures (KCP 2.7.2)			None			
Minimum content after heat stability testing (KCP 2.7.3)			Refer to KCP 2.7.1.			
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	Mandestrobin 40SC 400 g/L mandestrobin Batch No.: AE20-2F2102	No phase or material separation was observed following the 7-day storage period at 0 ± 2°C in a closed glass bottle. There was no significant variation in the suspensibility characteristics and wet sieve properties following storage (presented in Table 2.7-2 below).	Y	Lecocq, V., 2025, ROF-0025	Accepted
Ambient temperature shelf life (KCP 2.7.5)	CropLife Technical Monograph N°17	Mandestrobin 40SC 400 g/L mandestrobin Batch No.: AE20-	No significant variation in the active substance content was observed following the 2-year storage period at 20 ± 2°C in a 2L HDPE can. There was no variation in the packaging during study.  No significant variation in the individual parameters was observed following storage (presented in Table	Y	Lecocq, V., 2025, ROF-0025	Accepted  A shelf life of two years can be granted for this PPP.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		2F2102	2.7-3 below).			
Shelf life in months (if less than 2 years) (KCP 2.7.6)			Refer to KCP 2.7.5.			
Wettability (KCP 2.8.1)			Not applicable to suspension concentrates			
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	Mandestrobin 40SC 400 g/L mandestrobin Batch No.: AE20-2F2102	In CIPAC water D at 0.5% v/v and 25°C ± 5°C: After 10 seconds: 19 mL After 1 minute: 13 mL After 3 minutes: 13 mL After 12 minutes: 10 mL	Y	Lecocq, V., 2025, ROF-0025	Accepted
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184.1 (by a.s. content)	Mandestrobin 40SC 400 g/L mandestrobin Batch No.: AE20-2F2102	In CIPAC water D at 25°C ± 5°C after 30 minutes: 0.1% v/v: 96.1% 0.5% v/v: 95.7%	Y	Lecocq, V., 2025, ROF-0025	Accepted  Analytical method has been accepted in Part B section 5.
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160 (by a.s. content)	Mandestrobin 40SC 400 g/L mandestrobin Batch No.: AE20-	In CIPAC water D at 30°C ± 2°C after 5 minutes: Concentration: 12.5 mL/250 mL  96.8%	Y	Lecocq, V., 2025, ROF-0025	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		2F2102				
Dispersion stability (KCP 2.8.3.3)			Not applicable to suspension concentrates			
Degree of dissolution and dilution stability (KCP 2.8.4)			Not applicable to suspension concentrates			
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187 (laser diffraction)	Mandestrobin 40SC 400 g/L mandestrobin Batch No.: AE20-2F2102	D <sub>v,10</sub> : 1.089 µm D <sub>v,50</sub> : 2.969 µm D <sub>v,90</sub> : 11.884 µm	Y	Lecocq, V., 2025, ROF-0025	Accepted
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	Mandestrobin 40SC 400 g/L mandestrobin Batch No.: AE20-2F2102	Material retained on a 75 µm test sieve: 0.05% w/w	Y	Lecocq, V., 2025, ROF-0025	Accepted
Dust content (KCP 2.8.5.2.1)			Not applicable to suspension concentrates			
Particle size of dust (KCP 2.8.5.2.2)			Not applicable to suspension concentrates			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Attrition (KCP 2.8.5.3)			Not applicable to suspension concentrates			
Hardness and integrity (KCP 2.8.5.4)			Not applicable to suspension concentrates			
Emulsifiability (KCP 2.8.6.1)			Not applicable to suspension concentrates			
Emulsion stability (KCP 2.8.6.2)			Not applicable to suspension concentrates			
Re-emulsifiability (KCP 2.8.6.3)			Not applicable to suspension concentrates			
Flowability (KCP 2.8.7.1)			Not applicable to suspension concentrates			
Pourability (KCP 2.8.7.2)	CIPAC MT 148.1	Mandestrobin 40SC 400 g/L mandestrobin Batch No.: AE20-2F2102	Residue: 1.89%	Y	Lecocq, V., 2025, ROF-0025	Accepted
Dustability following accelerated storage (KCP 2.8.7.3)			Not applicable to suspension concentrates			

Annex point	Method used / deviations	Test materi- al	Findings	GLP Y/N	Reference	Acceptability / comments
Physical compatibility of tank mixes (KCP 2.9.1)			Not required, not intended to be mixed			
Chemical compatibility of tank mixes (KCP 2.9.2)			Not required, not intended to be mixed			
Adhesion to seeds (KCP 2.10.1)			Not required, not intended to be used in a seed treatment			
Distribution to seed (KCP 2.10.2)			Not required, not intended to be used in a seed treatment			
Other/special studies (KCP 2.11)			None			

**Table 2.7-1 Accelerated Storage Stability Results – 14 days at 54 ± 2°C (Lecocq, V., 2025, ROF-0025)**

Test	Method	Initial	After 14 days at 54 ± 2°C 2L HDPE can CIPAC MT 46.4
Mandestrobin content	Validated HPLC-UV method (MET/25587-A)	37.26 ± 0.30% w/w or 372.6 ± 3.0 g/kg or 403.3 ± 3.2 g/L	37.10 ± 0.17% w/w or 371.0 ± 1.7 g/kg or 401.6 ± 2.0 g/L  Difference : -0.4%
Isomer ratio of mandestrobin	Validated HPLC-UV method (MET/25587-B)	<i>S</i> -isomer : 50.08 ± 0.22% area <i>R</i> -isomer : 49.92 ± 0.22% area <i>S</i> isomer / <i>R</i> isomer ratio: 1.003	<i>S</i> -isomer : 50.07 ± 0.17% area <i>R</i> -isomer : 49.93 ± 0.17% area <i>S</i> isomer / <i>R</i> isomer ratio: 1.003
Appearance	Visual	Physical state at ambient temperature: liquid with a thin clear liquid layer on the top but without sediment on the bottom (no claying), homogeneous after gentle shaking. Colour: opaque white. Odour: chemical odour.	Physical state at ambient temperature: liquid with a thin clear liquid layer on the top but without sediment on the bottom (no claying), homogeneous after gentle shaking. Colour: opaque white. Odour: chemical odour. No modification of appearance.
pH	CIPAC MT 75.3	pH of the test item: 7.56 (20°C) pH at 1% in water: 7.75 (20°C)	pH of the test item: 7.49 (19°C) pH at 1% in water: 7.68 (20°C)
Persistent foam	CIPAC MT 47.3	In CIPAC water D at 0.5% v/v and 25°C ± 5°C: After 10 seconds: 19 mL After 1 minute: 13 mL After 3 minutes: 13 mL After 12 minutes: 10 mL	In CIPAC water D at 0.5% v/v and 25°C ± 5°C: After 10 seconds: 19 mL After 1 minute: 2 mL After 3 minutes: < 0.5 mL After 12 minutes: < 0.5 mL
Packaging stability	Visual	Outside aspect: Opaque white HDPE can of 2 L, closing with a screw white plastic cap, sealing with a paper/aluminium foil. Well closed can without deterioration or special anomaly. No observable sign of test item contamination on the outer surface. No leak during shaking or	Outside aspect: Opaque white HDPE can of 2 L, closing with a screw white plastic cap, sealing with a paper/aluminium foil. Well closed can without deterioration or special anomaly. No observable sign of test item contamination on the outer surface. No leak during shaking



Test	Method	Initial	After 14 days at $54 \pm 2^{\circ}\text{C}$ 2L HDPE can CIPAC MT 46.4
		turning. No noticeable odour before opening of the pack- age.	or turning. No noticeable odour before opening of the package. Inside aspect: No observable alteration of package material by the test item. No modification of appearance.
Pack weight change	Gravimetric	Mass of bottle 2/6: 2402.8 g	Mass of bottle 2/6: 2402.0 g (-0.0% difference)  No significant pack weight change
Suspensibility	CIPAC MT 184.1 (by a.s. content)	In CIPAC water D at $25^{\circ}\text{C} \pm 5^{\circ}\text{C}$ after 30 minutes: 0.1% v/v: 96.1% 0.5% v/v: 95.7%	In CIPAC water D at $25^{\circ}\text{C} \pm 5^{\circ}\text{C}$ after 30 minutes: 0.1% v/v: 95.0% 0.5% v/v: 93.8%
Spontaneity of dispersion	CIPAC MT 160 (by a.s. content)	In CIPAC water D at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ after 5 minutes: Concentration: 12.5 mL/250 mL  96.8%	In CIPAC water D at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ after 5 minutes: Concentration: 12.5 mL/250 mL  95.8%
Wet sieve test	CIPAC MT 185	Material retained on a 75 $\mu\text{m}$ test sieve: 0.05% w/w	Material retained on a 75 $\mu\text{m}$ test sieve: 0.03% w/w
Particle size distribution	CIPAC MT 187 (laser diffraction)	$D_{v,10}$ : 1.089 $\mu\text{m}$ $D_{v,50}$ : 2.969 $\mu\text{m}$ $D_{v,90}$ : 11.884 $\mu\text{m}$	$D_{v,10}$ : 1.207 $\mu\text{m}$ $D_{v,50}$ : 3.535 $\mu\text{m}$ $D_{v,90}$ : 14.488 $\mu\text{m}$
Pourability - rinsability	CIPAC MT 148.1	Residue: 1.89%	Residue: 2.04%

**Table 2.7-2 Low Temperature Storage Stability Results - 7 Days at  $0 \pm 2^{\circ}\text{C}$  (Lecocq, V., 2025, ROF-0025)**

Test	Method	Initial	After 7 days at $0 \pm 2^{\circ}\text{C}$ Closed glass bottle CIPAC MT 39.3
Appearance	Visual	Physical state at ambient temperature: liquid with a thin clear liquid layer on the top but without sediment on the bottom (no claying), homogeneous after gentle shaking.	Physical state at ambient temperature: homogeneous liquid without clear liquid layer on the top or sediment on the bottom (no claying).

Test	Method	Initial	After 7 days at 0 ± 2°C Closed glass bottle CIPAC MT 39.3
		Colour: opaque white. Odour: chemical odour.	Colour: opaque white. Odour: chemical odour. No modification of appearance.
Suspensibility	CIPAC MT 184.1 (by a.s. content)	In CIPAC water D at 25°C ± 5°C after 30 minutes: 0.1% v/v: 96.1% 0.5% v/v: 95.7%	In CIPAC water D at 25°C ± 5°C after 30 minutes: 0.1% v/v: 96.1% 0.5% v/v: 95.8%
Wet sieve test	CIPAC MT 185	Material retained on a 75 µm test sieve: 0.05% w/w	Material retained on a 75 µm test sieve: 0.04% w/w

**Table 2.7-3 Ambient Shelf-life Storage Stability Results (Lecocq, V., 2025, ROF-0025)**

Test	Method	Initial	After 1 year at 20 ± 2°C 2L HDPE can CropLife Technical Monograph N°17	After 2 years at 20 ± 2°C 2L HDPE can CropLife Technical Monograph N°17	After 3 years at 20 ± 2°C 2L HDPE can CropLife Technical Monograph N°17
Mandestrobin content	Validated HPLC-UV method (MET/25587-A)	37.26 ± 0.30% w/w or 372.6 ± 3.0 g/kg or 403.3 ± 3.2 g/L	37.09 ± 0.35% w/w or 370.9 ± 3.5 g/kg or 401.6 ± 3.7 g/L Difference : -0.5%	37.20 ± 0.22% w/w or 372.0 ± 2.2 g/kg or 402.7 ± 2.5 g/L Difference : -0.2%	Study ongoing, results due Dec 2025
Isomer ratio of mandestrobin	Validated HPLC-UV method (MET/25587-B)	S-isomer : 50.08 ± 0.22% area R-isomer : 49.92 ± 0.22% area S isomer / R isomer ratio: 1.003	S-isomer : 50.00 ± 0.15% area R-isomer : 50.00 ± 0.15% area S isomer / R isomer ratio: 1.000	S-isomer : 50.03 ± 0.47% area R-isomer : 49.97 ± 0.47% area S isomer / R isomer ratio: 1.001	

Appearance	Visual	Physical state at ambient temperature: liquid with a thin clear liquid layer on the top but without sediment on the bottom (no claying), homogeneous after gentle shaking. Colour: opaque white. Odour: chemical odour.	Physical state at ambient temperature: liquid with a clear liquid layer on the top ( $\pm 4\%$ of volume) but without sediment on the bottom (no claying), homogeneous after gentle shaking. Colour: opaque white. Odour: chemical odour.  No modification of appearance.	Physical state at ambient temperature: liquid with a clear liquid layer on the top ( $\pm 8\%$ of volume) but without sediment on the bottom (no claying), homogeneous after gentle shaking. Colour: opaque white. Odour: chemical odour.  No modification of appearance.	
pH	CIPAC MT 75.3	pH of the test item: 7.56 (20°C) pH at 1% in water: 7.75 (20°C)	pH of the test item: 7.51 (20°C) pH at 1% in water: 7.69 (20°C)	pH of the test item: 7.49 (22°C) pH at 1% in water: 7.72 (21°C)	
Persistent foam	CIPAC MT 47.3	In CIPAC water D at 0.5% v/v and 25°C $\pm$ 5°C: After 10 seconds: 19 mL After 1 minute: 13 mL After 3 minutes: 13 mL After 12 minutes: 10 mL	In CIPAC water D at 0.037% v/v and 25°C $\pm$ 5°C: After 10 seconds: 15 mL After 1 minute: 10 mL After 3 minutes: 8 mL After 12 minutes: 8 mL  In CIPAC water D at 0.5% v/v and 25°C $\pm$ 5°C: After 10 seconds: 20 mL After 1 minute: 2 mL After 3 minutes: 2 mL After 12 minutes: < 0.5 mL	In CIPAC water D at 0.037% v/v and 25°C $\pm$ 5°C: After 10 seconds: 15 mL After 1 minute: 11 mL After 3 minutes: 10 mL After 12 minutes: 9 mL  In CIPAC water D at 0.5% v/v and 25°C $\pm$ 5°C: After 10 seconds: 20 mL After 1 minute: 5 mL After 3 minutes: 3 mL After 12 minutes: < 0.5 mL	

Packaging stability	Visual	Outside aspect: Opaque white HDPE can of 2 L, closing with a screw white plastic cap, sealing with a paper/aluminium foil. Well closed can without deterioration or special anomaly. No observable sign of test item contamination on the outer surface. No leak during shaking or turning. No noticeable odour before opening of the package.	Outside aspect: Opaque white HDPE can of 2 L, closing with a screw white plastic cap, sealing with a paper/aluminium foil. Well closed can without deterioration or special anomaly. No observable sign of test item contamination on the outer surface. No leak during shaking or turning. No noticeable odour before opening of the package. Inside aspect: No observable alteration of package material by the test item.  No modification of appearance.	Outside aspect: Opaque white HDPE can of 2 L, closing with a screw white plastic cap, sealing with a paper/aluminium foil. Well closed can without deterioration or special anomaly. No observable sign of test item contamination on the outer surface. No leak during shaking or turning. No noticeable odour before opening of the package. Inside aspect: No observable alteration of package material by the test item.  No modification of appearance.	
Pack weight change	Gravimetric	Mass of bottle 3/6: 2468.0 g Mass of bottle 4/6: 2317.9 g	Mass of bottle 3/6: 2467.4 g (-0.0% difference)  No significant pack weight change	Mass of bottle 4/6: 2316.7 g (-0.1% difference)  No significant pack weight change	
Suspensibility	CIPAC MT 184.1 (by a.s. content)	In CIPAC water D at 25°C ± 5°C after 30 minutes: 0.1% v/v: 96.1% 0.5% v/v: 95.7%	In CIPAC water D at 25°C ± 5°C after 30 minutes: 0.1% v/v: 96.0% 0.5% v/v: 94.9%	In CIPAC water D at 25°C ± 5°C after 30 minutes: 0.1% v/v: 95.6% 0.5% v/v: 95.7%	
Spontaneity of dispersion	CIPAC MT 160 (by a.s. content)	In CIPAC water D at 30°C ± 2°C after 5 minutes: Concentration: 12.5 mL/250 mL  96.8%	In CIPAC water D at 30°C ± 2°C after 5 minutes: Concentration: 12.5 mL/250 mL  98.2%	In CIPAC water D at 30°C ± 2°C after 5 minutes: Concentration: 12.5 mL/250 mL  97.0%	
Wet sieve test	CIPAC MT 185	Material retained on a 75 µm test sieve: 0.05% w/w	Material retained on a 75 µm test sieve: 0.06% w/w	Material retained on a 75 µm test sieve: 0.06% w/w	
Particle size distribution	CIPAC MT 187 (laser diffraction)	D <sub>v,10</sub> : 1.089 µm D <sub>v,50</sub> : 2.969 µm D <sub>v,90</sub> : 11.884 µm	D <sub>v,10</sub> : 1.098 µm D <sub>v,50</sub> : 3.020 µm D <sub>v,90</sub> : 12.597 µm	D <sub>v,10</sub> : 1.103 µm D <sub>v,50</sub> : 3.022 µm D <sub>v,90</sub> : 11.903 µm	
Pourability - rinsability	CIPAC MT 148.1	Residue: 1.89%	Residue: 1.83%	Residue: 2.06%	

### **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 for 1 and 2 ~~liter~~ litre bottle**

Type	Description
Material:	HDPE, HDPE/PA, HDPE/F, HDPE/EVOH
Shape/size:	Wide neck container
Opening:	<b>63 mm</b> <del>42 mm</del> inner diameter
Closure:	polyethylene screw cap
Seal:	HF-seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-2: Packaging information for 3, 5 and 10 litre can**

Type	Description
Material:	HDPE, HDPE/PA, HDPE/F, HDPE/EVOH
Shape/size:	Wide neck container
Opening:	<b>63 mm</b> <del>42 mm</del> inner diameter
Closure:	polyethylene screw cap
Seal:	HF-seal
Manner of construction	extruded
UN/ADR	compliant

## Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

### List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1, KCP 2.3.1, KCP 2.4.1, KCP 2.4.2, KCP 2.5.1/1, KCP 2.5.1/2, KCP 2.5.2, KCP 2.6.1, KCP 2.7.1, KCP 2.7.4, KCP 2.7.5, KCP 2.8.2, KCP 2.8.3.1, KCP 2.8.3.2, KCP 2.8.5.1.1, KCP 2.8.5.1.2, KCP 2.8.7.2	Lecocq, V.	2025	Physical and Chemical Properties and Storage Stability Tests for Mandestrobin 40 SC (third interim report) Company Report No 25610 Walloon Agricultural Research Centre, CRA-W Gembloux, Belgium <del>Sumitomo Chemical Co., Ltd. XXXX</del> ROF-0025 GLP Unpublished	N	XXXX
KCP 2.2.1 KCP 2.2.2 KCP 2.3.3	Michnik, I.	2023	Regulatory Testing on a Sample of Mandestrobin 40 SC Company Report No GLP3016013429R1/2023 DEKRA UK Ltd, UK <del>Sumitomo Chemical Co., Ltd. XXXX</del> ROF-0022 GLP Unpublished	N	XXXX

\* XXXX).

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

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

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

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



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

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

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

### **A 2.1            Mandestrobin**

Not applicable.