

FINAL REGISTRATION REPORT

Part B

Section 1: Identity

Section 2: Physical and chemical properties

Section 4: Further information

Detailed summary of the risk assessment

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: July 2022, April 2023

Version history

When	What
February 2019	Initial version
December 2021	Version 2, Update for the renewal.
July 2022	ZRMS Assessment
April 2023	The final version of RR after commenting period.

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The product BARILOCHE 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.

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).

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.

The product, PP-113H, has been previously evaluated in other countries according to Uniform Principles.

	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 (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) Poland (Reg. No: R-26/2018wu) Czech Republic: (Reg. No: 5583-0) UK (Reg. No. 17577)

The SANCO report for Clopyralid (SANCO/10012/2006-rev.3 – 4/04/2006) 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.~~

The Annex I Inclusion Directive for Clopyralid (**2006/64/EC**) 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 pay particular attention to the:

- 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.

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

Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substance.

Noticed data gaps are:

- none

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name:	PROPLAN- Plant Protection Company, S.L
Address:	C/ Valle del Roncal 12-Oficina 7, 28232- Las Rozas, Madrid. Spain.
Contact:	xxx
Phone:	xxxx
FAX:	xxxx
E-mail:	xxx

EU Contact Point:

Name:	PROPLAN- Plant Protection Company, S.L
Address:	C/ Valle del Roncal 12-Oficina 7, 28232- Las Rozas, Madrid. Spain.
Contact:	xxx
Phone:	xxx
FAX:	xxx
E-mail:	xxx

1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

1.2.1 Producer(s) of the preparation

Confidential information or data are provided separately (Part C).

1.2.2 Producer(s) of the active substance(s)

Confidential information or data are provided separately (Part C).

1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

1.2.3.1 Active substance 1 (Clopyralid)

Active substance min. **970 975** g/kg

Information on impurities is included with all other confidential information in Part C.

1.2.3.2 Active substance 2

Not required. The product only has one active substance.

1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name: Bariloche / Bariloche 100

Company code number: PP-113H

1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

Information on the formulants is confidential and is included in Part C (Confidential information).

Table 1.4-1: Active substance and variant of the active substance

Active substance / variant	Declared content of the pure active substance / variant (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L)	Technical content** (%w/w)
Clopyralid	100 g/L (10.0% w/v)	92.79 – 113.4	103.1 102.6	9.86 9.75

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers (**970 975** g/kg)

** Based on the density of the formulation = 1.0516 g/ml.

On the basis of information currently available for the active substance notified by the applicant, none of the manufacturing impurities are considered of toxicological or ecotoxicological concern.

1.4.2 Information on the active substance(s) (KCP 1.4.2)

Table 1.4-2: Information on Clopyralid

Type	Clopyralid
ISO common name	Clopyralid
CAS No.	1702-17-6
EC No.	-
CIPAC No.	455

1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

CONFIDENTIAL information is provided separately (Part C).

1.5 Type and code of the plant protection product (KCP 1.5)

Type: Soluble Concentrate

[Code: SL]

1.6 Function (KCP 1.6)

Herbicide.

2 Section 2: Physical, chemical and technical properties of the plant protection product

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of 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.

Use concentration (proposed by the applicant):

maximum use concentration: 1.5% (v/v)

minimum use concentration: 0.3 % (v/v)

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

Not classified.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

Classification and Hazard Statements. According to Regulation (EC) No. 1272/2008.		Classification and <u>R- Phrases</u> . According to European Directive 67/548/EEC and Directive 1999/45 as amended	
Classification	Hazards Statements	Classification	Risk Phrases
Not classified	None	No classified	None

Compliance with FAO specifications:

The product PP-113H complies with FAO specifications.

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

Formulation used for tests

The product used in the tests has the same composition as the one cited in Part C.

Table 2-1: Physical, chemical and technical properties of the plant protection product

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Visual examination of the physical state and colour and olfactory test	PP-113H	The observations from three inspectors were quite similar. The results of the observations were: -Physical state: Liquid -Colour: Faint yellow -Odour: Characteristic	Y	Pardo, M. Report No: CH-390/2011	The study was submitted during the first registration of the product and is still acceptable. Accepted.
Explosive properties (KCP 2.2.1)	Method A.14-Explosive properties	PP-113H	PP-113H (Clopyralid 10% w/v SL) has not explosive properties.	Y	Špásová, R. Report No: 206-11-50	The study was submitted during the first registration of the product and is still acceptable. Accepted.
Oxidizing properties (KCP 2.2.2)	EEC Method A.21		PP-113H (Clopyralid 10% w/v SL) is not an oxidising substance.	Y	Mazzei, N. Report No: 201105437	The study was submitted during the first registration of the product and is still acceptable. Accepted.
Flash point (KCP 2.3.1)	-	-	Not relevant since the preparation is an aqueous solution and does not contain any flammable liquid.	-	-	The statement was submitted during the first registration of the product and is still acceptable. Accepted.
Flammability (KCP 2.3.2)	-	-	Not required because the preparation is a liquid.	-	-	
Self-heating (KCP 2.3.3)	Method A.15	PP-113H	Auto-ignition temperature is 475.6 ± 9.5 °C at 755.2 mmHg.	Y	Romo, S. Report No: E12097	The study was submitted during the first registration of the

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						product and is still acceptable. Accepted.
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 75.3	PP-113H	The pH value of 1% w/v aqueous dispersion of the PP-113H (Clopyralid 10% w/v SL) sample is 6.4 (rounded mean value of two measurements). Since the obtained pH value was in the range 4 to 10, the acidity or alkalinity was not performed.	Y	Pardo, M. Report No: CH-391/2011	In the case of aqueous preparations, the pH value of the neat preparation should be determined. However, it is not expected that pH of neat formulation would require performing the acidity/alkalinity test or trigger classification, therefore it can still be acceptable. Accepted.
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	PP-113H	The pH value of 1% w/v aqueous dispersion of the PP-113H (Clopyralid 10% w/v SL) sample is 6.4 (rounded mean value of two measurements).	Y	Pardo, M. Report No: CH-391/2011	The study was submitted during the first registration of the product and is still acceptable. Accepted.
Viscosity (KCP 2.5.1)	OECD No 114 and CIPAC MT 22.1	PP-113H	The kinematic viscosity ranges are: 20 °C = (2.41 cSt) 40.1 °C = (1.75 cSt) The dynamic viscosity ranges are: 20 °C = (2.53 cP) 40.1 °C = (1.84 cP)	Y	Pardo, M. Report No: CH-395/2011	The study was submitted during the first registration of the product and is still acceptable. Accepted.
Surface tension (KCP 2.5.2)	OECD No 115 EEC 4.5.	PP-113H	The surface tension at 20°C of the undiluted test item was 26.2 mN/m and the surface tension at 20°C of 0.125 L/hL and 1.0 L/hL test item aqueous solutions was 45.1 mN/m and 28.4 mN/m, respectively.	Y	Pardo, M. Report No: CH-694/2012	The study was submitted during the first registration of the product and is still

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			The PP-113H sample should be regarded as a surface-active material.			acceptable. The product is surface active. Accepted.
Relative density (KCP 2.6.1)	CIPAC MT 3.2 (iv)	PP-113H	The density of the PP-113H sample is 1.0516 g/mL at 20 ± 0.5 °C; the specific gravity is 1.0535 at 20 ± 0.5 °C, and the relative density (D ₂₀ ²⁰) is 1.0516.	Y	Pardo, M. Report No: CH-392/2011	The study was submitted during the first registration of the product and is still acceptable. Accepted.
	CIPAC MT 3.2 OECD No. 109 EC 440/2008 No. A3	PP-113H Batch no 20190506	Density: 1.0470 g/mL at 20°C. Relative density (D ₂₀ ²⁰): 1.0470 at 20°C.		Pardo, M. Report No. CH-406/2019.	Accepted.
Bulk density (KCP 2.6.2)	-	-	Not required, PP-113H is a liquid formulation.	-	-	
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46	PP-113H	PP-113H formulation sample is stable in its commercial packaging under the tested accelerated conditions.	Y	Pardo, M. Report No: CH-398/2011	The study was submitted during the first registration of the product and is still acceptable. Accepted.
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not applicable, product was stable after testing at 54°C (results table at the end of this point).	-	-	
Minimum content after heat stability testing (KCP 2.7.3)	-	-	Refer to Point IIIA 2.7.1. Product was stable after testing at 54°C.	-	-	
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	PP-113H	The PP-113H sample did not show separation of solid or liquid material, not changes in its physical state. PP-113H was stable at 0 ± 2 °C over the 7 days period.	-	Pardo, M. Report No: CH-396/2011	The study was submitted during the first registration of the product and is still

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						acceptable. Accepted.
Ambient temperature shelf life (KCP 2.7.5)	CIPAC MT 18 CIPAC MT 75.3 CIPAC MT 41	PP-113H	It can be concluded that the PP-113H formulation sample is physically and chemically stable in its commercial packaging during 24 months storage at ambient warehouse temperature.	Y	Pardo, M. Report No: CH-399/2011	The study was submitted during the first registration of the product and is still acceptable. The test was performed in HDPE commercial packaging. Accepted.
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Please refer to point 2.7.5.	-	-	
Wettability (KCP 2.8.1)	-	-	Not required, PP-113H is a SL liquid.	-	-	
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.2 and CIPAC MT 18	PP-113H	After one minute, the persistent foaming of PP-113H formulation sample was 1 mL for 0.125 L/hL suspension and 59 mL for 1.0 L/hL suspension.	Y	Pardo, M. Report No: CH-393/2011	According to GAP, the maximum recommended concentration is 1.5 L/hL. The persistent foam was tested at a concentration of 1% (report CH-393/2011) which was lower than the highest recommended concentration and results indicated that at the max recommended concentration the amount of foam would exceed the limit of 60
	CIPAC MT 47.1	PP-113H Batch no 20140917 (Clopyralid 10% w/v SL)	After one minute, the persistent foaming of PP-113H formulation sample was 0 mL for 0.075 and 1.25% w/v suspension in CIPAC standard water 4 D .	Y	Romi S Report No: E14103	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						mL. During the first commenting period, the Applicant submitted a statement that in the field trials the product did not produce any foam and a new study (report E14103) in which the concentration tested was 1.25% and with results of 0 mL of foam after 1 min. As the second study was accepted during the first authorisation and the results were within limits it should be still acceptable. Accepted
Suspensibility (KCP 2.8.3.1)	-	-	Not required, PP-113H is an SL formulation.	-	-	
Spontaneity of dispersion (KCP 2.8.3.2)	-	-	Not required, PP-113H is an SL formulation.	-	-	
Dispersion stability (KCP 2.8.3.3)	-	-	Not required, PP-113H is an SL formulation.	-	-	
Degree of dissolution and dilution stability (KCP 2.8.4)	CIPAC MT 41 and CIPAC MT 18	PP-113H	The PP-113H sample did not show separation of solid or liquid material, not changes in its physical state. PP-113 was stable at 20 ± 2 °C over 18 hours period.	Y	Pardo, M. Report No: CH-394/2011	The study was submitted during the first registration of the product and is still acceptable. Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	-	-	Not required, PP-113H is a liquid formulation.	-	-	
Wet sieve test (KCP 2.8.5.1.2)	-	-	Not required for a SL formulation	-	-	
Dust content (KCP 2.8.5.2.1)	-	-	Not required, PP-113H is a liquid formulation.	-	-	
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not required, PP-113H is a liquid formulation.	-	-	
Attrition (KCP 2.8.5.3)	-	-	Not required for a SL formulation	-	-	
Hardness and integrity (KCP 2.8.5.4)	-	-	Not required for a SL formulation	-	-	
Emulsifiability (KCP 2.8.6.1)	-	-	Not applicable, product does not from an emulsion.	-	-	
Emulsion stability (KCP 2.8.6.2)	-	-	Not applicable, product does not from an emulsion.	-	-	
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not applicable, product does not from an emulsion.	-	-	
Flowability (KCP 2.8.7.1)	-	-	Not applicable, product does not from an emulsion.	-	-	
Pourability (KCP 2.8.7.2)	-	-	Not applicable, product is not a suspension	-	-	
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not applicable, product is not a dustable powder.	-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not required, no mixtures are mentioned on product labels.	-	-	
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not required, no mixtures are mentioned on product labels.	-	-	
Adhesion to seeds (KCP 2.10.1)	-	-	Not required PP-113H is not used for seed treatment.	-	-	
Distribution to seed (KCP 2.10.2)	-	-	Not required PP-113H is not used for seed treatment.	-	-	
Other/special studies (KCP 2.11)	-	-	No other/special studies are necessary.	-	-	

Accelerated Storage Test Result

(Aftern 14 days of storage at 54°C, the data recorded for the sample from the **HDPE HDPE** bottle)

Test	Method	PP-113H (Clopyralid 10 % w/v SL) Initial characterisation	PP-113H (Clopyralid 10 % w/v SL) After 14 days at 54°C
Packaging	-	1 L HDPE bottle with screw cap	500 mL HDPE bottle with screw cap
Clopyralid a.i. content	No. 397/2011	9.5 ± 0.1 % w/w 99 ± 1 g/L	9.4 ± 0.1 % w/w 99 ± 1 g/L
Weight variation (%)	-	-	"A": - 0.05% "B": - 0.17%
Compatibility (resistance) of the packaging material	-	-	The container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena
Physical state (appearance), Colour and Odour	OPPTS 830.6302; OPPTS 830.6303; OPPTS 830.6304	Faint yellow liquid with characteristic odour	Faint yellow liquid with characteristic odour
pH value	CIPAC MT 75.3	6.4	6.2
Dilution stability	CIPAC MT 41 and MT 18	No visual separation of solid or liquid material in the homogeneous suspension.	No visual separation of solid or liquid material in the homogeneous suspension.

Results after 6, 12 and 24 months storage at ambient warehouse temperature

Test	After 6 months storage	After 12 months storage	After 24 months storage
Packaging	HDPE bottle "C"	HDPE bottle "D"	HDPE bottle "E"
Weight variation (%)	- 0.03%	- 0.01%	E:- 0.02% F:-0.02%
Clopyralid a.i. content	9.6 ± 0.1 % w/w 10.1 ± 0.1 % w/v 101 ± 1 g/L (*)	9.6 ± 0.1 % w/w 10.1 ± 0.1 % w/v 101 ± 1 g/L (*)	9.7 ± 0.1 % w/w 10.2 ± 0.1 % w/v 102 ± 1 g/L (*)
Appearance (Colour, odour and physical state)	Faint yellow liquid with characteristic odour	Faint yellow liquid with characteristic odour	Faint yellow liquid with characteristic odour
pH value (1% aqueous dilution)	6.1	6.0	4.5
Dilution stability of herbicide aqueous solutions	Homogeneous suspension after 18 hours at 20 ± 2°C	Homogeneous suspension after 18 hours at 20 ± 2°C	Homogeneous suspension after 18 hours at 20 ± 2°C
Compatibility (resistance) of the packaging material (Visual examination of packaging both externally and internally)	The container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena	The container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena	The container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena

(*) The value expressed in g/L was obtaining considering a 1.0516 g/mL density value, calculated in GLP Study CH – 392/2011

3 Section 3 is presented as a separate document

Please refer to the separate file "dRR Part B3".

4 Section 4: Further information on the plant protection product

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

Comments of zRMS:	In the shelf-life study, the formulation was stored in bottles made of HDPE and the packaging remained stable during the storage, therefore, the proposed commercial packs are considered acceptable.
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Table 4.1-1: Packaging information for 250 ml Packaging

Specification	3069.0
Description	ROUND BOTTLE
Article	818/842 250 ml
Material	HDPE HDPE
Colors	White / Crude/ others on demand
Weights	30 ± 2.0 g
Spill capacity	300 ml
Recommended tightening torque (PBI 7)	3.20 Nxm
Engravings	ALCION IDENTIFICATION FIGURE CLOCK CALENDAR SUPPORTS MATERIAL APPROVAL CODE: UN 1H1/Y1.3/150/... DANGER SYMBOL FOR THE BLIND
<i>Article dimensions</i>	
Inside neck Ø	41.70 mm
External threads Ø	49.60 mm
Neck height	18.70 mm
Total height	126.50 mm
Package Ø	62.50 mm

Table 4.1-2: Packaging information for 500 ml Packaging

Specification	3027.0
Description	ROUND BOTTLE
Article	818/842 500 ml
Material	HDPE HDPE
Colors	White
Weights	60 ± 3.4 g
Spill capacity	550 ml
Recommended tightening torque (PBI 7)	3.20 Nxm

Engravings	ALCION INDENTIFICATION FIGURE CLOCK CALENDAR SUPPORTS MATERIAL APPROVAL CODE: UN 1H1/Y1.3/150/... DANGER SYMBOL FOR THE BLIND
<i>Article dimensions</i>	
Inside neck Ø	41.70 mm
External threads Ø	49.60 mm
Neck height	18.70 mm
Total height	188.50 mm
Package Ø	69.50 mm

Table 4.1-3: Packaging information for 1000 ml Packaging

Specification	3014.0
Description	ROUND BOTTLE
Article	818/842 1000 ml
Material	HDPE HDPE
Colors	White
Weights	80 > 100 ± 3.4 g 100 > 120 ± 4.0 g
Spill capacity	1155 ml
Recommended tightening torque (PBI 7)	3.20 Nxm
Engravings	ALCION INDENTIFICATION FIGURE CLOCK CALENDAR MATERIAL TACTILE WARNING OF DANGER APPROVAL CODE: UN 1H1/Y1.3/150/...
<i>Article dimensions</i>	
Inside neck Ø	41.70 mm
External threads Ø	49.60 mm
Neck height	18.70 mm
Total height	240 mm
Package Ø	89.0 mm

Table 4.1-4: Packaging information for 5000 ml Packaging

Specification	3075.0
Article	813/248 5000 ml 813/848 5000 ml
Material	HDPE HDPE
Colors	Crude / White / other on demand
Weights	280<230 ± 6.25 g 230<200 ± 5.10 g
Spill capacity	5710 ± 30 ml
Recommended tightening torque (<i>PBI 7</i>)	3.85 Nxm
Engravings	ALCION VALENCIA IDENTIFICATION FIGURE CLOCK CALENDAR SUPPORTS/BARRIERE MATERIAL APPROVAL CODE: UN 3H1/Y1.3/150/...
<i>Article dimensions</i>	
Inside neck Ø	54.7 mm
External threads Ø	63.0 mm
Neck height	27.4 mm
Total height	285 mm
Width package	136 mm
Long package	192.0 mm
Long strip	189.0 mm

Appendix 1 Lists of data considered in support of the evaluation

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	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.l. (Italy) Report No: CH-390/2011 GLP, Unpublished	N	PROPLAN
KCP 2.2.1	Špásová, 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	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	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	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.l. (Italy) Report No: CH-391/2011 GLP, Unpublished	N	PROPLAN
KCP 2.5.1	Pardo, M	2011	PP-113H (Clopyralid 10% w/v SL): Determination of the viscosity. ChemService S.r.l. (Italy)	N	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	Owner
			Report No: CH-395/2011 GLP, Unpublished		
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	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	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	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	PROPLAN
KCP 2.7.4	Pardo, M	2011	PP-113H (Clopyralid 10% w/v SL): Determination of the low temperature stability. ChemService S.r.I. (Italy) Report No: CH-396/2011 GLP, Unpublished	N	PROPLAN
KCP 2.7.5	Pardo, M	2011	PP-113H (Clopyralid 10% w/v SL): Two years storage stability and corrosion characteristics. ChemService S.r.I. (Italy) Report No: CH-399/2011	N	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	Owner
			GLP, Unpublished		
KCP 2.8.2	Pardo, M	2011	PP-113H (Clopyralid 10% w/v SL): Determination of the persistent foaming. ChemService S.r.l. (Italy) Report No: CH-393/2011 GLP, Unpublished	N	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	PROPLAN
KCP 2.8.4	Pardo, M	2011	PP-113H (Clopyralid 10% w/v SL): Determination of the dilution stability. ChemService S.r.l. (Italy) Report No: CH-394/2011 GLP, Unpublished	N	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	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	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	Owner

Appendix 2 Additional data on the physical, chemical and technical properties of the active substance

Not required.