

FINAL REGISTRATION REPORT

Part A
Risk Management

Product code: 102000037599

Product name(s): Prohexadione-calcium OD 75 (75 g/L)

Active substance(s):

Central Zone
Zonal Rapporteur Member State: Poland

CORE ASSESSMENT
(Authorisation)

Applicant: Bayer CropScience Division

Date: 07/10/2022



M-767192-01-1

Version history

When	What
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
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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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application was submitted by Bayer to support the authorisation of prohexadione-Ca OD 75 (75 g/L) (PRL OD 75) in Poland for use as a plant growth regulator on winter rape.

Poland is the zRMS for the evaluation of the Core Assessment in the Central Zone.

PRL OD 75 is an oil dispersion (OD) formulation containing the active substance prohexadione-calcium, approved in accordance with Commission Implementing Regulation (EU) No. 702/2011, dated 20 July 2011, entry into force 1 January 2012.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-8 and Part C and where appropriate addenda for Poland.

The information, data and assessments provided in Registration Report, Parts B include assessment of further data or information as required at MS level by the EU review. It also includes assessment of data and information relating to PRL OD 75 where that data has not been considered in the EU review. Otherwise assessments for the safe use of PRL OD 75 have been made using endpoints agreed in the EU review of Prohexadione-Ca.

This document describes the specific conditions of use and labelling required in Poland for the authorisation of PRL OD 75.

1.2 Letters of Access

Bayer is the owner and producer of the product PRL OD 75. However, the owner and producer of the active substance prohexadione-Ca is Fine Agrochemicals Limited. A letter of access is therefore included in the dossier.

1.3 Justification for submission of tests and studies

The tests and studies on vertebrate animals submitted within this dossier are necessary to complete the data package as required in the Commission Regulation (EU) No 284/2013 setting out the data requirements for Plant Protection Products. Existing data was not available from another source.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as mentioned in the list of references.

2 Details of the authorization decision

2.1 Product identity

Product code	Prohexadione-Ca OD 75 (75 g/L) PRL OD 75 Specification No.: 102000037599
Product name in MS	HINGIOS 75 OD
Authorisation number	-
Function	Plant Growth Regulator
Applicant	Bayer S.A.S., France, Lyon

Active substance(s) (incl. content)	75 g/L prohexadione-Ca	
Formulation type	Oil dispersion [Code: OD]	
Packaging	Type: Materials: Capacity: Opening and type of closure: Compliance Outer packaging Type:	Bottle/Canister: co-extruded (HDPE/PA, HDPE/EV) COEX/PA Coextruded high density polyethylene (HDPE) with an internal barrier layer made of polyamide (PA) (HDPE/PA) COEX/EV Coextruded high density polyethylene (HDPE) with an internal barrier layer made of ethylene vinyl alcohol copolymer (EV) (HDPE/EV) EV can also be noted as EVOH 0.05 L up to 15 L bottle. Screw cap 32mm, 50 mm Cobra, 63 mm Glostar (with HF seal or internal wad) - to fit container neck as defined in ECPA One Trip Container Guidelines. The packaging complies with CropLife International recommendations for one way agrochemical packaging design criteria for liquids and solids [Guidelines for the safe formulation and packaging of crop protection products (Guideline 6)]. The product may or may not be packed in an outer corrugated fibreboard case like: 10 x 1 litre bottle; 4 x 5 litres bottles
Coformulants of concern for national authorisations	None	
Restrictions related to identity	None	
Mandatory tank mixtures	mandatory tank mixtures (if applicable)	
Recommended tank mixtures	recommended tank mixtures (if applicable)	

2.2 Conclusion

Residues: ~~The evaluation of the application for PRL OD 75 resulted in the decision to grant the authorization. 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.~~

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

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.

The authorization decision should be made by the risk managers.

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

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.

The evaluation of the application for PRL OD 75 resulted in the decision to grant the authorization.

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.

2.3 Substances of concern for national monitoring

No national monitoring data required for Prohexadione-Ca.


2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Skin sensitisation: Category 1 Skin irritation: Category 2 Eye irritation: Category 2 Specific target organ toxicity - single exposure: Category 3 Chronic aquatic toxicity: Category 3
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	 GHS07
Signal word:	Warning
Hazard statement(s):	H317 May cause an allergic skin reaction. H315 Causes skin irritation. H319 Causes serious eye irritation. H335 May cause respiratory irritation. H412 Harmful to aquatic life with long lasting effects.
Precautionary statement(s):	P261 Avoid breathing dust/fume/gas/mist/vapours/spray. P264 Wash hands thoroughly after handling. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor/ physician. P391 Collect spillage. P501 Dispose of contents/container in accordance with local regulation.
Additional labelling phrases:	EUH401 To avoid risks to human health and the environment, comply with the instructions

Special rule for labelling of plant protection product (PPP):

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Further labelling statements under Regulation (EC) No 1272/2008:

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
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2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
respective code if available	Work wear - arms, body and legs covered. No specific PPE requirement Protective clothing, protective gloves, face/eye protection during handling, mixing and loading and when handling contaminated surfaces during application due to hazard characterisation.
Worker protection:	
respective code if available	Arms, body and legs covered (workwear; bare hands). No specific PPE requirement
Integrated pest management (IPM)/sustainable use:	
respective code if available	
Environmental protection	
respective code if available	
Other specific restrictions	
respective code if available	

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
respective code if available		
Environmental protection:		Relevant for use no.
respective code if available		

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code): PRL OD 75 Formulation type: OD ^(a, b)
Active substance 1: Prohexadione-Ca Conc. of as 1: 75 g/L^(c)
Safener: none Conc. of safener: - ^(c)
Synergist: none Conc. of synergist: - ^(c)
Applicant: Bayer Professional use: ☒
Zone(s): Central^(d) Non professional use: ☐
Verified by MS: yes

Field of use: Plant growth regulator

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	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
National uses (field or outdoor uses, certain types of protected crops)													
1	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.

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
(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.

Remarks columns:	1	Numeration necessary to allow references	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
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	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)	9	Minimum interval (in days) between applications of the same product
	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	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	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.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	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.	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

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 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a light-yellow opaque liquid, without odour. It is not explosive and has no oxidising properties. The product has a flash point of 154 °C. It has a self-ignition temperature of 359 °C. In aqueous solution, it has a pH value around 4.3 at 25°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature based on the accelerated study results. Its technical characteristics are acceptable for an oil-based suspension concentrate formulation. The intended concentration of use is 0.2% to 1.5% (0.3 to 1.2 as presented in GAP table).

3.2 Efficacy (Part B, Section 3)

Please refer to 3.3.

3.3 Efficacy data

The distribution of efficacy trials conducted across the North-East, Maritime and the South-East EPPO climatic zones covers a wide and representative range of growing conditions and varieties for winter oilseed rape. The set of 35 validated trials (plus 4 additional trials in Czech Republic) is considered sufficient to evaluate the performance of PRL OD 75 as a plant growth regulator applied in autumn on winter oilseed rape.

Nineteen preliminary field trials were conducted in Germany, Poland, Ukraine, and France with two former OD75 formulations of prohexadione-calcium, coded SP102000035378 and SP102000036194 and applied on winter oilseed rape during Autumn 2017 and Autumn 2018, respectively. A dose rate of 90g prohexadione-calcium/ha showed satisfactory results when assessed 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) was achieved compared to untreated check. No difference in performances was observed between the two former PRL OD 75 formulations. When compared to standard co-formulated products applied at their full approved dose rates, the single compound prohexadione-calcium applied at 90g a.s./ha showed lower reduction of the plant height than Carax (mepiquat-chloride + metconazole) applied at 294 + 42g a.s./ha in 18 out of 19 trials, whereas it showed mostly equivalent reduction of the plant height than Tilmor (prothioconazole + tebuconazole) applied at 96 + 192g a.s./ha in all 4 trials.

Trials to evaluate the Minimum Effective Dose rate of PRL OD 75 on winter oilseed rape were applied during the Autumn periods 2019 and 2020, at major crop growth stages from BBCH 14 to BBCH 18, but in field from a minimum crop stage BBCH 12 up to a maximum crop stage BBCH 18 (BBCH 19 in 1 trial). The recommended dose rate of 1.2 L/ha (N) was therefore 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. The 2N dose rate was compared in all trials notably to evaluate crop safety. Based on the plant height measured at the end of the growing period before the winter in a total of 35 reliable trials, it could be concluded that the unique dose rate of 1.2 L/ha is justified for PRL OD 75 to be used in Autumn at the crop growth stages BBCH 12-18.

In accordance with the recommendations of the specific EPPO standard PP1/153(3), the efficacy of the test product PRL OD 75, was evaluated on **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). PRL OD 75 at the proposed dose rate of 1.2 L/ha was compared to the reference products Carax SL240 at dose rate of 1 L/ha (local 0.7 L/ha in 2 Romanian trials) and Tilmor EC240 at dose rate of 1.2 L/ha. Both PRL OD 75 and the reference products were applied once at same timing and growth stage in Autumn.

It is concluded that PRL OD 75 applied at 90 g/ha foliar sprayed in Autumn on winter oilseed rape could be considered as an efficient new active substance in the plant growth regulator tools available to reduce

the plant height resulting in a better crop plant survival after the winter.

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

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

3.3.2 Adverse effects on treated crops

All efficacy trials were assessed for crop safety and any phytotoxicity symptoms recorded. Yield and quality (oil content, weight of thousand seeds and protein content) of harvested seeds were also conducted on several of the efficacy trials harvested in summer 2020.

PRL OD 75 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 the reference products Carax SL240 and Tilmor EC240 applied at their recommended or approved dose rates (N) of 1 L/ha and 1.2 L/ha, respectively.

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, no phytotoxic symptom was seen on winter oilseed rape treated with PRL OD 75 in 34 out of 35 trials. Only a slight transient purple coloration (max. 2%) of the plants was observed in a Lithuanian trial the next spring, both for the test product as for reference products. Since the product demonstrated perfect crop safety, notably at double the proposed dose rate, in all trials where some plants were at the minimum crop growth stage BBCH 12, it is considered that the extended proposed use pattern from the crop growth stage BBCH 12 will not modify the crop safety behaviour of PRL OD 75 on winter oilseed rape. It is therefore concluded that autumn application of PRL OD 75 to the winter oilseed rape is safe to the host crop, when applied in accordance with the proposed use pattern.

Results from trials, all conducted in winter oilseed rape over 1 cropping season (application on Autumn 2019, harvested in Summer 2020, without strong winter 2019-2020), showed no significant adverse impact on seed yield resulting from an application with PRL OD 75 applied both at the maximum proposed dose rate (1.2 L/ha) and at the double of the proposed dose rate (2.4 L/ha).

Results from reliable efficacy trials conducted in winter oilseed rape over 1 cropping season (application on Autumn 2019, harvested on Summer 2020, without strong winter 2019-2020) 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 OD 75 applied both at the maximum proposed dose rate (1.2 L/ha) and the double of the proposed dose rate (2.4 L/ha).

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.

The evaluation of possible effects on the germination of harvested seeds showed a very similar pattern of seed germination (normal, abnormal and un-emerged) between the untreated check, the reference product PRL OD 75 at 1.2 L/ha and the reference product Carax SL240 at 0.7-1 L/ha. 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 OD 75, when applied in accordance with the proposed use pattern on winter oilseed rape.

3.3.3 Observations on other undesirable or unintended side-effects

A study on seedling emergence and growth in which the effect of PRL OD 75 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 EPPO standard PP1/207(2) *Effects on succeeding crops*, no specific field trials were required to assess the impact of PRL OD 75 on succeeding crops, as the uptake

of prohexadione-calcium residues through soil is very limited.

A study on vegetative vigour and growth in which PRL OD 75 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 at the 2-4 leaf stage. The lowest ER₅₀ 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 OD 75 /ha. Based on the EPPO 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.

No adverse effects were reported from efficacy trials and it is unlikely that this plant growth regulator used as recommended, will pose a significant risk to beneficial organisms.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

Analytical methods for the active substance in the formulation and for residues have been validated and are considered adequate.

3.4.2 Analytical methods for residues

Sufficiently sensitive and selective analytical methods are available and validated for all analytes included in the residue definition for plant and animal commodities, soil, drinking and surface water, body fluids and air.

3.5 Mammalian toxicology (Part B, Section 6)

3.5.1 Acute toxicity

Acute Toxicity Calculations (ATE) and other calculations were performed according to the ECHA CLP guidance ('Guidance on the Application of the CLP Criteria Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures Version 5.0 July 2017') to derive the classification for this formulation. Full summaries of the acute toxicity studies on the product have also been provided in the Core assessment.

Acute oral toxicity	Acute dermal toxicity	Acute inhalation toxicity	Eye irritation	Skin irritation	Skin sensitization	Specific target organ toxicity - single exposure
Not classified	Not classified	Not classified	Category 2, H319 Causes serious eye irritation	Category 2, H315 Causes skin irritation	Category 1, H317 May cause an allergic skin reaction	Category 3 H335 May cause respiratory irritation

3.5.2 Operator exposure

A risk assessment was conducted according to *Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874*. No unacceptable risk for operators, workers, bystanders and residents was identified when the product is used as intended and provided that the PPE/ risk mitigation measures are applied.

	Result	PPE / Risk mitigation measures
Operators	Acceptable	No PPE necessary according to the exposure assessment. Work wear - arms, body and legs covered Protective clothing, protective gloves, face/eye protection during handling, mixing and loading and when handling contaminated surfaces during application due to hazard characterisation.

	Result	PPE / Risk mitigation measures
Workers	Acceptable	None. Work wear - arms, body and legs covered
Bystanders	Acceptable	None
Residents	Acceptable	None

3.5.3 Worker exposure

Please refer to 3.5.2.

3.5.4 Bystander and resident exposure

Please refer to 3.5.2.

3.6 Residues and consumer exposure (Part B, Section 7)

The data available are considered **not** sufficient for risk assessment. For prohexadione-calcium, an exceedance of the current MRL of 0.015 mg/kg (EFSA, 2018) as laid down in EU Regulations is not expected.

The chronic and the short-term intakes of prohexadione-calcium residues are unlikely to present a public health concern.

According to available data, no specific mitigation measures should apply.

3.6.1 Residues

Additional data on oilseed rape is available which follows a more critical trial GAP (two applications instead of one) than the cGAP of this dRR. The residues of prohexadione-calcium in rape seed were present at or below the LOQ. According to the available data, the intended uses on oilseed rape in the central zone is therefore considered acceptable. The intended use patterns will be covered by the proposed MRL for prohexadione-calcium in oilseed rape, which was approved by SCOPAFF representatives in February/March 2021.

As residues of prohexadione-calcium do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

The intended uses (oilseed rape) can be grown in rotation with other crops. However, based on the confined rotational crop study, no quantifiable residues of prohexadione-calcium are expected in rotational and succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

No long-term risk has been identified for the supported crop. 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.

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.

3.6.2 Consumer exposure

TMDI (% ADI) according to EFSA PRIMo 3.1	2 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo 3.1	Not needed, TMDI $< 100\%$
UESTI (% ARfD) according to EFSA PRIMo 3.1*	Not relevant, no ARfD set
NTMDI (% ADI) **	-
NEDI (% ADI)**	-

NESTI (% ARfD) **	-
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* include raw and processed commodities if both values are required for PRIMo

** if national model is available

The proposed use of prohexadione-calcium in the formulation PRL OD 75 does not represent unacceptable chronic risks for the consumer.

After the date of submission of this dRR, the regulation changing the MRLs for oilseed crops entered into force, Reg. (EU) 2021/976. A chronic risk assessment using PRIMo Rev. 3.1 and taking into account all applicable MRL values (overestimated). The calculations do not change the results obtained by the Applicant. Calculated exposure (%ADI) does not exceed 2%.

3.7 Environmental fate and behaviour (Part B, Section 8)

There were no deviations from EU agreed endpoints.

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

Calculations were made for the product PRL OD 75 and the the parent compound prohexadione-calcium. These PEC_{soil} values have been taken into account in the ecotoxicological risk assessment.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

Presented calculations PEC_{gw} for the active substance Prohexadione calcium were accepted. Modelling was conducted using PEARL and PELMO models for a single maximum application rate for winter oil seed rape in all relevant scenarios. All used endpoints were agreed at the EU level. The maximum PEC_{GW} values for active substance is below the trigger value of 0.1 µg/L.

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

The submitted PEC_{sw} and PEC_{sed} calculations were accepted. The used endpoints were agreed at the EU level. The recommended FOCUS models were used: FOCUS Step 1 & 2. In accordance with EFSA, 2010, no metabolite was taken into consideration.

3.7.4 Predicted environmental concentrations in air (PEC_{air})

The fate and behaviour in air of Prohexadione-calcium has been evaluated, full details of these studies are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2010; 8(3):1555). No additional studies have been performed.

3.8 Ecotoxicology (Part B, Section 9)

Risk assessments according to Uniform Principles for the intended uses of the product PRL OD 75 on winter rape is provided in the Core assessment. When relevant, specific risk assessments for non-target organisms and risk mitigation measures adapted to national data requirements are proposed in the national addenda.

3.8.1 Effects on terrestrial vertebrates

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438).

The risk for birds and mammals from dietary exposure after the use supported for the product PRL OD 75 is acceptable. All TER values exceed the required regulatory trigger at Tier 1.

No unacceptable acute and long-term risk is expected for birds and mammals drinking water contaminated by residues from the use of PRL OD 75.

The risk of secondary poisoning for birds and mammals via contaminated food (fish or earthworms) is considered to be low.

3.8.2 Effects on aquatic species

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the “Guidance document on tiered risk assessment for plant protection

products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009”, as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).

For the intended use, calculated PEC/RAC ratios indicate an acceptable risk in all FOCUS Step 1 scenarios. PEC/RAC ratios for the formulated product also demonstrated acceptable risk for aquatic organisms. Based on the risk assessment presented in this document, it can be concluded that no mitigation is needed for the intended use in oil seed rape (winter).

3.8.3 Effects on bees

The evaluation of the risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002).

The hazard quotients for both contact and oral exposure are below the trigger of concern ($QH \leq 50$) for the formulated product PRL OD 75. Therefore, it can be concluded that no unacceptable risk to bees is expected using the product according to the proposed use pattern at a maximal application rate of 1 x 1.2 L product/ha in winter oil seed rape. Bumble bees did not exhibit greater sensitivity to PRL OD 75 compared to the honeybee, rendering the honeybee risk assessment protective of bumble bees. Studies assessing the toxicity to adults following chronic exposure and larvae following repeated exposure to the formulated product did not indicate delayed or cumulative toxicity effects to adult bees or risk to honeybee larvae. Overall, the risk to bees due to applications of PRL OD 75 in oil seed rape (winter) is considered to be low/acceptable.

3.8.4 Effects on other arthropod species other than bees

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

No unacceptable risk to non-target arthropods in the in-field and the off-field is to be expected based on the risk assessment. No mitigation measures are needed.

3.8.5 Effects on soil organisms

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

The long-term risk of the product was assessed for long-term exposure for earthworms and other soil macro-organisms (*Collembola*, *Hypoaspis*) and all TER values are greater than the relevant trigger values indicating a safe use of PRL OD 75 in oil seed rape (winter) according to the proposed use pattern. Furthermore, no adverse effects on soil micro-organisms are to be expected.

3.8.6 Effects on non-target terrestrial plants

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area.

All TER calculations are above the relevant trigger value of 5. Accordingly, a safe use of the product according to the use pattern can be concluded.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

No further information is available or considered to be necessary.

3.9 Relevance of metabolites (Part B, Section 10)

There are no metabolites considered in this assessment.

Appendix 1 Copy of the product label

Uwagi do etykiety:

Fizykochemia – badanie dwuletnie w toku. Wnioskodawca przedłożył tylko badanie przyspieszone, które zaakceptowano. Przyznanie warunkowego okresu ważności pozostawiono w gestii Ministerstwa.

Wnioskodawca nie przedłożył danych potwierdzających skuteczność procedury mycia opakowań jak wymagano w rozporządzeniu 284/2013.

Toksykologia – dodano zwroty: P261, P264, P272.

Pozostałości – ~~brak uwag do etykiety~~; ~~Brak zgody na autoryzację~~; Decyzja o autoryzacji należy do zarządzających ryzykiem.

Los i zachowanie w środowisku – brak uwag do etykiety.

Ekotoksykologia – brak uwag do etykiety.

Skuteczność działania – ~~brak uwag do etykiety~~. Zmieniono zalecaną ilość wody.

Załącznik do decyzji MRiRW nr R – z dnia .

Posiadacz zezwolenia:

Bayer SAS, 16, rue Jean-Marie Leclair, CS 90106, 69266 Lyon Cedex 09, Francja
Tel. + 33 4 72 85 41 93

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej: Bayer Sp. z o. o., Al. Jerozolimskie 158, 02-326 Warszawa, tel.: 22 572 35 00, www.agro.bayer.com.pl

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:

.....

HINGIOS 75 OD

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:

Proheksadion wapnia (związek z grupy cykloheksanodionów) - **75 g/l** (7,28%)

Zezwolenie MRiRW nr R -



Uwaga

H315 – Działa drażniąco na skórę.

H317 – Może powodować reakcję alergiczną skóry.

H319 – Działa drażniąco na oczy.

H335 – Może powodować podrażnienie dróg oddechowych

H412 – Działa szkodliwie na organizmy wodne, powodując długotrwałe skutki.

EUH 401 – W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.

P261 – Unikać wdychania pyłu/dymu/gazu/mgły/par/rozpylonej cieczy.

P264 – Dokładnie umyć ręce po użyciu.

P272 - Zanieczyszczonej odzieży ochronnej nie wnosić poza miejsce pracy.

P280 – Stosować rękawice ochronne, odzież ochronną, ochronę oczu i ochronę twarzy.

P308 + P311 – W przypadku narażenia lub styczości: Skontaktować się z OŚRODKIEM ZATRUĆ lub lekarzem.

P391 – Zebrać wyciek.

P501 – Zawartość i pojemnik usuwać zgodnie z lokalnymi przepisami

OPIS DZIAŁANIA

HINGIOS 75 OD to środek z grupy regulatorów wzrostu roślin w postaci zawiesiny olejowej do rozcieńczenia wodą (OD). Środek stosuje się w celu zapobiegania nadmiernemu wyrastaniu roślin w okresie jesiennym i wspomagania ich przezimowaniu.

Substancja czynna proheksadion wapnia wykazuje działanie systemiczne. Pobierana jest głównie przez liście, a następnie transportowana do pozostałych części rośliny. Proheksadion wapnia zaliczany jest do inhibitorów biosyntezy giberelin i wpływa na szybkie skrócenie łodygi rzepaku ozimego.

STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych.

Rzepak ozimy

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,2 l/ha

Termin stosowania środka: Środek stosować jesienią od fazy dwóch liści do fazy ośmiu liści (BBCH 12-18).

Zalecana ilość wody: 150-300 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):
nie wymagany

1. Środka nie stosować:

- na rośliny mokre, osłabione lub uszkodzone przez choroby, szkodniki czy przymrozki,
- przed spodziewanym silnym przymrozkiem,
- w okresie dużych wahań temperatur występujących między dniem, a nocą,

2. Podczas stosowania środka nie dopuścić do:

- znoszenia cieczy użytkowej na sąsiadujące plantacje roślin uprawnych,
- nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

NASTĘPSTWO ROŚLIN

Po zbiorze rośliny uprawnej, w której był stosowany środek HINGIOS 75 OD, można uprawiać wszystkie rośliny.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszałem), a następnie dodać adiuwant.

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlewniu środka do zbiornika opryskiwacza niewyposażonego w mieszało hydrauliczne, ciecz mechanicznie wymieszać.

W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy, ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy:

jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, lub

unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub

unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

W przypadku mycia aparatury przy użyciu środków myjących przeznaczonych do tego celu, z powstałymi popłuczynami należy postępować zgodnie z instrukcją dołączoną do środka myjącego.

Niewystarczające wymycie aparatury po zabiegu i pozostawienie resztek środka w opryskiwaczu może być przyczyną silnych uszkodzeń roślin uprawnych wrażliwych na ten środek.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

Stosować rękawice ochronne, ochronę oczu lub twarzy i odzież roboczą (kombinezon) w trakcie przygotowywania cieczy roboczej oraz odzież roboczą w trakcie wykonywania zabiegu.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):
nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od zbiorników i cieków wodnych.

W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od terenów nieużytkowanych rolniczo.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,

- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,

- w temperaturze 0°C – 30°C, z dala od źródeł ciepła

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W przypadku kontaktu ze skórą: Umyć dużą ilością wody z mydłem.

W przypadku dostania się do oczu: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać

W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Okres ważności - **2** lata

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 2 Letter of Access

A letter of access to the active substance prohexadione-Ca has been provided by Fine Agrochemicals Limited and is included in the dossier.

Appendix 3 Lists of data considered for national authorization

List of data submitted by the applicant and relied on

Please refer to the reference list.