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.03500.F.2.B
(alternative codes: ADM.3500.F.2.B; MCW-2075)

Product name(s): see part A

Chemical active substance(s):

Prothioconazole, 250 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorisation)

Applicant: Country organisation / representative
as specified in Part A

Submission date: June 2021

Finalisation date: November 2022 (initial Core Assessment)

April 2023 (final Core Assessment)

Version history

When	What
2021/06	Version 1 Applicant
November 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~~.
April 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.03500.F.2.B. Under Article 59, Regulation 1107/2009/EC, on behalf of the Sponsor Company the applicant claims data protection for the studies conducted with ADM.03500.F.2.B. 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The summaries and evaluations contained in this document may be based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority that prepared it.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authorities should not grant, amend, or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this document unless they have received the data on which the summaries and evaluation are based, either –

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- following expiry of any period of exclusive use, by offering – in certain jurisdictions – mandatory compensation, unless the period of protection of the proprietary data concerned has expired.

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zRMS conclusions:

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

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:	xxxxxxxxxxxxx
Telephone No.:	+49 (2203) 5039-535
Fax:	-
E-mail:	xxxxxxxxxxxxx@adama.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

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 (applicant's source)	min. 980 g/kg
Prothioconazole (Regulation (EU) No 540/2011)	min. 970 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)

A FAO specification does currently not exist for prothioconazole.

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.03500.F.2.B
Alternative codes:	ADM.3500.F.2.B; MCW-2075

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.03500.F.2.B was not the representative formulation in the EU review of prothioconazole.

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	250	250 g/L ± 15 g/L = 235 – 265 g/L pure prothioconazole	255.1 g/L (239.8 – 270.4)	23.6 % w/w

* Based on the minimum purity of 98.0% w/w of the active substance declared for registration in the applicant's active substance dossiers
** Based on the density of the formulation = 1.08 g/mL

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. (equivalent to 1.25 g/L ADM.03500.F.2.B)
Prothioconazole-desthio	0.5 g/kg a.s. (equivalent to 0.125 g/L ADM.03500.F.2.B)

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 ~~381~~	-

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 yellowish homogenous liquid with an aromatic odour. It is not explosive and has no oxidising properties. It has an auto ignition temperature of 430°C. In aqueous solution, it has a pH value around 7.0. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C, 2 weeks at 54 °C, 2-years at ambient temperature neither the active ingredient content nor the technical properties were changed, when stored in HDPE/PA containers. Its technical characteristics are acceptable for an emulsion concentrate formulation.
The intended concentration of use is 0.175% to 0.8%.

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.03500.F.2.B 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 and olfactoy investigation	ADM.03500.F.2.B 250 g/L prothioconazole Batch no.: 1109-210219-01 ADM.03500.F.2.B 250 g/L prothioconazole Batch no.: 3178-010519-01	Physical state: Homogenous liquid Colour: Yellowish Odour: Aromatic	Y Y	KCP 2.1/01: Tsesin, N. (2019) report no.: 000102642.035FL KCP 2.1/02: Padilla, P. (2020) report no.: 20-913017-024	**Accepted.**
Explosive properties (KCP 2.2.1)	Statement	ADM.03500.F.2.B 250 g/L prothioconazole	ADM.03500.F.2.B is not considered to have explosive properties.	N	KCP 2.2.1/01: Tzur, L. (2020), report no.: -	**Accepted.** ADM.03500.F.2.B 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)	Statement	ADM.03500.F.2.B 250 g/L prothioconazole	ADM.03500.F.2.B is not considered to have oxidising properties.	N	KCP 2.2.2/01 (filed in KCP 2.2.1/01): Tzur, L. (2020), report no.: -	**Accepted.** ADM.03500.F.2.B 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.03500.F.2.B 250 g/L prothioconazole Batch no.: 1109-210219-01	Flash point: 94.4°C	Y	KCP 2.3.1/01 (filed in KCP 2.1/01): Tsesin, N. (2019) report no.: 000102642.035FL	**Accepted.** The formulation is not flammable. 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.
Flammability (KCP 2.3.2)	-	-	**Justification for non-submission:** Not relevant for liquid formulations.	-	-	-
Self-heating (KCP 2.3.3)	EEC A.15	ADM.03500.F.2.B 250 g/L prothioconazole Batch no.: 3178-010519-01	The auto-ignition temperature of the test substance was determined to be 430°C.	Y	KCP 2.3.3/01: Halbwachs, P. (2020), report no.: 20-913017-020	**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.03500.F.2.B 250 g/L prothioconazole Batch no.: 1109-210219-01	pH of 1% of the test item in water: 7.0 **Temperature, °C** / **pH after 1 min** / **pH after 2 min** / **pH after 10 min** / **Mean pH** 20.6 / 9.03 / 8.63 / 7.28 / 7.0 20.3 / 7.76 / 7.06 / 6.72	Y	KCP 2.4.2/01 (filed in KCP 2.1/01): Tsesin, N. (2019) report no.: 000102642.035FL	**Accepted.**
Viscosity (KCP 2.5.1)	OECD 114	ADM.03500.F.2.B 250 g/L prothioconazole Batch no.: 1109-210219-01	Viscosity: Test temperature 20°C: Dynamic viscosity = 59.9 cP at a shear rate of 15.5 s^{-1} to 57.45 cP at a shear rate of 129 s^{-1}	Y	KCP 2.5.1/01 (filed in KCP 2.1/01): Tsesin, N. (2019) report no.: 000102642.035FL	**Accepted.**

			Test temperature 40°C: Dynamic viscosity = 25.65 cP at a shear rate of 15.5 s^{-1} to 22.95 cP at a shear rate of 129 s^{-1} Conclusion: The test substance is a Newtonian liquid.			
Surface tension (KCP 2.5.2)	EC A 5	ADM.03500.F.2.B 250 g/L prothioconazole Batch no.: 1109-210219-01	Surface tension on diluted test item: 36.0 mN/m (concentration: 0.8 %) 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. (2019) report no.: 000102642.035FL	**Accepted.** The formulation is surface active.
Relative density (KCP 2.6.1)	EEC A.3	ADM.03500.F.2.B 250 g/L prothioconazole Batch no.: 1109-210219-01	Relative density: 1.08	Y	KCP 2.6.1/01 (filed in KCP 2.1/01): Tsesin, N. (2019) report no.: 000102642.035FL	**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 46.3

Analytical method:
HPLC SOP
50.007.07
50.009.08
50.010.05
50.011.07

HDPE/PA</td>
<td>ADM.03500.F.2.B
250 g/L
prothioconazole
Batch no.: 1109-210219-01</td>
<td>All investigated parameters were within the international specifications. The formulation ADM.03500.F.2.B 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>Unchanged</td></tr>
<tr><td>Prothioconazole content [g/L]</td><td>248.2
23.0%</td><td>247.5
22.9</td></tr>
<tr><td>Relevant Impurity [312] content [ppm]</td><td>< 100</td><td>< 100</td></tr>
<tr><td>pH (1% dilution)</td><td>7.0</td><td>6.6</td></tr>
<tr><td>Emulsion characteristics
0.15% v/v in standard water A
Initially
After 30 minutes
After 2 hours
After 24 hours
After re-emulsification (30 sec)
30 minutes after re-emulsification

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

0.8% v/v in standard water A
Initially
After 30 minutes
After 2 hours
After 24 hours
After re-emulsification (30 sec)
30 minutes after re-emulsification

0.8% v/v in standard water D
Initially
After 30 minutes
After 2 hours
After 24 hours
After re-emulsification (30 sec)
30 minutes after re-emulsification</td><td>

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</table>
[1]Uniform liquid</td>
<td>Y</td>
<td>KCP 2.7.1/01 (filed in KCP 2.1/01):
Tsesin, N. (2019)
report no.:
000102642.035FL</td>
<td>Accepted.

The product showed no significant physical changes after accelerated storage and all performance properties were within acceptable limits.

No toxicologically, ecotoxicologically or environmentally relevant impurities are formed upon storage.

The accelerated stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE/PA.</td>
</tr>
</table>

			[2]Uniform emulsion with thin layer precipitation, not measurable volume of precipitated material on the bottom of cylinder 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 (KCP 5.1.1/01).			
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	**Justification for non-submission:** Not relevant, since the stability of the preparation was tested after 14 days at 54°C.	-	-	-
Minimum content after heat stability testing (KCP 2.7.3)	-	-	**Justification for non-submission:** Not relevant, since the active substance prothioconazole is not heat sensitive.	-	-	-
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	ADM.03500.F.2.B 250 g/L prothioconazole Batch no.: 1109-210219-01	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: Uniform[1] / Uniform After 30 minutes: Uniform / Uniform After 2 hours: Uniform / Uniform After 24 hours: U/TL[2] / U/TL After re-emulsification (30 sec): Uniform / Uniform 30 minutes after re-emulsification: Uniform / Uniform 0.15% v/v in standard water D Initially: Uniform / Uniform After 30 minutes: Uniform / Uniform After 2 hours: Uniform / Uniform After 24 hours: Uniform / Uniform After re-emulsification (30 sec): Uniform / Uniform 30 minutes after re-emulsification: Uniform / Uniform 0.8% v/v in standard water A Initially: Uniform / Uniform After 30 minutes: Uniform / Uniform After 2 hours: Uniform / Uniform After 24 hours: U/TL / U/TL After re-emulsification (30 sec): Uniform / Uniform 30 minutes after re-emulsification: Uniform / Uniform	Y	KCP 2.7.4/01 (filed in KCP 2.1/01): Tsesin, N. (2019) report no.: 000102642.035FL	**Accepted.**

			0.8% v/v in standard water D Initially After 30 minutes After 2 hours After 24 hours After re-emulsification (30 sec) 30 minutes after re-emulsification Uniform Uniform Uniform U/TL Uniform Uniform Uniform Uniform Uniform U/TL Uniform Uniform			
Ambient temperature shelf life (KCP 2.7.5)	Analytical method: HPLC MS-MS 50.007.07 50.009.08 50.010.05 50.011.07 HDPE/PA	ADM.03500.F.2.B 250 g/L prothioconazole Batch no.: 1109-210219-01	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) and 2-year of storage at ambient temperature. For full result after 2-years please refer to the Table 2-2. 3-year storage stability studies at ambient temperature have both been initiated. The final reports are anticipated ~~Q3-2021 and~~ Q3-2022 respectively.	Y	KCP 2.7.5/01: Tsesin, N. (2021) report no.: 000102643.036FL	**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. Period of validity: 2 years.
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	**Justification for non-submission:** 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.	-	-	Please refer to the point 2.7.5.
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.03500.F.2.B 250 g/L prothioconazole Batch no.: 1109-210219-01	Test concentration: 0.15 % of the preparation in CIPAC water D **Time** / **Vol. of foam [mL]** 0 s / 13 1 min / 0 12 min / 0	Y	KCP 2.8.2/01 (filed in KCP 2.1/01): Tsesin, N. (2019) report no.: 000102642.035FL	**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 (KCP 2.8.5.4)	-	-	**Justification for non-submission:** Not required for EC preparations.	-	-	-
Emulsifiability (KCP 2.8.6.1)	CIPAC MT 36.3	ADM.03500.F.2.B 250 g/L prothioconazole Batch no.: 1109-210219-01	Emulsifiability (test concentration 0.15%): In CIPAC standard water A: Uniform liquid In CIPAC standard water D: Uniform liquid Emulsifiability (test concentration 0.8%): In CIPAC standard water A: Uniform liquid In CIPAC standard water D: Uniform liquid	Y	KCP 2.8.6.1/01 (filed in KCP 2.1/01): Tsesin, N. (2019) report no.: 000102642.035FL	**Accepted.**

Emulsion stability (KCP 2.8.6.2)	CIPAC MT 36.3	ADM.03500.F.2.B 250 g/L prothioconazole Batch no.: 1109-210219-01	<u>Emulsion stability on standing for 30 minutes, 2 h and 24 h:</u> At a test concentration of 0.15 %:in CIPAC water A after 30 minutes ..... Uniform after 2 hours Uniform after 24 hours Uniform emulsion with thin layer precipitation At a test concentration of 0.15 %:in CIPAC water D after 30 minutes ..... Uniform after 2 hours Uniform after 24 hours Uniform At a test concentration of 0.8 %:in CIPAC water A after 30 minutes ..... Uniform after 2 hours Uniform after 24 hours Uniform emulsion with thin layer precipitation At a test concentration of 0.8 %:in CIPAC water D after 30 minutes ..... Uniform after 2 hours Uniform after 24 hours Uniform emulsion with thin layer precipitation	Y	KCP 2.8.6.2/01 (filed in KCP 2.1/01): Tsesin, N. (2019) report no.: 000102642.035FL	**Accepted.**
Re-emulsifiability (KCP 2.8.6.3)	CIPAC MT 36.3	ADM.03500.F.2.B 250 g/L prothioconazole Batch no.: 1109-210219-01	<u>Re-emulsifiability</u> At a test concentration of 0.15 %:in CIPAC water A after 24 hours Uniform after 24.5 hours ..... Uniform At a test concentration of 0.15 %:in CIPAC water D after 24 hours Uniform after 24.5 hours ..... Uniform At a test concentration of 0.8 %:in CIPAC water A after 24 hours Uniform after 24.5 hours ..... Uniform At a test concentration of 0.8 %:in CIPAC water D after 24 hours Uniform after 24.5 hours ..... Uniform	Y	KCP 2.8.6.3/01 (filed in KCP 2.1/01): Tsesin, N. (2019) report no.: 000102642.035FL	**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.	-	-	-

Table 2-2: Physical, chemical and technical properties of the plant protection product after one and two years of storage at ambient temperature:

Test	Specified Limits (SANCO)	Method of Examination	Initial Results[1]	Results after 1 year' storage	Results after 2 year' storage
Appearance of the product and stability of packaging	---	Visual examination	Homogeneous transparent yellowish liquid.	No sedimentation, phase separation or colour change was detected	No sedimentation, phase separation or colour change was detected
			Packaging: HDPE/PA containers. No change in packaging. No significant change in weight. No visible interaction of the formulation with its packaging.		
A.I. Content HPLC Prothioconazole, g/L (%, w/w)	235-265 (21.7-24.5)	SOP 50.007.07 50.009.08; 50.010.05; 50.011.07 HPLC/MS-MS	248.2 (23.0)	247.7 (23.0)	248.4 (23.0)
Relevant Impurity [312] Content (ppm)	<125 ppm		<LOQ of 100 ppm	<LOQ of 100 ppm (at after 6 months and 1 year)	<LOQ of 60 ppm[2]
Persistent foaming (mL) 0.15% v/v of product in standard water D after:	<60 ml after 1 min	SOP 60.010.01 Based on CIPAC MT 47.3			
0sec			13	13	19
1 min			0	4	0
12 min			0	2	0

Test	Specified Limits (SANCO)	Method of Examination	Initial Results	Results after 1 year' storage	Results after 2 year' storage
Persistent foaming (mL) 0.8% v/v of product in standard water D after:	<60 ml after 1 min	SOP 60.010.01 Based on CIPAC MT 47.3			
0sec			9	13	15
1 min			0	2	0
12 min			0	1	0
pH 1% w/w	---	SOP 60.012.01 Based on CIPAC MT 75.3	7.0	6.5	7.0
Viscosity [1] (cP) at 20°C	---	SOP 60.019.02 Based on ISO 2431:1993(E) According to OECD 114		---	---
SR 15.5 sec^{-1} (sp. 86)			59		
SR 129 sec^{-1} (sp. 87)			57		
at 40°C		Brookfield DV2TRV			
SR 15.5 sec^{-1} (sp. 86)			26		
SR 129 sec^{-1} (sp. 87)			23		

Test	Specified Limits (SANCO)	Method of Examination	Initial Results	Results after 1 year' storage	Results after 2 year' storage
Relative Density 20°C, (g/mL)	---	SOP 60.007.02 Based on EEC Method A.3	1.08	-	-
Surface Tension (mN/m) 0.175% v/v 25°C±0.5°C	---	SOP 60.014.00 Based on EEC Method A.5	36.0	-	-
Flash point Cup closed non-equilibrium method (ASTM D 93)	---	SOP 40.032.01 Based on EEC Method A.9	>90°C (94.4°C)	-	-

[1] From Study No 000102642.035FL "Determination of Storage Stability and Physical-Chemical Properties of Prothioconazole 250 EC (ADM.03500.F.2.B) Stored at 54°C for 14 Days and at 0°C for 7 Days", Study director Dr. Natalia Tsesin.
[2] The change in LOQ is due to analytical method replacement.

Test	Initial Results (from study 000102642.035FL)	Results after 1 year' storage	Results after 2 year' storage
a) 0.15% v/v, water A			
- initially	Uniform[1]	Uniform	Uniform
- after 30 minutes	Uniform	Uniform	Uniform
- after 2 hours	Uniform	Uniform	Uniform
- after 24 hours	U/TL[2]	U/TL	U/TL
- after re-emulsification (30 sec)	Uniform	Uniform	Uniform
- 30 minutes after re-emulsification (24 hours + 30 minutes)	Uniform	Uniform	Uniform
b) 0.15% v/v, water D			
- initially	Uniform	Uniform	Uniform
- after 30 minutes	Uniform	Uniform	Uniform
- after 2 hours	Uniform	Uniform	Uniform
- after 24 hours	Uniform	Uniform	Uniform
- after re-emulsification (30 sec)	Uniform	Uniform	Uniform
- 30 minutes after re-emulsification (24 hours+30 minutes)	Uniform	Uniform	Uniform
c) 0.8% v/v, water A			
- initially	Uniform	Uniform	Uniform
- after 30 minutes	Uniform	Uniform	Uniform
- after 2 hours	Uniform	U/TL	U/TL
- after 24 hours	U/TL	U/TL	U/TL
- after re-emulsification (30 sec)	Uniform	Uniform	Uniform
- 30 minutes after re-emulsification (24 hours + 30 minutes)	Uniform	Uniform	U/TL
d) 0.8% v/v, water D			
- initially	Uniform	Uniform	Uniform
- after 30 minutes	Uniform	Uniform	Uniform
- after 2 hours	Uniform	Uniform	Uniform
- after 24 hours	U/TL	U/TL	U/TL
- after re-emulsification (30 sec)	Uniform	Uniform	Uniform
- 30 minutes after re-emulsification (24 hours+30 minutes)	Uniform	Uniform	Uniform

[1] Uniform liquid

[2] Uniform emulsion with thin layer precipitation, not measurable volume of precipitated material on the bottom of cylinder.

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[#]
Oilseed rape:	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.03500.F.2.B in cereals and oilseeds 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)

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.03500.F.2.B 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:	0.8 L ADM.03500.F.2.B/ha, corresponding to 200 g Prothioconazole/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.03500.F.2.B 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]
Tank filling: Residues after spraying:	2000 20	8	2
1st step: 1/10 dilution of residual spray volume: Residues after spraying:	200 20	0.8	0.2
2nd step: 20% of tank volume added: Residues after spraying:	400 20	0.04	0.01
3rd step: 20% of tank volume added: Residues after spraying:	400 20	0.002	0.0005
Addition of fresh spray solution: Residues in the tank filling:	2000	2×10^{-5}	5×10^{-6}

PPP = ADM.03500.F.2.B

Based on the calculation above, residues remaining in the spraying equipment after the last of three cleaning steps are estimated at 2 µL ADM.03500.F.2.B per L of water corresponding to a total of 40 µL ADM.03500.F.2.B in 20 L water. Considering these residues to be completely dissolved in the next tank filling, residues of 0.02 µL ADM.03500.F.2.B 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 4-12 µL ADM.03500.F.2.B/ha corresponding to 1-3 mg Prothioconazole/ha 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 0.005 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 200 – 600 L/ha to be applied to other crops, residues of 1 – 3 mg a.s./ha will be applied to a non-target crop by re-use of the application equipment.

Data on the biological activity of ADM.03500.F.2.B 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.03500.F.2.B and tank residues, respectively. The tests were performed according to OEDC 208 (draft 2000), and the test substance ADM.03500.F.2.B was sprayed to the test plants or to the soil after seeding of plants. Both tests were performed in barley, corn, perennial ryegrass, onion, sugar beet, rape, sunflower, tomato, cucumber and soybean.
The acceptability of the predicted residue level of ADM.03500.F.2.B 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 = 0.012 mL ADM.03500.F.2.B /ha, corresponding to
0.003 g a.s./ha

Risk from spray residues for seedling emergence of non-target plants:
Toxicity endpoints obtained from reference:
KCP 10.6.2/02: Klix, V. (2020), Report no. 190403AR / TNK18620

Toxicity endpoints for seedling emergence

Lowest ER_{50}	> 200 g a.s./ha
TER (ER_{50}/PER)	**> 66667**

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

Toxicity endpoints obtained from reference:
KCP 10.6.2/01: Klix, V. (2020), Report no. 190403AR / TNW18620

Lowest ER_{50}	> 200 g a.s./ha
TER (ER_{50}/PER)	**> 66667**

As the ER_{50} 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.03500.F.2.B 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.

Study Comments: KCP 4.2/01	Acceptable.
Agreed endpoint: KCP 4.2/01	The proposed cleaning procedure (triple rinse) is considered sufficient.

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)

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.

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

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 4.4-1 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:	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

Comments of zRMS:	The results of the accelerated storage stability study and 2 years at ambient temperature stability study indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE/PA. Extrapolation from HDPE/PA to HDPE/EVOH is acceptable.

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	Tsesin, N.	2019	Determination of storage stability and physical-chemical properties of Prothioconazole 250 EC (ADM.3500.F.2.B) stored at 54°C for 14 days and at 0°C for 7 days Report no. 000102642.035FL, Sponsor no. 000102642 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP / GEP Unpublished	N	ADM
KCP 2.1/02	Padilla, P.	2020	Odor test on PROTHIOCONAZOLE 250 EC (ADM.3500.F.2.B) Report no. 20-913017-024, Sponsor no. 000105801 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP / GEP Unpublished	N	ADM
KCP 2.2.1/01	Tzur, L.	2020	Explosive and Flammability properties of Prothioconazole 250 EC Report no. -, Sponsor no. - ADAMA Makhteshim 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 Flammability properties of Prothioconazole 250 EC Report no. -, Sponsor no. - ADAMA Makhteshim Ltd., Beer-Sheva, Israel Not GLP / GEP Unpublished	N	ADM
KCP 2.3.1/01 filed in KCP KCP 2.1/01	Tsesin, N.	2019	Determination of storage stability and physical-chemical properties of Prothioconazole 250 EC (ADM.3500.F.2.B) stored at 54°C for 14 days and at 0°C for 7 days Report no. 000102642.035FL, Sponsor no. 000102642 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP / GEP Unpublished	N	ADM
KCP 2.3.3/01	Halbwachs, P.	2020	Determination of auto-ignition temperature for PROTHIOCONAZOLE 250 EC (ADM.3500.F.2.B) Report no. 20-913017-020, Sponsor no. 000105349 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**	**Vertebrate study Y/N**	**Owner**
			GLP / GEP Unpublished		
KCP 2.4.2/01 filed in KCP KCP 2.1/01	Tsesin, N.	2019	Determination of storage stability and physical-chemical properties of Prothioconazole 250 EC (ADM.3500.F.2.B) stored at 54°C for 14 days and at 0°C for 7 days Report no. 000102642.035FL, Sponsor no. 000102642 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP / GEP Unpublished	N	ADM
KCP 2.5.1/01 filed in KCP KCP 2.1/01	Tsesin, N.	2019	Determination of storage stability and physical-chemical properties of Prothioconazole 250 EC (ADM.3500.F.2.B) stored at 54°C for 14 days and at 0°C for 7 days Report no. 000102642.035FL, Sponsor no. 000102642 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.	2019	Determination of storage stability and physical-chemical properties of Prothioconazole 250 EC (ADM.3500.F.2.B) stored at 54°C for 14 days and at 0°C for 7 days Report no. 000102642.035FL, Sponsor no. 000102642 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.	2019	Determination of storage stability and physical-chemical properties of Prothioconazole 250 EC (ADM.3500.F.2.B) stored at 54°C for 14 days and at 0°C for 7 days Report no. 000102642.035FL, Sponsor no. 000102642 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.	2019	Determination of storage stability and physical-chemical properties of Prothioconazole 250 EC (ADM.3500.F.2.B) stored at 54°C for 14 days and at 0°C for 7 days Report no. 000102642.035FL, Sponsor no. 000102642 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP / GEP Unpublished	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
KCP 2.7.4/01 filed in KCP KCP 2.1/01	Tsesin, N.	2019	Determination of storage stability and physical-chemical properties of Prothioconazole 250 EC (ADM.3500.F.2.B) stored at 54°C for 14 days and at 0°C for 7 days Report no. 000102642.035FL, Sponsor no. 000102642 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP / GEP Unpublished	N	ADM
KCP 2.7.5/01	Tsesin, N.	2021	Determination of storage stability and physical-chemical properties of Prothioconazole 250 EC (ADM.3500.F.2.B) Stored at Ambient Temperature for Two Years. Report no. 000102643.036FL, Sponsor no. 000102643 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP / GEP Unpublished	N	ADM
KCP 2.8.2/01 filed in KCP KCP 2.1/01	Tsesin, N.	2019	Determination of storage stability and physical-chemical properties of Prothioconazole 250 EC (ADM.3500.F.2.B) stored at 54°C for 14 days and at 0°C for 7 days Report no. 000102642.035FL, Sponsor no. 000102642 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.	2019	Determination of storage stability and physical-chemical properties of Prothioconazole 250 EC (ADM.3500.F.2.B) stored at 54°C for 14 days and at 0°C for 7 days Report no. 000102642.035FL, Sponsor no. 000102642 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.	2019	Determination of storage stability and physical-chemical properties of Prothioconazole 250 EC (ADM.3500.F.2.B) stored at 54°C for 14 days and at 0°C for 7 days Report no. 000102642.035FL, Sponsor no. 000102642 ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP / GEP Unpublished	N	ADM
KCP 2.8.6.3/01 filed in KCP	Tsesin, N.	2019	Determination of storage stability and physical-chemical properties of Prothioconazole 250 EC (ADM.3500.F.2.B) stored at 54°C for 14 days and at 0°C for 7 days Report no. 000102642.035FL, Sponsor no. 000102642	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
KCP 2.1/01			ADAMA Makhteshim Ltd., Beer-Sheva, Israel GLP / GEP Unpublished		
KCP 4.2/01	Anonymous	2020	Safety Data Sheet – ADM.03500.F.2.B Report no. -, Sponsor no. - 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.