

REGISTRATION REPORT

Part A

Risk Management

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

(Mandestrobin 40 SC)

Chemical active substance:

Mandestrobin 400 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT POLAND

(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	<ul style="list-style-type: none">- 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 section 1: Letters of Access (paragraph 1.2) missing added- Update of Appendix 4: studies source and owner updated
January 2025	zRMS-PL evaluation
August 2025	Version revised to take into account cMSs’s and applicant’s comments
January 2026	Updated revision of the document

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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application is made for the authorisation for the product Mandestrobin 40SC containing 400 g/l of Mandestrobin, for use as a fungicide for professional use on oilseed rape.

The risk assessment conclusions provided in this document are based on the information, data and assessments provided in Parts B Sections 1-10 and C.

The zRMS is Poland and concerned Member States include Austria, Hungary, Romania, Germany, The Netherlands, Czech Republic, Slovakia and Slovenia.

1.2 Letters of Access

No letter of access is required for this submission, all studies are owned by the applicant, XXXX.

1.3 Justification for submission of tests and studies

The submitted tests and studies have been provided to support the authorisation of a new formulation Mandestrobin 40 SC on oilseed rape.

1.4 Data protection claims

Where data-protection is claimed it is indicated in the reference list within Appendix 4 of this document.

2 Details of the authorization decision

2.1 Product identity

Product code	-
Product name in MS	INTUITY PLUS
Authorization number	XXXX – XX
Function	Fungicide
Applicant	XXXX
Active substance(s) (incl. content)	Mandestrobin, 400 g/l
Formulation type	Suspension concentrate (SC)
Packaging	1 or 2 L HDPE, HDPE/PA, HDPE/F, HDPE/EVOH bottles and 3, 5 or 10 L HDPE, HDPE/PA, HDPE/F, HDPE/EVOH containers; professional

	user
Coformulants of concern for national authorizations	-
Restrictions related to identity	-
Mandatory tank mixtures	-
Recommended tank mixtures	-

2.2 Conclusion

The evaluation of the application for Intuity Plus (Mandestrobin 40SC) resulted in the decision to grant the authorization. All uses applied for were authorised.

Product INTUITY PLUS does not contain any unacceptable co-formulant/ingredient listed in the Commission Regulation (EU) 2021/383 of 3 March 2021 amending Annex III to Regulation (EC) No 1107/2009 at content above 0.1% w/w (- the limit for the acceptable presence of the substances listed in Annex III as unintentional impurity in the finished product).

According to the current knowledge and available information, none of the co-formulants of the plant protection product INTUITY PLUS meet the criteria set out in the Annex to Regulation (EU) 2023/574 for identification of co-formulants that are unacceptable for inclusion in a plant protection products.

2.3 Substances of concern for national monitoring

None



2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Skin Sens. 1 A Aquatic Acute 1, Aquatic Chronic 1
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label** is **formatted bold**:

Hazard pictograms:	  GHS07 GHS09
Signal word:	Warning
Hazard statement(s):	H317 H400 H410
Precautionary statement(s):	P261 , P280, P361 P362 + P364, P302 + P352, P391, P501
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

	Contains: 1,2-benzisothiazolin-3-one
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Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
SPe 1	To protect groundwater do not apply this or any other product containing mandestrobin more than every other year in acidic soils.
SPe 3	To protect aquatic organisms, respect a buffer zone of 1 m to surface water bodies
SPe 3	Basic and neutral soils (pH ≥ 7.2). To protect aquatic organisms, respect a vegetated and an unsprayed buffer zone of 20 m to surface water bodies.
SPe 3	Acidic soils (pH ≤ 5.9). To protect aquatic organisms the use of formulation is not allowed.
SPe 3	To protect non-target plants and non-target arthropods/insects respect an unsprayed buffer zone of 1 m to non-agricultural land.

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPo 2	Wash all protective clothing after use.
SPe 1	To protect groundwater do not apply this or any other product containing mandestrobin more than every other year
SPe 3	To protect aquatic organisms, respect a buffer zone of 1 m to surface water bodies
SPe 3	Basic and neutral soils (pH ≥ 7.2). To protect aquatic organisms, respect a vegetated and an unsprayed buffer zone of 20 m to surface water bodies.
SPe 3	Acidic soils (pH ≤ 5.9). To protect aquatic organisms the use of formulation is not allowed.
SPe 3	To protect non-target plants and non-target arthropods/insects respect an unsprayed buffer zone of 1 m to non-agricultural land.

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

	None
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2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection: Due to classification of the product with Skin Sens. 1A; H317 protective gloves, protective clothing and eye protection/face protection should be worn when mixing and loading.
Worker protection: None required

Integrated pest management (IPM)/sustainable use: None	
Environmental protection	
SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Aviod contamination via drains from farmyards and rows)
Other specific restrictions	
SPe 1	To protect groundwater do not apply this or any other product containing mandestrobin more than every other year
SPe 3	To protect aquatic organisms, respect a buffer zone of 1 m to surface water bodies
SPe 3	Basic and neutral soils (pH \geq 7.2). To protect aquatic organisms, respect a vegetated and an unsprayed buffer zone of 20 m to surface water bodies.
SPe 3	Acidic soils (pH \leq 5.9). To protect aquatic organisms the use of formulation is not allowed.
SPe 3	To protect non-target plants and non-target arthropods/insects respect an unsprayed buffer zone of 1 m to non-agricultural land.

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
	Not applicable

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Spe 1: to protect groundwater, on soils with a pH<7.2, do not apply more than once every two years on winter and spring oilseed rape.

SPe 3: To protect aquatic organisms, respect a buffer zone of 1 m to surface water bodies.

~~SPe 3: Basic and neutral soils (pH \geq 7.2). To protect aquatic organisms, respect a vegetated and an unsprayed buffer zone of 20 m to surface water bodies.~~

~~SPe 3: Acidic soils (pH \leq 5.9). To protect aquatic organisms the use of formulation is not allowed.~~

SPe 3: To protect non-target plants and non-target arthropods/insects respect an unsprayed buffer zone of 1 m to non-agricultural land.

2.6 Intended uses (only NATIONAL accepted GAP)

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

PPP (product name/code): mandestrobin 40SC / INTUITY PLUS

Formulation type: SC

Active substance 1: Mandestrobin

Conc. of as 1: 400 g/L

Applicant: XXXX

Professional use: ☒

Zone(s): Central 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: developmen- tal 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	PL	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 every year only on basic and neutral soils (pH ≥ 7.2) The formulation can be applied other year on acidic soils (pH ≤ 6.7)

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

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 $> 93^{\circ}\text{C}$. 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%

3.2 Efficacy (Part B, Section 3)

The submitted data demonstrates that:

- Mandestrobin 40SC efficacy level can be considered as satisfactory for the intended use.
- Mandestrobin 40SC phytotoxicity level can be considered as negligible for the intended use.
- Mandestrobin 40SC risk of negative impact on yield, quality, multiplication, succeeding and adjacent crops can be considered as negligible.
- The risk of development of resistant *S. sclerotiorum* strains to mandestrobin is moderate. The situation will be followed carefully by an appropriate monitoring.

Mandestrobin 40SC is proposed for use as a systemic contact fungicide with preventative and curative action, for the control of *Sclerotinia sclerotiorum* on winter and spring oilseed rape. The dossier is based on the bridging between the two formulations, Mandestrobin 40SC (mandestrobin 400 g/L) and Mandestrobin 25SC (250 g/L mandestrobin) for the control of *Sclerotinia sclerotiorum* in oilseed rape. As highlighted by the applicant, Mandestrobin 25SC is currently registered in several Member States from Central and Southern zones (Austria, Czech Republic, France, Germany, Hungary, The Netherlands, Poland, Romania, Slovenia and Slovakia) for the control of *Sclerotinia sclerotiorum* in oilseed rape. Mandestrobin 40SC has a proposed maximum individual dose of 0.5 l/ha (to deliver 200 g a.s mandestrobin). This product is applied with a water volume of 100-300 l/ha. Only 1 application may be made per season from BBCH 60 to 69.

The cMS are spread between the Maritime, North-East and South-East EPPO climatic zones. The GAP is identical across all Member States where authorisation is being requested.

Preliminary tests

The comparison of the Mandestrobin 40SC and Mandestrobin 25SC was done at the registered dose rate of 200 g a.s./ha to compare efficacy for differences between the formulations. Both formulations at the same rate of the single application, when considering disease incidence and severity, provided equivalent efficacy in the maritime and north EPPO zones. Therefore, the extrapolation of label claims from Mandestrobin 25SC to Mandestrobin 40SC is acceptable. No data were presented for the South East zone.

Minimum effective dose

The proposed rate of 0.5 L/ha should be considered the minimum effective dose to deliver optimum

control *Sclerotinia sclerotiorum* in oilseed rape, specifically under higher disease pressure conditions.

Efficacy tests

North-East zone

There is sufficient evidence of efficacy and crop safety to support the use of Mandestrobin 40SC at 0.5 L/ha on oilseed rape in the North-East zone.

Resistance

Principles for use of Mandestrobin 40SC given by the applicant are consistent with FRAC guidance. Overall, the risk of resistance development against Mandestrobin 40SC is considered to be moderate if the product is used in adherence with the management strategy and label recommendations.

Yield and Quality parameters

The data summarized confirmed that Mandestrobin 40SC was shown to be an effective product for fungicidal control in oilseed rape. Trials showed that the level of control was equal to or better than the reference standard products tested. In addition, Mandestrobin 40SC at the recommended label rate of 0.5 L/ha showed no adverse but rather positive effects on yield and quality parameters.

Adverse effects on succeeding or adjacent crops

Mandestrobin 40SC was tested on 6 different crops. No effects were observed on germination and vegetative vigour with any of crops tested. Mandestrobin 40SC does not pose a risk to succeeding or adjacent crops and justifies the recommendation of no restrictions on succeeding or adjacent crops when applying Mandestrobin 40SC.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Mandestrobin (sum of isomers), mandestrobin S-isomer and mandestrobin R-isomer are determined in the plant protection product by HPLC-UV. The method is fully validated according to the requirements of SANCO/3030/99 rev. 5.

The relevant impurities ethylbenzene and xylene isomers are determined in the plant protection product by GC-MS. The method is fully validated according to the requirements of SANCO/3030/99 rev. 5.

3.3.2 Analytical methods for residues


Analytical methods are available in the DAR and this dossier which are validated for the analysis of residues of mandestrobin for the generation of pre-authorisation data.

Analytical methods are available in the DAR and this dossier which are validated for the determination of residues of mandestrobin in plants (acceptable primary, confirmatory and ILVs in high water, high acid, high oil, high protein/starch (dry) crops), soil (acceptable primary and confirmatory method), water (acceptable primary and confirmatory method in surface water and in drinking water) and air (acceptable primary and confirmatory method). Analytical methods for the determination of residues of mandestrobin in animal matrices are not necessary as no residues are to be expected in these matrices and no MRLs are proposed (MRLs set at the LOQ level). There is no residue definition for mandestrobin in body fluids and tissues therefore no methods are required.

zRMS agrees with the above consideration of the applicant.

3.4 Mammalian toxicology (Part B, Section 6)

3.4.1 Acute toxicity

Type of test, species, model system (Guideline)	Result of calculation method acc. to the criteria in CLP Reg.	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat (calculation method)	> 2000 mg/kg	Yes the results of calculation method according to CLP Reg. is accepted	None	A 2.2 (KCP 7.1.1)
LD ₅₀ dermal, rat (calculation method)	> 2000 mg/kg		None	A 2.3 (KCP 7.1.2)
LC ₅₀ inhalation, rat (calculation method)	> 5 mg/L		None	A 2.4 (KCP 7.1.3)
Skin irritation (calculation method)	Non-irritant		None	A 2.5 (KCP 7.1.4)
Eye irritation (calculation method)	Non-irritant		None	A 2.6 (KCP 7.1.5)
Skin sensitisation (calculation method)	Sensitising		Skin Sens. 1  H317: May cause an allergic skin reaction	A 2.7 (KCP 7.1.6)
Supplementary studies for combinations of plant protection products	-	-	-	-

No unacceptable risk for operators, workers, residents and bystanders was identified when the product is used as intended. 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 mixing and loading.

3.4.2 Operator exposure

The predicted operator exposure following EFSA guidance 2022 is within acceptable limits for the intended use.

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal			
Number of applications and application rate: 1 x 0.2105 kg a.s./ha Dermal absorption (concentrate): 10 % Dermal absorption (in-use dilution): 50 %			
Mandestrobin	M/L: None App: None	0.1	61.9
	M/L: Workwear App: Workwear	0.08	40.1

3.4.3 Worker exposure

The predicted worker exposure following EFSA guidance 2022 is within acceptable limits for the intended use.

Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: NA Body weight: 60 kg TC (potential): 12500 cm ² /h TC (workwear (arms, body and legs covered)): 1400 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm ² /h TC (gloves): NA cm ² /h			
Number of applications & application rate: 1 x 0.2105 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Potential	0.1	69.2	0
Workwear	0.01	7.8	0
Workwear and gloves	0.01	6.9	0

3.4.4 Bystander and resident exposure

No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.

At this time, no acute AOEL has been set for mandestrobin. Consequently, no acute (bystander) risk assessment has been provided.

The predicted resident exposure following EFSA guidance 2022 is within acceptable limits for the intended use.

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 100 l			
Number of applications and application rate: 1 x 0.2105 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Resident child Body weight: 10 kg	Drift (75th perc.)	0.03	15
	Vapour (75th perc.)	0.0008	0.4
	Deposits (75th perc.)	0.002	0.9
	Re-entry (75th perc.)	0.02	9.3
	Sum (mean)	0.03	16.7
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.007	3.6
	Vapour (75th perc.)	0.0003	0.1
	Deposits (75th perc.)	0.0007	0.4
	Re-entry (75th perc.)	0.01	5.2
	Sum (mean)	0.01	6.2

3.5 Residues and consumer exposure (Part B, Section 7)

zRMS:

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. See also the Section B7.

3.5.1 Residues

A total of 12 supervised trials are available on oilseed rape that are supportive of the proposed GAP for Mandestrobin 40SC. The proposed GAP for Mandestrobin 40SC specifies applications up to BBCH 69, whereas the representative use in the DAR specified applications up to BBCH 67, since these are both within the same principle growth stage for oilseed rape (BBCH 67: decline of flowering, BBCH 69: end of flowering), then the trials conducted to support the DAR are considered supportive for the use of Mandestrobin 40SC.

According to the available data, no exceedance of the MRL will occur. The uses are considered acceptable.

3.5.2 Consumer exposure

The residue endpoints calculated in this submission, alongside the input values from the most recent EF-

SA Reasoned Opinions (EFSA, 2018a and 2018b) and all current EU MRLs for mandestrobin, have been used as input values for the consumer risk assessment.

TMDI (% ADI) according to EFSA PRIMo	See IEDI
IEDI (% ADI) according to EFSA PRIMo	2% (based on PT general diet)
IESTI (% ARfD) according to EFSA PRIMo	Not required
NTMDI (% ADI)	Not required
NEDI (% ADI)	Not required
NESTI (% ARfD)	Not required

The proposed uses of mandestrobin in the formulation Mandestrobin 40SC do not represent unacceptable acute or chronic risks for the consumer.

zRMS agrees with the above consideration of the applicant.

3.6 Environmental fate and behaviour (Part B, Section 8)

3.6.1 Predicted environmental concentrations in soil (PEC_{soil})

No deviation from EFSA (2015) agreed endpoints for mandestrobin, 5-COOH-S-2200 and 2-COOH-S-2200. Metabolite DX-CA-S-2200 observed in the additional aerobic degradation study on acidic soils is taken into account for PEC_{soil} calculations. A worst case DT₅₀ value of 18.5 days from a preliminary study (Kodaka, et al, 2016), was used for DX-CA-S-2200 in the Southern zone Registration Report for S-2200 (Intuity/Sisam) (ANSES, 2021). Therefore this is considered as the current EU endpoint, even though shorter DT₅₀ values were obtained in the definitive study (Lamond, 2017).

PEC_{soil} values were used for the ecotoxicological risk assessment.

3.6.2 Predicted environmental concentrations in groundwater (PEC_{gw})

A new aerobic degradation study on mandestrobin in acidic soils under laboratory conditions (Gilbert, 2016) has been performed since the EFSA conclusion. As this study identified DX-CA-S-2200 as requiring risk assessment, further studies were undertaken to obtain DT₅₀ (Lamond, 2017) and Koc (Kang, 2017) values.

