

**FINAL REGISTRATION REPORT**

**Part B**

**Section 3**

**Efficacy Data and Information**

**Concise summary**

Product code: **102000037599**

Product name(s): (Active substance(s)) **Prohexadione-Ca OD 75 (75 g/L)**

**Central Zone**

Zonal Rapporteur Member State: **Poland**

**CORE ASSESSMENT**

**(Authorisation)**

Applicant: **Bayer Crop Science Division**

**MS Finalisation date: 29/04/2022**



## Version history

<b>When</b>	<b>What</b>
April 2021	Original Bayer Crop Science Division submission
July 2021	Dossier sent for evaluation
January 2022	zRMS finalised evaluation
April 2022	Final version prepared by zRMS after Commenting period

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

This document is a summary of the data submitted to support the registration of the plant protection product prohexadione-calcium OD75 (75 g/L) which is proposed to be commonly named as PRL OD75 to ease the reading on this dossier. It refers to the Zonal BAD “Summary of the Efficacy Data and Information on the Plant Protection Product for prohexadione-calcium OD75.

Reference:	<b>KCP Section 6/01</b>
Title:	Biological assessment dossier - Efficacy data and information - Detailed summary - Prohexadione-calcium OD 75 (75 g/L) - Central zone - Zonal rapporteur member state: Poland - Core assessment (authorisation)
Report:	<a href="#">Pagani, V.; Peeters, D.; Bartlett, M.; Terhardt, J. T.; 2021; M-766607-01-1</a>
Authority registration No:	
Guideline(s):	--
Deviations:	--
GLP/GEP:	not applicable
Acceptability:	
Duplication (if vertebrate study):	

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

All other appendices are submitted together with the Biological Assessment Dossier and its respective studies or study compilations.

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

Evaluator comment: The text highlighted in grey was provided by the evaluator, The process chosen by the zRMS to transform the dRR into a RR involves creating commenting boxes.

Comments of zRMS:	The commenting boxes are filled-in by the zRMS. They are usually placed at the end of each chapter. Commenting boxes should be understandable alone and refer very precisely to the text commented. The main advantage of their use is to distinguish easily between the applicant and the zRMS text.
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#### 3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

##### Abstract

The presented document is prepared in accordance with Regulation (EC) No1107/2009, article 33 and concern of **plant growth regulator, code 102000037599, product names PRL OD75, Hingios OD75, chemical active substance: Prohexadione-calcium 75 g/L,(7,28%)**. The PRL OD75, Hingios OD75 was tested in one application, in dose 1,2 L/ha applied in winter oilseed rape at BBCH 12-18 growth stage in order to reduce plant height and growth as well as improving wintering. This Report is based on proper documentation and contains comprehensive description of tested product.

**35 experiments were carried out in two growing seasons 2019/2020 and 2020/2021** in the 3 different EPPO zones, in the North-East EPPO zone, (6 trials in Poland), Maritime, South-East. **23 experiments** were carried out in the North-eastern zone and in the neighboring countries of Poland. The number of

trials for tested plant growth regulator was consistent to required for registration in Poland. In addition, the applicant presented 12 supportive trials.

The tested plant growth regulator used in the growth stage of winter oilseed rape BBCH 12-18 at a dose of 1,2 l/ha resulted in an average shortening of stems by: mean 7,5cm which corresponds to mean of 74,5% reduction in relation UTC.(mean plant height 29-31,4 cm in UTC). Effectiveness of PRL OD75,Hingios OD75 is comparable to the effectiveness of the standards: mean 66,1 % and 76,9 % shortening relative to UTC. The obtained data indicate a good effect of the tested agent in shortening plants of winter oilseed rape. In experiments, a significant effect of the measure on the limitation of winter oilseed rape length was found.

The effectiveness of the measure applied can be summed up as not giving significant differences between the tested product PRL OD75, Hingios OD75 and two references product, and untreated in the number of plants that overwintering. Good wintering of plants was obtained in the conditions of poor winters in 2019/2020 and 2020/2021.

Data from the North-eastern zone and the neighboring countries of Poland is consistent and supports the effectiveness of the **PRL OD75, Hingios 75 OD** measure. This effectiveness is confirmed by the results of experiments with the other two EPPO zones, Maritime and South-Eastern. **The plant growth regulator PRL OD75, Hingios 75 OD** shows selectivity towards winter oilseed rape. Only temporary symptoms of discoloration were observed. No adverse plant symptoms or negative effects of the plant growth regulator on winter oilseed rape yield were observed. The data obtained in the experiments confirm these features.

**The results obtained in the experiments justify the needed for registration of the studied agent for shortening winter oilseed plant height and growth as well as improving wintering. The data provided in dRR confirm the above applications and authorize the registration of PRL OD75, Hingios OD75, chemical active substance: Prohexadione-calcium 75 g/L,(7,28%) in dose 1,2 L/ha in cultivation of winter oilseed rape in Poland. The measure is intended to be used once in the season, at BBCH 12-18 growth stage of WOSR. The RR is drafted correctly and contains appropriate and sufficient data on the performance of the product tested. These data provide the basis for registration of the studied agent in Poland. The presented results of plant growth regulator PRL OD75, Hingios 75 OD, chemical active substance: Prohexadione-calcium 75 g/L,(7,28%) in dose 1,2 L/ha in winter oilseed rape, applied at BBCH 12-18 growth stage in order to reduce plant height and growth as well as improving wintering**

**indicate compliance with the GAP table and with label of the measures tested and Uniform principles.**

**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
Use- No. (e)	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season  BBCH	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha*  min/ max		
<b>Zonal uses (field or outdoor uses, certain types of protected crops)</b>													
1	AUT	Rape, winter (BRSNW)	F	winter solidness, growth regulation of crop	spraying (broadcast, overall)	12-18	a) 1 b) 1	-	a) 1.2 b) 1.2	a) PRL 90 b) PRL 90	100-400 150-300	as per growth stage	PHI according to growth stage
2	AUT	Rape, winter (BRSNW)	F	resistance to lodging, growth regulation of crop	spraying (broadcast, overall)	30-59	a) 1 b) 1	-	a) 1.2 b) 1.2	a) PRL 90 b) PRL 90	100-400 150-300	as per growth stage	This spring use is not supported in the present application but indicated here to justify the worst case considered in some studies (i.e. autumn + spring application)
3	AUT	Rape, winter (BRSNW)	F	B1: winter solidness, growth regulation of crop B2: resistance to lodging, growth regulation of crop	spraying (broadcast, overall)	12-59  B1: 12-18 B2: 30-59	a) B1: 1 B2: 1 b) 2	B1: - B2: - 90 d after B1	a) B1: 1.2 B2: 1.2 b) 2.4	a) PRL 90 b) PRL 180	100-400 150-300	as per growth stage	This use is <b>not</b> supported in the present application but indicated here as information to justify the worst case considered in some studies.
4	CZE	Rape, winter (BRSNW)	F	winter solidness, growth regulation of crop	spraying (broadcast, overall)	12-18	a) 1 b) 1	-	a) 1.2 b) 1.2	a) PRL 90 b) PRL 90	100-400 150-300	as per growth stage	PHI according to growth stage

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. (e)	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season  BBCH	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha*  min/ max		
<b>Zonal uses (field or outdoor uses, certain types of protected crops)</b>													
5	CZE	Rape, winter (BRSNW)	F	resistance to lodging, growth regulation of crop	spraying (broadcast, overall)	30-59	a) 1 b) 1	-	a) 1.2 b) 1.2	a) PRL 90 b) PRL 90	400-400 150-300	as per growth stage	This spring use is not supported in the present application but indicated here to justify the worst case considered in some studies (i.e. autumn + spring application)
6	CZE	Rape, winter (BRSNW)	F	B1: winter solidness, growth regulation of crop B2: resistance to lodging, growth regulation of crop	spraying (broadcast, overall)	12-59  B1: 12-18 B2: 30-59	a) B1: 1 B2: 1 b) 2	B1: - B2: - 90 d after B1	a) B1: 1.2 B2: 1.2 b) 2.4	a) PRL 90 b) PRL 180	400-400 150-300	as per growth stage	This use is <b>not</b> supported in the present application but indicated here as information to justify the worst case considered in some studies.
7	DEU	Rape, winter (BRSNW)	F	winter solidness, growth regulation of crop	spraying (broadcast, overall)	12-18	a) 1 b) 1	-	a) 1.2 b) 1.2	a) PRL 90 b) PRL 90	400-400 150-300	as per growth stage	PHI according to growth stage
8	DEU	Rape, winter (BRSNW)	F	resistance to lodging, growth regulation of crop	spraying (broadcast, overall)	30-59	a) 1 b) 1	-	a) 1.2 b) 1.2	a) PRL 90 b) PRL 90	400-400 150-300	as per growth stage	This spring use is not supported in the present application but indicated here to justify the worst case considered in some studies (i.e. autumn + spring application)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. (e)	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fpn G, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season  BBCH	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha*  min/ max		
9	DEU	Rape, winter (BRSNW)	F	B1: winter solidness, growth regulation of crop B2: resistance to lodging, growth regulation of crop	spraying (broadcast, overall)	12-59  B1: 12-18 B2: 30-59	a) B1: 1 B2: 1 b) 2	B1: - B2: - 90 d after B1	a) B1: 1.2 B2: 1.2 b) 2.4	a) PRL 90 b) PRL 180	100-400 150-300	as per growth stage	This use is <b>not</b> supported in the present application but indicated here as information to justify the worst case considered in some studies.
10	HUN	Rape, winter (BRSNW)	F	winter solidness, growth regulation of crop	spraying (broadcast, overall)	12-18	a) 1 b) 1	-	a) 1.2 b) 1.2	a) PRL 90 b) PRL 90	100-400 150-300	as per growth stage	PHI according to growth stage
11	HUN	Rape, winter (BRSNW)	F	resistance to lodging, growth regulation of crop	spraying (broadcast, overall)	30-59	a) 1 b) 1	-	a) 1.2 b) 1.2	a) PRL 90 b) PRL 90	100-400 150-300	as per growth stage	This spring use is not supported in the present application but indicated here to justify the worst case considered in some studies (i.e. autumn + spring application)
12	HUN	Rape, winter (BRSNW)	F	B1: winter solidness, growth regulation of crop B2: resistance to lodging, growth regulation of crop	spraying (broadcast, overall)	12-59  B1: 12-18 B2: 30-59	a) B1: 1 B2: 1 b) 2	B1: - B2: - 90 d after B1	a) B1: 1.2 B2: 1.2 b) 2.4	a) PRL 90 b) PRL 180	100-400 150-300	as per growth stage	This use is <b>not</b> supported in the present application but indicated here as information to justify the worst case considered in some studies.
13	POL	Rape, winter (BRSNW)	F	winter solidness, growth regulation of crop	spraying (broadcast, overall)	12-18	a) 1 b) 1	-	a) 1.2 b) 1.2	a) PRL 90 b) PRL 90	100-400 150-300	as per growth stage	PHI according to growth stage A
14	POL	Rape, winter (BRSNW)	F	resistance to lodging, growth regulation of crop	spraying (broadcast, overall)	30-59	a) 1 b) 1	-	a) 1.2 b) 1.2	a) PRL 90 b) PRL 90	100-400 150-300	as per growth stage	This spring use is not supported in the present application but indicated here to justify the worst case

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. (e)	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season  BBCH	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha*  min/ max		
													considered in some studies (i.e. autumn + spring application)
15	POL	Rape, winter (BRSNW)	F	B1: winter solidness, growth regulation of crop B2: resistance to lodging, growth regulation of crop	spraying (broadcast, overall)	12-59  B1: 12-18 B2: 30-59	a) B1: 1 B2: 1 b) 2	B1: - B2: - 90 d after B1	a) B1: 1.2 B2: 1.2 b) 2.4	a) PRL 90 b) PRL 180	400-400 150-300	as per growth stage	This use is <b>not</b> supported in the present application but indicated here as information to justify the worst case considered in some studies.
16	ROU	Rape, winter (BRSNW)	F	winter solidness, growth regulation of crop	spraying (broadcast, overall)	12-18	a) 1 b) 1	-	a) 1.2 b) 1.2	a) PRL 90 b) PRL 90	400-400 150-300	as per growth stage	PHI according to growth stage
17	ROU	Rape, winter (BRSNW)	F	resistance to lodging, growth regulation of crop	spraying (broadcast, overall)	30-59	a) 1 b) 1	-	a) 1.2 b) 1.2	a) PRL 90 b) PRL 90	400-400 150-300	as per growth stage	This spring use is not supported in the present application but indicated here to justify the worst case considered in some studies (i.e. autumn + spring application)
18	ROU	Rape, winter (BRSNW)	F	B1: winter solidness, growth regulation of crop B2: resistance to lodging, growth regulation of crop	spraying (broadcast, overall)	12-59  B1: 12-18 B2: 30-59	a) B1: 1 B2: 1 b) 2	B1: - B2: - 90 d after B1	a) B1: 1.2 B2: 1.2 b) 2.4	a) PRL 90 b) PRL 180	400-400 150-300	as per growth stage	This use is <b>not</b> supported in the present application but indicated here as information to justify the worst case considered in some studies.

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. (e)	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season  BBCH	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha*  min/ max		
19	SVK	Rape, winter (BRSNW)	F	winter solidness, growth regulation of crop	spraying (broadcast, overall)	12-18	a) 1 b) 1	-	a) 1.2 b) 1.2	a) PRL 90 b) PRL 90	100-400 150-300	as per growth stage	PHI according to growth stage
20	SVK	Rape, winter (BRSNW)	F	resistance to lodging, growth regulation of crop	spraying (broadcast, overall)	30-59	a) 1 b) 1	-	a) 1.2 b) 1.2	a) PRL 90 b) PRL 90	100-400 150-300	as per growth stage	This spring use is not supported in the present application but indicated here to justify the worst case considered in some studies (i.e. autumn + spring application)
21	SVK	Rape, winter (BRSNW)	F	B1: winter solidness, growth regulation of crop B2: resistance to lodging, growth regulation of crop	spraying (broadcast, overall)	12-59  B1: 12-18 B2: 30-59	a) B1: 1 B2: 1 b) 2	B1: - B2: - 90 d after B1	a) B1: 1.2 B2: 1.2 b) 2.4	a) PRL 90 b) PRL 180	100-400 150-300	as per growth stage	This use is <b>not</b> supported in the present application but indicated here as information to justify the worst case considered in some studies.

PRL: Prohexadione-Calcium

\* 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

**Comment on GAP:**

The recommended amount of water for used with Hingios OD75 has been changed in the GAP table and label in accordance with the amount used in the experiments.

## 3.2 Efficacy data (KCP 6)

### Introduction

The plant protection product PRL OD75 which contains the active substance prohexadione-calcium is submitted for authorization as a new product in EU regulatory Central Zone on winter oilseed rape. It is submitted to be evaluated by Poland as zRMS. Authorisation of this product is claimed in EU member states belonging to the Maritime EPPO zone (Austria, the Czech Republic and Germany), to the North-East EPPO zone (Poland) and to the South-East EPPO zone (Hungary, Romania and Slovakia).

Submission type : New product,  
 Central zone RMS: Poland

c-MS	Nat Add (Y/N)	Justification for Nat Add
Austria	N	
the Czech Republic	N	
Germany	N	
Hungary	N	
Poland	N	
Romania	N	
Slovakia	N	

### Description of active substances

This product contains the following active substances

prohexadione-calcium	Existing*
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\*Annex I listed

### Mode of action

**Table 3.2-1: Details of the active substances**

Active substance	prohexadione-calcium
Concentration (Unit: g/kg or g/L...)	75 g/L
Chemical group	Inhibitor of gibberellin dioxygenases
Mode of action	Plant Growth regulator (PGR)
Biological action	Giberreline effect, plant growth reduction
Type	-

The active substance prohexadione-calcium is systemic and then transported within the growing plant to inhibit the later stages of gibberellin biosynthesis.

### Description of the plant protection product

PRL OD75 is an oil dispersion (OD) containing 75 grams per litre (g/L) prohexadione-calcium.

PRL OD75 is to be used on winter oilseed rape at the dose rate of 1.2 L/ha and in the Autumn season to reduce crop height before winter in order to improve winter hardiness.

The goal is to maintain an excellent crop stand after the winter (overwintering plants) to guarantee crop yield when the product is applied as a single autumn application on winter oilseed rape.

**Table 3.2-2: Simplified table of requested uses for the product code.**

Uses		Member State	Currently registered rate(s) L/ha	Requested rate(s) L/ha	Comments / Other relevant details on GAPS
Crop(s)	Target(s)				
BRSNW (winter oilseed rape)	PGR (Plant Growth Regulator)	AUT CZE DEU HUN POL ROU SVK	Not approved yet (New registration)	1.2	BBCH 12-18, (Autumn application before the winter)

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

The active substance prohexadione-calcium is not approved yet on the proposed crop winter oilseed rape in the concerned member states (cMSs) with this submission. Therefore, the present dossier consists of the first submission of a product containing the compound prohexadione-calcium as plant growth regulator (PGR) on winter oilseed rape in cMSs of the central EU regulatory zone. Nevertheless, the active substance prohexadione-calcium is already registered in ‘solo’ or in co-formulations on other crops, notably on cereals and pome fruits. All products containing prohexadione-calcium registered on cereals are used for spring applications mainly to control lodging, whereas on pome fruit the plant growth regulator is used on spring season to reduce excessive shoot growth, improve fruit sets and reduce the incidence of shoot fire blight.

This submission is the first proposed use of prohexadione-calcium both on winter oilseed rape and applied during the autumn season.

#### **Description of the claimed winter oilseed rape crop**

Winter planted oilseed rape is the main oilseed crop in Europe with most production areas located in France, Germany, Poland and the Czech Republic. Among the European cMSs included in this submission, there are two leading countries for growing winter oilseed rape, Germany and Poland with approximately 950 Kha and 830 Kha, respectively. These countries are followed by the Czech Republic (370 Kha), Romania (330 Kha) and Hungary (310 Kha). Slovakia (145 Kha) and Austria (32 Kha) are less important as producers at European level.

Despite the general reduction of winter oilseed rape cultivated area in the last recent years in Europe, due to adverse and suboptimal cultivation conditions (late frost and prolonged and extreme drought in autumn), this crop remains profitable thanks to offered economic benefits.

#### **Description of the targeted effects**

The Table 3.2-3 lists the target effects that are considered within this application.

**Table 3.2-3: Glossary of target effects mentioned in the dossier.**

Code	Name	Description
PGR	Plant growth reduction	Reduction of the crop height

In all the cMSs harsh winter seasons with minimum temperatures of -10°C or below can occur. Low winter temperatures can cause significant losses in winter oilseed rape, when there are short periods of very low temperature air frosts or when the crop is not covered by an insulating layer of snow before temperatures fall for prolonged periods. Plant survival over winter is strictly related to crop yields at harvest. If crop height exceeds 20-30 cm during the winter, crop losses caused by strong cold weather increase drastically, with a negative impact on the yield.

To reduce the effects of meteorological conditions on winter oilseed rape overwintering, farmers can adopt some agronomic tricks, such as rational fertilizations, proper plant density, seed quality and crop rotations. Moreover, the choice of the optimal sowing window is important, notably after the half August. With plant growth regulator application in autumn farmers main aim is to slow down plant growth, by reducing plant height and vegetative cone length, which should remain as close as possible to soil surface.

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

Crop and /or situation	Crop status		Targeted effect	Targeted effect status	
	Major	minor		Major	minor
Winter oilseed rape BRSNW	AUT, CZE, DEU, HUN, POL, ROU, SVK	-	Plant Growth Reduction (PGR)	AUT, CZE, DEU, HUN, POL, ROU, SVK	-

### Master Label

A master draft label is prepared here to facilitate the understanding on the product and help in the construction of the country labels that are submitted into Part A.

#### **PRODUCT**

Prohexadione-calcium OD75

An oil dispersion (OD) containing 75 grams per litre (g/L) prohexadione-calcium

#### **CROP**

Winter oilseed rape

#### **TARGETED EFFECT**

Plant growth reduction

Winter hardiness

#### **DOSE RATE**

1.2 L/ha

#### **APPLICATION TIMING**

Crop growth stages: from BBCH 12 to BBCH 18

#### **NUMBER OF APPLICATIONS**

One application

#### **RATE & WATER VOLUME**

100 – 400 L/ha

#### **APPLICATION DETAILS**

Spray (foliar)

Comments of zRMS:	<b>This study (RR)</b> is based on proper documentation and contains a comprehensive description of the presented product. Product code: <b>102000037599</b> , product name: <b>PRL OD 75 (Hingios 75 OD)</b> , chemical active substance: Prohexadione-Ca OD 75, 75 g/L,(7.28%). However, the applicant should standardize the definition of the formulation of the agent : OD 75 or 75 OD ? (dRR, Part A is 75 OD)
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### Compliance with the Uniform Principles

Studies summarized in this document are consistent with the Uniform Principles, being carried out following the EPPO standards and in accordance with GEP by officially recognised testing organisations.

The slight deviations from the proposed use pattern and/or from EPPO requirements reported in some trials are listed below, with explanations and reasonable justifications of the acceptance or of the rejection of data from these studies in the dossier.

Among the validated set of 35 efficacy trials on winter oilseed rape, 26 trials were conducted in cMSs of the EU Central Regulatory zone with 6 trials in the North-East EPPO climatic zone (Poland), 12 trials in the Maritime EPPO climatic zone (Germany, the Czech Republic, the United Kingdom) and 8 trials in the South-East EPPO climatic zone (Hungary, Romania, Slovakia), as set up in the EPPO standard PP1/241(2) “Guidance on comparable climates”. They therefore fully support the approval in the respective cMSs.

To support the submission on the claimed plant growth reduction effect, trials implemented in the concerned EPPO climatic zone in countries belonging to other EU regulatory zones, with a total of 9 trials carried out in North-Eastern France (2), Southern Denmark (3) and Sweden (1), Latvia (2) and Lithuania (1) are considered valid to support the respective EPPO zones (Maritime and North-East) as set up in the EPPO standard PP1/241(2) “Guidance on comparable climates”. No additional information is deemed to be presented to support their uses as supportive trials for the submission in cMSs of the EU Central regulatory zone.

Additionally, 4 Czech trials sited in the South-Eastern oilseed rape cultivation region in the Czech Republic, near the border with South-Western oilseed rape cultivation region in Poland, are considered valid to support the use in Poland. This is allowed in the specific Polish guidance document “Arrangements on making an assessment or comments on plant protection products by authorized entities – efficacy of plant protection products (June 2016; update January 2020)”. This global region of winter oilseed rape cultivation located in the two countries could be considered as an unique region of production and no additional agro-climatic comparison is considered to be presented to support the use of these 4 Czech trials as supportive trials for the submission in Poland.

Then, the applicant considers that all submitted trials are valid for the evaluation of the test product with this submission in cMSs of the EU Central regulatory zone. The evaluation is therefore made on the base of the global data set, however mostly focusing on the trials conducted in countries belonging to the EU Central Regulatory zone.

Among 35 validated trials, acceptable deviations from the proposed use pattern for PRL OD75 are considered in this dossier:

- PRL OD75 was applied in trials once in Autumn, reported at the major crop growth stage from BBCH 14 to BBCH 18, either at the most appropriate timing to apply PGR products to improve

crop hardiness before the winter. However, the crop emergence and crop growth are influenced by several factors, notably the soil conditions, and it is known that a high variation in crop growth stages could be observed in the same oilseed rape field. It is the case in several of submitted trials, with reported minimum crop growth stage from BBCH 12 and maximum crop growth stage BBCH 18 (up to BBCH 19 in 1 trial), at the application. Even if no efficacy and crop safety results are presented at the major crop growth stages BBCH 12 and BBCH 13, these were also reported as minimum crop growth stage at the application timing in several trials. The submitted trials set is therefore validated to support the recommended use pattern with application from the proposed earliest crop growth stage BBCH 12. The applicant considers that this deviation in crop growth stage is acceptable.

- In trials and depending on the available application equipment, products were applied using from 150 L/ha to 300 L/ha of slurry solution. There is clearly a deviation from the proposed use pattern (from 100 to 400 L/ha). It could be considered theroretically and it is also known in practice that increasing the slurry solution from 300 L/ha to 400 L/ha will not impact significantly both the efficacy and the crop safety of the products. Oppositely, reducing the slurry solution from 150 to 100 L/ha is know to be more challenging, mainly to maintain the efficacy. Nevertheless, since the product will be applied in Autumn conditions and then mostly on moist crop, the moisture present on the crop could compensate the reduction of the slurry solution. Therefore, it can be concluded that the application of PRL OD75 at 100 L/ha will not significantly impact the efficacy and the crop safety of the product when applied in Autumn on oilseed rape crop. The applicant therefore considers that these deviations in slurry solution are acceptable.

Acceptable deviations from the requirements of the EPPO standard PP1/153(3) - Control of lodging and growth regulation in brassica oil crops - are considered in this dossier:

- The reference product based on mepiquat-chloride+metconazole was mostly applied at its approved or recommended local dose rate of 1 L/ha in the majority of the trials, except at its local maximum rate of 0.7 L/ha in two Romanian trials. In particular, in Germany and Austria, the product is registered at a higher dose rate, 1.4 L/ha. Nevertheless, the applied dose rate in German trials is the highest dose recommended on company labels, which suggest to use the product as plant growth regulator in Autumn at a dose rate of 0.5-1 L/ha, notably to avoid some crop safety issues. The use of a reduced dose rate is authorized in Germany and in Austria. The applicant therefore considers that this deviation in applied dose rate for this reference product is acceptable.
- Based on prothioconazole+tebuconazole EC240, another reference product is approved at maximum dose rates lower than the one applied in trials, i.e 1.2 L/ha, in several of the cMSs. The product is registered at maximum 0.75 L/ha in Poland and 1 L/ha in the Czech Republic, Romania, and Slovakia, whereas it is approved at full 1.2 L/ha in Austria, Germany and Hungary. Since the dose rate of 1.2 L/ha is approved in at least one cMS of each EPPO zone, except for North-East zone (Poland), this deviation is considered as acceptable. Additionally, in trials where the applied dose rate is higher than the maximum locally approved, this reference product could be considered as a worst case for the evaluation of the efficacy. The applicant therefore considers that this deviation in applied dose rate for this reference product is acceptable.
- The validation of the trial is notably based on a plant height reduction of minimum 10% obtained at the most relevant assessment interval at the end of the growing period just before the winter and at least with one of the two reference products. It was the case in the majority of trials, except in one Polish trial where the plant height reduction was only maximum 6.8% (with Carax).

Because of specific agro-climatic conditions, such as cold and rainy conditions in clay and asphyxating soils, leading to weak growing of the plant after the application, the two reference products slightly reduced the plant height. This trial is maintained in the trial set to support the use in Poland, being sited in a specific winter oilseed rape cropping region in Poland (Donoslaskie region). The applicant considers that this slight deviation is acceptable, since data of this trial are supported by data of a second Polish trial sited in the same region with similar behaviors of the test product and of reference products. Both trials are representative of local specific conditions of this Polish region near the mountains.

- The assessment of the crop stand (winter survival) during the next spring was not executed in one Polish trial. However, the plant height was assessed at the end of the growing period just before the winter. Since the winter was not strong enough to impact the crop stand, such as reported in all other Polish trials and more globally in all submitted trials, the applicant therefore considers that this deviation is acceptable. The assessment executed before the winter is validated to be included in the dossier as unique data of this Polish trial.
- Some marginal data are included in summary table, separately. They are only presented in the core document but not averaged with others due to an evidence that they do not fully follow the EPPO requirements, i.e. not assessed per plot but only on a global base for all plots.
- Some assessments required in the EPPO standard PP1/153(3), notably the assessments made on mid-late spring (crop height, lodging) are also considered not relevant to be presented to support the effectiveness of the test product in this bio-dossier. Mainly these assessments are required and mainly relevant for spring application with PGR compound. Moreover, as reported in single trial report with data and/or only in the summary, no lodging occurred in all trials applied in Autumn 2019. For trials applied in Autumn 2020, such assessments should be still conducted in late spring 2021, then after the submission of this dossier. The applicant therefore considers that such data are not relevant and they are not deemed to be presented in this dossier, which is acceptable.
- In accordance with the EPPO standard PP1/226(3), visual phytotoxic symptoms to the treated crop were assessed in all efficacy trials, with PRL OD75 applied at its proposed dose rate of 1.2 L/ha (N) and the double dose rate of 2.4 L/ha (2N), whereas the reference products are only compared at their single dose rates (N). Even if the EPPO recommends to apply also reference products at the double dose rate (2N), since those trials are all efficacy trials and that no phytotoxic symptoms, no effect on the seed yield and no effect on the seed quality parameters were observed both with the test product PRL OD75 at N and 2N dose rates and with the reference products at the N dose rates, the applicant considers that this deviation is acceptable.
- Seed yield at harvest crop stage were reported for a total of 18 efficacy trials applied in Autumn 2019 and harvested in July 2020. Trials applied in Autumn 2020 should be still harvested in July 2021, then after the submission of this dossier. The requirements of the EPPO standard PP1/153(3) for a harvested surface of minimum 20m<sup>2</sup> (from 20 to 30m<sup>2</sup>) was respected in the half of harvested trials (in 9 out of 18 trials), whereas the harvested surface was from 15 to 19m<sup>2</sup> in the second half of the trials (in 9 out of 18 trials). Nevertheless, the coefficient of variation is inferior to 8.5 and due to the absence of a strong cold winter periods, there was no significant effect observed on the crop winter survival and then on the possible impact on the yield of the possible cold winters. Therefore, the possible effect on the yield will be only presented and discussed for the possible adverse effect to the crop. The applicant therefore considers that the slight deviation from the EPPO requirements in harvested surface is acceptable.

