

FINAL REGISTRATION REPORT

Part B

Section 1: Identity

Section 2: Physical and chemical properties

Section 4: Further information

Detailed summary of the risk assessment

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 2020/2096166
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.

Sufficient data on identity, physical and chemical properties and other information are **not** available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are:

- The ambient storage stability is on-going. It can be assessed in post-registration at national level when available.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

BASF Agro B.V., Arnhem (NL) - Freienbach Branch
Huobstrasse 3
8808 Pfaeffikon SZ
Switzerland

Contact: BASF SE
Agricultural solutions
P.O.Box 120
67114 Limburgerhof
Germany

Contact person: xxxxxxxxxxxxxxxx
Tel. No.: xxxxxxxxxxxxxxxx
Email: xxxxxxxxxxxxxxxx

1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

1.2.1 Producer(s) of the preparation

BASF Agro B.V., Arnhem (NL) - Freienbach Branch
Huobstrasse 3
8808 Pfaeffikon SZ
Switzerland

Contact: BASF SE
 Agricultural solutions
 P.O.Box 120
 67114 Limburgerhof
 Germany

Contact person: xxxxxxxxxxxxxxxxxxxx
Tel. No.: xxxxxxxxxxxxxxxxxxxx
Email: xxxxxxxxxxxxxxxxxxxx

Location of manufacturing plant(s):
Confidential information or data are provided separately (Part C).

1.2.2 **Producer(s) of the active substance(s)**

Manufacturer of mefentrifluconazole (legal entity):

BASF Agro B.V., Arnhem (NL) - Freienbach Branch
Huobstrasse 3
8808 Pfaeffikon SZ
Switzerland

Contact: BASF SE
 Agricultural solutions
 P.O.Box 120
 67114 Limburgerhof
 Germany

Contact person: xxxxxxxxxxxxxxxxxxxx
Tel. No.: xxxxxxxxxxxxxxxxxxxx
Email: xxxxxxxxxxxxxxxxxxxx

Location of manufacturing plant(s):
Confidential information or data are provided separately (Part C).

Manufacturer of Kresoxim-methyl (legal entity):

BASF SE
Carl-Bosch-Str. 38
67056 Ludwigshafen (Rhein)
Germany

Contact: BASF SE
 Agricultural solutions
 P.O.Box 120
 67114 Limburgerhof
 Germany

Contact person: xxxxxxxxxxxxxxxxxxxx
Tel. No.: xxxxxxxxxxxxxxxxxxxx
Email: xxxxxxxxxxxxxxxxxxxx

Location of manufacturing plant(s):
Confidential information or data are provided separately (Part C).

1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

1.2.3.1 Mefentrifluconazole

BAS 750 F: min. 970 g/kg

Impurities of toxicological, ecotoxicological or environmental concern:

N,N-dimethylformamide (DMF):	max. 0.5 g/kg
Toluene:	max. 1 g/kg
1,2,4-(1H)-triazole:	max. 1 g/kg

1.2.3.2 Kresoxim-methyl

BAS 490 F: min. 910 g/kg

Impurities of toxicological, ecotoxicological or environmental concern:

Methanol:	max. 5 g/kg
Methyl chloride:	max. 1 g/kg
Toluene:	max. 1 g/kg

1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name: Please refer to Registration Report Part A for the relevant country (or)

Company code number: BAS 765 00 F

1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)

Active substance / variant	Declared content of the pure active substance / variant (g/L)	FAO Limits (min – max)	Technical content* (g/L)	Technical content** (%w/w)
BAS 750 F	100.00	94.00 - 106.00	103.09	9.52
BAS 490 F	150.00	141.00 - 159.00	164.84	15.22

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers

** Based on the density of the formulation = 1.083 g/mL

The formulation was not the representative formulation.

None of the active substances in the formulation are present in the form of a salt, ester, anion or cation.

No safener or synergist is used in the formulation.

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content in formulation ¹⁾
Dimethylformamide (DMF)	47.6 mg/kg
Toluene	247.4 mg/kg
1,2,4-(1H)-triazole	95.2 mg/kg
Methanol	761.0 mg/kg
Methyl chloride	152.2 mg/kg

¹⁾ Based on the specified limits of the relevant impurities in BAS 750F TGAI and BAS 490F TGAI (see 1.2.3)

1.4.2 Information on the active substance(s) (KCP 1.4.2)

Table 1.4-3: Information on BAS 750 F

Type	Name/Code Number
ISO common name	mefentrifluconazole (ISO provisionally approved)
CAS No.	1417782-03-6
EC No.	currently not available
CIPAC No.	currently not available

Table 1.4-4: Information on BAS 490 F

Type	Name/Code Number
ISO common name	Kresoxim-methyl
CAS No.	143390-89-0
EC No.	currently not available
CIPAC No.	568

1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

The formulation does not contain any safeners or synergists.

CONFIDENTIAL information is provided separately (Part C).

1.5 Type and code of the plant protection product (KCP 1.5)

Type: Suspension Concentrate

[Code: SC]

1.6 Function (KCP 1.6)

Fungicide

2 Section 2: Physical, chemical and technical properties of the plant protection product

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 Somicidin Alpha. Studies regarding the combination with BAS 765 00 F were submitted and the application as tank mixture is acceptable.

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

No implication for labelling

Notifier Proposals for Risk and Safety Phrases (KCP 12)

None

Compliance with FAO specifications:

The product BAS 765 00 F complies with FAO specifications.

Formulation used for tests

All tests have been conducted with the preparation BAS 765 00 F.

Table 2-1: Physical, chemical and technical properties of the plant protection product

Annex point	Method used / deviations	Test material	Findings			GL P Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Visual examination; Subjective evaluation by independent persons.	FD-190128-0007: 100 g/l BAS 750 F 150 g/l BAS 490 F		Initial	14 days at 54 °C	Y	[see 2020/2031007 Kroehl T. 2020]	Accepted
			Condition	suspension	suspension			
			Physical state	liquid	liquid			
			Colour	off-white	Off-white			
			Odour	faint aromatic	faint aromatic			
Explosive properties (KCP 2.2.1)	OECD 113 EC A.14	FD-190128-0007: 100 g/l BAS 750 F 150 g/l BAS 490 F	DSC: energy of the exothermic decomposition is below 500 J/g. Additionally, the test item has no explosive properties according to the directive.			Y	[see 2019/1039216 Dreisch S. 2019]	Accepted
Oxidizing properties (KCP 2.2.2)	EC A.21	FD-190128-0007: 100 g/l BAS 750 F 150 g/l BAS 490 F	The test item showed no oxidizing properties according to the Regulation EC No. 440/2008 Method A.21. Oxidizing Properties of Liquids.			Y	[see 2019/1039216 Dreisch S. 2019]	Accepted

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments																																										
Viscosity (KCP 2.5.1)	CIPAC MT 192 OECD Guideline 114	FD-190128-0007: 100 g/l BAS 750 F 150 g/l BAS 490 F	<table border="1"> <thead> <tr> <th colspan="2">Meas. temp</th> <th colspan="5">Dynamic Viscosity</th> </tr> <tr> <th colspan="2">[°C]</th> <th colspan="5">[mPas]</th> </tr> <tr> <th>Storage Temp.</th> <th>Storage time</th> <th>at D = 1s⁻¹</th> <th>at D = 10s⁻¹</th> <th>at D = 100s⁻¹</th> <th>at D = 200s⁻¹</th> <th>Flow behaviour</th> </tr> <tr> <th>[°C]</th> <th>[weeks]</th> <th></th> <th></th> <th></th> <th></th> <th></th> </tr> </thead> <tbody> <tr> <td>-</td> <td>Initial</td> <td>4316</td> <td>698</td> <td>153</td> <td>108</td> <td>shear thinning</td> </tr> <tr> <td>54</td> <td>2</td> <td>3904</td> <td>658</td> <td>149</td> <td>105</td> <td>shear thinning</td> </tr> </tbody> </table>	Meas. temp		Dynamic Viscosity					[°C]		[mPas]					Storage Temp.	Storage time	at D = 1s ⁻¹	at D = 10s ⁻¹	at D = 100s ⁻¹	at D = 200s ⁻¹	Flow behaviour	[°C]	[weeks]						-	Initial	4316	698	153	108	shear thinning	54	2	3904	658	149	105	shear thinning	Y	[see 2020/2031007 Kroehl T. 2020]	Accepted Since there are no compounds classified under Cat.1 aspiration hazard in the formulation (10% is not triggered), the PPP there is no need for further calculating kinematic viscosity. There is no chance to H304 assigning anyway.
			Meas. temp		Dynamic Viscosity																																											
			[°C]		[mPas]																																											
			Storage Temp.	Storage time	at D = 1s ⁻¹	at D = 10s ⁻¹	at D = 100s ⁻¹	at D = 200s ⁻¹	Flow behaviour																																							
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-	Initial	5061	863	171	118	shear thinning																																										
54	2	4344	822	168	114	shear thinning																																										
Surface tension (KCP 2.5.2)	OECD 115 EC A.5 1.6.1	FD-190128-0007: 100 g/l BAS 750 F 150 g/l BAS 490 F	<table border="1"> <thead> <tr> <th>Storage Temp.</th> <th>Storage time</th> <th>Test Concentration</th> <th>Test Temp.</th> <th>Surface Tension</th> </tr> <tr> <th>[°C]</th> <th>[weeks]</th> <th>[%]</th> <th>[°C]</th> <th>[mN/m]</th> </tr> </thead> <tbody> <tr> <td>-</td> <td>Initial</td> <td>0.1</td> <td>20</td> <td>34.2</td> </tr> <tr> <td>-</td> <td>Initial</td> <td>1.0</td> <td>20</td> <td>29.6</td> </tr> </tbody> </table>	Storage Temp.	Storage time	Test Concentration	Test Temp.	Surface Tension	[°C]	[weeks]	[%]	[°C]	[mN/m]	-	Initial	0.1	20	34.2	-	Initial	1.0	20	29.6	Y	[see 2020/2031007 Kroehl T. 2020]	Accepted																						
			Storage Temp.	Storage time	Test Concentration	Test Temp.	Surface Tension																																									
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Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments															
Relative density (KCP 2.6.1)	OECD 109 EC A.3 1.4.4	FD-190128-0007: 100 g/l BAS 750 F 150 g/l BAS 490 F	<table border="1"> <thead> <tr> <th>Storage Temp. [°C]</th> <th>Storage time [weeks]</th> <th>Density at 20°C [g/cm³]</th> <th>Relative Density D²⁰₄</th> <th>Density at 40°C [g/cm³]</th> </tr> </thead> <tbody> <tr> <td>-</td> <td>Initial</td> <td>1.083</td> <td>1.083</td> <td>1.071</td> </tr> <tr> <td>54</td> <td>2</td> <td>1.083</td> <td>1.083</td> <td>n.d.</td> </tr> </tbody> </table>	Storage Temp. [°C]	Storage time [weeks]	Density at 20°C [g/cm ³]	Relative Density D ²⁰ ₄	Density at 40°C [g/cm ³]	-	Initial	1.083	1.083	1.071	54	2	1.083	1.083	n.d.	Y	[see 2020/2031007 Kroehl T. 2020]	Accepted
Storage Temp. [°C]	Storage time [weeks]	Density at 20°C [g/cm ³]	Relative Density D ²⁰ ₄	Density at 40°C [g/cm ³]																	
-	Initial	1.083	1.083	1.071																	
54	2	1.083	1.083	n.d.																	
Bulk density (KCP 2.6.2)			Not applicable for SC formulations																		
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3 HPLC/UPLC : AFL0999/01	FD-190128-0007: 100 g/l BAS 750 F 150 g/l BAS 490 F	<p>Before and after storage the product was completely homogeneous and no sediment or other separated material was observed.</p> <p>The user properties of the formulation are acceptable both initially and after storage, except for the Spontaneity of dispersion.</p> <p>Spontaneity of dispersion was found to be low with acceptable values before storage, but outside acceptable limits after storage. However, in an additional study (BASF Doc 2019/1023496) it was demonstrated that the preparation could be applied through appropriate application equipment without any problems</p> <table border="1"> <thead> <tr> <th></th> <th>Initial</th> <th>14 days at 54°C</th> <th>Deviation</th> </tr> </thead> <tbody> <tr> <td>BAS 750 F [g/L]</td> <td>100.4</td> <td>99.7</td> <td>-0.7 %</td> </tr> <tr> <td>BAS 490 F [g/L]</td> <td>148.9</td> <td>147.7</td> <td>-0.8 %</td> </tr> </tbody> </table> <p><u>Pack appearance / corrosion and weight check:</u></p> <p>No influence of the product on the original container, no corrosion, seal intact and no peculiarities inside of the original container was observed, initially and after accelerated storage for 14 days at 54 °C. Weight change: < 0.01 %</p>		Initial	14 days at 54°C	Deviation	BAS 750 F [g/L]	100.4	99.7	-0.7 %	BAS 490 F [g/L]	148.9	147.7	-0.8 %	Y	[see 2020/2031007 Kroehl T. 2020]	<p>Accepted</p> <p>The HDPE pack remained intact after storage. All tested physico-chemical parameters are accepted.</p> <p>The relevant impurities (both active substances) cannot be forming due the storage. They are forming during the technical materials of the active substances manufacturing process only. So, there is no</p>			
	Initial	14 days at 54°C	Deviation																		
BAS 750 F [g/L]	100.4	99.7	-0.7 %																		
BAS 490 F [g/L]	148.9	147.7	-0.8 %																		

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments								
						need for further testing at storage stability study								
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	OPPTS 830.6317 CIPAC MT 39.3 Low temperature storage stability at 0°C for 7 days	FD-190128-0007: 100 g/l BAS 750 F 150 g/l BAS 490 F	<table border="1"> <thead> <tr> <th>Storage Temp. [°C]</th> <th>Storage time [weeks]</th> <th>Assessment after storage</th> <th>Assessment after 24h standing, one inversion and following 1h standing</th> </tr> </thead> <tbody> <tr> <td>0</td> <td>1</td> <td>After 7 days at 0°C, the sample was homogeneous and no separated material was observed</td> <td>not required</td> </tr> </tbody> </table>	Storage Temp. [°C]	Storage time [weeks]	Assessment after storage	Assessment after 24h standing, one inversion and following 1h standing	0	1	After 7 days at 0°C, the sample was homogeneous and no separated material was observed	not required	Y	[see 2020/2031007 Kroehl T. 2020]	Accepted For suspensibility, please refer to KCP 2.8.3.1. Wet sieve data are present in KCP 2.8.5.1.2
Storage Temp. [°C]	Storage time [weeks]	Assessment after storage	Assessment after 24h standing, one inversion and following 1h standing											
0	1	After 7 days at 0°C, the sample was homogeneous and no separated material was observed	not required											
Minimum content after heat stability testing (KCP 2.7.3)			Not required, because there is less than 5 % decrease in the content of the actives substances.											
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	FD-190128-0007: 100 g/l BAS 750 F 150 g/l BAS 490 F	After 7 days at 0°C, the sample was homogeneous and no separated material was observed	Y	[see 2020/2031007 Kroehl T. 2020]	Please refer to the KCP 2.7.2								
Ambient temperature shelf life (KCP 2.7.5)			This study is on-going, data will be provided end of march 2022			On-going Each member state should consider granting the conditional shelf-life. The missing study can be assessed in post-registration at national level								

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments																																	
Shelf life in months (if less than 2 years) (KCP 2.7.6)			Not applicable																																				
Wettability (KCP 2.8.1)			Not applicable for SC formulations																																				
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.2	FD-190128-0007: 100 g/l BAS 750 F 150 g/l BAS 490 F	0.2 % and 1 % solutions in CIPAC water D before and after storage <table border="1"> <thead> <tr> <th rowspan="3"></th> <th colspan="4">Volume of foam [mL]</th> </tr> <tr> <th colspan="2">Initial</th> <th colspan="2">14 days at 54 °C</th> </tr> <tr> <th>0.2 %</th> <th>1 %</th> <th>0.2 %</th> <th>1 %</th> </tr> </thead> <tbody> <tr> <td>after 10 sec</td> <td>17</td> <td>3</td> <td>27</td> <td>6</td> </tr> <tr> <td>after 1 min</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td> </tr> <tr> <td>after 3 min</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td> </tr> <tr> <td>after 12 min</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td> </tr> </tbody> </table>		Volume of foam [mL]				Initial		14 days at 54 °C		0.2 %	1 %	0.2 %	1 %	after 10 sec	17	3	27	6	after 1 min	0	0	0	0	after 3 min	0	0	0	0	after 12 min	0	0	0	0	Y	[see 2020/2031007 Kroehl T. 2020]	Accepted
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after 10 sec	17	3	27	6																																			
after 1 min	0	0	0	0																																			
after 3 min	0	0	0	0																																			
after 12 min	0	0	0	0																																			
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184	FD-190128-0007: 100 g/l BAS 750 F 150 g/l BAS 490 F	0.2 % and 1 % solutions in CIPAC water D before and after storage (0 °C for 1 week, and 54 °C for 2 weeks) <table border="1"> <thead> <tr> <th colspan="2">Test Conc. [%]</th> <th colspan="2">0.2</th> <th colspan="2">1</th> </tr> <tr> <th>StorageTemp. [°C]</th> <th>Storage time [weeks]</th> <th colspan="4">Suspensibility [%]</th> </tr> <tr> <th colspan="2">Active ingredient(s)</th> <th>BAS 750 F</th> <th>BAS 490 F</th> <th>BAS 750 F</th> <th>BAS 490 F</th> </tr> </thead> <tbody> <tr> <td>-</td> <td>Initial</td> <td>99</td> <td>100</td> <td>97</td> <td>98</td> </tr> <tr> <td>0</td> <td>1</td> <td>99</td> <td>100</td> <td>99</td> <td>100</td> </tr> </tbody> </table>	Test Conc. [%]		0.2		1		StorageTemp. [°C]	Storage time [weeks]	Suspensibility [%]				Active ingredient(s)		BAS 750 F	BAS 490 F	BAS 750 F	BAS 490 F	-	Initial	99	100	97	98	0	1	99	100	99	100	Y	[see 2020/2031007 Kroehl T. 2020]	Accepted			
Test Conc. [%]		0.2		1																																			
StorageTemp. [°C]	Storage time [weeks]	Suspensibility [%]																																					
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0	1	99	100	99	100																																		

Annex point	Method used / deviations	Test material	Findings					GL P Y/N	Reference	Acceptability / comments															
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	OPPTS 830.7520 CIPAC MT 187	FD-190128-0007: 100 g/l BAS 750 F 150 g/l BAS 490 F	<table border="1"> <thead> <tr> <th data-bbox="710 341 860 459">Storage Temp. [°C]</th> <th data-bbox="860 341 1028 459">Storage time [weeks]</th> <th data-bbox="1028 341 1182 459">d10% [µm]</th> <th data-bbox="1182 341 1330 459">d50% [µm]</th> <th data-bbox="1330 341 1480 459">d90% [µm]</th> </tr> </thead> <tbody> <tr> <td data-bbox="710 459 860 504">-</td> <td data-bbox="860 459 1028 504">Initial</td> <td data-bbox="1028 459 1182 504">0.7</td> <td data-bbox="1182 459 1330 504">1.7</td> <td data-bbox="1330 459 1480 504">4.0</td> </tr> <tr> <td data-bbox="710 504 860 549">54</td> <td data-bbox="860 504 1028 549">2</td> <td data-bbox="1028 504 1182 549">0.9</td> <td data-bbox="1182 504 1330 549">2.4</td> <td data-bbox="1330 504 1480 549">6.2</td> </tr> </tbody> </table>					Storage Temp. [°C]	Storage time [weeks]	d10% [µm]	d50% [µm]	d90% [µm]	-	Initial	0.7	1.7	4.0	54	2	0.9	2.4	6.2	Y	[see 2020/2031007 Kroehl T. 2020]	Accepted
Storage Temp. [°C]	Storage time [weeks]	d10% [µm]	d50% [µm]	d90% [µm]																					
-	Initial	0.7	1.7	4.0																					
54	2	0.9	2.4	6.2																					
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	FD-190128-0007: 100 g/l BAS 750 F 150 g/l BAS 490 F	<table border="1"> <thead> <tr> <th data-bbox="710 569 860 687">Storage Temp. [°C]</th> <th data-bbox="860 569 1028 687">Storage time [weeks]</th> <th data-bbox="1028 569 1182 687">Mesh size [µm]</th> <th data-bbox="1182 569 1364 687">retained on sieve [%]</th> </tr> </thead> <tbody> <tr> <td data-bbox="710 687 860 732">-</td> <td data-bbox="860 687 1028 732">Initial</td> <td data-bbox="1028 687 1182 732">75</td> <td data-bbox="1182 687 1364 732">0.00</td> </tr> <tr> <td data-bbox="710 732 860 777">0</td> <td data-bbox="860 732 1028 777">1</td> <td data-bbox="1028 732 1182 777">75</td> <td data-bbox="1182 732 1364 777">0.00</td> </tr> <tr> <td data-bbox="710 777 860 821">54</td> <td data-bbox="860 777 1028 821">2</td> <td data-bbox="1028 777 1182 821">75</td> <td data-bbox="1182 777 1364 821">0.00</td> </tr> </tbody> </table>				Storage Temp. [°C]	Storage time [weeks]	Mesh size [µm]	retained on sieve [%]	-	Initial	75	0.00	0	1	75	0.00	54	2	75	0.00	Y	[see 2020/2031007 Kroehl T. 2020]	Accepted
Storage Temp. [°C]	Storage time [weeks]	Mesh size [µm]	retained on sieve [%]																						
-	Initial	75	0.00																						
0	1	75	0.00																						
54	2	75	0.00																						

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments
Dust content (KCP 2.8.5.2.1)			Not applicable for SC formulations			
Particle size of dust (KCP 2.8.5.2.2)			Not applicable for SC formulations			
Attrition (KCP 2.8.5.3)			Not applicable for SC formulations			
Hardness and integrity (KCP 2.8.5.4)			Not applicable for SC formulations			
Emulsifiability (KCP 2.8.6.1)			Not applicable for SC formulations			
Emulsion stability (KCP 2.8.6.2)			Not applicable for SC formulations			
Re-emulsifiability (KCP 2.8.6.3)			Not applicable for SC formulations			
Flowability (KCP 2.8.7.1)			Not applicable for SC formulations			

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments																																																
Pourability (KCP 2.8.7.2)	CIPAC MT 148	FD-190128-0007: 100 g/l BAS 750 F 150 g/l BAS 490 F	<table border="1"> <thead> <tr> <th colspan="2"></th> <th colspan="6">Residue [% w/w]</th> </tr> <tr> <th colspan="2"></th> <th colspan="2">Residue</th> <th colspan="2">Rinsed residue after 1st rinse</th> <th colspan="2">Rinsed residue after 2nd rinse</th> </tr> <tr> <th>Storage Temp. [°C]</th> <th>Storage time [weeks]</th> <th colspan="6">Poured from</th> </tr> <tr> <th></th> <th></th> <th>Glass cylinder</th> <th>Sales pack</th> <th>Glass cylinder</th> <th>Sales pack</th> <th>Glass cylinder</th> <th>Sales pack</th> </tr> </thead> <tbody> <tr> <td>-</td> <td>Initial</td> <td>4.87</td> <td>n.d.</td> <td>0.45</td> <td>n.d.</td> <td>n.d.</td> <td>n.d.</td> </tr> <tr> <td>54</td> <td>2</td> <td>3.71</td> <td>n.d.</td> <td>0.23</td> <td>n.d.</td> <td>n.d.</td> <td>n.d.</td> </tr> </tbody> </table> <p>n.d.: not determined</p>			Residue [% w/w]								Residue		Rinsed residue after 1 st rinse		Rinsed residue after 2 nd rinse		Storage Temp. [°C]	Storage time [weeks]	Poured from								Glass cylinder	Sales pack	Glass cylinder	Sales pack	Glass cylinder	Sales pack	-	Initial	4.87	n.d.	0.45	n.d.	n.d.	n.d.	54	2	3.71	n.d.	0.23	n.d.	n.d.	n.d.			Accepted
		Residue [% w/w]																																																				
		Residue		Rinsed residue after 1 st rinse		Rinsed residue after 2 nd rinse																																																
Storage Temp. [°C]	Storage time [weeks]	Poured from																																																				
		Glass cylinder	Sales pack	Glass cylinder	Sales pack	Glass cylinder	Sales pack																																															
-	Initial	4.87	n.d.	0.45	n.d.	n.d.	n.d.																																															
54	2	3.71	n.d.	0.23	n.d.	n.d.	n.d.																																															
Dustability following accelerated storage (KCP 2.8.7.3)			Not applicable for SC formulations																																																			
Physical compatibility of tank mixes (KCP 2.9.1)			In total 11 mixtures of BAS 765 00 F with other plant protection products were tested. All mixtures were determined to be physically compatible and can be used in spray applications. In all mixtures no lumping and no flocculation occurred. The mixtures appeared to be homogeneous. Therefore BAS 765 00 F is apparently physically compatible with following tested products: Imtrex, Priaxor, Flexity, Turbo, Medax Top, Camposan Extra, Medax Max, Duplosan DP, Biathlon Plus, Ariane C, Atlantis, Actirob, Pirimor Granulat and Sumicidin Alpha		[see 2019/1063195 Ott C. 2019]	Accepted Yet, according to the GAP table, the PPP is not intended to be used in tank mixture with other PPP																																																
Chemical compatibility of tank mixes (KCP 2.9.2)			Kresoxim-methyl and Mefentrifluconazole, the active substances of BAS 765 00 F, are stable in diluted aqueous conditions. Therefore, none of the functional groups are likely to react under normal tank mix conditions. Imtrex, Priaxor, Flexity, Turbo, Medax Top, Camposan Extra, Medax Max, Duplosan DP, Biathlon Plus, Ariane C, Atlantis, Actirob, Pirimor Granulat and Sumicidin Alpha are approved commercial products for applications in various tank mixtures as they are sufficiently stable in aqueous conditions. No indication of any chemical reaction between the mixed products was observed. Therefore BAS 765 00 F is apparently chemically compatible with the tested products.		[see 2019/1063195 Ott C. 2019]	Accepted Yet, according to the GAP table, the PPP is not intended to be used in tank mixture with other PPP																																																
Adhesion to seeds			Not applicable for SC formulations																																																			

Annex point	Method used / deviations	Test material	Findings	GL P Y/N	Reference	Acceptability / comments
(KCP 2.10.1)						
Distribution to seed (KCP 2.10.2)			Not applicable for SC formulations			
Other/special studies (KCP 2.11)	Application test of BAS 765 00 F with the 150-liter application device	FD-190125-0020: 100 g/l BAS 750 F 150 g/l BAS 490 F	The formulation of BAS 765 00 F is well applicable. No residues were observed during the four trials, neither in the suction filter nor in the calotte. Pressure and flow rate during the trials were constant. Also, the nozzle filters were residue-free, same as the pressure filter. In the application glass tank, no residues were observed. Using anti-foam agent was only necessary at the fourth trial. Cleaning of the sprayer with a water hose was easily accomplished. Addition of detergent or cleaning with a brush was not necessary.	Y	[see 2019/1023496 Ott C. 2019]	Accepted

3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

4 Section 4: Further information on the plant protection product

Safety intervals and other precautions to protect humans, animals and the environment (KCP 4.1)

Recommended methods and precautions (KCP 4.2)

Reference:	CP 4.2/1
Report	Effectiveness of Procedures for Cleaning Application Equipment and Protective Clothing BAS 765 00 F Simon Nord., 2020 Report No. N/A BASF DocID 2020/ 2036308 Authority registration No.
Guideline(s):	DIN EN ISO 16119-2 EPPO Guideline PP 1/292 (1)
Deviations:	No
GLP:	No, not subject to GLP regulations
Acceptability:	Yes

Common agricultural practice implies cleaning of application equipment with water. Although a small amount of the active ingredients Mefentrifluconazole and Kresoxim-methyl remains in the spray tank, a risk from this low concentration can be excluded. A more complex cleaning procedure is not necessary, water is sufficient for cleaning sprayers to prevent damage to plants.

Protective clothing will be cleaned effectively when washed with usual laundry detergents.

Emergency measures in the case of an accident (KCP 4.3)

Reference:	CP 4.3/1
Report	Safety data sheet - BAS 765 00 F, Anonymous, 2020 Report No Version 1.0 BASD DocID 2020/2100840 Authority registration No
Guideline(s):	EC 1907/2006
Deviations:	No
GLP:	No
Acceptability:	Yes

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

BAS 765 00 F is to be marketed in blow moulded high-density polyethylene (HDPE) or fluorinated 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.

Comments of zRMS:	Based on the accelerated study all HDPE made rigid packs are accepted. Furthermore, in case of SC formulation f-HDPE packs are considered as adequate too.
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Table 4.1-1: 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

Table 4.1-2: 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

Table 4.1-3: 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

Table 4.1-4: Packaging information for 1 liter bottle

Type	Description
Material:	HDPE or f-HDPE
Shape/size:	Cylindrical / approx. 88.5 mm diameter x 234 mm
Opening:	42 mm inner diameter
Closure:	screw cap
Seal:	Induction sealed
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-5: 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

Table 4.1-6: 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

Table 4.1-7: 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

Table 4.1-8: 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
Opening:	54 mm inner diameter
Closure:	Polyethylene screw cap
Seal:	Induction sealed
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-9: 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

Table 4.1-10: 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

Table 4.1-11: 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

Table 4.1-12: 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)
Opening:	52 mm inner diameter
Closure:	screw cap + valve
Seal:	Gasket
Manner of construction	extruded
UN/ADR	compliant

The pack complies with ADR/RID regulations. It was tested according to the pack type, material, classification of the contents as specified in ADR regulations. An appropriate UN certificate has been issued. They are labelled individually with all the use instructions.

Reference: CP 4.4/1
Report EU performance test product/filling good: BAS 765 00 F
Maurer B., 2019
Report No. 219.0084.0019 TB 01
BASF DocID 2019/1039218
Authority registration No.
Guideline(s): ADR/RID
Deviations: No
GLP: No, not subject to GLP regulations
Acceptability: Yes

The damaging effects of BAS 765 00 F on test specimen made of HDPE does not exceed the damaging effects of the Model liquid Pfl-Fr 2344. The chemical compatibility of HDPE with the intended product in comparison with Model liquid Pfl-Fr 2344 is verified. The rate of Permeation is less than 0.0089/lh. BAS 765 00 F can be packed in packaging made of HDPE, in case where there is an UN-approval for these packaging for Model liquid Pfl-Fr 2344 and there is no conflict on other transport regulations. The maximum allowable values of vapour pressure and density, given in the certificate of approval, may not be exceeded.

4.2 Procedures for the destruction or decontamination of the plant protection product and its packaging (KCP 4.5)

Reference:	CP 4.5/1
Report	Safety data sheet - BAS 765 00 F, Anonymous, 2020 Report No Version 1.0 BASF DocID 2020/2100840 Authority registration No
Guideline(s):	EC 1907/2006
Deviations:	No
GLP:	No
Acceptability:	Yes

The safety data sheet contains advice for the destruction or decontamination of BAS 765 00 F and its packaging.

4.2.1 Neutralisation procedure (KCP 4.5.1)

The pH of BAS 765 00 F has been determined to around 7.1 for undiluted solution and around 6.6 for a 1% aqueous solution. Therefore, the proposal of a neutralisation procedure is not considered to be necessary. Any spilled product and contaminated soil or water has to be absorbed and disposed according to the use instructions.

4.2.2 Controlled incineration (KCP 4.5.2)

For purposes of disposal, combustion of BAS 765 00 F in a licensed incinerator is recommended. This method of disposal applies also to contaminated packages, which cannot be cleaned or reused.

Although it is possible to incinerate the product at lower temperatures, combustion at approx. 1100 °C with a residence time of about 2 sec. is advised. By doing so, i.e., operating the incinerator according to the conditions laid down in council directive 94/67/EEC resp. directive 2000/76/EC of the European Parliament, one will achieve complete combustion and minimize the formation of undesired by-products in the off-gases.

Due to halogen content in the active ingredient and the formulants of less than 60%, combustion of BAS 765 00 F in a waste incinerator plant does not raise concern about the formation of halogenated dibenzodioxins/-furans.

To minimize waste of packages it is recommended that empty and rinsed containers be delivered to local container collection stations. If these do not exist, empty and rinsed containers must be rendered unusable and disposed of according to local regulations.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1/1	Keller, M.	2020	Physical and chemical properties of formula BAS 765 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2031007 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.2.1/1	Dreisch, S.	2019	Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008) 2019/1039216 consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.2.2/1	Dreisch, S.	2019	Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008) 2019/1039216 consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep. yes Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.3.1/1	Dreisch, S.	2019	Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008) 2019/1039216 consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.3.2/1	Dreisch, S.	2019	Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008) 2019/1039216 consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.3.3/1	Dreisch, S.	2019	Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008) 2019/1039216 consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.4.1/1	Keller, M.	2020	Physical and chemical properties of formula BAS 765 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2031007 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.4.2/1	Keller, M.	2020	Physical and chemical properties of formula BAS 765 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2031007 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.5.1/1	Keller, M.	2020	Physical and chemical properties of formula BAS 765 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2031007 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.5.2/1	Keller, M.	2020	Physical and chemical properties of formula BAS 765 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2031007 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.6.1/1	Keller, M.	2020	Physical and chemical properties of formula BAS 765 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2031007 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.7.1/1	Keller, M.	2020	Physical and chemical properties of formula BAS 765 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2031007 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.7.2/1	Keller, M.	2020	Physical and chemical properties of formula BAS 765 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2031007 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.7.4/1	Keller, M.	2020	Physical and chemical properties of formula BAS 765 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2031007 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.8.2/1	Keller, M.	2020	Physical and chemical properties of formula BAS 765 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2031007 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.8.3.1/1	Keller, M.	2020	Physical and chemical properties of formula BAS 765 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2031007 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.8.3.2/1	Keller, M.	2020	Physical and chemical properties of formula BAS 765 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2031007 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.8.3.2/2	Schlotterbeck, U.	2020	Application test of four batches of BAS 765 00 F after storage at different temperatures with the 150 Liter applica- tion device 2020/2099170 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCP 2.8.5.1.1/1	Keller, M.	2020	Physical and chemical properties of formula BAS 765 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2031007 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.8.5.1.2/1	Keller, M.	2020	Physical and chemical properties of formula BAS 765 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2031007 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.9.1/1	Ott, C.	2019	Physical and chemical compatibility in aqueous tank mixtures of BAS 765 00 F 2019/1063195 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCP 2.9.2/1	Ott, C.	2019	Physical and chemical compatibility in aqueous tank mixtures of BAS 765 00 F 2019/1063195 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCP 2.11/1	Ott, C.	2019	Application test of BAS 765 AE F with the 150-liter application device 2019/1023496 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 4.2/1	Nord, S.	2020	Effectiveness of Procedures for Cleaning Application Equipment and Protective Clothing BAS 765 00 F 2020/2036308 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCP 4.3/1	Anonymous	2020	Safety data sheet - BAS 765 00 F 2020/2100840 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. no Unpublished	No	BASF
KCP 4.4/1	Maurer, B.	2019	BAS 765 00 F EU Performance Test - Packaging made of HDPE 2019/1039218 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. no Unpublished	No	BASF
KCP 4.5/1	Anonymous	2020	Safety data sheet - BAS 765 00 F 2020/2100840 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. no Unpublished	No	BASF

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

BAS 765 00 F is a new product, no already evaluated product studies are available

Appendix 2 Additional data on the physical, chemical and technical properties of the active substance

A 2.1 Mefentrifluconazole

Not applicable

A 2.2 Kresoxim-methyl

Not applicable