

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: BAS 765 00 F

Product name(s): Daxur

Chemical active substance(s):

Mefentrifluconazole, 100 g/L

Kresoxim-methyl, 150 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: BASF

Submission date: December 2020

MS Finalisation date: 03/11/2021

Version history

When	What
12/2020	Initial dRR – BASF DocID 2020/2032084
02/2021	Dossier sent for evaluation to Merit Mark (PL)
08/2021	zRMS finalised evaluation
11/2021	Evaluation after commenting period - RR

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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 765 00 F, a new SC formulation containing 100 g/L mefenfentrifluconazole and 150 g/L kresoxim-methyl, 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	-	-
Central zone	Poland	Czechia, Hungary, Poland, Romania, Slovenia, Slovakia
Southern zone	Italy	Bulgaria, Croatia Italy, Spain
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	

* 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 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].	
Ecotoxicology ¹⁾		
Aquatic organisms		
Fish acute, 96 h <i>P. promelas</i>	–	LC ₅₀ = 0.65 mg a.s./L
Geomean (NOEC/EC ₁₀ data for 4 crustacean species)	--	Geomean _{chronic} = 0.0287 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 justification for using new/revised ecotoxicological endpoints please refer to the respective paragraphs in Part B, Section 9.

Endpoint	Metabolite M750F005 (Reg. No. 6003433)	
	EU agreed endpoint from EFSA Conclusion (2018)	Endpoint used*
Ecotoxicology ¹⁾		
Aquatic organisms		
Fish acute, 96 h <i>O. mykiss</i>	--	LC ₅₀ > 5 mg a.s./L _{nom}

* 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 Kresoxim-methyl

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 2019/337
RMS	Sweden
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	11.08.2011
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	31.12.2024
Low risk substance or Candidate for Substitution?	N/A

Table 0.1-4: Information on minimum purity of kresoxim-methyl

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equiv- alency report *, **
Minimum purity: 910 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	Kresoxim-methyl	
	EU agreed endpoint from EFSA Conclusion (2010)	Endpoint used*
Environmental fate		
K _{roc} for PEC _{gw} PEC _{sw/sed} calculations (B 8.8 & B 8.9)	Kresoxim-methyl: 308 mL/g (arithmetic mean, n=4) BF 490-5: 3.32 mL/g (arithmetic mean, n=4)	Kresoxim-methyl: 302 mL/g (geomean, n=4)** BF 490-5: 2.6 mL/g (geomean, n=4)**
Ecotoxicology ¹⁾		
Terrestrial organisms		
<i>Apis mellifera</i> (adults, chronic laboratory)	--	LD ₅₀ (10 d) = 124.1 µg a.s./bee/day NOED (10 d) = 72.7 µg a.s./bee/day
<i>Apis mellifera</i> (larvae, single exposure)	--	LD ₅₀ (72 h) > 50.0 µg a.s./larva NOED (72 h) ≥ 50.0 µg a.s./larva
<i>Eisenia fetida</i> (chronic laboratory)	—	NOEC = 13.5 mg a.s./kg dry soil NOEC _{CORR} = 6.75 mg a.s./kg dry soil EC ₁₀ = 27.4 mg a.s./kg dry soil EC _{10,CORR} = 13.7 mg a.s./kg dry soil
<i>Folsomia candida</i> (chronic laboratory)	—	NOEC ≥ 500 mg a.s./kg dry soil NOEC _{CORR} ≥ 250 mg a.s./kg dry soil

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

** The geometric mean was calculated from the data presented in the EFSA Conclusion on kresoxim-methyl (2010) as requested by Southern Zone guidance. There are no new studies.

¹⁾ For justification 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 (if relevant)

Not relevant as the product has not yet been authorised

0.2 zRMS conclusion

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

A conditional shelf life should be considered by each member state as the two years storage stability study is still ongoing.

Based on physicochemical properties the PPP is not classified.

Section 3. Efficacy

The evaluation of the application of BAS 765 00 F resulted in the decision to grant authorization for use according to the GAP table.

Section 5. Analytical Methods

The analytical methods used for analysing the active substances and relevant impurities in the PPP are accepted.

Section 6. Mammalian Toxicology

Based on hazard properties of the product or the ingredients contained BAS 765 0 F is to be classified for toxicological hazards as Carc.2, with H351 “Suspected of causing cancer”, Skin Sens.1, H317 “May cause an allergic skin reaction” and Skin Irrit. 2, H315 “ Causes skin irritation”.

Exposure assessment:

Operator: protective gloves and workwear during mixing and loading and workwear during application is required.

Worker: work wear is required.

Bystander/resident: the incidental short-time exposure of bystander and resident (children and adult) to active substances contained in the formulation BAS 765 00 F causes no risk to human health.

Section 7. Metabolism and Residues

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs of 0.6 mg/kg (barley) and 0.05 mg/kg (wheat, rye and triticale) for mefentrifluconazole and 0.15 mg/kg (barley) and 0.08 mg/kg (wheat, rye and triticale) for kresoxim-methyl as laid down in Reg (EU) 396/2005 is not expected. Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions of both actives. No data gaps are noticed. The product can be approved for all intended uses.

Section 8. Environmental Fate

In accordance with proposed pattern use, an exposure assessment for the formulation BAS 765 00 F was submitted and sufficient.

Section 9. Ecotoxicology

Based on the risk assessment in section B9 it can be concluded that the proposed use pattern of BAS 765 00 F poses acceptable risk to non-target organisms. Particular precautions to reduce the environmental concentrations resulting from BAS 765 00 F applications are required for aquatic organisms.

Section 10. Assessment of the relevance of metabolites in groundwater

Based on submitted PEC_{gw} assessment (see Section 8: Fate and Behaviour), the PEC_{gw} values for all relevant metabolites is below the trigger value of 0.1 µg/L.

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

All

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

none

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:

none

Zonal uses (field or outdoor uses, certain types of protected crops)													
1	CZ	wheat TRZAW, TRZAS TRZDU, TRZSP	F	B. graminis - ERYSGR Zymoseptoria tritici - SEPTTR Puccinia triticina - PUCCRT Fusarium sp. - FUSASP Oculimacula spp. - PSDCHE	Spraying	30 - 69	a) 1-2 b) 1-2	-14	a) 0.60 - 1.00 b) 0.60 - 1.00/2.0	a) 0.100 / 0.150 b) 0.100 / 0.150 b) 0.200/ 0.300	100-200- 100 - 300	35	For Fusarium Head Blight control, only one application at BBCH 61-69. *if first appl. after BBCH 49; min. 21 days spray interval. PSDCHE (= Eyespot): application BBCH 30-32
2	CZ	barley HORVW HORVS	F	Pyrenophora teres - PYR-NTE P. hordei - PUCCHD	Spraying	30 - 49	a) 1-2 b) 1-2	-14	a) 0.60 - 1.00 b) 0.60 - 1.00/2.0	a) 0.100 / 0.150 b) 0.100 / 0.150 b) 0.200/ 0.300	100-200- 100 - 300	35	
3	CZ	rye SECCW SECCS SECCE	F	Puccinia recondita - PUCCRE	Spraying	30 - 69	a) 1-2 b) 1-2	-14	a) 0.60 - 1.00 b) 0.60 - 1.00/2.0	a) 0.100 / 0.150 b) 0.100 / 0.150 b) 0.200/ 0.300	100-200- 100 - 300	35	*if first application after BBCH 49; min. 21 days spray interval.
4	CZ	triticale TTLWI TTLSO	F	Septoria spp. - SEPTSP Puccinia recondita - PUCCRE	Spraying	30 - 69	a) 1-2 b) 1-2	-14	a) 0.60 - 1.00 b) 0.60 - 1.00/2.0	a) 0.100 / 0.150 b) 0.100 / 0.150 b) 0.200/ 0.300	100-200- 100 - 300	35	For Fusarium Head Blight control, only one application at BBCH 61-69. *if first application after BBCH 49; min. 21 days spray interval.
5	HU	wheat TRZAW, TRZAS TRZDU, TRZSP	F	B. graminis - ERYSGR Zymoseptoria tritici - SEPTTR Puccinia triticina - PUCCRT Fusarium sp. - FUSASP Oculimacula spp. - PSDCHE P. tritici-repentis - PYRNTR	Spraying	30 - 69	a) 1-2 b) 1-2	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100-200- 100 - 300	35	*if first application after BBCH 49; min. 21 days spray interval. For Fusarium Head Blight control, only one application at BBCH 61-69. FUSASP - dose rate only 1.0 L/ha PSDCHE (= Eyespot): application BBCH 30-32

6	HU	barley HORVW HORVS	F	Pyrenophora teres - PYR-NTE P. hordei - PUCCHD Blumeria graminis - ERYSGR	Spraying	30 - 49	a) 1-2 b) 1-2	14	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100-200-100 - 300	35	
7	HU	rye SECCW SECCS SECCE		B. graminis - ERYSGR R. secalis - RHYNSE Puccinia recondita - PUCCRE	Spraying	30 - 49	a) 1-2 b) 1-2	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100-200-100 - 300	35	*if first application after BBCH 49; min. 21 days spray interval.
8	HU	triticale TTLWI TTLSO		B. graminis - ERYSGR Septoria spp. - SEPTSP Puccinia recondita - PUCCRE	Spraying	30 - 49	a) 1-2 b) 1-2	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100-200-100 - 300	35	*if first application after BBCH 49; min. 21 days spray interval. For Fusarium Head Blight control, only one application at BBCH 61-69.
9	PL	wheat TRZAW, TRZAS TRZDU, TRZSP	F	B. graminis - ERYSGR Zymoseptoria tritici - SEPTTR Puccinia triticina - PUCCRT Oculimacula spp.- PSDCHE	Spraying	30 - 69	a) 1-2 b) 1-2	14*	a) 1.00 b) 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100-200-100 - 300	35	*if first application after BBCH 49; min. 21 days spray interval. For Fusarium Head Blight control, only one application at BBCH 61-69. PSDCHE (= Eyespot): application BBCH 30-32
10.	PL	wheat TRZAS		B. graminis - ERYSGR Zymoseptoria tritici - SEPTTR	Spraying	30 - 69	a) 1 b) 2	14*	a) 1.00 b) 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100-300	35	*if first application after BBCH 49; min. 21 days spray interval
11	PL	barley HORVW HORVS	F	Pyrenophora teres - PYR-NTE P. hordei - PUCCHD	Spraying	30 - 69	a) 1-2 b) 1-2	14	a) 1.00 b) 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100-200-100 - 300	35	

12	PL	rye SECCW SECCS SECCE	F	Puccinia recondita - PUCCRE	Spraying	30 - 69	a) 1 2 b) 1 2	14*	a) 1.00 b) 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 200 - 100 - 300	35	*if first application after BBCH 49; min. 21 days spray interval.
13	PL	triticale TTLWI TTL SO	F	Septoria spp. - SEPTSP Puccinia recondita - PUCCRE	Spraying	30 - 69	a) 1 2 b) 1 2	14*	a) 1.00 b) 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 200 - 100 - 300	35	*if first application after BBCH 49; min. 21 days spray interval.
14	RO	wheat TRZAW, TRZAS TRZDU, TRZSP	F	B. graminis - ERYSGR Zymoseptoria tritici - SEPTTR Puccinia triticina - PUCCRT Fusarium sp. - FUSASP Oculimacula spp.- PSDCHE <i>P. tritici-repentis</i> - PYRNTR	Spraying	30 - 69	a) 1 2 b) 1 2	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 200 - 100 - 300	35	*if first application after BBCH 49; min. 21 days spray interval. For Fusarium Head Blight control, only one application at BBCH 61-69. FUSASP - dose rate only 1.0 L/ha PSDCHE (= Eyespot): application BBCH 30-32
15	RO	barley HORVW HORVS	F	Pyrenophora teres – PYR- NTE P. hordei – PUCCHD Blumeria graminis – ERYSGR	Spraying	30 - 49	a) 1 2 b) 1 2	14	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 200 - 100 - 300	35	
16	RO	rye SECCW SECCS SECCE		B. graminis – ERYSGR R. secalis – RHYNSE Puccinia recondita - PUCCRE	Spraying	30 - 49	a) 1 2 b) 1 2	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 200 - 100 - 300	35	*if first application after BBCH 49; min. 21 days spray interval.
17	RO	triticale TTLWI TTLSO		B. graminis – ERYSGR Septoria spp. - SEPTSP Puccinia recondita - PUCCRE	Spraying	30 - 49	a) 1 2 b) 1 2	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 200 - 100 - 300	35	*if first application after BBCH 49; min. 21 days spray interval. For Fusarium Head Blight control, only one application at BBCH 61-69.

18	SI	wheat TRZAW, TRZAS TRZDU, TRZSP	F	B. graminis - ERYSGR Zymoseptoria tritici - SEPTTR Puccinia triticina - PUCCRT Fusarium sp. - FUSASP Oculimacula spp.- PSDCHE <i>P. tritici-repentis</i> - <i>PYRNTR</i>	Spraying	30 - 69	a) 1 2 b) 1 2	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100-200- 100 - 300	35	*if first application after BBCH 49; min. 21 days spray interval. For Fusarium Head Blight control, only one application at BBCH 61-69. FUSASP - dose rate only 1.0 L/ha PSDCHE (= Eyespot): application BBCH 30-32
19	SI	barley HORVW HORVS	F	Blumeria graminis - ERYSGR Pyrenophora teres - PYRNTE P. hordei - PUCCHD	Spraying	30 - 49	a) 1 2 b) 1 2	14	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100-200- 100 - 300	35	
20	SI	rye SECCW SECCS SECCE		B. graminis - ERYSGR R. secalis - RHYNSE Puccinia recondita - PUCCRE	Spraying	30 - 49	a) 1 2 b) 1 2	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100-200- 100 - 300	35	*if first application after BBCH 49; min. 21 days spray interval.
21	SI	triticale TTLWI TTLSO		B. graminis - ERYSGR Septoria spp. - SEPTSP Puccinia recondita - PUCCRE	Spraying	30 - 49	a) 1 2 b) 1 2	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100-200- 100 - 300	35	*if first application after BBCH 49; min. 21 days spray interval. For Fusarium Head Blight control, only one application at BBCH 61-69.
22	SK	wheat TRZAW, TRZAS TRZDU, TRZSP	F	B. graminis - ERYSGR Zymoseptoria tritici - SEPTTR Puccinia triticina - PUCCRT Fusarium sp. - FUSASP Oculimacula spp.- PSDCHE <i>P. tritici-repentis</i> - <i>PYRNTR</i>	Spraying	30 - 69	a) 1 2 b) 1 2	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100-200- 100 - 300	35	*if first application after BBCH 49; min. 21 days spray interval. For Fusarium Head Blight control, only one application at BBCH 61-69. FUSASP - dose rate only 1.0 L/ha PSDCHE (= Eyespot): application BBCH 30-32

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/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
			13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions