

FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: SHA 1100 D

Product name: CANDELA

Chemical active substance:

Glyphosate 540 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

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Evaluator comments:

The text highlighted in grey was provided by the evaluator.

6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on CANDELA *

Product name and code	CANDELA
Formulation type	Soluble concentrate [Code: SL]
Active substance(s) (incl. content)	glyphosate; 540 g/L
Function	herbicide
Product already evaluated as the 'representative formulation' during the approval of the active substance(s)	No
Product previously evaluated in another MS according to Uniform Principles	No

* Information on the detailed composition of CANDELA can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification and labelling with regard to toxicological data is proposed for the preparation:

Table 6.1-2: Justified proposals for classification and labelling for CANDELA according to Regulation (EC) No 1272/2008

Hazard class(es), categories	Eye Irrit.2
Hazard pictograms or Code(s) for hazard pictogram(s)	GHS07
Signal word	Warning
Hazard statement(s)	H319: Causes serious eye irritation
Precautionary statement(s)	<p>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.</p> <p>Other section of the label: P270: Do not eat, drink or smoke when using this product. P501: Dispose of contents/container to ...</p> <p>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.</p> <p>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)”</p> <p>Section First Aid: P305+P351+P338: IF IN EYES P337 + P313</p>
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for Glyphosate 54% SL

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Classification: eye protection/face protection (M/L) Work wear (arms, body and legs covered) M/L and A + gloves M/L
Workers	Acceptable	Work wear (arms, body and legs covered) and gloves
Residents	Acceptable	None
Bystanders	Acceptable	None

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

No unacceptable risk for operators and workers was identified when the product is used as intended and provided that the PPE stated in Table 6.1-3 are applied.

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and residents/bystanders is presented in the following table.

Table 6.1-4 Critical uses and overall conclusion of exposure assessment

1	2	3	4	5	6	7	8	9	10			
Use- No .*	Crops and situation (e.g. growth stage of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Application		Application rate		PHI (d)	Remarks: (e.g. safener/syn- ergist (L/ha)) critical gap for operator, worker, resident or by- stander exposure based on [Expo- sure model]	Acceptability of exposure assess- ment			
			Method / Kind (incl. appli- cation tech- nique ***	Max. num- ber (min. in- terval be- tween appli- cations) a) per use b) per crop/ season	Max. appli- cation rate kg as/ha a) a.s. 1 b) a.s. 2	Water L/ha min / max			Operator	Worker	Residents	Bystander
1	Winter cereals (wheat, barley, rye, oats, triticale) (Application before seedling)	F	Spraying	1 ; 1	a) 1.08	200 - 400	-	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874				
2	Winter wheat (Desiccation before harvest)	F	Spraying	1 ; 1	a) 1.08	200 - 400	-					
3	Oilseed rape (Application before seedling)	F	Spraying	1 ; 1	a) 1.08	200 - 400	-					
4	Spring barley (Application before seedling)	F	Spraying	1 ; 1	a) 1.08	200 - 400	-					
5	Sunflower (Application before seedling)	F	Spraying	1 ; 1	a) 1.08	200 - 400	-					
6	Maize (Application before seedling)	F	Spraying	1 ; 1	a) 1.08	200 - 400	-					
7	Pome fruit (Apple, pear) (BBCH 31-69)	F	Spraying	1 ; 1	a) 1.08	800-1000	-					
8	Grapevine (BBCH 13-69)	F	Spraying	1 ; 1	a) 1.08	600-1000	-					
9	Stone fruit (Peach, apricot, plum, cherry) (BBCH 31-69)	F	Spraying	1 ; 1	a) 1.08	800-1000	-					

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** 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

*** e.g. LC: low crops, HC: high crop, TM: tractor-mounted, HH: hand-held

Explanation for column 10 "Acceptability of exposure assessment"

A	Exposure acceptable without PPE / risk mitigation measures
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable/ Evaluation not possible

6.2 Toxicological Information on Active Substance(s)

Information regarding classification of the active substances and on EU endpoints and critical areas of concern identified during the EU review are given in Table 6.2-1.

Table 6.2-1: Information on active substance(s)

	Glyphosate
Common Name	Glyphosate
CAS-No.	1071-83-6

Glyphosate	
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: Eye damage 1 Code(s) for hazard pictogram(s): GHS05 Signal word: Danger Hazard statement(s): H318
Additional C&L proposal	-
Agreed EU endpoints	
AOEL systemic	0.1 mg/kg bw/d (corrected for 20% oral absorption)
Reference	EFSA Journal 2015;13(11):4302
Conditions to take into account/critical areas of concern with regard to toxicology	
According to EFSA Conclusion for Glyphosate	None

6.3 Toxicological Evaluation of Plant Protection Product

Comments of zRMS:	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.
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A summary of the toxicological evaluation for CANDELA is given in the following tables. Full summaries of studies on the product that have not been previously considered within an EU peer review process are described in detail in Appendix 2.

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for CANDELA

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	Calculated Additivity formula B.S.Yogeesh, 2017
Eye irritation	Non-irritant	Yes Yes	Eye Dam.1, H318 None	Calculated Additivity formula B.S.Yogeesh, 2017

			experimental data	
			Eye Irrit 2, H319	see: explanation above
Skin sensitisation, guinea pig	Non-sensitising	Yes Supplementary data	None	Calculated Additivity formula xxxxxxxxxxxxxx, 2017
Supplementary studies for combinations of plant protection products	No data – not required			

Table 6.3-2: Additional toxicological information relevant for classification/labelling of CANDELA

	Substance (concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification of product (acc. to the criteria in Reg. 1272/2008)
Toxicological properties of active substance(s) (relevant for classification of product)	Glyphosate (isopropylamine salt, IPA salt) Glyphosate (54% w/v)	none H318	Reg. 1272/2008	N
Toxicological properties of non-active substance(s) (relevant for classification of product)	N-N-dimethyl-C12-14-(evennumbered)- alkyl-1- amines, reaction products with potassium hydroxide and chloroacetic acid	Skin irritation, Category 2; Skin Irrit. 2, H315 Eye Dam. 1, H318	Reg. 1272/2008	Y H314
Further toxicological information	No data – not required			

* Please use concentration range or concentration limit (e.g. 1-10% or > 1%) as provided in MSDS.

** Material safety data sheet by the applicant

6.4 Toxicological Evaluation of Groundwater Metabolites

Comments of zRMS:	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.
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All metabolite concentrations are predicted to stay below 0.1 µg/L – no groundwater assessment is required.

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in CANDELA are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in CANDELA

	Glyphosate	
	Value	Reference
Concentrate	10%	EFSA Journal 2017;15(6):4873
Dilution	20%	EFSA Journal 2017;15(6):4873

6.5.1 Justification for proposed values - Glyphosate

No data on dermal absorption for Glyphosate in CANDELA is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) are presented in the following table.

Table 6.5-2: Default dermal absorption rates for glyphosate

	Value	Justification for value	Acceptability of justification
Concentrate	10%	EFSA Journal 2017;15(6):4873	Accepted
Dilution	20%	EFSA Journal 2017;15(6):4873	Accepted

6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

Table 6.6-1: Product information and toxicological reference values used for exposure assessment

Product name and code	CANDELA
Formulation type	SL
Category	Herbicide
Active substance(s) (incl. content)	Glyphosate 540 g/L
AOEL systemic	0.1 mg/kg bw/d
Inhalation absorption	100%
Oral absorption	20%
Dermal absorption	Concentrate: 10% Dilution: 20%

6.6.1 Selection of critical use(s) and justification

The critical GAPs used for the exposure assessment of the plant protection product are shown in Table 6.1-4. A list of all intended uses within the central zone is given in Part B, Section 0.

6.6.2 Operator exposure (KCP 7.2.1)

Comments of zRMS:	<p>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.</p> <p>Conclusions:</p> <p>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.</p> <p>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:</p> <p>„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.</p> <p>“Wear eye protection/face protection and protective gloves when preparing in-use dilution</p>
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	and workwear (coverall) during mixing and loading and application.
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6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of CANDELA according to the critical uses is presented in Table 6.6-2. The outcome of the estimation is presented in Table 6.6-3 (longer term exposure). Detailed calculations are in 0.

Table 6.6-2: Exposure models for intended uses

Critical uses	Orchards (pome fruit/stone fruit) (max. 2 L product/ha)
	Grapevine (max. 2 L product/ha)
	Bare soil (max. 2 L product/ha) covering winter cereals, oilseed rape, spring barley, sunflower and maize
	Winter wheat (Desiccation before harvest) - (max. 2 L product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

It should be noted that since the product has to be applied before seedling on winter cereals, oilseed rape, spring barley, sunflower and maize, the “bare soil” scenario is considered appropriate for all these uses.

Table 6.6-3: Estimated operator exposure (longer term exposure)

			Glyphosate	
	Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Orchards (pome and stone fruits) and Grapevine	Tractor mounted boom spray application outdoors (downward spraying)			
	Application rate		1.08 kg a.s./ha	
	Spray application (AOEM; 75 th percentile) Body weight: 60 kg Treated area: 10 ha/day	Work wear (arms, body and legs covered)-Potential exposure	0.2224	222
		Work wear (arms, body and legs covered) M/L and A + gloves M/L	0.0617	62
	Manual-hand held application outdoors			
	Application rate		1.08 kg a.s./ha	
	Spray application (AOEM; 75 th percentile) Body weight: 60 kg Treated area: 4 ha/day	Without RPE/PPE	0.9114	911
		Work wear (arms, body and legs covered) M/L and A + gloves M/L and A	0.0876	88
	Manual knapsack application outdoors			
	Application rate		1.08 kg a.s./ha	
	Spray application (AOEM; 75 th percentile) Body weight: 60 kg Treated area: 1 ha/day	Without RPE/PPE	0.4025 0.3194	402 319
		Work wear (arms, body and legs covered)	0.0650 0.0515	65 52
Bare soil	Tractor mounted boom spray application outdoors			
	Application rate		1.08 kg a.s./ha	

Winter wheat (desiccation before harvest)	Spray application (AOEM; 75 th percentile) Body weight: 60 kg Treated area: 50 ha/day	Without RPE/PPE	0.3200	320
		Work wear (arms, body and legs covered) M/L and A + gloves M/L	0.0349	35
	Tractor mounted boom spray application outdoors			
	Application rate		1.08 kg a.s./ha	
	Spray application (AOEM; 75 th percentile) Body weight: 60 kg Treated area: 50 ha/day	Without RPE/PPE	0.3200	320
		Work wear (arms, body and legs covered) M/L and A + gloves M/L	0.0349	35

Conclusion

According to the AOEM model, calculations, it can be concluded that the risk for the operator using CANDELA is acceptable with the use of gloves and working clothing (long sleeved shirt and trousers) during mixing/loading.

Implication for labelling: P280: Wear protective gloves, protective clothing

6.6.2.2 Measurement of operator exposure

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and consideration of the above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

6.6.3 Worker exposure (KCP 7.2.3)

Comments of zRMS:	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.		
	Therefore, a new estimation based on the preferred model has been conducted:		
	Summary of worker exposure to glyphosate (540 g/L) contained in SHA 1100 D / CANDELA:		
	EUROPOEM II		
	Intended use: cereals – desiccation before harvest, 1.08 kg a.s./ha, 8 h		
		No PPE	PPE
	Total systemic exposure	12.96 mg a.s./d	2.60 mg a.s./d
	% of AOEL	216	43
	Intended use: pome & stone fruits, grapevine 1.08 kg a.s./ha, 8 h		
		No PPE	PPE
		23.33 mg a.s./d	4.67 mg a.s./day
	% of AOEL	389	78
	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.		

	<p>Following sentence regarding the use of PPE is recommended by the evaluator to be placed in the section of precautions for the workers:</p> <p>„Stosować rękawice ochronne oraz odzież roboczą (długie spodnie, koszula z długim rękawem).</p> <p>“Wear protective gloves and workwear (long trousers, long-sleeve shirt).</p>
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6.6.3.1 Estimation of worker exposure

Table 6.6-4 shows the exposure model used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with CANDELA according to the critical uses. Outcome of the estimation is presented in Table 6.6-5 to Table 6.6-7 (longer term exposure). Detailed calculations are in 0.

Table 6.6-4: Exposure models for intended uses

Critical uses	Orchards (pome fruit/stone fruit) and Grapevine (max. 2 L product/ha)
	Winter wheat (Desiccation before harvest) and Bare soil covering winter cereals, oilseed rape, spring barley, sunflower and maize (max. 2 L product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

It should be taken into account that CANDELA is a herbicide, applied to weeds on the ground in orchards and vinegrapes. Therefore the worker exposure estimations according to the EFSA model for the proposed uses on pome and stone fruit, grapes should not be considered since they take into account sorting, picking, reaching fruits or grapes what results in much higher TC values compared to contact with weeds treated with CANDELA. As a worst case scenario, we have estimated the exposure of workers according to the scenario of grassland and weeds for the workers. The model by default assumed 2 hours work rate for crop inspection, but we have extrapolated it to 8 hrs work rate since this duration can reasonably be expected for workers performing tasks on fruit trees and grapes above the treated ground.

Table 6.6-5: Estimated worker exposure (longer term exposure) – Orchards and Grapevine

		Glyphosate	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Orchards (pome/stone fruits) and Grapevine - the scenario of grassland and lawns Inspection, irrigation/Outdoor Work rate: 2 hours/day, DT ₅₀ : 3 days ¹ DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 365			
Number of applications and application rate		1 × 1.08 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	0.2700	270
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.0302	30
	Work wear (arms, body and legs covered) and gloves TC: 1250 cm ² /person/h ²	0.0270	27
Calculations for 8 h: Searching, reaching, picking and Hand harvesting /Outdoor Work rate: 8 hours/day			
Number of applications and application rate		1 × 1.08 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	1.0800	1080
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.1208	121
	Work wear (arms, body and legs covered) and gloves TC: 1250 cm ² /person/h ¹	0.1080	108
Proposal of Re-entry period of 1 day Calculations for 8 h: Searching, reaching, picking and Hand harvesting /Outdoor Work rate: 8 hours/day			
Number of applications and application rate		1 × 1.08 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	0.8572	857
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.0960	98 96
	Work wear (arms, body and legs covered) and gloves TC: 1250 cm ² /person/h ¹	0.0857	86

It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing for maintenance activities when for re-entering pome fruits, stone fruits and grapes with CANDELA a time period of 1 day after application is respected.

¹ According to EFSA (EFSA Journal 2014;12(10):3874)

² According to Guidance of EFSA (EFSA Journal 2014;12(10):3874): "Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products": for workers a factor of 10 % can be considered for re-entry activities.

Table 6.6-6: Estimated worker exposure (longer term exposure) - Winter wheat (Desiccation before harvest) and winter cereals, oilseed rape, spring barley, sunflower and maize (before seedling)

		Glyphosate	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Winter wheat Inspection, irrigation/Outdoor Work rate: 2 hours/day, DT ₅₀ : 3 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 365			
Number of applications and application rate		1 × 1.08 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	0.2700	270
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.0302	30
	Work wear (arms, body and legs covered) and gloves TC: no TC available for this assessment	-	-

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

If no DFR data for the specific compound are available, a conservative default value for the DFR may be taken as 3 µg/cm² (30 mg a.s./m²).

Refinement

Proposal of Re-entry period

The Applicant propose to consider as refinement a re-entry period of 1 day for activities without gloves and with gloves.

Body weight 60 kg.

For this calculation DT₅₀ value of 3 days is considered according to “EFSA Journal 2014;12(10):3874³”.

DFR_t is calculated according the following formula:

$$DFR_T = DFR_0 \times e^{-k \cdot t}$$

Where:

DFR_T Dislodgeable foliar residue at the time of re-entry (µg/cm²)

DFR₀ Dislodgeable foliar residue just after application (µg/cm²)

k Degradation constant (days⁻¹), calculated from the half life time:

$$k = \ln(2)/DT_{50},$$

DT₅₀ Foliar half-life time (days)

t Re-entry interval (days)

Dislodgeable foliar residue just after application is calculated as:

$$DFR_0 = DFR_{def} \times MAF$$

Where:

³ Guidance of EFSA (EFSA Journal 2014;12(10):3874): “Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products”

DFR_{def} default value (If no DFR data for the specific compound are available, a conservative default value for the DFR may be taken as 3 µg/cm² per kg s.a/ha)

MAF_m (multiple application factor for mean residue data for *n* application) is:

$$MAF = (1 - e^{-nki}) / (1 - e^{-ki})$$

where:

n is the number of applications

k is the rate constant for foliar dissipation $k = \ln(2)/DT_{50}$,

i is the interval between applications (days)

DFR factor was calculated for every crop based on above formula and according to the EFSA Journal 2014;12(10):3874⁴, corresponding to a half-life_{foliar} of 30 days.

Pome fruits and stone fruits and grapes:

For a number of 1 application and MAF is 1.0. The following DFR value is calculated:

DFR₀ = DFR_{def} × 1.0 = 3.0 µg/cm² (where DFR_{def} = 3 µg/cm² per kg s.a/ha)

Therefore for 1 day of re-entry interval:

$$DFR_T = DFR_0 \times e^{-k \cdot t} = 3.0 \mu\text{g/cm}^2 \times 0.7937 = 2.381 \mu\text{g/cm}^2$$

Therefore for $DFR_T = DFR_{def ref} \times MAF = 2.381 \mu\text{g/cm}^2$ the $DFR_{def ref} = 2.381 \mu\text{g/cm}^2$ per kg s.a/ha

6.6.3.3 Measurement of worker exposure

Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mention PPE, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

6.6.4 Resident and bystander exposure (KCP 7.2.2)

Comments of zRMS:	<p>The results of resident (child and adult) exposure estimation (acc. to AOEM) to glyphosate (540 g/L) contained in the formulation SHA 1100 D / CANDELA presented by the applicant are correct. The selection of worst-case scenario conditions are acceptable.</p> <p>The reference values acutely toxic active substance (RVAAS) for glyphosate is not allocated. Consequently, it is assumed that the estimation of bystander exposure is covered by the calculation of resident exposure towards glyphosate (540 g/L).</p> <p>Summary and conclusions of bystander and resident exposure to SHA 1100 D / CANDELA:</p> <p>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.</p> <p>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.</p>
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6.6.4.1 Estimation of resident and bystander exposure

The acute exposure assessment for bystanders covers the exposure that a resident could reasonably be expected to incur in a single day. Therefore, there is no need for a separate acute risk assessment for residents.

No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.

⁴ Guidance of EFSA (EFSA Journal 2014;12(10):3874): "Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products"

Table 6.6-7 shows the exposure model used for estimation of resident exposure to Glyphosate. The outcome of the estimation is presented in Table 6.6-9 (longer term resident exposure). Detailed calculations are in 0.

Table 6.6-7: Exposure models for intended uses

Critical uses	Orchards (pome fruit/stone fruit) and Grapevine (max. 2 L product/ha)
	Winter wheat (Desiccation before harvest) and Bare soil covering winter cereals, oilseed rape, spring barley, sunflower and maize (max. 2 L product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

CANDELA is a herbicide, applied to weeds on the ground. Therefore the resident exposure estimations according to the EFSA model for the proposed uses on pome and stone fruit, grapes and cereals is identical. As a worst case scenario, we have estimated the exposure of resident according to the scenario of bare soil.

Table 6.6-8: Estimated resident exposure (longer term exposure) – bare soil model

		Glyphosate	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors (downward spraying) Manual hand held and manual knapsack applications outdoors Drift reduction technology: no DT ₅₀ : 3 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 365 d			
Number of applications and application rate		1 × 1.08 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.02908	29.08
	Vapour (75 th perc.)	0.0011	1.07
	Deposits (75 th perc.)	0.00332	3.32
	Re-entry (75 th perc.)	0.03645	36.45
	Sum (mean)	0.04859	48.60
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.00695	6.95
	Vapour (75 th perc.)	0.00023	0.23
	Deposits (75 th perc.)	0.00147	1.47
	Re-entry (75 th perc.)	0.02025	20.25
	Sum (mean)	0.02076	20.76

6.6.4.2 Measurement of resident and/or bystander exposure

Since the bystander and/or resident exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for glyphosate will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of bystander/resident exposure was not necessary and was therefore not performed.

6.6.5 Combined exposure

Not relevant. The product contains only one active substance.

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 7.1.1	xxxxxxxxxx	2016	Glyphosate 54% SL: Acute oral toxicity study (acute toxic class method) in wistar rats, xxxxxxxxxxxxxxxxxxxxx, Report No. G11603 GLP, Unpublished	Y	Sharda Cropchem Limited
KCP 7.1.2	xxxxxxxxxx	2016	Glyphosate 54% SL: Acute dermal toxicity study in wistar rats, xxxxxxxxxxxxxxxxxxxxx, Report No. G11604 GLP, Unpublished	Y	Sharda Cropchem Limited
KCP 7.1.3	xxxxxxxxxx	2017	Glyphosate 54% SL: Acute inhalation toxicity study in wistar rats, xxxxxxxxxxxxxxxxxxxxx, Report No. G11605 GLP, Unpublished	Y	Sharda Cropchem Limited

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

Comments of zRMS:	Taking into account current regulations, i.e. Regulation (EC) No. 1272/2008; Regulation (EC) No. 1109/2009, Regulation (EC) 1907/2006 (REACH), as well as the requirements of Polish Authorities, the use of vertebrates for toxicity studies must be clearly justified. According to European law, the alternative methods should be used if reliable and validated methods are available. Consequently, the applicant was requested to provide alternative approach to generate data necessary for product classification (new data delivered by the applicant is highlighted in green).
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A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	<p>In the view of current regulation (EC Regulation 1272/2008, EC Regulation 1107/2009, EC Regulation 1907/2006), <i>in vivo</i> tests on animals should be avoided. In the view of Directive 86/609/EEC, studies on animals shall be undertaken only where no other alternative methods which provide adequate reliability and quality of data, are available. In case of acute oral toxicity, it is possible to classify the product based on the composition of the product SHA 1100 D. The formulation SHA 1100 D/CANDELA does not contain ingredients classified in regards to systemic oral toxicity (glyphosate isopropylamine salt is the active substance, the pure IPA does not influence the toxicity of the product).</p> <p>Taking into account the composition of the product and in accordance with the provisions of the Regulation EC 1272/2008, the formulation SHA 1100 D / CANDELA does not require classification in regards to oral toxicity.</p> <p>However, bearing in minds that the acute systemic toxicity of many formulations is not the sum of the ingredients' toxicity (additivity); but rather, ingredients in a formulation can interact to result in lower or higher toxicity than predicted by the GHS additivity formula (Corvaro et al., 2016¹; Van Cott et al., 2018²), it seems reasonable and justified to use the results of <i>in vivo</i> studies if such have been generated and their results are available.</p> <p>The study presented by the applicant (xxxxxxx, 2016) is accepted. In accordance with the provisions of the Regulation EC 1272/2008, the formulation SHA 1100 D / CANDELA is non-toxic for oral route (since the acute oral LD50 exceeds 2000 mg/kg b.w.). Thus, the formulation SHA 1100 D / CANDELA does not require classification in regards to acute oral toxicity.</p> <p>The results of the study are consistent with the results of additive formula calculation. All in all, it is concluded that the formulation SHA 1100 D / CANDELA does not require classification in regards to oral toxicity.</p> <p>¹ http://dx.doi.org/10.1016/j.vrtph.2016.10.007 ² https://doi.org/10.1016/j.vrtph.2017.12.024</p>
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Reference	KCP 7.1.1-01
Report	Glyphosate 54% SL: Acute oral toxicity study (acute toxic class method) in wistar rats, xxxxxxxxxx, 2016, Report No. G11603
Guideline(s)	Yes, OECD 423
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	Glyphosate 54% SL (Batch No. SCL-10894)
Species	Rat, Wistar
No. of animals (group size)	3 female rats per step
Dose(s)	2000 mg/kg bw
Exposure	Once by gavage
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 1: Results of acute oral toxicity study in rats of CANDELA

Dose (mg/kg bw)	Toxicological results *	Duration of signs	Time of death	LD ₅₀ (mg/kg bw) (14 days)
Female rats (step I)				
2000	0/0/3	-	-	> 2000
Female rats (step 2)				
2000	0/0/3	-	-	> 2000

* Number of animals which died/number of animals with clinical signs/number of animals used

Table A 2: Summary of findings of acute oral toxicity study in rats of Glyphosate 54% SL

Mortality	No mortality occurred.
Clinical signs	No clinical signs and pre-terminal deaths.
Body weight	Body weights of all the rats increased throughout the observation period.
Macroscopic examination	No abnormalities are detected at necropsy.

