

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: SHA 1100 D

Product name(s): CANDELA

Chemical active substance:

glyphosate, 540 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Sharda Cropchem España S.L.

Submission date: February 2018

MS Finalisation date: 18/10/2022

Version history

When	What
10/2018	Dossier sent for evaluation to Merit Mark (PL)
10/2021	zRMS finalised evaluation
10/2022	Final version prepared by zRMS after Commenting period

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Evaluator comments:

The text highlighted in grey was provided by the evaluator.

0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application was submitted by Sharda Cropchem España S.L. for the approval of CANDELA, a soluble concentrate formulation containing 540 g/l of Glyphosate, for use on winter cereals, spring barley, oilseed rape, sunflower, maize, pome fruit, grapevine and stone fruit as a herbicide and on winter wheat as a desiccant.

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

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)
Northern zone	NR	NR
Central zone	Poland CANDELA	Czech Republic Germany Hungary Netherlands Romania Slovakia Slovenia United Kingdom CANDELA
Southern zone	NR	NR

0.1.3 Regulatory history of the active(s)

0.1.3.1 Glyphosate

Table 0.1-2: Summary of regulatory history of CAS No: 1071-83-6

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) 2017/2324
RMS	Germany
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	16/12/2017
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	16/03/2018
Date of final Commission (re-registration) deadline (Step 2)	15/12/2018

Status	
Current expiration of approval	15/12/2022
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 protection of the groundwater in vulnerable areas, in particular with respect to non-crop uses,-
- the protection of operators and amateur users,
- the risk to terrestrial vertebrates and non-target terrestrial plants,
- the risk to diversity and abundance of non-target terrestrial arthropods and vertebrates via trophic interactions,
- compliance of pre-harvest uses with good agricultural practices.

Conditions of use shall include risk mitigation measures, where appropriate. Member States shall ensure that use of plant protection products containing glyphosate is minimised in the specific areas listed in Article 12(a) of Directive 2009/128/EC. Member States shall ensure equivalence between the specifications of the technical material, as commercially manufactured, and those of the test material used in the toxicological studies. Member States shall ensure that plant protection products containing glyphosate do not contain the co-formulant POE-tallowamine (CAS No 61791-26-2).

The review report for glyphosate (SANTE/10441/2017 Rev 2 – 9 November 2017) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report (EFSA Journal 2015;13(11):4302) was made available on 12 November 2015.

Table 0.1-3: Information on minimum purity of glyphosate

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
950 g/kg	minimum purity of active substance 950 g/kg 955 Equivalence report available: Y RMS: DE UK

* 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.

0.1.4 Regulatory history of the product (if relevant)

Not relevant as the product has not yet been authorised

0.2 zRMS conclusion

Section 1, 2 and 4. Identity, physical and chemical properties and further information

Missing data on levels of glyphosate's relevant impurities in the PPP in the two-year study should be available in 2022. They may be completed and assessed in post-registration at national level.

Section 3. Efficacy

The evaluation of the application of Candela Energy resulted in the decision to grant authorization for use according to the GAP table.

Section 5. Analytical methods

The analytical methods used accepted.

Section 6. Mammalian Toxicology

Operator: Taking into account the classification of the product (Eye Irrit.2, H319) and the exposure data, the product SHA 1100 D/Candela Energy containing glyphosate (540 g/L) in accordance to the list of intended uses presented in the GAP Table causes no health risk for the operator assuming the eye protection/face protection, protective gloves and work wear (arms, body and legs covered) during mixing and loading and work wear during application are used.

Worker: The estimations performed according to EUROPOEM II suggest that the use of SHA 1100 D/Candela Energy containing glyphosate (540 g/L) in accordance to the list of intended uses presented in the GAP Table, causes no health risk for the worker assuming the workwear (arms, body and legs covered) and gloves are used.

Bystander/resident: The incidental short-time exposure of bystander and resident (children and adult) to glyphosate (540 g/kg) contained in the formulation SHA 1100 D/Candela Energy causes no risk to human health if the product is used in accordance to the intended uses listed in the GAP Table.

Section 7. Metabolism and Residues

Within the presented dRR no new data were submitted. All the data presented were evaluated. On the basis of the presented data the intended GAP can be accepted within Central Zone except the desiccation use (2). The desiccation use should be considered on an individual basis at the level of each Member State.

Section 8. Environmental Fate

In accordance with proposed pattern use, an exposure assessment for the formulation Candela Energy was submitted and sufficient.

Section 9. Ecotoxicology:

Based on the risk assessment in section of ecotoxicology it can be concluded that the proposed use of SHA 1100 D/Candela Energy as herbicide poses acceptable risk to non-target organisms, if applied according to the recommended use pattern. Particular precautions to reduce the environmental concentrations resulting from SHA 1100 D/Candela Energy applications are required for non-target terrestrial plants.

Section 10. Assessment of the relevance of metabolites in groundwater

Since none of the metabolites can be found in groundwater in a concentration equal to or higher than 0.1 µg/L, there is no need to perform toxicological assessment.

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

1, 3-8

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

2, 9

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:

Section B9: Use No. 1, 3-6 – Risk assessment for mammals: the acceptability of the revised endpoint used in the higher-tier long-term assessment for uses before seedling should be reviewed at national level.

Appendix 1 ALL intended uses

PPP (product name/code): CANDELA/SHA 1100D
Active substance 1: glyphosate
Active substance 2: -
Safener: -
Synergist: -
Applicant: SHARDA Cropchem España S.L.
Zone(s): Central
Verified by MS: yes/~~no~~

Formulation type:
Conc. of as 1:
Conc. of as 2:
Conc. of safener:
Conc. of synergist:
Professional use:
Non professional use:

Field of use: Herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fnp G, Gn, Gnp or I **	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between appli- cations (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	CEU	Winter cereals (wheat, barley, rye, oats, triticale)	F	Annual and perennial grass and broadleaved weeds	Foliar Spray	Application before seedling	a) 1 b) 1	-	a) 2 b) 2	a) 1.08 b) 1.08	200-400		
2	CEU	Winter wheat	F	Dessication before harvest	Foliar Spray	BBCH 89	a) 1 b) 1	-	a) 2 b) 2	a) 1.08 b) 1.08	200-400	7	
3	CEU	Winter Oilseed rape	F	Annual and perennial grass and broadleaved weeds	Foliar Spray	Application before seedling	a) 1 b) 1	-	a) 2 b) 2	a) 1.08 b) 1.08	200-400		
4	CEU	Spring barley, spring wheat	F	Annual and perennial grass and broadleaved weeds	Foliar Spray	Application before seedling	a) 1 b) 1	-	a) 2 b) 2	a) 1.08 b) 1.08	200-400		
5	CEU	Sunflower	F	Annual and perennial grass and broadleaved weeds	Foliar Spray	Application before seedling	a) 1 b) 1	-	a) 2 b) 2	a) 1.08 b) 1.08	200-400		

6	CEU	Maize	F	Annual and perennial grass and broadleaved weeds	Foliar Spray	Application before seedling	a) 1 b) 1	-	a) 2 b) 2	a) 1.08 b) 1.08	200-400		
7	CEU	Pome fruit (Apple, pear)	F	Annual and perennial grass and broadleaved weeds	Foliar Spray	Spring application BBCH 31-69	a) 1 b) 1	-	a) 2 b) 2	a) 1.08 b) 1.08	800-1000		
8	CEU	Grapevine	F	Annual and perennial grass and broadleaved weeds	Foliar Spray	Spring application BBCH 13-69	a) 1 b) 1	-	a) 2 b) 2	a) 1.08 b) 1.08	600-1000		
9	CEU	Stone fruit (Peach, apricot, plum, cherry)	F	Annual and perennial grass and broadleaved weeds	Foliar Spray	Spring application BBCH 31-59	a) 1 b) 1	-	a) 2 b) 2	a) 1.08 b) 1.08	800-1000		

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