

FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: SHA 126085 A

Product name(s): MEPCY

Chemical active substance:

Chlormequat chloride, 345 g/L

Mepiquat chloride, 115 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem Ltd.

Submission date: February 2022

MS Finalisation date: May 2023, August 2023

Version history

When	What
April 2023	Applicant updated document
May 2023	ZRMs evaluated updated dRR by Applicant
August 2023	Final version of RR after commenting period.

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)	13
3.2.2	Minimum effective dose tests (KCP 6.2).....	14
3.2.3	Efficacy tests (KCP 6.2)	18
3.3	Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)	25
3.4	Adverse effects on treated crops (KCP 6.4).....	25
3.4.1	Phytotoxicity to host crop (KCP 6.4.1).....	27
3.4.1.1	Winter wheat (TRZAW)	28
3.4.1.2	Overall conclusion	28
3.4.2	Effect on the yield of treated plants or plant product (KCP 6.4.2)	30
3.4.2.1	Materials and methods	30
3.4.2.2	Summary and evaluation of the field trials conducted in winter wheat.....	30
3.4.2.3	Conclusion	32
3.4.2.4	Relationship between phytotoxicity and yield	32
3.4.3	Effects on the quality of plants or plant products (KCP 6.4.3).....	33
3.4.4	Effects on transformation processes (KCP 6.4.4)	34
3.4.5	Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)	35
3.5	Observations on other undesirable or unintended side-effects (KCP 6.5)...	35
3.5.1	Impact on succeeding crops (KCP 6.5.1).....	35
3.5.2	Impact on other plants including adjacent crops (KCP 6.5.2)	35
3.5.3	Effects on beneficial and other non-target organisms (KCP 6.5.3)	39
3.5.4	Tank cleaning	39
3.6	Other/special studies	39
3.7	List of test facilities including the corresponding certificates	39
Appendix 1	Lists of data considered in support of the evaluation	41

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 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 in grey).
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3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

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)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. (e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/synergist per ha (f)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	CEU	Winter wheat	F	Reduction of height to prevent lodging	Foliar Spray	BBCH 29-32	a) 1 b) 1	NA	a) 2.0 b) 2.0	a) 0.69 chlomequat chloride + 0.23 mepiquat chlo- ride b) 0.69 chlomequat chloride+ 0.23 mepiquat chlo- ride	200-400			To be confirmed by cMS. In PL is accepted.

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

3.2 Efficacy data (KCP 6)

Introduction

This document summarises the information related to the efficacy data of the plant protection product **Chlormequat chloride 34.5% + Mepiquat chloride 1.5% SL (MEPCY; Product code: SHA 126085 A)** containing the active substance chlormequat chloride and mepiquat chloride, which has been 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) and mepiquat chloride (SANCO/106/08-rev.2 – 20 May 2008) are 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 reports on the active substances chlormequat chloride and mepiquat chloride, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 January 2008 and 20 May 2008, respectively, 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 and mepiquat 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 34.5% + Mepiquat chloride 1.5% SL, Central

Description of the plant protection product

Chlormequat chloride 34.5% + Mepiquat chloride 11.5% SL is an Soluble Concentration (SL) formulation containing 345 grams per liter (g/L) chlormequat chloride and 115 grams per liter (g/L) mepiquat chloride for use in winter wheat.

According to the GAP, the proposed application rate of Chlormequat chloride 34.5% + Mepiquat chloride 11.5% SL in winter wheat is 2.0 L per hectare (L/ha), with one applications per season. This will deliver 690 g chlormequat chloride and 230 g mepiquat chloride per hectare. In the current document, results obtained in field trials with Chlormequat chloride 34.5% + Mepiquat chloride 11.5% SL applied at 2.0 L/ha will be presented where these have been tested against similar dose rates of chlormequat chloride + mepiquat chloride reference products currently marketed in the countries where the trials were conducted.

The data presented in this dossier fully support the label claim of Chlormequat chloride 34.5% + Mepiquat chloride 11.5% SL for reduction of height to prevent lodging in winter wheat.

Table 3.2-1: Simplified table of currently registered uses and requested uses for the product code.

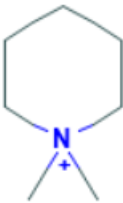
Crop / disease	Application method	Spray volume (L/ha)	Max. individual application rate (kg f.p./ha) [kg a.s./ha]	Max. number of applications	Application timing (e.g. BBCH)
Winter Wheat Reduction of height to prevent lodging	Spray	200-400	(2.0) [690 + 230]	1	BBCH 29-32

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

Description of active substance mepiquat

Mepiquat is a systemic plant growth regulator that reduce the synthesis of gibberellic acid, resulting in the suppression of cell enlargement. It is readily absorbed by the leaves and translocated to growing points of the plant.

Table 3.2-2: Identity of mepiquat

Common name	Mepiquat
IUPAC name	1,1-Dimethylpiperidinium chloride
CA name	1,1-dimethylpiperidinium chloride (mepiquat chloride)
CIPAC No	440.302 (mepiquat chloride) 440 (mepiquat)
CAS Registry No.	24307-26-4 (mepiquat chloride) 15302-91-7 (mepiquat)
EEC No	246-147-6 (mepiquat chloride)
Empirical formula	C ₇ H ₁₆ ClN
Molecular mass	114.21 g/mol
Minimum purity	615-665 g/l in the technical concentrate (TK)*, corresponding to a minimum purity in the theoretically dry technical material (TC) of 990 g/kg.
Structural formula¹	

Description of active substance chlormequat

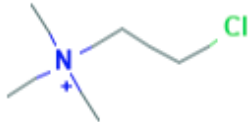
Chlormequat is used as a plant growth regulator. It is typically sold as the chloride salt, chlormequat chloride, a colourless hygroscopic crystalline substance that is soluble in water and ethanol. Chlormequat inhibits cell elongation, resulting in thicker stalks, which are sturdier, facilitating harvesting of cereal crops.

Today, chlormequat is registered and commercialised in several formulations, as straight product as well as in mixtures, around the world.

Table 3.2-3: Identity of chlormequat

Common name	Chlormequat
IUPAC name	2-chloroethyl(trimethyl)azanium
CA name	2-chloro-N,N,N-trimethylethanaminium chloride
CIPAC No	143.302 (chlormequat chloride) 143 (chlormequat)

¹ Source: Chem Service Inc. Internet, Thursday November 6th, 2018. URL: <https://www.chemservice.com/>

CAS Registry No.	999-81-5 (chlormequat chloride) 7003-89-6 (chlormequat)
EEC No	213-666-4 (chlormequat chloride)
Empirical formula	C ₅ H ₁₃ Cl ₂ N
Molecular mass	158.1 g/mol
Minimum purity	≥ 636 g/kg
Structural formula²	

Mode of action, mepiquat

Mepiquat is a systemic plant growth regulator that reduce the synthesis of gibberellic acid, resulting in the suppression of cell enlargement. It is readily absorbed by the leaves ~~and~~ and translocated to growing points of the plant.

Mode of action, chlormequat

Chlormequat 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.

Information on similar formulations and current approvals

Chlormequat 34.5% + Mepiquat 11.5% SL formulation containing 345 grams per liter (g/L) chlormequat and 115 grams per liter (g/L) mepiquat. Data presented in this dossier is generated using this formulation in comparison with reference product containing chlormequat + mepiquat. chlormequat + mepiquat is currently registered and formulations throughout Europe and a selection of these are described in table below.

Table 3.2-4: Current approvals of chlormequat and mepiquat containing products 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 310 g/L SL	2206-0
Belgium	Belcocel 750	Chlormequat 750 g/L SL	7384P/B
	Completo	Chlormequat 270 g/L + Nexapac-ethyl 22.5 g/L ME	10856P/B
Croatia	Medax top	Mepiquat 300 g/L	UP/I-320-20/17-03/290
Czech Republic	Caryx	Mepiquat 210 g/L + Metconazole 30 g/L	4688-0
	Invister 300 SL	Chlormequat 300 g/L SL	5381-1
France	Tyran	Chlormequat 460 g/L SL	9400336
	Cyter	Mepiquat 115 g/L + Chlormequat 345 g/L	9200461
Georgia	Stabilan SL	Chlormequat 750 g/L SL	538/09/14
Germany	Acucel	Chlormequat 720 g/L SL	034046-63
	Ormet Plus	Chlormequat 720 g/L + Ethephon 150 g/L SL	008489-0
	Carax	Mepiquat 210 g/L + Metconazole 30 g/L	006415-00

² Source: Chem Service Inc. Internet, Thursday November 6th, 2018. URL: <https://www.chemservice.com/>

Country	Product	Active ingredient	Approval number
Greece	Belcocel	Chlormequat 720 g/L SL	8170
	Pix 5 SL	Mepiquat chloride 50 g/L	8209
Spain	Pix	Mepiquat chloride 38 g/L	15150
	Quimurel 40	Chlormequat 400 g/L SL	19636
	Moddus	Trinexapac-etil 25% ME	25910
UK	Becocel	Chlormequat 720 g/L SL	16652

Description of the target pests

The damaging economic effects of not controlling the number of grains through reduction of growth in winter wheat are well established, both on this year's crop as well as following year's crop, and justification for their control well documented. As such, no further details are required.

Table 3.2-5: Glossary of pests mentioned in the dossier.

EPPO code	Scientific name	Common name
-	-	Reduction of growth

Table 3.2-6: 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	-	Reduction of growth	CEU	-

Compliance with the Uniform Principles

Comprehensive field trials were conducted in Poland, Czech Republic, France and Spain in 2017, 2018 and 2021. The trials followed the corresponding EPPO guidelines. The GEP-requirement and the Uniform Principles are taken care of.

Information on trials submitted (6.2 Testing effectiveness)

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). The GEP-requirement and the Uniform Principles are therefore taken care of.

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 34.5% + Mepiquat 11.5% SL, 15 efficacy trials with efficacy results were conducted in the Maritime, the North-east and the Mediterranean EPPO zones:

Table 3.2-7: Presentation of efficacy trials (efficacy trials, preliminary 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 (Height reduction)	Spain	MED + E		4			2017	GEP	
	France	MED + E	7				2017	GEP	
		MED + E		2			2018	GEP	
	Czech Republic	MED + E	2				2017	GEP	
	Poland	MED + E				3	2017	GEP	
	Poland	MED + E				4	2021	GEP	
	Total, Winter wheat (eff.)		9	6		7			

In the trials used to assess the level of control obtained with Chlormequat 34.5% + Mepiquat 11.5% SL, a different number of assessments were conducted during the course of the trials. In some trials, a single assessment was conducted on the specific plant part and in others, two or more assessments were conducted. Therefore, not to bias the data from any trial with more than one assessment, the summary tables contain the data from one assessment per plant part per trial. An assessment is only considered valid for evaluation if the lodging and height of the plant. The data selected from each trial is either the final assessment timing on each plant part or the assessment timing most commonly used.

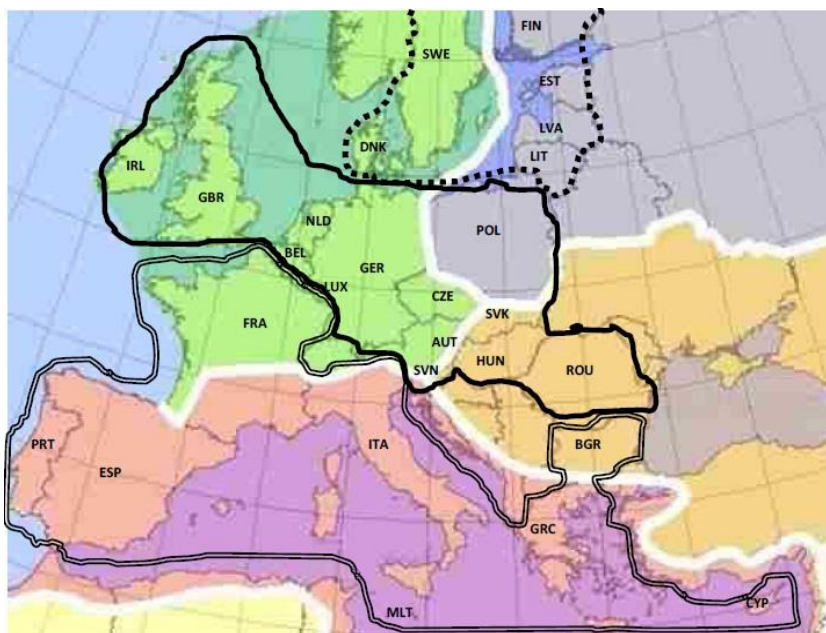
Climatic zones

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 country³.

Poland is located in the North-east EPPO zone; Czech Republic and N-France are located in the Maritime EPPO zone; and Spain as well as S-France are located in the Mediterranean EPPO zone (Figure 3.2-1).

³ 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)



This document is prepared to support the submission of Chloromequat 34.5% + Mepiquat 11.5% SL throughout the Central Registration zone, therefore data from the Maritime and the North-east EPPO zones are included. Data obtained in Mediterranean EPPO zone from winter wheat trials has also been added as supporting information, however, the data from each climatic zone is summarised separately.

Agronomic conditions

Cultural conditions and agronomy (e.g. cultivations used, application methods, cultivars, fertilizer regime, relative times of planting and harvest) do not differ significantly between the countries in the Southern and Central EU, but common is that pests attack foliar- and ear diseases of cereals attack from the South to the North, from East to West when the weather conditions are favourable for the pests to infest the crops.

The same chlormequat and mepiquat containing plant growth regulators are already registered and used in the countries where the trials were conducted to support the current application for registration. Please refer to Table 3.2-4 for the registration numbers in the different countries. In Central- and South zone countries, chlormequat + mepiquat-containing plant growth regulator are used as a protective fungicide, which should be applied during the growing season, before or shortly after outbreaks of the diseases claimed on the label are foreseen. Depending on the forecast and the diseases to be controlled, the important period may stretch from April to May.

(i) Site selection

Although trials were performed throughout the Southern and Central EU, in each country the sites were carefully selected to ensure that for each fungal disease, the level of control was assessed on a range of populations, when treated at the recommended application timings. To exert maximum control pressure and to exacerbate treatment differences in each country this included some trials, which contained high infestation levels. No differences in the level of control were apparent between the different countries or regions in which the trials were conducted.

(ii) Agronomic practices

Agronomic practices for cultivating cereals 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 also generally similar between the countries.

(iii) *Varieties*

Although crop varieties tend to differ between countries, observations on selectivity have not indicated any particular varietal sensitivity. The crop safety of Chlormequat 34.5% + Mepiquat 11.5% SL has been tested on a wide range of varieties in efficacy- and selectivity 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 other Member states. To increase the probability of high levels of disease in the trials, the varieties chosen in each country were the ones with the least resistance to the selected disease. Therefore, the results from each country can be considered as the worst case.

(iv) *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.

(v) *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.

(vi) *Soil*

It is not expected that a foliar applied fungicide will be affected in any way by soil type and so this factor can be ignored for the purposes of this document.

On the basis that the above factors do not influence the overall performance of Chlormequat 34.5% + Mepiquat 11.5% SL, it is the applicant's contention that data from Poland, Czech Republic and N-France is equally valid in demonstrating the products performance throughout the Central EU zone and the data from Spain and S-France is valid as supporting data.

In the efficacy trials with selectivity results, the performance of Chlormequat 34.5% + Mepiquat 11.5% SL was measured against a commercially available reference products containing chlormequat (Hidrofer-til; 400 g/L chlormequat SL) and chlormequat + mepiquat (Cyter; 345 g/L chlormequat + 115g/L mepiquat SL). In one Spanish trial, Chlormequat 34.5% + Mepiquat 11.5% SL was compared against a reference national registered product [Moddus (250g/l Trinexapac-etil)], in three Poland trials, a Medax Top (265g/l mepiquat + 44g/l prohexadion) and in four Poland trials, a Canopy (265g/l mepiquat + 44g/l prohexadion) was used and in two Czech trials, a Spatial Plus (150g/l Ethephon + 300g/l Chlormequat) reference product was used. The trials were carried out on winter wheat.

Table 3.2-8: Presentation of reference standards used in trials (efficacy trials, preliminary trials...)

Trade name	Formulation	Composition	Rates	Country	N° of Trials
Chlormequat and mepiquat formulation					
Cyter	SL	345 g/L chlormequat + 115 g/L mepiquat	1.75 L/ha 2.00 L/ha	Spain France	3 9
National reference product					
Hidrofertil	SL	400 g/L chlormequat	3.5 L/ha	Spain	3
Moddus	ME	250 g/L trinexapac-etil	0.5 L/ha	Spain	1
Spatial Plus	SL	150 g/l ethephon + 300 g/l chlormequat	2.4 L/ha	Czech Republic	2
Medax Top	SL	265 g/l Mepiquat + 44 g/l prohexadion	1.25 L/ha	Poland	3
CANOPY	SC	265 g/l Mepiquat + 44 g/l prohexadion	1.25 L/ha	Poland	4

Comments of zRMS:	<p>This document summarises the information related to the efficacy of the plant protection product – MEPCY (product code: SHA 126085 A).</p> <p>MEPCY (product code: SHA 126085 A) is characterized by a soluble concentration (SL) formulation containing 115 grams per liter (g/L) mepiquat chloride and 345 grams per liter (g/L) chlormequat chloride for use in winter wheat.</p> <p>Mepiquat chloride is absorbed by the plant primarily through leaves and translocated throughout the plant. It inhibits the biosynthesis of gibberellic acid and leads to a deeper green leaf colouring after 3-6 days. Mepiquat is used on cereals to reduce unwanted longitudinal shoot growth without lowering plant productivity.</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 11 plant protection products with mepiquat chloride and 14 with chlormequat chloride are registered and commonly used for protection crops. So far, no plant protection product, with both substances is registered in Poland.</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 and mepiquat is well known; both actives have been marketed by for the control of ~~fungal pests~~ **crop height** for a number of years. Based on the knowledge about the active substances (more than 20 years) and the experiences with the actives in the GAP claimed crops at the proposed dose rates, the necessary application rates to obtain sufficient control of the ~~pest organism~~ **control of crop height** 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.

Additionally, there are important benefits of applying a mixture of various active substances in comparison to formulations with just one active substance. One is the reduction in the number of applications done in the field what reduces the impact these product have on the environment and on operators. Co-formulated mixtures generally offer an advantage over tank mixtures where risks on beneficials or on environment have been evaluated and deemed acceptable.

Ready mixtures also provide higher or more consistent levels of reduction of growth since chlormequat and mepiquat act on different pathways within the plant. Using two active substances in a mixture may provide a more effective reduction than applied singly in sequence. For example, the mixture may provide both rapid action and more residual effect. This may be beneficial, especially where rapid control of growth is required.

For all these reasons applicant believes it is well justified to stimulate the registration of ready mix formulations.

Comments of zRMS:	<p>No results of the preliminary range-finding tests were submitted by the Applicant, however the active substances of MEPCY (product code: SHA 126085 A) – mepiquat chloride and chlormequat chloride are registered and have been commonly used in agricultural practice for many years (over 20). So, preliminary</p>
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	<p>range finding tests are deemed too not be necessary in the opinion of ZRMs.</p> <p>Applicant presented justification of the mixture. No trials were presented. However, ZRMs agree with Applicant that using two active substances in a mixture may provide a more effective reduction than applied singly in sequence. In CEU, they are already registered PPP with both these active compounds: mepiquat and chlormequat. For example – Cyter registered in Spain and France. So, lack of studies should be accepted. Especially that Cyter has the same composition as the product under evaluation (MEPCY). And its effectiveness and comparability were demonstrated during efficacy studies, as Cyter was used as a reference standard.</p>
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3.2.2 Minimum effective dose tests (KCP 6.2)

Chlormequat 34.5% + Mepiquat 11.5% SL was tested at a range of dose rates, but to demonstrate minimum effective dose rate, the control obtained with Chlormequat 34.5% + Mepiquat 11.5% SL applied at 1.5 L/ha, 1.75 L/ha and 2.0 L/ha or was evaluated in 22 winter wheat trials, for the reduction of height to prevent lodging. The dose rates tested in winter wheat reflects 75%, 88% and 100% of the recommended rate of Chlormequat 34.5% + Mepiquat 11.5% SL, in accordance with the EPPO guideline PP 1/225(2) “Minimum effective dose”. The dose rates are selected on the basis of its efficacy performance, product safety parameters and environmental limitations. Efficacy was tested under a range of environmental conditions to fully challenge the product. Data are presented from trials conducted in the Maritime EPPO zone (i.e. Czech Republic and N-France), the North-east EPPO zone (i.e. Poland) and the Mediterranean EPPO zone (i.e Spain and S-France).

Reduction of Height in winter wheat (CEU)

To prove and to support the proposed dose rate of 2.0 L/ha Chlormequat 34.5% + Mepiquat 11.5% SL [345 g chlormequat and 115 g mepiquat per hectare, per application] for the reduction of height to prevent lodging in winter wheat, the assessment results from 22 efficacy trials performed in the Maritime EPPO zone (15), in the North-east EPPO zone (7) and the Mediterranean EPPO zone (6) are reported. The trials were conducted in Poland (7), Spain (4), France (9) and Czech Republic (2) in 2017, 2018 and 2021 (see Table 3.2-9, Table 3.2-10 and

	No. of trials	Mean % Control from three trials in the North-east EPPO Zone at a range of doses of Chlormequat 34.5% + Mepiquat 11.5%						
		Untreated Mean % (range)	1.5 L/ha		1.75 L/ha		2.0 L/ha	
			Mean	Range	Mean	Range	Mean	Range
Winter wheat								
Mean % control, one observation on PLANT per trial, LODGING at 78-98 DAT	5	38.3 (26.0-50.0)	31.9	0.0-58.8	67.3	24.9-100	93.3	66.7-100
Mean % control, one observation on PLANT per trial, HEIGHT at 57-78 DAT	7	96.4 (85.0-120.2)	5.3	1.0-14.0	8.2	2.0-25.3	11.5	7.8-16.6

Table 3.2-11). Chlormequat 34.5% + Mepiquat 11.5% SL was included in these trials at 2.0 L/ha to demonstrate the recommended dose rate as well as at two lower dose rates (1.5 L/ha and 1.75 L/ha [518 g chlormequat and 173 g mepiquat per hectare, per application and 603 g chlormequat and 201 g mepiquat per hectare, per application]). In the trials, specifically targeted for height reduction to prevent lodging, one application was applied at growth stages ranging between BBCH 29 and BBCH 32.

The results obtained with Chlormequat 34.5% + Mepiquat 11.5% SL applied for reduce of height to prevent lodging in winter wheat are presented in **Table 3.2-9**, **Table 3.2-10** and

	No. of trials	Mean % Control from three trials in the North-east EPPO Zone at a range of doses of Chlormequat 34.5% + Mepiquat 11.5%						
		Untreated Mean % (range)	1.5 L/ha		1.75 L/ha		2.0 L/ha	
			Mean	Range	Mean	Range	Mean	Range
Winter wheat								
Mean % control, one observation on PLANT per trial, LODGING at 78-98 DAT	5	38.3 (26.0-50.0)	31.9	0.0-58.8	67.3	24.9-100	93.3	66.7-100
Mean % control, one observation on PLANT per trial, HEIGHT at 57-78 DAT	7	96.4 (85.0-120.2)	5.3	1.0-14.0	8.2	2.0-25.3	11.5	7.8-16.6

Table 3.2-11, for results obtained in the Maritime, the North-east and the Mediterranean EPPO zones.

Table 3.2-9: Maritime zone: Minimum effective dose of Chlormequat 34.5% + Mepiquat 11.5% SL for height reduction in winter wheat.

	No. of trials	Mean % Control from six trials in the Maritime EPPO Zone at a range of doses of Chlormequat 34.5% + Mepiquat 11.5%						
		Untreated Mean % (range)	1.5 L/ha		1.75 L/ha		2.0 L/ha	
			Mean	Range	Mean	Range	Mean	Range
Winter wheat								
Mean % control, one observation on PLANT per trial, LODGIN at 30-102 DAT	5	41.2 (30.0-67.5)	48.9	0.0-100	50.8	0.0-100	73.8	46.7-100
Mean % control, one observation on PLANT per trial, HEIGHT at 47-84 DAT	8	87.2 (61.1-104)	5.31	3.23-8.07	5.43	2.27-10.9	6.46	2.00-11.6

Table 3.2-10: North-east zone: Minimum effective dose of Chlormequat 34.5% + Mepiquat 11.5% SL for height reduction in winter wheat.

	No. of trials	Mean % Control from three trials in the North-east EPPO Zone at a range of doses of Chlormequat 34.5% + Mepiquat 11.5%						
		Untreated Mean % (range)	1.5 L/ha		1.75 L/ha		2.0 L/ha	
			Mean	Range	Mean	Range	Mean	Range
Winter wheat								
Mean % control, one observation on PLANT per trial, LODGING at 78-98 DAT	5	38.3 (26.0-50.0)	31.9	0.0-58.8	67.3	24.9-100	93.3	66.7-100
Mean % control, one observation on PLANT per trial, HEIGHT at 57-78 DAT	7	96.4 (85.0-120.2)	5.3	1.0-14.0	8.2	2.0-25.3	11.5	7.8-16.6

Table 3.2-11: Mediterranean zone: Minimum effective dose of Chlormequat 34.5% + Mepiquat 11.5% SL for height reduction in winter wheat.

	No. of trials	Mean % Control from six trials in the Mediterranean EPPO Zone at a range of doses of Chlormequat 34.5% + Mepiquat 11.5%						
		Untreated Mean % (range)	1.5 L/ha		1.75 L/ha		2.0 L/ha	
			Mean	Range	Mean	Range	Mean	Range
Winter wheat								
Mean % control, one observation on PLANT per trial, LODINT at 27-56 DAT	3	12.5 (8.75-15.0)	38.4	28.0-45.5	51.9	42.9-58.3	43.6	33.3-54.5
Mean % control, one observation on PLANT per trial, HEIGHT at 29-63 DAT	3	73.1 (57.5-82.4)	6.6	3.6-9.0	8.8	7.20-12.0	11.1	7.5-15.3

Summary and conclusions on the minimum effective dose

In summary, reducing the application rate of Chlormequat 34.5% + Mepiquat 11.5% SL from the proposed dose rate resulted in decreased efficacy against the reduction of height to prevent lodging.

According to the presented results, the dose rate of 2.0 L/ha per application, for control of height to prevent lodging provided the optimal overall control and should be considered as effective, for which activity of Chlormequat 34.5% + Mepiquat 11.5% SL is claimed. Only one application per season of Chlormequat 34.5% + Mepiquat 11.5% SL at the proposed rate should be used to efficiently control height claimed on the label.

This document clearly demonstrates – as will be demonstrated in the following sections – that the efficacy and crop safety of Chlormequat 34.5% + Mepiquat 11.5% SL is equivalent to the standard chlormequat + mepiquat containing products to which it was compared. The applicant therefore wishes to cite the data on chlormequat + mepiquat now out of protection in additional support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the zonal and national evaluators extrapolate from those data.

Comments of zRMS:	<p>The trials submitted to support the MED (minimum effective dose) of MEPCY (product code: SHA 126085 A) are the same as the efficacy trials described under section efficacy. 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>22 field trials carried out in different growing seasons (2017, 2018 and 2021) on winter wheat were established to determine the minimum effective dose of MEPCY. Trials were performed only in three EPPO zones – N-E in Poland (7 trials); MED in ES (4 trials) and FR (2 trials) and MAR in FR (7 trials) and CZ (2 trials). Three different doses were studied: 1,5 L/ha (0,75 N); 1,75 L/ha (0,88 N) and 2,0 L/ha (N dose). 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 33.</p> <p>The proposed doses were derived from registered doses of standard reference products with mepiquat chloride and chlormequat chloride as active compounds 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 logging and growth reduction is 2,0 L/ha applied once a season. Detailed results were presented by Applicant in the tables: Table 3.2-9; Table 3.2-10 and Table 3.2-12.</p>
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Minimum effective dose results:

- **N-E EPPO zone:** During 7 trials effect of reduction of height was observed. The most effective was dose 2,0 L/ha (average efficacy of reduction height: 11,5%). Effect of dose 1,5 l/ha (average: 5,34%) and 1,75 L/ha (average: 8.72%) was lower than recommended dose. The most effective against reduction of height was dose 2,0 L/ha and this dose should be recommended for use.

Lodging was observed in 5 trials on control plants (average: 38,3%). Dose 2,0 L/ha reduce of lodging with 93,34% efficacy. Dose 1,5 L/ha reduce of lodging with 26,46% efficacy and dose 1,75 L/ha with 67,32% efficacy. The most effective against lodging in winter wheat plants was dose 2,0 L/ha and this dose should be recommended for use.

Trial no.	Country	Assess. Type	Untreated	Chlormequat + Mepiquat SL 1.5 L/ha (518 + 173g ai/ha)		Chlormequat + Mepiquat SL 1.75 L/ha (603 + 201g ai/ha)		Chlormequat + Mepiquat SL 2.0 L/ha (690 + 230g ai/ha)	
			Mean	Mean	% Cont.	Mean	% Cont.	Mean	% Cont.
NUZ 18+19/17-1	PL	LODGING	26.0 a	22.0 ^a _b	15.4	11.0 b	57.7	0.0 b	100
NUZ 18+19/17-3	PL	LODGING	50.0 a	35.0 b	30.0	23.0 b	54.0	0.0 c	100
NUZ 18+19/17-2	PL	LODGING	34.0 a	14.0 c	58.8	0.0 d	100	0.0 d	100
NUZ 03/21/1	PL	LODGING	45.0 a	45.0 a	0.0	33.8 b	24.9	15.0 c	66.7
SRG21-SHA52	PL	LODGING	36.3 a	16.3 a	55.1	0.0 c	100	0.0 c	100

NUZ 18+19/17-1	PL	Height	93.6 a	90.5 ^{ab}	3.31	89.1 b	4.81	85.0 c	9.20
NUZ 18+19/17-3	PL	Height	85.0 a	81.0 a	4.70	81.0 a	4.70	75.0 ^b _c	11.8
NUZ 18+19/17-2	PL	Height	87.0 a	83.0 b	4.59	82.0 b	5.75	77.0 c	11.5
NUZ 03/21/1	PL	Height	120.2 a	119 ^{ab}	1.0	117.8 b	2.0	110.8 c	7.8
SRG21-SHA52	PL	Height	90.2 a	88.4 ^{ab}	2.0	87.0 b	3.5	80.8 c	10.4
SRG21-SHA53	PL	Height	98.8 a	85.0 b	14.0	73.8 d	25.3	82.4 c	16.6
SRG21-SHA54	PL	Height	99.9 a	92.1 b	7.8	88.4 b	11.5	86.9 b	13.0

- **Maritime EPPO zone:** During 8 trials effect of reduction of height was observed. The most effective was dose 2,0 L/ha (average efficacy of reduction height: 6,3%). Effect of dose 1,5 l/ha (average: 5,31%) and 1,75 L/ha (average: 5,43%) was lower than recommended dose. Differences between doses were slightly, however the most effective was 2,0 L/ha. So, this dose is recommended for use against reduction of height in winter wheat plants.

Lodging was observed in 5 trials on control plants (average: 41,16%). Dose 2,0 L/ha reduce of lodging with 73,76% efficacy. Dose 1,5 L/ha reduce of lodging with 48,98% efficacy and dose 1,75 L/ha with 50,76% efficacy. The most effective against lodging in winter wheat plants was dose 2,0 L/ha and this dose should be recommended for use.

Trial no.	Country	Assess. Type	Untreated	Chlormequat + Mepiquat SL 1.5 L/ha (518 + 173g ai/ha)		Chlormequat + Mepiquat SL 1.75 L/ha (603 + 201g ai/ha)		Chlormequat + Mepiquat SL 2.0 L/ha (690 + 230g ai/ha)	
			Mean	Mean	% Cont.	Mean	% Cont.	Mean	% Cont.
PC 17-05-31-NE2	FR	LODAN	67.5 a	61.3 a	9.18	70.0 a	0.0	22.5 a	66.7

G													
PC 17-05-31-NE4	FR	LODAN G	37.5	a	40.0	a	0.0	37.5	a	0.0	20.0	a	46.7
S17-00712-02	FR	LODG-IN	37.5	a	10.0	a	73.3	12.5	a	66.7	7.5	a	80.0
S17-00712-03	FR	LODG-IN	33.3	a	12.5	a	62.4	4.3	a	87.1	8.2	a	75.4
SWEPL-...-TRZAW-RYM20	CZ	LODG-IN	30.0	a	0.0	a	100	0.0	a	100	0.0	a	100
PC 17-05-31-NE1	FR	Height	74.8	a	71.6	a	4.27	72.4	a	3.20	73.3	a	2.00
PC 17-05-31-NE2	FR	Height	92.3	a	88.9	b	3.68	90.2	a b	2.27	87.8	b	4.88
PC 17-05-31-NE3	FR	Height	98.7	a	92.8	b	5.97	95.4	b	3.34	93.6	b	5.17
PC 17-05-31-NE4	FR	Height	82.5	a	77.5	b	6.07	77.2	b	6.42	77.1	b	6.54
S17-00712-01	FR	Height	92.9	a	90.0	b	3.23	90.0	b	3.23	90.5	b	7.3
S17-00712-03	FR	Height	91.2	a	87.1	b	4.49	84.9	b	6.90	85.9	b	5.81
SWEPL-...-TRZAW-RYM20	CZ	Height	61.1	a	57.0	b	6.71	56.7	b	7.20	56.6	a	7.36
SWEPL-...-TRZAW-DOM20	CZ	Height	104	a	95.6	b	8.07	92.7	b c	10.9	92.0	c	11.6
<ul style="list-style-type: none">Mediterranean EPPO zone: During 3 trials effect of reduction of height was observed. The most effective was dose 2,0 L/ha (average efficacy of reduction height: 11,07%). Effect of dose 1,5 l/ha (average: 6,6%) and 1,75 L/ha (average: 8,87%) was lower than recommended dose.													
Lodging was observed in 3 trials on control plants (average:12,52%). Dose 2,0 L/ha reduce of lodging with 43,57% efficacy. Dose 1,5 L/ha reduce of lodging with 38,4% efficacy and dose 1,75 L/ha with 51,9% efficacy. The most effective against lodging in winter wheat plants was dose 2,0 L/ha and this dose should be recommended for use.													
Trial no.	Country	Assess. Type	Untreated	Chlormequat + Mepiquat SL 1.5 L/ha (518 + 173g ai/ha)			Chlormequat + Mepiquat SL 1.75 L/ha (603 + 201g ai/ha)			Chlormequat + Mepiquat SL 2.0 L/ha (690 + 230g ai/ha)			
			Mean	Mean	% Cont.	Mean	% Cont.	Mean	% Cont.				
17-SHA-476	ES	LOD-INT	13.8 a	7.50 b	45.5	6.25 b	54.5	6.25 b	54.5				
17-SHA-477	ES	LOD-INT	8.75 a	6.25 a b	28.0	5.0 a b	42.9	5.0 a b	42.9				
17-SHA-478	ES	LOD-INT	15.0 a	8.75 a	41.7	6.25 a	58.3	10.0 a	33.3				
PC 18-05-45-1	FR	Height	79.5 a	73.8 b c	7.2	73.8 b c	7.2	71.3 c	10.4				
PC 18-05-45-2	FR	Height	82.4 a	79.4 a b	3.6	76.3 b	7.4	76.2 b	7.5				
SHA17OP2PGR248-02	ES	Height	57.5 a	52.3 a b	9.0	50.6 a b	12.0	48.7 a b	15.3				
Summary: In the opinion of ZRMs, presented results and knowledge about registered doses of standard reference products with mepiquat chloride and chlormequat chloride allow to consider dose 2.0 L/ha as the most effective for winter wheat against reduction of height and lodging.													

3.2.3 Efficacy tests (KCP 6.2)

Data from twenty two efficacy trials conducted in winter wheat in the Maritime EPPO zone (9; i.e. France (7) and the Czech Republic (2)), the North-east EPPO zone (7; i.e. Poland) and in the Mediterranean EPPO zone (6; i.e. Spain (4) and S-France (2)) 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.

Data from the Mediterranean trials have been added as the same diseases that are affecting the Central zone may also affect the cereals cultivation in the central zone as well.

Table 3.2-13: Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/152 (4), PP 1/181 (4), PP 1/135(4)
	Specific guidelines	EPPO PP 1/144 (3)
Experimental design	Plot design	RCBD (22)
	Plot size	12-30 m ²
	Number of replications	4 (22)
Crop	Trials per crop	Winter wheat (22)
	Varieties per crop	Winter wheat: Pakito, Fructidor, Arezzo, Boregar, Galibier, Advisor, Magister, Bohemia, Botticelli, Califa, Calumet, Soleiho, Alambra, Linus, Memory, KWS Ozon, KWS Spencer, Hondia, Anna
	Sowing period	Winter wheat: September 16 th 2016 to October 16 th 2020
Application	Application period	Winter wheat: April 7 th 2017 to May 26 th 2021
	Crop stage (BBCH)* at application	Winter wheat (48 22): BBCH 29-33
	Number of appl. Intervals between appl.	1(22) -
	Spray volumes	200-400 L/ha
Assessment	Assessment types	<ul style="list-style-type: none"> - Visual estimation of crop injury and crop stand reduction (thinning) compared to 'untreated' ('untreated' = 0% crop injury; 100% crop injury = total crop destruction). Where appropriate, this overall score was substituted or supplemented by assessments of individual symptoms. - crop vigour
	Assessment dates	As a rule 3 crop injury ratings
Other relevant information	Soil type	Clay, loamy sand, loam, sandy loam, clay loam, silt clay loam, silt loam, silt, loamy clay sand
	Organic matter content	1.0-3.1
	Natural / artificial inoculation...	Preferably disease-free conditions
	Field / Greenhouse...	Field

Use 001: Control of height reduction in winter wheat

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

Crop	Winter wheat
Use rate	2.0 L/ha Chlormequat 34.5% + Mepiquat 11.5% SL
Use frequency	Up to 1x
Application timing	BBCH 29-32
Target	Height reduction

The effectiveness of applying Chlormequat 34.5% + Mepiquat 11.5% SL against GAP claimed diseases in winter wheat was evaluated in 22 trials, assessed for lodging and height on specific plants. These trials were carried out in 2017, 2018 and 2021 in the Maritime EPPO zone (9; i.e. France (7) and Czech Republic (2)), the North-east EPPO zone (7; i.e. Poland) and the Mediterranean EPPO zone (6; i.e. Spain (4) and the France (2)). The objective was to confirm the performance of Chlormequat 34.5% + Mepiquat 11.5% SL at the proposed dose rate of 2.0 L/ha (i.e. 345 grams per liter (g/L) chlormequat and 115 grams per liter (g/L) mepiquat). In the trials specifically targeted for this pathogen, single application was applied at growth stages ranging between BBCH 29 and BBCH 33.

Maritime zone

To demonstrate the effectiveness of the test product at the proposed dose rate for height reduction to prevent lodging as well as compare it to the reference products included in the trial, the plant height and lodging of winter wheat was assessed in the trials. In the trials, height reduction and lodging on plants was evaluated at one assessment timings which was considered valid for the summary. In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-16 and Table 3.2-15 therefore only contains one assessment per plant part from the Maritime trials assessed repeatedly.

Table 3.2-14: Maritime zone: Efficacy of 2.0 L/ha Chlormequat 34.5% + Mepiquat 11.5% SL and standard formulated reference product at comparable dose rate applied in winter wheat in the efficacy tests – 64-102 DALT.

Part assessed	Days after Last Treatment. (DALT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Chlormequat 34.5% + Mepiquat 11.5% SL; 345 + 115g ai/ha is >, < or =, compared to the Reference product = : ± 5% control			
				Chlormequat 34.5% + Mepiquat 11.5% SL	CYTER				Overall
				Mean (min-max)					
				2.0 L/ha	1 N	>	=	<	
Lodging									
Plant	67-102 DAT	4	41.2 (30.0-67.5)	73.8 (46.7-100)	46.1 (29.6-100)	3		1	>
Height									
Plant	64-84 DAT	6	87.2 (61.1-100)	6.46 (2.0-11.6)	4.62 (3.12-5.81)	1	5		=

Table 3.2-15: Maritime zone: Efficacy of 2.0 L/ha Chlormequat 34.5% + Mepiquat 11.5% SL and national standard formulated reference product at comparable dose rate applied in winter wheat in the efficacy tests – 30-59 DALT.

Part assessed	Days after Last Treatment. (DALT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Chlormequat 34.5% + Mepiquat 11.5% SL; 345 + 115g ai/ha is >, < or =, compared to the Reference product = : ± 5% control			Overall
				Chlormequat 34.5% + Mepiquat 11.5% SL	Spatial Plus				
				Mean (min-max)					
				2.0 L/ha	2.4 L/ha	>	=	<	
Lodging									
Plant	30 DAT	1	30.0 (-)	100 (-)	100 (-)		1		=
Height									
Plant	47-59 DAT	2	82.6 (61.1-104)	9.48 (7.36-11.6)	10.7 (7.85-13.6)		2		=

In the trials, where height reduction on plants was assessed, the mean height in untreated plots was 87.2 at the assessments chosen for evaluation. At these assessments, carried out at 64-84 days after the last application, the test product applied at 2.0 L/ha achieved an average height reduction of 6.46%. At the same assessments, the formulated reference product applied at comparable dose rate achieved an average height reduction of 4.62%. In two Czech trials, where height reduction on plants was assessed also, the mean

height in untreated plots was 82.6 at the assessments chose for evaluation, the test product applied at 2.0 L/ha achieved an average height reduction of 9.48%. At the same assessments, the formulated national reference product applied at comparable dose rate achieved an average height reduction of 10.7%.

In the trials, where lodging on plants was assessed, the mean lodging in untreated plots was 41.2 at the assessments chosen for evaluation. At these assessments, carried out at 67-102 days after the last application, the test product applied at 2.0 L/ha achieved an average lodging of 73.8%. At the same assessments, the formulated reference product applied at comparable dose rate achieved an average height reduction of 46.1%. In one Czech trial, where lodging on plants was assessed also, the mean height in untreated plots was 30.0 at the assessments chose for evaluation, the test product applied at 2.0 L/ha achieved an average height reduction of 100%. At the same assessments, the formulated national reference product applied at comparable dose rate achieved the same average lodging.

The individual trial results show that Chlormequat 34.5% + Mepiquat 11.5% SL gave good control of height reduction, similar to that achieved by the formulated reference product and national reference products.

North-east zone

To demonstrate the effectiveness of the test product at the proposed dose rate for height reduction to prevent lodging as well as compare it to the reference products included in the trial, the plant height and lodging of winter wheat was assessed in the trials. In the trials, height reduction and lodging on plants was evaluated at one assessment timings which was considered valid for the summary. In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-16 therefore only contains one assessment per plant part from the trials assessed repeatedly.

Table 3.2-16: North-east zone: Efficacy of 2.0 L/ha Chlormequat 34.5% + Mepiquat 11.5% SL and standard formulated reference product at comparable dose rate applied in winter wheat in the efficacy tests – 57-98 DALT.

Part assessed	Days after Last Treatment. (DALT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Chlormequat 34.5% + Mepiquat 11.5% SL; 345 + 115g ai/ha is >, < or =, compared to the Reference product = : ± 5% control			Overall
				Chlormequat 34.5% + Mepiquat 11.5% SL	Medax Top				
				Mean (min-max)					
				2.0 L/ha	1 N	>	=	<	
Lodging									
Plant	78-98 DAT	5	38.3 (26.0-50.0)	93.3 (66.7-100)	96.7 (83.3-100)		5		=
Height									
Plant	57-78 DAT	7	96.4 (85.0-120.2)	11.5 (7.8-16.6)	13.6 (8.2-24.4)	1	5	1	=

In the trials, where height reduction on plants was assessed, the mean height in untreated plots was 96.4 at the assessments chosen for evaluation. At these assessments, carried out at 57-78 days after the last application, the test product applied at 2.0 L/ha achieved an average height reduction of 11.5%. At the same assessments, the formulated national reference product applied at comparable dose rate achieved an average height reduction of 13.6%.

In the trials, where lodging on plants was assessed, the mean lodging in untreated plots was 38.3 at the assessments chosen for evaluation. At these assessments, carried out at 78-98 days after the last application, the test product applied at 2.0 L/ha achieved an average lodging of 93.3%. At the same assessments, the formulated national reference product applied at comparable dose rate achieved an average height reduction of 96.7%.

The individual trial results show that Chlormequat 34.5% + Mepiquat 11.5% SL gave good control of

height reduction, similar to that achieved by the formulated reference product and national reference products.

Mediterranean zone

To demonstrate the effectiveness of the test product at the proposed dose rate for height reduction to prevent lodging as well as compare it to the reference products included in the trial, the plant height and lodging of winter wheat was assessed in the trials. In the trials, height reduction and lodging on plants was evaluated at one assessment timings which was considered valid for the summary. In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-17, Table 3.2-18 and Table 3.2-19 therefore only contains one assessment per plant part from the trials assessed repeatedly.

Table 3.2-17: Mediterranean zone: Efficacy of 2.0 L/ha Chlormequat 34.5% + Mepiquat 11.5% SL and standard formulated reference product at comparable dose rate applied in winter wheat in the efficacy tests – 27-63 DALT.

Part assessed	Days after Last Treatment. (DALT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Chlormequat 34.5% + Mepiquat 11.5% SL; 345 + 115g ai/ha is >, < or =, compared to the Reference product = : ± 5% control			Overall
				Chlormequat 34.5% + Mepiquat 11.5% SL	CYTER				
				Mean (min-max)					
				2.0 L/ha	1 N	>	=	<	
Lodging									
Plant	27-56 DAT	3	12.5 (8.75-15.0)	43.6 (33.3-54.5)	66.0 (42.9-91.7)		1	2	<
Height									
Plant	56-63 DAT	2	73.1 (57.5-82.4)	8.95 (7.5-10.4)	7.0 (5.8-8.2)		2		=

Table 3.2-18: Mediterranean zone: Efficacy of 2.0 L/ha Chlormequat 34.5% + Mepiquat 11.5% SL and national standard formulated reference product at comparable dose rate applied in winter wheat in the efficacy tests – 27-56 DALT.

Part assessed	Days after Last Treatment. (DALT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Chlormequat 34.5% + Mepiquat 11.5% SL; 345 + 115g ai/ha is >, < or =, compared to the National Reference product = : ± 5% control			Overall
				Chlormequat 34.5% + Mepiquat 11.5% SL	Hidrofertil				
				Mean (min-max)					
				2.0 L/ha	3.5 L/ha	>	=	<	
Lodging									
Plant	27-56 DAT	3	12.5 (8.75-15.0)	43.6 (33.3-54.5)	86.1 (72.7-100)			3	<

Table 3.2-19: Mediterranean zone: Efficacy of 2.0 L/ha Chlormequat 34.5% + Mepiquat 11.5% SL and national standard formulated reference product at comparable dose rate applied in winter wheat in the efficacy tests – 29 DALT.

Part assessed	Days after Last Treatment. (DALT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Chlormequat 34.5% + Mepiquat 11.5% SL; 345 + 115g ai/ha is >, < or =, compared to the National Reference product = : ± 5% control			Overall
				Chlormequat 34.5% + Mepiquat 11.5% SL	Moddus				
				Mean (min-max)					
				2.0 L/ha	0.5 L/ha	>	=	<	
Height									
Plant	29 DAT	1	57.5 (-)	15.3 (-)	27.5 (-)			1	<

In the trials, where height reduction on plants was assessed, the mean height in untreated plots was 73.1 at the assessments chosen for evaluation. At these assessments, carried out at 56-63 days after the last application, the test product applied at 2.0 L/ha achieved an average height reduction of 8.95%. At the same assessments, the formulated reference product applied at comparable dose rate achieved an average height reduction of 7.0%. In one Spanish trial, where height reduction on plants was assessed also, the mean height in untreated plots was 57.5 at the assessment chose for evaluation, the test product applied at 2.0 L/ha achieved an average height reduction of 15.3%. At the same assessment, the formulated national reference product applied at comparable dose rate achieved an average height reduction of 27.5%.

In the trials, where lodging on plants was assessed, the mean lodging in untreated plots was 12.5 at the assessments chosen for evaluation. At these assessments, carried out at 27-56 days after the last application, the test product applied at 2.0 L/ha achieved an average lodging of 43.6%. At the same assessments, the formulated reference product applied at comparable dose rate achieved an average height reduction of 66.0%. In the same three Spanish trials, where lodging on plants was assessed also, the formulated national reference product applied at comparable dose rate achieved an average height reduction of 86.1%.

The individual trial results show that Chlormequat 34.5% + Mepiquat 11.5% SL gave good control of height reduction, similar to that achieved by the formulated reference product and national reference products.

Summary and conclusion

Based on the results of 22 field efficacy trials carried out in 2017, 2018 and 2021, the following can be concluded for the intended use of Chlormequat 34.5% + Mepiquat 11.5% SL applied at 2.0 L/ha per application in winter wheat:

- Chlormequat 34.5% + Mepiquat 11.5% SL applied in winter wheat provided a good reduction of height to prevent lodging with the recommended dose rate of 2.0 L/ha. One application per season of Chlormequat 34.5% + Mepiquat 11.5% SL at the proposed dose rate should be used to efficiently reduce height to prevent lodging as claimed on the label.
- Compared to the reference product tested in the winter wheat trials, the efficacy obtained with Chlormequat 34.5% + Mepiquat 11.5% SL is comparable against the key disease tested.
- The trial results are considered valid for all intended Central zone countries.

Chlormequat 34.5% + Mepiquat 11.5% SL is suitable for the control of height to prevent lodging in winter wheat.

This document clearly demonstrates that the efficacy and crop safety of Chlormequat 34.5% + Mepiquat 11.5% SL is equivalent to the standard containing products to which the test product was compared. The applicant therefore wishes to cite the data on standard containing products now out of protection in additional support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the zonal and national evaluators 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 Maritime EPPO zone (all trials were carried out only in one growing season – 2017). In N-E (2017 and 2021) and MED (2017 and 2018) – two different growing seasons were studied in line to EPPO.</p> <p>We are dealing with the active substances used commonly for many years in many countries. On the basis on EPPO standard Applicant should submitted for reduction height and against lodging 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 all zones.</p>
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- **N-E EPPO zone:** Below, ZRMs presented detailed results from all trials separately for reduction of growth and lodging which was assessed.

Trial no.	Country	Assess. Type	Crop GS at Asses. BBCH	Untreated		Chlormequat + Mepiquat SL 2.0 L/ha (690 + 230g ai/ha)		Medax Top 350 SL 1.25 L/ha (265 + 44g ai/ha)	
				Mean		Mean	% Cont.	Mean	% Cont.
NUZ 18+19/17-1	PL	LODGING	85	26.0	a	0.0	b 100	0.0	b 100
NUZ 18+19/17-3	PL	LODGING	85	50.0	a	0.0	c 100	0.0	c 100
NUZ 18+19/17-2	PL	LODGING	85	34.0	a	0.0	d 100	0.0	d 100
NUZ 03/21/1	PL	LODGING	85	45.0	a	15.0	c 66.7	7.5	c 83.3
SRG21-SHA52	PL	LODGING	89	36.3	a	0.0	c 100	0.0	c 100
NUZ 18+19/17-1	PL	Height	85	93.6	a	85.0	c 9.20	84.3	c 9.93
NUZ 18+19/17-3	PL	Height	85	85.0	a	75.0	bc 11.8	70.0	c 17.6
NUZ 18+19/17-2	PL	Height	85	87.0	a	77.0	c 11.5	76.0	c 12.6
NUZ 03/21/1	PL	Height	69	120.2	a	110.8	c 7.8	110.3	c 8.2
SRG21-SHA52	PL	Height	75	90.2	a	80.8	c 10.4	68.2	e 24.4
SRG21-SHA53	PL	Height	77	98.8	a	82.4	c 16.6	86.1	b 12.9
SRG21-SHA54	PL	Height	77	99.9	a	86.9	b 13.0	90.2	b 9.7

Reduction of height was observed in 7 trials carried out on winter wheat. Observed average efficacy was 11,47% and it was lower than standard ref. product eff. 13,61%.

Lodging was observed in 5 trials at untreated control plants. MEPCY reduced lodging with 93,4% efficacy. Standard reference product was characterized by slightly better eff. (95,66%).

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

Trial no.	Country	Assess. Type	Crop GS at Asses. BBCH	Untreated		Chlormequat + Mepiquat SL 2.0 L/ha (690 + 230g ai/ha)		CYTER 2.0 L/ha (690 + 230g ai/ha)		Spatial Plus 2.4 L/ha [etheponh + chlormequat] (360 + 720g ai/ha)	
				Mean		Mean	% Cont.	Mean	% Cont.	Mean	% Cont.
PC 17-05-31-NE2	FR	LODAN G	87	67.5	a	22.5	a 66.7	47.5	a 29.6	-	-
PC 17-05-31-NE4	FR	LODAN G	85	37.5	a	20.0	a 46.7	40.0	a 0.0	-	-
S17-00712-02	FR	LODGIN	83	37.5	a	7.5	a 80.0	17.0	a 54.6	-	-
S17-00712-03	FR	LODGIN	89	33.3	a	8.2	a 75.4	0.0	a 100	-	-
SWEPL-....-TRZAW-RYM20	CZ	LODGIN	85	30.0	a	0.0	a 100	-	-	0.0	a 100
PC 17-05-31-NE1	FR	Height	85	74.8	a	73.3	a 2.00	71.7	a 4.14	-	-
PC 17-05-31-NE2	FR	Height	85	92.3	a	87.8	b 4.88	88.4	b 4.23	-	-
PC 17-05-31-NE3	FR	Height	83	98.7	a	93.6	b 5.17	93.8	b 4.96	-	-
PC 17-05-31-NE4	FR	Height	85	82.5	a	77.1	b 6.54	77.7	b 5.81	-	-
S17-00712-01	FR	Height	77	92.9	a	90.5	b 7.3	90.0	b 3.12	-	-
S17-00712-03	FR	Height	77	91.2	a	85.9	b 5.81	86.2	b 5.48	-	-
SWEPL-....-TRZAW-RYM20	CZ	Height	75	61.1	a	56.6	a 7.36	-	-	56.3	b 7.85
SWEPL-....-TRZAW-DOM20	CZ	Height	75	104	a	92.0	c 11.6	-	-	89.8	c 13.6

Reduction of height was observed in 9 trials carried out on winter wheat. Observed average efficacy

cy was 7,23% and it was slightly higher than standard ref. product eff. 7,03%.

Lodging was observed in 5 trials at untreated control plants (average: 41,16%). MEPCY reduced lodging with 73,76% efficacy. Standard reference product was characterized by lower eff. (56,84%).

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

Trial no.	Country	Asses. Type	Crop GS at Asses. BB CH	Un-treated		Chlormequat + Mepiquat SL 2.0 L/ha (690 + 230g ai/ha)		CYTER 2.0 L/ha (690 + 230g ai/ha)		Hidrofertel [Chlormequat 40% SL] 3.5 L/ha (1400g ai/ha)		Moddus [Trinexapac-etil 25% ME] 0.5 L/ha (125g ai/ha)	
				Me an	% Co nt.	Me an	% Co nt.	Me an	% Co nt.	Me an	% Co nt.	Me an	% Co nt.
17-SHA-476	ES	LOD-INT	92	13.8 a	54.5 b	6.25 b	63.6	5.00 b	72.7	3.75 b	85.7	-	-
17-SHA-477	ES	LOD-INT	85	8.75 a	42.9	5.00 b	42.9	5.00 b	85.7	1.25 b	85.7	-	-
17-SHA-478	ES	LOD-INT	85	15.0 a	33.3	10.0 a	91.7	1.25 a	100	0.00 b	100	-	-
PC 18-05-45-1	FR	Height	83	79.5 a	10.4	71.3 c	8.2	73.0 b	-	-	-	-	-
PC 18-05-45-2	FR	Height	77	82.4 a	7.5	76.2 b	5.8	77.6 b	-	-	-	-	-
SHA17OP2PG R248-02	ES	Height	39	57.5 a	15.3	48.7 b	-	-	-	-	42.8 b	25.5	-

Reduction of height was observed in 3 trials carried out on winter wheat. Observed average efficacy was 11,07% and it was lower than standard ref. product eff. 13,17%.

Lodging was observed in 3 trials at untreated control plants. MEPCY reduced lodging with 43,57% efficacy. Standard reference product was characterized by better eff. (66,7% and 86,13%).

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. Mepiquat chloride and 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 MEPCY (product code: SHA 126085 A) can be accepted by them only on the basis on extrapolation results from N-E EPPO, MED EPPO zone and/or Maritime EPPO zone.

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. MEPCY (product code: SHA 126085 A) 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 of 2,0 L/ha in winter wheat.

In summary, **ZRMs consents to the registration of the product in Poland as stated in the GAP table. Applicant submitted enough number of trials against reduction of height (9 trials: PL-7, CZ-2) and lodging (6 trials: PL-5, CZ-1).** It was demonstrated that the product reduces the height of plants (on average by several cm as compared with the control) and thus can counteract their overgrowth. The product showed positive effect, however slightly lower than the reference standard. **It is left to the Member States to decide on the acceptability of the results presented in this dRR and to consider registration of MEPCY.**

3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

Since Chlormequat 34.5% + Mepiquat 11.5% SL are 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 and mepiquat.

Comments of zRMS:	ZRMs agree with Applicant. An assessment of resistance risk is not required for a plant growth regulator. Mepiquat chloride and chlormequat chloride are on 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)

Data from 22 efficacy trials in winter wheat have been presented for selectivity results conducted in the Maritime EPPO zone (9, i.e. Czech Republic and France), the North-east EPPO zone (7, i.e. Poland) and the Mediterranean EPPO zone (6, i.e. Spain and S-France) have been included in this biological assessment dossier to support the label claims and recommendations on selectivity in the EU Central Registration zone.

The 22 efficacy trials were conducted in winter wheat.

Information on trials submitted (6.4 Adverse effects on treated crops)

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). The GEP-requirement and the Uniform Principles are therefore taken care of.

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 34.5% + Mepiquat 11.5% SL, 22 efficacy trials with selectivity results were conducted in the Maritime, the North-east and the Mediterranean EPPO zones:

Table 3.4-1: Presentation of efficacy 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 (Height reduction)	Spain	MED + E		4			2017	GEP	
	France	MED + E	7				2017	GEP	
		MED + E		2			2018	GEP	
	Czech Republic	MED + E	2				2017	GEP	
	Poland	MED + E				3	2017	GEP	

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			
	Poland	MED + E				4	2021	GEP	
	Total, Winter wheat (eff.)		9	6		7			

Table 3.4-2: Details on efficacy trial methodology

Guidelines	General guidelines	EPPO PP 1/152 (4), PP 1/181 (4), PP 1/135(4)
	Specific guidelines	EPPO PP 1/144 (3)
Experimental design	Plot design	RCBD (22)
	Plot size	12-30 m ²
	Number of replications	4 (22)
Crop	Trials per crop	Winter wheat (22)
	Varieties per crop	Winter wheat: Pakito, Fructidor, Arezzo, Boregar, Galibier, Advisor, Magister, Bohemia, Botticelli, Califa, Calumet, Soleiho, Alambra, Linus, Memory, KWS Ozon, KWS Spencer, Hondia, Anna
	Sowing period	Winter wheat: September 16 th 2016 to October 16 th 2020
Application	Application period	Winter wheat: April 7 th 2017 to May 26 th 2021
	Crop stage (BBCH)* at application	Winter wheat (48 22): BBCH 29-33
	Number of appl. Intervals between appl.	1(22) -
	Spray volumes	200-400 L/ha
Assessment	Assessment types	<ul style="list-style-type: none"> - Visual estimation of crop injury and crop stand reduction (thinning) compared to 'untreated' ('untreated' = 0% crop injury; 100% crop injury = total crop destruction). Where appropriate, this overall score was substituted or supplemented by assessments of individual symptoms. - crop vigour
	Assessment dates	As a rule 3 crop injury ratings
Other relevant information	Soil type	Clay, loamy sand, loam, sandy loam, clay loam, silt clay loam, silt loam, silt, loamy clay sand
	Organic matter content	1.0-3.1
	Natural / artificial inoculation...	Preferably disease-free conditions
	Field / Greenhouse...	Field

Reference products

In the efficacy trials with selectivity results, the performance of Chlormequat 34.5% + Mepiquat 11.5% SL was measured against a commercially available reference products containing chlormequat (Hidrofer-til; 400 g/L chlormequat SL) and chlormequat + mepiquat (Cyter; 345 g/L chlormequat + 115g/L mepiquat SL). In one Spanish trial, Chlormequat 34.5% + Mepiquat 11.5% SL was compared against a reference national registered product [Moddus (250g/l Trinexapac-etil)], in three Poland trials, a Medax Top (265g/l mepiquat + 44g/l prohexadion) and in four Poland trials, a Canopy (265g/l mepiquat + 44g/l pro-

hexadion) was used and in two Czech trials, a Spatial Plus (150g/l Ethephon + 300g/l Chlormequat) reference product was used. The trials were carried out on winter wheat.

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

Trade name	Formulation	Composition	Rates	Country	N° of Trials
Chlormequat and mepiquat formulation					
Cyter	SL	345 g/L chlormequat + 115 g/L mepiquat	1.75 L/ha	Spain	3
			2.00 L/ha	France	9
National reference product					
Hidrofertil	SL	400 g/L chlormequat	3.5 L/ha	Spain	3
Moddus	ME	250 g/L trinexapac-etil	0.5 L/ha	Spain	1
Spatial Plus	SL	150 g/l ethephon + 300 g/l chlormequat	2.4 L/ha	Czech Republic	2
Medax Top	SL	265 g/lMepiquat + 44 g/lprohexadion	1.25 L/ha	Poland	3
CANOPY	SC	265 g/lMepiquat + 44 g/lprohexadion	1.25 L/ha	Poland	4

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

As Chlormequat 34.5% + Mepiquat 11.5% SL is a plant growth regulator + fungicide, no specific studies are required as long as in the efficacy trials no negative effects are observed. The crop safety of applying Chlormequat 34.5% + Mepiquat 11.5% SL at a recommended dose rate in winter wheat was evaluated in 22 efficacy trials (9 MAR, 7 N-E and 6 MED). In the efficacy trials, Chlormequat 34.5% + Mepiquat 11.5% SL was applied at 1.5 to 2.0 L/ha.

The trials were conducted in Poland (7), Spain (4), France (9) and the Czech Republic (2) in winter wheat in 2017, 2018 and 2021 to evaluate the crop safety of Chlormequat 34.5% + Mepiquat 11.5% SL.

3.4.1.1 Winter wheat (TRZAW)

Crop phytotoxicity was evaluated in efficacy trials where Chlormequat 34.5% + Mepiquat 11.5% SL was applied at one application when the crop was at growth stages ranging from BBCH 29 to BBCH 33, at the rate of 2.0 L/ha in winter wheat. The 2.0 L/ha dose rate corresponds to 100% of the max. proposed dose rate in Central EU countries. Crop phytotoxicity was assessed in all trials at various intervals from first application and up to termination of the trial.

Phytotoxicity in winter wheat trials, Maritime EPPO zone

Nine efficacy trials were conducted in the Maritime EPPO zone to assess the crop safety of Chlormequat 34.5% + Mepiquat 11.5% SL when applied as recommended in winter wheat. The trials were conducted on commercially available varieties.

No adverse effects in regards to phytotoxicity and vigour were observed in any of the 9 efficacy trials treated with Chlormequat 34.5% + Mepiquat 11.5% SL in the Maritime EPPO zone.

Furthermore, harvest results from trials demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either.

Phytotoxicity in winter wheat trials, North-east EPPO zone

A total of 7 efficacy trials were conducted in the North-east EPPO zone to assess the crop safety of Chlormequat 34.5% + Mepiquat 11.5% SL when applied as recommended in winter wheat. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the 7 efficacy trials treated with Chlormequat 34.5% + Mepiquat 11.5% SL in the North-east EPPO zone.

Furthermore, harvest results from trials demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either.

Phytotoxicity in winter wheat trials, Mediterranean EPPO zone

A total of 6 efficacy trials were conducted in the Mediterranean EPPO zone to assess the crop safety of Chlormequat 34.5% + Mepiquat 11.5% SL when applied as recommended in winter wheat. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the 6 efficacy trials treated with Chlormequat 34.5% + Mepiquat 11.5% SL in the Mediterranean EPPO zone.

Furthermore, harvest results from trials demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either.

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 22 trials conducted in Poland, Czech Republic, France and Spain in 2017, 2018 and 2021. In all trials, Chlormequat 34.5% + Mepiquat 11.5% SL applied at the proposed label recommended rates in winter wheat proved to be crop safe and did not significantly affect the crop adversely when applied at a range of growth stages within and occasionally beyond the label recommended range.

As the data on winter wheat show, the crop safety and efficacy of Chlormequat 34.5% + Mepiquat 11.5% SL is equivalent to that of the standard formulated reference products tested in the trials. As comparability between the formulations has been demonstrated, the applicant therefore wishes to cite the original registrant's data on chlormequat and mepiquat 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.

Table 3.4-4: Phytotoxicity of product

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

Comments of zRMS:	The phytotoxicity trials about tested plant protection product (plant growth regula-
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	<p>tor) 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 and Maritime EPPO zone. 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).</p> <p>Applicant submitted in total 22 efficacy trials in which phytotoxicity assessment was carried out on winter wheat. Trials were performed during different growing season (2017, 2018 and 2021). Only one growing season was studied during Maritime trials (2017) During MED (2017 and 2018) and N-E EPPO zone (2017 and 2021) trials two growing seasons were studied. cMS from MAR should decide if trials performed only in one season can be acceptable.</p> <p>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 – MEPCY 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). No negative effects were observed during all trials.</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 trials for winter wheat: PL-7; CZ-2. 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 (2,0 L/ha). In the opinion of Evaluator, since no adverse symptom was observed at the recommended dose, it was not mandatory to submit doses of 2 N.</p> <p>Assessment for cMS: Applicant submitted for MAR – 9 trials (FR-7, CZ-2) and for MED – 6 trials (ES-4, FR-2). In the opinion of ZRMs the number of trials should be accepted. No negative effects were observed during trials at dose 2,0 L/ha (recommended). In the opinion of Evaluator, since no adverse symptom was observed at the recommended dose, it was not mandatory to submit doses of 2 N.</p>
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3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

Twenty two efficacy trials were conducted to obtain selectivity results with the same formulation currently under registration, Chlormequat 34.5% + Mepiquat 11.5% SL, in the Maritime EPPO zone (9; i.e. Czech Republic and France), the North-east EPPO zone (7; i.e. Poland) and the Mediterranean EPPO zone (6; i.e. Spain and France) to evaluate the effect of Chlormequat 34.5% + Mepiquat 11.5% SL on the quality of the harvested crop of winter wheat (TRZAW).

3.4.2.1 Materials and methods

Yield and quality trials presented in this section were designed and conducted to test the recommended dose rate of Chlormequat 34.5% + Mepiquat 11.5% SL in winter wheat. Chlormequat 34.5% + Mepiquat 11.5% SL is recommended applied in wheat at 2.0 L/ha. The trials harvested were Efficacy trials where harvest was conducted. For further information on materials and methods please refer to CP 3.4 for harvested efficacy trials.

3.4.2.2 Summary and evaluation of the field trials conducted in winter wheat

A summary of the mean yield assessments, expressed as %-relative of the untreated, are presented in Table 3.4-5 to Table 3.4-10 for trials conducted in winter wheat.

Maritime

A total of 9 efficacy trials in winter wheat were harvested. The trials were conducted in Czech Republic (2) and France (7) in 2017 and 2018. In the efficacy trials, Chlormequat 34.5% + Mepiquat 11.5% SL was applied at 1.5, 1.75 and 2.0 L/ha. The trials were sprayed at crop growth stages ranging between BBCH 29 and BBCH 33. In Table 3.4-5 and Table 3.4-6, the results obtained in the efficacy trials when treated with 1.5, 1.75 and 2.0 L/ha are presented.

Table 3.4-5: Maritime zone – Crop yield (t/ha) of winter wheat treated with Chlormequat 34.5% + Mepiquat 11.5% SL, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	Chlormequat 34.5% + Mepiquat 11.5% SL			Cyter. at:
		Mean (min-max)	% relative, compared to untreated (min-max, no. of trials)			
		t/ha	1.5 L/ha	1.75 L/ha	2.0 L/ha	1N
Winter wheat – Efficacy trials, all reference products						
Maritime EPPO zone	7	8.58 (5.9-10.2)	101 (93.2-107)	102 (95.1-111)	100 (95.9-108)	101 (95.6-107)

Table 3.4-6: Maritime zone – Crop yield (t/ha) of winter wheat treated with Chlormequat 34.5% + Mepiquat 11.5% SL, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	Chlormequat 34.5% + Mepiquat 11.5% SL			Nationa ref. product at,
		Mean (min-max)	% relative, compared to untreated (min-max, no. of trials)			
		t/ha	1.5 L/ha	1.75 L/ha	2.0 L/ha	1N
Winter wheat – Efficacy trials, all reference products						
Maritime EPPO zone	2	7.41 (6.88-7.95)	104 (98.1-109)	106 (100-112)	107 (101-113)	107 (100-113)

North-east

A total of 7 efficacy trials in winter wheat were harvested. The trials were conducted in Poland in 2017 and 2021. In the efficacy trials, Chlormequat 34.5% + Mepiquat 11.5% SL was applied at 1.5, 1.75 and 2.0 L/ha. The trials were sprayed at crop growth stages ranging between BBCH 30-32. In Table 3.4-7, the results obtained in the efficacy trials when treated with 1.5, 1.75 and 2.0 L/ha are presented.

Table 3.4-7: North-east zone – Crop yield (t/h) of winter wheat treated with Chlormequat 34.5% + Mepiquat 11.5% SL, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	Chlormequat 34.5% + Mepiquat 11.5% SL			Nationa ref. prod- uct at,
		Mean (min-max)	% relative, compared to untreated (min-max)			
		t/ha	1.5 L/ha	1.75 L/ha	2.0 L/ha	2.0 L/ha
Winter wheat – Efficacy trials, all reference products						
North-east Eppo zone	7	7.4 (5.7-9.9)	105.4 (101.2-112)	105.6 (92.9-117)	111.6 (103.6-118)	108.5 (94.7-116.3)

Mediterranean

A total of 6 efficacy trials in winter wheat were harvested. The trials were conducted in France (2) and Spain (4) in 2017 and 2018. In the efficacy trials, Chlormequat 34.5% + Mepiquat 11.5% SL was applied at 1.5, 1.75 and 2.0 L/ha. The trials were sprayed at crop growth stages ranging between BBCH 29 and BBCH 33. In Table 3.4-8 and Table 3.4-10, the results obtained in the efficacy trials when treated with 1.5, 1.75 and 2.0 L/ha are presented.

Table 3.4-8: Mediterranean zone – Crop yield (t/h) of winter wheat treated with Chlormequat 34.5% + Mepiquat 11.5% SL, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	Chlormequat 34.5% + Mepiquat 11.5% SL			Cyter. at:
		Mean (min-max)	% relative, compared to untreated (min-max)			
		t/ha	1.5 L/ha	1.75 L/ha	2.0 L/ha	
Winter wheat – Efficacy trials, all reference products						
Mediterranean EPPO zone	5	3.00 (1.26-5.33)	109 (91.7-133)	106 (96.0-126)	108 (99.6-120)	104 (82.1-130)

Table 3.4-9: Mediterranean zone – Crop yield (t/ha) of winter wheat treated with Chlormequat 34.5% + Mepiquat 11.5% SL, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	Chlormequat 34.5% + Mepiquat 11.5% SL			Nationa ref. product at,
		Mean (min-max)	% relative, compared to untreated (min-max)			
		t/ha	1.5 L/ha	1.75 L/ha	2.0 L/ha	2.0 L/ha
Winter wheat – Efficacy trials, all reference products						
Mediterranean EPPO zone	4	2.36 (1.26-4.56)	114 (99.1-133)	109 (100-126)	111 (101-120)	122 (101-139)

Neither Chlormequat 34.5% + Mepiquat 11.5% SL nor the reference standard significantly affected the yield when applied at the proposed dose rate (2.0 L/ha) in either of the 15 trials. Rather, overall Chlormequat 34.5% + Mepiquat 11.5% SL provided an increase in the yield mass of the treated crop which is most likely as a consequence of the disease control in the efficacy trials as presented in Section 3.2.3. The results obtained in the trials supports the label claim that Chlormequat 34.5% + Mepiquat 11.5% SL is safe to be applied at the recommended dose rate to winter wheat at the recommended number of applications.

3.4.2.3 Conclusion

Chlormequat 34.5% + Mepiquat 11.5% SL applied at the proposed dose rate, at a range of growth stages within or occasionally beyond the label recommended range, winter wheat did not affect crop yield significantly in any of the 22 trials harvested. In all efficacy trials as, Chlormequat 34.5% + Mepiquat 11.5% SL applied at recommended dose rates did not significantly affect the crop yield.

Furthermore, the data obtained in trials harvested demonstrate that Chlormequat 34.5% + Mepiquat 11.5% SL is as safe to the crop as the reference products used in the trials.

For recommendations on the label not sufficiently supported with trials harvested, the applicant wishes to bridge to the trials conducted in winter wheat where harvest data demonstrated the safe use following

application of Chlormequat 34.5% + Mepiquat 11.5% SL as recommended. Furthermore, the data presented in this document also clearly demonstrates that the efficacy and crop safety of Chlormequat 34.5% + Mepiquat 11.5% SL is equivalent to the standard reference products to which it was compared. The applicant therefore wishes to cite the original registrant's data on chlormequat and mepiquat 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.

3.4.2.4 Relationship between phytotoxicity and yield

No adverse effects were observed in any of the 22 cereals trials conducted. In the trials harvested, no significant reductions in crop yield were recorded in any of the plots treated with Chlormequat 34.5% + Mepiquat 11.5% SL at dose rates representative of the recommended dose rate.

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 Chlormequat 34.5% + Mepiquat 11.5% SL in winter wheat. Chlormequat 34.5% + Mepiquat 11.5% SL is recommended applied in wheat at 2.0 L/ha. No negative impact on yield was recorded during trials. MEPCY applied at the recommended dose did not significantly affect the yield. Applicant submitted in total 22 trials: MED – 6 (ES-4, FR-2), MAR – 9 (FR-7, CZ-2) and N-E – 7 (PL).</p> <p>In the opinion, of Evaluator submitted documentation is sufficient for N-E, MED and MAR EPPO zone.</p>
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3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

Twenty two efficacy trials treated with Chlormequat 34.5% + Mepiquat 11.5% SL were harvested and yields recorded. Besides recording yield, assessments were also carried out on the potential impact of treatment on a range of quality parameters including moisture content, hectolitre weight or thousand grain weight.

Winter wheat

The results obtained from assessments on the quality of the harvested winter wheat are presented in Table 3.4-11 and Table 3.4-11.

Table 3.4-10: Mediterranean and Maritime zone – Quality of harvested winter wheat grains – crop treated with Chlormequat 34.5% + Mepiquat 11.5% SL in efficacy trials, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	Chlormequat 34.5% + Mepiquat 11.5% SL			Cyter
		Mean (min-max)	% relative, compared to untreated (min-max, no. of trials)			
			1.5 L/ha	1.75 L/ha	2.0 L/ha	2.0 L/ha
Winter wheat – Efficacy trials, Mediterranean EPPO zone						
Moisture content	6	11.4 (9.5-12.9)	99.2 (97.6-100)	98.7 (91.9-103)	101 (97.1-109)	98.1 (93.1-101)
HLW	5	70.4 (69.3-71.4)	99.3 (99.3-99.4)	98.8 (98.7-98.8)	97.3 (96.8-97.7)	97.7 (96.7-98.7)
Crop, trial type	No. of trials	Untreated	Chlormequat 34.5% + Mepiquat 11.5% SL			Cyter
		Mean (min-max)	% relative, compared to untreated (min-max, no. of trials)			
			1.5 L/ha	1.75 L/ha	2.0 L/ha	2.0 L/ha
Winter wheat – Efficacy trials, Maritime EPPO zone						
Moisture content	7	14.7 (11.3-23.4)	98.9 (96.5-102)	98.6 (91.5-101)	100 (98.1-102)	100 (97.8-103)
TKW	3	40.7 (33.8-49.4)	99.6 (98.0-101)	101 (99.7-101)	100 (99.1-102)	101 (99.1-104)
HLW	7	74.7 (64.7-82.1)	99.1 (95.2-103)	99.5 (98.3-101)	98.8 (93.8-101)	99.4 (98.7-101)

Table 3.4-11: Maritime, North-east and Mediterranean zone – Quality of harvested winter wheat grains – crop treated with Chlormequat 34.5% + Mepiquat 11.5% SL in efficacy trials, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	Chlormequat 34.5% + Mepiquat 11.5% SL			Nationa ref. product at;
		Mean (min-max)	% relative, compared to untreated (min-max, no. of trials)			
			1.5 L/ha	1.75 L/ha	2.0 L/ha	1 N
Winter wheat – Moisture content						
Mediterranean EPPO zone	2	9.88 (9.55-10.2)	98.8 (97.6-100)	97.5 (91.9-103)	103 (97.1-109)	103 (101-105)
Maritime EPPO zone	2	14.5 (13.9-15.1)	100 (100-100)	99.7 (99.3-100)	99.7 (99.3-100)	98.6 (97.1-100)
North-east EPPO zone	7	13.6 (12.2-15.2)	98.6 (94.9-103)	99.7 (94.9-109)	99.3 (94.1-107)	100 (91.2-114)
Winter wheat – TKW						
Mediterranean EPPO zone	1	44.0 (-)	101 (-)	106 (-)	103 (-)	103 (-)
Maritime EPPO zone	1	53.5 (-)	99.6 (-)	99.4 (-)	99.1 (-)	98.7 (-)
North-east EPPO zone	6	38.4 (32.1-42.1)	100 (98.0-103)	98.5 (93.5-103.2)	99.3 (96.6-103.6)	100.5 (95.3-105)
Winter wheat – HLW						
Mediterranean EPPO zone	1	60.3 (-)	100 (-)	101 (-)	101 (-)	100 (-)
North-east EPPO zone	6	75.1 (70.7-81.2)	100.3 (99.6-101.2)	101.1 (99.0-102)	100.7 (99.5-104)	100.5 (99.6-103)

In the trials evaluated, Chlormequat 34.5% + Mepiquat 11.5% SL had no detrimental effect on the quality parameters assessed on the harvested winter wheat. When comparing the results obtained with Chlormequat 34.5% + Mepiquat 11.5% SL against the results obtained with the standard reference product at comparable dose rates, both products performed statistically similar on all quality parameters assessed.

Conclusion

Chlormequat 34.5% + Mepiquat 11.5% SL applied at the proposed dose rate, at a range of growth stages within the label recommended rate, in winter wheat did not significantly affect the quality of the harvested crop in any of the 22 trials harvested. In all efficacy trials as, Chlormequat 34.5% + Mepiquat 11.5% SL applied at recommended dose rates did not significantly affect the quality of the harvested crop either.

Furthermore, the data obtained in trials harvested demonstrate that Chlormequat 34.5% + Mepiquat 11.5% 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 34.5% + Mepiquat 11.5% SL is equivalent to the standard reference products to which it was compared. The applicant therefore wishes to cite the original registrant's data on chlormequat + mepiquat 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:	No negative impact on quality of yield was recorded during trials. Applicant submitted in total 22 trials: MAR – 9 trials, MED – 6 trials and N-E – 7 trials.
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	During those trials such quality parameters as moisture, TKW, HLW was studied. In the opinion, of Evaluator for winter wheat from N-E EPPO, MED EPPO zone and Maritime EPPO zone submitted documentation is sufficient.
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3.4.4 Effects on transformation processes (KCP 6.4.4)

Processing can include physical processing such as milling of seeds. It has already been shown in effects on the quality of plants section that the application of Chlormequat 34.5% + Mepiquat 11.5% SL at the proposed label rate and rates above this rate has no negative effect on the quality parameters assessed in efficacy trials harvested.

Other processes depend on biological activity and are referred to as 'transformation'. These include e.g. brewing and baking and are potentially sensitive to plant protection products. Fungicides are usually only considered with regards to their potential effect on transformation processes if applied close to harvest (EPPO standard PP 1/243(1) *Effects of plant protection products on transformation processes*). It is also the case that if residues cannot be detected at harvest (dRR Part B Section 7) then it is reasonable to assume that the likelihood of an effect on transformation processes is greatly reduced.

Finally, it should be noted that currently, chlormequat and mepiquat containing products do not have any label restrictions concerning their use on crops destined for processing. In addition, both actives are part of many products which have been used for a long time as fungicide in e.g. cereals. Since the market introduction, no effects on transformation processes have been recorded for any of these products.

Comments of zRMS:	Based on long term use of mepiquat chloride and chlormequat chloride without any problems and low residues in grain, the above-mentioned argumentation can be accepted. No negative impact on processing is to be expected in the opinion of Evaluator.
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3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

Chlormequat 34.5% + Mepiquat 11.5% SL is composed of chlormequat + mepiquat, which both have been widely used for several years on e.g. cereals, without identifying any issues in regard to ability of grains of treated plants to germinate.

Thus, negative effects of the active ingredient on parts of plant used for propagating purposes can be excluded due to the fungicidal nature of the product. Furthermore, phytotoxicity assessments in the performed trials demonstrated the crop safety of the product and the absence of any negative effect on the plants or plant products in the vast majority of the trials.

The product complies with the Uniform Principles.

3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

Since Chlormequat 34.5% + Mepiquat 11.5% 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 impact of succeeding crops of the crop towards chlormequat a mepiquat.

Comments of zRMS:	<p>No data were submitted. 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 mepiquat now out of protection. Therefore, the evaluators should consider such data and label restrictions/warnings regarding propagating on standard mepiquat products.</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 regulator nature of the product</p>
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3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

During the conduct of efficacy trials, no observations about negative or positive effects on other plants or neighbouring crops were reported. Furthermore, in efficacy trials, it was demonstrated that the formulation of **metoconazole mepiquat chloride and chlormequat chloride** is not phytotoxic to the crop claimed in the GAP.

EPPO guidelines PP1/256(1) is intended to examine whether the active substance of a plant protection product can cause negative effects on crop which would be in contact with that product. Based on the actual drift value calculated with the Ganzelmeier model and on the bio assay results from the Vegetative vigour test, TER values are obtained.

- If the active substance has no activity against plants at the highest doses tested in the bioassays. Then field trials are unnecessary.
- If the TER values are > 5 . Then no further testing is necessary.
- If the TER values are ≤ 5 . Damage to the relevant succeeding crop is possible and further field testing is necessary as described in the EPPO guideline.

The maximum individual proposed rate of Chlormequat 34.5% + Mepiquat 11.5% SL is 2.0 L/ha (equivalent to 345 grams per liter (g/L) chlormequat and 115 grams per liter (g/L) mepiquat). Studies on the toxicity to non-target terrestrial plants have been carried out with Chlormequat and Mepiquat. Full details of these studies are provided in the respective EU DAR and related documents

Chlormequat

In the vegetative vigor terrestrial non target plants study summarized in the DAR [Section 9.9.1, Volume 3, Annex B.,9, Frank, P. (2001)].

1.- Terrestrial plants germination and growth test ^[L]_[SEP]

The phytotoxicity of the test item chlormequat-chloride (720 g/l solution) to 6 terrestrial plant species (oat (*Avena sativa*), onion (*Allium cepa*), sugar beet (*Beta vulgaris*), rape (*Brassica napus*), carrot (*Daucus carota*) and soybean (*Glycine max*)) was determined over a period of 21 days. The test was conducted with the nominal concentrations 0, 0.188, 0.375, 0.75, 1.5 and 3.0 l/ha. Test plants were 2 monocotyledons and 4 dicotyledons. The test item was applied on the soil surface after the seeds were sown. The test container was bottom watered with nutrient solution as needed. There were 8 replicates per treatment. ^[L]_[SEP]The toxic effects of the test item were determined on day 7, 14 and 21 by visual observations (number of emerged seedlings and phytotoxicity rates, number of dead plants) and on day 21 by shoot height and fresh weight determination. Shoot height, fresh weight, number of emerged seedlings and number of dead plants were checked for significant differences. No statistically significant effects compared to the control (ANOVA, $\alpha > 0.05$) were determined for all tested species. The NOEL for all tested species and all assessment parameters was 3.0 l formulation/ha (2.1 kg a.s./ha). Therefore the EC50 will be > 2.1 kg a.s./ha. ^[L]_[SEP]This study was conducted according to OECD 208 and in compliance with GLP. This study can be considered suitable for use in risk assessment. ^[L]_[SEP]

2.- Terrestrial plants growth test ^{[1][2][3]}_{[SEP][SEP]}

The phytotoxicity of the test item 'BAS 062 03 W', a 765.8 g/l solution of chlormequat-chloride, to 6 terrestrial plant species (cabbage (*Brassica oleraceae*), pea (*Pisum sativum*), carrot (*Daucus carota*), sunflower (*Heliantus annus*), oats (*Avena sativa*) and onion (*Allium cepa*)) was determined over a period of 21 days. The test was conducted with the nominal concentrations 0, 312.5, 625, 1250, 2500 and 5000 ml formulation/ha (0, 234.4, 468.8, 937.5, 1875 and 3750 g a.s. /ha). Test plants were 2 monocotyledons and 4 dicotyledons. The test item was applied using a laboratory spraying system post emergence (pea growth stage 13-14, sunflower growth stage 14 and other species growth stage 12). The test container was bottom watered and fertilizer was added approximately once a week. There were 6 replicates per treatment except for sunflower with 9 replicates.

The toxic effects of the test item were assessed for phytotoxicity on day 7, 14 and 21 and on day 21 by shoot height and fresh weight determination. Shoot height and fresh weight were checked for significant differences.

Only sunflower showed slight symptoms of phytotoxicity (< 10% at a concentration of 468.8 g a.s./ha and higher). These symptoms were chlorosis, deformation and scorch. NOEC values for all other species are 3750 g a.s./ha.

The plant height and weight of carrot and sunflower were affected at all treatment rates. The maximum reduction compared to the control found for these species were 42% (weight) and 28% (height) at a concentration of 3750 g a.s. /ha.

All remaining plant species were not affected after the post emergence application of the test substance up to the rate of 3750 g a.s./ha.

Table 3.5-1: The effect of chlormequat-chloride on Non target plants

Plant	NOEC (g a.s./ha)	EC50 (g a.s./ha) plant height and fresh weight
Cabbage	3750	>3750
Carrot	<234.4	>3750
Pea	3750	>3750
Sunflower	<234.4	>3750
Oats	3750	>3750
Onion	3750	>3750

This study was conducted according to OECD 208 and in compliance with GLP. This study can be considered suitable for use in risk assessment.

Risk assesment

The compound has plant growth regulator activity so may pose a risk for non target plants. Data have been submitted from OECD 208 studies on more than 6 species of crop plants from a variety of taxa. These indicate and EC50 for growth effects of >3.8 kg a.s./ha. Using the deterministic method in the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 October 2002 section 7.3) an off-crop TER calculation may be conducted. Taking the spray drift at 1 m from the field edge of 2.77 % with an application rate of 1500 g a.s./ha and the lowest EC50 value of >2100 g a.s./ha gives a TER of

>50.5. This is in excess of the proposed trigger of 5 where 6 species have been tested. Although, as demonstrated by the data on carrot and sunflower, some stunting effects might occur at low levels of exposure, no biologically significant adverse effects are envisaged off-crop on non-target plants.

Mepiquat

In the vegetative vigor terrestrial non target plants study summarized in the DAR [Section 9.9.2, Volume 3, Annex B.,7-9, Siemoneits, S.. (2002)].

The effect of 'BAS 098 00W' containing 308.2 g mepiquat-chloride/L and 158.9 g ethephon/L (nominally 305 and 155 g/L respectively) on vegetative vigour of plant species was studied under glasshouse conditions. There were 4 dicotyledonous species i.e. carrot (*Daucus carota*), flax (*Linum usitatissimum*), oilseed rape (*Brassica napus*), pea (*Pisum sativum*), and 2 monocotylendon species i.e. oats (*Avena sativa*) and onion (*Allium cepa*). Seeds of the test species were planted in pots in a natural soil with added quartz sand. The organic carbon content was 1.3%. The number of seeds per pot and the depth of planting were dependent on species. There was a control and 6 treatment rates between 93.8 and 3000 mL/ha. Treatments were applied at the 2-4 leaf stage.

There was a statistically significant reduction in weight of carrot at ≥ 188 mL/ha. Plant height was significantly different from the control at ≥ 93.8 mL/ha, the lowest rate tested. These effects were dose related with a maximum of 35%. Symptoms of phytotoxicity were seen at the two highest rates, 1500 and 3000 mL/ha but in only 2 replicates at 1500 and at a maximum of 20%. The ER50 was calculated to be > 3000 mL/ha, the highest rate tested. The overall NOER could not be established but was <93.8 mL/ha, the lowest rate tested based on effects on plant height.

Application at 3000 mL/ha reduced plant height of flax but there was no statistically significant difference in plant weight. Symptoms of toxicity were seen at the highest rate 3000 mL/ha up to a maximum of 20% but these decreased with time. The ER50 was calculated to be >3000 mL/ha, the highest dose tested. The NOER was 1500 mL/ha based on effects on plant height and symptoms of phytotoxicity.

There were symptoms of phytotoxicity in oilseed rape at the highest rate tested 3000mL/ha which declined with time. The maximum effect was 15%. There were no effects on plant height or weight. The ER50 was > 3000 mL/ha, the highest rate tested and the NOER was 1500 mL/ha based on early phytotoxicity.

There were no effects on the other 3 species for which the ER50s and NOERs were >3000 mL/ha and 3000mL/ha respectively.

Table 3.5-2: Effects of 'BAS 098 00W' on vegative vigour of various crop plant

Species	ER50 mg formulation/ha	NOER mg formulation/ha
Carrot	> 3000	< 93.8
Flax	> 3000	1500 (effects reduced over time)
Oilseed rape	> 3000	1500 (effects reduced over time)
Pea	> 3000	3000
Oats	> 3000	3000
Onion	> 3000	3000

The ER50 for all plant species was > 3000 mL/ha, the highest rate tested. The NOER for the most sensitive species, carrot, could not be defined but was <93.8 mL/ha, the lowest rate tested.

The study was conducted according to OECD Guideline for the testing of chemicals: terrestrial non-target

plant test, 208 B vegetative vigour 2000 and in compliance with GLP .

Risk assesment

‘BAS 098 00W’ is to be applied to cereals at a maximum rate of 2.5 L product/ha. According to the ‘Guidance Document on Terrestrial Ecotoxicology’ dated 2002, ‘non-target plants are non-crop plants located outside the treatment area.’ Consideration of the risk posed by exposure to the full application rate within the crop, 2.5 L product/ha, is not, therefore relevant. The effect of the amount of product drifting at 1m from the crop will be considered. Drift at 1m is 2.77% of the applied dose (Rautmann et al 2001) which for ‘BAS 098 00W’ is 69.25 mL/ha.

Comparing predicted exposure, 69.25 mL/ha, with the ER50 for all species for both emergence and vegetative vigour, > 3000 mL/ha, gives a TER of 43.32. This exceeds the trigger of 5 which it is proposed in the Guidance Document on Terrestrial Ecotoxicology indicates acceptability of effects

One species, carrot, was noticeably more sensitive than the other species tested and showed phytotoxic effects in the vegetative test at low dose rates. This merits further consideration. A NOEC could not be established but was < 93.8 mL/ha and magnitude of effects was dose related. This is close to and above the estimated exposure of 69.25 mL/ha. Percentage of effect compared with control was 11% for plant height and 17% for plant weight at 93.8 mL/ha. Effects at the maximum field application rate (adjusted for drift) is therefore <50%. In line with ‘Guidance Document on Terrestrial Ecotoxicology’ this indicates that there is no need for further concern. Mepiquat-chloride, in the formulation ‘BAS 098 00W’, does not pose an unacceptable risk to non-target plants adjacent to the treated crop.

Comments of zRMS:	No negative effects of applications of mepiquat chloride and 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 MEPCY 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 34.5% + Mepiquat 11.5% SL in 2017 and 2018, 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 9.

The product complies with the Uniform Principles.

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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3.5.4 Tank cleaning

Relevant information on tank cleaning is included in dRR Part B124. Please refer to this section for complete evaluation.

Comments of zRMS:	Statement accepted.
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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		
			2017	2018	2021
			Efficacy		
Winter wheat					
Daye desarrollo agricola	MED	ES	3	-	-
Sicop	MED	ES	1	-	-
Agrostation	MED	FR	-	2	-
Agrostation	MAR	FR	4	-	-
Eurofins agrosience services	MAR	FR	3	-	-
Zkusebni stanice Rymarov	MAR	CZ	2	-	-
Institute of soil science and plant cultivation	N-E	PL	3	-	1
Sharda Poland	N-E	PL	-	-	3
Total, winter wheat			16	2	4

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
CP 6.0-001	Anonymous	2020	Biological Assessment Dossier: Chlormequat 34.5% + Mepiquat 11.5% SL (345 g/L chlormequat and 115 g/L mepiquat SL) – EU Central zone Sharda Cropchem España -, - Unpublished	N	SHA