Acceptable deviation from the requirements of the EPPO standard PP1/226(3) - Number of efficacy trials - is considered in this dossier:

- According to the requirements of the EPPO standard PP1/226(3), also reference products should be applied at both single (N) and double (2N) dose rates to evaluate the adverse effects of a plant growth regulator to the treated crop. However and as it will presented and evaluated in the respective chapters for adverse effects, no visual phytotoxic symptoms, no significant effects on seed yield, on seed quality parameters and on the propagation material, were observed with the N dose rates of both reference products and with the N and 2N dose rates of the test product PRL OD75, in all validated efficacy trials. The applicant therefore considers that the absence of the 2N dose rates for the reference products in efficacy trials is not relevant and that this deviation from the EPPO standard is acceptable.

Acceptable deviation from the requirements of the EPPO PP1/181(4) - Conduct and reporting of efficacy evaluation trials, including good experimental practice - is considered in this dossier:

- All trials conducted in 2019-2020 and harvested in July 2020 were reported in accordance with the requirements of the standard EPPO PP1/181. Nevertheless, all trials started in Autumn 2020 will be continued up to their harvest in July 2021, then after the submission of this dossier. It is firstly to consider that no significant effects due to the application of both the test product and of reference products were seen in mid-late spring assessments (crop height, lodging) and at harvest (seed yield, seed quality and propagation tests, see respective chapters 3.4.2, 3.4.3 and 3.4.5) in trials conducted in 2019-2020 (application in Autumn 2019 with harvest in July 2020). It is also to consider that the concerned winters (2019-2020 and 2020-2021) were quite similar and not strong enough to impact significantly the crop stand, as reported in chapter 3.2.3. The applicant therefore stated that no significant effect should be intended in the mid-late spring assessments and at harvest assessments in trials started in Autumn 2020 and still to be continued up to the harvest in July 2021. To conclude, the applicant considers that the submitted single trial reports for all trials started on Autumn 2020 contain the main parameters to evaluate the effectiveness and the crop safe use of PRL OD75 to the treated crop and they are therefore, at the timing of the submission, under a provisional version, which is acceptable.

**Otherwise, no major deviation both from the proposed use pattern and from the requirements of the EPPO standards, is noticed that would exclude the data from the analysis.**

Comments of zRMS:	<b>Compliance with the Uniform Principles:</b> In the presented RR, the compliance of the presented data with the required rules was broadly and precisely confirmed. All trials were conducted according to appropriate EPPO guidelines and GEP requirements <b>and Uniform Principles.</b>
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### **Information on trials submitted (3.1 Efficacy data)**

To ease the reading, the evaluation will be presented in accordance with the following USE numbering, which is based on the proposed GAP:

- **USE001** – PRL OD75 on winter oilseed rape (BRSNW), crop stages BBCH 12-18, 1.2 L/ha for the cMS of the North-East EPPO climatic zone (major use) - Poland
- **USE002** – PRL OD75 on winter oilseed rape (BRSNW), crop stages BBCH 12-18, 1.2 L/ha for the cMSs of the Maritime EPPO climatic zone (major use) – Austria, the Czech Republic and Germany
- **USE003** – PRL OD75 on winter oilseed rape (BRSNW), crop stages BBCH 12-18, 1.2 L/ha for the cMSs of the South-East EPPO climatic zone (major use) – Hungary, Romania and Slovakia

Based on the major/minor status of the claimed crops and diseases (Table 3.2-4), it can be considered that all the proposed uses are major in all cMSs with this submission in countries of the EU Central regulatory zone.

The following table 3.2-5 aims to give an overview of submitted trials. The list of all individual trials is available in the Biological Assessment Dossier (BAD).

**Table 3.2-5: Presentation of trials (including PRL OD75)**

Excluding trials only used in Chapter 3.2.1 – Preliminary test

Crop*	Target*	European Regulatory zone	Country	Year**	Type of trial***	Number of trials (number of validated trials)			GEP, non-GEP, official****	Comments (any other relevant information)  In relevant Chapter		
						North-East zone	Maritime zone	South-East zone				
						(USE001)	(USE002)	(USE003)				
Winter oilseed rape (BRSNW)	Plant growth regulator (PGR)	Central	CZE*****	2020-2021	MED+E		6 (6)		GEP			
			DEU	2020-2021	MED+E		5 (5)		GEP			
			HUN	2020	MED+E			2 (2)	GEP			
			POL	2020-2021	MED+E	6 (6)			GEP			
			ROU	2020	MED+E			3 (3)	GEP			
			SVK	2020-2021	MED+E			3 (3)	GEP			
			UK	2021	MED+E		1 (1)		GEP			
		North (supporting)	DNK	2020-2021	MED+E		3 (3)		GEP			
			LTU	2020	MED+E	1 (1)			GEP			
			LVA	2020-2021	MED+E	2 (2)			GEP			
			SWE	2020	MED+E		1 (1)		GEP			
		South (supporting)	FRA	2021	MED+E		2 (2)		GEP			
		<b>TOTAL</b>	-				<b>MED</b>	<b>9 (9)</b>	<b>18 (18)</b>	<b>8 (8)</b>	-	<b>35 trials, 3.2.2</b>
							<b>E</b>	<b>9 (9)*****</b>	<b>18 (18)</b>	<b>8 (8)</b>	-	<b>35 trials, 3.2.3</b>

\*According to the GAP table.

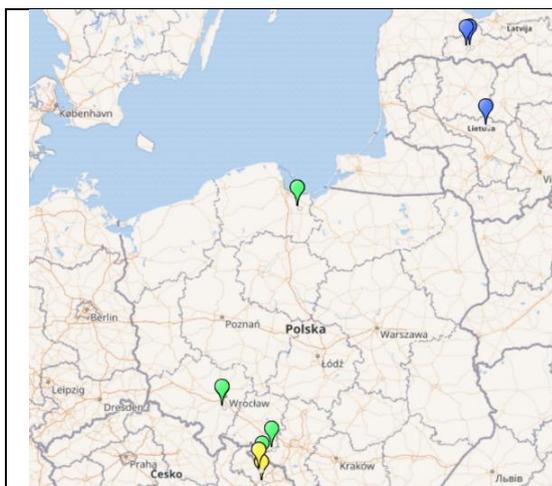
\*\* Years 2020 and 2021: application in Autumn 2019 and Autumn 2020, respectively.

\*\*\*MED = Minimum Effective Dose (Chapter 3.2.2), E = Efficacy trial (Chapter 3.2.3).

\*\*\*\* GEP: Good Experimental Practices. Official: carried out by a national official organisation.

\*\*\*\*\*Four Czech trials (Maritime EPPO zone) are additionally validated to support the justification of the effectiveness for the submission in Poland (North-East EPPO zone). Therefore, a total of 13 trials are considered to evaluate the effectiveness of the test product PRL OD75 in Chapter 3.2.3, with the submission in Poland.

### Justification for trialset, notably from outside country of submission



**Figure 3.2-1: Distribution of 13 efficacy trials carried out on winter oilseed rape – USE001 - North-East EPPO zone – 6 Polish trials + 7 supportive Latvian, Lithuanian and Czech trials**

To support the use in Poland, a set of 13 valid trials is evaluated. Among these 13 trials, 6 trials were implemented in Poland (green pins). It is sufficient to meet the minimum requirement of EPPO standard PP1/226(2).

Nevertheless 3 trials carried out in countries of the EU Northern Regulatory zone (blue pins) in Latvia and Lithuania, are selected to support the dossier as agro-climatic conditions are considered pertinent with the northern regions of Poland. Moreover, 4 trials implemented in the Czech Republic (yellow pins), near the border of the main winter oilseed rape cultivation area in Poland (where 4 of the 6 Polish trials were also sited), are submitted to support the use in Poland. This is acceptable on the ground of the Polish guidance document<sup>(1)</sup>. Especially, these supportive 7 trials also allow to complete the set of trials for the proposed use pattern, notably covering the crop growth stages from BBCH 12 up to BBCH 18.

Nevertheless, the 3 supportive Latvian and Lithuanian trials are included in set of trials to cover the GAP (BBCH 12-18) whereas the 4 supportive Czech trials are mainly submitted to enhance the set of available trials carried out in Poland.



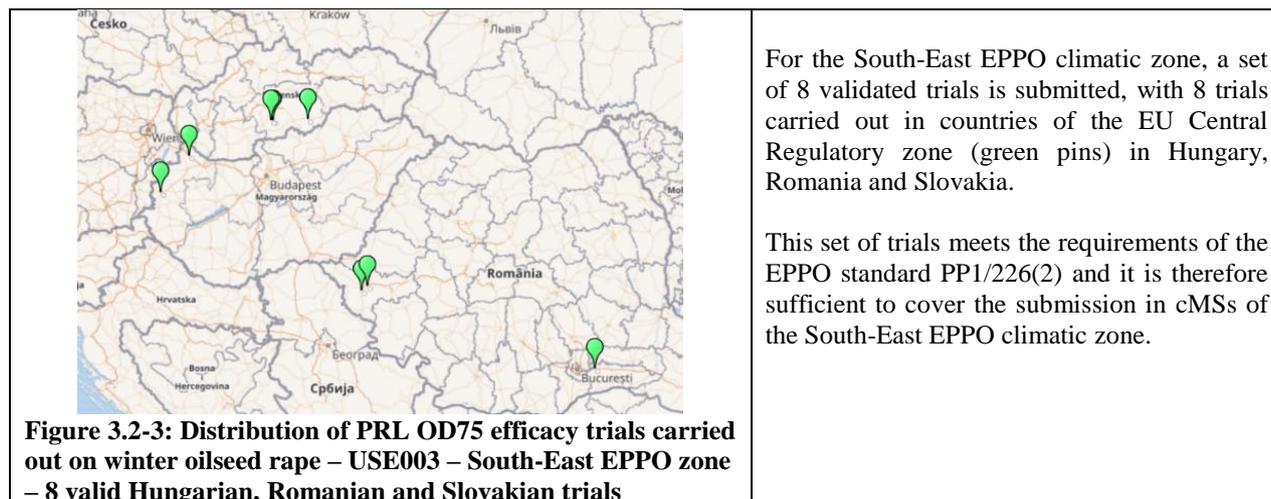
**Figure 3.2-2: Distribution of PRL OD75 efficacy trials carried out on winter oilseed rape – USE002 – Maritime EPPO zone – 12 valid Czech, German and UK trials + 6 supportive Danish, French and Swedish trials**

To support the use in cMSs of the Maritime EPPO zone, a set of 18 valid trials is evaluated.

Among these 18 Maritime trials, 12 trials were implemented in countries of the EU Central Regulatory zone (green pins), in the Czech Republic, Germany and the United Kingdom. The set of 12 trials meets the requirements of EPPO standard PP1/226(2).

Nevertheless, 4 supportive trials implemented in countries of the EU Northern Regulatory zone (blue pins, in Denmark and Sweden) were sited very close to the German border, with agro-climatic conditions pertinent with the northern regions of Germany. Similarly 2 trials implemented in a country of the EU Southern Regulatory zone (red pins, in France), can be considered as supportive of the western area in Germany. Especially, these 6 supportive trials allow to complete the set of trials for the proposed GAP, notably to cover the crop growth stages from BBCH 12 up to BBCH 18.

Nevertheless, these 6 supportive trials implemented in Denmark, France and Sweden, were mainly selected to cover the GAP and therefore to enhance the set of available trials carried out in the Czech Republic, Germany and the UK.



On these very general maps, the pins corresponding to geographically close trials may be merged. Green pins for the EU Central Regulatory zone, blue pins for the EU Northern Regulatory zone, red pins for the EU Southern Regulatory zone and yellow pins for Czech trials supporting the use in Poland.

<sup>(1)</sup>Arrangements on making an assessment or comments on plant protection products by authorized entities – efficacy of plant protection products (June 2016; update January 2020)

Justification for the use of biological efficacy data included in the dossier is made according to EPPO standard PP1/241(2) “Guidance on comparable climates.” So, all trials carried out in the respective EPPO zones can be extrapolated to each country belonging to this agro-climatic EPPO zone. Moreover supportive data from some neighbouring countries belonging to another EPPO climatic zone and/or European Regulatory zone could be considered as fully representative to provide a more robust data set.

The applicant therefore states that all submitted reliable trials are relevant for a submission in the European Central Regulatory zone, considering the justification in regards of maps showing the location of the selected trials per EPPO climatic zones, presented above.

For submission in cMSs of the EU Central Regulatory zone, the number of efficacy trials to demonstrate plant growth reduction in winter oilseed rape is sufficient and well distributed in the three concerned EPPO zones. Moreover, supportive data from some neighbouring countries belonging to another European Regulatory zone can be considered as fully representative to provide a more robust data set.

Therefore the applicant considered that the fully justified sets of trials in the North-East (USE001, set of 13 validated trials), in the Maritime (USE002, set of 18 validated trials) and in the South-East (USE003, set of 8 validated trials) EPPO climatic zones, meet the requirements of the EPPO standard PP1/226(3).

**Table 3.2-6: Validated trials per country and per year**

Valid trials for Chapter 3.2.2 (MED) and Chapter 3.2.3 (Effectiveness) are considered in the table

EPPO climatic zone	European Regulatory zone	Year	2020*	2021*	Total	Total	Total
		Country					
North-East	Central	Poland	3	3	6	6	9
	Northern (Supportive)	Latvia	1	1	2	3	
		Lithuania	1		1		
Maritime	Central	Czech Republic	3**	3**	6	12	18
		Germany	2	3	5		
		UK		1	1		
	Northern	Denmark	2	1	3	4	

	(Supportive)	Sweden	1		<b>1</b>		
	Southern (Supportive)	France		2	<b>2</b>	<b>2</b>	
South-East	Central	Hungary	2		<b>2</b>	<b>8</b>	<b>8</b>
		Romania	3		<b>3</b>		
		Slovakia	2	1	<b>3</b>		
<b>Total</b>			<b>20</b>	<b>15</b>	<b>35</b>	<b>35</b>	<b>35</b>

\*Years 2020 and 2021: application in Autumn 2019 and Autumn 2020, respectively.

\*\*Four Czech trials (2 trials per year, Maritime EPPO zone) are additionally validated to support the justification of the effectiveness in Chapter 3.2.3, for the submission in Poland (North-East EPPO zone).

Comments of zRMS:	<p><b><u>Trials submitted</u></b></p> <p>The applicant presents 35 trials carried out in accordance with the reports. Total of 35 (26+9 supportive) trials investigating the effectiveness of product code: <b>102000037599</b>, product name(s): <b>PRL OD 75, HINGIOS 75 OD</b> in order to reduce of the plant height and to limit plant growth in the cultivation of winter oilseed rape. Inhibition of plant development has a positive effect on wintering. The influence of the tested agent on better wintering of winter oilseed rape was assessed.</p> <p>Those trials were undertaken in winter oilseed rape: 2020 (20 trials), 2021 (15 trials).</p> <p>Trials were located in the 3 climatic EPPO zones: North-Eastern EPPO zone(Poland 6 trials), Maritime, South-East and European Regulatory zone. The localization of the experiments was appropriate.</p> <p>The more than required number of experiments on winter oilseed rape were carried out to evaluate the effectiveness of <b>PRL OD 75, HINGIOS 75 OD</b>. The 23 experiments in North-Eastern EPPO climatic zone: Poland, Lithuania Latvia and in the neighboring countries of Poland: Czech Rep., Germany, Slovakia on winter oilseed rape were performed in the two vegetation seasons 2020 and 2021 which is sufficient and justified. The list of experiments is presented in the table 3.2-6.</p> <p><b>The required number (23) of experiments on winter oilseed rape are carried out to evaluate the effectiveness of product PRL OD 75, HINGIOS 75 OD, chemical active substance: Prohexadione-calcium 75 g/L,(7,28 %)on winter oilseed rape in order to reduce plant growth and on better wintering.</b></p> <p><b>Experiments complied with GEP requirements, while the efficacy evaluation methods agreed with specific EPPO guidelines and Uniform Principles.</b></p>
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### Reference standards

Several official reference products with well-known properties were used in all reported trials by comparison with PRL OD75, to evaluate its performance and crop safety, along with to validate the reliability of trials.

The commercial products used as PGR standards were present in all trials and approved in all cMSs. They were therefore selected as reference standards in this dossier, approved locally under different trade names as presented in **Błąd! Nie można odnaleźć źródła odwołania..**

Due to the presence of triazole fungicide compounds, both reference products also control disease infections at early crop growth stages, notably when applied from BBCH 12 in Autumn on winter oilseed rape.

**Mepiquat-chloride+metconazole SL240** combines a plant growth regulator compound (mepiquat-chloride) with a fungicide compound (metconazole) belonging to triazole chemical group. It is considered as one of the main standard products used as PGR when applied in Autumn on winter oilseed rape, in all the cMSs.

In Germany and Austria, mepiquat-chloride+metconazole SL240 is registered at the maximum dose rate of 1.4 L/ha, which is higher than the one used in trials (1 L/ha). Nevertheless, the applied dose rate in German trials is the highest dose recommended on company labels, which suggest to use the product as plant growth regulator in Autumn at a dose rate of 0.5-1 L/ha. The use of a reduced dose rate is authorized in Germany.

In Poland and the Czech Republic, the product is approved at 1 L/ha and it was used in trials at this label recommended dose rate.

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

Source : <https://v5.homologa.com/en/>

Crop	Reference standard (trade name)	cMSs where the product is approved	Authorization number	Active substance	Formulation		Registered application rate	Application rate in trials (per treatment)	Remark			
					Type	Concentration of a.s.						
BRSNW (winter oilseed rape)	Carax®	AUT	3155	mepiquat-chloride + metconazole	SL	240 g/L (210 g/L + 30 g/L)	1.4 L/ha	No trial	Recommended dose of 0.7-1 L/ha			
		CZE	4688-0				1 L/ha	1 L/ha	Recommended dose of 0.5-1 L/ha			
		DEU	006415-00				1.4 L/ha					
		SVK	11-14-1172				0.7-1 L/ha					
	Caryx® 240 SL	POL	R-36/2021d				1 L/ha	0.7 L/ha	Applied at 1 L/ha in one trial			
	Caramba® Turbo	HUN	02.5/1313-1/2010				0.7-1.4 L/ha					
		ROU	2798/15.10.2008				0.7 L/ha					
	Tilmor®	AUT	3307				prothioconazole + tebuconazole			EC	240 g/L (80 g/L + 160 g/L)	1.2 L/ha
		CZE	4775-2					1 L/ha	1.2 L/ha			
		DEU	006855-00					1.2 L/ha				
		HUN	04.2/7910-1/2011					1.2 L/ha				

In countries of the South-East EPPO zone (Slovakia, Hungary and Romania), it is registered at minimum 0.7 L/ha, up to 1 L/ha (Slovakia, ranging 0.7-1 L/ha) or 1.4 L/ha (Hungary, ranging 0.7-1.4 L/ha). The product was applied at the intermediate dose rate of 1 L/ha in all trials, except for two Romanian trials where the local approved dose of 0.7 L/ha was used.

**Prothioconazole+tebuconazole EC240** combines two fungicide compounds belonging to triazole chemical group. Besides their fungicide effects, they showed also plant growth regulator properties when applied in Autumn on winter oilseed rape. The product is approved as PGR in all cMSs.

In several cMSs, prothioconazole+tebuconazole EC240 is registered at maximum dose rates lower than the one applied in trials, i.e 1.2 L/ha. The product is registered at maximum 0.75 L/ha (Poland), 1 L/ha (Czech Republic, Romania, and Slovakia) and 1.2 L/ha (Austria, Germany, Hungary). Since the dose rate of 1.2 L/ha is approved in at least one cMS of each EPPO zone, except for North-East zone (Poland), this deviation is considered as acceptable. Additionally, in trials where the applied dose rate is higher than the maximum locally approved, the reference product could be considered as a worst case for the evaluation of the efficacy.

Therefore, the efficacy data obtained with the reference product prothioconazole+tebuconazole EC240 applied at its maximum dose rate of 1.2 L/ha are validated to be presented in support of the dossier, essentially to justify the effectiveness of the test product PRL OD75.

#### **Formulation code used for the experimentation of PRL OD75**

PRL OD75 has been evaluated under the following formulations:

<b>Name</b>	<b>Formulation Code</b>
PRL OD75	<b>SP102000037599</b>

Except for all preliminary field trials conducted with two former OD75 formulations of prohexadione-calcium, coded SP102000035378 and SP102000036194 and evaluated in Chapter 3.2.1. Details of the comparability between SP102000035378 and SP102000036194 can be found in the confidential document [M-764940-01-1](#) (refer to the reference list of Part C of this submission) which demonstrates equivalence of these formulations. All validated trials submitted to support the minimum effective dose (Chapter 3.2.2), the effectiveness (Chapter 3.2.3) and possible adverse effects to the treated crop (Chapter 3.4) were conducted with the proposed formulation OD75 coded SP102000037599.

Comments of zRMS:	<b><u>Methodology I</u></b>
	Experiments included standard products which were appropriately selected from among the products registered in Poland and the cited countries of Europe <b>The methods of presenting the results of trials are appropriate.</b> <b>Experiments complied with GEP requirements, while the efficacy evaluation methods agreed with specific EPPO guidelines and uniform principles.</b> <u>Note:</u> The EPPO methodologies cited in the RR have the correct edition (version) numbers.

#### **Principles for data grouping and presentation - Efficacy trials**

Data are firstly presented per EPPO climatic zone as set up in the EPPO standard PP1/241(2) for the EU Central Regulatory zone and according to the proposed global use numbering, with:

- USE001 – North-East EPPO climatic zone,
- USE002 – Maritime EPPO climatic zone,
- USE003 – South-East EPPO climatic zone.

Additionally, a secondary synthesis was conducted by grouping data per European Regulatory zone (Central, Northern and Southern) in each EPPO climatic zone.

In accordance with the recommendations of the specific EPPO standard PP1/153(3), the efficacy of the test product PRL OD75, applied in Autumn to improve crop winter hardiness, is evaluated on the results obtained on the two main assessed parameters for this Autumn application:

- the **plant height** at the most relevant interval at the end of the growing period (just before the winter) and, additionally repeated but not required by the EPPO standard PP1/153(3), at the restart of crop growth (shortly after the winter),
- the **crop winter survival** in early spring, after the winter period and at the restart of the growing period.

In both Chapter 3.2.2 (Minimum Effective Dose) and Chapter 3.2.3 (Efficacy), only the most relevant assessment of plant height at the end of the growing period before the winter (when no further growth before winter is expected) is presented and evaluated.

Additionally in Chapter 3.2.3 (Efficacy) the assessments of both the plant height and of the crop stand at the restart of growing period after the winter are presented and evaluated, notably per requirement of the EPPO standard PP1/153(3).

Quantitative seed yield and qualitative seed parameters - oil content (%), thousand grains weight (g) or protein content (%) – were conducted at harvest or in post-harvest in several efficacy trials. Crop safety assessments through evaluation of general occurrence of phytotoxicity and seed germination tests were carried out. All these data are presented and discussed in Chapter 3.4 (Adverse effects on treated crops).

Then, all presented and evaluated efficacy results in the core part of this document are considered as the most appropriate to evaluate the performance of products active to reduce plant growth when applied in Autumn on winter oilseed rape.

### **Formula used**

From the crop height assessment, the efficacy was calculated as % Relative compared to the untreated.

## **3.2.1 Preliminary tests (KCP 6.1)**

The active substance prohexadione-calcium is a well-known plant growth regulator (PGR) compound already approved in several concerned European member states, notably on pome fruits and cereal crops.

To support the use on winter oilseed rape, preliminary field trials were conducted by Bayer with two former OD75 formulations of prohexadione-calcium, applied on winter oilseed rape during Autumn seasons 2017 and 2018. Nineteen trials were carried out in the most relevant winter oilseed rape growing regions of Central, Southern and Eastern Europe (Germany, Poland, Ukraine and France).

Prohexadione-calcium was applied at the targeted dose rate of 90g a.s./L on winter oilseed rape, once in Autumn at crop growth stages from BBCH 14 to BBCH 18, covering the main period for practical application of plant growth regulator products on winter oilseed rape before the winter. In 8 trials (Autumn 2017), besides the proposed dose rate of 90 g a.s./ha, lower dose rates (i.e., 50 and 75g a.s./L) were also tested.

Efficacy results in accordance with the plant height (cm) and expressed in % relative to the untreated are shown in Table 3.2-8, summarizing the most relevant plant height assessment made at an interval of 21-33 days after application (just before the winter).

**Table 3.2-8: Plant height reduction (%relative to the UTC) after single field spray with the test compound prohexadione-calcium (OD75) on winter oilseed rape - Dose rates expressed in g a.s./ha**

Year (appl. and assessment)	Number of trials	Untreated		% relative to the untreated									
				Test product						Reference products			
		Plant height (cm)		prohexadione-calcium						Ref. 1		Ref. 2	
				50 g a.s./ha		75 g a.s./ha		90 g a.s./ha		Σ336 g a.s./ha		Σ288 g a.s./ha	
Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max		
2017 Form. 1	8	26.0	19.6-38.6	84.0	64.5-97.3	78.2	60.6-88.9	72.6	57.6-84.6	-	-	-	-
	14	25.6	19.0-38.6	-	-	-	-	72.5	57.3-84.6	52.5	45.2-67.8	-	-
	4	25.4	20.1-33.4	-	-	-	-	73.9	57.6-84.6	-	-	66.8	65.2-69.7
2018 Form. 2	5	26.3	17.9-38.3	-	-	-	-	73.2	60.0-88.5	58.8	47.6-66.1	-	-
2017+2018	19	25.8	17.9-38.6	-	-	-	-	72.7	57.3-88.5	54.1	45.2-67.8	-	-

Ref. 1 - mepiquat-chloride+metconazole SL240 (210+30 g/L) applied at 1.4 L/ha  
 Ref. 2 - prothioconazole+tebuconazole EC240 (80+160 g/L) applied at 1.2 L/ha

A clear dose rate response of prohexadione-calcium from 50 to 90 g a.s./ha is observed in all 8 trials where the dose rates 50, 75 and 90 g a.s./ha were tested.

Overall the nineteen trials, 90g prohexadione-calcium/ha showed excellent results when assessed at the end of the growing season before the winter, at an interval of 21-33 days after application. A significant reduction of the plant height (mean reduction of 27.3% relative, 7.0cm absolute) is achieved when compared to untreated check, without difference in performances between the two former OD75 formulations tested in trials in 2017 and in 2018.

In comparison with standard products applied at their full approved dose rates and currently used in Autumn, the single compound prohexadione-calcium with less quantity of active substance applied in field (only 90 g/ha) showed lower reduction of the plant height than mepiquat-chloride+metconazole SL240 applied at full dose rate of 1.4 L/ha (294+42g a.s./ha, total of 19 trials), whereas it showed mostly equivalent reduction of the plant height than prothioconazole+tebuconazole EC240 applied at 1.2 L/ha (96+192g a.s./ha, total of 4 trials).

It is concluded that prohexadione-calcium applied at 90 g/ha and foliar sprayed in Autumn on winter oilseed rape could be considered as an efficient new active substance among the plant growth regulator tools available to reduce the plant height resulting in a better crop survival after the winter.

Comments of zRMS:	<p><b>Preliminary test</b>  <b>Prohexadione-calcium</b> is well known, registered and commercialised active substance for the use as plant growth regulator in horticulture and in cereals. Prohexadione-calcium is registered in Poland and EU in many products. In Poland, most of the products containing Prohexadion - calcium are registered for application in horticulture and cereals. The Applicant in the presented RR applies for the regis-</p>
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	<p>tration of <b>Prohexadione-calcium</b> in winter oilseed rape.</p> <p>Preliminary field trials were conducted with two former OD75 formulations of prohexadione-calcium, applied on winter oilseed rape during Autumn seasons 2017 and 2018. Nineteen trials were carried out in the most relevant winter oilseed rape growing regions of Central, Southern and Eastern Europe (Germany, Poland, Ukraine and France).The dose rates 50, 75 and 90 g a.s./ha of <b>Prohexadione-calcium</b> were tested.</p> <p>The results of the conducted experiments indicate that prohexadione-calcium applied at 90 g/ha and foliar sprayed in Autumn on winter oilseed rape is considered as an efficient active substance as the plant growth regulator to reduce the plant height resulting in a better crop survival after the winter,</p> <p>The obtained results are without difference in performances between the two former OD75 formulations tested in trials.</p> <p><b>The results of preliminary experiments indicate the usefulness of Prohexadione-calcium in use in winter oilseed rape as a growth regulator.</b></p>
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### 3.2.2 Minimum effective dose tests (KCP 6.2)

The evaluation of the Minimum Effective Dose rate of PRL OD75 as plant growth regulator on winter oilseed rape, when applied in accordance with the proposed use pattern, is based on the presented efficacy results from validated trials conducted in countries belonging to the North-East, the Maritime and the South-East EPPO climatic zones.

All submitted trials carried out to prove the effectiveness of PRL OD75 were also conducted to justify the minimum effective dose rate. Therefore, to avoid a duplicate information, methods used, main characteristics and details from these trials are described in introduction of Chapter 3.2.3 – Efficacy tests.

In accordance with the requirements of the EPPO standard PP1/225 – Minimum effective dose, the recommended dose rate of 1.2 L/ha (N) was compared to several dose rates, both lower and higher. Depending on trials, the tested dose rates were 0.5, 0.8, 1.2, and 2.4 L/ha, then from 0.42N to 2N.

In validated trials, PRL OD75 was applied during the Autumn seasons 2019 and 2020, on winter oilseed rape crop at the major crop growth stages from BBCH 14 to BBCH 18.

Nevertheless and depending on trial conditions, at application plants were at the minimum crop growth stage BBCH 12 and at the maximum crop growth stage BBCH 18 (BBCH 19 in 1 trial). It is therefore considered that the set of trials covers the proposed use pattern, from BBCH 12 to BBCH 18.

As the two winter periods (winter 2019-2020 and winter 2020-2021) were not strong enough to impact significantly the crop stand and winter survival, the justification of the minimum effective dose rate for the test product PRL OD75 is evaluated for the most relevant parameter assessed at the end of the growing season and just before the winter: **the plant height measured from the ground to the top of the canopy**. The applicant considers that this approach is acceptable.

#### General remarks:

- the two different reference products, which were applied at the same timing that the test product PRL OD75, performed mostly as expected in the majority of trials, depending on trial agro-climatic conditions..

- in regard to the untreated plots, there could be a high variation in assessed crop heights between trials implemented in same country and same year but in different oilseed rape cropping regions. These high variations in crop growth and crop development are mostly due to specific agronomical and/or climatic conditions. All trials are therefore validated for the dossier, allowing to evaluate the minimum effective dose rate of PRL OD75 in wide agro-climatic situations met in the cMSs.

**USE001 – PRL OD75 on BRSNW – NORTH-EAST EPPO CLIMATIC ZONE (major use)**

For submission as PGR in Poland, with a single Autumn application on winter oilseed rape, the justification of the minimum effective dose rate of PRL OD75 is based on the efficacy results of six reliable trials carried out in Poland, supported with efficacy data of three Latvian and Lithuanian trials. All trials were implemented in countries belonging to the North-East EPPO zone.

**Table 3.2-9: USE001 - Minimum Effective Dose - Distribution of efficacy trials with PRL OD75 applied during the Autumn season on winter oilseed rape - North-East EPPO climatic zone**

Target	EPPO climatic zone	European Regulatory zone	Country	Number of trials per year*		TOTAL (valid)	TOTAL (valid)
				2020	2021		
PGR (Plant Growth Regulator)	North-East	Central	Poland	3	3	6	6
		Northern (supportive)	Latvia	1	1	2	3
			Lithuania	1		1	
	<b>TOTAL North-East EPPO climatic zone</b>				<b>5</b>	<b>4</b>	<b>9</b>

\*Years 2020 and 2021: application in Autumn 2019 and Autumn 2020, respectively.

Out of the 6 Polish trials, a clear dose rate response is observed with PRL OD75, both between 0.5 L/ha (0.42N) and 1.2 L/ha (full N) in 3 concerned trials and between 0.8 L/ha (0.67N) and 1.2 L/ha (full N) in all 6 trials, statistically significant in at least 2 trials. This dose rate response is confirmed in the efficacy results of the three supportive Lithuanian and Latvian trials, particularly in 1 Latvian trial where the plant height reduction was the most pronounced.

Overall the 9 validated trials, there is a clear dose rate response 0.5-0.8-1.2 L/ha for PRL OD75 in the mean reduction of the plant height when assessed at the end of the growing period before the winter. The differences in plant heights between the proposed dose rate of 1.2 L/ha and the two lower dose rates of 0.5 L/ha and of 0.8 L/ha are statistically significant in 3 out of 4 trials and in 3 out of 9 trials, respectively. Increasing the dose rate to 2.4 L/ha only provides a slight additional reduction effect of the plant height. statistically significant in 1 out of 9 trials, again in the supportive Latvian trial previously mentioned where the PGR effect is the most pronounced. Nevertheless, in this trial, PRL OD75 at 1.2 L/ha provided satisfactory and excellent plant height reduction of 53.6% relative to UTC, i.e. a reduction of 19cm for a mean plant height of 35.8cm in untreated.

Based on the efficacy results of nine reliable trials, the minimum and optimum dose rate of 1.2 L/ha is therefore justified for the approval of the use of PRL OD75 in a single Autumn application on winter oilseed rape, for which the PGR activity of the test product is claimed in Poland.

**Table 3.2-10: USE001 – MED - Efficacy (% relative to the untreated) of PRL OD75 applied as PGR in Autumn on winter oilseed rape in the North-East EPPO climatic zone – Plant height (cm) assessed at 38-69 days after the application, at the end of the growing period and just before the winter.**

- For approval at 1.2 L/ha in cMS of the North-East EPPO zone (Poland)

EPPO zone	EU regulatory zone	Number of trials	Untreated PLANT HEIGHT (cm)		Plant height - % relative to the untreated								Stat. Anal.	Comparison
					Test product - PRL OD75									
			Mean	Min & Max	0.5 L/ha (0.42 N)		0.8 L/ha (0.67 N)		1.2 L/ha (Full 1 N)		2.4 L/ha (2 N)			
North-East	Central	6	31.2	17.7-40.5	-	-	87.5	77.9-98.0	<b>79.7</b>	66.7-93.2	75.7	67.3-85.3	= 4, < 0, > 2 = 6, < 0, > 0	1.2 vs. 0.8 1.2 vs. 2.4
		3	30.7	17.7-37.2	97.8	96.8-98.9	92.7	89.2-90.0	<b>82.0</b>	72.8-93.2	76.0	67.3-85.3	= 1, < 0, > 2 = 2, < 0, > 1 = 3, < 0, > 0	1.2 vs. 0.5 1.2 vs. 0.8 1.2 vs. 2.4
	North (support)	3	32.2	24.1-36.8	-	-	74.4	61.0-91.2	<b>64.6</b>	46.4-83.1	59.4	39.0-79.0	= 2, < 0, > 1 = 2, < 1, > 0	1.2 vs. 0.8 1.2 vs. 2.4
		1	35.8	-	73.4	-	61.0	-	<b>46.4</b>	-	39.0	-	= 0, < 0, > 1 = 0, < 0, > 1 = 0, < 1, > 0	1.2 vs. 0.5 1.2 vs. 0.8 1.2 vs. 2.4
	All 2 EU regulatory zones	9	31.5	17.7-40.5	-	-	83.1	61.0-98.0	<b>74.6</b>	46.4-93.2	70.3	39.0-85.3	= 6, < 0, > 3 = 8, < 1, > 0	1.2 vs. 0.8 1.2 vs. 2.4
		4	32.0	17.7-37.2	91.7	73.4-98.9	84.8	61.0-98.0	<b>73.1</b>	46.4-93.2	66.8	39.0-85.3	= 1, < 0, > 3 = 2, < 0, > 2 = 3, < 1, > 0	1.2 vs. 0.5 1.2 vs. 0.8 1.2 vs. 2.4

**USE002 – PRL OD75 on BRSNW – MARITIME EPPO CLIMATIC ZONE (major use)**

For submission as PGR in Austria, Germany and the Czech Republic, with a single Autumn application on winter oilseed rape, the justification of the minimum effective dose rate of PRL OD75 is based on the efficacy results of twelve reliable trials carried out in Germany, the Czech Republic and the United Kingdom, supported with efficacy data of four Danish and Swedish trials (EU Northern Regulatory zone) and two French trials (EU Southern Regulatory zone). All trials were implemented in countries belonging to the Maritime EPPO zone.

**Table 3.2-11: USE002 - Minimum Effective Dose - Distribution of efficacy trials with PRL OD75 applied during the Autumn season on winter oilseed rape - Maritime EPPO climatic zone**

Target	EPPO climatic zone	European Regulatory zone	Country	Number of trials per year*		TOTAL (valid)	TOTAL (valid)
				2020	2021		
PGR (Plant Growth Regulator)	Maritime	Central	Czech Republic	3	3	6	12
			Germany	2	3	5	
			United Kingdom		1	1	
		Northern (supportive)	Denmark	2	1	3	4
			Sweden	1		1	
		Southern (supportive)	France		2	2	2
		<b>TOTAL Maritime EPPO climatic zone</b>				<b>8</b>	<b>10</b>

\*Years 2020 and 2021: application in Autumn 2019 and Autumn 2020, respectively.

Out of the 12 Czech, German and UK trials, a clear dose rate response is observed with PRL OD75, both between 0.5 L/ha (0.42N) and 1.2 L/ha (full N) in 7 concerned trials and between 0.8 L/ha (0.67N) and 1.2 L/ha (full N) in 11 of 12 trials. This dose rate response is confirmed in the efficacy results of all six supportive Danish, Swedish and French trials.

Overall the 18 validated trials, there is a clear dose rate response 0.5-0.8-1.2 L/ha for PRL OD75 in the mean reduction of the plant height when assessed at the end of the growing period before the winter. The differences in plant heights between the proposed dose rate of 1.2 L/ha and the two lower dose rates of 0.5 L/ha and of 0.8 L/ha are statistically significant in 3 out of 10 trials and in 2 out of 18 trials, respectively. Increasing the dose rate to 2.4 L/ha only provides a slight additional reduction effect of the plant height, statistically significant only in 1 out of 18 trials, in a German trial where 1.2 L/ha showed satisfactory plant height reduction.

Based on the efficacy results of eighteen reliable trials, the minimum and optimum dose rate of 1.2 L/ha is therefore justified for the approval of the use of PRL OD75 in a single Autumn application on winter oilseed rape, for which the PGR activity of the test product is claimed in Austria, the Czech Republic and Germany.

**Table 3.2-12: USE002 – MED - Efficacy (% relative to the untreated) of PRL OD75 applied as PGR in Autumn on winter oilseed rape in the Maritime EPPO climatic zone – Plant height (cm) assessed at 26-62 days after the application, at the end of the growing period and just before the winter.**

- For approvals at 1.2 L/ha in CMSs of the Maritime EPPO zone (Austria, the Czech Republic and Germany)

EPPO zone	EU regulatory zone	Number of trials	Untreated		Plant height - % relative to the untreated								Stat. Anal.	Comparison
					Test product - PRL OD75									
			PLANT HEIGHT (cm)		0.5 L/ha (0.42 N)		0.8 L/ha (0.67 N)		1.2 L/ha (Full 1 N)		2.4 L/ha (2 N)			
			Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max		
Maritime	Central	12	28.4	10.1-40.8	-	-	75.5	58.8-90.2	<b>70.3</b>	55.3-87.1	66.3	47.1-85.7	= 11, <0, >1 = 11, <1, >0	1.2 vs. 0.8 1.2 vs. 2.4
		7	27.6	10.1-40.8	82.9	59.9-98.9	77.0	62.0-90.2	<b>71.8</b>	55.3-87.1	69.0	52.6-85.7	= 5, <0, >2 = 7, <0, >0 = 7, <0, >0	1.2 vs. 0.5 1.2 vs. 0.8 1.2 vs. 2.4
	North (supportive)	4	24.6	12.0-34.0	-	-	82.7	76.0-93.8	<b>76.2</b>	68.8-85.4	70.6	63.2-83.3	= 4, <0, >0 = 4, <0, >0	1.2 vs. 0.8 1.2 vs. 2.4
		1	29.4	-	80.4	-	76.0	-	<b>68.8</b>	-	63.2	-	= 1, <0, >0	1.2 vs. 0.5
	South (supportive)	2	41.6	29.6-53.5	90.6	84.9-96.3	80.5	64.7-96.3	<b>76.7</b>	67.3-86.0	73.8	64.4-83.2	= 1, <0, >1 = 1, <0, >1 = 2, <0, >0	1.2 vs. 0.5 1.2 vs. 0.8 1.2 vs. 2.4
	All 3 EU regulatory zones	18	29.0	10.1-53.5	-	-	77.6	58.8-96.3	<b>72.3</b>	55.3-87.1	68.1	47.1-85.7	= 16, <0, >2 = 17, <1, >0	1.2 vs. 0.8 1.2 vs. 2.4
		10	30.5	10.1-53.5	84.2	59.6-98.9	77.6	62.0-96.3	<b>72.5</b>	55.3-87.1	69.4	52.6-85.7	= 7, <0, >3 = 9, <0, >1 = 10, <0, >0	1.2 vs. 0.5 1.2 vs. 0.8 1.2 vs. 2.4

**USE003 – PRL OD75 on BRSNW – SOUTH-EAST EPPO CLIMATIC ZONE (major use)**

For submission as PGR in Hungary, Romania and Slovakia, with a single Autumn application on winter oilseed rape, the justification of the minimum effective dose rate of PRL OD75 is based on the efficacy results of eight reliable trials carried out in Hungary, Romania and Slovakia. All trials were implemented in countries belonging to the South-East EPPO zone.

**Table 3.2-13: USE003 - Minimum Effective Dose - Distribution of efficacy trials with PRL OD75 applied during the Autumn season on winter oilseed rape - South-East EPPO climatic zone**

Target	EPPO climatic zone	European Regulatory zone	Country	Number of trials per year*		TOTAL (valid)	TOTAL (valid)
				2020	2021		
PGR (Plant Growth Regulator)	South-East	Central	Hungary	2		2	8
			Romania	3		3	
			Slovakia	2	1	3	
	<b>TOTAL South-East EPPO climatic zone</b>			<b>7</b>	<b>1</b>	<b>8</b>	<b>8</b>

\*Years 2020 and 2021: application in Autumn 2019 and Autumn 2020, respectively.

Out of the 8 Hungarian, Romanian and Slovakian trials, a clear dose rate response is observed with the test product PRL OD75, both between 0.5 L/ha (0.42N) and 1.2 L/ha (full N) compared only in 1 trial and between 0.8 L/ha (0.67N) and 1.2 L/ha (full N) in all 8 trials.

The differences in plant heights between the proposed dose rate of 1.2 L/ha and the two lower dose rates of 0.5 L/ha and of 0.8 L/ha are statistically significant in 1 out of 1 trial and in 4 out of 8 trials, respectively.

The application at the double dose rate (2.4 L/ha) allowed to further reduce the plant height when compared to the proposed single dose rate of 1.2 L/ha, statistically significant in 4 out of 8 trials. Nevertheless, the dose rate of 1.2 L/ha provided satisfactory plant reduction and could be considered as the justified dose rate for the cMSs of the South-East EPPO zone.

Based on the efficacy results of eight reliable trials, the minimum and optimum dose rate of 1.2 L/ha is therefore justified for the approval of the use of PRL OD75 in a single Autumn application on winter oilseed rape, for which the PGR activity of the test product is claimed in Hungary, Romania and Slovakia.

**Overall conclusions – Minimum Effective Dose – PRL OD75 as PGR on BRSNW**

The minimum effective dose rate of PRL OD75 as plant growth regulator applied in Autumn on winter oilseed rape is justified on a wide and representative agro-climatic conditions for the EU countries of the Central Regulatory zone where the dossier is submitted for registration.

Based on the most relevant assessed parameter, i.e. the plant height measured at the end of the growing period before the winter, in a total of 35 reliable trials, it is concluded that the unique proposed dose rate of 1.2 L/ha for PRL OD75 is justified as the optimum to be used in Autumn at the crop growth stages BBCH 12-18, in the three EPPO zones concerned with this submission.

Therefore, an unique dose rate of 1.2 L/ha is proposed as the minimum effective dose rate for PRL OD75, when used as PGR in Autumn on winter oilseed rape, in all cMSs concerned with this submission, in the North-East EPPO zone (Poland), in the Maritime EPPO zone (Austria, the Czech Republic and Germany) and in the South-East EPPO zone (Hungary, Romania and Slovakia)

**Table 3.2-14: USE003 – MED - Efficacy (% relative to the untreated) of PRL OD75 applied as PGR in Autumn on winter oilseed rape in the Maritime EPPO climatic zone – Plant height (cm) assessed at 30-63 days after the application, at the end of the growing period and just before the winter.**

- For approvals at 1.2 L/ha in cMSs of the South-East EPPO zone (Hungary, Romania and Slovakia)

EPPO zone	EU regulatory zone	Number of trials	Untreated PLANT HEIGHT (cm)		Plant height - % relative to the untreated								Stat. Anal.	Comparison
					Test product - PRL OD75									
			Mean	Min & Max	0.5 L/ha (0.42 N)		0.8 L/ha (0.67 N)		1.2 L/ha (Full 1 N)		2.4 L/ha (2 N)			
South-East	Central	8	31.4	13.8-43.3	-	-	83.4	62.4-96.5	<b>75.6</b>	61.9-94.5	65.0	54.5-77.5	= 4, < 0, > 4 = 4, < 4, > 0	1.2 vs. 0.8 1.2 vs. 2.4
		1	31.7	-	89.7	-	81.9	-	<b>69.2</b>	-	60.9	-	= 0, < 0, > 1 = 0, < 0, > 1 = 0, < 1, > 0	1.2 vs. 0.5 1.2 vs. 0.8 1.2 vs. 2.4

Comments of zRMS:	<p><b><u>Minimum effective dose</u></b></p> <p>The identification of the minimum effective dose of <b>PRL OD75, Hingios 75 OD, chemical active substance: Prohexadione-calcium 75 g/L,(7,28%)</b> was conducted in 35 trials, in winter oilseed rape in North-East EPPO zone (Poland), in the Maritime EPPO zone (Austria, the Czech Republic and Germany) and in the South-East EPPO zone (Hungary, Romania and Slovakia).</p> <p>The identification of the minimum effective dose of <b>PRL OD75, Hingios 75 OD</b> was assessed at various doses: 0.5-0.8-1.2 L/ha. .</p> <p>The best, optimal effects of shortening the winter oilseed rape plants were obtained after applying a dose of 1,2 L/ ha of tested product at BBCH 12-18. The differences in plant heights between the proposed dose rate of 1.2 L/ha and the two lower dose rates of 0.5 L/ha and of 0.8 L/ha were statistically significant</p> <p><b>The minimum effective dose of PRL OD75, Hingios 75 OD, chemical active substance: Prohexadione-calcium 75 g/L,(7,28%) is 1,2 L/ha in winter oilseed rape applied at BBCH 12-18.</b></p> <p><b>The results indicate a dose appropriately selected for use, and this dose is consistent with the GAP table and proposed label.</b></p>
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### 3.2.3 Efficacy tests (KCP 6.2)

The evaluation will be presented in accordance with the proposed USE numbering, which is based on the proposed GAP.

#### Methodology

Methodology used in the efficacy trials is shown per EPPO zone in Tables 3.2-14.

The testing facilities responsible for the conduct of the trials were the development teams of the country subsidiary organisations of Bayer CropScience and external testing organisations. All these organizations were officially recognized by the competent authorities to be able to carry out field registration trials in accordance with the principles of GEP. They are listed under point 3.7 and link to the European Certibase is included in the table available under the same point.

All efficacy trials submitted to justify the effectiveness and the minimum effective dose rate of the test product PRL OD75 are conducted under GEP. They were designed, conducted and reported in accordance with general EPPO standards, PP1/152(4) on *Design and analysis*, PP1/181(4) on trial reporting, PP1/135(4) on phytotoxicity assessment and PP1/225(2) on minimum effective dose finding. Moreover, the specific EPPO standard **PP1/153(3)** “*Control of lodging and growth regulation in brassica oil crops*” was followed in all efficacy trials.

Acceptable deviations from EPPO requirements or from the proposed use patterns (for the test product and for the reference products), with reasonable justifications of the rejection or of the use of data in the dossier, were already presented previously in this BAD at the point “Compliance with the Uniform Principles” of the introduction chapter.

Trials were established following a randomised complete block design, in accordance with EPPO standard PP1/152 “*Design and analysis of efficacy evaluation trials*”. Plot size and number of replicates were compliant to the recommended minimum plot size of at least 12m<sup>2</sup> and implemented in 4 replicates, according to the EPPO standard PP1/153(3). All trials were carried out in farmer’s field or experimental farm conditions on well established crop.

The test product PRL OD75 and the reference products were applied at the same timing and in accordance with the proposed method of use (test product, foliar spray) or registered method of use (reference product, foliar spray). They were applied during the Autumn seasons 2019 and 2020, on winter oilseed rape crop at the major growth stages from BBCH 14 to BBCH 18, but depending on crop emergence heterogeneity in field trials, encompassing the crop growth stages BBCH 12-18 (up to BBCH 19 in 1 trial).

Depending on the used application equipment, the test product and the reference products were applied using from 150 L/ha to 300 L/ha of slurry solution (mainly 200-300 L/ha).

In accordance with the recommendations of the specific EPPO standard PP1/153(3), the efficacy of the test product PRL OD75, applied in Autumn to improve crop winter hardiness, is evaluated on the results obtained on the two main assessed parameters for this Autumn application, the **plant height** at the end of the growing period (just before the winter) and the **crop winter survival** in early spring (after the winter period and at the restart of the growing period). Additionally and not recommended in the EPPO standard PP1/153(3), the **plant height** at the end of the winter period in early spring and at the restart of the plant growth is included in the core evaluation to confirm the effectiveness of PRL OD75.

**Table 3.2-15: Details on trial methodology – North-East EPPO zone (USE001) – total of 13 trials, with 9 trials of the N-E EPPO zone + 4 supportive trials of the Maritime EPPO zone**

<b>EPPO standards</b>	General standards	PP1/135(4), PP1/152(4), PP1/181(4), PP1/225(2)
	Specific standard	PP1/153(3)
<b>Experimental design</b>	Plot design	RCB Randomized Complete Block design (13 trials)
	Plot size	15-19.5m <sup>2</sup> (2 trials), 20-25m <sup>2</sup> (6 trials), 30-32m <sup>2</sup> (5 trials)
	No. of replications	4 (13 trials)
<b>Crop</b>	Crop	Winter oilseed rape (BRSNW) - 13 trials
	Varieties (Trials from POL, + LVA, LTU, + CZE)	6 Polish trials: Bazalt (2), DK Exception (1), DK Excited (1), DK Extime (2) 2 supportive Latvian trials: Mercedes (1), Phantom (1) 1 supportive Lithuanian trial: DK Expertise (1) 4 supportive Czech trials: Dariot (1), DK Excited (1), DK Exotter (1), PT242 (1)
	Sowing period	Second half of August (from the 18 <sup>th</sup> ) - 13 trials
<b>Application</b>	Crop stage at appl.	Major: from BBCH 14 to BBCH 18 – 13 trials Minimum & Maximum : BBCH 12-13 (4 trials) & BBCH 18-19 (4 trials)
	Timing	From September 19 <sup>th</sup> to October 8 <sup>th</sup> - 13 trials
	Number of appl.	1 application – 13 trials
	Spray volumes	200-300 L/ha – 13 trials
<b>Assessment</b>	Assessment types	<u>Efficacy</u> : only for relevant assessments - plant height measured from the ground to the top of the canopy and assessed at five randomly chosen places (areas, spots) in each plot. Corresponding calculated efficacy (% relative to the untreated) – 13 trials - crop winter survival, with the number of plants assessed on a total of 10m of row, in all trials on 5x 2m row – validated in 11 out of 12 assessed trials. <u>Crop safety</u> : general phytotoxicity (%PHYGEN) on the whole plot – 13 trials <u>Seed yield, seed quality and propagation tests</u> (in a total of 6 trials with the application on Autumn 2019 and the harvest on Summer 2020): - seed yield at standard 9% moisture, for harvested surface of 15m <sup>2</sup> (2) or 19-21.6m <sup>2</sup> (4), depending on the harvest equipment, - seed quality parameters: Oil content (3), TKW (5), Protein content (1) - seed propagation test (3)
	Assessment dates	<u>Efficacy</u> : only for relevant assessments - plant height: at the end of the growing period and just before the winter, at 26-69 days after the application, with an assessment timing from half October to beginning of December (mostly in November) -13 trials - plant height: additional (non EPPO) at the restart of the growing period next Spring, and just after the winter, at 153-208 days after the application, with an assessment timing from end of February to beginning of April – 10 trials - crop winter survival: post winter assessment in early next spring, at 153-208 days after the application, with an assessment timing from end of February to beginning of April – 11 trials <u>Crop safety</u> : all occasions, mostly at efficacy assessment timings <u>Yield</u> : at harvest crop growth stage, from July 18 <sup>th</sup> to August 1 <sup>th</sup> <u>Seed quality analyses and propagation tests</u> : post harvest
<b>Other relevant information</b>	Soil type	Clay (3), Clay Loam (1), Gravelly Clay (2), Loam (3), Sandy Clay (2), Silty Clay (1), not reported (1)
	Site type	Field (13 trials)

**Table 3.2-15 continued: Details on trial methodology – Maritime EPPO zone (USE002) – 18 trials**

<b>EPPO standards</b>	General standards	PP1/135(4), PP1/152(4), PP1/181(4), PP1/225(2)
	Specific standard	PP1/153(3)
<b>Experimental design</b>	Plot design	RCB Randomized Complete Block design (9 trials)
	Plot size	20-29.7m <sup>2</sup> (6 trials), 30-36m <sup>2</sup> (12 trials)
	No. of replications	4 (18 trials)
<b>Crop</b>	Crop	Winter oilseed rape (BRSNW) - 18 trials
	Varieties (Trials from CZE, DEU, UK + DNK, SWE, + FRA)	11 Czech, German and UK trials: Avatar (1), Campus (1), DK Excited (1), DK Exotter (1), DK Expansion (1), DK Platinum (1), ES Imperio (1), PT242 (1), Ragt Muzzical (1), Zakari CS (2) 3 supportive Danish trials: Crome (1), DK Exclaim (2) 1 supportive Swedish trial: Dariot (1) 2 supportive French trials: Arome (1), Aspect (1)
	Sowing period	At the earliest on the 07 <sup>th</sup> of August (1 French trial) to the latest on the 08 <sup>th</sup> of September (1 German trial), other from mid August (from the 18 <sup>th</sup> , 16 trials)
<b>Application</b>	Crop stage at appl.	Major: from BBCH 14 to BBCH 18 – 18 trials Minimum & Maximum : BBCH 12-13 (7 trials) & BBCH 18 (7 trials)
	Timing	From September 18 <sup>th</sup> to October 19 <sup>th</sup> - 18 trials
	Number of appl.	1 application – 18 trials
	Spray volumes	150-300 L/ha – 18 trials
<b>Assessment</b>	Assessment types	<u>Efficacy</u> : only for relevant assessments - plant height measured from the ground to the top of the canopy and assessed at five randomly chosen places (spots) in each plot (16 trials) or on 10-20 plants in each plot (2 trials). Corresponding calculated efficacy (% relative to the untreated) – 18 trials - crop winter survival, with the number of plants assessed on a total of 1m <sup>2</sup> (2 trials), of 1.25m <sup>2</sup> (2 trials) or of 10m of row, with 5x 2m row (9 trials) or 10x 1m row (1 trial) – validated in 15 out of 18 assessed trials <u>Plant safety</u> : general phytotoxicity (%PHYGEN) on the whole plot – 18 trials <u>Seed yield, seed quality and propagation tests</u> (in a total of 7 trials with application on Autumn 2019 and the harvest on Summer 2020) - seed yield at standard 9% moisture, for harvested surface of 15-18m <sup>2</sup> (3), 20-25m <sup>2</sup> (3) or 30m <sup>2</sup> (1), depending on the harvest equipment, - seed quality parameters: Oil content (7), Protein content (3), TKW (7), - seed propagation test (7)
	Assessment dates	<u>Efficacy</u> : only for relevant assessments - plant height: at the end of the growing period and just before the winter, at 26-62 days after the application, with an assessment timing from half October to beginning of December (mostly in November, except in Danish and Swedish trials assessed in the second half of October) – 18 trials - plant height: additional (non EPPO) at the restart of the growing period next Spring, and just after the winter, at 134-196 days after the application, with an assessment timing from end of February to beginning of April (mostly on March) – 16 trials - crop winter survival: post winter assessment in early next spring, at 139-196 days after the application, with an assessment timing from end of February to beginning of April (mostly on March) – 15 validated trials <u>Plant safety</u> : all occasions, mostly at efficacy assessment timings <u>Yield</u> : at harvest crop growth stage, from July 16 <sup>th</sup> to August 6 <sup>th</sup>

