

# FINAL REGISTRATION REPORT

## **Part B**

### **Section 3**

#### **Efficacy Data and Information**

Concise summary

Product code: SHA 8500 A

Product name(s): MEPISHA

Chemical active substance:

Mepiquat 38 g/L

Central Zone

Zonal Rapporteur Member State: Poland

#### **CORE ASSESSMENT**

Applicant: Sharda Cropchem España

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## Version history

When	What
June 2021	Applicant updated document
September 2021	ZRMs evaluated dRR updated by Applicant.
December 2021	Applicant updated document
February 2022	ZRMs evaluated updated document during commenting period.
April 2022	ZRMS corrected evaluation according to comments from MRiRW

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

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

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

Comments of zRMS:	Comments of zRMS are presented in commenting boxes at the end of each chapter. The text of dRR was generally not changed or rewritten (small changes in the document are marked by grey colour). Changes in dRR during commenting period are marked by yellow. Changes in violet was made during correction after MRiRW comments.
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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 con- trolled  (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 prod- uct / 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, winter barley, spring barley	F	Reduction of crop height	Foliar Spray	BBCH 31-39	a) 1 b) 1	-	a) 0.75 b) 0.75	a) 0.0285 b) 0.0285	200-400			Acceptable for N-E and MAR EPPO zone. only for spring barley. Not accepted for winter wheat and winter barley.  to be confirmed by cMS from MED and S-E and Maritime EPPO zone
2	CEU	Winter Oilseed rape	F	Reduction of crop height	Foliar Spray	BBCH 31-39	a) 1 b) 1	-	a) 0.75 b) 0.75	a) 0.0285 b) 0.0285	200-400			Not acceptable for N-E and MAR EPPO zone.  to be confirmed by cMS from MED and S-E and Maritime EPPO zone

\* 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 **Mepiquat 3.8% SL (MEPISHA; Product code: SHA 8500 A)** containing the active substance mepiquat, which has been included into Annex I of Council Directive 91/414/EEC.

The SANCO report for mepiquat (SANCO/106/08-rev.2) is considered to provide the relevant review information or a reference to where such information can be found.

For the implementation of the uniform principles of Annex VI, the conclusions of the review reports on the active substances mepiquat, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17<sup>th</sup> June 2011, 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 mepiquat 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:**

<b>Report: KCP 6.0/001 Biological Assessment Dossier Mepiquat 3.8% SL, Central</b>
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### Description of the plant protection product

Mepiquat 3.8% SL is a Soluble Concentration (SL) formulation containing 38 grams per liter (g/L) mepiquat for use in winter wheat, winter barley, spring barley and winter oilseed rape.

According to the GAP, the proposed application rate of Mepiquat 3.8% SL in winter wheat, winter barley, spring barley and winter oilseed rape is 0.75 L per hectare (L/ha), with single application per season. This will deliver 28,5 g mepiquat per hectare. In the current document, results obtained in field trials with Mepiquat 3.8% SL applied at 0.5 L/ha will be presented where these have been tested against similar dose rates of mepiquat and prohexadione reference products currently marketed in the countries where the trials were conducted.

The data presented in this dossier fully support the label claim of Mepiquat 3.8% SL for reduction of crop height.

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

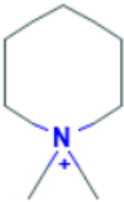
Crop / uses	Application method	Spray volume (L/ha)	Max. individual application rate (kg f.p./ha) [kg a.s./ha]	Max. number of applications	Application timing (e.g. BBCH)
Winter wheat, winter barley, spring barley Reduction of crop height	Spray	200-400	(0.75) [28,5]	1	BBCH 31-39
Winter oilseed rape Reduction of crop height	Spray	200-400	(0.75) [28,5]	1	BBCH 31-39

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 **abd** and translocated to growing points of the plant.

**Table 3.2-2: Identity of mepiquat**

<b>Common name</b>	Mepiquat
<b>IUPAC name</b>	1,1-Dimethylpiperidinium chloride
<b>CA name</b>	1,1-dimethylpiperidinium chloride (mepiquat chloride)
<b>CIPAC No</b>	440.302 (mepiquat chloride) 440 (mepiquat)
<b>CAS Registry No.</b>	24307-26-4 (mepiquat chloride) 15302-91-7 (mepiquat)
<b>EEC No</b>	246-147-6 (mepiquat chloride)
<b>Empirical formula</b>	C <sub>7</sub> H <sub>16</sub> ClN
<b>Molecular mass</b>	114.21 g/mol
<b>Minimum purity</b>	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.
<b>Structural formula<sup>1</sup></b>	

### 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 **abd** and translocated to growing points of the plant.

### Information on similar formulations and current approvals

Mepiquat 3.8% SL formulation containing 38 grams per liter (g/L) mepiquat. Data presented in this dossier is generated using this formulation in comparison with reference product containing mepiquat. Mepiquat is currently registered and formulations throughout Europe and a selection of these are described in table below.

**Table 3.2-3: Current approvals of 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	Medax top	Mepiquat 300 g/l + Prohexadione 50 g/l	3257-0
Croatia	Medax top	Mepiquat 300 g/l + Prohexadione 50 g/l	UP/I-320-20/17-03/290
Czech Republic	Medax top	Mepiquat 300 g/l + Prohexadione 50 g/l	4825-0V
	Regulato 300 SL	Mepiquat 300 g/L SL	5381-0
Denmark	Medax top	Mepiquat 300 g/l + Prohexadione 50 g/l	19-201

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

Country	Product	Active ingredient	Approval number
Estonia	Medax top	Mepiquat 300 g/l + Prohexadione 50 g/l	379
France	Medax top	Mepiquat 300 g/l + Prohexadione 50 g/l	2010030
Germany	Medax top	Mepiquat 300 g/l + Prohexadione 50 g/l	025620-00
Spain	Pix	Mepiquat 38 g/L SL	15150
Greece	Pix	Mepiquat 38 g/L SL	8209
	Hedin	Mepiquat 38 g/L SL	8211
	Gin	Mepiquat 38 g/L SL	8212
Poland	Medax top	Mepiquat 300 g/l + Prohexadione 50 g/l	R-213/2016
	Mepik 300 SL	Mepiquat 300 g/L SL	R-105/2017

**Table 3.2-4: Glossary of pests mentioned in the dossier.**

EPPO code	Scientific name	Common name
-	-	Reduction of crop height

**Table 3.2-5: Major / minor status of intended uses (for all cMS and zRMS).**

Crop and/or situation	Crop status		Pests or group of pests controlled	Status	
	Major	Minor		Major	Minor
Winter wheat	CEU	-	Reduction of crop height	CEU	-
Winter barley	CEU	-	Reduction of crop height	CEU	-
Spring barley	CEU	-	Reduction of crop height	CEU	-
Winter oilseed rape	CEU	-	Reduction of crop height	CEU	-

### Compliance with the Uniform Principles

Comprehensive field trials were conducted in Poland in 2017 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 agroclimatic 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 Mepiquat 3.8% SL, 55 efficacy trials with efficacy results were conducted in the North-east and Maritime EPPO zone:

**Table 3.2-6: 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	Poland	MED + E				3	2017	GEP	
	Poland	E				6	2021	GEP	
	Germany	E	3				2021	GEP	
	Czech Republic	E	2				2021	GEP	
	Total winter wheat (eff.)		5			9			
HORVS	Poland	MED + E				6	2017	GEP	
	Poland	E				4	2021	GEP	
	Germany	E	4				2021	GEP	
	Czech Republic	E	4				2021	GEP	
	Total spring barley (eff.)		8			10			
BRNSW	Germany	MED + E	4				2021	GEP	
	Czech Republic	MED + E	4				2021	GEP	
	Poland	E				4	2021	GEP	
Total winter oilseed rape (eff.)			8			4			
HORVW	Germany	MED + E	2				2021	GEP	
	Poland	MED + E				2	2021	GEP	
	Germany	E	3				2021	GEP	
	Czech Republic	E	4				2021	GEP	
	Total winter barley (eff.)		9			2			

In the trials used to assess the minimum effective dose rate of Mepiquat 3.8% 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 parameter and in others, assessments were repeated over time. In order not to bias the data from any trial with data from more than one assessment on each parameter, assessments from these were either summarised and only the sum of assessments were used in the summary or repeated assessments were excluded.

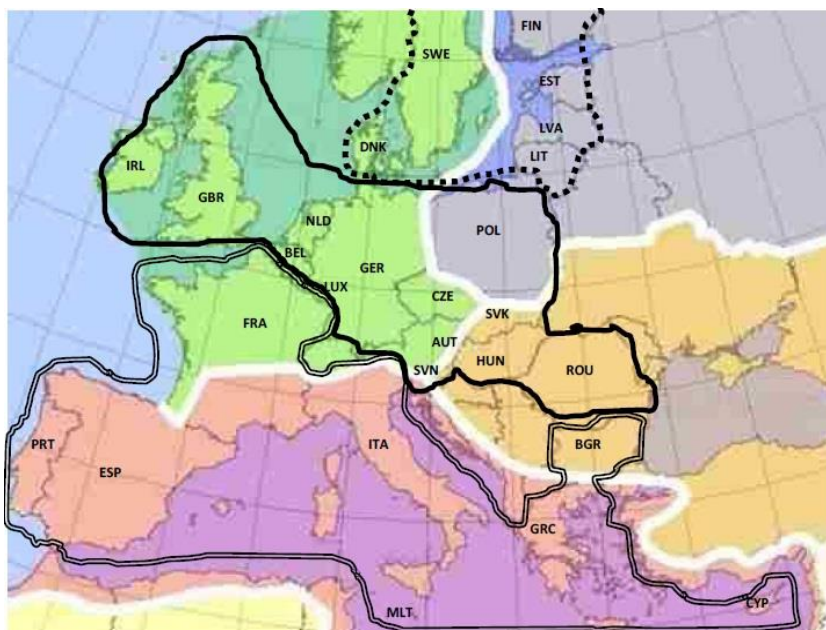
### Climatic zones

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 country<sup>2</sup>.

Poland is located in the North-east EPPO zone, Germany and Czech Republic in the Maritime EPPO zone (Figure 3.2-1).

<sup>2</sup> 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 Mepiquat 3.8% SL throughout the Central Registration zone, therefore data from the North-east and **the Maritime** EPPO zone are included.

### **Agronomic conditions**

Cultural conditions of the different crops and agronomy (e.g. cultivations used, application methods, cultivars, fertilizer regime, relative times of planting and harvest) do not differ significantly between the countries in the central EU. Mepiquat-containing growth regulators are used for reduction of crop height and it should be applied as recommended during the growing season.

The same mepiquat containing products are already registered and used in the countries where the trials were conducted to support the current application for registration. Please refer to Table 3.2-3 for the registration numbers in the different countries.

#### *(i) Reduction of crop height*

In favourable conditions, all crops set more fruit than is ideal. Sites and varieties were carefully selected to optimise conditions, to demonstrate the benefits obtained with PGR treatments. Although trials were performed in different countries, sites were selected to exert maximum control pressure and to exacerbate treatment differences. No difference in the level of control was apparent between the different countries or regions in which the trials were conducted.

#### *(ii) 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 uses, 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.

#### *(iii) Agronomic practices*

Agronomic practices for cultivating brassicas 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.

(iv) *Varieties*

Although crop varieties tend to differ between countries, observations on selectivity have not indicated any particular varietal sensitivity. The crop safety of Mepiquat 3.8% 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.

(v) *Trial methodology*

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

(vi) *Locations*

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

(vii) *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 dossier.

On the basis that the above factors do not influence the overall performance of Mepiquat 3.8% SL, it is the applicant's contention that data from Poland, Germany and Czech Republic is equally valid in demonstrating the products performance throughout the Central EU zone is valid as supporting data.

In the efficacy trials with selectivity results, the performance of Mepiquat 3.8% SL was measured against a commercially available reference products containing mepiquat and prohexadione (Medax top and Canopy; 300 g/L mepiquat + 50 g/L prohexadione SC) and Metconazol and Mepiquat (Carax, Caryx, Caryx 240 SL; 210 g/L mepiquat + 30 g/L Metconazol). The trials were carried out on winter oilseed rape, winter barley, winter wheat and spring barley.

**Table 3.2-7: Presentation of reference standards used in trials (efficacy trials, preliminary trials...)**

Trade name	Formulation	Composition	Rates	Country	N° of Trials
<b>Mepiquat formulation</b>					
Medax top	SC	300 g/L mepiquat + 50 g/L prohexadione	1.25 l/ha 1.5 l/ha 3.0 l/ha	Poland Germany Czech Republic	9 10 10
CANOPY	SL	30 g/L Metconazol + 210 g/L Mepiquat	1.25 l/ha 2.5 l/ha	Poland	15
CARAX	SL	30 g/L Metconazol + 210 g/L Mepiquat	1.4 l/ha 2.8 l/ha	Germany Czech Republic	4 2
CARYX	SL	30 g/L Metconazol + 210 g/L Mepiquat	1.4 l/ha 2.8 l/ha	Czech Republic	2
CARYX 240 SL	SL	30 g/L Metconazol + 210 g/L Mepiquat	1.4 l/ha 2.8 l/ha	Czech Republic	3

Comments of zRMS:	This document summarises the information related to the efficacy of the plant protection product – Mepisha (product code: SHA 8500 A).
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	<p>Mepisha (product code: SHA 8500 A) is characterized by a soluble concentration (SL) formulation containing 38 grams per liter (g/L) mepiquat for use in winter wheat, winter barley, spring barley and winter oilseed rape.</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>Currently there are dozens of products on the Polish CEU market, use to reduce of lodging in the cereals. In Poland 5 plant protection products with mepiquat are registered and commonly used for protection crops.</p> <p>Poland is a ZRMs. Applicant submitted in this dRR all needed information's about plant protection product, standard reference, etc.</p>
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### 3.2.1 Preliminary tests (KCP 6.1)

The activity of mepiquat is well known as it has been marketed by for the control of crop height for a number of years. Based on the knowledge about the active substance (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 are already known. Therefore, preliminary tests in glasshouses and field trials to assess the biological activity of the active substance or dose range for the plant protection product were not deemed necessary.

Comments of zRMS:	No results of the preliminary range-finding tests were submitted by the Applicant, however the active substance of Mepisha (product code: SHA 8500 A) – mepiquat is registered and has been commonly used in agricultural practice for many years (over 20). So, preliminary range finding tests are deemed too not be necessary.
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### 3.2.2 Minimum effective dose tests (KCP 6.2)

Mepiquat 3.8% SL was tested at a range of dose rates, but to demonstrate minimum effective dose rate, the control obtained with Mepiquat 3.8% SL applied at 0.40 L/ha, 0.50 L/ha and 0.75 L/ha was evaluated in 2 winter barley, 8 winter oilseed rape, 3 winter wheat and 6 spring barley trials, for reduction of crop height. The dose rates tested in winter oilseed rape, winter barley, winter wheat and spring barley reflects 55%, 66% and 100% of the recommended rate of Mepiquat 3.8% 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 North-east EPPO zone (i.e Poland) and Maritime EPPO zone (i.e. Germany and Czech Republic).

#### Reduction of Height (CEU)

To prove and to support the proposed dose rate of 0.75 L/ha Mepiquat 3.8% SL [28.5 g mepiquat per hectare, per application] for the reduction of height in winter oilseed rape, winter barley, winter wheat and spring barley, the assessment results from 19 efficacy trials performed in the North-east and Maritime EPPO zone are reported. The trials were conducted in Poland, Germany and Czech Republic in 2017 and 2021. Mepiquat 3.8% SL was included in these trials at 0.75 L/ha to demonstrate the recommended dose rate as well as the lower dose rate (0.4 L/ha [15.2 g mepiquat per hectare, per application] and 0.5 L/ha [19 g mepiquat per hectare, per application]). In the trials, specifically targeted for height reduction, single application was applied at growth stages ranging between BBCH 30 and BBCH 39.

The results obtained with Mepiquat 3.8% SL applied for the control on reduction of crop height in winter wheat plants is presented in **Table 3.2-8**, for results obtained in the North-east EPPO zone.

**Table 3.2-8: North-east zone: Minimum effective dose of Mepiquat 3.8% SL for height reduction on winter wheat.**

Target: reduction of crop height	No. of trials	Mean % Control from three trials in the North-east EPPO Zone at a range of doses of Mepiquat 3.8% SL				
		Untreated Mean % (range)	0.50 L/ha		0.75 L/ha	
			Mean	Range	Mean	Range
<b>Winter wheat</b>						
Mean % control, one observation on <b>PLANT</b> per trial, <b>HEIGHT</b> at 78 DALT	3	88.5 (85.0-93.6)	<b>5.99</b>	2.88-10.5	<b>11.6</b>	7.89-16.5
Mean % control, one observation on <b>PLANT</b> per trial, <b>LODGING</b> at 78 DALT	3	11.5 (8.8-14.0)	<b>46.5</b>	34.3-62.5	<b>100</b>	100-100

The results obtained with Mepiquat 3.8% SL applied for the control on reduction of crop height in spring barley plants is presented in **Table 3.2-9**, for results obtained in the North-east EPPO zone.

**Table 3.2-9: North-east zone: Minimum effective dose of Mepiquat 3.8% SL for height reduction on spring barley.**

Target: reduction of crop height	No. of trials	Mean % Control from six trials in the North-east EPPO Zone at a range of doses of Mepiquat 3.8% SL				
		Untreated Mean % (range)	0.50 L/ha		0.75 L/ha	
			Mean	Range	Mean	Range
<b>Spring barley</b>						
Mean % control, one observation on <b>PLANT</b> per trial, <b>HEIGHT</b> at 29-48 DALT	6	76.5 (70.9-82.5)	<b>1.3</b>	0.0-4.6	<b>1.9</b>	0.0-5.7
Mean % control, one observation on <b>PLANT</b> per trial, <b>LODGING</b> at 32-81 DALT	5	60.3 (33.4-90.0)	<b>33.5</b>	0.0-100	<b>29.4</b>	0.0-100

The results obtained with Mepiquat 3.8% SL applied for the control on reduction of crop height in winter barley plants is presented in **Table 3.2-9**, for results obtained in the Maritime EPPO zone.

**Table 3.2-10: Maritime zone: Minimum effective dose of Mepiquat 3.8% SL for height reduction on winter barley.**

Target: reduction of crop height	No. of trials	Mean % Control from 2 trials in the Maritime EPPO Zone at a range of doses of Mepiquat 3.8% SL					
		Untreated Mean % (range)	0.40 L/ha		0.50 L/ha		0.75 L/ha
			Mean	Range	Mean	Range	Mean Range
<b>Winter barley</b>							
Mean % control, one observation on <b>PLANT</b> per trial, <b>HEIGHT</b> at 55-79 DALT	2	107.1 (96.2-118)	<b>98.7</b> <b>0.0</b>	<b>96.4-104</b> <b>0.00-3.64</b>	<b>98.0</b> <b>2.08</b>	<b>95.9-100</b> <b>0.0-4.16</b>	<b>97.8</b> <b>2.23</b> <b>95.6-100</b> <b>0.0-4.47</b>
Mean % control, one observation on <b>PLANT</b> per trial, <b>LODGING</b> at 73-79 DALT	2	68.8 (47.5-90)	<b>93.8</b>	<b>87.5-100</b>	<b>100</b>	<b>100-100</b>	<b>92.4</b> <b>87.5-97.2</b>

The results obtained with Mepiquat 3.8% SL applied for the control on reduction of crop height in ~~spring barley~~ winter oilseed rape plants is presented in Table 3.2-9, for results obtained in the Maritime EPPO zone.

**Table 3.2-11: ~~North-east zone~~ Maritime EPPO zone: Minimum effective dose of Mepiquat 3.8% SL for height reduction on winter oilseed rape.**

Target: reduction of crop height		No. of trials	Mean % Control from 8 trials in the Maritime EPPO Zone at a range of doses of Mepiquat 3.8% SL						
			Untreated	0.40 L/ha		0.50 L/ha		0.75 L/ha	
			Mean % (range)	Mean	Range	Mean	Range	Mean	Range
Winter oilseed rape									
Mean % control, one observation on PLANT per trial, HEIGHT at 22-68 DALT	8	117.3 (87.3-144.1)	97.6 2,66	95.6-101.6 0,0-4,37	97.5 2,50	95.5-100 0,00-4,53	97.9 2,34	95-101 0,00-5,07	
Mean % control, one observation on PLANT per trial, LODARE at 105-125 DALT	8	0% (0-0)	100%	100-100%	100%	100-100%	100%	100-100%	

\* Results from field trials rejected by ZRMs from assessment– lodging phenomenon did not occur on the control plot

### Summary and conclusions on the minimum effective dose

Mepiquat 3.8% SL applied at the recommended dose rate in ~~winter oilseed rape, winter barley,~~ winter wheat and spring barley achieved excellent results in terms of reduction of crop height when tested under a range of conditions in the EU Central zone. The recommendation is therefore that Mepiquat 3.8% SL should be applied one time at the recommended dose rate as claimed on the label.

This BAD clearly demonstrates – as will be demonstrated in the following sections – that the efficacy and crop safety of Mepiquat 3.8% SL is equivalent to the standard mepiquat and prohexadione containing products to which it was compared. The applicant therefore wishes to cite the data on 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 Mepisha (product code: SHA 8500 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>9 field trials carried out in one growing season on winter wheat (3 trials) and spring barley (6 trials) were established to determine the minimum effective dose of Mepiquat 3.8% SL. Trials were performed only in one EPPO zone – N-E in Poland. Two different doses were studied: 0,50 l/ha (0,66 N) and 0,75 l/ha (N dose). All results were compared to standard reference product. In the trials, specifically targeted for height reduction, single application was applied at growth stages ranging between BBCH 30 and BBCH 39. During commenting period, Applicant presented new MED trials for winter barley in Maritime EPPO zone (2 trials), and 8 trials performed on winter oilseed rape in the N-E EPPO zone. So, in total Applicant submitted 19 MED trials carried out on winter barley (2), winter oilseed rape (8), winter wheat (3) and spring barley (6). In new trials following</p>
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	<p>doses were studied: 0,40 l/ha (0,55N), 0,50 l/ha (0,66N) and 0,75 l/ha (N dose) was studied.</p> <p>The proposed doses were derived from registered doses of standard reference products with mepiquat as active compound and, product safety parameters and environmental limitations. Such products are used across Europe for many years (over 20) and their MED is justified. The proposed dose against lodging and growth reduction is 0,75 l/ha applied once a season. Detailed results were presented by Applicant in the tables: Table 3.2 8 and 3.2. 9 and Table 3.2 10-3.2 11. No MED results were presented for winter oilseed rape – this use should be excluded from GAP table and label project. Also, for winter wheat and winter barley not enough research has been presented by Applicant, so this use is not accepted too.</p> <p><b>REDUCTION OF HEIGHT:</b></p> <ul style="list-style-type: none"> <li><b>N-E EPPO zone:</b></li> </ul> <p><b>Winter wheat</b> - During 3 trials slightly effect of reduction of height was observed (average efficacy: 2,88%) at dose 0,5 L/ha and slightly higher effect was observed at dose 0,75 L/ha – average eff. at level 7,89%.</p> <p><b>Spring barley</b> - During 6 trials only in 4 trials effect of reducing growth was observed. This effect was very slightly – efficacy from 0,6% to 4,60 at dose 0,5 L/ha and efficacy from 0,4% to 5,7 % at dose 0,75 L/ha. In 2 trials no effect was observed, both at 0,5 and 0,75 L/ha, because treated plants by Mepisha were higher than control plants.</p> <ul style="list-style-type: none"> <li><b>Maritime EPPO zone:</b></li> </ul> <p><b>Winter barley:</b> 2 trials – tested product reduce height in all doses tested (0,4 L/ha; 0,5 L/ha and 0,75 L/ha) in one trial (Sharda21-023). No significant differences were noted between the doses tested. But in second trial (SHA21-022) in all treatments tested plants were slightly higher than control plants. So, in this study no effect of reducing growth was observed.</p> <p><b>Winter oilseed rape</b> – 8 trials – Slightly effect of reducing growth was observed during 6 trials. But, in two trials (SWEPL-KUJ21-BRSNW52 and Sharda21-020) plants treated by Mepisha were higher than control ones, so no effect of reducing growth was observed.</p> <p><b>LODGING:</b></p> <ul style="list-style-type: none"> <li><b>N-E EPPO zone:</b></li> </ul> <p><b>Winter wheat</b> – 3 trials. Lodging was observed in all 3 trials on control plants (average:11,5%). Dose 0,5 L/ha reduce of lodging with 46,5% efficacy and dose 0,75 L/ha with 100% efficacy.</p> <p><b>Spring barley</b> – 5 trials. Lodging was observed in all studies (average:60,3%). Dose 0,5 L/ha reduce of lodging with 33,5% efficacy and dose 0,75 L/ha with 29,4% efficacy.</p> <ul style="list-style-type: none"> <li><b>Maritime EPPO zone:</b></li> </ul> <p><b>Winter barley</b> - 2 trials. Lodging was observed in all trials (average: 68,8%). Dose 0,4 L/ha reduce of lodging with 93,8%; 0,5 L/ha reduce of lodging with 100% efficacy and dose 0,75 L/ha with 92,4% efficacy.</p> <p><b>Winter oilseed rape</b> – 5 trials. No lodging at control area was observed. Those trials should not be assessed, because the phenomenon of lodging did not occur, and such tests should not be included in the table as a possible basis for calculating</p>
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	<p>the effectiveness of the tested agents.</p> <p>In the opinion of ZRMs, presented results and knowledge about registered doses of standard reference products with mepiquat can allow to consider dose 0,75 l/ha as the most effective for winter wheat, winter oilseed rape, spring barley and winter barley. But, the recorded results from field trials did not allow to draw clear conclusions about tested Mepisha. Slightly reducing of growth was observed after using Mepisha on cereal crops (winter wheat and barley; spring barley) and winter oilseed rape. In most studies, a dose of 0.75 L/ha was found to be the most effective. Also, reducing of lodging was observed on cereals crops. The best effect of counteracting this phenomenon was achieved at a dose of 0.75 L/ha. But, on winter oilseed rape crops phenomenon of lodging did not occur, so we cannot assess the effect of the different doses on the risk of lodging of oilseed rape. Only, a mild reduction in growth was observed for most studies carried out on winter oilseed rape (2 trials without shortening effect). During, efficacy trials carried out in N-E EPPO zone, Applicant shown that dose 0,75 l/ha have effect on reducing growth and lodging in winter oilseed rape crops.</p> <p>cMS should decide if lack of trials carried out in their EPPO zone can be accepted. In the opinion of Evaluator, each EPPO zone should be represented by enough trials. However, final decision is left to each cMS. Only for N-E EPPO zone and use on spring barley and on winter oilseed rape in Maritime EPPO zone and winter oilseed rape the acceptable number of MED trials was submitted. For winter wheat (N-E EPPO zone) and winter barley (Maritime EPPO zone) only limited number of trials were presented. However, given submitted by Applicant the efficacy studies which have shown that a dosage of 0.75 l/ha has satisfactory efficacy and the comparability of the results to the standard used for spring barley and winter wheat. So, those uses should also be accepted by the N-E and Maritime EPPO zone. cMS from MED and S-E EPPO zone should decide if lack of trials and only results from another climatic zone can be accepted.</p>
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### 3.2.3 Efficacy tests (KCP 6.2)

Data from 55 efficacy trials conducted in winter oilseed rape, winter barley, winter wheat and spring barley in the North-east EPPO zone (25; i.e. Poland) and Maritime EPPO zone (30; i.e. Germany and Czech Republic) 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.

**Table 3.2-12: Details on trial methodology**

<b>Guidelines</b>	General guidelines	EPPO PP 1/152 (4), PP 1/181 (4), PP 1/135(4)
	Specific guidelines	EPPO PP 1/144 (3)
<b>Experimental design</b>	Plot design	RCBD (9)
	Plot size	13,5-37,5 m <sup>2</sup>
	Number of replications	4 (19)
<b>Crop</b>	Trials per crop	Winter wheat (14) Spring barley (18) Winter barley (11) Winter oilseed rape (12)

	Varieties per crop	Winter wheat: Linus, KWS Ozon, Memory, Tobak, Initial, Akteur, Toras, Lemmy, Hondia, Bosporus, Esuforia, Julius, Ostroga, Emil. Spring barley: Olympic, Ella, Eunova, RTG Planet, Propino, Bojos, Grace, Malz, Kosmos, Solist, Etoile, Pilote, Olof. Winter barley: Orbit, Lotti, Kosmos, Morris, Paradies, Meridian, Higgins. Winter oilseed rape: Aganos, Exception, Architect, Excalibur, Quantiko, Ivo, Alibaba, Platon.
	Sowing period	Winter wheat: September 16 <sup>th</sup> 2016 to September 28 <sup>th</sup> 2016 Spring barley: April 4 <sup>th</sup> 2017 to April 10 <sup>th</sup> 2017 Winter barley: 21-22 <sup>nd</sup> September 2021 Winter oilseed rape: 19-27 <sup>th</sup> September 2021
<b>Application</b>	Application period	Winter wheat: April 25 <sup>th</sup> 2017 Spring barley: Juny 5 <sup>th</sup> 2017 to Juny 10 <sup>th</sup> 2017 Winter barley: 20 <sup>th</sup> September 2021 Winter oilseed rape: 24 <sup>th</sup> March- 27 <sup>th</sup> April 2021
	Crop stage (BBCH)* at application	Winter wheat (14): BBCH 30-39 Spring barley (18): BBCH 31-39 Winter barley (11): BBCH 31-32 Winter oilseed rape (12): BBCH 31-39
	Number of appl. Intervals between appl.	1 (55) n.a.
	Spray volumes	200-300 L/ha
<b>Assessment</b>	Assessment types	<ul style="list-style-type: none"> <li>- Measurement of plant height, compared to 'untreated' ('untreated' = 0 % reduction/increase) – based on the assessment of plants height setting on treated trees or plants, as compared to the untreated check.</li> <li>- Calculation of lodging in the plants</li> <li>- Crop yield was assessed in nine efficacy trials conducted on winter wheat and spring barley. Yield assessments included yield of grains [T/ha] and in all of these, also different quality parameters.</li> </ul>
	Assessment dates	From 6 days after treatment and up to 190 days after treatment
<b>Other relevant information</b>	Soil type	Loam (9), Loamy sand (14) Sandy loam (16), sand (1), Clayey sand (1), Silt loam (1), Grey-brown (10)
	Organic matter content	0.9 to 5.1
	Natural / artificial inoculation...	N.a.
	Field / Greenhouse...	Field

### Use 001: Control of height reduction

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

Crop	Winter wheat, winter barley and spring barley
Use rate	0.75 L/ha Mepiquat 3.8% SL
Use frequency	Up to 1x
Application timing	BBCH 31-39
Target	Reduction of crop height

The effectiveness of applying Mepiquat 3.8% SL against GAP claimed uses in winter wheat, winter barley and spring barley were evaluated in 41 trials, assessed plant height and lodging. These trials were carried out in 2017 and 2021 in the North-east EPPO zone (21; i.e. Poland) and in 2021 in the Maritime EPPO zone (20; i.e. Germany (10) and Czech Republic (10)). The objective was to confirm the per-

formance of Mepiquat 3.8% SL at the proposed dose rate of 0.75 L/ha (i.e. 28.5 grams per liter (g/L) mepiquat). In the trials specifically targeted for this pathogen, single application was applied at growth stages ranging between BBCH 31 and BBCH 39.

### North-east zone

To demonstrate the effectiveness of the test product at the proposed dose rate for reduction of crop height as well as compare it to the reference products included in the trial, the height plants, and lodging of winter wheat and spring barley was assessed in the trials. In the trials, height reduction on winter wheat and spring barley 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 3.2-13 and Table 3.2-14 therefore only contains one assessment per plant part from the trials assessed repeatedly.

**Table 3.2-13: North-east zone: Reduce of crop height from 9 trials treated with Mepiquat 3.8% SL and national reference product in the North-east EPPO zone (32-108 days after last treatment; mean and variation in % control as compared to untreated check.**

Part assessed	Days after Last Treatment. (DALT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Mepiquat 3.8% SL 38 g ai/ha is >, < or =, compared to the Reference product = : ± 5% control			Overall
				Mepiquat 3.8% SL	National reference Product				
				Mean (min-max)					
				0.75 L/ha	1 N	>	=	<	
<b>Height</b> cm									
Plant	32-78 DALT	9	88.8 (85.0-93.6)	4.9 (0.9-16.5)	10.0 (4.1-17.6)		5	4	≡ <
<b>Lodging</b> %									
Plant	78-108 DALT	9	20.3 (0*-70)	88.9 (55.4-100)	100 (100-100)		7	2	≡ <

\* Applicant submitted in table results from all trials. Results from field trials when lodging phenomenon did not occur on the control should be rejected from assessment. Lodging did not occur in one trial (SRG21-SHA113). Results from accepted trials were presented by ZRMs in commenting box.

In the trials, to observe the **reduction of crop height on winter wheat**, where height reduction on plants was assessed, the mean height in untreated plots was 88.8 cm (range: 85.0-93.6 cm) at the assessments chosen for evaluation. At these assessments, carried out at 32-78 days after the last application, the test product applied at 0.75 L/ha achieved an average of height reduction of 4.9%. At the same assessments, the formulated reference product applied at comparable dose rate achieved an average control of 10.0%.

In addition, an evaluation of the lodging of the **winter wheat** plants (LODGING) was carried out, where lodging on plants was assessed, the mean lodging in untreated plots was 20.3% (range: 0-70%) at the assessments chosen for evaluation. At these assessments, carried out at 78-108 days after the last application, the test product applied at 0.75 L/ha achieved an average of lodging control of 88.9% (range: 55.4-100%). At the same assessments, the formulated reference product applied at comparable dose rate achieved an average control of 100%.

**Table 3.2-14: North-east zone: Reduce of crop height from 10 trials treated with Mepiquat 3.8% SL and national reference product in the North-east EPPO zone (29-81 days after last treatment; mean and variation in % control as compared to untreated check.**

Part assessed	Days after Last Treatment. (DALT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Mepiquat 3.8% SL 38 g ai/ha is >, < or =, compared to the Reference product = : ± 5% control			Overall
				Mepiquat 3.8% SL	National reference Product				
				Mean (min-max)		>	=	<	
				0.75 L/ha	1 N				

Part assessed	Days after Last Treatment. (DALT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Mepiquat 3.8% SL 38 g ai/ha is >, < or =, compared to the Reference product = : ± 5% control			Overall
				Mepiquat 3.8% SL	National reference Product				
				Mean (min-max)					
				0.75 L/ha	1 N	>	=	<	
<b>Height</b> cm									
Plant	29-52 DALT	10	77.3 (70.9-85.6)	2.6 (0.0-7.9)	4.4 (0.0-14.4)		8	2	= <
<b>Lodging</b> %									
Plant	32-81 DALT	9	37.0 (3.0-90.0)	82.1 (0.0-100)	70.1 (0.0-100)		9		=

In the trials, to observe the **reduction of crop height on spring barley**, where height reduction on plants was assessed, the mean height in untreated plots was **77.3 cm** (range: 70.9-85.6 cm) at the assessments chosen for evaluation. At these assessments, carried out at 29-52 days after the last application, the test product applied at 0.75 L/ha achieved an average of height reduction of **2.6%**. At the same assessments, the formulated reference product applied at comparable dose rate achieved an average control of **4.4%**.

In addition, an evaluation of the lodging of the spring barley plants (LODGING) was carried out, where lodging on plants was assessed, the mean lodging in untreated plots was **37.0% (range: 3.0-90.0%)** at the assessments chosen for evaluation. At these assessments, carried out at 32-81 days after the last application, the test product applied at 0.75 L/ha achieved an average of lodging control of **82.1%**. At the same assessments, the formulated reference product applied at comparable dose rate achieved an average control of **70.1%**.

**Table 3.2-15: North-east zone – Reduce of crop height from 2 trials treated with Mepiquat 3.8% SL and national reference product in the North-east EPPO zone (63-84 days after last treatment; mean and variation in % control as compared to untreated check)**

Part assessed	Days after Last Treatment (DALT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Mepiquat 3.8% SL 38 g ai/ha is >, < or =, compared to the Reference product = : ± 5% control			Overall
				Mepiquat 3.8% SL	National reference Product				
				Mean (min-max)					
				0.75 L/ha	1 N	>	=	<	
Height cm									
Plant	63 DALT	2	106 (105.9-106)	2.9 (2.0-3.7)	7.6 (6.9-8.2)		1	1	=>
Lodging %									
Plant	63-84 DALT	2	51.5 (13-90)	59.8 (30.77-88.89)	54.9 (15.38-94.44)		2		=

In the trials, to observe the **reduction of crop height on winter barley**, where height reduction on plants was assessed, the mean height in untreated plots was **106 cm** (range: 105.9-106 cm) at the assessments chosen for evaluation. At these assessments, carried out at 63 days after the last application, the test product applied at 0.75 L/ha achieved an average of height reduction of **2.9%**. At the same assessments, the formulated reference product applied at comparable dose rate achieved an average control of **7.6%**.

In addition, an evaluation of the lodging of the **winter barley** plants (LODGING) was carried out, where lodging on plants was assessed, the mean lodging in untreated plots was **51.5% (range: 13.0-90.0%)** at the assessments chosen for evaluation. At these assessments, carried out at 63-84 days after the last application, the test product applied at 0.75 L/ha achieved an average of lodging control of **59.8%**. At the same assessments, the formulated reference product applied at comparable dose rate achieved an average control of **54.9%**.

#### Maritime EPPO zone

**Table 3.2-16: Maritime zone – Reduce of crop height from 7 trials treated with Mepiquat 3.8% SL and national reference product in the Maritime EPPO zone (55-79 days after last treatment; mean and variation in % control as compared to untreated check)**

Part assessed	Days after Last Treatment (DALT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Mepiquat 3.8% SL 38 g ai/ha is >, < or =, compared to the Reference product = : ± 5% control			Overall
				Mepiquat 3.8% SL	National reference Product				
				Mean (min-max)		>	=	<	
				0.75 L/ha	1 N				
Height cm									
Plant	42-79 DALT	7	97.6 (51.2-118)	1.6 1.74 (0-4.7)	8.3 8.41 (3.2-11.7)		4	3	=, <
Lodging %									
Plant	44-79 DALT	7	31.8 (0*-90)	97.0 (94.1-100)	95.8 (83.3-100)		6	1	=, <

\* Applicant submitted in table results from all trials. Results from field trials when lodging phenomenon did not occur on the control should be rejected from assessment. Lodging did not occur in four trials (PGR21-HORVW-2021-DOM26; PGR21-HORVW-2021-DOM27; SWEPL-KUJ21-HORVW49; SWEPL-RR21-WB-RYM). Results from accepted trials were presented by ZRMs in commenting box.

In the trials, to observe the **reduction of crop height on winter barley**, where height reduction on plants was assessed, the mean height in untreated plots was 97.6 cm (range: 51.2-118 cm) at the assessments chosen for evaluation. At these assessments, carried out at 42-79 days after the last application, the test product applied at 0.75 L/ha achieved an average of height reduction of 1.6%. At the same assessments, the formulated reference product applied at comparable dose rate achieved an average control of 8.3%.

In addition, an evaluation of the lodging of the **winter barley** plants (LODGING) was carried out, where lodging on plants was assessed, the mean lodging in untreated plots was 31.8% (range: 0-90%) at the assessments chosen for evaluation. At these assessments, carried out at 44-79 days after the last application, the test product applied at 0.75 L/ha achieved an average of lodging control of 97.0%. At the same assessments, the formulated reference product applied at comparable dose rate achieved an average control of 95.8%.

**Table 3.2-17: Maritime zone – Reduce of crop height from 8 trials treated with Mepiquat 3.8% SL and national reference product in the Maritime EPPO zone (55-79 days after last treatment; mean and variation in % control as compared to untreated check)**

Part assessed	Days after Last Treatment (DALT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Mepiquat 3.8% SL 38 g ai/ha is >, < or =, compared to the Reference product = : ± 5% control			Overall
				Mepiquat 3.8% SL	National reference Product	>	=	<	
				Mean (min-max)					
				0.75 L/ha	1 N				
Height cm									
Plant	31-50 DALT	8	73.2 (41-87.5)	1.5 (0-4.3)	6.7 (0.9-14.4) 6.05 (0.71-9.88)		4	4	=, >
Lodging %									
Plant	44-79 DALT	7	31.8 (0*-90)	97.0 (94.1-100)	95.8 (83.3-100)		6	1	=, <

\* Applicant submitted in table results from all trials. Results from field trials when lodging phenomenon did not occur on the control should be rejected from assessment. Lodging did not occur in three trials (PGR21-HORVS-2021-DOM28; SWEPL-RR21-SB-RYM; Sharda21-028). Results from accepted trials were presented by ZRMs in commenting box.

In the trials, to observe the **reduction of crop height on spring barley**, where height reduction on plants was assessed, the mean height in untreated plots was 73.2 cm (range: 41-87.5 cm) at the assessments chosen for evaluation. At these assessments, carried out at 31-50 days after the last application, the test product applied at 0.75 L/ha achieved an average of height reduction of 1.5%. At the same assessments, the formulated reference product applied at comparable dose rate achieved an average control of 6.7%.

In addition, an evaluation of the lodging of the **spring barley** plants (LODGING) was carried out, where lodging on plants was assessed, the mean lodging in untreated plots was 31.8% (range: 0-90%) at the assessments chosen for evaluation. At these assessments, carried out at 44-79 days after the last application, the test product applied at 0.75 L/ha achieved an average of lodging control of 97% (range: 94.1-100%). At the same assessments, the formulated reference product applied at comparable dose rate achieved an average control of 95.8% (range: 83.3-90%).

**Table 3.2-18: Maritime zone – Reduce of crop height from 5 trials treated with Mepiquat 3.8% SL and national reference product in the Maritime EPPO zone (42-85 days after last treatment; mean and variation in % control as compared to untreated check)**

Part assessed	Days after Last Treatment (DALT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Mepiquat 3.8% SL 38 g ai/ha is >, < or =, compared to the Reference product = : ± 5% control			Overall
				Mepiquat 3.8% SL	National reference Product				
				Mean (min-max)					
				0.75 L/ha	1 N	>	=	<	
Height cm									
Plant	42-66 DALT	5	86.7 (58.1-102.1)	1.6 1.78 (0.4-4.4) (0.61-4.11)	10.44 (7.24-13.2)	3	2		=, >
Lodging %									
Plant	56-85 DALT	5	6.0 (0-30)	90.0 (50-100)	100 (100-100)	5			=

\* Applicant submitted in table results from all trials. Results from field trials when lodging phenomenon did not occur on the control should be rejected from assessment. Lodging did not occur in four trials (GR21-TRZAW-2021-DOM25; Sharda21-030; Sharda21-032; SWEPL-RR21-WW-RYM). Results from accepted trials were presented by ZRMs in commenting box.

In the trials, to observe the **reduction of crop height on winter wheat**, where height reduction on plants was assessed, the mean height in untreated plots was 86.7 cm (range: 58.1-102.1 cm) at the assessments chosen for evaluation. At these assessments, carried out at 42-66 days after the last application, the test product applied at 0.75 L/ha achieved an average of height reduction of 1.6%. At the same assessments, the formulated reference product applied at comparable dose rate achieved an average control of 10.4%.

In addition, an evaluation of the lodging of the **winter wheat** plants (LODGING) was carried out, where lodging on plants was assessed, the mean lodging in untreated plots was 6.0% (range: 0-30%) at the assessments chosen for evaluation. At these assessments, carried out at 56-85 days after the last application, the test product applied at 0.75 L/ha achieved an average of lodging control of 90%. At the same assessments, the formulated reference product applied at comparable dose rate achieved an average control of 100%.

The individual trials results show that Mepiquat 3.8% SL gave good control of reduction of crop similar to that achieved by the formulated national reference product.

### 3.2.3.1 Use 002: Efficacy for the reduction of height

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

#### Description of Use 002

Crop	Winter oilseed rape
Use rate	0.75 L/ha Mepiquat 3.8% SL
Use frequency	Up to 1x
Application timing	BBCH 31-39
Target	Reduction of crop height

The effectiveness of applying Mepiquat 3.8% SL against GAP claimed uses in winter oilseed rape were evaluated in 14 trials, assessed plant height and lodging. These trials were carried out in 2021 in the North-east EPPO zone (6; i.e. Poland (6)) and in the Maritime EPPO zone (8; i.e. Germany (4) and Czech Republic (4)). The objective was to confirm the performance of Mepiquat 3.8% SL at the proposed dose rate of 0.75 L/ha (i.e. 28.5 grams per liter (g/L) mepiquat). In the trials specifically targeted for this pathogen, single application was applied at growth stages ranging between BBCH 31 and BBCH 39.

#### North-east EPPO zone

**Table 3.2-19:** North-east zone – Reduce of crop height from 6 trials treated with Mepiquat 3.8% SL and national reference product in the North-east EPPO zone (15-102 days after last treatment; mean and variation in % control as compared to untreated check)

Part assessed	Days after Last Treatment (DALT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Mepiquat 3.8% SL 38 g ai/ha is >, < or =, compared to the Reference product = : ± 5% control			Overall
				Mepiquat 3.8% SL	National reference Product				
				Mean (min-max)					
				0.75 L/ha	1 N	>	=	<	
Height cm									
Plant	15-97 DALT	6	139.9 (117.4-167.5)	0.9 (0.4-1.04)	5.7 (2.1-8.9)			6	>
Lodging %									
Plant	72-102 DALT	6	22.4 (4-45)	65.5 (25-94.4)	65.0 (23.08-100)	3		3	>

In the trials, to observe the **reduction of crop height on winter oilseed rape**, where height reduction on plants was assessed, the mean height in untreated plots was 139.9 cm (range: 117.4-167.5 cm) at the assessments chosen for evaluation. At these assessments, carried out at 15-97 days after the last application, the test product applied at 0.75 L/ha achieved an average of height reduction of 0.9%. At the same assessments, the formulated reference product applied at comparable dose rate achieved an average control of 5.7%.

In addition, an evaluation of the lodging of the **winter oilseed rape** plants (LODGING) was carried out, where lodging on plants was assessed, the mean lodging in untreated plots was 22.4% (range: 4-45%) at the assessments chosen for evaluation. At these assessments, carried out at 72-102 days after the last application, the test product applied at 0.75 L/ha achieved an average of lodging control of 65.5%. At the same assessments, the formulated reference product applied at comparable dose rate achieved an average control of 65.0%.

#### Maritime EPPO zone

**Table 3.2-20: Maritime zone – Reduce of crop height from 8 trials treated with Mepiquat 3.8% SL and national reference product in the Maritime EPPO zone (22-68 days after last treatment; mean and variation in % control as compared to untreated check)**

Part assessed	Days after Last Treatment (DALT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Mepiquat 3.8% SL 38 g ai/ha is >, < or =, compared to the Reference product = : ± 5% control			Overall
				Mepiquat 3.8% SL	National reference Product				
				Mean (min-max)	Mean (min-max)				
				0.75 L/ha	1 N	>	=	<	
<b>Height</b>									
			cm						
Plant	22-68 DALT	8	117.3 (87.3-144.1)	97.9-2.6 (95-101)	86.6-13.4 (69.5-95.3)		4	4	=<
<b>Lodare</b>									
			%						
Plant	105-125 DALT	6	0 (0-0)*	100 (100-100)	100 (100-100)		6		=

\* Applicant submitted in table results from all trials. Results from field trials when lodging phenomenon did not occur on the control should be rejected from assessment. Lodging did not occur in all six trials (Sharda21-019; PGR-WOSR-2021-DOM29; PGR21-WOSR-2021-DOM30; Sharda21-017; Sharda21-018; Sharda21-020). Results from accepted trials were presented by ZRMs in commenting box.

In the trials, to observe the **reduction of crop height on winter oilseed rape**, where height reduction on plants was assessed, the mean height in untreated plots was 117.3 cm (range: 87.3-144.1 cm) at the assessments chosen for evaluation. At these assessments, carried out at 22-68 days after the last application, the test product applied at 0.75 L/ha achieved an average of height reduction of 2.6±%. At the same assessments, the formulated reference product applied at comparable dose rate achieved an average control of 13.4%.

In addition, an evaluation of the lodging area of the winter oilseed rape plants (LODARE) was carried out, where lodging area on plants was assessed, the mean lodare in untreated plots was 0% (range: 0-0%) at the assessments chosen for evaluation. At these assessments, carried out at 105-125 days after the last application, the test product applied at 0.75 L/ha achieved an average of lodging control of 100%. At the same assessments, the formulated reference product applied at comparable dose rate achieved an average control of 100%.

The individual trials results show that Mepiquat 3.8% SL gave good control of reduction of crop similar to that achieved by the formulated national reference product.

## Summary and conclusion

Based on the results of 55 field efficacy trials carried out in 2017 and 2021, the following can be concluded for the intended use of Mepiquat 3.8% SL applied at 0.75 L/ha per application in **winter oilseed rape, winter barley, winter wheat and spring barley**:

- Mepiquat 3.8% SL applied in **winter oilseed rape, winter barley, winter wheat and spring barley** provided a good reduction of crop height with the recommended dose rate of 0.75 L/ha. Single application per season of Mepiquat 3.8% SL at the proposed dose rate should be used to efficiently reduce height as claimed on the label.
- Compared to the reference product tested in the **winter oilseed rape, winter barley, winter wheat and spring barley** trials, the efficacy obtained with Mepiquat 3.8% SL is comparable against the key uses tested.
- The trial results are considered valid for all intended Central zone countries.

Mepiquat 3.8% SL is suitable for reduction of crop height in winter oilseed rape, winter barley, winter wheat and spring barley.

This document clearly demonstrates that the efficacy and crop safety of Mepiquat 3.8% 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.

Applicant would like to refer to the EPPO standard PP 1/226(3) where is indicated that full number of trials in different years is required "particularly for plant protection products or active substances which not have been on the market in the EPPO region in which authorization is sought". It is important to remark that the EPPO standard is referring to the region where registration is sought and not to a specific country, thus applicant considers that presence of standards has to be evaluated taking into account the registers in the whole Central Zone. The same EPPO PP 1/226(3) indicates that reduced number of trials can be presented "where there is a large amount of supporting evidence from use of the product, or of similar products with the same active substance on closely related pests or against the same pests on different crops". Mepiquat formulations have been registered in Central Zone and in countries where trials were conducted for various years like Mepik 300 SL (reg nr R-105/2017) registered in Poland in 2017, Medax Top 350 SC (reg ne R-213/2016) registered in Poland in 2016, Medax top (reg nr 4825-0) registered in the Czech Republic in 2014, Medax top (reg nr 025620-00) registered in Germany in 2017. According to this, formulation has been widely proved in Central Zone where registration is sought, thus applicant considers that number of trials are enough to register formulation.

<p>Comments of ZRMS:</p>	<p>Lodging in cereals was evaluated in accordance with the EPPO standards PP 1/144(3). <del>Lack of trials for winter oilseed rape. Control of lodging and growth regulation in brassica oil crops was studied according to EPPO 1/153 (3).</del></p> <p>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 oilseed rape trials. <del>Because</del> Applicant submitted <del>only</del> results from <del>one two</del> growing seasons (2017 and 2021) for winter wheat, winter barley and spring barley. <del>However,</del> Explanations for conducting surveys in only one season are included in this dRR. These explanations were accepted by the ZRMs.</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 major crops at least six trials. <del>For Poland trials from neighbouring countries are acceptable.</del> Submitted documentations is sufficient in the opinion of Evaluator <del>only</del> for spring barley (18 trials: PL-10, DE-4, CZ-4), winter barley (11 trials: PL-2, DE-5, CZ-4), winter wheat (14 trials: PL-9, DE-3, CZ-2) and winter oilseed rape (12 trials: PL-2, DE-4, CZ-4) for N-E EPPO zone against reduction of growth and lodging. <del>However, also lodging in spring barley should be accepted on the basis on 5 valid trials in the opinion of Evaluator. For winter wheat at least 3 additional efficacy trials are required, for winter barley at least 2-3 phytotoxicity trials (when the number of tests for winter wheat will be acceptable, then the extrapolation results on winter barley will be possible) and at least 6 efficacy and phytotoxicity trials for winter oilseed rape. For Maritime EPPO zone only for winter barley (9 trials), winter oilseed rape (8 trials) and spring barley (8 trials) sufficient number of trials were presented. Also, 5 trials for winter wheat for Maritime EPPO zone should be acceptable (extrapolation results from winter barley or/and reduction of number of trials should be consider by cMS). In the opinion of ZRMs registration in MED or S-E is not possible without any trials conducted in those zones. However, final decision is left to cMS from S-E and MED EPPO zone.</del></p> <p>Regarding comment about number of results for each use (lodging and reduction of growth) it would be like to indicate that according to the EPPO standard PP 1/226: the full number of trials is needed particularly for plant protection products or active substances which have not been on the market in the region in which authorization is sought, or for intended uses for</p>
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which no extrapolation of any aspect of efficacy from other uses is possible. Mepiquat 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 Mepisha (product code: SHA 8500 A) can be accepted by them only on the basis on extrapolation results from N-E EPPO zone and/or Maritime EPPO zone.

According to EPPO PP 1/144 Reduction of lodging in cereals, an assessment of lodging (~~5 trials on spring barley and 3 trials on winter wheat~~) and height (~~6 trials on spring barley and 3 trials on winter wheat~~) 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. Mepisha (product code: SHA 8500 A) provided an **high acceptable** level of reduction in crop height as well as control of lodging in the GAP claimed crops with the recommended dose rate of 0,75 l/ha in spring barley, winter barley, winter wheat and winter oilseed rape. Compared to the mepiquat reference product, the efficacy obtained with Mepisha were **comparable lower in all most trials**. However, it is worth noting that the product was tested at a dose lower than the reference standards used during trials. Mepisha is recommended for once-a-season application at a rate of 0.75 L/ha, whereas in the trials conducted in the northeast zone, the reference standard used was Canopy at a rate of 1.25 l/ha (winter wheat spring barley, winter rape, winter barley), Medax Top at 1.0-1.25 L/ha (winter wheat, spring barley, Caryx 240 SL at 1.25 L/ha (spring barley, winter rape) and in the Maritime zone: Medax Top at 1.5 l/ha (cereal trials) and Caeyx at 1.4 l/ha (rapeseed trials). It is worth noting that the tested product showed a reduction in cereal growth and in lodging, but its efficacy was lower than standard ref. products used in higher doses. Also, those standards reference products contained 6 times (300 g/L) more active substance than the tested product (50 g/L). Therefore, the effectiveness of Mepisha will always be lower than products used in higher doses. One might wonder whether Mepisha applied twice a season would not be more effective than products already on the market. However, no study was conducted in which two doses of a test product were tested. For example, in Poland no plant protection products with mepiquat for use twice a season are registered. Also, used standard reference products during trials are registered for use only once a season. When we, change the method or number of applications, we are dealing with a new application for which efficacy studies must be presented. In our opinion, it is always advisable to register a product that contains a lower amount of active substance than those currently available on the market for environmental reasons. However, it would be worthwhile to consider applying Mepisha twice a season, the first time at BBCH 31. Then, a treatment at this stage of development would ensure a thickening of the stem base, the development of the root system and a permanent reduction in plant height as well as an even ripening of the canopy. The second growth regulation period would be at BBCH 39, the flag leaf stage. A farmer does not always have to decide on a two-stage shortening of wheat or other cereals, because a properly performed first adjustment may be sufficient. The decision about the second treatment should be made in situations where the plantation is managed intensively with high nitrogen fertilization and in the case of varieties susceptible to lodging. The aim of this treatment is to shorten and strengthen the spikelet. The minimum interval between two applications should be at least 14 days. What is important, both studies on selectivity and available reference products on the market, testify that the product at a dose of 1.5 L/ha is safe for winter oilseed rape and cereals. It is only necessary to demonstrate that the effectiveness of two doses at 14 days will be more effective than one application per season. Without studies with 2 applications, it's unfortunately just a guessing game.

In summary, **ZRMs consents to the registration of the product in Poland as stated in the GAP table**. 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 lower than the reference standard applied at a higher dose and containing more active compound. **At the same time, we point out that it is worth considering a conditional registration of Mepisha with an indication of a possible change in the number of applications in a season (with a maximum of 2 treatments, interval at least**

14 days), which could visibly increase the effectiveness of the product and reduce economic losses of farmers resulting from lodging of crops.

It is left to the Member States to decide on the acceptability of the results presented in this dRR and to consider registration of Mepisha (normal or conditional). Below are the detailed results from all submitted filed trials by Applicant, which will help cMS to make a more accurate decision.

#### REDUCTION IN HEIGHT and LODGING:

- *N-E EPPO zone*

#### Winter wheat

Below, ZRMs presented detailed results from all trials separately for reduction of growth and lodging which was assessed

Trial no.	No. of appl.	Interval between Appl.	Assess. Type	Untreated		Mepiquat 3.8% SL 0.75 L/ha (28.5g ai/ha)		Reference product 1 N	
				Mean		Mean	% Cont.	Mean	% Cont.
NUZ 18+19/17 I	1	-	HEIGHT	93.6	a	86.4	bc	84.3	c
NUZ 18+19/17 II	1	-	HEIGHT	87.0	a	78.0	c	76.0	c
NUZ 18+19/17 III	1	-	HEIGHT	85.0	a	71.0	c	70.0	c
21-po-11-Af	1	-	HEIGHT	86.3	a	85.1	a	79.8	b
21-po-12-Af	1	-	HEIGHT	86.3	a	85.1	a	79.8	b
21-po-13-Af	1	-	HEIGHT	85.8	a	85	a	82.3	b
SRG21-SHA111	1	-	HEIGHT	94.8	a	92.8	b	87.2	e
SRG21-SHA112	1	-	HEIGHT	92.8	a	91.8	a	76.6	e
SRG21-SHA113	1	-	HEIGHT	87.8	a	85.8	b	82.8	d
NUZ 18+19/17 I	1	-	LODGING	8.8	a	0.0	b	0.0	b
NUZ 18+19/17 II	1	-	LODGING	14.0	a	0.0	d	0.0	d
NUZ 18+19/17 III	1	-	LODGING	11.8	a	0.0	b	0.0	b
21-po-11-Af	1	-	LODGING	8		0		0	
21-po-12-Af	1	-	LODGING	8		0		0	
21-po-13-Af	1	-	LODGING	12		8	66,67	0	
SRG21-SHA111	1	-	LODGING	50	a	38.8	a	0	b
SRG21-SHA112	1	-	LODGING	70	a	38.8	b	0	c

Reduction of height was observed in 9 trials carried out on winter wheat. Observed average efficacy was 4,9% and it was lower than standard ref. product eff. 10%.

Lodging was observed in 8 trials at untreated control plants. In one trial lodging was not observed (SRG21-SHA113). This report was excluded from assessment and average efficacy. Mepisha reduced lodging with 87,6% efficacy. Standard reference product was characterized by better eff. (100%).

#### Spring barley

Below, ZRMs presented detailed results from all trials separately for reduction of growth and lodging which was assessed

Trial no.	No. of appl.	Interval between Appl.	Assess. Type	Untreated		Mepiquat 3.8% SL 0.75 L/ha (28.5g ai/ha)		Reference product 1 N	
				Mean		Mean	% Cont.	Mean	% Cont.
SGS/2017/032/PL01	1	-	HEIGHT	70.9	a	72.0	a	71.8	a
SGS/2017/032/PL02	1	-	HEIGHT	72.3	a	71.8	a	72.1	a
SGS/2017/032/PL03	1	-	HEIGHT	75.1	a	73.5	a	75.3	a
SGS/2017/032/PL04	1	-	HEIGHT	82.5	a	77.7	a	77.5	a
SGS/2017/032/PL05	1	-	HEIGHT	76.2	a	74.0	a	75.8	a

SGS/2017/032/PL06	1	-	HEIGHT	81.9	a	81.6	a	0.4	81.9	a	0.0
21-jj-16-Af	1	-	HEIGHT	72.6	a	68.8	b	5.3	65.4	b	0.9
21-jj-17-Af	1	-	HEIGHT	74.3	a	68.5	b	7.9	68.5	b	7.8
NUZ01-21-I	1	-	HEIGHT	85.6	a	85.1	a	0.6	73.9	d	13.7
NUZ01-21-II	1	-	HEIGHT	81.1	a	80.3	a	1.0	69.4	d	14.4
SGS/2017/032/PL01	1	-	LODGING	48.8	a	0.0	b	100	0.0	b	100
SGS/2017/032/PL02	1	-	LODGING	90.0	a	90.0	a	0.0	90.0	a	0.0
SGS/2017/032/PL03	1	-	LODGING	33.4	a	18.5	a	47.0	36.6	a	0.0
SGS/2017/032/PL04	1	-	LODGING	59.4	a	61.1	a	0.0	58.8	a	1.0
SGS/2017/032/PL06	1	-	LODGING	70.0	a	70.0	a	0.0	70.0	a	0.0
21-jj-16-Af	1	-	LODGING	11	a	0		100	0	b	100
21-jj-17-Af	1	-	LODGING	13	a	0		100	0	b	100
NUZ01-21-I	1	-	LODGING	3		2.4		80	0.4		13.33
NUZ01-21-II	1	-	LODGING	4.56	a	1.38	a	30.26	1.69	a	37.06
Reduction of height was observed in 10 trials carried out on spring barley. Observed average efficacy was 2,6% and it was compared to standard ref. product eff. 4,4%).											
Lodging was observed in 9 trials. Mepisha reduced lodging with 82,1% efficacy. Standard reference product was characterized by lower eff. (70,1%).											
<b>winter barley</b>											
Below, ZRMs presented detailed results from all trials separately for reduction of growth and lodging											
Trial no.	No. of appl.	Interval between Appl.	Assess. Type	Untreated		Mepiquat 3.8% SL 0.75 L/ha (28.5g ai/ha)		Reference product 1 N			
				Mean		Mean	% Cont.	Mean		% Cont.	
21-jo-14-Af	1	-	HEIGHT	105.9	a	103.8	a	2.0	98.6	b	6.9
21-jo-15-Af	1	-	HEIGHT	106	a	102.1	b	3.7	97.3	b	8.2
21-jo-14-Af	1	-	LODGING	90	a	80		88.89	85	a	94.44
21-jo-15-Af	1	-	LODGING	13	a	4		30.77	2		15.38
Reduction of height was observed in 2 trials carried out on winter barley. Observed average efficacy was 2,9% and it was compared to standard ref. product eff. 7,6%).											
Lodging was observed in 2 trials. Mepisha reduced lodging with 59,8% efficacy. Standard reference product was characterized by lower eff. (54,9%).											
<b>Winter oilseed rape</b>											
Below, ZRMs presented detailed results from all trials separately for reduction of growth and lodging which was assessed											
Trial no.	No. of appl.	Interval between Appl.	Assess. Type	Untreated		Mepiquat 3.8% SL 0.75 L/ha (28.5g ai/ha)		Reference product 1 N			
				Mean		Mean	% Cont.	Mean		% Cont.	
21-ro-08-Af	1	-	HEIGHT	167.5	a	166.8	a	0.4	164	b	2.1
21-ro-09-Af	1	-	HEIGHT	132.1	a	130.9	a	1.0	120.4	b	8.9
21-ro-10-Af	1	-	HEIGHT	162.7	a	161	a	1.04	156.7	b	3.7
NUZ01-21-III	1	-	HEIGHT	117.4		116.3		1.0	110.8		5.6
NUZ01/21/2	1	-	HEIGHT	127	a	125.9	a	0.9	118.3	b	6.8
NUZ01/21/2	1	-	HEIGHT	132.5	a	131.3	a	0.9	123.3	b	6.9
21-ro-08-Af	1	-	LODGING	5		3		60	0		100
21-ro-09-Af	1	-	LODGING	4		1		25	0		100
21-ro-10-Af	1	-	LODGING	8		4		50	0		100
NUZ01-21-III	1	-	LODGING	40		30		75	11.3		28.25

NUZ01/21/2	1	-	LODGING	45	a	42,5	a	94,44	17,5	d	38,89
NUZ01/21/2	1	-	LODGING	32,5	a	28,8	a	88,62	7,5	c	23,08

Reduction of height was observed in 6 trials carried out on winter oilseed rape. Ob-served average efficacy was 0,9% and it was lower than standard ref. product eff. 2,1%.

Lodging was observed in 6 trials. Mepisha reduced lodging with 65,5% efficacy. Standard reference product was characterized by compared eff. (65,0%).

● Maritime EPPO zone

**Winter barley**

Below, ZRMs presented detailed results from all trials separately for reduction of growth and lodging

Trial no.	No. of appl.	Interval between Appl.	Assess. Type	Untreated		Mepiquat 3.8% SL 0.75 L/ha (28.5g ai/ha)		Reference product 1 N			
				Mean		Mean	% Cont.	Mean	% Cont.		
Sharda21-022	1	-	HEIGHT	118	a	118,2	a	0,16	112,1	b	5,00
Sharda21-023	1	-	HEIGHT	96,2	a	91,9	a	4,47	90,9	a	5,51
Sharda21-021	1	-	HEIGHT	115	a	113,4	b	1,39	101,5	c	11,7
PGR21-HORVW-2021-DOM26	1	-	HEIGHT	84,9	a	82,9	a	2,36	75,5	b	11,7
PGR21-HORVW-2021-DOM27	1	-	HEIGHT	99,2	a	100	a	0,00	96	a	3,22
SWEPL-KUJ21-HORVW49	1	-	HEIGHT	118,4	a	114,4	b	3,38	100	d	15,5
SWEPL-RR21-WB-RYM	1	-	HEIGHT	51,2	a	51	b	0,39	48	d	6,25
Sharda21-022	1	-	LODGING	90	a	87,5	a	97,2	75	b	83,33
Sharda21-023	1	-	LODGING	47,5	a	22,5	b	87,5	37,5	a	87,5
Sharda21-021	1	-	LODGING	85	a	80	a	94,12	85	a	100

Reduction of height was observed in 7 trials carried out on winter barley. Observed average efficacy was 1,74% and it was lower than standard ref. product eff. 8,41%.

Lodging was observed in 3 trials. Mepisha reduced lodging with 92,9% efficacy. Standard reference product was characterized by compared eff. (90,3%).

**Winter oilseed rape**

Below, ZRMs presented detailed results from all trials separately for reduction of growth and lodging

Trial no.	No. of appl.	Interval between Appl.	Assess. Type	Untreated		Mepiquat 3.8% SL 0.75 L/ha (28.5g ai/ha)		Reference product 1 N			
				Mean		Mean	% Cont.	Mean	% Cont.		
Sharda21-019	1	-	HEIGHT	92,7	a	88,5	b	4,53	64,4	d	30,52
PGR21-WOSR-2021-DOM29	1	-	HEIGHT	87,3	a	86,3	a	1,15	76,2	b	12,71
PGR21-WOSR-2021-DOM30	1	-	HEIGHT	130,3	a	123,7	b	5,07	113,8	c	12,66
Sharda21-017	1	-	HEIGHT	80,1	a	77,9	a	2,75	58,2	b	27,34
Sharda21-018	1	-	HEIGHT	137,4	a	134,6	a	2,04	130,9	a	4,73
Sharda21-020	1	-	HEIGHT	155	a	157,3	a	1,48	147	b	5,16
SWEPL-KUJ21-BRSNW52	1	-	HEIGHT	144,1	a	144,9	a	0,56	135,7	b	5,83
SWEPL-KUJ21-BRSNW53	1	-	HEIGHT	111,8	a	108,2	ab	3,22	102,6	b	8,23

Reduction of height was observed in 8 trials carried out on winter barley. Observed average efficacy was 2,6% and it was much lower than standard ref. product eff. 13,4%.

No lodging was observed during 6 trials. Those trials should be excluded from assessment.

### Spring barley

Below, ZRMs presented detailed results from all trials separately for reduction of growth and lodging

Trial no.	No. of appl	Interval between Appl.	Assess. Type	Untreated		Mepiquat 3.8% SL 0.75 L/ha (28.5g ai/ha)		Reference product 1 N	
				Mean		Mean	% Cont	Mean	% Cont
PGR21-HORVS-2021-DOM28	1	-	HEIGHT	63,4	a	62,5	a	57,4	a
Sharda21-026	1	-	HEIGHT	74,6	a	71,4	b	67,6	c
Sharda21-027	1	-	HEIGHT	71,7	a	70,6	a	70,1	a
SWEPL-KUJ21-HORVS50	1	-	HEIGHT	76,9	a	75,6	a	69,3	c
SWEPL-KUJ21-HORVS51	1	-	HEIGHT	86,8	a	86,2	a	79	b
SWEPL-RR21-SB-RYM	1	-	HEIGHT	41	a	41	a	39	a
Sharda21-025	1	-	HEIGHT	83,8	a	81,7	a	77,3	c
Sharda21-028	1	-	HEIGHT	87,5	a	87,6	a	86,3	b
Sharda21-026	1	-	LODGING	17,5	a	7,5	a	15	a
Sharda21-027	1	-	LODGING	10	a	3,8	a	5	a
SWEPL-KUJ21-HORVS50	1	-	LODGING	33	a	26,4	b	8,3	b
Sharda21-025	1	-	LODGING	12,5	a	5	a	0	b

Reduction of height was observed in 8 trials carried out on spring barley. Observed average efficacy was 3,24% and it was lower than standard ref. product eff. 6,05%.

Lodging was observed in 4 trials. Mepisha reduced lodging with 50,2% efficacy. Standard reference product was characterized by compared eff. (65,2%).

### Winter wheat

Below, ZRMs presented detailed results from all trials separately for reduction of growth and lodging

Trial no.	No. of appl	Interval between Appl.	Assess. Type	Untreated		Mepiquat 3.8% SL 0.75 L/ha (28.5g ai/ha)		Reference product 1 N	
				Mean		Mean	% Cont	Mean	% Cont
PGR21-TRZAW-2021-DOM25	1	-	HEIGHT	80,8	a	80,7	a	72,9	b
Sharda21-030	1	-	HEIGHT	98,4	a	97,8	b	87,1	c
Sharda21-032	1	-	HEIGHT	93,9	a	94,3	a	87,1	a
SWEPL-RR21-WW-RYM	1	-	HEIGHT	58,1	a	56	b	52	c
Sharda21-029	1	-	HEIGHT	102,1	a	97,9	b	88,6	c
Sharda21-029	1	-	LODGING	30	a	15	b	0	b

Reduction of height was observed in 5 trials carried out on winter wheat. Observed average efficacy was 1,78% and it was lower than standard ref. product eff. 10,44%.

Lodging was observed in 1 trial. Mepisha reduced lodging with 50% efficacy. Standard reference product was characterized by compared eff. (100%). Studies in which lodging did not occur were not included in the evaluation and calculation of the average efficacy of the test

	<p>product.</p> <p>Mepiquat 3.8% SL applied in winter oilseed rape, winter barley, winter wheat and spring barley provided a good reduction of crop height and lodging with the recommended dose rate of 0.75 L/ha. Single application per season of Mepiquat 3.8% SL at the proposed dose rate should be used to efficiently reduce height as claimed on the label. Compared to the reference product tested in the winter oilseed rape, winter barley, winter wheat and spring barley trials, the efficacy obtained with Mepiquat 3.8% SL is comparable against the key uses tested. All detailed results were correctly presented by Applicant in tables above.</p> <p>Based on results, it can be concluded that for Mepisha (product code: SHA 8500 A) control lodging and reduces the growth when is uses according to GAP table and label project for spring barley, winter barley, winter wheat and winter oilseed rape. Winter oilseed rape, winter wheat and winter barley should be excluded from GAP table and label project.</p> <p><del>Reduction of crop height on spring barley:</del> The mean height in untreated plots was 76.5cm (range: 70.9-82.5 cm) at the assessments chosen for evaluation. At these assessments, carried out at 29-48 days after the last application, the test product applied at 0.75 L/ha achieved an average of height reduction of 1.9%. At the same assessments, the formulated reference product applied at comparable dose rate achieved an average control of 1.2%.</p> <p><del>Lodging of the spring barley plants:</del> The mean lodging in untreated plots was 60.3% (range: 33.4-90.0%) at the assessments chosen for evaluation. At these assessments, carried out at 32-81 days after the last application, the test product applied at 0.75 L/ha achieved an average of lodging control of 29.4%. At the same assessments, the formulated reference product applied at comparable dose rate achieved an average control of 20.2%.</p>
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### 3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

Since Mepiquat 3.8% SL is a plant growth regulator, the crop is the target of the application and not any pests as such. It is therefore not applicable to describe the possible development of resistance or cross-resistance of the crop towards mepiquat.

Comments of zRMS:	An assessment of resistance risk is not required for a plant growth regulator. Mepiquat-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 19 efficacy and 34 selectivity and selectivity trials in winter oilseed rape, winter barley, winter wheat and spring barley have been presented for selectivity results conducted in the North-east EPPO zone (25, i.e. Poland) and the Maritime EPPO zone (28, i.e. Germany (14) and Czech Republic (14)) have been included in this biological assessment dossier to support the label claims and recommendations on selectivity in the EU Central Registration zone.

The 19 efficacy and 34 selectivity trials were conducted in winter oilseed rape, winter barley, winter wheat and spring barley. Of these, 8 studies performed on winter oilseed rape in the Maritime zone determined both efficacy and selectivity assessment.

#### 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 Mepiquat 3.8% SL, 19 efficacy and 34 selectivity trials with selectivity results were conducted in the North-east and Maritime EPPO zone: Of these, 8 studies performed on winter oilseed rape in the Maritime zone determined both efficacy and selectivity assessment.

**Table 3.4-1: Presentation of selectivity trials**

Crop	Country	Type of trial**	Number of trials				Years	GEP, non-GEP, official***	Comments (any other relevant information)
			EPPO zone						
			MAR	MED	S-E	N-E			
TRZAW	Poland	MED + E				3	2017	GEP	
	Total winter wheat (eff.)					3			
HORVS	Poland	MED + E				6	2017	GEP	
	Total spring barley (eff.)					6			
BRNSW	Germany	MED + E	4				2021	GEP	
	Czech Republic	MED + E	4				2021	GEP	
	Total winter wheat oilseed rape (eff.)		8						
HORVW	Germany	MED + E	2				2021	GEP	
	Total spring winter barley (eff.)		2						
TRZAW	Poland	Q+Y+S				6	2021	GEP	
	Germany	Q+Y+S	3				2021	GEP	
	Czech Republic	Q+Y+S	2				2021	GEP	
	Total winter wheat (sel.)		5			6			
HORVS	Poland	Q+Y+S				4	2021	GEP	
	Germany	Q+Y+S	4				2021	GEP	
	Czech Republic	Q+Y+S	4				2021	GEP	
	Total spring barley (sel.)		8			4			
BRNSW	Poland	Q+Y+S				4	2021	GEP	
	Germany	Q+Y+S	4						
	Czech Republic	Q+Y+S	4						
	Total winter wheat oilseed rape (sel.)		8			4			
HORVW	Poland	Q+Y+S				2	2021	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			
	Germany	Q+Y+S	1				2021	GEP	
	Czech Republic	Q+Y+S	4				2021	GEP	
	Total spring winter barley (sel.)		5			2			

**Table 3.4-2: Details on selectivity trial methodology**

**Cereals:**

<b>Guidelines</b>	General guidelines	EPPO PP 1/152 (4), PP 1/181 (4), PP 1/135(4)
	Specific guidelines	EPPO PP 1/144 (3)
<b>Experimental design</b>	Plot design	RCBD (9)
	Plot size	21-37,5 m <sup>2</sup>
	Number of replications	4 (9)
<b>Crop</b>	Trials per crop	Winter wheat (3) Spring barley (6)
	Varieties per crop	Winter wheat: Linus, KWS Ozon, Memory Spring barley: Olympic, Ella, Eunova, RTG Planet, Propino
	Sowing period	Winter wheat: September 16 <sup>th</sup> 2016 to September 28 <sup>th</sup> 2016 Spring barley: April 4 <sup>th</sup> 2017 to April 10 <sup>th</sup> 2017
<b>Application</b>	Application period	Winter wheat: April 25 <sup>th</sup> 2017 Spring barley: Juny 5 <sup>th</sup> 2017 to Juny 10 <sup>th</sup> 2017
	Crop stage (BBCH)* at application	Winter wheat (3): BBCH 30 Spring barley (6): BBCH 31-39
	Number of appl. Intervals between appl.	1 (9) n.a.
	Spray volumes	200-300 L/ha
<b>Assessment</b>	Assessment types	<ul style="list-style-type: none"> <li>- 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.</li> <li>- crop vigour</li> </ul>
	Assessment dates	From 6 days after treatment and up to 190 days after treatment
<b>Other relevant information</b>	Soil type	Loam (3), Loamy sand (1) Sandy loam (3), sand (1), Clayey sand (1)
	Organic matter content	0.9 to 2.8
	Natural / artificial inoculation...	N.a.
	Field / Greenhouse...	Field

### Winter oilseed rape

<b>Guidelines</b>	General guidelines	EPPO PP 1/152 (4), PP 1/181 (4), PP 1/135(4)
	Specific guidelines	EPPO PP 1/153 (3)
<b>Experimental design</b>	Plot design	RCBD (12)
	Plot size	N-E EPPO zone: 20-23,4m <sup>2</sup> Maritime EPPO zone: 24-32 m <sup>2</sup>
	Number of replications	4 (12)
<b>Crop</b>	Trials per crop	N-E: 4 trials; Maritime: 8 trials
	Varieties per crop	N-E EPPO zone: Expansion, Exotter, Exima, Stefano Maritime EPPO zone: Aganos, Exception, Architect, Excalibur, Quantiko, Ivo, Alibaba, Platon
	Sowing period	N-E EPPO zone: 21/08/2020 to 03/09/2020 Maritime EPPO zone: 19/08/2020 to 27/08/2020
<b>Application</b>	Application period	N-E EPPO zone: 15/04/2021 to 20/04/2021 Maritime EPPO zone: 24/03/2021 to 27/04/2021
	Crop stage (BBCH)* at application	Winter oilseed rape (12): BBCH 31-39
	Number of appl. Intervals between appl.	1 (12) n.a.
	Spray volumes	N-E EPPO zone: 250-300 Maritime EPPO zone: 200-300
<b>Assessment</b>	Assessment types	<ul style="list-style-type: none"> <li>- 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.</li> <li>- crop vigour</li> </ul>
	Assessment dates	N-E EPPO zone: From 8 days after treatment and up to 36 days after treatment Maritime EPPO zone: From 7 days after treatment and up to 41 days after treatment
<b>Other relevant information</b>	Soil type	N-E EPPO zone: Grey-brown (3), class IIIa (1) Maritime EPPO zone: Loamy sand (4), Silt loam (1), Loam (2), sandy loam (1)
	Organic matter content	N-E EPPO zone: 0 to 1,25 Maritime EPPO zone: 1,1 to 5,1
	Natural / artificial inoculation...	N.a.
	Field / Greenhouse...	Field

### Reference products

In the efficacy trials with selectivity results, the performance of Mepiquat 3.8% SL was measured against a commercially available reference products containing mepiquat and prohexadione (Medax top; 300 g/L mepiquat + 50 g/L prohexadione SC). The trials were carried out on winter wheat and spring barley.

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

Trade name	Formulation	Composition	Rates	Country	N° of Trials
<b>Mepiquat formulation</b>					
Medax top	SC	300 g/L mepiquat + 50 g/l prohexadione	1.25 l/ha 1.5 l/ha 3.0 l/ha	Poland Germany Czech Republic	9 10 10
CANOPY	SL	30 g/L Metconazol + 210 g/L Mepiquat	1.25 l/ha 2.5 l/ha	Poland	13
CARAX	SL	30 g/L Metconazol + 210 g/L Mepiquat	1.4 l/ha 2.8 l/ha	Germany Czech Republic	4 2
CARYX	SL	30 g/L Metconazol + 210 g/L Mepiquat	1.4 l/ha 2.8 l/ha	Czech Republic	2
CARYX 240 SL	SL	30 g/L Metconazol + 210 g/L Mepiquat	1.4 l/ha 2.8 l/ha	Czech Republic	3

### 3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

As Mepiquat 3.8% SL is a plant growth regulator, no specific studies are required as long as in the efficacy trials no negative effects are observed. The crop safety of applying Mepiquat 3.8% SL at a recommended dose rate in winter oilseed rape, winter barley, winter wheat and spring barley was evaluated in 19 efficacy trials (9 N-E, 10 MAR) and 34 selectivity trials (16 N-E, 18 MAR). In the efficacy trials, Mepiquat 3.8% SL was applied at 0.75 L/ha. Of these, 8 studies performed on winter oilseed rape in the Maritime zone determined both efficacy and selectivity assessment.

The trials were conducted in Poland (25), Germany (14) and Czech republic (14), in winter oilseed rape, winter barley, winter wheat and spring barley in 2017 and 2021 to evaluate the crop safety of Mepiquat 3.8% SL. Of these, 8 studies performed on winter oilseed rape in the Maritime zone determined both efficacy and selectivity assessment.

#### 3.4.1.1 Winter wheat (TRZAW)

Crop phytotoxicity was evaluated in efficacy and selectivity trials where Mepiquat 3.8% SL was applied at single application when the crop was at growth stages ranging from BBCH 30 to BBCH 31, at the rate of 0.75 and 1.8 L/ha in winter wheat. The 0.75 and 1.8 L/ha dose rate corresponds to 100% and 240% 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, North-east EPPO zone

A total of 3 efficacy and 6 selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of Mepiquat 3.8% 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 3 efficacy and 6 selectivity trials treated with Mepiquat 3.8% 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, Maritime EPPO zone**

A total of 5 selectivity trials were conducted in the Maritime EPPO zone to assess the crop safety of Mepiquat 3.8% 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 5 selectivity trials treated with Mepiquat 3.8% SL in the Maritime EPPO zone.

#### **3.4.1.2 Spring barley (HORVS)**

Crop phytotoxicity was evaluated in efficacy and selectivity trials where Mepiquat 3.8% SL was applied at single application when the crop was at growth stages ranging from BBCH 31 to BBCH 39, at the rate of 0.75-1.8 L/ha in spring barley. The 0.75 and 1.8 L/ha dose rate corresponds to 100% and 240% 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 spring barley trials, North-east EPPO zone**

A total of 6 efficacy and 4 selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of Mepiquat 3.8% SL when applied as recommended in spring barley. 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 and 4 selectivity trials treated with Mepiquat 3.8% 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 spring barley trials, Maritime EPPO zone**

A total of 8 selectivity trials were conducted in the Maritime EPPO zone to assess the crop safety of Mepiquat 3.8% SL when applied as recommended in spring barley. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the 8 selectivity trials treated with Mepiquat 3.8% SL in the Maritime EPPO zone.

#### **3.4.1.3 Winter barley**

Crop phytotoxicity was evaluated in efficacy and selectivity trials where Mepiquat 3.8% SL was applied at single application when the crop was at growth stages ranging from BBCH 31 to BBCH 39, at the rate of 0.75-1.8 L/ha in winter barley. The 0.75-1.8 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 barley trials, North-east EPPO zone**

A total of 2 selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of Mepiquat 3.8% SL when applied as recommended in winter barley. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the 2 selectivity trials treated with Mepiquat 3.8% SL in the North-east EPPO zone.

#### **Phytotoxicity in winter barley trials, Maritime EPPO zone**

A total of 2 efficacy and 5 selectivity trials were conducted in the Maritime EPPO zone to assess the crop safety of Mepiquat 3.8% SL when applied as recommended in winter barley. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the 2 efficacy and 5 selectivity trials treated with Mepiquat 3.8% SL in the Maritime EPPO zone.

#### **3.4.1.4 Winter oilseed rape**

Crop phytotoxicity was evaluated in efficacy and selectivity trials where Mepiquat 3.8% SL was applied at single application when the crop was at growth stages ranging from BBCH 31 to BBCH 39, at the rate of 0.75-1.8 L/ha in Winter oilseed rape. The 0.75-1.8 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 oilseed rape trials, North-east EPPO zone**

A total of 4 selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of Mepiquat 3.8% SL when applied as recommended in winter oilseed rape. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the 4 selectivity trials treated with Mepiquat 3.8% SL in the North-east EPPO zone.

#### **Phytotoxicity in winter oilseed rape trials, Maritime EPPO zone**

A total of 8 efficacy/selectivity trials were conducted in the Maritime EPPO zone to assess the crop safety of Mepiquat 3.8% SL when applied as recommended in winter oilseed rape. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the 8 efficacy/selectivity trials treated with Mepiquat 3.8% SL in the Maritime EPPO zone.

#### **3.4.1.5 Overall conclusion**

Winter oilseed rape, winter barley, winter wheat and spring barley is claimed on the label. The claims of crop safety on winter oilseed rape, winter barley, winter wheat and spring barley are supported with a total of 53 trials conducted in Poland, Germany and Czech Republic in 2017 and 2021. In all trials, Mepiquat 3.8% SL applied at the proposed label recommended rates in winter oilseed rape, winter barley, winter wheat and spring barley 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 oilseed rape, winter barley, winter wheat and spring barley show, the crop safety and efficacy of Mepiquat 3.8% 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 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, in winter wheat**

Number of trials with...		Efficacy trials (3 trials)		Selectivity trials (11 trials)	
		Test product	Standard	Test product	Standard
		0.75 L/ha	1N	1.8 L/ha	2N
Maximum of phytotoxicity recorded during the trials	0% to 5%	3	3	11	11
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	3	3	11	11
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0

**Table 3.4-5: Phytotoxicity of product, in spring barley**

Number of trials with...		Efficacy trials (6 trials)		Selectivity trials (12 trials)	
		Test product	Standard	Test product	Standard
		0.75 L/ha	1N	1.8 L/ha	2N
Maximum of phytotoxicity recorded during the trials	0% to 5%	6	6	12	12
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	6	6	12	12
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0

**Table 3.4-6: Phytotoxicity of product, in winter oilseed rape**

Number of trials with...		Efficacy/Selectivity trials (8 trials)		Selectivity trials (4 trials)	
		Test product	Standard	Test product	Standard
		0.75 L/ha	1.2N (1,5 L/ha)	1.8 L/ha	2N
Maximum of phytotoxicity recorded during the trials	0% to 5%	8	8	4	4
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	8	8	4	4
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0

**Table 3.4-7: Phytotoxicity of product, in winter barley**

Number of trials with...		Efficacy trials (2 trials)		Selectivity trials (7 trials)	
		Test product	Standard	Test product	Standard
		0.75 L/ha	1N	1.8 L/ha	2N
Maximum of phytotoxicity recorded during the trials	0% to 5%	2	2	7	7
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	2	2	7	7
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0

Comments of zRMS:	<p><b>Assessment for Poland:</b> 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 spring barley (6 phytotoxicity trials were presented from efficacy trials and 12 selectivity trials: PL-4, DE-4, CZ-4), winter wheat (3 phytotoxicity trials were presented from efficacy trials and 11 selectivity trials: PL-6, DE-3, CZ-2), winter barley (2 phytotoxicity trials were presented from efficacy trials and 7 selectivity trials: PL-2, DE-1, CZ-4) and winter oilseed rape (8 phytotoxicity trials were presented from efficacy/selectivity trials in Maritime zone and 4 selectivity trials: PL-4). On the basis on presented results it can be concluded that tested product is safe for spring barley, winter barley, winter wheat and winter oilseed rape. No negative effects are expected at recommended dose (0,75 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. However, Applicant submitted 34 additional selectivity trials in which the double dose was studied. In all trials, no negative effect was observed. For winter oilseed rape Applicant also submitted eff./sel. trials carried out in Maritime EPPO zone (8 trials). In those trials, also dose 2 N was studied.</p> <p><del>For winter wheat – not sufficient documentation was presented (only 3 trials are not accepted). As winter wheat is a major crop in Poland, at least 4-5 phytotoxicity trials should be presented. Lack of trials for winter barley and winter oilseed rape (at least 4-5 are required).</del></p> <p><b>Assessment for cMS:</b> <del>in the opinion of Evaluator, trials from only one EPPO zone are not representative for other EPPO zones. However, final decision about possibility of taking results from N-E EPPO zone is left to each cMS. Applicant submitted additional selectivity trials carried out in the Maritime EPPO zone on winter wheat (5 trials: DE-3, CZ-2), spring barley (8 trials: DE-4, CZ-4), winter barley (5 trials: DE-1, CZ-4) and winter oilseed rape (8 trials in DE and CZ –</del></p>
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	those trials were the same as efficacy, but during them Applicant studied effect of N and 2 N dose on efficacy, phytotoxicity effect, yield and its quality). Only 6 from 8 trials carried out on winter oilseed rape were harvested. So only 6 trials were presented for effects on yield and its quality in Maritime zone. Lack of trials from Maritime EPPO zone for winter oilseed rape. However, in 8 efficacy trials carried out in DE (4 trials) and CZ (4 trials) the phytotoxicity effect of recommended dose (0,75 L/ha) was studied. No negative effects were observed during trials.
	No trials for MED and S-E EPPO zone were presented. In the opinion of Evaluator, registration of product in MED and S-E without any trials (eff. and sel.) is not possible. However, final decision is left to cMS.

### 3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

53 efficacy and selectivity trials were conducted to obtain selectivity results with the same formulation currently under registration, Mepiquat 3.8% SL, in the North-east EPPO zone (25; i.e. Poland) and Maritime EPPO zone (28; i.e. Germany (11) and Czech Republic (17)) to evaluate the effect of Mepiquat 3.8% SL on the quality of the harvested crop of winter barley (HORVW), winter oilseed rape (BRNSW) winter wheat (TRZAW) and spring barley (HORVS).

#### 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 Mepiquat 3.8% SL in winter wheat and spring barley. Mepiquat 3.8% SL is recommended applied in winter wheat and spring barley at 0.75 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 selectivity trials and 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 3.4-8 for trials conducted in winter wheat.

##### North-east

A total of 3 efficacy and 8 selectivity trials in winter wheat were harvested. The trials were conducted in Poland (11) in 2017 and 2021. In the efficacy and selectivity trials, Mepiquat 3.8% SL was applied at 0.5, 0.75 and 1.8 L/ha. The trials were sprayed at crop growth stages ranging between BBCH 30 and BBCH 31. In Błąd! Nie można odnaleźć źródła odwołania. and Błąd! Nie można odnaleźć źródła odwołania. the results obtained in the efficacy trials when treated with 0.5, 0.75 and 1.8 L/ha are presented.

**Table 3.4-8: North-east zone – Crop yield (t/ha or T-MET) of winter wheat treated with Mepiquat 3.8% SL, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated	Mepiquat 3.8% SL		Ref. prod. at:
		Mean (min-max)	% relative, compared to untreated (min-max)		
		t/ha	0.50 L/ha	0.75 L/ha	1N
<b>Winter wheat – Efficacy trials, all reference products</b>					
North-east EPPO zone	3	7.29 (5.97-8.25)	108 (106-109)	114 (110-118)	113 (110-116)

**Table 3.4-9: North-east zone – Crop yield (t/ha or T-MET) of winter wheat treated with Mepiquat 3.8% SL, as % of untreated (Untreated = 100%)**

No.	Untreated	Mepiquat 3.8% SL	Ref. prod. at:
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Crop, trial type	of trials	Mean (min-max)	% relative, compared to untreated (min-max)			
		t/ha	0.75 L/ha	1.8 L/ha	1N	2 N
Winter wheat – Selectivity trials, all reference products						
North-east Eppo zone	8	7.6 (5.8-8.57)	98.2 (87.2-103.7)	100.7 (98.8-102)	105.2 (96.2-119.7)	101.6 (93.1-112.8)

### Maritime zone

A total of 5 selectivity trials in winter wheat were harvested. The trials were conducted in Germany (3) and Czech Republic in 2021. In the selectivity trials, Mepiquat 3.8% SL was applied at 0.75 and 1.8 L/ha. The trials were sprayed at crop growth stages ranging between BBCH 30 and BBCH 31. In Błąd! Nie można odnaleźć źródła odwołania., the results obtained in the efficacy trials when treated with 0.75 and 1.8 L/ha are presented.

**Table 3.4-10: Maritime zone – Crop yield (t/ha or T-MET) of winter wheat treated with Mepiquat 3.8% SL, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated	Mepiquat 3.8% SL		Ref. prod. at:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		t/ha	0.75 L/ha	1.8 L/ha	1N	2 N
Winter wheat – Selectivity trials, all reference products						
Maritime EPPO zone	5	10.2 (6.8-14.6)	99.0 (94.6-101.4)	99.1 (97.6-100.3)	96.3 (83.4-102.2)	93.5 (86.9-100.3)

Neither Mepiquat 3.8% SL nor the national reference standard significantly affected the yield when applied at the proposed dose rate (0.75 L/ha) or 2N rate in either of the 16 trials. Rather, overall Mepiquat 3.8% SL provided an increase in the yield mass of the treated crop which is most likely as a consequence of the control in the efficacy and selectivity trials as presented in Section 6.2.2. The results obtained in the trials supports the label claim that Mepiquat 3.8% SL is safe to be applied at the recommended dose rate to winter wheat at the recommended number of applications.

### 3.4.2.3 Summary and evaluation of the field trials conducted in spring barley

A summary of the mean yield assessments, expressed as %-relative of the untreated, are presented in Błąd! Nie można odnaleźć źródła odwołania. for trials conducted in spring barley.

#### North-east

A total of 6 efficacy and 4 selectivity trials in spring barley were harvested. The trials were conducted in Poland (10) in 2017 and 2021. In the efficacy and selectivity trials, Mepiquat 3.8% SL was applied at 0.5, 0.75 and 1.8 L/ha. The trials were sprayed at crop growth stages ranging between BBCH 31 and BBCH 39. In

Table 3.4-11 and

Table 3.4-11 the results obtained in the efficacy and selectivity trials when treated with 0.5, 0.75 and 1.8 L/ha are presented.

**Table 3.4-11: North-east zone – Crop yield (t/ha or T-MET) of spring barley treated with Mepiquat 3.8% SL, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated	Mepiquat 3.8% SL		Ref. prod. at:
		Mean (min-max)	% relative, compared to untreated (min-max)		
		t/ha	0.50 L/ha	0.75 L/ha	1N
Spring barley – Efficacy trials, all reference products					
North-east EPPO zone	6	5.62 (3.38-6.86)	99.4 (90.1-113)	96.9 (86.9-107)	98.4 (91.4-108)

**Table 3.4-12: North-east zone – Crop yield (t/ha or T-MET) of spring barley treated with Mepiquat 3.8% SL, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated	Mepiquat 3.8% SL		Ref. prod. at:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		t/ha	0.75 L/ha	1.8 L/ha	1 N	2 N
Spring barley – Selectivity trials, all reference products						
North-east EPPO zone	4	4.9 (3.73-6.74)	102.1 (100-104.2)	102.1 (95.71-107.4)	101.6 (91.7-108)	98.9 (88.2-105.6)

### Maritime zone

A total of 8 selectivity trials in spring barley were harvested. The trials were conducted in Germany (4) and Czech Republic (4) in 2021 and 2021. In the selectivity trials, Mepiquat 3.8% SL was applied at 0.75 and 1.8 L/ha. The trials were sprayed at crop growth stages ranging between BBCH 31 and BBCH 39. In

Table 3.4-11 the results obtained in the efficacy and selectivity trials when treated with 0.75 and 1.8 L/ha are presented.

**Table 3.4-13: Maritime zone – Crop yield (t/ha or T-MET) of spring barley treated with Mepiquat 3.8% SL, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated	Mepiquat 3.8% SL		Ref. prod. at:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		t/ha	0.75 L/ha	1.8 L/ha	1 N	2 N
		Spring barley – Selectivity trials, all reference products				
Maritime EPPO zone	8	8.4 (5.73-15.39)	100.3 (98.1-101.4)	99.8 (93.8-106.1)	98.3 (86.1-107.9)	99.6 (87.1-108.8)

Neither Mepiquat 3.8% SL nor the national reference standard significantly affected the yield when applied at the proposed dose rate (0.75 L/ha) or the 2N rate in either of the 18 trials. Rather, overall Mepiquat 3.8% SL provided an increase in the yield mass of the treated crop which is most likely as a consequence of the control in the efficacy trials as presented in Section 6.2.2. The results obtained in the trials supports the label claim that Mepiquat 3.8% SL is safe to be applied at the recommended dose rate to spring barley at the recommended number of applications.

### 3.4.2.4 Summary and evaluation of the field trials conducted in winter barley

A summary of the mean yield assessments, expressed as %-relative of the untreated, are presented in

Table 3.4-11 and

Table 3.4-11. The summary table is based on yield data presented in Błąd! Nie można odnaleźć źródła odwołania. for results obtained in winter barley trials harvested in the North-east and Maritime EPPO zone.

### North-east zone

A total of 2 selectivity trials in winter barley were harvested. The trials were conducted in Poland (2) in 2021. In the efficacy and selectivity trials, Mepiquat 3.8% SL was applied at 0.75 and 1.8 L/ha. The trials were sprayed at crop growth stages ranging between BBCH 31 and BBCH 39. In

Table 3.4-11 the results obtained in the selectivity trials when treated with 0.75 and 1.8 L/ha are presented.

**Table 3.4-14: North-east zone – Crop yield (t/ha or T-MET) of winter barley treated with Mepiquat 3.8% SL, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated	Mepiquat 3.8% SL		Ref. prod. at:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		t/ha	0.75 L/ha	1.8 L/ha	1N	2 N
		Winter barley – Selectivity trials, all reference products				
North-east EPPO zone	2	10.4 (10.28-10.5)	100.2 (99.3-101)	99.9 (97.6-102.2)	96.3 (92.9-99.6)	87.8 (84.3-91.3)

#### Maritime zone

A total of 7 selectivity trials in winter barley were harvested. The trials were conducted in Germany (3) and Czech Republic (4) in 2021. In the selectivity trials, Mepiquat 3.8% SL was applied at 0.75 and 1.8 L/ha. The trials were sprayed at crop growth stages ranging between BBCH 31 and BBCH 39. In

Table 3.4-11 the results obtained in the selectivity trials when treated with 0.75 and 1.8 L/ha are presented.

**Table 3.4-15: Maritime zone – Crop yield (t/ha or T-MET) of winter barley treated with Mepiquat 3.8% SL, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated	Mepiquat 3.8% SL		Ref. prod. at:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		t/ha	0.75 L/ha	1.8 L/ha	1N	2 N
Winter barley – Selectivity trials, all reference products						
Maritime EPPO zone	7	10.8 (5.7-15.8)	101 (97.7-104.6)	100.5 (96.7-104.9)	100.1 (96.6-106.1)	100.4 (98-108.7)

Neither Mepiquat 3.8% SL nor the national reference standard significantly affected the yield when applied at the proposed dose rate (0.75 L/ha) or the 2N rate in either of the 9 trials. Rather, overall Mepiquat 3.8% SL provided an increase in the yield mass of the treated crop which is most likely as a consequence of the control in the efficacy trials as presented in Section 6.2.2. The results obtained in the trials supports the label claim that Mepiquat 3.8% SL is safe to be applied at the recommended dose rate to winter barley at the recommended number of applications.

### 3.4.2.5 Summary and evaluation of the field trials conducted in winter oilseed rape

A summary of the mean yield assessments, expressed as %-relative of the untreated, are presented in

Table 3.4-11 and

Table 3.4-11. The summary table is based on yield data presented in **Błąd! Nie można odnaleźć źródła odwołania.** for results obtained in winter oilseed rape trials harvested in the North-east and Maritime EPPO zone.

#### North-east zone

A total of 4 selectivity trials in winter oilseed rape were harvested. The trials were conducted in Poland (4) in 2021. In the selectivity trials, Mepiquat 3.8% SL was applied at 0.75 and 1.8 L/ha. The trials were sprayed at crop growth stages ranging between BBCH 31 and BBCH 39. In

Table 3.4-11 the results obtained in the selectivity trials when treated with 0.75 and 1.8 L/ha are presented.

**Table 3.4-16: North-east zone – Crop yield (t/ha or T-MET) of winter oilseed rape treated with Mepiquat 3.8% SL, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated	Mepiquat 3.8% SL		Ref. prod. at:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		t/ha	0.75 L/ha	1.8 L/ha	1N	2 N
		Winter oilseed rape – Selectivity trials, all reference products				
North-east EPPO zone	4	4.5 (3.65-5.26)	101.4 (98.4-104.4)	99.9 (96.0-1007.4)	101.2 (96.9-108.2)	98.2 (95.2-102.5)

#### Maritime zone

A total of 6 efficacy/selectivity trials in winter oilseed rape were harvested. The trials were conducted in Germany (3) and Czech Republic (3) in 2021. In the selectivity trials, Mepiquat 3.8% SL was applied at 0.75 and 1.8 L/ha. The trials were sprayed at crop growth stages ranging between BBCH 31 and BBCH 39. In

Table 3.4-11 the results obtained in the selectivity trials when treated with 0.75 and 1.8 L/ha are presented.

**Table 3.4-17: Maritime zone – Crop yield (t/ha or T-MET) of winter oilseed rape treated with Mepiquat 3.8% SL, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated	Mepiquat 3.8% SL		Ref. prod. at:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		t/ha	0.75 L/ha	1.8 L/ha	1 N	2 N
Winter oilseed rape – Selectivity trials, all reference products						
Maritime EPPO zone	6	7.3 (4.2-10.7)	97.6 (90.6-100.5)	101 (97.3-112)	98.3 (91-103.1)	95.5 (85.1-100.3)

Neither Mepiquat 3.8% SL nor the national reference standard significantly affected the yield when applied at the proposed dose rate (0.75 L/ha) or the 2N rate in either of the 10 trials. Rather, overall Mepiquat 3.8% SL provided an increase in the yield mass of the treated crop which is most likely as a consequence of the control in the efficacy trials as presented in Section 6.2.2. The results obtained in the trials supports the label claim that Mepiquat 3.8% SL is safe to be applied at the recommended dose rate to winter oilseed rape at the recommended number of applications.

### 3.4.2.6 Conclusion

Mepiquat 3.8% SL applied at the proposed dose rate, at a range of growth stages within or occasionally beyond the label recommended range, winter oilseed rape, winter barley, winter wheat and spring barley did not affect crop yield significantly in any of the 53 trials harvested. In all efficacy trials as, Mepiquat 3.8% SL applied at recommended dose rates did not significantly affect the crop yield.

Furthermore, the data obtained in trials harvested demonstrate that Mepiquat 3.8% 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 oilseed rape, winter barley, winter wheat and spring barley where harvest data demonstrated the safe use following application of Mepiquat 3.8% SL as recommended. Furthermore, the data presented in this BAD also clearly demonstrates that the efficacy and crop safety of Mepiquat 3.8% 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 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.

### 3.4.2.7 Relationship between phytotoxicity and yield

No adverse effects were observed in any of the winter oilseed rape, winter barley, winter wheat and spring barley trials conducted. In the trials harvested, no significant reductions in crop yield were recorded in any of the plots treated with Mepiquat 3.8% SL at dose rates representative of the recommended dose rate.

Comments of zRMS:	<p><b>No negative impact on yield was recorded during trials.</b> Mepiquat 3.8% SL applied at the recommended dose did not significantly affect the yield. Applicant submitted in total 9 trials: 3 trials for winter wheat and 6 trials for spring barley. Lack of trials for winter barley and winter oilseed rape. trials for: spring barley (6 phytotoxicity trials were presented from efficacy trials and 12 selectivity trials: PL-4, DE-4, CZ-4), winter wheat (3 phytotoxicity trials were presented from efficacy trials and 11 selectivity trials: PL-6, DE-3, CZ-2), winter barley (2 phytotoxicity trials were presented from efficacy trials and 7 selectivity trials: PL-2, DE-1, CZ-4) and winter oilseed rape (8 phytotoxicity efficacy/selectivity trials were presented from efficacy trials and 4 selectivity trials: PL-4). For assessing negative effect on yield in winter oilseed rape was used 6 trials from Maritime (6 from 8 trials were harvested and 4 trials from N-E EPPO zone. In the opinion, of Evaluator only for spring barley and N-E EPPO zone submitted documentation is sufficient for N-E and MAR EPPO zone. In the opinion of Evaluator, trials from only one two EPPO zone (N-E and MAR) are not representative for other EPPO zones. However, final decision about possibility of taking results from N-E EPPO zone and MAR EPPO zone is left to each CMS from MED and S-E.</p>
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### 3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

53 efficacy and selectivity trials treated with Mepiquat 3.8% 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, hectoliter weight and thousand grain weight.

#### Winter wheat

The results obtained from assessments on the quality of the harvested winter wheat are presented in Tables Table 3.4-18.

**Table 3.4-18: North-east zone – Quality of harvested winter wheat – crop treated with Mepiquat 3.8% SL in efficacy trials, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated	Mepiquat 3.8% SL		Ref. prod. at:
		Mean (min-max)	% relative, compared to untreated (min-max)		
			0.50 L/ha	0.75 L/ha	1N
Winter wheat – Efficacy trials, all reference products					
Moisture (%)	3	13.8 (12.6-15.2)	96.9 (91.9-103)	101 (92.6-109)	101 (91.6-114)
TKW (g)	3	40.5 (39.8-41.1)	99.2 (97.0-102)	100 (97.8-102)	102 (98.8-105)
HLW (kg/ha)	3	73.9 (70.9-77.0)	100 (99.6-101)	102 (99.1-103)	101 (99.6-103)

**Table 3.4-19: North-east zone – Quality of harvested winter wheat – crop treated with Mepiquat 3.8% SL in selectivity trials, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated	Mepiquat 3.8% SL		Ref. prod. at:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		t/ha	0.75 L/ha	1.8 L/ha	1N	2 N
Winter wheat – Selectivity trials, all reference products						
Moisture (%)	3	12.6 (11.9-13.8)	98.1 (96.7-99.8)	96.6 (94.1-100)	96.3 (94.5-99.8)	95.3 (91.9-99.6)
TGW (g)	3	44.9 (43.4-45.9)	100.7 (99.7-101.3)	99.8 (99.2-100.4)	99.1 (98.0-99.8)	98.0 (96.7-99.6)
HLW (kg/ha)	3	65.8 (65.1-66.3)	100.2 (100-100.5)	100.9 (99.7-102.1)	100.6 (99.4-102.3)	100.1 (98.2-101.5)

**Table 3.4-20: Maritime zone – Quality of harvested winter wheat – crop treated with Mepiquat 3.8% SL in selectivity trials, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated	Mepiquat 3.8% SL		Ref. prod. at:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		t/ha	0.75 L/ha	1.8 L/ha	1N	2 N
Winter wheat – Selectivity trials, all reference products						
Moisture (%)	5	13.5 (12.96-14.3)	97.8 (93.6-100.8)	98.9 (94.8-100.8)	98.7 (93.8-100.8)	98.8 (96.0-100.8)
TGW (g)	5	42.4 (35.9-51.3)	99.6 (98.8-101.1)	98.7 (97.8-102)	97.4 (94.7-100)	94.4 (89.7-100)
HLW (kg/ha)	3	80.4 (69.1-96.7)	99.0 (98.4-99.8)	99.2 (98.1-99.9)	99.5 (99-99.8)	98.5 (97.8-98.9)

In the trials evaluated, Mepiquat 3.8% SL had no detrimental effect on the quality parameters assessed on the harvested winter wheat. When comparing the results obtained with Mepiquat 3.8% SL against the results obtained with the standard reference product at comparable dose rates, both products performed statistically similar on all quality parameters assessed.

### Spring barley

The results obtained from assessments on the quality of the harvested spring barley are presented in Tables.

**Table 3.4-21: North-east zone – Quality of harvested spring barley – crop treated with Mepiquat 3.8% SL in efficacy trials, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated	Mepiquat 3.8% SL		Ref. prod. at:
		Mean (min-max)	% relative, compared to untreated (min-max)		
			0.50 L/ha	0.75 L/ha	1N
Spring barley – Efficacy trials, all reference products					
Moisture (%)	6	14.3 (13.1-15.2)	99.2 (97.9-101)	99.8 (99.0-101)	100 (98.9-103)
TKW (g)	6	46.5 (41.8-52.5)	99.9 (96.8-103)	99.9 (93.0-104)	100 (94.8-104)
HLW (kg/ha)	6	62.9 (60.7-65.6)	100 (98.8-101)	101 (99.6-101)	99.7 (98.5-101)
Protein content (%)	6	12.4 (12.0-13.1)	98.9 (96.2-103)	102 (98.4-106)	98.6 (95.9-102)

**Table 3.4-22: North-east zone – Quality of harvested spring barley – crop treated with Mepiquat 3.8% SL in selectivity trials, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated	Mepiquat 3.8% SL		Ref. prod. at:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		t/ha	0.75 L/ha	1.8 L/ha	1N	2 N
Spring barley – Selectivity trials, all reference products						
Moisture (%)	2	13.8 (13.3-14.3)	94.7 (92.3-97.0)	94.7 (90.9-98.5)	94.0 (90.2-97.7)	94.6 (93.7-95.5)
TGW (g)	4	41.5 (37.4-44.8)	100.6 (98.1-102.5)	100.7 (96.3-103.5)	101.9 (98.8-107.2)	100.6 (98.1-104.2)

Crop, trial type	No. of trials	Untreated	Mepiquat 3.8% SL		Ref. prod. at:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		t/ha	0.75 L/ha	1.8 L/ha	1N	2 N
HLW (kg/ha)	4	62.1 (49.7-73.6)	99.3 (98.3-101.9)	99.5 (97.4-101.6)	99.8 (98.6-101.6)	99.3 (97.2-102.6)

**Table 3.4-23: Maritime zone – Quality of harvested spring barley – crop treated with Mepiquat 3.8% SL in selectivity trials, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated	Mepiquat 3.8% SL		Ref. prod. at:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		t/ha	0.75 L/ha	1.8 L/ha	1N	2 N
Spring barley – Selectivity trials, all reference products						
Moisture (%)	8	13.4 (10-16.1)	99.7 (97.7-101.8)	100.1 (98.3-102.8)	99.7 (94.0-104.9)	98.6 (92.9-100.9)
TGW (g)	8	44.4 (38.7-56.3)	100.1 (97.5-104.2)	100.6 (97.7-106.3)	100.5 (96.4-108.2)	100.6 (95.7-109.4)
HLW (kg/ha)	6	68.3 (56.4-79.6)	100.2 (99.1-101.3)	99.5 (97.1-102.2)	98.4 (94.6-100.5)	98.1 (94.2-99.7)

### Winter barley

**Table 3.4-24: North-east zone – Quality of harvested winter barley – crop treated with Mepiquat 3.8% SL in selectivity trials, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated	Mepiquat 3.8% SL		Ref. prod. at:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		t/ha	0.75 L/ha	1.8 L/ha	1N	2 N
Winter barley – Selectivity trials, all reference products						
TGW (g)	2	39.6 (39.3-39.8)	100 (99.8-100.1)	100.1 (99.7-100.4)	99.6 (99-100.2)	96.3 (91.9-100.6)
HLW (kg/ha)	2	45.5 (44.9-46)	99.7 (99.1-100.2)	97.7 (96.3-99.1)	99.1 (98.9-99.3)	96.3 (92.8-99.8)

**Table 3.4-25: Maritime zone – Quality of harvested winter barley – crop treated with Mepiquat 3.8% SL in selectivity trials, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated	Mepiquat 3.8% SL		Ref. prod. at:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		t/ha	0.75 L/ha	1.8 L/ha	1N	2 N
Winter barley – Selectivity trials, all reference products						
Moisture (%)	7	13.4 (11.5-15.2)	100.7 (98.5-105.5)	97.6 (78.2-109.2)	96.5 (78.0-105.1)	96.3 (76.7-102.7)
TGW (g)	7	45.0 (38.6-48.8)	100.9 (98.5-101.9)	101.4 (98.4-106.5)	100 (95.1-105.3)	100.3 (94.1-106)
HLW (kg/ha)	4	60.9 (48.9-72.9)	99.3 (96.8-100.8)	100.2 (99.2-101)	98.3 (95.5-101.2)	97.0 (93.2-100.4)

### Winter oilseed rape

In the trials evaluated, Mepiquat 3.8% SL had no detrimental effect on the quality parameters assessed on the harvested winter oilseed rape. When comparing the results obtained with Mepiquat 3.8% SL against the results obtained with the formulated reference product at comparable dose rates, both products performed statistically similar on all quality parameters assessed.

**Table 3.4-26: North-east zone – Quality of harvested winter oilseed rape – crop treated with Mepiquat 3.8% SL in selectivity trials, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated	Mepiquat 3.8% SL		Ref. prod. at:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		t/ha	0.75 L/ha	1.8 L/ha	1N	2 N
Winter oilseed rape – Selectivity trials, all reference products						
Moisture (%)	1	11.6	92.2	91.4	90.5	94.0
TGW (g)	4	4.5 (4.04-4.9)	100.3 (99.6-100.7)	101.1 (98-104.1)	101.3 (99-106.1)	100.7 (99.3-106.1)
HLW (kg/ha)	4	44.1 (35.1-68)	100.3 (101.6-101.6)	99 (97.5-100.5)	100.4 (99.2-101.3)	100.3 (98-103.1)
Oilcon	1	44	94.3	98.2	94.1	98.4

**Table 3.4-27: Maritime zone – Quality of harvested winter oilseed rape – crop treated with Mepiquat 3.8% SL in selectivity trials, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated	Mepiquat 3.8% SL		Ref. prod. at:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		t/ha	0.75 L/ha	1.8 L/ha	1 N	2 N
<b>Winter oilseed rape – Selectivity trials, all reference products</b>						
Moisture (%)	6	8.4 (5.7-10.3)	102.5 (96.8-111.7)	100.7 (97-103.2)	103.3 (98-115.8)	101.1 (98-103.4)
TGW (g)	2	5.6 (5.6-5.7)	100.5 (96.7-104.3)	100.9 (97.9-103.8)	94.4 (93.8-95)	97.7 (90.7-104.6)
Oilcon	6	43.7 (39-47.1)	100.6 (99.3-101.8)	99.2 (95.1-100.5)	98.9 (94.1-101.8)	99.2 (95.1-100.5)

### Conclusion

Mepiquat 3.8% SL applied at the proposed dose rate, at a range of growth stages within the label recommended rate, in winter oilseed rape, winter barley, winter wheat and spring barley did not significantly affect the quality of the harvested crop in any of the 53 trials harvested. In all efficacy trials as, Mepiquat 3.8% 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 Mepiquat 3.8% SL is as safe to the crop as the reference products used in the trials.

As this BAD clearly demonstrates, the efficacy and crop safety of Mepiquat 3.8% 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 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 9 53 trials: 3 16 trials (N-E-11 trials, MAR-5 trials) for winter wheat (moisture, TKW and HLW was studied) and 6 18 trials (N-E- 10 trials, MAR-8 trials) for spring barley (moisture, TKW, HLW, protein content), 9 trials (N-E-2 trials, MAR: 7 trials) for winter barley (TGW, HLW, moisture) and 10 trials (N-E-4 trials, MAR-6 trials) for winter oilseed rape (moisture, TGW, HLW, oilcon). Lack of trials for winter barley and winter oilseed rape. In the opinion, of Evaluator only for spring barley, winter barley, winter wheat and winter oilseed rape from N-E EPPO and Maritime EPPO zone one submitted documentation is sufficient. In the opinion of Evaluator, trials from only one N-E and Maritime EPPO zone (N-E) are not representative for other EPPO zones (MED, S-E). However, final decision about possibility of taking results from N-E EPPO zone and Maritime EPPO zone is left to each CMS from MED and S-E.
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### 3.4.4 Effects on transformation processes (KCP 6.4.4)

Mepiquat 3.8% SL is composed of mepiquat which has been widely used for several years on a range of crops without identifying any quality problems on the treated crops. Effects on the processing procedure. In order to consider the potential effects of mepiquat chloride on the transformation processes associated with bread-making and brewing, reference is made to the British Beer and Pub Association (BBPA) and Brewing Research International (BRI) list of approved agrochemicals, based on testing.

Mepiquat 3.8% SL is recommended applied on cereal crops from emergence and up to BBCH 39, i.e. post-emergence, but before inflorescence emergence and heading. Therefore, it is not expected that the active ingredient is transferred to the grains, therefore according to EPPO standard PP 1/243(1) (*Effects of plant protection products on transformation processes*) no studies are necessary in this section.

Plant growth regulators 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*).

In addition, it should be noted that currently, mepiquat containing products do not have any label restrictions concerning their use on crops destined for processing. Additionally, the active is part of many products which have been used for a long time. Since the market introduction, no effects on transformation processes have been recorded for any of these products.

Finally applicant would like to refer and present data from dRR part B7 Metabolism and Residues where is presented European data from RAR and EFSA to demonstrate the result of a study carried out by the UK in March 2005 and January 2008 to use of Mepiquat 3.8% SL on cereals.

The study was conducted prior to implementation of GLP. Guidelines followed were not specified by the applicant. The study is, however, considered to fulfill the requirements of EC guideline 7028/VI/95 rev.3

### Materials and Methods;

The metabolism in barley was studied in glass house using ring-labelled parent compound at rate of 910g a.s./ha (1.2 N, growth stage not specified). Samples were taken at 16 and 37 days after treatment (forage), and at maturity (52 DAT, grain and straw). All samples were analysed by LSC following combustion. The samples were also extracted with acidified methanol. The ion exchange and LC purified extract were analysed by LSC, paper electrophoresis (PE) and TLC. The resulting unextractable solids were further extracted by HCl hydrolysis, and straw also with NaOH hydrolysis, before being analysed by LSC, PE and TLC. Samples were analysed in duplicates or triplicates. No storage time of the samples was indicated.

### Results;

In mature plant, most of the radioactive residue was located in straw. Acidified methanol extraction and subsequent acid hydrolysis were sufficient to recover parent mepiquat chloride representing 91% of TRR in forage, 80% in mature grain and 74% of TRR in mature straw (see **Table 3.4-28**). Strong HCl hydrolysis released further 4-8% of TRR in forage and straw and 29% (0.54 mg/kg) in grain.

**Table 3.4-28: Extractable and total radioactive residues and proportion of parent mepiquat chloride in barley forage, grain and straw.**

Plant part	TRR (mg/kg)*	MeOH-extractable residue*		Residue released by HCl hydrolysis*		Total extractable mepiquat chloride residue**		Non-extractable residue*	
		% of TRR	mg/kg	% of TRR	mg/kg	% of TRR	mg/kg	% of TRR	mg/kg
Forage 16 DAT	2.34	85.0	1.99	4.7	0.11	90.6	2.12	3.8	0.09
Forage 37 DAT	1.58	86.1	1.35	3.8	0.06	91.1	1.44	3.2	0.05
Grain 52 DAT	1.84	67.4	1.24	29.3	0.54	80.4	1.48	2.2	0.04
Straw 52 DAT	5.08	70.9	3.60	8.3	0.42	74.0	3.76	16.3	0.83

\* Total radioactive residue, expressed as mepiquat chloride equivalents

\*\* Residue identified as mepiquat chloride

Non-extractable residue in barley forage represented less than 4% of TRR (0.09 mg/kg), 0.04 mg/kg (3%) in grain and 0.83 mg/kg (16%) in straw. Further NaOH hydrolysis of the non-extractable residue of straw revealed that 1% of TRR was associated in raw cellulose, 1% in lignin precipitate and 15% in lignin filtrate, of which parent mepiquat chloride was identified in the last fraction. The non-extractable residue in straw was probably associated with the fragmentation of the ring and the natural incorporation of these fragments into the plant tissue.

Only residue in MeOH and HCl hydrolysis eluates with highest radioactivity were analysed for metabolites. Parent mepiquat chloride was the only residue identified in the analysed fractions of all samples. No N-methylpiperidine or piperidine, nor other metabolites, were identified, based on reference compound comparison.

Residues detected in non-analyzed fractions represented at maximum 2% (0.05 mg/kg) of TRR in the methanol extracts, and 5% (0.1 mg/kg) in acid hydrolyzates of straw and grain.



## Conclusions

All residues in barley forage and mature grain and straw were identified as parent mepiquat chloride. Residues were mostly located in straw of mature plant. Acidified methanol extraction coupled with hydrolysis treatments were sufficient to recover parent mepiquat chloride representing 80% of TRR in barley grain, 74% in barley straw, and 91% in barley forage. In grain 29% of TRR was released by strong acid hydrolysis, which indicates the presence of bound residues or conjugates. The study is considered acceptable.

Comments of zRMS:	Based on long term use of mepiquat 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)

Mepiquat 3.8% SL is composed of mepiquat, which has been widely used for several years on e.g. cereals, without identifying any issues in regards to the ability of treated plant part to be used for propagating purposes.

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.

Comments of zRMS:	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. 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
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### 3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

#### 3.5.1 Impact on succeeding crops (KCP 6.5.1)

The impact on succeeding crops is determined in accordance with guidance provided by EPPO standard PP 1/207(2) *'Effect on succeeding crops'*.

The EU requirements on plant protection products requires, that sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on succeeding crops if studies and evaluations presented in the other part of the dossier, show that significant residues of the active substance, its metabolites or degradation products, which have or may have biological activity on succeeding crops, remain in soil or in plant materials up to sowing or planting time of possible succeeding crops.

Therefore the Applicant presents the assessment of the possible effect of Mepiquat on crops grown as rotational or replacement crops following crops treated with that product, prepared in accordance to the EPPO Standard *Efficacy evaluation of plant protection products Effects on succeeding crops (PP 1/207 (2))*. This standard is intended as a general standard on the methods used to examine whether the active substance of a plant protection product can cause negative effects on crops grown after a crop treated with that product. These crops can be grown as normal rotational crops as well as replacement crops in case of crop failure.

A study of seedling emergence was carried out by Landesamt Fuer Umwelt, Wasserwirtschaft und Gewerbeaufsicht, Mainz, Germany in 2006, published in the RAR and titled "Effect of Pix 50 (BAS 083 34 W) on seedling emergence of terrestrial plants 2006/1018273 ", in which the following is detailed;

### Summary;

In a terrestrial plant study, the rate-related effects of BAS 083 34 W (aqueous solution containing 50 g/L mepiquat- chloride) on seedling emergence and phytotoxicity to six terrestrial non-target plant species following pre- emergence application were assessed.

Seeds of oilseed rape, pea, flax, carrot, onion and oat were planted in silty sand soil in pots and maintained in a greenhouse under controlled conditions. Each species was tested using 5 replicates (5 to 9 seed per pot, depending on plant species) per treatment level. BAS 083 34 W was applied (sprayed) to the soil surface of each pot one to two days after the seeds were sown at the following rates: 0 (control), 61, 155, 219, 416, 790 and 1500 mL product/ha. Assessments for seedling emergence and phytotoxicity were done at days 7, 14 and 21 ( $\pm$  1 day) for all plants. At test termination after the last assessment the plant fresh weight per replicate was determined.

Following pre-emergence application of BAS 083 34 W at a maximum rate of 1500 mL product/ha (75 g a.s./ha) no effects on seedling emergence were observed in any of the non-target terrestrial plant species tested. None of the plant species showed significant signs of phytotoxicity. Plants fresh weights at all test rates were comparable with the controls. Therefore the  $EC_{50}$  is greater than 1500 mL product/ha (75 g a.s./ha).

### Materials and methods;

Test material; BAS 08334 W (Pix 50)

Batch no: 4047

Active-substance: Mepiquat-chloride

Content: 50.2g/L analysed

Test species: Seeds of the following

Class	Family	Species	English Name	Variety
Dicotyledonae	Brassicaceae	Brassica napus	Oilseed rape	Jumbo
	Fabaceae	Pisum sativum	Pea	Lisa
	Linaceae	Linum usitatissimum	Flax	Bethume
	Apiaceae	Daucus carota	Carrot	Starca
Monocotyledonae	Poaceae	Avena sativa	Oats	Aragon
	Liliaceae	Allium cepa	Onion	Red Baron

### Study desing;

Seedling of oilseed rape, pea, flax, carrot, onion and oat were grown in silty sand soil in pots maintained in a greenhouse under controlled conditions. One to two days after the seeds were sown BAS 083 34 W (Pix 50) was applied on the soil surface of the pots, at the following application rates: 0 (deionised water control), 61, 155, 219, 416, 790, 1500 mL product/ha, chosen on the basis of a preliminary range-finder test. There were 5 replicate pots per treatment, each containing 5 to 9 seeds (exact number being species dependent).

Assesments for seedling emergence (number emerged) and phytotoxicity were carried out on 7, 14 and 21 days after application for all plants. Phytotoxicity was assessed on the basis of the % affected plannts per replciate compared to the control. One value for the sum of the parameters considered (e.g. chlorosis, necrosis, deformation and growth reduction) was obtained for each replicate pot. Ratings were based on a 0% -100% scale, with 0% = no damage on the plants in the pot and 100% = all plants in the pots died off.

At test termination after the last assessment the plants were cut directly above the ground and the plant fresh weight per replicate was determined (no later than 15 minutes after cutting).

Analysis of the active ingredient mepiquat-chloride (HPLC MS/MS method) was carried out in the control solution and at the highest application rate (1500 mL test item/400 L - used to prepare the subsequent lower rates by dilution).

## Statistics

Calculation of mean values; standard deviations; analysis of variance (ANOVA) followed by Dunnett's t-test ( $\alpha = 5\%$ ).

## Results and discussion

Analytical verification showed no active ingredient in the control and 121% of nominal concentration at the highest dose rate (1500 mL product/ha equivalent to 75 g a.s./ha).

No significant signs of phytotoxicity or effects on seedling emergence, and fresh weights were observed at any dose rate or time point for any of the plant species tested.

Recorded mean emergence rates in controls were 97% in oilseed rape, 96% in pea, 98% in flax, 82% in carrot, 87% in onion and 93% in oat, respectively; the seedling emergences at all treatment rates of BAS 083 34 W were comparable ( $\geq 78 - 100\%$ ) with the controls for each species tested (no statistically significant differences compared to the control, Dunnett's t-test,  $p > 0.05$ ).

No signs of phytotoxicity (0% visual effects) were observed in the controls or at any of the treatment rates tested throughout the test period. Recorded mean fresh weights in controls amounted to 10.15 g in oilseed rape, 16.27 g in pea, 2.79 g in flax, 0.70 g in carrot, 1.57 g in onion, and 12.29 g in oat; the fresh weights at all treatment rates of BAS 083 34 W were comparable with the controls for each species tested (no statistically significant differences compared to the control, Dunnett's t-test,  $p > 0.05$ ).

Based on the lack of phytotoxicity (0%) and adverse effects on seedling emergence and plant fresh weights the NOER (No Observed Effect Rate), ER<sub>25</sub> and ER<sub>50</sub> values were determined to be 1500 and  $> 1500$  mL product/ha respectively.

## Conclusion

Pre-emergence application of BAS 083 34 W at a maximum rate of 1500 mL/ha (75 g a.s./ha) to seeds of six terrestrial non-target plant species resulted in no treatment related effects (after 21-days) on seedling emergence, phytotoxicity or plant fresh weights.

### RMS comments and evaluation

The study has not been used before in the context of EU evaluation of mepiquat. The study was performed according to OECD 208 test guideline following GLP. No significant deviations from the test guideline are apparent. The quality criteria of the test guideline are fulfilled:

- seedling emergencies in controls were 82 – 98 % ( $> 70\%$ )
- control plants did not exhibit phytotoxic effects and their survival at test termination

was 100%

- environmental conditions and growing media were the same in controls as in treatments

Analytical verification showed that actual concentrations in the highest dose rate were 121% of nominal concentrations (1500 mL product/ha equivalent to 75 g a.s./ha)

The study and the resulting endpoints are considered valid. Based on no effects on seedling emergence, the lack of phytotoxicity and no adverse effects on plant fresh weights, the NOER (No observed effect rate) was determined to be 1500 mL BAS 083 34 W/ha, and the ER<sub>50</sub> values >1500mL BAS 083 34 W/ha (75 and >75g a.s./ha (nominal), 90 and >90g a.s./ha measured) respectively.

In addition, in the studies, the active substance was evaluated at 75g a.s./ha, which is higher than that required by the GAP.

Comments of zRMS:	<p>The Applicant presents the assessment of the possible effect of Mepiquat on crops grown as rotational or replacement crops following crops treated with that product, prepared in accordance with the EPPO Standard Efficacy evaluation of plant protection products Effects on succeeding crops (PP 1/207 (2)).</p> <p>Pre-emergence application of BAS 083 34 W at a maximum rate of 1500 mL/ha (75 g a.s./ha) to seeds of six terrestrial non-target plant species resulted in no treatment related effects (after 21-days) on seedling emergence, phytotoxicity or plant fresh weights.</p> <p>The submitted data and a review of available literature as well as the lack of phytotoxicity symptoms recorded during the field trials suggest that product application in accordance with label recommendation has no negative impact on succeeding crops.</p>
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### 3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

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 is not phytotoxic to the crop claimed in the GAP.

A study of vegetative vigour was carried out by Landesamt Fuer Umwelt, Wasserwirtschaft und Gewerbeaufsicht, Mainz, Germany in 2006, published in the RAR and titled "Effect of Pix 50 (BAS 083 34 W) on vegetative vigour of terrestrial plants 2006/1018269 ", in which the following is detailed.

#### Summary;

In a terrestrial plant study, the rate-related effects of BAS 083 34 W on the vegetative vigour and phytotoxicity of six terrestrial non-target plant species following post-emergence application was assessed. Seedlings of oilseed rape, pea, flax, carrot, onion and oats were grown in silty sand soil in pots maintained in a greenhouse under controlled conditions.

There were 6 replicate pots per treatment, with 3 to 5 plants per pot, BAS 083 34 W was applied as a foliar spray at the 2-4 leaf growth stage at the following application rates: 0, 61, 155, 219, 416, 790 and 1500 mL product/ha. Visual assessments for phytotoxicity were carried out on days 7, 14 and 21 using a 0-100% rating system (with 0% = no damage and 100% = all plants in the pots died). At test termination after the last assessment the plant fresh weight per replicate was determined.

Following post-emergence application of Pix 50 at a maximum rate of 1500mL product/ha (75g a.s./ha) none of the non-target terrestrial plant species tested showed significant signs of phytotoxicity and plant fresh weights at all test rates were comparable with the controls; therefore the EC<sub>50</sub> is greater than 1500mL product/ha (75g a.s./ha).

## Materials and methods;

Test material; BAS 08334 W (Pix 50)  
Batch no: 4047  
Active-substance: Mepiquat-chloride  
Content: 50.2g/L analysed  
Test species: Seeds of the following

Class	Family	Species	English Name	Variety
Dicotyledonae	Brassicaceae	Brassica napus	Oilseed rape	Jumbo
	Fabaceae	Pisum sativum	Pea	Lisa
	Linaceae	Linum usitatissimum	Flax	Bethume
	Apiaceae	Daucus carota	Carrot	Starca
Monocotyledonae	Poaceae	Avena sativa	Oats	Aragon
	Liliaceae	Allium cepa	Onion	Red Baron

## Study desing;

Seedling of oilseed rape, pea, flax, carrot, onion and oat were grown in silty and soil in pots maintained in a greenhouse under controlled conditions. Pots were treated with Pix 50 applied as a foliar spray at 2-4 leaf growth stage (BBCH-scale 12-14) at the following application rates: 0 (control), 61, 155, 219, 416, 790 and 1500mL product/ha.

There were 6 replicate pots per treatment each containing 3 to 5 plants (exactly number being species dependent).

Assessments for phytotoxicity were carried out on 7, 14 and 21 rating the effects in % affected plant per replicate compared to the control. One value for the sum of the parameters considered (e.g. chlorosis, necrosis, deformation and growth reduction) was obtained for each replicate pot. Ratings were based on a 0% -100% scale, with 0% = no damage on the plants in the pot and 100% = all plants in the pots died off.

At test termination after the last assessment the plants were cut directly above the ground and the plant fresh weight per replicate was determined (no later than 15 minutes after cutting).

Analysis of the active ingredient mepiquat-chloride (HPLC MS/MS method) was carried out in the control solution and at the highest application rate (1500 mL test item/400 L - used to prepare the subsequent lower rates by dilution).

## Statistics

Calculation of mean values; standard deviations; analysis of variance (ANOVA) followed by Dunnett's t-test ( $\alpha = 5\%$ ).

## Results and discussion

Analytical verification showed no active ingredient in the control and 122% of nominal concentration at the highest dose rate (1500mL product/ha equivalent to 75g a.s./ha).

No significant symptoms of phytotoxicity were observed in any of the terrestrial plant species tested at any dose rate. Some species appeared to be slightly affected, but average phytotoxicity scores at each test rate were always less than 10% compared to control, symptoms did not occur in every replicate and phytotoxic signs were not present at each time point. No visible phytotoxic or plant weight effects were observed in the controls. The next table (Table 3.5-1) summarises the phytotoxic response observed over the 21 days test period including.

**Table 3.5-1: Phytotoxic effects of BAS 083 34 W**

Terrestrial plant species	Symptoms	Time point (days)	Dose rate (ml/ha) / % effect rating
<b>Oilseed rape</b> <i>Brassica napus</i>	None	7	0
		14	0
		21	0
<b>Pes</b> <i>Pisum sativum</i>	Chlorosis	7	155 /2+-4.1; 790/4+-6.6; 1500/1+-2.0
	Chlorosis	14	155 /2+-4.1; 416 / 1+-2.0; 790/4+-6.6; 1500/1+-4.1
	None	21	0
<b>Flax</b> <i>Lilium usitatissimum</i>	Chlorosis	7	1500/1+-2.0
	None	14	0
	None	21	0
<b>Carrot</b> <i>Dacus carota</i>	None	7	0
	Chlorosis, necrosis, growth reduction	14	790/ 1+- 2.0; 1500/ 6+-6.6
	None	21	0
<b>Onion</b> <i>Allium cepa</i>	None	7	0
		14	0
		21	0
<b>Oat</b> <i>Avena Sativa</i>	None	7	0
		14	0
		21	0

At test termination no adverse affects on plant fresh weights were observed (see table 3.5-2); fresh weights at all the test rates of BAS 083 34 W were comparable with the controls, and no statistically significant differences were determined for any of the species tested.

**Table 3.5-2: Plant weight (g/replicate) at teste termination (day 21).**

Test rate (ml Product/ha)	oilseed rape	pea	flax	carrot	onion	oats
0	43.69	27,775	6,22	17,98	25,96	40,11
61	45,32	33,64	6,85	17,98	25,48	42,47
155	42,08	34,41	6,62	12,75	27,94	41,79
219	43,55	35,87	5,79	20,13	29,49	40,09
416	43,67	34,38	5,65	19,71	27,04	41,76
790	42,67	31,03	5,82	18,93	26,49	40,78
1500	40,52	30,08	5,35	17,3	27,64	40,99

Based on the lack of phytotoxicity (mean % rating for all plant species <10) and adverse effects on plant fresh weights the NOER (No observable Effect Rate). ER<sub>25</sub> and ER<sub>50</sub> values were determined to be 1500 and > 1500 mL product/ha respectively.

### Conclusion;

Post-emergence application of BAD 083 34 W at a maximum rate of 1500 mL/ha (75g a.s./ha) to 6 terrestrial non-target plant species resulted in no significant treatment related phytotoxicity or adverse affects on plant fresh weights.

### RMS comments and evaluations:

The study has not been used before in the context of EU evaluation of mepiquat. The study was performed according OECD 227 test guideline following GLP. No significant deviations from the test guideline are apparent.

The validity criteria of OECD 227 test guideline are fulfilled:

- seedling emergence was 75 – 97 % (> 70 %)
- control plants did not exhibit visible phytotoxic effects
- control plant survival at test termination was 100 % (> 90 %)
- environmental conditions and growing media were the same in controls as in treatments.

Analytical verification showed 122 % of nominal concentration at the highest dose rate (1500 mL product/ha equivalent to 75 g a.s./ha). The study and the resulting endpoints are considered valid. Based on the lack of phytotoxicity and adverse effects on plant fresh weights the NOER (No Observed Effect Rate) and ER50 values were determined to be 1500 and >1500 mL BAS 083 34 W /ha respectively, equivalent to 75 and >75 g a.s/ha (nominal), 95 and > 95g a.s / ha (measured).

Comments of zRMS:	<p>The Applicant submitted the results from study of vegetative vigour, which was carried out by Landesamt fuer Umwelt, Wasserwirtschaft und Gewerbeaufsicht, Mainz, Germany in 2006, published in the RAR and titled "Effect of Pix 50 (BAS 083 34 W) on vegetative vigour of terrestrial plants 2006/1018269. Post-emergence application of BAD 083 34 W at a maximum rate of 1500 mL/ha (75g a.s./ha) to 6 terrestrial non-target plant species resulted in no significant treatment related phytotoxicity or adverse effects on plant fresh weights.</p> <p>No negative effects of applications of mepiquat 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 Mepisha (product code: SHA 8500 A) on plants, there is no risk for adjacent crop to become injured, even in case of improper applications.</p>
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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 Mepiquat 3.8% SL in 2017, no problems regarding adverse effects on beneficial organisms were reported.

Special tests to investigate this purpose are not required.

For more information, see the results of the standard ecotoxicological tests being presented in dRR Part B section 9.

Comments of zRMS:	zRMS refers to Ecotoxicology evaluation.
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**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:	Statement accepted.
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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:	zRMS refers to dRR Part B124.
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#### **3.6 Other/special studies**

No other studies were conducted.

Comments of zRMS:	Accepted.
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### 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			Year and trial type		
			2017	2021	
			Efficacy	Efficacy	Selectivity
Winter wheat					
Institute of soil science and plant cultivation	N-E	PL	3		
Hetterich Fieldwork	MAR	DE			3
National Research Institute	N-E	PL			3
Sharda Poland SP.	N-E	PL			3
ZS Domaninek	MAR	CZ			1
ZZS Rymarov	MAR	CZ			1
Spring barley					
SGS Polska Sp. Z o.o.	N-E	PL	6		
Hetterich Fieldwork	MAR	DE			4
National Research Institute	N-E	PL			2
State Research Institute	N-E	PL			2
ZS Domaninek	MAR	CZ			1
ZZS Kujavy	MAR	CZ			2
ZZS Rymarov	MAR	CZ			1
Winter barley					
Hetterich Fieldwork	MAR	DE		2	1
ZS Domaninek	MAR	CZ			2
ZZS Kujavy	MAR	CZ			1
ZZS Rymarov	MAR	CZ			1
National Research Institute	N-E	PL			2
Winter oilseed rape					
Hetterich Fieldwork	MAR	DE		4	
ZS Domaninek	MAR	CZ		2	
ZZS Kujavy	MAR	CZ		2	
National Research Institute	N-E	PL	3		
State Research Institute	N-E	PL	1		
Total			13	8	32

## 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	2021	Biological Assessment Dossier: Mepiquat 3.8% SL (38 g/L mepiquat SL) – EU Central zone Sharda Cropchem España -, - Unpublished	N	SHA