

FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: PP-113H

Product name: BARILOCHE

Chemical active substance:

Clopyralid 100 g/L (10% w/V) SL

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: PROPLAN Plant Protection Company, S.L.U.

Submission date: December 2021

Correction on: 06/2022

**MS Finalisation date: 08/2022; 04/2023; 06/2023; 11/2023;
01/2024; 02/2024**

Version history

When	What
February 2019	Initial version
December 2021	Version 2, Update for the renewal.
June 2022	Correction of update for the renewal
August 2022	ZRMS Assessment
June 2023	The final version of RR after the commenting period
November 2023	Verification of the Report in accordance with the Polish National Authority's (Ministry of Agriculture and Rural Development) arrangements regarding the assessment of plant protection products containing the active substance clopyralid. Residues and consumer exposure.
January 2024	The final version of RR after 3 rd round of commenting period
February 2024	Verification of the list of data

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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This document describes the acceptable use conditions required for the re-registration of product BARILOCHE (Clopyralid 100 g/L (10% w/V) SL), containing the active substance Clopyralid which was included into Annex I of Directive 91/414 (Commission Directive 2008/69/EC and amended in Directive 2010/39/EU) on 1st of January, 2009.

Commission Implementing Regulation (EU) 2021/1191 of 19 July 2021, amending Implementing Regulation (EU) No. 540/2011 as regards the expiry dates of the approval of certain active substances prolongs the inclusion of Clopyralid until 30 September 2036. This renewal of inclusion of the active substance is justified to enable applicants to prepare their applications and to enable the Commission to evaluate and decide upon such applications.

The product was not the representative formulation.

BARILOCHE, has been previously evaluated in UK as zRMS and is registered via mutual recognition in Czech Republic, Germany, Poland and Romania in sugar beet.

Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
Central zone	zRMS: Poland Product code: PP-113H Product name: Bariloche Registration No: R-26/2018wu	Romania: (Reg No: 466PC) Germany (Reg. No: 008865-00) Czech Republic: (Reg. No: 5583-0) UK (Reg. No. 17577)

This new dossier has been carried out to support the renewal of BARILOCHE (PP-113H) according to Article 43 in the EU central zone.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections B0-B9 and Part C.

The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to PP-113H where that data has not been considered in the EU review. Otherwise assessments for the safe use of PP-113H have been made using endpoints agreed in the EU review of Clopyralid.

All the changes that have been made in this section, with respect to the original dossier, have been highlighted in yellow. It must be taken into account that the format of the dossier has changed.

1.2 Letters of Access

The TF, formed by Proplan, Plant Protection Company SL and PUH Chemirol z.o.o, has submitted to the zRMS Finland the list of information, tests and studies which are considered as relied upon by the RMS for the evaluation with a view to the approval of the active substance, in accordance with Article 60 of Commission Regulation (EU) N° 1107/2009.

1.3 Justification for submission of tests and studies

The list of studies that support this application is included at the end of this section.

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	PP-113H
Product name in MS	BARILOCHE
Authorization number	Romania (Reg. No. 466PC) UK (Re. No. 17577) Poland (Reg. No. R-26/2018wu) Germany (Reg. No. 008865-00) Czech Republic (Reg. No. 5583-0)
Function	Herbicide
Applicant	PROPLAN Plant Protection Company, S.L.
Active substance(s) (incl. content)	Clopyralid 100 g/L
Formulation type	SL (soluble concentrate)
Packaging	250, 500, 1000 and 5000 mL HPDE, professional user
Coformulants of concern for national authorizations	None
Restrictions related to identity	None
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

Physical-chemical properties and analytical methods:

No data gaps.

Efficacy section

In Poland BARILOCHE was registered (Reg. No. R-26/2018wu) in 2018 and now it can be re-registered in the opinion of ZRMs. For DE recommended water volume is 200-400 L/ha

Mammalian toxicology:

Under the experimental conditions, PP-113H (BARICHLORE) is not classified. According to the EFSA model operator, worker, resident and bystander exposure to Clopyralid from vehicle-mounted application outdoor to low crops (sugar beet) is below the AOEL and AAOEL Buffer zone 2-3 m.

Residues:

~~The intended use on sugar beet is not supported by the evaluated plant metabolism studies.~~

November 2023 Verification of the Report in accordance with the Polish National Authority's arrangements, from the meeting regarding the assessment of plant protection products containing the active substance clopyralid (4.10.2023).

Authority's (The Ministry of Agriculture and Rural Development) 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).

Use is **not** accepted.

Ecotoxicology:

The risk assessment for soil microorganism after exposure of ppp Bariloche couldn't be performed by the zRMS-PL. Calculation of soil nitrate-N transformation rate in the effect of Bariloche on the nitrogen transformation in soil study should be provided. After providing complementary information to this study, the study will be reassessed by RMS. The risk assessment for microorganism will be performed after supplementing provided by the Applicant.

Updated – April 2023

In order to answer the requirement from the zRMS a study effects on the nitrogen transformation has been included. The zRMS agrees that FAWORYT 300 SL can be considered as a worse case than BARILOCHE for the ecotoxicology studies. Comparison between formulation has been included in the attached Part C. The new risk assessment based on the study with the product Faworyt 300 SL was accepted by zRMS. The effects on the nitrogen transformations are acceptable (<25%) at concentration which is higher than the maximum relevant PECs for the maximum application rate of **BARILOCHE**. The results indicate no adverse effect on nitrogen transformation even at soil concentrations well higher than the ones expected following application of **BARILOCHE**.

Risk assessment for aquatic plants (*M. spicatum*) has been not performed (insufficient data set - data gap). The new study the product **BARILOCHE** and *M.spicatum* should be performed. In order to answer the requirement from the zRMS a study for *Myriophyllum spicatum* has been included.

Updated – April 2023

The study was carried out with the product Faworyt 300 SL that is considered worse case to **BARILOCHE**. The zRMS agrees that FAWORYT 300 SL can be considered as a worse case than BARILOCHE for the ecotoxicology studies. Comparison between formulation has been included in the attached Part C. The new risk assessment based on the study with the product Faworyt 300 SL was accepted by zRMS. The ratios between predicted environmental concentrations in surface water bodies (PEC_{SW} , PEC_{SED}) and regulatory acceptable concentrations (RAC) for for product **BARILOCHE** and *M.spicatum* based on the worst case for aquatic organisms were <1 indicating acceptable risk to aquatic organism.

The new study to determine a potential phytotoxic effect of the product **BARILOCHE** for non-target plant species in terms of vegetative vigour should be performed including phytotoxicity effect. Risk assessment for non-target plants has been not performed (insufficient data set - data gap).

Updated – April 2023

In order to answer the requirement from the zRMS a study effect on vegetative vigour has been included. The study was carried out with the product Faworyt 300 SL that is considered worse case to Bariloche. The risk based on the corrected $ER_{50} = 4.53 \text{ g s.a./ha}$ (*Mung bean*) from vegetative vigour test and $PER_{off\text{field}}$, not posing an unacceptable risk. The refinement risk assessment is not needed.

The risk following mitigation measures are proposed: BARILOCHE achieve the acceptability criteria $TER \geq 5$ with applying:

- 5 m buffer zone without drift-reducing nozzles
- 1 m and use of 75% drift reducing nozzles

Ecotoxicology: The evaluation of the application for Bariloche 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

There is not substance of concern.

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:	Not classified
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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:	None
Signal word:	None
Hazard statement(s):	None
Precautionary statement(s):	P273, P391, P501, P261, P262, SP1
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use.

	[EUH401]
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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).
SPe1	To protect ground water apply this or any other product contain-ing Clopyralid every two years when the product is applied at BBCH 10-19
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 75% drift reduction to non-agricultural land.

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

	Not required.
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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):

	Result	PPE / Risk mitigation measures
Operators	Acceptable	None Gloves
Workers	Acceptable	None
Bystanders	Acceptable	None
Residents	Acceptable	None

No unacceptable risk for operators, workers, bystanders and residents was identified when the product is used as intended. No specific PPE is necessary

2.5.2 Specific restrictions linked to the intended uses

Not required.

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code): Bariloche/ PP-113H
Active substance 1: Clopyralid
Applicant: PROPLAN Plant Protection Company, S.L.
Zone(s): Central zone ^(d)
Verified by MS: -
Field of use: herbicide

Formulation type: SL ^(a, b)
Conc. of as 1: 100 g/L ^(c)
Professional use: ☒
Non professional use: ☐

GAP rev.1, date: 01-12-2021

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop desti- nation / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmen- tal stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks:
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	Central zone (CZ, GE, PL, RO)	Sugar beet	F	CIRAR and COMPOSITAE	Tractor boom sprayer	BBCH 10-39	1	1.2	0.12	80 - 400		Do not use between the 31 st August and 1 st March To protect ground water apply this or any other product contain- ing Clopyralid every two years when the product is applied at BBCH 10- 19 Metabolism and Residues: Not Use is accepted Eff. section: For DE recom- mended water volume is 200-400 L/ha

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.

3 Background of authorization decision and risk management

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

Overall Summary: PP-113H was not the representative formulation for the inclusion of the active substance into Annex I of Directive 91/414/EEC. The product is a Soluble Concentrate formulation (SL). All studies have been performed in accordance with the current requirements, the critical GAP and the results are deemed to be acceptable.

The appearance of the product is that of faint yellow liquid, with a characteristic odour. It is not explosive, has no oxidising properties. It has a self-ignition temperature of 475.6 ± 9.5 °C at 755.2 mmHg. In aqueous solution, it has a pH value around 6.4. The stability data indicate a shelf life of at least 2 years at ambient temperature. Its technical characteristics are acceptable for a SL formulation.

Implications for labelling: None.

Compliance with FAO guidelines:

At the time of evaluation, there is no FAO specification for clopyralid.

Compatibility of mixtures: The product is used alone.

Nature and characteristics of the packaging: Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

Nature and characteristics of the protective clothing and equipment: Information regarding the required protective clothing and equipment for the safe handling of PP-113H has been provided and is considered to be acceptable.

3.2 Efficacy (Part B, Section 3)

3.3 Efficacy data

There is no change from the original dossier. Plant protection products based on clopyralid are known and used for many years. In Poland many herbicides with clopyralid are registered and used to control weeds in crops. BARILOCHE was submitted and positively evaluated during the authorization process of this product (Reg. No. R-26/2018wu). This report has been discontinued to re-registration of this product.

As stated in the draft registration report, the GAP has not been changed compared to current registration. Therefore, in intended uses, there has been no GAP change that impacts the previous efficacy evaluation of BARILOCHE 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.

This is an Article 43 application (of Reg. (EC) 1107/2009) and as such only specific new data in order to comply with changes in the assessment of the active substance (new endpoints, new guidance applied, conditions or re-strictions in the renewal regulation) can be considered (SANCO/2010/13170 rev 13).

All necessary information's were provided above by Applicant. This document summarises the information

related to the efficacy of the plant protection product – PP-113H (BARILOCHE). The data presented in this dossier fully support the renewal under Article 43 of BARILOCHE for the control of weeds in sugar beet in Poland. The formulation of this product is a soluble concentrate (SL) and it is containing one active substance: clopyralid (100 g/l). For now, this active compound is on the list of approved active substances. All needed information's are presented by Applicant in core dossier.

Summary: In Poland (ZRMs) BARILOCHE was registered (Reg. No. R-26/2018wu) in 2018 and now it can be re-registered. In our opinion each cMS should decide if presented documentation is sufficient for re-registered BARILOCHE.

For Germany - the present application is a renewal according to the Article 43 of EU Regulation 1107/2009. The GAP has not been changed and the proposed uses are nearly identical to the previous authorised uses in Germany. The assessment is still valid. ~~In this case, it means that the approval from Poland was taken over.~~

The water volume application rate in the GAP table for Germany should be adjusted to the currently applied and previously authorised rate of 200-400 L/ha.

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

To date no reports of resistance to clopyralid in target weeds has been received in over 25 years of use. Although resistance has been recorded within the herbicide group “synthetic auxins” to which clopyralid belongs, e.g., resistance to MCPA in *Cirsium arvensis* in Sweden, no cross resistance to clopyralid has been recorded. In addition, in New Zealand where *Carduus nutans* was found to be resistant to 2,4D, the addition of clopyralid gave complete control.

It is considered unlikely that resistance will occur as the product is generally used infrequently in rotational crops such as sugar beet and oil seed rape and in perennial crops (e.g., grass) thus the selection pressure for resistance is low. In addition, in many countries clopyralid is sold commercially in mixtures, e.g. in mixture with triclopyr or in mixture with triclopyr and fluroxypyr, further reducing the selection pressure for resistance. (DAR Clopyralid 2005. Annex B1-B5. Point B.3.1.6).

Clopyralid belongs to the pyridine carboxylic acids group. Applied post-emergence, clopyralid is effective on a broad spectrum of broad-leaved weeds.

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.

Clopyralid is rapidly degraded in soil ($DT_{50} = 34$ days) thus a prolonged exposure to weed populations does not occur which is a factor which decreases the resistance risk.

The risk of resistance was analysed following the EPPO-Standard (2003), the classification of the Herbicide Resistance Action Committee (HRAC) and the international Survey of Herbicide Resistant Weeds (Heap, 2016).

The probability of development of resistance or cross-resistance of weeds to BARILOCHE is considered as low **to moderate**. The evaluation of the agronomic risk concludes that BARILOCHE bears a low **to moderate** risk of resistance.

Plant protection products containing clopyralid are used from many years and no information's concerning weed resistance for this active substance was noted. However, the information on possible development of

resistance or cross-resistance is provided by scientific literature from many different countries and describes different weed species. Product should be used in rates neither lower nor higher than recommended in the label due to prevent resistance development.

According to weedsience.org, 24 cases of resistance were reported.

#	Year	Species	Country	MOAs	Actives	Situations
1	2013	<i>Centaurea stoebe ssp. micranthos</i>	Canada (British Columbia)	Auxin Mimics HRAC Group 4 (Legacy O)	clopyralid, picloram	Rangeland
2	1999	<i>Soliva sessilis</i>	New Zealand	Auxin Mimics HRAC Group 4 (Legacy O)	clopyralid, picloram, triclopyr	Golf courses, Turf
3	2005	<i>Chenopodium album</i>	New Zealand	Auxin Mimics HRAC Group 4 (Legacy O)	dicamba, clopyralid, aminopyralid	Corn (maize)
4	2022	<i>Ambrosia artemisiifolia</i>	United States (Michigan)	Auxin Mimics HRAC Group 4 (Legacy O)	clopyralid	Christmas Trees

Lack of resistance cases for Europe for clopyralid, only one case from Canada (2013), one case from USA (2022) and two cases from New Zealand (1999, 2005) have been already reported.

However, due to September 2022 January 2024, 44 cases of resistance to HRAC group 4 herbicides are reported on weedsience.org. Resistance cases for *Centaurea cyanus* (Dicamba, Poland), *Cirsium arvense* (MCPA, Sweden; 2,4-D and MCPA, Hungary), *Papaver rhoeas* [2,4-D, Spain, Italy (2 cases), Greece; 2,4-D and aminopyralid, France (2 cases)] and *Stellaria media* (mecoprop, UK) are reported from Europe. These cases show that cross-resistances within HRAC group 4 are possible. In addition, HRAC group 4 actives including clopyralid are increasingly applied in cereal crops in Europe. Sugar beet is rotated with cereal crops. Accordingly, consecutive applications of HRAC group 4 herbicides are likely to happen, increasing the selection pressure. In line with this, DE rates the resistance risk for the herbicide Bariloche moderate. ZRMs agree with this opinion. So, in general Bariloche should be characterized as moderate risk of resistance.

Weeds Resistant to Auxin Mimics (O/4) by species and country

#	Species	Country	First Year
1	<i>Amaranthus hybridus</i> (syn: <i>guttosus</i>) Smooth Pigweed	2016 - Argentina 2016 - Argentina	2016
2	<i>Amaranthus palmeri</i> Palmer Amaranth	2015 - United States (Kansas) 2018 - United States (Kansas) 2020 - United States (Tennessee)	2015
3	<i>Amaranthus powellii</i> Powell Amaranth	2019 - Canada (Ontario)	2019
4	<i>Amaranthus tuberculatus</i> (= <i>A. rudis</i>) Tall Waterhemp	2009 - United States (Nebraska) 2016 - United States (Illinois) 2021 - United States (Iowa)	2009
5	<i>Ambrosia artemisiifolia</i> Common Ragweed	2022 - United States (Michigan)	2022
6	<i>Arctotheca calendula</i> Capeweed	2015 - Australia (South Australia)	2015
7	<i>Brassica rapa</i> (= <i>B. campestris</i>) Birdsrape Mustard	2015 - Argentina	2015
8	<i>Carduus acanthoides</i> Plumeless Thistle	2019 - Argentina	2019
9	<i>Carduus nutans</i> Musk Thistle	1981 - New Zealand	1981
10	<i>Carduus pycnocephalus</i> Italian Thistle	1997 - New Zealand	1997
11	<i>Centaurea cyanus</i> Cornflower	2012 - Poland	2012

#	Species	Country	First Year
12	<i>Centaurea solstitialis</i> Yellow Starthistle	1988 - United States (Washington)	1988
13	<i>Centaurea stoebe</i> ssp. <i>micrantha</i> Spotted knapweed	2013 - Canada (British Columbia)	2013
14	<i>Chenopodium album</i> Common Lambsquarters	2005 - New Zealand	2005
15	<i>Cirsium arvense</i> Canada thistle	1979 - Sweden 1985 - Hungary	1979
16	<i>Commelina diffusa</i> Spreading Dayflower	1957 - United States (Hawaii)	1957
17	<i>Conyza sumatrensis</i> Sumatran Fleabane	2017 - Brazil	2017
18	<i>Daucus carota</i> Wild Carrot	1957 - Canada (Ontario) 1993 - United States (Michigan) 1994 - United States (Ohio)	1957
19	<i>Descurainia sophia</i> Flixweed	2011 - China	2011
20	<i>Digitaria ischaemum</i> Smooth Crabgrass	2002 - United States (California)	2002
21	<i>Echinochloa colona</i> Junglerice	2000 - Colombia	2000
22	<i>Echinochloa crus-galli</i> var. <i>crus-galli</i> Barnyardgrass	1998 - United States (Louisiana) 1999 - Brazil 1999 - United States (Arkansas) 2000 - China 2009 - Brazil 2013 - Uruguay 2018 - Brazil	1998
23	<i>Echinochloa crus-galli</i> var. <i>zizanioides</i> Gulf Cockspur Grass	2013 - China	2013
24	<i>Echinochloa crus-galli</i> var. <i>parviflora</i> Gulf Cockspur	1999 - Brazil	1999
25	<i>Fimbristylis miliacea</i> Globe Fringerush	1989 - Malaysia	1989
26	<i>Galeopsis tetrahyt</i> Common Hempnettle	1998 - Canada (Alberta)	1998
27	<i>Galium aparine</i> Catchweed Bedstraw	2014 - China 2016 - Iran 2017 - Iran	2014
28	<i>Galium spurium</i> False Cleavers	1996 - Canada (Alberta)	1996
29	<i>Hirschfeldia incana</i> Shortpod Mustard	2016 - Argentina	2016
30	<i>Kochia scoparia</i> Kochia	1994 - United States (Montana) 1995 - United States (North Dakota) 1997 - United States (Idaho) 1999 - United States (Colorado) 2009 - United States (Nebraska) 2013 - United States (Kansas) 2013 - United States (Kansas) 2015 - Canada (Saskatchewan) 2017 - Canada (Alberta)	1994
31	<i>Lactuca serriola</i> Prickly Lettuce	2007 - United States (Washington)	2007
32	<i>Limnorchis flava</i>	1995 - Indonesia	1995

#	Species	Country	First Year
	Sawah Flowering Rush	1998 - Malaysia	
33	<i>Limnophila erecta</i> Marshweed	2002 - Malaysia	2002
34	<i>Papaver rhoeas</i> Corn Poppy	1993 - Spain 1998 - Italy 1998 - Italy 2002 - Greece 2015 - France 2016 - France	1993
35	<i>Plantago lanceolata</i> Buckhorn Plantain	2016 - United States (Indiana)	2016
36	<i>Ranunculus acris</i> Tall Buttercup	1988 - New Zealand 2010 - New Zealand	1988
37	<i>Raphanus raphanistrum</i> Wild Radish	1999 - Australia (Western Australia) 2006 - Australia (South Australia) 2009 - Australia (Victoria) 2010 - Australia (Western Australia) 2011 - Australia (Victoria) 2013 - Australia (New South Wales) 2015 - Australia (Western Australia) 2020 - Australia (Western Australia)	1999
38	<i>Sagittaria montevidensis</i> California Arrowhead	2023 - Brazil	2023
39	<i>Sinapis arvensis</i> Wild Mustard	1990 - Canada (Manitoba) 2008 - Turkey	1990
40	<i>Sisymbrium orientale</i> Oriental Mustard	2005 - Australia (South Australia)	2005
41	<i>Solidia sexalis</i> Lawn Burweed	1999 - New Zealand	1999
42	<i>Sonchus oleraceus</i> Annual Sowthistle	2015 - Australia (South Australia) 2015 - Australia (Victoria)	2015
43	<i>Sphenoclea zeylanica</i> Gooseweed	1983 - Philippines 1995 - Malaysia 2000 - Thailand	1983
44	<i>Stellaria media</i> Common Chickweed	1985 - United Kingdom 2010 - China	1985

Since no resistance to clopyralid has developed in Europe, there is no demonstrated cross-resistant to other group 4 herbicides and that synthetic auxins have a multi-site mode of action the risk of practical resistance in unrestricted use is very low and the unmodified risk is acceptable. In view of the acceptable risk of unrestricted use no resistance management strategy is deemed necessary. In a crop rotation, herbicides belonging to HRAC group 4 can be applied in various crops and the agronomic practices may differ in the member states. To avoid inherent risk in group 4 herbicides the agronomic risk should be evaluated at member state level.

To avoid resistance, it is important to have a reasonable crop rotation and respect the label recommended application rates and doses. The risk of resistance to clopyralid is believed to be low for the following reasons:

- to minimize the risk of occurrence and development of weed resistance to herbicides, follow Good Agricultural Practice;
- follow strictly the directions on the label of the plant protection product use the product at the recommended dose, at the recommended time to ensure optimal weed control,
- adjust the choice of herbicide and the decision to carry out the treatment to the prevailing (possibly

- potential) weed infestation, taking into account the dominant species and damage thresholds,
- use a rotation of herbicides (active substances) with different mechanisms of action,
 - use a mixture of herbicides (active substances) with different mechanism of action,
 - use in rotation and/or mixture herbicides acting on several life processes of weeds (with different mechanism of action),
 - use an herbicide with a given mechanism of action only once during the growing season of the crop,
 - inform the permit holder of unsatisfactory weed control,
 - contact your advisor, the permit holder or the permit holder's representative for more information.

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 few cases have been reported, the risk for the development of clopyralid resistant weed biotypes in major crop production and vegetable production areas is considered low as moderate.

3.3.2 Adverse effects on treated crops

There is no change from the original dossier.

3.3.3 Observations on other undesirable or unintended side-effects

There is no change from the original dossier.

3.4 Methods of analysis (Part B, Section 5)

Analytical methods have been developed for the analysis of the active ingredient in the formulation and in water samples from aquatic ecotoxicological studies for the analysis of Clopyralid in all the crops requested in the GAP. All the analytical methods have been adequately validated, according to the existing guidelines.

3.4.1 Analytical method for the formulation

No new studies have been conducted. Please refer to the core dossier.

An analytical method has been developed for the determination of the active substance, Clopyralid, in PP-113H.

The following analytical method for the determination of the active substance in the plant protection product performed on PP-113H has not previously been reviewed and is provided in support of this assessment.

Report:	KCP 5.1.1-01: Pardo, M., 2011.
Title:	PP 113H (Clopyralid 10 % w/v SL): Validation of the analytical method for the determination of the active ingredient content
Document No:	CH 397/2011
Guidelines:	EEC: SANCO/3030/99 rev 4.
GLP	Yes

Specificity:

The specificity test was conducted injecting, in the adjusted chromatographic conditions, a solvent wash, Clopyralid reference material, Ethyl paraben internal standard, Placebo solution and test item solution and comparing the chromatograms in order to check possible cross contaminations.

Linearity and System Precision:

Linear regression analysis was performed using the least squares method.
The correlation coefficient was calculated using regression analysis.

Repeatability (Precision):

Six solutions of the test item (labelled from A to F) were prepared and injected as described in Internal Analytical Method No. 397/2011.

These injections were alternated with those of the Standard 1 and 2 according to the sequence of analysis reported in Table 6.

Precision (repeatability) of the analytical method was assessed with the obtained data.

Recovery (Accuracy):

The test was performed by spiking six aliquots of the Placebo (2905180 005) with the Clopyralid reference material at three levels in duplicate, corresponding to additions of 75 %, 100 % and 125 % of the nominal concentration of active ingredient.

Validation results:

Linearity:	$Y = 326321x - 233983$; $R^2 = 0.999948$ Linear range : 15.28 — 35.65 µg/mL
Accuracy:	99.26 — 99.90 %
Repeatability:	CV = 0.41 %; RSD = 1.91 %
Specificity:	No interfering peaks were observed

3.4.2 Analytical methods for residues

Minor data gaps:

- extraction efficiency (for plant and animal matrices). Not provided during the EU review.
- method for body fluids with the required LOQ of 0.01 mg/L set in SANTE/2020/12830 rev.1.
(minor data gaps are to be completed after registration)

Commodity/crop	Supported/ Not supported
Sugar beet	Supported

3.5 Mammalian toxicology (Part B, Section 6)

Acute toxicity studies for PP-113H were not evaluated as part of the EU review of the Clopyralid. Therefore, all relevant data were provided and are considered adequate.

3.5.1 Acute toxicity

The following tests were performed on PP-113H: acute LD₅₀ oral (rat), acute LD₅₀ dermal (rat), acute LC₅₀ inhalation (rat), skin irritation (rabbit), eye irritation (rabbit) and sensitization of the skin [maximisation test (guinea pig)]. The results are summarised in the following table.

Summary of Acute toxicological data obtained with PP-113H

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat (OECD 423)	LD ₅₀ = 2.500 mg/kg bw	Yes	None	xxx 2013 (401-1-01-5762)
LD ₅₀ dermal, rat (OECD 402)	LD ₅₀ > 2.000 mg/kg bw	Yes	None	xxx 2013 (403-1-01-5763)
LC ₅₀ inhalation, rat (OECD 403)	LC ₅₀ > 6.039 mg/L air	Yes	None	xxx 2013 (405-1-01-5764)
Skin irritation, rabbit (OECD 404)	Non- irritant	Yes	None	xxx 2013 (406-1-01-5765)
Eye irritation, rabbit (OECD 405)	Not irritating to eyes	Yes	None	xxx 2013 (IO-OCDE-PH-13/0217)
Skin sensitisation, mouse (OECD 442-B, LLNA: BrdU)	Non-irritant	Yes	None	xxx 2013 (408-1-01-5767)
Supplementary studies for combinations of plant protection products	Not required	Yes	None	

3.5.2 Operator exposure

The Plant Protection Product PP-113H containing 100 g/L of Clopyralid is intended to be used on sugar beet as an herbicide.

Operator exposure to PP-113H was not evaluated as part of the EU review of Clopyralid. Therefore, all relevant data and risk assessments are provided here and are considered adequate

Detailed calculations are in **Błąd! Nie można odnaleźć źródła odwołania.** (of section B6).

Operator exposure to PP-113H is estimated according to the AOEM model using the calculator provided in the EFSA guidance (2014) with the level of the 75th percentile.

End-points	Clopyralid	
	EU agreed endpoints (EFSA Journal 2018)	Endpoints used in risk assessment*
Dermal absorption	Concentrate: 25% Spray dilutions: 75%	Concentrate: 10% Spray dilutions: 50%
AOEL	0.15 mg/kg bw/day	0.15 mg/kg bw/day
AAOEL	0.17 mg/kg bw/day	0.17 mg/kg bw/day

* Guidance on Dermal Absorption (EFSA Journal 2017).

Estimated operator exposure

Model data	Level of PPE	Clopyralid			
		Long term		Acute	
		Total absorbed dose (mg/kg bw/day)	% of AOEL (0.15 mg/kg bw/day)	Total absorbed dose (mg/kg bw/day)	% of AA-OEL (0.17 mg/kg bw/day)
Tractor-mounted, downward spraying application to cereals, outdoors					
EFSA model	50 ha/d				
	No PPE (potential exposure)	0.0676796	45.12	0.0091281	6.09
Chemical protective gloves during mixing and loading + Work wear – arms, body and legs covered – during mixing/loading and application	0.4275771	251.52	0.0811906	47.76	

According to the model calculations, it can be concluded that the acute risk for the operator using the PP-113H product with the tractor mounted is acceptable with the use of gloves during mixing / loading and with workwear (covered arms, body and legs) during mixing, loading and application (AA-OEL wynosi 47.76%).

Long term risk for the operator using the PP-113H product with the tractor mounted is acceptable even without PPE (AOEL wynosi 45.12%)

3.5.3 Worker exposure

Estimated worker exposure

Crop	TC (cm ² /h)	Duration exposure (hours)	N° Applic. (interval days)	Clopyralid
				Total systemic exposure (mg/kg bw/d) % AOEL (0.15 mg/kg bw/day)
Root and tuber vegetables (Sugar beet)	12.500 (potential exposure)	2	1	52.08
	1.400 (arms, body and legs covered)	2	1	5.83

Conclusion: The worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mention PPE It is concluded that there is no risk for workers re-entering sugar beet' fields for inspection and harvesting activities after application of PP-113H

3.5.4 Bystander and resident exposure

Estimated resident exposure

1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0209828	0.0010700	0.0010115	0.0105469	0.0217778
% of RVNAS	13.99%	0.71%	0.67%	7.03%	14.52%
Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0050208	0.0002300	0.0004258	0.0058594	0.0075989
% of RVNAS	3.35%	0.15%	0.28%	3.91%	5.07%

Estimated bystander exposure

1-3 year old child				
	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0475813	0.0010700	0.0030281	0.0105469
% of RVNAS	27.99%	0.63%	1.78%	6.20%
Adult				
	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0129323	0.0002300	0.0012839	0.0058594
% of RVNAS	7.61%	0.14%	0.76%	3.45%

Conclusion:

According EFSA model, resident and bystander exposure to Clopyralid from vehicle-mounted application outdoor to low crops (sugar beet) is below the combined AOEL. Buffer zone 2-3 m.

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

3.6.1 Residues

The intended use on sugar beet is not supported by the evaluated plant metabolism studies. November 2023 Verification of the Report in accordance with the Polish National Authority's (Ministry of Agriculture and Rural Development) arrangements, from the meeting regarding the assessment of plant protection products containing the active substance clopyralid.

3.6.2 Consumer exposure

~~The intended use on sugar beet is not supported by the evaluated plant metabolism studies.~~

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).

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)

10 months in olive (fruit and oil) (high oil content matrix)

10 months in orange / orange peel (high acid 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)

Magnitude of residues in plants

Sugar beet

Proposed use: 1 application, BBCH 12-14 (Spring) 10-39, 120 g as/ha, PHI: not required

Applicant refers to unprotected EU data:

Trials GAP (sugar beets): 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 mg/kg

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

Livestock feeding studies, Magnitude of residues in processed commodities, Rotational study

No new data were submitted in the framework of this application.

New Dietary Burden calculations were performed by the zRMS, taking into account STMR and HR values from residues trials (only proposed use). These data fall within the data used for the calculations presented in EFSA Journal 2021;19(1):6389. Calculations were presented below in Animal model 2017. No additional calculation is needed.

Magnitude of residues in representative succeeding crops

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

A study to determine the residues of Clopyralid in honey has been submitted. The objective of the study was to determine residues of clopyralid, its salts and conjugates (expressed as clopyralid) in honey from *Phacelia tanacetifolia* after one application of PP-113H (Clopyralid 100 g/L SL) under semi-field conditions.

The study is acceptable.

Current MRL for clopyralid in honey is 0.05 mg/kg, and according to the provided study on magnitude of residues in honey, the MRL is potentially exceeded when Bariloche is applied to melliferous plants. Until the new MRL has been set for honey, use on melliferous target crops during flowering cannot be authorized.

As sugar beet is not melliferous plants according to SANTE/11956/2016 rev. 9, proposed use is accepted.

Estimation of exposure through diet and other means

The proposed uses of clopyralid in the formulation PP-113H do not represent unacceptable acute and chronic risks for the consumer.

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

No new studies are presented; all data were reviewed in the EU review Clopyralid. Appropriate endpoints from the EU review were used to calculate PECs for PP-113H and Clopyralid in soil, surface water, ground water and air for the intended use patterns.

No major soil metabolites of clopyralid were found.

The PEC(s,gw,sw) were modelled for 0.125kg a.s./ha. Submitted calculations were accepted by zRMS and cover proposed use in GAP.

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

The PEC of PP-113H and Clopyralid in soil has been assessed with the FOCUS model and the focus groundwater interception values and the DT₅₀ values established in the EU review.

The PEC_{soil} value has been calculated for multiple applications with different doses for different timings. To calculate the PEC_{soil} values was used the Excel spreadsheet 'multiple application pec calculator.xls' proposed by CRD. Based on the recommended use rate 0.125 kg a.s./ha as/ha, the maximum initial predicted environmental concentration in soil (PECs) of Clopyralid was 0,1333 mg/kg.

Furthermore, the PECs for rate 0,120 kg a.s./ha was calculated by zRMS. The PECs of clopyralid was 0.1280 mg/kg and 1.345 g/kg for formulation.

The results for PEC soil for the active substance and its metabolites were used for the eco-toxicological risk

assessment.

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

Annual and biennial application scenarios at a rate of 125 g a.s./ha not later than BBCH19 were simulated, according to the recommended use pattern.

Annual application scenarios at a rate of 125 g a.s./ha later than BBCH19 were simulated, according to the recommended use pattern.

PEC_{gw} modelling for clopyralid was performed using the EU agreed endpoints from the EFSA Conclusion for clopyralid (EFSA Journal 2018; 16(7):5389). Modelling was first performed using the agreed endpoints for sorption, which is the geometric mean K_{FOC} value of 1.41 mL/g and mean 1/n of 0.836. The modelling was repeated for corrected sorption endpoints.

EFSA derived the mean values after rejecting part the data that did not comply with the reliability criteria from the OECD 106 guideline. However, they rejected the 1/n values, but not the K_{foc} values, which is not in line with the guideline. New sorption endpoints were derived here using the correct procedure from the OECD 106 guideline. The modelling was repeated using the corrected sorption parameters.

Corrected sorption endpoints for clopyralid

According to the OECD 106 test guideline (point 71), accurate determination of the Freundlich isotherm is possible if the K_d multiplied with the soil/solution rate is > 0.3 (indirect method) or > 0.1 (direct method). When failing this criterion, no Freundlich parameters should be derived (K_{F,OC} and 1/n).

EFSA rejected the first four soils (K_d < 0.3, indirect method), and for the Longwoods and LUFA 2.1 soils (K_d < 0.1, direct method). EFSA rejected the sorption exponent 1/n for these six soils, but failed to reject the corresponding K_{F,OC} measurements. In our opinion it is incorrect to use the K_{F,OC} values from nonlinear fits in combination with the default 1/n value. The small K_{F,OC} values derived from nonlinear fits would underestimate the amount of sorption. Also, it is not in line with the OECD 106 guideline, which states that no K_{F,OC} values should be derived for these soils.

The more recent EFSA report on the OECD 106 checklist (EFSA, 2017¹; p.9-10) clarifies that the “estimate of sorption can be derived from the geometric mean of the individual distribution coefficient (K_d) values at each tested concentration... The organic carbon normalised adsorption coefficient (K_{oc}) for each soil should be derived from the geometric mean K_d. These K_{oc} values should be combined with a default 1/n value of 0.9 for inclusion in the regulatory database.” Note that this refers to the K_{d,oc}. So according to the EFSA report, one would use the K_{d,oc} in combination with the default 1/n value, not the (rejected) Freundlich K_{foc} values.

Selecting the K_{d,oc} instead of the K_{foc} for the soils for which EFSA rejected the Freundlich exponent. The K_{d,oc} was calculated from the K_d (K_d x 100/OC) and used in combination with the default 1/n of 0.9². The new geometric mean K_{oc} from combining the K_{d,oc} and K_{foc} values is 3.18 mL/g (n=9).

Calculations were carried out according to FOCUS (2000, 2009, 2012) using the FOCUS groundwater scenarios and the current version of FOCUS PEARL (version 4.4.4) and FOCUS PELMO (version 5.5.3). After simulations with FOCUS PEARL and FOCUS PELMO it can be concluded that clopyralid is not likely to pose an unacceptable risk to shallow groundwater if the active substance clopyralid is used in compliance with label recommendations.

¹ EFSA, 2017. Technical report on the outcome of the pesticides peer review meeting on the OECD 106 evaluators checklist. EFSA supporting publication 2017:EN-1326. 17 pp.

² The default 1/n value of 0.9 is acceptable when the K_{oc} value is derived from on a range of test concentrations. When derived from a single concentration, then according to the latest EFSA guidance, the default 1/n value is 1.

For sugar beet a BBCH 10-29 application, all calculated PEC_{gw} values were less than 0.1 µg/L in all scenarios using both models when the product is used an application every two years.
For BBCH 20-39 application all calculated PEC_{gw} values were less than 0.1 µg/L in all scenarios using both models.

PEC_{gw} calculations were performed with the FOCUS scenarios relevant for Poland Châteaudun, Hamburg, Kremsmünster, using the FOCUS PELMO (5.5.3) and FOCUS PEARL models.
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:
SPe1 To protect ground water apply this or any other product containing Clopyralid every two years when the product is applied at BBCH 10-29-19.

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

The PEC of Clopyralid in surface water (PEC_{sw} and PEC_{sed}) have been assessed with the FOCUS STEPS and the DT₅₀ water/sediment values established in the EU review or agreed in the assessment based on new data provided. Based on the recommended use rate of 0.125 kg a.s/ha.
The maximum PEC values for surface water and sediment have been calculated according to FOCUS for the parent Clopyralid.
Clopyralid poses an acceptable risk at STEPS 1&2. The formulation did not show an unacceptable risk..

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

The vapour pressure at 20 °C of the active substance clopyralid is $> 10^{-4}$ Pa. Hence the active substance is regarded as volatile (volatilisation from soil and plant surfaces). Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance clopyralid due to volatilization with subsequent deposition should be considered.

According to FOCUS Air guidance [SANCO/10553/2006 Rev 2 June 2008], deposition onto adjacent surface waters and terrestrial ecosystems due to volatilisation is small in comparison to spray drift. Hence, deposition from volatilisation only needs to be considered if spray drift mitigations are considered in the risk assessment. No drift mitigations were required for clopyralid for the proposed use of PP-113H.

The photochemical oxidative degradation in air for clopyralid is slow, with a calculated half-life of 19.5 days (Atkinson method, AOPWIN v1.90. However, the risk for long-range aerial transport of clopyralid was assessed as minimal in the first EU evaluation of clopyralid in 2005 (EFSA Scientific Report (2005) 50, 1–65) based on the low vapour pressure, Henry's law constant and experimental data on volatilization from plants and soil. During the renewal (Draft Renewal Assessment Report, RMS Finland, March 2018), the data on the fate and behaviour of clopyralid in air was considered still valid and acceptable, and no further studies were required to support the renewal for the approval of clopyralid.

Implications for labelling resulting from environmental fate assessment: None..

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

Birds

Clopyralid passed at the screening stage for both dietary and reproductive assessments. The Log Pow of Clopyralid are both below 3, thus the risks from secondary poisoning to birds does not require assessment.

No specific calculations of exposure for birds through drinking water for the puddle scenario were necessary.

Safe use of clopyralid for birds were confirmed based on TER_A and TER_{LT} above the trigger values of 10 and 5, respectively. Based on the intended use on for **BARILOCHE** no unacceptable risk for birds is expected from acute or long-term exposure. The risk assessment was calculated for 125 g/ha were accepted as worst case.

Terrestrial vertebrates (other than birds)

Clopyralid passed the acute dietary assessment. The reproductive assessment found that clopyralid passed at the screening stage. No specific calculations of exposure for mammals through drinking water for the puddle scenario are necessary. The Log P_{ow} of Clopyralid meant that the risks from secondary poisoning to mammals does not require assessment.

Safe use of clopyralid for mammals were confirmed based on TER_A and TER_{LT} above the trigger values of 10 and 5, respectively. Based on the intended use on for **BARILOCHE** no unacceptable risk for mammals is expected from acute or long-term exposure. The risk assessment was calculated for 125 g/ha were accepted as worst case.

3.8.2 Effects on aquatic species

Effects on aquatic organisms for PP-113H were not evaluated as part of the EU review of Clopyralid. However further data on PP-113H is not relevant as active substance data on toxicity to aquatic organisms is used and additional formulation data are not considered essential. Therefore all relevant data were assessed in the EU review. Risk assessments for PP-113H with the proposed use pattern are provided here and are considered adequate.

Clopyralid poses an acceptable risk at STEPS 1&2. The formulation did not show an unacceptable risk.

The evaluation of the risk for aquatic 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” (EFSA Journal 2013;11(7):3290). The ratios between predicted environmental concentrations in surface water bodies (PEC_{SW} , PEC_{SED}) and regulatory acceptable concentrations (RAC) for a.s.- clopyralid and for product **BARILOCHE** based on the worst case for aquatic organisms were <1 indicating acceptable risk to aquatic organism. The risk assessment was calculated for 125 g/ha were accepted as worst case.

However, as aquatic plants are the most sensitive group of aquatic organisms, further studies should be provided at Member State level. The study with *Myriophyllum* should be conducted in accordance with OECD 239 and the root weight and the shoot weight should be measured separately. A final conclusion on the risk to the aquatic environment from the formulation **BARILOCHE** can only be drawn after the studies with the formulation and aquatic plants are made available. This should be addressed during product authorisation at Member State level.

DATA GAP:

In case formulation **BARILOCHE**:

1. Risk assessment for aquatic plants (*M. spicatum*) has been not performed (insufficient data set - data gap).
2. The new study the product **BARILOCHE** and *M.spicatum* should be performed.

Data requirement

In order to answer the requirement from the zRMS a study for *Myriophyllum spicatum* has been included.

The study was carried out with the product Faworyt 300 SL that is considered worse case to **BARILOCHE**.

The zRMS agrees that FAWORYT 300 SL can be considered as a worse case than BARILOCHE for the ecotoxicology studies. Comparison between formulation has been included in the attached Part C. The new risk assessment based on the study with the product Faworyt 300 SL was accepted by zRMS. The ratios between predicted environmental concentrations in surface water bodies (PEC_{SW} , PEC_{SED}) and regulatory acceptable concentrations (RAC) for product **BARILOCHE** and *M.spicatum* based on the worst case for aquatic organisms were <1 indicating acceptable risk to aquatic organism. Further action is not needed.

3.8.3 Effects on bees

All the hazard quotients are considerably less than 50, indicating that the active substance Clopyralid poses a low risk to bees. Therefore, a low risk to bees is expected from the application of PP-113H.

The risk assessment was provided and assessed during first registration of the product **BARILOCHE** in 2013. According to recommendation given in "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002). Based on the acute risk assessment with the consideration SANCO/10329/2002 rev.2 (final), October 17, 2002), HQ values for adult bees from exposure of **BARILOCHE** are < 50, indicating un acceptable risk to adult bees. The HQ values are lower than the trigger of 50, indicating low risk to bees from following application of **BARILOCHE**. In addition, the chronic studies for bees were submitted by the applicant. The risk assessment based on these studies should be considered when GD for Bees, 2013 is implemented at EU level. **Final decision should be taken into account at MSs level.** The risk assessment was calculated for 125 g/ha were accepted as worst case.

3.8.4 Effects on other arthropod species other than bees

Effects on arthropods other than bees of PP-113H were not evaluated as part of the EU review of Clopyralid. Therefore, all relevant data and assessments are provided here and are considered adequate.

The off-field HQ values for *T. pyri* and *A. rhopalosiphi* fall below the trigger value, indicating that PP-113H does not pose an unacceptable risk to non-target arthropods in off-field areas.

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. The calculations of the risk assessment for in – field for 4 indicator species - *T. pyri*, *A. rhopalosiphi*, *P.cupreus* and *C. septempunctata* based on extended laboratory studies were accepted by zRMS as HQ values were below 1 for these species. No effect on mortality or reproduction reached 50% for any species and therefore the in-field risk to non-target arthropods from the use of **BARILOCHE** is acceptable. The calculations of the risk assessment for off – field for 4 indicator species - *T. pyri*, *A. rhopalosiphi*, *P. cupreus* and *C. septempunctata* based on extended laboratory studies were accepted by zRMS as HQ values were below 1 for these species. In addition, based on the results from extended laboratory tests for 4 indicator species - *T. pyri*, *A. rhopalosiphi*, *P. cupreus* and *C. septempunctata* the $PER_{in-field}$ of **BARILOCHE** the risk off-field for these species is considered acceptable as $PER_{off-field}$ was below rate with ≤50 % effect. Finally, the risk off-field for NTA is considered acceptable. The risk assessment was calculated for 125 g/ha were accepted as worst case.

Data requirement

In-field risk assessment for *A.rhopalosiphi*

The calculations of the risk assessment for in – field for *Aphidius rhopalosiphi* based on reproduction effect for extended laboratory studies was performed by zRMS. zRMS used the lowest toxicity endpoints from

study based on reproduction parameter (the worst case – $ER_{50} = 993.22$ g/ha). HQ values is slightly above 1 for this species – **1.26** (and $PER_{in-field}$ is slightly above rate with $\leq 50\%$ effect on reproduction), indicating further refinement. However - in this case - ZRMS proposes to accept the risk. (The hazard ratio is only slightly above the threshold 1 (being 1.26), no significant effects for mortality was observed for the highest tested dose as 3154 g formulation/ha ($2.5 \times PER_{in-field}$), the calculations of the risk assessment for in-field for 3 others species - *T. pyri*, *P. cupreus* and *C. septempunctata* based on extended laboratory were accepted by zRMS as HQ values were below 1 for these species. No effect on mortality or reproduction reached 50% for *T. pyri*, *P. cupreus* and *C. septempunctata*.

The risk assessment for *A. rhopalosiphii* was calculated for 120 g/ha. The risk assessment for *T. pyri*, *P. cupreus* and *C. septempunctata* was calculated for 125 g/ha were accepted as worst case. Finally - in-field risk assessment to non-target arthropods from the use of **BARILOCHE** is acceptable.

Additionally, the new risk assessment based on the study FAWORYT 300 SL was performed by RMS. FAWORYT 300 SL can be considered as a worse case than BARILOCHE for the ecotoxicology studies. Comparison between formulation has been included in the attached Part C. $PER_{in-field}$ is below rate with $\leq 50\%$ effect on reproduction for *Aphidius rhopalosiphii* based on study with Faworyt 300 SL, indicating no further action is needed (in-field risk assessment for *A. rhopalosiphii* is accepted).

Off-field risk assessment for *A. rhopalosiphii*

The calculations of the risk assessment for off-field for *Aphidius rhopalosiphii* based on reproduction effect for extended laboratory studies was performed by zRMS. zRMS used the lowest toxicity endpoints from study based on reproduction parameter (the worst case – $ER_{50} = 993.22$ g/ha). HQ values is below 1 and $PER_{off-field}$ is below rate with $\leq 50\%$ effect on reproduction, indicating no further refinement is needed. Finally-off-field risk assessment to non-target arthropods from the use of **BARILOCHE** is acceptable. No further action is required.

3.8.5 Effects on soil organisms

Earthworms

The acute and long-term risk of PP-113H to earthworms was assessed from acute and long-term toxicity exposure ratios (TERs) between the selected toxicity endpoints for the active ingredient and relevant metabolites, and the maximum soil PECs.

All the acute and long-term TER values are much higher than the Annex VI acute trigger value of 10 and 5, respectively, for Clopyralid, indicating that PP-113H poses low risk to earthworms when applied according to the proposed use rates.