		<u>Seed quality analyses and propagation tests: post harvest</u>
<b>Other relevant information</b>	Soil type	Clay (1), Clay Loam (1), Loam (2), Loamy Clay (1), Loamy Sand (3), Sandy Clay (2), Sandy Loam (4), Silt Loam (1), not reported (3)
	Site type	Field (18 trials)

**Table 3.2-15 continued: Details on trial methodology – South-East EPPO zone (USE003) – 8 trials**

<b>EPPO standards</b>	General standards	PP1/135(4), PP1/152(4), PP1/181(4), PP1/225(2)
	Specific standard	PP1/153(3)
<b>Experimental design</b>	Plot design	RCB Randomized Complete Block design (8 trials)
	Plot size	20-22.5m <sup>2</sup> (2 trials), 30m <sup>2</sup> (5 trials), 40.5m <sup>2</sup> (1 trial)
	No. of replications	4 (8 trials)
<b>Crop</b>	Crop	Winter oilseed rape (BRSNW) - 8 trials
	Varieties (Trials from HUN, ROU, SVK)	8 Hungarian, Romanian and Slovakian trials: Bonanza (1), DK Exception (1), DK Excited (1), DK Exstorm (1), InV1022 (1), PT225 (1), PT234 (1), Sergio (1)
	Sowing period	From the second half of August (from the 19th, 5 trials) up to the first week of September (up to the 8 <sup>th</sup> , 3 trials)
<b>Application</b>	Crop stage at appl.	Major: from BBCH 14 to BBCH 18 – 8 trials Minimum & Maximum : BBCH 12-13 (3 trials) & BBCH 18 (3 trials)
	Timing	From September 16 <sup>th</sup> to November 8 <sup>th</sup> - 8 trials
	Number of appl.	1 application – 8 trials
	Spray volumes	200-300 L/ha – 8 trials
<b>Assessment</b>	Assessment types	<u>Efficacy</u> : only for relevant assessments - plant height measured from the ground to the top of the canopy and assessed at five randomly chosen places (areas, spots) in each plot (4 trials) or on 5-10 plants in each plot (4 trials). Corresponding calculated efficacy (% relative to the untreated) – 8 trials - crop winter survival, with the number of plants assessed on a total of 10m of row, in all trials on 5x 2m row – 8 trials. <u>Crop safety</u> : general phytotoxicity (%PHYGEN) on the whole plot – 8 trials <u>Seed yield, seed quality and propagation tests</u> (in a total of 7 trials with the application on Autumn 2019 and the harvest on Summer 2020) - seed yield at standard 9% moisture, for harvested surface of 15m <sup>2</sup> (3), 20m <sup>2</sup> (2) or 30m <sup>2</sup> (2), depending on the harvest equipment, - seed quality parameters: Oil content (7), Protein content (2), TKW (7), - seed propagation test (7)
	Assessment dates	<u>Efficacy</u> : only for relevant assessments - plant height: at the end of the growing season and just before the winter, at 30-63 days after the application, with an assessment timing from half October to beginning of December (mostly in November) – 8 trials - plant height: additional (non EPPO) at the restart of the growing period next Spring, and just after the winter, at 132-211 days after the application, with an assessment timing from beginning of March up to mid of April - crop winter survival: post winter assessment in early next spring at 132-211 days after the application, with an assessment timing from beginning of March to mid of April – 8 trials <u>Crop safety</u> : all occasions, mostly at efficacy assessment timings <u>Yield</u> : at harvest crop growth stage, from June 12 <sup>th</sup> to July 28 <sup>th</sup> <u>Seed quality analyses and propagation tests</u> : post harvest
<b>Other relevant</b>	Soil type	Clay (2), Clay Loam (2), Loam (2), Loamy Sand (1), Sandy Clay (1)

<b>information</b>	Site type	Field (8 trials)
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The **plant height** was measured from the ground to the top of the canopy (using mostly a sheet of expanded polystyrene on the top), assessed on at least 5 places (reported areas or spots) or 5 plants (up to 10 plants). In all cases, the assessments were made at least on 5 observations per plot, at least twice, either before the winter with an assessment interval from 26 to 69 DAA (days after application) and after the winter with the first assessment in early next spring, with an interval from 132 to 211 DAA.

When considering the plant height reduction, the validation of the trial is notably based on a plant height reduction before the winter of minimum **10%** obtained at the most relevant assessment interval at least with one of the two reference products. One acceptable deviation was edited for one Polish trial where the plant height reduction was only of 6.8%. This trial is maintained in the trial set to support the use in Poland, being sited in a specific production region of Poland (Donoslaskie region).

The **crop winter survival** was measured counting the number of plants either on a total of minimum 10 meters of row per plot (on 5 x 2 m of row or 10 x 1 m of row) or at least on a total of one square meter per plot (on 4-5 x 0.25m<sup>2</sup>), made with an assessment interval from 132 to 211 DAA. Considering the different assessment methods used among trials and to simplify the reading, data are presented in the core document with the compute calculated number of survival plants per square meter (plants / m<sup>2</sup>).

Efficacy data are presented for each use (i.e., the three concerned EPPO climatic zones) as % relative to the untreated control and in comparison to the reference products.

Seed yield at harvest crop stage was reported for a total of 18 out of the 20 efficacy trials applied in Autumn 2019 and harvested in Summer 2020. Two trials were not harvested for a valid reason, either farmer cover sprayed with an herbicide or the crop was damaged by heavy rain just before the harvest. Trials applied in Autumn 2020 should be still harvested in Summer 2021, then after the submission of the dossier. The requirement of the EPPO standard PP1/153(3) for a harvested surface of minimum 20m<sup>2</sup> was respected in the half of harvested trials (20-30m<sup>2</sup> harvested), whereas the harvested surface was from 15 to 19m<sup>2</sup> in the second half of the trials, which is acceptable (max. coefficient of variation of 8.5). Due to the absence of strong cold winter periods, there was no significant effect observed on the crop winter survival which could affect the seed yield. Therefore, the applicant states that the effect on the seed yield could only be considered as a possible adverse effect to the crop and data are therefore only presented in the corresponding Chapter 3.4.2, evaluating the possible adverse effects on the yield of the treated crop.

Besides the seed yield, other adverse effects of the product on winter oilseed rape were assessed such as the phytotoxic symptoms (%PHYGEN) in all 35 efficacy trials, whereas the seed quality analysis according to the thousand seed weight (TKW), the seed oil content (OILCON), the seed protein content (PROCON) and finally the test of germination of seeds (propagation test) were measured in some harvested trials.

The results will be presented in Chapters 3.4.1 (crop safety), 3.4.3 (seed quality parameters) and 3.4.5 (propagation tests).

Comments of zRMS:	<p><b><u>Methodology II</u></b>                  The applicant presents 35 trials carried out in accordance with the reports. Total of 35 trials investigating the effectiveness of product <b>PRL OD75, Hingios 75 OD, chemical active substance: Prohexadione-calcium 75 g/L,(7,28%)</b></p>
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	<p><b>in dose 1,2 L/ha in winter oilseed rape, applied once at BBCH 12-18</b> in order to reduce plant height and growth as well as improving wintering. Those trials were undertaken in winter oilseed rape in 2020 and 2021.</p> <p>The 23 trials were located in the North-Eastern EPPO zone and neighboring countries ( in Poland 6 trials).</p> <p>The more than required number of experiments on winter oilseed rape were carried out (23) in two vegetation seasons 2020 and 2021. The list of experiments is presented in the table 3.2-17-27.</p> <p>The required number of experiments on winter oilseed rape were carried out to evaluate the effectiveness of <b>PRL OD75, Hingios 75 OD</b>. The experiments in winter oilseed rape were performed in the two vegetation seasons which is sufficient and justified.</p> <p>All trials were conducted in the field conditions that took into account a variety of environmental and agrotechnical conditions. The crop safety and efficacy of <b>PRL OD75, Hingios 75 OD</b>, product name(s) has been tested on a different varieties of winter oilseed rape. The localizations of the experiments were appropriate and produced representative results.</p> <p><b>The required number of experiments on winter oilseed rape were carried out to evaluate the effectiveness of product: PRL OD75, Hingios 75 OD, chemical active substance: Prohexadione-calcium 75 g/L, (7,28%) in dose 1,2 L/ha in winter oilseed rape, applied once at BBCH 12-18 growth stage in order to reduce plant height and growth as well as improving wintering.</b></p> <p><b>The methods used in the trials were appropriate and trials submitted for evaluation are satisfactorily representative. Experiments complied with GEP requirements, while the efficacy evaluation methods agreed with EPPO guidelines, GAP and Uniform Principles.</b></p>
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### Efficacy results

Efficacy was tested under a wide range of representative European varieties, agronomical and climatic conditions for winter oilseed rape, to fully challenge the product in typical regions of oilseed rape cropping for submission in cMSs of the EU Central regulatory zone.

### General remarks:

- In regard to the untreated plots, there could be a high variation in assessed crop heights between trials implemented in same country and same year but in different oilseed rape cropping regions. These high variations in crop growth and crop development are mostly due to specific agronomical and/or climatic conditions. Concerning the agronomical conditions, previous crop capturing nitrogen could induce faster growth of oilseed rape plants. About the impact of climatic conditions in some regions of the concerned countries, heavy rains reduced the amount of air in the soil, slowing down the growth of oilseed rape plants. All trials are therefore validated for the dossier, allowing to evaluate the performance of PRL OD75 in wide agro-climatic situations met in the cMSs.
- As the two winter periods (winter 2019-2020 and winter 2020-2021) were mostly not strong enough to impact significantly the crop stand and winter survival, notably because snow protected the crop during the coldest period, the effectiveness of PRL OD75 is mainly evaluated

for the most relevant assessed parameter, which is the plant height assessed at the end of the growing season (just before the winter). Therefore, the two assessments made at the restart of crop growth in early spring, i.e. the plant height (not required by the EPPO 1/153(3) and the crop winter survival, are only briefly evaluated. They are considered less relevant, notably because trial conditions were not favourable.

**USE001 – PRL OD75 on BRSNW – NORTH-EAST EPPO CLIMATIC ZONE (major use)**

For submission in Poland, the evaluation of the effectiveness as PGR of the test product PRL OD75, when applied in accordance with the proposed use pattern, is based on the efficacy results of 13 reliable trials, with scheduled single application during the Autumn periods 2019 and 2020 (harvest in 2020 and 2021, respectively), in six Polish trials supported with three Latvian and Lithuanian trials and four Czech trials. All those trials are considered valid to support the claimed use for submission in Poland. The distribution across EPPO zones, European regulatory zones, countries and years is shown in Table 3.2-16.

**Table 3.2-16: USE001 - Distribution of efficacy trials with PRL OD75 applied during the Autumn season on winter oilseed rape -North-East EPPO climatic zone**

Target	EPPO climatic zone	European Regulatory zone	Country	Number of trials per year*		TOTAL (valid)	TOTAL (valid)	
				2020	2021			
PGR (Plant Growth Regulator)	North-East	Central	Poland	3	3	6	6	
		Northern (supportive)	Latvia	1	1	2	3	
			Lithuania	1		1		
	<b>TOTAL North-East EPPO climatic zone</b>				<b>5</b>	<b>4</b>	<b>9</b>	<b>9</b>
	Maritime (supportive)	Central	Czech Republic (supportive)	2	2	4	4	
	<b>TOTAL Maritime EPPO climatic zone</b>				<b>2</b>	<b>2</b>	<b>4</b>	<b>4</b>
<b>TOTAL two EPPO climatic zones</b>				<b>7</b>	<b>6</b>	<b>13</b>	<b>13</b>	

\*Years 2020 and 2021: application in Autumn 2019 and Autumn 2020, respectively.

**Assessment of the plant height just before the winter (at the end of the growing period)**

Overall tested conditions of these thirteen reliable trials, the test product PRL OD75, applied in accordance with the proposed use pattern, showed excellent and sufficient plant height reduction of winter oilseed rape plant, when assessed at the end of the growing period, at 26-69 days after the single Autumn application.

It is noticeable that considering the mean of untreated plots, the lower measured plant heights assessed in 2 Polish trials (17.7cm and 18.3cm) were quite different than plant height measured in the other Polish trials (mainly from 35cm). These 2 trials were conducted in the Donoslaskie region of Poland, under heavy rains during the Autumn period which caused the slow development of the crop after the application in such trial conditions.

Especially, the two reference products mostly showed the expected plant height reduction, except in 2 Polish trials, where the scarce PGR effects were explained by the slow development of the vegetation after the application, leading to a weak progression of the plant height at assessment times.

Even if marginal, the applicant considers that data of these two Polish trials are quite representative of some local Polish agro-climatic conditions, and they are therefore considered valid for the evaluation of the effectiveness of PRL OD75, which is acceptable.

Out of all six Polish trials, the mean plant height reduction with the test product PRL OD75 at 1.2 L/ha (mean of 79.7% relative to untreated) is either comparable to the PGR effect obtained with the reference product Ref. 1 (mean of 78.6% relative to untreated) or slightly better than the lower plant height reduction observed with the reference product Ref. 2 (mean of 82.5% relative to untreated). Differences in plant height between PRL OD75 and Ref. 1 are statistically significant in 1 out of 6 Polish trials, in favour of the reference product. Comparing PRL OD75 with Ref. 2, mean plant height is different, statistically significant in 2 out of 6 trials, 1 in favour of the reference product Ref. 2 and 1 in favour of the test product PRL OD75.

This global trend of Polish trials is mostly confirmed in the plant height results of the three supportive Latvian and Lithuanian trials, notably in the two Latvian trials applied at the BBCH 18. Overall the 3 reliable trials, the mean plant height reduction with PRL OD75 at 1.2 L/ha (64.6% relative to untreated) is lower than the effect obtained with the reference product Ref. 1 (mean of 57.3% relative to untreated) and better than the PGR effect with the reference product Ref. 2 (mean of 78.1% relative to untreated). Differences in plant height between PRL OD75 and Ref. 1 are statistically significant in 2 out of 3 trials, both in favour of the reference product, in the two Latvian trials applied at BBCH 18. Particularly in 1 out of these 2 trials, PRL OD75 showed an excellent effect on the plant height (mean of 46.4% relative to untreated), significantly better than the reference product Ref. 2.

In the four supportive Czech trials sited close to the Polish border, the PGR effects with PRL OD75 applied at 1.2 L/ha (mean of 78.6% relative to untreated) are comparable to those obtained in the Polish trials. However in all trials, the two reference products, Ref. 1 (mean of 60.0% relative to untreated) and Ref. 2 (mean of 70.5% relative to untreated), showed more pronounced reductions of plant height than the test product PRL OD75 (mean of 78.6% relative to untreated), statistically significant in 1 out of 4 trials.

Overall the 13 validated trials, the test product PRL OD75 at 1.2 L/ha (mean of 75.8% relative to untreated) reduced the plant height in all trials, with a calculated mean reduction of 7.6cm, which is statistically significant in 8 out of 13 trials, when compared to the untreated (mean plant height of 31.3cm).

The reference product Ref. 1 (mean of 67.9% relative to untreated) showed better reduction of the plant height (mean reduction of 10.0cm) than the PRL OD75, statistically significant in 4 out of 13 trials.

When compared to the reference product Ref. 2 (mean of 77.8% relative to untreated, which corresponds to a mean reduction of the plant height of 7.0cm), the differences in plant height with PRL OD75 are statistically significant in 4 out of 13 trials, 2 in favour of the reference product Ref. 2 and 2 in favour of the test product PRL OD75.

**Table 3.2-17: USE001 – Efficacy (% relative to the untreated) of PRL OD75 applied at 1.2 L/ha as PGR in Autumn on winter oilseed rape in the North-East EPPO climatic zone – Plant height (cm) assessed at 26-69 days after the application, at the end of the growing period and just before the winter.**

- For approval at 1.2 L/ha in cMS of the North-East EPPO zone (Poland)

EPPO zone	European regulatory zone	Number of trials	Untreated (UTC)		Plant height - % relative to the untreated						Stat. Anal.	Comparison
					PLANT HEIGHT (cm)		Test product		Reference products			
			Mean	Min & Max	PRL OD75		Ref. 1		Ref. 2			
					1.2 L/ha		1 L/ha		1.2 L/ha			
Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max			
North-East	Central	6	31.2	17.7-40.5	<b>79.7</b>	66.7-93.2	78.6	51.9-93.2	82.5	55.5-99.7	= 3, < 0, > 3 = 5, < 1, > 0 = 4, < 1, > 1	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2
	North (supportive)	3	32.2	24.1-36.8	<b>64.6</b>	46.4-83.1	57.3	36.6-67.7	78.1	66.6-91.7	= 0, < 0, > 3 = 1, < 2, > 0 = 2, < 0, > 1	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2
	All 2 EU regulatory zones	9	31.5	17.7-40.5	<b>74.6</b>	46.4-93.2	71.5	36.6-93.2	81.1	55.5-99.7	= 3, < 0, > 6 = 6, < 3, > 0 = 6, < 1, > 2	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2
Maritime (supportive)	Central (CZE)	4	30.9	27.2-35.9	<b>78.6</b>	75.2-84.2	60.0	41.7-77.9	70.5	53.6-77.7	= 2, < 0, > 2 = 3, < 1, > 0 = 3, < 1, > 0	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2
All 2 EPPO zones	All 2 EU regulatory zones	13	31.3	17.7-40.5	<b>75.8</b>	46.4-93.2	67.9	36.6-93.2	77.8	53.6-99.7	= 5, < 0, > 8 = 9, < 4, > 0 = 9, < 2, > 2	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2

Ref. 1 - mepiquat-chloride+metconazole SL240 (210+30 g/L) applied at 1 L/ha

Ref. 2 - prothioconazole+tebuconazole EC240 (80+160 g/L) applied at 1.2 L/ha

Based on the results of the PGR effect assessed on the plant height at the end of the growing period before the winter in 9 reliable North-East trials supported with 4 Maritime (Czech) reliable trials, it is concluded that the test product PRL OD75 is mainly inferior to Ref. 1 (based on mepiquat-chloride+metconazole SL240) and mostly comparable to Ref. 2 (based on prothioconazole+tebuconazole EC240), when applied in accordance with the proposed use pattern. PRL OD75 at the proposed dose rate of 1.2 L/ha showed an excellent and sufficient reduction of the plant height if applied in a single Autumn application on winter oilseed rape, for which the PGR activity of the test product is claimed in Poland.

#### **Assessment of the plant height just after the winter (at restart of crop growth) – EPPO not required**

Efficacy results based on the not required by the EPPO PP1/153(3) and then additional assessment made on the plant height in early spring, are evaluated in 10 out of the 13 trials, then excluding 3 trials, where:

- either this assessment was not recorded (in 1 Polish and 1 Latvian trials)
- or, due to favourable conditions, the oilseed rape crop was already well developed (about 80cm height) at the assessment timing, then out of the main criteria to select the data, i.e. the crop should be just at the restart of plant growth.

Depending on the trial conditions, this early spring and additional assessment was made from 153 to 208 days after the single Autumn application of products.

It is noticeable that when compared with the assessment made before the winter, a general reduction of the plant height is observed in all plots, untreated and treated, which is explained with the “winter” stunting effect. This impacted the PGR effects obtained with the two reference products, which showed slight residual effects on plant height reduction, with % relative to untreated ranging from 85.7% to 98.9% for Ref. 1 and from 89.1% to 97.4% for Ref. 2.

Out of all four Polish trials, mean plant height reduction with the test product PRL OD75 at 1.2 L/ha is slightly lower than the PGR effect obtained with the two reference products.

This global trend of Polish trials is mostly confirmed in the plant height results of the two supportive Latvian and Lithuanian trials, where the residual PGR effect is more pronounced, with PRL OD75 performing better than the two reference products.

In the four Czech trials trials sited close to the Polish border, the residual PGR effects with PRL OD75 applied at 1.2 L/ha are mostly similar to those of the two reference products.

Overall the 10 validated trials, the test product PRL OD75 at 1.2 L/ha (mean of 91.7% relative to untreated) reduced the plant height of 1.8cm, when compared to the untreated (mean plant height of 21.5cm), which is statistically significant in 1 out of 10 trials.

The reference products, Ref. 1 (mean of 90.9% relative to untreated) and Ref. 2 (mean of 91.7% relative to untreated), showed similar reduction of the plant height (1.9cm and 1.6cm, respectively) to PRL OD75, statistically not significant in all 10 trials.

It is concluded that PRL OD75 showed a good residual PGR effect when assessed on the plant height in early spring, when applied in accordance with the proposed use pattern in a single Autumn application on winter oilseed rape, for which the PGR activity of the test product is claimed in Poland.

This effect is similar to the one obtained with standard products.

**Table 3.2-18: USE001 – Efficacy (% relative to the untreated) of PRL OD75 applied at 1.2 L/ha as PGR in Autumn on winter oilseed rape in the North-East EPPO climatic zone – Plant height (cm) assessed at 153-208 days after the application, at the restart of the growing period at the end of the winter.**

- For approval at 1.2 L/ha in cMS of the North-East EPPO zone (Poland)

EPPO zone	European regulatory zone	Number of trials	Untreated (UTC)		Plant height - % relative to the untreated						Stat. Anal.	Comparison
					PLANT HEIGHT (cm)		Test product		Reference products			
			Mean	Min & Max	PRL OD75		Ref. 1		Ref. 2			
					1.2 L/ha		1 L/ha		1.2 L/ha			
					Mean	Min & Max	Mean	Min & Max	Mean	Min & Max		
North-East	Central	4	26.2	19.6-29.8	<b>96.9</b>	93.4-99.5	94.0	85.7-98.9	94.6	89.1-97.4	= 4, < 0, > 0 = 4, < 0, > 0 = 4, < 0, > 0	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2
	North (supportive)	2	23.2	19.8-26.6	<b>84.3</b>	78.7-89.9	86.5	81.5-91.4	91.3	85.5-97.0	= 1, < 0, > 1 = 2, < 0, > 0 = 2, < 0, > 0	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2
	All 2 EU regulatory zones	6	25.2	19.6-29.8	<b>92.7</b>	78.7-99.5	91.5	81.5-98.9	93.5	85.5-97.4	= 5, < 0, > 1 = 6, < 0, > 0 = 6, < 0, > 0	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2
Maritime (supportive)	Central (CZE)	4	16.0	8.5-25.6	<b>90.4</b>	86.8-95.3	90.1	72.3-100.3	90.7	84.3-95.5	= 4, < 0, > 0 = 4, < 0, > 0 = 4, < 0, > 0	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2
All 2 EPPO zones	All 2 EU regulatory zones	10	21.5	8.5-29.8	<b>91.7</b>	78.7-99.5	90.9	72.3-100.3	92.3	84.3-97.4	= 9, < 0, > 1 = 10, < 0, > 0 = 10, < 0, > 0	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2

Ref. 1 - mepiquat-chloride+metconazole SL240 (210+30 g/L) applied at 1 L/ha

Ref. 2 - prothioconazole+tebuconazole EC240 (80+160 g/L) applied at 1.2 L/ha

### **Assessment of the crop winter survival after the winter (in early next spring)**

Efficacy results based on the crop winter survival in early spring and just at the beginning of crop growth restart after the winter, are evaluated in 11 trials.

Depending on the trial conditions, this early spring assessment was made from 153 to 208 days after the single Autumn application of product.

Since no significant effects on the crop stand were observed at the end of the winter in trials conducted in countries of the same EPPO zone (North-East) of different EU regulatory zones (Central and North) or even of different EPPO zones (North-East and Maritime of the EU Central regulatory zone) considered with this submission in Poland, the applicant considers that it is acceptable that the results are discussed and evaluated on a global level for all 11 validated trials.

Comparing the test product PRL OD75 at 1.2 L/ha (mean of 47.3 plants/m<sup>2</sup>) both with the two reference products, Ref. 1 (mean of 45.7 plants/m<sup>2</sup>) and Ref. 2 (mean of 45.6 plants/m<sup>2</sup>), and to the untreated (mean of 45.9 plants/m<sup>2</sup>), statistically no significant differences were shown in plant density.

When compared to the two standard products, the highest mean effect observed in average of 11 trials with PRL OD75 was positively impacted by the highest effect obtained in a Czech trial, where a high coefficient of variation was calculated and then a quite high heterogeneity should be considered on plant density.

Consequently and in absence of critical winter conditions, overall 7 reliable North-East trials supported with 4 Maritime (Czech) trials, it could be concluded that there were statistically no significant differences between the test product PRL OD75 at 1.2 L/ha, the two reference products and the untreated, when evaluated according to the plant winter survival at the spring restart of the crop growth.

### **USE001 – PRL OD75 on winter oilseed rape – North-East EPPO zone - Conclusions on the Efficacy**

For submission in Poland, the evaluation of the effectiveness as PGR of the test product PRL OD75, when applied in accordance with the proposed use pattern, is based on the efficacy results of 13 reliable trials, with scheduled single application during the Autumn periods 2019 and 2020, in six Polish trials supported with three Latvian and Lithuanian trials and four Czech trials. All those trials are considered valid to support the claimed use for submission in Poland.

The evaluation of the effectiveness of PRL OD75 is based on the main relevant assessed parameter, the measured plant height at the end of the growing period.

Overall tested conditions of these thirteen reliable trials, the test product PRL OD75 applied in accordance with the proposed use pattern, showed excellent plant height reduction (mean reduction of 7.6cm) of winter oilseed rape, when compared to the two reference products, either mepiquat-chloride+metconazole SL240 at 1 L/ha (mean reduction of 10.0cm) or prothioconazole+tebuconazole EC240 at 1.2 L/ha (mean reduction of 7.0cm), for a global mean plant height of 31.3cm in untreated. Difference in plant height between the test product PRL OD75 and untreated is statistically significant in 8 out of 13 trials.

Repeated after the winter in 10 reliable trials, the results confirmed that PRL OD75 showed a good residual reduction of the plant height, similar to the effect obtained with reference products, statistically significant different than the untreated in 1 out of 10 trials.

Nevertheless, the crop stand, both in untreated plots and in treated plots, was not impacted during the concerned smooth winters. Statistically, no significant difference was found in the crop plant survival assessed in early spring, out of 11 reliable trials.

**Table 3.2-19: USE001 – Efficacy (absolute value - number of plants /m<sup>2</sup>) of PRL OD75 applied at 1.2 L/ha as PGR in Autumn on winter oilseed rape in the North-East EPPO climatic zone – Plant winter survival (plants/m<sup>2</sup>) assessed at 153-208 days after the application, at the restart of the growing period.**

- For approval at 1.2 L/ha in cMS of the North-East EPPO zone (Poland)

EPPO zone	European regulatory zone	Number of trials	Untreated (UTC) (Number of plants /m <sup>2</sup> )		Number of plants /m <sup>2</sup>						Stat. Anal.	Comparison
					Test product		Reference products					
			PRL OD75		Ref. 1		Ref. 2					
			1.2 L/ha		1 L/ha		1.2 L/ha					
			Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max		
North-East	Central	4	44.3	19.0-72.1	<b>44.4</b>	19.1-72.2	44.9	19.6-72.1	44.2	19.4-72.1	= 4, < 0, > 0 = 4, < 0, > 0 = 4, < 0, > 0	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2
	North (supportive)	3	33.9	28.1-44.2	<b>34.9</b>	29.7-45.0	33.9	29.1-42.8	33.4	27.3-43.0	= 3, < 0, > 0 = 3, < 0, > 0 = 3, < 0, > 0	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2
	All 2 EU regulatory zones	7	39.8	19.0-72.1	<b>40.3</b>	19.1-72.2	40.2	19.6-72.1	39.6	19.4-72.1	= 7, < 0, > 0 = 7, < 0, > 0 = 7, < 0, > 0	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2
Maritime (supportive)	Central (CZE)	4	56.6	47.0-67.6	<b>59.5</b>	47.2-77.2	55.3	50.2-58.8	56.2	49.4-66.6	= 4, < 0, > 0 = 4, < 0, > 0 = 4, < 0, > 0	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2
All 2 EPPO zones	All 2 EU regulatory zones	11	45.9	19.0-72.1	<b>47.3</b>	19.1-77.2	45.7	19.6-72.1	45.6	19.4-72.1	= 11, < 0, > 0 = 11, < 0, > 0 = 11, < 0, > 0	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2

Ref. 1 - mepiquat-chloride+metconazole SL240 (210+30 g/L) applied at 1 L/ha

Ref. 2 - prothioconazole+tebuconazole EC240 (80+160 g/L) applied at 1.2 L/ha

Based on the plant growth regulator results of thirteen reliable trials carried out in Poland, Latvia, Lithuania and the Czech Republic, the effectiveness of PRL OD75 is therefore proved when applied in accordance with the proposed use pattern on winter oilseed rape, for which the PGR activity of the test product is claimed in Poland.

**USE002 – PRL OD75 on BRSNW – MARITIME EPPO CLIMATIC ZONE (major use)**

For submission in Austria, Germany and the Czech Republic, the evaluation of the effectiveness of the test product PRL OD75, as PGR when applied in accordance with the proposed use pattern, is based on the efficacy results of 18 reliable trials with scheduled single application during the Autumn periods 2019 and 2020 (harvest in 2020 and 2021, respectively), with twelve Czech, German and UK trials supported with four Danish and Swedish trials and two French trials.

All these trials were implemented in countries belonging to the Maritime EPPO zone and they are therefore considered valid to support the claimed use in Austria, Germany and the Czech Republic.

The distribution across European regulatory zones, countries and years is shown in Table 3.2-20.

**Table 3.2-20: USE002 - Distribution of efficacy trials with PRL OD75 applied during the Autumn season on winter oilseed rape - Maritime EPPO climatic zone**

Target	EPPO climatic zone	European Regulatory zone	Country	Number of trials per year*		TOTAL (valid)	TOTAL (valid)
				2020	2021		
PGR (Plant Growth Regulator)	Maritime	Central	Czech Republic	3	3	6	12
			Germany	2	3	5	
			United Kingdom		1	1	
		Northern (supportive)	Denmark	2	1	3	4
			Sweden	1		1	
		Southern (supportive)	France		2	2	2
		<b>TOTAL Maritime EPPO climatic zone</b>				<b>8</b>	<b>10</b>

\*Years 2020 and 2021: application in Autumn 2019 and Autumn 2020, respectively.

**Assessment of the plant height just before the winter (at the end of the growing period)**

Overall tested conditions of these eighteen reliable trials, the test product PRL OD75, applied in accordance with the proposed use pattern, showed excellent and sufficient plant height reduction of winter oilseed rape plant, when assessed at the end of the growing period, at 26-62 days after the single Autumn application.

It is noticeable that considering the mean of untreated plots, the lower measured plant height assessed in 1 Danish trial (12.0cm) and 1 Czech trial (10.1cm) was quite different than plant height measured in the other trials (mostly ranging from 20cm to 40cm).

In the Danish trial, the heavy rains during the Autumn period caused the slow development of the crop in such trial conditions, whereas in the Czech trial the delay of sowing (one week later than the typical sowing period of this area) and the rainy autumn season caused the slowdown of crop growth in this trial.

Finally, the highest measured plant height in the French trial HR21FRAR01MAF1 (53.5cm) is above values measured in the other trials (mainly lower than 40cm) carried out in the Maritime EPPO climatic zone. This French trial was sown in excellent conditions at the beginning of August 2020. The favourable climatic conditions accelerated the crop growth, notably in October 2020.

The two standard products showed expected plant height reduction in the conditions of these 18 trials.

Out of 12 trials carried out in the Czech Republic (6), Germany (5) and the UK (1), PRL OD75 at 1.2 L/ha showed an excellent PGR effect when assessed according to the plant height (mean of 70.3% relative to untreated). This effect is lower than the plant height reduction obtained with the reference product Ref. 1 (mean of 58.3% relative to untreated) and mostly comparable to the PGR effect observed with the reference product Ref. 2 (mean of 68.3% relative to untreated). Differences in plant height between PRL OD75 and the two reference products are statistically significant, in 4 out of 12 trials when compared to Ref. 1 (in favour of the reference product) and in 2 out of 12 trials when compared to Ref. 2 (in favour of the reference product).

This global trend is mostly confirmed in the plant height results of the four supportive Danish and Swedish trials. Overall the 4 reliable trials, the mean plant height with PRL OD75 at 1.2 L/ha (76.2% relative to untreated) is lower than the mean obtained with the reference product Ref. 1 (mean of 64.6% relative to untreated) and comparable to the mean plant height with the reference product Ref. 2 (mean of 77.0% relative to untreated). Differences in plant height are statistically significant in 1 out of 4 trials when compared to Ref. 1 (in favour of the reference product) and in 2 out 4 trials when compared to Ref. 2 (one in favour of the reference product and one in favour of the test product).

The PGR effect of PRL OD75 when assessed according to the plant height is confirmed in the 2 supporting French trials, notably in a trial applied at the BBCH 18, with a mean of 76.7% relative to untreated, which is comparable to the reference product Ref. 1 (mean of 77.4% relative to untreated) and better than the reference product Ref. 2 (mean of 80.0% relative to untreated).

Differences in plant height are statistically either significant in 1 out of 2 trials when compared to Ref. 1 (in favour of the reference product) or not significant in all 2 trials when compared to Ref. 2.

Overall the 18 validated trials, the test product PRL OD75 at 1.2 L/ha (mean of 72.3% relative to untreated) reduced the plant height in all trials, with a mean reduction of 8.0cm, which is statistically significant in 14 out of 18 trials, when compared to the untreated (mean plant height of 29.0cm).

The reference product Ref. 1 (mean of 61.8% relative to untreated) showed better reduction of the plant height (mean reduction of 11.1cm) than PRL OD75, statistically significant in 6 out of 18 trials.

When compared to the reference product Ref. 2 (mean of 71.5% relative to untreated, which corresponds to a mean reduction of the plant height of 8.3cm), the differences in plant height with PRL OD75 are statistically significant in 4 out of 18 trials, 3 in favour of the reference product Ref. 2 and 1 in favour of the test product PRL OD75.

Based on the results of the PGR effect assessed on the plant height at the end of the growing period before the winter in 18 reliable Maritime trials, it is concluded that the test product PRL OD75 is mainly inferior to Ref. 1 (based on mepiquat-chloride+metconazole SL240) and mostly comparable to Ref. 2 (based on prothioconazole+tebuconazole EC240), when applied in accordance with the proposed use pattern.

PRL OD75 at the proposed dose rate of 1.2 L/ha showed an excellent and sufficient reduction of the plant height if applied in a single Autumn application on winter oilseed rape, for which the PGR activity of the test product is claimed in Austria, the Czech Republic and Germany.

**Table 3.2-21: USE002 – Efficacy (% relative to the untreated) of PRL OD75 applied at 1.2 L/ha as PGR in Autumn on winter oilseed rape in the Maritime Eppo climatic zone – Plant height (cm) assessed at 26-62 days after the application, at the end of the growing period and just before the winter.**

- For approval at 1.2 L/ha in cMSs of the Maritime Eppo zone (Austria, the Czech Republic and Germany)

Eppo zone	European regulatory zone	Number of trials	Untreated (UTC)		Plant height - % relative to the untreated						Stat. Anal.	Comparison
					PLANT HEIGHT (cm)		Test product		Reference products			
			Mean	Min & Max	PRL OD75		Ref. 1		Ref. 2			
					1.2 L/ha		1 L/ha		1.2 L/ha			
Maritime	Central	12	28.4	10.1-40.8	<b>70.3</b>	55.3-87.1	58.3	37.8-77.9	68.3	48.7-85.1	= 3, < 0, > 9 = 8, < 4, > 0 = 10, < 2, > 0	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2
	North (supportive)	4	24.6	12.0-34.0	<b>76.2</b>	68.8-85.4	64.6	54.6-70.8	77.0	65.1-83.0	= 1, < 0, > 3 = 3, < 1, > 0 = 2, < 1, > 1	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2
	South (supportive)	2	41.6	29.6-53.5	<b>76.7</b>	67.3-86.0	77.4	75.3-79.4	80.0	73.1-86.9	= 0, < 0, > 2 = 1, < 1, > 0 = 2, < 0, > 0	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2
	All 3 EU regulatory zones	18	29.0	10.1-53.5	<b>72.3</b>	55.3-87.1	61.8	37.8-79.4	71.5	48.7-86.9	= 4, < 0, > 14 = 12, < 6, > 0 = 14, < 3, > 1	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2

Ref. 1 - mepiquat-chloride+metconazole SL240 (210+30 g/L) applied at 1 L/ha

Ref. 2 - prothioconazole+tebuconazole EC240 (80+160 g/L) applied at 1.2 L/ha

### **Assessment of the plant height just after the winter (at restart of crop growth) – EPPO not required**

Efficacy results based on the not required by the EPPO PP1/153(3) and then additional assessment made on the plant height in early spring, are evaluated in 16 out of the 18 trials, then excluding 2 trials where, due to favourable conditions, the oilseed rape crop was already well developed (90-106cm height) at the assessment timing, then out of the main criteria to select the data, i.e. the crop should be just at the restart of plant growth.

Depending on the trial conditions, this early spring and additional assessment was made from 134 to 196 days after the single Autumn application of products.

It is noticeable that when compared with the assessment made before the winter, a general reduction of the plant height is observed in all plots, untreated and treated, which is explained with the “winter” stunting effect. This impacted the residual PGR effects obtained with the two reference products. In few trials one or both reference products showed a plant height almost comparable or slightly higher than the untreated check. Nevertheless, at least one of the two reference products showed a good PGR residual effect in such trial conditions.

Out of 11 trials carried out in the Czech Republic (6), Germany (4) and the UK (1), PRL OD75 at 1.2 L/ha showed a good PGR effect with a mean plant height of 82.4% relative to untreated. This residual PGR effect is comparable to the one obtained with the reference product Ref. 1 (mean of 82.1% relative to untreated) and better than the effect observed with the reference product Ref. 2 (mean of 85.7% relative to untreated).

The good residual PGR effect of PRL OD75 after the winter is confirmed in the four supporting Danish and Swedish trials and in the supportive French trial (applied at the BBCH 18).

Overall the 16 validated trials, the test product PRL OD75 at 1.2 L/ha (mean of 85.5% relative to untreated) reduced the plant height of 3.2cm, when compared to the untreated (mean plant height of 21.8cm), which is statistically significant in 6 out of 16 trials.

The reference product Ref. 1 (mean of 86.4% relative to untreated) showed similar reduction of the plant height (3.0cm) than PRL OD75, whereas Ref. 2 (mean of 90.6% relative to untreated) showed lower residual PGR effect with a mean plant reduction of 2.0cm (impacted by the absence of measured effect in 3 trials (2 nordics and the French)).

It is concluded that PRL OD75 showed a good residual PGR effect when assessed on the plant height in early spring, when applied in accordance with the proposed use pattern in a single Autumn application on winter oilseed rape, for which the PGR activity of the test product is claimed in Austria, the Czech Republic and Germany. The residual PGR effect with PRL OD 75 is similar to or better than the ones obtained with standard products.

**Table 3.2-22: USE002 – Efficacy (% relative to the untreated) of PRL OD75 applied at 1.2 L/ha as PGR in Autumn on winter oilseed rape in the Maritime EPP0 climatic zone – Plant height (cm) assessed at 134-196 days after the application, at the restart of the growing period at the end of the winter.**

- For approval at 1.2 L/ha in cMSs of the Maritime EPP0 zone (Austria, the Czech Republic and Germany)

EPP0 zone	European regulatory zone	Number of trials	Untreated (UTC)		Plant height - % relative to the untreated						Stat. Anal.	Comparison
			PLANT HEIGHT (cm)		Test product		Reference products					
					PRL OD75		Ref. 1		Ref. 2			
			1.2 L/ha		1 L/ha		1.2 L/ha					
			Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max		
Maritime	Central	11	21.5	8.5-37.3	<b>82.4</b>	57.0-95.3	82.1	55.8-100.3	85.7	68.5-95.5	= 6, < 0, > 5 = 9, < 1, > 1 = 10, < 0, > 1	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2
	North (supportive)	4	25.0	14.0-43.3	<b>93.9</b>	90.1-100.0	96.9	88.2-103.6	98.0	93.3-102.9	= 3, < 0, > 1 = 4, < 0, > 0 = 4, < 0, > 0	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2
	South (supportive)	1	11.9	-	<b>85.3</b>	-	90.5	-	114.5	-	= 1, < 0, > 0 = 1, < 0, > 0 = 0, < 0, > 1	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2
	All 3 EU regulatory zones	16	21.8	8.5-43.3	<b>85.5</b>	57.0-100.0	86.4	55.8-103.6	90.6	68.5-114.5	= 10, < 0, > 6 = 14, < 1, > 1 = 14, < 0, > 2	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2

Ref. 1 - mepiquat-chloride+metconazole SL240 (210+30 g/L) applied at 1 L/ha

Ref. 2 - prothioconazole+tebuconazole EC240 (80+160 g/L) applied at 1.2 L/ha

### **Assessment of the crop winter survival after the winter (in early next spring)**

Efficacy results based on the crop winter survival in early spring and just at the beginning of crop growth restart after the winter, are evaluated in 15 trials.

Depending on the trial conditions, this early spring assessment was made from 134 to 196 days after the single Autumn application of product.

Since no significant effects on the crop stand were observed at the end of the winter in trials conducted in countries of the same EPPO zone (Maritime) of different EU regulatory zones (Central, North and South) considered with this submission in Austria, Germany and the Czech Republic, the applicant considers that it is acceptable that the results are discussed and evaluated on a global level for all 15 validated trials.

Comparing the test product PRL OD75 at 1.2 L/ha (mean of 53.4 plants/m<sup>2</sup>) to the two reference products, Ref. 1 (mean of 53.0 plants/m<sup>2</sup>) and Ref. 2 (mean of 53.3 plants/m<sup>2</sup>), and to the untreated (52.3 plants/m<sup>2</sup>), statistically no significant differences were shown in plant density.

Consequently and in absence of critical winter conditions, overall 15 reliable Maritime trials, it could be concluded that there were statistically no significant differences between the test product PRL OD75 at 1.2 L/ha, the two reference products and the untreated, when evaluated according to the plant winter survival at the spring restart of the crop growth.

### **USE002 – PRL OD75 on winter oilseed rape – Maritime EPPO zone - Conclusions on the Efficacy**

For submission in Austria, Germany and the Czech Republic, the evaluation of the effectiveness of the test product PRL OD75, as PGR when applied in accordance with the proposed use pattern, is based on the efficacy results of 18 reliable trials with scheduled single application during the Autumn periods 2019 and 2020, with twelve Czech, German and UK trials supported with four Danish and Swedish trials and two French trials. All these trials were implemented in countries belonging to the Maritime EPPO zone and they are therefore considered valid to support the claimed use in Austria, Germany and the Czech Republic.

The evaluation of the effectiveness of PRL OD75 is based on the main relevant assessed parameter, the measured plant height at the end of the growing period.

Overall tested conditions of these eighteen reliable trials, the test product PRL OD75 applied in accordance with the proposed use pattern, showed excellent plant height reduction (mean reduction of 8.0cm) of winter oilseed rape, when compared to the two reference products, either mepiquat-chloride+metconazole SL240 at 1 L/ha (mean reduction of 11.1cm) or prothioconazole+tebuconazole EC240 at 1.2 L/ha (mean reduction of 8.3cm), for a global mean plant height of 29.0cm in untreated. Difference in plant height between the test product PRL OD75 and untreated is statistically significant in 14 out of 18 trials.

Repeated after the winter in 16 reliable trials, the results confirmed that PRL OD75 showed a good residual reduction of the plant height, similar to (Ref. 1) or better than (Ref. 2) the effects obtained with reference products. Nevertheless, the crop stand, both in untreated plots and in treated plots, was not impacted during the concerned smooth winters. Statistically no significant difference was found in the crop plant survival assessed in early spring, in 15 reliable trials.

Based on the plant growth regulator results of eighteen reliable trials carried out in the Czech Republic, Denmark, Germany, France, the United Kingdom and Sweden, the effectiveness of PRL OD75 is therefore proved when applied in accordance with the proposed use pattern on winter oilseed rape, for which the PGR activity of the test product is claimed in Austria, the Czech Republic and Germany.

**Table 3.2-23: USE002 – Efficacy (absolute value - number of plants /m<sup>2</sup>) of PRL OD75 applied at 1.2 L/ha as PGR in Autumn on winter oilseed rape in the Maritime EPPO climatic zone – Plant winter survival (plants/m<sup>2</sup>) assessed at 134-196 days after the application, at the restart of the growing period.**

- For approval at 1.2 L/ha in cMSs of the Maritime EPPO zone (Austria, the Czech Republic and Germany)

EPPO zone	European regulatory zone	Number of trials	Untreated (UTC) (Number of plants /m <sup>2</sup> )		Number of plants /m <sup>2</sup>						Stat. Anal.	Comparison
					Test product		Reference products					
			PRL OD75		Ref. 1		Ref. 2					
			1.2 L/ha		1 L/ha		1.2 L/ha					
			Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max		
Maritime	Central	11	51.4	23.8-72.8	<b>52.8</b>	22.2-77.2	52.5	32.4-73.0	53.2	31.2-76.2	= 11, < 0, > 0 = 11, < 0, > 0 = 11, < 0, > 0	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2
	North (supportive)	3	55.5	54.4-57.0	<b>57.1</b>	51.8-60.0	57.1	55.2-58.6	56.2	50.2-60.6	= 3, < 0, > 0 = 3, < 0, > 0 = 3, < 0, > 0	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2
	South (supportive)	1	53.0	-	<b>49.3</b>	-	47.5	-	45.8	-	= 1, < 0, > 0 = 1, < 0, > 0 = 1, < 0, > 0	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2
	All 3 EU regulatory zones	15	52.3	23.8-72.8	<b>53.4</b>	22.2-77.2	53.0	32.4-73.0	53.3	31.2-76.2	= 15, < 0, > 0 = 15, < 0, > 0 = 15, < 0, > 0	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2

Ref. 1 - mepiquat-chloride+metconazole SL240 (210+30 g/L) applied at 1 L/ha

Ref. 2 - prothioconazole+tebuconazole EC240 (80+160 g/L) applied at 1.2 L/ha

**USE003 – PRL OD75 on BRSNW – SOUTH-EAST EPPO CLIMATIC ZONE (major use)**

For submission in Hungary, Romania and Slovakia, the evaluation of the effectiveness of PRL OD75, as PGR when applied in accordance with the proposed use pattern, is based on the efficacy results of 8 reliable trials with scheduled single application during the Autumn periods 2019 and 2020. Trials were carried out in Hungary, Romania and Slovakia, then all were implemented in countries belonging to the South-East EPPO zone. The distribution across countries and years is shown in Table 3.2-24.

**Table 3.2-24: USE003 - Distribution of efficacy trials with PRL OD75 applied during the Autumn season on winter oilseed rape -South-East EPPO climatic zone**

Target	EPPO climatic zone	European Regulatory zone	Country	Number of trials per year*		TOTAL (valid)	TOTAL (valid)
				2020	2021		
PGR (Plant Growth Regulator)	South-East	Central	Hungary	2		2	8
			Romania	3		3	
			Slovakia	2	1	3	
	<b>TOTAL South-East EPPO climatic zone</b>			<b>7</b>	<b>1</b>	<b>8</b>	<b>8</b>

\*Years 2020 and 2021: application in Autumn 2019 and Autumn 2020, respectively.

Remark: The reference product mepiquat-chloride+metconazole SL240 (Ref. 1) was applied at the local registered dose rate of 0.7 L/ha in two Romanian trials, whereas it was applied at 1 L/ha in other trials. Particularly, the best PGR effect with this reference product were obtained in these two Romanian trials. Therefore, a general mean of the eight trials is presented and evaluated, which is acceptable.

**Assessment of the plant height just before the winter (at the end of the growing period)**

Overall tested conditions of these eight reliable trials, the test product PRL OD75, applied in accordance with the proposed use pattern, showed excellent and sufficient plant height reduction of winter oilseed rape plant, when assessed at the end of the growing period, at 30-63 days after the single Autumn application.

It is noticeable that considering the mean of untreated plots, the lower plant height assessed in 1 Romanian trial (13.8cm) was quite different than plant height measured in the other South-East trials (mainly from 30 to 40cm). Scarce rainfall after the drilling in the Călărași district, where the trial was sited, caused a late emergence of the crop and a global delay in plant development and finally low plant height.

The two standard products showed expected plant height reduction in the conditions of these 8 trials.

Overall the 8 validated trials, the test product PRL OD75 at 1.2 L/ha (mean of 75.6% relative to untreated) reduced the plant height in all trials, with a mean reduction of 7.7cm, which is statistically significant in 7 out of 8 trials, when compared to the untreated (mean plant height of 31.4cm)

The reference product Ref. 1 (mean of 68.8% relative to untreated) showed better reduction of the plant height (mean reduction of 9.8cm) than PRL OD75. The differences in plant height between the two product are statistically significant in 4 out of 8 trials, 3 in favour of the reference product Ref. 1 and 1 in favour of the test product PRL OD75.

When compared to the reference product Ref. 2 (mean of 81.6% relative to untreated, which corresponds to a mean reduction of the plant height of 5.8cm), the differences in plant height are statistically significant in 4 out of 8 trials, all in favour of the test product PRL OD75.

Based on the results of the PGR effect assessed on the plant height at the end of the growing period before the winter in 8 reliable South-East trials, it is concluded that the test product PRL OD75 is mainly inferior to Ref. 1 (based on mepiquat-chloride+metconazole SL240) and mostly superior to Ref. 2 (based on prothioconazole+tebuconazole EC240), when applied in accordance with the proposed use pattern.

PRL OD75 at the proposed dose rate of 1.2 L/ha showed an excellent and sufficient reduction of the plant height if applied in a single Autumn application on winter oilseed rape, for which the PGR activity of the test product is claimed in Hungary, Romania and Slovakia.

#### **Assessment of the plant height just after the winter (at restart of crop growth) – EPPO not required**

Efficacy results based on the not required by the EPPO PP1/153(3) and then additional assessment made on the plant height in early spring, are evaluated in all 8 trials.

Depending on the trial conditions, this early spring and additional assessment was made from 132 to 211 days after the single Autumn application of products.

It is noticeable that when compared with the assessment made before the winter, a general reduction of the plant height is observed in all plots, untreated and treated, which is explained with the “winter” stunting effect. This impacted the residual PGR effects for all products.

Overall the 8 validated trials, the test product PRL OD75 at 1.2 L/ha (mean of 92.6% relative to untreated) reduced the plant height of 2.0cm, when compared to the untreated (mean plant height of 27.2cm), which is statistically significant in 5 out of 8 trials.

The reference product ref. 1 (mean of 93.8% relative to untreated) showed similar reduction of the plant height (1.7cm) than PRL OD75, whereas the reference product Ref. 2 (mean of 95.4% relative to untreated) showed lower residual PGR effect with a mean plant reduction of 1.3cm. Differences in plant height between the test product and both reference products are statistically significant in 2 out of 8 trials (1 trial per reference product), all in favour of the test product PRL OD75.

It is concluded that PRL OD75 showed a good residual PGR effect when assessed on the plant height in early spring, when applied in accordance with the proposed use pattern in a single Autumn application on winter oilseed rape, for which the PGR activity of the test product is claimed in Hungary, Romania and Slovakia. This PGR effect with PRL OD75 is slightly better than the ones obtained with reference products.

#### **Assessment of the crop winter survival after the winter (in early next spring)**

Efficacy results based on the crop winter survival in early spring and just at the beginning of crop growth restart after the winter, are evaluated in all 8 trials.

Depending on the trial conditions, this early spring assessment was made from 132 to 211 days after the single Autumn application of products.

Comparing the test product PRL OD75 applied at 1.2 L/ha (mean of 44.1 plants/m<sup>2</sup>) to the reference products, Ref. 1 (mean of 44.5 plants/m<sup>2</sup>) and Ref. 2 (mean of 44.9 plants/m<sup>2</sup>), and to the untreated (44.4 plants/m<sup>2</sup>), statistically no significant differences were shown in plant density.

Consequently and in absence of critical winter conditions, overall 8 reliable South-Eastern trials, it could be concluded that there were statistically no significant differences between the test product PRL OD75 at 1.2 L/ha, the two reference products and the untreated, when evaluated according to the plant winter survival at the spring restart of the crop growth.

**Table 3.2-25: USE003 – Efficacy (% relative to the untreated) of PRL OD75 applied at 1.2 L/ha as PGR in Autumn on winter oilseed rape in the South-East EPPO climatic zone – Plant height (cm) assessed at 30-63 days after the application, at the end of the growing period and just before the winter.**

- For approval at 1.2 L/ha in cMS of the South-East EPPO zone (Hungary, Romania and Slovakia)

EPPO zone	European regulatory zone	Number of trials	Untreated (UTC)  PLANT HEIGHT (cm)		Plant height - % relative to the untreated						Stat. Anal.	Comparison
					Test product		Reference products					
					PRL OD75		Ref. 1		Ref. 2			
					1.2 L/ha		0.7-1 L/ha		1.2 L/ha			
Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max			
South-East	Central	8	31.4	13.8-43.3	<b>75.6</b>	61.9-94.5	68.8	55.9-80.0	81.6	70.0-90.6	= 1, < 0, > 7 = 4, < 3, > 1 = 4, < 0, > 4	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2

Ref. 1 - mepiquat-chloride+metconazole SL240 (210+30 g/L) applied at 1 L/ha - In two Romanian trials, Ref. 1 was applied at the local approved dose rate of 0.7 L/ha

Ref. 2 - prothioconazole+tebuconazole EC240 (80+160 g/L) applied at 1.2 L/ha

**Table 3.2-26: USE003 – Efficacy (% relative to the untreated) of PRL OD75 applied at 1.2 L/ha as PGR in Autumn on winter oilseed rape in the South-East EPPO climatic zone – Plant height (cm) assessed at 132-211 days after the application, at the restart of the growing period at the end of the winter.**

- For approval at 1.2 L/ha in cMS of the South-East EPPO zone (Hungary, Romania and Slovakia)

EPPO zone	European regulatory zone	Number of trials	Untreated (UTC)  PLANT HEIGHT (cm)		Plant height - % relative to the untreated						Stat. Anal.	Comparison
					Test product		Reference products					
					PRL OD75		Ref. 1		Ref. 2			
					1.2 L/ha		0.7-1 L/ha		1.2 L/ha			
Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max			
South-East	Central	8	27.2	18.6-39.4	<b>92.6</b>	83.8-102.6	93.8	83.7-102.5	95.4	85.5-101.3	= 3, < 0, > 5 = 7, < 0, > 1 = 7, < 0, > 1	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2

Ref. 1 - mepiquat-chloride+metconazole SL240 (210+30 g/L) applied at 1 L/ha - In two Romanian trials, Ref. 1 was applied at the local approved dose rate of 0.7 L/ha

Ref. 2 - prothioconazole+tebuconazole EC240 (80+160 g/L) applied at 1.2 L/ha

**Table 3.2-27: USE003 – Efficacy (absolute value - number of plants /m<sup>2</sup>) of PRL OD75 applied at 1.2 L/ha as PGR in Autumn on winter oilseed rape in the South-East EPPO climatic zone – Plant winter survival (plants/m<sup>2</sup>) assessed at 132-211 days after the application, at the restart of the growing period.**

- For approval at 1.2 L/ha in cMS of the South-East EPPO zone (Hungary, Romania and Slovakia)

EPPO zone	European regulatory zone	Number of trials	Untreated (UTC) (Number of plants /m <sup>2</sup> )		Plant height - % relative to the untreated						Stat. Anal.	Comparison
					Test product		Reference products					
					PRL OD75		Ref. 1		Ref. 2			
					1.2 L/ha		0.7-1 L/ha		1.2 L/ha			
Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max			
South-East	Central	8	44.4	36.0-55.8	<b>44.1</b>	35.3-54.8	44.5	34.0-57.2	44.9	37.0-57.2	= 8, < 0, > 0 = 8, < 0, > 0 = 8, < 0, > 0	PRL OD75 vs. UTC PRL OD75 vs. Ref. 1 PRL OD75 vs. Ref. 2

Ref. 1 - mepiquat-chloride+metconazole SL240 (210+30 g/L) applied at 1 L/ha - In two Romanian trials, Ref. 1 was applied at the local approved dose rate of 0.7 L/ha

Ref. 2 - prothioconazole+tebuconazole EC240 (80+160 g/L) applied at 1.2 L/ha

### **USE003 – PRL OD75 on winter oilseed rape – South-East EPPO zone - Conclusions on the Efficacy**

For submission in Hungary, Romania and Slovakia, the evaluation of the effectiveness of PRL OD75, as PGR when applied in accordance with the proposed use pattern, is based on the efficacy results of 8 reliable trials with scheduled single application during the Autumn periods 2019 and 2020. Trials were carried out in Hungary, Romania and Slovakia, then all were implemented in countries belonging to the South-East EPPO zone and they are therefore considered valid to support the claimed use in Hungary, Romania and Slovakia.

The evaluation of the effectiveness of PRL OD75 is based on the main relevant assessed parameter, the measured plant height at the end of the growing period.

Overall tested conditions of these eight reliable trials, the test product PRL OD75 applied in accordance with the proposed use pattern, showed excellent plant height reduction (mean reduction of 7.7cm) of winter oilseed rape, when compared to the two reference products, either mepiquat-chloride+metconazole SL240 at 0.7-1 L/ha (mean reduction of 9.8cm) or prothioconazole+tebuconazole EC240 at 1.2 L/ha (mean reduction of 5.8cm), for a global mean plant height of 31.4cm in untreated. Difference in plant height between PRL OD75 and untreated is statistically significant in 7 out of 8 trials.

Repeated after the winter in all 8 reliable trials, the results confirmed that PRL OD75 showed a good residual reduction of the plant height, slightly superior to the effect obtained with reference products, statistically significant different that the untreated in 2 out of 8 trials (1 per reference product), when assessed on the plant height.

Nevertheless, the crop stand, both in untreated plots and in treated plots, was not impacted during the concerned smooth winters. Statistically no significant difference was found in the crop plant survival assessed in early spring, in 8 reliable trials.

Based on the plant growth regulator results of eight reliable trials carried out in Hungary, Romania and Slovakia, the effectiveness of PRL OD75 is therefore proved when applied in accordance with the proposed use pattern on winter oilseed rape, for which the PGR activity of the test product is claimed in Hungary, Romania and Slovakia.

### **OVERALL CONCLUSIONS FOR EFFICACY – PRL OD75 as PGR on BRSNW**

The effectiveness of PRL OD75 as PGR on oilseed rape is based on the efficacy results of a total of 35 reliable efficacy trials carried out in a wide range of EU agro-climatic conditions, with 26 trials conducted in countries of the EU Central regulatory zone, i.e. in the Czech Republic (6), Germany (5), the United Kingdom (1), Poland (6), Hungary (2), Romania (3) and Slovakia (3), supported with 9 trials implemented in the EU Northern (i.e. Denmark, Latvia, Lithuania and Sweden, 7 trials) and Southern (France, 2 trials) regulatory zones.

The test product PRL OD75 at the proposed dose rate of 1.2 L/ha was compared to two reference products, mepiquat-chloride+metconazole SL240 at its recommended dose rate of 1 L/ha (locally at 0.7 L/ha in 2 Romanian trials) and prothioconazole+tebuconazole EC240 at the approved dose rate of 1.2 L/ha.

Both PRL OD75 and reference products were applied once at same timing in Autumn, on winter oilseed rape at the recommended growth stages from BBCH 14 to BBCH 18. However and due to some heterogenities in field trials, the application was executed from a minimum crop growth stage BBCH 12 up to a maximum crop growth stage BBCH 18 (BBCH 19 in 1 trial), then covering the proposed use pattern (from BBCH 12 to BBCH 18).

In accordance with the recommendations of the specific EPPO standard PP1/153(3), the efficacy of the test product PRL OD75, applied in Autumn to improve crop winter hardiness, is evaluated on the results obtained on the two main assessed parameters for this Autumn application, the **plant height** at the end of the growing period (just before the winter) and the **crop winter survival** in early spring (after the winter period and at the restart of the growing period). Additionally and not recommended in the EPPO standard PP1/153(3), the **plant height** at the end of the winter period in early spring and at the restart of the plant growth is included in the core evaluation to confirm the effectiveness of PRL OD75, notably in term of residual PGR effect.

Nevertheless, overall tested conditions of 30 reliable trials where the assessment was made or validated, winter was not harsh enough to impact on **plant survival**. Consequently, overall assessed seven North-Eastern trials, fifteen Maritime trials and eight South-Eastern trials, it could be concluded that there were statistically no significant differences between the test product PRL OD75 at 1.2 L/ha, the two reference products and the untreated, when evaluated according to the plant winter survival just after the winter and at the restart of the crop growth.

Therefore the conclusions on the PGR effect of PRL OD75 are mostly driven on the most relevant assessment made on the **plant height** at the end of growing period just before the winter, confirmed by the same assessment repeated just after the winter and at the restart of the plant growth in early spring. Overall tested conditions of the 35 reliable trials, the test product PRL OD75 applied in accordance with the proposed use pattern, showed excellent and satisfactory plant height reduction on winter oilseed rape, in the 3 EPPO climatic zone concerned with this submission, the North-East, the Maritime and the South-East. Its PGR effect assessed at the end of the growing period and just before the winter was variably “lower than”, “comparable to” or “better than” those obtained with standard products. When assessed in early spring, even if the PGR effects due to all treatments decreased in all trials, PRL OD75 showed quite interesting residual reduction of the plant height, mostly “comparable to” or “better than” the reference products.

When applied in accordance with the proposed use pattern on winter oilseed rape, the effectiveness of the test product PRL OD75 is therefore proved in the three EPPO zones concerned with this submission in the EU Central regulatory zone and for which the PGR activity of the test product is claimed on winter oilseed rape in the North-East (Poland), the Maritime (Austria, the Czech Republic and Germany) and the South-East (Hungary, Romania and Slovakia) EPPO zones.

<p>Comments zRMS:</p>	<p>of <b>Efficacy effects</b></p> <p>The Applicant presented 35 experiments on winter oilseed rape, carried out in the two growing seasons 2019/2020 and 2020/2021 in 3 different EPPO zones.</p> <p>In the experiments from the 2020/2021 season, the yield was not assessed.</p> <p><b>23 experiments</b> were carried out in the North-eastern zone or in the neighboring countries of Poland:</p> <ul style="list-style-type: none"> <li>- <b>6 trials</b> in Poland: 3 in 2019/2020 and 3 in 2020/2021 vegetation seasons.</li> </ul> <p>In 4 experiments, a significant shortening of plants was found in the autumn period, and in 2 - a certain tendency to shorten the plants.</p> <ul style="list-style-type: none"> <li>- <b>1 trial</b> in Lithuania in the 2019/2020 season, a significant shortening of the plants was noted in this experiment</li> <li>- <b>2 trials</b> in Latvia - 1 in 2019/2020 and 1 in 2020/2021. In both experiments, significant plant shortening was noted.</li> </ul>
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- **6** trials in the Czech Republic - 3 in 2019/2020 and 3 in 2020/2021. In 4 experiments, a significant shortening of the plants was found, in 1 a certain tendency to shorten the plants, and in 1, the tested agent did not shorten the rapeseed plants.

- **3** trials in Slovakia - 2 in 2019/2020 and 1 in 2020/2021. Significant plant abbreviation was noted in all studies.

- **5** trials in Germany - 2 in 2019/2020 and 3 in 2020/2021. In 4 experiments, significant shortening of plants was found, and in 1, the tested agent did not affect the shortening of winter oil seeds rape plants.

The number of trials for tested plant growth regulator was consistent to required for registration in Poland.

In addition, the applicant presented 12 supportive trials:

- 3 carried out in Denmark,
- 1 in Sweden
- 2 in Hungary,
- 3 in Romania, ,
- 1 in Great Britain
- 2 in France

The product **PRL OD75, Hingios 75 OD, chemical active substance: Prohexadione-calcium 75 g/L,(7,28%) in dose 1,2 L/ha was tested in winter oilseed rape, applied at BBCH 12-18** growth stage in order to reduce plant height and growth as well as improving wintering.

In the conducted experiments the active substances: mepiquat - chloride + metconazole (Carax, Caramba Turbo, Caryx) were used as Reference product 1 and prothioconazole + tebuconazole (Tilmor) as a Reference product 2.

The reference products were used at the doses registered in the countries where the experiments were conducted.

The effectiveness of the measure applied can be summed up as not giving significant differences between the tested product PRL OD75 and two references product and untreated in the number of plants that overwintering. Good wintering of plants was obtained in the conditions of poor winters in 2019/2020 and 2020/2021.

The tested plant growth regulator used in the growth stage of winter oilseed rape BBCH 12-18 at a dose of 1,2 l/ha resulted in an average shortening of stems by:

-PRL OD75,Hingios OD75: 7,6 cm (001)\*, 8,0 cm (002), 7,7 cm (003), (mean plant height 29- 31,4 cm in UTC).

The standard “Ref.1” resulted in a stronger shortening of the stems, amounting to:

- Ref.1 : 10 cm(001), 11,1cm (002), 9,8cm (003)
- Ref.2 : 7 cm (001), 8,3 cm (002), 5,8 cm (003)

The percentage comparison to UTC shows the following effectiveness of plant shortening by the PRL OD75,Hingios 75OD growth regulator.

	<p>-PRL OD75, Hingios: OD75-(001 Use) 75,8 % , (002 Use) 72,3 % , (003 Use) 75,6 %                  -Ref.1 : (001) 67,9%, (002) 61,8% (003) 68,8 % ,                  -Ref.2 : (001) 77,8 % , (002)71,5 % , (003) 81,6%</p> <p>* according to the grouping of the applicant- 001, 002 ,003 :-                  USE numbering in accordance to proposed GAP</p> <p>The obtained data indicate a good effect of the tested agent in shortening plants of winter oilseed rape.                  In experiments, a significant effect of the measure on the limitation of winter oilseed rape length was found.</p> <p>The effectiveness of tested growth regulator in shortening winter oilseed rape was slightly better than the action of Ref. 2 and slightly weaker than the actions of Ref. 1. It should be considered that <b>PRL OD75, Hingios 75 OD</b> worked well at the performance level of the reference measures. Data from the North-eastern zone and the neighboring countries of Poland is consistent and supports the effectiveness of the <b>PRL OD75, Hingios 75 OD</b> measure. This effectiveness is confirmed by the results of experiments with the other two Eppo zones- Maritime and South-Eastern .</p> <p>The results of the experiments show a good effectiveness of the tested-growth regulator.</p> <p><b>It is justified to claim the registration of one application of PRL OD75, Hingios 75 OD, chemical active substance: Prohexadione-calcium 75 g/L,(7,28%) in dose 1,2 L/ha in winter oilseed rape, applied at BBCH 12-18 growth stage in order to reduce plant height and growth as well as improving wintering.</b></p> <p><b>The presented results of plant growth regulator PRL OD75, Hingios 75 OD, chemical active substance: Prohexadione-calcium 75 g/L,(7,28%) in dose 1,2 L/ha applied once in winter oilseed rape at BBCH 12-18 growth stage in order to reduce plant height and growth as well as improving wintering indicate compliance with the GAP table and with label of the measures tested and Uniform principles.</b></p>
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### 3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

Since the active substance prohexadione-calcium is not used for the control of any harmful organism and as it serves to regulate the natural metabolism of the plant, it is considered that potential resistance issue is not concerned.

This is confirmed by other specific active ingredient having only plant growth regulator effect and used since years on winter oilseed rape and other crops or even by prohexadione-calcium in cereals and pome fruits.

Comments of zRMS:	There are no known cases of resistance to prohexadione-calcium.
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### 3.4 Adverse effects on treated crops (KCP 6.4)

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

In accordance with requirements of the EPPO standard PP1/226(3), trials with the proposed (N) and double (2N) recommended dose rates were carried out to test the adverse effects of the tested plant growth regulator PRL OD75 on the treated crop, winter oilseed rape. Therefore, in all efficacy trials presented and discussed in Chapter 3.2.3 (Efficacy tests), the 2N dose rate was included in comparison with the proposed dose rate N. The applicant therefore considers that the set of efficacy trials is sufficient to evaluate the possible adverse effects on the treated winter oilseed rape and no additional trial is deemed to be conducted.

To avoid a duplicate information, methods used, main characteristics and details from these trials are described in introduction of Chapter 3.2.3 – Efficacy tests.

Nevertheless, the specific methodology used to perform the adverse effect assessments will be described in introduction of each concerned chapter, **3.4.1** (phytotoxicity to the crop), **3.4.2** (yield), **3.4.3** (quality parameters) and **3.4.5** (propagation tests).

**Table 3.4-1: Presentation of trials (selectivity, yield, quality, propagation tests)**

PRL OD75 applied at 1.2 L/ha and 2.4 L/ha in efficacy trials

Crop(s) *	European Regulatory zone	Country	Year** (Harvest)	Type of trial***	Number of trials			GEP, non-GEP, official ****	Comments (any other relevant information)	
					EPPO North-East zone	EPPO Maritime zone	EPPO South-East zone			
					(USE001)	(USE002)	(USE003)			
Winter oilseed rape (BRSNW)	Central	CZE	2020*****	S + Y + Q + P		3		GEP		
			2021*****	S		3		GEP		
		DEU	2020	S + Y + Q + P		2		GEP		
			2021	S		3		GEP		
		HUN	2020	S + Y + Q + P			2	GEP		
		POL	2020	S + Y	3			GEP		
			2021	S	3			GEP		
		ROU	2020	S + Y + Q + P			3	GEP		
		SVK	2020	S + Y + Q + P			2	GEP		
			2021	S			1	GEP		
	UK	2021	S		1		GEP			
	North (supporting)	DNK	2020	S + Y + Q + P		1		GEP		
			2020	S		1		GEP	Sprayed with wrong herbicide, not harvested	
			2021	S		1		GEP		
		LTU	2020	S + Y + Q + P	1			GEP		
		LVA	2020	S	1			GEP	Damaged by heavy rain, not harvested	
			2021	S	1			GEP		
	SWE	2020	S + Y + Q + P		1		GEP			
	South (supporting)	FRA	2021	S		2		GEP		
	<b>TOTAL</b>	-	-	<b>2020 -2021</b>	-	<b>9 (+4) trials*****</b> S – 9 (+4) Y – 4 (+2) Q – 1 (+2) P – 1 (+2)	<b>18 trials</b> S – 18 Y – 7 Q – 7 P – 7	<b>8 trials</b> S – 8 Y – 7 Q – 7 P – 7	-	<b>Total of 35 trials</b> S – 35 Y – 18 Q – 15 P – 15

\* According to the GAP table

\*\* Years 2020 and 2021: application in Autumn 2019 and Autumn 2020, respectively

\*\*\* S = trial with crop safety assessment, Y = trial with yield assessment, Q = trial with quality assessment (at least the oil content required by the EPPO standard PP1/153(3))

\*\*\*\* Official: carried out by a national official organisation

\*\*\*\*\* Four Czech trials (Maritime EPPO zone), with two in 2020 and two in 2021, are additionally validated to support the evaluation of the adverse effects of PRL0D75 to the treated crop for the submission in Poland (North-East EPPO zone). Therefore a total of 13 trials are considered to evaluate the possible adverse effects of PRL OD75 with this submission in Poland. The assessment of the phytotoxic symptoms on the treated crop was made in all efficacy trials in presence of claimed targeted effect (PGR) to the winter oilseed rape. The crop safety results will be presented and evaluated in Chapter **3.4.1**.

The crop safety has been assessed to the host crop in all 35 efficacy trials in presence of the claimed targeted effect (PGR) on winter oilseed rape, results will be presented and evaluated in Chapter 3.4.1.

Yield of seed was also conducted in most of trials harvested in summer 2020 (in 18 out of 20 trials). Seed quality parameters, with the oil content, the thousand seed weight and the protein content, and additionally the seed propagation tests, were performed in several of these harvested efficacy trials. Results will be presented and evaluated in the respective chapters, **3.4.2** (yield), **3.4.3** (quality parameters) and **3.4.5** (propagation tests).

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

#### Methodology

Phytotoxicity to the host crop (winter oilseed rape, BRSNW), as visual crop effects on all parts (whole plant, leaf, stem, flowering) was determined at the proposed dose rate of 1.2 L/ha (N rate) and at the double dose rate of 2.4 L/ha (2N) for PRL OD75 in all 35 Efficacy trials, in presence of the expected PGR effects.

The test product PRL OD75 applied at the proposed maximum dose rate of 1.2 L/ha and at the double dose rate of 2.4 L/ha was compared to two reference products, mepiquat-chloride+metconazole SL240 and prothioconazole+tebuconazole EC240 applied at the recommended or approved dose rates of 1 L/ha and 1.2 L/ha, respectively. Both PRL OD75 and the reference products were applied once in Autumn on winter oilseed rape at the major growth stages from BBCH 14 to BBCH 18. Nevertheless and depending on trial conditions, at application, the minimum crop growth stage was from the minimum crop growth stage BBCH 12 up to the maximum crop growth stage BBCH 18 (BBCH 19 in 1 Latvian trial), then covering the proposed use pattern (BBCH 12-18).

For each crop safety assessment, the percentage of general phytotoxicity was estimated taking into account the intensity of the different phytotoxic symptoms observed. The visual estimation, of general phytotoxicity (PHYGEN) or of other specific phytotoxic symptoms (such as PHYCOL, reporting coloration change), is expressed as a percentage, in comparison with the untreated control and according to the following scale of phytotoxicity: 0 % = no phytotoxic symptom, 100 % = all plants are dead.

The crop safety assessment was made at all occasions visiting the trial, mainly at relevant efficacy assessments and depending on trial, from 13 to 261 days after the autumn application.

#### **USE001 – PRL OD75 on BRSNW – NORTH-EAST EPPO CLIMATIC ZONE – Major crop**

In 9 efficacy trials carried out in countries of the North-East EPPO zone (Poland, Latvia and Lithuania) supported with 4 efficacy trials implemented in the Czech Republic (Maritime EPPO zone), PRL OD75 at the proposed maximum dose rate of 1.2 L/ha and at the double dose rate of 2.4 L/ha was applied at the major crop growth stage BBCH 14-18, on a total of 10 representative winter oilseed rape varieties.

Depending on the trial, crop safety observations were conducted from 38 to 261 days after the single Autumn application.

Overall the 13 trials, slight transient plant purple coloration was seen in 1 out of 13 trials. In a Lithuanian efficacy trial (variety DK Expertise), a slight transient symptom was seen both with PRL OD75 (at 1.2 and 2.4 /ha) and with both reference products, when assessed 211 days after the autumn application (maximum 1% PHYGEN score, maximum 2% PHYCOL score).

Moreover, this slight colour change disappeared at later assessment timing made at 218 days after the application and it is therefore considered as negligible and not relevant.

Overall, it can be considered that the autumn application of PRL OD75 to winter oilseed rape at the major crop growth stage BBCH 14-18, but encompassing the crop growth stages BBCH 12-19, is safe to the host crop. A single application of PRL OD75 at 1.2 L/ha appears to cause no significant phytotoxic symptom in all 13 trials. This excellent crop safety is confirmed with the absence of phytotoxic symptom when the test product was applied at the double of the proposed dose rate (2N of 2.4 L/ha).

It is concluded that application of PRL OD75 to the winter oilseed rape is safe to the host crop, in all wide representative agro-climatic conditions of 13 reliable validated trials to support the use in Poland.

It is therefore unlikely that phytotoxic symptoms will occur with PRL OD75 on winter oilseed rape crop, when applied in accordance with the proposed use pattern in Poland.

An overview of the 10 winter oilseed rape varieties in test in the 13 efficacy trials is given in Table 3.4-2.

**Table 3.4-2: List of tested varieties with PRL OD75 applied at 1.2 and 2.4 L/ha on winter oilseed rape (BRSNW) in efficacy trials (total of 13 validated trials, 2020-2021) – 9 trials of the North-East EPPO zone + 4 supportive Czech trials of the Maritime EPPO zone**

EU regulatory zone	Central		North		All
EPPO zone	Maritime	North-East			
Country	*Czech Republic (supportive)	Poland	Latvia (supportive)	Lithuania (supportive)	Total
BAZALT		2			2
DARIOT	1				1
DK EXCEPTION		1			1
DK EXCITED	1	1			2
DK EXOTTER	1				1
DK EXPERTISE				1	1
DK EXTIME		2			2
MERCEDES			1		1
PHANTOM			1		1
PT242	1				1
<b>Total</b>	<b>4</b>	<b>6</b>	<b>2</b>	<b>1</b>	<b>13</b>

\*Four Czech trials (Maritime EPPO zone) sited close to the border with Poland are additionally validated to support the evaluation of the adverse effects of PRL0D75 to the treated crop for the submission in Poland (North-East EPPO zone).

In 18 efficacy trials conducted in countries of the Maritime EPPO zone (the Czech Republic, Germany, France, Denmark, Sweden and the UK), PRL OD75 at the proposed maximum dose rate of 1.2 L/ha and at the double dose rate of 2.4 L/ha was applied at the major crop growth stage BBCH 14-18, on a total of 15 representative winter oilseed rape varieties. Depending on the trial, crop safety observations were conducted from 13 to 213 days after the single Autumn application.

Overall, it can be considered that the autumn application of PRL OD75 to winter oilseed rape at the major crop growth stage BBCH 14-18, but encompassing the crop growth stages BBCH 12-18, is safe to the host crop. A single application of PRL OD75 at 1.2 L/ha appears to cause no phytotoxic symptom in all 18 trials. This excellent crop safety is confirmed with the absence of phytotoxic symptom when the test product was applied at the double of the proposed dose rate (2N of 2.4 L/ha).

It is concluded that application of PRL OD75 to the winter oilseed rape is safe to the host crop, in all wide representative agro-climatic conditions of 18 reliable Maritime trials. It is therefore unlikely that phytotoxic symptoms will occur with PRL OD75 on winter oilseed rape crop, when applied in accordance with the proposed use pattern in Austria, the Czech Republic and Germany.

An overview of the 15 winter oilseed rape varieties in test in the 18 efficacy trials is given in Table 3.4-3.

**Table 3.4-3: List of tested varieties with PRL OD75 applied at 1.2 and 2.4 L/ha on winter oilseed rape (BRSNW) in efficacy trials (18 trials, 2020-2021) – Maritime EP-PO zone**

EU regulatory zone	Central			North		South	All
Country	Czech Republic	Germany	United Kingdom	Denmark (supportive)	Sweden (supportive)	France (supportive)	Total
AROME						1	1
ASPECT						1	1
AVATAR		1					1
CAMPUS			1				1
CROME				1			1
DARIOT	1				1		2
DK EXCITED	1						1
DK EXCLAIM				2			2
DK EXOTTER	1						1
DK EXPANSION		1					1
DK PLATINUM		1					1
ES IMPERIO		1					1
PT242	1						1
RAGT MUZZICAL		1					1
ZAKARI CS	2						2
<b>Total</b>	<b>6</b>	<b>5</b>	<b>1</b>	<b>3</b>	<b>1</b>	<b>2</b>	<b>18</b>

**USE003 – PRL OD75 on BRSNW – SOUTH-EAST EPPO CLIMATIC ZONE – Major crop**

In 8 efficacy trials implemented in countries of the South-East EPPO zone (Hungary, Romania and Slovakia), PRL OD75 at the proposed maximum dose rate of 1.2 L/ha and at the double dose rate of 2.4 L/ha was applied at the major crop growth stage BBCH 14-18, on a total of 8 local representative winter

oilseed rape varieties. Depending on the trial, crop safety observations were conducted from 29 to 237 days after the single Autumn application.

Overall, it can be considered that the autumn application of PRL OD75 to winter oilseed rape at the major crop growth stage BBCH 14-18, but encompassing the crop growth stages BBCH 12-18, is safe to the host crop. A single application of PRL OD75 at 1.2 L/ha appears to cause no phytotoxic symptom in all 8 trials. This excellent crop safety is confirmed with the absence of phytotoxic symptom when the test product was applied at the double of the proposed dose rate (2N of 2.4 L/ha).

It is concluded that application of PRL OD75 to the winter oilseed rape is safe to the host crop, in all wide representative agro-climatic conditions of 8 reliable South-Eastern trials. It is therefore unlikely that phytotoxic symptoms will occur with PRL OD75 on winter oilseed rape crop, when applied in accordance with the proposed use pattern in Hungary, Romania and Slovakia.

An overview of the 8 winter oilseed rape varieties in test in all 8 efficacy trials is given in Table 3.4-4.

**Table 3.4-4: List of tested varieties with PRL OD75 applied at 1.2 and 2.4 L/ha on winter oilseed rape (BRSNW) in efficacy trials (8 trials, 2020-2021) – South-East EP-PO zone**

EU regulatory zone	Central			All
Country	Hungary	Romania	Slovakia	Total
BONANZA			1	1
DK EXCEPTION	1			1
DK EXCITED			1	1
DK EXSTORM		1		1
INV1022	1			1
PT 225		1		1
PT234		1		1
SERGIO			1	1
<b>Total</b>	<b>2</b>	<b>3</b>	<b>3</b>	<b>8</b>

**OVERALL CONCLUSIONS FOR CROP SAFETY TO TREATED CROP (BRSNW)**

The crop safety of PRL OD75 at the proposed maximum dose rate of 1.2 L/ha and at the double dose rate of 2.4 L/ha was evaluated in all 35 efficacy trials submitted to support the effectiveness of the test product as plant growth regulator on winter oilseed rape, then in presence of the expected PGR effect.

Trials were applied in Autumn 2019 and Autumn 2020 and conducted in a wide representative agro-climatic conditions in oilseed rape cultivation regions of countries belonging to different EPPO climatic zones (North-East, Maritime and South-East) and EU regulatory zones (Central, supported with South and North).

Overall plant safety results assessed at several occasions from 13 to 261 days after the autumn application at the major crop growth stages BBCH 14-18, on 24 local representative winter oilseed rape varieties, no phytotoxic symptom was seen on winter oilseed rape treated with PRL OD75 in 34 out of 35 trials.

Only a slight transient purple coloration of the plants (max. 2% score) was observed in a Lithuanian trial when assessed in spring, both for the test product as for reference products. This slight colour change disappeared at later assessment timing it is therefore considered as negligible and not relevant.

The product as demonstrated its perfect crop safety, notably at the double of the proposed dose rate, in all trials where some plants were at the minimum crop growth stage BBCH 12 up to maximum BBCH 19.

The applicant therefore consider that it is unlikely that phytotoxic symptoms will occur on the claimed winter oilseed rape crop BRSNW, when PRL OD75 will be applied in accordance with the proposed use pattern in cMSs with this submission in Austria, the Czech Republic, Germany, Hungary, Poland, Romania and Slovakia.

Comments of zRMS:	<p>The applicant presented the results of 35 trials carried out in two growing seasons 2019/2020 and 2020/2021. 23 experiments were carried out in Poland, in the countries of the North-East EPPO zone or in countries neighboring with Poland. The remaining 12 trials were conducted in Denmark (3), Hungary (2), Romania (3), Sweden (1), UK (1) and France (2).</p> <p>In these studies, the tested product were used in a dose of 1N and 2N.</p> <p>The methods used in the presented trials were appropriate and trials submitted for evaluation are satisfactorily representative for winter oilseed rape.</p> <p>The number of tests and their location was sufficient to conduct an evaluation.</p> <p>Symptoms of phytotoxic effects of the tested product, mainly in the form of discoloration, were noted in two (GR20LTUGA1BCS2 and GR20DNKA011111) out of thirty five experiments. In the same studies, the phytotoxicity after the application of the standard product was at least at the same level as after the application of the test product. In all cases, the phytotoxicity was transient and had no effect on the winter oilseed rape yielding.</p> <p><b>In this situation, it can be concluded that the results presented for evaluation were considered satisfactory, stating that PRL OD75, Hingios 75 OD applied in autumn (BBCH 12 - 18) was selective for winter oilseed rape</b></p>
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### 3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

The potential effect of the autumn application with PRL OD75 on the seed yield at harvest is evaluated in already available data of 18 efficacy trials submitted to support the effectiveness of the test product as plant growth regulator on winter oilseed rape. All these efficacy trials were applied on Autumn 2019 and harvested on Summer 2020. They were conducted in a wide range of agro-climatic conditions in oilseed rape cultivation regions of countries belonging to different EPPO climatic zones (Maritime, North-East and South-East) and EU regulatory zones (Central, supported with South and North). Since the winter conditions were not strong enough to impact the crop stand after the winter, the effect on seed yield is considered as being only possible adverse effect on the treated crop, winter oilseed rape (BRSNW).

Remark: No lodging occurred in all 20 trials, but two Danish and Latvian trials were not harvested. The first was accidentally sprayed with a wrong herbicide in spring and the second was severely damaged (90% of the plots) by heavy rain and strong winds the day before the scheduled harvest.

The test product PRL OD75 applied at the proposed maximum dose rate of 1.2 L/ha and at the double dose rate of 2.4 L/ha was compared to two reference products, mepiquat-chloride+metconazole SL240 and prothioconazole+tebuconazole EC240 applied at their recommended or approved dose rates.

Both PRL OD75 and reference products were applied once in Autumn in winter oilseed rape at the reported major growth stages from BBCH 14 to BBCH 18. Nevertheless and depending on trial conditions, at application the minimum crop growth stage was BBCH 12 up to the maximum crop growth stage BBCH 18, then covering the proposed use pattern (BBCH 12-18).

Depending on the equipment and of the plot surface, the harvested plot area was minimum 15m<sup>2</sup> and respecting the minimum requirement of the EPPO standard PP1/026 (minimum 20m<sup>2</sup>) in the half of trials. The high reliability of the seed yield in the second half of efficacy trials with a low coefficient of variation (inferior to 8.5) allows to validate the seed yield results of these efficacy trials to evaluate the adverse effects to the seed yield of treated crop BRSNW.

The fresh weight was measured for the harvested seeds at harvest crop stage and the seed humidity determined in post harvest from a sample taken from each plot at the harvest timing. Afterwards, the seed yield and the relative seed yield to untreated are compute calculated, at commercial standard 9% seed moisture.

Even if the expected PGR effect was present both before and after the winter (reported in Chapter 3.2.3), no visual crop safety issue was seen on plant parts (reported in Chapter 3.4.1) in the concerned trials.

#### **Supporting USE001 - cMS of the North-East EPPO zone (Poland)**

– Table 3.4-5: From 3 reliable Polish trials, supported by 1 reliable Lithuanian efficacy trial and 2 reliable Czech efficacy trials, no significant adverse effect was found on seed yield resulting from an Autumn application with PRL OD75, both at the maximum proposed dose rate (1.2 L/ha) and at the double of the proposed dose rate (2.4 L/ha), in all the 6 trials on BRSNW.

#### **Supporting USE002 - cMSs of the Maritime EPPO zone (Austria, the Czech Republic and Germany)**

– Table 3.4-6: From 5 reliable Czech and German efficacy trials, supported by 2 reliable Danish and Swedish efficacy trials, no significant adverse effect was found on seed yield resulting from an Autumn application with PRL OD75, both at the maximum proposed dose rate (1.2 L/ha) and at the double of the proposed dose rate (2.4 L/ha), in all the 7 trials on BRSNW.

**Table 3.4-5: USE001 - Overview of the effects on the seed yield in treated winter oilseed rape crop – Efficacy trials in presence of PGR effect**

- For approval at 1.2 L/ha in cMS of the North-East EPPO zone (Poland)

EPPO zone	European regulatory zone	Number of trials	Untreated SEED YIELD (t/ha)		% relative to the untreated								Stat. Anal.	Comparison
					Test product				Reference products					
					PRL OD75				Ref. 1		Ref. 2			
					1.2 L/ha (1N)		2.4 L/ha (2N)		1 L/ha		1.2 L/ha			
			Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max		
North-East	Central	3	3.94	3.24-4.64	<b>100.5</b>	95.8-103.8	99.5	94.1-104.7	98.8	94.6-103	104.5	100.6-109.6	= 3, < 0, > 0	All
	North (supportive)	1	4.31	-	<b>103.8</b>	-	105.1	-	99.8	-	104.4	-	= 1, < 0, > 0	All
	All 2 EU Regulatory zones	4	4.04	3.24-4.64	<b>101.3</b>	95.8-103.8	100.9	94.1-105.1	99.1	94.6-103	104.5	100.6-109.6	= 4, < 0, > 0	All
Maritime (supportive)	Central (CZE)*	2	4.61	3.88-5.33	<b>99.8</b>	99.7-99.9	98.4	97.4-99.3	102.0	99.2-104.7	102.0	97.2-106.8	= 2, < 0, > 0 = 2, < 0, > 0 = 1, < 1, > 0 = 2, < 0, > 0  = 2, < 0, > 0	PRL OD75 1N vs. UTC PRL OD75 1N vs. Ref. 1 PRL OD75 1N vs. Ref. 2 PRL OD75 2N vs. UTC  PRL OD75 2N vs. PRL OD75 1N
All 2 EPPO zones	All 2 EU Regulatory zones	6	4.23	3.24-5.33	<b>100.8</b>	95.8-103.8	100.1	94.1-105.1	100.0	94.6-104.7	103.7	97.2-109.6	= 6, < 0, > 0 = 6, < 0, > 0 = 5, < 1, > 0 = 6, < 0, > 0  = 6, < 0, > 0	PRL OD75 1N vs. UTC PRL OD75 1N vs. Ref. 1 PRL OD75 1N vs. Ref. 2 PRL OD75 2N vs. UTC  PRL OD75 2N vs. PRL OD75 1N

\*Two Czech trials (Maritime EPPO zone) sited close to the border with Poland are additionally validated to support the evaluation of the adverse effects on the seed yield of PRL0D75 applied to the treated crop, for the submission in Poland (North-East EPPO zone).

Ref. 1 - mepiquat-chloride+metconazole SL240 (210+30 g/L) applied at 1 L/ha

Ref. 2 - prothioconazole+tebuconazole EC240 (80+160 g/L) applied at 1.2 L/ha

**Table 3.4-6: USE002 - Overview of the effects on the seed yield in treated winter oilseed rape crop – Efficacy trials in presence of PGR effect**  
 - For approval at 1.2 L/ha in cMSs of the Maritime EPP0 zone (Austria, the Czech Republic and Germany)

EPP0 zone	European regulatory zone	Number of trials	Untreated SEED YIELD (t/ha)		% relative to the untreated								Stat. Anal.	Comparison
					Test product				Reference products					
			PRL OD75				Ref. 1		Ref. 2					
			1.2 L/ha (1N)		2.4 L/ha (2N)		1 L/ha		1.2 L/ha					
Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max			
Maritime	Central	5	4.28	3.67-5.33	<b>101.9</b>	99.7-106.4	100.6	97.4-105.5	103.1	99.1-110.5	102.3	97.2-106.8	= 5, < 0, > 0 = 5, < 0, > 0 = 4, < 1, > 0 = 5, < 0, > 0  = 5, < 0, > 0	PRL OD75 1N vs. UTC PRL OD75 1N vs. Ref. 1 PRL OD75 1N vs. Ref. 2 PRL OD75 2N vs. UTC  PRL OD75 2N vs. PRL OD75 1N
	North (supportive)	2	4.49	4.27-4.71	<b>103.2</b>	101.8-104.6	104.7	104.2-105.2	103.9	100.1-107.7	104.4	101.0-107.8	= 2, < 0, > 0	All
	All 2 EU Regulatory zones	7	4.34	3.67-5.33	<b>102.3</b>	99.7-106.4	101.8	97.4-105.5	103.3	99.1-110.5	102.9	97.2-107.8	= 7, < 0, > 0 = 7, < 0, > 0 = 6, < 1, > 0 = 7, < 0, > 0  = 7, < 0, > 0	PRL OD75 1N vs. UTC PRL OD75 1N vs. Ref. 1 PRL OD75 1N vs. Ref. 2 PRL OD75 2N vs. UTC  PRL OD75 2N vs. PRL OD75 1N

Ref. 1 - mepiquat-chloride+metconazole SL240 (210+30 g/L) applied at 1 L/ha

Ref. 2 - prothioconazole+tebuconazole EC240 (80+160 g/L) applied at 1.2 L/ha

**Table 3.4-7: USE003 - Overview of the effects on the seed yield in treated winter oilseed rape crop – Efficacy trials in presence of PGR effect**  
 - For approval at 1.2 L/ha in cMS of the South-East EPPO zone (Hungary, Romania and Slovakia)

EPPO zone	European regulatory zone	Number of trials	Untreated SEED YIELD (t/ha)		% relative to the untreated								Stat. Anal.	Comparison
					Test product				Reference products					
			PRL OD75				Ref. 1		Ref. 2					
			1.2 L/ha (1N)		2.4 L/ha (2N)		0.7-1.0 L/ha		1.2 L/ha					
			Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max		
South-East	Central	7	3.88	3.41-4.63	<b>101.3</b>	97.2-107.0	100.5	96.3-104.6	103.3	101.1-107.0	102.0	97.6-105.5	= 7, < 0, > 0	All

Ref. 1 - mepiquat-chloride+metconazole SL240 (210+30 g/L) applied at 1 L/ha - In two Romanian trials, Ref. 1 was applied at the local approved dose rate of 0.7 L/ha

Ref. 2 - prothioconazole+tebuconazole EC240 (80+160 g/L) applied at 1.2 L/ha

**Supporting USE003 - cMSs of the South-East EPPO zone (Hungary, Romania and Slovakia)**

– Table 3.4-7: From 7 reliable Hungarian, Romanian and Slovakian efficacy trials, no significant adverse effect was found on seed yield resulting from an Autumn application with PRL OD75, both at the maximum proposed dose rate (1.2 L/ha) and at the double of the proposed dose rate (2.4 L/ha), in all the 7 trials on BRSNW.

**OVERALL CONCLUSIONS FOR POSSIBLE EFFECTS ON SEED YIELD FROM TREATED CROP (BRSNW)**

No significant effect was found on winter oilseed rape treated on Autumn with PRL OD75 at both the proposed dose rate of 1.2 L/ha or its double 2.4 L/ha, when compared both with the untreated and with the reference products in all 18 reliable European trials.

A significant positive effect on seed yield is only observed with the reference product Ref. 1 (based on prothioconazole+tebuconazole EC240) in 1 Czech trial.

Based on the seed yield results of 18 trials (1 year), it is concluded that there is no risk of seed yield reduction and therefore unlikely that negative effect on the seed yield will occur on winter oilseed rape crop (BRSNW), when the new PGR product PRL OD75 will be applied in accordance with the proposed use pattern in cMSs with this submission in Austria, the Czech Republic, Germany, Hungary, Poland, Romania and Slovakia.

Comments of zRMS:	<p>The yield of winter rape was assessed in 18 experiments in the growing season 2019/2020. 11 of them were carried out in Poland, in the countries of the North-East EPPO zone or in countries neighboring with Poland. The remaining 7 trials were conducted in Denmark (1), Hungary (2), Romania (3) and Sweden (1).</p> <p><b>The lack of a negative effect on the yield in all 18 experiments proved that the growth regulator PRL OD75, Hingios 75 OD applied once (BBCH 12-18) in autumn is a safety for winter oilseed rape.</b></p>
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**3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)**

The potential effect of the autumn application with PRL OD75 on the seed quality parameters analysed post-harvest is evaluated in already available data of 17 efficacy trials submitted to support the effectiveness of the test product as plant growth regulator on winter oilseed rape. All these efficacy trials were applied on Autumn 2019 and harvested on Summer 2020. They were conducted in a wide range of agro-climatic conditions in oilseed rape cultivation regions of countries belonging to different EPPO climatic zones (Maritime, North-East and South-East) and EU regulatory zones (Central, supported with South and North). Since the winter conditions were not strong enough to impact the crop stand after the winter, the effect on seed quality parameters is mostly considered as being only possible adverse effect on the treated crop, winter oilseed rape (BRSNW).

The test product PRL OD75 applied at the proposed maximum dose rate of 1.2 L/ha and at the double dose rate of 2.4 L/ha was compared to two reference products, mepiquat-chloride+metconazole SL240 and prothioconazole+tebuconazole EC240 applied at the recommended or approved dose rates.

Both PRL OD75 and reference products were applied once in Autumn on winter oilseed rape at the reported major growth stages from BBCH 14 to BBCH 18. Nevertheless and depending on trial conditions, at application the minimum crop growth stage was BBCH 12 up to the maximum crop growth stage BBCH 18, then covering the proposed use pattern (BBCH 12-18).

The seed samples were taken at harvest from the harvested seeds in all 18 harvested trials (notably to determine the moisture), and the seed quality analyses were conducted in 17 out of the 18 trials.

The seed samples consisted to a sample for each replicate or overall the 4 replicates, depending on the local decision and material availabilities.

The thousand seed weight (TKW) was assessed using the specific equipment approved to perform this quality analyse under GEP certification. The seed oil content (OILCON) and seed protein content (PROCON) were determined using international and standard methods with specific equipment, in laboratory.

Remark: OILCON and TKW were analysed in 13 trials; PROCON, which is not strictly required by EPPO standard PP1/153(3), is reported in 5 trials.

Even if the expected PGR effect was present both before and after the winter (reported in Chapter 3.2.3), no visual crop safety issue was seen on plant parts (reported in Chapter 3.4.1) and no significant impact was found on seed yield at harvest (reported in Chapter 3.4.2), in all concerned trials.

Effects on seed quality parameters in efficacy trials, then in presence of the PGR effect reported in Chapter 3.2.3, are summarised in Table 3.4-8 (OILCON), Table 3.4-9 (TKW) and Table 3.4-10 (PROCON).

#### **Supporting USE001 - CMS of the North-East EPPO zone (Poland)**

- Table 3.4-8: From 3 supportive Lithuanian and Czech efficacy trials, no significant adverse effect was found on seed OILCON resulting from an Autumn application with PRL OD75, both at the maximum proposed dose rate (1.2 L/ha) and at the double of the proposed dose rate (2.4 L/ha).
- Table 3.4-9: From 2 Polish efficacy trials, supported by 3 supportive Lithuanian and Czech efficacy trials, no significant adverse effect was found on TKW resulting from an Autumn application with PRL OD75, both at the maximum proposed dose rate (1.2 L/ha) and at the double of the proposed dose rate (2.4 L/ha), in 4 out of the 5 trials on BRSNW. When compared to the untreated, the positive calculated means for all treatments is clearly impacted with the high positive effects obtained in 1 marginal Polish trial, where the TKW was measured from one single sample for the 4 replicates.
- Table 3.4-10: From 1 Polish efficacy trial, no significant adverse effect was found on seed PROCON resulting from an Autumn application with PRL OD75, both at the maximum proposed dose rate (1.2 L/ha) and at the double of the proposed dose rate (2.4 L/ha).

#### Conclusions USE001

Excluding the marginal TKW data of 1 Polish efficacy trial, results from 5 reliable efficacy trials conducted in winter oilseed rape over 1 cropping season (application on Autumn 2019, harvested on Summer 2020) showed no significant adverse impact on seed quality parameters (i.e. oil content, thousand seed weight, and protein content) of harvested seeds after application of PRL OD75 applied both at the maximum proposed dose rate (1.2 L/ha) and the double of the proposed dose rate (2.4 L/ha).

It is therefore concluded that there is no risk of a significant negative effect to the main seed quality parameters in winter oilseed rape with the test product PRL OD75, when applied in accordance with the proposed use pattern in Poland.

### **Supporting USE002 - cMSs of the Maritime EPP0 zone (Austria, the Czech Republic and Germany)**

- Table 3.4-8: From 5 reliable Czech and German efficacy trials, supported with 2 reliable Danish and Swedish efficacy trials, no significant adverse effect was found on seed OILCON resulting from an Autumn application with PRL OD75, both at the maximum proposed dose rate (1.2 L/ha) and at the double of the proposed dose rate (2.4 L/ha), in all the 7 trials on BRSNW.
- Table 3.4-9: From 5 reliable Czech and German efficacy trials, supported with 2 reliable Danish and Swedish efficacy trials, no significant adverse effect was found on TKW resulting from an Autumn application with PRL OD75, both at the maximum proposed dose rate (1.2 L/ha) and at the double of the proposed dose rate (2.4 L/ha), in all the 7 trials on BRSNW.
- Table 3.4-10: From 1 reliable Czech efficacy trial, supported with 2 reliable Danish and Swedish efficacy trials, no significant adverse effect was found on seed PROCON resulting from an Autumn application with PRL OD75, both at the maximum proposed dose rate (1.2 L/ha) and at the double of the proposed dose rate (2.4 L/ha), in all the 7 trials on BRSNW.

#### Conclusions USE002

Results from 7 reliable efficacy trials conducted in winter oilseed rape over 1 cropping season (application on Autumn 2019, harvested on Summer 2020) showed no significant adverse impact on seed quality parameters (i.e. oil content, thousand seed weight, and protein content) of harvested seeds after application of PRL OD75 applied both at the maximum proposed dose rate (1.2 L/ha) and the double of the proposed dose rate (2.4 L/ha).

It is therefore concluded that there is no risk of a significant negative effect to the main seed quality parameters in winter oilseed rape with the test product PRL OD75, when applied in accordance with the proposed use pattern in Austria, the Czech Republic and Germany.

### **Supporting USE003 - cMSs of the South-East EPP0 zone (Hungary, Romania and Slovakia)**

- Table 3.4-8: From 7 reliable Hungarian, Romanian and Slovakian efficacy trials, mostly no significant adverse effect was found on seed OILCON resulting from an Autumn application with PRL OD75, both at the maximum proposed dose rate (1.2 L/ha) and at the double of the proposed dose rate (2.4 L/ha). The positive difference in OILCON between the test product and the untreated is statistically significant in 1 out of 7 trials, similarly to the reference products.
- Table 3.4-9: From 7 reliable Hungarian, Romanian and Slovakian efficacy trials, mostly no significant adverse effect was found on TKW resulting from an Autumn application with PRL OD75, both at the maximum proposed dose rate (1.2 L/ha) and at the double of the proposed dose rate (2.4 L/ha). On this quality parameter, a high variability is observed between trials. When compared to the untreated, the effect of PRL OD75 on TKW is statistically significant in 1 out of 7 trials, either negatively at 1.2 L/ha or positively at 2.4 L/ha.
- Table 3.4-10: From 2 reliable Romanian efficacy trials, no significant adverse effect was found on seed PROCON resulting from an Autumn application with PRL OD75, both at the maximum proposed dose rate (1.2 L/ha) and at the double of the proposed dose rate (2.4 L/ha), in all the 2 trials on BRSNW.

#### Conclusions USE003

Results from 7 reliable efficacy trials conducted in winter oilseed rape over 1 cropping season (application on Autumn 2019, harvested on Summer 2020) showed mostly no significant adverse impact on seed quality parameters (i.e. oil content, thousand seed weight, and protein content) of harvested seeds after application of PRL OD75 applied both at the maximum proposed dose rate (1.2 L/ha) and the double of the proposed dose rate (2.4 L/ha).

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The differences in seed oil content (OILCON), thousand seed weight (TKW) or seed protein content (PROCON), between either all products or each product and the untreated, are statistically not significant in the majority of trials. When comparing PRL OD 75 at 1.2 and 2.4 L/ha to untreated, no significant effect was found either in 6 out of 7 trials (OILCON), in 6 out of 7 trials (TKW) or in 2 out of 2 trials (PROCON).

It is therefore concluded that there is no risk of a significant negative effect to the main seed quality parameters (i.e. oil content, thousand seed weight, and protein content) in winter oilseed rape with the test product PRL OD75, when applied in accordance with the proposed use pattern in Hungary, Romania and Slovakia.

**Table 3.4-8: Overview of the effects on the quality of harvest seeds from treated BRSNW crop with PRL OD75 – Efficacy trials in presence of PGR effect Seed oil content (OILCON)**

EPPO zone	European regulatory zone	Number of trials	Untreated OIL CONTENT (%)		% relative to the untreated							
					Test product				Reference products			
			PRL OD75				Ref. 1		Ref. 2			
			1.2 L/ha (1N)		2.4 L/ha (2N)		1 L/ha*		1.2 L/ha			
Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	
North-East (USE001)	All 2 EU Regulatory Zones (supportive)	3	41.9	40.1-44.6	<b>99.4</b>	98.7-99.8	99.8	99.3-100.5	100.3	99.2-102.0	100.7	99.0-102.5
	North (supportive)	1	44.6	-	<b>98.7</b>	-	99.6	-	99.2	-	100.7	-
	Central –Czech trials (Supportive - EPPO Maritime)	2	40.6	40.1-41.0	<b>99.8</b>	99.8-99.8	99.9	99.3-100.5	100.8	99.6-102.0	100.8	99.0-102.5
Maritime (USE002)	All 2 EU Regulatory zones	6	44.3	40.1-49.2	<b>99.7</b>	98.7-100.7	99.7	98.7-100.5	100.3	99.4-102.0	100.3	98.9-102.5
		7	43.7	40.1-49.2	<b>100.0</b>	98.7-101.9	-	-	99.9	97.3-102.0	-	-
	Central	4	42.5	40.1-46.1	<b>100.1</b>	99.8-100.7	100.1	99.3-100.5	100.7	99.6-102.0	100.8	99.0-102.5
		5	42.1	40.1-46.1	<b>100.4</b>	99.8-101.9	-	-	100.0	97.3-102.0	-	-
	North (supportive)	2	47.8	46.3-49.2	<b>99.0</b>	98.7-99.3	98.9	98.7-99.0	99.4	-	99.5	98.9-100.0
South-East (USE003)	Central	7	42.9	40.2-45.8	<b>100.4</b>	98.4-102.0	100.5	98.8-102.2	100.6*	98.5-102.4	100.8	99.2-102.2

Ref. 1 - mepiquat-chloride+metconazole SL240 (210+30 g/L) applied at 1 L/ha - \*In two Romanian trials, Ref. 1 was applied at the local approved dose rate of 0.7 L/ha

Ref. 2 - prothioconazole+tebuconazole EC240 (80+160 g/L) applied at 1.2 L/ha

**Table 3.4-9: Overview of the effects on the quality of harvest seeds from treated BRSNW crop with PRL OD75 – Efficacy trials in presence of PGR effect Thousand seed weight (TKW)**

EPPO zone	European regulatory zone	Number of trials	Untreated TKW (g)		% relative to the untreated							
					Test product				Reference products			
			PRL OD75				Ref. 1		Ref. 2			
			1.2 L/ha (1N)		2.4 L/ha (2N)		1 L/ha*		1.2 L/ha			
Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	
North-East (USE001)	All 2 EU Regulatory Zones + CZE trials (supportive)	5	4.0	3.4-4.8	<b>100.4</b>	95.2-106.3	104.0	97.8-121.2	104.4	97.1-122.7	99.5	91.3-106.0
	All 2 EU Regulatory Zones (supportive)	3	4.3	4.0-4.8	<b>100.9</b>	95.2-106.3	106.5	97.8-121.2	107.2	97.1-122.7	99.3	91.3-106.0
	Central	2	4.0	4.0-4.0	<b>100.8</b>	95.2-106.3	109.5	97.8-121.2	109.9	97.1-122.7	98.7	91.3-106.0
	North (supportive)	1	4.8	-	<b>101.1</b>	-	100.6	-	101.8	-	100.5	-
	Central –Czech trials (Supportive - EPPO Maritime)	2	3.6	3.4-3.8	<b>99.7</b>	97.5-101.8	100.1	97.9-102.3	100.2	99.3-101.1	99.8	99.6-100.0
Maritime (USE002)	All 2 EU Regulatory zones	7	4.6	3.4-6.3	<b>101.2</b>	97.3-106.4	100.5	94.7-105.9	100.0	92.0-104.5	100.2	92.0-105.1
	Central	5	4.5	3.4-6.3	<b>101.7</b>	97.5-106.4	101.4	97.9-105.9	100.7	95.0-104.4	101.2	96.8-105.1
	North (supportive)	2	5.0	4.7-5.3	<b>99.8</b>	97.3-102.3	98.1	94.7-101.4	98.3	92.0-104.5	97.8	92.0-103.5
South-East (USE003)	Central	7	4.6	3.7-5.3	<b>98.8</b>	95.8-103.7	100.9	98.2-106.2	98.4*	91.8-102.5	99.8	95.7-103.1

Ref. 1 - mepiquat-chloride+metconazole SL240 (210+30 g/L) applied at 1 L/ha - \*In two Romanian trials, Ref. 1 was applied at the local approved dose rate of 0.7 L/ha

Ref. 2 - prothioconazole+tebuconazole EC240 (80+160 g/L) applied at 1.2 L/ha

**Table 3.4-10: Overview of the effects on the quality of harvest seeds from treated BRSNW crop with PRL OD75 – Efficacy trials in presence of PGR effect Seed protein content (PROCON)**

EPPO zone	European regulatory zone	Number of trials	Untreated PROTEIN CONTENT (%)		% relative to the untreated							
					Test product				Reference products			
			PRL OD75				Ref. 1		Ref. 2			
			1.2 L/ha (1N)		2.4 L/ha (2N)		1 L/ha*		1.2 L/ha			
Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	
North-East (USE001)	Central	1	21.3	-	<b>99.8</b>	-	101.0	-	100.4	-	97.2	-
Maritime (USE002)	All 2 EU Regulatory zones	3	20.1	19.2-21.3	<b>101.8</b>	99.8-103.5	101.6	101.0-102.7	101.0	100.4-101.7	99.7	97.2-101.5
	Central	1	21.3	-	<b>99.8</b>	-	101.0	-	100.4	-	97.2	-
	North (supportive)	2	19.6	19.2-19.9	<b>102.8</b>	102.1-103.5	101.9	101.0-102.7	101.4	101.0-101.7	101.0	100.4-101.5
South-East (USE003)	Central	2	14.7	14.3-15.1	<b>100.6</b>	97.2-103.9	100.1	98.2-102.0	95.5*	90.0-100.9	101.3	97.8-104.7

Ref. 1 - mepiquat-chloride+metconazole SL240 (210+30 g/L) applied at 1 L/ha - \*In two Romanian trials, Ref. 1 was applied at the local approved dose rate of 0.7 L/ha

Ref. 2 - prothioconazole+tebuconazole EC240 (80+160 g/L) applied at 1.2 L/ha

**OVERALL CONCLUSIONS FOR POSSIBLE EFFECTS ON THE QUALITY OF HARVESTED SEEDS FROM A TREATED CROP (BRSNW)**

Overall, from seed quality parameter results of 17 trials, mostly no significant effect was found on winter oilseed rape treated at the major crop growth stages BBCH 14-18 (but covering minimum BBCH 12 up to maximum BBCH 18) on Autumn with PRL OD75, at both the proposed dose rate of 1.2 L/ha or its double 2.4 L/ha, when compared both with the untreated and with the reference products.

In all 10 trials conducted in the North-East EPPO zone (5) and the Maritime EPPO zone (5), no significant difference was found on the three quality parameters (OILCON, TKW and PROCON) between either all products or each product and the untreated, excluding a marginal TKW result in a Polish trial.

In two out of 7 trials carried out in the South-East EPPO zone, some statistically significant difference were found on the seed oil content (OILCON) and the thousand seed weight (TKW). In all other 5 trials, the differences between PRL OD75 and untreated are statistically not significant, in both OILCON and TKW. Additionally, the differences in the third quality parameter analysed, i.e. the seed protein content PROCON, between either all products or each product and the untreated, are statistically not significant in the two concerned Romanian trials.

It is therefore unlikely that negative effect on the seed quality parameters will occur on winter oilseed rape crop, when PRL OD75 will be applied in accordance with the proposed use pattern in cMSs with this submission in Austria, the Czech Republic, Germany, Hungary, Poland, Romania and Slovakia.

Comments of zRMS:	<p>The impact on the quality of plants or plant products was assessed on the basis of the weight of one thousand seeds (17 trials, including 10 from the EPPO zone north-east or from neighboring countries of Poland), oil content (13 trials, including 6 from the North-East EPPO zone or from neighboring countries with Poland), the protein content of the seeds (5 experiments, including 1 from the North-East EPPO zone or from countries neighboring Poland).</p> <p>The lack of negative impact on the thousand seeds weight, oil content and protein content confirms that the growth regulator PRL OD75 applied once (BBCH 12-18) in autumn is safe for winter oilseed rape.</p> <p><b>No negative impact on the weight of a thousand seeds, oil content and protein content in the experiments carried out in the countries of the North-East EPPO zone or in neighboring countries with Poland, confirms that the one-time use of the PRL growth regulator OD 75, Hingios 75 OD (BBCH 12-18) in the fall is safe for winter oilseed rape.</b></p>
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**3.4.4 Effects on transformation processes (KCP 6.4.4)**

No data concerning effects on the processing procedure are presented according to the EPPO standard PP 1/243 *Effects of plant protection products on transformation processes*, which provides an indication of the circumstances under which data on transformation processes are required.

According to EPPO standard PP1/243, no specific study is deemed to be conducted on oilseed rape.

**3.4.5 Impact on treated plants or plant products to be used for propagation (KCP**

#### 6.4.5)

The potential effect of the autumn application with PRL OD75 on the seed germination test conducted post-harvest is evaluated in already available data of 15 efficacy trials submitted to support the effectiveness of the test product as plant growth regulator on winter oilseed rape. All these efficacy trials were applied on Autumn 2019 and harvested on Summer 2020. They were conducted in a wide range of agro-climatic conditions in oilseed rape cultivation regions of countries belonging to different EPPO climatic zones (Maritime, North-East and South-East) and EU regulatory zones (Central, supported with South and North). Since the winter conditions were not strong enough to impact the crop stand after the winter, the effect on seed germination is mostly considered as being only possible adverse effect on the treated crop, winter oilseed rape (BRSNW).

The test product PRL OD75 applied at the proposed maximum dose rate of 1.2 L/ha and at the double dose rate of 2.4 L/ha was compared to two reference products, mepiquat-chloride+metconazole SL240 and prothioconazole+tebuconazole EC240 applied at their recommended or approved dose rates.

Both PRL OD75 and reference products were applied once in Autumn on winter oilseed rape at the reported major growth stages from BBCH 14 to BBCH 18. Nevertheless and depending on trial conditions, at application the minimum crop growth stage was BBCH 12 up to the maximum crop growth stage BBCH 18, then covering the proposed use pattern (BBCH 12-18).

The seed samples were taken at harvest from the yielded seeds of oilseed rape crop. The seed samples consisted of a sample of 4 replicates taken in the relevant factors. Therefore, the grain samples were taken at least in the untreated, PRL OD75 at the proposed maximum dose rate of 1.2 L/ha and the main reference product based mepiquat-chloride+metconazole at its local recommended or approved dose rate of 1.0 L/ha. In 4 out of 15 trials also the double dose rate of 2.4 L/ha PRL OD75 was taken in consideration in the germination test.

#### Germination test method

The germination tests were implemented according to the international standard seed testing methods established by ISTA (International Seed Testing Association).

From sampled seeds, 800, 400 or 200 seeds per treatment (split in 4 replicates of 200, 100 or 50 seeds each) were used for germination test. Samples were preheated (20-30°C) with 8 hours of light per 24 hours, during the period of the test.

Assessments were done at the end of the germination test on:

- % of normal emerged seedlings. Seedlings possessing the essential structures that are indicative of their ability to produce plants under favourable conditions;
- % of abnormal emerged seedlings. Seedlings that do not show the potential for continued development into satisfactory plants under favourable environmental conditions;
- % of un-emerged seeds.

The germination test was performed either in a short period after the harvested of seeds or after a long period of storage in excellent dry conditions.

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– Table 3.4-11: From 3 supportive Lithuanian and Czech efficacy trials, a very similar pattern of seed germination (normal, abnormal and un-emerged) to the untreated control and the reference product Ref. 1 was found for PRL OD75 at 1.2 L/ha, in 2 out of 3 trials. In a Czech trial, abnormal seedlings were found in harvested seeds from oilseed rape crop treated both with the test product (2.5%) and with the reference product (3.3%), statistically significant when compared to the untreated (0%). This effect could be considered marginal and negligible (< to 5%).

The absence of a possible effect on the germination tests of harvested seeds was confirmed at the double dose rate of 2.4 L/ha in the Lithuanian trial.

#### **Supporting USE002 - cMSs of the Maritime EPP0 zone (Austria, the Czech Republic and Germany)**

– Table 3.4-11: From 5 reliable Czech and German efficacy trials, supported with 2 reliable Danish and Swedish efficacy trials, a very similar pattern of seed germination (normal, abnormal and un-emerged) to the untreated control and the reference product Ref. 1 was found for PRL OD75 at 1.2 L/ha, in 6 out of 7 trials. In a Czech trial, abnormal seedlings were found in harvested seeds from oilseed rape crop treated both with the test product (2.5%) and with the reference product (3.3%), statistically significant when compared to the untreated (0%). This effect could be considered marginal and negligible (< to 5%).

**Table 3.4-11: Overview of the effects on the propagation tests on harvest seeds from treated BRSNW crop with PRL OD75 – Efficacy trials in presence of PGR effect - % Germination (absolute value)**

EPPO zone	European regulatory zone	Number of trials	Seedling type	Untreated		% SEEDLING (%)							
						Test product				Reference products			
				% SEEDLING (%)		PRL OD75				Ref. 1		Ref. 2	
						1.2 L/ha (1N)		2.4 L/ha (2N)		1 L/ha		1.2 L/ha	
				Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
North-East (USE001)	All 2 EU Regulatory Zones (supportive)	3	Normal	97.3	96.0-99.0	<b>95.4</b>	91.5-100	-	-	96.2	91.8-100	-	-
			Abnormal	0.0	0.0-0.0	<b>0.9</b>	0.0-2.5	-	-	1.1	0.0-3.3	-	-
			Un-emerged	2.8	1.0-4.0	<b>3.7</b>	0.0-6.0	-	-	2.8	0.0-5.0	-	-
	North (supportive)	1	Normal	96.8	-	<b>94.8</b>	-	95.3	-	96.8	-	96.0	-
			Abnormal	0.0	-	<b>0.3</b>	-	1.0	-	0.0	-	1.5	-
			Un-emerged	3.3	-	<b>5.0</b>	-	3.8	-	3.3	-	2.5	-
	Central – Czech trials (Supportive - EPPO Maritime)	2	Normal	97.5	96.0-99.0	<b>95.8</b>	91.5-100	-	-	95.9	91.8-100	-	-
			Abnormal	0.0	0.0-0.0	<b>1.3</b>	0.0-2.5	-	-	1.6	0.0-3.3	-	-
			Un-emerged	2.5	1.0-4.0	<b>3.0</b>	0.0-6.0	-	-	2.5	0.0-5.0	-	-
Maritime (USE002)	All 2 EU Regulatory Zones (supportive)	7	Normal	97.8	95.9-100	<b>97.6</b>	91.5-100	-	-	97.2	91.8-100	-	-
			Abnormal	0.1	0.0-0.6	<b>0.5</b>	0.0-2.5	-	-	0.6	0.0-3.3	-	-
			Un-emerged	2.1	0.0-4.0	<b>1.9</b>	0.0-6.0	-	-	2.3	0.0-5.0	-	-
	Central	1	Normal	95.9	-	<b>96.3</b>	-	95.9	-	95.6	-	95.0	-
			Abnormal	0.6	-	<b>1.0</b>	-	1.0	-	0.6	-	0.9	-
			Un-emerged	3.5	-	<b>2.8</b>	-	3.1	-	3.8	-	4.1	-
		5	Normal	97.9	95.9-100	<b>97.2</b>	91.5-100	-	-	97.1	91.8-100	-	-
			Abnormal	0.2	0.0-0.6	<b>0.7</b>	0.0-2.5	-	-	0.8	0.0-3.3	-	-
			Un-emerged	2.0	0.0-4.0	<b>2.1</b>	0.0-6.0	-	-	2.1	0.0-5.0	-	-
	North (supportive)	2	Normal	97.6	97.0-98.3	<b>98.4</b>	97.5-99.3	-	-	97.4	97.0-97.8	-	-
			Abnormal	0.0	0.0-0.0	<b>0.0</b>	0.0-0.0	-	-	0.0	0.0-0.0	-	-
			Un-emerged	2.4	1.8-3.0	<b>1.6</b>	0.8-2.5	-	-	2.6	2.3-3.0	-	-

**Table 3.4-11 - continued: Overview of the effects on the propagation tests on harvest seeds from treated BRSNW crop with PRL OD75  
 – Efficacy trials in presence of PGR effect - % Germination (absolute value)**

Eppo zone	European regulatory zone	Number of trials	Seedling type	Untreated % SEEDLING (%)		% SEEDLING (%)							
						Test product				Reference products			
				PRL OD75				Ref. 1		Ref. 2			
				1.2 L/ha (1N)		2.4 L/ha (2N)		1 L/ha*		1.2 L/ha			
Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max		
South-East (USE003)	Central	2	Normal	95.8	92.3-99.3	<b>94.8</b>	91.8-97.8	96.9	94.0-99.8	95.9	93.0-98.8	96.1	93.0-99.3
			Abnormal	0.0	0.0-0.0	<b>0.0</b>	0.0-0.0	0.0	0.0-0.0	0.0	0.0-0.0	0.1	0.0-0.3
			Un-emerged	4.3	0.8-7.8	<b>5.3</b>	2.3-8.3	3.1	0.3-6.0	4.1	1.3-7.0	3.8	0.5-7.0
		7	Normal	96.2	92.3-99.3	<b>95.0</b>	91.8-99.0	-	-	94.3	89.5-99.5	-	-
			Abnormal	0.9	0.0-3.5	<b>1.3</b>	0.0-5.0	-	-	2.0	0.0-9.0	-	-
			Un-emerged	3.0	0.8-7.8	<b>3.6</b>	0.8-8.3	-	-	3.7	0.3-10.5	-	-

Ref. 1 - mepiquat-chloride+metconazole SL240 (210+30 g/L) applied at 1 L/ha - \*In two Romanian trials, Ref. 1 was applied at the local approved dose rate of 0.7 L/ha

Ref. 2 - prothioconazole+tebuconazole EC240 (80+160 g/L) applied at 1.2 L/ha

**Supporting USE003 - cMSs of the South-East EPPO zone (Hungary, Romania and Slovakia)**

– Table 3.4-11: From 7 reliable Hungarian, Romanian and Slovakian efficacy trials, a very similar pattern of seed germination (normal, abnormal and un-emerged) to the untreated control and the reference product Ref. 1 was found for PRL OD75 at 1.2 L/ha, in 6 out of 7 trials. In one Slovakian trial, less normal seedlings were found in harvested seeds from oilseed rape crop treated both with the test product (93.0%) and with the reference product (93.5%), statistically significant when compared to the untreated (98.0%). In this trial, all other seeds were not emerged both for the untreated plots as for the treated plots. Since the effect is maximum of 5% when compared with the untreated, it is considered marginal. The absence of a possible effect on the germination tests of harvested seeds was confirmed at the double dose rate of 2.4 L/ha in 2 trials. PRL OD 75 at both 1.2 and 2.4 L/ha and the two reference products showed excellent normal emergence, similar to the untreated, in the 2 reliable trials.

**OVERALL CONCLUSIONS FOR POSSIBLE EFFECTS ON THE GERMINATION TESTS OF HARVESTED SEEDS FROM A TREATED CROP (BRSNW)**

Germination test results showed a very similar pattern of seed germination (normal, abnormal and un-emerged) between the untreated check, the reference product PRL OD75 at 1.2 L/ha and the reference product Ref. 1 (mepiquat-chloride+metconazole SL240) in the majority of the trials.

When compared to the untreated check, significant effects were found with the test product PRL OD75 at 1.2 L/ha in a total of 2 out 15 trials, similarly to the reference product Ref. 1, with either more abnormal seedlings in 1 Czech or less normal seedlings (more not-emerged) in 1 Slovakian. The effects on seedlings is maximum of 5% when compared to the untreated, then it is considered negligible and marginal.

Moreover, when applied at 2.4 L/ha (2N) in 4 trials, PRL OD75 showed no effect on germination of seed, similarly to the untreated check, PRL OD75 at N dose rate (1.2 L/ha) and the reference products.

It could be concluded that no negative impact on treated plants or plant products to be used for propagation are expected from the use of PRL OD75, when applied in accordance with the proposed use pattern on winter oilseed rape, in the cMSs, Austria, the Czech Republic, Germany, Hungary, Poland, Romania and Slovakia.

Comments of zRMS:	<p>Impact on treated plants or plant products to be used for propagation was assessed by assessing the germination of the seeds. Eight such experiments were carried out in the North-Eastern EPPO zone or in the neighboring countries of Poland: Lithuania (1), the Czech Republic (3), Slovakia (2) and Germany (2). In only one experiment (GR21CZE010OP01) there was a significant reduction in normally germinated seeds. The seeds germinated at a similar level after comparative treatment. Despite the reduction in the amount of normally germinated seeds, this % was still very high and amounted to 93%.</p> <p>Additionally, the applicant presented 7 experiments carried out in other zones: Denmark (1), Hungary (2), Romania (3) and Sweden (1). In all these studies, no negative influence of the tested growth regulator on the germination of winter oilseed rape seeds was found.</p> <p><b>On the basis of the presented results, it can be concluded that PRL OD75, Hingios 75 OD has no negative effect on the treated plants or plant products intended for propagation.</b></p>
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### 3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

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

Data from eco-toxicology on non-target treated plants are presented in details in Part B section 9 of the draft Registration Report.

Pre-emergence tests with PRL OD75 at 1.2 L/ha were conducted under greenhouse conditions in 2020, resulted in no noteworthy negative impacts to succeeding crops. The active substance pre emergence crop sensitivity data submitted indicate limited adverse effects at the maximum proposed application rate of 1.2 L/ha which is equivalent to 90g prohexadione-calcium /ha.

**Table 3.4-12: Effects of 90 g prohexadione-calcium /ha (OD 75) in the seedling emergence test**

Plant Species	Observations at the test item rate of 90 g a.s./ha					BBCH control min - max	BBCH treated min - max
	Emergence (% inhibition) N	Survival (% inhibition) N	Shoot dry weight (% inhibition) N	Plant height(% inhibition)	Phyto-toxicity (%)		
<i>Beta vulgaris</i>	-5.3	0.0	-0.2	3.7	0.0	16-17	16-17
<i>Brassica rapa</i>	5.0	0.0	8.1	2.9	0.0	16-19	16-19
<i>Cucumis sativus</i>	0.0	0.0	-5.1	5.3	0.0	12-15	11-16
<i>Glycine max</i>	5.6	0.0	-2.4	-1.1	0.0	22-25	21-25
<i>Lactuca sativa</i>	-5.6	0.0	<b>12.7</b>	-2.0	1.0 a	41-41	41-41
<i>Solanum</i>	0.0	0.0	-4.6	-3.5	0.0	15-16	15-16
<i>Allium cepa</i>	-14.3	-7.7	8.2	3.8	0.0	12-13	12-13
<i>Avena sativa</i>	0.0	0.0	-0.5	0.9	0.0	31-31	31-31
<i>Lolium perenne</i>	15.0	0.0	-2.5	-6.3	0.0	22-26	12-27
<i>Zea mays</i>	-5.6	0.0	-14.1	-6.2	0.0	14-15	14-15

<sup>N</sup> A negative value indicates an increase compared to the control

**Bold figures** are statistically significant (Pairwise Mann-Whitney-U-test, one sided smaller;  $p \leq 0.05$ ).

Codes for phytotoxic symptoms: a = change of colour (e.g. chlorosis, reddening, bleaching)

The conclusions of this Tier 1 study are: this seedling emergence and growth study in which the effect of prohexadione-calcium OD 75 (75 g/L) on ten non-target terrestrial plant species was tested under greenhouse conditions resulted in no adverse effects on emergence, survival, shoot length and shoot dry weight above the 50% effect level at the test item rate of 90 g a.s./ha.

Additionally and with reference to the EPP0 standard PP1/207(2) Effects on succeeding crops, no specific field trials were required to assess the impact of FLU OD75 on succeeding crops.

Moreover, field studies and practical uses over several years on prohexadione-calcium applied in cereals have shown no negative influence on succeeding crops. Therefore, there is no minimum waiting period or other precaution between the last application and the sowing or planting of succeeding crops.

Based on the existing evidence, it can be concluded that PRL OD75 when used as recommended, will be safe to any succeeding crops. No further information and no succeeding crop safety warnings are considered necessary.

Comments of zRMS:	The results of the experiment carried out in greenhouse conditions presented by
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	the applicant and the long-term use of prohexadione calcium in cereals, where no negative effects on succeeding crops are noted, allow to conclude that PRL OD75 Hingios 75 OD when used in accordance with the recommendations, will be safe for any succeeding crops.
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### 3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

Data from eco-toxicology on non-target treated plants are presented in details in Part B section 9 of the draft Registration Report.

The effects of PRL OD75 at the proposed dose rate of 1.2 L/ha (90 g a.s./ha) were tested on a range of monocot- and dicotyledenous crops, post emergence, under greenhouse conditions in screening tests.

The conclusions of this Tier 1 study are: this vegetative vigour and growth study in which the effect of prohexadione-calcium OD 75 (75 g/L) on ten non-target terrestrial plant species was tested under greenhouse conditions resulted in a plant height reduction of 69.5% in *Cucumis sativus* at the test item rate of 90 g a.s./ha. The effects in all other tested species were below the 50% effect level.

**Table 3.4-13: Effects of 90 g prohexadione-calcium /ha (OD 75) in the vegetative vigour test**

Plant Species	Observations at the test item rate of 90 g a.s./ha				BBCH control min - max	BBCH treated min - max
	Survival (% inhibition)	Shoot dry weight (% inhibition) N	Shoot length (% inhibition) N	Phyto-toxicity (%)		
<i>Beta vulgaris</i>	0.0	<b>36.8</b>	<b>29.9</b>	0.0	19-19	17-19
<i>Brassica rapa</i>	0.0	<b>12.0</b>	<b>8.3</b>	16.0 bc	42-42	42-42
<i>Cucumis sativus</i>	0.0	37.1	<b>60.5</b>	2.0 ab	53-66	53-66
<i>Glycine max</i>	0.0	5.4	4.9	0.0	55-59	51-59
<i>Lactuca sativa</i>	0.0	<b>21.9</b>	-3.7	0.0	44-46	44-45
<i>Solanum</i>	0.0	<b>6.7</b>	-7.1	0.0	51-51	51-51
<i>Allium cepa</i>	0.0	<b>21.5</b>	5.5	0.0	15-41	14-41
<i>Avena sativa</i>	0.0	<b>16.4</b>	<b>20.7</b>	2.0 b	43-43	43-43
<i>Lolium perenne</i>	0.0	<b>22.8</b>	<b>20.1</b>	0.0	19-19	18-19
<i>Zea mays</i>	0.0	10.3	<b>14.5</b>	1.0 ab	31-31	15-31

<sup>N</sup> A negative value indicates an increase compared to the control

**Bold figures** of the inhibitions are statistically significant (Pairwise Mann-Whitney-U-test, one sided smaller;  $p \leq 0.05$ ).

Codes for phytotoxic symptoms:

- a: change of color (e.g. chlorosis, reddening, bleaching)
- b: necrosis (e.g. dry brown shoot tissue, parts of the plant are dead)
- c: deformation (e.g. leaf curl, abnormal leaf shape, abnormal plant habitus, wilting)

Therefore a Tier 2 study was conducted with the objective to evaluate the potential effects of prohexadione-calcium OD 75 in a rate-response study on the vegetative vigour of the non-target terrestrial plant species *Cucumis sativus* following a post-emergence application of the product onto the foliage and above-ground portions of plants.

**Table 3.4-14: Effects of 90 g prohexadione-calcium /ha (OD 75) in the vegetative vigour test on *Cucumis sativus***

Test item rates (g a.s./ha)	Survival (% inhibition)	Shoot dry weight (% inhibition) N	Plant height (% inhibition) N	Phytotoxicity (%)	BBCH min - max
Control	-	-	-	0.0	66-69
5	0	7.8	<b>21.61</b>	0.0	65-69
10.3	0	10.3	<b>30.02</b>	1.0 a	65-69
21.2	0	8.1	<b>43.69</b>	4.0 a	64-69
43.7	0	2.7	<b>43.98</b>	7.0 a	63-69
90	0	8.0	<b>60.28</b>	11.0 a	63-69
	<b>Survival [g a.s./ha]</b>	<b>Shoot dry weight [g a.s./ha]</b>		<b>Plant height [g a.s./ha]</b>	
NOER	90	90		<5	
ER <sub>25</sub>	>90	>90		6.1 (c.l. 2.1-10.0)	
ER <sub>50</sub>	>90	>90		48.8 (c.l. 32.4-65.1)	

<sup>N</sup> A negative value indicates an increase compared to the control

**Bold figures** of the inhibitions are statistically significant (estimated with Weibull model).

Codes for phytotoxic symptoms: a= change of color (e.g. chlorosis, reddening, bleaching)

ER<sub>25</sub> and ER<sub>50</sub> values: effect rate causing 25% and 50% effect

The conclusions of this Tier 2 study are: in this vegetative vigour and growth study, prohexadione-calcium OD 75 (75 g/L) was tested under greenhouse conditions for effects on the survival, growth and shoot dry weight of the non-target terrestrial plant species *Cucumis sativus*, following a post-emergence application of the test item the foliage of plants at the 2-4 leaf stage. The lowest ER<sub>50</sub> was found for plant height at 48.8 g a.s./ha.

Moreover, the risk to adjacent crops is assessed at the edge of the treated crops and is based on the estimated drift (2.5% at the 1 m distance), resulting in a predicted exposure equivalent to 0.03 L PRL OD75 /ha. Based on the EPP0 PP 1/256 scheme for adjacent crops the Toxicity:Exposure ratio is >40 indicating a low risk of toxicity to adjacent crop plants. No further information and no crop safety drift warnings are considered necessary.

Based on the existing evidence, it can be concluded that PRL OD75 when used as recommended, will be safe to the majority of adjacent crops.

Comments of zRMS:	The PRL OD75, Hingios 75 OD is plant growth regulator. In this situation, this measure may also cause damage to non-target foliage other plants, including adjacent crops. The information in this registration report and label to warn against overlapping and drift of the spray liquid is sufficient.
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### Tank cleaning

The product can be easily removed from spray tanks with water detergent. Any remaining diluted product or spray tank residues should they fail to be removed prior to treating another crop, would be unlikely to result in any damage even if used at full rate, based on the absence of damage in the adjacent crops test reported above.

It is concluded that PRL OD75 sprayed as recommended poses no risk to other crops should tank residues fail to be fully removed.

No specific recommendation for tank cleaning after PRL OD75 treatment is proposed as no negative impact of PRL OD75 on crops treated after tank cleaning is expected.

Comments of zRMS:	The information regarding the tank cleaning contained in registration report and in the label is quite sufficient.
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### **3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)**

Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in Part B, Section 9 (Ecotoxicology) of the draft Registration Report. No presentation of further data is required in Section 3.

Compatibility with current management practices including IPM

This is not an EC data requirement/not required by Directive 1107/2009/EC.

### **3.6 Other/special studies**

No special studies were carried out.

### 3.7 List of test facilities including the corresponding certificates

**Table 3.7-1: List of test facilities**

Organisation	Town	Country	Valid From	Valid To	Link
Bayer CropScience Deutschland GmbH	Langenfeld	Germany	21-nov-18	10-Dec-2023	<a href="#">1d68f6b6ff7</a>
Bayer Cropsience France	Lyon	France	1-Oct-2018	30-Sep-2023	<a href="#">1d68f6b6fc3</a>
BAYER, SIA	Jelgava	Latvia	17-Dec-2015	16-Dec-2020	<a href="#">1d68f6b6ea2</a>
BAYER, SIA	Jelgava	Latvia	8-Dec-2020	7-Dec-2025	<a href="#">1d68f6b711c</a>
Bayer Sp. z o. o.	Warszawa	Poland	16-Jun-2010	31-Dec-2100	<a href="#">1d68f6cf325</a>
Agrolab A/S	Middelfart	Denmark	1-Jan-2014	1-Jan-2020	<a href="#">1d68f6b6dc8</a>
Agrolab A/S	Middelfart	Denmark	1-Jan-2020	31-Dec-2025	<a href="#">1d68f6b7072</a>
Agrolab Sverige AB	Eslov	Sweden	21-Dec-2016	20-Dec-2021	<a href="#">1d68f6b7048</a>
AGROPASS Hungaria Kft	Gyor	Hungary	06-feb-18	05-feb-23	<a href="#">1d68f6b700e</a>
CPR Europe Kft.	Szombathely	Hungary	09-apr-20	20-Sep-2022	<a href="#">1d68f6b70cc</a>
Eurofins Agroscience Services Srl (Romania)	Timisoara	Romania	27-feb-15	27-feb-20	<a href="#">1d68f6b6dfd</a>
Eurofins Agroscience Services Srl (Romania)	Giarmata	Romania	24-nov-20	24-nov-25	<a href="#">1d68f6b7125</a>
Envirofield	Drinkstone	UK	25-Jan-2016	24-Jan-2021	<a href="#">1d68f77a649</a>
Envirofield	Drinkstone	UK	25-Jan-2021	24-Jan-2026	<a href="#">1d68f77a648</a>
Fundulea National Institute for Agricultural Research and Development	jud. Calarasi	Romania	20-Aug-2015	20-Aug-2020	<a href="#">1d68f6b6f5d</a>
FYSE s.r.o. Odd. AgroLab Kolare	Kolare	Slovakia	04-feb-16	04-feb-21	<a href="#">1d68f6b6e3d</a>
Gemerprodukt Valice ovocinarsko-vinohradnicke druzstvo	Rimavska Sobota	Slovakia	12-apr-16	12-apr-21	<a href="#">1d68f6b6e4d</a>
Institute of Agriculture, Lithuanian Research Centre for Agriculture and Forestry	Akademija, Kedainiai district	Lithuania	12-Dec-2013	12-Dec-2019	<a href="#">1d68f6b6d6e</a>
LAMMC - Lietuvos agrariniu ir misku mokslu centro	Kedainiu r.	Lithuania	6-Dec-2019	5-Dec-2024	<a href="#">1d68f6cf75e</a>
OSEVA PRO s.r.o., odstepny zavod Vyzkumny ustav olejnin Opava	Opava	Czech Republic	1-Sep-2016	31-Aug-2021	<a href="#">1d68f6b6e91</a>
University of Aarhus	Slagelse	Denmark	1-Jan-2014	31-Dec-2019	<a href="#">1d68f6cf6df</a>
University of Aarhus	Slagelse	Denmark	1-Jan-2020	31-Dec-2025	<a href="#">1d68f6cf721</a>
Zemedelska zkusebni stanice Kujavy, s.r.o.	Fulnek	Czech Republic	1-Sep-2016	31-Aug-2021	<a href="#">1d68f6b6eb0</a>
Zkusebni stanice Kluky, spol. S r.o.	Kluky u Pisku	Czech Republic	1-Sep-2016	31-Aug-2021	<a href="#">1d68f6b6e84</a>

## Appendix 1 Lists of data considered in support of the evaluation

### List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP Section 6 / 01	Pagani, V.; Peeters, D.; Bartlett, M.; Terhardt, J. T.	2021	Biological assessment dossier - Efficacy data and information - Detailed summary - Prohexadione-calcium OD 75 (75 g/L) - Central zone - Zonal rapporteur member state: Poland - Core assessment (authorisation) Report No.: <a href="#">M-766607-01-1</a> Bayer S.A.S., Crop Science Division, Lyon, France GLP/GEP: n.a. unpublished	No	Bayer
KCP 6.1 / 01	Pagani, V.; Peeters, D.	2021	Preliminary findings field trials with prohexadione-calcium applied in autumn on winter oilseed rape Report No.: <a href="#">M-766204-01-1</a> Bayer CropScience SA-NV, Diegem, Belgium GLP/GEP: Yes unpublished	No	Bayer
KCP 6.2 / 01 ... also filed: KCP 6.4 / 01	Pagani, V.	2021	Compilation of trial reports for PRL OD75 - Efficacy trials as PGR on winter oilseed rape Report No.: <a href="#">M-766442-01-1</a> Bayer CropScience SA-NV, Diegem, Belgium GLP/GEP: n.a. unpublished	No	Bayer
KCP 6.5.1 / 01 ... also filed: KCP 10.6.1 / 01	Köhler, P.	2020	Effects on the seedling emergence and growth of 10 species of non-target terrestrial plants (Tier 1); prohexadione-calcium OD 75 (75 g/L) Report No.: SE20/022, Edition Number: <a href="#">M-691185-01-1</a> Bayer AG, Crop Science Division, Frankfurt am Main, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 6.5.2 / 01 ... also filed: KCP 10.6.1 / 02	Köhler, P.	2020	Amendment no. 01: Effects on the vegetative vigor of 10 species of non-target terrestrial plants (Tier 1); prohexadione-calcium OD 75 (75 g/L) Report No.: VV20/021, Edition Number: <a href="#">M-691184-02-1</a>	No	Bayer

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
			Bayer AG, Crop Science Division, Frankfurt am Main, Germany <b>... amended: 2020-09-07</b> GLP/GEP: Yes unpublished		
KCP 6.5.2 / 02 <b>... also filed:                      KCP 10.6.2 / 01</b>	Köhler, P.	2020	Effects on the vegetative vigor of the non-target terrestrial plant species Cucumis sativus (Tier 2); prohexadione-calcium OD 75 (75 g/L) Report No.: VV20/039, Edition Number: <a href="#">M-758398-01-1</a> Bayer AG, Crop Science Division, Frankfurt am Main, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 6.5.2 / 03	Friessleben, R.	2008	Summary and conclusive report of studies on spray tank cleaning realized in the years 2000 - 2008 Report No.: <a href="#">M-357166-01-1</a> Bayer CropScience AG, Monheim, Germany GLP/GEP: n.a. unpublished	No	Bayer