Conclusion

Under the experimental conditions, the oral LD₅₀ of CANDELA is higher than 2000 mg/kg bw in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.3 Acute percutaneous (dermal) toxicity (KCP 7.1.2)

Comments of zRMS:	<p>In the view of current regulation (EC Regulation 1272/2008, EC Regulation 1107/2009, EC Regulation 1907/2006), <i>in vivo</i> tests on animals should be avoided. In the view of Directive 86/609/EEC, studies on animals shall be undertaken only where no other alternative methods which provide adequate reliability and quality of data, are available. In case of acute dermal toxicity, it is possible to evaluate the product based on the composition of the product SHA 1100 D. The formulation SHA 1100 D/CANDELA does not contain ingredients classified in regards to systemic dermal toxicity (glyphosate isopropylamine salt is the active substance, the pure IPA does not influence the toxicity of the product).</p> <p>Taking into account the composition of the product and in accordance with the provisions of the Regulation EC 1272/2008, the formulation SHA 1100 D/CANDELA does not require classification in regards to dermal toxicity.</p> <p>However, bearing in minds that the acute systemic toxicity of many formulations is not the sum of the ingredients' toxicity (additivity); but rather, ingredients in a formulation can interact to result in lower or higher toxicity than predicted by the GHS additivity formula</p>
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	<p>(Corvaro et al., 2016¹; Van Cott et al., 2018²), it seems reasonable and justified to use the results of <i>in vivo</i> studies if such have been generated and their results are available.</p> <p>The study presented by the applicant (xxxxxxx, 2016) is accepted. In accordance with the provisions of the Regulation EC 1272/2008, the formulation SHA 1100 D / CANDELA is non-toxic for dermal route (since the acute oral LD₅₀ exceeds 2000 mg/kg b.w.). Thus, the formulation SHA 1100 D / CANDELA does not require classification in regards to acute dermal toxicity.</p> <p>The results of the study are consistent with the results of additive formula calculation. All in all, it is concluded that the formulation SHA 1100 D / CANDELA does not require classification in regards to dermal toxicity.</p> <p>¹ http://dx.doi.org/10.1016/j.vrtph.2016.10.007 ² https://doi.org/10.1016/j.vrtph.2017.12.024</p>
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A 2.3.1 Study 1

Reference	KCP 7.1.2-01
Report	Glyphosate 54% SL: Acute dermal toxicity study in wistar rats xxxxxxxxxx, 2016, Report No. G11604
Guideline(s)	Yes, OECD 402
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	Glyphosate 54% SL (Batch No. SCL-10894)
Species	Rat, Wistar
No. of animals (group size)	5 rats/sex
Dose(s)	2000 mg/kg bw
Exposure	24 hours (dermal, semi-occlusive)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 3: Results of acute dermal toxicity study in rats of CANDELA

Dose (mg/kg bw)	Toxicological results *	Duration of signs	Time of death	LD ₅₀ (mg/kg bw) (14 days)
Male rats				
2000	0/0/5	-	-	> 2000
Female rats				
2000	0/0/5	-	-	> 2000

* Number of animals which died/number of animals with clinical signs/number of animals used

Table A 4: Summary of findings of acute dermal toxicity study in rats of CANDELA SL

Mortality	No mortality occurred.
Clinical signs	No clinical signs of toxicity were observed.
Body weight	Body weight gain was considered to be normal.
Macroscopic examination	No abnormalities are detected at necropsy.

Conclusion

Under the experimental conditions, the dermal LD₅₀ of Glyphosate 54% SL is higher than 2000 mg/kg bw in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	<p>In the view of current regulation (EC Regulation 1272/2008, EC Regulation 1107/2009, EC Regulation 1907/2006), <i>in vivo</i> tests on animals should be avoided. In line with Directive 86/609/EEC, studies on animals shall be undertaken only where no other alternative methods which provide adequate reliability and quality of data, are available. In case of acute inhalation toxicity, it is possible to evaluate the product based on the composition of the product. The formulation SHA 1100 D/CANDELA does not contain ingredients classified in regards to systemic inhalation toxicity (glyphosate isopropylamine salt is the active substance, the pure IPA does not influence the toxicity of the product). Taking into account the composition of the product and in accordance with the provisions of the Regulation EC 1272/2008, the formulation SHA 1100 D/CANDELA does not require classification in regards to inhalation toxicity.</p> <p>However, bearing in minds that the acute systemic toxicity of many formulations is not the sum of the ingredients' toxicity (additivity); but rather, ingredients in a formulation can interact to result in lower or higher toxicity than predicted by the GHS additivity formula (Corvaro et al., 2016¹; Van Cott et al., 2018²), it seems reasonable and justified to use the results of <i>in vivo</i> studies if such have been generated and their results are available.</p> <p>The study presented by the applicant (xxxxxxxxxx, 2017) is accepted. In accordance with the provisions of the Regulation EC 1272/2008, the formulation SHA 1100 D / CANDELA is non-toxic for inhalatory route (since the acute oral LC₅₀ exceeds 3.22 mg/L). Thus, the formulation SHA 1100 D / CANDELA does not require classification in regards to acute inhalation toxicity.</p> <p>The results of the study are consistent with the results of additive formula calculation. All in all, it is concluded that the formulation SHA 1100 D / CANDELA does not require classification in regards to inhalation toxicity.</p> <p>¹ http://dx.doi.org/10.1016/j.vrtph.2016.10.007 ² https://doi.org/10.1016/j.vrtph.2017.12.024</p>
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A 2.4.1 Study 1

Reference	KCP 7.1.3-01
Report	Glyphosate 54% SL: Acute inhalation toxicity study in wistar rats, xxxxxxxxxxxxxxxxx. M, 2017, Report No. G11605
Guideline(s)	Yes, OECD 403
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	Glyphosate 54% SL (Batch No. SCL-10894)
Species	Rat, Wistar
No. of animals (group size)	3 rats/sex
Concentration(s)	3.22 mg/L air
Exposure	4 hours (nose only)
Vehicle/Dilution	70% w/v in Milli-Q water
Post exposure observation period	14 days
Remarks	The particle size was measured by using online particle size analyser (Galai Particle size analyser) instead of normal Cascade Impacter. So, the participle size is reported as Mean aerosol particle size instead of Mass Median Aerodynamic Diameter (MMAD)

Results and discussions

Table A 5: Concentration(s) and exposure conditions

Actual conc. (mg/L air)	Mean aerosol particle size (µm)	GSD * (µm)
3.22	1.64	2.23

* GSD = Geometric Standard Deviation

Table A 6: Results of acute inhalation toxicity study in rats of CANDELA

Concentration (mg/L air)	Toxicological results *	Duration of signs	Time of death	LC₅₀ (mg/L air) (14 days)
Male rats				
3.22	0/0/3	-	-	> 3.22
Female rats				
3.22	0/0/3	-	-	> 3.22

* Number of animals which died/number of animals with clinical signs/number of animals used

Table A 7: Summary of findings of acute inhalation toxicity study in rats of CANDELA

Mortality	No mortality occurred.
Clinical signs	Clinical sign of clear nasal discharge was observed in all rats immediately after exposure and were normal at approximately 1 hour after exposure period on day 1.
Body weight	The body weights of all the rats slightly decreased on day 2 when compared to their initial weights. The body weights increased on day 4 in all rats except in two rats when compared to their initial weights. However, the body weights of all the rats increased on days 8 and 15 when compared to their weights.
Macroscopic examination	No abnormality was detected at necropsy in any of the rats.

Conclusion

Under the experimental conditions, the inhalation LC₅₀ of CANDELA is higher than 3.22 mg/L air in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	Taking into account current EU regulations, the specific concentration limit for
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	<p>ingredient (<i>Proprietary Surfactant Blend</i>) revealed in the SDS of the co-formulant is not justified. Based on the composition of the product SHA 1100 D and in accordance with the Reg. 1272/2008, the product is classified in regards to skin corrosion (Skin Corr. 1B, H314).</p> <p>Acc. to Polish Authorities, the results of classification obtained using calculation method presented above justify the use of the experimental data for the purpose of product evaluation. The study presented by the applicant (B.S. Yogeesh, 2017, Report No. G11606) is accepted. In accordance with the provisions of the Regulation EC 1272/2008, the formulation SHA 1100 D / CANDELA is not irritating to the skin.</p> <p>The results of the study does not confirm the results of additive formula calculation. All in all, it is concluded that the formulation SHA 1100 D / CANDELA does not require classification in regards to skin irritation.</p>
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The toxicity studies for CANDELA were not evaluated as part of the EU review of glyphosate. Therefore, all relevant data are provided here and are considered adequate.

Details of the co-formulants and their classification and the calculation methodology that was used to assess the skin irritation of CANDELA can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

Conclusion

CANDELA is not considered as skin irritant (classified as: Skin Irrit. 2; H315). Under the GHS classification system this component is below the additive trigger value of the classification according to Regulation (EC) no. 1272/2008. According to the Regulation EC No. 1272/2008, CANDELLA is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	<p>Taking into account current EU regulations, the specific concentration limit for one ingredient (<i>Proprietary Surfactant Blend</i>) revealed in the SDS of the co-formulant is not justified. Based on the composition of the product SHA 1100 D and in accordance with the Reg. 1272/2008, the product is classified regarding eye corrosion (Eye Dam. 1, H318). Acc. to Polish Authorities, the results of classification obtained using calculation method presented above justify the use of the experimental data for the product evaluation. The study presented by the applicant (B.S. Yogeesh, 2017, Report No. G11607) is accepted. In accordance with the provisions of the Regulation EC 1272/2008, the formulation SHA 1100 D / CANDELA is not irritating to the eye.</p> <p>The results of the study does not confirm the results of additive formula calculation. All in all, it is concluded that the formulation SHA 1100 D / CANDELA does not require classification in regards to eye irritation.</p> <p>10/2022:</p> <p><i>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</i></p>
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The toxicity studies for CANDELA were not evaluated as part of the EU review of glyphosate. Therefore, all relevant data are provided here and are considered adequate.

Details of the co-formulants and their classification and the calculation methodology that was used to assess the eye irritation of CANDELA can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

Conclusion

CANDELA is classified as eye irritant (classified as: Eye Irrit 2, H319).

According to the Regulation EC No. 1272/2008, for this classification signal word Warning hazard statement H319 is required on the label

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	<p>Taking into account the composition of the product, the formulation SHA 1100 D / CANDELA does not require classification in regards to skin sensitization. Noteworthy, retrospective data indicate that 30–45% of <i>in vivo</i> classified PPPs were not classified in regards to skin sensitization, based on calculation method (Bloch et al., 2019)*. Therefore, the M&K skin sensitization test on SHA 1100 D / CANDELA was used as the supplementary data. The study attached by the applicant (xxxxxxxxxx, 2017, Report No. G11608) was verified and accepted. The results of the study revealed that the formulation is not skin sensitizer.</p> <p>Conclusion: The formulation SHA 1100 D / CANDELA does not require classification in regards to skin sensitization.</p> <p>*https://onlinelibrary.wiley.com/doi/epdf/10.1002/ps.6034</p>
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The toxicity studies for CANDELA were not evaluated as part of the EU review of glyphosate. Therefore, all relevant data are provided here and are considered adequate.

Details of the co-formulants and their classification and the calculation methodology that was used to assess the skin sensitization of CANDELA can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

Conclusion

CANDELA is not considered a potential skin sensitiser. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.8 Supplementary studies for combinations of plant protection products (KCP 7.1.7)

No supplementary studies are necessary.

A 2.9 Data on co-formulants (KCP 7.4)

A 2.9.1 Material safety data sheet for each co-formulant

Information regarding material safety data sheets of the co-formulants can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.9.2 Available toxicological data for each co-formulant

Available toxicological data for each co-formulant can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.10 Studies on dermal absorption (KCP 7.3)

Comments of zRMS:	<p>Taking into account:</p> <ul style="list-style-type: none"> - the prerequisites presented in EFSA Guidance on dermal absorption (EFSA Journal 2017;15(6):4873), in the Chapter 6.1.1. "Consideration of the oral absorption value when setting a default value"; - the data on glyphosate and glyphosate-containing product absorption (RAR. 2013); - the composition and no irritation potency of the formulation SHA 1100 D / CANDELA, <p>the absorption rates of 10 and 20 % for the concentrate and in-use dilution are acceptable.</p>
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According to the new EFSA guidance on dermal absorption (EFSA Journal 2017;15(6):4873 adopted: 24 May 2017) a default dermal absorption value 10 % (concentrate) and 50% (diluted) of may be applied for products that are water-based/dispersed^(c) or solid ^(d)

^(c) Formulation types: soluble concentrate (SL), suspension concentrate (SC), flowable concentrate for seed treatment (FS), flowable (FL) (=SC).

^(d) Formulation types: wettable powder (WP), water-dispersible granules (WG/WDG), water-soluble granules (SG), water-soluble powder (SP), powder for dry seed treatment (DS).

According to the new EFSA guidance on dermal absorption (EFSA Journal 2017;15(6):4873 adopted: 24 May 2017): *“In exceptional cases, if oral absorption is less than 70% for organic solvent-based or other formulations or less than 50% for water-based/dispersed or solid formulations, this can be used as a surrogate dermal absorption value for (in-use) dilutions. If oral absorption is less than 25% for organic solvent-based or other formulations or less than 10% for water-based/dispersed or solid formulations, it can be used instead of the default value for concentrated products. There are usually no oral ADME studies for formulations that include co-formulants which are possibly modifying dermal absorption. For these reasons, estimates based on oral absorption should be applicable in only a limited range of circumstances after careful consideration of doses and vehicle used in the ADME studies, where bile-cannulation was also performed.”*

Therefore, it has been considered to calculate the exposure for operator, bystander and worker using the dermal absorption values of 10% (concentrate) and 20% for a spray dilution.

A 2.11 Other/Special Studies

No new additional other/special studies.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for Glyphosate

Table A 8: Estimation of longer term operator exposure towards Glyphosate according to EFSA guidance for orchards (pome/stone fruits) and grapes using vehicle-mounted

Operator exposure for CANDELA outdoor spray applications

Application rate of active substance	1.08	kg a.s./ha	i_AppRate		
Assumed area treated	10	ha/day	d_AreaTreated		
Amount of active substance applied	10.8	kg a.s./day	i_AmountAS		
Dermal absorption of the product	10.00%		i_AbsorpProduct		
Dermal absorption of in-use dilution	20.00%		i_AbsorInuse		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Indoor or Outdoor application	Outdoor				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Season	not relevant				
OutdoorSoluble concentrates, emulsifiable concentrate, etc. Downward sprayingVehicle-mounted					
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	30333	113504	AOEM	
	Body	19000	143785	AOEM	
	Head	560	3073	AOEM	
	Protected hands (gloves)	162	2139	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	196	1580	AOEM	
	Protected head (hood and face shield)	9	174	AOEM	
	Inhalation	8	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	17500	21415	AOEM	This scenario assumes that small area equipment is used
	Body	24010	30424	AOEM	
	Head	144	1687	AOEM	
	Protected hands (gloves)	79	28	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	300	355	AOEM	
	Inhalation	18	159	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	
				Without RPE/PPE	With RPE/PPE
Longer term					
Total systemic exposure from mixing, loading and application (mg a.s./day)			13.3450389	3.7055593	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)			0.2224173	0.0617593	
% of RVNAS			222.42%	61.76%	

Table A 9: Estimation of longer term operator exposure towards Glyphosate according to EFSA guidance for orchards (pome/stone fruits) and grapes using Manual-hand held application

Operator exposure for CANDELA outdoor spray applications

Application rate of active substance	1.08 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	4 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	4.32 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	10.00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	20.00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Manual-Hand held	
Season	not relevant	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	14982	55610	AOEM	
	Body	9978	110179	AOEM	
	Head	224	1229	AOEM	
	Protected hands (gloves)	89	856	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	87	632	AOEM	
	Protected head (hood and face shield)	4	70	AOEM	
	Inhalation	6	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	4447	12133	AOEM	
	Body	255940	394580	AOEM	
	Head	35	245	AOEM	
	Protected hands (gloves)	14	63	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	25641	180374	AOEM	
	Inhalation	75	75	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	54.6832258	5.2585543
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.9113871	0.0876426
% of RVNAS	911.39%	87.64%

Table A 10: Estimation of longer term operator exposure towards Glyphosate according to EFSA guidance for orchards (pome/stone fruits) and grapes using Manual knapsack application

Operator exposure for CANDELA outdoor spray applications

Application rate of active substance	1.08 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	1 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	1.08 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	10.00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	20.00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Manual-Knapsack	
Season	not relevant	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	9495	25482	AOEM	
	Body	803	2787	AOEM	
	Head	5	11	AOEM	
	Protected hands (gloves)	18	164	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	25	103	AOEM	
	Protected head (hood and face shield)	5	11	AOEM	
	Inhalation	25	26	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	1544	4213	AOEM	
	Body	88868	137007	AOEM	
	Head	12	85	AOEM	
	Protected hands (gloves)	5	22	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	8903	62630	AOEM	
	Inhalation	26	26	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	19.1661000	1.8398000
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.3194350	0.0306633
% of RVNAS	319.44%	30.66%

Table A 11: Estimation of longer term operator exposure towards Glyphosate according to EFSA guidance for winter wheat (desiccation before harvest) and for Bare soil covering winter cereals, oilseed rape, spring barley, sunflower and maize using vehicle-mounted application

Operator exposure for CANDELA outdoor spray applications

Application rate of active substance	1.08 kg a.s./ha	i_AppRate
Assumed area treated	50 ha/day	d_AreaTreated
Amount of active substance applied	54 kg a.s./day	i_AmountAS
Dermal absorption of the product	10.00%	i_AbsorpProduct
Dermal absorption of in-use dilution	20.00%	i_AbsorInuse
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	
OutdoorSoluble concentrates, emulsifiable concentrate, etc. Downward sprayingVehicle-mounted		

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	104715	397440	AOEM	
	Body	58895	229499	AOEM	
	Head	2802	15366	AOEM	
	Protected hands (gloves)	462	10696	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	816	7898	AOEM	
	Protected head (hood and face shield)	45	870	AOEM	
	Inhalation	12	32	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
Water soluble bag	No		1		

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	8009	42559	AOEM	
	Body	4478	23086	AOEM	
	Head	212	638	AOEM	
	Protected hands (gloves)	370	5307	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	123	301	AOEM	
	Inhalation	8	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	19.2008798	2.0964969
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.3200147	0.0349416
% of RVNAS	320.01%	34.94%

Worker Exposure Estimation - Re-entry in field																
Crop - Activity	AR	Napp	i	DT50	MAF	DFR (default)	DFR (0)	DALA	DFR (h)	TC (coveral)	WR	Exp (0)	Exp (h)	% AOEL	%AOEL(h)	
Total potential exposure	1.08	1		365	3	1.000	3	3.000	1	2.3811	12500	8	1.08	0.85719657	1080	857
Arms, body and legs covered	1.08	1		365	3	1.000	3	3.000	1	2.3811	1400	8	0.12096	0.09600602	121	96
Hands, arms, body and legs covered	1.08	1		365	3	1.000	3	3.000	1	2.3811	1250	8	0.108	0.08571966	108	86
Body weight		60	kg						$e^{-k \cdot t}$	0.7937005						
DA		20	%						$DFR_{def/ref}$	2.3811016						
AOEL		0.1	mg/kg/day													
AR = Application rate (kg a.s/ha)																
N app = application numbers																
i = interval between the applications (days)																
DT50 = foliar half-life (days)																
MAF = decay due to a DT50																
DFR def = Dislodgeable Foliar Residue (mga.s/m2/kg a.s/ha)																
DFR(0) = DFR shortly after the treatment - DFR def x AR x MAF (mg a.s./m2)																
DALA = Days After the Last Application (days)																
DFR(h) = DFR at DALA calculated by the following formula: $DFR(h)=DFR(0) \times e^{-k \cdot h}$; where $k=(\ln(2)/DT50) \times DALA$																
TC = Transfer coefficient (m2/h)																
WR = Work Rate - duration of activity (h/day)																
EXP(0) = exposure shortly after the treatment per activity (mg/person/day)																
EXE(t) = exposure at DALA																
%AOEL(0): risk characterization considering the exposure shortly after the treatment (%) - worker with coveral but bare hands																
%AOEL(h): risk characterization considering the exposure at DALA (%) - worker with coveral but bare hands																
%AOEL(0)(PPP EFSA): risk characterization considering the exposure shortly after the treatment (%) - worker with coveral and gloves (protection factor by EFSA)																
%AOEL(h)(PPP EFSA): risk characterization considering the exposure at DALA (%) - worker with coveral and gloves (protection factor by EFSA)																

Table A 15: Input parameters considered for the estimation of worker exposure for winter wheat (desiccation before harvest) and for Bare soil covering winter cereals, oilseed rape, spring barley, sunflower and maize using vehicle-mounted application

Intended use(s)	Winter wheat	Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s./ha
Application rate (AR)	1.08 kg a.s./ha	Dermal absorption (DA)	20	% (worst case)
Number of applications (NA)	1	Inhalation absorption (IA)	100	%
Interval between applications	365 days	Work rate per day (WR)	8	h/d
Half-life of active substance	3 days	TC dermal (potential)	12500	cm ² /h
Multiple application factor (MAF)	1	TC dermal (work wear)	1400	cm ² /h
Body weight (BW)	60 kg/person	TC dermal (work wear, gloves)	No TC	cm ² /h
AOEL	0.1 mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 ⁻³
AAOEL	mg/kg bw/d			

Table A 16: Estimation of longer term worker exposure towards glyphosate according to EFSA guidance for winter wheat (desiccation before harvest) and for Bare soil covering winter cereals, oilseed rape, spring barley, sunflower and maize using vehicle-mounted application

	Potential	With work wear	With work wear and gloves
Worker (re-entry): Dermal exposure after application			
(DFR x TC x WR x AR x MAF x DA) / BW			
Systemic exposure	0,2700000 mg/kg bw/d	0,0302400 mg/kg bw/d	- mg/kg bw/d

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for Glyphosate

Table A 17: Input parameters considered for the estimation of longer term resident exposure

Resident exposure for CANDELA	
Croptype	Bare soil
Application method	Downward spraying
Application equipment	Vehicle-mounted
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Buffer strip	2-3 m
Application rate of the product	1.08 kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	5.4 g a.s./l
Dermal absorption of product	10.00%
Dermal absorption of in-use dilution	20.00%
Oral absorption	20.00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	3.24 µg a.s./cm ²
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa Pa
Concentration in air	0.001 mg/m ³
Resident dermal spray drift exposure 75th percentile - adult	0.47 ml spray dilution/person
Resident dermal spray drift exposure 75th percentile - child	0.327 ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - adult	0.00010 ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - child	0.00022 ml spray dilution/person
Resident dermal spray drift exposure mean - adult	0.22318 ml spray dilution/person
Resident dermal spray drift exposure mean - child	0.18 ml spray dilution/person
Resident inhal. spray drift exposure mean - adult	0.00009 ml spray dilution/person
Resident inhal. spray drift exposure mean - child	0.00017 ml spray dilution/person
Exposure duration dermal	2 hours
Exposure duration inhalation	24 hours
Exposure duration entry into treated crops	0.25 hours
Light clothing adjustment factor	18.0%
Breathing rate adult	0.23 m ³ /day/kg
Breathing rate child (1-3 year old)	1.07 m ³ /day/kg
Drift percentage on surface (75th percentile)	5.60%
Drift percentage on surface (mean)	4.10%
Turf transferable residues percentage	5.00%
Transfer coeff. of surface deposits-adult	7300 cm ² /hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm ² /hour
Saliva extraction percentage	50.00%
Surface area of hands mouthed	20 cm ²
Frequency of hand to mouth activity	9.5 events/hour
Ingestion rate for mouthing of grass per day	25 cm ²
Dislodgeable residues percentage transferability for object to mouth	20.00%
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm ² /h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm ² /h
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm ² /h
Transfer coefficient for entry into treated crops (mean) - child	1794 cm ² /h

Table A 18: Estimation of longer term resident exposure towards Glyphosate according to EFSA guidance

1.1 1-3 year old child					
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.2907792	0.0107000	0.0332035	0.3645000	0.4859637
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0290779	0.0010700	0.0033204	0.0364500	0.0485964
% of RVNAS	29.08%	1.07%	3.32%	36.45%	48.60%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.4167720	0.0138000	0.0883008	1.2150000	1.2453430
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0069462	0.0002300	0.0014717	0.0202500	0.0207557
% of RVNAS	6.95%	0.23%	1.47%	20.25%	20.76%

**Appendix 4 Detailed evaluation of exposure and/or DFR studies relied upon
(KCP 7.2, KCP 7.2.1.1, KCP 7.2.2.1, KCP 7.2.3.1)**

Not relevant.