

FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: SHA 126000 B

Product name(s): CLARA

Chemical active substance:

Chlormequat chloride, 720 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Sharda Cropchem Ltd.

Submission date: February 2022

MS Finalisation date: May 2023; October 2023 **February 2024**

Version history

When	What
May 2023	ZRMs evaluated dRR submitted by Applicant.
10/2023	The Final Registration Report
02/2024	ZRMs made changes in the final version due to reviewed comments from MRiRW

Table of Contents

3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6).....	4
3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)	4
3.2 Efficacy data (KCP 6)	6
3.2.1 Preliminary tests (KCP 6.1)	12
3.2.2 Minimum effective dose tests (KCP 6.2)	12
3.2.3 Efficacy tests (KCP 6.2).....	17
3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)	25
3.3.1 Summary and Conclusions.....	25
3.3.2 Mode of Action	26
3.3.3 Mechanism(s) of resistance	26
3.3.4 Evidence of resistance	26
3.3.5 Cross-resistance.....	27
3.3.6 Sensitivity data	27
3.3.7 Use pattern.....	27
3.3.8 Resistance Risk Assessment of unrestricted use patterns	27
3.3.9 Acceptability of the resistance risk	27
3.3.10 Management strategy for Chlormequat chloride 72% SL.....	27
3.3.11 Implementation of the management strategy	27
3.3.12 Monitoring, reporting and reaction to changes in performance	27
3.4 Adverse effects on treated crops (KCP 6.4).....	28
3.4.1 Phytotoxicity to host crop (KCP 6.4.1)	29
3.4.1.1 Winter wheat	30
3.4.1.2 Overall conclusion.....	31
3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2).....	33
3.4.2.1 Materials and methods	33
3.4.2.2 Summary and evaluation of the field trials conducted in winter wheat, treated post-emergence	34
3.4.2.3 Conclusion.....	35
3.4.2.4 Relationship between phytotoxicity and yield	35
3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)	35
3.4.3.1 Conclusion.....	37
3.4.4 Effects on transformation processes (KCP 6.4.4)	38
3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)....	39
3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)	39
3.5.1 Impact on succeeding crops (KCP 6.5.1).....	39
3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)	40
3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)	40
3.6 Other/special studies	40
3.7 List of test facilities including the corresponding certificates.....	40
Appendix 1 Lists of data considered in support of the evaluation.....	42

3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

Transformation of the dRR (applicant version) into the RR (zRMS version)

The process chosen by the zRMS to transform the dRR into a RR should be explained. Options are to rewrite the document (with track change or not) or to use commenting boxes such as the following:

Comments of zRMS:	Comments of zRMS are presented in commenting boxes at the end of each chapter. The text of dRR was generally not changed or rewritten (small changes in the document are marked by grey colour). Changes to comments from MRiRW were marked by yellow.
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3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Comments of zRMS: Overall summaries are not necessary here. It was provided at the end of each chapter of the dRR.

Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)

[illegible]

3.2 Efficacy data (KCP 6)

Introduction

This document summarises the information related to the efficacy data of the plant protection product **Chlormequat chloride 72% SL (CLARA; Product code: SHA 126000 B)** containing the active substance chlormequat chloride, which was included into Annex I of Council Directive 91/414/EEC.

The SANCO report for chlormequat chloride (SANCO/175/08 final rev 2 – 29 May 2015) is considered to provide the relevant review information or a reference to where such information can be found.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on chlormequat chloride, and in particular Appendixes I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 January 2008 shall be taken into account. Consideration of active substances for Annex I inclusion does not include an evaluation of efficacy. Therefore, there are no concerns to address arising from the inclusion directive of chlormequat chloride relating to efficacy.

These concerns have been addressed within the current submission.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

The detailed assessment of the individual trial and study data is located in the following report:

Report:	KCP 6.0/001 Biological Assessment Dossier Chlormequat chloride 72% SL, Central
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Description of active substance Chlormequat chloride

Chlormequat chloride appears as white crystals with a fishlike odor. Used as a plant growth regulator. Said to be effective for cereal grains, tomatoes, and peppers. (EPA, 1998). Chlormequat chloride is an organic chloride salt comprising equal numbers of chlormequat and chloride ions. A gibberellin biosynthesis inhibitor, it is used as a plant growth retardant to produce plants with sturdier, thicker stalks, facilitating the harvesting of ornamental flowers and cereal crops. It has a role as a plant growth retardant and an agrochemical.

Chlormequat chloride belongs to the chemical group of trimethylammonium chloride.

Today, Chlormequat chloride is registered and commercialised in several formulations around the world.

Table 3.2-1: Current approvals of Chlormequat chloride in the EU Central zone as well as connected EPPO zones where trials were conducted

Country	Product	Active ingredient	Approval number
Austria	Stabilan 400	Chlormequat chloride 400 g/L SL	2206-0
	Regulador 720	Chlormequat chloride 400 g/L SL	4235-0
Czech Republic	Agri CCC 750 SL	Chlormequat chloride 400 g/L SL	R-28/2009
	Agrostabilan 750 SL	Chlormequat chloride 400 g/L SL	3219-1D / 3
	Celstar 750 SL	Chlormequat chloride 400 g/L SL	3219-3
	Clormequat E 750	Chlormequat chloride 400 g/L SL	3219-1D / 4
	Stabilan 750 SL	Chlormequat chloride 400 g/L SL	3219-1V
France	TYRAN	Chlormequat chloride 400 g/L SL	9400336
	C3-CHOC	Chlormequat chloride 400 g/L SL	9300040
	STABILAN	Chlormequat chloride 400 g/L SL	8600031
	CECECE 750	Chlormequat chloride 400 g/L SL	8000468
Germany	Stabilan 720	Chlormequat chloride 400 g/L SL	034046-62
	REGULADOR 720	Chlormequat chloride 400 g/L SL	00A045-00
	Clormequat 720	Chlormequat chloride 400 g/L SL	034046-00
	Acucel	Chlormequat chloride 400 g/L SL	034046-63

Hungary	Cycocel 750 Stabilan SL	Chlormequat chloride 400 g/L SL Chlormequat chloride 400 g/L SL	A415 A1432
Italy	BELCOCEL STABILAN WYLOM OP	Chlormequat chloride 400 g/L SL Chlormequat chloride 400 g/L SL Chlormequat chloride 400 g/L SL	009835 013792 014392
Ireland	Stabilan 750 Jadex-o-720 CeCeCe 750 7C Chlormequat	Chlormequat chloride 400 g/L SL Chlormequat chloride 400 g/L SL Chlormequat chloride 400 g/L SL Chlormequat chloride 400 g/L SL	04767 04771 04736 04744
Lithuania	Stabilan 750 SL	Chlormequat chloride 400 g/L SL	AS12-20AR
Netherlands	Stabilan	Chlormequat chloride 400 g/L SL	8828
Poland	Stabilan 750 SL CCC 720 SL	Chlormequat chloride 400 g/L SL Chlormequat chloride 400 g/L SL	R-248/2014 R-293/2021d
Spain	Stabilan 750 SL	Chlormequat chloride 400 g/L SL	25935
UK	3C Chlormequat 750 Adjust Agrovista 3 SEE 750 BEC CCC 720	Chlormequat chloride 400 g/L SL Chlormequat chloride 400 g/L SL Chlormequat chloride 400 g/L SL Chlormequat chloride 400 g/L SL	16690 17141 15975 19009

Mode of action

Chlormequat chloride primarily acts as a gibberellin biosynthesis inhibitor. Chlormequat-chloride, has no activity as a herbicide, fungicide nor as an insecticide or nematicide. Chlormequat-chloride 720 g/L is a plant growth regulator to be used in cereals.

Table 3.2-2: Details of the formulation and the active substance

Proposed trade name	Chlormequat chloride 72% SL
A.S. content:	Chlormequat chloride 720 g/L
Formulation type:	SL
Synonyms:	Chlormequat chloride
Active substance	Chlormequat chloride
IUPAC name:	2-chloroethyltrimethylammonium chloride
Chemical group:	quaternary ammonium compounds
Mode of action:	inhibition of gibberellin biosynthesis
Plant translocation:	Absorbed primarily by leaves
Biological action:	Selective

For further physico-chemical properties, please refer to Registration Report Part B Section 1: Identity, physical and chemical properties, other information.

Description of the plant protection product

Chlormequat chloride 72% SL is a soluble concentrate (SL) formulation containing 720 g/l chlormequat-chloride, that acts as a growth regulator for the use in winter wheat. Please refer to Table 3.1-1 to see the GAP covered by this document.

To support the registration of Chlormequat chloride 72% SL in the GAP claimed crops, trials have been set up in winter wheat. In all trials, the Chlormequat chloride formulation prepared by Sharda Cropchem Ltd. – Chlormequat chloride 72% SL – was compared against a reference Chlormequat chloride formulation currently on the market in Europe. The trials were conducted in 2016 and 2017 in a range of European countries in the North-east (i.e. Poland and Lithuania), the Maritime (i.e. Germany, France, United

Kingdom and Czech Republic), the Mediterranean (i.e. Italy and France) and the South-east (i.e. Hungary) EPPO zones.

According to the GAP, the proposed application rate of Chlormequat chloride 72% SL is 1.3 - 2.1 L per hectare (L/ha), with one application per season, for the post-emergence use in winter wheat. This will deliver 936 - 1510 g Chlormequat chloride per hectare, depending on the applied dose. In the treated crops, the test product was tested against equivalent dose rates of the Chlormequat chloride reference product currently marketed in the countries where the trials were conducted.

The data presented in this dossier fully support the label claim for Chlormequat chloride for the use as plant growth regulator in winter wheat.

Table 3.2-3: Simplified table of currently registered uses and requested uses for the product code.

Uses		Member State	Requested rate(s)	Comments / Other relevant details on GAPs
Crop(s)	Target(s)			
Winter wheat.	Regulation of growth, prevention of lodging	CEU	1.3 - 2.1 L/ha	

Further details are in the table “All intended uses” in Part B - Section 0.

Table 3.2-4: Major / minor status of intended uses (for all cMS and zRMS).

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
Winter wheat	CEU	-	Regulation of growth, prevention of lodging	CEU	-

Compliance with the Uniform Principles

Comprehensive field trials were conducted in Poland, Lithuania, France, United Kingdom, Germany, Czech Republic, Italy and Hungary in 2016 and 2017. The trials followed the corresponding EPPO guidelines. The GEP-requirement and the Uniform Principles are taken care of.

Information on trials submitted (3.1 Efficacy data)

Trials in this dossier were carried out by contractor companies and Official Research institutes, all of which follow the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

On the basis of the EPPO guideline 1/241(1) "Guidance on comparable climates", the trials included in this dossier have been grouped and summarized by EPPO zones. EPPO zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region.

In general, the trials were conducted according to the respective EPPO guidelines.

In support of the current application for registration of Chlormequat chloride 72% SL, 23 efficacy trials and 22 selectivity trials were conducted in the North-east (9 eff. and 6 sel.), the Maritime (10 eff. and 10 sel.), the Mediterranean (4 eff. and 4 sel.), and the South-east (2 sel.) EPPO zone.

Table 3.2-5: Presentation of efficacy trials (efficacy trials, preliminary trials...)

Use(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non- GEP, official***	Comments (any other relevant information)
					EPPO zone					
					MAR	MED	S-E	N-E		
Winter wheat	Growth regulator	Poland	2016	MED + E + S	-	-	-	4 (4)	GEP	
		Poland	2017	MED + E + S	-	-	-	2 (2)	GEP	
		Lithuania	2016	MED + E + S	-	-	-	3 (3)	GEP	
		France	2016	MED + E + S	2 (2)	2 (2)	-	-	GEP	
		United Kingdom	2016	MED + E + S	2 (2)	-	-	-	GEP	
		Germany	2017	MED + E + S	2 (2)	-	-	-	GEP	
		Czech Republic	2016	MED + E + S	2 (2)	-	-	-	GEP	
		France	2017	MED + E + S	2 (2)	-	-	-		
		Italy	2016	MED + E + S		2 (2)	-	-		
						10 (10)	4(4)	-	9 (9)	-
		Total, all crops		10 (10)	4 (4)	-	9 (9)			

Climatic zones

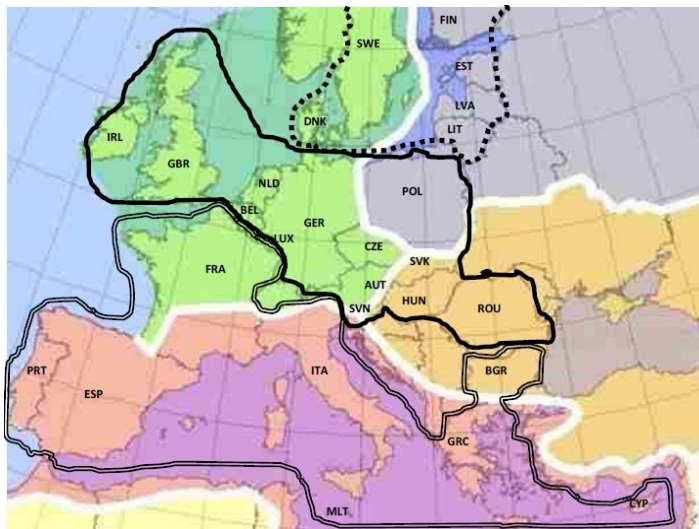
Europe is divided into four climatic zones, according to EPPO standard PP 1/241 (1). Besides providing guidance in determining comparability of climatic conditions between geographical areas where efficacy evaluation trials are performed, the standard also supports the use of data generated in one country to support registration in another country¹.

Germany, United Kingdom, France and Czech Republic are located in the Maritime EPPO zone; Hungary is located in the South-east EPPO zone; Poland and Lithuania are located in the North-east EPPO zone; and the south of France and Italy are located in the Mediterranean EPPO zone (**Błąd! Nieprawidłowy odsyłacz do zakładki: wskazuje na nią samą.**).

This document is prepared to support the submission of Chlormequat chloride 72% SL throughout the Central Registration zone, therefore data from the Maritime, the North-east, the South-east, and the Mediterranean zones are included. The data from each climatic zone is summarised separately.

¹ Development of Comparable Agro-Climatic Zones for the International Exchange of Data on the Efficacy and Crop Safety of Plant Protection Products, E. Bouma, 2005 OEPP/EPPO, Bulletin OEPP/EPPO Bulletin 35, 233-238.

Figure 3.2-1: Representation of EPPO climatic zones (in colour: EPPO Standard PP1/241, Guidance on comparable climates) superimposed with the 3 European zones (EC Regulation 1107/2009) (Source: EPPO)



Agronomic conditions

Cultural conditions of the different crops and agronomy (e.g. cultivations used, application methods, cultivars, fertilizer regime, relative times of planting and harvest) do not differ significantly between Germany, Poland, Lithuania, United Kingdom, Czech Republic, France, Italy and Hungary. The same Chlormequat chloride products are already registered and used in all countries for the same uses, i.e. the plant growth regulation in winter wheat.

(i) Weed physiology

The damaging economic effects of lodging in the label claimed crop are controlled by Chlormequat chloride 72% SL. In each country the effects of lodging are very common and can cause large reductions in yield.

(ii) Site selection

Although trials were performed throughout the EU, in each country the sites were carefully selected to ensure that the effect of the plant growth regulator was assessed on a range of varieties and application timings. No differences in the level of efficacy were apparent between the different countries or regions in which the trials were conducted.

(iii) Agronomic practices

Agronomic practices in cereal field crops are similar throughout the Central zone as well as in the countries in the connected EPPO zones where trials were conducted. The levels of inorganic fertilizers and other crop inputs are similar between the countries.

(iv) Varieties

Although crop varieties tend to differ between countries, the crop safety of Chlormequat chloride 72% SL has been tested on a wide range of varieties in both the selectivity and efficacy trials. The results from these trials show that there are no particularly sensitive varieties. Crop tolerance and yield data generated in one country is therefore relevant in another Member state.

(v) Trial methodology

Similar trial methodology was used in all countries. All trials were conducted to GEP by officially recognised testing organisations and in accordance with relevant EPPO standards.

(vi) Locations

Trials were performed in the major crop growing areas in each respective country. These areas have been found to be particularly suitable for cereal production due to their innate similarity in terms of soil type and climate.

(vii) *Soil*

Chlormequat chloride is a plant growth regulator with no mentionable residual activity. In each country, trials have been conducted on a range of soil types with no difference seen in the level of control.

On the basis that the above factors do not influence the overall performance of Chlormequat chloride 72% SL, it is the applicant's contention that data from Germany, Poland, Lithuania, Czech Republic, United Kingdom and France is equally valid in demonstrating the products performance throughout the Central EU zone and the data from Italy, South France and Hungary is valid as supporting data.

Efficacy and crop safety trials were carried out with Chlormequat chloride 72% SL in comparison a commercial standard SL formulation of 750 g/L Chlormequat chloride (STABILAN 750 SL) currently on the market in Europe. The trials were carried out on field crops of winter wheat.

The reference products used in the efficacy trials are listed in **Błąd! Nieprawidłowy odsyłacz do zakładki: wskazuje na nią samą..**

Table 3.2-6: Presentation of reference standards used in trials (efficacy trials, preliminary trials...)

Trade name	Formulation	Composition	Rates [L/ha]	Indication	Country	N° of trials
STABILAN 750 SL	SL	750 g/L Chlormequat chloride	1.0 l/ha 1.2 l/ha 1.25 l/ha 1.3 l/ha 1.5 l/ha 2.0 l/ha 2.1 l/ha 3.0 l/ha 3.28 l/ha 4.0 l/ha 4.2 l/ha 6.56 l/ha	Regulation of growth, prevention of lodging	PL LT FR UK DE CZ IT	6 3 6 2 2 2 2

Comments of zRMS:	<p>This document summarises the information related to the efficacy of the plant protection product – CLARA (product code: SHA 126000 B).</p> <p>CLARA (product code: SHA 126000 B) is characterized by a soluble concentration (SL) formulation containing 720 grams per liter (g/L) chlormequat chloride for use in winter wheat.</p> <p>Chlormequat chloride is used as a plant growth regulator. It is typically sold as the chloride salt, chlormequat chloride, a colourless hygroscopic crystalline substance that is soluble in water and ethanol. Chlormequat inhibits cell elongation, resulting in thicker stalks, which are sturdier, facilitating harvesting of cereal crops.</p> <p>Currently there are dozens of products on the CEU market, use to reduce of lodging in the cereals. In Poland – 14 with chlormequat chloride are registered and commonly used for protection crops.</p> <p>Poland is a ZRMs. Applicant submitted in this dRR all needed information's about plant protection product, standard reference, etc.</p>
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3.2.1 Preliminary tests (KCP 6.1)

The activity of Chlormequat chloride is well known, as it has been marketed since the end of the 1980's, by e.g. Nufarm, as a plant growth regulator in cereals. Based on the knowledge about the active substance (+30 years) and the experiences with Chlormequat chloride 72% SL in the label claimed crops, the necessary application rates to prevent or significantly reducing lodging are already known. Therefore, preliminary tests in glasshouses and field trials to assess the biological activity of the active substance or dose range for the plant protection product were not deemed necessary.

Comments of zRMS:	No results of the preliminary range-finding tests were submitted by the Applicant, however the active substances of CLARA (product code: SHA 126000 B) – chlormequat chloride is registered and have been commonly used in agricultural practice for many years (over 30). So, preliminary range finding tests are deemed too not be necessary in the opinion of ZRMs.
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3.2.2 Minimum effective dose tests (KCP 6.2)

To determine the minimum effective dose rate, 23 efficacy trials have been included in this section.

In the 23 trials, the level of efficacy obtained by Chlormequat chloride 72% SL was assessed on winter wheat.

Summary and evaluation of Minimum Effective Dose trial results for 1.3-2.1 L/ha Chlormequat chloride 72% SL target rate for winter wheat.

In order to prove and to support the requested dose rate of 1.3-2.1 L/ha Chlormequat chloride 72% SL [936-1510 g Chlormequat chloride per hectare] for the prevention of lodging in winter wheat, the assessment results of 23 efficacy trials performed in the North-east (9), the Maritime (10) and the Mediterranean (4) EPPO zone in 2016 and 2017, are reported. In the trials Chlormequat chloride 72% SL was included at 2.1 L/ha to demonstrate the maximum recommended dose rate and at 1.3 L/ha to demonstrate the minimum recommended dose rate as well as at one lower than recommended dose rates (1.0 L/ha). The rates reflect the proposed label rate as well as 77-47.6% of the recommended rate of Chlormequat chloride 72% SL, in accordance with the EPPO standard PP 1/225(2) '*Minimum effective dose*' and the Central zone efficacy requirements. As the most accurate representation of whole plot product performance, the assessment data at 30-98 days after the application, obtained by visually estimating control obtained by the applied products are summarised and presented in the results tables in the following subsection.

The results obtained with Chlormequat chloride 72% SL applied in winter wheat, when evaluating the reduction in height, control of lodging as well as the lodging area obtained in the harvested trials are presented in **Błąd! Nieprawidłowy odsyłacz do zakładki: wskazuje na nią samą.** for results obtained in the North-east EPPO zone, the Maritime EPPO zone and the Mediterranean EPPO zone. The crop height was assessed at different timings throughout the trial period, but presented in the tables below is the data obtained from an assessment carried out at approximately four weeks to three months after application. Lodging and yield was assessed at harvest.

Table 3.2-7: North-East, Maritime and Mediterranean zone - Efficacy of reduced rate and recommended rates of Chlormequat chloride 72% SL applied for the limitation of growth in winter wheat; Evaluation: mean values [avg] and variation [min/max] across trials, in % control;

Parameter evaluated	Total No. of trials	Untreated	Efficacy obtained with Chlormequat chloride 72% SL at:		
		Mean (min-max)	Mean (min-max)		
		cm / %	720 g ai/ha	936 g ai/ha	1510 g ai/ha
Height reduction		cm	Height reduction (cm)		
Nort.East EPPO zone	9	87.35 (74.6-120.7)	86.9 (65.2-110.1)	85.1 (64.9-107.4)	83.78 (63.9-105.8)
Maritime EPPO zone	10	89.0 (61.3-111.0)	85.5 (57.4-107.0)	85.0 (56.5-107.0)	83.3 (56.1-104.0)

Parameter evaluated	Total No. of trials	Untreated	Efficacy obtained with		
		Mean (min-max) cm / %	Chlormequat chloride 72% SL at:		
			Mean (min-max)		
			720 g ai/ha	936 g ai/ha	1510 g ai/ha
Mediterranean EPPO zone	4	94.29 (68.6-116.7)	91.82 (65.2-114.8)	88.75 (62.7-111.2)	86.5 (61.4-102.2)
Mean of all assessments	23	90.2 (61.3-120.7)	88.0 (57.4-114.8)	86.2 (56.5 -111.2)	84.5 (56.1-105.8)
Lodging		%	% Control (reduction in lodging)		
Nort.East EPPO zone	9	54.4 (33.8-75.0)	32.55 (21.3-43.8)	25.0 (22.5-27.5)	10.9 (10.8-11.0)
Maritime EPPO zone	4	40.75 (40.75-40.75)	30.75 (30.75-30.75)	31.25 (31.25-31.25)	30.0 (30.0-30.0)
Mediterranean EPPO zone	2	0.2 (0.2-0.2)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)
Mean of all assessments	15	31.7 (0.2-75.0)	21.1 (0.0-43.8)	18.7 (0.0-31.25)	13.6 (0.0-30.0)
Lodging area		%	% Control (reduction in lodging area)		
Maritime EPPO zone	5	16.9 (1.0-31.3)	3.4 (0.0-12.0)	2.2 (0.0-6.3)	1.8 (0.0-6.8)
Mediterranean EPPO zone	2	28.8 (16.3-41.3)	15.65 (15.0-16.3)	14.15 (10.0-18.3)	8.9 (7.5-10.3)
Mean of all assessments	7	22.85 (1.0-41.3)	9.5 (0.0-16.3)	8.1 (0.0-18.3)	5.35 (0.0-10.3)

On an overall level, when summarizing the results obtained in the three zones, the centimeters in crop height was 86.2 – 84.5 cm following an application of Chlormequat chloride 72% SL at 1.3-2.1 L/ha, compared to 88.0 cm achieved by 1.0 L/ha. Thus a dose response was observed when evaluating the ability of Chlormequat chloride 72% SL to act as a crop growth regulator. Shortly before harvest, the lodging was evaluated in the trials. In the ~~fiveteen~~ fifteen trials, the average control of lodging following an application of Chlormequat chloride 72% SL at 1.3-2.1 L/ha was 18.7-13.6%, compared to 21.1% achieved by 1.0 L/ha. Therefore, when evaluating the ability of Chlormequat chloride 72% SL to control lodging, a dose response was observed between the three dose rates applied in all trials. Finally, when evaluating the lodging area, in the seven trials, the average control of lodging area following an application of Chlormequat chloride 72% SL at 1.3-2.1 L/ha was 8.1-5.35%, compared to 9.5% achieved by 1.0 L/ha. Therefore, when evaluating the ability of Chlormequat chloride 72% SL to control lodging, a dose response was observed between the three dose rates applied in all trials.

Thus, it can be concluded that for Chlormequat chloride 72% SL to control lodging, and thereby protect the crop, Chlormequat chloride 72% SL has to be applied at 1.3-2.1L/ha to winter wheat.

Summary of all uses claimed on the label

Chlormequat chloride 72% SL applied at the recommended dose rates in winter wheat achieved excellent results in terms of reducing crop height as well as control of lodging when tested under a range of conditions in the three EPPO zones. The recommendation is therefore that Chlormequat chloride 72% SL should be applied once at the recommended dose rates to limit crop growth and thus, to protect the crop from lodging, as claimed on the label.

As will be demonstrated in the following section, this document clearly demonstrates that the efficacy and crop safety of Chlormequat chloride 72% SL is equivalent to that of the standard Chlormequat chloride reference products to which it was compared. The applicant therefore wishes to cite the original registrant's data on Chlormequat chloride now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Comments of zRMS:	<p>The trials submitted to support the MED (minimum effective dose) of CLARA (product code: SHA 126000 B) are the same as the efficacy trials described under section efficacy.</p> <p>To provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least two lower dose(s) than recommended dose. In the appropriate research of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance with EPPO 1/225 (2).</p> <p>23 field trials carried out in different growing seasons (2016 and 2017) on winter wheat were established to determine the minimum effective dose of CLARA. Trials were performed in three EPPO zones – N-E in PL (6 trials) and LT (3 trials); MED in FR (2 trials) and IT (2 trials) and</p>
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MAR in FR (4 trials), UK (2 trials), DE (2 trials) and CZ (2 trials). Three different doses were studied: 1,0 L/ha; 1,3 L/ha and 2,1 L/ha. All results were compared to standard reference products. In the trials, specifically targeted for height reduction, single application was applied at growth stages ranging between BBCH 29 and BBCH 32.

The proposed doses were derived from registered doses of standard reference products with chlormequat chloride as active compound and, product safety parameters and environmental limitations. Such products are used across Europe for many years and their MED (minimum effective dose) is justified. The proposed dose against lodging and growth reduction is 1,3 -2,1 L/ha applied once a season. Detailed results were presented by Applicant in the table: Table 3.2-8.

Minimum effective dose results:

- **N-E EPPO zone:** During 9 trials effect of reduction of height was observed. Control plants were characterized by average of 84,93 cm height. The most effective was dose 2,1 L/ha (average: 13,76% reduction of height in comparable to control plants). Effect of dose 1,3 L/ha (average: 12,59%) was slightly lower than dose 2,1 L/ha. Dose of 1,0 L/ha was characterized by 11,06% of reduction height of plants in comparable to control. The most effective against reduction of height was range of dose 1,3 -2,1 L/ha and this dose should be recommended for use.

Lodging was observed only in 2 trials on control plants (average: 54,4%). Dose 2,1 L/ha was the most effective in reducing of lodging (average: 10,9%). Dose 1,3 L/ha reduce of lodging (average: 25,0%) with average of efficacy and dose 1,0 L/ha (32,55%) average: was least effective. Applicant submitted too few studies to support anti-lodging action. At least 6 studies should have been submitted. However, even on such little number of trials it can be seen that the most effective against lodging is dose 2.1 L/ha. Also, dose 1.3 L/ha was characterized by good efficiency against lodging.

Trial ID	Country	Assess. Type	Untreated		Clormequat 72% SL 720 g ai/ha		Clormequat 72% SL 936 g ai/ha		Clormequat 72% SL 1510 g ai/ha	
			Mean	Stat.	Control	Stat.	Control	Stat.	Control	Stat.
110/2016	PL	Height (cm)	85.4	a	74.7	b	72.7	bc	71.9	bc
121/2016	PL	Height (cm)	119.9	a	103.1	b	97.3	c	95.5	c
122/2016	PL	Height (cm)	104.0	a	85.9	ab	86.5	ab	85.8	ab
142/2016	PL	Height (cm)	74.6	a	65.2	b	64.9	b	63.9	b
184 /2017	PL	Height (cm)	93.78	a	86.93	b	85.95	b	85.78	b
185/2017	PL	Height (cm)	85.78	a	77.9	b	77.18	b	76.45	b
LTZI2016PGR-02-01	LT	Height (cm)	55.2	a	53.4	ab	52.5	b	51.1	b
LTZI2016PGR-02-02	LT	Height (cm)	74.9	a	68.4	bc	67.5	bc	66.3	c
LTZI2016PGR-02-03	LT	Height (cm)	70.8	a	64.3	b	63.6	bc	62.4	c

Trial ID	Country	Crop GS at assessment	Assessm. Days after appl.	Assess. Type	Untreated		Clormequat 72% SL 720 g ai/ha		Clormequat 72% SL 936 g ai/ha		Clormequat 72% SL 1510 g ai/ha	
					Me an	Sta t.	% Con- trol	Sta t.	% Con- trol	Sta t.	% Con- trol	Sta t.
110/2016	PL	83	68	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
121/2016	PL	87	60	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
122/2016	PL	87	71	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
142/2016	PL	73	54	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
184 /2017	PL	87	83	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
185/2017	PL	77	77	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
LTZI2016PGR-02-01	LT	75	67	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		89	98	Lodging (0-100)	33.8	a	21.3	bc	22.5	b	11.0	d

					100)							
LTZI2016PGR-02-02	LT	75	55	Lodging (0-100)	27.5	a	0.0	a	0.0	a		
		89	84	Lodging (0-100)	75.0	a	43.8	b	27.5	bc		
LTZI2016PGR-02-03	LT	75	66	Lodging (0-100)	0.0	a	0.0	a	0.0	a		
		89	95	Lodging (0-100)	0.0	a	0.0	a	0.0	a		
<ul style="list-style-type: none">Maritime EPPO zone: During 10 trials effect of reduction of height was observed. Control plants were characterized by average of 89,01 cm height. The most effective was dose 2,1 L/ha (average: 6,3% reduction of height in comparable to control plants). Effect of dose 1,3 l/ha (average: 4,48%) was slightly lower than dose 2,1 L/ha. Dose of 1,0 L/ha was characterized by 3,91% of reduction height of plants in comparable to control. The most effective against reduction of height was dose 2,1 L/ha and this dose should be recommended for use. The dose of 1,3 l/ha as well as the dose of 1,0 had only retardant properties and their effectiveness was lower than 5%. So, cMS form Maritime should consider the acceptance of dose 2,1 L/ha, not range of doses 1,3-2,1 L/ha in the opinion of ZRMs. However, final decision is left to each cMS. <p>Lodging as LODARE (lodging area) was observed only in 4 trials (average: 16,83%) and as a LODANG (lodging angle) in 1 trial on control plants (average: 40,75%). Dose 2,1 L/ha was the most effective in reducing of lodging. Dose 1,3 L/ha reduce of lodging with average of efficacy and dose 1,0 L/ha average: was least effective. Applicant submitted too few studies to support anti-lodging action. At least 6 studies should have been submitted. cMS should decide if presented trials against lodging can be acceptable.</p>												
					Untreated		Clormequat 72% SL 720 g ai/ha		Clormequat 72% SL 936 g ai/ha		Clormequat 72% SL 1510 g ai/ha	
					Me an	Sta t.	% Con- trol	Sta t.	% Con- trol	Sta t.	% Con- trol	Sta t.
PC 16-05-12-NE1	FR	75	Height (cm)	79.9	a	78.1	a	79.4	a	77.5	a	
PC 16-05-12-WE1	FR	75	Height (cm)	95.0	a	92.3	b	91.6	bc	90.8	c	
SHA835-16-EFF001-001	UK	75	Height (cm)	91.25	a	85.7	b	86.25	b	85.0	b	
SHA835-16-EFF001-002	UK	-	Height (cm)	88.25	a	93.0	a	93.0	a	88.75	a	
Sharda16-046	DE	37	Height (cm)	71.6	a	68.3	b	67.0	b	67.4	b	
		73	Height (cm)	108.3	a	102.5	b	102.9	b	102.6	b	
Sharda16-047	DE	71	Height (cm)	111.0	a	107.0	b	107.0	b	104.0	c	
SWEPL-CZE16-CLOR-TRZAW-KUJ32	CZ	85	Height (cm)	79.8	a	75.6	b	74.4	bc	70.9	c	
SWEPL-CZE16-CLOR-TRZAW-RYM3	CZ	75	Height (cm)	61.3	a	57.4	a	56.5	c	56.1	c	
P17GC01UEN01	FR	31	Height (cm)	45.28	a	44.35	a	42.58	a	42.03	a	
		41	Height (cm)	76.6	a	67.3	b	63.7	b	62.38	b	
		89	Height (cm)	88.18	a	78.13	b	73.5	b	73.5	b	
P17GC01UEN02	FR	59	Height (cm)	84.1	a	82.98	a	83.45	a	82.68	a	
		69	Height (cm)	88.48	a	87.35	a	88.55	a	87.8	a	
		89	Height (cm)	87.15	a	85.6	a	85.68	a	84.83	a	
					Untreated		Clormequat 72% SL		Clormequat 72% SL		Clormequat 72% SL	
					Me	Sta	%	Sta	%	Sta	%	Sta

Trial ID	Country	assess- ment	Assess. Type			720 g ai/ha		936 g ai/ha		1510 g ai/ha	
				Mean	Stat.	% Con- trol	Sta- t.	% Con- trol	Sta- t.	% Con- trol	Sta- t.
PC 16-05-12-NE1	FR	61	LODARE (%)	0.0	a	0.0	a	0.0	a	0.0	a
		99	LODARE (%)	7.5	a	1.3	b	2.5	b	0.5	b
PC 16-05-12-WE1	FR	85	LODARE (%)	31.3	a	12.0	b	6.3	b	6.8	b
SHA835-16-EFF001-001	UK	89	LODARE (%)	1.0	a	0.3	b	0.0	a	0.0	a
SHA835-16-EFF001-002	UK	-	LODARE (%)	0.0	a	0.0	a	0.0	a	0.0	a
SWEPL-CZE16-CLOR-TRZAW-RYM3	CZ	77	LODARE (%)	27.5	-	0.0	a	0.0	a	0.0	a
		77	LODARE (%)	27.5	-	0.0	a	0.0	a	0.0	a

Trial ID	Country	Crop GS at as- sessment	Assess. Type	Untreated		Clormequat 72% SL 720 g ai/ha		Clormequat 72% SL 936 g ai/ha		Clormequat 72% SL 1510 g ai/ha	
				Mean	Stat.	% Con- trol	Stat.	% Con- trol	Stat.	% Con- trol	Stat.
Sharda16-046	DE	83	Lodging (0-100)	40.75	a	30.75	a	31.25	a	30.0	a
Sharda16-047	DE	63	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		71	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		81	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		89	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
P17GC01UEN01	FR	30	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		31	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		41	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		89	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
P17GC01UEN02	FR	41	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		59	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		69	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		89	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a

• **Mediterranean EPPO zone:** During 4 trials effect of reduction of height was observed. Control plants were characterized by average of 94,48 cm height. The most effective was dose 2,1 L/ha (average: 9,4% reduction of height in comparable to control plants). Effect of dose 1,3 L/ha (average: 6,06%) was lower than dose 2,1 L/ha. Dose of 1,0 L/ha was characterized by 2,82% of reduction height of plants in comparable to control. The most effective against reduction of height was range of dose 1,3 -2,1 L/ha and this dose should be recommended for use. However, cMS should decide if limited number of trials can be accepted or consider possibility of usage results from other zones.

Lodging as LODARE (lodging area) was observed only in 2 trials (average: 28,8%) and as a LODANG (lodging angle) in 1 trial on control plants (average: 0,2%). Dose 2,1 L/ha was the most effective in reducing of lodging. Dose 1,3 L/ha reduce of lodging with average of efficacy and dose 1,0 L/ha average: was least effective. Applicant submitted too few studies to support anti-lodging action. At least 6 studies should have been submitted. cMS should decide if present

ed trials against lodging can be acceptable.															
				Untreated		Clormequat 72% SL 720 g ai/ha		Clormequat 72% SL 936 g ai/ha		Clormequat 72% SL 1510 g ai/ha					
				Mea n	Stat .	% Con- trol	Stat .	% Con- trol	Stat .	% Con- trol	Stat .				
Trial ID	Coun- try	Crop GS at as- sessment	Assess. Type	036.H.SAG16/e	IT	75	Height (cm)	84.0 8	a	78.18	b	77.4	b	76.48	b
037.H.SAG15/e	IT	83	Height (cm)	68.6	a	65.2	ab	62.7	bc	61.4	bc				
PC 16-05-12-SW1	FR	83	Height (cm)	107. 8	a	109.1	a	103.7	a	106.3	a				
PC 16-05-12-SW2	FR	83	Height (cm)	116. 7	a	114.8	ab	111.2	b	102.2	d				
				Untreated		Clormequat 72% SL 720 g ai/ha		Clormequat 72% SL 936 g ai/ha		Clormequat 72% SL 1510 g ai/ha					
				Mea n	Stat .	% Con- trol	Stat .	% Con- trol	Stat .	% Con- trol	Stat .				
036.H.SAG16/e	IT	89	Lodging (0-100)	0.2	a	0.0	a	0.0	a	0.0	a				
037.H.SAG15/e	IT	73	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a				
		89	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a				
				Untreated		Clormequat 72% SL 720 g ai/ha		Clormequat 72% SL 936 g ai/ha		Clormequat 72% SL 1510 g ai/ha					
				Mea n	Stat .	% Con- trol	Stat .	% Con- trol	Stat .	% Con- trol	Stat .				
PC 16-05-12-SW1	FR	63	LODARE (%)	41.3	a	16.3	b	18.3	b	10.3	b				
		89	LODARE (%)	80.0	a	75.0	b	72.5	b	65.0	c				
PC 16-05-12-SW2	FR	75	LODARE (%)	16.3	a	15.0	a	10.0	a	7.5	a				
		89	LODARE (%)	26.3	a	27.5	a	15.0	b	11.3	b				
Summary: In the opinion of ZRMs, presented results and knowledge about registered doses of standard reference products with chlormequat chloride allow to consider range of dose 1,3 – 2,1 L/ha as the most effective for winter wheat against reduction of height for N-E and MED EPPO zone. cMS from MAR should consider only dose 2,1 L/ha as MED for CLARA.															
For lodging Applicant submitted too small number of trials. However, the most effective was dose 1,3 -2,1 L/ha. In PL this use can be accepted only conditionally.															

3.2.3 Efficacy tests (KCP 6.2)

Data from 23 efficacy trials conducted in the North-east (i.e. Poland (6) and Lithuania (3)), in the Maritime (i.e. France (4), United Kingdom (2), Germany (2) and Czech Republic (2)), and in the Mediterranean (i.e. France (2) and Italy (2)) EPPO zones have been included in this biological assessment dossier to support the label claims and recommendations on efficacy and selectivity in the EU Central Registration zone.

In the efficacy trials, the performance of Chlormequat chloride 72% SL was measured against a commercial standard SL formulation of Chlormequat chloride (Stabilan 750 SL) currently on the market in Europe. The trials were carried out on field crops of winter wheat.

In the 23 trials, the level of control obtained by Chlormequat chloride 72% SL was assessed by measuring the crop height at different timings as well as visually evaluating the lodging that occurred in some of the trials.

Table 3.2-8: Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/152(3/4), PP 1/181(3/4), PP 1/135(3/4)
	Specific guidelines	EPPO PP 1/93(3)
Experimental design	Plot design	RCBD (23)
	Plot size	14-30 m ²
	Number of replications	4 (23)
Crop	Trials per crop	Winter wheat (23)
	Varieties per crop	Winter wheat: Memory (2), Julius (4), Skagen (2), Ada, Famulus (2), Legenda, SY-MOISSON, Garcia, Silverstone, Edgar, Mescal, Elixer, Svitava, Magister, CELLULE (3), Descartes (2), FRUCTIDOR, GRANAMAX, Gallant, Evolution, Patras, Bohemia, Rumor, Genius, Balaton, ARKEOS, Palesio (2), Solehio, GALIBIER , Bologna, Oregrain
	Sowing period / plantation age	Winter wheat: Sep 10 th to Jun 29 th
Application	Crop stage (BBCH) * at application	Winter wheat (23): BBCH 29-32
	Timing Pest stage at appl. (1)	Post-emergence Prevention of lodging
	Number of appl. Intervals between appl.	1 (23) n.a.
	Spray volumes	200 - 300 L/ha
Assessment	Assessment types	-Measuring of average crop height (cm) per plot compared to 'untreated' ('untreated' = 0 % control); Reduction in crop height [(treated – untreated) / Untreated] = % control] -Visual estimation of lodging per plot compared to 'untreated' ('untreated' = 0 % control); total control = 100 % control)
	Assessment dates	30 to 95 DAT
Other relevant information	Soil type	Light to heavy soils
	Natural / artificial inoculation...	Natural
	Field / Greenhouse...	Field

Use 001: Limitation of growth, and thus control of lodging after a single application of 1.3-2.1 L/ha Chlormequat chloride 72% SL to winter wheat.

The efficacy trials were conducted to prove the following label claims:

Description of Use 01

Crop, stage	Winter wheat, post-emergence BBCH 29-32
-------------	--------------------------------------------

Use rate	1.3-2.1 L/ha Chlormequat chloride 72% SL
Use frequency	1x
Application timing	Post-emergence to crop in the spring
Target weeds	Limitation of growth and thus, prevention of Lodging in winter wheat

The summary of efficacy results obtained with the application of Chlormequat chloride 72% SL at 1.3-2.1 L/ha for the limitation of crop growth and as a consequence of this, control of lodging in winter wheat are listed in Table 3.2- for results from trials conducted in in the North-east (i.e. Poland (6) and Lithuania (3)), in the Maritime (i.e. France (4), United Kingdom (2), Germany (2) and Czech Republic (2)), and in the Mediterranean (i.e. France (2) and Italy (2)) EPPO zones. To demonstrate the effectiveness of the formulations, results obtained on crop height and lodging are presented. The data on crop height have been included in the summary when it appeared that the crop was most actively growing in the respective trials. Lodging was assessed at various timings, by visually estimating the lodging of the crop at a scale of 1-5, but included in the summary tables was the data from the assessment close to harvest.

On an overall level, when summarizing the results obtained in the three zones, the centimeters in crop height was 84.5-85.7 cm following an application of Chlormequat chloride 72% SL at the maximum recommended dose range rate (1.3-2.1 L/ha), compared to 85.03 cm achieved by the Chlormequat chloride reference product applied at the same dose rate (2.0 L/ha, i.e. 1500 g Chlormequat chloride /ha). Thus, when evaluating the ability of Chlormequat chloride 72% SL to act as a crop growth regulator, the two products performed equally. Shortly before harvest, the lodging was evaluated in the trials. In the fifteen trials, the average control of lodging following an application of Chlormequat chloride 72% SL at the maximum recommended dose range rate was 13.6-20.0%, compared to 15.9% achieved by the Chlormequat chloride reference product applied at the same dose rate. Thus, also when evaluating the ability of Chlormequat chloride 72% SL to control lodging, it was observed that the two products performed equally. Regarding the lodging area, the average control of lodging following an application of Chlormequat chloride 72% SL at the maximum recommended dose rate was 5.35-5.6%, compared to 4.1% achieved by the Chlormequat chloride reference product applied at the same dose rate. Thus, also when evaluating the ability of Chlormequat chloride 72% SL to control lodging, it was observed that the two products performed equally.

Table 3.2-11: North-east, Maritime and Mediterranean zone – Height reduction and lodging control results in winter wheat by 1.3-2.1 L/ha Chlormequat chloride 72% SL in the efficacy tests 2016 and 2017 (mean and variation in % control as compared to untreated check)

Parameter evaluated	Total No. of trials	Untreated	Efficacy obtained with			No. of trials where Chlormequat chloride 72% SL at 936-1510 g Chlormequat chloride /ha is >, < or =, compared to the Chlormequat chloride Ref. product at 1510 g Chlormequat chloride /ha = ; ± 5% control			Overall
			Chlormequat chloride 72% SL at:	Chlormequat chloride Ref. prod. At:					
		Mean (min-max)	Mean (min-max)						
		cm / %	936 g ai/ha	1510 g ai/ha	1500 g ai/ha	>	=	<	
Height reduction		cm		Height reduction (cm)					
Nort.East EPPO zone	9	87.35 (74.6-120)	85.1 (64.9-107)	83.78 (63.9-105.8)	84.1 (64.8-108.4)	4		5	<
Maritime EPPO zone	10	89.0 (61.3-111)	85.0 (56.5-107)	83.3 (56.1-104.0)	84.27 (55.8-105.0)	7		3	>
Mediterranean EPPO zone	4	94.29 (68.6-116)	88.8 (62.7-111)	86.5 (61.4-102.2)	86.72 (62.9-106.5)	3		1	>
Mean of all assessments	23	90.2 (61.3-120)	85.7 (56.5-111)	84.5 (56.1-105.8)	85.03 (55.8-108.4)	14		9	>
Lodging		%		% Control (reduction in lodging)					
Nort.East EPPO zone	7	54.4 (33.8-75.0)	25.0 (22.5-27.5)	10.9 (10.8-11.0)	21.9 (13.8-30.0)	7			>
Maritime EPPO zone	4	40.75 (40.75-40.75)	31.3 (31.3-31.3)	30.0 (30.0-30.0)	25.8 (25.8-25.8)			4	<
Mediterranean EPPO	2	0.2	0.0	0.0	0.0		2		=

Parameter evaluated	Total No. of trials	Untreated	Efficacy obtained with			No. of trials where Chlormequat chloride 72% SL at 936-1510 g Chlormequat chloride /ha is >, < or =, compared to the Chlormequat chloride Ref. product at 1510 g Chlormequat chloride /ha = : ± 5% control			Overall
			Chlormequat chloride 72% SL at:		Chlormequat chloride Ref. prod. At:				
		Mean (min-max)	Mean (min-max)						
		cm / %	936 g ai/ha	1510 g ai/ha	1500 g ai/ha	>	=	<	
zone		(0.2-0.2)	(0.0-0.0)	(0.0-0.0)	(0.0-0.0)				
Mean of all assessments	15	31.7 (0.2-75.0)	20.0 (0.0-31.3)	13.6 (0.0-30.0)	15.9 (0.0-30.0)	7	2	4	>
Lodging area		%	% Control (reduction in lodging area)						
Maritime EPPO zone	5	16.9 (1.0-31.3)	2.2 (0.0-6.3)	1.8 (0.0-6.8)	1.57 (0.0-5.3)	1	3	1	=
Mediterranean EPPO zone	2	28.8 (16.3-41.3)	14.2 (10.0-18.3)	8.9 (7.5-10.3)	6.65 (2.5-10.8)	2			>
Mean of all assessments	7	22.85 (1.0-41.3)	5.6 (0.0-18.3)	5.35 (0.0-10.3)	4.1 (0.0-10.8)	3	3	1	>

Thus, in all parameters evaluated, the effect obtained with Chlormequat chloride 72% SL was similar to slightly superior to the effect obtained with the Chlormequat chloride reference products applied in the trials.

Summary and conclusion

Based on the results of 23 field trials carried out in spring 2016 and 2017, the following can be concluded for the intended use '*Limitation of growth in cereals*' from Chlormequat chloride 72% SL applied at the recommended dose rates:

- Chlormequat chloride 72% SL provides a high level of reduction in crop height as well as control of lodging in the GAP claimed crops with the recommended dose rate of 1.3-2.1 L/ha in winter wheat.
- Compared to the Chlormequat chloride reference product, the efficacy obtained with Chlormequat chloride 72% SL is comparable in winter wheat.
- The trial results are considered valid for all intended Central zone countries.

Chlormequat chloride 72% SL is suitable for the limitation of growth and thus control of lodging in the GAP claimed crops.

The same level of reductions in crop height as well as control of lodging was observed in winter wheat treated with Chlormequat chloride 72% SL. When treating the crop at similar growth stages, the same level of control would be expected in all GAP claimed crops and this has been seen in the trials.

This document also clearly demonstrates that the efficacy and crop safety of Chlormequat chloride 72% SL is equivalent to the efficacy and crop safety of the standard Chlormequat chloride reference product (i.e. Stablan 750 SL) against which Chlormequat chloride 72% SL was compared. The applicant therefore wishes to cite the original registrant's data on Chlormequat chloride now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Comments of zRMS:	<p>Lodging in cereals was evaluated in accordance with the EPPO standards PP 1/144(3). Details of experiment are presented in the table above by Applicant. All used methodology is in accordance with GEP rules and EPPO standards, in the exception with EPPO 1/181 (4) for winter wheat in MED EPPO zone (all trials were carried out only in one growing season – 2016). In N-E (2016 and 2017) and MAR (2016 and 2017) – two different growing seasons were studied in line to EPPO.</p> <p>We are dealing with the active substance used commonly for many years in many countries. On the basis on EPPO standard Applicant should submitted for reduction height and against lodging</p>
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at least six trials for each EPPO zone. For Poland trials from neighbouring countries are acceptable. Submitted documentations is sufficient in the opinion of Evaluator for winter wheat for MAR (10 trials) and N-E (9 trials) against reduction of height. cMS from MED should decide if limited number of trials (only 4 trials) carried out in one growing season can be acceptable or consider possibility of usage results from other EPPO zones.

Prevention use against lodging can **not** be acceptable in Polish label due to **not-enough limited** number of trials **only conditionally**. cMS from N-E, MAR and MED should consider if it is possible to use results from other chlormequat chloride products due to very limited number of trials against lodging.

- **N-E EPPO zone:** Below, ZRMs presented detailed results from all trials separately for reduction of growth and lodging which was assessed.

Trial ID	Country	Crop GS at assessment	Assess. Type	Untreated		Clormequat 72% SL 936 g ai/ha		Clormequat 72% SL 1510 g ai/ha		Clormequat ref. prod. 1125-1500 g ai/ha	
				Mean	Stat.	% Control	Stat.	% Control	Stat.	% Control	Stat.
110/2016	PL	83	Height (cm)	85.4	a	72.7	bc	71.9	bc	70.2	c
121/2016	PL	87	Height (cm)	119.9	a	97.3	c	95.5	c	94.7	d
122/2016	PL	87	Height (cm)	104.0	a	86.5	ab	85.8	ab	84.6	b
142/2016	PL	73	Height (cm)	74.6	a	64.9	b	63.9	b	64.8	b
184 /2017	PL	87	Height (cm)	93.78	a	85.95	b	85.78	b	85.38	b
185/2017	PL	77	Height (cm)	85.78	a	77.18	b	76.45	b	75.53	b
LTZI2016PGR-02-01	LT	39	Height (cm)	55.2	a	52.5	b	51.1	b	52.3	b
		51	Height (cm)	77.6	a	73.2	bc	71.7	c	73.5	bc
		75	Height (cm)	92.6	a	86.9	cd	84.4	e	86.3	d
		89	Height (cm)	89.8	a	83.9	cd	82.4	d	85.2	bc
LTZI2016PGR-02-02	LT	45	Height (cm)	74.9	a	67.5	bc	66.3	c	67.5	bc
		55	Height (cm)	120.7	a	107.4	cd	105.8	d	108.4	bc
		75	Height (cm)	117.5	a	105.6	cd	103.5	d	106.4	bc
		89	Height (cm)	109.7	a	103.3	b	100	c	101.8	bc
LTZI2016PGR-02-03	LT	39	Height (cm)	70.8	a	63.6	bc	62.4	c	63.0	bc
		51	Height (cm)	90.8	a	78.4	bc	75.6	d	77.9	c
		75	Height (cm)	99.4	a	87.1	cd	84.5	e	87.0	cd
		89	Height (cm)	99.7	a	86.2	c	84.2	d	86.2	c

Trial ID	Country	Crop GS at assessment	Assess. Type	Untreated		Clormequat 72% SL 936 g ai/ha		Clormequat 72% SL 1510 g ai/ha		Clormequat ref. prod. 1125-1500 g ai/ha	
				Mean	Stat.	% Control	Stat.	% Control	Stat.	% Control	Stat.
110/2016	PL	83	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
121/2016	PL	87	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a

122/2016	PL	87	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
142/2016	PL	73	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
184 /2017	PL	87	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
185/2017	PL	77	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
LTZI2016PGR-02-01	LT	75	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		89	Lodging (0-100)	33.8	a	22.5	b	11.0	d	13.8	cd
LTZI2016PGR-02-02	LT	75	Lodging (0-100)	27.5	a	0.0	a	0.0	a	0.0	a
		89	Lodging (0-100)	75.0	a	27.5	bc	10.8	c	30.0	bc
LTZI2016PGR-02-03	LT	75	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		89	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a

During 9 trials effect of reduction of height was observed. Control plants were characterized by average of 84,93 cm height. The most effective was dose 2,1 L/ha (average: 13,76% reduction of height in comparable to control plants). Effect of dose 1,3 l/ha (average: 12,59%) was slightly lower than dose 2,1 L/ha. The most effective against reduction of height was range of dose 1,3 - 2,1 L/ha and this dose should be recommended for use. CLARA at both recommended doses (1,3 and 2,1 L/ha) has better efficacy in reduction of height than standard ref. product (average; 0,97%).

Lodging was observed only in 2 trials on control plants (average: 54,4%). Dose 2,1 L/ha was the most effective in reducing of lodging (average: 10,9%). Dose 1,3 L/ha reduce of lodging (average: 25,0%) with average of efficacy. St. ref. product has lower efficiency in control of lodging (average: 21,9%) than CLARA used at 2,1 L/ha dose and slightly better than CLARA at dose 1,3 L/ha. Applicant submitted too few studies to support anti-lodging action. **At least 6 studies should have been submitted. So, only conditional registration in PL is recommended by ZRMs.**

- Maritime EPPO zone:** Below, ZRMs presented detailed results from all trials separately for reduction of growth and lodging which was assessed.

Trial ID	Country	Crop GS at assessment	Assess. Type	Untreated		Clomequat 72% SL 936 g ai/ha		Clomequat 72% SL 1510 g ai/ha		Clomequat ref. prod 1500-1575 g ai/ha	
				Me an	Sta t.	% Con- trol	Sta t.	% Con- trol	Sta t.	% Con- trol	Sta t.
PC 16-05-12-NE1	FR	75	Height (cm)	79.9	a	79.4	a	77.5	a	77.7	a
PC 16-05-12-WE1	FR	75	Height (cm)	95.0	a	91.6	bc	90.8	c	90.9	c
SHA835-16-EFF001-001	UK	75	Height (cm)	91.2 5	a	86.25	b	85.0	b	85.75	b
SHA835-16-EFF001-002	UK	-	Height (cm)	88.2 5	a	93.0	a	88.75	a	96.75	a
Sharda16-046	DE	37	Height (cm)	71.6	a	67.0	b	67.4	b	66.6	b
		73	Height (cm)	108. 3	a	102.9	b	102.6	b	102.2	b
Sharda16-047	DE	71	Height (cm)	111. 0	a	107.0	b	104.0	c	105.0	c
SWEPL-CZE16-CLOR-TRZAW-KUJ32	CZ	85	Height (cm)	79.8	a	74.4	bc	70.9	c	71.1	c
SWEPL-CZE16-CLOR-TRZAW-RYM3	CZ	75	Height (cm)	61.3	a	56.5	c	56.1	c	55.8	c
P17GC01UEN01	FR	31	Height (cm)	45.2 8	a	42.58	a	42.03	a	42.8	a
		41	Height	76.6	a	63.7	b	62.38	b	62.35	b

			89	(cm) Height (cm)	88.1 8	a	73.5	b	73.5	b	72.6	b
	P17GC01UEN02	FR	59	Height (cm)	84.1	a	83.45	a	82.68	a	82.0	a
			69	Height (cm)	88.4	a	88.55	a	87.8	a	87.55	a
			89	Height (cm)	87.1	a	85.68	a	84.83	a	84.93	a
					Untreated		Clormequat 72% SL 936 g ai/ha		Clormequat 72% SL 1510 g ai/ha		Clormequat ref. prod. 1500-1575 g ai/ha	
Trial ID	Coun- try	Crop GS at as- essment	Assess. Type		Mea n	Sta t.	% Con- trol	Sta t.	% Con- trol	Sta t.	% Con- trol	Sta t.
PC 16-05-12-NE1	FR	61	LODARE (%)		0.0	a	0.0	a	0.0	a	0.0	a
		99	LODARE (%)		7.5	a	2.5	b	0.5	b	1.0	b
PC 16-05-12-WE1	FR	85	LODARE (%)		31.3	a	6.3	b	6.8	b	5.3	b
SHA835-16-EFF001-001	UK	89	LODARE (%)		1.0	a	0.0	a	0.0	a	0.0	b
SHA835-16-EFF001-002	UK	-	LODARE (%)		0.0	a	0.0	a	0.0	a	0.0	a
SWEPL-....-TRZAW-RYM3	CZ	77	LODARE (%)		27.5	-	0.0	a	0.0	a	0.0	a
		77	LODARE (%)		27.5	-	0.0	a	0.0	a	0.0	a
					Untreated		Clormequat 72% SL 936 g ai/ha		Clormequat 72% SL 1510 g ai/ha		Clormequat ref. prod. 1500-1575 g ai/ha	
Trial ID	Coun- try	Crop GS at as- essment	Assess. Type		Mea n	Stat .	% Con- trol	Stat .	% Con- trol	Stat .	% Con- trol	Stat .
Sharda16-046	DE	83	Lodging (0-100)		40.7	a	31.25	a	30.0	a	25.8	a
Sharda16-047	DE	63	Lodging (0-100)		0.0	a	0.0	a	0.0	a	0.0	a
		71	Lodging (0-100)		0.0	a	0.0	a	0.0	a	0.0	a
		81	Lodging (0-100)		0.0	a	0.0	a	0.0	a	0.0	a
		89	Lodging (0-100)		0.0	a	0.0	a	0.0	a	0.0	a
P17GC01UEN01	FR	30	Lodging (0-100)		0.0	a	0.0	a	0.0	a	0.0	a
		31	Lodging (0-100)		0.0	a	0.0	a	0.0	a	0.0	a
		41	Lodging (0-100)		0.0	a	0.0	a	0.0	a	0.0	a
		89	Lodging (0-100)		0.0	a	0.0	a	0.0	a	0.0	a
P17GC01UEN02	FR	41	Lodging (0-100)		0.0	a	0.0	a	0.0	a	0.0	a
		59	Lodging (0-100)		0.0	a	0.0	a	0.0	a	0.0	a
		69	Lodging (0-100)		0.0	a	0.0	a	0.0	a	0.0	a
		89	Lodging (0-100)		0.0	a	0.0	a	0.0	a	0.0	a
<p>During 10 trials effect of reduction of height was observed. Control plants were characterized by average of 89,01 cm height. The most effective was dose 2,1 L/ha (average: 6,3% reduction of height in comparable to control plants). Effect of dose 1,3 l/ha (average: 4,48%) was slightly lower than dose 2.1 L/ha. The most effective against reduction of height was dose 2.1 L/ha and</p>												

this dose should be recommended for use. The dose of 1,3 l/ha had only retardant properties and their effectiveness was lower than 5%. CLARA at recommended dose 2,1 L/ha has better efficacy and at dose 1,3 L/ha slightly lower (average: 4,48%) in reduction of height than standard ref. product (average; 5,32%). Final decision about accepted dose is left to each cMs.

Lodging as LODARE (lodging area) was observed only in 4 trials (average: 16,83%) and as a LODANG (lodging angle) in 1 trial on control plants (average: 40,75%). Dose 2,1 L/ha was the most effective in reducing of lodging. Dose 1,3 L/ha reduce of lodging with average of efficacy was less effective than dose 2,1 L/ha. Results were similar to st. ref. product. Applicant submitted too few studies to support anti-lodging action. At least 6 studies should have been submitted. cMS should decide if presented trials against lodging can be acceptable.

- **Mediterranean EPPO zone:** Below, ZRMs presented detailed results from all trials separately for reduction of growth and lodging which was assessed.

Trial ID	Country	Crop GS at assessment	Assess. Type	Untreated		Clormequat 72% SL 936 g ai/ha		Clormequat 72% SL 1510 g ai/ha		Clormequat ref. prod. 1515-1575 g ai/ha	
				Mean	Stat.	% Control	Stat.	% Control	Stat.	% Control	Stat.
036.H.SAG16/e	IT	75	Height (cm)	84.08	a	77.4	b	76.48	b	75.58	b
037.H.SAG15/e	IT	83	Height (cm)	68.6	a	62.7	bc	61.4	bc	62.9	bc
PC 16-05-12-SW1	FR	83	Height (cm)	107.8	a	103.7	a	106.3	a	106.5	a
PC 16-05-12-SW2	FR	83	Height (cm)	116.7	a	111.2	b	102.2	d	101.9	d

Trial ID	Country	Crop GS at appl. BBCH	Crop GS at assessment	Assess. Type	Untreated		Clormequat 72% SL 936 g ai/ha		Clormequat 72% SL 1510 g ai/ha		Clormequat ref. prod 1515 g ai/ha	
					Mean	Stat.	% Control	Stat.	% Control	Stat.	% Control	Stat.
036.H.SAG 16/e	IT	29	89	Lodging (0-100)	0.2	a	0.0		0.0	a	0.0	a
037.H.SAG 15/e	IT	31 (29-31)	73	Lodging (0-100)	0.0	a	0.0		0.0	a	0.0	a
			89	Lodging (0-100)	0.0	a	0.0		0.0	a	0.0	a

Trial ID	Country	Crop GS at assessment	Assess. Type	Untreated		Clormequat 72% SL 936 g ai/ha		Clormequat 72% SL 1510 g ai/ha		Clormequat ref. prod. 1575 g ai/ha	
				Mean	Stat.	% Control	Stat.	% Control	Stat.	% Control	Stat.
PC 16-05-12-SW1	FR	63	LODARE (%)	41.3	a	18.3	b	10.3	b	10.8	b
		89	LODARE (%)	80.0	a	72.5	b	65.0	c	66.3	c
PC 16-05-12-SW2	FR	75	LODARE (%)	16.3	a	10.0	a	7.5	a	2.5	a
		89	LODARE (%)	26.3	a	15.0	b	11.3	b	7.8	b

During 4 trials effect of reduction of height was observed. Control plants were characterized by average of 94,48 cm height. The most effective was dose 2,1 L/ha (average: 9,4% reduction of height in comparable to control plants). Effect of dose 1,3 l/ha (average: 6,06%) was lower than dose 2,1 L/ha. The most effective against reduction of height was range of dose 1,3 -2,1 L/ha and this dose should be recommended for use. CLARA at recommended dose 2,1 L/ha has better

	<p>efficacy and at dose 1,3 L/ha has lower (average: 4,48%) in reduction of height than standard ref. product (average; 8,21%). However, cMS should decide if limited number of trials can be accepted or consider possibility of usage results from other zones.</p> <p>Lodging as LODARE (lodging area) was observed only in 2 trials (average: 28,8%) and as a LODANG (lodging angle) in 1 trial on control plants (average: 0,2%). Dose 2,1 L/ha was the most effective in reducing of lodging. Results were comparable to st. ref. product. Dose 1,3 L/ha reduce of lodging with average of efficacy. Applicant submitted too few studies to support anti-lodging action. At least 6 studies should have been submitted. cMS should decide if presented trials against lodging can be acceptable.</p> <p>Regarding comment about number of results for each use (lodging and reduction of growth) it would be like to indicate that according to the EPPO standard PP 1/226: the full number of trials is needed particularly for plant protection products or active substances which have not been on the market in the region in which authorization is sought, or for intended uses for which no extrapolation of any aspect of efficacy from other uses is possible. Chlormequat chloride is well known, as it has been marketed for many years for use in a broad number of crops to act as a regulation of growth. In addition, comparability of performance of the tested product with the reference is proved. So, cMS should decide if CLARA (product code: SHA 126000 B) can be accepted by them only on the basis on extrapolation results from N-E EPPO, MED EPPO zone and/or Maritime EPPO zone.</p> <p>According to EPPO PP 1/144 Reduction of lodging in cereals, an assessment of lodging and height was done during efficacy trials. The crop height reduction led to a reduction of lodging in trials where lodging was observed. The target dose reached the highest efficacy. CLARA (product code: SHA 126000 B) provided an acceptable level of reduction in crop height as well as control of lodging in the GAP claimed crop with the recommended dose rate in winter wheat.</p> <p>In summary, ZRMs consents to the registration of the product in Poland against reduction of height (13 trials: PL-6, LT-3, CZ-2, DE-2) in winter wheat in the range of dose 1,3 -2,1 L/ha. Due to not enough number of trials (4 trials: LT-2, CZ-1, DE-1), lodging in PL cannot be accepted only conditionally. At least 6 valid trials carried out in N-E EPPO zone or neighbouring country to PL from another zone. Considering the fact that the retardant action is intended to contribute to the limitation of lodging and, as confirmed in many years of practice, such an effect of products containing CCC, it would be advisable to consider conditional registration of the substance (without limitations in the description/scope of action on its label). Within two years of registration, the Applicant should submit at least two studies from the North-Eastern EPPO zone on the efficacy of the registered substance in limiting/preventing lodging. ZRMs recommend the conditionally registration of prevention against lodging in PL.</p> <p>It is left to the Member States to decide on the acceptability of the results presented in this dRR and to consider registration of CLARA on the basis on submitted documentation.</p>
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3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

3.3.1 Summary and Conclusions

Resistance is a natural phenomenon embodied in the process of the evolution of biological systems and has been experienced over and over again in the past. According to Heap (2018²) resistance is the naturally occurring inheritable ability of some weed biotypes within a population to survive an herbicide treat-

² Heap, I. M., 2018: The International Survey of Herbicide Resistant Weeds. Web site visited January 2018.
<http://www.weedscience.com>

ment that would, under normal conditions of use, effectively control that weed population. Selection of resistant biotypes may eventually result in control failures.

This category does not apply since quaternary ammonium compounds like chlormequat-chloride have been used successfully for decades in plant production systems for the reduction of unwanted longitudinal shoot growth. The applicant proposes that from the type of use and the nature of the underlying mode of action it is extremely unlikely that any plant species would lose its sensitivity to this type of plant growth regulator.

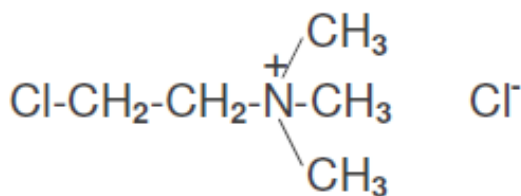
The Registration of Chlormequat chloride 72% SL is endorsed.

3.3.2 Mode of Action

Chlormequat-chloride belongs to the group of quaternary ammonium compounds that inhibit gibberellin (GA) metabolism. The biosynthesis of GAs can be separated into three stages according to the nature of the enzymes involved and the corresponding localisation in the cell: Terpene cyclases acting in proplastids, monooxygenases associated with the endoplasmatic reticulum and dioxygenases located in the cytosol. Chlormequat-chloride blocks the cyclases copalyl diphosphate synthase and ent-kaurene synthase involved in the early steps of GA metabolism. Then primarily through the conversion of geranylgeranyl diphosphate into copalyl diphosphate, but also to a lower degree of activity, the formation of ent-kaurene is inhibited.

The chemical structure of Chlormequat-chloride is shown in Figure 3.3-1.

Figure 3.3-1: Structure of Chlormequat-chloride (Source: Draft Assessment Report (DAR). Initial risk assessment provided by the rapporteur Member State United Kingdom for the existing active substance CHLORMEQUAT of the third stage (part B) of the review programme referred to in Article 8(2) of Council Directive 91/414/EEC Volume 1. Thursday, March 18th, 2021.



3.3.3 Mechanism(s) of resistance

Since Chlormequat chloride 72% SL is a plant growth regulator, the crop is the target of the application and not any pests as such. It is therefore not applicable to describe the possible development of resistance or cross-resistance of the crop towards Chlormequat chloride.

3.3.4 Evidence of resistance

Since Chlormequat chloride 72% SL is a plant growth regulator, the crop is the target of the application and not any pests as such. It is therefore not applicable to describe the possible development of resistance or cross-resistance of the crop towards Chlormequat chloride.

3.3.5 Cross-resistance

Since Chlormequat chloride 72% SL is a plant growth regulator, the crop is the target of the application and not any pests as such. It is therefore not applicable to describe the possible development of resistance or cross-resistance of the crop towards Chlormequat chloride.

3.3.6 Sensitivity data

The extent of growth reduction varies with the rate and timing of application also different plant species may have different degrees of sensitivity towards chlormequat-chloride.

3.3.7 Use pattern

Chlormequat chloride 72% SL is based on the activity of Chlormequat chloride which is a post-emergence plant growth regulator. In the EU Central zone, the formulation is proposed for use as a prevention of lodging in winter wheat during the growing season (BBCH 29-32). The recommended dose rate is 1.3-2.1 L/ha (936-1510 g ai/ha) in winter wheat, The maximum number of applications is one application per growing season.

3.3.8 Resistance Risk Assessment of unrestricted use patterns

This category does not apply since quaternary ammonium compounds like chlormequat-chloride have been used successfully for decades in plant production systems for the reduction of unwanted longitudinal shoot growth. The applicant proposes that from the type of use and the nature of the underlying mode of action it is extremely unlikely that any plant species would lose its sensitivity to this type of plant growth regulator.

3.3.9 Acceptability of the resistance risk

Not applicable.

3.3.10 Management strategy for Chlormequat chloride 72% SL

This category does not apply since quaternary ammonium compounds like chlormequat-chloride have been used successfully for decades in plant production systems for the reduction of unwanted longitudinal shoot growth. The applicant proposes that from the type of use and the nature of the underlying mode of action it is extremely unlikely that any plant species would lose its sensitivity to this type of plant growth regulator.

3.3.11 Implementation of the management strategy

Not applicable

3.3.12 Monitoring, reporting and reaction to changes in performance

Not applicable.

Comments of zRMS:	ZRMs agree with Applicant. An assessment of resistance risk is not required for a
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	plant growth regulator. Chlormequat chloride is successful use since decades in plant production systems for the reduction of unwanted longitudinal shoot growth. From the type of use and the nature of the underlying mode of action it is extremely unlikely that any plant species would lose its sensitivity to this type of plant growth regulator.
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3.4 Adverse effects on treated crops (KCP 6.4)

Information on trials submitted (3.4: Adverse effects on treated crops)

Table 3.4-1: Presentation of selectivity trials

Crop*	Country	Type of trial**	Number of trials				Years	GEP, non-GEP, official***	Comments (any other relevant information)
			EPPO zone						
			MAR	MED	S-E	N-E			
TRZAW	Poland	Q + Y + S	-	-	-	2 (2)	2016	GEP	
	Poland	Q + Y + S	-	-	-	2 (2)	2017	GEP	
	Lithuania	Q + Y + S	-	-	-	2 (2)	2016	GEP	
	France	Q + Y + S	2 (2)	2 (2)	-	-	2016	GEP	
	United Kingdom	Q + Y + S	2 (2)	-	-	-	2016	GEP	
	Germany	Q + Y + S	2 (2)	-	-	-	2017	GEP	
	Czech Republic	Q + Y + S	2 (2)	-	-	-	2016	GEP	
	France	Q + Y + S	2 (2)	-	-	-	2017	GEP	
	Italy	Q + Y + S		2 (2)	-	-	2016	GEP	
	Hungary	Q + Y + S	-	-	2 (2)	-	2016	GEP	
	Total, Winter wheat (Sel.)		10 (10)	4 (4)	2 (2)	6 (6)			
	Total		10 (10)	4 (4)	2 (2)	6 (6)			

Table 3.4-2: Details on selectivity trial methodology

Guidelines	General guidelines	EPPO PP 1/152 (3/4), PP 1/181 (3/4), PP 1/135(3/4)
	Specific guidelines	EPPO PP 1/93(3)
Experimental design	Plot design	RCBD (22)
	Plot size	10.5-30 m ²
	Number of replications	4 (22)
Crop	Trials per crop	Winter wheat (22)
	Varieties per crop	Winter wheat: Legenda, Julius (3), Memory, Famulus, Skagen, FRUCTIDOR, GRANAMAX, Gallant, Evolution, Patras, Bohemia, Rumor, CELLULE (2), Descartes, Genius, Balaton, Bologna, Palesio, Oregain
	Sowing period	Winter wheat: Sep 10 th to Jun 29 th
Application	Application period	Post-emergence Prevention of lodging
	Crop stage (BBCH)* at application	Winter wheat (22): BBCH 29-32

	Number of appl. Intervals between appl.	1 (22 trials) n.a.
	Spray volumes	200-300 L/ha
Assessment	Assessment types	-Measuring of average crop height (cm) per plot compared to 'untreated' ('untreated' = 0 % control); Reduction in crop height [(treated – untreated) / Untreated] = % control) - Visual estimation of lodging per plot compared to 'untreated' ('untreated' = 0 % control); total control = 100 % control)
	Assessment dates	30 to 95 DAT
Other relevant information	Soil type	Sandy loam (7), Sandy clay (2), Loam (3), Clay loam (3), clay sandy loam (2), Clay, Sandy silt loam, Sand, Silt, Sandy silt
	Organic matter content	<1.5%(6), 1.5 to 2.49%(5); 2.5 to 3.5%(5), >3.5%(3); not indicated(2)
	pH	6.1-8.31
	Natural / artificial inoculation...	Preferably weed-free conditions
	Field / Greenhouse...	Field

In selectivity trials, the performance of Chlormequat chloride 72% SL was measured against a commercial standard formulation of Chlormequat chloride currently on the market in Central, Northern and Southern Europe (Stabilan 750 SL). The trials were carried out on winter wheat.

The reference products used in the trials are listed in Table 3.4-3.

Table 3.4-3: Presentation of reference standards used in trials (selectivity trials, transformation trials...)

Trade name	Formulation	Composition	Rates [l/ha]	Indication	Country	N° of trials
STABILAN 750 SL	SL	Chlormequat chloride 750 g/l	1.5 l/ha	Regulation of growth, prevention of lodging	PL	4
			2.0 l/ha		LT	2
			2.1 l/ha		FR	6
			3.0 l/ha		UK	2
			3.28 l/ha		DE	2
			4.0 l/ha		CZ	2
			4.2 l/ha		IT	2
			6.56 l/ha		HU	2

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

The crop safety of Chlormequat chloride 72% SL was assessed in winter wheat in 23 efficacy trials (9 N-E, 10 MAR, and 4 MED) where Chlormequat chloride 72% SL was applied at dose ranging from 1.0 L/ha to 3.28 L/ha and in 22 crop safety trials (6 N-E, 10 MAR, 2 S-E and 4 MED) where Chlormequat chloride 72% SL was applied at dose ranging from 1.5 L/ha to 6.56 L/ha.

The trials were conducted in the North-east zone (15; Poland (10) and Lithuania (5)), the Maritime zone (20; France (8), United Kingdom (4), Germany (4) and Czech Republic (4)), the South-east zone (2; Hungary (2)) and the Mediterranean zone (8; Italy (4) and France (4)) in 2016 and 2017 to evaluate the crop safety of Chlormequat chloride 72% SL in winter wheat.

3.4.1.1 Winter wheat

Crop phytotoxicity was evaluated in efficacy- and selectivity trials where Chlormequat chloride 72% SL was applied post-emergence, at growth stages ranging between BBCH 29 and BBCH 32, at the rate of 1.3 to 4.2 L/ha. 4.2 L/ha corresponds to 200% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals, from application and up to harvest (BBCH 89).

Phytotoxicity in winter wheat trials, North-east EPPO zone

9 efficacy trials and 6 selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of Chlormequat chloride 72% SL when applied as recommended in winter wheat. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in any of the 9 efficacy trials as well as no adverse effects were observed in the 6 selectivity trials conducted in the North-east EPPO zone. Furthermore, the applied treatments did not have any detrimental effects on the yield or grain quality, as will be demonstrated in the following sections.

Phytotoxicity in winter wheat trials, Maritime EPPO zone

10 efficacy trials and 10 selectivity trials were conducted in the Maritime EPPO zone to assess the crop safety of Chlormequat chloride 72% SL when applied as recommended in winter wheat. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in any of the 10 efficacy trials as well as no adverse effects were observed in the 10 selectivity trials conducted in the Maritime EPPO zone. Furthermore, the applied treatments did not have any detrimental effects on the yield or grain quality, as will be demonstrated in the following sections.

Phytotoxicity in winter wheat trials, South-east EPPO zone

Two selectivity trials were conducted in the South-east EPPO zone to assess the crop safety of Chlormequat chloride 72% SL when applied as recommended in winter wheat. The trials were conducted on a range of commercially available varieties.

No adverse effects in regard to phytotoxicity, or lodging were observed in any of the two selectivity trials. Furthermore, the applied treatments did not have any detrimental effects on the yield or grain quality, as will be demonstrated in the following sections.

Phytotoxicity in winter wheat trials, Mediterranean EPPO zone

Four efficacy trials and four selectivity trials were conducted in the Mediterranean EPPO zone to assess the crop safety of Chlormequat chloride 72% SL when applied as recommended in winter wheat. The trials were conducted on a range of commercially available varieties

No adverse effects in regard to phytotoxicity were observed in three of the 4 efficacy trials as well as no adverse effects were observed in three of the 4 selectivity trials conducted in the Mediterranean EPPO zone. In one efficacy trial and in one selectivity trial, conducted on the variety Arkeos and the variety Palesio, minor phytotoxicity was observed as reduction of vigor in the plots treated with Chlormequat chloride 72% SL. Comparable phytotoxicity was also observed in the plots treated with the standard Chlormequat chloride reference product.

The phytotoxicity observed in the Mediterranean trials is presented in **Błąd! Nie można odnaleźć źródła odwołania..**

Table 3.4-6: Visual assessment of crop phytotoxicity in winter wheat treated with Chlormequat chloride 72% SL in efficacy and selectivity trials (maximum crop phytotoxicity observed).

Trial number	Crop	Variety	Ass. date DAA	UTC	Max. phytotoxicity [%]				Type of phytotoxicity
					Chlormequat chloride 72% SL		Chlormequat chloride Ref.		
					1.3 L/ha	2.1 L/ha	1.25 L/ha	2.0 L/ha	Symptom
Efficacy trials									
036.H.SAG16/e	TRZAW	ARKEOS	30	100.0	97.8	95.0	94.8	94.0	VIGOR (%)
Trial number	Crop	Variety	Ass. date DAA	UTC	Max. phytotoxicity [%]				Type of phytotoxicity
					Chlormequat chloride 72% SL		Chlormequat chloride Ref.		
					2.1 L/ha	4.2 L/ha	2.0 L/ha	4.0 L/ha	Symptom
Selectivity trials									
039.H.SAG16/e	TRZAW	Palesio	30	95.0	94.0	94.0	94.0	94.0	VIGOR (%)

Furthermore, the applied treatments did not have any detrimental effects on the yield or grain quality, as will be demonstrated in the following sections.

Table 3.4-7: Phytotoxicity of product

Number of trials with...		Selectivity trials (22 trials)				Efficacy trials (23 trials)	
		Test product		Standard 1		Test product	Standard 1
		2.1 L/ha	4.2 L/ha	2.0 L/ha	4.0 L/ha	1.3/2.1 L/ha	1.3/2.1 L/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	21	21	21	21	22	22
	>5% to 10%	1	1	1	1	1	1
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	21	21	21	21	22	22
	>5% to 10%	1	1	1	1	1	1
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0

3.4.1.2 Overall conclusion

Winter wheat is claimed on the label. The claims of crop safety on winter wheat are supported with a total of 45 trials conducted in Poland, Germany, Lithuania, United Kingdom, France, Czech Republic, Italy and Hungary. In all trials, Chlormequat chloride 72% SL proved to be crop safe and in the vast majority of the trials did not significantly affect the crop adversely when applied at a range of growth stages within and occasionally beyond the label recommended range at the maximum proposed label recommended rates of 2.1 L/ha in winter wheat. The same was observed in the treatments where Chlormequat chloride 72% SL was applied at twice the recommended rates or more, representative of sprayer overlap.

This document also clearly demonstrates that the efficacy and crop safety of Chlormequat chloride 72% SL is equivalent to the standard Chlormequat chloride 72% SL products to which it was compared. The applicant therefore wishes to cite the original registrant's data on Chlormequat chloride now out of pro-

tection in additional support of any recommendations on the draft label that are not adequately supported by the applicant's data and requests that the zonal evaluator extrapolate from those data.

<p>Comments of zRMS:</p>	<p>The phytotoxicity trials about tested plant protection product (plant growth regulator) have been carried out in accordance with EPPO Guidelines (1/181 (4)). The conduct of the field work is principally compliant with “Good Agricultural Practice” and in accordance with EPPO Guidelines PP 1/135.</p> <p>The trials were performed with the use of different agricultural practice in North-East EPPO zone, Mediterranean EPPO zone, South-East EPPO zone and Maritime EPPO zone.</p> <p>All presented trials were performed with the use of cultivars, differing in growth strength as well as soil and water requirements. The appropriate experimental design was applied. In all trials studied product was compared to the standard reference products. Statistical analysis of the data was performed. Also, quality of yield was evaluated in submitted trials.</p> <p>Both EU Directive 91/414 (EU, 1991) and EPPO PP 1/226 (3) – Number of efficacy trials requires testing phytotoxicity at normal (N) and double (2N) recommended dose. However, EPPO 1/135 (3) – Phytotoxicity assessment states: ‘EPPO Standards on fungicides, insecticides and plant growth regulators or seed treatments, on the other hand, include only a relatively simple special section on phytotoxicity assessment, because, for these types of plant protection products, phytotoxic effects will be less frequent’. Selectivity trials and studied dose 2N were not required, which is in accordance with EPPO 1/135 (3). However, Applicant submitted 22 trials in which dose N and 2 N was studied. Those selectivity trials were carried out in MAR 10 (FR-4, UK-2, DE-2, CZ-2), MED 4 (FR-2, IT-2); S-E 2 (HU) and N-E 6 (PL-4, LT-2).</p> <p>Also, Applicant submitted in total 23 efficacy trials in which phytotoxicity assessment was carried out on winter wheat. Those trials were carried out in MAR 10 (FR-4, UK-2, DE-2, CZ-2), MED 4 (FR-2, IT-2) and N-E 9 (PL-6, LT-3). Lack of trials for S-E EPPO zone. Trials were performed during different growing season. The evaluation of phytotoxicity effects was done according to EPPO Standard 1/135 (4) of plant growth regulators applied on crops of winter wheat was performed visually by comparing the condition of the plants in the plots treated with PPP – CLARA in comparison to untreated plots (no PPP). The intensity of damage to the plant was expressed as a percentage (0%-no symptoms of phytotoxic effects of PPP, 100% - total destruction).</p> <p>Assessment for Poland: Research should be conducted in the Poland or/and in other countries from the North-East EPPO zone or neighbouring countries not belonging to the zone. According to the Polish guidelines for well-known active substance should be submitted at least 4-5 phytotoxicity studies performed in two growing seasons on 3-4 varieties. Also, Applicant can use CIRCA for the assessment, but into account must be taken issues related to data protection. Alternatively, Applicant can use the data from the records of other / neighbouring countries – but the justification for using this part by Applicant must be submitted.</p> <p>In the opinion of Evaluator, the Applicant submitted enough phytotoxicity and selectivity trials for winter wheat. On the basis on presented results it can be concluded that tested product is safe for winter wheat. No negative effects are expected at recommended dose (1,3 L/ha and 2,1 L/ha).</p> <p>Assessment for cMS:</p> <ul style="list-style-type: none"> • <i>N-E EPPO zone:</i> No adverse effects in regard to phytotoxicity were observed
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	<p>in any of the 9 efficacy trials as well as no adverse effects were observed in the 6 selectivity trials conducted in the North-east EPPO zone.</p> <ul style="list-style-type: none"> • <i>MAR EPPO zone</i>: No adverse effects in regard to phytotoxicity were observed in any of the 10 efficacy trials as well as no adverse effects were observed in the 10 selectivity trials conducted in the Maritime EPPO zone. • <i>S-E EPPO zone</i>: No adverse effects in regard to phytotoxicity, or lodging were observed in any of the two selectivity trials. • <i>MED EPPO zone</i>: No adverse effects in regard to phytotoxicity were observed in three of the 4 efficacy trials as well as no adverse effects were observed in three of the 4 selectivity trials conducted in the Mediterranean EPPO zone. In one efficacy trial and in one selectivity trial, conducted on the variety Arkeos and the variety Palesio, minor phytotoxicity was observed as reduction of vigor in the plots treated with Chlormequat chloride 72% SL. Comparable phytotoxicity was also observed in the plots treated with the standard Chlormequat chloride reference product. <p>In the opinion, of Evaluator submitted documentation is sufficient for N-E, MED and MAR EPPO zone. cMS from S-E should decide if limited trials in number of 2 can be acceptable or/and consider possibility of use results from other zones.</p>
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3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

To evaluate the effect of Chlormequat chloride 72% SL on the yield of winter wheat, the results obtained in 23 efficacy trials and in 22 selectivity trials conducted in 2016 and 2017 have been included to support the registration of Chlormequat chloride 72% SL in the label claimed crops.

The 45 trials were conducted on winter wheat. Chlormequat chloride 72% SL was applied on cereal crops at growth stages ranging between BBCH 29 to BBCH 32, i.e. post-emergence. All trials presented in this section of the Biological Assessment Dossier were located within the North-east, the Maritime, the South-east and the Mediterranean EPPO zone, as defined by EPPO Standard PP1/241(1).

3.4.2.1 Materials and methods

Yield and quality trials presented in this section were designed and conducted to test the highest recommended dose rate in winter wheat of Chlormequat chloride 72% SL as well as the overlapping dose in winter wheat. Chlormequat chloride 72% SL is applied post emergence at 1.3 to 2.1 L/ha.

All trials were conducted under GEP by certified testing units.

Statistical analysis was generated based on the analysis of variance and, where appropriate, the Student-Newman-Keuls test (SNK) was used for result discrimination. All statistical analysis is done at a 95 % confidence limit.

Trial sites, crop varieties, sowing, application details (weed-free crop tolerance trials only)

The crop safety trials and the efficacy trials were carried out in commercially grown winter wheat crops. Sites were expected to be weed free or with low weed infestation to avoid competition with the crop in order to express only the effect of the growth regulator on the crop. All normal crop husbandry, were applied to the whole trial area by the grower, according to crop requirements and in accordance with good agricultural practice.

Herbicides and standards used in weed-free crop tolerance trials

All herbicides, formulation description, active ingredient content, applied use rates used in the crop toler-

ance trials are described in Table 3.4-3 in section CP 3.4.

Data evaluation and -processing

Plot yield was measured at harvest. The data of the treated plots are presented as relative values in relation to the fresh weight for the untreated plots.

3.4.2.2 Summary and evaluation of the field trials conducted in winter wheat, treated post-emergence

A summary of the mean yield assessments expressed as %-relative of the untreated, from trials treated once, conducted in the North-east, the Maritime, the South-east and the Mediterranean EPPO zone, are presented in Table 3.4-4.

Winter wheat (TRZAW)

23 efficacy trials and 22 selectivity trials conducted in winter wheat were harvested. The trials were conducted in Germany (4), Poland (10), the Czech republic (4), Lithuania (5), Italy (4), France (12), United Kingdom (4) and Hungary (2) in 2016 and 2017. In these trials, Chlormequat chloride 72% SL was applied post-emergence, at growth stages ranging between BBCH 29 and 32, at 1.2 L/ha and 2.4 L/ha.

Neither Chlormequat chloride 72% SL nor the Chlormequat chloride reference product (Stabilan 750 SL) significantly affected the yield (Table 3.4-4) when applied at the recommended dose rate (1.3-2.1 L/ha) or at the overlapping dose rate (4.2 L/ha), in any of the 45 trials. The results obtained in these trials supports the label claim that Chlormequat chloride 72% SL is safe to be applied post-emergence at the recommended dose rate in winter wheat at the recommended application interval.

Table 3.4-4: North-east, Maritime, South-east and Mediterranean zone – Crop yield (t/ha) of winter wheat treated with Chlormequat chloride 72% SL, single application post-emergence, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	Chlormequat chloride 72% SL at:		Chlormequat chloride Ref. prod. at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	1.3 L/ha	2.1 L/ha	1.0-1.3 L/ha	2.0-2.1 L/ha
North-east zone, efficacy trials						
Winter wheat (t/ha)	9	7.5 (4.74-9.27)	100.8 (94.9-106.8)	102.9 (93.5-115.0)	100.5 (94.8-109.5)	102.2 (96.6-108.4)
Maritime zone, efficacy trials						
Winter wheat (t/ha)	10	9.5 (4.9-19.12)	99.3 (87.2-108.1)	97.6 (80.4-110.2)	96.7 (84.9-110.2)	100 (88.9-110.2)
Mediterranean zone, efficacy trials						
Winter wheat (t/ha)	4	6.22 (4.6-9.3)	108.4 (100.8-116.4)	108.4 (98.6-114.7)	108.4 (100.6-119.6)	106.9 (100.1-114.7)
Crop, trial type	No. of trials	Untreated	Chlormequat chloride 72% SL at:		Chlormequat chloride Ref. prod. at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	2.1 L/ha	4.2 L/ha	2.0 L/ha	4.0 L/ha
North-east zone, selectivity trials						
Winter wheat (t/ha)	6	7.6 (5.89-8.85)	104.2 (100-109.3)	103.6 (97.1-105.2)	104.6 (98.7-118.2)	104.6 (97.6-105.5)
Maritime zone, selectivity trials						
Winter wheat (t/ha)	10	19.3 (4.9-79.2)	97.7 (85.0-106.1)	99.7 (79.5-108.1)	100 (89.5-107.3)	98.2 (89.4-110.2)
South-east zone, selectivity trials						
Winter wheat (t/ha)	2	6.1 (5.5-6.7)	94.3 (85.5-101.5)	100 (98.5-101.8)	100 (96.3-102.9)	100 (97.0-103.6)
Mediterranean zone, selectivity trials						
Winter wheat (t/ha)	4	5.8 (3.7-7.6)	103.3 (96.0-135.1)	108.4 (95.8-159.4)	106.2 (94.3-148.6)	105.5 (91.4-148.6)

3.4.2.3 Conclusion

affect crop yield significantly in the any of the 45 trials taken to harvest. In all trials, Chlormequat chloride 72% SL applied at dose rates higher than the recommended rate – representative for sprayer overlap – did not significantly affect the crop yield.

Furthermore, the data obtained in trials harvested demonstrate that Chlormequat chloride 72% SL is as safe to the crop as the Chlormequat chloride reference products used in the trials.

As this document clearly demonstrates, the efficacy and crop safety of Chlormequat chloride 72% SL is equivalent to the standard Chlormequat chloride product to which it was compared. The applicant therefore wishes to cite the original registrant's data on Chlormequat chloride now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Comments of zRMS:	<p>According to EPPO 1/144 - For the purposes of quantitative and qualitative recording of yields, the yield should be collected only from the experimental plot without shelterbelts. In the case of cereals, the following should be recorded the following data:</p> <ul style="list-style-type: none"> (a) grain yield in kg ha⁻¹ adjusted to the established moisture content (according to the national standard); (b) moisture content; (c) weight of grain in hectoliters (optional); (d) weight of 1,000 grains (optional); (e) grain size assessment (optional); (f) protein content (optional). <p>Yield and quality trials presented were designed and conducted to test the recommended dose rate of CLARA in winter wheat.</p> <p>CLARA is recommended applied in wheat at 1,3 -2,1 L/ha. No negative impact on yield was recorded during trials. CLARA applied at the recommended range of dose did not significantly affect the yield. Applicant submitted in total 45 trials: MED – 8 (ES-4, FR-4), MAR – 20 (FR-8, UK-4, DE-4, CZ-4); S-E -2 (HU) and N-E – 15 (PL-10, LT-5). In the opinion, of Evaluator submitted documentation is sufficient for N-E, MED and MAR EPPO zone. cMS from S-E should decide if limited trials in number of 2 can be acceptable or/and consider possibility of use results from other zones.</p>
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3.4.2.4 Relationship between phytotoxicity and yield

No adverse effects were observed in any of the 45 trials in which crop yields were assessed.

Comments of zRMS:	ZRMs agree with Applicant.
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3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

23 efficacy trials and 22 selectivity trials treated with Chlormequat chloride 72% SL were harvested and yields recorded. Besides recording yields, assessments were also carried out on the potential impact of treatment on a range of quality parameters including grain density, Thousand grain weight, starch, Thousand Protein, weight fresh, moisur content, germination percentage, and hectolitre weight

The materials and methods of these trials are described in Section 0.

Winter wheat (TRZAW)

The results obtained from assessments on the quality of the harvested winter wheat grains are presented in Table 3.4-.

In the trials evaluated, Chlormequat chloride 72% SL had no detrimental effect on the quality parameters assessed on the harvested winter wheat grains. When comparing the results obtained with Chlormequat chloride 72% SL against the results obtained with the Chlormequat chloride reference product at comparable dose rates, both products performed statistically similar.

Table 3.4-15: North-east, Maritime, South-east and Mediterranean zone– Quality of harvested winter wheat – crop treated with Chlormequat chloride 72% SL with single application, post-emergence as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	Chlormequat chloride 72% SL at:		Chlormequat chloride Ref. prod. at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	1.3 L/ha	2.1 L/ha	1.0-1.3 L/ha	2.0-2.1 L/ha
Efficacy trials – North-east zone						
Grain density (kg/hL)	6	77.25 (74.4-80.5)	98.9 (97.9-100)	99.0 (97.8-99.5)	99.1 (98.3-99.7)	99.0 (92.5-99.6)
Thousand Grain Weight (g)	9	44.63 (39.6-50.9)	99.1 (93.1-102.5)	98.6 (94.0-105.3)	99.2 (92.9-102.7)	99.7 (94.0-103.7)
Starch (%)	1	70.7	102.2	99.4	99.4	100.1
Protein content (%)	3	11.12 (10.33-12.5)	99.7 (98.5-100.2)	99.0 (99.0-100)	99.2 (98.3-100)	97.6 (96.0-99.2)
Gluten conten (%)	1	25.5	98.0	99.6	97.6	94.1
Weight fresh (Kg/plot)	3	14.69 (13.53-15.55)	102.3 (99.5-107.5)	106.5 (101.9-116.0)	102.7 (99.2-109.6)	102.9 (99.8-108.7)
Moisture content (%)	3	15.7 (14.5-16.4)	100.6 (97.5-105.5)	101.2 (98.7-106.2)	101.9 (100.6-103.4)	101.4 (100-104.1)
HectoLitre Weight (kg/hL)	3	75.26 (70.1-82.1)	100.1 (99.7-100.9)	100.1 (99.4-101.5)	100.05 (99.1-101.3)	100.1 (99.1-101.3)
Germin (%)	3	98.35 (97.3-99.77)	99.3 (98.3-100)	99.6 (99.1-99.8)	98.9 (97.5-100)	99.9 (99.4-100.3)
Efficacy trials – Maritime zone						
Thousand Grain Weight (g)	6	45.25 (35.49-56.45)	97.7 (87.0-101.0)	97.7 (87.6-103.6)	99.7 (92.4-105.3)	98.1 (86.4-101.9)
Nitrogen conten (%)	1	8.2	103.6	99.6	99.3	98.7
Weight fresh (Kg/plot)	5	9.0 (4.88-13.05)	98.0 (88.8-108.1)	95.5 (80.5-108.1)	99.5 (88.8-110.2)	98.8 (90.8-112.2)
Moisture content (%)	10	13.9 (10.4-18.33)	99.6 (97.5-101.9)	99.6 (96.77-104.8)	98.8 (91.5-101.3)	99.1 (95.3-101.2)
HectoLitre Weight (kg/hL)	6	73.8 (69.6-86.7)	98.6 (92.5-100.5)	98.6 (94.4-100.9)	100.3 (96.6-102.4)	99.5 (94.1-101.5)
Germin (%)	1	94.38	103.5	104.3	104.4	104.9
Efficacy trials – Mediterranean zone						
Thousand Grain Weight (g)	4	44.3 (43.35-46.1)	100 (96.8-103.8)	103.1 (95.7-108.4)	100.5 (97.8-104.3)	100.9 (96.8-104.1)
Weight fresh (Kg/plot)	4	11.7 (4.7-24.17)	106.5 (101.6-115.5)	105.9 (99.5-114.9)	105.7 (101.4-118.9)	105.1 (100.7-115.4)
Moisture content (%)	4	14.1 (11.98-19.65)	101.1 (99.8-103.3)	101.4 (99.3-103.9)	101.1 (100-103.0)	100.7 (98.9-102.7)
HectoLitre Weight (kg/hL)	4	78.0 (73.4-81.3)	99.9 (98.7-100.3)	99.8 (97.5-100.6)	100 (98.0-100.4)	99.9 (97.9-100.8)
Crop, trial type	No. of trials	Untreated	Chlormequat chloride 72% SL at:		Chlormequat chloride Ref. prod. at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	2.1 L/ha	4.2 L/ha	2.0 L/ha	4.0 L/ha
Selectivity trials – North-east zone						
Grain density (kg/hL)	4	78.2 (75.3-80.44)	99.3 (99.1-100.1)	99.3 (99.3-99.7)	99.4 (99.3-99.9)	99.2 (96.0-99.6)
Thousand Grain Weight (g)	6	45.2 (42.36-47.95)	99.6 (96.4-102.4)	98.4 (94.2-102.8)	98.4 (95.2-101.8)	99.1 (94.4-103.3)
Protein content (%)	2	10.17 (10.15-10.2)	101.7 (100.4-102.9)	102.0 (100.3-103.7)	100.6 (99.9-101.4)	101.1 (100-102.7)
Weight fresh (Kg/plot)	2	14.96 (14.93-15.0)	100.4 (99.6-101.2)	100.8 (97.8-103.8)	100.4 (98.2-102.5)	102.0 (98.9-105.0)
Moisture content (%)	2	16.75 (16.6-16.9)	98.2 (97.5-98.8)	97.9 (96.4-99.4)	98.8 (98.7-98.8)	99.4 (99.4-99.4)
HectoLitre Weight (kg/hL)	2	70.5 (69.7-71.3)	99.6 (99.5-99.7)	99.3 (98.7-100)	99.3 (99.2-99.4)	99.3 (98.9-99.7)
Germin (%)	2	98.45 (97.7-99.2)	100.1 (100-100.3)	99.5 (99.4-99.5)	99.8 (99.7-100)	99.3 (99.2-99.4)
Selectivity trials – Maritime zone						
Thousand Grain Weight (g)	5	45.65 (33.4-56.25)	98.1 (92.7-103.6)	96.7 (91.3-100.4)	95.9 (84.8-100.7)	96.7 (88.0-100.4)
Weight fresh (Kg/plot)	5	9.2 (4.68-12.11)	100 (85.5-112.1)	102.0 (96.0-116.6)	100 (90.3-113.0)	100 (89.1-112.2)

Crop, trial type	No. of trials	Untreated	Chlormequat chloride 72% SL at:		Chlormequat chloride Ref. prod. at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	1.3 L/ha	2.1 L/ha	1.0-1.3 L/ha	2.0-2.1 L/ha
Moisture content (%)	9	13.89 (10.55-17.45)	99.6 (93.8-105.7)	99.0 (95.8-104.3)	99.4 (93.6-107.2)	99.1 (94.4-105.7)
HectoLitre Weight (kg/hL)	5	73.0 (59.8-86.65)	100.6 (100-101.8)	99.3 (96.0-100.7)	98.8 (94.4-100.7)	101.9 (95.8-113.8)
Germin (%)	1	94.38	103.4	103.5	104.3	104.4
Selectivity trials – South-east zone						
Thousand Grain Weight (g)	2	38.8 (37.93-39.74)	101.4 (101.1-101.6)	100.6 (99.2-101.8)	101.2 (100.0-102.2)	102.8 (102.5-103.0)
Weight fresh (Kg/plot)	2	14.78 (13.35-16.21)	102.5 (110.4-103.3)	100.8 (99.2-102.8)	99.4 (99.6-100.9)	100.7 (99.1-102.8)
Moisture content (%)	2	13.95 (13.93-13.97)	99.5 (98.0-101.0)	100.7 (100.5-101.0)	99.0 (97.4-100.6)	100.3 (98.9-101.7)
HectoLitre Weight (kg/hL)	2	80.47 (80.22-80.72)	99.2 (99.1-99.4)	100.3 (100.3-100.4)	100.1 (99.9-100.4)	99.8 (99.7-100.0)
Selectivity trials – Mediterranean zone						
Thousand Grain Weight (g)	4	40.78 (33.2-47.1)	99.6 (96.3-103.7)	97.8 (94.5-99.2)	99.0 (96.5-100.4)	97.8 (95.5-101.9)
Weight fresh (Kg/plot)	4	11.5 (4.35-21.3)	100.4 (96.2-133.3)	104.4 (95.9-158.6)	102.6 (94.3-147.1)	102.2 (96.1-147.1)
Moisture content (%)	4	12.98 (11.18-15.7)	99.6 (98.0-100.7)	99.5 (98.0-100.8)	99.3 (98.0-100.1)	99.3 (98.0-100.6)
HectoLitre Weight (kg/hL)	4	80.37 (78.6-83.05)	100.1 (99.7-100.6)	99.8 (99.4-100.4)	99.6 (99.0-100)	100.0 (99.3-100.8)

3.4.3.1 Conclusion

Chlormequat chloride 72% SL applied at dose rates representative of the recommended dose rate did not affect crop yield nor the quality of the crop yield significantly in the any of the 45 trials taken to harvest. In all trials, Chlormequat chloride 72% SL applied at dose rates higher than the recommended rate – representative for sprayer overlap – did not significantly affect the crop yield.

Furthermore, the data obtained in trials harvested demonstrate that Chlormequat chloride 72% SL is as safe to the crop as the reference products used in the trials.

As this document clearly demonstrates, the efficacy and crop safety of Chlormequat chloride 72% SL is equivalent to the standard Chlormequat chloride product to which it was compared. The applicant therefore wishes to cite the original registrant's data on Chlormequat chloride now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Comments of zRMS:	<p>No negative impact on quality of yield was recorded during trials. Applicant submitted in total 45 trials: MAR – 20 trials, MED – 8 trials, S-E – 2 trials and N-E – 15 trials.</p> <p><u>During submitted trials following parameters was studied:</u></p> <ul style="list-style-type: none"> <i>N-E EPPO zone:</i> Grain density (10 trials), Thousand Grain Weight (15 trials), starch (1 trial), Protein content (5 trials), Gluten content (1 trial), Weight fresh (5 trials), moisture content (5 trials), HectoLitre Weight (5 trials) and Germin (5 trials). <i>Maritime EPPO zone:</i> Thousand Grain Weight (11 trials), Nitrogen content 1 (trial), Weight fresh (10 trials), Moisture content (19 trials), HectoLitre Weight (11 trials) and Germin (2 trial). <i>MED EPPO zone:</i> Thousand Grain Weight (8 trials), Weight fresh (8 trials), Moisture content (8 trials) and HectoLitre Weight (8 trials). <i>S-E EPPO zone:</i> Thousand Grain Weight (2 trials), Weight fresh (2 trials), Moisture content (2 trials) and HectoLitre Weight (2 trials). <p>In the opinion, of Evaluator for winter wheat from N-E EPPO, MED EPPO zone</p>
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	and Maritime EPPO zone submitted documentation is sufficient. CMS from S-E should decide if limited trials in number of 2 can be acceptable or/and consider possibility of use results from other zones.
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3.4.4 Effects on transformation processes (KCP 6.4.4)

Chlormequat chloride 72% SL is composed of Chlormequat chloride which has been widely used for several years on cereals without identifying any quality problems on the treated crops.

Chlormequat chloride 72% SL is recommended applied on cereal crops from BBCH 29 to BBCH 32, i.e. post-emergence, but before inflorescence emergence and heading. Therefore, it is not expected that the active ingredient is transferred to the grains.

Comments of zRMS:	<p>The impact of chlormequat chloride on grain processing processes can encompass several aspects:</p> <ul style="list-style-type: none"> – Rheological Properties: chlormequat chloride can influence the rheological properties of grain dough. It may affect viscosity, elasticity, and other parameters, which can have consequences for baking processes, dough formation, etc. – Flour Quality: The application of chlormequat chloride can affect the properties of flour obtained from processed grains. This can be significant for the quality of bakery products. – Dough Stability: Chlormequat chloride may impact the stability of dough, which can be crucial during processing processes such as kneading or bread shaping. – Effect on Plant Structure: By controlling plant growth, chlormequat chloride can influence the structure of the plant itself, which may have implications for yield and ease of processing during harvest. <p>Based on long term use of chlormequat chloride without any problems and low residues in grain, the above-mentioned argumentation can lack of studies can be accepted. No negative impact on processing is to be expected in the opinion of Evaluator. According to EPPO 1/243 in the case of low or lack of residues in grain, it can be concluded that if the applicant can demonstrate that the residues of plant protection products are trace amounts or that they will not impact yeast, supported by arguments, a case-by-case basis may be sufficient to meet these requirements. Data from preliminary screening of biological activity can provide valuable evidence of no impact on yeast or lactic acid bacteria. However, their absence seems acceptable given that chlormequat chloride has been used for many years on cereals, and market-available product labels do not contain warnings that the product may affect processing processes.</p> <p>ZRMs agree with Applicant that: “Chlormequat chloride 72% SL is recommended applied on cereal crops from BBCH 29 to BBCH 32, i.e. post-emergence, but before inflorescence emergence and heading. Therefore, it is not expected that the active ingredient is transferred to the grains.”</p> <p>It is important to note that the impact of chlormequat chloride may depend on various factors, such as the substance dosage, type of grains, and specific cultivation conditions. It is always crucial to adhere to recommendations regarding the use of plant protection products and to meticulously follow the instructions provided on product labels.</p> <p>CLARA seems to be safe for transformation processes. However, this assessment was made only on the basis on argumentations. In the opinion of ZRMs, entry in label about no negative effect on transformation processes should not been put in</p>
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	label. Such provisions should be primarily considered based on research findings.
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3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

Special tests to investigate this purpose are not required.

Comments of zRMS:	<p>No data were submitted by Applicant. Also, lack of Applicant's argumentation about effect on propagating. Thus, restriction regarding use in crops to be used for propagation should appear on the label. The applicant generally wishes to cite the original registrant's data on isopiquat chlormequat chloride now out of protection. Therefore, the evaluators should consider such data and label restrictions/warnings regarding propagating on standard isopiquat chlormequat chloride products. According to Polish rules we cannot use data from other PPPs label. The assessment should be done on the basis on trials or expert's judgement.</p> <p>In the opinion of Evaluator Applicant's argumentation about propagating is acceptable. Thus Negative effects of the active ingredient on parts of plant used for propagating purposes can be excluded due to the growth of regulator nature of the product. GERMIN was studied during 5 trials carried out in NE and 2 trials carried out in Maritime EPPO zone. No reduction in winter wheat grain germination rate recorded in treated compare to untreated plots during those trials. According to EPPO 1/135 (4) in table 2 – for PGRs PPP including desiccants the studies about germination are needed. So, on the basis on data from selectivity trials about GERMIN and lack of phytotoxicity effects observed during trials, it can be concluded that CLARA can be considered as a safe PPP for propagation purposes of cereals accepted in GAP table and label project. Due to the fact that in labels containing chlormequat chloride as the active substance, no information was found regarding its impact or lack thereof on processing processes. It seems to us that in the case of CLARA as well, such information does not need to be included on the label. The absence of such information simultaneously implies that negative impacts on processing processes are not expected.</p>
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3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

Not relevant.

No significant residue levels are to be expected in rotational crops following application of Chlormequat chloride according to the proposed GAP.

The applicant advises that the use of Chlormequat-chloride 720g/L does not pose any risk of adverse effects on succeeding crops. There is no need to restrict the range of possible succeeding crop species or to provide for minimum waiting periods or other precautions. This includes situations of potential emergency replanting.

Comments of zRMS:	ZRMs agree with Applicant. However, the Applicant should present the assessment of the possible effect of CLARA on crops grown as rotational or replacement crops following crops treated with that product, prepared in accordance with the EPPO Standard Efficacy evaluation of plant protection products Effects on suc-
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	<p>succeeding crops (PP 1/207 (2)).</p> <p>The submitted information's and a review of available literature as well as the lack of phytotoxicity symptoms recorded during the field trials suggest that product application in accordance with label recommendation has no negative impact on succeeding crops.</p>
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3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

Risk assessments were conducted according to EPPO Guideline PP1/256 and the results confirm that no further testing is necessary and that no negative impact on adjacent crops is expected.

Comments of zRMS:	No negative effects of applications of chlormequat chloride containing products on adjacent crops are known, neither from field trials nor from long term agricultural use when the products were applied according to the use instructions. Drift onto adjacent crops should be generally avoided. However, due to the good safety of CLARA on plants, there is no risk for adjacent crop to become injured, even in case of improper applications.
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3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

From the experimentation carried out with Chlormequat chloride 72% SL in 2016 and 2017, no problems regarding adverse effects on beneficial organisms were reported.

Special tests to investigate this purpose are not required.

For more information, see the results of the standard ecotoxicological tests being presented in dRR Part B section 6.

Compatibility with current management practices including IPM

This is not an EC data requirement/ not required by Directive 91/414/EEC.

Comments of zRMS:	zRMS refers to Ecotoxicology evaluation
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3.6 Other/special studies

No other studies were conducted

3.7 List of test facilities including the corresponding certificates

The following table gives information about the testing facilities where trials mentioned in this document were conducted. All facilities are certified, and the trials were conducted according to GEP guidelines.

Table 3.7-1: List of test facilities

Testing facility	Zone	Country	Year and trial type		Year and trial type	
			2016		2017	
			Efficacy	Selectivity	Efficacy	Selectivity
SAGEA, IT	MED	IT	2	2		

INSTITUTE OF PLANT PROTECTION - NATION- AL RESEARCH INSTITUTE, PL	N-E	PL	3	2	3	2
INSTITUTE OF AGRICULTURE, LT	N-E	LT	3	2		
Agrostation, FR	MAR	FR	2	2		
Agrostation, FR	MED	FR	2	2		
SGS GROUP, UK	MAR	UK	2	2		
Hetterich Fieldwork GbR, DE	MAR	DE			2	2
Zemědělská zkušební stanice Kujavy, s.r.o.,CZ	MAR	CZ	1	1		
Zkušební stanice Rýmařov, s.r.o., CZ	MAR	CZ	1	1		
Plant-Art Research Kft., HU	S-E	HU		2		
SARL Cotesia, FR	MAR	FR			2	2
Total, All crops			16	16	7	6

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 6.0-001	Anonymous	2022	Biological Assessment Dossier: Chlormequat chloride 72% SL (720 g/L Chlormequat chloride) – EU Central zone Sharda Cropchem España -, - Unpublished	N	SHA