Effects on other soil non-target macro-organisms

Risk assessments from Toxicity Exposure Ratios, TER_A and TER_{LT} show that use of PP-113H will not result in unacceptable risks to earthworms. No studies are required for additional soil macro-organisms.

The relevant PECsoil for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate). The intended is covered by the presented PEC_{soil} calculations, however zRMS performed new calculations PEC_{soil} (mg/kg) for proposed use in GAP 120 g/ha. The TER_{LT} values for active substance and for product are above trigger value of 5, indicating an acceptable risk for earthworm and soil macroorganism for proposed use of the product **BARILOCHE**.

Effects on soil microbial activity

The risk assessment for soil micro-organism after exposure of ppp **BARILOCHE** couldn't be performed by the zRMS-PL. The study effects on the nitrogen transformations are not accepted. RMS pointed out that The Applicant should provide the following data in this study:

- ☒ calculation of soil nitrate-N transformation rate.

DATA GAP: Calculation of soil nitrate-N transformation rate in the effect of BARILOCHE on the nitrogen transformation in soil study should be provided. After providing complementary infor-

mation to this study, the study will be reassessed by RMS. The risk assessment for microorganism will be performed after supplementing provided by the Applicant.

Data requirement:

In order to answer the requirement from the zRMS a study effect on the nitrogen transformation has been included. The study was carried out with the product Faworyt 300 SL that is considered worse case to BARILOCHE.

N-mineralisation

Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC _{soil} (mg/kg dw)	Risk acceptable?
Faworyt 300 SL	3.7152	1.345	YES

The new risk assessment based on the study with the product Faworyt 300 SL was accepted by zRMS. The effects on the nitrogen transformations are acceptable (<25%) at concentration which is higher than the maximum relevant PECs for the maximum application rate of BARILOCHE. The results indicate no adverse effect on nitrogen transformation even at soil concentrations well higher than the ones expected following application of BARILOCHE.

3.8.6 Effects on non-target terrestrial plants

Non-Target Plants

Effects on non-target plants for PP-113H were not evaluated as part of the EU review of Clopyralid. However further data on PP-113H is not relevant as active substance data on toxicity to non-target plants is used and additional formulation data are not considered essential. Therefore all relevant data were assessed in the EU review. Risk assessments for PP-113H with the proposed use pattern have been provided and are considered adequate.

PP-113 H had an observed effect at the GAP application rate. A quantitative risk assessment was re-quired and found that the most sensitive species passed at tier 2 and no mitigation was needed.

The risk assessment for non-target plants after exposure of ppp BARILOCHE couldn't be performed by the zRMS-PL. The study to determine a potential phytotoxic effect of the product BARILOCHE for non-target plant species in terms of vegetative vigour are not accepted. Although the validity criteria are met, the study cannot be accepted by RMS. Due to an inadequately selected dose range, in this case, ER₅₀ based on phytotoxicity effect cannot be determined. Even at the lowest tested concentration at 1 L BARILOCHE/ha, the phytotoxicity effect was above 75% (chlorosis). *All phytotoxicity endpoint should be considered in the risk assessment, in line with EFSA Technical Report (2019), i.e. all effects and endpoints will be reported in the study summary and the lowest endpoint should be used by the zRMS ensuring a harmonized risk assessment at zonal level.* Therefore, the new study to determine a potential phytotoxic effect of the product BARILOCHE for non-target plant species in terms of vegetative vigour should be performed.

Peer review of the pesticide risk assessment of the active substance clopyralid in 2018 also confirmed that a data gap was identified for a new study with non-target plants for the formulation which should be addressed at Member States level.

DATA GAP:

1. The new study to determine a potential phytotoxic effect of the product BARILOCHE for non-target plant species in terms of vegetative vigour should be performed including phytotoxicity effect.
2. Risk assessment for non-target plants has been not performed (insufficient data set - data gap).

The risk assessment for non-target plants will be performed after supplementing provided by the Applicant.

Data requirement:

In order to answer the requirement from the zRMS a study effect on vegetative vigour has been included. The study was carried out with the product Faworyt 300 SL that is considered worse case to Bariloche.

Risk assessment for non-target terrestrial plants due to the use of BARILOCHE in sugar beet considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use		Sugar beet			
Active substance/product		clopyralid/BARILOCHE			
Application rate		1 × 1.25 L product/ha (1 × 125 g ai/ha)			
MAF		n.a.			
Buffer strip (m)	Drift rate (%)	PER_{off-field} (L product/ha)	PER_{off-field} 50 % drift red. (L product/ha)	PER_{off-field} 75 % drift red. (L product/ha)	PER_{off-field} 90 % drift red. (L product/ha)
4	2.77	0.0346	0.0173	-	-
5	0.57	0.0071	-	-	-
Toxicity value		TER			
ER₅₀ = 0.151 (L product/ha)		criterion: TER ≥ 5			
4		4.4	8.7	-	-
5		21.3	-	-	-

The new risk assessment based on the study with the product **Faworyt 300 SL** was accepted by zRMS.

The risk based on the ER₅₀ = 0.151 L formulation/ha value (*Mung bean*) from vegetative vigour test and PER_{off-field} indicated needs for further refinement.

The risk following mitigation measures are proposed: **BARILOCHE** achieve the acceptability criteria TER ≥ 5 with applying:

- 5 m buffer zone without drift-reducing nozzles
- 1 m and use of 50% drift-reducing nozzles

Updated June 2023

For the risk assessment of NTP, the new study with formulation Faworyt 300 SL was used (is considered worse case to Bariloche). Therefore, for the risk assessment the endpoint from this study should be expressed as amount of active substance/ha and not as amount of amount PPP/ha. In particular because the formulations are not identical and therefore the application rate for Bariloche and the endpoint for Faworyt 300 SL cannot be used in the evaluation.

Intended use		Sugar beet			
Active substance/product		clopyralid/PP113H			
Application rate		1 × 1.25 L product/ha (1 × 125 g ai/ha)			
MAF		n.a.			
Test species	ER₅₀	Drift rate	PER_{off-field}	TER criterion: TER ≥ 5	

Cucumber Carrot Broccoli Mung bean Oat Corn	ER ₅₀ plant fresh weight = 0.151 L product/ha Equivalent to 45.3 g s.a./ha	2.77%	0.0346 L product/ha Equivalent to 3.4625 g s.a./ha	13
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The risk based on the ER₅₀ = 0.151 L formulation/ha value (*Mung bean*) from vegetative vigour test and PER_{off-field}, not posing an unacceptable risk. The refinement risk assessment is not needed.

The final version of RR after 3rd round of commenting period January 2024

The risk assessment is finally performed based on a new study data. The study was carried out with the product Faworyt 300 SL that is considered worse case to Bariloche.

Problem description (DE comment): Currently, it is assumed that the formulation Faworyt 300 SL is worst case in comparison to PP-113 H and, thus, can be taken for the risk assessment of the later. This makes sense looking at the formulation data. With respect to the NTT data, however, more considerations might be needed. Although, the study with PP-113 H was not accepted by the zRMS, this is not due to a missing validity (the study was fully valid), but the fact that phytotoxic effects were observed even in the lowest doses. Therefore, the effect value for phytotoxic effects should be below lowest ER₅₀ of that test, which is currently 0.19 L product/ha (for *Medicago sativa*). In case the test with Faworyt 300 SL is worst case for PP-113 H the lowest ER₅₀ of the test with Faworyt 300 SL should be lower. This is the case for the unit expressed in L product/ha (the ER₅₀ is 0.151 L product/ha). However, a comparison based with respect to the active substance leads to the fact that the formulation is not worst case for PP-113 H. The recalculated endpoints would be equivalent to 45.3 g a.s./ha (Faworyt 300 SL) vs. 19.5 g a.s./ha (PP-113 H). The endpoint expressed in g a.s./ha would be 2.3 times lower for the actual formulation and, in addition, according to the test this isn't even based on the most sensitive endpoint (because high phytotoxicity is already occurring at the lowest concentration). Even though we are late in the authorization procedure we would advise reconsidering if an extrapolated test which is not worst case should be the sole base for risk assessment.

zRMS comments: There are no methods for quantitative analysis of the phytotoxicity parameter. The toxicity endpoint based on the phytotoxicity parameter may be subject to uncertainty as it is estimated based on the expert judgment of a laboratory test rather than on quantitative chemical analysis. Let us anticipate that in the future there will be a refined method for measuring this parameter and this will be taken into account in the current methodology for evaluation of OECD 227 study. In this case, the method of estimating this parameter raises great uncertainty. Additionally, after converting the toxicity endpoint from L formulation/ha to g a.s./ha, it can be seen that the use in the evaluation of the study for FAWORYT 300 SL, although the composition of the agent appears to be the worst case, in practice this is not in this case. The endpoint expressed in g a.s./ha would be 2.3 times lower for the actual formulation and, in addition, according to the test this isn't even based on the most sensitive endpoint (because high phytotoxicity is already occurring at the lowest concentration). Even though we are late in the authorization procedure we consider adding an additional uncertainty factor to address the additional uncertainty in this situation (uncertainties = extrapolation with not worst case formulation as well as phytotoxic effects even in the lowest concentration with the actual formulation). We propose used the recalculated endpoints 45.3 g a.s./ha (Faworyt 300 SL) divided by 10 for risk assessment. ER₅₀ = 4.53 g a.s./ha with risk mitigation to protect non-target plant.

Risk assessment for non-target terrestrial plants due to the use of BARILOCHE in sugar beet considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use	Sugar beet
Active substance/product	clopyralid/BARILOCHE
Application rate	(1× 120 g ai/ha)

MAF		n.a.			
Buffer strip (m)	Drift rate (%)	PER _{off-field} (L product/ha)	PER _{off-field} 50 % drift red. (L product/ha)	PER _{off-field} 75 % drift red. (L product/ha)	PER _{off-field} 90 % drift red. (L product/ha)
1	2.77	3.324	1.662	0.831	-
5	0.57	0.684	-	-	-
Toxicity value		TER			
ER ₅₀ = 4.53 g a.s./ha		criterion: TER ≥ 5			
1		1.3	2.73	5.45	-
5		6.36	-	-	-

The new risk assessment based on the study with the product **Faworyt 300 SL** was accepted by zRMS.

The risk based on the ER₅₀ = 4.53 g s.a./ha (*Mung bean*) from vegetative vigour test and PER_{off-field}, indicated needs for further refinement.

The risk following mitigation measures are proposed: **BARILOCHE** achieve the acceptability criteria TER ≥ 5 with applying:

- 5 m buffer zone without drift-reducing nozzles
- 1 m and use of 75% drift reducing nozzles

On the other hand the lowest toxicity endpoint for Faworyt 300 SL and non-target plants is ER₅₀ = 0.031 L product/ha (mung bean) (seedling emergence test based on plant fresh weight), equivalent to 9.3 g a.s./ha. Based on this toxicity endpoint the Faworyt 300 SL is the worst case compared on formulation Bariloche.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Other non-target species (Flora and Fauna)

Tests on other non-target species are not required.

Implications for labelling resulting from ecotoxicological assessment:

Hazard Symbol: none

Indication of danger: none

Risk Phrases:

Phrases under Regulation (EU) No 547/2011

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).

EUH401: To avoid risks to man and the environment, comply with the instructions for use.

SPe1: To protect ground water apply this or any other product containing Clopyralid every two years when the product is applied at BBCH 10-19.

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 75% drift reduction to non-agricultural land.

Other phrases: --

3.9 Relevance of metabolites (Part B, Section 10)

No metabolite from Clopyralide are predicted to occur above 0.1 µg/L.
A non-relevance assessment is therefore not required

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

Not required, clopyralid is not a candidate for substitution.

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

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Appendix 1 Copy of the product authorization

Registration Certificates are included in their respective folder of the dRR Dossier.

Appendix 2 Copy of the product label

Approved labels of BARILOCHE in their respective folder of the dRR Dossier.

Uwaga do etykiety

Sekcja właściwości fizyko-chemiczne

Brak uwag

Sekcja metabolizm i pozostałości:

Brak akceptacji proponowanego zastosowania

Korekta zapisu dotyczącego upraw następnych. Proponuje się dodatkowo następujący zapis: Nie stosować środków zawierających klopypirid na tym samym polu przez 125 dni po zastosowaniu niezależnie od uprawianej rośliny

Sekcja losu:

wprowadzono następujący zapis - w celu ochrony wód podziemnych środków należy stosować co dwa lata, gdy produkt jest stosowany w BBCH 10-19.

Sekcja toksykologii:

W części: **ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH**

Powinno być:

Stosować rękawice i nitrylowe odzież roboczą (kombinezon), podczas sporządzania cieczy użytkowej stosowania środka i kontaktu z obszarami potraktowanymi środkiem

Sekcja skuteczności:

Do etykiety dodano strategię zarządzania odpornością. Pozostałe zapisy zaakceptowano bez zmian.

Sekcja ekotoksykologii:

Brak akceptacji proponowanego zastosowania

Approved labels of BARILOCHE in their respective folder of the dRR Dossier.

Posiadacz zezwolenia:

Proplan, Plant Protection Company, SL., Valle del Roncal, 12. 1ª, 7., 28232 Las Rozas, Madryt, Królestwo Hiszpanii tel.: 902 108 165.

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:

BARILOCHE

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

chlopypirid (substancja z grupy pochodnych kwasu karboksylowego) - 100 g/l (9,51 %)

Zezwolenie MRiRW nr R - z dnia

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

HERBICYD z grupy regulatorów wzrostu, selektywny o działaniu układowym, stosowany dolistnie w postaci rozpuszczalnego koncentratu (SL).

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

DZIAŁANIE NA CHWASTY

Środek pobierany jest poprzez liście chwastów. Powoduje blokadę auksyn, tj. hormonów roślinnych odpowiedzialnych za podziały komórek, tym samym hamuje wzrost roślin. Ponadto zakłóca proces oddychania na poziomie komórkowym. Najskuteczniej niszczy młode, intensywnie rosnące chwasty, od fazy 2 – 3 liści właściwych do fazy rozety, powodując deformacje liści i pędów, po czym pojawia się chloroza i powolne zasychanie tkanek.

Chwasty wrażliwe	maruna nadmorska, mlecz zwyczajny, ostrożeń polny (z nasion), rumianek bezpromieniowy, rumianek pospolity, starzec zwyczajny, złocień polny.
Chwasty średniowrażliwe	rdestówka powojowata.
Chwasty średnioodporne	rdest szczawiolistny (syn. rdest kolankowy), rdest plamisty.

STOSOWANIE ŚRODKA

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

Burak cukrowy

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

Termin stosowania środka: środek stosować od fazy liścieni ułożonych horyzontalnie: widocznego pierwszego liścia właściwego (wielkości łebka od szpilki) do całkowitego zakrycia międzyrzędzi, liście zakrywają 90% powierzchni gleby (BBCH 10-39).

Zalecana dawka dla jednorazowego zastosowania: 1,0 – 1,2 l/ha.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 80 - 400 l/ha.

Zalecane opryskiwanie: średniokropliste.

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

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

Burak cukrowy – 42 dni

1. Materiału roślinnego, który opryskano środkiem nie wolno używać do kompostowania ani ściółkowania.
2. Obornika pochodzącego od zwierząt żywionych materiałem roślinnym, na który zastosowano środek nie wolno używać do kompostowania.
3. Pozostałości środka w tkankach roślinnych (w tym w oborniku i odpadach pofermentacyjnych), które nie uległy całkowitemu rozkładowi mogą wpływać na kolejne wrażliwe uprawy. Jeśli pozostałości roślin, na które zastosowano środek nie uległy całkowitemu rozkładowi do momentu uprawy kolejnych roślin, należy wówczas unikać wysiewu/sadzenia: groszku, fasoli i innych roślin strączkowych; marchwi i innych selerowatych; ziemniaków; sałaty i innych astrowatych.
4. Resztki roślin uprawnych, pozostałe po zbiorach, należy rozdrobnić i wymieszać z glebą możliwie w najkrótszym okresie po zbiorze, tak aby przyspieszyć ich rozkład. Przed siewem lub sadzeniem gatunków wrażliwych należy upewnić się, że resztki pozbiornicze, słoma, obornik pozostawione na polu uległy całkowitemu rozkładowi.

5. W celu uzyskania najlepszego efektu chwastobójczego środek należy stosować w trakcie aktywnego wzrostu chwastów. Działanie w przypadku rumianu polnego może być ograniczone, jeśli w momencie zabiegu rośliny będą narażone na suszę.
6. Działanie w przypadku ostrożnia polnego i innych chwastów wieloletnich może być ograniczone w wyniku czynności związanych z uprawą ziemi przed zastosowaniem środka lub w okresie dwóch tygodni po wykonaniu zabiegu.
7. Środka nie stosować:
 - w uprawach z wsiewką koniczyny ani innych roślin bobowatych;
 - na rośliny uprawne będące pod wpływem stresu spowodowanego np. chłodem, suszą, uszkodzeniami wywołanymi przez choroby czy szkodniki, niedoborami pokarmowymi;
 - w temperaturze powietrza poniżej 8°C i powyżej 25°C;
 - gdy minimalna temperatura dobowa w dniu zabiegu oraz przez 6 kolejnych dni wynosi mniej niż 8°C;
 - w czasie nadmiernej suszy;
 - po nocnych przymrozkach oraz przed spodziewanymi przymrozkami;
 - na rośliny mokre oraz uszkodzone przez choroby i szkodniki
8. Podczas stosowania środka nie dopuścić do:
 - znoszenia cieczy użytkowej na sąsiednie rośliny uprawne,
 - nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.
9. Przed zastosowaniem środka w uprawie buraka cukrowego przeznaczonego do przetwarzania należy skonsultować się z zakładem przetwórczym.
10. Przed zastosowaniem środka w uprawie przeznaczonej do zebrania materiału siewnego należy skonsultować się z przedstawicielami firmy nasiennej.
11. Środek może być stosowany w mieszaniu z innymi środkami ochrony roślin tylko i wyłącznie w przypadku, gdy ich wymagania lub ograniczenia są zgodne z wymaganiami lub ograniczeniami zawartymi w etykiecie przedmiotowego środka.

12. Strategia zarządzania odpornością:

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

- postępować ściśle zgodnie ze wskazówkami zawartymi w etykiecie środka ochrony roślin
- stosować środek w zalecanej dawce, w zalecany terminie zapewniającym optymalne zwalczanie chwastów,
- stosować rotację herbicydów o różnym mechanizmie działania,
- stosować mieszkankę herbicydów o różnym mechanizmie działania,
- stosować w rotacji i/lub mieszaniu herbicydy działające na kilka procesów życiowych chwastów (o różnym mechanizmie działania),
- dostosować zabiegi uprawowe do warunków panujących na polu, zwłaszcza do rodzaju i nasilenia chwastów,
- informować posiadacza zezwolenia o niesatysfakcjonującym zwalczaniu chwastów,
- w celu uzyskania szczegółowych informacji należy się skontaktować z doradcą, posiadaczem zezwolenia lub przedstawicielem posiadacza zezwolenia.

NASTĘPSTWO ROŚLIN

Środek rozkłada się w glebie w ciągu okresu wegetacji nie stwarzając zagrożenia dla roślin uprawianych następczo. Po zbiorze rośliny uprawnej, wiosną kolejnego roku kalendarzowego można uprawiać wszystkie rośliny z jednoczesnym uwzględnieniem ograniczeń dotyczących uprawy roślin następczych, wynikających z terminu stosowania środka oraz stopnia rozkładu resztek pozbiorczych. Groch, fasola i inne rośliny strączkowe, marchew i inne rośliny z rodziny baldaszkowatych, ziemniaki, sałata i inne gatunki z rodziny astrowatych można uprawiać wiosną następnego sezonu wegetacyjnego, tylko wtedy gdy środek był stosowany na danym polu, ale nie później niż do końca lipca poprzedniego roku kalendarzowego.

W przypadku konieczności wcześniejszej likwidacji plantacji potraktowanej środkiem na tym samym polu można uprawiać rzepak jary, rzepak ozimy, zboża lub burak cukrowy.

Resztki roślin uprawnych, pozostałe po zbiorach, należy rozdrobnić i wymieszać z glebą możliwie w najkrótszym okresie po zbiorze, tak aby przyspieszyć ich rozkład.

Przed siewem lub sadzeniem gatunków wrażliwych należy upewnić się, że resztki pozbiornicze pozostawione na polu uległy całkowitemu rozkładowi.

Nie stosować środków zawierających kłopyralid na tym samym polu przez 125 dni po zastosowaniu niezależnie od uprawianej 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 mieszadłem).

Opróżniony pojemnik dokładnie wypłukać za pomocą ciśnieniowego urządzenia płuczącego lub wykonując trzykrotne płukanie ręczne wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wleciu środka do zbiornika opryskiwacza niewyposażonego w mieszadło 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 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.

Bezpośrednio po pracy aparaturę dokładnie wymyć.

Wyposażenie używane do przeprowadzenia zabiegu należy dokładnie umyć wodą oraz płynnym detergentem bezpośrednio po użyciu. Napełnić czystą wodą i pozostawić na noc. Ponownie rozpylić przed przystąpieniem do przechowywania lub zastosowania innego produktu, zwłaszcza w przypadku zmiany produktu z herbicydów na insektycydy. Śladowe ilości produktu mogą być szkodliwe dla wrażliwych upraw (np. ziemniaków uprawianych na nasiona) opryskiwanych w późniejszym czasie.

Z wodą użytą do mycia aparatury postąpić tak, jak z resztkami cieczy użytkowej, stosując te same środki ochrony osobistej. W przypadku mycia aparatury przy użyciu środków myjących przeznaczonych do tego celu, z powstałymi popłuczynami należy postępować stosownie do instrukcji dołączonej do środka myjącego

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, odzież roboczą (kombinezon), podczas sporządzania cieczy użytkowej stosowania środka i kontaktu z obszarami potraktowanymi środkiem.

Należy myć ręce i odsłoniętą skórę przed posiłkami i po pracy.

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 podziemnych środek należy stosować co dwa lata, gdy produkt jest stosowany w BBCH 10-19.

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:~~

- ~~– 5 m od terenów nieużytkowanych rolniczo lub,~~
- ~~– 1 m od terenów nieużytkowanych rolniczo z równoczesnym zastosowaniem technik redukujących zanieczyszczenie cieczy użytkowej podczas zabiegu o 75%.~~

W celu ochrony roślin niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości:

- 5 m od terenów nieużytkowanych rolniczo lub,
- 1 m od terenów nieużytkowanych rolniczo z równoczesnym zastosowaniem technik redukujących zanieczyszczenie cieczy użytkowej podczas zabiegu o 75%.

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 - 25°C,
- chronić przed mrozem.

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

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów.

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 poradzić 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 - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

The letters of access have been included in their specific folder

Appendix 4 Lists of data considered for national authorization

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 protec- tion claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1	Pardo, M.	2011	PP-113H (Clopyralid 10% w/v SL): Determination of the colour, odour and physical state. ChemService S.r.I. (Italy) Report No: CH-390/2011 GLP, Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 2.2.1	Špášová, R.	2012	PP-113H (Clopyralid 10% w/v SL): Explosive properties. Research Institute for Organic Syntheses Inc. Report No: 206-11-57 GLP, Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 2.2.2	Mazzei, N.	2012	Oxidizing properties (liquids) on the sample PP-113H (Clopyralid 10% w/v SL) Innovhub stazioni sperimentali per l'industria Report No: 201105437 GLP, Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 2.3.3	Romo, S.	2012	PP-113H (Clopyralid 10% w/v SL): Auto-Ignition Test. CAMBIUM, S.L. Report No: E12097 GLP, Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 2.4.1 KCP 2.4.2	Pardo, M	2011	PP-113H (Clopyralid 10% w/v SL): Determination of the pH value and acidity or alkalinity ChemService S.r.I. (Italy) Report No: CH-391/2011 GLP, Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 2.5.1	Pardo, M	2011	PP-113H (Clopyralid 10% w/v SL): Determination of the viscosity.	N	Y	Data protected still	PROPLAN

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 protec- tion claimed Y/N	Justification if data protection is claimed	Owner
			ChemService S.r.I. (Italy) Report No: CH-395/2011 GLP, Unpublished			in force since the first authorization	
KCP 2.5.2	Pardo, M	2012	PP-113H (Clopyralid 10% w/v SL): Determination of the surface tension. ChemService S.r.I. (Italy) Report No: CH-694/2012 GLP, Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 2.6.1	Pardo, M	2011	PP-113H (Clopyralid 10% w/v SL): Determination of the relative density. ChemService S.r.I. (Italy) Report No: CH-392/2011 GLP, Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 2.6.1	Pardo, M	2019	PP-113H (Clopyralid 100 g/L SL): Determination of the Relative Density and the Active Ingredient Content. ChemService S.r.I. (Italy) Report No: CH-406/2019 GLP, Unpublished	N	Y	Data/study report never submitted before	PROPLAN
KCP 2.7.1	Pardo, M	2011	PP-113H (Clopyralid 10% w/v SL): Determination of the accelerated storage stability and corrosion characteristics. ChemService S.r.I. (Italy) Report No: CH-398/2011 GLP, Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 2.7.4	Pardo, M	2011	PP-113H (Clopyralid 10% w/v SL): Determination of the low tempera- ture stability. ChemService S.r.I. (Italy) Report No: CH-396/2011 GLP, Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 2.7.5	Pardo, M	2011	PP-113H (Clopyralid 10% w/v SL): Two years storage stability and cor- rosion characteristics. ChemService S.r.I. (Italy)	N	Y	Data protected still in force since the first authorization	PROPLAN

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
			Report No: CH-399/2011 GLP, Unpublished				
KCP 2.8.2	Pardo, M	2011	PP-113H (Clopyralid 10% w/v SL): Determination of the persistent foaming. ChemService S.r.I. (Italy) Report No: CH-393/2011 GLP, Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 2.8.2	Romo, S.	2014	Persistent foam test on PP-113H (Clopyralid 10% w/v, SL). Cambium, S.L. Report No. E14103. GLP, Unpublished.	N	Y	Data/study report never submitted before	PROPLAN
KCP 2.8.4	Pardo, M	2011	PP-113H (Clopyralid 10% w/v SL): Determination of the dilution stability. ChemService S.r.I. (Italy) Report No: CH-394/2011 GLP, Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 5.1.1	Pardo, M.	2011	PP-113H (Clopyralid 10 % w/v SL): Validation of the analytical method for the determination of the active ingredient content. ChemService S.r.I. (Italy) Report No: CH-397/2011 GLP, Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 5.2	Garagna, D. and Tediosi, E.	2011	Validation of the analytical method for the determination of Clopyralid residues in water samples from aquatic ecotoxicological studies. ChemService S.r.I. (Italy) Report No: CH-606/2011 GLP, Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 5.2/01	Matthias Knop	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	N	Y	Clopyralid TF - DMT Data/study report used to support the renewal of approval of Barilo-	Proplan, Plant Protection Company, SL

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 protec- tion claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished			che (art 43) and never used before to support other product owned by Proplan Plant Protection Company	PUH Chem- irol Sp. zo.o
KCP 5.2/02	Steffi Richer	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 Data/study report used to support the renewal of approval of Bariloche (art 43) and never used before to support other product owned by Proplan Plant Protection Company	Proplan, Plant Protection Company, SL PUH Chem- irol Sp. zo.o
KCP 5.2/03	Chizuko Abe	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 Data/study report used to support the renewal of approval of Bariloche (art 43) and never used before to support other product owned by Proplan Plant Protection Company	Proplan, Plant Protection Company, SL PUH Chem- irol Sp. zo.o
KCP 5.2/04	Martin Schweizer	2019	Independent Laboratory Validation of an Analytical Method for the Determination of Clopyralid in Different Matrices of Animal Origin	N	Y	Clopyralid TF - DMT Data/study report used to support	Proplan, Plant Protection

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
			P 5210 G EAG Laboratories GmbH GLP Unpublished			port the renewal of approval of Bariloche (art 43) and never used before to support other product owned by Proplan Plant Protection Company	Company, SL PUH Chemirol Sp. zo.o
KCP 5.2/05	Matthias Knop	2019	Validation of an Analytical Method for the Determination of Clopyralid in Soil S19-00448 Eurofins Agroscience Services EcoChem GmbH GLP Unpublished	N	Y	Clopyralid TF - DMT Data/study report used to support the renewal of approval of Bariloche (art 43) and never used before to support other product owned by Proplan Plant Protection Company	Proplan, Plant Protection Company, SL PUH Chemirol Sp. zo.o
KCP 5.2/06	Matthias Knop	2019	Validation of an Analytical Method for the Determination of Clopyralid in Water S19-00449 Eurofins Agroscience Services EcoChem GmbH GLP Unpublished	N	Y	Clopyralid TF - DMT Data/study report used to support the renewal of approval of Bariloche (art 43) and never used before to support other product owned by Proplan Plant Protection Company	Proplan, Plant Protection Company, SL PUH Chemirol Sp. zo.o
KCP 5.2/07	Steffi Rich-	2019	Independent Laboratory Validation of an Analytical Method for the	N	Y	Clopyralid TF -	Proplan,

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 protec- tion claimed Y/N	Justification if data protection is claimed	Owner
	ter		Determination of Clopyralid in Water P 5211 G EAG Laboratories GmbH GLP Unpublished			DMT Data/study report used to sup- port the renewal of approval of Barilo- che (art 43) and never used before to support other prod- uct owned by Pro- plan Plant Protec- tion Company	Plant Pro- tection Company, SL PUH Chem- irol Sp. zo.o
KCP 5.2/08	Monika Kirchherr	2019	Clopyralid Validation of an Analytical Method for the Determination in Air S19-00451 Eurofins Agroscience Services EcoChem GmbH GLP Unpublished	N	Y	Clopyralid TF - DMT Data/study report used to sup- port the renewal of approval of Barilo- che (art 43) and never used before to support other prod- uct owned by Pro- plan Plant Protec- tion Company	Proplan, Plant Pro- tection Company, SL PUH Chem- irol Sp. zo.o
KCP 5.2/09	Chizuko Abe	2019	Development and Validation of an Analytical Method for the Determination of Clopyralid in Body Fluids S19-00450 Eurofins Agroscience Services EcoChem GmbH GLP Unpublished	N	Y	Clopyralid TF - DMT Data/study report used to sup- port the renewal of approval of Barilo- che (art 43) and never used before to support other prod- uct owned by Pro- plan Plant Protec- tion Company	Proplan, Plant Pro- tection Company, SL PUH Chem- irol 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 protec- tion claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.3	Antón, B.	2020	Determination of Residues of Clopyralid (Common Moiety Method- Sum of Clopyralid, its Salts and Conjugates Expressed as Clopyralid) in Honey, after One Application of PP-113H (Clopyralid 100 g/L SL) in Phacelia tanacetifolia under semi- field conditions, at 4 Sites in Central and Southern Europe in 2020. Analytical phase report. Eurofins. Report No: S20-01463 GLP, Unpublished	N	Y	Data/study report never submitted before	PROPLAN
KCP 6.2 KCP 6.4	Blanco, J.	2011	Determination of efficacy and selectivity of PP-113H (Clopyralid 10% w/v SL) against compositae weeds on sugar beet. 1 trial in Germany and 2 trials in UK. Season 2011 Eurofins Agrosience Services (Spain) Report No: S11-00370 GLP, Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 6.2 KCP 6.4	Blanco, J.	2011	Determination of efficacy of PP-113H against <i>Cirsium arvense</i> on sugar beet. 2 trials in Germany and 1 trial in UK. Season 2011 Eurofins Agrosience Services (Spain) Report No: S11-00371 GLP, Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 6.2 KCP 6.4	Blanco, J.	2011	Determination of efficacy of PP-113H against compositae weeds and <i>cirsium arvense</i> on sugar beet. 3 trials in France. Season 2011 Eurofins Agrosience Services (Spain) Report No: S11-00372 GLP, Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 6.2	Blanco, J.	2012	Determination of efficacy of PP-113H against <i>Cirsium arvense</i> , <i>Matri-</i>	N	Y	Data protected still	PROPLAN

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 protec- tion claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4			<i>caria</i> sp. and compositae weeds on sugar beet. 1 trial in Czech Republic. Season 2012 Eurofins Agroscience Services (Spain) Report No: S12-00585-01 GLP, Unpublished			in force since the first authorization	
KCP 6.2 KCP 6.4	Blanco, J.	2012	Determination of efficacy of PP-113H against <i>Cirsium arvense</i> , <i>Matri- caria</i> sp. and compositae weeds on sugar beet. 1 trial in Czech Republic. Season 2012 Eurofins Agroscience Services (Spain) Report No: S12-00585-02 GLP, Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 6.2 KCP 6.4	Blanco, J.	2012	Determination of efficacy of PP-113H against <i>Cirsium arvense</i> , <i>Matri- caria</i> sp. and compositae weeds on sugar beet. 1 trial in Romania. Season 2012 Eurofins Agroscience Services (Spain) Report No: S12-00585-03 GLP, Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 6.2 KCP 6.4	Blanco, J.	2012	Determination of efficacy of PP-113H against <i>Cirsium arvense</i> , <i>Matricar- ia</i> sp. and compositae weeds on sugar beet. 1 trial in Romania. Season 2012 Eurofins Agroscience Services (Spain) Report No: S12-00585-04 GLP, Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 6.2 KCP 6.4	Blanco, J.	2012	Determination of efficacy of PP-113H against <i>Cirsium arvense</i> , <i>Matricar- ia</i> sp. and compositae weeds on sugar beet. 1 trial in Poland. Season 2012. Eurofins Agroscience Services (Spain) Report No: S12-00585-05	N	Y	Data protected still in force since the first authorization	PROPLAN

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 protec- tion claimed Y/N	Justification if data protection is claimed	Owner
			GLP, Unpublished				
KCP 6.2 KCP 6.4	Blanco, J.	2012	Determination of efficacy of PP-113H against <i>Cirsium arvense</i> , <i>Matri- caria</i> sp. and compositae weeds on sugar beet. 1 trial in Poland. Season 2012. Eurofins Agroscience Services (Spain) Report No: S12-00585-06 GLP, Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 6.2 KCP 6.4	Blanco, J.	2012	Determination of efficacy of PP-113H against <i>Cirsium arvense</i> , <i>Matri- caria</i> sp. and compositae weeds on sugar beet. 1 trials in Hungary. Sea- son 2012. Eurofins Agroscience Services (Spain) Report No: S12-00585-07 GLP, Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 6.2 KCP 6.4	Blanco, J.	2012	Determination of efficacy of PP-113H against <i>Cirsium arvense</i> , <i>Matri- caria</i> sp. and compositae weeds on sugar beet. 1 trial in Hungary. Season 2012 Eurofins Agroscience Services (Spain) Report No: S12-00585-08 GLP, Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 6.2 KCP 6.4	Blanco, J.	2012	Determination of efficacy of PP-113H against <i>Cirsium arvense</i> , <i>Matri- caria</i> sp. and compositae weeds on sugar beet. 1 trial in UK. Season 2012 Eurofins Agroscience Services (Spain) Report No: S12-00585-09 GLP, Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 6.2 KCP 6.4	Blanco, J.	2011	Determination of selectivity of PP-113H on sugar beet. 1 trial in Germany and 1 trial in UK. Season 2011	N	Y	Data protected still in force since the first authorization	PROPLAN

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 protec- tion claimed Y/N	Justification if data protection is claimed	Owner
			Eurofins Agrosience Services (Spain) Report No: S11-00373 GLP, Unpublished				
KCP 6.2 KCP 6.4	Blanco, J.	2011	Determination of selectivity of PP-113H on sugar beet. 2 trials in France. Season 2011 Eurofins Agrosience Services (Spain) Report No: S11-00374 GLP, Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 6.10-01	Antón, B.	2020	Determination of Residues of Clopyralid (Common Moiety Method- Sum of Clopyralid, its Salts and Conjugates Expressed as Clopyralid) in Hon- ey, after One Application of PP-113H (Clopyralid 100 g/L SL) in Phace- lia tanacetifolia under semi- field conditions, at 4 Sites in Central and Southern Europe in 2020. Analytical phase report. Eurofins. Report No: S20-01463 GLP, Unpublished	N	Y	Data/study report never submitted before	PROPLAN
KCP 7.1.1	xxx	2013	Acute oral toxicity study of PP-113H (Clopyralid 10 % w/v) in rats xxx Report N°: 401-1-01-5762 GLP, Unpublished	N Y	Y	Data protected still in force since the first authorization	PROPLAN
KCP 7.1.2	xxx	2013	Acute dermal toxicity study of PP-113H (Clopyralid 10 % w/v) in rats xxx Report N°: 403-1-01-5763 GLP, Unpublished	N Y	Y	Data protected still in force since the first authorization	PROPLAN
KCP 7.1.3	xxx	2013	Acute inhalation toxicity study of PP-113H (Clopyralid 10 % w/v) in rats xxx Report N°: 405-1-01-5764 GLP, Unpublished	N Y	Y	Data protected still in force since the first authorization	PROPLAN

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 protec- tion claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.1.4	xxx	2013	Acute dermal irritation study of PP-113H (Clopyralid 10 % w/v) in rabbits xxx Report N°: 406-1-01-5765 GLP, Unpublished	N Y	Y	Data protected still in force since the first authorization	PROPLAN
KCP 7.1.5	xxx	2013	Assessment of acute eye irritation xxx Report N°: IO-OCDE-PH-13/0217 GLP, Unpublished	N Y	Y	Data protected still in force since the first authorization	PROPLAN
KCP 7.1.6	xxx	2013	Skin sensitization study of PP-113H (Clopyralid 10% w/v SL) in guinea pigs (Guinea Pig Maximization Test) xxx Report N°: 408-1-01-5767 GLP, Unpublished	N Y	Y	Data protected still in force since the first authorization	PROPLAN
KCP 9.1.3 KCP 9.2.4 KCP 9.2.5	Domingo J.	2021	Predicted environmental concentrations of clopyralid following use of BARILOCHE (PP-113-H) on sugar beet Proplan Report PP113-011221 Non GLP Unpublished	N	N	-	PROPLAN
KCP 10.2.1	Tediosi E., Garagna D.	2011	PP-113H (clopyralid 10 % w/v sl): acute toxicity to Daphnia magna in a 48-hour immobilization test under static exposure Chemservice S-L.R. Report CH-602-2011 GLP Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 10.2	Tediosi E., Dini R.	2011	PP-113H (CLOPYRALID 10 % w/v SL): toxicity to green algae <i>Pseudo-kirchneriella subcapitata</i> determined in a growth inhibition study CH603-2011 GLP :yes	N	Y	Data protected still in force since the first authorization	PROPLAN

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
			Unpublished				
KCP 10.2.1	Juckeland D.	2012	Effects of PP-113H (Clopyralid 10% w/v SL) on Lemna minor in a growth inhibition test under static test conditions Bio Chem Agrar Report 12 10 48 004 w GLP: yes Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
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 Data/study report used to support the renewal of approval of Bariloche (art 43) and never used before to support other product owned by Proplan Plant Protection Company Letter of access	CIECH Sarzyna S.A.
KCP 10.3.1	Barcarotti M.	2011	EFFECTS, ACUTE ORAL AND ACUTE CONTACT TOXICITY, OF PP-113H (Clopyralid 10% w/v SL) ON THE HONEYBEE APIS MELLIFERA L. IN THE LABORATORY (LIMIT TEST) Biotechnologie BT Document No: BT102/11 GLP YES Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 10.3.1	Ansaloni T.	2020	PP-113H (Clopyralid 100 g/L SL): Chronic Oral Toxicity Test (10-Day Feeding) to the Honey Bee, Apis mellifera L. under Laboratory Conditions	N	Y	Data/study report never submitted before	PROPLAN

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 protec- tion claimed Y/N	Justification if data protection is claimed	Owner
			Trialcamp S-L.U Report N°: S19-03760 GLP YES Unpublished				
KCP 10.3.1	Ansaloni T.	2020	PP-113H (Clopyralid 100 g/L SL): Honey Bee (<i>Apis mellifera</i> L.) Larval Toxicity Test Following Repeated Exposure Under Laboratory Conditions Trialcamp S-L.U Report N°: S19-03761 GLP YES Unpublished	N	Y	Data/study report never submitted before	PROPLAN
KCP 10.3.2	Colli, M.	2011	Effects of the product PP-113H (CLOPYRALID 10% w/v SL) on the aphid parasitoid <i>Aphidius rhopalosiphii</i> De Stefani-Perez (Hymenoptera: Braconidae) under Extended Laboratory Conditions (Rate Response Test) Biotechnologie BT Document No: BT098/11 GLP yes Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 10.3.2.2/01	Moll M.	2019	Faworyt 300 SL: Effects on the Parasitoid <i>Aphidius rhopalosiphii</i> , Extended Laboratory Study - Dose Response Test – Ibacon GmbH Study No. 140601002 GLP Unpublished	N	Y	Data/study report never submitted before Data/study report used to support the renewal of approval of Bariloche (art 43) and never used before to support other product owned by Proplan Plant Protection Company Letter of access	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 protec- tion claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.2	Colli, M.	2011	Effects of the product PP-113H (CLOPYRALID 10% w/v SL) on the predatory mite, Typhlodromus pyri Scheuten (Acari: Phytoseiidae) under Extended Laboratory Conditions (Rate Response Test) Biotechnologie BT Document No: BT099/11 GLP yes Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 10.3.2	Luna F.	2020	PP-113H (Clopyralid 100 g/L SL): Toxicity to the Predatory Bug, Orius laevigatus Fieber (Heteroptera, Anthocoridae) Using an Extended Laboratory Test with Freshly Applied Spray Deposits Trialcamp S-L.U Report N°: S19-03762 GLP YES Unpublished	N	Y	Data/study report never submitted before	PROPLAN
KCP 10.3.2	Luna F.	2020	PP-113H (Clopyralid 100 g/L SL): Toxicity to the Ladybird, Coccinella septempunctata L. (Coleoptera: Coccinellidae) Using an Extended Laboratory Test with Freshly Applied Spray Deposits Trialcamp S-L.U Report N°: S19-03763 GLP YES Unpublished	N	Y	Data/study report never submitted before	PROPLAN
KCP 10.4	Tediosi E., Dini R.,	2011	PP-113H (clopyralid 10 % w/v sl): acute toxicity to earthworm determined in an artificial soil study Chemservice S-L.R. Document No: DR-CH60511 GLP YES Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 10.4	Anton B.	2020	PP-113H (Clopyralid 100 g/L SL): Sublethal Toxicity to the Earthworm Eisenia fetida (Oligochaeta, Lumbricidae) in Artificial Soil with 10 % Peat	N	Y	Data/study report never submitted before	PROPLAN

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 protec- tion claimed Y/N	Justification if data protection is claimed	Owner
			Trialcamp S-L.U Report N°: S20-02714 GLP YES Unpublished				
KCP 10.4	Anton B.	2020	PP-113H (Clopyralid 100 g/L SL): Effects on the Reproductive Output of the Springtail Folsomia candida Willem (Collembola, Isotomidae) in Artificial Soil Trialcamp S-L.U Report N°: S20-02712 GLP YES Unpublished	N	Y	Data/study report never submitted before	PROPLAN
KCP 10.4	Lozano J.	2020	PP-113H (Clopyralid 100 g/L SL): Effects on the Reproductive Output of the Predatory Soil Mite Hypoaspis (Geolaelaps) aculeifer Canestrini (Acari: Laelapidae) in Artificial Soil Trialcamp S-L.U Report N°: S20-02713 GLP YES Unpublished	N	Y	Data/study report never submitted before	PROPLAN
KCP 10.5	Dottorini, F.	2011	Assessment of the effects of PP-113H (CLOPIRALIDE 10% w/v SL) on soil microorganism respiration and nitrification Biotechnologie BT Document No: BT154/11 GLP Yes Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
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	N	Study report never submitted before Data/study report used to support the renewal of approval of Bariloche (art	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
						43) and never used before to support other product owned by Proplan Plant Protection Company Letter of access	
KCP 10.6.2	Corbolli M,	2011	Vegetative vigour rate response test for non-target plants following application of the product PP-113H (Clopyralid 10% w/v SL) Biotechnologie BT Document No: BT 100/11 GLP yes Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
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 Data/study report used to support the renewal of approval of Bariloche (art 43) and never used before to support other product owned by Proplan Plant Protection Company Letter of access	CIECH Sarzyna S.A.
KCP 10.6.1	Corboli, M.	2012	“Seedling emergence rate response test for non-target plants following application of the product PP-113H (Clopyralid 10% w/v SL)” Biotechnologie BT Document N°: BT 101/2011 GLP: yes	N	Y	Data protected still in force since the first authorization	PROPLAN

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 protec- tion claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 10.3.2	Colli, M.	2011	Effects of the product PP-113H (CLOPYRALID 10% w/v SL) on the predatory mite, Typhlodromus pyri Scheuten (Acari: Phytoseiidae) under Extended Laboratory Conditions (Rate Response Test) Biotechnologie BT Document No: BT099/11 GLP yes Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 10.3.2	Luna F.	2020	PP-113H (Clopyralid 100 g/L SL): Toxicity to the Predatory Bug, Orius laevigatus Fieber (Heteroptera, Anthocoridae) Using an Extended Laboratory Test with Freshly Applied Spray Deposits Trialcamp S-L.U Report N°: S19-03762 GLP YES Unpublished	N	Y	Data/study report never submitted before	PROPLAN
KCP 10.3.2	Luna F.	2020	PP-113H (Clopyralid 100 g/L SL): Toxicity to the Ladybird, Coccinella septempunctata L. (Coleoptera: Coccinellidae) Using an Extended Laboratory Test with Freshly Applied Spray Deposits Trialcamp S-L.U Report N°: S19-03763 GLP YES Unpublished	N	Y	Data/study report never submitted before	PROPLAN
KCP 10.4	Tediosi E., Dini R.,	2011	PP-113H (clopyralid 10 % w/v sl): acute toxicity to earthworm determined in an artificial soil study Chemservice S-L.R. Document No: DR-CH60511 GLP YES Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 10.4	Anton B.	2020	PP-113H (Clopyralid 100 g/L SL):	N	Y	Data/study report	PROPLAN

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 protec- tion claimed Y/N	Justification if data protection is claimed	Owner
			Sublethal Toxicity to the Earthworm <i>Eisenia fetida</i> (Oligochaeta, Lumbricidae) in Artificial Soil with 10 % Peat Trialcamp S-L.U Report N°: S20-02714 GLP YES Unpublished			never submitted before	
KCP 10.4	Anton B.	2020	PP-113H (Clopyralid 100 g/L SL): Effects on the Reproductive Output of the Springtail <i>Folsomia candida</i> Willem (Collembola, Isotomidae) in Artificial Soil Trialcamp S-L.U Report N°: S20-02712 GLP YES Unpublished	N	Y	Data/study report never submitted before	PROPLAN
KCP 10.4	Lozano J.	2020	PP-113H (Clopyralid 100 g/L SL): Effects on the Reproductive Output of the Predatory Soil Mite <i>Hypoaspis</i> (Geolaelaps) <i>aculeifer</i> Canestrini (Acari: Laelapidae) in Artificial Soil Trialcamp S-L.U Report N°: S20-02713 GLP YES Unpublished	N	Y	Data/study report never submitted before	PROPLAN
KCP 10.5	Dottorini, F.	2011	Assessment of the effects of PP-113H (CLOPIRALIDE 10% w/v SL) on soil microorganism respiration and nitrification Biotechnologie BT Document No: BT154/11 GLP Yes Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN
KCP 10.6.2	Corbolli M,	2011	Vegetative vigour rate response test for non-target plants following application of the product PP-113H (Clopyralid 10% w/v SL) Biotechnologie BT Document No: BT 100/11	N	Y	Data protected still in force since the first authorization	PROPLAN

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			GLP yes Unpublished				
KCP 10.6.1	Corboli, M.	2012	“Seedling emergence rate response test for non-target plants following application of the product PP-113H (Clopyralid 10% w/v SL)” Biotechnologie BT Document N°: BT 101/2011 GLP: yes Unpublished	N	Y	Data protected still in force since the first authorization	PROPLAN

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

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