

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: FGG01

Product name: Lozzare Pro, Miller Pro, Palator Pro

Chemical active substance:

Boscalid, 500 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Article 33 application for a new product registration)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: 08/05/2024

MS Finalisation date: 12/2024 03/2025

FGG01 / LOZZARE PRO
Part B – Section 0 - Core Assessment
Applicant version

Version history

When	What
08 May 2024	V0 – Version from applicant for submission to z-RMS Poland in the frame of the PPP Authorization according to Article 33 of Regulation (EC) No 1107/2009.
December 2024	ZRMs evaluated dRR submitted by Applicant
March 2025	ZRMs made changes according to the commenting period

Table of Contents

0	Product background, regulatory context and GAP information	4
0.1	Introduction.....	4
0.1.1	Reason for application	4
0.1.2	Details of zRMS(s) and concerned MS	5
0.1.3	Regulatory history of the active	5
0.1.4	Regulatory history of the product	7
0.2	zRMS conclusion.....	7
Appendix 1	ALL intended uses	9

0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application is for a first registration of the product LOZZARE PRO (FGG01) in grapevine (wine and table), oilseed rape (winter and spring) and fresh beans and peas to member states Austria, Belgium, Czech Republic, Hungary, Netherlands, Poland (zRMS), Romania, Slovakia and Slovenia. A similar application is submitted concurrently to the southern zone member states Bulgaria, Croatia, France, Greece (zRMS), Italy, Portugal and Spain, with additional uses in flax, pome fruit and stone fruit and post-harvest use in kiwi.

The product is a water dispersible granules (WG) formulated fungicide containing 500 g/kg of the active substance boscalid.

This application follows the data requirements for plant protection products laid down in Regulation (EC) No. 284/2013¹. A summary of the data and risk assessments is provided in dRR format and prepared according to SANCO/6895/2009 rev 2.2². A full risk assessment according to Uniform Principles is provided to demonstrate the product is safe for the user, consumer and the environment.

Details of the intended uses are provided in the GAP table in Appendix 1. This submission presents new data where necessary to support the product, as well as up to date risk assessments based on current EU agreed endpoints for the active substance.

Please refer to Part C for confidential information on the equivalence status of the active substance used in the product.

Access to active substance data is via unprotected data.

¹ Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

² SANCO/6895/2009 rev 2.2, 26 January 2018. Technical guidelines on the presentation and evaluation of plant protection product dossiers in the format of a (draft) Registration Report

0.1.2 Details of zRMS(s) and concerned MS

Poland is the zonal RMS; Austria, Belgium, Czech Republic, Hungary, Netherlands, Romania and Slovakia are concerned member states. A concurrent application is being made to the southern zone with zonal RMS Greece and France, Italy, Portugal and Spain as concerned member states.

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)
Northern zone	Not applicable	Not applicable
Central zone	Poland This submission is for registration of a new product	Austria, Belgium, Czech Republic, Hungary, Netherlands, Romania, Slovakia, Slovenia This submission is for registration of a new product
Southern zone	Greece This submission is for registration of a new product	Bulgaria, Croatia, France, Italy, Portugal, Spain This submission is for registration of a new product

0.1.3 Regulatory history of the active

Table 0.1-2: Summary of regulatory history of boscalid, CAS No: 188425-85-6

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2008/44/EC Approval period extended to 15 April 2026 by Commission Implementing Regulation (EU) no. 2023/918 of 04 May 2023.
RMS	Slovakia (Co-RMS France)
Date of Approval of Active Substance	01.08.2008
Current expiration of approval	15.04.2026
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 operator safety,
- the long term risk to birds and soil organisms,
- the risk of accumulation in soil if the substance is used in perennial crops or in succeeding crops in

FGG01 / LOZZARE PRO
Part B – Section 0 - Core Assessment
Applicant version

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

The SANCO report for boscalid (SANCO/3919/2007-rev.5) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. No EFSA Scientific Report was requested by the Commission for boscalid.

Boscalid is currently under EU review for renewal. The RAR has been published in November 2018. Public consultation was completed in March 2019. Assessments following the clock stop on endocrine disruption properties has been completed. The review is currently under assessment by EFSA.

Table 0.1-3: Information on minimum purity of boscalid

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 *, **
≥ 960 g/kg	The minimum purity of Boscalid used in the product FGG01 is 980 g/kg. Equivalence report available: Y RMS: Technical equivalence was confirmed by Czech Republic in November 2020 (for Source n°1) and by France and Spain in 2022 (for Source n°2)

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

**. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

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

Endpoint	Active Substance	
	EU agreed endpoint from SANCO/3919/2007-rev.5	Endpoint used*
PECsoil DT ₅₀ in soil	314.5 (Maximum at 15°C, field study, Q ₁₀ = 2.2)	340.5 (Maximum at 15°C, field study, Q ₁₀ = 2.58)
Ecotoxicology, effects on aquatic organisms	Algae: E _r C ₅₀ = 3.75 mg a.s./L _{mm} E _y C ₅₀ = 1.34 mg a.s./L _{mm}	Algae: E _r C ₅₀ = 1.960 mg a.s./L _{nom} ^a
Ecotoxicology, effects on bees	Honeybees: Acute oral LD ₅₀ > 100 µg a.s./bee Acute contact LD ₅₀ > 100 µg a.s./bee	Honeybees: Acute oral LD ₅₀ > 200.7 µg a.s./bee ^a Acute contact LD ₅₀ > 249.3 µg a.s./bee ^a Chronic adult LDD ₁₀ = 38.2 µg a.s./bee/d ^a Larvae NOED = 31.84 µg a.s./larva ^a Bumble bees: Acute oral LD ₅₀ > 544.4 µg a.s./bee ^a Acute contact LD ₅₀ > 497 µg a.s./bee ^a
Ecotoxicology, effects on arthropods other than bees	<i>Aphidius rhopalosiphi</i> LR ₅₀ / ER ₅₀ > 1800	<i>Aphidius rhopalosiphi</i> LR ₅₀ / ER ₅₀ >

FGG01 / LOZZARE PRO
 Part B – Section 0 - Core Assessment
 Applicant version

Endpoint	Active Substance	
	EU agreed endpoint from SANCO/3919/2007-rev.5	Endpoint used*
	g a.s./ha ^b <i>Typhlodromus pyri</i> LR ₅₀ > 1800 g a.s./ha ^b	4108.4 g a.s./ha ^a <i>Typhlodromus pyri</i> LR ₅₀ > 853.7 g a.s./ha ^a , ER ₅₀ > 513.6 g a.s./ha ^a
Ecotoxicology, effects on earthworms and other non-target soil organisms (meso- and macrofauna)	<i>Eisenia fetida</i> NOEC _{corr.} = 1.197 mg a.s./kg dw soil ^b	<i>Eisenia fetida</i> EC _{10 corr.} = 10.58 mg a.s./kg dw soil ^a <i>Folsomia candida</i> EC _{10 corr.} = 18.67 mg a.s./kg dw soil ^a <i>Hypoaspis aculeifer</i> NOEC _{corr.} = 256.8 mg a.s./kg dw soil ^a
Ecotoxicology, effects on soil microorganisms	< 25% effects at 8 mg a.s./kg d.w. soil ^b	< 25% effects at 4.11 mg/kg d.w. soil ^a
Ecotoxicology, effects on non-target terrestrial plants	Vegetative vigour: Maximum 8.8% effect at 3.6 kg/ha ^b	Vegetative vigour: NOER = 1000 g a.s./ha ^a Seedling emergence: NOER = 1000 g a.s./ha ^a

* Since EU approval new data has been generated. Refer to the respective section documents for details.

a Studies performed with product FGG01

b Studies performed with representative product from Annex I inclusion

0.1.4 Regulatory history of the product

Not relevant as the product has not yet been authorised.

The product was not already evaluated as the 'representative formulation' (same uses and same GAPs) during the EU review of the active substance.

