

FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: K-300 SL-RR

Product name(s): FAWORYT 300 SL

Chemical active substance:

Clopyralid, 300 g/l

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT – POLAND - Art. 43

(Renewal of Authorization)

Applicant: CIECH Sarzyna S.A.

Submission date: 12/2021

Correction: 02/2022, 05/2022

MS Finalisation date: 07/2022, 10/2022, 05/2023, 10/2023;
11/2023 12.2023

Version history

When	What
December 2021	dRR version 1 submitted by applicant
February 2022	Section updated by a 3-year storage stability study
May	First correction for product authorization
July 2022	zRMS first evaluation
October 2022	ZRMs made some changes according to reviewed comments
May 2023	Evaluation updated for the residues section
October 2023	Verification of the Report in accordance with the Authority's arrangements regarding the assessment of plant protection products containing the active substance clopyralid.
November 2023	Correction in GAP and the label.
December 2023	Supplement to point 5 of the RR part A: <i>Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization.</i>

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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This documentation has been submitted for the renewal of the authorisation of a plant protection product Faworyt 300 SL (according to the Article 43 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009).

This documentation is submitted in order to meet legal requirements resulting from renewing the approval of the active substance clopyralid in EU (Commission Implementing Regulation (EU) 2021/1191 of 19 July 2021) which is assessment of a plant protection product with the trade name FAWORYT 300 SL in terms of risks to human and animal health and to the impact on the environment.

This application has been submitted in accordance with Art. 43 of Regulation 1107/2009, by the applicant in December 2021, and concerns the renewal of the authorization for the product Faworyt 300 SL, containing 300 g / l of clopyralid in the form of monoethanolamine salt for use in the protection of winter rape, winter wheat and sugar beet.

1.2 Letters of Access

CIECH Sarzyna S.A. possess Letter of Access from the Task Force Clopyralid to alternative data package for active substance Clopyralid. Task Force Clopyralid has submitted its Data Matching List to zRMS, Finland. This Data Matching List covers all the protected studies from the main notifier.

Letter of Access from the PROPLAN, Plant Protection Company, S.L has been attached to the Application for the renewal of the authorization of the product Faworyt 300 SL as Appendix No. 20.

For formulation FAWORYT 300 SL Applicant has also conducted and submitted own studies which are sufficient to evaluate of the product.

1.3 Justification for submission of tests and studies

All tests and studies for Faworyt 300 SL are submitted to meet the requirements of Regulation (EC) No. 284/2013. These studies are necessary for the renewal of an authorization.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

2 Details of the authorization decision

2.1 Product identity

Product code	K-300 SL-RR
Product name in MS	FAWORYT 300 SL
Authorization number	R - 140/2013
Function	Herbicide
Applicant	CIECH Sarzyna S.A.
Active substance(s) (incl. content)	Clopyralid, 300 g/l (25,8%)
Formulation type	SL
Packaging	100 mL, 250 mL, 500 mL, 1 L, 3 L, 5 L, 10 L, 20 L, 60 L, 120 L, 200 L and 1000 L HDPE containers Professional user
Coformulants of concern for national authorizations	Not Applicable. Please refer to Part C (Confidential Section)
Restrictions related to identity	N/A
Mandatory tank mixtures	N/A
Recommended tank mixtures	N/A

2.2 Conclusion

GENERAL: the evaluation of the application for product Faworyt 300 SL resulted in the decision to grant the renewal authorization.

Efficacy: The evaluation of the application for product ~~name~~ Faworyt 300 SL resulted in the decision to grant the authorization

Toxicology: FAWORYT 300 SL is classified Eye Irrit.2/ H319. No risk for operator, worker and residents and bystanders (adults and children). ~~Buffer zone: 2-3 m~~

Residues: The evaluation of the application for product ~~name~~ Faworyt 300 SL resulted in the decision to grant the authorization. ~~Only use on wheat is~~ All uses are acceptable.

According to the available data following label restriction is proposed: not to use clopyralid on the same field for 125 days after the initial application regardless of the crop grown (see EFSA Journal 2021;19(1):6389).

Tests on residues in honey must be submitted within two years from the date of receipt of the authorization.

After the publication of the results of additional studies, assessed at EU level, filling the gaps in data on the metabolism of clopyralid in winter rapeseed and sugar beet, it will be necessary to verify the assessment. The authorization holder will be obliged to confirm that the product can be used in the above-mentioned uses.

Fate and behaviour: The evaluation of the application for product Faworyt 300 SL resulted in the deci-

sion to grant the renewal authorization.

Ecotoxicology: The evaluation of the application for Faworyt 300 SL on area of Ecotoxicology resulted in the decision to grant the authorization for all proposed uses in the GAP

2.3 Substances of concern for national monitoring

Not applicable. National monitoring data is not available/known to the applicant.

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:	Eye Irrit. 2 ; H319
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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:	GHS 07
Signal word:	Warning
Hazard statement(s):	H319 - Causes serious eye irritation
Precautionary statement(s):	P280 - Wear protective gloves/ protective clothing/eye protection/ face protection P305 +P351 +P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do continue rinsing P310 - Immediately call a POISON CENTER/doctor
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
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). In order to protect groundwater, do not use a product containing Chlopyralid more frequently than every 2 years in the cultivation of winter wheat and winter oilseed rape in the same field.
SPe3	To protect aquatic organisms, it is necessary to designate a protection zone 1 m wide from reservoirs and watercourses aquatic. To protect non-target plants respect an unsprayed buffer zone of 5 m or 1 m with 50% drift reduction to non-agricultural land.

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No

1107/2009)

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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) and gloves during mixing and loading
Worker protection:	
respective code if available	None
Integrated pest management (IPM)/sustainable use:	
Mode of action (HRAC-group):	Clopyralid : O
Environmental protection	
SP1	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). In order to protect groundwater, do not use a product containing Clopyralid more frequently than every 2 years in the cultivation of winter wheat and winter oilseed rape in the same field.
SPe3	To protect aquatic organisms, it is necessary to designate a protection zone 1 m wide from reservoirs and watercourses aquatic. To protect non-target plants respect an unsprayed buffer zone of 5 m or 1 m with 50% drift reduction to non-agricultural land.
Other specific restrictions	
respective code if available	None

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	None	

Environmental protection:		Relevant for use no.
respective code if available	None	

2.6 Intended uses (only NATIONAL GAP)

GAP rev. V, date: 2021-12

PPP (product name/code): FAWORYT 300 SL
 Active substance 1: Clopyralid 300 g/l
 Safener: Full composition in Part C
 Synergist: Full composition in Part C
 Applicant: CIECH Sarzyna S.A.
 Zone(s): Central Zone ^(d)
 Verified by MS: yes/no
 Field of use: Herbicide

Formulation type: SL ^(a, b)
 Conc. of as 1: 300 g/l ^(c)
 Conc. of safener: N/A ^(c)
 Conc. of synergist: N/A ^(c)
 Professional use: X
 Non professional use:

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use -No. ^(e)	Mem-ber state(s)	Crop and/or situa-tion (crop destina-tion / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests con-trolled (additional-ly: develop-mental 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 biannual applica-tions	Max. number a) per use b) per crop/season	Min. interval between applica-tions (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/seaso-n	g as/ha a) max. rate per appl. b) max. total rate per crop/seaso-n	Water L/ha min / max		

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 (additional-ly: develop-mental 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 biannual applica-tions	Max. number a) per use b) per crop/ season	Min. interval between applica-tions (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		
1	PL	Winter wheat	F	Dicotyle-donous weeds (from coty-ledon stage to the ro-sette stage)	Spray-ing, broad-cast-foliar	BBCH 21-29 (Spring)	a) 1* b) 1*	N/A	a) 0.3-0.4 b) 0.3-0.4	a) 90-120 b) 90-120	200/300	N/A	None Fate*Once application every 2 years R Acceptable for biannual application Metabolism and residues: According to the available data following label restriction is proposed: not to use clocyralid on the same field for 125 days after the initial application regardless of the crop grown (see EFSA Journal 2021;19(1):6389).
2	PL	Winter rape	F	Dicotyle-donous weeds (from coty-ledon stage to the ro-sette stage)	Spray-ing, broad-cast-foliar	BBCH 10-50 (Spring)	a) 1 b) 1	N/A	a) 0.3-0.4 b) 0.3-0.4	a) 90-120 b) 90-120	200/300	N/A	None Fate: One application every 2 years Metabolism and residues: not acceptable According to the available data following label restriction is proposed: not to use clocyralid on the same field for 125 days after the initial application regardless of the crop grown (see EFSA Journal 2021;19(1):6389).
3	PL	Sugar beet	F	Dicotyle-donous weeds (from coty-ledon stage to the ro-	Spray-ing, broad-cast-foliar	BBCH 12-14 (Spring)	a) 1 b) 1	N/A	a) 0.3 b) 0.3	a) 90 b) 90	200/300	N/A	none Metabolism and residues: not acceptable According to the available data following label restriction

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use -No. (e)	Mem-ber 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 (additional-ly: develop-mental 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 biannual applica-tions	Max. number a) per use b) per crop/season	Min. interval between applica-tions (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		
				sette stage)									is proposed: not to use clopyralid on the same field for 125 days after the initial application regardless of the crop grown (see EFSA Journal 2021;19(1):6389).

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
 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.

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

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 bright yellow liquid, with a characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature above of 650 °C. In aqueous solution, it has a pH value around 8.5 at 20 °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 that a shelf life of at least 3 years at ambient temperature has to be expected when stored in *high density polyethylene (HDPE) bottles*.

Its technical characteristics are acceptable for a *SL* formulation.
 The intended concentration of use is 0.1% to 0.2%.

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

Studies	Method	Findings	Classification acc. to Regulation (EC) No. 1272/2008
Explosive properties	EEC A.14 and UN Recommendations	Not explosive	None
Oxidising properties	UN Recommendations Screening Procedure	Not oxidizing	None
Flammability	--	Not applicable for SL-formulation	--
Flash point	--	Not applicable. The product is water solution (contains about 60% of water) and does not contain flammable solvents	--
Auto-flammability	EEC A.15	Self-ignition temperature > 650 °C	None
pH	CIPAC MT 75.3	pH = 9.17 (neat formulation) pH = 8.49 (1% in distilled water)	None
Viscosity	OECD 114	Kinematic viscosity 4.46 mm ² /s at 40 °C	None
Surface tension	EEC A.5	undiluted = 25.2 mN/m; 0,2 % concentration = 37.2 mN/m	None
Relative density	CIPAC MT 3.3	1.156 g/mL at 20 °C	None

Notifier Proposals for Risk and Safety Phrases (KCP 12)

Risk and safety phrases relevant for this section: none

Compliance with FAO specifications:

The product FAWORYT 300 SL complies with FAO specifications.

Formulation used for tests

The product used in the tests has the composition as described in Part C.

3.2 Efficacy (Part B, Section 3)

The Annex I Renewal process of clopyralid has triggered the application for renewal of authorisation of all clopyralid containing products, including FAWORYT 300 SL. Since the evaluation of clopyralid did not raise a request for new information concerning efficacy and no changes compared to previous authorisations are sought, the application for Product Renewal is done under Article 43 of Regulation (EC) 1107/2009.

According to the SANCO guidance 2010/13170 (rev. 14, 7 Oct 2016)¹, the previous efficacy assessment remains valid and only an updated resistance statement is required if there are no GAP changes: “Where a GAP change is triggered e.g. by new endpoints, new guidance, efficacy data addressing the new GAP should be submitted. Otherwise, for renewal applications, only resistance data are required.”

The only change in GAP is withdrawal of use FAWORYT 300 SL in tank mix with Acord 180 OF in sugar beet. Therefore, in intended uses, there has been no GAP change that impacts the previous efficacy evaluation of FAWORYT 300 SL and the effectiveness does not have to be reassessed (according to the regulations). No new efficacy and selectivity data trials of this product have been submitted and no new uses will be considered in this application. Thus, the conclusions of previous assessments are still considered valid and the only aspect that will be considered is the resistance risk assessment, which requires updating at renewal.

All necessary information's were provided above by Applicant. **The data presented in this dossier fully support the renewal under Article 43 of Faworyt 300 SL for the control of weeds in cereals, sugar beets and winter oilseed rape in Poland.** The formulation of this product is a soluble concentrate (SL), and it is containing one active substance: clopyralid (300 g/l).

The change in the label regarding the application of the product once per season every two years in winter rapeseed is due to PEC_{gw} calculations – clopyralid was renewed with such endpoints, which do not allow the product to be applied every year. In addition, the calculations made for winter wheat (PEC_{gw} conversions) by Applicant show that also in winter wheat the tested plant protection product can be applied only once in two years. For details, please refer to the ecotoxicology Environmental Fate section. Considering, the above, an appropriate change has been made in the GAP for winter wheat and winter oilseed rape, as well as in the product label, that the product can be applied once a season every two years. Other provisions remain unchanged.

3.3 Efficacy data

There has been no GAP change that impacts the previous efficacy evaluation of FAWORYT 300 SL. Therefore, no new information is provided under this point in accordance with SANCO/2010/13170 rev. 14, 7 October 2016, Guidance Document on the Renewal of Authorizations according to Article 43 of Regulation (EC) No 1107/2009. Information on the efficacy of the product FAWORYT 300 SL was submitted and positively evaluated during the authorization process of this product (Authorization No: R-140/2013 dated of 08.11.2013). Please refer to Registration Report (Part B – Section 3) for the product FAWORYT 300 SL with March 2013.

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

The possibility of development of resistance or cross-resistance to the active substance contained in the proposed formulation FAWORYT 300 SL (clopyralid, 300 g/L) is discussed thereafter based on the requirements detailed in EPPO standard PP1/213(3) “Resistance risk analysis”. FAWORYT 300 SL is used as post-emergence herbicide to control broadleaved weeds in winter wheat, winter rape and sugar beet.

Mode of action

Clopyralid belongs to the chemical group of the pyridine carboxylic acid herbicide family, described as a synthetic auxin and classified by HRAC as Group 4 (Legacy HRAC Group O). It acts as systemic herbicide, absorbed by the leaves and roots, with translocation both acropetally and basipetally, and accumulation in meristematic tissue. This type of herbicide kills the target weed by mimicking the plant growth hormone auxin (indole acetic acid), and when administered at effective doses, cause uncontrolled and disorganized plant growth that leads to plant death in a few days or weeks, depending on the species. The exact mode of action of clopyralid has not been fully described but it is believed to acidify the cell wall, which results in cell elongation. Low concentrations of clopyralid can stimulate RNA, DNA, and protein synthesis leading to uncontrolled cell division and disorganized growth, and ultimately, vascular tissue destruction. High concentrations of clopyralid can inhibit cell division and growth.

Evidence of resistance

For group 4, the latest (November 2021) HRAC data base lists 82 cases of 40 resistant species worldwide and only 11 cases of 5 resistant species across Europe. Clopyralid resistance has been described for 3 weed species worldwide since 1999 in altogether 3 confirmed cases. None of these cases were reported Europe and in crops, which are target use in this submission.

Cross resistance

Target site cross resistances for Auxin Mimics HRAC Group 4 (Legacy O) in Europe have been reported for two dicotyledonous species: *Cirsium arvense* and *Papaver rhoeas*. However, none of these cases concerned clopyralid.

Non-target site cross resistance is defined as cross resistance to dissimilar herbicide classes conferred by a mechanism(s) other than resistant enzyme target sites. Non-target site cross resistances in Europe for Auxin Mimics HRAC Group 4 (Legacy O) and Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B) have been reported for two weed species: *Papaver rhoeas* and *Sinapis arvensis*. None of these cases concerned clopyralid.

Acceptability of the resistance risk

Generally, evidences of resistance to HRAC Group 4 and specifically to clopyralid are well documented by Weed Science organization and Herbicide Resistance Action Committee. The risk of resistance development of weeds to substances belongs to Group 4 is defined as low. Three cases of weeds specie resistance for clopyralid are reported worldwide, out of which none were reported in Europe so far. The resistance risk is really low if FAWORYT 300 SL is used under adherence to the management strategy and label recommendations.

Appropriate resistance-management strategies should be followed.

- Where possible, rotate the use of FAWORYT 300 SL with different herbicide groups that control the same weeds in a field.
- Use tank mixtures with herbicides from a different group when such use is permitted.
- Herbicide use should be based on an IPM program that includes scouting, historical information related to herbicide use and crop rotation, and considers tillage (or other mechanical), cultural, biological and other chemical control practices.
- Monitor treated weed populations for resistance development.
- Prevent movement of resistant weed seeds to other fields by cleaning harvesting and tillage equipment and planting clean seed.
- Contact your local extension specialist or certified crop advisors for any additional pesticide resistance-management and/or integrated weed-management recommendations or specific crops and weed biotypes.

Lack of resistance cases for Europe, only one case from Canada (2013) and two cases from New Zealand (1999, 2005) have been already reported. Taking into consideration inherent factors from weeds and herbicide, the agronomic risks, and the fact that despite many years of intensive use of clopyralid only five

proven problems with weed resistance have been reported in Europe, the risk for the development of clopyralid resistant weed biotypes in major crop production and vegetable production areas is considered low.

3.3.2 Adverse effects on treated crops

There has been no GAP change that impacts the previous efficacy evaluation of FAWORYT 300 SL. Therefore no new information is provided under this point in accordance with SANCO/2010/13170 rev. 14, 7 October 2016, Guidance Document on the Renewal of Authorizations according to Article 43 of Regulation (EC) No 1107/2009. Information on the adverse effects of the product FAWORYT 300 SL was submitted and positively evaluated during the authorization process of this product (Authorization No: R-140/2013 dated of 08.11.2013). Please refer to Registration Report (Part B – Section 3) for the product FAWORYT 300 SL with March 2013.

3.3.3 Observations on other undesirable or unintended side-effects

There has been no GAP change that impacts the previous efficacy evaluation of FAWORYT 300 SL. Therefore no new information is provided under this point in accordance with SANCO/2010/13170 rev. 14, 7 October 2016, Guidance Document on the Renewal of Authorizations according to Article 43 of Regulation (EC) No 1107/2009.

3.4 Methods of analysis (Part B, Section 5)

Sufficiently sensitive and selective analytical methods are available for the active substance in the plant protection product. Validation criteria are compliant with EU requirements given in SANCO/3030/99 Rev.4.

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions. All of the methods are validated and compliant with requirements given in SANCO/825/00 rev. 8.1.

3.4.1 Analytical method for the formulation

Methods suitable for the determination of Clopyralid in plant protection product Faworyt 300 SL is available and fully compliant with all requirements given in SANCO/3030/99 Rev.4 and rev. 5 (see Part B5).

Faworyt 300 SL does not contain relevant impurities which are of toxicological, ecotoxicological or environmental concern which could be arisen in the manufacturing process or as a result of degradation during storage of the product.

3.4.2 Analytical methods for residues

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

Minor data gap: extraction efficiency (for plant and animal matrices). Not provided during the EU review.

Commodity/crop	Supported/ Not supported
Winter wheat	Supported

Commodity/crop	Supported/ Not supported
Winter rape	Supported
Sugar beet	Supported

3.5 Mammalian toxicology (Part B, Section 6)

The toxicity profile of Faworyt 300 SL, containing the active substance clopyralid at 300 g/L was assessed in several acute toxicity studies, which were already evaluated and accepted by the zRMS (Poland) during the first authorisation process (Authorization No: R - 140/2013 from 08.11.2013 r. with further amendments).

Taking into account all those submitted data, only eye irritation classification with H319 statement is required for the formulation according to Regulation (EC) No. 1272/2008.

No unacceptable risk for operators, workers, residents and bystanders was identified when the product is used as intended and provided that the PPE/risk mitigation measures stated in the following sections are applied.

3.5.1 Acute toxicity

The following tests were performed on Faworyt 300 SL: acute LD₅₀ oral, acute LD₅₀ dermal, skin irritation, eye irritation and skin sensitization (LLNA). In case of acute inhalation properties the calculation method according to principles of Regulation 1272/2008 was applied.

Based on the data, no acute toxicity, skin irritation or skin sensitization for Faworyt 300 SL is expected. However, the product is irritant to eyes. Consequently, H319 statement according to CLP Regulation (EC) 1272/2008 is necessary to be put on the product label.

3.5.2 Operator exposure

Operator exposure and risk assessment was calculated based on the EFSA (2014) 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). Acute and long – term exposure based on the AAOEL and AOEL value for clopyralid were taken into account.

It is concluded that the use of Faworyt 300 SL is at an acceptable risk for the operator considering that workwear and gloves are worn during mixing and loading phase.

3.5.3 Worker exposure

Worker exposure was calculated based on the EFSA (2014) 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). Within this the EFSA-OPEX and EUROPOEM II model was considered.

It is concluded that there is no unacceptable risk anticipated for the worker exposure (acute and longer term) wearing adequate work clothing, for inspection and irrigation when for re-entering treated with FAWORYT 300 SL.

3.5.4 Bystander and resident exposure

Estimated bystander exposure

Bystander risk assessment is required for plant protection products that have significant acute toxicity or the potential to exert toxic effects after a single exposure, based on the 95th percentile data values. Since AAOEL value for clopyralid is available, the risk assessment for bystanders was performed in addition to the residents assessment.

For all crops, the calculated total systemic exposure for residents and by-standers are below the reference clopyralid values for both – adults and children. Therefore, it is concluded that bystander and resident exposure to Faworyt 300 SL is acceptable in all crops. Buffer zone: 2-3 (m).

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

The summary for clopyralid is given below:

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Winter wheat	Yes	Yes (17)	NR PHI covered by the time between the last application and harvest	Yes	Yes	No	No
2	Winter oilseed rape	Yes	Yes (8)	NR PHI covered by the time between the last application and harvest	Yes	Yes		
3	Sugar beet	Yes	Yes (10)	NR PHI covered by the time between the last application and harvest	Yes	Yes		

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 3 mg/kg in wheat, 0.5 mg/kg in oilseed rape and 1 mg/kg in sugar beet for clopyralid as laid down in Reg. (EU) 396/2005 is not expected.

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

Number of residue trials fulfils requirement for N-Zone for winter wheat, sugar beet and winter oilseed rape.

3.6.1 Residues

October 2023 Verification of the Report in accordance with the Authority's arrangements, from the meeting of July 28, 2023, regarding the assessment of plant protection products containing the

active substance clopyralid.

Stability of residues during storage of samples

Stability of residues during storage of samples was provided during the EU review of clopyralid.

Residues of clopyralid were found to be stable at $\leq -18^{\circ}\text{C}$ for up to:

13 months in maize fodder and forage (high water content matrix)

13 months in maize grain (high starch content matrix)

17 months in pasture grass (high water content matrix)

24 months in rape seed (high oil content matrix)

Metabolism in plants and animals

Residue definition for monitoring (Commission Regulation (EU) 2021/1807 of 13 October 2021): clopyralid (plants and animals)

Residue definition for risk assessment:

Clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid) – pending the outstanding clarification on the nature of “polar clopyralid” (EFSA Journal 2018;16(7):5389)

During the peer review, the data gap related to the identification of an unknown compound observed in sugar beet and oilseed rape metabolism studies was identified.

EFSA Journal 2021;19(1):6389:

Based on the metabolic pattern identified in metabolism studies with cereals, rotational crops and the results of hydrolysis studies, the residue definitions were proposed as clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid) both, for enforcement and risk assessment. These residue definitions are applicable to cereals/grass crop group, rotational crops and processed products.

Since the clarification of the unknown polar metabolite (called ‘polar clopyralid’) in mature sugar beet and oilseeds identified by the EU pesticides peer review was not sufficiently addressed under the current assessment, EFSA concludes that the proposed residue definitions are applicable only to cereals/grass crop group for which a new metabolism study was submitted under the current assessment and for which the data gap identified by the peer review is not relevant. For remaining crop groups, the data gap as identified by the EU pesticides peer review remains open.

Authority's arrangements:

- in the case of clopyralid, assessment of residue data for the uses proposed by the Applicants, including, among others, on oilseeds, roots or tubers (crops other than representative crops assessed in RAR (2019) for the substance clopyralid) should be carried out in accordance with the general residue definition for clopyralid proposed by EFSA in the document EFSA Journal 2018;16(8):5389 - applies all administrative proceedings conducted by the Ministry of Agriculture and Rural Development (Article 33, Article 43, Article 40, Article 45, Article 51).

Plant residue definition for monitoring: Clopyralid (Reg. (EU) 2021/1807)

Plant residue definition for risk assessment: clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid) – pending the outstanding clarification on the nature of “polar clopyralid” (EFSA Journal 2018;16(7):5389).

~~According to EFSA, the residue definition should be limited to cereals/grass only. Taking this into account, application on winter rape and sugar beet are not acceptable until the data gap is filled.~~

The intended uses **on cereals** are supported by the evaluated plant metabolism studies.

One new hydrolysis study has been submitted by the applicant in the framework of this application. The study was submitted as equivalent to protected hydrolysis study and was accepted in data matching (Finland 2022). Study is acceptable. The test compound clopyralid was stable under all conditions of high temperature hydrolysis for simulation of food processing. Equivalent endpoint have been received.

New metabolism studies in rotational crops have been submitted by the applicant in the framework of this application. The study was submitted as equivalent to protected study and was accepted in data matching (Finland 2022). The requirement for alternative tests has been met. This study should be evaluated at EU level.

Magnitude of residues in plants

Winter wheat

Proposed uses: 1 application, BBCH 21-29 (Spring), 90 – 120 g as/ha, PHI: not required

Applicant refers to the unprotected EU data. GAP on which EU a.s. assessment is based: 1 x 0.150 kg as/ha, BBCH 39

Additionally new data are submitted in the framework of this application.

Study S20-04397-01 (1 x 0.153,9 kg as/ha, BBCH 39):

Residues: 0.79 mg/kg

Study S19-01810-01 (1 x 0.159 kg as/ha, BBCH 39)

Residues: 0.76 mg/kg

Sufficient data are available to support the proposed use. The residues arising from the proposed uses will not exceed the MRLs established for wheat (Reg. (EU) 2021/1807)

Winter rape, Sugar beet

~~According to EFSA, the residue definition should be limited to cereals/grass only. Taking this into account, application on winter rape and sugar beet are not acceptable (until the data gap is filled).~~

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Winter rape

Proposed use: 1 application, BBCH 10-50 (Spring), 90 – 120 g as/ha, PHI: not required

Applicant refers to unprotected EU data:

Trials GAP: 1 x 0.1 kg as/ha + 1 x 0.2 kg as/ha, outdoor

Residues: <0.01, 0.01, 2 x 0.02, 0.03, 0.04, 0.05, 0.1 mg/kg

Sufficient data are available to support the proposed use. The residues arising from the proposed uses will not exceed the MRLs established for oilseed rape (Reg. (EU) 2021/1807).

Sugar beet

Proposed use: 1 application, BBCH 12-14 (Spring), 90 g as/ha, PHI: not required

Applicant refers to unprotected EU data:

Trials GAP: 1 x 0.1 kg as/ha + 1x 0.2 kg/ha latest timing of BBCH 39

Residues: 0.12, 0.17, 0.21, 0.29, 0.34, 0.35, 0.36, 0.41, 0.56, 0.80

Sufficient data are available to support the proposed use. The residues arising from the proposed uses will not exceed the MRLs established for sugar beet roots (Reg. (EU) 2021/1807).

Livestock feeding studies

The requested uses do not modify the theoretical maximum daily intake for animals, and there is no risk for animal MRLs to be exceeded.

Magnitude of residues in processed commodities

New acceptable, alternative to the protected studies were provided by the applicant (White T., 2021, S19-01810; White T., 2021, S20-04397). No further data is required.

Rotational study

According to the available data following label restriction is proposed: not to use clopyralid on the same field for 125 days after the initial application regardless of the crop grown (see EFSA Journal 2021;19(1):6389).

Other / special studies

- Clopyralid is systemic compound and potential residues in honey might occur in honey even from applications before flowering. Therefore, information about residue level in pollen and bee products should be provided by the applicant (post registration requirement). **The requirement concerns the use in the protection of oilseed rape.**

Noticed data gaps are:

- Information about residue level in pollen and bee products should be provided by the applicant (post registration requirement – **within 2 years after authorisation**). **The requirement concerns the use in the protection of oilseed rape.**
- Data gap on residue definitions should be filled at EU level.

May 2023

Where the renewal authorization is granted for cereals only, no information about residue level in pollen and bee products is required. According to the SANTE/11956/2016 rev. 9 wheat have not melliferous capacity.

October 2023 Verification of the Report in accordance with the Authority's arrangements regarding the assessment of plant protection products containing the active substance clopyralid.

Proposed uses are accepted

Post registration requirement: Information about residue level in pollen and bee products

3.6.2 Consumer exposure

A consumer risk assessment was performed using the EFSA PRIMo model rev. 3.1. TMDI calculations were performed taking into account all commodities for which MRLs have been set for the active substance clopyralid, using as input values the EU-MRLs in force. The chronic exposure was up to 39% of the ADI for clopyralid. IESTI calculations for the intended crops were well below (up to 17%) the respective ARfD.

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

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

Predicted environmental concentrations in soil for clopyralid and formulation FAWORYT 300 SL were calculated for the use on winter cereals, winter rape and sugar beet using the ESCAPE 2.0 software. Full details of the proposed use pattern are shown in dRR Part B8.

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

Predicted environmental concentrations for clopyralid in groundwater (PEC_{gw}) were calculated using the leaching models FOCUS PEARL (v 4.4.4), FOCUS PELMO (v 5.5.3) and FOCUS MACRO (v. 5.5.4) following a single application of the product FAWORYT 300 SL on cereal and winter oilseed rape at a rate of 120 g a.s./ha and sugar beet at a rate of 90 g a.s./ha.

Application Faworyt 300 SL for winter cereals and winter rape was accepted for 120g/ha and for biannual applications and for sugar beet for 90 g/ha every year.

Based on the assessment, the use of clopyralid is not expected to lead to leaching into groundwater at levels that would be unacceptable when applied according to the recommended use pattern.

Following mitigation measure is required:

SP1 In order to protect groundwater, do not use a product containing Chlopyralid more frequently than every 2 years in the cultivation of winter wheat and winter oilseed rape in the same field.

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

In accordance with the applicable requirements calculation of the PEC_{SW} and PEC_{SED} values for the active substance in surface waters were presented.

The PEC_{SW} and PEC_{SED} were calculated for single application to all intended uses acc. To GAP. The calculations were carried out taking into consideration of data for active substance listed in the “EFSA Journal 2018;16(7):5389, Conclusion on peer review of the pesticide risk assessment of the active substance clopyralid”

The initial, short-term and long-term values (actual and average time-weighted) of PEC_{SW} and PEC_{SED} were calculated for clopyralid using „STEPS 1-2 in FOCUS”. The highest values of PEC_{SW} were used to determine the risk factors for aquatic organisms. Calculations of the PEC_{SW} and PEC_{SED} using the Step 3 and Step 4 are not required since all trigger values were achieved for aquatic organisms.

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

The fate and behaviour in air of clopyralid was evaluated during the Annex I Inclusion. No additional studies have been performed.

There was no need to calculate PEC_A due to low volatility of clopyralid.

3.8 Ecotoxicology (Part B, Section 9)

The risk for non-target organisms from the exposure to Faworyt 300 SL at the intended uses in winter wheat, winter rape and sugar beet was assessed. The risk was considered acceptable for terrestrial verte-

brates, aquatic organisms, bees, non-target arthropods other than bees and soil meso- and macrofauna as well as soil microflora without the necessity to apply risk mitigation measures. For non-target plants, the risk was also considered acceptable when either 50% drift reduction or a 5 m unsprayed buffer zone to non-crop land was applied.

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; hereafter referred to as EFSA/2009/1438).

The risk assessment performed for birds and mammals indicate acceptable acute and long-term risk to birds and mammals exposed to clopyralid following application of Faworyt 300 SL acc. to intended GAP.

Regarding effects on other terrestrial vertebrate wildlife (reptiles and amphibians), no data/information available.

3.8.2 Effects on aquatic species

The risk assessment for aquatic organisms was carried out according to the Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013;11(7):3290).

The risk for aquatic organisms from exposure to clopyralid applied as Faworyt 300 SL in winter wheat, rape and sugar beet is indicated to be acceptable based on Tier 1 data and FOCUS Step 1 calculations. No mitigation is required for all proposed uses in the GAP (winter wheat, oilseed rape and sugar beet).

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).

Effects on bees of Faworyt 300 SL were not evaluated as part of the EU assessment of clopyralid. Faworyt 300 SL was tested in acute (oral and contact exposure) and chronic studies (oral exposure of adults and larvae). Data submitted with this application are listed in Appendix 1 and summarised in Appendix 2 of Part B, Section 9 (Ecotoxicology).

The acute risk assessments for the active substance as well as for the formulated product Faworyt 300 SL with Hazard Quotients well below the trigger for acceptability of effects indicate an acceptable risk for bees exposed in accordance with the intended uses in winter wheat, winter rape and sugar beet. The chronic studies for bees are submitted by the applicant. The chronic risk to bees assessment with consideration of these studies will be required in Poland when Bee GD for Bees, 2013 will be applied at EU level.

3.8.4 Effects on other arthropod species other than bees

The evaluation of the risk for non-target arthropods was principally 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.

Effects on non-target arthropods other than bees of Faworyt 300 SL were not evaluated as part of the EU assessment of clopyralid. Faworyt 300 SL was tested on *Aphidius rhopalosiphi* (Tier 1 data and 2 data), *Typhlodromus pyri* (Tier 1) and *Chrysoperla carnea* (Tier 2 data). Data submitted with this application are listed in Appendix 1 and summarised in Appendix 2 of Part B, Section 9 (Ecotoxicology).

The in-field and off-field risk from exposure to clopyralid applied as Faworyt 300 SL for the intended uses in winter wheat, winter rape and sugar beet is indicated to be acceptable for non-target arthropods other than bees based on Tier 2 data without the need for risk mitigation measures.

3.8.5 Effects on soil organisms

The risk assessment was conducted according to the Guidance Document on Terrestrial Ecotoxicology (2002).

Meso- and macrofauna

Effects on soil meso- and macrofauna of Faworyt 300 SL were not evaluated as part of the EU assessment of clopyralid. Faworyt 300 SL was tested on earthworms, *Folsomia* and *Hypoaspis*. Data submitted with this application are listed in Appendix 1 and summarised in Appendix 2 of Part B, Section 9 (Ecotoxicology).

The risk from exposure to clopyralid applied as Faworyt 300 SL for the intended uses in winter wheat, winter rape and sugar beet is indicated to be acceptable for the soil meso- and macrofauna.

Microbial activity

Effects on soil microorganisms of Faworyt 300 SL were not evaluated as part of the EU assessment of clopyralid. Effects of Faworyt 300 SL on the nitrification of soil microorganisms have been determined. Data submitted with this application are listed in Appendix 1 and summarised in Appendix 2 of Part B, Section 9 (Ecotoxicology).

The risk from exposure to clopyralid applied as Faworyt 300 SL for the intended uses in winter wheat, winter rape and sugar beet is indicated to be acceptable for soil microorganisms.

3.8.6 Effects on non-target terrestrial plants

The risk assessment was based on the “Guidance Document on Terrestrial Ecotoxicology” (SAN-CO/10329/2002 rev.2 final, 2002).

Effects on non-target terrestrial plants of Faworyt 300 SL were not evaluated as part of the EU assessment of clopyralid. Effects of Faworyt 300 SL on the seedling emergence and vegetative vigour of non-target plants have been determined. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2 of Part B, Section 9 (Ecotoxicology).

The risk for non- target plants was considered acceptable when either 50% drift reduction or a 5 m unsprayed buffer zone to non - crop land was applied for all proposed uses in the GAP (winter wheat, oilseed rape and sugar beet).

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

No further relevant data available and considered necessary.

3.9 Relevance of metabolites (Part B, Section 10)

No relevance assessment of groundwater metabolites is required - no data submitted.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Faworyt 300 SL contains clopyralid which is not approved as a candidate for substitution. A comparative assessment is therefore not needed/applicable.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

Metabolism and residues:

1. Tests on residues in honey must be submitted within two years from the date of receipt of the authorization.
2. After the publication of the results of additional studies, assessed at EU level, filling the gaps in data on the metabolism of clopyralid in winter rapeseed and sugar beet, it will be necessary to verify the assessment. The authorization holder will be obliged to confirm that the product can be used in the above-mentioned uses.

Appendix 1 Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

Appendix 2 Copy of the product label

Fizykochemia: bez uwag

Skuteczność: nie wprowadzono zmian do etykiety

Toksykologia:

- Dodać P305 +P351 +P338, ~~P310~~

~~Zmiany w sekcji "ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH". Dodać strefę buforową~~

Pozostałości:

~~Zgoda na zastosowanie tylko w ochronie pszenicy.~~

Korekcja zapisu dotyczącego upraw następczych. Proponuje się następujący zapis: Nie stosować środków zawierających kloparylid na tym samym polu przez 125 dni po zastosowaniu niezależnie od uprawianej rośliny.

Los i zachowanie w środowisku:

Dodano pominiętą przez wnioskodawcę informację: stosowanie w uprawie pszenicy i rzepaku ozimym co dwa lata

Ekotoksykologia:

Środki ograniczające ryzyko dla roślin lądowych zamieszczone w etykiecie dotyczą zastosowania w pszenicy ozimej, zaakceptowanego przez wszystkie Sekcje.

Załącznik do decyzji MRiRW nr R – z dnia
odnawiającej zezwolenie MRiRW nr R - 140/2013-z dnia 08.11.2013 r.

Posiadacz zezwolenia:

CIECH Sarzyna S.A., ul. Chemików 1, 37-310 Nowa Sarzyna,
tel.: +48 17 24 07 111, fax: +48 17 24 07 122, e-mail: sarzyna@ciechgroup.com.
www.ciechagro.pl

Faworyt 300 SL

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

Chlopyralid (substancja z grupy pochodnych kwasu karboksylowego) – **300 g/l** (25,8%).

Zezwolenie MRiRW nr R - 140/2013 z dnia 08.11.2013 r.
odnowione decyzją MRiRW nr R – z dnia

W celu ochrony wód gruntowych nie stosować na tym samym polu produktu zawierającego Chlopyralid częściej niż co 2 lata w uprawie pszenicy ozimej i rzepaku ozimego.



UWAGA

H 319	Działa drażniąco na oczy.
EUH 401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P280	Stosować ochronę oczu np. gogle i/lub ochronę twarzy.
P305 +P351 +P338	W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
P310	Natychmiast skontaktować się z OŚRODKIEM ZATRUCÍ/lekarzem

OPIS DZIAŁANIA

HERBICYD w formie koncentratu do sporządzania roztworu wodnego (SL), stosowany nalistnie, przeznaczony do powszodowego zwalczania głównie chwastów rumianowatych i ostrożnia polnego a także innych chwastów dwuliściennych w pszenicy ozimej, rzepaku ozimym i buraku cukrowym. W roślinie wrażliwej powoduje blokadę auksyn tj. hormonów roślinnych odpowiedzialnych za wzrost roślin, co prowadzi do wstrzymania syntezy aminokwasów. Ponadto zakłóca proces oddychania na poziomie komórkowym.

Zgodnie z klasyfikacją HRAC substancja czynna chlopypirald zaliczana jest do grupy O.

DZIAŁANIE NA CHWASTY

Środek jest herbicydem selektywnym o działaniu układowym, pobieranym przez liście chwastów. Najskuteczniej zwalcza młode, intensywnie rosnące chwasty od fazy liścieni do fazy rozety, powodując deformacje liści i pędów, po czym pojawia się chloroza i powolne zasychanie tkanek.

Chwasty wrażliwe: chaber bławatek, dymnica pospolita, maruna bezwonna, ostrożeń polny, psianka czarna, rdest plamisty, rumian polny, starzec zwyczajny.

Chwasty odporne: chwastnica jednostronna, fiołek polny, gwiazdnica pospolita, jasnota purpurowa, komosa biała, mak polny, niezapominajka polna, przytulia czepna, rdest kolankowaty, rdest powojowy, rdest ptasi, tasznik pospolity.

STOSOWANIE ŚRODKA

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

Uwaga:

Środka ochrony roślin nie stosować w parkach i ogrodach publicznych, na terenach sportowych, rekreacyjnych, szkół, przedszkoli, żłobków oraz placówek opieki zdrowotnej.

Rzepak ozimy

Środek stosować wiosną w momencie ruszenia wegetacji, jednak nie później, niż do rozpoczęcia tworzenia przez rośliny rzepaku pąków kwiatowych (BBCH 10 - 50).

Maksymalna dawka dla jednorazowego zastosowania: 0,4 l/ha

Zalecana dawka do jednorazowego stosowania: 0,3-0,4 l/ha

Maksymalna liczba zabiegów w sezonie wegetacyjnym – 1 co 2 lata

Zalecana ilość wody: 200-300 l/ha
Zalecane opryskiwanie: średniokropliste.

Pszenvica ozima

Środek stosować wiosną w fazie krzewienia pszenicy (BBCH 21-29).

Maksymalna dawka dla jednorazowego zastosowania: 0,4 l/ha

Zalecana dawka dla jednorazowego stosowania: 0,3-0,4 l/ha

Maksymalna liczba zabiegów w sezonie wegetacyjnym – 1 **co dwa lata**

Zalecana ilość wody: 200-300 l/ha
Zalecane opryskiwanie: średniokropliste.

Burak cukrowy

Środek stosować w fazie rozwoju liści buraka (2 do 4 liści) (BBCH 12-14).

Maksymalna dawka dla jednorazowego zastosowania: 0,3 l/ha

Zalecana dawka do jednorazowego stosowania: 0,3 l/ha

Maksymalna liczba zabiegów w sezonie wegetacyjnym – 1

Zalecana ilość wody: 200-300 l/ha
Zalecane opryskiwanie: średniokropliste.

UWAGI

1. W ochronie rzepaku ozimego i pszenicy ozimej dawkę środka Faworyt 300 SL dostosować do fazy rozwojowej i liczebności chwastów.
2. Niekorzystny dla wegetacji buraków przebieg pogody po opryskiwaniu może spowodować przejściowe zahamowanie wzrostu lub rozjaśnienie liści buraków.

NASTĘPSTWO ROŚLIN

~~Środek rozkłada się w glebie (degradacja mikrobiologiczna) w ciągu okresu wegetacji nie stwarzając zagrożeń dla roślin uprawianych następczo.~~

~~W przypadku konieczności likwidacji plantacji potraktowanej środkiem na tym samym polu można uprawiać rzepak lub inne rośliny, w których zaleca się stosowanie środka.~~

Okres od ostatniego zastosowania środka na rośliny do dnia w którym można siać lub sadzić rośliny uprawiane następczo: ~~nie dotyczy.~~

~~Nie stosować środków zawierających klopuralid na tym samym polu przez 125 dni po zastosowaniu niezależnie od uprawianej rośliny.~~

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

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

Okres od ostatniego zastosowania środka na rośliny przeznaczone na paszę do dnia w którym zwierzęta mogą być karmione tymi roślinami (okres karencji dla pasz): nie dotyczy

1. Strategia zarządzania odpornością

W celu zminimalizowania ryzyka wystąpienia i rozwoju odporności chwastów na herbicydy należy zgodnie z Dobrą Praktyką Rolniczą:

- postępować ściśle zgodnie ze wskazówkami zawartymi w etykiecie środka ochrony roślin stosować środek w zalecanej dawce, w zalecanym terminie zapewniającym optymalne zwalczanie chwastów,
- dostosować dobór środka chwastobójczego oraz decyzji o wykonaniu zabiegu do panującego (ewentualnie potencjalnego) zachwaszczenia, z uwzględnieniem gatunków dominujących i progów szkodliwości,
- stosować rotację herbicydów (substancji czynnych) o różnym mechanizmie działania,
- stosować mieszankę herbicydów (substancji czynnych) o różnym mechanizmie działania,
- stosować w rotacji i/lub mieszaninie herbicydy działające na kilka procesów życiowych chwastów (o różnym mechanizmie działania),
- stosować herbicyd o danym mechanizmie działania tylko 1 raz w ciągu sezonu wegetacyjnego rośliny uprawnej,
- dostosować zabiegi uprawowe do warunków panujących na polu, zwłaszcza do rodzaju i nasilenia chwastów,
- używać różnych metod kontroli zachwaszczenia, w tym zmianowania upraw itp.,
- używać kwalifikowanego materiału siewnego,
- czyścić maszyny rolnicze, aby zapobiec przenoszeniu materiału rozmnożeniowego chwastów na inne stanowiska,
- informować posiadacza zezwolenia o niesatysfakcjonującym zwalczaniu chwastów,
- w celu uzyskania szczegółowych informacji należy się skontaktować z doradcą, posiadaczem zezwolenia lub przedstawicielem posiadacza zezwolenia.

2. Środka nie stosować:

- na plantacjach roślin chorych lub osłabionych przez szkodniki,
- na rośliny mokre,
- w temperaturze powietrza (mierzonej przy gruncie) poniżej 12°C i powyżej 25°C,
- w okresie spodziewanych przymrozków,
- w ilości wody większej niż 300 l/ha,
- podczas wiatru stwarzającego możliwość znoszenia cieczy użytkowej na sąsiednie rośliny uprawne.

3. Podczas stosowania środka nie dopuścić do:

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

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem. Przed otwarciem opakowania wstrząsnąć jego zawartością.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Środek przed użyciem dokładnie wymieszać. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).

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

Sporządzoną w zbiorniku opryskiwacza ciecz użytkową niezwłocznie zużyć.

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

Warunkiem optymalnego działania środka jest równomierne pokrycie chwastów cieczą użytkową.

W przypadku stosowania środka w mieszaninach z innymi środkami przestrzegać ściśle zaleceń dotyczących sporządzania cieczy użytkowej tych środków.

Najlepiej opryskiwać suche rośliny podczas wilgotnej i ciepłej pogody, na co najmniej 6 godzin przed spodziewanym deszczem – zawsze z włączonym mieszadłem.

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.

Uwaga:

Ze względu na bardzo dużą wrażliwość niektórych roślin uprawnych nawet na znikome ilości środka, bardzo ważne jest dokładne wymycie opryskiwacza po zabiegu, zwłaszcza przed użyciem w uprawach innych roślin niż zalecane w etykiecie.

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 (nitrylowe), ochronę oczu i twarzy oraz odzież ochronną i obuwie (np. kalosze) zabezpieczającą przed oddziaływaniem środków ochrony roślin w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

Strefa buforowa: 2-3 m

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.

W celu ochrony wód gruntowych nie stosować w uprawie pszenicy i rzepaku na tym samym polu produktu zawierającego chlopuralid częściej niż co 2 lata w uprawie pszenicy ozimej oraz rzepaku ozimego.

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 niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej w odległości:

- 5 m od terenów nieużytkowanych rolniczo lub,
- 1 m od terenów nieużytkowanych rolniczo z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%.

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.

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 zaleca się zwrócić do sprzedawcy środków ochrony roślin lub można je potraktować jako odpady komunalne. W razie wątpliwości dotyczących postępowania z opakowaniami poradź się sprzedawcy środków ochrony roślin.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

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

Okres ważności - 3 lata

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

Letter of Access from the PROPLAN, Plant Protection Company, S.L has been attached to the Application for the renewal of the authorization of the product Faworyt 300 SL as Appendix No. 20.

Appendix 4 Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1	Al Amin I.	2011	Faworyt 300 SL – Evaluation of appearance Institute of Industrial Organic Chemistry, Poland Report No.: BF-23/11 - 01 GLP Unpublished	N	Y	Period of data protection: 10 years from first registration (first approval data 08.11.2013)	CIECH Sarzyna S.A.
KCP 2.1 KCP 2.4.1 KCP 2.4.2 KCP 2.5.1 KCP 2.5.2 KCP 2.6.1 KCP 2.7.1 KCP 2.7.4 KCP 2.8.2 KCP 2.8.4	Al Amin I.	2019	Faworyt 300 SL – Part I: Determination of physicochemical properties of the initial, after accelerated and low temperature stosage Institute of Industrial Organic Chemistry, Poland Report No.: BF-05/19 GLP Unpublished	N	Y	Data/study report never submitted before	CIECH Sarzyna S.A.
KCP 2.2.1	Parobek B	2021	Statement concerning explosives properties of the plant protection product Faworyt 300 SL CIECH Sarzyna S.A. Non GLP Unpublished	N	N	Data/study report never submitted before	CIECH Sarzyna S.A.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.2.2	Parobek B	2021	Statement concerning oxidising properties of the plant protection product Faworyt 300 SL CIECH Sarzyna S.A. Non GLP Unpublished	N	N	Data/study report never submitted before	CIECH Sarzyna S.A.
KCP 2.3.1	Parobek B	2021	Statement concerning flashpoint of the plant protection product Faworyt 300 SL CIECH Sarzyna S.A. Non GLP Unpublished	N	N	Data/study report never submitted before	CIECH Sarzyna S.A.
KCP 2.3.3	Flasińska, P	2019	Faworyt 300 SL – Determination of auto-ignition temperature Institute of Industrial Organic Chemistry, Poland Report No.: BC-04/19 GLP Unpublished	N	Y	Data/study report never submitted before	CIECH Sarzyna S.A.
KCP 2.4.1 KCP 2.4.2	Al Amin I.	2011	Faworyt 300 SL – Determination of pH Institute of Industrial Organic Chemistry, Poland Report No.: BF-23/11 - 02 GLP Unpublished	N	Y	Period of data protection: 10 years from first registration (first approval data 08.11.2013)	CIECH Sarzyna S.A.
KCP 2.5.2	Lewandowska M	2011	Faworyt 300 SL – Physicochemical properties study. Determination of surface tension Institute of Industrial Organic Chemistry, Poland Report No.: BS-03/11 GLP Unpublished	N	Y	Period of data protection: 10 years from first registration (first approval data 08.11.2013)	CIECH Sarzyna S.A.
KCP 2.6.1	Al Amin I.	2011	Faworyt 300 SL – Determination of Relative Density Institute of Industrial Organic Chemistry, Poland Report No.: BF-23/11 - 03 GLP Unpublished	N	Y	Period of data protection: 10 years from first registration (first approval data 08.11.2013)	CIECH Sarzyna S.A.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.7.1	Palen P.	2011	Test przyspieszonego starzenia środka ochrony roślin Faworyt 300 SL Zakłady Chemiczne "Organika-Sarzyna" S.A., Poland Report No.: TS/7/11 no GLP Unpublished	N	N	-	CIECH Sarzyna S.A.
KCP 2.7.4	Palen P.	2011	Badanie wpływu niskich temperatur na trwałość środka ochrony roślin Faworyt 300 SL Zakłady Chemiczne "Organika-Sarzyna" S.A., Poland Report No.: TS/6/11 no GLP Unpublished	N	N	-	CIECH Sarzyna S.A.
KCP 2.7.5	Palen P	2012	Badanie trwałości środka ochrony roślin Faworyt 300 SL po składowaniu przez 3 lata w temperaturze otoczenia Zakłady Chemiczne "Organika-Sarzyna" S.A., Poland Report No.: TS/3/12 no GLP Unpublished	N	N	-	CIECH Sarzyna S.A.
KCP 2.7.5	Enzo Arevalo	2021	Faworyt 300 SL – Part II: Determination of physicochemical properties after two years of storage Łukasiewicz Research Network - Institute of Industrial Organic Chemistry, Poland Report No.: BF-05/19 GLP Unpublished	N	Y	Data/study report never submitted before	CIECH Sarzyna S.A.
KCP 2.7.5	Enzo Arevalo	2022	Faworyt 300 SL – Part III: Determination of physicochemical properties after three years of storage Łukasiewicz Research Network - Institute of Industrial Organic Chemistry, Poland Report No.: BF-05/19 GLP Unpublished	N	Y	Data/study report never submitted before	CIECH Sarzyna S.A.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.8.2	Filip W	2011	Oznaczenie trwałości piany preparatu Faworyt 300 SL Zakłady Chemiczne "Organika-Sarzyna" S.A., Poland Report No.: HC1/W60/11 no GLP Unpublished	N	N	-	CIECH Sarzyna S.A.
KCP 2.8.4	Filip W	2011	Oznaczenie trwałości roztworu wodnego preparatu Faworyt 300 SL Zakłady Chemiczne "Organika-Sarzyna" S.A., Poland Report No.: HC1/W61/11 no GLP Unpublished	N	N	-	CIECH Sarzyna S.A.
KCP 5.1.1	Gutowska I.	2019	FAWORYT 300 SL Method validation for determination of the active substance content (clopyralid) in the preparation BA-01/19 INSTITUTE OF INDUSTRIAL ORGANIC CHEMISTRY GLP Unpublished	N	Y	Data/study report never submitted before	CIECH Sarzyna S.A.
KCP 5.1.2/01 (KCA 6.5.2-6.5.3/01)	White T. Analytical phase: Sayed S., Hamoum N., Hernandez Ch.	2021	Determination of Residues of Clopyralid after One Application of Major 300 SL (CHR/H/CPD 300SL) in Winter Wheat. One site in Northern France and One Site in Southern France During 2019 S19-01810 Eurofins Agrosience Services Ltd. GLP Unpublished	N	Y	Clopyralid TF - DMT	Proplan, Plant Protection Company SL PUH Chemirol Sp. zo.o
KCP 5.1.2/02 (KCA 6.5.2-6.5.3/02)	White T. Analytical Phase: Sayed S. Souchier M.	2021	Determination of Residues of Clopyralid after One Application of Major 300 SL (CHR/H/CPD 300SL) in Spring Wheat. One site in Northern France During 2020 S20-04397 Eurofins Agrosience Services Ltd. GLP Unpublished	N	Y	Clopyralid TF - DMT	Proplan, Plant Protection Company SL PUH Chemirol Sp. zo.o

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2/01 5.1.2/03	Świstak M.	2019	Validation of analytical method for the determination of test item Faworyt 300 SL in 50% sucrose solution 0016/0051/FA SORBOLAB Research Laboratory LLC GLP Unpublished	N	Y	Data/study report never submitted before	CIECH Sarzyna S.A.
KCP 5.1.2/02 5.1.2/04	Świstak M.	2019	Validation of analytical method for the determination of test item Faworyt 300 SL in media for breeding aquatic organisms and deionized water 0016/0055/FA SORBOLAB Research Laboratory LLC GLP Unpublished	N	Y	Data/study report never submitted before	CIECH Sarzyna S.A.
KCP 5.2/01	Knop M.	2019	Validation of the Multi-Residue Method QuEChERS for the Determination of Clopyralid and X36538 in Different Plant Matrices S19-00446 Eurofins Agrosience Services EcoChem GmbH GLP Unpublished	N	Y	Clopyralid TF - DMT	Proplan, Plant Protection Company, SL PUH Chemirol Sp. zo.o.
KCP 5.2/02	Richer S.	2020	Independent Laboratory Validation of an Analytical Method for the Determination of Clopyralid and X36538 in Different Plant Matrices S19-00438 EAG Laboratories GmbH GLP Unpublished	N	Y	Clopyralid TF - DMT	Proplan, Plant Protection Company, SL PUH Chemirol Sp. zo.o.
KCP 5.2/03	Abe Ch.	2019	Validation of an Analytical Method for the Determination of Clopyralid in Different Matrices of Animal Origin S19-00447 Eurofins Agrosience Services EcoChem GmbH GLP Unpublished	N	Y	Clopyralid TF - DMT	Proplan, Plant Protection Company, SL PUH Chemirol Sp. zo.o.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2/04	Schweizer M.	2019	Independent Laboratory Validation of an Analytical Method for the Determination of Clopyralid in Different Matrices of Animal Origin P 5210 G EAG Laboratories GmbH GLP Unpublished	N	Y	Clopyralid TF - DMT	Proplan, Plant Protection Company, SL PUH Chemirol Sp. zo.o.
KCP 5.2/05	Knop M.	2019	Validation of an Analytical Method for the Determination of Clopyralid in Soil S19-00448 Eurofins Agrosience Services EcoChem GmbH GLP Unpublished	N	Y	Clopyralid TF - DMT	Proplan, Plant Protection Company, SL PUH Chemirol Sp. zo.o.
KCP 5.2/06	Knop M.	2019	Validation of an Analytical Method for the Determination of Clopyralid in Water S19-00449 Eurofins Agrosience Services EcoChem GmbH GLP Unpublished	N	Y	Clopyralid TF - DMT	Proplan, Plant Protection Company, SL PUH Chemirol Sp. zo.o.
KCP 5.2/07	Richter S.	2019	Independent Laboratory Validation of an Analytical Method for the Determination of Clopyralid in Water P 5211 G EAG Laboratories GmbH GLP Unpublished	N	Y	Clopyralid TF - DMT	Proplan, Plant Protection Company, SL PUH Chemirol Sp. zo.o.
KCP 5.2/08	Kirchherr M.	2019	Clopyralid Validation of an Analytical Method for the Determination in Air S19-00451 Eurofins Agrosience Services EcoChem GmbH GLP Unpublished	N	Y	Clopyralid TF - DMT	Proplan, Plant Protection Company, SL PUH Chemirol Sp. zo.o.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2/09	Abe Ch.	2019	Development and Validation of an Analytical Method for the Determination of Clopyralid in Body Fluids S19-00450 Eurofins Agrosience Services EcoChem GmbH GLP Unpublished	N	Y	Clopyralid TF - DMT	Proplan, Plant Protection Company, SL PUH Chemirol Sp. zo.o.
KCA 6.5.1	Hamnett K	2019	Nature of ¹⁴ C-Clopyralid in Processed Commodities – High Temperature Hydrolysis Fera Study Number: FR/001648 Fera GLP Unpublished	N	Y	Data/study report never submitted before	Clopyralid TF
KCA 6.6.1	Rooney P.	2021	[¹⁴ C]-Clopyralid Metabolism in Rotational Crops Fera GLP Unpublished	N	Y	Data/study report never submitted before	Clopyralid TF
KCA 6.5.2-6.5.3/01	White T.	2021	Determination of Residues of Clopyralid after One Application of Major 300 SL (CHR/H/CPD 300SL) in Winter Wheat. One site in Northern France and One Site in Southern France During 2019 S19-01810 GLP Unpublished	N	Y	Data/study report never submitted before	Clopyralid TF
KCA 6.5.2-6.5.3/02	White T.	2021	Determination of Residues of Clopyralid after One Application of Major 300 SL (CHR/H/CPD 300SL) in Spring Wheat. One site in Northern France During 2020 S20-04397 GLP Unpublished	N	Y	Data/study report never submitted before	Clopyralid TF

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.1.1	Xxx	2011a	Faworyt 300 SL – Acute oral toxicity study – fixed dose method on rats xxx, Poland Report No.: PO-5/11 GLP Unpublished	Y	Y	Period of data protection:10 years from first registration (first approval data 08.11.2013)	CIECH Sarzyna S.A.
KCP 7.1.2	Xxx	2011b	Faworyt 300 SL – Acute dermal toxicity study on rats xxx, Poland Report No.: DER-6/11 GLP Unpublished	Y	Y	Period of data protection:10 years from first registration (first approval data 08.11.2013)	CIECH Sarzyna S.A.
KCP 7.1.4	Xxx	2011c	Faworyt 300 SL – Acute skin irritation/corrosion study on rabbits xxx, Poland Report No.: DDR-5/11 GLP Unpublished	Y	Y	Period of data protection:10 years from first registration (first approval data 08.11.2013)	CIECH Sarzyna S.A.
KCP 7.1.5	Xxx	2011d	Faworyt 300 SL – Acute eye irritation/corrosion study on rabbits xxx, Poland Report No.: ODR-7/11 GLP Unpublished	Y	Y	Period of data protection:10 years from first registration (first approval data 08.11.2013)	CIECH Sarzyna S.A.
KCP 7.1.6	Xxx	2011e	Faworyt 300 SL – Skin sensitization study xxx, Poland Report No.: AI-6/11 GLP Unpublished	Y	Y	Period of data protection:10 years from first registration (first approval data 08.11.2013)	CIECH Sarzyna S.A.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 9.2.4	Łożuk I.	2021	Calculation of the predicted environmental concentrations of clopyralid in groundwater after application of Faworyt 300 SL (FOCUS PEARL, FOCUS PELMO, MACRO in FOCUS) CIECH Sarzyna S.A., Poland RR/14/21 non GLP Unpublished	N	N	Data/study report never submitted before	CIECH Sarzyna S.A.
KCP 9.2.5	Siwiec I.	2021	Calculation of the predicted environmental concentrations of clopyralid in surface water after application of Faworyt 300 SL (FOCUS Step 1 and 2) CIECH Sarzyna S.A., Poland RR/15/21 non GLP Unpublished	N	N	Data/study report never submitted before	CIECH Sarzyna S.A.
KCP 10.2.1/01	xxx	2001	Ocena toksycznego działania preparatu Chlopyralid 300 SL na organizmy wodne xxx W/10/01 GLP	Y	Y	Period of data protection: 10 years from first registration (first approval data 08.11.2013)	CIECH Sarzyna S.A.
KCP 10.2.1/02	Woźniak A.	2019	Freshwater alga growth inhibition according to OECD 201 Sorbolab Research Laboratory LLC 0016/0057/E GLP Unpublished	N	Y	Data/study report never submitted before	CIECH Sarzyna S.A.
KCP 10.2.1/02	Kamińska A.	2019	Water-sediment <i>Myriophyllum spicatum</i> toxicity test according to OECD 239 Sorbolab Research Laboratory LLC 0016/0061/E GLP Unpublished	N	Y	Data/study report never submitted before	CIECH Sarzyna S.A.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.2.2	Woźniak A.	2019	Reproduction test of <i>Daphnia magna</i> according to guideline OECD 211 Sorbolab Research Laboratory LLC 0016/0058/E GLP Unpublished	N	Y	Data/study report never submitted before	CIECH Sarzyna S.A.
KCP 10.3.1.1/01	Irzyk M.	2001	Ocena toksycznego działania preparatu Chloryalid 300 SL dla pszczoły miodnej (<i>Apis mellifera L.</i>) Instytut Przemysłu Organicznego Oddział w Pszczynie OSZ-09/01, OSD-10/01 GLP	N	Y	Period of data protection: 10 years from first registration (first approval data 08.11.2013)	CIECH Sarzyna S.A.
KCP 10.3.1.2/01	Orzechowska U.	2019	Honey Bee, Chronic Oral Toxicity Test according to OECD 245 Sorbolab Research Laboratory LLC 0016/0015/E GLP Unpublished	N	Y	Data/study report never submitted before	CIECH Sarzyna S.A.
KCP 10.3.1.3/01	Orzechowska U.	2019	Chronic Toxicity Test for Bee Larvae Sorbolab Research Laboratory LLC 0016/0056/E GLP Unpublished	N	Y	Data/study report never submitted before	CIECH Sarzyna S.A.
KCP 10.3.2.1/01	Moll M.	2019	Faworyt 300 SL: Effects on the Parasitoid <i>Aphidius rhopalosiphi</i> in the Laboratory - Dose Response Test – Ibacon GmbH Study No. 140601001 GLP Unpublished	N	Y	Data/study report never submitted before	CIECH Sarzyna S.A.
KCP 10.3.2.1/02	Moll M.	2019	Faworyt 300 SL: Effects on the Predatory Mite <i>Typhlodromus pyri</i> in the Laboratory - Dose Response Test- Ibacon GmbH Study No. 140601063 GLP Unpublished	N	Y	Data/study report never submitted before	CIECH Sarzyna S.A.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.2.2/01	Moll M.	2019	Faworyt 300 SL: Effects on the Parasitoid <i>Aphidius rhopalosiphi</i> , Extended Laboratory Study - Dose Response Test – Ibacon GmbH Study No. 140601002 GLP Unpublished	N	Y	Data/study report never submitted before	CIECH Sarzyna S.A.
KCP 10.3.2.2/02	Moll M.	2019	Faworyt 300 SL: Effects on the Lacewing <i>Chrysoperla carnea</i> , Extended Laboratory Study - Dose Response Test - Ibacon GmbH Study No. 140601047 GLP Unpublished	N	Y	Data/study report never submitted before	CIECH Sarzyna S.A.
KCP 10.4.1.1	Woźniak A.	2019	Earthworm reproduction test according to OECD 222 SORBOLAB Research Laboratory LLC Study code: 0016/0054/E GLP Unpublished	N	Y	Data/study report never submitted before	CIECH Sarzyna S.A.
KCP 10.4.2.1_01	Straube D.	2019	Faworyt 300 SL: Collembola <i>Folsomia candida</i> in Artificial Soil Ibacon GmbH Study No. 140601016 GLP Unpublished	N	Y	Data/study report never submitted before	CIECH Sarzyna S.A.
KCP 10.4.2.1_02	Straube D.	2019	Faworyt 300 SL: Effects on Reproduction of the Predatory Mite <i>Hypoaspis aculeifer</i> in Artificial Soil Ibacon GmbH Study No. 140601089 GLP Unpublished	N	Y	Data/study report never submitted before	CIECH Sarzyna S.A.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.5	Woźniak A.	2021	Study of impact of test item Faworyt 300 SL on soil micro-organisms - nitrogen transformation test according to guideline OECD 216 SORBOLAB Research Laboratory LLC Study code: 0016/0138/E GLP Unpublished	N	Y	Data/study report never submitted before	CIECH Sarzyna S.A.
KCP 10.6_01	Kamińska A.	2019	Seedling emergence and seedling growth test according to OECD 208 SORBOLAB Research Laboratory LLC Study code: 0016/0059/E GLP Unpublished	N	Y	Data/study report never submitted before	CIECH Sarzyna S.A.
10.6-01a	Woźniak A.	2021	Annex No. 1 to the Final report: Seedling emergence and seedling growth test according to guideline OECD 208 SORBOLAB Research Laboratory LLC Study code: 0016/0059/E GLP Unpublished	N	Y	Data/study report never submitted before	CIECH Sarzyna S.A.
KCP 10.6_02	Kamińska A.	2019	Vegetative Vigour Test according to OECD 227 SORBOLAB Research Laboratory LLC Study code: 0016/0060/E GLP Unpublished	N	Y	Data/study report never submitted before	CIECH Sarzyna S.A.
10.6_02a	Woźniak A.	2021	Annex No. 1 to the Final report: Vegetative Vigour Test according to OECD 227 SORBOLAB Research Laboratory LLC Study code: 0016/0060/E GLP Unpublished	N	Y	Data/study report never submitted before	CIECH Sarzyna S.A.

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

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
KCA 6.1/01	Foster, D.R., Blakeslee, B.A., Rutherford, B.S.	1996	Frozen Storage Stability of Clopyralid, 2,4-D in Corn Grain, Straw and Fodder DAS Study No. RES93050.01 DowElanco, Indianapolis, Indiana, US GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCA 6.1/02	Clements, B, Bolton, A	1996	Determination of the Stability of Clopyralid Residues in Pasture under Frozen Storage Conditions DAS Study No. GHE-P-5350 CEM Analytical Services (CEMAS), North Ascot, Berkshire, UK GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCA 6.1/03	Dial, E., Lindsay, D	2006	Frozen Storage Stability of Clopyralid in Oilseed Rape DAS Study No. 020122.02 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCA 6.1/04	-	2015	Frozen Storage Stability of Clopyralid in Bovine Fat Study No. 120602 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KC 6.1/05	-	2004	Frozen Storage Stability of Clopyralid in Beef Muscle, Liver, Kidney, Milk and Chicken Egg Study No. 020120.01 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCA 6.2.1/01	Chapleo, S. ; Caley, C. Y.	2002	The Metabolism of [14C]-Clopyralid in Sugar Beet DAS Study No. GHE-P-9939 Inveresk Research International, Tranent, East Lothian, United Kingdom GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCA	Chapleo, S.,	2002	The Metabolism of (14C)-Clopyralid in Oilseed Rape	N	DAS

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
6.2.1/02	Caley, C. Y., White, D. E.		DAS Study No. GHE-P 9938 Inveresk Research International, Tranent, East Lothian, UK GLP/GEP (Y/N): Yes Published (Y/N): No		
KCA 6.2.1/03	Guo, C.	1996	Metabolism of ¹⁴ C -Clopyralid in Cabbage DAS Study No. RES95095 DAS Report No. GH-C-4289 ABC Laboratories Inc, Columbia, Missouri, USA GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCA 6.2.2- 6.2.5/01	xxx	1974	The Fate of ¹⁴ C-labelled DOWCO 290 Fed as a Single Oral Dose to Broiler Chicken DAS Report No: GH-C 740 GLP/GEP (Y/N): N Published (Y/N): N	N	DAS
KCA 6.2.2- 6.2.5/02	xxx	1974	Fate of ¹⁴ C-DOWCO 290 in Laying Hens DAS Report No: GH-C 726 GLP/GEP (Y/N): N Published (Y/N): N	N	DAS
KCA 6.2.2- 6.2.5/03	-	2014	A Nature of the Residue Study in the Laying Hen with [¹⁴ C]- Clopyralid Study No. 130906 GLP/GEP (Y/N): Yes Published (Y/N): No	Y	DAS
KCA 6.2.2- 6.2.5/04	-	2015	A Nature of the Residue Study in the Ruminant with [¹⁴ C]Clopyralid Study No. 130202 GLP/GEP (Y/N): Yes Published (Y/N): No	Y	DAS
KCA 6.6.1/01	Yackovich, P. R. ; Lardie, T. S. ; Brink, D. L.	1993	A 10-1/2 Month Rotational Crops Study With ¹⁴ C - Labeled Clopyralid - MET90080 DAS Study No. GH-C 2992 Dow AgroSciences LLC, Indianapolis, Indiana, United States GLP/GEP (Y/N): Yes	N	DAS

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
			Published (Y/N): No		
KCA 6.6.1/02	Yackovich, P.R.; Lardie T.S.; Miller J.H.	1989	A 125-Day Rotational Crops Study with 14C Labelled Clopyralid DAS Study No. GH-C 2277 DowElanco, Midland, Michigan, USA GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCA 6.6.1/03	Hall, L (Y/N): No	2015	14C -Clopyralid: Metabolism in Confined Rotational Crops with a 30-Day Plant-back Interval DAS Study No. 130733 ABC Laboratories, Inc., Columbia, Missouri 65202, USA GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCA 6.3/01	Jones E.M., Yuill M.M	1976	Determination od residues of 3,6-dichloropicolinic Acid (DOWCO 290) in Rape Seed, Oil and Cake from 1975 Trials Carried Out by the Boots Company Limited DAS Report No. GHE-P-325 GLP/GEP (Y/N): No Published (Y/N): No	N	DAS
KCA 6.3/02	Jones E.M., Yuill M.M	1976	Determination od residues of 3,6-dichloropicolinic Acid (DOWCO 290) in Rape Seed, Cake, Oil and Straw from a Trial Carried Out in 1975 in Sweden by BT KEMI DAS Report No. GHE-P-337 GLP/GEP (Y/N): No Published (Y/N): No	N	DAS
KCA 6.3/03	Rawle N.W., Khoshab A.	2002	Residues of Clopyralid in Oilseed Rape at Intervals and at Harvest Following Multiple Applications of Lontrel 100 (EF-1136), EU Northern Zone – 2001 DAS Report No. GHE-P-9380 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCA 6.3/04	Freeman J.M.H, Walker S.S.	1980	Determination od residues of 3,6-dichloropicolinic Acid (DOWCO* 290) in Sugar Beet, Roots and Tops, Treated with FORMAT** - UK 1980 DAS Report No. GHE-P-803	N	DAS

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
			GLP/GEP (Y/N): No Published (Y/N): No		
KCA 6.3/05	Rawle N.W., Khoshab A	2002	Residues of Clopyralid in Sugarbeet at Intervals Under Open Field Conditions Following Multiple Applications of Lontrel 100 (EF-1136), Northern France and UK -2000 DAS Report No. GHE-P-9356 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCA 6.3/06	Rawle N.W., Khoshab A	2002	Residues of Clopyralid in Sugarbeet at Harvest Under Open Field Conditions Following Multiple Applications of Lontrel 100 (EF-1136), Northern France and UK -2000 DAS Report No. GHE-P-9357 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCA 6.3/07	Rawle N.W., Khoshab A	2002	Residues of Clopyralid in Sugarbeet at Intervals and at Harvest Following Multiple Applications of Lontrel 100 (EF-1136), EU Northern Zone -2001 DAS Report No. GHE-P-9381 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCA 6.3/08	Freeman, JHM et al	1982	Effect of Length of Peiod Between Application of Cyronal* and Harvest on Residues of 3,6-dichloropicolinic Acid (DOWO 290**) in Winter Wheat, Winter Barley and Maize- Belgium 1981 DAS Report No. GHE-P-943 GLP/GEP (Y/N): No Published (Y/N): No	N	DAS
KCA 6.3/09	Freeman, JHM	1984	Clopyralid Residues in Wheat Grain and Straw Treated with Either LONPAR* or LONTREL * 100 from French Trials, 1983 DAS Report No. GHE-P-1258 GLP/GEP (Y/N): No Published (Y/N): No	N	DAS
KCA 6.3/10	Rawle N.W., Khoshab A	2002	Residues of Clopyralid in Wheat at Intervals Under Open Field Conditions Following a Single Application of Lontrel 100 (EF-1136), UK and Germany -2000	N	DAS

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
			DAS Report No. GHE-P-9358 GLP/GEP (Y/N): Yes Published (Y/N): No		
KCA 6.3/11	Rawle N.W., Khoshab A	2002	Residues of Clopyralid in Wheat at Intervals Following a Single Application of Lontrel 100 (EF-1136), EU Northern Zone -2001 DAS Report No. GHE-P-9385 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCA 6.3/12	Rawle N.W., Khoshab A	2002	Residues of Clopyralid in Barley at Intervals and at Harvest Following a Single Application of Lontrel 100 (EF-1136), EU Northern Zone -2001 DAS Report No. GHE-P-9383 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCA 6.3/13	Rawle N.W., Khoshab A	2002	Residues of Clopyralid in Barley at Intervals Under Open Field Conditions Following a Single Application of Lontrel 100 (EF-1136), EU Northern Zone -2000 DAS Report No. GHE-P-9360 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCA 6.3/14	Rawle N.W., Khoshab A	2002	Residues of Clopyralid in Barley at Harvest in Open Field Conditions Following a Single Application of Lontrel 100 (EF-1136), EU Northern Zone -2000 DAS Report No. GHE-P-9359 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCA 6.5.1	Adusumilli, H.	2014	Processing Study to Determine the Nature of Residues of 14C -Clopyralid Following the Industrial or Household Preparation DAS Study No. 140574 Dow AgroSciences LLC, Indianapolis, Indiana, USA GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS

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
KCA 6.4.1-6.4.3	-	2015	Summary of Clopyralid Livestock Feeding Study: Magnitude of Residue in Eggs, Muscle, Liver and Fat of Laying Hens Study No. 150031 Lab Study No. 6921 GLP/GEP (Y/N): Yes Published (Y/N): No	Y	DAS
KCA 6.5.2-6.5.3	Device H	2006	Residues of clopyralid in wheat and process fractions at harvest following a single application of EF-1498, Northern France - 2005 DAS Study No. GHE-P-11274 CEM Analytical Services - UK GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS

The following tables are to be completed by MS

List of data submitted by the applicant and not 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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
-	-	-	-	-	-	-	-

List of data relied on and not submitted by the applicant but necessary for evaluation

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
-	-	-	-	-	-	-	-