Compound	Parameter	EFSA conclusion (2014)	Current agreed endpoint in the Central-zone ^a	Endpoint used in this assessment ^b
mandestrobin	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	DT ₅₀ [d]	36.91	41.75	41.75
	Formation fraction	0.502	0.424	0.424
DX-CA-S-2200	DT ₅₀ [d]	Not observed	6.0	5.1
	Koc, l/n		10, 1	5.3, 0.907
	Formation fraction		1	1

^aRegistration Report for S-2200 25SC (Intuity/Sisam), AGES, 2016

^bRegistration Report for S-2200 25SC (Intuity/Sisam), ANSES, 2021

Models used for PEC_{gw} calculations include FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4, FOCUS MACRO v5.5.4

In basic conditions, mandestrobin was always < 0.1 µg/L and the non-relevant metabolites, 5-COOH-S-2200 and 2-COOH-S-2200 were always <0.75 µg/L following annual application. In acidic soil conditions, the non-relevant metabolites, 5-COOH-S-2200 and 2-COOH-S-2200 were always <0.1 µg/L following annual application. However, biennial application simulations were necessary to achieve PEC_{GW} values of < 0.1 µg/L for mandestrobin and DX-CA-S-2200 in all relevant scenarios (Jokioinen is not considered a relevant scenario in CEU conditions).

In acidic soils (pH ≤ 6.7 5.9), the formulation could be applied every other year in spring and winter oilseed rape.

3.6.3 Predicted environmental concentrations in surface water (PEC_{sw})

A new aerobic degradation study on mandestrobin in acidic soils under laboratory conditions (Gilbert, 2016) has been performed since the EFSA conclusion. As this study identified DX-CA-S-2200 as requiring risk assessment, further studies were undertaken to obtain DT₅₀ (Lamond, 2017) and Koc (Kang, 2017) values.

Compound	Parameter	EFSA conclusion (2014)	Current agreed endpoint in the Central zone ^a	Endpoint used in this assessment ^b
mandestrobin	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	DT ₅₀ [d]	36.91	41.75	41.75
DX-CA-S-2200	DT ₅₀ [d]	Not observed	Not considered	5.1
	Koc			5.3
	% Formation soil/water/sediment			8.3/-/-

^a Registration Report for S-2200 25SC (Intuity/Sisam), AGES, 2016

^b Registration Report for S-2200 25SC (Intuity/Sisam), ANSES, 2021

Models used for PEC_{sw} calculations include FOCUS STEPS 1-2 v 3.2 SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v 5.5.4, FOCUS TOXSWA v4.4.3.

Additionally, the PEC_{sw} assessment in Step 4, including the mitigation measures was provided.

PEC_{sw} values were used for the ecotoxicological risk assessment.

3.6.4 Predicted environmental concentrations in air (PEC_{air})

The vapour pressure at 20 °C of the active substance mandestrobin is < 10⁻⁵ Pa (3.36 x 10⁻⁸ Pa). Hence the active substance mandestrobin is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance mandestrobin due to volatilization with subsequent deposition is considered negligible.

3.7 Ecotoxicology (Part B, Section 9)

3.7.1 Effects on terrestrial vertebrates

An acceptable acute and long-term (reproductive) dietary risk to birds and mammals is concluded based on screening level assessments. Furthermore, an acceptable risk to birds and mammals from exposure via contaminated drinking water is concluded.

An assessment of the risk of secondary poisoning to earthworm-eating birds and mammals was required for the active substance mandestrobin, and an assessment of the risk to fish-eating birds and mammals was required for mandestrobin and metabolites S-2200-OR and S-2200-ORC. An acceptable risk to earthworm- and fish-eating birds and mammals is demonstrated for mandestrobin and both metabolites.

3.7.2 Effects on aquatic species

~~For the active substance mandestrobin, an acceptable risk to aquatic organisms is demonstrated for uses in both winter and spring oilseed rape based on FOCUS Step 3 PEC_{sw} modelling for the worst case uses in acidic soils.~~

~~The risk assessment for aquatic organisms is based on EU agreed endpoints. The new studies (chronic toxicity for aquatic invertebrates) were submitted, but not evaluated as they were conducted with active substance as a test item.~~

~~**Basic and neutral soils (pH ≥ 7.2).** For the active substance mandestrobin, an acceptable risk to aquatic organisms is demonstrated for uses in both winter and spring oilseed rape based on FOCUS Step 4 PEC_{sw} modelling. The risk mitigation measures are required: 20 m VFS + 20 m NSS.~~

~~**Acidic soils (pH ≤ 5.9).** The risk is unacceptable if formulation is applied in winter and spring OSR.~~

The new studies on active substance were submitted and evaluated as they were necessary for risk refinement (Tier 2B).

Based on accepted new endpoint (SSD-RAC) for active substance mandestrobin, an acceptable risk to aquatic organisms is demonstrated for uses in both winter and spring oilseed rape based on FOCUS Step 3 PEC_{sw} assessment for the worst-case uses in acidic soils.

For the metabolites, an acceptable risk for uses in both winter and spring oilseed rape could be demonstrated based on FOCUS Step 1 and FOCUS Step 2 PEC_{sw} modelling.

In addition, a risk assessment based on PEC_{sw} values calculated for the formulation arising from the drift loading into surface water indicated an acceptable risk.

Therefore, overall, an acceptable risk to aquatic organisms is demonstrated without a requirement for risk mitigation.

3.7.3 Effects on bees

Overall, an acceptable risk to honeybees is demonstrated based on a SANCO risk assessment (acute risk to adults) and a risk assessment based on the EPPO scheme (chronic risk to adult honeybees and honeybee larvae).

In addition, acute oral and contact toxicity data on bumblebees were submitted, but not evaluated as they were conducted with active substance as a test item.

3.7.4 Effects on other arthropod species other than bees

A first-tier risk assessment demonstrates an acceptable in-field and off-field risk to non-target arthropods for the proposed use of Mandestrobin 40SC in oilseed rape with no requirement for risk mitigation.

3.7.5 Effects on soil organisms

An acceptable risk to non-target soil meso- and macrofauna and soil microorganisms is demonstrated for the proposed use of Mandestrobin 40SC in oilseed rape.

3.7.6 Effects on non-target terrestrial plants

Vegetative vigour and seedling emergence limit tests with the formulation S-2200 25 SC indicated no effects greater than 50% at 200 g a.s./ha. As this rate corresponds to the maximum proposed application rate of 200 g a.s./ha, an acceptable risk to non-target terrestrial plants for the proposed use of Mandestrobin 40SC is concluded.

3.7.7 Effects on other terrestrial organisms (Flora and Fauna)

Not required.

3.8 Relevance of metabolites (Part B, Section 10)

The relevance of the groundwater metabolite 2-COOH-S-2200 has already been assessed and the assessment agreed at EU level (see EFSA Journal 2015;13(5):4100 and final addendum to the DAR, March 2015), and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR). 2-COOH-S-2200 is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000.

The relevance of the groundwater metabolite 5-COOH-S-2200 has already been assessed and the assessment agreed at EU level (see EFSA Journal 2015;13(5):4100 and final addendum to the DAR, March 2015), and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR). 5-COOH-S-2200 is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000.

The relevance of the groundwater metabolite DX-CA-S-2200 has not been assessed at EU level.

When considering the mitigation measures needed for mandestrobin to pass the risk assessment for groundwater contamination (application every other year on winter and summer oilseed rape, for soils with $pH\ CaCl_2 < 7.2$), the maximum PEC_{gw} for DX-CA-S-2200 are below 0.1 µg/L. Therefore a relevance assessment according to SANCO/221/2000 is not required.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

The active substance mandestrobin is not approved as a candidate for substitution, therefore a comparative assessment is not foreseen.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

Physicochemical 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.~~

Appendix 1 Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

Appendix 2 Copy of the product label

MS assessor to present a copy of the approved product label for MS country.

Appendix 3 Letter of Access

The applicant is the data-owner and no letter of access is required.

Appendix 4 Lists of data considered for national authorization

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
XXXX	XXXX	XXX	XXXX	XX	XX	XXXX	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
XXXX	XXXX	XXX	XXXX	XX	XX	XXXX	XXXX

* XXXX.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
XXXX	XXXX	XXX	XXXX	XX	XX	XXXX	XXXX

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of first authorization>	Owner