

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: BAS 768 00 F

Product name(s): Revytur

Chemical active substance(s):

Mefentrifluconazole, 25 g/L

Sulfur, 600 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: BASF

Submission date: March 2023

MS Finalisation date: 11/12/2023

Version history

When	What
03/2023	Initial dRR – BASF DocID 2022/2030241
04/2023	Dossier sent for evaluation
08/2023	zRMS evaluation of dRR
12/2023	Final version prepared by zRMS after Commenting period

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Evaluator comments:

The text highlighted in grey was provided by the Evaluator.

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 768 00 F, a new SC formulation containing 25 g/L mefentrifluconazole and 600 g/L Sulfur, for the use as fungicide in 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

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
Northern zone	Latvia	Denmark, Estonia, Finland, Latvia, Lithuania, Norway
Central zone	Poland	Austria, Czech Republic, Germany, Ireland, Netherlands
Southern zone	France	n/a

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	United Kingdom
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

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 protection of operators, ensuring that conditions of use include the application of adequate

- personal protective equipment.
- the protection of aquatic organisms.

An EFSA Scientific Report was made available in 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 *, **
<p>minimum purity: 970 g/kg</p> <p>The impurity N, N-dimethylformamide shall not exceed 0,5 g/kg in the technical material.</p> <p>The impurity toluene shall not exceed 1 g/kg in the technical material</p> <p>The impurity 1,2,4-(1H)-triazole shall not exceed 1 g/kg in the technical material</p>	

* 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	
	EU agreed endpoint from EFSA Journal 2018;16(7):5379	Endpoint used*
Environmental fate		
DT₅₀ [d] sediment	1000 (default)	163.4 (geometric mean of whole system DT ₅₀ , n = 2)
Ecotoxicology ¹⁾		
Aquatic organisms		
Fish acute, <i>Pimephales promelas</i>	--	LC ₅₀ = 0.65 mg a.s./L

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

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

Endpoint	M750F005 (Reg. No. 6003433)	
	EU agreed endpoint from EFSA Journal 2018;16(7):5379	Endpoint used*
Ecotoxicology ¹⁾		
Aquatic organisms		
Fish acute, <i>Oncorhynchus mykiss</i>	--	LC ₅₀ > 5 mg/L

* 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 Sulfur

While CAS and IUPAC follow the spelling “sulfur”, the spelling of the in not consistent in regulatory context: “sulphur” is used in the EU Pesticide Database of the European Commission and in the EC review report (2009); “sulfur” is used in the RAC opinion by ECHA (2022) and in the EFSA conclusions (2008). This diversity in reference documents resulted in a consecutive diversity within this dossier and related reports, depending on which source (EFSA/EC/ECHA/IUPAC) was predominantly used as reference during the compilation of individual chapters.

Table 0.1-4: Summary of regulatory history of CAS No: 7704-34-9

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Sulphur was listed in Annex I of Directive 91/414/EEC on 1st January 2010 (Commission Directive 2009/70/EC)
RMS	FR
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.01.2010
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	
Date of final Commission (re-registration) deadline (Step 2)	
Current expiration of approval	31.12.2023
Low risk substance or Candidate for Substitution?	

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:

- Only uses as fungicide and acaricide may be authorized
- The protection of birds, mammals, aquatic organisms and non-target arthropods. Conditions of authorisation shall include risk mitigation measures, where appropriate

An EFSA Scientific Report was made available in December 2008. The draft review report was finalised in the Standing Committee on the Food Chain and Animal Health on 13 March 2009. The review report containing the conclusions of the final examination by the Standing Committee was finalised on 22 October 2009 (Sulphur SANCO/2676/08 final, dated on 22 October 2009).

Table 0.1-5: Information on minimum purity of sulphur

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: 990 g/kg	

* 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	Sulfur	
	EU agreed endpoint from EFSA Scientific Report (2008) 221, 1-70	Endpoint used*
Environmental fate		
Surface water		
Acute and chronic exposure of all groups of aquatic organisms	> 0.063 mg a.s./L (water solubility limit)	> 0.016 mg a.s./L (water solubility limit)
Ecotoxicology ¹⁾		
Aquatic organisms		
Acute and chronic exposure of all groups of aquatic organisms	> 0.063 mg a.s./L (water solubility limit)	> 0.016 mg a.s./L (water solubility limit)
Terrestrial organisms		
Honey bee adults (acute oral) <i>Apis mellifera</i>	--	LD ₅₀ > 700.1 µg a.s./bee ²⁾
Honey bee adults (acute contact) <i>Apis mellifera</i>	--	LD ₅₀ > 700.1 µg a.s./bee ²⁾
Honey bee adults <i>Apis mellifera</i>	--	LDD ₅₀ (10 d) > 149.3 µg a.s./bee/day ²⁾ NOEDD (10 d) ≥ 149.3 µg a.s./bee/day ²⁾
Honey bee larvae <i>Apis mellifera</i>	--	LD ₅₀ = 149.7 µg a.s./larva ²⁾ NOED (8 d) = 60.1 µg a.s./larva ²⁾
Honey bee larvae <i>Apis mellifera</i>	--	ED ₁₀ (22 d) = 1.25 µg a.s./bee/day ²⁾ ED ₅₀ (22 d) = 10.4 µg a.s./bee/day ²⁾ NOED (22 d) = 0.90 µg a.s./bee/day ²⁾
Honey bee colonies <i>Apis mellifera</i>	--	Semi-field tunnel test: no unacceptable lethal or sublethal effects on honey bee colonies exposed to 12.5 kg product/ha (equivalent to 10 kg a.s./ha) ²⁾
Earthworm <i>Eisenia fetida</i>	--	EC ₁₀ = 740 mg/kg dry soil (equivalent to 728.9 mg a.s./kg dry soil) ³⁾
Collembola <i>Folsomia candida</i>	--	EC ₁₀ = 144.8 mg/kg dry soil (equivalent to 142.6 mg a.s./kg dry soil) ³⁾
Predatory mite <i>Hypoaspis aculeifer</i>	--	NOEC ≥ 1000 mg/kg dry soil (equivalent to 985 mg a.s./kg dry soil) ³⁾

* 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.

²⁾ Studies conducted with Sulphur 80% WG

³⁾ Studies conducted with Sulphur Dust

0.1.4 Regulatory history of the product

Not relevant as the product has not yet been authorized.

0.2 zRMS conclusion

Section 1, 2 and 4. Identity, physical and chemical properties and further information

A two-year study is ongoing. It has to be provided when available to confirm the two-year shelf life.

Section 3. Efficacy

Uses in the GAP table no 1-2; 6-7; 9-11 are to be confirmed by cMSs, in the Efficacy section.

Uses 3-4, 8 are considered safe for PL, in the Efficacy section.

Section 5. Analytical methods

The analytical methods have been accepted.

Section 6. Mammalian Toxicology

Human Health classification: Skin Irrit. 2 (H315), Eye Irrit. 2 (H319), Skin Sens. 1 (H317).

Exposure is acceptable if: the operator wears gloves and workwear during mixing/loading and workwear during application, and the worker wears workwear. No unacceptable risk for residents and bystanders was identified.

Section 7. Metabolism and Residues

The chronic and the short-term intakes of BAS 750 F residues are unlikely to present a public health concern. Barley and wheat are crops with no melliferous capacity. As far as consumer health protection is concerned, PL agrees with the authorization of the intended uses. According to available data, no specific mitigation measures should apply.

Section 8. Environmental Fate

In accordance with proposed pattern use, an exposure assessment for the formulation of BAS 768 00 F was submitted.

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

Section 9. Ecotoxicology

Based on the risk assessment in section of ecotoxicology it can be concluded that the proposed use of BAS 768 00 F as a fungicide on winter and spring cereals poses acceptable risk to non-target organisms, if it is applied according to the recommended use pattern.

No mitigation measures were required.

Section 10. Assessment of the relevance of metabolites in groundwater

No metabolites of mefentrifluconazole exceeded trigger value 0.1 µg/L, therefore the relevance assessment of the metabolites is not required. Sulfur and sulfates are of no toxicological relevance, and as sulfur is a mineral, the consideration of metabolites is not applicable.

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

Uses in the GAP table no 1-2; 6-7; 9-11 are to be confirmed by cMSs, in the Efficacy section.
Uses 3-4, 8 are considered safe for PL, in the Efficacy section.

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

Use 5 is not considered safe for PL, in the Efficacy section. For PL, efficacy in use 5 was not confirmed by the zRMS, in the Efficacy section.

Appendix 1 ALL intended uses

PPP (product name/code):	product name / BAS 768 00 F	Formulation type:	GAP rev. 19, date: 2023-january-30 SC ^(a, b)
Active substance 1:	mefentrifluconazole	Conc. of as 1:	25 g/L ^(c)
Active substance 2:	sulphur	Conc. of as 2:	600g/L ^(c)
Safener:	-	Conc. of safener:	- ^(c)
Synergist:	-	Conc. of synergist:	- ^(c)
Applicant:	BASF	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	central ^(d)	Non professional use:	<input type="checkbox"/>
Verified by MS:	yes/ no		
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 destina- tion / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ sea- son	Min. interval between ap- plications (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 Mefentrifluconazole / Sulfur	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	DE, AT, IE, NL	wheat TRZAW, TRZAS TRZDU, TRZSP	F	<i>Zymoseptoria tritici</i> - SEPTTR <i>Blumeria graminis</i> - ER- YSGR <i>Puccinia triticina</i> - PUCCRT <i>Puccinia striiformis</i> - PUCCST	Spraying (SP)	30 - 59	a) 2 b) 2	14	a) 4 b) 8	a) 0.100 / 2.400 b) 0.200 / 4.800	100 - 300	F*	

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 destina- tion / purpose of crop)	F, Fn, Gn, Gpn or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ sea- son	Min. interval between ap- plications (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 Mefentrifluconazole / Sulfur	Water L/ha min / max		
2	IE	wheat TRZAW, TRZAS TRZDU, TRZSP	F	<i>P. tritici-repentis</i> - PYRNTR	Spraying (SP)	30 - 59	a) 2 b) 2	14	a) 4 b) 8	a) 0.100 / 2.400 b) 0.200 / 4.800	100 - 300	F*	will be addressed by national ad- dendum
3	PL	wheat TRZAW, TRZAS TRZDU, TRZSP	F	<i>Zymoseptoria tritici</i> - SEPTTR <i>Blumeria graminis</i> - ER- YSGR <i>Puccinia triticina</i> - PUCCRT	Spraying (SP)	30 - 59	a) 2 b) 2	14	a) 4 b) 8	a) 0.100 / 2.400 b) 0.200 / 4.800	100 - 300	F*	
4	DE, AT, IE, NL	barley HORVW, HORVS	F	<i>Ramularia collo-cygni</i> - RAMUCC <i>Pyrenophora teres</i> - PYRNTE <i>Puccinia hordei</i> – PUCCHD <i>Rhynchosporium secalis</i> - RHYNSE	Spraying (SP)	30 - 59	a) 2 b) 2	14	a) 4 b) 8	a) 0.100 / 2.400 b) 0.200 / 4.800	100 - 300	F*	
5	DE, AT, IE, NL	triticale TTLWI	F	<i>Septoria species</i> - SEPTSP <i>Blumeria graminis</i> - ER- YSGR <i>Puccinia triticina</i> - PUCCRT <i>Puccinia striiformis</i> - PUC CST	Spraying (SP)	30 - 59	a) 2 b) 2	14	a) 4 b) 8	a) 0.100 / 2.400 b) 0.200 / 4.800	100 - 300	F*	
6	PL	triticale TTLWI	F	<i>Septoria species</i> - SEPTSP <i>Blumeria graminis</i> - ER- YSGR <i>Puccinia triticina</i> - PUC CRT	Spraying (SP)	30 - 59	a) 2 b) 2	14	a) 4 b) 8	a) 0.100 / 2.400 b) 0.200 / 4.800	100 - 300	F*	

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 destina- tion / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ sea- son	Min. interval between ap- plications (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 Mefentrifluconazole / Sulfur	Water L/ha min / max		
7	CZ	wheat TRZAW, TRZAS TRZDU, TRZSP	F	<i>Zymoseptoria tritici</i> - SEPTTR <i>Blumeria graminis</i> - ER- YSGR <i>Puccinia triticina</i> - PUCCRT <i>Puccinia striiformis</i> - PUCCST	Spraying (SP)	30 - 59	a) 1 b) 1		a) 3 - 4 b) 3 - 4	a) 0.100 / 2.400 b) 0.100 / 2.400	100 - 300	F*	
8	CZ	barley HORVW, HORVS	F	<i>Ramularia collo-cygni</i> - RAMUCC <i>Pyrenophora teres</i> - PYRNTE <i>Puccinia hordei</i> – PUCCHD <i>Rhynchosporium secalis</i> - RHYNSE	Spraying (SP)	30 - 59	a) 1 b) 1		a) 3 - 4 b) 3 - 4	a) 0.100 / 2.400 b) 0.100 / 2.400	100 - 300	F*	
9	CZ	triticale TTLWI	F	<i>Septoria species</i> - SEPTSP <i>Blumeria graminis</i> - ER- YSGR <i>Puccinia triticina</i> - PUCCRT <i>Puccinia striiformis</i> - PUCCST	Spraying (SP)	30 - 59	a) 1 b) 1		a) 3 - 4 b) 3 - 4	a) 0.100 / 2.400 b) 0.100 / 2.400	100 - 300	F*	
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)													
Minor uses according to Article 51 (zonal uses)													
Minor uses according to Article 51 (interzonal uses)													

F*= Defined by latest application timing. Fixed by professional use

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	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