

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 736 00 F

Product name(s): **Miralon**

Chemical active substances:

Fluxapyroxad, 50 g/L

Azoxystrobin, 75 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(new authorization)

Applicant: BASF

Submission date: 12/2021

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MS Finalisation date: January 2023

Version history

When	What
12/2021	Initial dRR - BASF DocID 2021/2048068
09/2022	zRMS-PL evaluation
12/2022	Updated version - BASF DocID 2022/2060354
01/2023	zRMS-PL changes as result of MSs comments

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zRMS's comments or conclusions are highlighted in grey colour.

Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substances.

Noticed data gap:

- Ambient temperature shelf life study (KCP 2.7.5) is required to support the proposed shelf life of 2 years for the product BAS 736 00 F. (The study in the commercial container is in progress. The final report will be available in September 2022.)
- data on Z-isomer content in the product (before and after storage) should be provided by the applicant.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

BASF is the applicant for this product.

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 Agricultural Solutions Division
 P.O. Box 120
 D-67117 Limburgerhof
 Germany

Contact person: Anne Berck
 Tel.No.: +32 2 373-2711
 e-mail: anne.berck@basf.com

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

1.2.1 Producer(s) of the preparation

Manufacturer of BAS 736 00 F (legal entity)

BASF SE
 Carl-Bosch Strasse 38
 D-67056 Ludwigshafen,
 Germany

Contact person: Anne Berck
 Tel.No.: +32 2 373-2711
 e-mail: anne.berck@basf.com

Location of manufacturing plant(s):

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

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

Manufacturer of azoxystrobin (legal entity):

Syngenta Crop Protection AG
 Rosentalstrasse 67
 4058 – Basel
 Switzerland

Manufacturer of fluxapyroxad (legal entity):

BASF SE
 Carl-Bosch Strasse 38
 D-67056 Ludwigshafen,
 Germany

Location of manufacturing plant(s) for the active substances:

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 Azoxystrobin

Minimum purity	930 g/kg
Relevant impurity toluene	max. 2.0 g/kg

Relevant impurity z-isomer	max 25 g/kg
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The detailed statement on impurities in azoxystrobin and their levels in the technical substances was part of the submission documents for Annex I inclusion.

According to Commission Implementing Regulation (EU) No 703/2011, the following component were identified as toxicological relevant for azoxystrobin:

Toluene, maximum content 2 g/kg

Z-isomer, maximum content 25 g/kg.

Therefore, data on Z-isomer content in the product should be provided by the applicant.

However, as part of the Confirmatory Data from 2015, SANCO/11027/2011 Rev 3, 20 March 2015, only toluene was identified as toxicological relevant. Therefore, data on the content of the z-isomer of azoxystrobin, before and after storage, in the formulation is not required.

1.2.3.2 Fluxapyroxad

Minimum purity	980 g/kg
Relevant impurity toluene	max. 0.6 g/kg

The detailed statement on impurities in fluxapyroxad and their levels in the technical substances was part of the submission documents for Annex I inclusion. For more information, please refer to confidential document.

zRMS : above specification of the technical material is reported by the applicant according to the review report for the active substance fluxapyroxad: SANCO/10692/2012 Rev 2, 25 March 2021. However according to Regulation (EU) No 540/2011 (version 01/11/2022) the minimum content of fluxapyroxad in the technical material is 95%, and the maximum content of toluene is 1 g/kg as implemented with Regulation (EU) No 589/2012. Taking into account that given specification reflects a worse case, it may be used in this submission.

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

Trade name: please refer to Registration Part A for the relevant country

Company code number: BAS 736 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	Declared content of the pure active substance (g/L)	FAO Limits (min – max)	Technical content* (g/L)	Technical content** (%w/w)
azoxystrobin	75.0	67.5 – 82.5	80.7	7.48
fluxapyroxad	50.0	45 - 55	51.0	4.73

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers, 93% for azoxystrobin and 98% for fluxapyroxad.

** Based on the density of the formulation of 1078 g/L at 20°C

The preparation BAS 736 00 F was not a representative formulation.
 The active substances in the formulation are not in a form of a salt nor a variant.

No safener nor synergist is used in the formulation.

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content in the technical material (g/kg)	Maximum content in the formulation (g/L)
toluene	2.0 (in azoxystrobin)	0.19

Relevant impurity	Maximum content in the technical material (g/kg)	Maximum content in the formulation (g/L)
	0.6 (in fluxapyroxad)	(0.16 coming from azoxystrobin and 0.03 coming from fluxapyroxad)
z-isomer	25.0 (in azoxystrobin)	2.02

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

Table 1.4-3: Information on the active substances

Type	Name/Code Number	
ISO common name	azoxystrobin	fluxapyroxad
CAS No.	131860-33-8	907204-31-3
EC No.	Not allocated	Not allocated
CIPAC No.	571	828
Salt, ester, anion or cation	none	none

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

The formulation does not contain any safeners or synergists.

Information on co-formulants is confidential and 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. BAS 736 00 F is an emulsifiable concentrate containing 50 g/L of fluxapyroxad and 75 g/L of azoxystrobin. BAS 736 00 F was not a representative formulation and therefore has not been previously evaluated at EU level.

The appearance of the product is a dark yellow clear liquid, with a strong sweet odour. It is not explosive, has no oxidising properties. The product is not flammable and has a flash point of 96.5 °C. It has a self-ignition temperature of 425°C. In aqueous solution, it has a pH value around 6.1 at 1% dilution. 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 in F-HDPE bottles, neither the active substances content nor the technical properties were changed.

Since the relevant impurity of azoxystrobin and fluxapyroxad – toluene (used as solvent) cannot be formed upon storage of the formulation thus their determination in storage studies is not needed. Toluene content is controlled within the technical specifications of active substances. The analytical methods for the determination of the active substances and the relevant impurity - toluene in the formulation BAS 736 00 F are available and validated (see section B5 of this dossier).

An analytical method for the determination of the Z-isomer of azoxystrobin in the product BAS 736 00 F is ongoing.

The shelf life study in the commercial container is ongoing. The results will be available in September 2022.

The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in F-HDPE packaging. Its technical characteristics are acceptable for an EC formulation.

The investigations of the physical and chemical properties have shown that BAS 736 00 F meets the general requirements for an EC-formulation according to the FAO specifications. This indicates that no particular problems are to be expected if the preparation is used as recommended.

A minimum shelf life of 2 years would be expected for this product according to FAO specifications.

However an ambient temperature shelf life study is required to confirm the proposed shelf life of 2 years for the product BAS 736 00 F.

The samples were stored, in their commercial packaging made from F-HDPE, however PA/PE (COEX) containers were additionally proposed (section 4.1). The PA/PE co-extruded packs are supported based on accelerated storage data for F-HDPE container (for details see findings of storage stability test KCP 2.7.1). The other study report BASF Ref. 2019/1039595 (see section 4.1) demonstrate that PA/PE co-extruded packaging material is stable after storage (8 weeks at 40°C) of product BAS 736 00 F.

A seepage study with BAS 736 00 F for the Coex PE/PA material (see section BASF DocID 2022/2027756) has been provided. Acceptable seepage data show that the formulation BAS 736 00 F is compatible with all tested packaging material. Therefore, for organic solvent based formulation type, like emulsifiable concentrate (EC), data can be extrapolated between packaging material of f-HDPE and coex-HDPE/PA, as acceptable seeping data is provided¹.

The intended concentration of use is 0.33% to 2% v/v.

The product BAS 736 00 F can be mixed in the tank together with Medax Max, Revysol, BAS 832 00 F, Actirob, Adigor, Atlantis and Axial 50. Studies regarding the combination with BAS 736 00 F were submitted and the application as tank mixture is acceptable.

¹ SANCO/10473/2003 –rev.5; 21.10.2021

However, no tank mixtures are recommended on the label (PL version) of this product.

Statement recommended to include on the label: “Apply spray liquid under permanent agitation” (see comment in Table 2-1 - KCP 2.8.6.3)

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

No implication for labelling.

Although the kinematic viscosity is lower than 20.5 mm²/sec, the formulation does not contain any substance classified as a category 1 for aspiration toxicity hazards (see composition in the confidential Part C). Therefore the product BAS 736 00 F is not considered as hazardous after aspiration.

Product BAS 736 00 F does not contain any co-formulant or active substance classified (according to CLP regulation) for physical hazard, including corrosion to metals, self-reactiveness, when in contact with water emits flammable gases, organic peroxides and pyrophoric behaviour. Therefore classification of the product BAS 736 00 F for physical hazard is not required.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

None

Compliance with FAO specifications:

The product BAS 736 00 F complies with FAO specifications.

Formulation used for tests

All tests have been conducted with the preparation BAS 736 00 F.
Dilutions used for tests were 0.17 % and 2.0%

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 examination and organoleptic determination	Batch FD-190220-0002; azoxystrobin: 73.9 g/L, fluxapyroxad: 49.4 g/L	BAS 736 00 F is a dark yellow clear liquid, with a strong sweet odour. No change after 2 week storage at 54°C	Y Y	[see 2020/2079771] Keller M, 2020 [see 2021/2041812] Keller M, 2021	Acceptable
Explosive properties (KCP 2.2.1)	OECD 113 Screening procedure according to A6.3 of UN Recommendations on the TRANSPORT OF DANGEROUS GOODS: Manual of Tests and Criteria, 6th edition, New York and Geneva, 2015: Class 1	Batch FD-190220-0002; azoxystrobin: 73.9 g/L, fluxapyroxad: 49.4 g/L	The DSC measurement of test item BAS 736 00 F in a closed gold plated stainless steel crucible showed only one exothermic effects in the temperature ranges of 150 °C – 230 °C with an average decomposition energy of -40 J/g. Therefore the exothermic decomposition energy is less than 500 J/g and no further test is necessary. The preparation BAS 736 00 F has no explosive properties.	Y	[see 2019/1039592] Dreisch S, 2019	Acceptable Explosive properties of the formulation can be excluded based on UN RTDG criteria.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Oxidizing properties (KCP 2.2.2)	UN Recommendations on the TRANSPORT OF DANGEROUS GOODS: Manual of Tests and Criteria, 6th edition, New York and Geneva, 2015: Division 5.1: Test series O.2	Batch FD-190220-0002; azoxystrobin: 73.9 g/L, fluxapyroxad: 49.4 g/L	The mean pressure rise time for the test item is greater than the mean pressure rise time for the reference item. The test item BAS 736 00 F showed no oxidizing properties according to the UN Transport Regulation, division 5.1	Y	[see 2019/1039592] Dreisch S, 2019	Acceptable The formulation is not oxidizing liquid.
Flash point (KCP 2.3.1)	EC 440/2008 Method A.9 (closed cup)	Batch FD-190220-0002; azoxystrobin: 73.9 g/L, fluxapyroxad: 49.4 g/L	The flash point is 96.5 °C. BAS 736 00 F is not a flammable liquid	Y	[see 2019/1039592] Dreisch S, 2019	Acceptable The formulation is not flammable liquid (flash point >60°C)
Flammability (KCP 2.3.2)		Batch FD-190220-0002; azoxystrobin: 73.9 g/L, fluxapyroxad: 49.4 g/L	It is known that the EC formulation BAS 736 00 F can form stable mixture in water. Therefore, the test on flammability (contact with water) does not need to be performed.	Y	[see 2019/1039592] Dreisch S, 2019	The test A.12 is not required.
Self-heating (KCP 2.3.3)	EC 440/2008 Method A.15	Batch FD-190220-0002; azoxystrobin: 73.9 g/L, fluxapyroxad: 49.4 g/L	The auto-ignition temperature was determined to be 425 °C	Y	[see 2019/1039592] Dreisch S, 2019	Acceptable The formulation is not considered as self-heating

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments																																										
Acidity or alkalinity and pH (KCP 2.4.1)			Not required, as the pH of the preparation is not <4 or >10.						Since BAS 736 00 F is non-aqueous formulation, the pH value of the neat plant protection product is not determined.																																										
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Batch FD-190220-0002; azoxystrobin: 73.9 g/L, fluxapyroxad: 49.4 g/L	<table><tr><td>Storage period</td><td>Initial</td><td>After 7 days at 0°C</td><td>After 2 weeks at 54°C</td></tr><tr><td>pH of 1.0 % in pure water</td><td>6.1 at 24°C</td><td>6.1 at 23°C</td><td>5.8 at 23°C</td></tr><tr><td>pH of 1.0 % in CIPAC water D</td><td>6.2 at 24°C</td><td>6.2 at 23°C</td><td>6.2 at 24°C</td></tr></table>				Storage period	Initial	After 7 days at 0°C	After 2 weeks at 54°C	pH of 1.0 % in pure water	6.1 at 24°C	6.1 at 23°C	5.8 at 23°C	pH of 1.0 % in CIPAC water D	6.2 at 24°C	6.2 at 23°C	6.2 at 24°C	Y Y	[see 2020/2079771] Keller M, 2020 [see 2021/2041812] Keller M, 2021	Acceptable																														
Storage period	Initial	After 7 days at 0°C	After 2 weeks at 54°C																																																
pH of 1.0 % in pure water	6.1 at 24°C	6.1 at 23°C	5.8 at 23°C																																																
pH of 1.0 % in CIPAC water D	6.2 at 24°C	6.2 at 23°C	6.2 at 24°C																																																
Viscosity (KCP 2.5.1)	CIPAC MT 192 OECD 114 Rotational viscometer	Batch FD-190220-0002; azoxystrobin: 73.9 g/L, fluxapyroxad: 49.4 g/L	<table><tr><td colspan="6">Dynamic viscosity [mPa.s] is:</td></tr><tr><td>Storage periode</td><td colspan="2">Initial</td><td colspan="3">After 2 weeks at 54°C</td></tr><tr><td>Temperature [°C]</td><td>20</td><td>40</td><td>20</td><td colspan="2">40</td></tr><tr><td>at D = 1 s⁻¹</td><td>26</td><td>13</td><td>27</td><td colspan="2">13</td></tr><tr><td>at D = 10 s⁻¹</td><td>27</td><td>12</td><td>26</td><td colspan="2">12</td></tr><tr><td>at D = 100 s⁻¹</td><td>27</td><td>13</td><td>26</td><td colspan="2">12</td></tr><tr><td>at D = 200 s⁻¹</td><td>27</td><td>13</td><td>27</td><td colspan="2">13</td></tr></table> <p>The formulation has a newtonian flow behaviour.</p> <p>Kinematic viscosity @ 40°C is 12 mm²/s</p> <p>Although the kinematic viscosity is lower than 20.5 mm²/sec, the formulation does not contain any substance classified as a category 1 (see composition in the confidential Part C)</p>				Dynamic viscosity [mPa.s] is:						Storage periode	Initial		After 2 weeks at 54°C			Temperature [°C]	20	40	20	40		at D = 1 s ⁻¹	26	13	27	13		at D = 10 s ⁻¹	27	12	26	12		at D = 100 s ⁻¹	27	13	26	12		at D = 200 s ⁻¹	27	13	27	13		Y Y	[see 2020/2079771] Keller M, 2020 [see 2021/2041812] Keller M, 2021	Acceptable The product does not contain hydrocarbons thus is not considered as hazardous after aspiration.
Dynamic viscosity [mPa.s] is:																																																			
Storage periode	Initial		After 2 weeks at 54°C																																																
Temperature [°C]	20	40	20	40																																															
at D = 1 s ⁻¹	26	13	27	13																																															
at D = 10 s ⁻¹	27	12	26	12																																															
at D = 100 s ⁻¹	27	13	26	12																																															
at D = 200 s ⁻¹	27	13	27	13																																															

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments
Surface tension (KCP 2.5.2)	OECD 115 EC 440/2008, Test A5 1.6.1 Plate method	Batch FD-190220-0002; azoxystrobin: 73.9 g/L, fluxapyroxad: 49.4 g/L					Y	[see 2020/2079771] Keller M, 2020 [see 2021/2041812] Keller M, 2021	Acceptable The formulation is surface active (surface tension <60 mN/m)
			Test concentration (%)	Test temp. (°C)	Surface tension (mN/m)				
			0.17	20	31.8				
			2.0	20	31.5				
			neat product	25	33.4				
Relative density (KCP 2.6.1)	OECD 109 EC 440/2008, Test A3 1.4.4 Oscillating densimeter	Batch FD-190220-0002; azoxystrobin: 73.9 g/L, fluxapyroxad: 49.4 g/L					Y	[see 2020/2079771] Keller M, 2020 [see 2021/2041812] Keller M, 2021	Acceptable
			Storage period	Density at 20°C (g/cm³)	Relative density D ²⁰ ₄	Density at 40°C (g/cm³)			
			Initial	1.078	1.078	1.061			
			After 2 weeks at 54°C	1.078	1.078	n.d.			
Bulk density (KCP 2.6.2)			Not applicable for a EC formulation.						-
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3 Analytical assay by HPLC method AFL1000/01	Batch FD-190220-0002; azoxystrobin: 73.9 g/L, fluxapyroxad: 49.4 g/L	In F-HDPE packaging				Y	[see 2020/2079771] Keller M, 2020 [see 2021/2041812] Keller M, 2021	Acceptable The formulation is stable upon the heat stability test. No significant changes in content active substance and technical properties observed upon accelerated storage at 54°C for 2 weeks.
			Storage period	Initial	After 2 weeks at 54°C	Deviation of initial			
			Fluxapyroxad (g/L)	49.4	49.5	± 0.2 %			
			Azoxystrobin (g/L)	72.8	72.5	± 0.4 %			
			<5% decrease in active substance contents was observed. The results of the physical properties after accelerated storage are reported in the corresponding annex points. The observed changes of the physical properties are negligible. BAS 736 00 F is chemically and physically stable for 2 weeks at						

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			54°C in F-HDPE packaging			<p>The analytical method for the determination of the active substances is available and validated according to the guideline SANCO/3030/99 rev. 5 (see section B5 of this dossier). Since the relevant impurity of azoxystrobin and fluxapyroxad – toluene (used as solvent) cannot be formed upon storage of the formulation thus their determination in storage studies is not needed. Toluene content is controlled within the technical specifications of active substances.</p> <p>The test item does not change significantly after the accelerated storage</p>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						procedure. The lowest and highest in use dilutions are covered within concentrations tested. The samples were stored, in their commercial F-HDPE packaging. No change in packaging was observed after the accelerated storage of the product. There was no significant reduction in weight of unopened container (-0.02%).
Stability after storage for other periods and/or temperatures (KCP 2.7.2)			Not applicable as the product is not heat sensitive.			-
Minimum content after heat stability testing (KCP 2.7.3)			Not applicable, the active substance contents did not decrease by more than 5% rel. after storage for 2 weeks at 54°C.			-
Effect of low	CIPAC MT 39.3	Batch FD-	After 7 days at 0°C, the sample was homogeneous and no separated	Y	[see	Acceptable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																								
temperatures on stability (KCP 2.7.4)		190220-0002; azoxystrobin: 73.9 g/L, fluxapyroxad: 49.4 g/L	material was observed. See also KCP 2.4.2 (pH), KCP 2.8.6.2 and KCP 2.8.6.3 emulsion stability	Y	2020/2079771] Keller M, 2020 [see 2021/2041812] Keller M, 2021	The product is stable when stored at low temperature																								
Ambient temperature shelf life (KCP 2.7.5)	<div>Analytical assay by HPLC method AFL1000/01</div> <div>EC 440/2008, Test A3 1.4.4</div> <div>Visual examination, organoleptic determination</div> <div>CIPAC MT 75.3</div> <div>CIPAC MT 192 OECD 114</div> <div>CIPAC MT 47.3</div>	Batch FD-190220-0002; azoxystrobin: 73.9 g/L, fluxapyroxad: 49.4 g/L	<div>The 2 year stability study is in progress. The final report will be available in September 2022</div> <div>Storage in F-HDPE packaging</div> <table><tr><th>Test</th><th>Initial</th><th>After 2 years at 25°C</th></tr><tr><td>Azoxystrobin</td><td>72.8 g/L</td><td>73.2 g/L (deviation + 0.55%)</td></tr><tr><td>Fluxapyroxad</td><td>49.4 g/L</td><td>49.2 g/L (deviation - 0.40%)</td></tr><tr><td>Density D₂₀⁴</td><td>1.078</td><td>1.077</td></tr><tr><td>Appearance</td><td>Dark yellow clear liquid with a strong sweet odour</td><td>Dark yellow clear liquid with a strong sweet odour</td></tr><tr><td>pH value</td><td>1% in pure water: 6.1 1 % in CIPAC D: 6.2</td><td>1% in pure water: 5.9 1% in CIPAC D: 5.9</td></tr><tr><td>Viscosity (mPa.s) @ 20°C</td><td>@ 10s⁻¹: 27 @ 100 s⁻¹: 27 @ 200 s⁻¹: 27 Newtonian</td><td>@ 10s⁻¹: 26 @ 100 s⁻¹: 27 @ 200 s⁻¹: 27 Newtonian</td></tr><tr><td>Foam persistence</td><td>@ 0.17%, 22 mL after 1 min</td><td>@ 0.17%, 12 mL after 1 min</td></tr></table>	Test	Initial	After 2 years at 25°C	Azoxystrobin	72.8 g/L	73.2 g/L (deviation + 0.55%)	Fluxapyroxad	49.4 g/L	49.2 g/L (deviation - 0.40%)	Density D ₂₀ ⁴	1.078	1.077	Appearance	Dark yellow clear liquid with a strong sweet odour	Dark yellow clear liquid with a strong sweet odour	pH value	1% in pure water: 6.1 1 % in CIPAC D: 6.2	1% in pure water: 5.9 1% in CIPAC D: 5.9	Viscosity (mPa.s) @ 20°C	@ 10s ⁻¹ : 27 @ 100 s ⁻¹ : 27 @ 200 s ⁻¹ : 27 Newtonian	@ 10s ⁻¹ : 26 @ 100 s ⁻¹ : 27 @ 200 s ⁻¹ : 27 Newtonian	Foam persistence	@ 0.17%, 22 mL after 1 min	@ 0.17%, 12 mL after 1 min	Y	[see 2022/2040478] Keller M, 2022	<div>Acceptable</div> <div>The formulation is stable during 2 years stability study. No significant changes in content active substance and technical properties observed at ambient temperature shelf life study.</div> <div>The analytical method for the determination of the active substances is available and validated according to the guideline SANCO/3030/99 rev. 5 (see section B5 of this dossier). Since the relevant</div>
Test	Initial	After 2 years at 25°C																												
Azoxystrobin	72.8 g/L	73.2 g/L (deviation + 0.55%)																												
Fluxapyroxad	49.4 g/L	49.2 g/L (deviation - 0.40%)																												
Density D ₂₀ ⁴	1.078	1.077																												
Appearance	Dark yellow clear liquid with a strong sweet odour	Dark yellow clear liquid with a strong sweet odour																												
pH value	1% in pure water: 6.1 1 % in CIPAC D: 6.2	1% in pure water: 5.9 1% in CIPAC D: 5.9																												
Viscosity (mPa.s) @ 20°C	@ 10s ⁻¹ : 27 @ 100 s ⁻¹ : 27 @ 200 s ⁻¹ : 27 Newtonian	@ 10s ⁻¹ : 26 @ 100 s ⁻¹ : 27 @ 200 s ⁻¹ : 27 Newtonian																												
Foam persistence	@ 0.17%, 22 mL after 1 min	@ 0.17%, 12 mL after 1 min																												

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
	CIPAC MT 36.3		Emulsion stability	<p>@ 2.0%, 26 mL after 1 mn</p> <p>@ 0.17% in CIPAC water A and D: Spontaneous emulsion, without froth. No cream, no oil but a sediment < 1 mL starting after 2 hours</p> <p>@2.0 % in CIPAC water A and D: Spontaneous emulsion, without froth. No cream, no oil but a sediment < 1 mL starting after 2 hours</p>	<p>@ 2.0%, 24 mL after 1 mn</p> <p>@ 0.17% in CIPAC water A and D: Spontaneous emulsion, without froth. No cream, no oil but a sediment < 1 mL starting after 30 minutes</p> <p>@2.0 % in CIPAC water A and D: Spontaneous emulsion, without froth. sediment < 1 mL starting after 30 minutes, bottom cream < 1 mL starting after 24 hours and bottom oil after 24 hours in CIPAC D</p>			<p>impurity of azoxystrobin and fluxapyroxad – toluene (used as solvent) cannot be formed upon storage of the formulation thus their determination in storage studies is not needed. Toluene content is controlled within the technical specifications of active substances.</p> <p>The test item does not change significantly after 2-y storage procedure. The lowest and highest in use dilutions are covered within concentrations tested. The samples were stored, in their commercial F-HDPE packaging.</p>
	CIPAC MT 36.3		Re-emulsification	<p>@ 0.17% in CIPAC water A and D: Completely redispersed, homogeneous emulsion sediment < 1 mL starting after 30 minutes</p> <p>@ 2.0% in CIPAC water A and D: Completely redispersed, homogeneous emulsion</p>	<p>@ 0.17% in CIPAC water A and D: Completely redispersed, homogeneous emulsion sediment < 1 mL starting after 30 minutes</p> <p>@ 2.0% in CIPAC water A and D: Completely redispersed, homogeneous emulsion</p>			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments			
	No guideline available		<table border="1"><tr><td></td><td>sediment < 1 mL starting after 30 minutes</td><td>sediment < 1 mL starting after 30 minutes</td></tr></table> <p><5% decrease in active substance contents was observed. The observed changes of the physical properties are negligible. BAS 736 00 F is chemically and physically stable for 2 years at 25°C in F-HDPE packaging. The level of the z-isomer in the formulation will be determine within the method validation. Study will be provided as soon as available.</p> <p>The seepage data performed with Coex PE/PA standard bottle shows that the formulation BAS 736 00 F is compatible with all tested packaging material</p>				sediment < 1 mL starting after 30 minutes	sediment < 1 mL starting after 30 minutes	N	[see 2022/2027756] Mecfel-Mar-czewski J., 2022	No change in packaging was observed after 2-y storage of the product. There was no significant change in weight of unopened container (+0.03%). The Coex PE/PA-packaging material is compatible with product BAS 736 00 based on seepage data performed with Coex PE/PA.
	sediment < 1 mL starting after 30 minutes	sediment < 1 mL starting after 30 minutes									
Shelf life in months (if less than 2 years) (KCP 2.7.6)			<p>The 2 year stability study is in progress. The final report will be available in September 2022</p> <p>Not applicable. The formulation is stable for 2 years at 25°C</p>					-			
Wettability (KCP 2.8.1)			Not applicable for an EC formulation.					-			

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 FD-190220-0002; azoxystrobin: 73.9 g/L, fluxapyroxad: 49.4 g/L	Foam volume in mL:						Y	[see 2020/2079771] Keller M, 2020 [see 2021/2041812] Keller M, 2021	Acceptable foam volume <60ml after 1 min.
			In CIPAC water D	Initial		After 2 weeks at 54°C					
			Test conc.	0.17%	2.0%	0.17%	2.0%				
			after 10 sec.	22	28	18	30				
			after 1 min.	22	26	14	20				
			after 3 min.	20	20	10	20				
			after 12 min.	16	16	8	12				
Suspensibility (KCP 2.8.3.1)			Not applicable for an EC formulation.								-
Spontaneity of dispersion (KCP 2.8.3.2)			Not applicable for an EC formulation.								-
Dispersion stability (KCP 2.8.3.3)			Not applicable for an EC formulation.								-
Degree of dissolution and dilution stability (KCP 2.8.4)			Not applicable for an EC formulation.								-
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)			Not applicable for an EC formulation.								-
Wet sieve test			Not applicable for an EC formulation.								-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments															
(KCP 2.8.5.1.2)																					
Dust content (KCP 2.8.5.2.1)			Not applicable for an EC formulation.			-															
Particle size of dust (KCP 2.8.5.2.2)			Not applicable for an EC formulation.			-															
Attrition (KCP 2.8.5.3)			Not applicable for an EC formulation.			-															
Hardness and integrity (KCP 2.8.5.4)			Not applicable for an EC formulation.			-															
Emulsifiability (KCP 2.8.6.1)			Not applicable for an EC formulation.			-															
Emulsion stability (KCP 2.8.6.2)	CIPAC MT 36.3	Batch FD-190220-0002; azoxystrobin: 73.9 g/L, fluxapyroxad: 49.4 g/L	<div>At 25°C Concentration 0.17 % in CIPAC water A and D:</div> <table><tr><td colspan="2">At 0.17 % concentration in CIPAC water</td><td>Initial A D</td><td>7 days 0°C A D</td><td>2 weeks 54°C A D</td></tr><tr><td>Time interval</td><td>Description of separation</td><td colspan="3">Separation in mL</td></tr><tr><td>30 sec.</td><td>spontaneous emulsion, froth</td><td>Yes, no froth</td><td>Yes, no froth</td><td>Yes, no froth</td></tr></table>	At 0.17 % concentration in CIPAC water		Initial A D	7 days 0°C A D	2 weeks 54°C A D	Time interval	Description of separation	Separation in mL			30 sec.	spontaneous emulsion, froth	Yes, no froth	Yes, no froth	Yes, no froth	Y Y	[see 2020/2079771] Keller M, 2020 [see 2021/2041812] Keller M, 2021	Acceptable However taking into account that half an hour after re-emulsification, less than 1 ml of sediment emerging from 100 ml of the dissolved formulation was reported, without specifying the exact amount Therefore
At 0.17 % concentration in CIPAC water		Initial A D	7 days 0°C A D	2 weeks 54°C A D																	
Time interval	Description of separation	Separation in mL																			
30 sec.	spontaneous emulsion, froth	Yes, no froth	Yes, no froth	Yes, no froth																	

Annex point	Method used / deviations	Test material	Findings								GLP Y/N	Reference	Acceptability / comments
			30 min.	sediment top cream bottom cream top oil bottom oil	0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0					statement “Apply spray liquid under permanent agitation” is recommended to include on the label
			2 hours	sediment top cream bottom cream top oil bottom oil	<1 <1 0 0 0 0 0 0 0 0	<1 <1 0 0 0 0 0 0 0 0	<1 <1 0 0 0 0 0 0 0 0	<1 <1 0 0 0 0 0 0 0 0					
			24 hours	sediment top cream bottom cream top oil bottom oil	<1 <1 0 0 0 0 0 0 0 0	<1 <1 0 0 0 0 0 0 0 0	<1 <1 0 0 0 0 0 0 0 0	<1 <1 0 0 0 0 0 0 0 0					
			Concentration 2.0 % in CIPAC water A and D:										
			At 2.0% concentration in CIPAC water		Initial		7 days 0°C		2 weeks 54°C				
					A	D	A	D	A	D			
			Time interval	Description of separation	Separation in mL								
			30 sec.	spontaneous emulsion, froth	Yes, no froth		Yes, no froth		Yes, no froth				
			30 min.	sediment top cream bottom cream	0 0 0 0 0 0	0 0 0 0 0 0	0 0 0 0 0 0	0 0 0 0 0 0	0 0 0 0 0 0	0 0 0 0 0 0			

Annex point	Method used / deviations	Test material	Findings						GLP Y/N	Reference	Acceptability / comments
				top oil bottom oil	0 0	0 0	0 0				
			2 hours	sediment top cream bottom cream top oil bottom oil	<1 <1 0 0 0 0 0 0 0 0	<1 <1 0 0 0 0 0 0 0 0	<1 <1 0 0 0 0 0 0 0 0				
			24 hours	sediment top cream bottom cream top oil bottom oil	<1 <1 0 0 0 0 0 0 0 0	<1 <1 0 0 0 0 0 0 0 0	<1 <1 0 0 0 0 0 0 0 0				
Re-emulsifiability (KCP 2.8.6.3)	CIPAC MT 36.3	Batch FD-190220-0002; azoxystrobin: 73.9 g/L, fluxapyroxad: 49.4 g/L	At 25°C, Concentration 0.17 % in CIPAC water A and D:						Y Y	[see 2020/2079771] Keller M, 2020 [see 2021/2041812] Keller M, 2021	
				At 0.17 % concentration in CIPAC water	Initial A D	7 days 0°C A D	2 weeks 54°C A D				
			Time interval	Description of separation	Separation in mL						
			30 sec.	Completely redispersed	yes, homog. emulsion	yes, homog. emulsion	yes, homog. emulsion				
			30 min.	sediment top cream bottom cream top oil	<1 <1 0 0 0 0 0 0 0 0	<1 <1 0 0 0 0 0 0 0 0	<1 <1 0 0 0 0 0 0 0 0				

Annex point	Method used / deviations	Test material	Findings										GLP Y/N	Reference	Acceptability / comments																																																				
			<table><tr><td></td><td colspan="2">bottom oil</td><td></td><td></td><td></td><td></td></tr></table> <p>Concentration 2.0 % in CIPAC water A and D:</p> <table><tr><td colspan="3">At 0.17 % concentration in CIPAC water</td><td colspan="2">Initial</td><td colspan="2">7 days 0°C</td><td colspan="2">2 weeks 54°C</td></tr><tr><td colspan="3"></td><td>A</td><td>D</td><td>A</td><td>D</td><td>A</td><td>D</td></tr><tr><td>Time interval</td><td colspan="2">Description of separation</td><td colspan="6">Separation in mL</td></tr><tr><td>30 sec.</td><td colspan="2">Completely redispersed</td><td colspan="2">yes, homog. emulsion</td><td colspan="2">yes, homog. emulsion</td><td colspan="2">yes, homog. emulsion</td></tr><tr><td>30 min.</td><td colspan="2">sediment top cream bottom cream top oil bottom oil</td><td><1 0 0 0 0</td><td><1 0 0 0 0</td><td><1 0 0 0 0</td><td><1 0 0 0 0</td><td><1 0 0 0 0</td><td><1 0 0 0 0</td></tr></table>											bottom oil						At 0.17 % concentration in CIPAC water			Initial		7 days 0°C		2 weeks 54°C					A	D	A	D	A	D	Time interval	Description of separation		Separation in mL						30 sec.	Completely redispersed		yes, homog. emulsion		yes, homog. emulsion		yes, homog. emulsion		30 min.	sediment top cream bottom cream top oil bottom oil		<1 0 0 0 0	<1 0 0 0 0	<1 0 0 0 0	<1 0 0 0 0	<1 0 0 0 0	<1 0 0 0 0			
	bottom oil																																																																		
At 0.17 % concentration in CIPAC water			Initial		7 days 0°C		2 weeks 54°C																																																												
			A	D	A	D	A	D																																																											
Time interval	Description of separation		Separation in mL																																																																
30 sec.	Completely redispersed		yes, homog. emulsion		yes, homog. emulsion		yes, homog. emulsion																																																												
30 min.	sediment top cream bottom cream top oil bottom oil		<1 0 0 0 0	<1 0 0 0 0	<1 0 0 0 0	<1 0 0 0 0	<1 0 0 0 0	<1 0 0 0 0																																																											
Flowability (KCP 2.8.7.1)			Not applicable for an EC formulation.												-																																																				
Pourability (KCP 2.8.7.2)			Not applicable for an EC formulation.												-																																																				

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Dustability following accelerated storage (KCP 2.8.7.3)			Not applicable for an EC formulation.			-
Physical compatibility of tank mixes (KCP 2.9.1)	ASTM, E 1518-05	Batch FD-190207-0004; azoxystrobin: 75 g/L nominal, fluxapyroxad: 50 g/L nominal	<p>BAS 736 00 F has been tested in tank mixtures with 7 plant protection products; Medax Max WG, prohexadione-calcium + trinexapac-ethyl; Revysol EC, mefentrifluconazole; BAS 832 00 F, methyltetrapole + mefentrifluconazole; Actirob EC, rapsoilmethylester; Adigor EC, no active substance; Atlantis WG, lodosulfuron methyl sodium + mesosulfuron methyl; Axial 50 EC, cloquintocet-mexyl + pixonaden.</p> <p>Evaluations of the mixtures have been conducted under static and dynamic tests. Assumption is made that modern commercially used field sprayers are equipped with continuous pumping system as well as an agitator system.</p> <p>In total 5 mixtures 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. In a mixture with Atlantis and Actirob foaming is possible². Therefore BAS 736 00 F is apparently physically compatible with the tested products.</p>	N	[see 2021/2004054] Schlotterbeck U, 2019	<p>No incompatibilities of the product BAS 736 00 F were observed in acceptable test when mixed with other plant protection products, described in the study report 2021/2004054.</p> <p>However, no tank mixtures are recommended on the label (PL version). Physical and chemical compatibility of tank mixes should be considered at national level of assessment where</p>

² Information provided by MS: DE during the comment procedure.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						tank mixes are recommended on the label.
Chemical compatibility of tank mixes (KCP 2.9.2)		Batch FD-190207-0004; azoxystrobin: 75 g/L nominal, fluxapyroxad: 50 g/L nominal	Fluxapyroxad and azoxystrobin, the active substances of BAS 736 00 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 are approved commercial products for applications in various tank mixtures as they are sufficient stable in aqueous conditions. No indication of any chemical reaction between the mixed products was observed. Therefore BAS 736 00 F is apparently chemically compatible with the tested products.	N	[see 2021/2004054] Schlotterbeck U, 2019	See above
Adhesion to seeds (KCP 2.10.1)			Not applicable since the plant protection product is not intended for seed treatment.			-
Distribution to seed (KCP 2.10.2)			Not applicable since the plant protection product is not intended for seed treatment.			-
Other/special studies (KCP 2.11)	CIPAC MT 30.5 Karl-Fischer titration	Batch FD-190220-0002; azoxystrobin: 73.9 g/L, fluxapyroxad: 49.4 g/L	Determination of water: The content of water is 0.3 % initially	Y Y	[see 2020/2079771] Keller M, 2020 [see 2021/2041812] Keller M, 2021	Acceptable Product BAS 736 00 F does not contain any co-formulant or active substance classified (according to CLP regulation) for physical hazard, including corrosion

Annex point	Method used / deviations	Test mate- rial	Findings	GLP Y/N	Reference	Acceptability / comments
						to metals, self-reac- tiveness, when in contact with water emits flammable gases, organic per- oxides and pyro- phoric behaviour. No other data are required.

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:	Study is acceptable. Only small amount (within the expected range) of residues of the active ingredients Fluxapyroxad and Azoxystrobin remains in the spray tank after standard cleaning with water, a risk to the operator or crops from this low concentration can be excluded.
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Reference:	CP 4.2/1
Report	Effectiveness of Procedures for Cleaning Application Equipment and Protective Clothing BAS 736 00 F, Nord, S., 2020 report No 848504 BASF Ref. 2020/2036309 Authority registration No
Guideline(s):	None, no guidelines available
Deviations:	No
GLP:	No, not subject to GLP regulations
Acceptability:	Yes

Good agricultural practice includes appropriate cleaning direct 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. The user must rinse all tubes and dead volumes sufficiently, as described in the sprayer's manual.

In the cleaning procedure, the active substances are diluted to such an extent that the simulated "double rinse procedure" is proved to be efficient enough.

Even if a large amount of water and a large volume per hectare is sprayed out in the next application, which leads to a high concentration of the displaced active substance 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 736 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 736 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)**

Comments of zRMS:	-
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Reference: CP 4.3/1
Report Safety Data Sheet - Miralon
Anonymous, 2021
report No Version 2.0
BASF Ref. 2021/2047854
Authority registration No
Guideline(s): (EC) No. 1907/2006
Deviations: No
GLP: No, not subject to GLP regulations
Acceptability: Yes

The safety data sheet contains advice for emergency measures in case of an accident with BAS 736 00 F, based on scientific tests.

4.4 Packaging and Compatibility with the Preparation (KCP 4.4)

BAS 736 00 F is to be marketed in high-density polyethylene containers with an inner barrier, e.g., polyamide (PA/PE) or fluorination (f-HDPE), 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.

0,15 litre bottle	material: shape/size: opening: closure: seal:	PA/PE (Coex) or f-HDPE Cylindrical / approx. 63 mm diameter x 92 mm 42 mm inner diameter screw cap Induction sealed or gasket
0,25 litre bottle	material: shape/size: opening: closure: seal:	PA/PE (Coex) or f-HDPE Cylindrical / approx. 63 mm diameter x 127 mm 42 mm inner diameter screw cap Induction sealed or gasket
0.5 litre bottle	material: shape/size: opening: closure: seal:	PA/PE (Coex) or f-HDPE Cylindrical / approx. 69 mm diameter x 196 mm 42 mm inner diameter screw cap Induction sealed or gasket
1 litre bottle	material: shape/size: opening: closure: seal:	PA/PE (Coex) or f-HDPE Cylindrical / approx. 88.5 mm diameter x 234 mm 42 mm inner diameter screw cap Induction sealed
1 litre eco-bottle	material: shape/size: opening: closure: seal:	PA/PE (Coex) or f-HDPE Cylindrical / approx. 88.5 mm diameter x 234 mm 54 mm inner diameter screw cap gasket
5 litre container	material: shape/size: opening: closure: seal:	PA/PE (Coex) or f-HDPE Rectangular / approx. 190 mm x 140 mm x 313 mm 54 mm inner diameter screw cap Induction sealed
5 litre eco-container	material: shape/size: opening: closure: seal:	PA/PE (Coex) or f-HDPE Rectangular / approx. 185 mm x 136 mm x 313 mm 54mm inner diameter screw cap gasket

10 litre container	material: shape/size: opening: closure: seal:	PA/PE (Coex) or f-HDPE Rectangular / approx. 230 mm x 165 mm x 375 mm 54 mm inner diameter screw cap Induction sealed
10 litre eco-container	material: shape/size: opening: closure: seal:	PA/PE (Coex) or f-HDPE Rectangular / approx. 230 mm x 187 mm x 358 mm 54mm inner diameter screw cap gasket
15 litre eco-container	material: shape/size: opening: closure: seal:	PA/PE (Coex) or f-HDPE Rectangular / approx. 265 mm x 215 mm x 400 mm 54 mm inner diameter screw cap Gasket
20 litre container	material: shape/size: opening: closure: seal:	F-HDPE Rectangular / approx. 285 x 237 x 424 mm 52 mm inner diameter screw cap Gasket
50 litre container	material: shape/size: opening: closure: seal:	F-HDPE Cylindrical / approx. 380 mm x 618 mm (d x h) 52 mm inner diameter screw cap or valve gasket

zRMS:

For organic solvent based formulation type, like emulsifiable concentrate (EC), extrapolation between HDPE/F and HDPE/PA material is acceptable, **when acceptable seeping data is presented**³. The PA/PE (Coex) packs are supported based on accelerated storage data for F-HDPE container (for details see findings of storage stability test (KCP 2.7.1). The study report BASF Ref. 2019/1039595 (below) demonstrate that PA/PE co-extruded packaging material is stable after storage (8 weeks at 40°C) of product BAS 736 00 F. **A seepage study with BAS 736 00 F for the Coex PE/PA material was performed (see BASF DocID 2022/2027756). No relevant anomalies in seepage data (leakage, ballooning, panelling, deformation, corrosion, condition of closure etc.) of the coex PE/PA bottles were observed during storage (2 and 6 months) of formulation BAS 763 00 F at 40°C. Therefore seepage data show that the formulation BAS 736 00 F is compatible with all tested packaging material.**

³ SANCO/10473/2003 –rev.5; 21.10.2021

Comments of zRMS:	Study is acceptable. The tested PA/PE co-extruded bottles were visual unchanged after storage (8 weeks at 40°C) of BAS 736 00 F. The weight change of tested bottle on storage was +0.12%. Rate of permeation <0.001g/Lh (Required value: ≤0.008g/Lh). PA/PE COEX packaging material is stable with the product BAS 736 00 F.
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Reference: CP 4.4/1
Report BAS 736 00 F - EU Performance Test in PA/PE COEX,
Maurer M., 2019
report No
BASF Ref. 2019/1039595
Authority registration No
Guideline(s): ADR/RID
Deviations: No
GLP: No, not subjected to GLP regulations
Acceptability: Yes

The damaging effects of BAS 736 00 F on test specimen made of Coex (PA/PE) material does not exceed the damaging effects of the Model liquid Pfl-Fr 2323. The chemical compatibility of Coex (PA/PE) material with the intended product in comparison with Model liquid Pfl-Fr 2323 is verified.

BAS 736 00 F can be packed in packaging made of Coex (PA/PE) 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 regulation.

The maximum allowable values of the vapour pressure and the density given in the certificate of approval may not be exceeded

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

Comments of zRMS:	<p>Study is acceptable. The tested F-HDPE bottles were visual unchanged after storage (8 weeks at 40°C) of BAS 736 00 F.</p> <p>The weight change of tested bottle on storage was +0.35%.</p> <p>Rate of permeation <0.001g/Lh (Required value: ≤0.008g/Lh).</p> <p>F-HDPE packaging material is stable with the product BAS 736 00 F</p>
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Reference: CP 4.4/2

Report BAS 736 00 F - EU Performance Test in HDPE, fluoriert,
Maurer M., 2019
report No
BASF Ref. 2019/1039594
Authority registration No

Guideline(s): ADR/RID

Deviations: No

GLP: No, not subjected to GLP regulations

Acceptability: Yes

The damaging effects of BAS 736 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.

BAS 736 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 regulation.

The maximum allowable values of the vapour pressure and the density given in the certificate of approval may not be exceeded.

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

Comments of zRMS:	Study is acceptable
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Reference: CP 4.4/3

Report Physical and chemical properties of BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C),
Keller, M., 2020
report No 848512_1
BASF Ref. 2020/2079771
Authority registration No

Guideline(s): CLI Technical Monograph No. 17, EPA 830.6302, EPA 830.6303, EPA 830.6304, EPA 830.6317, EPA 830.7000, EPA 830.7100, EPA 830.7300, FAO and WHO Specifications for Pesticides third revision of the first edition Rome 2016, OECD 115, US EPA 830.6303, US EPA 830.6320

Deviations: No

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

Acceptability: Yes

Comments of zRMS:	Study is acceptable
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Reference: CP 4.4/4

Report Physical and chemical properties of formula BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C),
Keller, M.,
report No 848512_1
BASF Ref. 2021/2041812
Authority registration No

Guideline(s): none,

Deviations: No

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

Acceptability: Yes

BAS 736 00 F was stored for 2 weeks at 54°C in F-HDPE bottles. Pack appearance was assayed by visual examination of the containers. No significant change in pack appearance was observed. No deformation, corrosion, or leakage was observed. The seal remains intact. There is no change in the weight of the unopened container before and after storage.

The data show the F-HDPE container to remain in good condition over the storage period. An interaction between the product and its original container was not observed.

Seepage data with Coex PE/PA material are available, see also KCP 2.7.5. The seepage data performed with Coex PE/PA standard bottle shows that the formulation BAS 736 00 F is compatible with all tested packaging material

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

Comments of zRMS:	-
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Reference:	CP 4.5/1
Report	Safety Data Sheet - Miralon, Anonymous, 2021 report No Version 2.0 BASF Ref. 2021/2047854 Authority registration No
Guideline(s):	(EC) No. 1907/2006
Deviations:	No
GLP:	No, not subject to GLP regulations
Acceptability:	Yes

The safety data sheet contains advice for the destruction or decontamination of the plant protection product and its packaging.

4.5.1 Neutralisation procedure (KCP 4.5.1)

Chemical neutralization is not recommended for spillage of this product. It is easier and simpler to contain and absorb spillages as explain in the safety data sheet. Final destruction of contaminated adsorbent/product will then be in a properly licensed, high temperature incinerator.

4.5.2 Controlled incineration (KCP 4.5.2)

For purposes of disposal, combustion of BAS 736 00 F in a licensed incinerator is required. 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, a 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 (respectively directive 2000/76/EEC 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 736 00 F in a waste incinerator plant does not raise concern about the formation of halogenated dibenzodioxins/-furans.

Users are requested to triple rinse empty primary packages as described in the ECPA "Guidelines for the rinsing of agrochemical containers", 1993.

Pressure rinsing or integrated pressure rinsing of the packaging material achieves a similar or even better result. The rinsate must be added to the spray liquid.

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

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1/1	Keller, M.	2020	Physical and chemical properties of BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2079771 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.1/2	Keller, M.	2021	Amendment 1: Physical and chemical properties of formula BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2021/2041812 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.2.1/1	Dreisch, S.	2019	BAS 736 00 F - Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008) 2019/1039592 consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.2.2/1	Dreisch, S.	2019	BAS 736 00 F - Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008) 2019/1039592 consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep. yes Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.3.1/1	Dreisch, S.	2019	BAS 736 00 F - Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008) 2019/1039592 consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.3.2/1	Dreisch, S.	2019	BAS 736 00 F - Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008) 2019/1039592 consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.3.3/1	Dreisch, S.	2019	BAS 736 00 F - Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008) 2019/1039592 consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.4.2/1	Keller, M.	2020	Physical and chemical properties of BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2079771 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.4.2/2	Keller, M.	2021	Amendment 1: Physical and chemical properties of formula BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2021/2041812 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 2.5.1/1	Keller, M.	2020	Physical and chemical properties of BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2079771 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.5.1/2	Keller, M.	2021	Amendment 1: Physical and chemical properties of formula BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2021/2041812 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.5.2/1	Keller, M.	2020	Physical and chemical properties of BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2079771 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.5.2/2	Keller, M.	2021	Amendment 1: Physical and chemical properties of formula BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2021/2041812 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.6.1/1	Keller, M.	2020	Physical and chemical properties of BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2079771 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 2.6.1/2	Keller, M.	2021	Amendment 1: Physical and chemical properties of formula BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2021/2041812 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.7.1/1	Keller, M.	2020	Physical and chemical properties of BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2079771 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.7.1/2	Keller, M.	2021	Amendment 1: Physical and chemical properties of formula BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2021/2041812 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.7.4/1	Keller, M.	2020	Physical and chemical properties of BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2079771 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.7.4/2	Keller, M.	2021	Amendment 1: Physical and chemical properties of formula BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2021/2041812 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 2.7.5/1	Keller, M.	2022	Physical and Chemical Properties of formula BAS 736 00 F: Storage stability for up to 156 weeks at 25°C in F- HDPE bottles 2022/2040478 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.7.5/2	Mecfel-Marczewski, J.	2022	BAS 736 00 F: Compatibility testing and seepage assessment of packaging materials with formulations after storage 2022/2027756 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCP 2.8.2/1	Keller, M.	2020	Physical and chemical properties of BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2079771 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.8.2/2	Keller, M.	2021	Amendment 1: Physical and chemical properties of formula BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2021/2041812 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.8.6.2/1	Keller, M.	2020	Physical and chemical properties of BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2079771 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF

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KCP 2.8.6.2/2	Keller, M.	2021	Amendment 1: Physical and chemical properties of formula BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2021/2041812 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.8.6.3/1	Keller, M.	2020	Physical and chemical properties of BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2079771 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.8.6.3/2	Keller, M.	2021	Amendment 1: Physical and chemical properties of formula BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2021/2041812 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 2.9.1/1	Schlotterbeck, U.	2019	Physical and Chemical Compatibility in aqueous tank mixtures of BAS 736 00 F 2021/2004054 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCP 2.9.2/1	Schlotterbeck, U.	2019	Physical and Chemical Compatibility in aqueous tank mixtures of BAS 736 00 F 2021/2004054 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCP 2.11/1	Keller, M.	2020	Physical and chemical properties of BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2079771 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 2.11/2	Keller, M.	2021	Amendment 1: Physical and chemical properties of formula BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2021/2041812 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 4.2/1	Nord, S.	2020	Effectiveness of Procedures for Cleaning Application Equipment and Protective Clothing BAS 736 00 F 2020/2036309 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCP 4.3/1	Anonymous	2021	Safety Data Sheet - Miralon 2021/2047854 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. no Unpublished	No	No
KCP 4.4/1	Maurer M.	2019	BAS 736 00 F - EU Performance Test in COEX 2019/1039595 BASF SE no Unpublished	No	BASF
KCP 4.4/2	Maurer M.	2019	BAS 736 00 F EU Performance Test in HDPE, fluoriert 2019/1039594 BASF SE no Unpublished	No	BASF
KCP 4.4/3	Keller, M.	2020	Physical and chemical properties of BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2020/2079771 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 4.4/4	Keller, M.	2021	Amendment 1: Physical and chemical properties of formula BAS 736 00 F including Low temperature stability (7 days at 0°C) and Accelerated storage stability (14 days at 54°C) 2021/2041812 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 4.5/1	Anonymous	2021	Safety Data Sheet - Miralon 2021/2047854 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. no Unpublished	No	No

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

BAS 736 00 F is a new product, no product data have been evaluated previously.

The following tables are to be completed by MS.

List of data submitted by the applicant and not 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 XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

List of data relied on and not submitted by the applicant but necessary for evaluation

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 XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner