

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.00900.I.1.C

Product name: COSAYR

Chemical active substance:

Chlorantraniliprole, 200 g/L SC

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(New authorization)

Applicant: Adama country organisation / representative
as specified in Part A

Submission date: October 2022

MS Finalisation date: August 2023 (initial Core Assessment)

November 2023 (final Core Assessment)

Version history

When	What
October 2022	Part B - Section 1,2,4 - Core Assessment – Central Zone, Initial version
June 2023	Update of packaging details
August 2023	<p>Initial zRMS assessment</p> <p>The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency.</p>
November 2023	<p>Final report (Core Assessment updated following the commenting period)</p> <p>Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Not agreed or not relevant information are struck through and shaded for transparency.</p>

DATA PROTECTION CLAIM

Under Article 59, Regulation 1107/2009/EC, on behalf of the Sponsor Company the applicant claims data protection for these studies conducted with ADM.00900.I.1.C (former code ADM.0900.I.1.C). 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The summaries and evaluations contained in this document may be based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority that prepared it.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authorities should not grant, amend, or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this document unless they have received the data on which the summaries and evaluation are based, either –

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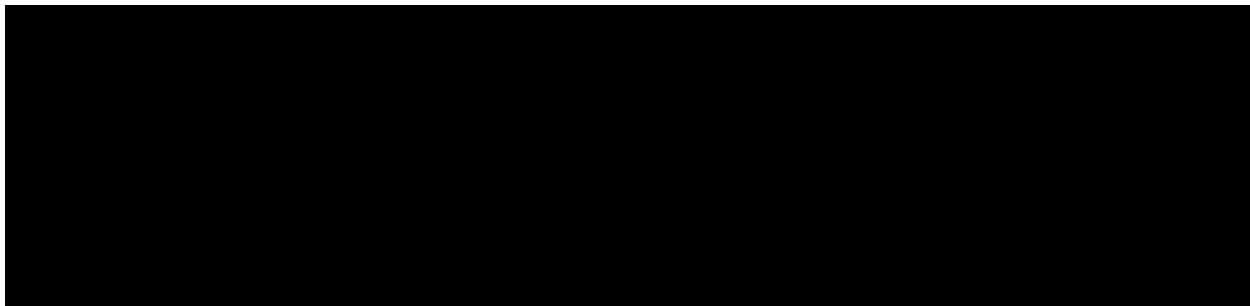
Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are:

- None.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)



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

1.2.1 Producer(s) of the preparation

CONFIDENTIAL information - data provided separately (Part C).

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

CONFIDENTIAL information - data provided separately (Part C).

1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

1.2.3.1 Chlorantraniliprole

Chlorantraniliprole: min. 950 g/kg

Impurities of toxicologically or ecotoxicologically concern are:

Acetonitrile Max. 3 g/kg

3-picoline Max. 3 g/kg

Methanesulfonic acid Max. 2 g/kg

(please refer to Review Report (SANCO/12081/2013 rev 2 final 26 January 2018).

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

Trade name: COSAYR

Company code number: ADM.00900.I.1.C

Alternative codes: ADM.0900.I.1.C (former code, used in studies included in this application)

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)

The information of the composition of ADM.00900.I.1.C is confidential and is provided separately in Part C. It was not the representative formulation during evaluation of Chlorantraniliprole at EU level.

Table 1.4.1-1: Active substance(s) and variant(s) of the active substance(s)

Active substance / variant	Declared content of the pure active substance / variant (g/L or g/kg)	FAO Limits (min – max) $\pm 6 \%$	Technical content* (g/L or g/kg)	Technical content** (% w/w)
Chlorantraniliprole	200	188 - 212	208.3	19.3

* Based on the minimum purity of 96% as declared for registration in the active substance dossiers

** Calculated with the average density of the formulation = 1.09 g/cm³ (density of 1.06-1.12 g/cm³)

Please refer to Part C for information on impurities.

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

Table 1.4.2-1: Information on active substance

Type	Name/Code Number	
ISO common name	Chlorantraniliprole	No Variant
IUPAC name	3-bromo-4'-chloro-1-(3-chloro-2-pyridyl)-2'-methyl-6'-(methylcarbamoyl)pyrazole-5-carboxanilide	-
CAS No.	500008-45-7	-
EC No.	610-489-8	-
CIPAC No.	794	-

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: Suspension Concentrate

[Code: SC]

1.6 Function (KCP 1.6)

Insecticide.

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 white – off-white slightly viscous liquid, with light alcoholic odour. It is not explosive and has no oxidising properties. No flash point was observed below 90°C. No self-ignition temperature is observed up to 600 °C. The pH of the neat formulation is 7.8 and in aqueous solution, it has a pH value around 8.3 at 21 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C in HDPE commercial container, neither the active ingredient content nor the technical properties changed. The 2 years shelf life study confirms the stability of the product during 2 years when stored at ambient temperature in HDPE commercial containers. Its technical characteristics are acceptable for a Suspension Concentrate formulation.

The intended concentration of use is from ~~0.01~~ 0.008 – 0.2 %.

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

- No classification is required based on physical and chemical properties of ADM.00900.I.1.C

Notifier Proposals for Risk and Safety Phrases (KCP 12)

- No risk and safety phrases are relevant for this section.

Compliance with FAO specifications:

The product ADM.00900.I.1.C complies with FAO specifications.

Formulation used for tests

The following table presents the physical and chemical properties for the formulation Chlorantraniliprole 200 SC (Suspension Concentrate).

GLP-certified laboratories have performed all physical chemical tests using

- Batch No: 3188-220519-01, containing 206.0 g/L Chlorantraniliprole (see Certificate of Analysis attached to report KCP 2.1/01, Tsesin, N., 2019)

For details please refer to Part C.

Table 2-1: Physical, chemical and technical properties of the plant protection product

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Visual examintaion	ADM.0900.I.1.C Batch No.: 3188-220519-01	White – off-white flowable, slightly viscous, homogeneous liquid	Y	KCP 2.1/01 Tsesin, N. (2019) Adama No.: 000102562	Accepted.
	OPPTS 830.6304	ADM.0900.I.1.C Batch No.: 3188-220519-01	The odour of the plant protection product is defined as light alcohol odour at room temperature.	Y	KCP 2.1/02 Halbwachs, P. (2019a) Study No.: 19-913017-029 Adama No.: 000103879	Accepted.
Explosive properties (KCP 2.2.1)	EC A.14	ADM.0900.I.1.C Batch No.: 3188-220519-01	The plant protection product does not have explosive properties	Y	KCP 2.2.1/01 Halbwachs, P. (2019b) Study No.: 19-913017-030 Adama No.: 000103880	Accepted. ADM.0900.I.1.C 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)	EC A.21	ADM.0900.I.1.C Batch No.: 3188-220519-01	The plant protection product does not show oxidising properties.	Y	KCP 2.2.2/01 Halbwachs, P. (2019c) Study No.: 19-913017-032 Adama No.: 000103881	Accepted. ADM.0900.I.1.C 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.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Flash point (KCP 2.3.1)	Internal SOP 40.032.01 based on EC A.9 Cup closed method (ASTM D 93)	ADM.0900.I.1.C Batch No.: 3188-220519-01	No flash point was observed below 90°C	Y	KCP 2.3.1/01 Tsesin, N. (2019) Adama No.: 000102562 (submitted in KCP 2.1/01)	Accepted. The formulation is not flammable. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.
Flammability (KCP 2.3.2)	-	-	Not required for liquid preparation	-	-	-
Self-heating (KCP 2.3.3)	EC A.15	ADM.0900.I.1.C Batch No.: 3188-220519-01	No auto-ignition temperature is observed up 600 °C	Y	KCP 2.3.3/01 Halbwachs, P. (2019d) Study No.: 19-913017-031 Adama No.: 000103882	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)	Internal SOP 60.012.01 based on CIPAC MT 75.3	ADM.0900.I.1.C Batch No.: 3188-220519-01	pH = 7.8 (undiluted formulation at ~ 20 °C) Acidity/alkalinity: Not required (pH is not lower than 4 or higher than 10)	Y	KCP 2.4.1/01 Tsesin, N. (2019) Adama No.: 000102562 (submitted in KCP 2.1/01)	Accepted.
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	Internal SOP 60.012.01 based on CIPAC MT 75.3	ADM.0900.I.1.C Batch No.: 3188-220519-01	1% v/v of formulation in deionized water at ~ 21 °C pH = 8.3	Y	KCP 2.4.2/01 Tsesin, N. (2019) Adama No.: 000102562 (submitted in KCP 2.1/01)	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Viscosity (KCP 2.5.1)	Internal SOP 60.019.02 based on OECD 114	ADM.0900.I.1.C Batch No.: 3188-220519-01	<u>Dynamic viscosity</u> Measurement at 20 °C: 340 mPa·S; with 19.8 s ⁻¹ shear rate 100 mPa·S; with 118.8 s ⁻¹ shear rate Measurement at 40 °C: 281 mPa·S; with 19.8 s ⁻¹ shear rate 81 mPa·S; with 118.8 s ⁻¹ shear rate <u>Non-Newtonian behaviour</u>	Y	KCP 2.5.1/01 Tsesin, N. (2019) Adama No.: 000102562 (submitted in KCP 2.1/01)	Accepted.
	Calculation using density of 1.09 g/mL		<u>Kinematic viscosity</u> Measurement at 20 °C: 311.9 mm ² /s; with 19.8 s ⁻¹ shear rate 91.74 mm ² /s; with 118.8 s ⁻¹ shear rate	N	-	Accepted.
Surface tension (KCP 2.5.2)	Internal SOP 60.014.01 based on EC A.5	ADM.0900.I.1.C Batch No.: 3188-220519-01	32.1 mN/m (0.1 % v/v of product in deionized water at 22.1 °C) The formulated product is considered as surface active formulation.	Y	KCP 2.5.2/01 Tsesin, N. (2019) Adama No.: 000102562 (submitted in KCP 2.1/01)	Accepted.
Relative density (KCP 2.6.1)	Internal SOP 60.007-02 based on EC A.3	ADM.0900.I.1.C Batch No.: 3188-220519-01	Density at 20 °C (g/mL) = 1.09	Y	KCP 2.5.2/01 Tsesin, N. (2019) Adama No.: 000102562 (submitted in KCP 2.1/01)	Accepted.
Bulk density (KCP 2.6.2)	-	-	Not required	-	-	-
Storage Stability after 14 days at 54° C (KCP 2.7.1)	Internal SOP 60.004.01 based on CIPAC MT 46.3 Validated method according SANCO/3030/00 rev.5	ADM.0900.I.1.C Batch No.: 3188-220519-01	No damage to the container shape or size was observed after storage for 14 days at 54 °C ± 2 °C in HDPE commercial container. <u>Weight change after storage: 0.03%</u> None of the properties under evaluation showed any deviation from specified limits when the results after storage were compared to the results before storage. Based on the results of this study the product can be classified as stable when stored in original HDPE commercial containers.		KCP 2.7.1/01 Tsesin, N. (2019) Adama No.: 000102562 (submitted in KCP 2.1/01)	Accepted. The product showed no significant physical changes after accelerated storage. No significant changes were observed in the packaging and therefore it can be

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
	Internal SOP 60.012.01 based on CIPAC MT 75.3 Internal SOP 60.010.01 based on CIPAC MT 47.3 Internal SOP 60.008.00 based on CIPAC MT 184 Internal SOP 60.006.00 based on CIPAC MT 160 Internal SOP 60.003.00 based on CIPAC MT 185 Internal SOP 60.005.00 based on CIPAC MT 148			Initial	After 2 weeks at 54 °C			concluded that the test item was not corrosive to the container material. The accelerated stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging (HDPE).
			Physical state and colour	White-off-white flowable slightly viscous homogenous liquid. After storage : no colour change , claying or sedimentation.				
			Content g/L (% w/w)	199.5 g/L (18.3 % w/w)	203.3 g/L (18.6 % w/w)			
			pH (undiluted)	7.8	7.5			
			pH of a 1% dispersion	8.3	8.3			
			Persistent foam					
			Low appl. rate (0.01 % v/v)	Initial: 5 mL 1 min: 0 mL 12 min: 0 mL	Initial: 6 mL 1 min: 0 mL 12 min: 0 mL			
				Initial: 9 mL 1 min: 0 mL 12 min: 0 mL	Initial: 9 mL 1 min: 0 mL 12 min: 0 mL			
			Suspensibility					
			Low appl. rate (0.01 % v/v)	Not tested (outside scope of method)	Not tested (outside scope of method)			
				High appl. rate (0.2 % v/v)	97 %			
			Spontaneity of dispersion (%) 5% v/v of product in standard water D	95 %	96 %			
			Wet sieve test (%)	0.0	0.0			
			Pourability [%] Rinsed [%]	2.5 % 0.17 %	2.6 % 0.21 %			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments												
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 184.1	ADM.0900.I.1.C Batch No.: AIPL/R&D/1017-080622-01	<table><tr><td>Suspensibility</td><td>T0</td><td>After 2 weeks at 54°C</td></tr><tr><td>Low appl. rate (0.1 % v/v*)</td><td>97.91 %</td><td>99.40 %</td></tr></table> * i.e the lowest recommended concentration within the scope of the method CIPAC MT 184.1.	Suspensibility	T0	After 2 weeks at 54°C	Low appl. rate (0.1 % v/v*)	97.91 %	99.40 %	Y	KCP 2.7.1/02 Srinu J. (2023) Adama No.: 000116493	Accepted.						
Suspensibility	T0	After 2 weeks at 54°C																
Low appl. rate (0.1 % v/v*)	97.91 %	99.40 %																
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not required as the product was proven to be stable under exaggerated conditions (i.e. 14 days at 54 °C).	-	-	-												
Minimum content after heat stability testing (KCP 2.7.3)	-	-	Not required as the product was proven to be stable under exaggerated conditions (i.e. 14 days at 54 °C).	-	-	-												
Effect of low temperatures on stability (KCP 2.7.4)	Internal SOP 60.013.00 based on CIPAC MT 39.3 Internal SOP 60.008.00 based on CIPAC MT 184 Internal SOP 60.003.00 based on CIPAC MT 185	ADM.0900.I.1.C Batch No.: 3188-220519-01	<p>The aspect of the test item was considered to be stable after low temperature stability for 7 days at 0 ± 2 °C, no change was observed in the test item appearance (no precipitation, no crystallization).</p> <p>Wet sieve test (CIPAC MT 185) Before: 0.0 % After: 0.0 %</p> <p>Suspensibility in water D (CIPAC MT 184) Before:</p> <table><tr><td>App. rate</td><td>0.01 % v/v</td><td>0.2 % v/v</td></tr><tr><td>Chlorantraniliprole</td><td>-</td><td>97</td></tr></table> <p>After:</p> <table><tr><td>App. rate</td><td>0.01 % v/v</td><td>0.2 % v/v</td></tr><tr><td>Chlorantraniliprole</td><td>-</td><td>98</td></tr></table>	App. rate	0.01 % v/v	0.2 % v/v	Chlorantraniliprole	-	97	App. rate	0.01 % v/v	0.2 % v/v	Chlorantraniliprole	-	98		KCP 2.7.4/01 Tsesin, N. (2019) Adama No.: 000102562 (submitted in KCP 2.1/01)	Accepted.
App. rate	0.01 % v/v	0.2 % v/v																
Chlorantraniliprole	-	97																
App. rate	0.01 % v/v	0.2 % v/v																
Chlorantraniliprole	-	98																

Ambient temperature shelf life (KCP 2.7.5)		ADM.0900.I.1.C Batch No.: 3188-220519-01	Results of the analysis before and after storage indicated that ADM.0900.I.1.C is physically and chemically stable when stored at 20°C for 2 years.		
			Test	Initial results	Results after storage 2 years at 20 °C
			Appearance	White - off-white flowable, slightly viscous, homogeneous liquid.	Bleeding about 1%, homogeneous after 3 inversions. No sedimentation or colour change sedimentation was detected.
			Packaging	Packaging: HDPE containers. No change in packaging. No significant change in weight (Technical Monograph N°17, 3rd edition, 22/03/2021). No visible interaction of the formulation with its packaging.	
			A.I. content		
			Chlorantraniliprole, g/L (% , w/w)	199.5 (18.3)	203.2 (18.6)
			Pourability		
			Pourability (%)	2.5	3.0
			Rinsed(%)	0.17	0.16
			Suspensibility (%) 0.2% v/v of product in standard water D	97	97
			Wet sieve test (%)	0.0	0.0
			pH		
			Undiluted product	7.8	7.5
			1% v/v solution	8.3	7.5
			Spontaneity of dispersion (%) 5% v/v of product in standard water D	95	93
			Persistence foaming (%) in CIPAC water D Volume of foam [mL]		
				T0 After 1 min	
			0.1% dilution	9 0	10 0
			0.01% dilution	5 0	10 0
			Y	KCP 2.7.5/01 Tsesin, N. (2021a) Adama No.: 000102563	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																									
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Not required as the product was proven to be stable in a 2 years ambient storage	-	-	-																									
Wettability (KCP 2.8.1)	-	-	Not required for a SC formulation	-	-	-																									
Persistence of foaming (KCP 2.8.2)	Internal SOP 60.010.01 based on CIPAC MT 47.3	ADM.0900.I.1.C Batch No.: 3188-220519-01 and 1452-030422-01	<table><tr><td colspan="5">Persistent foaming at highest and lowest application rate in water D at 25 °C: Volume of foam</td></tr><tr><td>App. rate</td><td>0.01 % v/v</td><td>0.1 % v/v</td><td>0.2% v/v</td><td>1% v/v</td></tr><tr><td>Initial</td><td>5 mL</td><td>9 mL</td><td>0 mL</td><td>0 mL</td></tr><tr><td>1 min</td><td>0 mL</td><td>0 mL</td><td>0 mL</td><td>0 mL</td></tr><tr><td>12 min</td><td>0 mL</td><td>0 mL</td><td>0 mL</td><td>0 mL</td></tr></table>	Persistent foaming at highest and lowest application rate in water D at 25 °C: Volume of foam					App. rate	0.01 % v/v	0.1 % v/v	0.2% v/v	1% v/v	Initial	5 mL	9 mL	0 mL	0 mL	1 min	0 mL	0 mL	0 mL	0 mL	12 min	0 mL	0 mL	0 mL	0 mL	Y	KCP 2.8.2/01 Tsesin, N. (2019) Adama No.: 000102562 (submitted in KCP 2.1/01) KCP 2.8.2/02 Stern, N. (2022) Adama No.: 000111770 (submitted in KCP 2.8.2/02)	Accepted.
Persistent foaming at highest and lowest application rate in water D at 25 °C: Volume of foam																															
App. rate	0.01 % v/v	0.1 % v/v	0.2% v/v	1% v/v																											
Initial	5 mL	9 mL	0 mL	0 mL																											
1 min	0 mL	0 mL	0 mL	0 mL																											
12 min	0 mL	0 mL	0 mL	0 mL																											
Suspensibility (KCP 2.8.3.1)	Internal SOP 60.008.00 based on CIPAC MT 184	ADM.0900.I.1.C Batch No.: 3188-220519-01	<table><tr><td colspan="3"><u>Suspensibility</u> in water D (CIPAC MT 184)</td></tr><tr><td>App. rate</td><td>0.01 % v/v</td><td>0.2 % v/v</td></tr><tr><td>Chlorantraniliprole</td><td>-</td><td>97</td></tr></table>	<u>Suspensibility</u> in water D (CIPAC MT 184)			App. rate	0.01 % v/v	0.2 % v/v	Chlorantraniliprole	-	97	Y	KCP 2.8.3.1/01 Tsesin, N. (2019) Adama No.: 000102562 (submitted in KCP 2.1/01)	Accepted.																
<u>Suspensibility</u> in water D (CIPAC MT 184)																															
App. rate	0.01 % v/v	0.2 % v/v																													
Chlorantraniliprole	-	97																													
	CIPAC MT 184.1	ADM.0900.I.1.C Batch No.: AIPL/R&D/1017-080622-01	<table><tr><td>Suspensibility</td><td>T0</td><td>After 2 weeks at 54°C</td></tr><tr><td>Low appl. rate (0.1 % v/v*)</td><td>97.91 %</td><td>99.40 %</td></tr></table> <p>* i.e the lowest recommended concentration within the scope of the method CIPAC MT 184.1.</p>	Suspensibility	T0	After 2 weeks at 54°C	Low appl. rate (0.1 % v/v*)	97.91 %	99.40 %	Y	KCP 2.8.3./02 Srinu J. (2023) Adama No.: 000116493 (submitted in KCP 2.7.1/02)	Accepted.																			
Suspensibility	T0	After 2 weeks at 54°C																													
Low appl. rate (0.1 % v/v*)	97.91 %	99.40 %																													
Spontaneity of dispersion (KCP 2.8.3.2)	Internal SOP 60.006.00 based on CIPAC MT 160	ADM.0900.I.1.C Batch No.: 3188-220519-01	Spontaneity of dispersion in water D at 25 °C (5 % v/v, in line with the method CIPAC MT 160) Chlorantraniliprole in Chlorantraniliprole 200SC formulation: 95 %	Y	KCP 2.8.3.2/01 Tsesin, N. (2019) Adama No.: 000102562 (submitted in KCP 2.1/01)	Accepted.																									

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments										
Dispersion stability (KCP 2.8.3.3)	-	-	Not required for SC formulation	-	-	-										
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not required for SC formulation	-	-	-										
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187	ADM.0900.I.1.C Batch No.: 3188-220519-01	<table border="1"><tr><td>Test</td><td>After storage</td></tr><tr><td colspan="2">Particle size distribution (µm)</td></tr><tr><td>D(10)</td><td>0.94</td></tr><tr><td>D(50)</td><td>2.65</td></tr><tr><td>D(90)</td><td>7.36</td></tr></table> <p>Particle size distribution was determined for the product after ambient storage, using laser diffraction. According to the Manual on the development and use of FAO and WHO specifications for chemical pesticides (2nd edition, 2022), particle size diffraction methodology, following CIPAC MT 187, may not be ideal to ensure the suitability of a suspension concentrate formulation, which should be evaluated by wet sieve test (CIPAC MT 185) and suspensibility (MT 184.1) or spontaneity of dispersion (MT180). These three tests were performed for the product before and after accelerated and ambient storage stability and were found to be well within the acceptable limits.</p> <p>Thus, the data generated and provided is considered sufficient to conclude that the product is stable and there is no risk of blockage of spray nozzles or filters in spray tanks.</p>	Test	After storage	Particle size distribution (µm)		D(10)	0.94	D(50)	2.65	D(90)	7.36		KCP 2.8.5.1.1/01 Tsesin, N. (2021b) Adama No.: 000109194	Accepted.
Test	After storage															
Particle size distribution (µm)																
D(10)	0.94															
D(50)	2.65															
D(90)	7.36															
Wet sieve test (KCP 2.8.5.1.2)	Internal SOP 60.003.00 based on CIPAC MT 185	ADM.0900.I.1.C Batch No.: 3188-220519-01	Wet sieve test (10g of Chlorantraniliprole 200 SC in 100 mL of water, 10 %) 0.0 % (sieve at 75 µm)	Y	KCP 2.8.5.1.2/01 Tsesin, N. (2019) Adama No.: 000102562 (submitted in KCP 2.1/01)	Accepted.										
Dust content (KCP 2.8.5.2.1)	-	-	Not required for SC formulation	-	-	-										
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not required for SC formulation	-	-	-										

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Attrition (KCP 2.8.5.3)	-	-	Not required for SC formulation	-	-	-
Hardness and integrity (KCP 2.8.5.4)	-	-	Not required for SC formulation	-	-	-
Emulsifiability (KCP 2.8.6.1)	-	-	Not required for SC formulation	-	-	-
Emulsion stability (KCP 2.8.6.2)	-	-	Not required for SC formulation	-	-	-
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not required for SC formulation	-	-	-
Flowability (KCP 2.8.7.1)	-	-	Not required for SC formulation	-	-	-
Pourability (KCP 2.8.7.2)	Internal SOP 60.005.00 based on CIPAC MT 148	ADM.0900.I.1.C Batch No.: 3188-220519-01	<u>Pourability:</u> 2.5 % <u>Residue after rinsed:</u> 0.17 %	Y	KCP 2.8.7.2/01 Tsesin, N. (2019) Adama No.: 000102562 (submitted in KCP 2.1/01)	Accepted.
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not required for SC formulation	-	-	-
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	No recommendation concerning particular possible tank mixes is intended to appear on the label.	-	-	-
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	No recommendation concerning particular possible tank mixes is intended to appear on the label.	-	-	-
Adhesion to seeds (KCP 2.10.1)	-	-	Not required, since the product is not for seed treatment	-	-	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Distribution to seed (KCP 2.10.2)	-	-	Not required, since the product is not for seed treatment	-	-	-
Other/special studies (KCP 2.11)	-	-	Not required	-	-	-

3 **Section 3 is presented as a separate document**

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

4 Section 4: Further information on the plant protection product

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

Comments of zRMS:	The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in in commercial packaging HDPE.
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The packaging has been designed in accordance with the criteria and guidelines specified in the FAO “Guideline for the Packaging of Pesticides” and has been approved according to criteria of ADR, IATA, IMDG (IMO) regulations.

The formulated product (SC formulation) is intended for containment in 50, 100, 200, 250 and 500 mL as well as 1, 5, 10 and 20 L high density polyethylene (HDPE) bottles/cans and will be distributed in cartons (outer packaging).

Tightness of the intended packaging and compatibility of the packaging material with the preparation have been demonstrated in storage stability tests under accelerated and ambient conditions.

50 milliliter bottle	Material	HDPE
	shape/size	Rectangular / 45 x 50 x 63 mm, each dimension ± 1 mm
	Opening	40 ± 1 mm
	Closure	HDPE, pilfer proof induction seal with ADAMA logo, Purple – Pantone 254 CP
	outer package	Outer corrugated single wall cardboard
	Final Pallet	CP1 standard pallet Closed with rain & dust proof coverage and film wrap L x W = 1200 x 1000
100 milliliter bottle	Material	HDPE
	shape/size	Rectangular / 45 x 50 x 90 mm, each dimension ± 1 mm
	Opening	40 ± 1 mm
	Closure	HDPE, pilfer proof induction seal with ADAMA logo, Purple – Pantone 254 CP
	outer package	Outer corrugated single wall cardboard (50 x 100 mL)
	Final Pallet	8 Layers of 12 Boxes on CP1 standard Pallet (50x96=4800lt) Closed with rain & dust proof coverage and film wrap L x W = 1200 x 1000 x 2130
200 milliliter bottle	Material	HDPE
	shape/size	Rectangular / 55 x 63 x 104 mm, each dimension ± 1 mm
	Opening	40 ± 1 mm
	Closure	HDPE, pilfer proof induction seal with ADAMA logo, Purple – Pantone 254 CP
	outer package	Outer corrugated single wall cardboard (50 x 200 mL)
	Final Pallet	7 Layers of 12 Boxes on CP1 standard Pallet (50x64=3200lt) Closed with rain & dust proof coverage and film wrap L x W = 1200 x 1000 x 2900
250 milliliter bottle	Material	HDPE
	shape/size	Cylindrical/ 128 × 62 Ø mm, each dimension ± 2 mm
	Opening	35 ± 1 mm
	Closure	White 50 mm cap with HIS with tamper evidence or colored 50 mm screw cap with PE+PER sealing and tamper evidence
	outer package	Outer corrugated fiberboard case (24 × 0.25 L)
	Final Pallet	CP1 standard pallet Closed with rain & dust proof coverage and film wrap L x W = 1200 x 1000

250 milliliter bottle	Material	HDPE
	shape/size	Rectangular / 55 x 63 x 134 mm, each dimension ± 1 mm
	Opening	40 ± 1 mm
	Closure	HDPE, pilfer proof induction seal with ADAMA logo, Purple – Pantone 254 CP
	outer package	Outer corrugated single wall cardboard (50 x 250 mL)
	Final Pallet	7 Layers of 12 Boxes on CP1 standard Pallet (50x64=3200lt) Closed with rain & dust proof coverage and film wrap L x W = 1200 x 1000 x 2900
500 milliliter bottle	Material	HDPE
	shape/size	Rectangular / 63 x 71 x 182 mm, each dimension ± 1 mm
	Opening	40 ± 1 mm
	Closure	HDPE, pilfer proof induction seal with ADAMA logo, Purple – Pantone 254 CP
	outer package	Outer corrugated fiberboard case (20 \times 0.5 L)
	Final Pallet	CP1 standard pallet Closed with rain & dust proof coverage and film wrap L x W = 1200 x 1000
500 milliliter bottle	Material	HDPE
	shape/size	Cylindrical/ 189 \times 96 \varnothing mm, each dimension ± 2 mm
	Opening	35 ± 1 mm
	Closure	White 50 mm cap with HIS with tamper evidence or colored 50 mm screw cap with PE+PER sealing and tamper evidence
	outer package	Outer corrugated fiberboard case (20 \times 0.5 L)
	Final Pallet	CP1 standard pallet Closed with rain & dust proof coverage and film wrap L x W = 1200 x 1000
1 litre bottle	Material	HDPE
	shape/size	Cylindrical/ 240 \times 90 \varnothing mm, each dimension ± 2 mm
	Opening	38 - 41 mm
	Closure	HDPE cap DIN 50 non IHS with temper evident
	outer package	carton, corrugated single wall cardboard (12 \times 1 L)
	Final Pallet	3 layers of 11 boxes on CP1 standard pallet (12x33=396 Lt) Closed with rain & dust proof coverage and film wrap L x W x H = 1200 x 1000 x 820 mm
1 litre bottle	Material	HDPE
	shape/size	Rectangular / 94.3 x 77.3 x 207.5 mm
	Opening	51 – 53 mm
	Closure	HDPE cap DIN 63 non IHS with temper evident
	outer package	carton, corrugated single wall cardboard (12 \times 1 L)
	Final Pallet	4 layers of 12 boxes on CP1 standard pallet (12x48=576 Lt) Closed with rain & dust proof coverage and film wrap L x W x H = 1200 x 1000 x 1050 mm
5 litre bottle	Material	HDPE
	shape/size	Rectangular / 190 \times 140 \times 307, each dimension ± 3 mm
	Opening	51 – 53 mm
	Closure	HDPE cap DIN 63 non IHS with temper evident
	outer package	carton, corrugated board (4 \times 5 L)
	Final Pallet	3 layers of 10 boxes on CP1 standard pallet (4 x 5 x 30 = 600 Lt) Closed with rain & dust proof coverage and film wrap L x W x H = 1200 x 1000 x 1120 mm
10 litre bottle	Material	HDPE

	shape/size	Rectangular / 227 × 157 × 401 mm, each dimension ± 2 mm
	Opening	51 – 53 mm
	Closure	HDPE cap DIN 63 non IHS with temper evident
	outer package	carton, corrugated board (2 × 10 L)
	Final Pallet	2 layers of 15 boxes on CP1 standard pallet (2 x 10 x 30 = 600 Lt) Closed with rain & dust proof coverage and film wrap L x W x H = 1200 x 1000 x 665 mm
20 litre jerry can	Material	HDHWPPE (High Density High Molecular Weight Poly-Ethylene)
	shape/size	Rectangular / 297 × 246 × 398 mm
	Opening	48 mm
	Closure	HDPE cap DIN 61
	outer package	Stackable (no carton)
	Final Pallet	2 layers of 16 canisters on CP1 standard pallet (2 x 16 x 20 = 640 Lt) Closed with rain & dust proof coverage and film wrap L x W x H = 1200 x 1000 x 926 mm

4.2 Recommended methods and precautions (KCP 4.2)

4.2.1 Procedures for cleaning application equipment and protective clothing (KCP 4.2.1)

Wash all application equipment with water (for cleaning efficiency see chapter 4.2.2 below). Suitable cleaners (commercial detergents) can be used in addition.

Wash protective clothing with washing agents in commercial quality.

4.2.2 Effectiveness of the cleaning procedures (KCP 4.2.2)

Comments of zRMS:	The proposed cleaning procedure is considered sufficient. Triple rinsing is recommended.
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At the time of compilation of this dossier, no specific study had been conducted for the product ADM.00900.I.1.C to investigate the effectiveness of the cleaning procedure. Instead, such investigations were replaced by an assessment 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). It was taken into account that by the dilution of the formulation during the cleaning process to levels below 0.01% v/v, the water solubility of the Chlorantraniliprole is limited to 0.88 mg/L.

For the assessment of residues remaining in the spraying equipment after cleaning, a standard sprayer of 2000 litres was considered. Cleaning is performed by a small volume rinse of 200 L of water 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 was considered to remain in the spray lines and pump after each rinse. Furthermore, the maximum concentration of ADM.00900.I.1.C in the initial spray solution was used as a conservative starting point. In summary, the following prerequisites were considered for a worst-case assessment:

**Highest product concentration in tank
(product/water %v/v)**

0.045 %v/v

Product volume from use resulting in highest
product concentration in tank:

0.18 L ADM.00900.I.1.C, corresponding to 36 g
chlorantraniliprole/ha

Spray volume from use resulting in highest
product concentration in tank:

400 L/ha

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:

Cleaning step	Water volume [L]	Concentration of residues	
		Product/Water* (% v/v)	Active substance
			chlorantraniliprole
Tank filling: Residues after spraying:	2000 20	0.045%	90 mg/L 90 mg/L *20L=1800mg
1st step: 1/10 dilution of residual spray volume: Residues after spraying:	200 20	0.00409%	1800mg $1800/(200+20)L = 8.182\text{mg/L}$
2nd step: 20% of tank volume added: Residues after spraying:	400 20	0.00019%	$1800-0.88*400=1448\text{mg}$ $1448\text{ mg}/(400+20)L=3.448\text{ mg/L}$
3rd step: 20% of tank volume added: Residues after spraying:	400 20	0.00001%	$1448-0.88*400=1096\text{mg}$ $1096\text{ mg}/(400+20)=2.610\text{ mg/L}$
Addition of fresh spray solution: Residues in the tank filling:	2000		$1096-0.88*400=744\text{mg}$ $744\text{mg}/2000L=0.548\text{ mg/L}$

Product = ADM.00900.I.1.C

* levels below 0.01%v/v, the water solubility of the Chlorantraniliprole is limited to 0.88 mg/L

Based on the calculation above, residues remaining in the spraying equipment after the last of three cleaning steps were estimated at 20 L at a concentration of about 0.548 mg/L of chlorantraniliprole.

Residues of 744 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.00900.I.1.C are available from the standard test model "seedling vegetative vigour" (KCP 10.6.2/01), and data on the standard model "seedling emergence" are available as agreed EU endpoints (EFSA, 2013). Both tests are considered to be most relevant for the assessment of effects on non-target plants (including non-target crops) after broadcast spraying of ADM.00900.I.1.C and tank residues, respectively. The tests were performed according to OECD 208 (2006) and OECD 227 (2006), respectively, and the test substance ADM.00900.I.1.C was sprayed to the test plants or to the soil after sowing of plants. Each test was performed in 10 representative plant species.

The acceptability of the predicted residue level of ADM.00900.I.1.C was assessed by a comparison of the exposure concentration predicted for the re-use of the application equipment with the effect rates (NOER, 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 = 0.744 g a.s./ha

Risk from spray residues for seedling emergence of non-target plants:

Toxicity endpoints obtained from reference:

EFSA, 2013. Conclusion on the peer review of the pesticide risk assessment of the active substance chlorantraniliprole. EFSA Journal 2013; 11(6):3143.

Lowest ER ₅₀	> 300 g a.s./ha (<i>Rye grass</i>)
Lowest NOER	Not available

TER (ER ₅₀ /PER)	> 403
NOER/PER	Not available

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

Toxicity endpoints obtained from reference:

KCP 10.6.2/01: Colli, M. (2020): *Effects of Chlorantraniliprole 200 SC (product code ADM.0900.I.1.C) on terrestrial plants - Vegetative Vigour Test.*

Lowest ER ₅₀	> 160 g a.s./ha (<i>Beta vulgaris</i>)
Lowest NOER	≥ 160 g a.s./ha (<i>Beta vulgaris</i>)

TER (ER ₅₀ /PER)	> 215
NOER/PER	≥ 215

According to the PSD efficacy guideline 302, a cleaning method can be considered to be acceptable, if the predicted exposure rate of the plant protection product (when the application equipment is re-used after cleaning) is at least an order of magnitude less than the no observable effect level or ED₁₀ value for the most sensitive crop species.

Since no NOER values are available from seedling emergence and a vegetative testing by : Colli, M.. (2020), the assessment is based on worst-case median effective rates and Toxicity/Exposure Ratios are compared to the standard trigger of 5 for acceptability of risk for terrestrial non-target plants as in accordance with the guidance document SANCO/10329/2002 rev.2 final (October 17, 2002)¹. The ER₅₀ based TER values for the most sensitive plant species of the vegetative vigour test are greater than 5² by more than 2 orders of magnitude. Therefore, the potential risk for non-target terrestrial plants from product residues remaining in tanks following cleaning is considered to be acceptable.

Conclusion: The effectiveness of standard cleaning procedures according to Good Agriculture Practice was assessed for the product ADM.00900.I.1.C 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, 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.

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

For the safety intervals and other precautions to protect humans, animals and the environment please refer to the national labels provided in Part A. Further information can be found in the dRR Sections 6, 7, 8, 9, respectively.

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

Please refer to the MSDS of the product ADM.00900.I.1.C filed under KCP 4.3/01.

¹ Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC

² A trigger of 5 can be applied, if at least 6 plant species have been tested

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

The product and its container must be disposed of in a safe way.

Small amounts of the product and unclean empty packaging should be packaged and sealed, labelled and transferred to a suitable incinerator in accordance with the local regulations.

Disposal by incineration in an authorised special waste incineration plant and in compliance with the local legislation. For larger quantities contact the manufacturer of the product.

EU waste keys for the packaging with product: 02 01 08 (Agrochemical waste containing dangerous substances), 20 01 19 (Pesticides).

Where local recycling schemes exist, these should be considered. Empty packaging rinsed with water should be disposed off. For further information please refer to the MSDS of the product ADM.00900.I.1.C filed under KCP 4.3/01.

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 1.3/01	Anonymous	2021	Safety Data Sheet – ADM.00900.I.1.C ADAMA Makhteshim Ltd Report no.: not available No GLP Published: no Submitted in KCP 1.3/01	N	ADM
KCP 2.1/01	Tsesin, N.	2019	DETERMINATION OF STORAGE STABILITY AND PHYS-CHEM PROPERTIES OF CHLORANTRANILIPROLE 200 SC (ADM.0900.I.1.C) STORED AT 54 °C FOR 14 DAYS AND AT 0 °C FOR 7 DAYS Adama Makhteshim Ltd., Israel Report No.:000102562.054FL Sponsor No.: 000102562 GLP: yes Published: no Submitted in KCP 2.1/01	N	ADM
KCP 2.1/02	Halbwachs, P.	2019a	Odor test on CHLORANTRANILIPROLE 200 SC (ADM.0900.I.1.C) Defitraces (Anadiag group) Report No.: 19-913017-029 Sponsor No.: 000103879 GLP: yes Published: no Submitted in KCP 2.1/02	N	ADM
KCP 2.2.1/01	Halbwachs, P.	2019b	Explosive properties of liquids on CHLORANTRANILIPROLE 200 SC (ADM.0900.I.1.C) Defitraces (Anadiag group) Report No.: 19-913017-030 Sponsor No.: 000103880 GLP: yes Published: no Submitted in KCP 2.2.1/01	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 2.2.2/01	Halbwachs, P.	2019c	Oxidising properties of liquids on CHLORANTRANILIPROLE 200 SC (ADM.0900.I.1.C) Defitraces (Anadiag group) Report No.: 19-913017-032 Sponsor No.: 000103881 GLP: yes Published: no Submitted in KCP 2.2.2/01	N	ADM
KCP 2.3.1/01	Tsesin, N.	2019	DETERMINATION OF STORAGE STABILITY AND PHYS-CHEM PROPERTIES OF CHLORANTRANILIPROLE 200 SC (ADM.0900.I.1.C) STORED AT 54 °C FOR 14 DAYS AND AT 0 °C FOR 7 DAYS Adama Makhteshim Ltd., Israel Report No.:000102562.054FL Sponsor No.: 000102562 GLP: yes Published: no Submitted in KCP 2.1/01	N	ADM
KCP 2.3.3/01	Halbwachs, P.	2019d	Auto ignition temperature of liquids on CHLORANTRANILIPROLE 200 SC (ADM.0900.I.1.C) Defitraces (Anadiag group) Report No.: 19-913017-031 Sponsor No.: 000103882 GLP: yes Published: no Submitted in KCP 2.3.3/01	N	ADM
KCP 2.4.1/01	Tsesin, N.	2019	DETERMINATION OF STORAGE STABILITY AND PHYS-CHEM PROPERTIES OF CHLORANTRANILIPROLE 200 SC (ADM.0900.I.1.C) STORED AT 54 °C FOR 14 DAYS AND AT 0 °C FOR 7 DAYS Adama Makhteshim Ltd., Israel Report No.:000102562.054FL Sponsor No.: Report No.: 000102562GLP: yes Published: no Submitted in KCP 2.1/01	N	ADM
KCP	Tsesin, N.	2019	DETERMINATION OF STORAGE STABILITY AND PHYS-CHEM PROPERTIES OF	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*
2.4.2/01			CHLORANTRANILIPROLE 200 SC (ADM.0900.I.1.C) STORED AT 54 °C FOR 14 DAYS AND AT 0 °C FOR 7 DAYS Adama Makhteshim Ltd., Israel Report No.:000102562.054FL Sponsor No.: 000102562 GLP: yes Published: no Submitted in KCP 2.1/01		
KCP 2.5.1/01	Tsesin, N.	2019b	DETERMINATION OF STORAGE STABILITY AND PHYS-CHEM PROPERTIES OF CHLORANTRANILIPROLE 200 SC (ADM.0900.I.1.C) STORED AT 54 °C FOR 14 DAYS AND AT 0 °C FOR 7 DAYS Adama Makhteshim Ltd., Israel Report No.:000102562.054FL Sponsor No.: 000102562 GLP: yes Published: no Submitted in KCP 2.1/01	N	ADM
KCP 2.5.2/01	Tsesin, N.	2019	DETERMINATION OF STORAGE STABILITY AND PHYS-CHEM PROPERTIES OF CHLORANTRANILIPROLE 200 SC (ADM.0900.I.1.C) STORED AT 54 °C FOR 14 DAYS AND AT 0 °C FOR 7 DAYS Adama Makhteshim Ltd., Israel Report No.:000102562.054FL Sponsor No.: 000102562 GLP: yes Published: no Submitted in KCP 2.1/01	N	ADM
KCP 2.6.1/01	Tsesin, N.	2019	DETERMINATION OF STORAGE STABILITY AND PHYS-CHEM PROPERTIES OF CHLORANTRANILIPROLE 200 SC (ADM.0900.I.1.C) STORED AT 54 °C FOR 14 DAYS AND AT 0 °C FOR 7 DAYS Adama Makhteshim Ltd., Israel Report No.:000102562.054FL Sponsor No.: 000102562 GLP: yes Published: no	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*
			Submitted in KCP 2.1/01		
KCP 2.7.1/01	Tsesin, N.	2019	DETERMINATION OF STORAGE STABILITY AND PHYS-CHEM PROPERTIES OF CHLORANTRANILIPROLE 200 SC (ADM.0900.I.1.C) STORED AT 54 °C FOR 14 DAYS AND AT 0 °C FOR 7 DAYS Adama Makhteshim Ltd., Israel Report No.:000102562.054FL Sponsor No.: 000102562 GLP: yes Published: no Submitted in KCP 2.1/01	N	ADM
KCP 2.7.1/02	Srinu, J.	2023	DETERMINATION OF SUSPENSIBILITY OF CHLORANTRANILIPROLE 200 SC BEFORE AND AFTER 14 DAYS ACCELERATED STORAGE RCC Laboratories Inddia Private Limited Report No.:13257 Sponsor No.: 000116493 GLP: yes Published: no	N	ADM
KCP 2.7.4/01	Tsesin, N.	2019	DETERMINATION OF STORAGE STABILITY AND PHYS-CHEM PROPERTIES OF CHLORANTRANILIPROLE 200 SC (ADM.0900.I.1.C) STORED AT 54 °C FOR 14 DAYS AND AT 0 °C FOR 7 DAYS Adama Makhteshim Ltd., Israel Report No.:000102562.054FL Sponsor No.: 000102562 GLP: yes Published: no Submitted in KCP 2.1/01	N	ADM
KCP 2.7.5/01	Tsesin, N.	2021a	DETERMINATION OF STORAGE STABILITY AND PHYSICAL-CHEMICAL PROPERTIES OF CHLORANTRANILIPROLE 200 SC (ADM.0900.I.1.C) STORED AT AMBIENT TEMPERATURE FOR TWO YEARS Adama Makhteshim Ltd., Israel Report No.:000102563.055FL Report No.: 000102563 GLP: yes Published: no	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*
			Submitted in KCP 2.7.5/01		
KCP 2.8.2/01	Tsesin, N.	2019	DETERMINATION OF STORAGE STABILITY AND PHYS-CHEM PROPERTIES OF CHLORANTRANILIPROLE 200 SC (ADM.0900.I.1.C) STORED AT 54 °C FOR 14 DAYS AND AT 0 °C FOR 7 DAYS Adama Makhteshim Ltd., Israel Report No.:000102562.054FL Sponsor No.: 000102562 GLP: yes Published: no Submitted in KCP 2.1/01	N	ADM
KCP 2.8.2/02	Stern,N	2022	Persistent Foaming Test before storage (non-GLP) Adama Makhteshim Ltd., Israel Adama No.: 000111770 GLP: no Published: no Submitted in KCP 2.8.2/02	N	ADM
KCP 2.8.3.1/01	Tsesin, N.	2019	DETERMINATION OF STORAGE STABILITY AND PHYS-CHEM PROPERTIES OF CHLORANTRANILIPROLE 200 SC (ADM.0900.I.1.C) STORED AT 54 °C FOR 14 DAYS AND AT 0 °C FOR 7 DAYS Adama Makhteshim Ltd., Israel Report No.:000102562.054FL Sponsor No.: 000102562 GLP: yes Published: no Submitted in KCP 2.1/01	N	ADM
KCP 2.8.3.2/01	Tsesin, N.	2019	DETERMINATION OF STORAGE STABILITY AND PHYS-CHEM PROPERTIES OF CHLORANTRANILIPROLE 200 SC (ADM.0900.I.1.C) STORED AT 54 °C FOR 14 DAYS AND AT 0 °C FOR 7 DAYS Adama Makhteshim Ltd., Israel Report No.:000102562.054FL Sponsor No.: 000102562 GLP: yes Published: no Submitted in KCP 2.1/01	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 2.8.5.1.1/01	Tsesin, N.	2021b	PARTICLE SIZE DISTRIBUTION FOR CHLORANTRANILIPROLE 200 SC (ADM.00900.I.1.C) Adama Makhteshim Ltd., Israel Report No.:000109194.087FL Sponsor No.: 000109194 GLP: yes Published: no Submitted in KCP 2.8.5.1.1/01	N	ADM
KCP 2.8.5.1.2/01	Tsesin, N.	2019	DETERMINATION OF STORAGE STABILITY AND PHYS-CHEM PROPERTIES OF CHLORANTRANILIPROLE 200 SC (ADM.0900.I.1.C) STORED AT 54 °C FOR 14 DAYS AND AT 0 °C FOR 7 DAYS Adama Makhteshim Ltd., Israel Report No.:000102562.054FL Sponsor No.: 000102562 GLP: yes Published: no Submitted in KCP 2.1/01	N	ADM
KCP 2.8.7.2/01	Tsesin, N.	2019	DETERMINATION OF STORAGE STABILITY AND PHYS-CHEM PROPERTIES OF CHLORANTRANILIPROLE 200 SC (ADM.0900.I.1.C) STORED AT 54 °C FOR 14 DAYS AND AT 0 °C FOR 7 DAYS Adama Makhteshim Ltd., Israel Report No.:000102562.054FL Sponsor No.: 000102562 GLP: yes Published: no Submitted in KCP 2.1/01	N	ADM

* ADM = proprietary of ADAMA Agricultural Solutions 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
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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
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