

REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

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

Evaluation date: January 2025

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.
January 2025	zRMS-PL evaluation
August 2025	Version revised to take into account cMSs's and applicant's comments

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

The application is submitted for the authorisation of Mandestrobin 40SC for use as a plant protection product.

Mandestrobin 40SC is an SC formulation containing 400 g/L of Mandestrobin used as a fungicide in winter and spring oilseed rape.

Parts B and C of this draft Registration Report outline the information, data, and risk assessments to demonstrate a safe use for Mandestrobin 40 SC in winter and spring oilseed rape.

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 544/2011 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
Central zone	PL	AT, HU, RO, DE, NL, CZ, SK, SI
Southern zone	FR	Not relevant

0.1.2 Regulatory history of the active(s)

0.1.2.1 Mandestrobin

Table 0.1-2: Summary of regulatory history of CAS No: 173662-97-0

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 2015/2085
RMS	Austria/Sweden
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	09.12.2015
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	N/A
Date of final Commission (re-registration) deadline (Step 2)	N/A

Status	
Current expiration of approval	09.12.2025
Low risk substance or Candidate for Substitution?	N/A

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

- the risk to aquatic organisms;
- the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions.

Conditions of use shall include risk mitigation measures, where appropriate.

The SANCO report for mandestrobin (SANTE/11647/2015/rev 1, 9 October 2015) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was published on 5 May 2015 (EFSA Journal 2015; 13(5):4100).

Table 0.1-3: Information on minimum purity of Mandestrobin

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report
The EU agreed minimum purity of mandestrobin is 940 g/kg (see Reg. 2015/2085)	Source 2 : 950 g/kg (RMS:AT, 2018)
Source 1 950g/kg (EFSA Supporting Publications 2017; 14 (10):1302E; amended Review Report, March 2021)	

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

Compound	Endpoint	EFSA conclusion (2015) a	Current EU agreed endpoint b	Endpoint used in this assessment
Environmental Fate				
Mandestrobin	Soil DT ₅₀ [d]	Soil pH CaCl ₂ ≤ 5.9 : 276.4	Soil pH CaCl ₂ ≤ 6.7 : 231.2	Soil pH CaCl ₂ ≤ 6.7 : 231.2
5-COOH-S- 2200	Soil DT ₅₀ [d]	36.91	41.75	41.75
	Formation fraction	0.502	0.424	0.424
DX-CA-S- 2200	Soil DT ₅₀ [d]	Not observed	5.1	5.1
	Koc, 1/n		5.3, 0.907	5.3, 0.907
	Formation fraction		1	1
Ecotoxicology				
Mandestrobin	Avian acute oral	LDD ₅₀ > 1136 mg a.s./kg bw/day (<i>C. virginianus</i> short-term dietary)	LDD ₅₀ > 1136 mg a.s./kg bw/day (<i>C. virginianus</i> short-term dietary)	LD ₅₀ > 2250 mg a.s./kg bw (<i>C. virginianus</i> acute oral)
Mandestrobin	Chronic invertebrates	NOEC = 0.0056 mg/L (<i>A. bahia</i>)	-	HC ₅ = 0.056 mg a.s./L AF = 3 HC ₅ = 0.060 mg a.s./L AF = 3
Mandestrobin	Algae	E _b C ₅₀ = 0.38 mg a.s./L (R-isomer)	E _r C ₅₀ = 2.2 mg a.s./L (R-isomer)	E _r C ₅₀ = 2.2 mg a.s./L (R-isomer)

S-2200-OR	Algae	E _b C ₅₀ = 0.038 mg/L (10 x toxicity of R-isomer)	-	E _r C ₅₀ = 0.22 mg/L (10 x toxicity of R-isomer)
S-2200-ORC	Algae	E _b C ₅₀ = 0.038 mg/L (10 x toxicity of R-isomer)	-	E _r C ₅₀ = 0.22 mg/L (10 x toxicity of R-isomer)
2-COOH-S-2200	Algae	E _b C ₅₀ = 58 mg/L	-	E _r C ₅₀ = 62 mg/L
5-COOH-S-2200	Algae	E _b C ₅₀ > 54 mg/L	-	E _r C ₅₀ > 54 mg/L
Mandestrobin 40SC	Honeybee acute oral	-	-	LD ₅₀ = 322.04 µg a.s./bee
Mandestrobin 40SC	Honeybee acute contact	-	-	LD ₅₀ > 506.25 µg a.s./bee
Mandestrobin	Honeybee chronic oral (adult)	-	-	LDD ₅₀ > 45 µg a.s./bee/day
Mandestrobin	Honeybee larvae	-	-	NOED = 100 µg a.s./larva/dev. period
Mandestrobin 40SC	Non-target arthropods	-	-	LR/ER ₅₀ > 1000 g a.s./ha (<i>A. rhopalosiphi</i> and <i>T. pyri</i>)

^a EFSA journal 2015;13(5):4100. ^b Registration Report for Mandestrobin 25SC; ANSES, 2021

0.1.3 Regulatory history of the product

Not relevant as the product has not yet been authorised.

0.2 zRMS conclusion

Identity, physical and chemical properties:

~~Missing validation data on the active substances content determination in water and water suspension to cover the KCP 2.8.3.1 suspensibility parameter from the physicochemical section.~~

~~The two year (and three year as well) storage stability study is ongoing. It has to be provided for the evaluation when available. Two-year shelf life is accepted for the PPP.~~

Efficacy:

Sufficient evidence of the efficacy and safety of Mandestrobin 40SC was provided for the North-Eastern EPPO zone. This evaluation is to be confirmed by the relevant Member States belonging to the Maritime and South-Eastern zones.

Toxicology and health risk:

For the aspect human health, the intended use is considered safe.

Due to the classification of the product with Skin Sens. 1; H317, protective gloves, protective clothing and eye protection/face protection should be worn when handling the concentrate.

Residues:

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0,01 mg/kg for mandestrobin in oilseed rape as laid down in Reg. (EU) 2021/1247 is not expected.

According to the data provided by the applicant the current MRL of 0,05 mg/kg for mandestrobin in honey is not expected to be exceeded when the PPP is applied consistently with the intended critical GAP.

The chronic and the short-term intakes of mandestrobin residues are unlikely to present a public health concern. As far as consumer health protection is concerned, PL agrees with the authorization of the intended use.

Fate and behaviour:

In accordance with proposed pattern use, an exposure assessment for active substance and its metabolites and formulation Intuity Plus was submitted.

PECsw. The mitigation measures were proposed, and final decision will be made in ecotoxicological section.

PECgw: In acidic soils ($\text{pH} \leq 6.7$) the formulation could be applied every other year in spring and winter oilseed rape.

In neutral and alkaline soils ($\text{pH} \geq 7.2$) the formulation could be applied every year in spring and winter oilseed rape.

Ecotoxicology:

In accordance with proposed pattern use, the risk assessment for active substance and its metabolites and formulation Intuity Plus was submitted. The safe use of formulation Intuity Plus was proved.

~~To protect the aquatic organisms the mitigation measures were considered: in basic and neutral spoils ($\text{pH} \geq 7.2$) — 20 m VFS + 20 m NSS~~

~~The risk is unacceptable if formulation is applied in winter and spring OSR on acidic soils ($\text{pH} \leq 5.9$).~~

Uses to be considered safe on the basis of EU methodology:

Use 1

Ecotoxicology: Use 1 ~~in basic and neutral soils ($\text{pH} \geq 7.2$)~~

Uses to be considered non-safe on the basis of EU methodology:

~~Ecotoxicology: Use 1 in acidic soils ($\text{pH} \leq 5.9$)~~

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant CMS:

Insert relevant use number from GAP table in Appendix 1 and refer to relevant RR chapter with assessment to be confirmed.

The following text is to be shortened or to be amended as necessary.

All uses/ GAPs are covered by established MRLs except for use in **crop**. An application for amending the MRL has been submitted by **MS** to EFSA **EFSA Project Number** (if applicable).

Appendix 1 ALL intended uses

GAP rev.1.0, date: 2023-02-21

PPP (product name/code): mandestrobin 40SC

Formulation type: SC

Active substance 1: Mandestrobin

Conc. of as 1: 400 g/L

Applicant: XXXX

Professional use: ☒

Zone(s): EU

Non professional use: ☐

Verified by MS: yes

Field of use: Fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops) – Central zone													
1	Central Zone (PL, AT, HU, RO, DE, NL, CZ, SK, SI)	Winter and Spring Oilseed rape	F	<i>Sclerotinia sclerotiorum</i>	Foliar	BBCH 60-69	1	-	a) 0.5 L/ha b) 0.5 L/ha	a) 200 g/ha b) 200 g/ha	100- 300	-	the PHI is covered by the time remaining between application and harvest; The formulation can be applied only on basic and neutral soils (pH ≥ 7.2);
Zonal uses (field or outdoor uses, certain types of protected crops) – Southern zone													
1	Southern Zone (FR)	Winter and spring oilseed rape	F	<i>Sclerotinia sclerotiorum</i>	Foliar	BBCH 60-69	1	-	a) 0.5 L/ha b) 0.5 L/ha	a) 200 g/ha b) 200 g/ha	100- 300	-	the PHI is covered by the time remaining between application and harvest

Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(f)	No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
Remarks columns:	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
			13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions