FINAL REGISTRATION REPORT

Part A

Risk Management

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

NATIONAL ASSESSMENT

Poland

(authorization)

Applicant: BASF

Submission date: May 2021

MS Finalisation date: 23/02/2022

Version history

When	What
12/2020	Initial dRR – BASF DocID 2020/2032161
02/2021	Dossier sent for evaluation to Merit Mark (PL)
05/2021	Update dRR – BASF DocID 2021/2016702 Update classification and toxicology section, changes highlighted in yellow Update Appendix 4
08/2021	zRMS finalised evaluation
11/2021	Evaluation after commenting period - RR
02/2022	Additional comments and the final evaluation

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PART A

RISK MANAGEMENT

1 Details of the application

This document describes the acceptable use conditions required for the national registration of BAS 765 00 F, containing 100 g/L Mefentrifluconazole and 150 g/L Kresoxim-methyl in Poland.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-10 and Part C as well as in the national addendum where appropriate.

The Registration Report includes the assessment of further data or information as required for a registration at national level in accordance with the conclusions from the EU review of the active substance. It also includes assessment of data and information relating to BAS 765 00 F where that data has not been considered in the EU review.

Appendix 1 of this document provides a copy of the final product authorization in the Poland.

Appendix 2 of this document is a copy of the approved product label for the Poland.

Appendix 3 of this document contains copies of the letters of access. (not relevant for this formulation)

Appendix 4 of this document contains the lists of data considered for national authorization.

1.1 Application background

Applicant:

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The application was submitted for the approval of BAS 765 00 F, a ~~FS~~ SC formulation containing ~~5~~100 g/L mefentrifluconazole and 150 g/L Kresoxim-methyl. ~~for the seed treatment use in wheat~~

1.2 Letters of Access

Not relevant.

1.3 Justification for submission of tests and studies

Testing is conducted according to the data requirements for the authorisation of plant protection products and is conducted in compliance with national and international animal welfare regulations. The testing strategy takes into account methods compliant with the 3R concept for refinement, reduction and replacement of animal testing where applicable and acceptable.

Reasoning is provided in Section B documents.

Testing has been conducted in order to fulfil the data requirements for plant protection products and in order to demonstrate an acceptable use of the plant protection product.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

2 Details of the authorization decision

2.1 Product identity

Product code	BAS 765 00 F
Product name in MS	Not yet determined
Authorization number	xxxx – xx
Function	fungicide
Applicant	BASF
Active substance(s) (incl. content)	Mefentrifluconazole 100 g/L Kresoxim-methyl 150 g/L
Formulation type	Suspension Concentrate [SC]
Packaging	See table below, professional user
Coformulants of concern for national authorizations	not applicable
Restrictions related to identity	For detailed information see Part B section 1
Mandatory tank mixtures	not applicable

Recommended tank mixtures	not applicable

Packaging:

BAS 765 00 F is to be marketed in blow moulded high-density polyethylene (HDPE) or fluorinates high-density polyethylene (f-HDPE) containers, with a minimum wall thickness of 0.5 mm. They are sealed by either a foil seals or gasket, protected by a polyethylene screw cap.

Packaging information for 0.15 liter bottle

Type	Description
Material:	HDPE or f-HDPE
Shape/size:	Cylindrical / approx. 63 mm diameter x 92 mm
Opening:	42 mm inner diameter
Closure:	screw cap
Seal:	HF-seal or gasket
Manner of construction	extruded
UN/ADR	compliant

Packaging information for 0.25 liter bottle

Type	Description
Material:	HDPE or f-HDPE
Shape/size:	Cylindrical / approx. 63 mm diameter x 127 mm
Opening:	42 mm inner diameter
Closure:	screw cap
Seal:	HF-seal or gasket
Manner of construction	extruded
UN/ADR	compliant

Packaging information for 0.5 liter bottle

Type	Description
Material:	HDPE or f-HDPE
Shape/size:	Cylindrical / approx. 69 mm diameter x 196 mm
Opening:	42 mm inner diameter
Closure:	screw cap
Seal:	HF-seal or gasket
Manner of construction	extruded
UN/ADR	compliant

Packaging information for 1 liter bottle

Type	Description
Material:	HDPE or f-HDPE
Shape/size:	Cylindrical / approx. 88.5 mm diameter x 234 mm

Type	Description
Opening:	42 mm inner diameter
Closure:	screw cap
Seal:	Induction sealed
Manner of construction	extruded
UN/ADR	compliant

Packaging information for 1 liter eco-bottle

Type	Description
Material:	HDPE or f-HDPE
Shape/size:	Cylindrical / approx. 88.5 mm diameter x 234 mm
Opening:	54 mm inner diameter
Closure:	screw cap
Seal:	gasket
Manner of construction	extruded
UN/ADR	compliant

Packaging information for 5 liter container

Type	Description
Material:	HDPE or f-HDPE
Shape/size:	Rectangular / approx. 190 mm x 140 mm x 313 mm
Opening:	54 mm inner diameter
Closure:	screw cap
Seal:	HF-seal
Manner of construction	extruded
UN/ADR	compliant

Packaging information for 5 liter eco-container

Type	Description
Material:	HDPE or f-HDPE
Shape/size:	Rectangular / approx. 185 mm x 136 mm x 313 mm
Opening:	54 mm inner diameter
Closure:	screw cap
Seal:	Gasket
Manner of construction	extruded
UN/ADR	compliant

Packaging information for 10 liter container

Type	Description
Material:	HDPE or f-HDPE
Shape/size:	Rectangular / approx. 230 mm x 165 mm x 375 mm

Type	Description
Opening:	54 mm inner diameter
Closure:	Polyethylene screw cap
Seal:	Induction sealed
Manner of construction	extruded
UN/ADR	compliant

Packaging information for 10 liter eco-container

Type	Description
Material:	HDPE or f-HDPE
Shape/size:	Rectangular / approx. 230 mm x 187 mm x 358 mm
Opening:	54 mm inner diameter
Closure:	screw cap
Seal:	Gasket
Manner of construction	extruded
UN/ADR	compliant

Packaging information for 15 liter eco-container

Type	Description
Material:	HDPE or f-HDPE
Shape/size:	Rectangular / approx. 265 mm x 215 mm x 400 mm
Opening:	54 mm inner diameter
Closure:	screw cap
Seal:	Gasket
Manner of construction	extruded
UN/ADR	compliant

Packaging information for 20 liter container

Type	Description
Material:	HDPE or f-HDPE
Shape/size:	Rectangular / approx. 285 x 237 x 424 mm
Opening:	52 mm inner diameter
Closure:	screw cap + valve
Seal:	Gasket
Manner of construction	extruded
UN/ADR	compliant

Packaging information for 50 liter container

Type	Description
Material:	HDPE or f-HDPE
Shape/size:	Cylindrical / approx. 380 mm x 618 mm (d x h)

Type	Description
Opening:	52 mm inner diameter
Closure:	screw cap + valve
Seal:	Gasket
Manner of construction	extruded
UN/ADR	compliant

2.2 Conclusion

Section 7: The evaluation of the application for Daxur resulted in the decision to grant the authorization (please, see approved GAP in the table of paragraph 2.6).

2.3 Substances of concern for national monitoring

No further information required

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:	Carc. 2 Skin Sens. 1 Aquatic acute 1; Aquatic chronic 2

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:	 **GHS08**, GHS07, **GHS09**
Signal word:	Warning
Hazard statement(s):	H315: Causes skin irritation H317: May cause an allergic skin reaction H351: Suspected of causing cancer H410: Very toxic to aquatic life with long lasting effects
Precautionary statement(s):	**WARNING SECTION OF THE LABEL (first page):** **P202: Do not handle until all safety precautions have been read and understood** **P261: Avoid breathing mist/spray.** **P280: Wear protective gloves.** **P302+PP352: IF ON SKIN: Wash with plenty of water.** **P308 + P313: IF exposed or concerned: Get medical advice/attention** P391: Collect spillage. Other section of the label: P102: Keep out of reach of children. P264: Wash hands thoroughly after handling. P362 + P364: Take off contaminated clothing and wash it before reuse. P272: Contaminated work clothing should not be allowed out of the workplace. And P280 as follows: „*Stosować rękawice ochronne oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy roboczej oraz odzież roboczą w trakcie wykonywania zabiegu*" "Wear protective gloves and work wear (coverall) during mixing/loading and

	work wear during application". Storage: P405: Store locked up. Disposal: P501: : Dispose of contents/container to hazardous or special waste collection point. **Section First aid:** P101: If medical advice is needed, have product container or label at hand. P302+P352: IF ON SKIN: Wash with plenty of water. P333+P313: If skin irritation or rash occurs: Get medical advice/attention. P308 + P313: IF exposed or concerned: Get medical advice/attention
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	Contains isothiazolinones (CIT, MIT and BIT). May produce an allergic reaction. [EUH208]

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).

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

None-

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:	
	Protective gloves and work wear during mixing/loading, workwear during application.
Worker protection:	
	Wearing work wear is required.
Environmental protection	
Aquatic buffer zone	10 m non-sprayed vegetated buffer zone

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

None proposed.

2.5.2 Specific restrictions linked to the intended uses

None proposed.

2.6 Intended uses (only NATIONAL GAP)

GAP rev. , date: year-month-day

PPP (product name/code):	product name / BAS 765 00 F	Formulation type:	SC
Active substance 1:	Mefentrifluconazole	Conc. of as 1:	100 g/L (c)
Active substance 2:	Kresoxim-methyl	Conc. of as 2:	150 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:	☒
Zone(s):	central (d)	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: 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 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)													
1	PL	wheat TRZAW	F	B. graminis - ERYSGR Zymoseptoria tritici - SEPTTR Puccinia triticina - PUCCRT Oculimacula spp.- PSDCHE	Spraying	30 - 69	a) 2 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. For Fusarium Head Blight control, only one application at BBCH 61-69.
2	PL	barley HORVW HORVS	F	Pyrenophora teres - PYRNTE P. hordei - PUCCHD	Spraying	30 - 69	a) 2 b) 2	14	a) 1.00 b) 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	

3	PL	rye SECCW SECCS SECCE	F	Puccinia recondita - PUCCRE	Spraying	30 - 69	a) 2 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.
4	PL	triticale TTLWI	F	Septoria spp. - SEPTSP Puccinia recondita - PUCCRE	Spraying	30 - 69	a) 2 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.
5	PL	wheat, TRZAS	F	*Blumeria graminis - ERYSGR* *Zymoseptoria tritici – SEPTTR*	SP	30-69	a) 2 b) 2	14	a) 1.0 b) 2.0	a) 0.100/ 0.150 b) 0.200/ 0.300	100 - 300	35	*if first appl. after BBCH 49; min. 21 days spray interval.
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)													
5													
6													
Minor uses according to Article 51 (interzonal uses)													
7													
8													

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

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 white suspension in liquid, with a faint aromatic odour. It is not explosive, has no oxidising properties. The product has a flash point of 114 °C. It has a auto-ignition temperature of 450 °C. As an aqueous solution, it has a pH value around 7 at 24 °C. There is no effect of low and high temperature on the stability of the formulation except for the parameter spontaneity of dispersion. The spontaneity of dispersion is not acceptable after storage tests, because it is lower than 60% which is the FAO limitation either after 7 days at 0 °C or 14 days at 54 °C. Therefore, the application tests were carried out and it was found that this formulation is well applicable. The shelf life study indicating at least 2 years at ambient temperature when stored in HDPE is still ongoing and will be provided by end of March 2022. Its technical characteristics are acceptable for a SC formulation.
The intended concentration of use is 0.2% to 1%.

The product BAS 765 00 F can be mixed in the tank together with.following plant protection products: Imtrex, Priaxor, Flexity, Turbo, Medax Top, Camposan Extra, Medax Max, Duplosan DP, Biathlon Plus, Ariane C, Atlantis, Actirob, Pirimor Granulat and Sumicidin Alpha. Studies regarding the combination with BAS 765 00 F were submitted and the application as tank mixture is acceptable.

3.2 Efficacy (Part B, Section 3)

3.3 Efficacy data

BAS 765 00 F is to be used in cereals (wheat, barley, rye and triticale). The main targets for the use of BAS 765 00 F are the pathogens: *Zymoseptoria tritici*, *Puccinia* spp., *Pyrenophora* spp. and *Blumeria graminis* as well as *Fusarium spp*. A total dataset of 113 efficacy trials on winter wheat, winter barley, spring barley, rye and triticale were used to support the efficacy on the different diseases in Central registration zone. All the efficacy trials are performed according to GEP and EPPO-Guidelines. The data show very good effects on the various diseases. Especially the performance towards Septoria leaf blotch and brown rust is outstanding. The trials confirm the claim made in the introduction that BAS 765 00 F is a highly effective fungicide, offering a valid opportunity for the control of important pathogens of cereals.
What is more in additional trails BAS 765 00 F effectively controlled ERYSGR and medium effectively controlled SEPTTR in spring wheat at dose rate 1,0 L/ha.

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

Mefentrifluconazole is a fungicide belonging to the group of the sterol biosynthesis inhibitors (SBI, mode of action class G). Within the SBIs, it belongs to the subgroup of demethylation inhibitors (DMI, G1, FRAC 2017) and the chemical group of triazoles. Mefentrifluconazole is the first isopropanol azole.
Pathogens have shown a shift towards lower sensitivity in the period since DMI introduction. Mefentrifluconazole has shown to be highly active on many strains of *Zymoseptoria tritici*, which show lower sensitivity to other DMIs. The mefentrifluconazole molecule is probably more flexible in its structure than other DMIs and might therefore be able to bind even if the binding shape is altered.
Kresoxim-methyl belongs to the Mode of Action Group C (Respiration) and to the subgroup C3 (inhibition of complex III) with the target site cytochrome *bc*1 at QoI site and the FRAC code 11 with the group name QoI fungicides (Quinone outside inhibitors). The mode of action of QoI fungicides is the inhibition of mitochondrial respiration.
The evidence of resistance to QoIs comes from cases of field resistance shown by different plant pathogens. The pathogens have been isolated and found to be resistant to high concentrations of QoIs indicating a disruptive (single step) resistance. An actual list of plant pathogenic fungi where QoI resistance has been detected can be found on the FRAC webpage.
Management strategies are necessary for BAS 765 00 F to reduce risk of resistance development. Therefore such strategies (including good agricultural practice, limited number of sprays etc.) were proposed.

3.3.2 Adverse effects on treated crops

No phytotoxicity was observed in the efficacy trials after treatments with the maximum target dose rate 1.0 L/ha. For yield and quality, a positive impact of BAS 765 00 F is measured. The same was observed in trials without diseases. Moreover foliar treatments with BAS 765 00 F do not have any impact on germination of harvested cereal seeds.

3.3.3 Observations on other undesirable or unintended side-effects

Result of the studies indicate that there is no necessity for restrictions in the choice of succeeding crops after the application of BAS 765 00 F. Moreover the data presented justifies the recommendation of no restrictions on adjacent crops after the application of BAS 765 00 F.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

The method AFL0999/01 was developed for the determination of the content of Kresoxim-methyl (Reg.No.242009) and Mefentrifluconazole (Reg.No.5834378) in BAS 765 00 F SC-Formulation. This method is also applicable for the determination of the content of Kresoxim-methyl (Reg.No.242009) and Mefentrifluconazole (Reg.No.5834378) in suspensions of BAS 765 00 F SC-Formulation in CIPAC standard water D at use rates of 0.1% (v/v) to 10% (v/v).
With respect to the conditions described for the analytical method AFL0999/01 all validation parameters (identity, specificity, accuracy, precision, intermediate precision and stability) are acceptable for Kresoxim-methyl (Reg.No. 242009) and Mefentrifluconazole (Reg.No. 5834378). Therefore, the method is valid without restriction in the tested concentration range and is suitable for the determination of Kresoxim-methyl (Reg.No. 242009) and Mefentrifluconazole (Reg.No. 5834378) in BAS 765 00 F and in aqueous suspensions of BAS 765 00 F.

Relevant impurity dimethylformamide (DMF)
Mefentrifluconazole contains ≤ 0.5 g/kg dimethylformamide (DMF) which is considered to be an impurity of toxicological concern (equivalent to 47.65 mg/kg DMF in the SC-formulation BAS 765 00 F). The analytical method AFL1010/01 has been developed for the determination of dimethylformamide (Reg. No. 159267) in the SC-formulation BAS 765 00 F and has been validated.
With respect to the conditions described for the analytical method AFL1010/01 all validation parameters (identity, specificity, accuracy, precision, stability and the limit of quantification (LoQ) are acceptable for the determination of DMF in BASS 765 00 F. These investigations have shown that the analytical conditions employed in the respective method (AFL1010/01) are suitable for these quantifications.

Relevant impurity 1,2,4-(1H)-triazole
Mefentrifluconazole contains ≤ 1 g/kg 1,2,4-(1H)-triazole which is considered to be an impurity of toxicological concern (equivalent to 103.1 mg/L or 95.20 mg/kg 1,2,4-(1H)-triazole in the SC-formulation BAS 765 00 F).
The analytical method AFL0977/01 has been originally developed for the determination of 1,2,4-(1H)-triazole (Reg. No. 87084) in the EC-formulation BAS 750 01 F. A new version of the method (AFL0977/03) was created and validated to add one new analytical procedure (Part B) and calculation for the determination of Triazole in BAS 763 00 F, and it is also validated for BAS 765 00 F as described in BASF DocID 2020/2034385. Therefore analytical method AFL0977/03 was used for the determination of Triazole in BAS 765 00 F.
With respect to the conditions described for the analytical method AFL0977/03 all validation pa-rameters (accuracy, precision, linearity and specificity) are acceptable. Therefore, the method is valid without restriction in the tested concentration range and is suitable for the determination of Reg.No. 87084 in BAS 765 00 F.

Relevant impurity Toluene
Mefentrifluconazole contains ≤ 1 g/kg Toluene which is considered to be an impurity of toxicological concern. Kresoximmethyl contains ≤ 1 g/kg Toluene as well. In total, BAS 765 00 F contains max. 267.9 mg/l or 247.4 mg/kg toluene as the impurity of toxicological concern.
The analytical method AFL0948/01 has been originally developed for quantitative determination of toluene

(Reg. No. 4005250) in EC formulation BAS 751 05 F. Based on that the analytical method AFL0948/02 has been developed for the determination of toluene (Reg. No. 4005250) in the SC-formulation BAS 765 00 F and has been validated. With respect to the conditions described in the analytical method AFL0948/01 the validation pa-rameters are acceptable with the addition of a bake out step at the end of the temperature gradient. Therefore, the method is valid. A new version of the method (AFL0948/02) was created.
This additional validation confirms that the analytical method AFL0948/02 is applicable for the determination of Reg.No. 4005250 in the test item BAS 765 00 F.

3.4.2 Analytical methods for residues

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions of both actives.

Mefentrifluconazole

The analytical methods developed for mefentrifluconazole (BAS 750 F) in plant and animal matrices were already submitted and evaluated in context of the previous process of Annex I Inclusion of mefentrifluconazole excepting of two new pre-authorization water methods, a new enforcement water method with its ILV, and a new enforcement body fluids method, which are submitted with the current dossier.

Plant and plant products:

The analytical method for determination of mefentrifluconazole in foodstuffs of plant origin (BASF Method L0076/09) is based on LC-MS/MS (using HPLC or UPLC) with an LOQ of 0.01 mg/kg. It was validated for a diverse range of representative plant matrices (all OECD crop groups). This method is used for data generation purposes.

An analytical LC-MS/MS method (L0295/01) based on QuEChERS was developed and validated, analyzing the parent compound with an LOQ of 0.01 mg/kg. This method based on LC-MS/MS determination is suitable for enforcement purposes. An independent laboratory validation (ILV) was carried out successfully. Therefore, this method can be use as enforcement method for BAS 750 F in plant matrices.

Food of animal origin:

An analytical LC-MS/MS method (L0272/01) was developed and validated, analyzing BAS 750 F with an LOQ of 0.01 mg/kg, for cow liver, kidney, muscle, fat, milk and cream and hen egg. This method based on LC-MS/MS determination is suitable for enforcement and data generation purposes.

An analytical GC-MS method (L0309/01) was developed and validated, analyzing the metabolite M750F022 with an LOQ of 0.01 mg/kg for animal matrices. This method based on GC-MS determination is suitable for enforcement purposes and data generation.

An independent laboratory validation (ILV) was carried out successfully for both methods (L0272/01 and L0309/01). The EU residue definition for BAS 750 F for monitoring purposes is parent only in food of animal origin.

Soil

An analytical LC-MS/MS method (L0214/01) was developed and validated, analyzing BAS 750 F with an LOQ of 0.002 mg/kg. This method based on LC-MS/MS determination is suitable for enforcement purposes and data generation. The EU residue definition for BAS 750 F for monitoring purposes is parent only.

Water

BAS 750 F can be determined using BASF analytical method L0359/01 using LC/MS/MS with a limit of quantification of 30 ng/L. An independent laboratory validation (ILV) was carried out successfully in drinking and surface water. The EU residue definition for BAS 750 F for monitoring purposes is parent only.

Beyond that, LC/MS/MS-based analytical methods APL0500/03 (determination of BAS 750 F in test water and mixing water with LOQ 0.001 mg/L) and L0631/01 (determination of BAS 750 F in tap water or M4-medium with LOQ 0.1 µg/L) were developed and validated.

Air

BAS 750 F in air can be determined (L0327/01) by sucking air through adsorption tubes (ORBO™) for about 6 hours. The tube content is then extracted with acetonitrile and analysed by LC/MS-MS. The limit of quantification corresponded to a concentration of 0.01 ng/L air.

Body Fluids

An analytical method was developed and validated for the determination of BAS 750 F in body fluids (L0339/01) with a limit of quantification of 0.01 mg/L. Additionally, analytical method L0339/02 was successfully validated, allowing the determination of M750F015, M750F016 and M750F017 in body fluids with a LOQ of 0.01 mg/L.

Kresoxim-methyl

Plant and plant products:

Single residue methods for the determination of kresoxim-methyl, metabolite BF 490-1, metabolite BF 490-2 and metabolite BF 490-9 in foodstuff of plant origin for the generation or pre-registration residues data have been evaluated and approved at EU level (RAR, revised 2010). These methods are based on either GC-MS, GC-PND (methods 351/2 and 350/1), HPLC-UV (methods D9611 and 350/3) or HPLC-MS/MS (method 445/0, also called method L0010/01 and method L0095/1) with LOQs of either 0.01 mg/kg or 0.05 mg/kg in apples (including processed fractions), cereals (including grain, green material and straw), pecan nuts, grapes, cucumber, soy bean and peas. A single residue method for the determination of kresoxim-methyl in corn oil (feeding vehicle) based on HPLC-UV with an associated LOQ of 2 mg/mL has also been evaluated and approved at EU level (RAR, revised 2010).
New residue studies using HPLC-MS/MS method L0095/01 provide procedural recovery data and additional validation data for the determination of kresoxim-methyl, metabolite BF 490-2 and metabolite BF 490-9 in cereal plants, ears, and grain with an associated LOQ of 0.01 mg/kg and for cereal straw with an LOQ of 0.05 mg/kg.

Food of animal origin:

Single residue methods for the determination of metabolite BF 490-1, metabolite BF 490-2 and metabolite BF 490-9 in foodstuff of animal origin for the generation or pre-registration residues data have been evaluated and approved at EU level (RAR, revised 2010). These methods are based on HPLC-UV (methods 354/1 and 354/2) with LOQs of 2 ppb (milk products) and 10 ppb (muscle, liver, kidney and fat). A new method for the determination of metabolite BF 490-1, metabolite BF 490-2 and metabolite BF 490-9 in foodstuff of animal origin is included. This method is based on HPLC-MS/MS (two transitions) with an associated LOQ of 0.01 mg/kg.
A new enforcement method (R0062/01) and its related ILV for the determination of BF 490-9 in different matrices of animal origin, based on HPLC-MS/MS with an LOQ of 0.01 mg/kg is included.

Soil

Single residue methods for the determination of kresoxim-methyl, metabolite BF 490-1 and metabolite BF 490-5 in soil and sediment for the generation or pre-registration environmental fate data have been evaluated and approved at EU level (RAR, revised 2010). These methods are based on either HPLC-MS/MS (Method L0084/02, LOQ 0.005 mg/kg) or GC-ECD (methods 329 and 325, LOQ 0.01 mg/kg).

Water

Single residue methods for the determination of kresoxim-methyl, metabolite BF 490-1 and metabolite BF 490-5 in drinking- and surface water for the generation or pre-registration environmental fate data have been evaluated and approved at EU level (RAR, revised 2010). These methods are based on either HPLC-MS/MS (method L0156/01 and method L0112/01, LOQ 0.05 µg/L) or GC-ECD (method 323, LOQ 0.05 µg/kg) with LC-MS confirmatory data (method 417, LOQ 0.05 µg/L).

Ecotoxicology

Single residue methods for the determination of kresoxim-methyl and metabolite BF 490-1 in water, aqueous growth media and sediment for the generation or pre-registration ecotoxicological data have been evaluated and approved at EU level (RAR, revised 2010). These methods are based on either HPLC-UV (methods CP-No.138, CP-No.138/1, CF-A 405/1, CP-No. 213, CP-No. 187 and CP No.186 with LOQs of 0.05 ppm, 1.44 mg/L, 9.94 mg/L, 1.002 µg/L and 0.1 mg/L, respectively) or GC-ECD (methods D9209 and 233, with LOQs 0.5 µg/L and 1 µg/kg sediment, respectively). A single residue method for the determination of kresoxim-methyl in avian diet has also been evaluated and approved at EU level (RAR, revised 2010). This method is based on HPLC-UV and has an associated LOQ of 50 mg/kg. A single residue method for the determination of metabolite BF 490-5 in water/aqueous growth media for the generation or pre-registration ecotoxicological data have been evaluated and approved at EU level (RAR, revised 2010). This method (APL0574/01) is based on HPLC-MS and has an associated LOQ of 6.25 mg/L.
A LC/MS/MS-based analytical method L0631/03 (determination of BAS 490 F in tap water or M4-medium with LOQ 0.1 µg/L) was developed and validated.
A new method for the determination of kresoxim-methyl in stock solutions used in a study on bee larvae is also included. This method is based on HPLC-UV with an associated LOQ of 8414 mg/L.

Body fluids

As kresoxim-methyl is not classified toxic or highly toxic no analytical method is required for the analysis of body fluids and tissues.

3.5 Mammalian toxicology (Part B, Section 6)

BAS 765 00 F is an SC product containing the active ingredients mefentrifluconazole and kresoxim-methyl at concentrations of 100 g/L and 150 g/L, respectively. It is intended to be used for tractor-mounted applications to cereal crops.

Based on hazard properties of the product or the ingredients contained in the formulation, BAS 765 0 F is 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”. Gloves should be worn when handling the undiluted product.

A toxicological relevance assessment for potential groundwater metabolites of mefentrifluconazole and kresoxim-methyl was not required, because all concentrations are predicted to stay below 0.1 µg/L.

Studies with BAS 765 00 F to derive dermal absorption estimates for its active ingredients were not performed. Therefore, default dermal absorption estimates of 10% for the undiluted concentrate and 50% for the spray-strength dilutions of BAS 765 00 F will be used to estimate non-dietary exposure to mefentrifluconazole and kresoxim-methyl, in accordance to EFSA’s Guidance on Dermal absorption (EFSA Journal 2017; 15(6):4873).

The relevant reference values for the non-dietary risk assessment (AOEL) are 0.035 mg/kg bw/day for mefentrifluconazole and 0.9 mg/kg bw/d for kresoxim-methyl, to be used for longer-term exposure scenarios. For acute exposures, an AAOEL of 0.15 mg/kg bw has been derived for mefentrifluconazole. An AAOEL for kresoxim-methyl is currently not assigned.

3.5.1 Acute toxicity

The acute classification of BAS 765 00 F was derived considering the products composition, *in vitro* studies for assessment of skin and eye irritation, an acute oral toxicity study in rats and a skin irritation study in rabbits carried out with the product.
BAS 765 00 F is assessed to be of low acute toxicity by oral, dermal and inhalation routes not warranting classification for these endpoints. BAS 765 00 F is not a eye irritant. BAS 765 00 F is classified as a skin sensitizer based on the product composition, thus requiring a classification with Skin Sens. 1, H317. Based on the *in vivo* test the formulation is classified as skin irritant.

3.5.2 Operator exposure

Operator exposure and risk evaluations were performed following the EFSA guidance (2014) [European Food Safety Authority (2014) Guidance on the Assessment of Exposure for Operators, Workers, Residents and Bystanders in Risk Assessment for Plant Protection Products (EFSA Journal 2014;12(10):3874 [55 pp.]. doi:10.2903/j.efsa.2014.3874]). The critical use of 2x1.0 L/ha BAS 765 00 F applied with tractor operated application systems was investigated. Based on EFSA model assumptions safe uses could be shown for operators wearing work wear during all operations and gloves during mixing/loading.

Considering the exposure data and toxicological properties of the product BAS 765 00 F, the following sentence regarding the use of PPE is recommended by the evaluator to be placed in the label:

„*Stosować rękawice ochronne oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy roboczej oraz odzież roboczą w trakcie wykonywania zabiegu*"

"Wear protective gloves and work wear (coverall) during mixing/loading and work wear during application".

3.5.3 Worker exposure

Worker exposure and risk evaluations were performed following the EFSA guidance (2014) [European Food Safety Authority (2014) Guidance on the Assessment of Exposure for Operators, Workers, Residents and Bystanders in Risk Assessment for Plant Protection Products (EFSA Journal 2014;12(10):3874 [55 pp.]. doi:10.2903/j.efsa.2014.3874]). The critical use of 2x1.0 L/ha BAS 765 00 F was investigated. The relevant re-entry scenario investigated was crop inspection. Based on EFSA model assumptions safe uses could be shown for workers wearing work wear.
Nevertheless, it is forbidden to re-enter area treated with BAS 765 00 F until spray deposit on plant surfaces has dried.

Bearing in minds the hygienic rules and the classification of the product (H317, including the risk to the most sensitive individuals and no dose-effect relationship in case of sensitization potential), the use of protective gloves is recommended by the evaluator during inspection of the treated area.

3.5.4 Bystander and resident exposure

Resident and bystander exposure and risk evaluations were performed following the EFSA guidance (2014) [European Food Safety Authority (2014) Guidance on the Assessment of Exposure for Operators, Workers, Residents and Bystanders in Risk Assessment for Plant Protection Products. EFSA Journal 2014;12(10):3874 [55 pp.]. doi:10.2903/j.efsa.2014.3874]. The critical use of 2x1.5 L/ha BAS 517 01 F was investigated. Based on EFSA model assumptions safe uses could be shown for residents and bystanders. The **incidental short-time exposure of bystander and resident (children and adult**) to mefentrifluconazole and kresoxim-methyl contained in the formulation BAS 765 00 F **causes no risk** to human health if the product is used in accordance to the intended uses listed in the GAP Table.

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

3.6.1 Residues

<u>Mefentrifluconazole</u>

The metabolism and residue studies of mefentrifluconazole (BAS 750 F) have been evaluated by the

Rapporteur Member State (United Kingdom) and the EFSA in context of the Approval procedure (DAR and EFSA conclusion). Further MRLs for BAS 750 F were recently published in Europe.
BAS 765 00 F was not the representative formulation in the EU dossier of BAS 750 F. Therefore, additional studies in cereals are submitted to support the registration of the formulated product BAS 765 00 F.
No new MRLs are proposed for BAS 750 F for cereals in this document.

Kresoxim-methyl

The MRLs for kresoxim-methyl are published in Regulation (EU) 2020/856, including the crops (barley, rye, wheat and triticale) applied for in this submission. The proposed uses of BAS 765 00 F are within those supported for the EU MRL assessment. Therefore, no further evaluation is required for national authorisation.

3.6.2 Consumer exposure

Mefentrifluconazole

Dietary risk assessments for mefentrifluconazole (BAS 750 F) and the TDMs 1,2,4-T, TA, TLA and TAA were carried out based on the EFSA PRIMo model vers. 3.1.

The results of the IEDI calculations taking into account residues in food commodities of plant and animal origin, show that there is no chronic risk for consumers. Regarding the IESTI calculations, also no acute risk for consumers was identified.

BAS 750 F: A long-term consumer intake concern was not identified for any of the diets incorporated in the EFSA model. In context of IEDI calculations the ADI utilization ranges from 0.4 to 7% of the ADI. The diet with the highest IEDI is "NL toddler" with 7% of the ADI. For this diet, the highest contributor is apple with 2% of the ADI. The diet with the second highest IEDI is “DE child” with 6% of the ADI, in which also apple is the major contributor with 3% of the ADI.

For children, the highest ARfD utilization was 0.4% for consumption of barley. For adults, the highest ARfD utilization was 0.3% for consumption of barley as well.
For processed commodities, the highest ARfD utilization for children was 2% for consumption of barley/milling (flour). For adults, the highest ARfD utilization was 0.4% for consumption of barley/beer.

1,2,4-T: A long-term consumer intake concern was not identified for any of the diets incorporated in the EFSA model. In context of IEDI calculations the ADI utilization ranges from 0.3 to 48% of the ADI. The diet with the highest IEDI is "NL toddler" with 48% of the ADI. For this diet, the highest contributor is milk/cattle with 42% of the ADI. The diet with the second highest IEDI is “UK infant” with 30% of the ADI, in which also milk/cattle is the major contributor with 27% of the ADI.

For children, the highest ARfD utilization was 0.7% for consumption of wheat. For adults, the highest ARfD utilization was 0.4% for consumption of wheat as well.
For processed commodities, the highest ARfD utilization for children was 0.6% for consumption of wheat/milling (flour). For adults, the highest ARfD utilization was 0.4% for consumption of barley/beer.

TA: A long-term consumer intake concern was not identified for any of the diets incorporated in the EFSA model. In context of IEDI calculations the ADI utilization ranges from 0.4 to 4% of the ADI. The diet with the highest IEDI is "NL toddler" with 4% of the ADI. For this diet, the highest contributor is maize/corn with 1% of the ADI. The diet with the second highest IEDI is “DK child” with 3% of the ADI, in which rye is the major contributor with 1% of the ADI.

For children, the highest ARfD utilization was 3% for consumption of wheat. For adults, the highest ARfD utilization was 2% for consumption of wheat as well.
For processed commodities, the highest ARfD utilization for children was 1% for consumption of wheat/milling (flour). For adults, the highest ARfD utilization was 0.9% for consumption of wheat / bread/pizza.

TLA: A long-term consumer intake concern was not identified for any of the diets incorporated in the EFSA model. In context of IEDI calculations the ADI utilization ranges from 0.0 to 1% of the ADI. The diet with the highest IEDI is "NL toddler" with 1% of the ADI. For this diet, the highest contributor is milk/cattle with 0.6% of the ADI. The diet with the second highest IEDI is "UK infant" with 0.5% of the ADI, in which also milk/cattle is the major contributor with 0.4% of the ADI.

For children, the highest ARfD utilization was 0.1% for consumption of barley. For adults, the highest ARfD utilization was 0.06% for consumption of barley as well.
For processed commodities, the highest ARfD utilization for children was 0.2% for consumption of barley/milling (flour). For adults, the highest ARfD utilization was 2% for consumption of barley/beer.

TAA: A long-term consumer intake concern was not identified for any of the diets incorporated in the EFSA model. In context of IEDI calculations the ADI utilization ranges from 0.0 to 1% of the ADI. The diet with the highest IEDI is "NL toddler" with 1% of the ADI. For this diet, the highest contributor is maize/corn with 0.6% of the ADI. The diet with the second highest IEDI is "DK child" with 0.9% of the ADI, in which rye is the major contributor with 0.4% of the ADI.

For children, the highest ARfD utilization was 1% for consumption of wheat. For adults, the highest ARfD utilization was 0.7% for consumption of wheat as well.
For processed commodities, the highest ARfD utilization for children was 0.8% for consumption of wheat/milling (flour). For adults, the highest ARfD utilization was 0.4% for consumption of barley/beer.

Based on above results it can be concluded that the use of the product BAS 765 00 F does not lead to an unacceptable risk for consumers when applied according to the recommendations.

Kresoxim-methyl

The dietary risk assessment for kresoxim-methyl using EFSA PRIMo (rev. 3.1) was carried out and the results are presented in chapter 7.3.8 and Appendix A3.
The TMDI calculation was performed considering the current EU MRLs laid down in Regulation (EC) 2020/856 multiplied by the conversion factors given in the EFSA RO (2014), except for ruminants and pigs, where the new calculated conversion factors (see chapter 7.3.4.2) for meat, fat, liver and kidney were used.
The diet with the highest TMDI is "DE child" with 5% of the ADI (0.4 mg/kg bw/day).
As ARfD was not deemed necessary, acute risk assessment is not relevant.

Based on the TMDI calculation made to estimate the risk for consumer through diet and other means it can be concluded that the use of the product BAS 765 00 F does not lead to an unacceptable risk for consumers when applied according to the recommendations.

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

The results of the peer review are summed up in the EU Review Report/ EFSA Conclusion and draft assessment reports on mefentrifluconazole [EFSA Journal (2018) 16(7): 5379] and kresoxim-methyl [*EFSA Journal 2010;*8(11):1891, *Draft Assessment Report (original version January 1997, revised in March 2010), Final Addendum to Assessment Report (August 2010), Addendum – Confirmatory Data (2014)*].

Based on the EU review appropriate endpoints were used to calculate PEC for mefentrifluconazole and kresoxim-methyl as well as its main metabolites in soil, surface water, ground water for the intended use patterns of 2 x 1.0 L/ha BAS 765 00 F in winter and spring cereals.

All environmental fate studies performed with the active substances or metabolites are adequate to support the proposed use of the formulated product BAS 765 00 F. Thus, no extra studies with the product were conducted.

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

The submitted reports were accepted.
Calculations of PEC_S for active substances, their metabolites and formulation for cereals were accepted.
The endpoints used for PECs assessment were agreed at the EU level.
The interception of 80% was accepted.

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

All used endpoints were agreed at the EU level. For 1,2,4-triazole the endpoints were also agreed at the EU level (EFSA, 2018).

The recommended FOCUS models were used: FOCUS PELMO, FOCUS PEARL and FOCUS MACRO.
Calculations of PEC_{GW} for active substances and its relevant metabolite were provided with PUF = 0.
The winter and spring cereals and multiple application were taken into consideration.
The application dates used in modeling differ from recommended in AppDate tool. This deviation does not affect final PECgw results.

Mefentrifluconazole. A tiered approach was used in PECgw assessment and it was accepted. At Tier 2 the biphasic degradation of 1,2,4-triazole was implemented for PEC_{gw} modeling in accordance with FOCUS Groundwater guidance.
The 80th percentiles PEC_{GW} values for active substance and 1,2,4-triazole were below the trigger value of 0.1 µg/L in Tier 2 to 4 modeling.

Kresoxim-methyl. The 80th percentiles of the predicted annual leachate concentrations of kresoxim-methyl and its both metabolites were below 0.1 µg/L in all tested scenarios.

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

The calculations for PEC in surface water (PEC_{sw}) and sediment (PEC_{sed}) were performed according to the recommendations of the FOCUS working group on surface water scenarios [*FOCUS surface water (2001, 2015)*] in a stepwise approach considering the pathways spray drift, drainage and runoff for mefentrifluconazole as well as for kresoxim-methyl and their metabolites.

Calculations were carried out at Step 1 to Step 4 level. The software packages STEPS1-2 (version 3.2) for Step 1 and Step 2, SWASH 5.3 in combination with MACRO 5.5.4, PRZM 4.3.1 and TOXSWA 5.5.3 for Step 3, and SWAN 5.0.0 for Step 4 were used for the calculations. At Steps 3-4, all FOCUS surface water scenarios relevant for the examined crop and the national assessment were considered for the calculations. Relevant scenarios for the Southern Zone are D2-D6 and R1-R4.

The results are considered acceptable for the subsequent ecotoxicological assessment.

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

Mefentrifluconazole
The vapour pressure at 20°C of the active substance mefentrifluconazole is $<10^{-5}$ Pa. Hence the active substance mefentrifluconazole is regarded as non-volatile.

Kresoxim-methyl
The vapour pressure at 20°C of the active substance kresoxim-methyl is $<10^{-5}$ Pa. Hence the active substance kresoxim-methyl is regarded as non-volatile.

3.8 Ecotoxicology (Part B, Section 9)

Following the intended uses of the formulated product BAS 765 00 F, no risk or unacceptable effects are expected for birds, mammals, honey bees, non-target arthropods others than bees, non-target meso- and macrofauna, soil nitrogen transformation processes and non-target higher plants with no need for additional mitigation measures. For aquatic organisms, no risk or unacceptable effect are expected, if 10 m non-sprayed, vegetated buffer zone is considered.

3.8.1 Effects on terrestrial vertebrates

Birds:

Dietary risk assessment
In the screening step and/or tier1 risk assessment, all TER_A values and all TER_{LT} values for mefentrifluconazole and kresoxim-methyl exceed the trigger set by Commission Regulation (EU) 546/2011 for acceptability of effects.

Drinking water risk assessment
Following EFSA/2009/1438, the puddle scenario is considered relevant for application of BAS 765 00 F according to the proposed use pattern. Since the ratio of the effective application rate to the relevant endpoints is below the value of 3000 for mefentrifluconazole and below 50 for kresoxim-methyl, a quantitative risk assessment for the proposed use pattern of BAS 765 00 F is not necessary.

Secondary poisoning and biomagnification
The log P_{OW} of both mefentrifluconazole and kresoxim-methyl was determined to be 3.4, which triggers an assessment of the potential risk from secondary poisoning. According to the tier1 risk assessment for earthworm- and fish-eating birds, the TER values for mefentrifluconazole and kresoxim-methyl are both above the trigger value of 5 for acceptability of effects. The potential for bioaccumulation of both mefentrifluconazole and kresoxim-methyl was considered low in the respective EU reviews and therefore further evaluation of biomagnification is not necessary.

Overall conclusion
It can be concluded that the risk to birds from application of BAS 765 00 F according to good agricultural practice is acceptable.

Mammals:

Dietary risk assessment
In the screening step and/or tier1 risk assessment, all TER_A values and all TER_{LT} values for mefentrifluconazole and kresoxim-methyl exceed the trigger set by Commission Regulation (EU) 546/2011 for acceptability of effects.

Drinking water risk assessment
Following EFSA/2009/1438, the puddle scenario is considered relevant for application of BAS 765 00 F according to the proposed use pattern. Since the ratio of the effective application rate to the relevant endpoints is below the value of 3000 for mefentrifluconazole and below 50 for kresoxim-methyl, a quantitative risk assessment for the proposed use pattern of BAS 765 00 F is not necessary.

Secondary poisoning and biomagnification
The log P_{OW} of both mefentrifluconazole and kresoxim-methyl was determined to be 3.4, which triggers an assessment of the potential risk from secondary poisoning. According to the tier1 risk assessment for earthworm- and fish-eating mammals, the TER values for mefentrifluconazole and kresoxim-methyl are both above the trigger value of 5 for acceptability of effects. The potential for bioaccumulation of both mefentrifluconazole and kresoxim-methyl was considered low in the respective EU reviews and therefore further evaluation of biomagnification is not necessary.

Overall conclusion
It can be concluded that the risk to mammals from application of BAS 765 00 F according to good agricultural practice is acceptable.

Amphibians and reptiles:

In the EU, there is no requirement to test terrestrial amphibians or reptiles and there is also no guidance available on how to conduct risk assessments for these groups.

In the absence of toxicity data on mefentrifluconazole and kresoxim-methyl, the active substances in the formulation BAS 765 00 F, and considering the lack of guidance for risk assessment, it is assumed that the risk assessments for birds and mammals are protective for terrestrial life-stages of amphibians and reptiles, an approach that is also used by US-EPA (2004).

Reference
US-EPA 2004. Overview of the ecological risk assessment process in the Office of Pesticide Programs, U.S. Environmental Protection Agency. Endangered and Threatened Species Effects Determinations. Office of Prevention, Pesticides and Toxic Substances; Office of Pesticide Programs, Washington, D.C. 92 pp.

3.8.2 Effects on aquatic species

The following risk assessment is based on more detailed information given in the core dossier (Section B09, chapter 9.5), considering in addition the national requirements relevant for Poland.

The standard and refined risk assessment for the active substances mefentrifluconazole and kresoxim-methyl indicates an acceptable risk for all groups of aquatic organisms following the intended uses of the formulation BAS 765 00 F in ‘spring and winter cereals’, if 10 m non-sprayed, vegetated buffer zone is considered.

The PEC/RAC ratios for the metabolites of mefentrifluconazole and kresoxim-methyl are significantly below the trigger of 1 based on standard worst-case assumptions; they are thus considered not to be of ecotoxicological relevance.

The formulation risk assessment revealed an acceptable risk to aquatic organisms following the intended uses of BAS 765 00 F in ‘spring and winter cereals’.

The standard and refined risk assessment provided for the fungicidal product BAS 765 00 F, the active substances mefentrifluconazole and kresoxim-methyl as well as their major metabolites demonstrate that the application of BAS 765 00 F in ‘spring and winter cereals’ according to good agricultural practice is of low risk to aquatic ecosystems, if 10 m non-sprayed, vegetated buffer zone is considered.

3.8.3 Effects on bees

The risk to honey bees from the use of mefentrifluconazole, kresoxim-methyl and BAS 765 00 F was assessed using the maximum single application rate and the LD_{50} values to calculate hazard quotients (HQ) for oral exposure (Q_{HO}) and contact exposure (Q_{HC}) [*OEPP/EPPO, 2010: Environmental risk assessment scheme for plant protection products, Chapter 10: Honeybees (PP 3/10 (3), Bulletin OEPP/EPPO Bulletin 40, 323–331*]. Furthermore, under Regulation (EC) No 1107/2009, no risk assessment scheme exists currently for chronic honey bee or honey bee larvae studies. In the absence of clear guidance (noted and agreed by member states) a preliminary risk assessment according to the current legal requirements (SANCO/10329/2002 and EPPO 2010) has been conducted.

The hazard quotients for BAS 765 00 F and the active substances mefentrifluconazole and kresoxim-methyl for acute oral and acute contact exposure of honey bees are considerably below the Commission Regulation (EU) 546/2011 trigger value of 50. Additionally, the chronic TER for larvae and adult bees exceed

the suggested trigger. Considering the very protective assumptions the risk can be considered acceptable.

Based on these results it can be concluded that low risk to honey bees is expected from applications of BAS 765 00 F according to the proposed uses. This is confirmed by a worst case assessment following EPPO (2010) for chronic adult and honey bee larvae.

No studies on chronic effects of the formulation to adult bees or to larvae were provided in the risk assessment to bees, although this is a data requirement set by the Commission Regulation (EU) 284/2013. For Poland, the deficiencies need to be fill by 31.12.2021.

3.8.4 Effects on other arthropod species other than bees

The testing and risk assessment strategy used here follow the approach recommended in the ESCORT 2 guidance document, ESCORT 3, and the EC Guidance Document on Terrestrial Ecotoxicology (SANCO/10329, 17 October 2002). The risk assessment for BAS 765 00 F is based on Tier I tests with the standard test species *A. rhopalosiphi* and *T. pyri*. The risk assessment is based on the worst-case application rate according to the proposed use pattern.

Based on the results of the conducted first and higher tier risk assessments it can be concluded that low risk for non-target arthropods is expected from the use of BAS 765 00 F according to the proposed use pattern. No unacceptable effects on non-target arthropods are expected in in-field and off-field habitats.

3.8.5 Effects on soil organisms

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna), as well as for soil microorganisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

Effects on non-target soil meso- and macrofauna
The potential risk of BAS 765 00 F, mefentrifluconazole, kresoxim-methyl (as sum of active substances in the formulation) and the relevant metabolites to earthworms and other non-target soil macro-organisms was assessed by comparing the maximum PEC_{soil} values with NOEC or EC_{10} values, to generate long-term TER values (TER_{lt}).

All TER values for BAS 765 00 F, mefentrifluconazole, kresoxim-methyl and the relevant metabolites for chronic exposure of earthworms and other non-target soil organisms (meso- and macrofauna) are considerably higher than the Commission Regulation (EU) 546/2011 trigger value of 5. This indicates that BAS 765 00 F poses no unacceptable risk to earthworms and other non-target soil organisms (meso- and macrofauna) when applied according to the proposed use rate.

Effects on soil microbial activity
The potential risk of BAS 765 00 F, mefentrifluconazole, kresoxim-methyl and the relevant metabolites to soil micro-organisms was assessed by comparing the maximum PEC_{soil} values with the maximum concentration with effects ≤ 25%.

For the formulation BAS 765 00 F, the active substances mefentrifluconazole, kresoxim-methyl as well as their relevant metabolites, the maximum concentration with effects < 25% (SANCO/10329/2002 trigger) are all above the maximum PEC_{soil} values. Therefore, it is concluded that the use of BAS 765 00 F will not pose an unacceptable risk to non-target soil micro-organisms, if applied according to good agricultural practice.

3.8.6 Effects on non-target terrestrial plants

The toxicity of BAS 765 00 F to non-target terrestrial plants has been investigated by carrying out vegetative vigor and seedling emergence studies with up to six dicotyledonous and four monocotyledonous non-

target plant species. Plants showed no sensitivity to pre- and post-emergence exposure at the highest concentration tested.

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field areas, as non-target plants are non-crop plants located outside the treated area. The amount of spray drift reaching off-crop habitats is calculated using the 90th percentile estimates in Appendix IV of ESCORT 2. For a single application to field crops, 2.77% of the application rate was assumed to reach areas at 1 m from the edge of the crop (worst-case scenario). The highest single application rate of BAS 765 00 F is used to calculate the maximum off-field predicted environmental rate ($PER_{off\text{-}field}$). The potential risk of BAS 765 00 F to non-target plants was assessed by comparing the calculated PER value to the ER_{50} values in order to generate TER values (TER).

Based on the results of the greenhouse trials, the TER values for all tested plant species were above the standard trigger of 5.

Based on the risk assessment it can be concluded that BAS 765 00 F poses no unacceptable risk to non-target plants, if applied according to the recommended use pattern. Particular precautions to reduce the environmental concentrations resulting from BAS 765 00 F applications are not required for the protection of terrestrial non-target plants.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Not relevant.

3.9 Relevance of metabolites (Part B, Section 10)

Mefentrifluconazole
The metabolites of mefentrifluconazole were not predicted to occur in groundwater at concentrations exceeding 0.1 µg L^{-1}. Therefore, no assessment of the relevance of these metabolites is required.

The metabolites M700F001 and M700F002 are predicted to occur in groundwater at concentrations above 0.1 µg L^{-1} (see Part B, Chapter 8.8.2). The relevance of M700F001 and M700F002 has already been assessed at EU level (EFSA conclusion, 2012). The relevance assessment is applicable 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).

The metabolites M700F001 and M700F002 are considered not relevant in terms of toxicological properties according to EC guidance document SANCO/221/2000 –rev.10.

Kresoxim-methyl
Metabolites BF 490-1 and BF 490-5 of kresoxim-methyl were not predicted to occur in groundwater at concentrations exceeding 0.1 µg/L (chapter 8.8.2 in Part B, Section 8). An assessment of the relevance of these metabolites was therefore not required.

Appendix 1 Copy of the product label

Uwagi do etykiety:
Fizykochemia – Wnioskodawca nie przedłożył do oceny badania dwuletniego. Z tego powodu przyznanie warunkowego okresu ważności pozostawiono w gestii Ministerstwa.
Toksykologia – usunięto zwrot P272, dodano zwrot H315 i P202, zmieniono treść etykiety w zakresie „Środki ostrożności dla osób stosujących środek, pracowników oraz osób postronnych" i „Pierwsza pomoc".
Pozostałości – brak uwag do etykiety.
Los i zachowanie w środowisku – dodano zwrot P501.
Ekotoksykologia – wprowadzono zwrot H410, w celu ochrony organizmów wodnych wyznaczono nieopryskiwaną, zadarnioną strefę ochronną od zbiorników i cieków wodnych o szerokości 10 m.
Skuteczność działania – zmieniono zalecaną ilość wody, dodano stosowanie w pszenicy jarej, doprecyzowano skuteczność w pszenicy jarej względem septriozy paskowanej liści oraz sposób stosowania środka.

Załącznik do zezwolenia MRiRW nr R- z dnia r.

Posiadacz zezwolenia:
BASF Agro B.V. Arnhem (NL), Oddział w Freienbach, Huobstrasse 3, 8808 Pfäffikon Sz, Konfederacja Szwajcarska, tel.: +41 0 44 781 99 11, fax: +41 0 44 781 99 12

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:
BASF Polska Sp. z.o.o., Al. Jerozolimskie 142B, 02-305 Warszawa, tel.: 22 570 99 99, fax: 22 570 97 92, e-mail: poczta@basf.com

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin: …
Podmiot odpowiedzialny za końcowe etykietowanie środka ochrony roślin:……."

DAXUR

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:
mefentriflukonazol (związek z grupy triazoli) – 100 g/l (9,23%)
krezoksym metylowy (związek z grupy strobiluryn) – 150 g/l (13,85%)

Zezwolenie MRiRW nr R- z dnia r.

Uwaga

H315 H317 H351 H410	Działa drażniąco na skórę. Może powodować reakcję alergiczną skóry. Podejrzewa się, że powoduje raka Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH 401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P202	Nie używać przed zapoznaniem się i zrozumieniem wszystkich środków bezpieczeństwa.

P261	Unikać wdychania par/rozpylonej cieczy.
P280	Stosować rękawice ochronne. ~~/ochronę oczu/ochronę twarzy.~~
P302 + P352	W PRZYPADKU KONTAKTU ZE SKÓRĄ: Umyć dużą ilością wody/mydłem.
P308 + P 313	W przypadku narażenia lub styczności: zasięgnąć porady/zgłosić się pod opiekę lekarza.
P391	Zebrać wyciek.
P501	Zawartość/pojemnik usuwać zgodnie z lokalnymi przepisami

OPIS DZIAŁANIA
FUNGICYD w formie koncentratu zawiesinowego do rozcieńczania wodą (SC), o działaniu układowym i translaminarnym, do stosowania zapobiegawczego, interwencyjnego oraz wyniszczającego w ochronie przed chorobami grzybowymi.
Substancja czynna krezoksym metylowy należy do grupy FRAC C3, mefentriflukonazol do grupy FRAC G1.

STOSOWANIE ŚRODKA
Środek do stosowania przy użyciu samobieżnego lub ciągnikowego opryskiwacza polowego.
Środek Daxur skutecznie zwalcza choroby po jednokrotnej aplikacji, zapewniając długotrwałą ochronę roślin przed chorobami. Ponowny zabieg w tym samym sezonie wegetatywnym należy wykonać w sytuacji zwiększenia presji chorób.

Pszenica ozima
mączniak prawdziwy zbóż i traw, septorioza paskowana liści pszenicy, rdza brunatna pszenicy, łamliwość źdźbła zbóż i traw
Maksymalna /zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha
Termin stosowania: Środek stosować zapobiegawczo lub z chwilą wystąpienia pierwszych objawów chorób, od początku fazy strzelania w źdźbło do końca fazy kwitnienia (BBCH 30-69). W przypadku zwalczania łamliwości źdźbła zabieg wykonać od początku fazy strzelania w źdźbło do fazy drugiego kolanka (BBCH 30-32).
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2
Odstęp między zabiegami: co najmniej 14 dni lub 21 dni (tylko w przypadku, gdy pierwszy zabieg został wykonany po fazie BBCH 49 (widoczne pierwsze ości)).
Zalecana ilość wody: 100-300 l/ha
Zalecane opryskiwanie: drobnokropliste

Pszenica jara
mączniak prawdziwy zbóż i traw, septorioza paskowana liści pszenicy.
Środek jest średnio skuteczny przeciwko septoriozie paskowanej liści pszenicy jarej.
Maksymalna /zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha
Termin stosowania: Środek stosować zapobiegawczo lub z chwilą wystąpienia pierwszych objawów chorób, od początku fazy strzelania w źdźbło do końca fazy kwitnienia (BBCH 30-69).
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2
Odstęp między zabiegami: co najmniej 14 dni lub 21 dni (tylko w przypadku, gdy pierwszy zabieg został wykonany po fazie BBCH 49 (widoczne pierwsze ości)).
Zalecana ilość wody: 100-300 l/ha
Zalecane opryskiwanie: drobnokropliste

Pszenżyto ozime
septoriozy liści, rdza brunatna
Maksymalna /zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha
Termin stosowania: Środek stosować zapobiegawczo lub z chwilą wystąpienia pierwszych objawów chorób, od początku fazy strzelania w źdźbło do końca fazy kwitnienia (BBCH 30-69).
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2
Odstęp między zabiegami: co najmniej 14 dni lub 21 dni (tylko w przypadku, gdy pierwszy zabieg został wykonany po fazie BBCH 49 (widoczne pierwsze ości)).

Zalecana ilość wody: 100-300 l/ha
Zalecane opryskiwanie: drobnokropliste

Żyto ozime
rdza brunatna żyta
Maksymalna /zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha
Termin stosowania: Środek stosować zapobiegawczo lub z chwilą wystąpienia pierwszych objawów chorób, od początku fazy strzelania w źdźbło do końca fazy kwitnienia (BBCH 30-69).
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2
Odstęp między zabiegami: co najmniej 14 dni lub 21 dni (tylko w przypadku, gdy pierwszy zabieg został wykonany po fazie BBCH 49 (widoczne pierwsze ości)).
Zalecana ilość wody: 100-300 l/ha
Zalecane opryskiwanie: drobnokropliste

Jęczmień ozimy
plamistość siatkowa jęczmienia, rdza brunatna jęczmienia
Maksymalna /zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha
Termin stosowania: Środek stosować zapobiegawczo lub z chwilą wystąpienia pierwszych objawów chorób, od początku fazy strzelania w źdźbło do fazy, gdy widoczne są pierwsze ości (BBCH 30-49).
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2
Odstęp między zabiegami: co najmniej 14 dni.
Zalecana ilość wody: 100-300 l/ha
Zalecane opryskiwanie: drobnokropliste

Jęczmień jary
plamistość siatkowa jęczmienia, rdza brunatna jęczmienia
Maksymalna /zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha
Termin stosowania: Środek stosować zapobiegawczo lub z chwilą wystąpienia pierwszych objawów chorób, od początku fazy strzelania w źdźbło do fazy, gdy widoczne są pierwsze ości (BBCH 30-49).
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2
Odstęp między zabiegami: co najmniej 14 dni.
Zalecana ilość wody: 100-300 l/ha
Zalecane opryskiwanie: drobnokropliste

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):
Pszenica ozima, jęczmień jary, jęczmień ozimy, pszenżyto ozime, żyto ozime – 35 dni

1. Środek zawiera następujące substancje czynne: krezoksym metylowy (substancja z grupy strobiluryn, grupa FRAC C3) zakłóca procesy oddechowe grzybów co powoduje hamowanie kiełkowania zarodników, wzrostu grzybni i zarodnikowania) oraz mefentriflukonazol z grupy triazoli (fungicydy inhibitory biosyntezy steroli – inhibitory demetylacji SBI-DMI, wg FRAC Grupa G1).
2. W ramach strategii antyodpornościowej środki grzybobójcze zawierające substancje czynne z tych grup należy stosować maksymalnie w dwóch zabiegach w sezonie na danej plantacji zbóż. Ponadto zaleca się:
   - stosować środek głównie w zabiegach zapobiegawczych (profilaktycznie),
   - zgodnie z zaleceniami zamieszczonymi na etykiecie.
3. Podczas stosowania środka nie dopuścić do znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Przed użyciem wstrząsnąć zawartością opakowania.
Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W

przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).
Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlaniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać.
W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy:
- jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć oraz przepłukać co najmniej trzykrotnie wodą.

W przypadku mycia aparatury przy użyciu środków myjących przeznaczonych do tego celu, z powstałymi popłuczynami należy postępować zgodnie z instrukcją dołączoną do środka myjącego.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.
Stosować rękawice ochronne i odzież roboczą (kombinezon) ~~oraz ochronę oczu/twarzy~~ w trakcie przygotowywania cieczy użytkowej oraz odzież roboczą w trakcie wykonywania zabiegu.
Dokładnie umyć zanieczyszczone powierzchnie ciała po użyciu.
Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.
Zanieczyszczonej odzieży ochronnej nie wynosić poza miejsce pracy.

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie nieopryskiwanej, zadarnionej strefy ochronnej od zbiorników i cieków wodnych o szerokości:
- 10 m ~~lub~~
- ~~5 m z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%.~~

W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od terenów nieużytkowanych rolniczo.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta:
Nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):
-

Okres od ostatniego zastosowania środka na rośliny przeznaczone na paszę do dnia w którym zwierzęta mogą być karmione tymi roślinami (okres karencji dla pasz):
-

Okres od ostatniego zastosowania środka na rośliny do dnia w którym można siać lub sadzić rośliny uprawiane następczo:
Nie ma żadnych ograniczeń dotyczących siewu lub sadzenia roślin uprawianych następczo.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA
Chronić przed dziećmi.
Środek ochrony roślin przechowywać:
- pod zamknięciem,
- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0 ºC - 30ºC.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.
Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC
Antidotum: brak, stosować leczenie objawowe.
W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.
W przypadku narażenia lub styczności: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
W przypadku kontaktu ze skórą: Umyć dużą ilością wody z mydłem.
W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

~~W przypadku dostania się do dróg oddechowych: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić warunki do odpoczynku w pozycji umożliwiającej swobodne oddychanie.~~
~~W przypadku dostania się do oczu: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.~~
~~W przypadku połknięcia: W przypadku złego samopoczucia skontaktować się z ośrodkiem zatruć lub lekarzem. Wypłukać usta.~~

Okres ważności - 2 lata
Data produkcji - .....
Zawartość netto - .....
Nr partii - .....

Appendix 2 Letter of Access

Not relevant.

Appendix 3 Lists of data considered for national authorization

List of data submitted by the applicant and relied on

Please refer to the reference list.

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Please refer to the reference list.