0.2 zRMS conclusion

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

Efficacy section: all uses
 Residues section: 1, 3-11; 2 for decisions at Member State level
 Fate and behaviour: all uses
 Ecotox section: all uses

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

Efficacy section: none
 Residues section: none
 Fate and behaviour: none
 Ecotox section: none

Uses for which safety has been established only following additional risk mitigation at a national (non-

FGG01 / LOZZARE PRO
Part B – Section 0 - Core Assessment
Applicant version

core) level or for which the evaluation is to be confirmed by relevant cMS: **none**

All accepted uses/ GAPs are covered by established MRLs.

Efficacy section:

Decision about possibility of authorisation of FGG01 was left to cMS (on the basis on submitted and assessed data and bridging approach from st. ref. product – CANTUS). **SI not accepted use against *Botrytis cinerea* and *Uncinula necator* on grapevines. SK – accepted use on winter oilseed rape against ALTEBA, SCLESC and LEPTMA on oilseed rape. AT-accepted information in GAP – to be confirmed by cMS.** In Poland, FGG01 can be granted on winter oilseed rape against SCLESC and LEPTMA and grapevines against Powdery mildew. All minor uses claimed in GAP table for authorisation in line to Article 51 are accepted. Use on peas and beans against BOTRSP and spring oilseed rape against SCLESC and LEPTMA is not accepted (only authorisation in line to Article 51 is possible).

Mammalian toxicology:

LOZZARE PRO is unclassified.. No risk for the operator and worker using FGG01 / LOZZARE PRO is anticipated for all intended uses should be use work wear (arms, body and legs covered) M/L and risk for residents and bystanders with buffer zone 2-3m except for viticulture where the buffer zone is 5m.

Metabolism and residues:

Acceptance of use No2 left to decisions at Member State level. In Poland this use was accepted.

Legumes: accepted fresh with pods **only and without pods.**

Noticed data gaps are:

- **Residue trials for beans or peas without pods.**

Fate and behaviour:

Boscalid is not predicted to leach into ground water above the critical 0.1 µg/L threshold following a 26-year period of application to vines, winter and spring oilseed rape, beans and peas. The results indicate that any contamination of groundwater at concentrations relevant for the environment and for consumer exposure by the active substance boscalid must not be expected follow-ing the GAP proposed uses of LOZZARE PRO (FGG01)..

FGG01 / LOZZARE PRO
 Part B – Section 0 - Core Assessment
 Applicant version

Appendix 1 ALL intended uses

GAP rev. 1, date: 2024-May -08

PPP (product name/code): LOZZARE PRO / FGG01
 Active substance 1: Boscalid
 Safener: None
 Synergist: None
 Applicant: UPL Holdings Coöperatief U.A.
 Zone(s): Central
 Verified by MS: **yes**

Formulation type: Water dispersible granules (WG)
 Conc. of as 1: 500 g/kg
 Conc. of safener: -
 Conc. of synergist: -
 Professional use: ☒
 Non professional use: ☐

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 product / ha a) max. rate per appl. b) max. total rate per crop/season	g 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)													
1	AT, BE, CZ, SI	Grapevine, wine & table	F	<i>Botrytis cinerea</i> (BOTRCI)	Spraying overall	BBCH 60-85	a) 1 per use b) 1 per crop / season	-	a) 1.0 kg/ha b) 1.0 kg/ha	a) 500 g/ha b) 500 g/ha	100- 1000	21	0.72 kg product / 10000 m² LWA (optional) Eff. section: to be confirmed by cMS.
2	AT, BE, CZ, SI, PL	Grapevine, wine & table	F	<i>Uncinula necator</i> , Powdery mildew (UNCINE)	Spraying overall	BBCH 15-81	a) 3 per use b) 3 per crop / season	10-14	a) 0.2 kg/ha b) 0.6 kg/ha	a) 100 g/ha b) 300 g/ha	100- 1000	21	0.14 kg product / 10000 m² LWA 0.02 kg/100 L (optional)

FGG01 / LOZZARE PRO
Part B – Section 0 - Core Assessment
Applicant version

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, 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 product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
													Eff. section: to be confirmed by cMS. Use accepted in PL Metabolism and residues: Acceptance of use No2 left to decisions at Member State level. In Poland this use was accepted..
3	AT, BE, CZ, HU, NL, PL, RO, SK	Oilseed rape (winter and spring)	F	<i>Sclerotinia sclerotiorum</i> (SCLESC)	Spraying overall	BBCH 57-69	a) 1 per use b) 1 per crop / season	-	a) 0.5 kg/ha b) 0.5 kg/ha	a) 250 g/ha b) 250 g/ha	100-300	35	Eff. section: to be confirmed by cMS. Use accepted in PL on winter oilseed rape..
4	AT, BE, CZ, NL, SK, HU, RO	Oilseed rape (winter and spring)	F	<i>Alternaria</i> species (ALTESP)	Spraying overall	BBCH 57-69	a) 1 per use b) 1 per crop / season	-	a) 0.5 kg/ha b) 0.5 kg/ha	a) 250 g/ha b) 250 g/ha	100-300	35	Eff. section: to be confirmed by cMS.
5	HU, PL, RO, SK, AT, CZ	Oilseed rape (winter and spring)	F	<i>Leptosperia maculans</i> (LEPTMA)	Spraying overall	BBCH 13-57	a) 1 per use b) 1 per crop / season	-	a) 0.5 kg/ha b) 0.5 kg/ha	a) 250 g/ha b) 250 g/ha	100-300	35	Eff. section: to be confirmed by cMS. Use accepted in PL on winter oilseed rape.
6	AT, BE, CZ, NL, PL	Beans and peas (fresh) with pods 0260010 0260030 and without pods 026020	F	<i>Botrytis</i> (BOTRSP)	Spraying overall	BBCH 60-69	a) 2 per use b) 2 per crop / season	7	a) 1.0 kg/ha b) 2.0 kg/ha	a) 500 g/ha b) 1000 g/ha	150-600	7	Eff. section: to be confirmed by cMS. Not accepted in PL in line to Art. 33 Metabolism and residues: Accepted fresh with

FGG01 / LOZZARE PRO
Part B – Section 0 - Core Assessment
Applicant version

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, 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 product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
		026040											Pods only and without pods (legumes)
7	AT, BE, CZ	Beans and peas (fresh) with pods 0260010 0260030 and without pods 026020 026040	F	<i>Sclerotinia</i> (SCLESP)	Spraying overall	BBCH 60-69	a) 2 per use b) 2 per crop / season	7	a) 1.0 kg/ha b) 2.0 kg/ha	a) 500 g/ha b) 1000 g/ha	150- 600	7	Eff. section: to be confirmed by cMS. residues: Accepted fresh with pods only and without pods (legumes)
Minor uses according to Article 51 (zonal uses)													
8	PL	Spring rape gold of pleasure, winter turnip rape, mustard, sunflower, poppy linseed, flax, hemp, borage	F	<i>Alternaria</i> species (ALTESP) <i>Sclerotinia sclerotiorum</i> (SCLESC)	Spraying overall	BBCH 57-69	a) 1 per use b) 1 per crop / season	-	a) 0.5 kg/ha b) 0.5 kg/ha	a) 250 g/ha b) 250 g/ha	100- 300	35	Eff. use accepted.
9	PL	Spring rape gold of pleasure, winter turnip rape, mustard, poppy linseed, flax, hemp, borage	F	<i>Leptosperia maculans</i> (LEPTMA)	Spraying overall	BBCH 13-57	a) 1 per use b) 1 per crop / season	-	a) 0.5 kg/ha b) 0.5 kg/ha	a) 250 g/ha b) 250 g/ha	100- 300	35	Eff. use accepted.

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		
	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)	8	The maximum number of application possible under practical conditions of use must be provided.
	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	9	Minimum interval (in days) between applications of the same product
	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.	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
			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	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions