

FINAL REGISTRATION REPORT

Part B

Section 0

**Product Background, Regulatory Context and
GAP information**

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**

Date: 07/10/2022



M-766620-02-1

Version history

When	What
April 2021	Original Bayer submission
July 2021	Dossier sent for evaluation
January 2022	zRMS finalised evaluation
April 2022	Final version prepared by zRMS after Commenting period
July 2022	Supplementing the dRR by zRMS with the data provided by the Applicant (regarding honey) after the commenting period
October 2022	Final version prepared by zRMS after Commenting period (regarding honey)

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Evaluator comments:

The text highlighted in grey was provided by the evaluator.

The text highlighted in blue was provided after the comment period.

The text in green relates to the evaluation of the additional data submitted by the Applicant after the commenting period.

The product Prohexadione-Ca OD 75 (75 g/L) (PRL OD 75 / Product Code 102000037599) has not been previously evaluated at zonal level. It was not the representative formulation during the renewal of approval of Prohexadione-Ca. All data and information assessed during the EU re-evaluation of Prohexadione-Ca is considered EU peer-reviewed data.

0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This dossier is prepared to support the authorisation of Prohexadione-Ca OD 75 (75 g/L) (other code: PRL OD 75) for uses in the Central Zone.

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
Central zone	Poland	Austria Czech Republic Germany Hungary Romania Slovak Republic
National Submission	United Kingdom	United Kingdom

0.1.3 Regulatory history of the active(s)

0.1.3.1 Prohexadione-Ca

Table 0.1-2: Summary of regulatory history of CAS No: 127277-53-6

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2000/50/EC, dated 26 July 2000, entry into force 1 October 2000. Commission Implementing Regulation (EU) No. 540/2011, dated 25 May 2011, entry into force 14 June 2011. Commission Implementing Regulation (EU) No. 702/2011, dated 20 July 2011, entry into force 1 January 2012. Commission Implementing Regulation (EU)

Status	
	No. 2019/291, dated 19 February 2019.
RMS	RMS: France, Co-RMS: Ireland
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/01/2012. Commission Implementing Regulation (EU) No. 702/2011
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	-
Date of final Commission (re-registration) deadline (Step 2)	-
Current expiration of approval	31/12/2022
Low risk substance or Candidate for Substitution?	Low risk substance

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

PART A Only uses as plant growth regulator may be authorised.

PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on prohexadione and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account.

The SANCO review report for prohexadione (SANCO/11023/2011 Rev 2, 17 June 2011) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA conclusion is available (EFSA Journal 2010; 8(3):1555).

Table 0.1-3: Information on minimum purity of Prohexadione-Ca

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
≥ 920 g/kg (expressed as prohexadione-calcium)\ 890 g/kg	No change in minimum purity of active substance 920 g/kg Equivalence report available: Y RMS:Netherlands

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

** If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

Endpoint	Prohexadione-Ca	
	EU agreed endpoint from EFSA scientific report	Endpoint used*
Endpoint		

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data)

0.1.4 Regulatory history of the product (if relevant)

Not relevant as the product has not yet been authorised.

0.2 zRMS conclusion

Section 1, 2 and 4. Identity, physical and chemical properties and further information

The two-year shelf life is ongoing. It has to be assessed in the post-registration. No data on effectiveness of the cleaning procedure were provided in Poland. The missing information has to be provided by applicant. Based on physicochemical properties the PPP is not classified.

Section 3. Efficacy

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.

Section 5. Analytical Methods

The analytical method used for analysing the active substance in the PPP is accepted.

Section 6. Mammalian Toxicology

Based on the calculation method and study results, Prohexadione-Ca OD 75 is classified as Skin Sens. 1 (H317), Skin Irrit. 2 (H315), Eye Irrit. 2 (H319), STOT-SE 3 (H335).

According to the exposure assessment Prohexadione-Ca OD 75 is safe for operators, workers as well as bystanders and residents (both adult and child). No specific PPE requirement, work wear (arms, body and legs covered) for operators and workers. Due to hazard characterisation for operators - **protective clothing, protective gloves, face/eye protection** during **handling**, mixing and loading **and when handling contaminated surfaces during application.**

Section 7. Metabolism and Residues

Critical GAP proposed for PRL OD 75 on oilseed rape: 1 appl. in max. BBCH-59, max application rate per treatment: 90 g a.s./ha, PHI- as per growth stage

Critical EU GAP on oilseed rape (EFSA Journal 2018;16(8):5397): max 2 appl. in max BBCH-59, max application rate per treatment 50 g a.s./ha, PHI-not applicable

The formulation OD has not been assessed at Community level.

The Applicant provided additional studies on the stability of the residues and magnitude of the residues of prohexadione-calcium in winter oilseed rape following application in NEU.

A new storage stability study was provided for oilseed rape at 18°C and the storage stability of prohexadione-calcium has been demonstrated for at least 6 months (183 days) in oilseed rape seeds (as well as whole plant and haulm) when stored frozen at -18°C.

All residue data reported within the present submission (maximal storage period in oilseed rape, whole plant: 161 days, 5.4 months) are covered by the storage stability data for prohexadione-calcium. Additional studies are not required.

The use on oilseed rape is covered by the evaluated at EU level metabolism studies (EFSA Journal 2010; 8(3):1555). The following residue definitions were proposed by the EU pesticides peer review and confirmed by the MRL review:

- residue for risk assessment: prohexadione and its salts, expressed as prohexadione-calcium
- residue definition for enforcement: prohexadione and its salts, expressed as prohexadione-calcium

The residue definition for enforcement set in Regulation (EC) No 396/2005 (currently in force Reg. (EU) 2021/976) is identical with the above mentioned residue definition.

Standard hydrolysis studies investigating the stability of prohexadione under conditions representative for pasteurisation, boiling/cooking and sterilisation are not available. Considering that the total calculated theoretical maximum daily intake (TMDI) is low (less than 10% of the acceptable daily intake (ADI) and residues in raw agricultural commodity (RAC) are below 0.1 mg/kg, such studies are currently not necessary.

EFSA Journal 2018;16(8):5397: Based on the results of the livestock metabolism studies, the EU pesticides peer review and the MRL review concluded that at the calculated dietary burdens prohexadione residues above the LOQ are not expected in ruminant matrices (EFSA, 2013). Compared to the MRL review, the dietary burdens calculated in the current assessment were lower for ruminants (0.7 N), but higher for swine (1.9 N) and poultry (1.6 N), when using the OECD calculator. Since the calculated exposure is still significantly lower than the lowest dose levels in metabolism studies for which no residues above the LOQ of 0.01 mg/kg were observed, EFSA concludes that residues above the LOQ are not expected in ruminant, swine and poultry matrices.

Animal residue definition for monitoring and risk assessment: prohexadione and its salts expressed as prohexadione-calcium.

The Applicant has provided residue results from 8 independent field trials following a more critical GAP (two applications instead of one) than the critical GAP of this dRR. The residues of prohexadione-calcium in rape seed were present at or below LOQ. The results show no residue above the applicable MRL (0.015 mg/kg according to the Reg. (EU) 2021/976).

Studies on the magnitude of residues in processed commodities are not necessary because the trigger value of 0.1 mg/kg was not reached for rape seed and intakes of prohexadione-calcium from this commodity are very low (<10% of the ADI).

EFSA Journal 2018;16(8):5397: *Oilseeds can be grown in a crop rotation. According to the soil degradation studies assessed in the EU pesticides peer review, DT90 values of prohexadione are expected to be lower than 39 days which is below the trigger value of 100 days (EFSA, 2010). According to the European guidelines, further investigation of residues in rotational crops is therefore not required (European Commission, 1997b). Nevertheless, studies investigating the nature of prohexadione in rotational crops have been submitted for the EU pesticides peer review, which concluded that no quantifiable prohexadione residues are expected in rotational crops (EFSA, 2010).* The same conclusion is applicable for the use on the crops under consideration in this dRR.

The proposed use of prohexadione-calcium in the formulation Prohexadione-Ca OD 75 (75 g/L) does not represent unacceptable chronic risks for the consumer. An acute risk assessment was not performed as an ARfD has not been set.

Prohexadione-calcium is a systemic substance, oilseed rape is a melliferous plant and residues in the whole plant during the flowering period (BBCH 60-69) indicate above 0.05 mg/kg. Residues studies for flowers, leaves or nectar were not provided. It is not clear from which studies the Applicant claims that there are no residues above 0.05 mg/kg in aerial parts of the crop. Studies determining the residues of prohexadione-calcium in honey should be provided ~~— data gap.~~

~~Prior to authorization, attention should be paid to the above mentioned lack of data and possibly indicate to the Applicant the need to provide residue trials in honey after authorization.~~

zRMS is of the opinion that the Applicant should provide a study in honey showing no residues above 0.05 mg/kg. Authorization will also be possible after completing the documentation with the study mentioned in RT by the Applicant and changing the MRL value to 0.4 mg/kg.

Authorization is not possible due to the lack of appropriate residue studies in honey.

Following the commenting process, the Applicant provided a residue study of prohexadione-calcium in honey, i.e. ‘Determination of residues of Prohexadione-Calcium in honey after one application of BAS 125 13 W in winter oilseed rape at 4 sites in Germany in 2019’, Kugel, D.; 2019; report No 780427_14, S19-00556; Document No 2019/1057826 (GLP-Yes), including a study indicating the validation of the determination method: ‘Development and Validation of an Analytical Method for the Determination of Prohexadione Calcium and its metabolite Despropionyl Prohexadione in Honey using LC-MS/MS’, Tushar Rastogi and Sandro Jooß, 2020, EAG Laboratories ID: P 5132 G. The owner of the submitted studies is Fine Agrochemicals Ltd so the Applicant provided a letter of access as well. The aforementioned studies were performed in accordance with the applicable requirements. The formulation BAS 125 13W (10% WG), a water dispersible granule formulation containing a nominal content of 100 g/kg prohexadione-calcium, was applied to plots with winter oilseed rape by spraying once at a nominal application rate of 250 g a.s./ha and a water rate of 200 L/ha. The application was performed at BBCH of 64-65 (40%-50% of flowers open). Honey was collected from initially empty combs which were introduced in the hive shortly before the application. Honey was collected at the end of flowering of the oilseed rape crop 2-11 days after treatment for subsequent residue analysis. Honey samples were transported on dry ice to the analytical test site and stored deep frozen ($\leq -18^{\circ}\text{C}$) until analysis. Residues of prohexadione-calcium in honey were determined according to the previously validated analytical method P 5132 G by LC-MS/MS, by extraction with water and acidified acetonitrile. Residues were quantified using matrix matched standards. Concurrent recovery determinations were included in each set of analyses. The Limit of Quantification (LOQ) for prohexadione-calcium in honey, defined as the lowest validated fortification level, was 0.01 mg/kg, expressed as prohexadione-calcium. The corresponding respective Limit of Detection (LOD) was 0.002 mg/kg. The storage period of the honey samples before analysis was 14-26 days. Since analysis was performed within 30 days of collection, storage stability data are not required. Mean recoveries at each fortification level were in the range of 86-95%. The RSDs values, if applicable, were $<15\%$. The obtained recovery data are in accordance with the general requirements for residue analytical methods (SANTE/2020/12830 rev.1); therefore, the method was validated successfully. Residues of prohexadione-calcium in honey from treated plots showed one value below LOQ (<0.01 mg/kg at PHI 7 days), two values below the threshold value of 0.05 mg/kg (0.0308 and 0.0380 mg/kg at PHI 7 and 11 days, respectively) or one higher value (0.157 mg/kg at PHI 2 days). No residues of the analyte above the LOQ were found in any of the control samples of honey. The results were not corrected for concurrent recoveries.

Taking into account that the dose used in the study (1x250 g a.s./ha) was much higher when comparing to the intended use of PRL OD 75 (1x90 g a.s./ha) and the fact that in the study the application was in spring BBCH 60-69, and the PRL OD 75 is intended for use in autumn BBCH 12-18, it should be considered that the provided study represents a worst-case scenario. It therefore seems that for the intended use of PRL OD 75 in autumn, the residues in honey will not exceed the trigger value of 0.05 mg/kg, thus confirming that the current honey MRL of 0.05 mg/kg will adequately cover this use. In addition it should be noted that honey is known to be acidic (pH approx.4) and prohexadione active substance DT50 in hydrolytic conditions is 2.5 days at pH 4 and 3.2 days at pH 5 (EFSA 2010; 8(3):1555). Based on this, prohexadione residues in honey will decrease in a short-time period as confirmed by the 3 lower residue values in the honey residue study. However, it should be noted that formulation in the provided study (WG) was different than intended for PRL OD 75 (OD) and that one of the results showed a residue significantly above the applicable MRL. The authorization decision should be made by the risk managers.

Section 8. Environmental Fate

In accordance with proposed pattern use of PRL OD 75, all relevant information was submitted. No mitigation measure was proposed.

Section 9. Ecotoxicology

Based on the risk assessment in section of ecotoxicology it can be concluded that the proposed use of PRL OD 75 used as the plant growth regulator on winter oilseed rape poses acceptable risk to non-target organisms if applied according to the recommended use pattern.

Precautions to reduce the environmental concentrations resulting from PRL OD 75 applications are not required.

Section 10. Assessment of the relevance of metabolites in groundwater

No groundwater metabolites assessment is required.

Uses to be considered safe on the basis of EU methodology:

~~1,4,7,10,13,16,19~~ None The authorization decision should be made by the risk managers.

Uses to be considered non-safe on the basis of EU methodology:

All The authorization decision should be made by the risk managers.

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant CMS:

-

All uses/ GAPS are covered by established MRLs.

Appendix 1 ALL intended uses

GAP rev. January , date: 2022

PPP (product name/code): PRL OD 75
 Active substance 1: Prohexadione-Ca
 Safener: none
 Synergist: none
 Applicant: Bayer
 Zone(s): Central Zone ^(d)
 Verified by MS: yes
 Field of use: Plant Growth Regulator

Formulation type: OD ^(a, b)
 Conc. of as 1: 75 g/L ^(c)
 Conc. of safener: -
 Conc. of synergist: -
 Professional use:
 Non professional use:

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 ^(f) (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ⁽ⁱ⁾
					Method / Kind	Timing / Growth stage of crop & season	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		
Zonal uses (field or outdoor uses, certain types of protected crops)													
See table provided below													
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
None													
Minor uses according to Article 51 (zonal uses)													
None													
Minor uses according to Article 51 (interzonal uses)													
None													

* A glossary of the pests mentioned in the dossier is provided in the Part B section 3 "Efficacy data"

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		
Zonal uses (field or outdoor uses, certain types of protected crops)													
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 The authorization decision should be made by the risk managers.
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	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	as per growth stage	This use is not 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 The authorization decision should be made by the risk managers.
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	100-400	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

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		
													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	100-400	as per growth stage	This use is not 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	100-400 150-300	as per growth stage	PHI according to growth stage The authorization decision should be made by the risk managers.
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	100-400	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)
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	as per growth stage	This use is not 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 The authorization

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		
													decision should be made by the risk managers.
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	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	as per growth stage	This use is not 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 The authorization decision should be made by the risk managers.
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	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)
15	POL	Rape, winter (BRSNW)	F	B1: winter solidness, growth regulation of crop	spraying (broadcast,	12-59	a) B1: 1 B2: 1	B1: - B2: -	a) B1: 1.2 B2: 1.2	a) PRL 90 b) PRL 180	100-400	as per growth	This use is not supported in the

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		
				B2: resistance to lodging, growth regulation of crop	overall)	B1: 12-18 B2: 30-59	b) 2	90 d after B1	b) 2.4			stage	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	100-400 150-300	as per growth stage	PHI according to growth stage The authorization decision should be made by the risk managers.
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	100-400	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	100-400	as per growth stage	This use is not supported in the present application but indicated here as information to justify the worst case considered in some studies.
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 The authorization decision should be made by the risk managers.
20	SVK	Rape, winter	F	resistance to lodging,	spraying	30-59	a) 1	-	a) 1.2	a) PRL 90	100-400	as per	This spring use is not

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		
		(BRSNW)		growth regulation of crop	(broadcast, overall)		b) 1		b) 1-2	b) PRL 90		growth stage	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	as per growth stage	This use is not supported in the present application but indicated here as information to justify the worst case considered in some studies.

PRL: Prohexadione-Calcium

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
 (c) g/kg or g/l
 (d) Select relevant

Remarks columns:

1 Numeration necessary to allow references
 2 Use official codes/nomenclatures of EU Member States
 3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
 4 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
 5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
 6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

(e) Use number(s) in accordance with the list of all intended GAPS in Part B, Section 0 should be given in column 1
 (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
 8 The maximum number of application possible under practical conditions of use must be provided.
 9 Minimum interval (in days) between applications of the same product
 10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
 12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
 13 PHI - minimum pre-harvest interval
 14 Remarks may include: Extent of use/economic importance/restrictions