

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 758 00 F

Product name(s): Revyflex Plus

Chemical active substance(s):

Mefentrifluconazole, 66.6 g/L

Metrafenone, 100 g/L

Pyraclostrobin, 80 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: BASF

Submission date: March 2022

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Version history

When	What
03/2022	Initial dRR – BASF DocID 2021/2048333
04/2022	Dossier sent for evaluation
06/2022	Updates based on feedback from zRMS Poland
10/2022	zRMS evaluation of dRR
January 2023	Final version prepared by zRMS after Commenting period

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Evaluator comments:

The text highlighted in grey was provided by the evaluator.

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:

- A two-year storage stability study is ongoing and has to be provided for evaluation in post-registration. It can be assessed at a national level.
- ~~data gap 2~~
- ~~data gap 3~~

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 Pfaffikon SZ

Switzerland

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

Contact person: xxxxxxxxxxxxxxxxxxxx
Tel. No.: xxxxxxxxxxxxxxxxxxxx
Fax No.: xxxxxxxxxxxxxxxxxxxx
E-mail: xxxxxxxxxxxxxxxxxxxx

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 Pfaffikon SZ

Switzerland

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

Contact person: xxxxxxxxxxxxxxxxxxxx
Tel. No.: xxxxxxxxxxxxxxxxxxxx
E-mail: 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)

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: xxxxxxxxxxxxxxxxxxxx
Tel. No.: xxxxxxxxxxxxxxxxxxxx
E-mail: 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

	EU agreed minimum purity Reference: Reg. (EU) 2019/337
Mefentrifluconazole	≥ 970 g/kg
N, N-dimethylformamide	≤ 0.5 g/kg
Toluene	≤ 1 g/kg
1,2,4-(1H)-triazole	≤ 1 g/kg

1.2.3.2 Pyraclostrobin

	EU agreed minimum purity Reference: Reg. (EU) 540/2011
Pyraclostrobin	≥ 975 g/kg
Dimethylsulfate (DMS)	≤ 1 mg/kg

1.2.3.3 Metrafenone

	Reference:
Metrafenone	≥ 940 g/kg (SANCO/10280/06 - rev. final 14 July 2006) ≥ 980 g/kg (proposed new reference specification); used in the dossier

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 each relevant country

Company code number: BAS 758 00 F, 758 BB F (formerly internal experimental code)

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	66.6	60.0 – 73.3	68.7	6.29
Pyraclostrobin	80.0	72.0 – 88.0	82.1	7.52
Metrafenone	100.0	90.0 – 110.0	102.0	9.34

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

** Based on the density of the formulation = 1.091 g/cm³.

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
N, N-dimethylformamide	≤ 0.031 g/kg
Toluene	≤ 0.063 g/kg
1,2,4-(1H)-triazole	≤ 0.063 g/kg
Dimethylsulfate	≤ 0.075 mg/kg

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

1.4.2.1 Table 1.4-3: Information on 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	

1.4.2.2 Table 1.4-4: Information on Metrafenone

Type	Name/Code Number	
ISO common name	Metrafenone	No other variant
CAS No.	220899-03-6	
EC No.	606-928-8	
CIPAC No.	752	

1.4.2.3 Table 1.4-5: Information on Pyraclostrobin

Type	Name/Code Number	
ISO common name	Pyraclostrobin	No other variant
CAS No.	175013-18-0	
EC No.	605-747-1	
CIPAC No.	657	

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

The formulation does not contain any safeners and synergists.

CONFIDENTIAL information is provided separately (Part C).

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

Type: Emulsifiable concentrate

[Code: EC]

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 a yellow, clear liquid, with a moderate sweet odour. It is not explosive, has no oxidizing properties. The product has no flash point up to a temperature of 105.0°C. It has a self-ignition temperature of 275.0°C. In aqueous solution, it has a pH value around 5.6 at 23°C. 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. Extrapolation of the results of the accelerated storage stability at 54°C for 14 days indicate that for a period of a least two years the product remains suitable for use and continues to comply with the specifications. The 2-year shelf life study is ongoing. Its technical characteristics are acceptable for an EC formulation.

The intended concentration of use is 0.17% to 1.5%.

Studies regarding the combination of BAS 758 00 F with other plant protection products were submitted and the application as tank mixture is acceptable. The following preparations were tested in combination with BAS 758 00 F and all were compatible and good applicability remained: Imtrex XE (BAS 700 09 F, EC), No tradename (BAS 830 01 F, EC), Proline (BAS 9314 1 F, EC), Turbo (BAS 008 00 D, GR), Medax Top (BAS 122 08 W, SC), Camposan Extra (BAS 067 10 W, SL), Medax Max (BAS 139 00 W, WG), CCC 750 (BAS 062 03 W, SL), Moddus Start (BAS 9053 7 W, DC), Calma (BAS 9053 6 W, EC), Duplosan DP (BAS 044 26 H, SL), Biathlon 4 D (BAS 812 00 H, WG), Dash EC (BAS 160 00 S, EC), Ariane C (BAS 9517 0 H, EC), Axial 50 EC (BAS 9438 1 H, EC), Adigor (BAS 9126 0 S, EC), Atlantis Flex (BAS 9583 1 H, WG), Biopower (BAS 9140 1 S, SL), Atlantis (BAS 9377 0 H, WG), Actirob B (BAS 9101 0 S, EC), Avoxa (BAS 9673 0 H, EC), Broadway (BAS 9512 0 H, WG), Pixxaro EC (BAS 9628 1 H, EC), Zypar (BAS 9647 0 H, OD), Pirimor Granulat (BAS 9005 0 I, GR), Sumicidin Alpha (BAS 314 03 I, EC), Decis forte (BAS 9034 4 I, EC), Karate Zeon (BAS 9158 2 I, CS), Teppeki (BAS 9146 0 I, WG), Broadway Netzmittel (BAS 9101 1 S, EC). Yet, according to GAP table - REVYFLEX PLUS is not intended to be used in tank mixture with other product. So, the information is considered as supplementary.

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

Studies	Method	Findings	Classification acc. to Regulation (EC) No. 1272/2008
Explosive properties	UN Class 1	Not explosive	None
Oxidising properties	UN O.2	Not oxidizing	None
Flammability	--	Not applicable for EC-formulation	--
Flash point	EEC A.9	No flash point	None
Auto-flammability	EEC A.15	The test item has an auto-ignition temperature of 275°C.	None
pH	CIPAC MT 75.3	5.6	None
Viscosity	CIPAC MT 192 OECD 114 OPPTS 830.7100	Kinematic viscosity: 23 mm ² /s at 40°C and D = 100 s ⁻¹	None
Surface tension	EEC A.5	Surface tension (plate method) 33.8 mN/m (neat, 25°C) 33.2 mN/m (0.15% v/v dilution, 20°C) 31.6 mN/m (1.5% v/v dilution, 20°C)	None
Relative density	EEC A.3	D ₄ ²⁰ = 1.092	None

Notifier Proposals for Risk and Safety Phrases (KCP 12)

With respect to physical/chemical data	Risk phrases:	Hazard statements:
	None	None
	Safety phrases:	Precautionary statements
	None	None

Compliance with FAO specifications:

The product BAS 758 00 F complies with FAO specifications.

Formulation used for tests

All tests have been performed with the preparation BAS 758 00 F (or the formerly internal experimental code BAS 758 BB F).

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)	OPPTS 830.6302 OPPTS 830.6303 OPPTS 830.6304	Batch No. FD-200124-0004 Mefentrifluconazole: 68.2 g/L Pyraclostrobin: 81.9 g/L Metrafenone: 99.8 g/L	Colour: yellow Physical state: Clear liquid Odour: Moderate sweet	Y	[see 2020/2109344 Keller, M. 2021]	Accepted
Explosive properties (KCP 2.2.1)	UN Class 1 EC A.14 OPPTS 830.6316	Batch No. FD-200124-0004 Mefentrifluconazole: 66.7g/L Pyraclostrobin: 81.0 g/L Metrafenone: 94.9 g/L	In the DSC-measurement the test item BAS 758 00 F in closed crucibles showed a decomposition of the test item with combined and averaged decomposition energies of -70 J/g and -310 J/g, respectively. The decomposition energy does not go beyond the threshold of -500 J/g, therefore, explosive properties can be excluded and further tests on explosive properties were not necessary. The test item showed no explosive properties.	Y	[see 2020/2027414 Dreisch, S. 2020]	Accepted
Oxidizing properties (KCP 2.2.2)	UN O.2 EC A.21	Batch No. FD-200124-0004 Mefentrifluconazole: 66.7g/L Pyraclostrobin: 81.0 g/L Metrafenone: 94.9 g/L	The mean pressure rise time for the test item BAS 758 00 F (21.28 s) is greater than the mean pressure rise time for the reference item nitric acid 65% (2.87 s). The test item showed no oxidizing properties.	Y	[see 2020/2027414 Dreisch, S. 2020]	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Flash point (KCP 2.3.1)	EC A.9 OPPTS 830.6315 CIPAC MT 12	Batch No. FD-200124-0004 Mefentrifluconazole: 66.7g/L Pyraclostrobin: 81.0 g/L Metrafenone: 94.9 g/L	The test item BAS 758 00 F has no flash point up to a temperature of 105.0°C. The test item does not need have to be classified as flammable liquid.	Y	[see 2020/2027414 Dreisch, S. 2020]	Accepted
Flammability (KCP 2.3.2)	not required - the formulation is a liquid					
Self-heating (KCP 2.3.3)	OECD 113 DIN EN ISO 11357-1 EC A.15 DIN 51794	Batch No. FD-200124-0004 Mefentrifluconazole: 66.7g/L Pyraclostrobin: 81.0 g/L Metrafenone: 94.9 g/L	The test item has an auto-ignition temperature of 275°C.	Y	[see 2020/2027414 Dreisch, S. 2020]	Accepted
Acidity or alkalinity and pH (KCP 2.4.1)	Acidity/Alkalinity not required, pH value is in range between 4-10					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3 OPPTS 830.7000	Batch No. FD-200124-0004 Mefentrifluconazole: 68.2 g/L Pyraclostrobin: 81.9 g/L Metrafenone: 99.8 g/L	<u>Pure water:</u> Neat (23°C): 5.9 1.0% dilution (23°C): 5.6 <u>CIPAC Water D:</u> Neat (23°C): 6.5 1.0% dilution (23°C): 5.7	Y	[see 2020/2109344 Keller, M. 2021]	Accepted
Viscosity (KCP 2.5.1)	CIPAC MT 192 OECD 114 OPPTS 830.7100	Batch No. FD-200124-0004 Mefentrifluconazole: 68.2 g/L Pyraclostrobin: 81.9 g/L Metrafenone: 99.8 g/L	<u>Dynamic viscosity:</u> 65 mPa.s (20°C, 1 s ⁻¹) 66 mPa.s (20°C, 10 s ⁻¹) 66 mPa.s (20°C, 100 s ⁻¹) 66 mPa.s (20°C, 200 s ⁻¹) 24 mPa.s (40°C, 1 s ⁻¹) 25 mPa.s (40°C, 10 s ⁻¹) 25 mPa.s (40°C, 100 s ⁻¹) 25 mPa.s (40°C, 200 s ⁻¹) Flow behaviour: Newtonian <u>Kinematic viscosity:</u> 23 mm ² /s at 40°C and D = 100 s ⁻¹	Y	[see 2020/2109344 Keller, M. 2021]	Accepted A Category 1 aspiration hazard cannot be assigned since kinematic viscosity is a little bit above a trigger value of 20.5 mm ² /s

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	Batch No. FD-200124-0004 Mefentrifluconazole: 68.2 g/L Pyraclostrobin: 81.9 g/L Metrafenone: 99.8 g/L	Surface tension (plate method) 33.8 mN/m (neat, 25°C) 33.2 mN/m (0.15% v/v dilution, 20°C) 31.6 mN/m (1.5% v/v dilution, 20°C) Based on the investigations the product is surface active	Y	[see 2020/2109344 Keller, M. 2021]	Accepted
Relative density (KCP 2.6.1)	OECD 109 EC A.3 OPPTS 830.7300	Batch No. FD-200124-0004 Mefentrifluconazole: 68.2 g/L Pyraclostrobin: 81.9 g/L Metrafenone: 99.8 g/L	$D_4^{20} = 1.092$ Density (20.0 °C) = 1.092 g/cm ³ Density (40.0 °C) = 1.075 g/cm ³	Y	[see 2020/2109344 Keller, M. 2021]	Accepted
Bulk density (KCP 2.6.2)	Not applicable for EC formulation.					
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CLI Technical Mono-graph No. 17	Batch No. FD-200124-0004 Mefentrifluconazole: 68.2 g/L Pyraclostrobin: 81.9 g/L Metrafenone: 99.8 g/L	Accelerated storage stability for 14 days at 54°C in fluorinated high-density polyethylene (F-HDPE) bottles. The physical and chemical properties of BAS 758 00 F (Batch FD-200124-0004), as determined in this study, were acceptable initially and after storage for 14 days at 54°C in fluorinated high-density polyethylene (F-HDPE) bottles. For detailed results see table 2-2 below.	Y	[see 2020/2109344 Keller, M. 2021]	Accepted

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)	Not required.											
Minimum content after heat stability testing (KCP 2.7.3)	AFL1019/01	Batch No. FD-200124-0004 Mefentrifluconazole: 68.2 g/L Pyraclostrobin: 81.9 g/L Metrafenone: 99.8 g/L	The active substance content did not decline to less than 95% of the content prior to the test (packaging material: F-HDPE).	Y	[see 2020/2109344 Keller, M. 2021]	Accepted						
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3 OPPTS 830.6317	Batch No. FD-200124-0004 Mefentrifluconazole: 68.2 g/L Pyraclostrobin: 81.9 g/L Metrafenone: 99.8 g/L	<table><tr><td colspan="2">Effect of low temperatures for 7 days at 0°C in fluorinated high-density polyethylene (F-HDPE) bottles.</td></tr><tr><td>Assessment after storage (7 days at 0°C)</td><td>Assessment after 24h standing, one inversion and following 1h standing</td></tr><tr><td>The sample was homogeneous with crystals on the cylinder wall</td><td>The sample was homogeneous with 0.3 mL crystal precipitation</td></tr></table> <p>The physical and chemical properties of BAS 758 00 F (Batch FD-200124-0004), as determined in this study, were acceptable initially and after storage for 7 days at 0°C in fluorinated high-density polyethylene (F-HDPE) bottles.</p> <p>For detailed results see table 2-2 below.</p>	Effect of low temperatures for 7 days at 0°C in fluorinated high-density polyethylene (F-HDPE) bottles.		Assessment after storage (7 days at 0°C)	Assessment after 24h standing, one inversion and following 1h standing	The sample was homogeneous with crystals on the cylinder wall	The sample was homogeneous with 0.3 mL crystal precipitation	Y	[see 2020/2109344 Keller, M. 2021]	Accepted
Effect of low temperatures for 7 days at 0°C in fluorinated high-density polyethylene (F-HDPE) bottles.												
Assessment after storage (7 days at 0°C)	Assessment after 24h standing, one inversion and following 1h standing											
The sample was homogeneous with crystals on the cylinder wall	The sample was homogeneous with 0.3 mL crystal precipitation											

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Ambient temperature shelf life (KCP 2.7.5)			<p>The study is ongoing and will be provided after finalization. Expected date: March 2023.</p> <p>Extrapolation of the results of the accelerated storage stability at 54°C for 14 days indicate that for a period of a least two years the product remains suitable for use and continues to comply with the specifications.</p>			<p>Ongoing</p> <p>The study has to be provided when available. It can be assessed in post-registration.</p>
Shelf life in months (if less than 2 years) (KCP 2.7.6)	Not required, as storage stability indicates a shelf life of at least 2 years.					
Wettability (KCP 2.8.1)	Not required, formulation is a liquid.					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.2	Batch No. FD-200124-0004 Mefentrifluconazole: 68.2 g/L Pyraclostrobin: 81.9 g/L Metrafenone: 99.8 g/L	<u>0.15% v/v dilution (CIPAC D)</u> 50 mL after 10 sec. 22 mL after 1 min. 18 mL after 3 min. 10 mL after 12 min. <u>1.5% v/v dilution (CIPAC D)</u> 65 mL after 10 sec. 30 mL after 1 min. 12 mL after 3 min. 8 mL after 12 min. <u>0.15% v/v dilution (CIPAC D)*</u> 0 mL after 10 sec. 0 mL after 1 min. 0 mL after 3 min. 0 mL after 12 min. <u>1.5% v/v dilution (CIPAC D)*</u> 0 mL after 10 sec. 0 mL after 1 min. 0 mL after 3 min. 0 mL after 12 min. * With antifoam-agent added to the test solution (0.014 mL/L)	Y	[see 2020/2109344 Keller, M. 2021]	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Suspensibility (KCP 2.8.3.1)	Not required for EC formulation.					
Spontaneity of dispersion (KCP 2.8.3.2)	Not required for EC formulation.					
Dispersion stability (KCP 2.8.3.3)	Not required for EC formulation.					
Degree of dissolution and dilution stability (KCP 2.8.4)	Not required for EC formulation.					
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	Not required for EC formulation.					
Wet sieve test (KCP 2.8.5.1.2)	Not required for EC formulation.					
Dust content (KCP 2.8.5.2.1)	Not required, formulation is not a powder or granule.					
Particle size of dust (KCP 2.8.5.2.2)	Not required, formulation is not a powder or granule.					
Attrition (KCP 2.8.5.3)	Not required, formulation is not a powder or granule.					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Hardness and integrity (KCP 2.8.5.4)	Not required, formulation is not a tablet.					
Emulsifiability (KCP 2.8.6.1)	CIPAC MT 36.3	Batch No. FD-200124-0004 Mefentrifluconazole: 68.2 g/L Pyraclostrobin: 81.9 g/L Metrafenone: 99.8 g/L	<u>0.15% v/v dilution (CIPAC A)</u> After 30 sec.: Spontaneous emulsion with no froth <u>0.15% v/v dilution (CIPAC D)</u> After 30 sec.: Spontaneous emulsion with no froth <u>1.5% v/v dilution (CIPAC A)</u> After 30 sec.: Spontaneous emulsion with no froth <u>1.5% v/v dilution (CIPAC D)</u> After 30 sec.: Spontaneous emulsion with no froth	Y	[see 2020/2109344 Keller, M. 2021]	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Emulsion stability (KCP 2.8.6.2)	CIPAC MT 36.3	Batch No. FD-200124-0004 Mefentrifluconazole: 68.2 g/L Pyraclostrobin: 81.9 g/L Metrafenone: 99.8 g/L	<u>0.15% v/v dilution (CIPAC A)</u> After 30 min.: No sediment, no top cream, no bottom cream, no top oil, no bottom oil After 2 h: No sediment, no top cream, no bottom cream, no top oil, no bottom oil After 24 h: No sediment, no top cream, no bottom cream, no top oil, no bottom oil <u>0.15% v/v dilution (CIPAC D)</u> After 30 min.: No sediment, no top cream, no bottom cream, no top oil, no bottom oil After 2 h: No sediment, no top cream, no bottom cream, no top oil, no bottom oil After 24 h: No sediment, no top cream, no bottom cream, no top oil, no bottom oil <u>1.5% v/v dilution (CIPAC A)</u> After 30 min.: No sediment, no top cream, no bottom cream, no top oil, no bottom oil After 2 h: No sediment, no top cream, no bottom cream, no top oil, no bottom oil After 24 h: No sediment, no top cream, no bottom cream, no top oil, no bottom oil <u>1.5% v/v dilution (CIPAC D)</u> After 30 min.: No sediment, no top cream, no bottom cream, no top oil, no bottom oil After 2 h: No sediment, no top cream, no bottom cream, no top oil, no bottom oil After 24 h: No sediment, no top cream, no bottom cream, no top oil, no bottom oil	Y	[see 2020/2109344 Keller, M. 2021]	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Re-emulsifiability (KCP 2.8.6.3)	CIPAC MT 36.3	Batch No. FD-200124-0004 Mefentrifluconazole: 68.2 g/L Pyraclostrobin: 81.9 g/L Metrafenone: 99.8 g/L	<u>0.15% v/v dilution (CIPAC A)</u> After 30 sec.: Completely re-dispersed, homog. emulsion After 30 min.: No sediment, no top cream, no bottom cream, no top oil, no bottom oil <u>0.15% v/v dilution (CIPAC D)</u> After 30 sec.: Completely re-dispersed, homog. emulsion After 30 min.: No sediment, no top cream, no bottom cream, no top oil, no bottom oil <u>1.5% v/v dilution (CIPAC A)</u> After 30 sec.: Completely re-dispersed, homog. emulsion After 30 min.: No sediment, no top cream, no bottom cream, no top oil, no bottom oil <u>1.5% v/v dilution (CIPAC D)</u> After 30 sec.: Completely re-dispersed, homog. emulsion After 30 min.: No sediment, no top cream, no bottom cream, no top oil, no bottom oil	Y	[see 2020/2109344 Keller, M. 2021]	Accepted
Flowability (KCP 2.8.7.1)	Not required, formulation is not a granule.					
Pourability (KCP 2.8.7.2)	Not required for EC formulation.					
Dustability following accelerated storage (KCP 2.8.7.3)	Not required.					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Physical compatibility of tank mixes (KCP 2.9.1)	ASTM method: E 1518-05 Internal method: CF-F 019	Batch No. FD-200129-1006, FD-200129-1007 Mefentrifluconazole: 66.6 g/L Pyraclostrobin: 80.0 g/L Metrafenone: 100.0 g/L (registered content)	In total 24 mixtures of BAS 758 BB 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 758 BB F is apparently physically compatible with the following tested products: Imtrex XE, BAS 830 01 F (no tradename), Proline, Turbo, Medax Top, Camposan Extra, Medax Max, CCC 750, Moddus Start, Calma, Duplosan DP, Biathlon 4 D, Dash EC, Ariane C, Axial 50 EC, Adigor, Atlantis Flex, Biopower, Atlantis, Actirob B, Avoxa, Broadway, Pixxaro EC, Zypar, Pirimor Granulat, Sumicidin Alpha, Decis forte, Karate Zeon, Teppeki, Broadway Netzmittel.	N	see 2021/2000193 Schlotterbeck, U. 2021]	Accepted. Nevertheless, the study is redundant for the evaluation purpose. According to GAP table the PPP is not intended to be used with other products in tank mixture.
Chemical compatibility of tank mixes (KCP 2.9.2)	ASTM method: E 1518-05 Internal method: CF-F 019	Batch No. FD-200129-1006, FD-200129-1007 Mefentrifluconazole: 66.6 g/L Pyraclostrobin: 80.0 g/L Metrafenone: 100.0 g/L (registered content)	Mefentrifluconazole, Metrafenone and Pyraclostrobin, the active substances of BAS 758 BB F, are stable in diluted aqueous conditions. Therefore, none of the functional groups are likely to react under normal tank mix conditions. No indication of any chemical reaction between the mixed products was observed. Therefore, BAS 758 BB F is apparently chemically compatible with the following tested products: Imtrex XE, BAS 830 01 F (no tradename), Proline, Turbo, Medax Top, Camposan Extra, Medax Max, CCC 750, Moddus Start, Calma, Duplosan DP, Biathlon 4 D, Dash EC, Ariane C, Axial 50 EC, Adigor, Atlantis Flex, Biopower, Atlantis, Actirob B, Avoxa, Broadway, Pixxaro EC, Zypar, Pirimor Granulat, Sumicidin Alpha, Decis forte, Karate Zeon, Teppeki, Broadway Netzmittel.	N	see 2021/2000193 Schlotterbeck, U. 2021]	Accepted Please refer to the point above

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Adhesion to seeds (KCP 2.10.1)	Not required, formulation is not being used for seed treatment.					
Distribution to seed (KCP 2.10.2)	Not required, formulation is not being used for seed treatment.					
Other/special studies (KCP 2.11)	OECD 113	Batch No. FD-200124-0004 Mefentrifluconazole: 66.7g/L Pyraclostrobin: 81.0 g/L Metrafenone: 94.9 g/L	<p>Thermal Stability (OECD 113): The test item BAS 758 00 F in closed gold-plated stainless steel crucibles showed two to three exothermic effects starting at temperatures of 130°C, 170°C and 270°C, respectively, with combined and averaged energy releases of -70 J/g and -310 J/g.</p> <p>SADT: The test item BAS 758 00 F showed no significant temperature increase at 75°C in the adiabatic heat storage test. Therefore, it can be stated that the test item BAS 758 00 F has a SADT of > 75°C, when stored in a package with a heat loss of 63 mW/(kgK) (e.g.: 50 L steel drum (liquid product), UN-Code 1A1). According to the results the test item is classified as follows concerning self-reactive properties:</p> <p>UN-Transport Regulation: The test item does not have to be classified as a self-reactive substance in Class 4, Division 4.1 since the SADT is > 75°C. It has to be noted here, that the transport of any substance with a dangerous emission of toxic, corrosive or flammable gasses or vapours under normal transport conditions is forbidden.</p> <p>GHS (CLP-Regulation (EC) No. 1272/2008 Annex I: 2.8): The test item does not have to be classified as a self-reactive substance since the SADT is > 75°C.</p>	N	[see 2020/2027415 Dreisch, S. 2020]	Accepted

Table 2-2: Accelerated Storage stability for 14 days at 54°C, and 7 days at 0°C in F-HDPE packaging (see 2020/2109344)

Parameter	Method	Initial value	After 14 days (54°C)	After 7 days (0°C)
Active ingredient content (BAS 758 00 F)	AFL1019/01	Mefentrifluconazole: 68.2 g/L Pyraclostrobin: 81.9 g/L Metrafenone: 99.8 g/L	Mefentrifluconazole: 68.0 g/L Pyraclostrobin: 81.7 g/L Metrafenone: 99.7 g/L	-
Water content	CIPAC MT 30.5	0.24%	-	-
Appearance	OPPTS 830.6302 OPPTS 830.6303 OPPTS 830.6304	Colour: yellow Physical state: Clear liquid Odour: Moderate sweet	Colour: yellow Physical state: Clear liquid Odour: Moderate sweet	-
pH value	CIPAC MT 75.3 OPPTS 830.7000	<u>Pure water:</u> 1.0% dilution (23°C): 5.6 <u>CIPAC Water D:</u> 1.0% dilution (23°C): 5.7	<u>Pure water:</u> 1.0% dilution (23°C): 5.5 <u>CIPAC Water D:</u> 1.0% dilution (24°C): 5.5	<u>Pure water:</u> 1.0% dilution (23°C): 5.6 <u>CIPAC Water D:</u> 1.0% dilution (24°C): 5.6
Viscosity	CIPAC MT 192 OECD 114 OPPTS 830.7100	65 mPa.s (20°C, 1 s ⁻¹) 66 mPa.s (20°C, 10 s ⁻¹) 66 mPa.s (20°C, 100 s ⁻¹) 66 mPa.s (20°C, 200 s ⁻¹) 24 mPa.s (40°C, 1 s ⁻¹) 25 mPa.s (40°C, 10 s ⁻¹) 25 mPa.s (40°C, 100 s ⁻¹) 25 mPa.s (40°C, 200 s ⁻¹) Flow behaviour: Newtonian	67 mPa.s (20°C, 1 s ⁻¹) 68 mPa.s (20°C, 10 s ⁻¹) 68 mPa.s (20°C, 100 s ⁻¹) 69 mPa.s (20°C, 200 s ⁻¹) 25 mPa.s (40°C, 1 s ⁻¹) 25 mPa.s (40°C, 10 s ⁻¹) 25 mPa.s (40°C, 100 s ⁻¹) 26 mPa.s (40°C, 200 s ⁻¹) Flow behaviour: Newtonian	-
Relative density	OECD 109 EC A.3 OPPTS 830.7300	D ₄ ²⁰ = 1.092 Density (20.0 °C) = 1.092 g/cm ³ Density (40.0 °C) = 1.075 g/cm ³	D ₄ ²⁰ = 1.092 Density (20.0 °C) = 1.092 g/cm ³ Density (40.0 °C) = n.d.	-

Parameter	Method	Initial value	After 14 days (54°C)	After 7 days (0°C)
Persistent foaming	CIPAC MT 47.2	<u>0.15% v/v dilution (CIPAC D)</u> 50 mL after 10 sec. 22 mL after 1 min. 18 mL after 3 min. 10 mL after 12 min. <u>1.5% v/v dilution (CIPAC D)</u> 65 mL after 10 sec. 30 mL after 1 min. 12 mL after 3 min. 8 mL after 12 min. <u>0.15% v/v dilution (CIPAC D)*</u> 0 mL after 10 sec. 0 mL after 1 min. 0 mL after 3 min. 0 mL after 12 min. <u>1.5% v/v dilution (CIPAC D)*</u> 0 mL after 10 sec. 0 mL after 1 min. 0 mL after 3 min. 0 mL after 12 min. * With antifoam-agent added to the test solution (0.014 mL/L)	<u>0.15% v/v dilution (CIPAC D)</u> 43 mL after 10 sec. 43 mL after 1 min. 43 mL after 3 min. 43 mL after 12 min. <u>1.5% v/v dilution (CIPAC D)</u> 74 mL after 10 sec. 74 mL after 1 min. 64 mL after 3 min. 34 mL after 12 min. <u>0.15% v/v dilution (CIPAC D)*</u> 0 mL after 10 sec. 0 mL after 1 min. 0 mL after 3 min. 0 mL after 12 min. <u>1.5% v/v dilution (CIPAC D)*</u> 0 mL after 10 sec. 0 mL after 1 min. 0 mL after 3 min. 0 mL after 12 min. * With antifoam-agent added to the test solution (0.014 mL/L)	-

Parameter	Method	Initial value	After 14 days (54°C)	After 7 days (0°C)
Emulsifiability	CIPAC MT 36.3	<u>0.15% v/v dilution (CIPAC A)</u> After 30 sec.: Spontaneous emulsion with no froth <u>0.15% v/v dilution (CIPAC D)</u> After 30 sec.: Spontaneous emulsion with no froth <u>1.5% v/v dilution (CIPAC A)</u> After 30 sec.: Spontaneous emulsion with no froth <u>1.5% v/v dilution (CIPAC D)</u> After 30 sec.: Spontaneous emulsion with no froth	<u>0.15% v/v dilution (CIPAC A)</u> After 30 sec.: Spontaneous emulsion with no froth <u>0.15% v/v dilution (CIPAC D)</u> After 30 sec.: Spontaneous emulsion with no froth <u>1.5% v/v dilution (CIPAC A)</u> After 30 sec.: Spontaneous emulsion with no froth <u>1.5% v/v dilution (CIPAC D)</u> After 30 sec.: Spontaneous emulsion with no small froth	<u>0.15% v/v dilution (CIPAC A)</u> After 30 sec.: Spontaneous emulsion with no froth <u>0.15% v/v dilution (CIPAC D)</u> After 30 sec.: Spontaneous emulsion with no froth <u>1.5% v/v dilution (CIPAC A)</u> After 30 sec.: Spontaneous emulsion with no froth <u>1.5% v/v dilution (CIPAC D)</u> After 30 sec.: Spontaneous emulsion with no small froth

[illegible]

Parameter	Method	Initial value	After 14 days (54°C)	After 7 days (0°C)
Re-emulsifiability		<u>0.15% v/v dilution (CIPAC A)</u> After 30 sec.: Completely re-dispersed, homog. emulsion After 30 min.: No sediment, no top cream, no bottom cream, no top oil, no bottom oil <u>0.15% v/v dilution (CIPAC D)</u> After 30 sec.: Completely re-dispersed, homog. emulsion After 30 min.: No sediment, no top cream, no bottom cream, no top oil, no bottom oil <u>1.5% v/v dilution (CIPAC A)</u> After 30 sec.: Completely re-dispersed, homog. emulsion After 30 min.: No sediment, no top cream, no bottom cream, no top oil, no bottom oil <u>1.5% v/v dilution (CIPAC D)</u> After 30 sec.: Completely re-dispersed, homog. emulsion After 30 min.: No sediment, no top cream, no bottom cream, no top oil, no bottom oil	<u>0.15% v/v dilution (CIPAC A)</u> After 30 sec.: Completely re-dispersed, homog. emulsion After 30 min.: No sediment, no top cream, no bottom cream, no top oil, no bottom oil <u>0.15% v/v dilution (CIPAC D)</u> After 30 sec.: Completely re-dispersed, homog. emulsion After 30 min.: No sediment, no top cream, no bottom cream, no top oil, no bottom oil <u>1.5% v/v dilution (CIPAC A)</u> After 30 sec.: Completely re-dispersed, homog. emulsion After 30 min.: No sediment, no top cream, no bottom cream, no top oil, no bottom oil <u>1.5% v/v dilution (CIPAC D)</u> After 30 sec.: Completely re-dispersed, homog. emulsion After 30 min.: No sediment, no top cream, no bottom cream, no top oil, no bottom oil	<u>0.15% v/v dilution (CIPAC A)</u> After 30 sec.: Completely re-dispersed, homog. emulsion After 30 min.: No sediment, no top cream, no bottom cream, no top oil, no bottom oil <u>0.15% v/v dilution (CIPAC D)</u> After 30 sec.: Completely re-dispersed, homog. emulsion After 30 min.: No sediment, no top cream, no bottom cream, no top oil, no bottom oil <u>1.5% v/v dilution (CIPAC A)</u> After 30 sec.: Completely re-dispersed, homog. emulsion After 30 min.: No sediment, no top cream, no bottom cream, no top oil, no bottom oil <u>1.5% v/v dilution (CIPAC D)</u> After 30 sec.: Completely re-dispersed, homog. emulsion After 30 min.: No sediment, no top cream, no bottom cream, no top oil, no bottom oil
Packaging evaluation	-	Weight: 1186.95 g	Weight: 1186.83 g (0.01% weight loss)	-
	FP0063/004	Appearance: Clear	Appearance: Clear	-
	OPPTS 830.6317	There is no influence of the product on the original container.	Except a slight deformation of the pack, no other influence of the product on the original container was observed	-
	OPPTS 830.6320 (Corrosion)	No corrosion, seal intact and no peculiarities inside of the original container were observed.	No corrosion, seal intact and no peculiarities inside of the original container were observed.	-

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

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

4.2 Recommended methods and precautions (KCP 4.2)

Comments of zRMS:	Provided calculations are considered sufficient to support the proposed cleaning procedure.
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Reference:	CP 4.2/1
Report	Effectiveness of Procedures for Cleaning Application Equipment and Protective Clothing - BAS 758 00 F, Nord, S., 2020 report No 868711 2020/2108630 Authority registration No
Guideline(s):	DIN EN ISO 16119-2 EPPO PP 1/292 (1)
Deviations:	No
GLP:	No
Acceptability:	Yes

BAS 758 00 F is a fungicide with a broad spectrum of activity. For example, it can be used in wheat, barley, oat and rye against *Zymoseptoria tritici*, *Blumeria graminis* and *Puccinia strii-formis*. The highest recommended concentration of the fungicide is 1.5 L Formulation/ ha in a minimum of 100 L/ ha water.

In the cleaning procedure, the active ingredient is diluted to such an extent that the simulated “Double rinse Procedure” is proved to be efficient enough.

The amount of active substance that could be carried over into a following application is 0.82 g A.I./ha with a water rate of 400 L/ ha. After cleaning, the active ingredient was reduced by a factor of 1 : 1800.

Even if a large amount of water and thus a large volume per hectare is sprayed out in the next application, which leads to a high concentration of the displaced Active ingredient per hectare, no plant damage will occur.

Common agricultural practice implies cleaning of application equipment direct after use. If the field sprayer is cleaned with water immediately after the use of BAS 758 00 F, even in the most unfavorable case, the contamination in the immediately following application is negligible. Therefore, cleaning the sprayer solely with water may be regarded as completely adequate in the case of BAS 758 00 F. It is not necessary to add cleaning agents.

Protective clothing will be cleaned effectively when washed with usual laundry detergents, by the reason that agrochemical formulations are designed for excellent mixing with water.

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

Reference:	CP 4.3/1
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Report Safety data sheet - BAS 758 00 F,
Anonymous, 2022
report No EU-version 1.0
2022/2005510
Authority registration No

Guideline(s): EEC 1907/2006

Deviations: No

GLP: No, not subject to GLP Regulation

Acceptability: Yes

The safety data sheet contains advice for emergency measures in case of an accident with BAS 758 00 F based on scientific tests.

4.4 Packaging and Compatibility with the Preparation (KCP 4.4)

BAS 758 00 F is to be marketed in high-density polyethylene (HDPE) containers with an inner barrier, e.g., polyamide (PA/PE) or fluorination (f-HDPE), with a minimum wall thickness of 0.7 mm. They are sealed by foil seals or gasket, protected by screw caps of polyethylene.

RMS comment:

Based on the accelerated storage stability studies all the proposed below packages are accepted for the PPP from physicochemical perspective.

Table 4.1-1: Packaging information for 0.15 litre bottle

Type	Description
Material:	PA/PE (Coex) or f-HDPE
Shape/size:	cylindrical / approx. 63 mm diameter x 92 mm
Opening:	42 mm inner diameter
Closure:	screw cap
Seal:	Induction sealed or gasket

Table 4.1-2: Packaging information for 0.25 litre bottle

Type	Description
Material:	PA/PE (Coex) 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

Table 4.1-3: Packaging information for 0.5 litre bottle

Type	Description
Material:	PA/PE (Coex) or f-HDPE
Shape/size:	cylindrical / approx. 69 mm diameter x 185.5 mm
Opening:	42 mm inner diameter
Closure:	screw cap
Seal:	Induction sealed or gasket

Table 4.1-4: Packaging information for 1 litre eco-bottle

Type	Description
Material:	PA/PE (Coex) 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

Table 4.1-5: Packaging information for 5 litre eco-container

Type	Description
Material:	PA/PE (Coex) or f-HDPE
Shape/size:	rectangular / approx. 185 mm x 136 mm x 313 mm
Opening:	54 mm inner diameter
Closure:	screw cap
Seal:	Induction sealed or gasket

Table 4.1-6: Packaging information for 10 litre eco-container

Type	Description
Material:	PA/PE (Coex) 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

Table 4.1-7: Packaging information for 20 litre container

Type	Description
Material:	f-HDPE (fluorinated)
Shape/size:	Rectangular / approx.. 285 x 237 x 424 mm
Opening:	52 mm inner diameter
Closure:	screw cap
Seal:	Gasket

Table 4.1-8: Packaging information for 50 litre container

Type	Description
Material:	f-HDPE (fluorinated)
Shape/size:	cylindrical / approx. 380 mm x 618 mm (d x h)
Opening:	52 mm inner diameter
Closure:	screw cap or valve
Seal:	Gasket

Reference:	CP 4.4/1
Report	BAS 758 00 F EU Performance Test - AGRO-Packaging made of Co-ex-materials (HDPE with barrier layer), Maurer M., 2020 report No 868717_1, 220.0084.0020 TB02 2020/2027416 Authority registration No
Guideline(s):	ADR/RID
Deviations:	No
GLP:	No
Acceptability:	Yes

Verification of the chemical compatibility using Coex (PE/PA) material with dangerous goods. Test be carried out in acc. With lab test procedure – rule of method for barrier materials (Coex) provided for AGRO-packaging ≤ 10 L (described in BAM GGR 015) with 1L- test bottles after storage. It shall be proved by lab tests that the damaging effects of the intended product on test specimen does not exceed the damaging effects of the Mode liquid Pfl-Fr 2323.

The damaging effects of BAS 758 00 F on test specimen made of Coex (PE/PA) material does not exceed the damaging effects of the Model liquid Pfl-Fr 2323. The chemical compatibility of Coex (PE/PA) material with the intended product in comparison with Model liquid Pfl-Fr 2323 is verified.

Rate of permeation of ≤ 0.008 g/lh; approved

BAS 758 00 F can be packed in packaging made of Coex (PE/PA) material, in case where there is an UN-approval for these packaging for Model liquid Pfl-Fr 2323 and there is no conflict on other transport regulations. The maximum allowable values of the vapour pressure and the density given in the certificate of approval may not be exceeded.

Reference:	CP 4.4/2
Report	BAS 758 00 F - EU Performance Test - AGRO-Packaging made of HDPE with fluorinated barrier, Maurer M., 2020 report No 868717_2, 220.0084.0020 TB01 2020/2027417

	Authority registration No
Guideline(s):	ADR/RID
Deviations:	No
GLP:	No
Acceptability:	Yes

Verification of the chemical compatibility using HDPE with fluorinated barrier with dangerous goods. Test be carried out in acc. With lab test procedure – rule of method for barrier materials (Coex) provided for AGRO-packaging ≤ 10 L (described in BAM GGR 015) with 1L- test bottles after storage. It shall be proved by lab tests that the damaging effects of the intended product on test specimen does not exceed the damaging effects of the Mode liquid Pfl-Fr 2323.

The damaging effects of BAS 758 00 F on test specimen made of HDPE with fluorinated barrier does not exceed the damaging effects of the Model liquid Pfl-Fr 2323. The chemical compatibility of HDPE with fluorinated barrier with the intended product in comparison with Model liquid Pfl-Fr 2323 is verified.

Rate of permeation of ≤ 0.008 g/lh; approved

BAS 758 00 F can be packed in packaging made of HDPE with fluorinated barrier, in case where there is an UN-approval for these packaging for Model liquid Pfl-Fr 2323 and there is no conflict on other transport regulations. The maximum allowable values of the vapour pressure and the density given in the certificate of approval may not be exceeded.

4.5 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 758 00 F, Anonymous, 2022 report No EU-version 1.0 2022/2005510 Authority registration No
Guideline(s):	EEC 1907/2006
Deviations:	No
GLP:	No, not subject to GLP Regulation
Acceptability:	Yes

The safety data sheet contains advice for the destruction or decontamination of BAS 758 00 F and its packaging.

4.5.1 Neutralisation procedure (KCP 4.5.1)

The pH of BAS 758 00 F has been determined to around 6.5 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.

4.5.2 Controlled incineration (KCP 4.5.2)

For purposes of disposal, combustion of BAS 758 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 758 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.	2021	Physical and chemical properties of BAS 758 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2109344 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.2.1/1	Dreisch, S.	2020	BAS 758 00 F Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008) 2020/2027414 consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.2.2/1	Dreisch, S.	2020	BAS 758 00 F Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008) 2020/2027414 consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.3.1/1	Dreisch, S.	2020	BAS 758 00 F Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008) 2020/2027414 consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.3.3/1	Dreisch, S.	2020	BAS 758 00 F Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008) 2020/2027414 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 2.4.2/1	Keller, M.	2021	Physical and chemical properties of BAS 758 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2109344 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.5.1/1	Keller, M.	2021	Physical and chemical properties of BAS 758 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2109344 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.5.2/1	Keller, M.	2021	Physical and chemical properties of BAS 758 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2109344 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.6.1/1	Keller, M.	2021	Physical and chemical properties of BAS 758 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2109344 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.7.1/1	Keller, M.	2021	Physical and chemical properties of BAS 758 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2109344 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 2.7.3/1	Keller, M.	2021	Physical and chemical properties of BAS 758 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2109344 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.7.4/1	Keller, M.	2021	Physical and chemical properties of BAS 758 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2109344 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.8.2/1	Keller, M.	2021	Physical and chemical properties of BAS 758 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2109344 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.8.6.1/1	Keller, M.	2021	Physical and chemical properties of BAS 758 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2109344 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.8.6.2/1	Keller, M.	2021	Physical and chemical properties of BAS 758 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2109344 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 2.8.6.3/1	Keller, M.	2021	Physical and chemical properties of BAS 758 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2109344 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.9.1/1	Schlotterbeck, U.	2021	Physical and chemical compatibility in aqueous tank mixtures of BAS 758 BB F 2021/2000193 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCP 2.9.2/1	Schlotterbeck, U.	2021	Physical and chemical compatibility in aqueous tank mixtures of BAS 758 BB F 2021/2000193 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCP 2.11/1	Dreisch, S.	2020	BAS 758 00 F - Determination of the SADT in the adiabatic heat-storage test according to UN Transport Regulation 2020/2027415 consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep. no Unpublished	No	BASF
KCP 4.2/1	Nord, S.	2020	Effectiveness of Procedures for Cleaning Application Equipment and Protective Clothing - BAS 758 00 F 2020/2108630 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCP 4.3/1	Anonymous	2022	Safety Data Sheet - BAS 758 00 F, BASF 2022/2005510 BASF SE, Ludwigshafen/Rhein, 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 4.4/1	Maurer M.	2020	BAS 758 00 F EU Performance Test - AGRO-Packaging made of Coex-materials (HDPE with barrier layer) 2020/2027416 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. no Unpublished	No	BASF
KCP 4.4/2	Maurer M.	2020	BAS 758 00 F - EU Performance Test - AGRO-Packaging made of HDPE with fluorinated barrier 2020/2027417 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. no Unpublished	No	BASF
KCP 4.5/1	Anonymous	2022	Safety Data Sheet - BAS 758 00 F, BASF 2022/2005510 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 data/studies submitted in this Section

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

A 2.1 Mefentrifuclonazole

Not applicable

A 2.2 Metrafenone

Not applicable

A 2.3 Pyraclostrobin

Not applicable