

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: ADM.03503.F.1.A

Product name(s): see Part A

Chemical active substances:

Fluxapyroxad, 75 g/L

Prothioconazole, 150 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Country organisation / representative
as specified in Part A

Submission date: April 2022

MS Finalisation date: August 2023 (initial Core Assessment)

December 2023 (final Core Assessment)

Version history

When	What
April 2022	Version 1 Applicant
June 2023	Version 2 Applicant – Results of the 2 year stability study are included
August 2023	Version 3 Applicant – Update proposed packaging materials
August 2023	<p>Initial assessment by the zRMS</p> <p>The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency.</p> <p>Following the evaluation and before sending the document for commenting, all coloured highlighting was removed, from the parts updated by the Applicant, for better legibility.</p>
December 2023	<p>Final report (Core Assessment updated following the commenting period)</p> <p>Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Information no longer relevant is struck through and shaded.</p>

DATA PROTECTION CLAIM

In order to present a dossier fully compliant with today's requirements (Reg. 284/2013), studies have been performed on ADM.03503.F.1.A. Under Article 59, Regulation 1107/2009/EC, on behalf of the Sponsor Company the applicant claims data protection for the studies conducted with ADM.03503.F.1.A. The data protection status and corresponding justification as valid for the respective country will be confirmed in the respective PART A.

STATEMENT FOR OWNERSHIP

The summaries and evaluations contained in this document may be based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority that prepared it. Other registration authorities should not grant, amend, or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this document unless they have received the data on which the summaries and evaluation are based, either –

- from the owner of the data, or
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Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substance.

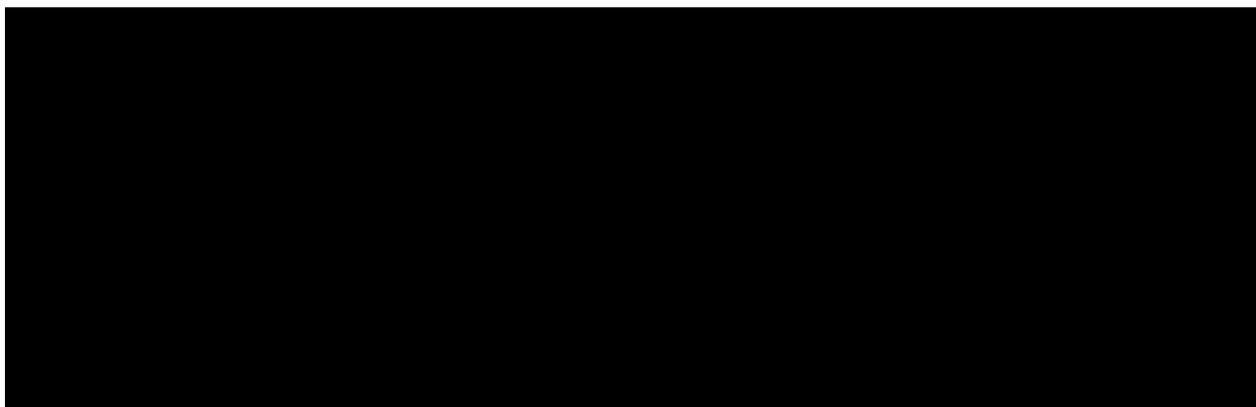
Noticed data gaps are:

—none

- pH < 4, the applicant was requested to provide information on the effects on metals. The study for corrosion to metals has been planned and will be provided once available.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)



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

1.2.1 Producer(s) of the preparation

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

1.2.2 Producer(s) of the active substance(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 Fluxapyroxad

Fluxapyroxad	min. 980 g/kg
Toluene	max. 0.6 g/kg

1.2.3.2 Prothioconazole

Prothioconazole	min. 970 g/kg
Toluene	max. 5 g/kg
Prothioconazole-desthio	max. 0.5 g/kg

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

Trade name:	Please refer to Registration Report Part A for the relevant country
Company code number	ADM.03503.F.1.A
Alternative codes:	ADM.3503.F.1.A

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)

ADM.03503.F.1.A was not the representative formulation for the renewal of either of the active substances.

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)
Fluxapyroxad	75	67.5 – 82.5	76.53	7.09
Prothioconazole	150	141 - 159	154.6	14.33

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers (980 g/kg fluxapyroxad, 970 g/kg prothioconazole)

** Based on the density of the formulation = 1.08

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content (g/L)
Toluene	0.7545 (0.045+0.75) (0.70% w/w)
Prothioconazole-desthio	0.075 (0.069% w/w) relative to technical material 0.077 g/L

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

Table 1.4-3: Information on fluxapyroxad

Type	Name/Code Number
ISO common name	Fluxapyroxad
CAS No.	907204-31-3
EC No.	620-041-3
CIPAC No.	828

Table 1.4-4: Information on prothioconazole

Type	Name/Code Number
ISO common name	Prothioconazole
CAS No.	178928-70-6
EC No.	605-841-2
CIPAC No.	745

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

CONFIDENTIAL information is provided separately (Part C).

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

Type: 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 light yellow to light brown, clear, homogeneous liquid. It is neither explosive nor oxidising. The product has a flash point of 92.5°C and an auto-ignition temperature of 420°C. In aqueous solution, it has a pH value of 3.67 at 20.7 °C and neat it has a pH value of 2.67 at 20.4 °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. The stability data indicate a shelf life of at least 2 years (extrapolated) at ambient temperature when stored in commercial packaging material. Its technical characteristics are acceptable for an emulsifiable concentrate type formulation. The intended concentration of use is 0.31% to 1.00% (concentration of use included in the studies: 0.19% to 1.6%). The product is not intended for tank mixing.

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

None.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

None.

Compliance with FAO specifications:

The product ADM.03503.F.1.A complies with FAO specifications.

Formulation used for tests

The product used in the tests has the same composition as the one cited in Part C.

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	ADM.03503.F.1.A Batch: 1162-230719-011	Clear, homogeneous liquid	Y	Riedl, S. (2021a) (000105596)	Accepted.
	OPPTS 830.6303	ADM.03503.F.1.A Batch: 1162-230719-011	Light yellow to light brown	Y	Riedl, S. (2021a) (000105596)	Accepted.
Explosive properties (KCP 2.2.1)	UN-MTC, Appendix 6 OECD 113 EC Method A.14	ADM.03503.F.1.A Batch: 1162-230719-011	In a DSC screening experiment, the exothermic decomposition energy is < 500 J/g. ADM.03503.F.1.A is not classified as an explosive.	Y	Bender, D. (2020a) (000105599)	Accepted. ADM.03503.F.1.A is not explosive. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.
Oxidizing properties (KCP 2.2.2)	UN Test O.2 EC Method A.21	ADM.03503.F.1.A Batch: 1162-230719-011	A pressure of 2,070 kPa was not reached within 60 seconds in any of the tests with ADM.03503.F.1.A, meaning that pressure rise time for the test item is greater than the mean pressure rise time for a 1:1 mixture of reference item nitric acid 65% and cellulose. ADM.03503.F.1.A is not classified as an oxidising liquid.	Y	Bender, D. (2020b) (000105600)	Accepted. ADM.03503.F.1.A has no oxidizing properties. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.
Flash point (KCP 2.3.1)	EC Method A.9	ADM.03503.F.1.A Batch: 1162-230719-011	92.5°C ADM.03503.F.1.A is not classified as a flammable liquid.	Y	Bender, D. (2020c) (000106480)	Accepted. The formulation is not flammable. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Flammability (KCP 2.3.2)	-	-	Not required for an EC formulation.	-	-	-
Self-heating (KCP 2.3.3)	EC Method A.15 DIN 51794 DIN EN 14522	ADM.03503.F.1.A Batch: 1162-230719-011	Auto-ignition temperature: 420°C	Y	Bender, D. (2020d) (000106481)	Accepted. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 75.3 OPPTS 830.7000	ADM.03503.F.1.A Batch: 1162-230719-011	Neat pH: 2.67 at 20.4 °C	Y	Riedl, S. (2021a) (000105596)	pH < 4, the applicant was requested to provide information on the effects on metals. Applicant: Based on the experimental data for skin effects the applicants do not expect that this product would be corrosive to metals. However UN Test C.1 is being conducted to confirm this. This point should have no impact on the authorization of the product as a PPP. Accepted. The study for corrosion to metals has been planned and will be provided once available.
	CIPAC MT 191	ADM.03503.F.1.A Batch: 1162-230719-011	Acidity: 0.206% (as H ₂ SO ₄)	Y	Riedl, S. (2021a) (000105596)	Accepted.

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	ADM.03503.F.1.A Batch: 1162-230719-011	pH of a 1% dilution: 3.67 at 20.7 °C	Y	Riedl, S. (2021a) (000105596)	Accepted.																												
Viscosity (KCP 2.5.1)	OECD 114	ADM.03503.F.1.A Batch: 1162-230719-011	<p>At 20°C:</p> <table border="1"> <thead> <tr> <th>Shear rate (s-1)</th> <th>Viscosity (cP)</th> </tr> </thead> <tbody> <tr><td>105</td><td>30.2</td></tr> <tr><td>90</td><td>30.2</td></tr> <tr><td>70</td><td>30.2</td></tr> <tr><td>50</td><td>30.2</td></tr> <tr><td>35</td><td>30.1</td></tr> <tr><td>18</td><td>29.8</td></tr> </tbody> </table> <p>At 40°C:</p> <table border="1"> <thead> <tr> <th>Shear rate (s-1)</th> <th>Viscosity (cP)</th> </tr> </thead> <tbody> <tr><td>105</td><td>12.8</td></tr> <tr><td>90</td><td>12.8</td></tr> <tr><td>70</td><td>12.8</td></tr> <tr><td>50</td><td>12.7</td></tr> <tr><td>35</td><td>12.6</td></tr> <tr><td>18</td><td>12.0</td></tr> </tbody> </table> <p>The viscosity is independent of shear rate, therefore the test item is a Newtonian fluid.</p>	Shear rate (s-1)	Viscosity (cP)	105	30.2	90	30.2	70	30.2	50	30.2	35	30.1	18	29.8	Shear rate (s-1)	Viscosity (cP)	105	12.8	90	12.8	70	12.8	50	12.7	35	12.6	18	12.0	Y	Tsesin, N. (2020) (000106627)	Accepted. The content of hydrocarbon is less than 10% and it does not contain components classified as H304. The product is not considered as aspiration hazard (H304).
Shear rate (s-1)	Viscosity (cP)																																	
105	30.2																																	
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18	12.0																																	
Surface tension (KCP 2.5.2)	EC Method A.5 OECD 115	ADM.03503.F.1.A Batch: 1162-230719-011	<p>Neat at 20°C: 36.29 mN/m</p> <p>1.6% v/v at 20°C: 31.99 mN/m</p> <p>The product is surface active.</p>	Y	Riedl, S. (2020b) (000106704)	Accepted.																												
Relative density (KCP 2.6.1)	EC Method A.3	ADM.03503.F.1.A Batch: 1162-230719-011	1.08	Y	Tsesin, N. (2020) (000106627)	Accepted.																												
	EC Method A.3 OECD 109	ADM.03503.F.1.A Batch: 1162-230719-011	1.0792	Y	Riedl, S. (2021b) (000106478)	Accepted.																												
Bulk density (KCP 2.6.2)	-	-	Not required for an EC formulation.	-	-	-																												
Storage Stability after 14	SANCO/3030/99 rev. 5	ADM.03503.F.1.A	The T = 0 determinations of the content of active	Y	Riedl, S. (2021b)	Accepted.																												

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
days at 54° C (KCP 2.7.1)		Batch: 1162-230719-011	substances and associated impurities in the product were determined. Results are presented in Table 2.7.1 below.		(000106478)	
	CIPAC MT 46.3	ADM.03503.F.1.A Batch: 1162-230719-011	No significant decrease in the content of the active substances or increase in the content of relevant impurities was observed following the 2 week storage period at 54°C in HDPE/PA packaging. No significant variation in any technical characteristics of the product was observed following the 2 week storage period at 54°C. Results for individual parameters are presented in Table 2.7.1 below.	Y	Riedl, S. (2021a) (000105596)	Accepted. The product showed no significant physical changes after accelerated storage. No significant changes were observed in the packaging and therefore it can be concluded that the test item was not corrosive to the container material. The accelerated stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging (HDPE/PA).
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	No other storage periods and/or temperatures tested.	-	-	-
Minimum content after heat stability testing (KCP 2.7.3)	-	-	Not required, as no significant loss of active substances following storage.	-	-	-
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	ADM.03503.F.1.A Batch: 1162-230719-011	No separation / sedimentation and no significant changes in the emulsion characteristics of the test item were observed following the 7-day storage period at 0°C. Results for individual parameters are presented in Table 2.7.1 below.	Y	Riedl, S. (2020b) (000106479)	Accepted.
Ambient temperature	CropLife International	ADM.03503.F.1.A	No significant decrease in the content of the active	Y	Riedl, S. (2022)	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
shelf life (KCP 2.7.5)	Monograph 17	Batch: 1162-230719-011	substances or increase in the content of relevant impurities was observed following the 2 year storage period at 20°C in HDPE/PA packaging. No significant variation in any technical characteristics of the product was observed following the 2 year storage period at 20°C. Results for individual parameters are presented in Table 2.7.1 below.		(000105597)	The product showed no significant physical changes after storage. No significant changes were observed in the packaging and therefore it can be concluded that the test item was not corrosive to the container material. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging (HDPE/PA).
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	As the preparation does not show any signs of significant chemical or physical changes after accelerated storage at 54°C for 14 days and at 20°C for 2 years, it is considered that the product is stable for at least two years at ambient temperature.	-	-	Accepted.
Wettability (KCP 2.8.1)	-	-	Not required for an EC formulation.	-	-	-
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3		0.19% v/v, CIPAC water D: Time Volume of Foam (mL) 1 minute 23 12 minutes 21.5 1.6% v/v, CIPAC water D: Time Volume of Foam (mL) 1 minute 49 12 minutes 31.5	Y	Riedl, S. (2021a) (000105596)	Accepted.
Suspensibility (KCP 2.8.3.1)	-	-	Not required for an EC formulation.	-	-	-
Spontaneity of dispersion (KCP 2.8.3.2)	-	-	Not required for an EC formulation.	-	-	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Dispersion stability (KCP 2.8.3.3)	-	-	Not required for an EC formulation.	-	-	-
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not required for an EC formulation.	-	-	-
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	-	-	Not required for an EC formulation.	-	-	-
Wet sieve test (KCP 2.8.5.1.2)	-	-	Not required for an EC formulation.	-	-	-
Dust content (KCP 2.8.5.2.1)	-	-	Not required for an EC formulation.	-	-	-
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not required for an EC formulation.	-	-	-
Attrition (KCP 2.8.5.3)	-	-	Not required for an EC formulation.	-	-	-
Hardness and integrity (KCP 2.8.5.4)	-	-	Not required for an EC formulation.	-	-	-
Emulsifiability (KCP 2.8.6.1)	CIPAC MT 36.3	ADM.03503.F.1.A Batch: 1162-230719-011	0.19% v/v, CIPAC water A: Initial emulsification: Time Observation 30 sec No oil or cream Emulsion stability: 0 hours No oil or cream 0.5 hours No oil or cream 2 hours No oil or cream 24 hours No oil, < 1 mL cream Re-emulsification: 30 sec No oil or cream Final emulsion stability: 0.5 hours No oil, < 1 mL cream 1.6% v/v, CIPAC water A: Initial emulsification: Time Observation	Y	Riedl, S. (2021a) (000105596)	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			30 sec No oil or cream Emulsion stability: 0 hours No oil or cream 0.5 hours No oil or cream 2 hours No oil or cream 24 hours No oil, ~ 0.5 mL cream Re-emulsification: 30 sec No oil or cream Final emulsion stability: 0.5 hours No oil or cream 0.19% v/v, CIPAC water D: Initial emulsification: Time Observation 30 sec No oil or cream Emulsion stability: 0 hours No oil or cream 0.5 hours No oil or cream 2 hours No oil or cream 24 hours No oil, < 1mL cream Re-emulsification: 30 sec No oil or cream Final emulsion stability: 0.5 hours No oil, < 1 mL cream 1.6% v/v, CIPAC water D: Initial emulsification: Time Observation 30 sec No oil or cream Emulsion stability: 0 hours No oil or cream 0.5 hours No oil or cream 2 hours No oil or cream 24 hours No oil, < 1 mL cream Re-emulsification: 30 sec No oil or cream Final emulsion stability: 0.5 hours No oil, < 1 mL cream			
Emulsion stability	CIPAC MT 36.3	-	See 2.8.6.1	-	-	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.6.2)						
Re-emulsifiability (KCP 2.8.6.3)	CIPAC MT 36.3	-	See 2.8.6.1	-	-	-
Flowability (KCP 2.8.7.1)	-	-	Not required for an EC formulation.	-	-	-
Pourability (KCP 2.8.7.2)	-	-	Not required for an EC formulation.	-	-	-
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not required for an EC formulation.	-	-	-
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	ADM.03503.F.1.A is not intended for tank mixing.	-	-	-
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	ADM.03503.F.1.A is not intended for tank mixing.	-	-	-
Adhesion to seeds (KCP 2.10.1)	-	-	Not required for an EC formulation.	-	-	-
Distribution to seed (KCP 2.10.2)	-	-	Not required for an EC formulation.	-	-	-
Other/special studies (KCP 2.11)	-	-	None	-	-	-

Table 2.7.1 Storage Stability Results (Riedl, S., 2020c, 2021a, 2021b and 2022)

Test	Method	Initial	7 Days at 0°C	After 14 Days at 54°C	After 1 Year at 20°C	After 2 Years at 20°C
Fluxapyroxad content (g/L)	HPLC-UV (validated acc. to SANCO/3030)	77.4	-	76.5	73.8	74.1
Prothioconazole content (g/L)	HPLC-UV (validated acc. to SANCO/3030)	148	-	149	146	141
Prothioconazole-desthio content (g/L)	HPLC-MS (validated acc. to SANCO)	0.01	-	0.0094	0.0191	0.0242
Toluene content (g/L)	GC-MS	0.21	-	-	As the toluene cannot be formed during the formulation process or during the storage of the formulation, in accordance with SANCO/10473/2003 –rev.5, it is not required to investigate its level during the storage testing.	As the toluene cannot be formed during the formulation process or during the storage of the formulation, in accordance with SANCO/10473/2003 – rev.5, it is not required to investigate its level during the storage testing.
Appearance	OPPTS 830.6302 OPPTS 830.6303	Physical State: Clear, homogeneous liquid Colour: Light yellow to light brown	Physical State: Clear, homogeneous liquid Colour: Light yellow to light brown	Physical State: Clear, homogeneous liquid Colour: Light yellow to light brown	Physical State: Clear, homogeneous liquid Colour: Light yellow to light brown	Physical State: Clear, homogeneous liquid Colour: Light yellow to light brown
Pack appearance	Visual	1 litre light grey, non-transparent HDPE/PA bottle with white non-transparent plastic screw cap, with locking ring and grey insert. Packs were closed and leak proofed.	-	1 litre light grey, non-transparent HDPE/PA bottle with white non-transparent plastic screw cap, with locking ring and grey insert. Packs were closed and leak proofed.	1 litre light grey, non-transparent HDPE/PA bottle with white non-transparent plastic screw cap, with locking ring and grey insert. Packs were closed and leak proofed.	1 litre light grey, non-transparent HDPE/PA bottle with white non-transparent plastic screw cap, with locking ring and grey insert. Packs were closed and leak proofed.
Weight change	Gravimetric	19043_2: 1211.44 g 19043_3: 1211.45 g	-	19043_2: 1211.40 g (-0.04 g) 19043_3: 1211.40 g (-0.05 g)	19043_5: 1211.92 g (+0.009%)	19043_7: 1211.00 g (+0.02%)
pH (neat)	CIPAC MT 75.3	2.67 at 20.7 °C	-	2.38 at 21.0 °C	2.60 at 21.7 °C	2.58 at 21.7 °C
pH (1%)	CIPAC MT 75.3	3.67 at 20.4 °C	-	3.76 at 21.1 °C	3.68 at 22.1 °C	3.61 at 21.7 °C
Acidity	CIPAC MT 191	0.206% (as H ₂ SO ₄)	-	0.196% (as H ₂ SO ₄)	0.194% (as H ₂ SO ₄)	0.186% (as H ₂ SO ₄)

Test	Method	Initial	7 Days at 0°C	After 14 Days at 54°C	After 1 Year at 20°C	After 2 Years at 20°C
Persistence of foam	CIPAC MT 47.1	0.19% v/v, CIPAC water D: Time Volume of Foam (mL) 1 minute 23 12 minutes 21.5 1.6% v/v, CIPAC water D: Time Volume of Foam (mL) 1 minute 49 12 minutes 31.5	-	0.19% v/v, CIPAC water D: Time Volume of Foam (mL) 1 minute 23.5 12 minutes 21 1.6% v/v, CIPAC water D: Time Volume of Foam (mL) 1 minute 47 12 minutes 36	0.19% v/v, CIPAC water D: Time Volume of Foam (mL) 1 minute 21 12 minutes 18.5 1.6% v/v, CIPAC water D: Time Volume of Foam (mL) 1 minute 39.5 12 minutes 33.5	0.19% v/v, CIPAC water D: Time Volume of Foam (mL) 1 minute 24 12 minutes 17.5 1.6% v/v, CIPAC water D: Time Volume of Foam (mL) 1 minute 41 12 minutes 34
Emulsion Characteristics	CIPAC MT 36.3	0.19% v/v, CIPAC water A: Initial emulsification: Time Observation 30 sec No oil or cream Emulsion stability: 0 hours No oil or cream 0.5 hours No oil or cream 2 hours No oil or cream 24 hours No oil, < 1 mL cream Re-emulsification: 30 sec No oil or cream Final emulsion stability: 0.5 hours No oil, < 1 mL cream 1.6% v/v, CIPAC water A: Initial emulsification: Time Observation 30 sec No oil or cream Emulsion stability:	0.19% v/v, CIPAC water A: Initial emulsification: Time Observation 30 sec No oil or cream Emulsion stability: 0 hours No oil or cream 0.5 hours No oil or cream 2 hours < 1 mL oil, no cream 24 hours < 1 mL oil and cream Re-emulsification: 30 sec No oil or cream Final emulsion stability: 0.5 hours No oil, < 1 mL cream 1.6% v/v, CIPAC water A: Initial emulsification: Time Observation 30 sec No oil or cream Emulsion stability:	0.19% v/v, CIPAC water A: Initial emulsification: Time Observation 30 sec No oil or cream Emulsion stability: 0 hours No oil or cream 0.5 hrs No oil or cream 2 hours No oil or cream 24 hrs No oil, < 1 mL cream Re-emulsification: 30 sec No oil or cream Final emulsion stability: 0.5 hrs No oil, < 1 mL cream 1.6% v/v, CIPAC water A: Initial emulsification: Time Observation 30 sec No oil or cream Emulsion stability: 0 hours No oil or cream 0.5 hrs No oil or cream 2 hours No oil, < 1 mL cream 24 hrs No oil, < 1 mL cream	0.19% v/v, CIPAC water A: Initial emulsification: Time Observation 30 sec No oil or cream Emulsion stability: 0 hours No oil or cream 0.5 hrs No oil or cream 2 hours No oil, < 1 mL cream 24 hrs No oil, < 1 mL cream Re-emulsification: 30 sec No oil or cream Final emulsion stability: 0.5 hrs No oil, < 1 mL cream 1.6% v/v, CIPAC water A: Initial emulsification: Time Observation 30 sec No oil or cream Emulsion stability: 0 hours No oil or cream 0.5 hrs No oil or cream 2 hours No oil, < 1 mL cream 24 hrs No oil, < 1 mL cream	0.19% v/v, CIPAC water A: Initial emulsification: Time Observation 30 sec No oil or cream Emulsion stability: 0 hours No oil or cream 0.5 hrs No oil or cream 2 hours No oil, < 1 mL cream 24 hrs No oil, < 1 mL cream Re-emulsification: 30 sec No oil or cream Final emulsion stability: 0.5 hrs No oil or cream 1.6% v/v, CIPAC water A: Initial emulsification: Time Observation 30 sec No oil or cream Emulsion stability: 0 hours No oil or cream 0.5 hrs No oil or cream 2 hours No oil, < 1 mL cream 24 hrs No oil, < 1 mL cream

Test	Method	Initial	7 Days at 0°C	After 14 Days at 54°C	After 1 Year at 20°C	After 2 Years at 20°C
		cream 0.5 hours No oil or cream 2 hours No oil or cream 24 hours No oil, < 1 mL cream Re-emulsification: 30 sec No oil or cream Final emulsion stability: 0.5 hours No oil, < 1 mL cream	30 sec No oil or cream Emulsion stability: 0 hours No oil or cream 0.5 hours No oil or cream 2 hours < 1 mL oil and cream 24 hours < 1 mL oil and cream Re-emulsification: 30 sec No oil or cream Final emulsion stability: 0.5 hours < 1 mL oil, and cream	0 hours No oil or cream 0.5 hours No oil or cream 2 hours < 1 mL oil and cream 24 hours < 1 mL oil and cream Re-emulsification: 30 sec No oil or cream Final emulsion stability: 0.5 hours < 1 mL oil, no cream		

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 Packaging and Compatibility with the Preparation (KCP 4.4)

Comments of zRMS:	<p>The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in in commercial packaging (HDPE/PA).</p> <p>Taking into account that all physicochemical parameters indicate the stability of the composition and no problems were observed during mixing, all packaging can be considered acceptable as well as the 20 L packaging.</p>
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The packaging has been designed in accordance with the criteria and guidelines specified in the FAO “Guideline for the Packaging of Pesticides” and has been approved according to criteria of ADR, IATA, IMDG (IMO) regulations.

The formulated product (EC formulation) is intended for containment in co-extruded high density polyethylene including PA ~~or EVOH~~ layer (HDPE/PA; HP) bottles/cans with seal-less screw caps.

Details of the packaging are listed in Table 4.1-1 to 4.1-7.

Table 4.1-1: Packaging information for 0.5 litre packaging

Capacity (nominal):	500 mL
Type:	Blow moulded cylindrical plastics bottle with screw cap
Material:	COEX HDPE/PA
Size (approx):	External diameter: 50-90 mm, normal 69 mm
	Overall height: 150-220 mm, normal 193 mm
Opening (approx):	Inner diameter: 42-48-54.7 mm, normal 42mm
Closure:	Screw cap closure size: 50-61-63 mm, normal 50mm
	Screw cap closure construction material: HDPE or PP
	Seal: Induction seal, membrane vented liner, or foam disk liner
UN/ADR	Compliant

Table 4.1-2: Packaging information for 1 litre packaging

Capacity (nominal):	1 L
Type:	Blow moulded rectangular plastics bottle with screw cap
Material:	COEX HDPE/PA,
Size (approx):	Dimensions approx. 77 x 94 x 207 mm
Opening (approx):	Inner diameter: 32-42-48-53,5 mm, normal 53.5 mm
Closure:	Screw cap closure size: 40-50-61-63 mm, normal 50mm normal 63 mm
	Screw cap closure construction material: HDPE or PP
	Seal: Induction seal, membrane vented liner, or foam disk liner
UN/ADR	Compliant

Table 4.1-3: Packaging information for 1 litre packaging

Capacity (nominal):	1 L
Type:	Blow moulded cylindrical plastics bottle with screw cap
Material:	COEX HDPE/PA,
Size (approx):	External diameter: 65-100 mm, normal 89 mm
	Overall height: 200-260 mm, normal 234 mm
Opening (approx):	Inner diameter: 32-38-48-54.7 mm, normal 38mm
Closure:	Screw cap closure size: 40-50-61-63 mm, normal 50mm
	Screw cap closure construction material: HDPE or PP
	Seal: Induction seal, membrane vented liner, or foam disk liner
UN/ADR	Compliant

Table 4.1-4: Packaging information for 5 litre packaging

Capacity (nominal):	5 L
Type:	Blow moulded plastics bottle or canister with screw cap
Material:	HDPE/PA,
Size (approx):	Depth 170-210 mm, normal 193 mm Width 120-160 mm, normal 142 mm Height 260-350 mm, normal 298 mm
Opening (approx):	Inner diameter: 42-48-53.5 mm, normal 53.5 mm
Closure:	Screw cap closure size: 50-61-63 mm, normal 63 mm Screw cap closure construction material: HDPE or PP Seal: Induction seal, membrane vented liner, or foam disk liner
UN/ADR	Compliant

Table 4.1-5: Packaging information for 10 litre packaging

Capacity (nominal):	10 L
Type:	Blow moulded plastics bottle or canister with screw cap
Material:	COEX HDPE/PA,
Size (approx):	Depth 210-250 mm, normal 227 mm Width 130-170 mm, normal 157 Height 350-450 mm, normal 402 mm
Opening (approx):	Inner diameter: 42-48-53.5 mm, normal 53.5 mm
Closure:	Screw cap closure size: 50-61-63 mm, normal 63 mm Screw cap closure construction material: HDPE or PP Seal: Induction seal, membrane vented liner, or foam disk liner
UN/ADR	Compliant

Table 4.1-6: Packaging information for 15 litre packaging

Capacity (nominal):	15 L
Type:	Blow moulded plastics bottle or canister with screw cap
Material:	COEX HDPE/PA
Size (approx):	Depth 240-280 mm Width 190-240 mm Height 350-450 mm
Opening (approx):	Inner diameter: 42-48-53,5 mm, normal 53.5 mm
Closure:	Screw cap closure size: 50-61-63 mm, normal 63 mm Screw cap closure construction material: HDPE or PP Seal: Induction seal, membrane vented liner, or foam disk liner
UN/ADR	Compliant

Table 4.1-7: Packaging information for 20 litre packaging

Capacity (nominal):	20 L
Type:	Blow moulded plastics bottle or canister with screw cap
Material:	COEX HDPE/PA
Size (approx):	Depth 260-320 mm, normal 297 mm Width 220-270 mm, normal 246 mm Height 350-450 mm, normal 393 mm
Opening (approx):	Inner diameter: 42-48-53,5 mm, normal 48, 53.5 mm
Closure:	Screw cap closure size: 50-61-63 mm, normal 61-63 mm Screw cap closure construction material: HDPE or PP Seal: Induction seal, membrane vented liner, or foam disk liner
UN/ADR	Compliant

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 2.1/01	Riedl, S.	2021a	Fluxapyroxad 75 Prothioconazole 150 g/L EC (ADM.03503.F.1.A): Accelerated Storage Procedure at 54 °C for 2 Weeks Noack Laboratorien GmbH, Germany, Report No. SO20253 / CPL19043 ADAMA Reference No. 000105596 GLP Unpublished	N	ADM
KCP 2.1/02	Riedl, S.	2021a	Fluxapyroxad 75 Prothioconazole 150 g/L EC (ADM.03503.F.1.A): Accelerated Storage Procedure at 54 °C for 2 Weeks Noack Laboratorien GmbH, Germany, Report No. SO20253 / CPL19043 ADAMA Reference No. 000105596 GLP Unpublished	N	ADM
KCP 2.2.1	Bender, D.	2020a	ADM.03503.F.1.A Determination of physico-chemical properties Screening Explosive Substances (UN Class 1) Consilab Gesellschaft für Anlagensicherheit mbH, Germany, Report No. CSL-20-0595.02 ADAMA Reference No. 000105599 GLP Unpublished	N	ADM
KCP 2.2.2	Bender, D.	2020b	ADM.03503.F.1.A Determination of physico-chemical properties Oxidizing properties of liquids (UN Class 5, Division 5.1 Test O.2) Consilab Gesellschaft für Anlagensicherheit mbH, Germany, Report No. CSL-20-0595.04 ADAMA Reference No. 000105600 GLP Unpublished	N	ADM
KCP 2.3.1	Bender, D.	2020c	ADM.03503.F.1.A Determination of physico-chemical properties Flash Point (EC A.9.) Consilab Gesellschaft für Anlagensicherheit mbH, Germany, Report No. CSL-20-0595.01 ADAMA Reference No. 000106480 GLP Unpublished	N	ADM
KCP 2.3.3	Bender, D.	2020d	ADM.03503.F.1.A Determination of physico-chemical properties Auto-Ignition Temperature (Liquids and Gases) (EC A.15) Consilab Gesellschaft für Anlagensicherheit mbH, Germany, Report No. CSL-20-0595.03 ADAMA Reference No. 000106481	N	ADM

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
			GLP Unpublished		
KCP 2.4.1/01	Riedl, S.	2021a	Fluxapyroxad 75 Prothioconazole 150 g/L EC (ADM.03503.F.1.A): Accelerated Storage Procedure at 54 °C for 2 Weeks Noack Laboratorien GmbH, Germany, Report No. SO20253 / CPL19043 ADAMA Reference No. 000105596 GLP Unpublished	N	ADM
KCP 2.4.1/02	Riedl, S.	2021a	Fluxapyroxad 75 Prothioconazole 150 g/L EC (ADM.03503.F.1.A): Accelerated Storage Procedure at 54 °C for 2 Weeks Noack Laboratorien GmbH, Germany, Report No. SO20253 / CPL19043 ADAMA Reference No. 000105596 GLP Unpublished	N	ADM
KCP 2.4.2	Riedl, S.	2021a	Fluxapyroxad 75 Prothioconazole 150 g/L EC (ADM.03503.F.1.A): Accelerated Storage Procedure at 54 °C for 2 Weeks Noack Laboratorien GmbH, Germany, Report No. SO20253 / CPL19043 ADAMA Reference No. 000105596 GLP Unpublished	N	ADM
KCP 2.5.1	Tsesin, N.	2020	Determination of Viscosity Properties of Fluxapyroxad 75 g/L + Prothioconazole 150 g/L EC (ADM.03503.F.1.A) Registration Laboratory, Research and Development Division, ADAMA Makhteshim Ltd., Israel, Report No. 000106627.075FL ADAMA Reference No. 000106627 GLP Unpublished	N	ADM
KCP 2.5.2	Riedl, S.	2020b	Fluxapyroxad 75 Prothioconazole 150 g/L EC (ADM.03503.F.1.A): Determination of Surface Tension Noack Laboratorien GmbH, Germany, Report No. SO20258 / CPT19043 ADAMA Reference No. 000106704 GLP Unpublished	N	ADM
KCP 2.6.1/01	Tsesin, N.	2020	Determination of Viscosity Properties of Fluxapyroxad 75 g/L + Prothioconazole 150 g/L EC (ADM.03503.F.1.A) Registration Laboratory, Research and Development Division, ADAMA Makhteshim Ltd., Israel, Report No. 000106627.075FL	N	ADM

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
			ADAMA Reference No. 000106627 GLP Unpublished		
KCP 2.6.1/02	Riedl, S.	2021b	Determination of the Content of the Active Substances and Impurities including Analytical Method Validation and Determination of Density Noack Laboratorien GmbH, Germany, Report No. SO20252 / CGB19043 ADAMA Reference No. 000106478 GLP Unpublished	N	ADM
KCP 2.7.1/01	Riedl, S.	2021b	Determination of the Content of the Active Substances and Impurities including Analytical Method Validation and Determination of Density Noack Laboratorien GmbH, Germany, Report No. SO20252 / CGB19043 ADAMA Reference No. 000106478 GLP Unpublished	N	ADM
KCP 2.7.1/02	Riedl, S.	2021a	Fluxapyroxad 75 Prothioconazole 150 g/L EC (ADM.03503.F.1.A): Accelerated Storage Procedure at 54 °C for 2 Weeks Noack Laboratorien GmbH, Germany, Report No. SO20253 / CPL19043 ADAMA Reference No. 000105596 GLP Unpublished	N	ADM
KCP 2.7.4	Riedl, S.	2020c	Fluxapyroxad 75 Prothioconazole 150 g/L EC (ADM.03503.F.1.A): Low Temperature Stability of Liquid Formulations Noack Laboratorien GmbH, Germany, Report No. SO20256 / CLN19043 ADAMA Reference No. 000106479 GLP Unpublished	N	ADM
KCP 2.7.5	Riedl, S.	2022	Fluxapyroxad 75 Prothioconazole 150 g/L EC (ADM.03503.F.1.A): 2-Year Storage Stability Test Noack Laboratorien GmbH, Germany, Report No. SO20254 / CLR19043 ADAMA Reference No. 000105597 GLP Unpublished	N	ADM
KCP 2.8.2	Riedl, S.	2021a	Fluxapyroxad 75 Prothioconazole 150 g/L EC (ADM.03503.F.1.A): Accelerated Storage Procedure at 54 °C for 2 Weeks	N	ADM

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
			Noack Laboratorien GmbH, Germany, Report No. SO20253 / CPL19043 ADAMA Reference No. 000105596 GLP Unpublished		
KCP 2.8.6.1	Riedl, S.	2021a	Fluxapyroxad 75 Prothioconazole 150 g/L EC (ADM.03503.F.1.A): Accelerated Storage Procedure at 54 °C for 2 Weeks Noack Laboratorien GmbH, Germany, Report No. SO20253 / CPL19043 ADAMA Reference No. 000105596 GLP Unpublished	N	ADM

ADM = Property of ADAMA Agricultural Solutions and all affiliates.

Under Article 59 of Regulation 1107/2009/EC, the Sponsor Company claims data protection for all ADM studies.

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

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
-	-	-	-	-	-

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
-	-	-	-	-	-

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
-	-	-	-	-	-

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

A 2.1 Fluxapyroxad

No additional data.

A 2.2 Prothioconazole

No additional data.