

FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: SHA 1100 D

Product name(s): CANDELA

Chemical active substance:

glyphosate, 540 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT

Poland

(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

Table of Contents

1	Details of the application	5
1.1	Application background	5
1.2	Letters of Access	5
1.3	Justification for submission of tests and studies	5
1.4	Data protection claims	5
2	Details of the authorization decision	5
2.1	Product identity	5
2.2	Conclusion	5
2.3	Substances of concern for national monitoring	5
2.4	Classification and labelling	6
2.4.1	Classification and labelling under Regulation (EC) No 1272/2008	6
2.4.2	Standard phrases under Regulation (EU) No 547/2011	7
2.4.3	Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)	7
2.5	Risk management	7
2.5.1	Restrictions linked to the PPP	7
2.5.2	Specific restrictions linked to the intended uses	7
2.6	Intended uses (only NATIONAL GAP)	8
3	Background of authorization decision and risk management	10
3.1	Physical and chemical properties (Part B, Section 2)	10
3.2	Efficacy (Part B, Section 3)	10
3.3	Efficacy data	10
3.3.1	Information on the occurrence or possible occurrence of the development of resistance	13
3.3.2	Adverse effects on treated crops	13
3.3.3	Observations on other undesirable or unintended side-effects	14
3.4	Methods of analysis (Part B, Section 5)	14
3.4.1	Analytical method for the formulation	14
3.4.2	Analytical methods for residues	16
3.5	Mammalian toxicology (Part B, Section 6)	16
3.5.1	Acute toxicity	16
3.5.2	Operator exposure	17
3.5.3	Worker exposure	18
3.5.4	Bystander and resident exposure	18
3.6	Residues and consumer exposure (Part B, Section 7)	18
3.6.1	Residues	18
3.6.2	Consumer exposure	19
3.7	Environmental fate and behaviour (Part B, Section 8)	19
3.7.1	Predicted environmental concentrations in soil (PEC _{soil})	19
3.7.2	Predicted environmental concentrations in groundwater (PEC _{gw})	20
3.7.3	Predicted environmental concentrations in surface water (PEC _{sw})	20
3.7.4	Predicted environmental concentrations in air (PEC _{air})	20
3.8	Ecotoxicology (Part B, Section 9)	20

3.8.1	Effects on terrestrial vertebrates	20
3.8.2	Effects on aquatic species	20
3.8.3	Effects on bees	20
3.8.4	Effects on other arthropod species other than bees.....	20
3.8.5	Effects on soil organisms	20
3.8.6	Effects on non-target terrestrial plants	21
3.8.7	Effects on other terrestrial organisms (Flora and Fauna).....	21
3.9	Relevance of metabolites (Part B, Section 10)	21
Appendix 1	Copy of the product authorization	21
Appendix 2	Copy of the product label	22
Appendix 3	Letter of Access	27
Appendix 4	Lists of data considered for national authorization.....	28

PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application was submitted by Sharda Poland Sp. z o.o.

The application is 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.

1.2 Letters of Access

The information was provided that the sufficient LoA is in possession of the relevant authority (MRiRW).

1.3 Justification for submission of tests and studies

This dossier relies on test and studies providing data and information specific to the formulation Glyphosate 54% SL as required by EU regulations.

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	SHA 1100 D
Product name in MS	CANDELA
Authorization number	First authorisation
Function	Herbicide and desiccant
Applicant	Sharda Poland Sp. z o.o
Active substance(s) (incl. content)	Glyphosate; 540 g/L
Formulation type	Soluble concentrate [Code: SL]
Packaging	1 L, 5 L, 10 L, 20 L HDPE, 200 L professional user
Coformulants of concern for national authorizations	-
Restrictions related to identity	-
Mandatory tank mixtures	-
Recommended tank mixtures	-

2.2 Conclusion

2.3 Substances of concern for national monitoring

Not relevant

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Eye Irrit.2 Aquatic Chronic 2
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label** is **formatted bold**:

Hazard pictograms:	GHS 07 GHS09
Signal word:	-
Hazard statement(s):	H319: Causes serious eye irritation H411
Precautionary statement(s):	WARNING SECTION OF THE LABEL (first page): P280: Wear protective eye protection/face protection. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Other section of the label: P270: Do not eat, drink or smoke when using this product. P501: Dispose of contents/container to ... And P280 as follows: Section of precautions for the operators: „Stosować ochronę oczu/twarzy i rękawice ochronne w trakcie przygotowywania cieczy użytkowej oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy użytkowej i w trakcie wykonywania zabiegu.” “Wear eye protection/face protection and protective gloves when preparing in-use dilution and workwear (coverall) during mixing and loading and application. Section of precautions for the workers: „Stosować rękawice ochronne oraz odzież roboczą (długie spodnie, koszula z długim rękawem)” “Wear protective gloves and workwear (long trousers, long-sleeve shirt Section First aid: P305+P351+P338: IF IN EYES P337 + P313 P391, P501
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	-
	-

Special rule for labelling of plant protection product (PPP):

EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
-	-

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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).
SPe3	To protect non-target plants: Respect an unsprayed buffer zone of 10 m to non-agricultural land. OR Respect an unsprayed buffer zone of 5 m associated with a 50% drift reducing methods to non-agricultural land. OR Respect an unsprayed buffer zone of 1 m associated with a 90% drift reducing methods to non-agricultural land.

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

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2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
-	Classification: eye protection/face protection (M/L) Work wear (arms, body and legs covered) M/L and A + gloves M/L
Worker protection:	
-	Work wear (arms, body and legs covered) and gloves
Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
Other specific restrictions	
-	-

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
-	-

2.5.2 Specific restrictions linked to the intended uses

Not relevant.

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code): Glyphosate 54%SL/SHA 1100 D
Active substance 1: glyphosate
Active substance 2: -
Safener: -
Synergist: -
Applicant: SHARDA Cropchem España
Zone(s): central
Verified by MS: yes

Formulation type: SL (Soluble Concentrate)
Conc. of as 1: 540 g/L
Conc. of as 2: -
Conc. of safener: -
Conc. of synergist: -
Professional use: ☒
Non professional use: ☐

GAP rev. 0, date: 2017-September-12th

Field of use: Herbicide, desiccant

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, 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	PL	Winter cereals (wheat, barley, 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	PL	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		
3	PL	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		
4	PL	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		

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		
5	PL	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		
6	PL	Pome fruit (Apple)	F	Annual and perennial grass and broadleaved weeds	Foliar Spray	Spring applica- tion BBCH 31- 69	a) 1 b) 1	-	a) 2 b) 2	a) 1.08 b) 1.08	800-1000		
7	PL	Grapevine	F	Annual and perennial grass and broadleaved weeds	Foliar Spray	Spring applica- tion BBCH 13- 69	a) 1 b) 1	-	a) 2 b) 2	a) 1.08 b) 1.08	600-1000		

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

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, Fnp: 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.

(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.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorization decision and risk management

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of pale yellow liquid, with a non characteristic odour. It is not explosive. The product has a flash point > 100°C. It has a self-ignition temperature of 510°C. In aqueous solution, it has a pH value around 4.52 at 20.5°C. There is no effect of low temperature on the stability of the formulation.

The intended concentration of use is 0.2% to 1%.

3.2 Efficacy (Part B, Section 3)

CANDELA is an herbicide for post-emergence application to a range of crops for the control of annual and perennial grasses and broadleaved weeds. CANDELA is a Soluble Concentrate (SL) formulation containing 540 g/L glyphosate.

In compliance with the GAP the following dose rates are applied for registration:

- Before seeding, single post-emergence application to annual and perennial mono- and dicotyledonous weeds; target rate: 2.0 l/ha
- During growing season (BBCH 31-69) in orchards, single post-emergence application to annual and perennial mono- and dicotyledonous weeds; target rate: 2.0 l/ha
- Pre-harvest, single application for desiccation in winter wheat; target rate: 2.0 L/ha

This document serves the registration of CANDELA in the Central zone of the EU. The objective of this biological assessment dossier is to prove and support the label claims of the herbicidal efficacy and crop safety of CANDELA when applied as proposed in the GAP, i.e. pre-sowing in a range of crops, during the growing season in orchards as well as pre-harvest in winter wheat.

Comprehensive field trials were conducted in Poland, Lithuania, Latvia and the Czech Republic in 2016 and 2017. The trials followed the corresponding EPPO guidelines. The GEP-requirement and the Uniform Principles are taken care of.

The data demonstrate that the weed control and safety to the crop of CANDELA is comparable to that of the glyphosate reference products registered in the EU Central zone, and the applicant therefore wishes to cite the original registrants data on glyphosate now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal evaluator extrapolate from those data.

All efficacy and selectivity trials have been performed in accordance with current requirements and results are deemed to be acceptable.

Evaluator changed target dose of CANDELA product from 3.5 l/ha to 2.0 l/ha because selectivity trials were done for a dose 2.0 l/ha.

The zRMS considers that there is sufficient data to support registration Candela product for control grass and broadleaved weeds in winter cereals (wheat, barley triticale), winter oilseed rape, spring barley, spring wheat, maize, sunflower and orchards (apple, grape vine) in Central zone.

3.3 Efficacy data

Preliminary tests

The activity of glyphosate is well known, as it has been marketed since the beginning of the 1970's by e.g. Monsanto for broad-spectrum control of annual and perennial mono- and dicotyledonous weeds in a wide range of cropping, utility and industrial situations. Based on the knowledge about the active substance (+40 years) and the experiences with CANDELA in the label claimed crops at similar dose rates, the necessary application rates to obtain sufficient control of the weeds are already known. Therefore, preliminary tests in glasshouses and field trials to assess the biological activity of the active substance or dose range for the plant protection product were not deemed necessary.

Minimum effective dose tests

CANDELA was tested in the efficacy trials at a range of dose rates. The purpose of “Section 6.1.2, Minimum effective dose tests” is to demonstrate the dose response of CANDELA on annual and perennial mono- and dicotyledonous weeds when treated post-emergence in a range of crops.

To determine the minimum effective dose rate, 18 trials from the North-east zone (12 trials at seeding, i.e. seven autumn trials and five spring trials, and six apple orchard trials) and two trials from the Maritime zone (vine orchard trials), have been included in this section. In the 20 trials, the level of control obtained by CANDELA was assessed on annual and perennial mono- and dicotyledonous weeds present in the trials.

Control of annual and perennial grass- and broadleaved weeds with autumn application: In order to prove and to support the requested dose rate of 2.0 l/ha CANDELA [1080 g glyphosate per hectare] for the control of annual and perennial grass- and broadleaved weeds in field crops before sowing in the autumn, the assessment results of seven efficacy trials performed in the North-east EPPO zone in 2016 are reported. CANDELA was included in these trials at 2.0 l/ha to demonstrate the recommended dose rate as well as at a lower than recommended dose rate (2.0 l/ha). As the most accurate representation of whole plot product performance, the assessment data at 17-63 days after the application, obtained by visually estimating control obtained by the applied products are summarised and presented.

Based on results achieved in 7 trials, it can be concluded that the recommended dose rate of 2.0 l/ha CANDELA applied once in the autumn is required for consistent control of frequently occurring annual and perennial weed species.

Control of annual and perennial grass- and broadleaved weeds with spring application: In order to prove and to support the requested dose rate of 2.0 l/ha CANDELA [1080 g glyphosate per hectare] for the control of annual and perennial grass- and broadleaved weeds in field crops at sowing in the spring, the assessment results of five efficacy trials performed in the North-east EPPO zone in 2016 (1) and 2017 (4) are reported. CANDELA was included in these trials at 2.0 l/ha to demonstrate the recommended dose rate as well as at lower than recommended dose rates (1.5 l/ha and 2.0 l/ha). As the most accurate representation of whole plot product performance, the assessment data at 12-14 days after the application, obtained by visually estimating control obtained by the applied products are summarised and presented.

Based on results achieved in 5 trials, it can be concluded that the recommended dose rate of 2.0 l/ha CANDELA applied once in the spring is required for consistent control of frequently occurring annual and perennial weed species.

Control of annual and perennial grass- and broadleaved weeds in orchards with application during growing season: In order to prove and to support the requested dose rate of 2.0 l/ha CANDELA [1080 g glyphosate per hectare] for the control of annual and perennial grass- and broadleaved weeds in orchards during the growing season, the assessment results of eight efficacy trials performed in the North-east (6) EPPO zone and the Maritime (2) EPPO zone in 2016 are reported. CANDELA was included in these trials at 3.5 l/ha to demonstrate the recommended dose rate as well as at a lower than recommended dose rate (2.0 l/ha). As the most accurate representation of whole plot product performance, the assessment data at 26-63 days after the application, obtained by visually estimating control obtained by the applied products are summarised and presented.

Based on results achieved in 8 trials, it can be concluded that the recommended dose rate of 3.5 l/ha CANDELA applied once during the growing season is required for consistent control of frequently occurring annual and perennial weed species in orchards.

Conclusion: CANDELA applied at 2.0 l/ha to control annual and perennial grasses broadleaved weeds achieved excellent control of all target weeds. As grasses and broadleaved weeds often occur as a complex of several weed species with different susceptibility towards glyphosate, one application of CANDELA at the recommended rates should be used to efficiently control all weeds claimed on the label.

This document clearly demonstrates that the efficacy and crop safety of CANDELA is equivalent to that of the standard glyphosate reference product from Monsanto. The applicant therefore wishes to cite the original registrant's data on glyphosate now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Efficacy tests and conclusions regarding authorization of intended uses

In total, data from 24 efficacy trials have been included in this biological assessment dossier to support the label claims and recommendations on efficacy and selectivity in the EU Central Registration zone. The included efficacy trials have been conducted in the North-east EPPO zone (22; Poland (10), Latvia (6) and Lithuania (6)) and the Maritime EPPO zone (2; the Czech Republic) in 2016 and 2017.

Desiccation, pre-harvest in winter wheat: CANDELA is recommended applied for desiccation of winter wheat crops before harvest at 2.0 l/ha, however, the glyphosate applied will also have an effect on the annual and perennial weeds present in the winter wheat field. When applied at 2.0 l/ha in the North-east zone, CANDELA obtained good to excellent control when applied to annual and perennial grasses and broadleaved weeds commonly found in cereal field crops. In all species evaluated, the effect obtained with CANDELA was similar to the effect obtained with the glyphosate reference product applied in the trials.

Pre-sowing, post-emergence to weeds: When applied at 2.0 l/ha in the North-east zone, CANDELA obtained good to excellent control when applied to annual and perennial grasses and broadleaved weeds commonly found in cereal-, oilseed rape, maize and sunflower field crops. In all species evaluated, the effect obtained with CANDELA was similar to the effect obtained with the glyphosate reference product applied in the trials.

Orchards, post-emergence to weeds: When applied at 2.0 l/ha in the North-east and the Maritime EPPO zone, CANDELA obtained good to excellent control when applied to annual and perennial grasses and broadleaved weeds commonly found in orchards. In all species evaluated, the effect obtained with CANDELA was similar to the effect obtained with the glyphosate reference product applied in the trials.

Conclusion: Based on the results of 24 field trials carried out in 2016 and 2017, the following can be concluded for the intended use '*Control of annual and perennial grasses and broadleaved weeds*' from CANDELA applied on actively growing weeds at the dose rate of 2.0 l/ha and for the use '*Desiccation before harvest*' at the dose rate of 2.0 L/ha:

- CANDELA provides a high level control of a wide range of annual and perennial mono- and dicotyledonous weeds when applied to emerged, actively growing weeds with the recommended dose rate of 2.0 l/ha. As weeds often occur as a complex of several weeds with different susceptibility towards glyphosate, one application of CANDELA at the recommended rate 2.0 l/ha rate should be used to efficiently control all weeds claimed on the label.
- A high level of control of weeds may also be obtained if CANDELA is used at 2.0 l/ha for desiccation of winter wheat, before harvest.
- Compared to the glyphosate reference product, the efficacy obtained with CANDELA is comparable against all weed species.
- The trial results are considered valid for all intended Central zone countries.

CANDELA is suitable for the control of annual and perennial weeds in a range of crops, when applied before sowing of cereals, oilseed rape, sunflower, maize in the spring or autumn or when applied during the growing season in orchards.

Glyphosate is a broad-spectrum herbicide and irrespective of the cropping system, the same mono- and dicotyledonous weeds are controlled by glyphosate if the weeds are actively growing. When treating actively growing weeds, the same level of control would be expected irrespective if treated in the spring,

summer or autumn and this has been seen in the trials. Therefore, for any label claims not adequately supported for one use, Sharda Cropchem España requests that the Zonal Evaluators reads across to the data on other uses. This document also clearly demonstrates that the efficacy and cropsafety of CANDELA is equivalent to the efficacy and cropsafety of the standard glyphosate reference products against which CANDELA was compared. The applicant therefore wishes to cite the original registrant's data on glyphosate now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

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

Resistance is a natural phenomenon embodied in the process of the evolution of biological systems and has been experienced over and over again in the past. According to Heap (2018¹) resistance is the naturally occurring inheritable ability of some weed biotypes within a population to survive an herbicide treatment that would, under normal conditions of use, effectively control that weed population. Selection of resistant biotypes may eventually result in control failures.

The risk of resistance was analysed following the EPPO-Standard (2015²), the classification of the Herbicide Resistance Action Committee (HRAC)³ and the international Survey of Herbicide Resistant Weeds (Heap 2018). So far, 290 cases in 40 weed species have been reported worldwide to have developed resistance to glyphosate. In Europe, 23 cases of resistance was reported in six weed species. Glyphosate is originally classified as having a low inherent risk of resistance, but excessive use of glyphosate as sole products has greatly increased the incidence of resistance.

The evaluation of the agronomic risk comes to the conclusion, that CANDELA bears a moderate risk of resistance.

The Registration of CANDELA is endorsed.

3.3.2 Adverse effects on treated crops

Phytotoxicity to host crop

Phytotoxicity was assessed in 30 trials, i.e. 24 efficacy trials and 6 crop safety trials, which were conducted in the North-east zone (28; Poland (15), Lithuania (7) and Latvia (6)) and the Maritime zone (2; Czech Republic) in 2016 and 2017.

CANDELA applied at the recommended dose rate did not caused phytotoxicity in any of the trials conducted on cereal-, oilseed rape-, maize- and sunflower field crops as well as in vine- and apple orchards. In the trials where CANDELA was applied at dose rates higher than the recommended, no unacceptable detrimental effects were observed on selectivity, when assessed in any of the trials.

As this document also clearly demonstrates, then the efficacy and crop safety of CANDELA is equivalent to the standard glyphosate product to which it was compared. The applicant wishes to cite the original registrant's data on glyphosate now out of protection in additional support of any recommendations on the draft label that are not adequately supported by the applicant's data and requests that the zonal evaluator extrapolate from those data.

Effects on yield and quality

Five selectivity trials and two efficacy trials were harvested. The trials harvested were conducted in the North-east zone (5) and the Maritime zone (2) in 2016 and 2017 to evaluate the effect of CANDELA on yield of a range of crops where glyphosate was applied before seeding or shortly after seeding.

CANDELA applied at the recommended dose rate did not affect crop yield nor the quality of the crop yield significantly in the any of the seven trials taken to harvest. In all trials, CANDELA applied at dose

¹ Heap, I. M., 2018: The International Survey of Herbicide Resistant Weeds. Web site visited January 2018.
<http://www.weedscience.com>

² EPPO 2015: Standard PP 1/213 (4): Resistance risk analysis.

³ HRAC: <http://www.HRACglobal.com>. Web site visited January 2018.

rates higher than the recommended rate – representative for sprayer overlap – did not significantly affect the crop yield.

Furthermore, the data obtained in trials harvested demonstrate that CANDELA is as safe to the crop as the reference products used in the trials.

As this document clearly demonstrates, the efficacy and crop safety of CANDELA is equivalent to the standard glyphosate product to which it was compared. The applicant therefore wishes to cite the original registrant's data on glyphosate now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Effect on transformation processes

CANDELA is composed of glyphosate which has been widely used for a number years on a range of crops without identifying any quality problems on the treated crops.

CANDELA is recommended applied early in the season (before seeding) or as a desiccant of winter wheat before harvest (BBCH 89). When applied early in the season or as a desiccant before harvest, it is not expected that any significant amounts of residues are present in the grains at harvest. This was also confirmed with data presented in the RAR on glyphosate, section 7.7.2 (Renewal Assessment Report (2013), Vol. III, B7), where results obtained with a number of residue trials are presented.

Impact on treated plants or plant products to be used for propagations

Special tests to investigate this purpose are not required.

Not applicable.

3.3.3 Observations on other undesirable or unintended side-effects

Impact on succeeding crops.

Not relevant.

No significant residue levels are to be expected in rotational crops following application of glyphosate according to the proposed GAP.

Impact on other plants including adjacent crops

Risk assessments were conducted according to EPPO Guideline PP1/256 and the results confirm that no further testing is necessary and that no negative impact on adjacent crops is expected, if applied as recommended.

Effects on beneficial and other non-target organisms

There were no adverse effects on beneficial and other non-target organisms observed in any of the efficacy and crop safety trials conducted.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

	Glyphosate
Author(s), year	Hetal K. Desai, 2017
Principle of method	high performance liquid chromatography on a reversed phase column [C 8 (Inertsil)] using 0.1% ortho phosphoric acid in milli-Q water (100%) as mobile phase and UV detection at 195 nm
Linearity (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as	Concentration range: 50.55 to 407.15 Intercept (a): 3437.74 Slope (b): 1385.76 Correlation coefficient: 0.999

	Glyphosate
r)	
Precision – Repeatability Mean n = 7 (%RSD)	Mean Glyphosae content: 44.06 ± 0.04 %w/w (543.84 ± 0.51 g/L) Mean Glyphosate IPA salt: 59.46 ± 0.06 %w/w (733.91 ± 0.70 g/L) % RSD: 0.09 Acceptable % RSD (Horwitz): 1.52
Accuracy n = 7 (% Recovery)	Lower level (154.90) % recovery: 100.37 Nominal level (203.86) % recovery: 99.65 Upper level (250.78) % recovery: 100.65 Mean % recovery: 100.22 Acceptable limit (SANCO): 98 – 102
Interference/ Specificity	No interference
Comment	-
	N-Nitroso-glyphosate (max. limit 0.44 µg/g (0.44 mg/kg))
Author(s), year	Mercedes Pardo Martinez, 2020
Principle of method	HPLC/UV Confirmatory: HPLC/DAD
Linearity (linear between mg/L) (correlation coefficient, expressed as r)	Five Working Standard Solutions. Nominal injected range from 20 ng/mL to 200 ng/mL, corresponding to a nominal content in the test item from 0.08 µg/g to 0.80 µg/g. Correlation coefficient r > 0.99
Precision – Repeatability Mean n = 5 (%RSD)	1.89
Accuracy (% Recovery)	Low level: 96 % High level: 100.4 %
Interference/ Specificity	The N-Nitroso-glyphosate (N-NO Glyphosate) impurity content in the Glyphosate 54% w/v SL test item was quantified by use of liquid chromatography HPLC/UV. The quantity of the impurity in sample solutions was determined by external standard method. The analytical method was shown to be specific for N-Nitroso-glyphosate impurity in Glyphosate 54% w/v SL sample.
LOQ	0.10 µg/g
Comment	

	Formaldehyde (max. limit 0.44 µg/g (0.44 mg/kg))
Author(s), year	Mercedes Pardo Martinez, 2020
Principle of method	HPLC/UV Confirmatory: HPLC/MS/DAD.
Linearity (linear between mg/L) (correlation coefficient, expressed as r)	Five Working Standard Solutions. Nominal injected range from 80 ng/mL to 8000 ng/mL, corresponding to a nominal content in the test item from 6.00 µg/g to 600.00 µg/g. Each correlation coefficient r > 0.99
Precision – Repeatability Mean n = 5 (%RSD)	the Formaldehyde impurity content was not quantifiable in repeatability test, the precision was determined via the accuracy test with the lowest fortification level.

	Formaldehyde (max. limit 0.44 µg/g (0.44 mg/kg))
	3.01%
Accuracy (% Recovery)	Low level: 79.7 % High level: 93.3 %
Interference/ Specificity	The analytical method results to be specific for formaldehyde impurity in Glyphosate 54% w/v SLsamples.
LOQ	16 µg/g
Comment	

All provided analytical methods used for analysing glyphosate and its relevant impurities in the PPP have been accepted by RMS.

3.4.2 Analytical methods for residues

Data should never be given without reference or source. Data accepted and evaluated during glyphosate renewal.

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC-MS/MS of underivatised analytes with phenyl-hexyl column; LOQ = 0.05 mg/kg for glyphosate and <i>N</i> -acetyl-glyphosate all commodity groups, ILV available For glyphosate confirmatory methods by HPLC with post-column derivatization or by GC-MS after derivatization with trifluoroacetic acid and heptafluorobutanol are available.
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC-MS/MS of underivatised analytes with phenyl-hexyl column; ILV available LOQ = 0.025 mg/kg in meat, milk and egg and 0.05 mg/kg in liver, kidney and fat for glyphosate and <i>N</i> -acetyl-glyphosate A confirmatory GC-MS method based on derivatization with a mixture of trifluoroacetic anhydride and trifluoroethanol.
Soil (analytical technique and LOQ)	GC-MS after derivatization in a mixture of trifluoroacetic anhydride and trifluoroethanol, LOQ = 0.05 mg/kg for glyphosate and AMPA
Water (analytical technique and LOQ)	LC-MS/MS after derivatization with 9-Fluorenylmethylchlorformate (FMOC), LOQ = 0.03 µg/L for glyphosate and AMPA in drinking, ground and surface water, confirmatory LC-MS/MS transition with LOQ = 0.03 µg/L validated, independent laboratory validation for drinking water successfully conducted
Air (analytical technique and LOQ)	GC-MS after derivatization in a mixture of trifluoroacetic anhydride and trifluoroethanol, LOQ = 5 µg/m ³ for glyphosate
Body fluids and tissues (analytical technique and LOQ)	Not required, not classified as toxic or very toxic

3.5 Mammalian toxicology (Part B, Section 6)

Acute toxicity studies for CANDELA were not evaluated as part of the EU review of glyphosate. Therefore, all relevant data were provided and are considered adequate.

The results of *in vivo* acute toxicity studies, as well as additivity formula, we used for toxicity assessment and classification.

3.5.1 Acute toxicity

The results are summarised in the table below:

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)	> 2000 mg/kg bw	Yes	None	XXXXXXXXXXXXX, 2016
LD ₅₀ dermal, rat (OECD 402)	> 2000 mg/kg bw	Yes	None	XXXXXXXXXXXXX, 2016
LC ₅₀ inhalation, rat (OECD 403)	> 3.22 mg/L air	Yes	None	XXXXXXXXXXXXX, 2017
Skin irritation	Non-irritant	Yes Yes	Skin Irrit.2, H315 None (experimental data)	Additivity formula B.S.Yogeesh, 2017
Eye irritation	Non-irritant	Yes Yes	Eye Dam.1, H318 None (experimental data)	Additivity formula B.S.Yogeesh, 2017
Skin sensitisation, guinea pig	Non-sensitising	Yes Supplementary data	None None	Additivity formula XXXXXXXXXXXXX, 2017
Supplementary studies for combinations of plant protection products	No data – not required			

Acc. to Polish Authorities, the results of classification obtained using calculation method presented above justify the use of the experimental data. The results of experimental trials **do not confirm** the data generated with additive formula method and the product SHA 1100 D **should not be classified** regarding acute toxicity. However, despite the conclusions set out above, the applicant requests the product to be classified regarding eye irritation in order to increase the safety of its use by applying appropriate risk mitigation measures. The ZRMS agrees with this approach. Therefore, the formulation SHA 1100 D is classified as: **Eye Irrit. 2, H319**.

3.5.2 Operator exposure

The estimation of operator exposure to glyphosate (540 g/L) contained in the formulation SHA 1100 D / CANDELA based on AOEM is correct. The use of the product CANDELA is safe using tractor mounted sprayer and hand held equipment if appropriate PPE are implemented. Minor calculation corrections (with no effect on the final conclusion) are included.

Conclusions:

The estimations performed according to AOEM indicate that the use of SHA 1100 D / CANDELA 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 work wear (arms, body and legs covered) during mixing, loading and application and gloves during mixing and loading are used.

Taking into account the classification of the product (Eye Irrit.2, H319) and the exposure data, the following sentence regarding the use of PPE is recommended by the evaluator to be placed in the section of precautions for the operators:

„Stosować ochronę oczu/twarzy i rękawice ochronne w trakcie przygotowywania cieczy użytkowej oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy użytkowej i w trakcie wykonywania zabiegu.

“Wear eye protection/face protection and protective gloves when preparing in-use dilution and workwear (coverall) during mixing and loading and application.”

3.5.3 Worker exposure

The estimation of worker exposure to glyphosate (540 g/L) contained in the formulation SHA 1100 D / CANDELA is correct. However, according to the current guidelines of Polish Authorities, the preferred calculation model for worker exposure estimation in case of single use of PPP is EUROPOEM II.

Conclusions:

The estimations performed according to EUROPOEM II suggest that the use of SHA 1100 D / CANDELA 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.

Following sentence regarding the use of PPE is recommended by the evaluator to be placed in the section of precautions for the workers:

„Stosować rękawice ochronne oraz odzież roboczą (długie spodnie, koszula z długim rękawem).

“Wear protective gloves and workwear (long trousers, long-sleeve shirt).

3.5.4 Bystander and resident exposure

The estimations performed according to AOEM, indicate that the systemic exposure to glyphosate (540 g/L) contained in the formulation SHA 1100 D / CANDELA does not exceed the value of AOEL for this active substance.

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 causes no risk to human health if the product is used in accordance to the intended uses listed in the GAP Table.

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

The preparation Glyphosate 54% SL is composed of Glyphosate

Toxicological reference values for the dietary risk assessment of Glyphosate.

Reference value	Source	Year	Value	Study relied upon	Safety factor
Glyphosate					
ADI	Note taking of new reference values Standing Committee on Plants, Animals, Food and Feed of 10/11 December	2015	0.5 mg/kg bw per day	Developmental toxicity, rabbit	100
ARfD		2015	0.5 mg/kg bw	Developmental toxicity, rabbit	100

No risk for consumer was identified.

3.6.1 Residues

The proposed by the applicant GAP was accepted.

February 2021: Dessication use in wheat was removed according to the current authority arrangements in the residues area. All decisions regarding the restoration of desiccation will be taken by MRiRW (PL). The data provided by the applicant are the generally known data in EU and currently not considered a good basis for the approval of desiccation.

Within the presented Candela dRR no new data were submitted. The presented data were taken by the

applicant from EFSA opinions on glyphosate (2015) and glyphosate Renewal Assessment Report to support the intended uses. All the data presented were discussed and evaluated during glyphosate renewal. It can be concluded that the chosen data supports properly the proposed GAP. Moreover the proposed lowered GAP (the twice less rate than EU) for debatable desiccation use does not pose the probability of the adopted MRL exceedance.

Residue definition and MRL

Glyphosate

The **current** residue definition for food of plant origin according to Reg. (EU) No 293/2013 is Glyphosate.

According to the EFSA 2015 - Peer review of the pesticide risk assessment of the active substance glyphosate (EFSA Journal 2015;13(11):4302) the **proposal** of residue definition for monitoring is **sum of glyphosate and N-acetyl-glyphosate, expressed as glyphosate**, for Sweet corn, oilseed rape, soya beans and maize (non-tolerant and tolerant, all modifications), and **glyphosate** for the rest of plant commodities.

For risk assessment the residue definition is Sum of glyphosate, AMPA, N-acetyl-glyphosate and N-acetyl-AMPA, all expressed as glyphosate.

MRLs

The MRLs for Glyphosate are published in Commission Regulation (EU) No 1004/2013 of 06 April 2013 amending the Annex II and IIIB to Regulation (EC) No 396/2005 and are listed in Table 3.1.6.1-1 below.

Table 3.1.6.1-1: EU MRLs set for the uses of Glyphosate

Code number	Crop/group	(mg/kg)
0500090	Wheat	10
0500010	Barley	20
0500070	Rye	10
0500050	Oat	20
0401060	Oilseed rape	10
0401050	Sunflower	20
0500030	Maize	1
0130010	Apple	0.1*
0130020	Pear	0.1*
0140030	Peach	0.1*
0140010	Apricot	0.1*
0140040	Plum	0.1*
0140020	Cherry	0.1*
0151000	Grapevine	0.5

3.6.2 Consumer exposure

The proposed uses of Glyphosate in the formulation CANDELA do not represent unacceptable acute and chronic risks for the consumer.

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

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

The predicted environmental concentrations in soil were calculated based on the EU agreed endpoints for glyphosate, EFSA Journal 2015;13(11):4302.

The risk envelope approach was considered.

Considering the accumulation of active substance, the PEC_{soil} values for glyphosate and its metabolite AMPA were 2.895 mg/kg soil and 2.703 mg/kg soil respectively. For formulation the PEC_{soil} = 5.774 mg a.s./kg soil.

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

The predicted environmental concentrations in ground water and sediment were calculated based on the EU agreed endpoints for glyphosate, EFSA Journal 2015;13(11):4302.

The PEC_{gw} values for active substance glyphosate and its metabolite AMPA were below 0.001 µg/L and below the trigger value of 0.1 µg/L.

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

The predicted environmental concentrations in surface water and sediment were calculated based on the EU agreed endpoints for glyphosate, EFSA Journal 2015;13(11):4302.

The PEC_{SW/SED} of CANDELA has been assessed with the models FOCUS STEP 1/2 for parent and metabolites. No mitigation measures have to be considered for the intended uses.

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

Not relevant.

3.8 Ecotoxicology (Part B, Section 9)

The risk was considered acceptable for terrestrial vertebrates, aquatic organisms, bees, non-target arthropods other than bees and soil meso- and macrofauna as well as soil microflora without the necessity to apply risk mitigation measures. For non-target plants, the risk was considered acceptable based on the deterministic approach including risk mitigation measures such as either 10 m drift buffer OR 5 m drift buffer + 50% drift-reducing nozzles OR 90 % drift-reducing nozzles.

3.8.1 Effects on terrestrial vertebrates

The acute and chronic risks of CANDELA to birds and mammals were assessed from toxicity exposure ratios between toxicity endpoints, estimated from study with active ingredient and maximum residues occurring on food items.

All TER values exceed the relevant triggers indicating that CANDELA does not pose an unacceptable risk to birds and mammals following applications according to recommended use pattern.

Evaluation of exposing to birds and mammals through the drinking water demonstrated the acceptable risk. The risk to earthworm- and fish-eating animals from secondary poisoning is low.

3.8.2 Effects on aquatic species

The risk assessment for aquatic organisms has been done. For all the intended uses, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms in all FOCUS Step 1 for Glyphosate and its metabolites (AMPA and HMPA). A risk to aquatic organisms following the application of CANDELA at the proposed label rate can be excluded.

3.8.3 Effects on bees

The evaluation of the risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SAN-CO/10329/2002 rev.2 (final), October 17, 2002).

The submitted risk assessment, based on laboratory studies, has been accepted. It can therefore be concluded that there will be negligible risk associated with the exposure of bees to CANDELA.

3.8.4 Effects on other arthropod species other than bees

Based on the results of the conducted risk assessment it can be concluded that low risk for non-target arthropods is expected from the use of CANDELA according to the proposed use pattern. No unacceptable effects on non-target arthropods are expected in in-field and off-field habitats.

3.8.5 Effects on soil organisms

All TER values for CANDELA, the active substance and relevant metabolites for chronic exposure of

earthworms and other non-target soil organisms (meso- and macrofauna) are considerably higher than the Commission Regulation (EU) 546/2011 trigger value of 5. This indicates that CANDELA poses no unacceptable risk to earthworms and other non-target soil organisms (meso- and macrofauna) when applied according to the proposed use pattern.

For the formulation CANDELA, the active substances as well as for the relevant metabolites, the maximum concentration with effects < 25% (SANCO/10329/2002 trigger) are all above the maximum PEC_{soil} values. Therefore, it is concluded that the use of CANDELA will not pose an unacceptable risk to non-target soil micro-organisms, if applied according to good agricultural practice.

3.8.6 Effects on non-target terrestrial plants

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev.2 final, 2002).

Based on the probabilistic risk assessment it can be concluded that the proposed use of CANDELA poses acceptable risk to non-target plants, if applied according to the recommended use pattern. Particular precautions to reduce the environmental concentrations resulting from CANDELA applications are required (10 m buffer zone or 5 m with 50% or 1 m with 90% drift reduction techniques).

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

No further relevant data available and considered necessary.

3.9 Relevance of metabolites (Part B, Section 10)

The PEC_{gw} of the AMPA metabolite was <0.001 µg/L for all scenarios and uses, therefore no relevance evaluation is needed.

Appendix 1 Copy of the product authorization

Appendix 2 Copy of the product label

Fizykochemia – brakuje danych dotyczących poziomów istotnych zanieczyszczeń glifosatu w środku przed i po 2 latach przechowywania środka w temperaturze otoczenia. Wnioskodawca poinformował, że te badania są aktualnie wykonywane i zostaną zakończone w 2022 roku. Z tego powodu po ich zakończeniu Wnioskodawca musi przedłożyć te badania do oceny w Polsce w celu pokrycia aktualnych braków w badaniu dwuletnim.

Toksykologia – **zmieniono treść etykiety w zakresie toksykologii.**

Pozostałości – z powodów pozamerytorycznych wykreślono desykacyjne zastosowanie w pszenicy.

Los i zachowanie w środowisku –w uprawie winorośli i jabłoni dodano zapis: „Środek przeznaczony do stosowania przy użyciu opryskiwaczy ręcznych.”

Ekotoksykologia – usunięto hasło ostrzegawcze, skorygowano zapis dotyczący zarządzania ryzykiem dla roślin niebędących celem zwalczania.

Skuteczność działania - w grupie chwastów wrażliwych usunięto chaber bławatek, ponieważ skuteczność była znacznie poniżej wrażliwości, dodano następujące gatunki, które wystąpiły w doświadczeniach: mniszek pospolity, komosa biała, gwiazdnica pospolita (przeniesiona z grupy chwastów średnio wrażliwych), pięciornik gęsi. W akapicie Zakres stosowania, terminy i dawki usunięto żyto i owies ponieważ nie były badane, dodano pszenicę jara, ponieważ była badana, dodano cały akapit Pszenica ozima - zabieg po zbiorze na ściernisko. Usunięto gruszę oraz cały akapit Brzoskwinia, morela, śliwka, wiśnia z powodu braku badań selektywności.

Załącznik do decyzji MRiRW nr R - z dnia r.

Posiadacz zezwolenia: Sharda Poland Sp. z o.o., ul. Bonifraterska 17, 00-203 Warszawa,
xx

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin: ...

CANDELA ENERGY

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji aktywnej:

(związek z grupy aminofosfonianów) w postaci soli izopropylaminowej- 540 g w 1 litrze środka.

Zezwolenie MRiRW nr R - z dnia r.



UWAGA

H319: działa drażniąco na oczy

H411 Działa toksycznie na organizmy wodne, powodując długotrwałe skutki.

EUH401 W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska należy postępować zgodnie z instrukcją użycia.

P280: Stosować ochronę oczu/ochronę twarzy.

P305+P351+P338: W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.

P391 Zebrać wyciek.

P501 Zawartość / pojemnik usuwać zgodnie z przepisami krajowymi.

OPIS DZIAŁANIA

Środek chwastobójczy w formie koncentratu do sporządzania roztworu wodnego, stosowany nalistnie, przeznaczony do zwalczania chwastów jednoliściennych i dwuliściennych (jednorocznych i wieloletnich) na polach uprawnych. Środek przeznaczony do stosowania przy użyciu opryskiwaczy polowych lub opryskiwaczy ręcznych.

DZIAŁANIE NA CHWASTY

CANDELA ENERGY jest dolistnym herbicydem o działaniu układowym. Pobierany jest przez zielone części roślin (liście, zielone pędy i niezdrewniałą korę), a następnie przemieszcza się po całej roślinie i dociera do jej części podziemnych (korzenie, rozłogi itp.) powodując ich zamieranie. Pierwsze objawy działania środka (żółknięcie i więdnienie) są widoczne po upływie 7-10 dni od zabiegu. Całkowite zamieranie roślin następuje po około 3 tygodniach. Wysoka temperatura i wilgotność powietrza oraz silne nasłonecznienie przyspieszają działanie środka.

Chwasty wrażliwe: perz właściwy, ~~ehaber bławatek~~, rogownica polna, rdest ptasi, gorczyca polna, tobołki polne, fiołek polny, mniszek pospolity, komosa biała, gwiazdnica pospolita, pięciornik gęsi

Chwasty średnio wrażliwe: przytulia czepna, jasnota różowa, mak polny, rdestówka powojowata, ~~gwiazdnica pospolita~~, koniczyna biała, przetacznik perski

ZAKRES STOSOWANIA, TEMRINY I DAWKI

Pszenica ozima, jęczmień ozimy, ~~żyto, owies~~, pszenżyto ozime, rzepak ozimy

Jęczmień jary, pszenica jara, ~~rzepak~~, kukurydza, słonecznik

Maksymalna dawka dla jednorazowego zastosowania: 2.0 l/ha

Zalecana dawka dla jednorazowego zastosowania: 2.0 l/ha.

Środek stosować po wschodach chwastów ale przed wschodami rośliny uprawnej

Zalecana ilość wody: 200 – 400 l/ha.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Pszenica ozima – zabieg po zbiorze na ściernisko

Maksymalna dawka dla jednorazowego zastosowania: 2,0 l/ha

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

Środek stosować po wschodach chwastów

Zalecana ilość wody: 200 – 400 l/ha.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Pszenica ozima

Maksymalna dawka dla jednorazowego zastosowania: 2.0 l/ha

Zalecana dawka dla jednorazowego zastosowania: 2.0 l/ha.

Środek stosować w fazie dojrzałości pełnej rośliny : ziarniaki twarde, trudne do podzielenia paznokciem (BBCH 89).

Zalecana ilość wody: 200 – 400 l/ha.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Winorośl

Maksymalna dawka dla jednorazowego zastosowania: 2.0 l/ha

Zalecana dawka dla jednorazowego zastosowania: 2.0 l/ha.

Środek przeznaczony do stosowania przy użyciu opryskiwaczy ręcznych.

Środek stosować w fazie rozwiniętych 3-liści aż do końca kwitnienia rośliny (BBCH 13-69).

Zalecana ilość wody: 600 – 1000 l/ha.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Jabłoń, grusza

Maksymalna dawka dla jednorazowego zastosowania: 2.0 l/ha

Zalecana dawka dla jednorazowego zastosowania: 3.5 2.0 l/ha.

Środek przeznaczony do stosowania przy użyciu opryskiwaczy ręcznych.

Środek stosować od początku wzrostu pędu (widoczny rozwój pędu) aż do końca fazy kwitnienia (wszystkie płatki opadły) (BBCH 31-69).

Zalecana ilość wody: 800 – 1000 l/ha.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Brzoskwinia, morela, śliwka, wiśnia

Maksymalna dawka dla jednorazowego zastosowania: 2.0 l/ha

Zalecana dawka dla jednorazowego zastosowania: 3.5 l/ha.

Środek stosować od początku wzrostu pędu (widoczny rozwój pędu) do końca fazy rozwoju kwiatostanu (BBCH 31-59).

Zalecana ilość wody: 800 – 1000 l/ha.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

NASTĘPSTWO ROŚLIN

Na polu, na którym stosowano CANDELA ENERGY można uprawiać wszystkie rośliny. Zabiegi uprawowe, siew lub sadzenie można rozpocząć po dwóch dniach gdy zwalczano chwasty jednoroczne i po 5 dniach gdy zwalczano chwasty wieloletnie.

ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ

W celu niedopuszczenia do powstania odporności chwastów, środek stosować przemiennie z herbicydami z innych grup chemicznych o odmiennym mechanizmie działania.

Środka nie stosować:

- na rośliny mokre,
- przed spodziewanym deszczem (opad występujący przed upływem 1 godziny po opryskiwaniu może obniżyć skuteczność zabiegu),
- podczas wiatru stwarzającego możliwość znoszenia cieczy użytkowej.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość. Zawartość opakowania przed użyciem wstrząsnąć. Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem) i uzupełnić wodą do potrzebnej ilości.

Po wleciu środka do zbiornika opryskiwacza nie wyposażonego w mieszadło hydrauliczne ciecz w zbiorniku mechanicznie wymieszać.

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową.

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

Po pracy aparaturę dokładnie wymyć.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Z resztkami cieczy użytkowej po zabiegu należy postępować w sposób ograniczający ryzyko skażenia wód powierzchniowych i podziemnych, w rozumieniu przepisów Prawa wodnego oraz skażenia gruntu, tj.:

- po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, jeżeli jest to możliwe, lub,

- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub,
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wmyć.

WARUNKI BEZPIECZNEGO STOSOWANIA ŚRODKA

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy roboczej i które zwróciły się o taką informację.

Środki ostrożności dla osób stosujących środek:

Nie jeść, nie pić ani nie palić podczas używania produktu.

Stosować ochronę oczu/twarzy i rękawice ochronne w trakcie przygotowywania cieczy użytkowej oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy użytkowej i w trakcie wykonywania zabiegu.

Unikać wdychania rozpylonej cieczy.

Środki ostrożności dla pracowników polowych:

Stosować rękawice ochronne oraz odzież roboczą (długie spodnie, koszula z długim rękawem).

Środki ostrożności związane z ochroną środowiska naturalnego:

Zebrać wyciek.

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 roślin niebędących obiektem zwalczania konieczne jest określenie strefy ochronnej w odległości 10m lub 5m lub + 50% lub 90% redukcje znosu przy pomocy dysz od terenów nieużytkowanych rolniczo.~~

W celu ochrony roślin niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 10 m od terenów nieużytkowanych rolniczo lub strefy ochronnej o szerokości 5 m od terenów nieużytkowanych rolniczo z równoczesnym zastosowaniem metod redukujących znoszenie cieczy użytkowej podczas zabiegu o 50 %, lub 1m i redukcji znosu chmury oprysku na poziomie 90%.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta:

Nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin

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

Pszenica ozima – 7 dni

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

Nie dotyczy

Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następnie:

Nie dotyczy

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,

- w oryginalnych opakowaniach, w sposób uniemożliwiających kontakt z żywnością, napojami lub paszą

- w temperaturze 0°C - 30°C.

Zabrania się wykorzystywania opróżnionych.

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

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych. Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza należy pokazać pojemnik lub etykietę.

W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.

W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

W PRZYPADKU DOSTANIA SIĘ DO DRÓG ODDECHOWYCH: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić warunki do odpoczynku w pozycji umożliwiającej swobodne oddychanie.

W przypadku złego samopoczucia skontaktować się z OŚRODKIEM ZATRUĆ lub lekarzem.

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access



镇江江南化工有限公司
ZHENJIANG JIANGNAN CHEMICALS CO., LTD.
ADD: International Chemical Industry Park,
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TEL: +86-511-83362910 FAX: +86-511-83357692
P.O.: 212152

**Ministry of Agriculture and Rural Development
Department of Plant Breeding and Plant Protection
00-930 Warsaw, Wspólna No. 30, Poland**

LETTER OF SUPPLY FOR GLYPHOSATE

TO WHOM IT MAY CONCERN:

We, Zhenjiang Jiangnan Chemicals Co. Ltd., hereby certify that we supply Glyphosate technical (min. 95.5% w/w) from our manufacturing facilities located at International Chemical Industry Park, Zhenjiang New Area, 212152 Jiangsu - China to Sharda Cropchem Ltd. to formulate the plant protection product **CANDELA ENERGY** (Glyphosate 540g/L SL).

Our glyphosate technical was evaluated by (COP number 201502039) UK in March 2016 and the report on equivalence assessment was uploaded on CIRCABC website under UK ref.: W001693810. Considered as equivalent to the approved Annex I source in Europe after the renewal of glyphosate and it is the glyphosate source supporting the dossier for the renewal of WYNCA UK LTD., member of the Glyphosate Task Force (GTF). We also authorize hereby the Poland regulatory authorities to have access to the protected data supporting the equivalence dossier when evaluating the application of Sharda Cropchem España S.L. (property of Sharda Cropchem Ltd.) for registration of **CANDELA ENERGY** (Glyphosate 540g/L SL) in Poland.

Date: March 09, 2021

Tina Wang
Signature:
Name and position of the signee : Tina Wang
Registration manager

镇江江南化工有限公司
ZHENJIANG JIANGNAN CHEMICALS CO., LTD.
王同平

Letter of access has been provided by applicant.

Appendix 4 Lists of data considered for national authorization

List of data submitted by the applicant and relied on

Please refer to the reference list.

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

Please refer to the reference list.