REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: BAS 762 02 F

Product name(s): Revydas / Brelyco

Chemical active substances:

Mefentrifluconazole, 100 g/L
Boscalid, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: BASF

Submission date: April 2021

MS Finalisation date: November 2021 (initial Core Assessment)
April 2022 (final Core Assessment)

Version history

When	What
April 2021	Applicant initial dRR
November 2021	Initial assessment by the zRMS The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through and shaded for transparency~~.
April 2022	Final report (Core Assessment after the commenting period) Additional information/assessments included by the zRMS in the report in response to comments recieved from the cMS and the Applicant are highlighted in yellow, while not agreed use pattern is ~~struck through and shaded~~.

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

The application was submitted for the approval of BAS 762 02 F, a new SC formulation containing 100 g/L mefentrifluconazole and 200 g/L boscalid, for the use as fungicide in oil seed rape, sunflower and cereals.

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013, and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

Northern zone	Lithuania	Denmark, Estonia, Finland, Latvia, Lithuania, Sweden
Central zone	Poland	Austria, Belgium, Czechia, Germany, Hungary, Ireland, Poland, Romania, Slovenia, Slovakia
Southern zone	France	Bulgaria, Croatia, France
Inter-zonal	-	-

0.1.3 Regulatory history of the active(s)

0.1.3.1 Mefentrifluconazole

Table 0.1-2: Summary of regulatory history of CAS No: 1417782-03-6

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 2019/337
RMS	UK
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	20.03.2019
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
Current expiration of approval	20.03.2029
Low risk substance or Candidate for Substitution?	N/A

Critical area of concern identified: none.

An EFSA Scientific Report was made available on July 2018.

Table 0.1-3: Information on minimum purity of mefentrifluconazole

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 *, **
Minimum purity: 970 g/kg	970 g/kg according to SANTE/11612/2018 Rev. 3; 980 g/kg based on revision 2 of the equivalence report by Austria

* 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	Mefentrifluconazole		zRMS comments
	EU agreed endpoint from EFSA Conclusion (2018)	Endpoint used	
Environmental fate			
PEC_{sw} calculation method for metabolites from aquatic photolysis	During the evaluation of the active substance at EU level STEP 3 PEC_{sw} was estimated for the metabolites M750F005, M750F006, M750F007, and M750F008 based on PEC_{sw} of mefentrifluconazole, while only STEP 1-2 PEC_{sed} values were reported [*EFSA, 2018*]. In current dossier the applicant submitted STEP 3 PEC_{sw} and PEC_{sed} values for these metabolites calculated according to the FOCUS surface water generic guidance [*FOCUS 2015*].		Step 3 simulation for metabolites were not validated by the zRMS as being not necessary to finalise the aquatic risk assessment.
Ecotoxicology [1)]			
Aquatic organisms			
Fish acute, 96 h *P. promelas*	--	LC_{50} = 0.65 mg a.s./L	Study not validated by the zRMS since sufficient information was available from the EU review and generation of the new active substance data should be avoided at the zonal level.

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data)

[1)] For justification for using new/revised ecotoxicological endpoints please refer to the respective paragraphs in Part B, Section 9.

Endpoint	Metabolite M750F005 (Reg. No. 6003433		zRMS comments
	EU agreed endpoint from EFSA Conclusion (2018)	Endpoint used*	
Ecotoxicology [1)]			
Aquatic organisms			
Fish acute, 96 h *O. mykiss*	--	LC_{50} > 5 mg a.s./L_{nom}	Study evaluated and accepted by the zRMS (no information on acute toxicity of M750F005 to fish was available from the EU review)

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data)

[1)] For justification for using new/revised ecotoxicological endpoints please refer to the respective paragraphs in Part B, Section 9.

0.1.3.2 Boscalid

Table 0.1-4: Summary of regulatory history of CAS No: 188425-85-6

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2008/44/EC and Commission Implementing Regulation (EU) No 540/2011 amended by Regulation (EU) 2020/869
RMS	Slovakia
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.08.2008
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31.01.2009
Date of final Commission (re-registration) deadline (Step 2)	31.01.2010
Current expiration of approval	31.07.~~2021~~ 2022
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 crop rotation.

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.

Table 0.1-5: 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	Not relevant ~~n/a~~

* 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	Boscalid		zRMS comments
	EU agreed endpoint from Monograph (2002)	Endpoint used*	
Environmental Fate [1)]			
DT_{50} in soil for PEC_{gw} and PEC_{sw} (d)	139 (arithmetic mean)	130 (geometric mean)	Deviation agreed for surface water calculations, please refer to Core Assessment, Part B, Section 8 for details. For groundwater modelling the zRMS performed additional simulations using longer DT_{50}.
Ecotoxicology [2)]			
Birds			
Acute oral, *Colinus virginianus*	LD_{50} > 2000 mg a.s./kg b.w.	$LD_{50\ (extrapolated)}$ = 3776 mg/kg bw	Deviation agreed, please refer to Core Assessment, Part B, Section 9 for details.
Terrestric			
Honey bee chronic adult, *Apis mellifera*	--	NOED (10 d) ≥ 150.9 µg/bee	Endpoint as such not validated, but already agreed during the ongoing renewal process of boscalid. However, not used in the risk assessment.
Honey bee chronic larvae, *Apis mellifera*	--	NOED (22 d) ≥ 50.0 µg/larva	Study not evaluated, so endpoint not agreed.
Earthworm, chronic *Eisenia fetida*	--	NOEC = 25 mg/kg dry soil $NOEC_{CORR}$ = 12.5 mg/kg dry soil ° EC_{10} = 37 mg/kg dry soil $EC_{10\ CORR}$ = 18.5 mg/kg dry soil °	Endpoint as such not validated, but already agreed during the ongoing renewal process of boscalid. However, not used in the risk assessment.
Soil meso- and macrofauna chronic, *Folsomia candida*	--	NOEC ≥ 1000 mg/kg dry soil $NOEC_{CORR}$ ≥ 500 mg/kg dry soil	Endpoint as such not validated, but already agreed during the ongoing renewal process of boscalid. However, not used in the risk assessment.

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data)

° $NOEC_{CORR}$ /$EC_{10\ CORR}$ reflects that the endpoint has been divided by a factor of 2 due to the log P_{ow}.

1) For justifications for using new / revised modeling endpoints please refer to the respective paragraphs in Part B, Section 8.

2) For justifications for using new / revised ecotoxicological endpoints please refer to the respective paragraphs in Part B, Section 9.

0.1.4 Regulatory history of the product

Not relevant as the product has not yet been authorised.

0.2 zRMS conclusion

Authorisation of the product BAS 762 02 F / Revydas / Brelyco is recommended to the control of Sclerotinia sclerotiorum, Alternaria spp., Erysiphe cruciferarum, Neopseudocercosporella brassicae in oilseed rape; Diaporthe helianthi, Plenodomus lindquistii, Sclerotinia sclerotiorum, Alternaria helianthi in sunflower; Pseudocercosporella herpotrichoides, Septoria tritici and Blumeria graminis in wheat. For some uses, due to no or limited efficacy data, Member States will need to make their own decision based on the available efficacy data and extrapolation possibility according to their national requirements.

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

See column 15 of the GAP table presented in Appendix 1 of this document.

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

See column 15 of the GAP table presented in Appendix 1 of this document.

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:

See column 15 of the GAP table presented in Appendix 1 of this document.

All uses/ GAPs are covered by established MRLs.

Appendix 1 ALL intended uses

GAP rev. 2~~1~~, date: 2022-04 ~~2021-11~~

PPP (product name/code):	BAS 762 02 F	Formulation type:	SC [a, b]
Active substance 1:	Mefentrifluconazole*	Conc. of as 1:	100 g/L [c]
Active substance 2:	Bocalid**	Conc. of as 2:	200 g/L [c]
Safener:	n.r.	Conc. of safener:	n.r. [c]
Synergist:	n.r.	Conc. of synergist:	n.r. [c]
Applicant:	BASF	Professional use:	x
Zone(s):	central [d]	Non professional use:	☐
Verified by MS:	yes ~~no~~		
Field of use:	fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15*							
*	**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]	**Overall conclusions**							
					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			Phys-chem	Analytical methods	Toxicology	Residues	Fate & bevaviour	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
Zonal uses (field or outdoor uses, certain types of protected crops)																					
1	AT, BE, DE, PL, IE	Oilseed Rape, winter and spring (BRSNN)	F	*Sclerotinia sclerotiorum* (SCLESC) *Alternaria* spp. (ALTESP) *Erysiphe cruciferarum* (ERYSCR) *Neopseudocercosporella brassicae* (MYCOBR)	SP	BBCH 57-75	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 100* +200** b) 100* + 200**	100-400	F	F is defined by latest application timing.	**A**	**A**	**A**	**A**	**A**	**A**	**A**	**A** BRSNW: SCLESC, ALTESP, ~~BRSNW:~~ ERYSCR (PL) **N** BRSNS (PL) possible registration under art. 51; BRSNW: MYCOBR (PL)

																				C BRSNS: SCLESC, ALTESP, ERYSCR, MYCOBR (BE, IE); BRSNW: ERYSCR (AT, BE, DE, IE), MYCOBR (AT, BE, IE) MYCOBR not accepted in DE BRSNS accepted in AT, DE
2	HU, RO, SI, SK	Oilseed Rape, winter and spring (BRSNN)	F	*Sclerotinia sclerotiorum* (SCLESC) *Alternaria* spp. (ALTESP)	SP	BBCH 57-75	a) 1 b) 1	-	a)0.6-1.0 b) 0.6-1.0	a) 60-100* +120-200**	100-400	F	Dose rate range 0.6 - 1.0 L/ha F is defined by latest application timing.	**A**	**A**	**A**	**A**	**A**	**A**	**A**	**A** BRSNW: SCLESC **C** BRSNS: SCLESC, ALTESP; BRSNW: ALTESP
3	CZ	Oilseed Rape, winter and spring (BRSNN)	F	*Sclerotinia sclerotiorum* (SCLESC) *Alternaria* spp. (ALTESP) *Erysiphe cruciferarum* (ERYSCR) *Neopseudocercosporella brassicae* (MYCOBR)	SP	BBCH 57-75	a) 1 b) 1	-	a) 0.6-1.0 b) 0.6-1.0	a) 60-100* + 120-200**	100-400	F	Dose rate range 0.6 - 1.0 L/ha F is defined by latest application timing.	**A**	**A**	**A**	**A**	**A**	**A**	**A**	**A** BRSNW: SCLESC, ALTESP **C** BRSNS: SCLESC, ALTESP, ERYSCR, MYCOBR; BRSNW: ERYSCR, MYCOBR
4	AT, DE, PL	Sunflower (HELAN)	F	*Diaporthe helianthi* (DIAPHE) *Plenodomus lindquistii* (LEPTLI) *Sclerotinia sclerotiorum* (SCLESC) *Alternaria helianthi* (ALTEHE)	SP	BBCH 31-69	a) 2 b) 2	7	a) 1.0 b) 2.0	a) 100* +200** b) 200* + 400**	100-400	F	Maximum 2 applications per crop and season. 1st appl. BBCH 31-59 2nd appl. BBCH 61-69.	**A**	**A**	**A**	**A**	**A**	**A**	**A**	**A** ~~LEPTLI~~ (AT) ~~DE)~~ **C** DIAPHE, SCLESC, ALTEHE, LEPTLI (DE)

													F is defined by latest application timing.								**N** (PL) possible registration under art. 51
5	HU, RO, SI, SK, ~~CZ~~	Sunflower (HELAN)	F	*Diaporthe helianthi* (DIAPHE) *Plenodomus lindquistii* (LEPTLI) *Sclerotinia sclerotiorum* (SCLESC) *Alternaria helianthi* (ALTEHE)	SP	BBCH 31-69	a) 2 b) 2	7	a)0.6 – 1.0 b)1.2 - 2.0	a) 60-100* +120-200** b) 120-200* + 240-400**	100-400	F	Maximum 2 applications per crop and season. Dose rate range 0.6 - 1.0 L/ha 1st appl. BBCH 31-59 2nd appl. BBCH 61-69. F is defined by latest application timing.	**A**	**A**	**A**	**A**	**A**	**A**	**A**	**A**
6	CZ	Sunflower (HELAN)	F	*Diaporthe helianthi* (DIAPHE) *Plenodomus lindquistii* (LEPTLI) *Sclerotinia sclerotiorum* (SCLESC) *Alternaria helianthi* (ALTEHE)	SP	BBCH 31-69	a) 1 b) 1	-	a) 0.6-1.0 b) 0.6-1.0	a) 60-100* +120-200**	100-400	F	Dose rate range 0.6 - 1.0 L/ha	**A**	**A**	**A**	**A**	**A**	**A**	**A**	**A** LEPTLI **C** DIAPHE, SCLESC, ALTEHE
7	DE; AT	Wheat, (winter and spring) (TRZAW, TRZAS))	F	*Oculimacula* ~~spp~~. yallundae- PSDCHE *Septoria tritici* - SEPTTR *Blumeria graminis* - ERYSGR	SP	BBCH 30 -49	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 100* +200** b) 100* + 200**	100 - 300	56	For eyespot control, only one application at BBCH 30-32	**A**	**A**	**A**	**A**	**A**	**A**	**A**	**A** TRZAW: PSDCHE, SEPTTR **C** ~~TRZAS: PSDCHE, SEPTTR, ERYSCR;~~ TRZAW: ERYSCR TRZAS accepted in AT, DE; ERYSCR to be confirmed

8	CZ	Wheat, (winter and spring) (TRZAW, TRZAS)	F	*Oculimacula* spp. yallundae - PSDCHE *Septoria tritici* - SEPTTR *Blumeria graminis* - ERYSGR	SP	BBCH 30 -49	a) 1 b) 1	-	a) 0.6-1.0 b) 0.6-1.0	a) 60-100* +120-200**	100 - 300	56	Dose rate range 0.6 - 1.0 L/ha For eyespot control, only one application at BBCH 30-32	**A**	**A**	**A**	**A**	**A**	**A**	**A**	**A** TRZAW: PSDCHE, SEPTTR **C** TRZAS: PSDCHE, SEPTTR, ERYSCR; TRZAW: ERYSCR
9	PL	Wheat, (winter and spring) (TRZAW, TRZAS)	F	*Oculimacula* spp. yallundae - PSDCHE *Septoria tritici* - SEPTTR *Blumeria graminis* - ERYSGR	SP	BBCH 30 -49	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 100* +200** b) 100* + 200**	100 - 300	56	For eyespot control, only one application at BBCH 30-32	**A**	**A**	**A**	**A**	**A**	**A**	**A**	**A** TRZAW **N** TRZAS
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)																				
None.																				
Minor uses according to Article 51 (zonal uses)																				
None.																				
Minor uses according to Article 51 (interzonal uses)																				
None.																				

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(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
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)
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
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.
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.
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
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
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.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
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
15 Overall conclusions - explanation for the column 15 is below*

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible