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.03502.F.1.A
(alternative code: MCW-2091)

Product name(s): see part A

Chemical active substance(s):

Fenpropidin 250 g/L

Prothioconazole 175 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorisation)

Applicant: Country organisation / representative
as specified in Part A

Submission date: September 2021, updated July 2022

Finalisation date: December 2022 (initial Core Assessment)

May 2023 (final Core Assessment)

Version history

When	What
2021/09	Version 1 Applicant
July 2022	Version 2 Applicant. Updated with shelf-life stability data. Changes are higligted in green.
December 2022	Initial zRMS assessment. 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~~. Following the evaluation and before sending the document for commenting, all coloured high-lighting was removed, from the parts updated by the Applicant, for better legibility.
May 2023	Final report (Core Assessment updated following the commenting period) 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~~.

DATA PROTECTION CLAIM

In order to present a dossier fully compliant with today's requirements (Reg. 284/2013), studies have been performed on ADM.03502.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.03502.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The summaries and evaluations contained in this document may be based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority that prepared it.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authorities should not grant, amend, or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this document unless they have received the data on which the summaries and evaluation are based, either –

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Table of Contents

1 Section 1: Identity of the plant protection product 5

1.1 Applicant (KCP 1.1) 5
1.2 Producer of the plant protection product and of the active substances (KCP 1.2) 5
1.2.1 Producer(s) of the preparation 5
1.2.2 Producer(s) of the active substance(s) 5
1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s) 5
1.2.3.1 Prothioconazole 5
1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3) 6
1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4) 6
1.4.1 Composition of the plant protection product (KCP 1.4.1) 6
1.4.2 Information on the active substance(s) (KCP 1.4.2) 6
1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3) 7
1.5 Type and code of the plant protection product (KCP 1.5) 7
1.6 Function (KCP 1.6) 7

2 Section 2: Physical, chemical and technical properties of the plant protection product 8

3 Section 3 is presented as a separate document 19

4 Section 4: Further information on the plant protection product 20

Safety intervals and other precautions to protect humans, animals and the environment (KCP 4.1) 20
4.2. Recommended methods and precautions (KCP 4.2) 20
4.3. Emergency measures in the case of an accident (KCP 4.3) 22
4.4 Packaging and Compatibility with the Preparation (KCP 4.4) 22

Appendix 1 Lists of data considered in support of the evaluation 25

Appendix 2 Additional data on the physical, chemical and technical properties of the active substance 29

A 2.1 Prothioconazole 29

zRMS summary and conclusions:

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 gaps are: none.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Country organisation/representative as specified in Part A.

On behalf of:

Address:	ADAMA Deutschland GmbH Edmund-Rumpler-Str. 6 51149 Köln Germany
Contact:	…
Telephone No.:	..
Fax:	-
E-mail:	…

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 Prothioconazole

Prothioconazole	min. 980 g/kg

According to the Commission Implementing Regulation (EU) No 540/2011 (amending Regulation (EU) No 1107/2009), for Prothioconazole the following manufacturing impurities are of toxicological concern and each of them must not exceed a certain amount in the technical material:

- Toluene: < 5 g/kg
- Prothioconazole-desthio: < 0.5 g/kg (LOD)

1.2.3.2 Fenpropidin

Fenpropidin	min. 960 g/kg

According to the “Conclusion on the peer review of the pesticide risk assessment of the active substance fenpropidin” fenpropidin as manufactured does not contain an impurity of toxicological or ecotoxicological concern.

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

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

Company code number: ADM.03502.F.1.A
Alternative codes: MCW-2091, ADM.3502.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.03502.F.1.A was not the representative formulation in the EU review of prothioconazole or fenpropidin.

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)
Prothioconazole	175	175 g/L ± 10.5 g/L = 164.5 – 185.5 g/L pure prothioconazole	178.6 g/L (167.9 – 189.3)	17.2 %w/w
Fenpropidin	250	250 g/L ± 15 g/L = 235.0 – 265.0 g/L pure fenpropidin	260.4 g/L (244.8 – 276.0)	25.0 %w/w

* Based on the minimum purity of the active substances declared for registration in the active substance dossiers
** Based on the density of the formulation = 1.04 g/L

Formulants
CONFIDENTIAL information is provided separately (Part C).

Safeners or synergists are not present in the formulation.

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
Toluene	5 g/kg a.s for prothioconazole. (equivalent to 0.88 g/L ADM.03502.F.1.A)*
Prothioconazole-desthio	0.5 g/kg a.s. for prothioconazole (equivalent to 0.088 g/L ADM.03502.F.1.A)*

* Considering the nominal content of 175 g prothiconalzole/L ADM.03502.F.1.A.
NOTE: Toluene origins from the technical active substance. As the toluene cannot be formed during the formulation process or during the storage of the formulation, it is not required to investigate their levels during the storage testing. Please find further information in the respective Part C of this submission.

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

Table 1.4-3: Information on Prothioconazole

Type	Name/Code Number	
ISO common name	Prothioconazole	-
CAS No.	178928-70-6	-
EC No.	Not allocated	-
CIPAC No.	745	-

Table 1.4-4: Information on Fenpropidin

Type	Name/Code Number	
ISO common name	Fenpropidin	-
CAS No.	67306-00-7	-
EC No.	Not allocated	-
CIPAC No.	520	-

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 yellow homogenous transparent liquid. It is not explosive and has no oxidising properties. It has an auto ignition temperature of 372°C. In aqueous solution, it has a pH value around 7.3. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 2 weeks at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data ~~indicate~~ shows a shelf life of at least 2 years at ambient temperature when stored in HDPE/PA containers. Its technical characteristics are acceptable for an emulsion concentrate formulation.
The intended concentration of use is 0.25% to 1.0%.

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

Hazard class(es), categories:	-
Hazard pictograms or Code(s) for hazard pictogram(s):	-
Signal word:	-
Hazard statement(s):	-
Precautionary statement(s):	-
Additional labelling phrases:	-

Notifier Proposals for Risk and Safety Phrases (KCP 12)

See above.

Compliance with FAO specifications:

The product ADM.03502.F.1.A complies with FAO specifications.

Formulation used for tests

Please note, that the composition as presented in Part C of this submission is the composition of the formulation used for the data presented in this section.

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 investigation	ADM.03502.F.1.A 175.9 g/L prothioconazole 253.7 g/L fenpropidin Batch no.: 1191-101219-01	Physical state: Homogeneous transparent liquid Colour: Yellow	Y	KCP 2.1/01: Tsesin, N. (2020) report no.: 000105029.061FL	Accepted.
Explosive properties (KCP 2.2.1)	Statement	n.a.	ADM.03502.F.1.A is not considered to have explosive properties.	N	KCP 2.2.1/01: Tzur, L. (2020) report no.: 000108617	Accepted. Considered as 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)	Statement	n.a.	ADM.03502.F.1.A is not considered to have oxidising properties.	N	KCP 2.1/01 (filed in KCP 2.2.2/01): Tzur, L. (2020) report no.: 000108617	Statement accepted. ADM.03502.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)	EEC A.9	ADM.03502.F.1.A 175.9 g/L prothioconazole	Flash point: > 95°C	Y	KCP 2.3.1/01 (filed in KCP 2.1/01): Tsesin, N. (2020) report no.:	Accepted. The formulation is

		253.7 g/L fenpropidin Batch no.: 1191-101219-01			000105029.061FL	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.
Flammability (KCP 2.3.2)	-	-	**Justification for non-submission:** Not relevant for liquid formulations.	-	-	-
Self-heating (KCP 2.3.3)	EEC A.15	ADM.03502.F.1.A 175.9 g/L prothioconazole 253.7 g/L fenpropidin Batch no.: 1191-101219-01	The auto-ignition temperature of the test substance was determined to be 372°C ± 3°C.	Y	KCP 2.3.3/01: Halbwachs, P. (2020) report no.: 20-913017-012	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)	-	-	**Justification for non-submission:** As the pH value of the test item is > 4 and < 10, the determination of the acidity / alkalinity is not required.	-	-	-
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	ADM.03502.F.1.A 175.9 g/L prothioconazole 253.7 g/L fenpropidin Batch no.: 1191-101219-01	Mean pH of 1% of the test item in water: 7.3 (determined after 1, 2 and 10 minutes) Test temperature 20°C	Y	KCP 2.4.2/01 (filed in KCP 2.1/01): Tsesin, N. (2020) report no.: 000105029.061FL	Accepted.
Viscosity (KCP 2.5.1)	OECD 114	ADM.03502.F.1.A 175.9 g/L prothioconazole 253.7 g/L fenpropidin Batch no.: 1191-101219-01	Viscosity: Test temperature 20°C: Dynamic viscosity = 120.3 cP at a shear rate of 18 s^{-1} to 119.25 cP at a shear rate of 105 s^{-1} (max. viscosity 120.9 at a shear rate of 35 s^{-1}) Test temperature 40°C:	Y	KCP 2.5.1/01 (filed in KCP 2.1/01): Tsesin, N. (2020) report no.: 000105029.061FL	Accepted. No hydrocarbons are present at levels ≥ 10% and none of the co-formulants in the composition is classified as H304.

			Dynamic viscosity = 37.0 cP at a shear rate of 18 s^{-1} to 38.5 cP at a shear rate of 105 s^{-1} (max. viscosity 38.6 at a shear rate of 90 and 70 s^{-1}) Conclusion: The test substance is a Newtonian liquid.			The formulation does not need to be classified as an aspiration hazard.
Surface tension (KCP 2.5.2)	EC A 5	ADM.03502.F.1.A 175.9 g/L prothioconazole 253.7 g/L fenpropidin Batch no.: 1191-101219-01	Surface tension on diluted test item: 32.9 mN/m (concentration: 1.67 % v/v) Surface tension on neat test item: 32.3 mN/m The test item has to be regarded to be surface active (surface tension < 60 mN/m).	Y	KCP 2.5.2/01 (filed in KCP 2.1/01): Tsesin, N. (2020) report no.: 000105029.061FL	Accepted.
Relative density (KCP 2.6.1)	EEC A.3	ADM.03502.F.1.A 175.9 g/L prothioconazole 253.7 g/L fenpropidin Batch no.: 1191-101219-01	Relative density: D^{20}_4 = 1.04	Y	KCP 2.6.1/01 (filed in KCP 2.1/01): Tsesin, N. (2020) report no.: 000105029.061FL	Accepted.
Bulk density (KCP 2.6.2)	-	-	**Justification for non-submission:** Not required for liquid preparations.	-	-	-

<table>
<tr>
<td>Storage Stability after 14 days at 54º C
(KCP 2.7.1)</td>
<td>CIPAC MT 46

HDPE/PA packaging;
A.I. Content: HPLC
SOP 50.007.07
50.010.05
50.011.07;
Relevant Impurity Content: LC/MS/MS
SOP 50.007.07
50.009.08;
50.010.05
50.011.07</td>
<td>ADM.03502.F.1.A
175.9 g/L prothioconazole
253.7 g/L fenpropidin
Batch no.: 1191-101219-01</td>
<td>All investigated parameters were within the international specifications. The formulation ADM.03502.F.1.A is considered to be stable for at least 14 days at 54 C. The results before and after storage are summarised below:
<table>
<tr><td>Testing time</td><td>Initial</td><td>after 14 days at 54°C</td></tr>
<tr><td>Appearance</td><td>See 2.1</td><td>Uniform yellowish slightly viscous liquid</td></tr>
<tr><td>Prothioconazole content [g/L]</td><td>175.9</td><td>174.6</td></tr>
<tr><td>Fenpropidin content [g/L]</td><td>253.7</td><td>247.7</td></tr>
<tr><td>Prothiconazole desthio content [g/kg]</td><td>< LOQ</td><td>< LOQ</td></tr>
<tr><td>pH (1% dilution)
Test temperature 20°C</td><td>7.3</td><td>7.3</td></tr>
<tr><td>Persistent foaming (at 0.15% v/v)
Foam vol. [mL] after 0 sec.
Foam vol. [mL] after 1 min.
Foam vol. [mL] after 12 min.

Persistent foaming (at 1.67% v/v)
Foam vol. [mL] after 0 sec.
Foam vol. [mL] after 1 min.
Foam vol. [mL] after 12 min.</td><td>
40
14
10

58
17
6</td><td>
46
15
11

60
18
8</td></tr>
<tr><td>Emulsion characteristics
0.15% v/v in standard water A
Initially
After 30 minutes, 2 hours, 24 hours
After re-emulsification (30 sec)
30 minutes after re-emulsification

0.15% v/v in standard water D
Initially
After 30 minutes, 2 hours, 24 hours
After re-emulsification (30 sec)
30 minutes after re-emulsification</td><td>

FD[1]
U[3]
U
U

FD[1]
U[3]
U
U</td><td>

FD[1]
U[3]
U
U

FD[1]
U[3]
U
U</td></tr>
</table>
</td>
<td>Y</td>
<td>KCP 2.7.1/01 (filed in KCP 2.1/01):
Tsesin, N. (2020)
report no.:
000105029.061FL</td>
<td>Accepted.

The product showed no significant physical changes after accelerated storage. No significant changes were observed in the HDPE/PA 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 HDPE/PA.</td>
</tr>
</table>

			1.67% v/v in standard water A Initially After 30 minutes, 2 hours, 24 hours After re-emulsification (30 sec) 30 minutes after re-emulsification 1.67% v/v in standard water D Initially After 30 minutes, 2 hours, 24 hours After re-emulsification (30 sec) 30 minutes after re-emulsification Physical state of the packaging Before, g: 1179.27; 1179.53 After, g: 1179.09; 1179.36 Change, %: -0.01; -0.01 [1] Floating white dots suspended in water phase, dissolved while falling and leaving the white band [2] Thin layer at the bottom of the cylinder [3]Uniform liquid For detailed descriptions of the methods for the determination of the a.s. and the relevant impurity and validations please refer to Section 5, point 5.1.1.			
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	**Justification for non-submission:** Not relevant, since the active substances prothioconazole and fenpropidin are not heat sensitive.	-	-	-
Minimum content after heat stability testing (KCP 2.7.3)	-	-	**Justification for non-submission:** Not relevant, since the active substances prothioconazole and fenpropidin are not heat sensitive.	-	-	-
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	ADM.03502.F.1.A 175.9 g/L prothioconazole 253.7 g/L fenpropidin Batch no.: 1191-101219-01	The emulsion stability was tested after 7 days at 0°C. The results before and after storage are summarised below: Testing time: Initial; after 7 days at 0°C Appearance: See 2.1; unchanged Emulsion characteristics 0.15% v/v in standard water A Initially: FD[1]; FD[1] After 30 minutes, 2 hours, 24 hours: U[3]; U After re-emulsification (30 sec): U; U	Y	KCP 2.7.4/01 (filed in KCP 2.1/01): Tsesin, N. (2020) report no.: 000105029.061FL	Accepted.

			30 minutes after re-emulsification: U / U 0.15% v/v in standard water D Initially: FD[1] / FD[1] After 30 minutes, 2 hours, 24 hours: U / U After re-emulsification (30 sec): U / U 30 minutes after re-emulsification: U / U 1.67% v/v in standard water A Initially: U, TL[2] / U, TL After 30 minutes, 2 hours, 24 hours: U, / U, After re-emulsification (30 sec): U / U 30 minutes after re-emulsification: U / U 1.67% v/v in standard water D Initially: U, TL / U, TL After 30 minutes, 2 hours, 24 hours: U / U After re-emulsification (30 sec): U / U 30 minutes after re-emulsification: U / U [1] Floating white dots suspended in water phase, dissolved while falling and leaving the white band [2] Thin layer at the bottom of the cylinder [3]Uniform liquid			
Ambient temperature shelf life (KCP 2.7.5)	GIFAP Monograph No 17 A.I. Content: HPLC SOP 50.007.07 50.009.08; 50.010.05; 50.011.07 Relevant Impurity Content: LC/MS/MS method validated according to SANCO/3030/99 rev. 5.	ADM.03502.F.1.A 175.9 g/L prothioconazole 253.7 g/L fenpropidin Batch no.: 1191-101219-01	All investigated parameters were within the international specifications. Packaging (HDPE/PA, 1 L) remained stable throughout the storage period. The for-mulation ADM.03502.F.1.A is considered to be stable for at least two years at ambient temperature. The re-sults before and after storage are summarised below: Testing time: Initial / after 2 years at ambient temp. Appearance: See 2.1 / Uniform yellowish slightly viscous liquid Prothioconazole content [g/L]: 175.9 / 175.1 Fenpropidin content [g/L]: 253.7 / 250.5 Prothiconazole desthio content [mg/kg] formulation: < LOQ / 79 pH (1% dilution): 7.3 / 7.4 Test temperature before storage 20°C. Test temperature after storage 22°C.	Y	KCP 2.7.5/01: Tsesin, N. (2022) report no.: 000105030.062FL	Study accepted. The HDPE/PA container showed no indications of significant weight loss or physical deterioration that would interfere with the safe handling of the product. Based on the results obtained it is recommended to mix the product before use and to mix/agitate the product during use. Period of validity: 2

						years (HDPE/PA).

Persistent foaming (at 0.15% v/v)		
Foam vol. [mL] after 0 sec.	40	45
Foam vol. [mL] after 1 min.	14	13
Foam vol. [mL] after 12 min.	10	6
Persistent foaming (at 1.67% v/v)		
Foam vol. [mL] after 0 sec.	58	60
Foam vol. [mL] after 1 min.	17	22
Foam vol. [mL] after 12 min.	6	4
Emulsion characteristics		
0.15% v/v in standard water A		
Initially	FD[1]	FD[1]
After 30 minutes, 2 hours, 24 hours	U[3]	U[3]
After re-emulsification (30 sec)	U	U
30 minutes after re-emulsification	U	U
0.15% v/v in standard water D		
Initially	FD[1]	FD[1]
After 30 minutes, 2 hours, 24 hours	U[3]	U[3]
After re-emulsification (30 sec)	U	U
30 minutes after re-emulsification	U	U
1.67% v/v in standard water A		
Initially	U, TL[2]	U, TL[2]
After 30 minutes, 2 hours, 24 hours	U	U, TL[2]
After re-emulsification (30 sec)	U	U
30 minutes after re-emulsification	U	U
1.67% v/v in standard water D		
Initially	U, TL[2]	U, TL[2]
After 30 minutes, 2 hours, 24 hours	U	U, TL[2]
After re-emulsification (30 sec)	U	U
30 minutes after re-emulsification	U	U

[1] Floating white dots suspended in water phase, dissolved while falling and leaving the white band
[2] Thin layer at the bottom of the cylinder
[3]Uniform liquid

For a detailed description of the methods for the determination of the a.s. and the relevant impurity and validations please refer to Section 5, point 5.1.1.

~~The preparation does not show any signs of significant chemical or physical changes after accelerated storage at 54°C for 14 days (KCP 2.7.1). 2 year and 3 year storage stability studies at ambient temperature have both been initiated. The final reports are anticipated Q3 2022 and Q3 2023 respectively.~~

Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	**Justification for non-submission:** The preparation is stable for at least two years at ambient temperature. ~~As the preparation does not show any signs of significant chemical or physical changes after accelerated storage at 54°C for 14 days. Therefore, it is considered that the product is stable for at least two years at ambient temperature.~~	-	-	-
Wettability (KCP 2.8.1)	-	-	**Justification for non-submission:** Not required for EC preparations.	-	-	-

Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	ADM.03502.F.1.A 175.9 g/L prothioconazole 253.7 g/L fenpropidin Batch no.: 1191-101219-01	Foam persistence in CIPAC water D at a test concentration of 0.15 % v/v: Time — Foam volume [mL] 0 sec — 40 1 min — 14 12 min — 10 Foam persistence in CIPAC water D at a test concentration of 1.67 % v/v: Time — Foam volume [mL] 0 sec — 58 1 min — 17 12 min — 6	Y	KCP 2.8.2/01 (filed in KCP 2.1/01): Tsesin, N. (2020) report no.: 000105029.061FL	Accepted.
Suspensibility (KCP 2.8.3.1)	-	-	**Justification for non-submission:** Not required for EC preparations.	-	-	-
Spontaneity of dispersion (KCP 2.8.3.2)	-	-	**Justification for non-submission:** Not required for EC preparations.	-	-	-
Dispersion stability (KCP 2.8.3.3)	-	-	**Justification for non-submission:** Not required for EC preparations.	-	-	-
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	**Justification for non-submission:** Not required for EC preparations.	-	-	-
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	-	-	**Justification for non-submission:** Not required for EC preparations.	-	-	-
Wet sieve test (KCP 2.8.5.1.2)	-	-	**Justification for non-submission:** Not required for EC preparations.	-	-	-
Dust content (KCP 2.8.5.2.1)	-	-	**Justification for non-submission:** Not required for EC preparations.	-	-	-
Particle size of dust (KCP 2.8.5.2.2)	-	-	**Justification for non-submission:** Not required for EC preparations.	-	-	-
Attrition (KCP 2.8.5.3)	-	-	**Justification for non-submission:** Not required for EC preparations.	-	-	-
Hardness and integrity	-	-	**Justification for non-submission:**	-	-	-

(KCP 2.8.5.4)			Not required for EC preparations.			
Emulsifiability (KCP 2.8.6.1)	CIPAC MT 36.3	ADM.03502.F.1.A 175.9 g/L prothioconazole 253.7 g/L fenpropidin Batch no.: 1191-101219-01	Emulsifiability (test concentration 0.15 % v/v): In CIPAC standard water A: FD[1] In CIPAC standard water D: FD Emulsifiability (test concentration 1.67 % v/v): In CIPAC standard water A: U[3], TL[2] In CIPAC standard water D: U[3], TL [1] Floating white dots suspended in water phase, dissolved while falling and leaving the white band [2] Thin layer at the bottom of the cylinder [3]Uniform liquid	Y	KCP 2.8.6.1/01 (filed in KCP 2.1/01): Tsesin, N. (2020) report no.: 000105029.061FL	Accepted. Based on the results obtained it is recommended to mix the product before use and to mix/agitate the product during use.
Emulsion stability (KCP 2.8.6.2)	CIPAC MT 36.3	ADM.03502.F.1.A 175.9 g/L prothioconazole 253.7 g/L fenpropidin Batch no.: 1191-101219-01	Emulsion stability on standing for 30 minutes, 2 h and 24 h: At a test concentration of 0.15 % v/v: In CIPAC standard water A: Uniform liquid. In CIPAC standard water D: Uniform liquid. At a test concentration of 1.67 % v/v: In CIPAC standard water A: Uniform liquid. In CIPAC standard water D: Uniform liquid.	Y	KCP 2.8.6.2/01 (filed in KCP 2.1/01): Tsesin, N. (2020) report no.: 000105029.061FL	Accepted.
Re-emulsifiability (KCP 2.8.6.3)	CIPAC MT 36.3	ADM.03502.F.1.A 175.9 g/L prothioconazole 253.7 g/L fenpropidin Batch no.: 1191-101219-01	Re-emulsifiability At a test concentration of 0.15 % v/v in CIPAC water A after 24 hours Uniform liquid. after 24.5 hours Uniform liquid. At a test concentration of 0.15 % v/v in CIPAC water D after 24 hours Uniform liquid. after 24.5 hours Uniform liquid. At a test concentration of 1.67 % v/v in CIPAC water A after 24 hours Uniform liquid. after 24.5 hours Uniform liquid. At a test concentration of 1.67 % v/v in CIPAC water D after 24 hours Uniform liquid. after 24.5 hours Uniform liquid.	Y	KCP 2.8.6.3/01 (filed in KCP 2.1/01): Tsesin, N. (2020) report no.: 000105029.061FL	Accepted.
Flowability (KCP 2.8.7.1)	-	-	**Justification for non-submission:** Not required for EC preparations.	-	-	-
Pourability (KCP 2.8.7.2)	-	-	**Justification for non-submission:** Not required for EC preparations.	-	-	-

Dustability following accelerated storage (KCP 2.8.7.3)	-	-	**Justification for non-submission:** Not required for EC preparations.	-	-	-
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	**Justification for non-submission:** The application does not consider the mixing with other products.	-	-	-
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	**Justification for non-submission:** The application does not consider the mixing with other products.	-	-	-
Adhesion to seeds (KCP 2.10.1)	-	-	**Justification for non-submission:** Not applicable since the product is not intended to be used for seed treatment.	-	-	-
Distribution to seed (KCP 2.10.2)	-	-	**Justification for non-submission:** Not applicable since the product is not intended to be used for seed treatment.	-	-	-
Other/special studies (KCP 2.11)	-	-	**Justification for non-submission:** Not applicable since the product is not intended to be used for seed treatment.	-	-	-

3 Section 3 is presented as a separate document

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

4 Section 4: Further information on the plant protection product

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

Pre-harvest interval (in days) for each relevant crop:
Wheat, rye, triticale: n/a[#]
Barley, oat: n/a[#]

[#]The pre-harvest interval for the envisaged area of application is covered by the growing period remaining between the envisaged application and harvest; it is not necessary to indicate a pre-harvest interval in days.

Re-entry period (in days) for livestock, to areas to be grazed:
Not required, since any application on areas to be grazed is not envisaged.

Re-entry period (in hours or days) for man to crops, buildings or spaces treated:
Estimations of worker exposure did not indicate any undue risk for workers in consideration of work wear covering arms, body and legs. Thus, the use of ADM.03502.F.1.A in cereals is acceptable for re-entry of workers wearing work wear covering arms, body and legs. (please refer to M-CP Section 7, CP 7.2).

Withholding period (in days) for animal feeding stuffs:
Any relevant residues in products of animal origin are not to be expected. Therefore, there is no additional withholding period needed for animal feeds.

Waiting period (in days) between application and handling of treated products:
This is not relevant here since a post-harvest treatment is not intended.

Waiting period (in days) between last application and sowing or planting succeeding crops:

a) With regard to potential residues in succeeding crops:
Not relevant

b) With regard to potential phytotoxic effects on succeeding crops:
Not relevant

4.2. Recommended methods and precautions (KCP 4.2)

Comments of zRMS:	Based on the results obtained, a triple rinsing procedure is recommended.

In the absence of a field study, the effectiveness of the cleaning procedure is assessed on a theoretical basis involving a calculation of the predicted residues remaining in the spray tank after cleaning, and subsequently addressing the risk to other crops from these residues applied to the field during another spraying operation.
The efficacy of cleaning the application equipment with regard to impacts on non-target crops was estimated according to the recommendations of the PSD Efficacy Guideline 302 (December, 2001).

For the assessment of residues remaining in the spraying equipment after cleaning, a standard sprayer of 2000 litres is considered. Cleaning is performed by a small volume rinse of 200 L in the first cleaning step, followed by another two rinses, each with volumes of 400 L corresponding to 20% of the tank volume. A maximum volume of 20 L spray solution is considered to remain in the spray lines and pump after each rinse. Furthermore, the maximum concentration of ADM.03502.F.1.A in the initial spray solution was used as a conservative starting point. In summary, the following prerequisites are considered for a worst-case assessment:

Maximum rate per application: 1.0 L ADM.03502.F.1.A/ha, corresponding to
175 g prothioconazole/ha and 250 g fenpropidin/ha

Spray volumes:	100 – 400 L/ha
Spray volume used for the assessment of effectiveness:	100 L/ha (lowest spray volume corresponding to the maximum concentration of ADM.03502.F.1.A in diluted spray)
Tank volume:	2000 L
Volume remaining in spray lines and pump after spraying:	20 L

Based on these prerequisites and in consideration of 3 rinses each with 200-400 L of water based on good agricultural cleaning procedures described above, residues remaining in the tank after spraying will be diluted to the following levels:

Calculation of maximum residues in the application equipment

Cleaning step	Water volume [L]	Concentration of residues		
		Product [mL PPP/ L of water]	Prothioconazole [g a.s./L]	Fenpropidin [g a.s./L]
Tank filling: Residues after spraying:	2000 20	10	1.75	2.5
1st step: 1/10 dilution of residual spray volume: Residues after spraying:	200 20	1.0	0.175	0.25
2nd step: 20% of tank volume added: Residues after spraying:	400 20	0.05	0.00875	0.0125
3rd step: 20% of tank volume added: Residues after spraying:	400 20	0.0025	0.00044	0.00063
Addition of fresh spray solution: Residues in the tank filling:	2000	2.0×10^{-4}	2.5×10^{-5}	6.25×10^{-6}

PPP = ADM.03502.F.1.A

Based on the calculation above, residues remaining in the spraying equipment after the last of three cleaning steps are estimated at 2.5 µL ADM.03502.F.1.A per L of water corresponding to a total of 50 µL ADM.03502.F.1.A in 20 L water. Considering these residues to be completely dissolved in the next tank filling, residues of 0.025 µL ADM.03502.F.1.A per litre of water can be expected after refilling the tank with 2000 L of water for another spraying operation. Assuming a range of spray volumes of 100-600 L/ha to be applied to other crops, **residues of 2.5 – 15 µL ADM.03502.F.1.A/ha corresponding to 0.44-2.6 mg prothioconazole/ha and 0.63 – 3.75 mg fenpropidin will be applied to a non-target crop by re-use of the application equipment**.

Evaluation of the impacts of tank residues on non-target crops

Based on the results and considering a worst-case approach residues of 0.025 mg a.s./L per litre of water can be expected after refilling (the stainless steel) tank for another spraying operation. Assuming a range of spray volumes of 100 – 600 L/ha to be applied to other crops, residues of 4 – 12 µL ADM.03502.F.1.A /ha will be applied to a non-target crop by re-use of the application equipment.

Data on the biological activity of ADM.03502.F.1.A are available from the two standard test models "seedling emergence" and "vegetative vigour", which are considered to be most relevant for the assessment of effects on non-target plants (including non-target crops) after broadcast spraying of ADM.03502.F.1.A and tank residues, respectively. The tests were performed according to OEDC 208 (draft 2000), and the test substance ADM.03502.F.1.A was sprayed to the test plants or to the soil after seeding of plants. Both tests were performed in sugar beet, oilseed rape, tomato, onion, ryegrass and soybean.
The acceptability of the predicted residue level of ADM.03502.F.1.A was assessed by a comparison of the exposure concentration predicted for the re-use of the application equipment with the effect rates (NOEL/LOEL, ER50) in the most sensitive plant species of the “vegetative vigour” and “seedling emergence” test. Effects on shoot height and plant weight were considered as reliable endpoints for toxic effects and the most sensitive of these toxicity figures was used for the following risk assessment:

Maximum predicted exposure of non-target crops with spray residues:

PER = 0.015 mL ADM.03502.F.1.A /ha, corresponding to
0.0026 g/ha prothioconazole and 0.0038 g/ha fenpropidin

Risk from spray residues for seedling emergence of non-target plants:
Toxicity endpoints obtained from reference:
KCP 10.6.1/01: Kästner, K., 2020, report no.: 2046PSE0007, sponsor no.: 000104852

Toxicity endpoints for seedling emergence

Lowest ER_{50}	> 1 L ADM.03502.F.1.A./ha (corresponding to 175 g/ha prothioconazole and 250 g/ha fenpropidin)
TER (ER_{50}/PER)	**> 66667**

Risk from spray residues for vegetative vigour of non-target plants:

Toxicity endpoints obtained from reference:
KCP 10.6.1/02: Kästner, K., 2020, report no.: 2035CRX0012, sponsor no.: 000104853

Lowest NOER	> 1 L ADM.03502.F.1.A./ha (corresponding to 175 g/ha prothioconazole and 250 g/ha fenpropidin)
TER (NOER/PER)	**> 66667**

As the ER_{50}/NOER based TER values for the most sensitive plant species of both plant toxicity tests are far above 5 [(1)], a ratio that is defined as trigger for concluding a low risk for terrestrial non-target plants according to the guidance document SANCO/10329/2002 rev.2 final (October 17, 2002). after cleaning of the spraying equipment, effects of these spray residues on crops are considered to be acceptable.

The effectiveness of standard cleaning procedures according to Good Agriculture Practice was assessed for the product ADM.03502.F.1.A on a theoretical basis. Residues of the plant protection product remaining in the tank after 3 rinses with water and the predicted exposure of non-target crops after re-use of the application equipment were calculated for worst case conditions. Compared to the effect levels for non-target plants, which are most likely to be affected by herbicide residues, residue levels are far below concentrations that might pose a risk for the terrestrial flora including non-target crops. Thus, any detrimental effect on plants from tank residues can widely be excluded. The cleaning method is therefore considered to be acceptable, and the performance of any small-scale or a large-scale tests is not considered to be required.

For further information on recommended precautions, please refer to the MSDS submitted under KCP 4.2/01.

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

Please refer to the MSDS submitted under KCP 4.2/01.

4.4 Packaging and Compatibility with the Preparation (KCP 4.4)

Comments of zRMS:	The packaging material HDPE/PA tested in the 2 storage stability study has been approved and is suitable for the storage of the plant protection product. Extrapolation from HDPE/PA to HDPE/EVOH is acceptable.

1 a trigger of 5 can be applied, if at least 6 plant species have been tested

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~~ HDPE/EVOH) bottles/cans with seal-less screw caps. Details of the packaging are listed in Table 4.4-1 to 4.4-7.

Table 4.4-1: Packaging information for 0.5 litre packaging

Capacity (nominal):	500 mL
Type:	Blow moulded cylindrical plastics bottle with screw cap
Material:	COEX HDPE/PA, COEX HDPE/EVOH
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 4.4-2: Packaging information for 1 litre packaging

Capacity (nominal):	1 L
Type:	Blow moulded rectangular plastics bottle with screw cap
Material:	COEX HDPE/PA, COEX HDPE/EVOH
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 4.4-3: Packaging information for 1 litre packaging

Capacity (nominal):	1 L
Type:	Blow moulded cylindrical plastics bottle with screw cap
Material:	COEX HDPE/PA, COEX HDPE/EVOH
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 4.4-4: Packaging information for 5 litre packaging

Capacity (nominal):	5 L
Type:	Blow moulded plastics bottle or canister with screw cap
Material:	COEX HDPE/PA, COEX HDPE/EVOH
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 4.4-5: Packaging information for 10 litre packaging

Capacity (nominal):	10 L
Type:	Blow moulded plastics bottle or canister with screw cap
Material:	COEX HDPE/PA, COEX HDPE/EVOH
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 4.4-6: Packaging information for 15 litre packaging

Capacity (nominal):	15 L
Type:	Blow moulded plastics bottle or canister with screw cap
Material:	COEX HDPE/PA, COEX HDPE/EVOH
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 4.4-7: Packaging information for 20 litre packaging

Capacity (nominal):	20 L
Type:	Blow moulded plastics bottle or canister with screw cap
Material:	COEX HDPE/PA, COEX HDPE/EVOH
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	Verte-brate study Y/N	Owner
KCP 2.1/01	Tsesin, N.	2020	Determination of storage stability and physical-chemical properties of prothioconazole 175 g/L + fenpropidin 250 g/L EC (ADM.03502.F.1.A) stored at 54 °C for 14 days and at 0°C for 7 days Report no. 000105029.061FL, Sponsor no. 000105029 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP / GEP Unpublished	N	ADM
KCP 2.2.1/01	Tzur, L.	2020	Explosive and oxidising properties of Prothioconazole 175 + Fenpropidin 250 EC Report no. -, Sponsor no.000108617 ADAMA Agricultural Solutions Ltd., Beer-Sheva, Israel Not GLP / GEP Unpublished	N	ADM
KCP 2.2.2/01 filed in KCP 2.2.1/01	Tzur, L.	2020	Explosive and oxidising properties of Prothioconazole 175 + Fenpropidin 250 EC Report no. -, Sponsor no. 000108617 ADAMA Agricultural Solutions Ltd., Beer-Sheva, Israel Not GLP / GEP Unpublished	N	ADM
KCP 2.3.1/01 filed in KCP 2.1/01	Tsesin, N.	2020	Determination of storage stability and physical-chemical properties of prothioconazole 175 g/L + fenpropidin 250 g/L EC (ADM.03502.F.1.A) stored at 54 °C for 14 days and at 0°C for 7 days Report no. 000105029.061FL, Sponsor no. 000105029 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP / GEP Unpublished	N	ADM
KCP 2.3.3/01	Halbwachs, P.	2020	Auto-ignition temperature of liquids on fenpropidine 250 + prothioconazol 175 EC (ADM.03502.F.1.A) Report no. 20-913017-012, Sponsor no. 000105554 DEFITRACES, Brindas, France Not GLP / GEP Unpublished	N	ADM
KCP 2.4.2/01 filed in KCP KCP 2.1/01	Tsesin, N.	2020	Determination of storage stability and physical-chemical properties of prothioconazole 175 g/L + fenpropidin 250 g/L EC (ADM.03502.F.1.A) stored at 54 °C for 14 days and at 0°C for 7 days Report no. 000105029.061FL, Sponsor no. 000105029 ADAMA Makhteshim Ltd., Beer-Sheva, Israel	N	ADM

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
			GLP / GEP Unpublished		
KCP 2.5.1/01 filed in KCP 2.1/01	Tsesin, N.	2020	Determination of storage stability and physical-chemical properties of prothioconazole 175 g/L + fenpropidin 250 g/L EC (ADM.03502.F.1.A) stored at 54 °C for 14 days and at 0°C for 7 days Report no. 000105029.061FL, Sponsor no. 000105029 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP / GEP Unpublished	N	ADM
KCP 2.5.2/01 filed in KCP KCP 2.1/01	Tsesin, N.	2020	Determination of storage stability and physical-chemical properties of prothioconazole 175 g/L + fenpropidin 250 g/L EC (ADM.03502.F.1.A) stored at 54 °C for 14 days and at 0°C for 7 days Report no. 000105029.061FL, Sponsor no. 000105029 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP / GEP Unpublished	N	ADM
KCP 2.6.1/01 filed in KCP KCP 2.1/01	Tsesin, N.	2020	Determination of storage stability and physical-chemical properties of prothioconazole 175 g/L + fenpropidin 250 g/L EC (ADM.03502.F.1.A) stored at 54 °C for 14 days and at 0°C for 7 days Report no. 000105029.061FL, Sponsor no. 000105029 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP / GEP Unpublished	N	ADM
KCP 2.7.1/01 filed in KCP KCP 2.1/01	Tsesin, N.	2020	Determination of storage stability and physical-chemical properties of prothioconazole 175 g/L + fenpropidin 250 g/L EC (ADM.03502.F.1.A) stored at 54 °C for 14 days and at 0°C for 7 days Report no. 000105029.061FL, Sponsor no. 000105029 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP / GEP Unpublished	N	ADM
KCP 2.7.4/01 filed in KCP KCP 2.1/01	Tsesin, N.	2020	Determination of storage stability and physical-chemical properties of prothioconazole 175 g/L + fenpropidin 250 g/L EC (ADM.03502.F.1.A) stored at 54 °C for 14 days and at 0°C for 7 days Report no. 000105029.061FL, Sponsor no. 000105029 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP / GEP Unpublished	N	ADM
KCP 2.7.5/01	Tsesin, N.	2022	Determination of storage stability and physical-chemical properties of prothioconazole 175 g/L + fenpropidin 250 g/L EC (ADM.03502.F.1.A) stored at ambient temperature for two years.	N	ADM

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Verte-brate study Y/N	Owner
			Report no. 000105030.062FL, Sponsor no. 000105030 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP / GEP Unpublished		
KCP 2.8.2/01 filed in KCP KCP 2.1/01	Tsesin, N.	2020	Determination of storage stability and physical-chemical properties of prothioconazole 175 g/L + fenpropidin 250 g/L EC (ADM.03502.F.1.A) stored at 54 °C for 14 days and at 0°C for 7 days Report no. 000105029.061FL, Sponsor no. 000105029 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP / GEP Unpublished	N	ADM
KCP 2.8.6.1/01 filed in KCP KCP 2.1/01	Tsesin, N.	2020	Determination of storage stability and physical-chemical properties of prothioconazole 175 g/L + fenpropidin 250 g/L EC (ADM.03502.F.1.A) stored at 54 °C for 14 days and at 0°C for 7 days Report no. 000105029.061FL, Sponsor no. 000105029 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP / GEP Unpublished	N	ADM
KCP 2.8.6.2/01 filed in KCP KCP 2.1/01	Tsesin, N.	2020	Determination of storage stability and physical-chemical properties of prothioconazole 175 g/L + fenpropidin 250 g/L EC (ADM.03502.F.1.A) stored at 54 °C for 14 days and at 0°C for 7 days Report no. 000105029.061FL, Sponsor no. 000105029 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP / GEP Unpublished	N	ADM
KCP 2.8.6.3/01 filed in KCP KCP 2.1/01	Tsesin, N.	2020	Determination of storage stability and physical-chemical properties of prothioconazole 175 g/L + fenpropidin 250 g/L EC (ADM.03502.F.1.A) stored at 54 °C for 14 days and at 0°C for 7 days Report no. 000105029.061FL, Sponsor no. 000105029 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP / GEP Unpublished	N	ADM
KCP 4.2/01	Anonymous	2022	Safety Data Sheet – ADM.03502.F.1.A – Revision date 07-Jul-2022 Report no. FNG56966-M ADAMA Makhteshim Ltd., Beer-Sheva, Israel Not GLP / GEP Published	N	ADM

ADM = Property of ADAMA Agricultural Solution and all affiliates.

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 Prothioconazole

Not relevant.

A 2.2 Fenpropidin

Not relevant.