

# 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 768 00 F

Product name(s): Revytur

Chemical active substance(s):

Mefentrifluconazole, 25 g/L

Sulphur, 600 g/L

Central Zone

Zonal Rapporteur Member State: Poland

National Addendum

Applicant: BASF

Submission date: July 2023

MS Finalisation date: 23/02/2024

Date: 17/06/2025

## Version history

When	What
03/2023	Initial dRR – BASF DocID 2023/2003989
04/2023	Dossier sent for evaluation
07/2023	Update dRR – BASF DocID 2023/2035954
08/2023	zRMS evaluation of dRR
12/2023	Final version prepared by zRMS after Commenting period
02/2024	zRMS update
05/2025	Applicant update – BASF DocID 2025/2013036 2-year shelf life study included (KCP 2.7.5 and Table 2-2)
06/2025	Evaluation of the two-year study in Poland

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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 available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are: **none.**

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

## **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 Pfäffikon SZ  
 Switzerland

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

Contact person: xxxxxxxxxxxx  
 Tel. No.: xxxxxxxxxxxx  
 E-mail: xxxxxxxxxxxx

### **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 Pfäffikon SZ**  
**Switzerland**

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

Contact person: xxxxxxxxxxxx

Tel. No.: xxxxxxxxxxxx  
Fax No.: xxxxxxxxxxxx  
E-mail: xxxxxxxxxxxx

Location of the 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: xxxxxxxxxxxx  
Tel. No.: xxxxxxxxxxxx  
Fax No.: xxxxxxxxxxxx  
E-mail: xxxxxxxxxxxx

Location of the manufacturing plant(s):

Confidential information or data are provided separately (Part C).

Manufacturer of Sulfur (legal entity):

**BASF SE**  
**Carl-Bosch-Str. 38**  
**67056 Ludwigshafen**  
**Germany**

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

Contact person: xxxxxxxxxxxx  
Tel. No.: xxxxxxxxxxxx  
Fax No.: xxxxxxxxxxxx

E-mail: xxxxxxxxxxxx

Location of the 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

Mefentrifluconazole min. 970 g/kg

Impurities of toxicological, ecotoxicological or environmental concern:

Dimethylformamide (DMF)	max. 0.5 g/kg
Toluene	max. 1.0 g/kg
1,2,4-(1H)-Triazol	max. 1.0 g/kg

#### 1.2.3.2 Sulphur

Sulfur min. 990 g/kg

For further information please refer to Part C

### 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 768 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)
Mefentrifluconazole	25.0	21.25 – 28.75	25.77	1.90
Sulphur	600.0	575.0 – 625.0	606.06	44.56

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

\*\* Based on the density of the formulation = 1.36 g/cm<sup>3</sup>

None of the active substances in the formulation are present in the form of a variant, 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 the plant protection product
Dimethylformamide (DMF)	max. 9.48 mg/kg
Toluene	max. 18.95 mg/kg
1,2,4-(1H)-triazole	max. 18.95 mg/kg

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

**Table 1.4-3: Information on active substance Mefentrifluconazole**

Type	Name/Code Number	
ISO common name	Mefentrifluconazole	No other variant
CAS No.	1417782-03-6	
EC No.	822-682-6	
CIPAC No.	1004	

**Table 1.4-4: Information on active substance Sulfur**

Type	Name/Code Number	
ISO common name	Sulphur	No other variant
CAS No.	7704-34-9	
EC No.	231-722-6	
CIPAC No.	18	

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

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 off-white liquid suspension, with a faint fruity odour. It is not explosive, has no oxidising properties. The product is not flammable. It has an auto-ignition temperature of 235 °C. In aqueous solution, it has a pH value around 7 at ambient temperature. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data for shelf life of at least 2 years at ambient temperature when stored in HDPE containers has been provided showing acceptable results. Its technical characteristics are acceptable for a SC formulation.

The intended concentration of use is 1.0 % to 4.0 %.

The product BAS 768 00 F can be mixed in the tank together with the plant protection products Balaya and Ortiva. Studies regarding the combination with BAS 768 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 768 00 F complies with FAO specifications.

### **Formulation used for tests**

All test have been conducted with the preparation BAS 768 00 F respectively with the precursor SC formulation BAS 768 AL F. The formulation BAS 768 00 F contains a biocide system in difference to BAS 768 AL F. As the content of active ingredients and co-formulants (except preservatives) did not change at all, the same chemical-physical and technical properties of both SC-formulations (BAS 768 00 F and BAS 768 AL F) are expected.

For further details see Part C, Tabel 1.2-2.



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

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Visual assessment and organoleptic determination	BAS 768 00 F, batch FD-210120-1029 25 g/L Mefentrifluconazole 600 g/L Sulphur	The test item is an off-white, liquid with a faint fruity odour, initially and after accelerated storage for 14 days at 54 °C.	Y	[see 2022/2014755 Keller, M. 2022]	Accepted
Explosive properties (KCP 2.2.1)	OECD 113 (DSC), EC A.14;	BAS 768 00 F, batch FD-210120-1029 25 g/L Mefentrifluconazole 600 g/L Sulphur	In the DSC-measurement the energy of the exothermic decomposition of the test item BAS 768 00 F does not go beyond the threshold of -500 J/g. Therefore explosive properties can be excluded. Due to this further test were not necessary.	Y	[see 2021/2008055 Dreisch, S. 2021]	Accepted
Oxidizing properties (KCP 2.2.2)	UN O.2	BAS 768 00 F, batch FD-210120-1029 25 g/L Mefentrifluconazole 600 g/L Sulphur	The test item BAS 768 00 F shows no oxidizing properties according to UN RTDG regulation, test UN O.2.	Y	[see 2021/2008055 Dreisch, S. 2021]	Accepted
Flash point (KCP 2.3.1)	EC A.9 CIPAC MT 12	BAS 768 00 F, batch FD-210120-1029 25 g/L Mefentrifluconazole 600 g/L Sulphur	The test item has no flash point up to the temperature of 125 °C.	Y	[see 2021/2008055 Dreisch, S. 2021]	Accepted
Flammability (KCP 2.3.2)		BAS 768 00 F, batch FD-210120-1029 25 g/L Mefentrifluconazole 600 g/L Sulphur	The flammability test UN N.5 (contact with water) has not been carried out because the test item is known to form a stable mixture in water. It is known that the test item BAS 768 00 F forms a stable mixture in water, therefore the test on flammability (contact with water; UN N.5, EEC A.12)) does not need to be performed	Y	[see 2021/2008055 Dreisch, S. 2021]	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																											
Self-heating (KCP 2.3.3)	EC A.15	BAS 768 00 F, batch FD-210120-1029 25 g/L Mefentrifluconazole 600 g/L Sulphur	The test item has an auto-ignition temperature of 235 °C.	Y N	[see 2021/2008055 Dreisch, S. 2021] [see 2021/2008056 Dreisch, S. 2021]	Accepted																											
Acidity or alkalinity and pH (KCP 2.4.1)			Not applicable. Only required for preparations, which are acidic (pH < 4) or alkaline (pH > 10).																														
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	BAS 768 00 F, batch FD-210120-1029 25 g/L Mefentrifluconazole 600 g/L Sulphur	<table><tr><td colspan="3">pH of 1 % aqueous solutions before and after storage</td></tr><tr><td></td><td colspan="2">pH value</td></tr><tr><td></td><td>Initial</td><td>14 days at 54 °C</td></tr><tr><td></td><td>measured at approx. 23°C</td><td>measured at approx. 24°C</td></tr><tr><td>Pure water</td><td>5.9</td><td>5.9</td></tr><tr><td>1 % in pure water</td><td>7.1</td><td>6.8</td></tr><tr><td>CIPAC water D</td><td>6.5</td><td>6.4</td></tr><tr><td>1 % in CIPAC water D</td><td>7.0</td><td>6.8</td></tr><tr><td>Neat product</td><td>8.0</td><td>7.7</td></tr></table>	pH of 1 % aqueous solutions before and after storage				pH value			Initial	14 days at 54 °C		measured at approx. 23°C	measured at approx. 24°C	Pure water	5.9	5.9	1 % in pure water	7.1	6.8	CIPAC water D	6.5	6.4	1 % in CIPAC water D	7.0	6.8	Neat product	8.0	7.7	Y	[see 2022/2014755 Keller, M. 2022]	Accepted
pH of 1 % aqueous solutions before and after storage																																	
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	Initial	14 days at 54 °C																															
	measured at approx. 23°C	measured at approx. 24°C																															
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CIPAC water D	6.5	6.4																															
1 % in CIPAC water D	7.0	6.8																															
Neat product	8.0	7.7																															

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments					
Viscosity (KCP 2.5.1)	CIPAC MT 192 OECD 114	BAS 768 00 F, batch FD-210120-1029 25 g/L Mefentrifluconazole 600 g/L Sulphur	Dynamic viscosity at 20 °C and 40 °C, before and after storage	Y	[see 2022/2014755 Keller, M. 2022]	Accepted  No a Category 1 aspiration hazard can be assign					
								Dynamic viscosity [mPa*s]			
			Shear rate				Temp. [°C]	Initial	14 days at 54 °C		
			at D = 1 s <sup>-1</sup>				apparent	20	8908	8394	
			at D = 10 s <sup>-1</sup>				apparent	20	1307	1185	
			at D = 100 s <sup>-1</sup>				apparent	20	264	237	
			at D = 200 s <sup>-1</sup>				apparent	20	181	162	
			Flow behaviour				20	Shear thinning	Shear thinning		
			at D = 1 s <sup>-1</sup>				apparent	40	8583	8078	
			at D = 10 s <sup>-1</sup>				apparent	40	1223	1121	
			at D = 100 s <sup>-1</sup>				apparent	40	229	208	
			at D = 200 s <sup>-1</sup>				apparent	40	152	137	
			Flow behaviour				40	Shear thinning	Shear thinning		
			BAS 768 00 F is a non-Newtonian fluid.								
			Kinematic viscosity = 170 mm²/s (at 40°C (Initial, 100 s-1))								

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																				
Surface tension (KCP 2.5.2)	OECD 115 EC A.5 1.6.1	BAS 768 00 F, batch FD-210120-1029 25 g/L Mefentrifluconazole 600 g/L Sulphur	0.5% and 4.0% solutions in pure water, initially <table border="1"><thead><tr><th>Test Concentration</th><th>Test Temp.</th><th>Surface Tension</th></tr><tr><th>[%]</th><th>[°C]</th><th>[mN/m]</th></tr></thead><tbody><tr><td>0.5</td><td>20</td><td>35.1</td></tr><tr><td>4.0</td><td>20</td><td>33.5</td></tr></tbody></table> Based on the provided values BAS 768 00 F should be noted as surface active.	Test Concentration	Test Temp.	Surface Tension	[%]	[°C]	[mN/m]	0.5	20	35.1	4.0	20	33.5	Y	[see 2022/2014755 Keller, M. 2022]	Accepted								
Test Concentration	Test Temp.	Surface Tension																								
[%]	[°C]	[mN/m]																								
0.5	20	35.1																								
4.0	20	33.5																								
Relative density (KCP 2.6.1)	OECD 109 EC A.3 1.4.4	BAS 768 00 F, batch FD-210120-1029 25 g/L Mefentrifluconazole 600 g/L Sulphur	<table border="1"><thead><tr><th></th><th>Temp. [°C]</th><th>Initial</th><th>14 days at 54 °C</th></tr></thead><tbody><tr><td>Density [g/cm³]</td><td>20</td><td>1.360</td><td>1.348</td></tr><tr><td>Relative density D<sup>20</sup><sub>4</sub></td><td>20</td><td>1.360</td><td>-</td></tr><tr><td>Density [g/cm³]</td><td>40</td><td>1.359</td><td>Not measured</td></tr><tr><td>Relative density D<sup>20</sup><sub>4</sub></td><td>40</td><td>1.359</td><td>-</td></tr></tbody></table>		Temp. [°C]	Initial	14 days at 54 °C	Density [g/cm³]	20	1.360	1.348	Relative density D <sup>20</sup> <sub>4</sub>	20	1.360	-	Density [g/cm³]	40	1.359	Not measured	Relative density D <sup>20</sup> <sub>4</sub>	40	1.359	-	Y	[see 2022/2014755 Keller, M. 2022]	Accepted
	Temp. [°C]	Initial	14 days at 54 °C																							
Density [g/cm³]	20	1.360	1.348																							
Relative density D <sup>20</sup> <sub>4</sub>	20	1.360	-																							
Density [g/cm³]	40	1.359	Not measured																							
Relative density D <sup>20</sup> <sub>4</sub>	40	1.359	-																							
Bulk density (KCP 2.6.2)			Not applicable to SC-formulations																							

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments															
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3  Analytical assay AFL1047/01, HPLC-UV	BAS 768 00 F, batch FD-210120-1029 25 g/L Mefentrifluconazole 600 g/L Sulphur	The physical and chemical properties of BAS 768 00 (SC) when stored in a sealed HDPE bottles, as determined in this study, have not changed adversely after accelerated storage for 14 days at 54 °C.	Y	[see 2022/2014755 Keller, M. 2022]	Accepted															
			<u>Active ingredient content:</u>																		
			<table><tr><th>a.i. content</th><th>Initial</th><th>14 days at 54°C</th><th>Deviation</th></tr><tr><td>Mefentrifluconazole* [g/L]</td><td>27.3</td><td>26.1</td><td>-4.4 %</td></tr><tr><td>Sulphur [g/L]</td><td>620.4</td><td>624.7</td><td>0.69</td></tr></table>				a.i. content	Initial	14 days at 54°C	Deviation	Mefentrifluconazole* [g/L]	27.3	26.1	-4.4 %	Sulphur [g/L]	620.4	624.7	0.69			
			a.i. content				Initial	14 days at 54°C	Deviation												
			Mefentrifluconazole* [g/L]				27.3	26.1	-4.4 %												
Sulphur [g/L]	620.4	624.7	0.69																		
*The content of the relevant impurities N,N-dimethylformamide, toluene and 1,2,4-(1H)-Triazol were not determined because they cannot be generated from the active ingredients or the related impurities during storage. Further information is provided in Part B, section 5 (5.2.1.2).																					
<u>Pack appearance / corrosion and weight check</u>  The HDPE pack to remain in good condition over the storage period, with no corrosion and no other influence of the product on the original container. Weight change over the storage period was negligible. An interaction between the product and its original container was not observed.																					
			<table><tr><th>Storage Temp.</th><th>Storage time</th><th>Weight initial</th><th>Weight after storage</th><th>Weight change</th></tr><tr><th>[ °C ]</th><th>[ weeks ]</th><th>[ g ]</th><th>[ g ]</th><th>[ % ]</th></tr><tr><td>54</td><td>2</td><td>1442.97</td><td>1443.52</td><td>0.04</td></tr></table>	Storage Temp.	Storage time	Weight initial	Weight after storage	Weight change	[ °C ]	[ weeks ]	[ g ]	[ g ]	[ % ]	54	2	1442.97	1443.52	0.04			
Storage Temp.	Storage time	Weight initial	Weight after storage	Weight change																	
[ °C ]	[ weeks ]	[ g ]	[ g ]	[ % ]																	
54	2	1442.97	1443.52	0.04																	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Stability after storage for other periods and/or temperatures (KCP 2.7.2)						
Minimum content after heat stability testing (KCP 2.7.3)						
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	BAS 768 00 F, batch FD-210120-1029 25 g/L Mefentrifluconazole 600 g/L Sulphur	After 7 days at 0°C, the sample was homogeneous and no separated material was observed Therefore, BAS 768 00 F is considered to be stable at low temperatures. Regarding suspensibility and wet sieve properties at low temperature see under KCP 2.8.3.1, KCP 2.8.3.2 and KCP 2.8.5.1.2, respectively.	Y	[see 2022/2014755 Keller, M. 2022]	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Ambient temperature shelf life (KCP 2.7.5)			<p><del>Study is still ongoing and will be provided as soon as possible.</del></p> <p>The formulation BAS 768 00 F has been stored for 24 months at 25 °C in HDPE packs. BAS 768 00 F meets the requirements of the shelf life specifications for at least 2 years under practical conditions for SC-formulation type. Detailed results are shown below in Table 2-2.</p>	Y	[see 2025/2014479 Keller, M, 2025]	<p><b>Accepted</b></p> <p>The HDPE container remained intact after storage. All physicochemical properties presented in the table 2-2 are accepted for this SC formylation. In summary, <u>the two-year shelf life can be granted for the PPP.</u></p> <p><del>Ongoing</del></p> <p><del>According to the applicant the study should be completed by Q1, 2025. The study should be submitted when available. It can be assessed in post registration. Temporary shelf life may be granted for the PPP.</del></p>
Shelf life in months (if less than 2 years) (KCP 2.7.6)			Not applicable			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																		
Wettability (KCP 2.8.1)			Not applicable to SC-formulations																																					
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	BAS 768 00 F, batch FD-210120-1029 25 g/L Mefentrifluconazole 600 g/L Sulphur	0.5 % and 4.0 % solutions in CIPAC water D before and after storage <table><tr><td rowspan="2">0.5% w/v dilution in CIPAC D</td><td colspan="2">Volume of foam [mL]</td></tr><tr><td>Initial</td><td>14 days at 54 °C</td></tr><tr><td>After 10 sec</td><td>6</td><td>8</td></tr><tr><td>After 1 min</td><td>0</td><td>0</td></tr><tr><td>After 3 mins</td><td>0</td><td>0</td></tr><tr><td>After 12 mins</td><td>0</td><td>0</td></tr></table> <table><tr><td rowspan="2">4.0 % w/v dilution in CIPAC D</td><td colspan="2">Volume of foam [mL]</td></tr><tr><td>Initial</td><td>14 days at 54 °C</td></tr><tr><td>After 10 sec</td><td>0</td><td>0</td></tr><tr><td>After 1 min</td><td>0</td><td>0</td></tr><tr><td>After 3 mins</td><td>0</td><td>0</td></tr><tr><td>After 12 mins</td><td>0</td><td>0</td></tr></table>	0.5% w/v dilution in CIPAC D	Volume of foam [mL]		Initial	14 days at 54 °C	After 10 sec	6	8	After 1 min	0	0	After 3 mins	0	0	After 12 mins	0	0	4.0 % w/v dilution in CIPAC D	Volume of foam [mL]		Initial	14 days at 54 °C	After 10 sec	0	0	After 1 min	0	0	After 3 mins	0	0	After 12 mins	0	0	Y	[see 2022/2014755 Keller, M. 2022]	Accepted
0.5% w/v dilution in CIPAC D	Volume of foam [mL]																																							
	Initial	14 days at 54 °C																																						
After 10 sec	6	8																																						
After 1 min	0	0																																						
After 3 mins	0	0																																						
After 12 mins	0	0																																						
4.0 % w/v dilution in CIPAC D	Volume of foam [mL]																																							
	Initial	14 days at 54 °C																																						
After 10 sec	0	0																																						
After 1 min	0	0																																						
After 3 mins	0	0																																						
After 12 mins	0	0																																						



Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184  Analytical method AFL1047/01 HPLC-UV	BAS 768 00 F, batch FD-210120-1029 25 g/L Mefentrifluconazole 600 g/L Sulphur	Test Conc.	[ % ]	0.5		Y	[see 2022/2014755 Keller, M. 2022]	Accepted
			StorageTemp.	Storage time	Suspensibility				
			[ °C ]	[ weeks ]	[ % ]				
			Active ingredient(s)		Mefentrifluconazole	Sulfur			
			-	Initial	99	99			
			0	1	99	100			
			54	2	97	100			
			Test Conc.	[ % ]	4.5				
			StorageTemp.	Storage time	Suspensibility				
			[ °C ]	[ weeks ]	[ % ]				
			Active ingredient(s)		Mefentrifluconazole	Sulfur			
			-	Initial	99	100			
			0	1	100	101			
54	2	95	96						

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160  Analytical method AFL1047/01 HPLC-UV	BAS 768 00 F, batch FD-210120-1029 25 g/L Mefentrifluconazole 600 g/L Sulphur	Test Conc.	[ % v/v]	5.0		Y	[see 2022/2014755 Keller, M. 2022]	Accepted
			StorageTemp.	Storage time	Spontaneity of dispersion				
			[ °C ]	[ weeks ]	[ % ]				
			Active ingredient(s)		Mefentrifluconazole	Sulfur			
			-	Initial	97	100			
			0	1	98	101			
			54	2	96	99			
Dispersion stability (KCP 2.8.3.3)			Not applicable to SC-formulations						
Degree of dissolution and dilution stability (KCP 2.8.4)			Not applicable to SC-formulations						
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187	BAS 768 00 F, batch FD-210120-1029 25 g/L Mefentrifluconazole 600 g/L Sulphur		D <sub>10</sub> ( μ m)	D <sub>50</sub> ( μ m)	D <sub>90</sub> ( μ m)	Y	[see 2022/2014755 Keller, M. 2022]	Accepted
			Initial	0.3	1.0	2.5			
			2 weeks at 54°C	0.3	0.9	2.4			

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	BAS 768 00 F, batch FD-210120-1029 25 g/L Mefentrifluconazole 600 g/L Sulphur		% w/w Retention >75 μm	Y	[see 2022/2014755 Keller, M. 2022]	Accepted
			Initial	0.00			
			7 days at 0°C	0.00			
			2 weeks at 54°C	0.00			
			No wet sieve retentions were observed before and after storage, showing no evidence of a significant increase in particle size.				
Dust content (KCP 2.8.5.2.1)			Not applicable to SC-formulations				
Particle size of dust (KCP 2.8.5.2.2)			Not applicable to SC-formulations				
Attrition (KCP 2.8.5.3)			Not applicable to SC-formulations				
Hardness and integrity (KCP 2.8.5.4)			Not applicable to SC-formulations				
Emulsifiability (KCP 2.8.6.1)			Not applicable to SC-formulations				
Emulsion stability (KCP 2.8.6.2)			Not applicable to SC-formulations				
Re-emulsifiability (KCP 2.8.6.3)			Not applicable to SC-formulations				
Flowability (KCP 2.8.7.1)			Not applicable to SC-formulations				

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																		
Pourability (KCP 2.8.7.2)	CIPAC MT 148	BAS 768 00 F, batch FD-210120-1029 25 g/L Mefentrifluconazole 600 g/L Sulphur	<div>Glass cylinder<table><tr><td></td><td>% Poured residue</td><td>% Rinsed residue after 1<sup>st</sup> rinse</td></tr><tr><td>Initial</td><td>5.72</td><td>0.11</td></tr><tr><td>2 weeks at 54°C</td><td>5.07</td><td>0.13</td></tr></table></div> <div>HDPE pack<table><tr><td></td><td>% Poured residue</td><td>% Rinsed residue after 1<sup>st</sup> rinse</td></tr><tr><td>Initial</td><td>3.37</td><td>0.15</td></tr><tr><td>2 weeks at 54°C</td><td>3.34</td><td>0.12</td></tr></table></div> <div>Due to the measured values no further rinse steps has been conducted.</div>		% Poured residue	% Rinsed residue after 1 <sup>st</sup> rinse	Initial	5.72	0.11	2 weeks at 54°C	5.07	0.13		% Poured residue	% Rinsed residue after 1 <sup>st</sup> rinse	Initial	3.37	0.15	2 weeks at 54°C	3.34	0.12	Y	[see 2022/2014755 Keller, M. 2022]	Accepted
	% Poured residue	% Rinsed residue after 1 <sup>st</sup> rinse																						
Initial	5.72	0.11																						
2 weeks at 54°C	5.07	0.13																						
	% Poured residue	% Rinsed residue after 1 <sup>st</sup> rinse																						
Initial	3.37	0.15																						
2 weeks at 54°C	3.34	0.12																						
Dustability following accelerated storage (KCP 2.8.7.3)			Not applicable to SC-formulations																					
Physical compatibility of tank mixes (KCP 2.9.1)	ASTM method E 1518-05	BAS 768 AL F, batch FD-210112-1003 25 g/L Mefentrifluconazole 600 g/L Sulphur	In total 2 mixtures of BAS 768 AL F with other plant protection products were tested, Balaya and Ortiva. 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 768 AL F is apparently physically compatible with the tested products.	N	[see 2021/2028791 Schlotterbeck U., 2021]	Accepted Yet, according to the GAP table this PPP is not intended to be used with other PPP																		

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Chemical compatibility of tank mixes (KCP 2.9.2)	ASTM method E 1518-05	BAS 768 AL F, batch FD-210112-1003 25 g/L Mefentrifluconazole 600 g/L Sulphur	Mefentrifluconazole and Sulfur, the ingredients of BAS 768 AL F, are stable in diluted aqueous conditions. Therefore, none of the functional groups are likely to react under normal tank mix conditions. The tank mix partners Balaya and Ortiva 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 768 AL F is apparently chemically compatible with the tested products.	N	[see 2021/2028791 Schlotterbeck U., 2021]	Accepted  Yet, according to the GAP table this PPP is not intended to be used with other PPP
Adhesion to seeds (KCP 2.10.1)			Not applicable to SC-formulations			
Distribution to seed (KCP 2.10.2)			Not applicable to SC-formulations			
Other/special studies (KCP 2.11)			Not available			

**Table 2-2: Storage stability at ambient temperature after 24 months storage at 25 °C**  
**SC-formulation BAS 768 00 F; intended product dose: 0.5 to 4.0 % v/v; HDPE package**  
[see DocID 2025/2014479, Keller M. 2025]: BAS 768 00 F, Batch No. FRE-002386, 25 g/L Mefentrifluconazole and 600 g/L Sulfur

Annex point	Method used / deviations	Initial	After 104 weeks
Colour and physical state (KCP 2.1)	Visual assessment and organoleptic determination	The test substance is an off-white liquid suspension with a faint fruity odour.	The test substance is an off-white liquid suspension with a faint fruity odour.

pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	pH of 1 % w/v dispersions / solutions at room temperature:		pH of 1 % w/v dispersions / solutions at room temperature:	
			pH value (Temp.)		pH value (Temp.)
		pure water	5.7 (22 °C)	pure water	5.8 (23 °C)
		1 % in pure water	6.6 (22 °C)	1 % in pure water	6.1 (23 °C)
		CIPAC water D	6.3 (22 °C)	CIPAC water D	6.3 (23 °C)
		1 % in CIPAC water D	6.6 (21 °C)	1 % in CIPAC water D	6.2 (23 °C)
		neat	7.7 (22 °C)	neat	6.7 (23 °C)
Viscosity (KCP 2.5.1)	OECD 114 CIPAC MT 192		at 20 °C	at 40 °C	
		Dynamic viscosity (mPa s)			Dynamic viscosity (mPa s)
		at D = 1 s <sup>-1</sup>	10640	10700	at D = 1 s <sup>-1</sup>
		at D = 10 s <sup>-1</sup>	1567	1560	at D = 10 s <sup>-1</sup>
		at D = 100 s <sup>-1</sup>	314	292	at D = 100 s <sup>-1</sup>
		at D = 200 s <sup>-1</sup>	214	190	at D = 200 s <sup>-1</sup>
		Flow behaviour	shear thinning	shear thinning	Flow behaviour
Relative density (KCP 2.6.1)	OECD 109 EC A.3 1.4.4	Density [g/cm <sup>3</sup> ] at 20°C	1.363		Density [g/cm <sup>3</sup> ] at 20°C
		Relative density D <sub>4</sub> <sup>20</sup>	1.363		Relative density D <sub>4</sub> <sup>20</sup>
Persistence of foam (KCP 2.8.2)	CIPAC MT 47.3	0.5 % and 4.0 % dispersions / solutions in CIPAC water D:		0.5 % and 4.0 % dispersions / solutions in CIPAC water D:	
			Volume of foam [mL]		Volume of foam [mL]
			0.5 %	4.0 %	
		after 10 sec	0	0	after 10 sec
		after 1 min	0	0	after 1 min
		after 3 min	0	0	after 3 min
		after 12 min	0	0	after 12 min

Suspensibility (KCP 2.8.3.1)	CIPAC MT 184.1  Analytical method AFL1002/01 HPLC-UV	Dilution rate 0.5% in CIPAC water D: <table><tr><td>Active ingredi-ent</td><td>Mefentrifluconazole</td><td>Sulfur</td></tr><tr><td></td><td colspan="2">% suspensibility</td></tr><tr><td></td><td>99</td><td>100</td></tr></table> Product showed acceptable active substance suspensibility.  Dilution rate 4.0% in CIPAC water D: <table><tr><td>Active ingredi-ent</td><td>Mefentrifluconazole</td><td>Sulfur</td></tr><tr><td></td><td colspan="2">% suspensibility</td></tr><tr><td></td><td>99</td><td>104</td></tr></table> Product showed acceptable active substance suspensibility.	Active ingredi-ent	Mefentrifluconazole	Sulfur		% suspensibility			99	100	Active ingredi-ent	Mefentrifluconazole	Sulfur		% suspensibility			99	104	Dilution rate 0.5% in CIPAC water D: <table><tr><td>Active ingredi-ent</td><td>Mefentrifluconazole</td><td>Sulfur</td></tr><tr><td></td><td colspan="2">% suspensibility</td></tr><tr><td></td><td>99</td><td>100</td></tr></table> Product showed acceptable active substance suspensibility.  Dilution rate 4.0% in CIPAC water D: <table><tr><td>Active ingredi-ent</td><td>Mefentrifluconazole</td><td>Sulfur</td></tr><tr><td></td><td colspan="2">% suspensibility</td></tr><tr><td></td><td>98</td><td>97</td></tr></table> Product showed acceptable active substance suspensibility.	Active ingredi-ent	Mefentrifluconazole	Sulfur		% suspensibility			99	100	Active ingredi-ent	Mefentrifluconazole	Sulfur		% suspensibility			98	97
Active ingredi-ent	Mefentrifluconazole	Sulfur																																					
	% suspensibility																																						
	99	100																																					
Active ingredi-ent	Mefentrifluconazole	Sulfur																																					
	% suspensibility																																						
	99	104																																					
Active ingredi-ent	Mefentrifluconazole	Sulfur																																					
	% suspensibility																																						
	99	100																																					
Active ingredi-ent	Mefentrifluconazole	Sulfur																																					
	% suspensibility																																						
	98	97																																					
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160  Analytical method AFL1002/01 HPLC-UV	Spontaneity of dispersion at 5.0 % [%]: <table><tr><td>Mefentrifluconazole</td><td>Sulfur</td></tr><tr><td>93</td><td>94</td></tr></table> Product showed acceptable spontaneity.	Mefentrifluconazole	Sulfur	93	94	Spontaneity of dispersion at 5.0 % [%]: <table><tr><td>Mefentrifluconazole</td><td>Sulfur</td></tr><tr><td>93</td><td>95</td></tr></table> Product showed decreased spontaneity throughout the storage period, but in tolerable range.	Mefentrifluconazole	Sulfur	93	95																												
Mefentrifluconazole	Sulfur																																						
93	94																																						
Mefentrifluconazole	Sulfur																																						
93	95																																						
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187	<table><tr><td>D<sub>10</sub> (μ m)</td><td>D<sub>50</sub> (μ m)</td><td>D<sub>90</sub> (μ m)</td></tr><tr><td>0.3</td><td>0.9</td><td>2.3</td></tr></table>	D <sub>10</sub> (μ m)	D <sub>50</sub> (μ m)	D <sub>90</sub> (μ m)	0.3	0.9	2.3	<table><tr><td>D<sub>10</sub> (μ m)</td><td>D<sub>50</sub> (μ m)</td><td>D<sub>90</sub> (μ m)</td></tr><tr><td>0.3</td><td>0.9</td><td>2.3</td></tr></table> No change in Particle size over the storage period.	D <sub>10</sub> (μ m)	D <sub>50</sub> (μ m)	D <sub>90</sub> (μ m)	0.3	0.9	2.3																								
D <sub>10</sub> (μ m)	D <sub>50</sub> (μ m)	D <sub>90</sub> (μ m)																																					
0.3	0.9	2.3																																					
D <sub>10</sub> (μ m)	D <sub>50</sub> (μ m)	D <sub>90</sub> (μ m)																																					
0.3	0.9	2.3																																					

Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	<table><tr><td>% w/w Retention &gt;75 μm</td></tr><tr><td>0.00</td></tr></table> <p>No wet sieve retentions were observed at initial time.</p>	% w/w Retention >75 μm	0.00	<table><tr><td>% w/w Retention &gt;75 μm</td></tr><tr><td>0.00</td></tr></table> <p>No wet sieve retentions were observed before and after storage, showing no evidence of a significant increase in particle size.</p>	% w/w Retention >75 μm	0.00				
% w/w Retention >75 μm											
0.00											
% w/w Retention >75 μm											
0.00											
Pourability (KCP 2.8.7.2)	CIPAC MT 148	<table><tr><td>% Poured residue</td><td>% Rinsed residue after 1<sup>st</sup> rinse</td></tr><tr><td>4.02</td><td>0.22</td></tr></table> <p>The product showed acceptable pouring and rinsing properties</p>	% Poured residue	% Rinsed residue after 1 <sup>st</sup> rinse	4.02	0.22	<table><tr><td>% Poured residue</td><td>% Rinsed residue after 1<sup>st</sup> rinse</td></tr><tr><td>4.23</td><td>0.17</td></tr></table> <p>The product showed acceptable pouring and rinsing properties after storage.</p>	% Poured residue	% Rinsed residue after 1 <sup>st</sup> rinse	4.23	0.17
% Poured residue	% Rinsed residue after 1 <sup>st</sup> rinse										
4.02	0.22										
% Poured residue	% Rinsed residue after 1 <sup>st</sup> rinse										
4.23	0.17										



Other/special studies (KCP 2.11)	Analytical method AFL1047/01 HPLC-UV	<b>Content of active ingredients:</b> <table><tr><th></th><th>a.i. content [g/L]</th><th>Nominal content [g/L]</th></tr><tr><td>Mefentrifluconazole <sup>1)</sup></td><td>25.7</td><td>25</td></tr><tr><td>Sulfur</td><td>605.3</td><td>600</td></tr></table>		a.i. content [g/L]	Nominal content [g/L]	Mefentrifluconazole <sup>1)</sup>	25.7	25	Sulfur	605.3	600	<b>Content of active ingredients:</b> <table><tr><th></th><th>a.i. content [g/L]</th><th>Nominal content [g/L]</th></tr><tr><td>Mefentrifluconazole <sup>1)</sup></td><td>25.6</td><td>25</td></tr><tr><td>Sulfur</td><td>605.6</td><td>600</td></tr></table>		a.i. content [g/L]	Nominal content [g/L]	Mefentrifluconazole <sup>1)</sup>	25.6	25	Sulfur	605.6	600		
		a.i. content [g/L]	Nominal content [g/L]																				
Mefentrifluconazole <sup>1)</sup>	25.7	25																					
Sulfur	605.3	600																					
	a.i. content [g/L]	Nominal content [g/L]																					
Mefentrifluconazole <sup>1)</sup>	25.6	25																					
Sulfur	605.6	600																					
	Analytical methods: AFL1010/01 GC-MS (DMF) AFL0948/03 GC-MS (Toluene) AFL0977/03 HPLC-MS (1,2,4-(1H)-triazole)	<b>Initial values before storage:</b> N,N-DMF <sup>1)</sup> : 8.5 mg/kg Toluene <sup>1)</sup> : 15.3 mg/kg 1,2,4-(1H)-triazole <sup>1)</sup> : 20.2 mg/kg  Values based on the precision results of the analytical method validations provided in RR, part B section 5.  <b>Weight check, product stability, pack (HDPE) appearance and corrosion:</b> <table><tr><td><b>Appearance</b></td><td>completely homogenous; no sediment</td></tr><tr><td><b>Weight [g]</b></td><td>1459.40</td></tr><tr><td><b>Weight change [%]</b></td><td>---</td></tr><tr><td><b>Package appearance</b></td><td>---</td></tr><tr><td><b>Corrosion</b></td><td>No corrosion, seal intact and no peculiarities inside of the original container were observed (visual inspection).</td></tr></table>	<b>Appearance</b>	completely homogenous; no sediment	<b>Weight [g]</b>	1459.40	<b>Weight change [%]</b>	---	<b>Package appearance</b>	---	<b>Corrosion</b>	No corrosion, seal intact and no peculiarities inside of the original container were observed (visual inspection).	<sup>1)</sup> The contents of the relevant impurities N,N- dimethylformamide (N,N-DMF), toluene and 1,2,4-(1H)-Triazol were not determined because it is considered that they cannot be formed from degradation of the active ingredients mefentrifluconazole and azoxystrobin, there impurities or hydrolysis products during storage.  <b>Weight check, product stability, pack (HDPE) appearance and corrosion:</b> <table><tr><td><b>Appearance</b></td><td>26% v/v supernatant layer; no sediment after storage. Small amount of supernatant layer (&lt; 1cm); no sediment after 3 inversion</td></tr><tr><td><b>Weight [g]</b></td><td>1458.36</td></tr><tr><td><b>Weight change [%]</b></td><td>&lt; 0.1</td></tr><tr><td><b>Package appearance</b></td><td>no influence of the product on the original container</td></tr><tr><td><b>Corrosion</b></td><td>No corrosion, seal intact and no peculiarities inside of the original container were observed (visual inspection).</td></tr></table>	<b>Appearance</b>	26% v/v supernatant layer; no sediment after storage. Small amount of supernatant layer (< 1cm); no sediment after 3 inversion	<b>Weight [g]</b>	1458.36	<b>Weight change [%]</b>	< 0.1	<b>Package appearance</b>	no influence of the product on the original container	<b>Corrosion</b>	No corrosion, seal intact and no peculiarities inside of the original container were observed (visual inspection).
<b>Appearance</b>	completely homogenous; no sediment																						
<b>Weight [g]</b>	1459.40																						
<b>Weight change [%]</b>	---																						
<b>Package appearance</b>	---																						
<b>Corrosion</b>	No corrosion, seal intact and no peculiarities inside of the original container were observed (visual inspection).																						
<b>Appearance</b>	26% v/v supernatant layer; no sediment after storage. Small amount of supernatant layer (< 1cm); no sediment after 3 inversion																						
<b>Weight [g]</b>	1458.36																						
<b>Weight change [%]</b>	< 0.1																						
<b>Package appearance</b>	no influence of the product on the original container																						
<b>Corrosion</b>	No corrosion, seal intact and no peculiarities inside of the original container were observed (visual inspection).																						

## RMS conclusion

Considering given data it is acceptable to set the two-year shelf life for the PPP.

### 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)

Comments of zRMS:	Accepted
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Reference:	CP 4.2/1
Report	Effectiveness of Procedures for Cleaning Application Equipment and Protective Clothing - BAS 768 00 F., Langknecht, T., 2021 Report No 871265 BASF DocID 2021/2034436 Authority registration No
Guideline(s):	DIN EN ISO 16119-2, EPPO PP 1/292 (1)
Deviations:	No
GLP:	No, not subject to GLP regulations
Acceptability:	Yes

Instead of a large-scale test, a calculation was carried out with a high safety margin for all relevant parameters. A “double rinse procedure” was assumed for the calculation. The result of the calculation, based on the recommendation for the use of the formulation, the parameters of the proposed cleaning procedure and application equipment, is within the expected range. Although a small amount of the active ingredients Mefentrifluconazole and Sulfur remain 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. It is not necessary to add cleaning agents.

The protective clothes of the applicators are usually made of cotton. The polar surface of the fiber presents affinity to the non-polar active ingredient. Agrochemical formulations are designed for excellent mixing with water by adding detergents and emulsifiers. Therefore, usual laundering with detergents will suspend or dissolve any contamination efficiently.

Good agricultural practice includes appropriate cleaning directly after use, as the removal of dried residues in the tank is difficult and may require the use of additional cleaning agents. As the tank interior is typically cleaned with cleaning nozzles, these need to have sufficient strength and reach all surfaces inside the tank. They therefore should be installed by an especially skilled technician and their function should be tested regularly. Moreover, the operator must rinse all tubes and dead volumes sufficiently, as described in the sprayer’s manual.

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

Comments of zRMS:	Accepted
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Reference: CP 4.3/1

Report Safety Data Sheet - Revytur,  
Anonymous, 2023  
report No Version 1.0  
BASF DocID 2023/2007492  
Authority registration No

Guideline(s): EC 1907/2006

Deviations: No

GLP: No, not subject to GLP regulations

Acceptability: Yes

### 4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

BAS 768 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

**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 104 mm
Opening:	42 mm inner diameter
Closure:	screw cap
Seal:	Induction sealed or gasket
Manner of construction	blow moulded
UN/ADR	compliant

**Table 4.1-2: Packaging information for 0.25 litre 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:	Induction sealed or gasket
Manner of construction	blow moulded

Type	Description
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:	Induction sealed or gasket
Manner of construction	blow moulded
UN/ADR	compliant

**Table 4.1-4: Packaging information for 1 litre 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 or gasket
Manner of construction	blow moulded
UN/ADR	compliant

**Table 4.1-5: Packaging information for 1 litre 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:	Induction sealed or gasket
Manner of construction	blow moulded
UN/ADR	compliant

**Table 4.1-6: Packaging information for 5 litre 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:	Induction sealed or gasket

Type	Description
Manner of construction	blow moulded
UN/ADR	compliant

**Table 4.1-7: Packaging information for 5 litre 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 sealed or gasket
Manner of construction	blow moulded
UN/ADR	compliant

**Table 4.1-8: Packaging information for 10 litre 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 or gasket
Manner of construction	blow moulded
UN/ADR	compliant

**Table 4.1-9: Packaging information for 10 litre 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:	Induction sealed or gasket
Manner of construction	blow moulded
UN/ADR	compliant

**Table 4.1-10: Packaging information for 15 litre 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:	Induction sealed or gasket

Type	Description
Manner of construction	blow moulded
UN/ADR	compliant

**Table 4.1-11: Packaging information for 20 litre container**

Type	Description
Material:	HDPE or f-HDPE
Shape/size:	Rectangular / approx. 290 x 235 x 424 mm
Opening:	52 mm inner diameter
Closure:	screw cap
Seal:	Induction sealed or gasket
Manner of construction	blow moulded
UN/ADR	compliant

**Table 4.1-12: Packaging information for 50 litre 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, plug or valve
Seal:	Gasket
Manner of construction	blow moulded
UN/ADR	compliant

**Table 4.1-13: Packaging information for 100 litre 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, plug or valve
Seal:	Gasket
Manner of construction	blow moulded
UN/ADR	compliant

**Table 4.1-14: Packaging information for 200 litre container**

Type	Description
Material:	HDPE or f-HDPE
Shape/size:	Cylindrical / approx. 581 mm x 935 mm (d x h)
Opening:	52 mm and/or 65 inner diameter
Closure:	screw cap, plug or valve
Seal:	Gasket

Type	Description
Manner of construction	blow moulded
UN/ADR	compliant

**Table 4.1-15: Packaging information for 1000 litre container**

Type	Description
Material:	HDPE or f-HDPE
Shape/size:	Rectangular / approx. 1200 mm x 1000 x 1150 mm
Opening:	54 mm and 155 inner diameter
Closure:	screw cap, plug or valve
Seal:	Gasket
Manner of construction	blow moulded
UN/ADR	compliant

**RMS comment on packages**

Based on the accelerated study and the two-year one done in HDPE pack, all the pack (that are presented above) are accepted.

Comments of zRMS:	Accepted
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Reference: CP 4.4/1

Report BAS 768 00 F - EU Performance Test in HDPE,  
Maurer, B., 2021  
Report No 871255, 221.0084.0017 TB01  
BASF DocID 2021/2008057  
Authority registration No

Guideline(s): no guidelines available

Deviations: No

GLP: No, not subject to GLP regulations

Acceptability: Yes

The chemical compatibility of HDPE with BAS 768 00 F in comparison with Model liquid Pfl-Fr 2344 is verified. The permeation rate is less than 0.008 g/lh.

BAS 768 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.

Comments of zRMS:	Accepted
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Reference: CP 4.4/2

Report Physical and chemical properties of formula BAS 768 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C),  
Keller, M., 2022  
Report No 871256\_1  
BASF DocID 2022/2014755  
Authority registration No

Guideline(s): CLI Technical Monograph No. 17, EU Regulation 1107/2009 with Regulation 284/2013, FAO and WHO Specifications for Pesticides third revision of the first edition Rome 2016

Deviations: No

GLP: Yes, (certified by Landesamt fuer Umwelt, Mainz, Germany)

Acceptability: Yes

Comments of zRMS:	Accepted
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Reference: CP 4.4/2

Report Physical and Chemical Properties of BAS 768 00 F: Storage stability for up to 156 weeks at 25°C in HDPE packs,  
Keller, M., 2025  
Report No 949471\_1  
BASF DocID 2025/2014479  
Authority registration No

Guideline(s): CLI Technical Monograph No. 17, EPA 40 CFR 158, EU Regulation 1107/2009 with Regulation 283/2013, OCSPP-Numbers see chapter 2.6 Methods, Manual on the Development and Use of FAO and WHO Specifications for Chemical Pesticides, Second Edition, Rome and Geneva, 2022

Deviations: No

GLP: Yes, (certified by Landesamt fuer Umwelt, Mainz, Germany),

Acceptability: Yes



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

Comments of zRMS:	Accepted
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Reference:	CP 4.5/1
Report	Safety Data Sheet - Revytur, Anonymous, 2023 report No Version 1.0 BASF DocID 2023/2007492 Authority registration No
Guideline(s):	EC 1907/2006
Deviations:	No
GLP:	No, not subject to GLP regulations
Acceptability:	Yes

### **4.2.1 Neutralisation procedure (KCP 4.5.1)**

The pH of BAS 768 00 F has been determined to around 7 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 768 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 768 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.	2022	Physical and chemical properties of formula BAS 768 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C)  2022/2014755  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	BASF
KCP 2.2.1/1	Dreisch, S.	2021	BAS 768 00 F - Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008)  2021/2008055  consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep.  yes  Unpublished	No	BASF
KCP 2.2.2/1	Dreisch, S.	2021	BAS 768 00 F - Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008)  2021/2008055  consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep.  yes  Unpublished	No	BASF

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCP 2.3.1/1	Dreisch, S.	2021	BAS 768 00 F - Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008)  2021/2008055  consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep.  yes  Unpublished	No	BASF
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KCP 2.3.3/1	Dreisch, S.	2021	BAS 768 00 F - Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008)  2021/2008055  consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep.  yes  Unpublished	No	BASF
KCP 2.3.3/2	Dreisch, S.	2021	BAS 768 00 F: Determination of the SADT according to UN Transport Regulation  2021/2008056  consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, 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 2.4.2/1	Dreisch, S.	2021	<del>BAS 768 00 F – Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008)</del>  <del>2021/2008055</del>  <del>consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep.</del>  <del>yes</del>  <del>Unpublished</del>	No	BASF
KCP 2.4.2/1	Keller, M.	2022	Physical and chemical properties of formula BAS 768 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C)  2022/2014755  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	BASF
KCP 2.5.1/1	Dreisch, S.	2021	<del>BAS 768 00 F – Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008)</del>  <del>2021/2008055</del>  <del>consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep.</del>  <del>yes</del>  <del>Unpublished</del>	No	BASF
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KCP 2.5.2/1	Keller, M.	2022	Physical and chemical properties of formula BAS 768 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C)  2022/2014755  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	BASF
KCP 2.6.1/1	Dreisch, S.	2021	<del>BAS 768 00 F – Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008)</del>  <del>2021/2008055</del>  <del>consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep.</del>  <del>yes</del>  <del>Unpublished</del>	No	BASF
KCP 2.6.1/1	Keller, M.	2022	Physical and chemical properties of formula BAS 768 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C)  2022/2014755  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	BASF

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KCP 2.7.1/1	Dreisch, S.	2021	<del>BAS 768 00 F – Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008)</del>  <del>2021/2008055</del>  <del>consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep.</del>  <del>yes</del>  <del>Unpublished</del>	No	BASF
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KCP 2.7.5/1 KCP 2.1 KCP 2.4.2 KCP 2.5.1 KCP 2.6.2 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.3.2 KCP 2.8.5.1.1 KCP 2.8.5.1.2 KCP 2.8.7.2 KCP 2.11	Keller, M.	2025	Physical and Chemical Properties of BAS 768 00 F: Storage stability for up to 156 weeks at 25°C in HDPE packs 2025/2014479 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.8.2/1	Dreisch, S.	2021	BAS 768 00 F – Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008) 2021/2008055 consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep. yes Unpublished	No	BASF
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KCP 2.8.3.1/1	Dreisch, S.	2021	<del>BAS 768 00 F – Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008)</del>  <del>2021/2008055</del>  <del>consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep.</del>  <del>yes</del>  <del>Unpublished</del>	No	BASF
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KCP 2.8.5.1.1/1	Dreisch, S.	2021	<del>BAS 768 00 F – Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008)</del>  <del>2021/2008055</del>  <del>consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep.</del>  <del>yes</del>  <del>Unpublished</del>	No	BASF



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KCP 2.8.5.1.1/1	Keller, M.	2022	Physical and chemical properties of formula BAS 768 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C)  2022/2014755  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	BASF
KCP 2.8.5.1.2/1	Dreisch, S.	2021	<del>BAS 768 00 F – Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008)</del>  <del>2021/2008055</del>  <del>consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep.</del>  yes  Unpublished	No	BASF
KCP 2.8.5.1.2/1	Keller, M.	2022	Physical and chemical properties of formula BAS 768 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C)  2022/2014755  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished	No	BASF
KCP 2.8.7.2/1	Dreisch, S.	2021	<del>BAS 768 00 F – Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008)</del>  <del>2021/2008055</del>  <del>consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep.</del>  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 2.8.7.2/1	Keller, M.	2022	Physical and chemical properties of formula BAS 768 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2022/2014755 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.9.1/1	Gilbert, S., Schlotterbeck, U.	2021	Physical and Chemical Compatibility in Aqueous Tank Mixtures of BAS 768 00 F (BAS 768 AL F, MIPS: L2021/0005) 2021/2028791 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCP 2.9.2/1	Gilbert, S., Schlotterbeck, U.	2021	Physical and Chemical Compatibility in Aqueous Tank Mixtures of BAS 768 00 F (BAS 768 AL F, MIPS: L2021/0005) 2021/2028791 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCP 4.2/1	Langknecht, T.	2021	Effectiveness of Procedures for Cleaning Application Equipment and Protective Clothing - BAS 768 00 F. 2021/2034436 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCP 4.3/1	Anonymous	2023	Safety Data Sheet - Revytur 2023/2007492 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. no Unpublished	No	BASF
KCP 4.4/1	Maurer, B.	2021	BAS 768 00 F - EU Performance Test in HDPE 2021/2008057 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCP 4.4/2	Keller, M.	2025	Physical and Chemical Properties of BAS 768 00 F: Storage stability for up to 156 weeks at 25°C in HDPE packs 2025/2014479 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
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<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCP 4.5/1	Anonymous	2023	Safety Data Sheet - Revytur  2023/2007492  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**

There are no already evaluated studies in this Section

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

### **A 2.1                    Mefentrifluconazole**

Not applicable.

### **A 2.2                    Sulfur**

Not applicable.