FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: PP-113H

Product name(s): 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.

Submission date: December 2021

MS Finalisation date: August 2022, April 2023, June 2023, November 2023, January 2024

Version history

When	What
February 2019	Initial version
December 2021	Version 2, Update for the renewal.
August 2022	ZRMS Assessment
April 2023	Revision based on comments received
June 2023	Revision made after second round of commenting
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 3rd round of commenting period

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0 Product background, regulatory context and GAP information

The product BARILOCHE (Clopyralid 10% w/v SL), is currently registered in Italy (16096), Spain (ES-00493), UK (Re. No. 17577), Poland (Reg. No. R-26/2018wu), Germany (Reg. No. 008865-00), Czech Republic (Reg. No. 5583-0) and Romania (Reg. No. 466PC) in Sugar beet.

This new dossier has been carried out to support the renewal of the approval of the active substance 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.

0.1 Introduction

This document summarises the information related to the identity, the physical and chemical properties, the data on application, further information and the classification for the plant protection product PP-113H containing the Clopyralid which was included into Annex I of Directive 91/414 (2006/64/EC) According to Regulation (EU) No 2021/1191 of 19 July 2021, active substance clopyralid was renewed in 1 October 2021.

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.
Commission Implementing Regulation (EU) 2021/566 of 30 March 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substance Clopyralid and other active substances.

Where appropriate this document refers to the conclusions of the EU review of the Clopyralid. This will be where:

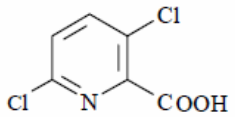
- the active substance data is relied upon in the risk assessment of the formulation, or when
- the EU review concluded that additional data/information should be considered at national re-registration.

Note: this Part B document only reviews data (Annex II or Annex III) and additional information that has not previously been considered within the EU review process, as part of the Annex I inclusion decision. New annex II data must only be included if they are considered essential for the evaluation and in this case a full study summary must be provided.

This product was not the representative formulation. The product has not been previously evaluated in other countries according to Uniform Principles.

The SANCO report for Clopyralid (~~SANCO/10012/2006-rev.3 – 4/04/2006~~ SANTE/10206/2021 Rev 1- 20 May 2021) is considered to provide the relevant review information or a reference to where such information can be found. The following table provides the EU endpoints to be used in the evaluation.

Agreed EU End-points (*EFSA Journal 2018;16(7):5389*)

End-Point	Active Substance
Common name (ISO)	Clopyralid
Chemical Name (IUPAC)	3,6-dichloropyridine-2-carboxylic acid
Chemical Name (CA)	3,6-dichloro-2-pyridinecarboxylic acid
CIPAC No	455
CAS No	1702-17-6
EEC No	216-935-4
FAO SPECIFICATION	Not available
Minimum purity	950 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	Open
Molecular formula	$C_6H_3Cl_2NO_2$
Molecular mass	191.96
Structural formula	
Melting point	149.6 ±2ºC (99.8%)
Boiling point	Decomposes at 164 ± 2 °C (99.8%) A thermal effect due to boiling was not observed.
Temperature of decomposition	164 ºC (998 g/kg)
Appearance	(95.3%): Color - Cream Physical State - Powdery Solid (99.8%): Color - white Physical State - Crystalline Solid
Surface tension	71.5 mN/m at 20ºC (1 g/L aqueous solution) (99.9%)
Vapour pressure (in mBar and Pa, state temperature)	1.36×10^{-6} Pa at 25 °C (996 g/kg)
Henry´s law constant (Pa m^3 mol^{-1})	Unbuffered 3.28×10^{-10} Pa m^3 mol^{-1} at 20 ºC pH 5 2.18×10^{-11} Pa m^3 mol^{-1} at 20 ºC pH 7 1.8×10^{-11} Pa m^3 mol^{-1} at 20 ºC pH 9 1.64×10^{-11} Pa m^3 mol^{-1} at 20 ºC
Solubility in water (g/L or mg/L, state temperature)	Unbuffered: 7.85 g/L at 20 ºC H pH 5: 118 g/L at 20 ºC pH 7: 143 g/L at 20 ºC pH 9: 157 g/L at 20 ºC (all 992 g/kg)

<table>
<tr><td>Solubility in organic solvents (g/kg, 20 ºC)</td><td>964 g/kg:
n-hexane: 0.6 wt% at 20 ºC
methanol: 10.4 wt% at 20 ºC
959 g/kg:
acetone: >250 g/L at 20 ºC,
ethyl acetate: 102 g/L at 20 ºC,
xylene: 4.6 g/L at 20 ºC
1,2-dichlorethane: 20.7 g/L at 20 ºC</td></tr>
<tr><td>Partition co-efficient (log POW) (state pH and temperature)</td><td>pH 5: - 1.81 at 20 ºC
pH 7: - 2.63 at 20 ºC
pH 9: - 2.55 at 20 ºC (all 992 g/kg)</td></tr>
<tr><td>Dissociation constant</td><td>pKa= 2.01±1 at 25 ºC (996 g/kg)</td></tr>
<tr><td>UV/VIS absortion (max.) (if absorption >290 nm state: Ɛ at wavelength)</td><td>
<table>
<tr><th>pH</th><th>Concentration (µg/mL)</th><th>ε (L mol^{-1}.cm^{-1})</th><th>λ (nm)</th></tr>
<tr><td><2</td><td>19.4</td><td>19468
8771
3609
2777</td><td>201
226
282
290</td></tr>
<tr><td><2</td><td>58.3</td><td>11247
8263
3614
2820</td><td>206
223
282
290</td></tr>
<tr><td>7</td><td>19.4</td><td>16355
8951
4640
2832</td><td>198
221
280
290</td></tr>
<tr><td>7</td><td>58.3</td><td>9581
8533
4592
2875</td><td>202
220
280
290</td></tr>
<tr><td>>10</td><td>19.4</td><td>15262
9395
4904
3072</td><td>199
221
280
290</td></tr>
<tr><td>>10</td><td>58.3</td><td>9695
8884
4788
3019</td><td>203
219
280
290</td></tr>
</table>
</td></tr>
<tr><td>Flammability</td><td>Not flammable (95.9%)</td></tr>
<tr><td>Explosive properties</td><td>No sign of ignition or explosion (95.4%)</td></tr>
<tr><td>Oxidizing properties</td><td>non-oxidizing (95.9%)</td></tr>
</table>

0.1.1 Reason for application

The Annex I Inclusion Directive for Clopyralid (**2006/64/EC)**, amended by Commission Implementing Regulation (EU) 2021/1191 provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation:

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on clopyralid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 April 2006 shall be taken into account.

Member States ~~should/must/may~~ shall pay particular attention to the:

- specification of the technical material as commercially manufactured;
- protection of operators, ensuring that conditions of use for operators include the application of adequate personal protective equipment;
- possible presence of clopyralid residues in rotational crops;
- possible transfer of clopyralid residues via compost or manure of animals whose feed originates from treated areas, to avoid damage to susceptible crops;
- the protection of ~~non target plants and~~ groundwater under vulnerable conditions.

Conditions of authorisation should include risk mitigation measures and monitoring programmes should be initiated to verify potential groundwater contamination in vulnerable zones, where appropriate.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation. Appendix 2 of this document is the table of intended uses for PP-113H.

Information on the detailed composition of PP-113H can be found in the confidential dossier of this submission (Registration Report - Part C).

In addition to the submission of studies, exemption from the submission of studies is requested in accordance with Article 34 of Regulation (EC) No. 1107/2009.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	**(if relevant) Concerned MS, MS' product name and authorization number (if applicable)**
Southern zone	zRMS: Italy Product code: PP-113H Product name: Bariloche **Registration No: 16096**	Spain (Bariloche: Reg. No. ES-00493)
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)

0.1.3 Regulatory history of the active(s)

0.1.3.1 Active substance 1 (Clopyralid)

Table 0.1-2: Summary of regulatory history of CAS No: 1702-17-6

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	06/64/EC , Reg. (EU) No 540/2011 Reg. (EU) No. 2021/566
RMS	FI
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	~~01/05/2007~~ 01/10/2021
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	~~30/04/2022~~ 30/09/2036
Date of final Commission (re-registration) deadline (Step 2)	~~30/04/2022~~ 30/09/2036
Current expiration of approval	~~30/04/2022~~ 30/09/2036
Low risk substance or Candidate for Substitution?	N/A

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

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

- the specification of the technical material as commercially manufactured;
- the protection of operators, ensuring that conditions of use for operators include the application of adequate personal protective equipment;
- possible presence of clopyralid residues in rotational crops;
- the possible transfer of clopyralid residues via compost or manure of animals whose feed originates from treated areas, to avoid damage to susceptible crops;
- the protection of ~~non target plants~~ and groundwater under vulnerable conditions.

Conditions of authorisation should include risk mitigation measures and monitoring programmes should be initiated to verify potential groundwater contamination in vulnerable zones, where appropriate.

The SANCO report for Clopyralid (SANCO/2012/11251-rev. 4) is considered to provide the relevant review information or a reference to where such information can be found. The following table provides the EU endpoints to be used in the evaluation.

Table 0.1-3: Information on minimum purity of Clopyralid

EU agreed minimum purity from Inclusion Directive or Implementing regulation ***(~~EFSA Scientific Report (2005) 50, 1–65~~ EFSA Scientific Report (2018); 16(8):5389)***	**(if different) Minimum purity of active substance used in the product / information on available equivalency report *, ****
minimum purity of active substance: 950 g/kg	~~970 g/kg /~~ 975 g/kg (see confidential information, Part C) Equivalence report available: Y RMS: ~~FR &~~ ~~SP~~ ES

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

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

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

Endpoint	Active Substance	
	EU agreed endpoint from (*EFSA Journal 2018;16(7):5389*)	**Endpoint used***
Dermal Absorption	10% as default for concentration and spray dilution.	Concentrate: 10% Spray: 50%

* Guidance on Dermal absorption (EFSA Journal 2017:15(6):4873).

0.1.3.2 Active substance 2

Not required. The product only has one active substance.

0.1.4 Regulatory history of the product (if relevant)

The following table provides corresponding information of product codes, product names and authorizations in different EU Member States.

Table 0.1-4: Summary of regulatory history of the product PP-113H/ BARILOCHE

Product code	Product name(s)	MS	Authorization No.	Date of initial registration	Date of the last re-registration
PP-113H	Bariloche	IT	16096	11/07/2017	30/04/2022
PP-113H	Bariloche	SP	ES-00493	07/11/2018	30/04/2022
PP-113H	Bariloche	UK	17577	30/04/2017	30/04/2023
PP-113H	Bariloche	RO	466PC	15/1172018	30/04/2022
PP-113H	Bariloche	DE	008865-00	22/11/2017	30/04/2022
PP-113H	Bariloche	PL	R-26/2018wu	25/05/2018	30/04/2022
PP-113H	Bariloche	CZ	5583-0	13/12/2017	30/04/2022

0.2 zRMS conclusion

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

Efficacy section: 1

Residues section: ~~none~~ 1

Environmental fate and behavior section: 1

Ecotoxicology section: 1

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

Efficacy section: none

Residues section: ~~1~~ none

Environmental fate and behavior section: none

Ecotoxicology section: none

Insert relevant use number from GAP table in Appendix 1 and refer to relevant RR chapter with identified risk.

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

Fate section: For application at BBCH 10-29 product should be applied every two years.

The main conclusions:

Section phys-chem:

No data gaps

Efficacy section:

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. **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.~~ For DE recommended water volume is 200-400 L/ha

Mammalian of 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.

Metabolism and Residues:

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

Use is accepted.

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).

Ecotoxicology section:

~~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. 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. 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).~~

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.

Appendix 1 ALL intended uses

GAP rev.1, date: sept, 2021.

PPP (product name/code):	Bariloche (PP-113H)	Formulation type:	SL [a, b]
Active substance 1:	Clopyralid	Conc. of as 1:	100 g/L [c]
Applicant:	PROPLAN Plant Protection Company, S.L.	Professional use:	☒
Zone(s):	Central zone [d]	Non professional use:	☐
Verified by MS:	-		

Field of use: herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	C. EU (CZ, DE, PL, RO)	Sugar beet	F	CIRAR and COMPOSITAE	Tractor boom sprayer	BBCH 10-39	1	-	1.2	120	80-400	None	Do not use between the 31st August and 1st March Metabolism and Residues Use ~~not~~ accepted **Eff. section**: For DE recommended 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.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions